Abstract

A pilot randomized controlled trial was conducted in El Salvador of an intervention ('Thula Sana') previously shown in South African sample to enhance maternal sensitivity and infant security of attachment. In El Salvador trained community workers delivered the intervention from late pregnancy to six months postpartum as part of a home-visiting programme. The sample comprised 64 pregnant adolescent women, aged 14 to 19 years, living in predominantly rural settings. They were randomised to receive either the intervention or normal care. Demographic information was collected at baseline and, immediately post-intervention, blind assessments were made of parental sensitivity and infant emotion regulation. The intervention was found to have a substantial positive impact on maternal sensitivity. Further, compared to control group, infants in the intervention group showed more regulated behaviour: in a social challenge task they showed more attempts to restore communication, and in a non-social challenge task they showed more social and goal-directed behaviour. This replication and extension of the South African findings in a small El Salvador sample shows promise and justifies the conduct of a large scale RCT in a Central or South American context.

Keywords: parenting intervention, maternal sensitivity, and infant emotional regulation.

Key findings and implications:

1. The current study supports the feasibility and preliminary efficacy of an early parenting intervention, 'Thula Sana' (or *Crianza Temprana*), that sensitizes mothers to their infant's individual capacities and needs, and encourages them to engage in responsive interactions with their infants.
2. The intervention had a positive impact on maternal sensitivity and infants' responses to social and non-social challenges. Early parenting interventions targeting maternal sensitivity have the potential to enhance child socio-emotional development.
3. Trained lay personnel successfully implemented the non-intensive intervention. Low-cost parenting interventions for adolescent mothers should be further evaluated and, potentially, scaled up in low- and middle-income countries, utilizing available resources and personnel.

Statement of relevance to infant and early childhood mental health:

This study contributes to the growing body of evidence on the positive impact of early parenting interventions on maternal sensitivity and child development. The results of this study are consistent with those of a previous trial investigating the 'Thula Sana' parenting intervention, which demonstrated a positive impact on parenting and child socio-emotional development in South Africa. These two studies are highly relevant to addressing parenting challenges faced by vulnerable populations in resource-poor settings.

The Impact of a Mother-Infant Intervention on Parenting and Infant Response to Challenge: a pilot randomized controlled trial with Adolescent Mothers in El Salvador

Heightened parenting difficulties occur in the context of the poverty and mental health problems that are commonly seen in low and middle-income countries (LMICs) (Walker et al, 2011; Grantham-McGregor et al, 2007), and pose significant strains on vulnerable populations, such as adolescent mothers (Terry-Humen et al, 2005; Borkowski et al, 2007). These parenting

difficulties have been found, in turn, to be associated with problems in infant psychological development, such as insecure attachment and poor cognitive functioning (Tomlinson et al, 2005; Murray et al, 2016; Belsky & Fearon, 2002; De Wolff & Van Ijzendoorn, 1997).

Early developmental difficulties are important because they predict a range of problems that affect children's life course trajectories, such as behavioural disturbance, poor social functioning, educational failure, and compromised employment prospects (Bornstein, 2014). Consequently, interventions are needed that target parenting in infancy. Indeed, there is a growing body of evidence on the effectiveness of parenting-support interventions that strengthen protective factors for infants, including parental sensitivity and responsiveness (e.g., Van Zeijl et al, 2006; Moss et al, 2011; Bakermans-Kranenburg et al, 2003; Yousafzai et al, 2014; Yousafzai et al, 2016; Velderman et al, 2006). Such interventions have the potential to enhance child socio-emotional development, including reducing behaviour problems and aggression (Cicchetti et al, 2006).

Home visiting and community based interventions, broadly designed to support mothers and enhance parenting, have been evaluated in LMIC contexts. These have shown impressive improvements in both parenting and child outcomes, especially child cognition (Walker et al, 2005; Obradović et al, 2016; Betancourt et al, 2020). However, the prospect of wide-scale delivery of home visiting interventions in LMIC contexts is constrained in two respects. First, they tend to be of long duration and therefore, given scarce resources, could have only very limited reach. Second, they commonly require high levels of expertise, such the use of video feed-back, which, again, puts a constraint on delivery.

Brief home visiting interventions appear to be more effective than longer ones in enhancing maternal sensitivity (Bakermans-Kranenburg et al, 2003). Some brief interventions that facilitate mother-infant interaction have been successful at enhancing parent-infant interactions and increasing sensitive and responsive parenting practices (Armstrong et al, 1999; Brophy, 1997; Larson, 1980). Additionally, there is emerging evidence on the effectiveness of home visiting programs provided by paraprofessionals, who received adequate training, support and supervision, that lead to modest improvements in parenting and child outcomes (Peacock et al, 2013; Barnhart et al, 2020). To respond to the specific needs of low resource context, more evidence is needed on the effectiveness of brief parenting interventions delivered by trained lay personnel.

