Clinical evidence tables for review question: What interventions in the postnatal period are effective at promoting emotional attachment?

Table 4: Clinical evidence table

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Guedeney, A., Wendland, J., Dugravier, R., Saias, T., Tubach, F., Welniarz, B., Guedeney, N., Greacen, T., Tereno, S., Pasquet, B., Impact of a randomized home-visiting trial on infant social withdrawal in the CAPEDP prevention study, Infant Mental Health Journal, 34, 594-601, 2013 **Ref Id** 885246	**Sample size** N=440 women randomised to intervention group (n=222) or comparison group (n=218). At 18 month follow-up, n=90/222 and n=62/218 were included in the analysis. **Characteristics** Age (median): 22.3 years; Participants with less than 12 years of schooling: 307 (83.9%); 99 (27.1%) declared that they were planning to bring up their child without the child's father.	**Interventions** <u>Intervention group:</u> In addition to usual care and assessment visits, families received the Parental Skills and Attachment in Early Childhood: Reducing Mental Health Risks and Promoting Resilience (The Competences parentales et Attachement dans la Petite Enfance: Diminution des risques lies aux troubles de sante mentale et Promotion de la resilience (CAPEDP)) home visiting program. It is as an evidence-based, home-visiting, infant	**Details** <u>Randomisation</u> After completing baseline screening and informed consent procedures, participants were randomly and alternatively assigned to either the intervention or the usual care group using a computer-generated randomisation sequence, stratified by recruitment centre, with random block sizes of 2, 4, or 6 participants. <u>Concealment</u> Investigators, psychologists performing the CAPEDP intervention, and participants were blinded to assignment before, but not after randomisation.	**Results** <u>The Alarm Distress Baby Scale (ADBB) at child age 18 months in women with Edinburgh Postnatal Depression Scale Score >11 or ≤11 (mean (SD))*:</u> Intervention Group/EPDS>11 (n=38): 3.3 (3.9) Intervention Group/EPDS≤11 (n=52): 2 (2.6) Control Group/EPDS>11 (n=27): 3.3 (4.5) Control Group/EPDS≤11 (n=35): 4.1 (4.7) *Edinburgh Postnatal Depression Scale	**Limitations** Risk of bias assessed with Cochrane risk of bias tool for randomised trials Selection Bias: Low risk Performance Bias: High risk (investigators, psychologists performing the intervention and participants were blinded to assignment before, but not after randomisation) Detection Bias: low risk Attrition Bias: High risk (data at 18 months was available for n=90 (40.5%) in the intervention group and for n=62 (28%) in the

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Country/ies where the study was carried out France **Study type** RCT **Aim of the study** To measure the impact of the intervention on children's sustained social withdrawal behaviour at 18 months of age. **Study dates** Not reported **Source of funding** Not reported	**Inclusion criteria** Young mothers (<26 years of age) and primiparous, with sufficient fluency in French to be able to understand the informed consent procedure, and had at least one of three additional risk criteria concerning their future child's mental health: planning to raise the child alone, low socioeconomic status (defined as receiving welfare benefits, or being close to the poverty threshold, that is with an income of ≤800 euros per month), and having less than 12 years of schooling. **Exclusion criteria** Not reported	mental health promotion program carried out in France. The intervention was conducted by a team of supervised psychologists with specific training on working alliance skills, early child development, attachment issues, and health promotion and prevention during pregnancy. Mothers were recruited in 10 public hospital maternity wards. The intervention was manualised and tailored to each family's needs. It consisted of home visits during pregnancy and up to the child's second birthday, with decreasing frequency of visits over time: 6 visits during the antenatal period, 8 in the first 3 months' postpartum, 15 between the fourth and twelfth months' postpartum, and another 15 during the	Outcome assessors were blinded to assignment, and no investigators, psychologists, or participants had any knowledge of aggregate outcomes at any point during the course of the study. Psychologists who assessed the families were not involved in any aspect of care and had no knowledge of the family's group assignment. group. <u>Outcomes</u> The Alarm Distress Baby Scale (ADBB) The scale consists of 8 items and aims to assess prolonged reactions of social withdrawal in infants. The 8 items are: facial expression, eye contact, general level of activity, self-stimulation gestures, vocalizations, rapidity of response to stimulation, relationship with the observer, and attractiveness to the observer. Each item is rated on a scale of 0 (no	was used to assess **prenatal** depression. Total scores range from 0 to 30; higher scores indicate higher levels of depressive symptoms. A cut-off score of >11 was chosen by the authors because it had good sensitivity (0.80) and specificity (0.80).	comparison group; reasons for attrition: no evaluation visit during the first year, refusal after inclusion, missing data, excluded (baby deceased or medical interruption of pregnancy), included wrongly, lost consent forms, moved away; mothers with a greater number of risk factors for later infant mental health problems were significantly more likely to dropout of the program, with comparable dropout rates in the intervention and the comparison groups)

