

# **The Impact of Past Maternal Abuse on Mother-Infant Interaction at 12 months**

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## **Abstract**

**Question:** How does maternal history of childhood abuse affect mother-infant interaction at 12 months?

**Background:** Previous studies have demonstrated conflicting results on the influence of maternal childhood trauma on mother-infant interaction within the first year of life, with studies suggesting maternal childhood trauma may induce either maternal unresponsive behaviour or maternal controlling behaviour. A failure of most of these studies is they only evaluate one end of the maternal non-sensitivity spectrum. In addition, the infants contribution to mother-infant interaction is often overlooked, despite evidence that infant cooperation may affect maternal sensitivity.

**Method:** 50 dyads who had completed the Childhood Experiences of Care and Abuse Questionnaire (CECA-Q) and a CARE-Index video at 12 months old, from the Psychiatry Research and Motherhood Depression (PRAM-D) study were selected for analysis. 27 of these dyads formed the trauma group and the remaining 23 dyads formed the non-trauma group based on CECA-Q scores. Dyadic synchrony, maternal sensitivity, maternal unresponsiveness, maternal control and infant cooperativeness were evaluated using the CARE-Index method, and group scores were compared using independent samples T-tests.

**Result:** Maternal childhood trauma did not significantly affect dyadic synchrony ( $p = 0.31$ ), maternal sensitivity ( $p = 0.20$ ), maternal unresponsiveness ( $p = 0.73$ ), maternal control ( $p = 0.10$ ) or infant cooperativeness ( $p = 0.43$ ).

**Conclusions:** Consistent with other studies, dyadic synchrony, maternal sensitivity and maternal unresponsiveness scores were not associated with maternal childhood experiences of abuse at 12 months. However, maternal control and infant cooperativeness scores were not found to be affected by trauma, in contrast to prior studies. This is thought to be largely caused by the relatively small sample size and not accounting for the effect of trauma type.

## **Introduction**

The role of maternal trauma in mother-infant interaction is highly contested. Whilst some studies have suggested that maternal trauma has no impact on mother-infant interaction (Leon *et al.*, 2004; Stacks *et al.*, 2014), others have suggested maternal trauma significantly impairs mother-infant dyadic synchrony (Lyons-Ruth & Block, 1996; Buist, 1998; Dixon *et al.*, 2005; Driscoll & Easterbrooks, 2007; Fuchs *et al.*, 2015). However, even within studies which demonstrate a link between maternal child abuse and mother-infant interaction there is conflict, with some studies suggesting mothers who have experienced abuse are more likely to engage in controlling maternal behaviours (Lyons-Ruth & Block, 1996), and others suggesting they are more likely to engage in unresponsive maternal behaviours (Fuchs *et al.*, 2015). As a result of this, studies analysing the relationship between maternal child abuse and mother-infant interaction must use a measure which accounts for both ends of the maternal sensitivity spectrum: unresponsiveness and control (Crittenden, 2010). Subsequently, the aim of this study was to determine what impact, if any, maternal childhood physical, emotional, sexual or neglectful abuse has on mother and infant behaviours, and ultimately mother-infant interaction, in dyads where infants were 12 months old.

## **Methods**

This study is a secondary analysis of the Psychiatry Research and Motherhood Depression study (PRAM-D) data set. The PRAM-D was a prospective, longitudinal study of 172 depressed and non-depressed mothers and their offspring, designed to determine if changes to the maternal hypothalamic-pituitary-adrenal axis (HPAA) during pregnancy induced changes in the infant HPAA within the first year of life.

### **Recruitment**

All participants were expectant mothers who were 18 to 50 years old at recruitment, carrying singleton pregnancies and attending King's College Hospital (KCH) for prenatal care. Women attending the KCH Ultrasound Department for their 20-week scan were approached by researchers to take part in the study. A further group of expectant mothers with depressive symptoms were identified by the Perinatal Psychiatry Clinical Liaison (PPCL) team at KCH. Expectant mothers identified by the PPCL who had an appointment scheduled before 25 weeks gestation were invited to take part by researchers during their next appointment. If their next appointment was scheduled after 25 weeks gestation researchers would telephone mothers to invite them to participate. The same script was used to invite mothers from both the KCH Ultrasound Department and the PPCL (Appendix A). All mothers who were approached were asked to provide basic sociodemographic information, even if they did not wish to participate, to attempt to minimise differences in socioeconomic status (SES) between the mothers with depressive symptoms, and the mothers without.

All potential participants who expressed an interest in taking part in the study received phone calls three to four days later by researchers, where they were screened for past and current physical and psychological conditions. Mothers were excluded from the study if they had

experienced obstetric complications, chronic pulmonary, cardiac, autoimmune or endocrine conditions, were taking medication other than nutritional supplements, were unable to communicate in English, or if they had a psychiatric history other than an affective or anxiety disorder. Those who fulfilled the study criteria and expressed an interest in participating were sent a detailed information sheet about the study (Appendix B). If mothers were still willing to participate a baseline assessment was booked to take place at 25 weeks gestation. Postnatally, dyads were excluded if the infant suffered from any kind of physical or mental disability.