In earlier epidemiological work of our group in a disadvantaged peri-urban settlement in South Africa – Khayelitsha - we found high rates of maternal depression, parenting difficulties, and insecure infant attachment (Cooper et al, 1999; Tomlinson et al, 2005). In light of these findings, and commensurate with effective brief and focused parenting interventions (Bakermans-Kranenburg et al, 2003), we developed a brief parenting intervention that included simple strategies for encouraging the mother in sensitive and responsive interactions with her infant.

This intervention was based on the following developmental model. Poverty, mental health problems, and other contextual challenges can compromise parenting practices (Walker et al, 2011; Grantham-McGregor et al, 2007) by contributing to a lack of awareness of infant capacities, especially infant capacities for social engagement. They also contribute to a lack of appreciation of infant vulnerabilities, and difficulty in managing them. This leads to insensitive interactions between mothers and their infants and a tendency for mothers to engage in an insensitive and intrusive manner. Infants react to such dysfunctional interactions by being emotionally dysregulated. This in turn contributes to later insecure infant attachment (Tomlinson et al, 2005; Murray et al, 2016; Belsky & Fearon, 2002; De Wolff & Van Ijzendoorn, 1997), itself associated with the development of later emotional and behavioural disturbance (Bornstein, 2014).

Following successful piloting of this intervention - named 'Thula Sana' - (Cooper et al, 2002), a large-scale randomized controlled trial (RCT) was conducted, with a sample of 342 women (mean age = 25.86 years, sd=5.54), recruited in late

pregnancy, assigned to the index intervention or a no intervention control condition (Cooper et al, 2009). This study showed significant benefits to both parenting practices and infant attachment. Thus, in their interactions with their infants, at both six and 12 months postpartum, compared with control mothers, mothers in the intervention group were significantly more sensitive and significantly less intrusive; and the intervention was associated with a higher rate of secure infant attachment at 18 months. These findings are consistent with a body of evidence on the successful promotion of maternal sensitivity and secure infant attachment through brief interventions that focus on maternal sensitive behaviour (Larson, 1980; Bakermans-Kranenburg et al, 2003; Letourneau et al, 2015).

While the Thula Sana intervention has been adopted by NGOs in South Africa, it has not, to our knowledge, been formally evaluated in other LMIC contexts, or with different populations. We therefore conducted a pilot randomized RCT in the region of Sonsonate in El Salvador that focused on a particularly vulnerable group, first-time adolescent mothers (Barnet et al, 2007; DuMont et al, 2008; Koh, 2014; McKelvey et al, 2012).

El Salvador is the smallest and the most densely populated nation in Central America. It has a young population (54% are 30 years or younger) with poor education and employment prospects (Ministerio de Economía, 2017). Motherhood at a young age is prevalent in El Salvador with 18% of women between 20 and 24 years of age having had their first-born child before they were 18 years old (Ministerio de Salud, 2014). The country is severely affected by organized crime and domestic violence. The homicide rate amongst 15 to 19-year-olds is the highest in the world at 27 per 100,000. In one out of four households, women suffer violence from their partner or other family members (UNICEF, 2014).

In El Salvador, harsh parenting practices are prevalent, with 52% of children being verbally or physically abused (Ministerio de Salud, 2014). In this context, there is a sizeable group of young pregnant women who are at multiple risks by virtue of poverty, social isolation, low level of educational attainment (Koh, 2014; Barnet et al, 2007; McKelvey et al, 2012), and at high risk of violence from the family, partners, and other agencies (Bott et al, 2012). Adolescent mothers are more prone to have unrealistic expectations regarding infant behaviour and tend to interact less with them than adult mothers (Barnet et al, 2007).

Studies on the effectiveness of home visit interventions targeting adolescent mothers have mainly been conducted in developed countries. These studies have shown a positive impact on parenting attitudes (Barnet et al, 2007; McKelvey et al, 2012), and reduction in maternal reports of physical and psychological aggression, physical abuse, and harsh parenting (DuMont et al, 2008). Home visiting interventions delivered by paraprofessionals have also shown positive effects on adolescent mothers' capacity to cope with the stress of parenting (Jacobs et al, 2016), on their parenting knowledge, and on self-efficacy and control as parents (Barlow et al, 2015).

