ORIGINAL ARTICLE

Randomised trial of a parenting intervention during neonatal intensive care

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Objective: To evaluate the influence of parenting intervention on maternal responsiveness and infant neurobehavioural development following a very premature birth.
Design: Cluster-randomised controlled trial, with a crossover design and three-month washout period.
Setting: Six neonatal intensive care units.
Patients: Infants born <32 weeks' gestation.
Intervention: The Parent Baby Interaction Programme (PBIP) is a supportive, educational intervention delivered by research nurses in the neonatal intensive care unit, with optional home follow-up for up to six weeks after discharge.
Main outcome measures: Parenting stress at 3 months adjusted age, as measured by the Parenting Stress Index (PSI). Other outcomes included the Neurobehavioural Assessment of the Preterm Infant (NAPI) and maternal interaction as assessed by the Nursing Child Assessment Teaching Scale (NCATS) and the responsivity subscale for Home Observation for Measurement of the Environment (HOME).
Results: 112 infants were recruited in the intervention phases and 121 in the control phases. Mean standardised NAPI scores at 35 weeks did not differ between the PBIP and control groups. Both groups had low but similar NCATS caregiver scores before discharge (36.6 in the PBIP group and 37.4 in control, adjusted mean difference −0.7, 95% CI −2.7 to 1.4). At three months, adjusted age mean PSI scores for the PBIP group were 71.9 compared with 67.1 for controls (adjusted mean difference 3.8, 95% CI −4.7 to 12.4). NCATS scores and HOME responsivity scores were similarly distributed between the groups.
Conclusion: This early, nurse-delivered, parent-focused interaction programme intervention had no measurable effects on short-term infant neurobehavioural function, mother–child interaction or parenting stresses.

Infants born very preterm at less than 32 weeks' gestation have poorer neurobehavioural outcomes than those born at term, including poorer school performance and higher rates of attention deficit disorder.[1 2] Although brain abnormalities may account for some of these cognitive and behavioural difficulties, the child's social environment is also strongly predictive of outcome.[3] The quality of early parenting has been shown to be an important determinant of later development in children born prematurely or with low birth weight.[4 5] Mothers of fragile infants are likely to be under significant emotional pressure.[6 7] Within the neonatal intensive care unit, disruption to the parental role, the behaviour and appearance of the infant, and disturbing sights and sounds within the unit all contribute to parental distress.[8] Such stress reduces maternal sensitivity to infant cues[9 10] with negative implications for social and behavioural outcomes.[11]

Parenting interventions can promote sensitive parenting,[12] particularly if targeted at groups in which the child rather than the parent has an identifiable risk factor.[13] The Parent Baby Interaction Programme (PBIP)[14] is a supportive, educational programme for parents of premature infants that aims to promote contingent sensitivity to infant cues, and thus more responsive and developmentally appropriate infant behaviour. By improving infant developmental outcomes and enhancing confidence in the parental role the programme also aims to reduce levels of parental stress, thus further promoting maternal sensitivity.

PBIP was developed from the Avon Premature Infant Project a structured long-term, developmental programme that showed some modest benefits over parental support alone.[15] PBIP focuses on delivering developmental support to parents in the neonatal care unit, at a time when lack of responsibility for infant care can undermine parents' sense of competence[16] and before patterns of interaction have been firmly established. The effectiveness of such an early intervention has yet to be evaluated in a randomised trial.

We hypothesised that PBIP will be associated with more sensitive and responsive parenting, better infant neurobehavioural function and lower levels of parenting stress.

METHODS

The study was approved by the South-West Multicentre Research Ethics Committee, and the local research ethics committee in each participating hospital. This trial is registered with the International Standard Randomised Controlled Trial Register (ISRCTN56341521).

Study design

We conducted a cluster-randomised controlled trial with a crossover design in two regions of the UK, the South West and Trent regions. The rationale for a cluster-randomised design was that individual randomisation would inevitably result in intervention and control mothers mixing, exchanging experiences and

Abbreviations: HOME, Home Observation for Measurement of the Environment; IMD, index of multiple deprivation; NAPI, Neurobehavioural Assessment of the Preterm Infant; NCATS, Nursing Child Assessment Teaching Scale; PBIP, Parent Baby Interaction Programme; PSI(-SF), Parenting Stress Index (short form)

thus "contaminating" the control group with a variable dose of intervention.

Six neonatal centres, three from each region, participated. Within each region, two centres with similar indices of deprivation were paired.[17] The outlier centre from each region formed the third pair. One centre from each pair was randomised by the toss of a coin to recruit babies to the intervention from July 2002 (August 2002 in Trent) for six months (seven months in the South West to meet the recruitment target). The remaining centres recruited to normal care. Following a three-month washout period, the control centres crossed over to intervention and the intervention centres reverted to normal care for a further six months (seven months in Trent to meet the recruitment target). The rationale for a crossover design was to eliminate variation between centres and thus improve precision and power. The rationale for a washout period was to allow mothers from one phase of the trial (intervention or control) to leave the hospital without mixing with mothers from the other phase of the trial. Participants were followed up when the infants reached 3 months adjusted age.