All participants gave informed signed consent prior to commencing the baseline interview (Appendix C). Participants also consented to all interviews being audio-recorded and for clinicians to be able to review these recordings, to ensure agreement on final psychiatric diagnoses. All participants received £10 per visit and were thanked for their time and commitment to the study.

## **Participants**

172 mother-infant dyads completed all visits, though not necessarily all measures. Of the 172 dyads, 53 dyads were selected for analysis in this study by a researcher who was not involved in the coding, so the coders remained blind to the trauma status of the participants. Only 50 of these dyads completed CECA-Q and 12-month CARE-Index video, and were subsequently included in the analysis (Figure 1). 27 of these mothers had experienced trauma before the age of 17 (the trauma group or TG), whilst the remaining 23 had not experienced any form of trauma before the age of 17 (the non-trauma group or NTG).

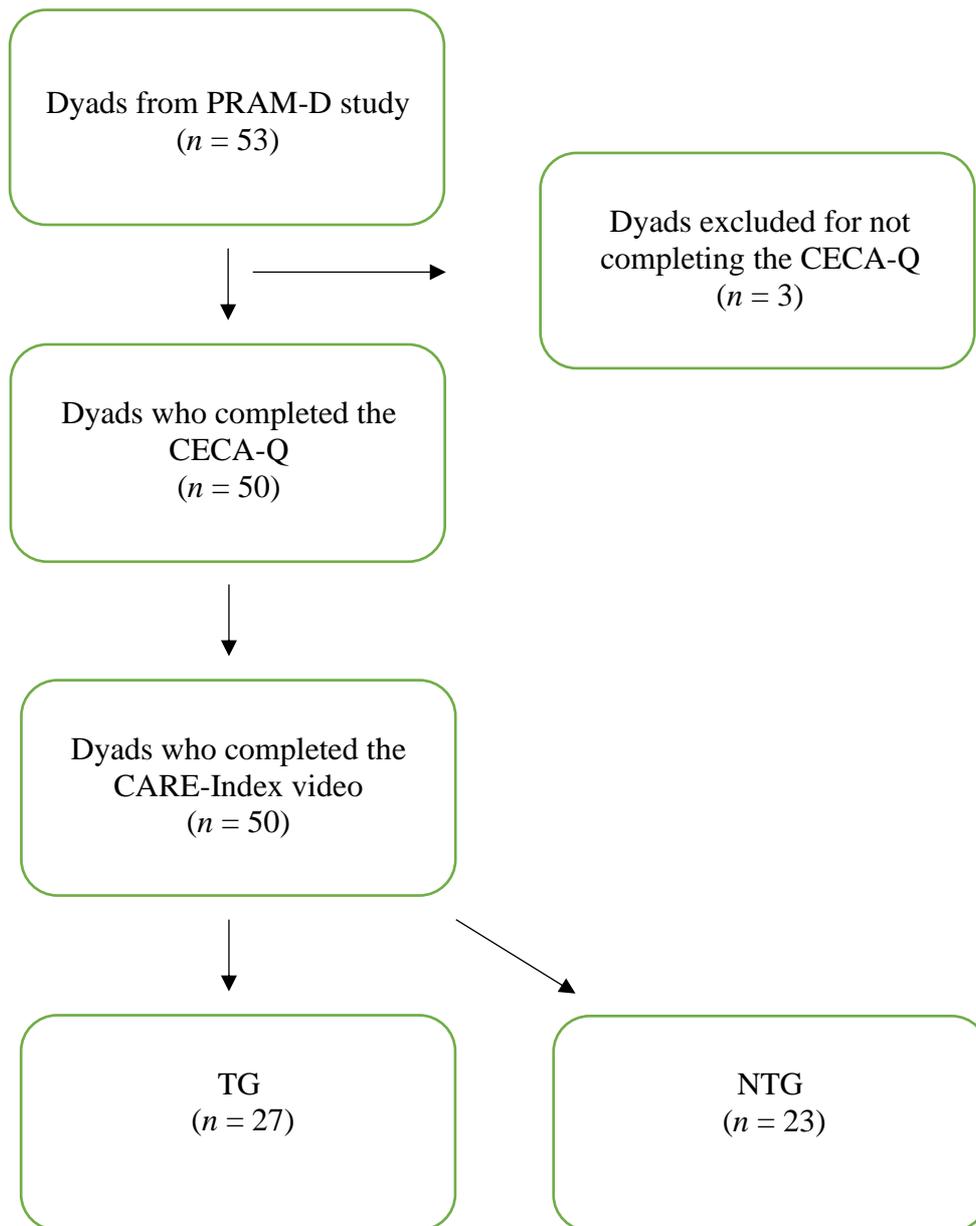


Figure 1 – Flow chart of study participants

## **Measures**

### *Maternal socioeconomic status*

Mothers self-reported their ethnicity, education level and employment status during the baseline visit. Mothers self-reported their marital status at the 12 months postpartum visit.