In the current study, we assessed the impact of the intervention on maternal behaviour with the infant during play (i.e., sensitivity and intrusiveness). Since both long-term follow-up and a formal assessment of infant attachment were beyond the scope of the current study, we assessed, as our primary infant outcome, responses to the Still Face paradigm (Tronick et al, 1978) at six-month postpartum. This procedure has been shown to elucidate the infant's capacity for self-regulation; and infant regulated behaviour during the procedure has been found to be predicted by early maternal sensitivity (Gunning et al, 2013; Lowe et al, 2017).

In addition to assessing the infant's reaction to the social challenge of maternal unresponsiveness during the Still Face paradigm, we also assessed their response to a non-social challenge, namely an attractive toy being removed whilst remaining in view of the infant (the 'Barrier task'). This task is also widely used in research to assess infant capacities to cope with a challenge

in a regulated way (Adrian et al., 2011; Buss & Goldsmith, 1998; Cole et al., 2018; Goldsmith & Rothbart, 1993; Roque et al., 2013), but, as with the Still Face, it also presents the opportunity to assess the infant's use of social communication as a means of dealing with a stressful situation.

The aim of the study was to determine if similar benefits to the mother-infant relationship and child outcome could be achieved in this vulnerable El Salvador population as in the original South African study. A research protocol was drafted and the study was registered (ISRCTN86435545). In line with the findings of the earlier study (Cooper et al, 2009), we predicted that, compared to controls, mothers who received the intervention would, by six months postpartum, be more sensitive in interactions with their infants and less intrusive. We also predicted that infants in the intervention group would be more likely than controls to be regulated and evidence more social and fewer non-social responses under both social and non-social stress.

We evaluated the effects of the intervention on the mothers by assessing mother-infant interactions - specifically, the level of maternal sensitivity and intrusiveness during face-to-face play interactions. We also evaluated the impact of the intervention on the infants by assessing their capacity to maintain regulated behaviour and to show bids to restore communication with the mother in the 'Still Face' procedure and the 'Barrier task'.

Methods

The Intervention: Content and Delivery

The Thula Sana intervention, renamed '*Crianza Temprana'* (i.e., 'Early Parenting') in El Salvador, was developed for delivery to a poor peri-urban community in South Africa (Cooper et al, 2002). It was based on the principles concerning parenting and early child development outlined in the book 'The Social Baby' (Murray & Andrews, 2000). Using a non-directive counselling approach for its delivery, it incorporated the key principles of the World Health Organization's document 'Improving the Psychosocial Development of Children' (WHO, 1995). A core feature of each postnatal session was the facilitator using selected items from the Neonatal Behavioural Assessment Scale (Brazelton and Nugent, 1995) to sensitize the mother to her infant's individual capacities and needs, and to their potential for social communication (for example, demonstrations of social orienting to the mother's voice, and visual tracking of the mother's face). Following demonstration by the facilitator, the mother's were supported in using the same techniques to engage their baby in social interactions.

The content and conduct of the intervention were specified in a manual (see www.reading.ac.uk/web/files/cls/Khayelitsha_manual.pdf). There were 16 home visiting sessions between a facilitator and the mother, each session lasting approximately one hour. The intervention comprised two visits in the late antenatal period, then 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 (16 visits in all).

The visits provided basic supportive guidance, including topics such as the mother's support structure, the birth process, infant care, and early child development. During the visits, mothers were given support in sympathetically managing infant caregiving challenges (sleeping, feeding and crying). In the context of being made aware of their infants' capacity for social engagement, mothers were also encouraged to respond sensitively, by talking to their infants and engaging in play; and where positive responses were elicited from the infant, the mother's behaviour was reinforced by the facilitator pointing out to her how her behaviour supported the infant's social engagement. Where appropriate, the facilitator modelled certain interactive behaviours, and guided the mother in using them. Other caregivers, particularly fathers and grandmothers, were strongly encouraged to be present for the intervention sessions.

Facilitators: Training and Supervisory Support

The facilitators were five non-professional outreach workers with several years of experience working in their communities on sexual and reproductive health issues, as part of ADS/Pro-Familia's community outreach program. All the facilitators were also mothers, who lived in their outreach communities, and had experience working with adolescents. High school was the highest level of education for four facilitators, and one had a nursing degree. No additional experience or academic background was required. Facilitators participated on a part-time basis and were assigned to study participants living in the same localities where they carried out their community outreach work.

Training of facilitators was conducted in two phases. First, a group of three senior managers from the local implementing partner organization in El Salvador, *Asociación Demográfica Salvadoreña (ADS/Pro-Familia),* spent a week in the UK being trained by the developers of the Thula Sana Programme (PJC and LM). These three managers, together with the study coordinator (JV), then trained five facilitators and a local coordinator and manager of ADS/Pro-Familia's clinic in Sonsonate, El Salvador. During the week-long training, facilitators had the opportunity to practise the intervention and receive feedback from trainers and fellow trainees. In addition, before the commencement of the trial, facilitators practised delivering the full intervention to volunteer mother-infant dyads. The local coordinator and senior manager supervised these sessions to provide direct instruction to the facilitators.