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		child's second year of life, resulting in a total of 44 home visits per family. Comparison group: Usual care and assessment visits at participant's home across the study period. All families, whether they were in the intervention group or in the control group, could access usual care.	unusual behaviour) to 4 (very unusual behaviour), resulting in 0 as the minimum and 32 as the maximum ADBB total score; the higher the ADBB score, the greater the signs of social withdrawal shown by the infant. Statistical analysis Modified intention to treat principle (in participants with at least one evaluation visit during the first year) Follow-up At 18 months postpartum		
Full citation Hans, S. L., Thullen, M., Henson, L. G., Lee, H., Edwards, R. C., Bernstein, V. J., Promoting Positive Mother-Infant Relationships: A Randomized Trial of Community Doula Support For Young Mothers, Infant Mental Health Journal, 34, 446-457, 2013	**Sample size** N=248 randomised to Doula group (n=124) or control group (n=124). n=107 and n=112 were analysed at 12 month follow-up in Doula group and control group, respectively. **Characteristics** All participants were African American. 94 % of the participating	**Interventions** Intervention group: The program was established 1 year in advance of the planned start of the study to ensure that services were being appropriately delivered before the beginning of the study. 4 African American doulas worked in the program. The doulas each had previous experience as helpers, through	**Details** Randomisation Immediately following completion of the baseline interview, participants were randomly assigned to either intervention or control groups. Randomisation took place in blocks of 4, 6, or 8 (with equal numbers to intervention and comparison group within a block) to ensure balanced numbers in the 2 groups throughout the study period. Randomisation was done	**Results** Parent-child interaction assessed using The Parent–Child Observation Guide (PCOG) at child-age 12 months*: Mother Variables (mean (SD)): Mother sensitive responsiveness: Doula group (n=107): 7.75 (1.56) Control group (n=112): 7.65 (1.44)	**Limitations** Risk of bias assessed with Cochrane risk of bias tool for randomised trials Selection Bias: Low risk Performance Bias: Low risk Detection Bias: Low risk Attrition Bias: High risk (data at 12 months was available for n=107 (86%) in the intervention group