### *Maternal experiences of trauma*

The Childhood Experiences of Care and Abuse questionnaire (CECA-Q) is a self-report questionnaire which is used to evaluate respondents' experiences of trauma between 0 and 17 years of age (Bifulco, 2005). If a mother had experienced severe neglect or severe emotional, sexual or physical abuse between the ages of 0 and 17 she was identified as part of the trauma group, whereas if the mothers experienced no or minimal trauma they were identified as part of the non-trauma group. Mothers completed the CECA-Q at the 12 months postpartum visit.

### *CARE-Index*

The CARE-Index is a video coding system which assesses mother-infant relationships. At the 12 months postpartum visit, mothers and infants were videoed for three minutes in a non-threatening, free-play situation in their homes, where mothers were asked to interact with their babies as they usually would, using infants' toys if they wished. From these videos, the CARE-Index was used to assess seven aspects of interactional behaviour – facial expression, vocal expression, positioning and body control, affection and arousal, turn-taking, control and choice of activity. The final three aspects evaluate the dyads success in completing a developmental task, which for a 12 to 15 month old infant involves using language to regulate play.

For each of the seven aspects of the scale mothers and infants are awarded two items, which may be the same or different. There are three maternal items: sensitive, control and

unresponsive. There are four infant items: cooperative, compulsive, difficult and passive. Mothers are awarded one point for each 'sensitive' item they are awarded, and infants are awarded one point for each 'cooperative' item they are awarded, for a maximum score of 14 points each.

In most dyads, the dyadic synchrony score is the mean of the mother and the infants score. However, the coder may make exceptions if the mean score is not representative of the dyad, according to the dyadic synchrony score scale shown below (adapted from Crittenden, 2010, Figure 2).



**0 -4: At risk**

Child development at risk

**5- 6: Inept**

Serious risk of harm to child development if no intervention. Clear, unresolved problems.

**7 – 10: Adequate**

No glaring issues, or risk to child development. Periods of synchrony.

**11 – 14: Sensitive**

Mother and infant understand each others needs, cooperate to complete task.

Figure 2 – Dyadic synchrony score scale (adapted from Crittenden, 2010)

## **Statistical analysis**

Data were analysed using SPSS Statistical Software, Version 24.0 (IBM Ltd, Portsmouth, UK).

All statistical values are given to one decimal place, except in situations where two decimal places are needed to provide additional information. Non-significant  $p$  values ( $p > 0.05$ ) are reported to two decimal places whilst significant  $p$  values ( $p \leq 0.05$ ) are given to 3 decimal places. Dyadic synchrony, maternal sensitivity, maternal unresponsiveness, maternal control and infant cooperativeness are all thought to be affected by maternal childhood abuse, thus these measures are the focus of the data analysis.

Z-Scores were computed to determine if there were differences in the number of depressed mothers in the trauma group and the non-trauma group. Chi-squared tests were used to determine if there were significant differences in SES between the trauma group and the non-trauma group. Independent samples T-tests were used to compare mean dyadic synchrony, maternal sensitivity, maternal unresponsiveness, maternal control and infant cooperativeness between the trauma group and the non-trauma group.

## Results

### Sample characteristics

The sample consists of 50 dyads, 27 (54%) of which form the trauma group and 23 (46%) which form the non-trauma group. 16 out of 27 (69.6%) mothers in the trauma group had experienced antenatal or postnatal depression, which was significantly higher than in the non-trauma group (7 out of 23, 30.4%,  $Z = 2.0$ ).

### *Sociodemographic information*

Sociodemographic characteristics of the mothers in the sample are presented in table 1. Employment status and marital status data were missing from 9 participants - 2 in the trauma group and 7 in the non-trauma group. Full sociodemographic data was available for all other participants.

The trauma group was comprised of significantly more black and ethnic minority mothers (40.7% vs 8.7%,  $\chi^2_{(1)} = 6.629$ ,  $p = 0.010$ ), significantly fewer working or studying mothers (40.0% vs 87.5%,  $\chi^2_{(1)} = 9.069$ ,  $p = 0.003$ ) and significantly fewer mothers educated beyond GCSE level (59.3% vs 95.7%,  $\chi^2_{(1)} = 9.018$ ,  $p = 0.003$ ) than the non-trauma group. Mothers who had experienced childhood trauma were also significantly younger than mothers who had not experienced childhood trauma (30.3 years vs 34.6 years,  $p = 0.014$ ). There was no significant difference in marital status between mothers who had experienced maternal trauma and mothers who had not experienced maternal trauma ( $\chi^2_{(1)} = 1.476$ ,  $p = 0.22$ ). Moreover, compared to national data, SES was relatively low in both groups, with higher rates of unemployment and lower educational attainment compared to national averages.