During the delivery of the intervention for the study, the facilitators received support through monthly meetings with their local coordinator. In these meetings, facilitators reviewed the main components of the intervention, received feedback on its delivery, and reflected on complex cases. Emphasis was placed on building a trusting relationship with the adolescent mothers and their immediate families, empowering the adolescent mothers, and managing the role of other family members (in particular the infant's grandmothers).

The manual was translated into Spanish (and is available from the corresponding author). Some supplementary materials were developed in the training of the facilitators to simplify the implementation of the intervention by highlighting its main components, and enabling the progress made with each mother-infant dyad to be tracked.

Study Design

The study was a two-year pilot randomized controlled trial of an early mother-infant intervention - *Crianza Temprana*. The sample was randomized to either the intervention or a control group who received the basic obstetric and paediatric care available to all families over parturition in public health clinics, including a pelvic and breast exam for the mother, and physical exam, measurements, and immunization of the infant. In addition, all participants were offered an additional gynaecological exam in ADS/Pro-familia's clinic, including family planning advice, pap smear, and HIV testing.

An interview-administered baseline assessment of demographic characteristics was made in the last trimester of pregnancy before the delivery of the intervention. It included age, education attainment, employment, marital status, living conditions, and socioeconomic level. Participants were also screened prenatally and at six months postpartum for gender-based violence using International Planned Parenthood Federation - Western Hemisphere Region's GBV screening protocol (Bott et al, 2010). Additionally, participants were screened prenatally, three, and six months postpartum for maternal depression using the Edinburgh Postnatal Depression Scale (Cox et al, 1987; Murray & Carothers, 1990). Throughout the study, three participants were referred to mental health services for maternal depression, one participant for gender-based violence, and two participants for gender-based violence and maternal depression.

Outcome was assessed at six months postpartum. The two primary outcomes were the mothers' behaviour during interaction with the infant (i.e., sensitivity and intrusiveness), and the infants' responses to the social challenge of the Still Face condition (i.e. regulated versus dysregulated behaviour, and social versus non-social responses). The secondary outcome was the infants' responses to the non-social challenge of the Barrier task.

The research protocol was approved by the Salvadorian Public Health Ethics Committee *Comité de Nacional de Ética de la Investigación en Salud Bioética del Consejo Superior de Salud Pública* on December 15th, 2015 (No. CNEIS 2015/035).

Data Collection Staff

Two female research assistants were hired and trained. The first of these received a one-week training and was tasked with recruiting research participants and administering the baseline assessment. The second research assistant was trained to assess the infant outcomes using a manual that outlined the steps of the 'Still Face' procedure (Tronick et al., 1978) and the Barrier task (Goldsmith & Rothbart, 1993). The week-long training included theoretical and practical components where she familiarized herself with the procedures and practised them with volunteer mothers and their infants.

Sample recruitment

Over a period of three and a half months, a sample of young pregnant women was recruited from public health clinics that provide antenatal care and ADS/Pro-Familia's community outreach program in four Sonsonate Municipalities. The Municipalities of Izalco and Nahizalco were oversampled because of safety concerns in the other Municipalities (i.e., Acajutla and Juayúa) and the size of the population. The following criteria were used to recruit participants: primiparous women in their third trimester of pregnancy; between 14 and 19 years of age; without medical complications during pregnancy; and residing in one of the four participating Municipalities.

The study was explained to potential participants and informed consent was obtained. Participants were randomized, 1:1, to the index and control conditions, using a random number generator.

Post-Intervention Assessment

At the six-month assessment, when the infant was content and alert, mothers and infants were first filmed during the 'Still Face' procedure (Tronick et al., 1978). This assessment procedure involves an initial face-to-face play interaction, followed by the mother ceasing to respond to the infant, and sustaining a 'still face' for a few minutes before engaging again with the infant. Mothers were seated opposite their infant and asked to play with their infant without toys. This phase lasted three minutes. Following this period of play, mothers were signalled to stop responding to their infant, while remaining in an *en face* position - i.e., adopting a 'Still Face'- for a period of 1.5 minutes, before resuming normal face-to-face communication for two additional minutes.

Longitudinal research has revealed regulated infant behaviour during the Still Face procedure to be a reliable predictor of later security of attachment (Abbott, 2016; Hill, et al 2018). Infant dysregulated responses to the Still Face paradigm have also been shown to be associated with later behaviour problems (Halligan et al, 2013). Of particular interest are findings that infant communicative bids to restore interaction with the mother during the Still Face appear to reflect the history of the mother-infant relationship, with infants who have previously received sensitive parenting making more such bids, possibly reflecting their expectation for positive maternal responsiveness (Bigelow et al, 2018).