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Ref Id 823139 **Country/ies where the study was carried out** USA **Study type** RCT **Aim of the study** To examine the efficacy of a community doula intervention in supporting behavioural, attitudinal, and emotional aspects of the early parent–child relationship. **Study dates** Not reported	women were receiving Medicaid. Age (mean (SD)): Doula group = 18.2 (1.7), intervention group = 17.9 (1.7); Private health insurance: Doula group = 6 (4.8%), intervention group = 9 (7.3%); Mother Expecting First Child: Doula group = 110 (88.7%), intervention group = 109 (87.9%) Mother in School at Enrolment: Doula group = 67 (54.0%), intervention group = 68 (54.8%) Baby Gestational Age (in weeks) at Enrolment: Doula group = 23.3 (4.6), intervention group = 23.8 (5.3) **Inclusion criteria** Pregnant women attending two affiliated prenatal clinics, one	counselling pregnant teenagers at their churches, working as peer lactation counsellors, or working as home health care assistants, but had no formal training as doulas or as child development professionals prior to being hired by this program. The doulas participated in an intensive 10 week training session provided by the Chicago Health Connection, which was a developer of the community doula model and offers training to community-based doula programs nationally. Doulas were supervised in their work by an experienced paediatric nurse who also had been trained as a doula. Participating mothers were assigned to one of the four doulas by the supervisor. Doulas	from a series of sealed opaque envelopes prepared by the biostatistician before the study was begun, each labelled with a sequential subject identification number and each containing an assignment to either the intervention group or the comparison group. Concealment Investigators and staff members responsible for recruitment, interviewing, or providing intervention were not able to influence the process of assignment to the intervention group. Outcomes Parent-child interaction The Parent–Child Observation Guide (PCOG) was used to code parent–child interaction from the video recordings made at the 4-, 12-, and 24 month sessions. It consists of multi-item scales and addresses interaction that is occurring in general social interaction.	Mother encouragement and guidance: Doula group (n=107): 4.82 (1.87) Control group (n=112): 4.51 (1.84) Mother prompt responsiveness to upset (for children who displayed upset): Doula group (n=14): 0.64 (0.5) Control group (n=14): 0.36 (0.5) Child Variables (mean (SD)): Child positive involvement with mother: Doula group (n=107): 5.63 (2.04) Control group (n=112): 5.7 (1.79) Infant displayed no uncomfortably long period of distress: Doula group (n=107): 0.98 (0.14) Control group (n=112): 0.96 (0.21)	and for n=112 (90%) in the comparison group; attrition was related to the inability to locate mothers, some declined to participate in follow-up interviews, few babies die due to sudden infant death syndrome, and some mothers lost custody of their children because of child endangerment); sample retention was not statistically different between the 2 trial groups).

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Source of funding Not reported	located in a community health centre and one in a nearby teaching hospital, were approached to participate in the study if they were under the age of 22 and were less than 34 weeks gestation. **Exclusion criteria** Not reported	initiated contact with the participants by telephone and then made an appointment to meet at the participant's home. Doulas scheduled weekly visits with each woman throughout her pregnancy and until 3 months postpartum. These visits occurred at mothers' homes, at the prenatal clinic, and at specialty clinics, such as for ultrasound examination. Doulas also joined the mother at the hospital during labour and birth. Mothers were encouraged to call their doulas when they went into labour. The average mother in the doula group received 2.49 prenatal home visits from her doula with an average duration of 56 min and 3.82 prenatal clinic visits with her doula with an	Mother Variables: Mother sensitive responsiveness Mother encouragement and guidance Mother prompt responsiveness to upset (for children who displayed upset) Child Variables Child positive involvement with mother Infant displayed no uncomfortably long period of distress The PCOG forms used for the 4- and 12 month-old infants also include a single dichotomous item to assess whether children displayed "no uncomfortably long period of upset" and whether the parent responded to child upset with prompt responsiveness (with parents whose children did not cry not coded on this scale). <u>Statistical analysis</u> Intention to treat <u>Follow-up</u>	*items were coded dichotomously 0=not observed, 1=observed, so assume higher number is better	

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		average duration of 61 min. The mean amount of contact across settings prenatally was 11.6 hr (SD = 12.0, range = 0–70.9), with a mean of 1.8 hr (SD = 2.0) of contact focused on preparing for parenting/childcare. Doulas made an average of 12 contacts with each mother during the 3 months postpartum and the mean number of hours of contact postnatally was 10.2 (SD = 6.6, range = 0–31.5), with a mean of 4.3 (SD = 3.1) hr of contact focused on parenting/childcare. Comparison group: Received routine medical and social services.	Follow-ups were at the time points when the infant was 4 months, 12 months, and 24 months of age.		
Full citation Kemp, L, Harris, E, McMahon, C,	**Sample size** N=208 pregnant women randomised to sustained nurse home visiting	**Interventions** All participating women received usual antenatal	**Details** Randomisation Eligible mothers were randomised to the	**Results** Parent–child interaction during free play at child-age 18	**Limitations** Risk of bias assessed with Cochrane risk of bias tool for randomised trials