Table 1 – Sociodemographic characteristics of mothers in the sample

	<b>TG</b>	<b>NTG</b>	<b>Statistic and significance</b>
<b>Age at baseline, mean years (SD)</b>	<b>n = 27</b>	<b>n = 23</b>	$p = 0.014$
	30.3 (6.7)	34.6 (4.9)	
<b>Maternal Ethnicity, % (n)</b>	<b>n = 27</b>	<b>n = 23</b>	$\chi^2_{(1)} = 6.629,$ $p = 0.010$
White	59.3 (16)	91.3 (21)	
Black or minority ethnic	40.7 (11)	8.7 (2)	
<b>Maternal Education, % (n)</b>	<b>n = 27</b>	<b>n = 23</b>	$\chi^2_{(1)} = 9.018,$ $p = 0.003$
GCSE or lower	40.7 (11)	4.3 (1)	
A Level or higher	59.3 (16)	95.7 (22)	
<b>Maternal employment status, % (n)</b>	<b>n = 25</b>	<b>n = 16</b>	$\chi^2_{(1)} = 9.069,$ $p = 0.003$
Working or student	40.0 (10)	87.5 (14)	
Not working or on maternity leave	60.0 (15)	12.5 (2)	
<b>Marital Status, % (n)</b>	<b>n = 25</b>	<b>n = 16</b>	$\chi^2_{(1)} = 1.476,$ $p = 0.22$
Single	20.0 (5)	6.25 (1)	
In a relationship with original partner	80.0 (20)	93.75 (15)	
In a relationship with a new partner	0.0 (0)	0.0 (0)	

### **Relationship between maternal experience of trauma and mother-infant interaction**

There was no significant difference in dyadic synchrony, maternal sensitivity, maternal unresponsiveness, maternal control, or infant cooperativeness scores between dyads in the trauma group and dyads in the non-trauma group (Table 2), suggesting maternal childhood trauma does not affect mother-infant interaction in dyads where infants are 12 months old.

Table 2 – Mean and differences in dyadic synchrony, maternal sensitivity, maternal unresponsiveness, maternal control and infant cooperativeness scores in the trauma group and non-trauma group

	t	df	Signifi- cance (p)	Mean (Standard Deviation)		Mean difference	95% Confidence interval	
				NTG	TG		Lower	Upper
<b>Dyadic Synchrony</b>	1.0	48	0.31	7.5 (3.9)	6.3 (3.9)	1.2	-1.1	3.4
<b>Maternal Sensitivity</b>	1.3	48	0.20	7.8 (3.8)	6.4 (3.8)	1.4	-0.8	3.6
<b>Maternal Unrespon- -siveness</b>	0.3	48	0.73	4.5 (3.9)	4.1 (3.6)	0.4	-1.8	2.5
<b>Maternal Control</b>	-1.6	48	0.11	1.7 (3.5)	3.5 (4.2)	-1.8	-4.0	0.4
<b>Infant Cooperati- veness</b>	0.8	48	0.43	6.7 (4.0)	5.8 (4.2)	0.9	-1.4	3.3

## Discussion

### Dyadic Synchrony

Given that dyadic synchrony is determined by both maternal sensitivity and infant cooperativeness, neither of which were found to be significantly affected by maternal experiences of child abuse, it is unsurprising that dyadic synchrony scores were not found to be affected by maternal trauma in this sample (7.5 in the NTG, 6.3 in the TG, 95% CI [-1.1, 3.4],  $p = 0.31$ ). The findings in this study are supported by another observational study of 12 month old infants and their adolescent mothers, where physical and sexual abuse before the age of 16 was not found to be associated with reduced dyadic interactive quality when compared to other adolescent mother-infant dyads (Lesser & Koniak-Griffin, 2000). This study also has similarities to the current study, as most of the dyads were found to be living below the poverty line, whilst the SES of participants in this study was also below the national average. Conversely, Fuchs *et al.*'s (2015) study of 12 month old mother-infant dyads with high SES found all types of maternal childhood abuse were associated with poorer quality of mother-infant interaction and increased parental stress.

Overall, this suggests the overall quality of mother-infant communication is affected by maternal SES. Indeed, Pereira and colleagues (2012) demonstrated that overall mother-infant interaction quality was determined by levels of parental stress, which is known to be higher in dyads with low SES (Katz *et al.*, 2007). It is thought a threshold of stress needs to be met to significantly impair mother-infant interaction, and this may occur without a history of trauma in dyads with low SES, due to the stress caused by lack of social support and resources, thus causing it to appear as if there was no significant difference in dyadic synchrony between the trauma group and the non-trauma group in this study. As maternal stress levels are comparatively lower in high SES dyads this means an additional social or environmental effect

must occur to induce impaired mother-infant interaction, which in Fuchs *et al.*'s study may be maternal past history of trauma.