Following the Still Face procedure, infants were filmed during the Barrier task (Goldsmith & Rothbart, 1993). An interesting toy was presented to the infant, who initially played with it for 30 seconds. The toy was then removed and placed

behind a see-through Perspex barrier for one minute, in the infant's sight but out of their reach. During this sequence, the mother was seated near the infant but was required to remain neutral and not communicate with the infant.

Video Coding

The face-to-face play session was coded on five-point scales for maternal sensitivity and intrusiveness using a well-established scale, the Global Rating Scales (Murray et al., 1996a; 1996b). High scores reflected more positive behaviour- i.e. high sensitivity (well attuned responsiveness to infant cues) and low intrusiveness (absence of behaviour that interrupts or cuts across the infant's behaviour).

The Still Face episode was coded to derive measures of infant responses to social challenge. The coding was based on an established rating scheme (Gunning et al., 2013). Videos were coded on a one-second time basis, with behaviours scored as present or absent. These comprised regulated behaviours (social and non-social) and dysregulated behaviours.

The regulated behaviours comprised: a) Social 'Positive vocalisations' (coos, laughter, gurgles); 'Positive communicative expressions' (smiles, pre-speech (i.e. active tongue protrusions, wide open shaping of the mouth) while gazing toward the mother); and 'Direct protest' (frowning at mother, combined with grunting vocalization); and b) Non-social 'Active exploratory gaze' (alert and focused attention toward mother or environment). Dysregulated behaviours comprised: 'Negative vocalizations' (i.e., fussing, crying).

The infants' responses to the 'Barrier task' were used to derive measures of infant responses to a non-social challenge. The coding was done based on a scheme developed by Bozicevic and colleagues (2016). Videos were coded on a one-second time basis, with behaviours scored as present or absent. These encompassed different types of regulated and dysregulated behaviours.

Regulated behaviours comprised: a) Social: 'Social gaze' (looking toward mother or experimenter without engaging in any other activity); and 'Social referencing' (signalling desire for toy, through pointing or vocalizing, combined with gaze to mother); b) Non-social goal directed: 'Gaze to toy' (looking toward the toy without engaging in any other activity); and 'Reach for the toy' (directed attempts to retrieve the toy); and c) Non-social not goal directed: 'Distraction' comprising: 'Attentiodirected at other objects'; and 'Play/exploration' (e.g., the high-chair, own clothes/shoes).

Dysregulated behaviours comprised: 'Escape/aversion' (leaning back, arching back, attempting to get out of the highchair); and 'Tantrum'.

Reliability

Videos were coded by a UK-based independent researcher (LB), who was blind to group assignment. Reliability was obtained between LB and another independent trained rater for the coding of the measures described. Intraclass correlations ranged between 0.70 and 0.95.

Data Analysis

The two groups were compared on the assessments made at six months postpartum. Since there were no important differences between the two groups at baseline, no adjustments were made for baseline differences. Group comparisons for continuous variables were conducted using either t-tests or Mann-Whitney U tests, according to whether the variables were normally distributed, as assessed through Shapiro-Wilk tests. Group comparisons for categorical variables were performed using either Pearson's Chi Square tests or Fisher's Exact tests. Finally, given the nature of the coding for the 'Still-Face' and 'Barrier Task' variables, group comparisons for these were performed using generalized linear models, with a Poisson distribution, a log link, and using either 'Still-Face' or 'Barrier Task' episode time duration as offset. Indirect paths in mediation models were

estimated using bias corrected and accelerated (BCa) bootstrapping with 2000 samples. False Discovery Rate adjustment (FDR; Benjamini & Hochberg, 1995) was used to correct p-values for multiple testing.

Results

Sample

Of 92 women approached, 64 agreed to take part in the study. One family from the intervention group was lost to follow–up because the mother started working shortly after giving birth and decided to withdraw from the project, citing difficulty finding time to participate. Two families from the control group were lost to follow up: one moved away from the area and the other declined to participate in the final evaluation. The analyses presented below were conducted on the per protocol sample – that is, comparing the two groups of 31 index and 30 control.

The sample ranged in age from 14 to 19 years, and for both groups the average age was 17. The great majority lived in a rural setting. As can be seen from Table 1, the randomization was effective, as no difference emerged between the two groups in relation to the main demographic characteristics, such as age of the participant, marital status, education, and employment. The two groups were also very similar with respect to weeks of gestation at delivery. No group difference was found in the kinds of community organizations (churches, social clubs) the mothers were affiliated to, and the frequency of attendance. Finally, the groups showed similar rates of house moves over the period of the study (i.e., up to six months postpartum).