The inclusion criteria for the study were that infants should be born at less than 32 weeks' gestation and admitted to one of the six neonatal centres in the study. Exclusion criteria were an illness incompatible with life and residence outside the study catchment areas.

Measures and procedure

Participants were recruited to the study by a research nurse who also collected demographic and clinical information through mothers' and infants' medical notes and through maternal interviews. Neither the research nurses nor the participants were blind to group allocation. An index of multiple deprivation (IMD)[17] was calculated for each infant by postcode analysis. The IMD score is derived from data on deprivation at the small area level in seven domains, including income, employment and crime. Scores for England range from 0.59 (least deprived) to 86.36 (most deprived) with a median of 17.02.

Primary outcome

Parenting Stress Index short form (PSI-SF)[18]

The Parenting Stress Index (PSI) is a widely used self-report questionnaire which assesses stress in the parent–child system. It has well established validity and reliability[18 19] and has been used with mothers of premature infants.[6 20] The 36-item short form of the PSI (PSI-SF) correlates highly with the full-length PSI ($r = 0.94$) and psychometric evidence supports the internal consistency of its component items.[21] Importantly the PSI-SF has been used successfully with lower socioeconomic groups[21] and with mothers of 3-month-old infants.[10]

The PSI-SF comprises three subscales (parenting distress, parent–child dysfunctional interaction, difficult child). Higher scores indicate poorer function, and the three subscales are summed to produce a total stress score. Total PSI score was used as a primary outcome measure with scores above 85 (80th centile) considered high. The PSI was posted to parents at three months (by corrected age) and collected at a home visit approximately one week later.

Secondary outcomes

Neurobehavioural Assessment of the Preterm Infant (NAPI)[22]

This assessment measures newborn competence in seven functional domains (scarf sign, motor development and vigour, popliteal angle, alertness and orientation, irritability, cry quality and percentage time asleep). Scores were converted to z scores based on age-standardised norms and the seven scores averaged to give a mean z score for each baby. Higher NAPI scores indicate more optimal development. Two trained research nurses administered NAPI at about 35 weeks' gestation. We established reliability by comparing the research nurses' scores with those of an experienced rater (CI) for 11 assessments. Intraclass correlation coefficients (ICC) ranged between 0.86 for irritability and 1.00 for popliteal angle.

Nursing Child Assessment Teaching Scale (NCATS)[23]

NCATS is a widely used, standardised assessment of the quality of caregiver–child interaction. The caregiver is shown a list of sensorimotor skills in ascending order of difficulty and asked to select the first skill on the list which has not yet been acquired by the child (eg, following toy with eyes, grasping a toy, reaching for toy). The caregiver then attempts to teach the child the task and the interaction, which usually takes less than five minutes, is rated on 73 binary items related to child and parent behaviours. Some items also reflect contingency between infant and parent. The child total score comprises the child's clarity of cues subscale and the responsiveness to the caregiver subscale. The caregiver total score was a secondary outcome measure for our study. It comprises combined subscale scores for sensitivity to cues (11 items, eg, caregiver avoids physically forcing child to complete task), response to distress (11 items, eg, caregiver makes sympathetic/soothing noises), social-emotional growth fostering (11 items, eg, caregiver gently pats, caresses, strokes, hugs or kisses child during interaction) and cognitive growth fostering (17 items, eg, caregiver describes perceptual qualities of task materials to the child). Possible caregiver total scores range from 0 to 50 with higher scores indicating more sensitive and responsive interactions. The caregiver total scores have good internal consistency with a Cronbach's α of 0.87. Moreover, NCATS has been validated for the assessment of interactions of children up to 3 years of age.[23] NCATS has been used effectively with both newborn infants[24] and 3-month-old premature infants.[25]

The NCATS assessments were conducted in the week prior to discharge (videotaped by research nurse) and again at a home visit when the infant reached 3 months corrected age (videotaped by psychologist). Each videotaped interaction was rated by the same rater (CS), trained to >90% reliability and blinded to study group. Any uncertainty regarding ratings was resolved by discussion with second blind rater (CG), also trained to >90% reliability. Forty teaching sessions (10%), balanced for time and phase, were re-rated a minimum of six months later. Test-retest reliability for the caregiver total was excellent with an ICC of 0.93.