### **Maternal Sensitivity**

The majority of the focus in mother-infant interaction studies in infants under 12 months is the effect of maternal sensitivity, largely due to its role in secure attachment in infancy (Beckwith *et al.*, 1999). In this study maternal experiences of childhood trauma were not found to significantly affect maternal sensitivity scores (7.8 in the NTG, 6.4 in the TG, 95% CI [-0.8, 3.6],  $p = 0.20$ ), although interpreting these results in relation to other studies is somewhat challenging, as most longitudinal studies of mother-infant interaction suggest that maternal sensitivity increases during the first 12 months postpartum, but decreases after 12 months, largely because increased infant autonomy at this point enables infants to become less cooperative, inducing decreased maternal sensitivity (Liang *et al.*, 2015, Bornstein *et al.*, 2010). Therefore, it is possible that the effect of infant autonomy on maternal sensitivity is so great that the effect of past maternal trauma on maternal sensitivity is no longer significant in infants 12 months old and over, explaining the similar maternal sensitivity scores in the trauma group and the non-trauma group.

### **Maternal Unresponsiveness**

In this study, maternal experiences of childhood trauma did not significantly affect maternal unresponsiveness (4.5 in the NTG, 4.1 in TG, 95% CI [-1.8, 2.5],  $p = 0.73$ ). This is well supported, as other studies have demonstrated increased maternal unresponsiveness only occurring in dyads where mothers have suffered severe sexual abuse and not in mothers who

have suffered severe physical abuse (Lyons-Ruth & Block, 1996; Madigan *et al.*, 2015), whilst the effect of multiple forms of childhood abuse was analysed in this study. Furthermore, Nuttall *et al.* (2012) demonstrated that severe maternal childhood physical and sexual abuse was not associated with increased maternal unresponsiveness in a cohort of mixed mother-son and mother-daughter dyads, but that there was increased maternal unresponsiveness when only mother-son dyads were analysed. This indicates that both type of trauma and infant sex may contribute to maternal unresponsiveness. Overall, these findings highlight the importance of conducting further analyses which consider the effect of both infant gender and type of maternal abuse on mother-infant interaction, as it is possible these differences were present in the current study, but were not identified because the study was underpowered to analyse these effects.

### **Maternal Control**

There was no significant difference in maternal control score between mothers who had suffered childhood abuse and mothers who had not suffered childhood abuse in the current study (1.7 in the NTG, 3.5 in the TG, 95% CI [-4.0, 0.4],  $p = 0.11$ ). Interestingly, Fuchs *et al.* (2015) also investigated the effect of maternal childhood trauma on maternal control in dyads where infants were 12 months old and found that mothers who had suffered either severe sexual or physical childhood abuse were significantly more hostile and intrusive towards their infants in free-play situations than mothers who had not suffered childhood abuse. It is thought the relatively high SES of dyads in Fuchs *et al.*'s (2015) study may contribute to this effect, as mothers with low SES are more likely to live more demanding lifestyles and have less social support, leading to them adopting authoritarian parenting styles in order to cope with motherhood independent of past maternal abuse, which could explain the non-significant

differences seen in this study (see Katz *et al.*, 2007). As a result, history of maternal childhood trauma may have a more significant effect on maternal control in high SES dyads than in low SES dyads, which could explain the significant increase in maternal hostility and intrusiveness scores in Fuchs *et al.*'s study compared to the current study.

Another factor is type of maternal child abuse. Two further studies of maternal control were conducted in two low SES cohorts with 18 month old infants (Lyons-Ruth & Block, 1996; Driscoll & Easterbrooks, 2007). Both of these studies found that maternal childhood experiences of physical abuse were associated with maternal controlling behaviours, although the severity of the abuse was not related to the severity of maternal control. Indeed, research has demonstrated mothers who have suffered physical child abuse are likely to continue to be controlling throughout their offspring's childhood, due to lack of reflective parenting (Zalewski *et al.*, 2013). Once again, it is difficult to compare findings from these studies to findings from the current study, given the effect of infant age and the isolation of one specific type of abuse. However, this demonstrates the importance of exploring the effect of childhood trauma type on subsequent maternal behaviour. Overall, maternal experiences of trauma appear to induce maternal control in mothers with infants who are over 12 months old, particularly if mothers have suffered from physical abuse.

### **Infant Cooperativeness**

In this sample, history of maternal trauma had no significant effect on infant cooperativeness scores at 12 months (6.7 in the NTG, 5.8 in the TG, 95% CI [-1.4, 3.3],  $p = 0.43$ ). These findings are in contrast to other studies conducted in 12 to 18 month old infants which have demonstrated that infants born to mothers who have experienced childhood trauma are

significantly less cooperative than infants born to mothers who have not experienced trauma (Lyons-Ruth & Block, 1996; Fuchs *et al.*, 2015; Morelen *et al.*, 2016). Given that mother-infant interaction is bidirectional (Morelen *et al.*, 2016), a decline in maternal sensitivity may induce a decrease in infant cooperativity by reducing positive affect within the dyad (Crittenden, 2010). Indeed, in Fuchs *et al.*'s (2015) cohort it was noted that decreases in maternal sensitivity were associated with a proportional decrease in infant responsiveness. Thus, it is possible that the similarity in infant cooperativeness scores between groups in this study is due to the similarity in maternal sensitivity scores between the trauma group and the non-trauma group.