Parenting

As can be seen in Table 2, showing ratings of the face-to-face play assessment, a group difference was found in maternal sensitivity scores, with the intervention group showing significantly higher levels of sensitivity (d= 0.74). No significant difference emerged in relation to maternal intrusiveness, with both group showing low levels.

Child Response to Social Challenge (Still-Face)

The behaviour of the infants in the Still-Face is shown in Table 3. There were significant differences between the two groups on all but one of the variables: positive communicative expressions (smiles or pre-speech) were equally frequent in index and control groups. For all other variables, a clear pattern was apparent: compared to control group infants, index group infants showed significantly more regulated social behaviour (i.e., positive vocalizations and direct protest), more regulated non-social behaviour (i.e., higher levels of active gaze), and less dysregulated behaviour (i.e. lower levels of negative vocalization).

A trend emerged in relation to the indirect path leading from intervention to infant 'Direct protest' through maternal sensitivity (Table 4). This indirect effect explained 38% of the intervention effect, which, albeit remaining significant (p = .004), was reduced in magnitude by the inclusion of sensitivity in the model. Thus, the positive impact the intervention had on maternal sensitivity was seemingly associated with higher levels of infant 'Direct protest' during the 'Still-Face' episode.

Child Response to Non-Social Challenge (Barrier task)

The behaviour of the infants in the 'Barrier task' is shown in Table 3. The two dysregulation variables –'Escape/aversion', and 'Tantrums' – were not analysed because of their low frequency (i.e., observed in less than 10% of the sample). Significant intervention effects were found for all the other, regulated, variables, with the exception of 'Reach for Toy'. Thus, compared to control group infants, the intervention group infants showed more social regulation strategies (i.e., they gazed for longer at the mother or the experimenter, and they showed higher rates of social referencing), and they also showed more goal-directed non-

social behaviour (i.e. gazing at the toy). The control group, instead, devoted more time attending to other objects and playing or exploring their close surroundings.

Finally, we explored the mediating role of maternal sensitivity in the context of intervention effects on 'Barrier Task' variables. Significant mediation was found in relation to the infant's 'Gaze to Toy', 'Attention to Other Objects', and 'Play/Exploration' (see Table 4): the indirect paths leading from intervention to these infant variables, through maternal sensitivity, explained 73%, 59%, and 57% of the variance of the intervention effect respectively. The inclusion of maternal sensitivity in the models rendered non-significant the intervention effect on 'Gaze to Toy' ($p = .319$) and 'Play/Exploration' ($p = .084$) and reduced its magnitude in the case of 'Attention to Other Objects', where it nonetheless remained significant ($p = .043$). Thus, in the context of the 'Barrier Task', the positive impact the intervention had on maternal sensitivity was associated with longer times gazing at the toy, and reduced attention to other objects and instances of play or exploration.

Discussion

The Thula Sana intervention to enhance early maternal sensitivity, trialled in South Africa, has the merit of being relatively brief (16 home visits over eight months), and of producing good outcomes when delivered by lay personnel who have received modest levels of training. To date, however, there has been no demonstration of the efficacy of this intervention beyond the original pilot and RCT (Cooper et al, 2002; Cooper et al, 2009). The current pilot RCT is, therefore, important in two particular respects. First, it is only the third systematic evaluation of this intervention. Second, under RCT conditions, it applied the intervention in a very different cultural context from the original South African trial (i.e., in a Central American country), with a very different community (i.e., teenage mothers), and with a different cadre of facilitators (i.e., lay community outreach workers). It is notable that the findings of the current study are highly consistent with those of the original South African study, in terms of its impact on both parenting and on child socio-emotional development. This speaks to the possibility of wide-scale dissemination of this intervention.

In the current study, the intervention was found to have a substantial impact on maternal sensitivity ($d=0.74$). This is especially significant given the stressful context in which the participants were living and the importance of early sensitivity to child developmental outcomes (Deans et al, 2018; Mesman et al 2012). The absence of an impact of the intervention on maternal intrusiveness seems not to be of significance, as the low intrusiveness scores of both the index and the control groups suggest that intrusive parenting is not a feature of adolescent mothers in this culture.

An assessment was made at six months postpartum of infant responses to a social challenge in the 'Still Face' paradigm, when the mother withdraws her responsiveness to the infant. This particular challenge to infant regulation abilities was chosen as there are good empirical grounds for regarding its outcome as an early predictor of attachment status (Abbott, 2016; Abbott et al, 2018; Cohn et al, 1991; Hill, et al, 2018); and early maternal sensitivity has been found to predict both infant regulation in the Still Face condition (Gunning et al, 2013; Lowe et al, 2017) and later infant attachment (Letourneau et al, 2015; Bakersman-Kranenburg et al, 2003).