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Matthey, S, Vimpani, G, Anderson, T, Schmied, V, Aslam, H, Zapart, S, Child and family outcomes of a long-term nurse home visitation program: a randomised controlled trial, Archives of Disease in Childhood, 96, 533-540, 2011 **Ref Id** 698828 **Country/ies where the study was carried out** Australia **Study type** RCT **Aim of the study** To investigate the impact of a long-	intervention (n=111) or to comparison group receiving usual care (n=97). N=108 analysed at 18 month follow-up, no sample size for each group reported. **Characteristics** Mean age (SD): intervention = 27.6 (6.7); comparison = 27.7 (5.9). Married (registered marriage): intervention = 67 (62%); comparison = 62 (67%); n=7 missing data Parity >=1: intervention = 80 (72%); comparison = 63 (65%). Country of birth Australia: intervention = 56 (50%); comparison = 50 (52%). Number of risk factors: One: intervention = 56 (50%); comparison = 49 (50%);	midwifery, obstetric and birthing services. Intervention group: Women received an average of 16.3 (range 0–52) visits, each of 60–90 min duration, by a child health nurse commencing at on average 26 weeks gestation (range 12–40), and continuing to their child's second birthday (average duration of participation in program to child-age 57.0 weeks (range 0–122): 82% visited antenatally, 95% visited in the first year postnatally, and 53% visited in the second year). Comparison group: Comparison group participating women were expected to receive a home visit by a child health nurse within 2 weeks of giving birth, in accordance with	intervention or comparison group prior to collection of baseline data. No details provided. Concealment Not reported Outcomes Parent–child interaction during free play (sensitive stimulating parenting, detached flat parenting, child engagement) observed in a structured clinic environment at child-age 18 months, measured using the National Institute for Child Health and Development scales of parent–child interaction. Statistical analysis Intention to treat Follow-up Data were collected antenatally on recruitment, and then at 1, 6, 12, 18 and 24 months postnatally.	months, measured using the National Institute for Child Health and Development (NICHD) scales of parent–child interaction: Sensitive stimulating parenting** (mean (SD)): Intervention group (n=60): 9.57 (2.47) Comparison group (n=50): 10.16 (2.85) Detached flat parenting** (mean (SD)): Intervention group (n=60): 3.95 (1.58) Comparison group (n=50): 3.63 (1.47) Child engagement** (mean (SD)): Intervention group (n=60): 6.88 (1.40) Comparison group (n=50): 6.63 (1.25)	Selection Bias: High risk (no information provided how women were randomised to intervention and comparison groups). Performance Bias: Unclear risk (no information provided whether personnel were aware of the group allocation). Detection Bias: Unclear risk (no information provided whether researchers assessing outcomes were aware of the group allocation) Attrition Bias: High risk (data at 18 months was available for n=60 (54.1%) in the intervention group and for n=50 (51.5%) in the comparison group; no reasons for attrition given). Other bias: no information provided what scale was used to measure sensitive stimulating parenting, detached flat parenting and

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term nurse home visiting program, embedded within a universal child health system, on the health, development and well-being of the child, mother and family. **Study dates** Not reported **Source of funding** The trial was funded by the Australian Research Council (LP0560285), Sydney South West Area Health Service, the NSW Department of Community Services and the NSW Department of Health.	2 or more: intervention = 55 (50%); comparison = 48 (50%). **Inclusion criteria** Mothers were eligible to participate if they did not require the use of an interpreter, and reported one or more of the following risk factors for poor maternal or child outcomes in their responses to routine standardised psychosocial and domestic violence screening conducted by midwives for every mother booking in to the local hospital for confinement: • maternal age under 19 years; • current probable distress (assessed as an Edinburgh Depression Scale score of 10 or more) (as a lower cut-off	standard practice in New South Wales.		*Not clear from the paper the direction of the scale	child engagement, so the direction of the scale is not clear. No statistical comparison was made between mothers who dropped out of the study and those who remained.