### **Strengths of the study**

The longitudinal, prospective nature of the study is one of its main strengths, as researchers were able to standardise criteria for child abuse, and follow up with participants at multiple time points. Secondly, the CARE-Index is an observational measure, which has higher reliability than self-reported measures of mother-infant interaction and thus improves the validity of the data (Crittenden, 2010). Finally, extensive information was collected about all participants, which allowed in-depth comparisons of SES between groups, which is an important predictor of mother-infant interaction (Stein *et al.*, 2008).

### **Limitations of the study**

A major limitation of the study was the relatively small sample size, making the results vulnerable to type II error. In addition, the prevalence of postnatal depression was also not controlled for, despite extensive literature demonstrating that mothers with postpartum depression are significantly more likely to adopt unresponsive parenting styles and subsequently raise passive infants than healthy mothers (Beck, 1998). This was justified as trauma was found to have no main effect on mother-infant interaction, and therefore it was not necessary to control for other variables. Moreover, differences in maternal education level, employment status and ethnicity between the trauma and non-trauma group are of great significance, as these factors are thought to adversely affect infant attachment and maternal sensitivity at 12 months, which may conceal the effect of maternal childhood abuse (Teti *et al.*, 1990; Bouvette-Turcott *et al.*, 2016).

## **Conclusions**

Overall, no significant differences were found in mother-infant interaction between dyads in the trauma group and dyads in the non-trauma group. Whilst similar studies have been conducted before, they have primarily focused on the effect of maternal trauma on maternal sensitivity, rather than overall dyadic synchrony, which gives a more accurate insight into mother-infant interaction. Moreover, this is the first study in infants of this age which evaluated the impact of maternal trauma on both ends of the maternal insensitivity spectrum, which is important given findings in the previous body of research. In the future, it would be interesting to analyse CARE-Index scores from all 172 dyads included in the PRAM-D study, to see if differences in CARE-Index scores became significant in a larger cohort.

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## Appendices

### Appendix A: Participant recruitment script

Call name of potential participant.

Hello \_\_\_\_\_, (shake hands)

I'm [name] ... I'm not calling you for your scan ... I work at Kings College doing research with pregnant women. Whilst you're waiting for your scan, I wonder if I could talk to you about a study we're conducting to see if you would be interested in taking part?

Shall we find somewhere to sit?

I would like to tell you about the study. You don't have to decide now, I will give you an information leaflet to take home and read if you are interested.

You may have seen one of our leaflets about the research programme (show & gesture to stand)

If no: hand one to person.

If yes: have you had a chance to look at it?

You don't have to decide now, I will give you this information leaflet to take home and read if you are interested.

We know that pregnancy can be a time of joy but also a stressful time – we are interested in looking at how mothers cope with their pregnancy.

Let me tell you a bit more about what taking part involves...

There are four key time points that we are in touch with you.

For the first visit we would like to see you in pregnancy where we ask you some questions about your health and wellbeing.

I know it's a long time before the baby comes – but we would like to come and see you and your new baby at around 6 days. During this visit we will see how you and your newborn are getting on and demonstrate some of the amazing abilities of your baby.

Most mothers like to have their baby's immunised at around 8 weeks and 1 year and so we would like to come and see how you and your baby are getting on at these time points.

For your time we are able to offer you a small thank you amount of £40 for taking part in our study.

How does that sound to you? Do you think you would like to take part? Do you have any questions about the study?

## **Participant Information Sheet**

### **Study title**

Does the maternal stress system during pregnancy modify stress responses in babies following birth?

### **Invitation paragraph**

We would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish.

Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

## **PART 1**

### **What is the purpose of the study?**

We are studying the response to stress of babies born to mothers who have been depressed during pregnancy compared with babies whose mothers have not been depressed during pregnancy. It is commonly believed that pregnancy is a time of good mental health; in fact, research suggests that depression during pregnancy is relatively common, occurring in up to 10% of pregnant women and its occurrence may also have an impact on baby outcome; it is therefore an important area for further research.

We are particularly interested in the endocrine system known as the hypothalamic-pituitary-adrenal (HPA) axis. The HPA axis is sometimes known as the “stress system” because it is activated by stress; we can measure the level of hormones from this system in the body. Cortisol is a major hormone from this “stress system”; during normal pregnancy, levels of cortisol become very high and are linked to the timing of birth. Of particular importance is that abnormally high levels of cortisol in pregnancy may be associated with premature birth and lower birth-weight babies. Depression is also associated with high levels of cortisol. Our previous research has suggested that pregnant women who are also depressed tend to have higher levels of cortisol & related hormones than those who are not depressed; also that their babies may have higher levels of cortisol and have a different hormone response to stress than the babies of women who have not been depressed in pregnancy. We wish to study this further,

and look at other hormones related to this stress system and the way that genetic material (DNA) might influence the “stress system”.