In the current study, the intervention had a positive impact on four of the five dimensions of infant responding assessed: 'Active exploratory gaze', 'Positive vocalisations', 'Direct protest', and the absence of dysregulated 'Negative vocalisations' – i.e., crying or fussing. This pattern of regulatory features is very much in line with our original hypotheses in that it reflects an infant strategy for dealing with the interpersonal stress by actively attempting to get the mother to respond and restore harmonious communication. Moreover, in the case of infant 'Direct protest' there was an indication that maternal sensitivity mediated the impact of the intervention on infant behaviour.

It is notable that when confronted by a non-social challenge (i.e., in the Barrier task), compared to control infants, the infants whose mothers had received the intervention showed more social responses and more goal directed behaviour. In particular, in this stressful condition, the infants of the mothers who had received the intervention looked more to the mothers (or the experimenter), made more reference to the mother of their desire to retrieve the toy, and looked longer at the toy itself. The control infants showed more distraction by looking more at other objects and engaging in play or exploration that was not focused on the toy. There was evidence that both the enhanced goal directed behaviour and the reduced distraction found in the infants of the index group were associated with the enhanced sensitivity evidenced by the group of mothers who had received the intervention.

These results support growing evidence of the effectiveness of parenting-support interventions in improving child development outcomes by strengthening parental sensitivity during early childhood (Cicchetti et al, 2006; Fearon et al, 2010). This is particularly relevant to addressing parenting challenges faced by vulnerable populations in resource-poor settings (Walker et al, 2011; Grantham McGregor et al, 2007), such as adolescent mothers ho are disproportionately affected by poverty, social isolation, and violence (Bott et al, 2012; Koh, 2014; Barnet et al, 2007; McKelvey et al, 2012) and who face particular parenting challenges (Barnet et al, 2007).

While no formal assessment was made of the process of change, it is of interest to speculate on how it was that such an impressive improvement in maternal sensitivity was effected. Although the facilitators were home visitors with particular experience in working with adolescents, the South African findings suggest that this training and experience was not a critical factor. In the South African study, the facilitators were lay women from the community with no experience of home visiting. Indeed, as in the South African study, it was the impression of the El Salvador facilitators that the demonstration to mothers of their infant's social capacities, and of their infant's demonstrated preference for them, was revelatory and deeply moving, and this served as the spur to more sensitive maternal engagement in face interaction.

No formal assessment was made of the outreach workers' experience of delivering the intervention, but from the monthly supervision meetings, the supervisors reported that they regarded all five facilitators as having fully committed to the intervention model. Although these facilitators received only one week of training in the intervention, they were experienced in working with adolescents and the extension of their skills from the realm of sexual and reproductive health to the mother -infant relationship was one they were keen to make and which, according to the supervisors, they all made well.

Our findings suggest that future adaptation and implementation of this parenting intervention adopt our practice of including facilitators who have been mothers themselves and who are familiar with the target population. Additionally, access to regular supervisory meetings with facilitators promotes reflection on local challenges that can then be harnessed to respond better to the specific circumstances and needs of the target population.

The findings of the current pilot study support the feasibility and promise of the Thula Sana/ Crianza Temprana intervention. However, there are two notable limitations to this study, which indicate caution in interpreting the findings. First, this was a pilot study involving a relatively small sample. While the findings were wholly consistent with the large scale South African randomized controlled trial, replication is essential before a definitive conclusion can be drawn. Second, it was only possible to conduct an end of intervention assessment when the infants were six months of age, and therefore no assessment of infant security of attachment could be made. Longer-term follow up is needed to be confident of the interventions positive impact of infant socio-emotional development.

Conclusion

This pilot study constitutes a successful replication and extension of the original trial of the Thula Sana intervention conducted in South Africa. The same positive impact on early maternal sensitivity was observed, as was a benefit to infant responses to a social challenge (i.e. the attachment relevant Still Face procedure). Notably, there was also a positive impact on infant responses to non-social challenge, and, in particular, there was evidence that several of the enhanced infant responses were associated with the impact of the intervention on maternal sensitivity. These results indicate that the conduct of a large scale RCT in a Central or South American context is to be recommended.