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	score was used than the antenatal validated cut-off score for depression, the term 'distress' is used rather than 'depression'; use of this cut-off to indicate those distressed approximated the subgroups labelled in other trials as 'psychologically vulnerable' or as having 'low psychological resources'); • lack of emotional and practical support; • late antenatal care (after 20 weeks gestation); • major stressors in the past 12 months; • current substance misuse; • current or history of mental health problem or disorder;				

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	• history of abuse in mother's own childhood; • history of domestic violence. **Exclusion criteria** Not reported				
Full citation Walkup, Jt, Barlow, A, Mullany, Bc, Pan, W, Goklish, N, Hasting, R, Cowboy, B, Fields, P, Baker, Ev, Speakman, K, Ginsburg, G, Reid, R, Randomized controlled trial of a paraprofessional-delivered in-home intervention for young reservation-based American Indian mothers, Journal of the American Academy of Child and Adolescent	**Sample size** N=167 pregnant women were randomised to Family Spirit intervention (n=81) or Breastfeeding/nutrition education program (n=86). At 12 month follow-up, 35/81 (43%) and 30/86 (35%) were included in the analysis, respectively. **Characteristics** Age (median) for the whole study population: 18 years	**Interventions** Mothers received home-visiting lessons from 28 weeks' gestation to 6 months postpartum and were evaluated with their children at baseline and 2, 6, and 12 months postpartum. Intervention group: Family Spirit intervention The curricular content for the Family Spirit intervention was based on recommendations and standards documented in the American Academy of Pediatrics' Caring for Your Baby and Child:	**Details** Randomisation Expectant young American Indian mothers were randomised (1:1) to one of two home-visiting interventions: the Family Spirit intervention versus a breastfeeding/nutrition education program. Prospective participants were recruited from prenatal and school-based clinics in four Indian Health Service catchment areas on the Navajo and White Mountain Apache reservations in New Mexico and Arizona. Follow-up of study participants was completed in May 2005. Incentives in the form of gift	**Results** Social emotional problems and competencies of the infant at 12 months, measured using Infant Toddler Social Emotional Assessment (ITSEA)*: Externalising domain (includes activity/impulsivity, aggression/defiance, peer aggression (mean (SD)): Intervention group (n=35): 0.39 (0.29) Control group (n=30): 0.57 (0.27) Internalising domain (includes	**Limitations** Risk of bias assessed with Cochrane risk of bias tool for randomised trials Selection Bias: High risk (no information provided how women were randomised to intervention and comparison groups; only stated that the website http://randomization.com w as used) Performance Bias: High risk (participants and interventionist were aware of the group allocation) Detection Bias: Unclear risk (no information

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Psychiatry, 48, 591-601, 2009 **Ref Id** 886054 **Country/ies where the study was carried out** US **Study type** RCT **Aim of the study** To evaluate the efficacy of a paraprofessional-delivered, home-visiting intervention among young, reservation-based American Indian mothers on parenting knowledge, involvement, and maternal and infant outcomes.	Age 14-17 years at time of conception: intervention group = 36 (44%), control group = 43 (50%). Parity >=1: intervention group = 8 (10%), comparison group = 8 (9%). Currently married: intervention group = 9 (11%), comparison group = 5 (6%). Gestational age ≤20 weeks: intervention group = 39 (48), comparison group = 53 (62) **Inclusion criteria** Pregnant American Indian mothers aged 12 to 22 years and with 28 weeks or lesser of gestation. **Exclusion criteria** Women if they had extreme medical, legal,	Birth to Age 5. This includes developmentally timed prenatal and infant-care parenting lessons, as well as family planning, substance abuse prevention, and problem-solving and coping-skills lessons. Mothers were expected to receive 25 home visits, each lasting approximately 1 hour. The intervention was carefully crafted to reflect local native practices but not community-specific traditions or spiritual beliefs. Comparison group: Breastfeeding/nutrition education program. The curricular content included a previously developed breastfeeding/nutrition education program. Mothers were to receive 23 home visits, each lasting approximately 1 hour. The control	cards to a local grocery store were provided to all participants after completion of study assessments. The randomisation sequence was generated by a Web site and stored confidentially by the data manager in Baltimore. Concealment Randomisation was revealed to participants after the baseline assessment. Neither the participants nor the interventionists were blind to study group assignment. Outcomes Infant Toddler Social Emotional Assessment (ITSEA) (range 0–2 for individual items and 0–2 for domains). A 126-item parent report that assesses four primary domains of child behaviour for ages 12 to 36 months including Externalising, Internalizing, Dysregulation, and Competence. It was	depression/withdraw, general anxiety, separation distress, inhibition to novelty): Intervention group (n=35): 0.48 (0.16) Control group (n=30): 0.55 (0.23) Dysregulation domain (includes sleep, negative emotionality, eating, sensory sensitivity): Intervention group (n=35): 0.43 (0.27) Control group (n=30): 0.49 (0.26) Competence domain (includes compliance, attention, imitation/play, mastery motivation, empathy, prosocial peer relations): Intervention group (n=35): 0.94 (0.36) Control group (n=30): 0.95 (0.33) *It is a proxy outcome for baby's social behaviour; scale	provided whether researchers assessing outcomes were aware of the group allocation) Attrition Bias: High Risk (data at 12 months was available for n=35 (43%) in the intervention group and for n=30 (35%) in the comparison group; no reasons for attrition given, only stated that "high attrition rates were likely related to participant factors such as Family Spirit intervention time burden and transient living status post-delivery"; reported rates of attrition were similar in both groups at 12 month follow-up and that participants lost to follow-up at 12 months were not different in baseline demographic characteristics or outcome variables from those still in the study).