### **Why have I been invited?**

You have been invited to participate because you are pregnant and routine screening at your initial meeting with your midwife either has not identified you as someone who is suffering from depression or has identified you as someone who may be at risk of developing, or actually suffering from, depression. At Kings College Hospital, pregnancy services are linked closely with a team of specialists concerned with the mental health of pregnant women and new mothers. In total, we will include 204 pregnant women; 62 with depression and 142 who are not depressed; we will also include their babies after they are born.

### **Do I have to take part?**

It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason; this would not affect the standard of care you receive.

### **What will happen to me and my baby if I take part?**

Your participation will be for up to 18 months, the study will go on for 3 years in total. There will be up to 5 study visits, each visit lasting from 30 minutes to 4 hours:

**Visit 1** occurs when you are about 25 weeks pregnant. You will be seen by a clinical researcher who will ask you some background questions such as age, number of children, employment and ethnic origin, life events and childhood experiences. You will also complete some brief questionnaires, *a cognitive assessment*, and be asked about any symptoms of depression/anxiety. You will have a blood test to look at hormone levels and DNA for genetic studies (30mls blood - about 2 tablespoons). The researcher may also obtain background information from your medical notes. You will be asked to provide 6 specimens of your saliva on one day, during the week after this visit. You will be shown how to do this at visit 1. We are looking at cortisol (“stress hormone”) levels in saliva samples.

When you are about 32 weeks pregnant we will ask you to repeat the saliva samples and complete some brief questionnaires and post them back to us. There is no need for a visit at this stage.

Following the delivery of your baby, the midwives will take a small section of the umbilical cord or some blood from the umbilical cord after it has been removed from your baby. We will use this to look at the baby’s DNA for genetic studies. A study visit is not required at this stage; the sample will be collected by the researcher at a later point.

**Visit 2** occurs 6 days after your baby is born. A clinical researcher will visit you at home to assess your baby’s behaviour; they will use a standardised rating scale to make this assessment,

which takes about 30 minutes. The researcher will collect a specimen of your baby's saliva shortly before and after the assessment, to look at levels of the stress hormone - cortisol, cotinine (a marker of exposure to tobacco) and DNA, and ask you to complete some brief questionnaires.

**Visit 3** occurs the day before your baby is due for routine immunizations, 8 weeks after birth. At this time, as for visit 1, we will evaluate any symptoms of depression/anxiety. We will also look at the interactions between you and your baby; to do this we will make a 3-5 minute video recording at your home, you will be asked to play and talk to your baby as you normally would. The video data will be analysed using existing, validated observational scales by a trained observer.

We will also obtain saliva samples from your baby, to look at "stress hormone" levels, cotinine and DNA. The clinical researcher will meet with you and your baby when you attend for the baby's routine vaccinations, and show you how to obtain the sample by inserting a cotton swab between your baby's upper lip & gum prior to & 20 minutes after the immunization. We would then ask you to repeat this procedure twice on the following day, 12 hours apart and in between feeds. You will also be asked to provide 6 of your own saliva samples on the day after your baby's vaccination.

**Visit 4** occurs the day before your baby is due for routine immunizations at one year of age. At this time, as for visit 3, we will evaluate any symptoms of depression/anxiety and observe interactions between you and your baby. We will also make an assessment of your child's development at that stage, using a standardised rating scale. We will obtain saliva samples from you and your baby as for visit 3.

The study assessments are over and above those involved in standard care; normal treatment will not be withheld during the study and will continue as needed after this. All video recordings are treated as confidential, will not be used for commercial purposes and will be destroyed when the study is completed.

#### **Expenses and payments.**

You will be reimbursed for travel expenses you incur in attending for study visits and as a token of our appreciation you will receive a £20 gift voucher at the end of the study.

#### **What will I have to do?**

If you wish to take part in the study, you will be asked to sign the consent form at the end of this document; you will be given a copy to keep. You should be prepared to undertake the 4 study visits, as detailed above, either in your own home or at the hospital. Please also consider that in agreeing to participate, you are also providing consent on behalf of the baby you are expecting. If you have recent or current participation in other research studies please consider whether you should also participate in this study.

**What are the possible disadvantages and risks of taking part?**

You may experience some discomfort and/or bruising from the blood test. Although it is not painful, your baby may experience some distress on collection of saliva samples.

You may find the study visits/procedures inconvenient, particularly after your baby is born, as this is often a busy period for new mothers.

During the study, it is possible that other conditions are discovered of which you were unaware, which may have implications for your future health, or otherwise impacts on your interests. If anything is identified, your GP or hospital consultant will be informed, with your agreement.