Home Observation for Measurement of the Environment (HOME)[26]

HOME measures the appropriateness of a child's environment for promoting development. The instrument's responsiveness subscale was used as a secondary outcome measure for this study. Scores range from 0 to 11, with higher HOME scores indicating greater verbal and emotional responsivity. The assessment was made during a home visit at 3 months adjusted age and scored primarily from observation of maternal behaviours (10/11 items). One psychologist (SJ) conducted all HOME assessments in the Trent region (45.5% of total). Most of the assessments in the South West were conducted by one psychologist (41.5% of total) with the remaining conducted by a third psychologist (13% of total). All raters were blind to the group allocation of the participant. Inter-rater reliability was good with 92.9% item agreement for eight assessments.

Intervention[14]

PBIP aims to enhance parents' observations of their baby and sensitivity to cues through a series of activities which follow the progression of care from incubator to home. Activities that are components of PBIP can be classified in four ways: tactile (eg, stroking infant), discussion (eg, infant development), verbal (eg, greeting infant) and observation (eg, identifying different states). It also incorporates some principles of developmental care, such as use of incubator covers to shield infants.

Seven neonatal nurses were trained to deliver the intervention by the clinical trial manager (CI), a senior neonatal nurse and the author of the PBIP programme manual.[14] The research nurses maintained a log for each participant in the intervention phase and these records were reviewed by the clinical trial manager during regular meetings. Although PBIP can involve the whole family, the mother was the principal recipient of the intervention, which was delivered in the neonatal care unit via weekly, one-hour sessions commencing in the first weeks after birth. There was also an option to continue the intervention in the home for up to six weeks after discharge. The overall number of sessions received was largely determined by the length of time needed to deliver the programme and the mother's availability in the neonatal unit. The regular (non-research) nursing staff were not taught PBIP and did not change nursing procedures or support to parents during the intervention period.

Statistical power

The statistical power calculation was based on the PSI total score assuming a mean score of 64.3 and a standard deviation of 17.7.[27] A sample size of 172 (86 in a group) would have 90% chance of detecting a 0.5 SD difference between the groups at $p<0.05$. To allow for possible clustering, we increased the planned sample size by 45% to 250 (125 in a group).[28]

Analysis

To allow for possible similarity between infants born in the same period at the same centre, our primary analysis consisted of a two-stage analysis.[29] In the first stage, for each cluster, the difference (d) between the mean outcome in period 2 and the mean outcome in period 1 was computed. In the second stage, a weighted t test was used to compare the mean of d between clusters which received the experimental intervention in period 2 and clusters which received the experimental intervention in period 1. The estimated treatment effect was half the difference between these means of d. To allow for clusters having different sample sizes, each cluster was weighted in this analysis by $n1 \times n2/(n1+ n2)$ where n1 and n2 are the number of infants in periods 1 and 2, respectively. This approach also ensures that standard errors are valid when twins are enrolled in the study, and as it does not extend easily to assessing interactions, subgroup effects are estimated and interactions are tested using a linear mixed model.[30]

Following the prespecified analysis plan, subgroup analyses were done only for primary outcomes and only for first-time mothers verus not and younger versus older gestational age. Missing values were excluded from the analysis; the results were little changed on adjustment for nine key covariates, so they are valid under a missing at random assumption.[31]

RESULTS

Of the 496 babies born at less than 32 weeks' gestational age and admitted to the study centres, 156 were resident outside the study catchment area and therefore excluded. The numbers of babies excluded in units in the intervention phase and in the control phase were not significantly different. A total of 33 babies died during the consent period. Thus 307 babies were eligible for the study, of whom 233 (76%) were recruited into the study, 112 (80.6%) in the intervention phase and 121 (72%) in the control phase. These babies included 23 pairs of twins. We found no significant differences between consent and non-consented infants in terms of birth weight, gestational age, sex or whether they had been a multiple pregnancy. Participant flow is shown in figure 1.

Maternal demographic characteristics were similar between the groups (table 1). The groups were also well matched in terms of infant characteristics and clinical markers, including the index of multiple deprivation[15] (table 2).

Of the 112 babies in the intervention group, 108 received at least one PBIP session, with a mean (SD) of 8.04 (4.34). The median number of sessions received was 8 (interquartile (IQ) range 5–10.75) with more sessions delivered in the neonatal intensive care unit (median 5, IQ range 2.25–7) than at home (median 2, IQ range 1–4). We did not find any associations between the number of sessions and independent variables such as birth weight, gestational age or index of deprivation. Number of PBIP sessions received was also unrelated to primary and secondary outcome scores including neurodevelopmental status. Number of sessions delivered in the neonatal unit, however, correlated negatively with gestational age ($r_s = -0.35$, $n = 112$, $p<0.001$) and positively with days in hospital ($r_s = 0.51$, $n = 112$, $p<0.001$). This relationship was reversed for number of sessions delivered in the home. PBIP sessions after discharge correlated positively with gestational age ($r_s = 0.31$, $n = 112$, $p<0.001$) and negatively with days in hospital ($r_s = -0.23$, $n = 112$, $p = 0.014$).