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Table 1

Prenatal Assessment - Demographic Characteristics

	Experimental	Control	Statistic	p
Age at Delivery – Mean (sd)	17.22(1.60)	17.38(1.07)	U = 507.000	.951
Marital Status – N (%)				
Single	9(28.13)	7(21.88)	Fisher's exact test	.911
Married	2(6.25)	2(6.25)		
In Relationship	21(65.63)	23(71.88)		
Education – N (%)				
None	1(3.13)	1(3.13)	Fisher's exact test	.452
Primary	8(25.00)	10(31.25)		
Secondary	18(56.25)	12(37.50)		
Undergraduate Studies	5(15.63)	9(28.13)		
Employment – N (%)				
Student	2(6.25)	4(12.50)	Fisher's exact test	.239
Employed	3(9.38)	0(0.00)		
Housewife	27(84.38)	28(87.50)		
People Living with the Mother – N (%)				
Partner	23(25.00)	25(27.47)	Fisher's exact test	.992
Mother	13(14.13)	9(9.89)		
Father	6(6.52)	8(8.79)		
Sisters	8(8.70)	8(8.79)		
Brothers	10(10.87)	7(7.69)		
Grandmother	2(2.17)	1(1.10)		
Grandfather	1(1.09)	1(1.10)		

Mother-in-Law	10(10.87)	11(12.09)		
Father-in-Law	5(5.43)	5(5.49)		
Stepfather	0(0.00)	1(1.10)		
Stepmother	2(2.17)	1(1.10)		
Other Relatives	12(13.04)	14(15.38)		
Number of People per Room – M(sd)	1.96(1.42)	1.49(1.90)	U = 623.500	.134
Overcrowding – N (%)				
No	28(87.50)	29(90.63)	Fisher's exact test	>.999
Yes	4(12.50)	3(9.38)		
Socioeconomic Level Index – M(sd)	7.16(2.63)	6.50(2.05)	U = 603.000	.217
Socioeconomic Level – N (%)				
Low	7(21.88)	4(12.50)	$\chi^2(2) = 4.067$	.131
Medium/Low	14(43.75)	22(68.75)		
Medium	11(34.38)	6(18.75)		

Note: Overcrowding refers to households where three or more people share one dormitory. The socioeconomic level index is an asset-based wealth index that ranges from 0 (the household has no assets) 12 points (the household has all 12 basic assets, including indoor plumbing, gas or electric cooking stove, indoor bathroom, flooring, garbage collection services, electricity, overcrowding, television, conventional phone, blender, refrigerator, and vehicle). The socioeconomic levels specify the number of assets per household, where: Low - 0 to 4 assets; Medium 5 to 8 assets; and High 9 to 12 assets.

Table 2

Mother-Infant Interaction Scales – Mean (sd) – 1-5 scale

	Experimental	Control	U	P*	d (95%CI)
Sensitivity	3.42(0.99)	2.70(0.95)	644	.015	0.740 (0.223, 1.256)
Intrusiveness	4.23(0.80)	3.80(1.19)	550	.198	0.420 (-0.085, 0.925)

* FDR corrected

Table 3

Infant Responses to Social (Still Face episode) and Non-Social (Barrier Task) Challenges – Rate per Minute (Mean(sd))

	Index	Control	$X^2(1)$	p*	R^2
Still Face					
a) Regulated behaviours					
1. Social					
Positive vocalisations	0.54(1.96)	0.24(0.41)	5.141	.029	.085
Positive Communicative expressions	4.04(6.01)	3.47(5.44)	2.024	.155	.033
Direct protest	1.94(5.96)	0.71(2.59)	26.851	<.001	.356

2. Non-social					
Active gaze	50.69(13.35)	45.07(15.84)	15.098	<.001	.219
b) Dysregulated behaviours					
Negative vocalisations	4.45(8.98)	6.51(13.68)	17.820	<.001	.253
Barrier Task					
1. Social					
Gaze to mother/experimenter	15.39(14.57)	10.97(7.96)	22.695	<.001	.311
Social referencing	8.06(7.30)	5.73(4.26)	12.056	.001	.179
2. Non-social					
Gaze to toy (goal-directed)	39.71(19.83)	33.57(18.24)	15.714	<.001	.227
Reach for toy (goal-directed)	6.94 (7.28)	7.23(6.84)	0.191	.662	.003
Attention to other objects (distraction)	21.90(16.98)	28.60(18.83)	27.176	<.001	.360
Play/exploration (distraction)	5.74(5.97)	8.70(10.51)	18.627	<.001	.263

*FDR corrected

Table 4

Mediation Models – Indirect Effects

		95% BCa CI		
Outcome	**b**	**Upper**	**Lower**	**p***
Direct Protest	0.71	0.15	2.19	.064
Gaze to Toy	4.43	1.13	10.34	.040
Attention to Other Objects	-4.01	-9.69	-0.87	.040
Play/Exploration	-1.75	-4.52	-0.26	.050

*FDR corrected