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Study dates From 2002 to 2004 **Source of funding** One author has received research grant support from Eli Lilly, Pfizer, and Abbott. He has been a consultant to GlaxoSmithKline, Eli Lilly, and the Cliff's Communities and received speaker's honoraria from the Tourette Syndrome Association. Financial support for this work was provided by the Substance Abuse Mental Health Services Administration (SAMHSA I: Grant No. UD1SP08860, SAMHSA II: Grant No. UD1SP09588),	or social problems that precluded their ability to participate in visits or assessments, for example, women with medical, psychiatric, or substance abuse problems that required extended hospitalization or residential care off the reservation or legal problems that resulted in incarceration. Also those women who were at acute risk for self or others at the time of consent.	condition was selected to provide participating mothers a valuable home-visiting experience and hold constant the amount of supportive contact for mothers, so between-group differences could be linked to intervention content. For both groups: lessons were delivered by trained native bilingual American Indian paraprofessionals to participants in their homes or setting of participant's choice. The paraprofessionals received approximately 500 hours of training in home-visiting methods and curricular content. They were tested on their knowledge through oral and written examinations.	conducted at 12 months postpartum. NGA note: This is a proxy outcome for child's social behaviour. Interpretation of the scale: "On the Externalising, Internalising, and Dysregulation scales, a T-score of 65 or higher are termed "of concern". T-scores of 35 or lower on the Competence scale are also termed "of concern" (Baxter, 2007)" (from: https://cloudfront.ualberta.ca/-/media/ualberta/faculties-and-programs/centres-institutes/community-university-partnership/resources/tools---assessment/itseajun2012.pdf). <u>Statistical analysis</u> Multivariate generalised linear mixed models <u>Follow-up</u> Both groups were assessed at 4 intervals: baseline (~28 weeks' gestation), and 2, 6, and 12 months postpartum	interpretation: the higher the worse **Adjusted for age, parity, gestational age, educational status, whether the participant resided with her partner, whether her partner was also enrolled in the Family Spirit program, and study site	**Other information** Proxy outcome for child's social behaviour

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and the Ford Foundation, the Annie E. Casey Foundation, and the C.S. Mott Foundation.					

ADBB: Alarm Distress Baby Scale; CAPEDP: Competences parentales et Attachement dans la Petite Enfance: Diminution des risques lies aux troubles de sante mentale et Promotion de la resilience (home visiting program); EPDS: Edinburgh Postnatal Depression Scale; ITSEA: Infant Toddler Social Emotional Assessment; NGA: National Guideline Alliance; NICHD: National Institute for Child Health and Development; NSW: New South Wales; PCOG: Parent-Child Observation Guide; RCT: randomised controlled trial; SD: standard deviation