**What are the possible benefits of taking part?**

There are no direct benefits to you of taking part in the study; however the knowledge gained from this study may be of help to other people in the future.

**What if there is a problem?**

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed; detailed information on this is given in Part 2.

**Will my taking part in the study be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence; details are included in Part 2.

**If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.**

**PART 2****What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (tel. 020 7848 5009). If you remain unhappy & wish to complain formally, you can do this through the NHS Complaints Procedure; details can be obtained from the hospital.

In the event that something does go wrong & you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against King's College Hospital Foundation NHS Trust or the study sponsor, King's College London, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

**Will my taking part in this study be kept confidential?**

Yes, your confidentiality will be safeguarded during and after the study, which is conducted in accordance with the Data Protection Act 1998.

An identification code will be allocated to you and later to your baby. The information we collect will be recorded and put into electronic databases using this code rather than your name. Paper and electronic records are stored securely at the Institute of Psychiatry; the custodian of all study materials is Dr Carmine Pariante (Chief Investigator).

The researcher will have access to your clinical notes, and those of your baby, and by signing the consent from you will be giving consent for the researcher to examine your notes and those of your baby.

Study data will be analysed and results will be submitted for publication; your identity will not be revealed. Study data will be retained and may be used in future studies, if this happens, further Research Ethics Committee approval will be sought.

Authorised persons such as researchers, sponsors, regulatory authorities and Research and Development audit will have access to view identifiable data, for monitoring of the quality of the research.

Study data will be retained for 10 years after completion of the study; and will be disposed of securely.

You have the right to check the accuracy of data held about you and correct any errors according to local law and procedures.

### **Involvement of the General Practitioner/Family doctor (GP)**

If you consent, we will write to your GP to inform them of your participation, and provide a brief study outline.

### **What will happen to any samples I give?**

All samples from you and your baby will be processed then stored prior to analysis using the identification code already described. The researchers and laboratory scientists will have access to the samples; the researcher will be able to link your other study data to data from the analysis of your sample by the identification code. All samples will be destroyed once the study is completed.

### **Will any genetic tests be done?**

Yes, we will look at genetic material (DNA) which might be relevant to the development of stress and depression.

### **What will happen to the results of the research study?**

The data and results from this study may be published in medical journals or used in scientific reports and may be communicated to the regulatory authorities. You will not be identified by name. Once the study has been completed, a report of the findings will be prepared for participants; you can request a copy using the contact details below.

### **Who is organising and funding the research?**

The Chief Investigator, Dr Carmine M. Pariante is organising the research, which is sponsored by the Institute of Psychiatry, King's College London. Funding is being sought from medical research charities.

**Who has reviewed the study?**

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing & dignity. This study has been reviewed & given favourable opinion by The Kings College Hospital Research Ethics Committee.

**Further information and contact details.**

Chief Investigator:

Dr Carmine M, Pariante  
Head of the Joint Sections of Perinatal Psychiatry & Stress, Psychiatry and Immunology Institute of Psychiatry  
Reader, MRC Clinician Scientist Fellow  
Division of Psychological Medicine and Psychiatry  
Centre for the Cellular Basis of Behaviour,  
Room 2-055  
The James Black Centre  
125 Coldharbour Lane  
London SE5 9NU

Tel. 020 7848 5009

You will receive a copy of the information leaflet and signed consent form to keep.

**Thank you for reading this information sheet.**

# King's College Hospital

NHS Trust

## Consent Form

**Title: Does the maternal stress system during pregnancy modify stress responses in babies following birth?**

Participant Identification Number: _____ - _____	Please initial each box
I confirm that I have read & understood the participant information sheet dated <b>03.10.11</b> ( <i>version 4.1</i> ) for the above study. I have had the opportunity to consider the information, ask questions & have had these answered satisfactorily.	
I understand that my participation is voluntary & that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
I understand that relevant sections of my medical notes & data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
I agree to my GP being informed of my participation in the study.	
I agree that my GP or hospital consultant will be informed if, during the study, other conditions are discovered of which I was unaware.	
<b><i>I agree to give samples of blood, saliva or hair for the above study. I understand how the samples will be collected and that giving the sample is voluntary.</i></b>	

<p><i>I understand that the samples I give will be used (hormone and genetic analysis) for research rather than clinical purposes, and that these results will have no implications for me personally.</i></p>		
<p><i>I agree that I may be contacted in the future regarding the study, should the research be extended, but I am under no obligation to participate. I understand that information held by the NHS and records maintained by the General Register Office may be used to keep in touch with me.</i></p>		
<p>I agree to take part in the above study, and that my baby will be included after birth.</p>		

**Name of Participant:** \_\_\_\_\_

**Signature of Participant:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Name of Investigator:** \_\_\_\_\_

**Signature of Investigator:** \_\_\_\_\_ **Date:** \_\_\_\_\_