Primary outcome

Parenting stress questionnaires were returned for 199/204 infants. Total parenting stress in the intervention and control groups did not differ significantly (table 3). High levels of parenting stress (scores above the 85th centile) were found in mothers of 23 (25.3%) babies in the intervention group and 21 (19.4%) mothers in the control group, compared with the expected 15% in the normative population. Subgroup analyses with the primary outcome measure found no significant difference in intervention effect between first born and other infants ($p = 0.72$) or between more and less premature infants ($p = 0.64$).

Secondary predischarge outcomes

NAPI neurobehavioural assessments were completed for 211/213 infants. The average NAPI z scores or neurophysiologic function in the groups, as measured by the averaged standardised NAPI scores, did not differ significantly (table 3). NCATS scores were available for 196/213 infants. One baby was too ill for assessment, 12 babies were too sleepy, 2 mothers refused to be filmed and 2 tapes could not be analysed due to recording errors. Scores for caregiver total interaction in the intervention and control groups did not differ (table 3). Over a quarter (25 (26.6%)) of mothers in the intervention group and 21 (20.6%) in the control group had scores below the 10th centile, which are considered worrisome (table 3).

Secondary three-month outcomes

NCATS and HOME responsivity assessments were conducted for 200/204 infants. Total NCATS caregiver scores in the intervention and control groups did not differ significantly. At three months' follow-up, 21 (22.6%) in the intervention and 21 (19.9%) in the control group had caregiver scores below the 10th centile cut-off. HOME responsiveness scores in the intervention did not differ significantly from those in the control group (table 3).

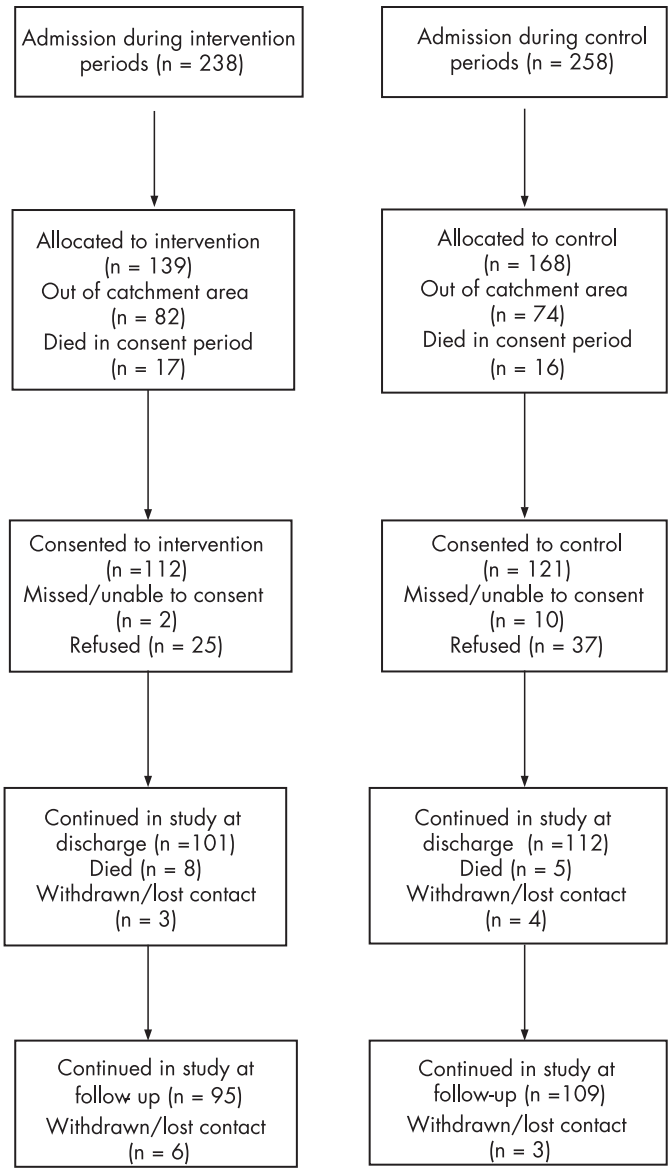

Figure 1 Flow diagram of participants through the study.

DISCUSSION

Despite a controlled parenting intervention, continuing through the neonatal period and after discharge, we were unable to detect any differences on a range of measures of parenting and infant behaviours between the intervention and control. The confidence interval for the primary outcome suggests that the benefit of the intervention is at most 4.7, which is substantially less than the 0.5 standard deviation (approximately 9.6) that we a priori regarded as clinically significant. Thus the lack of statistical significance was not due to low power.

Most successful parenting programmes have been aimed at mothers with specific difficulties such as low socioeconomic status and adolescent pregnancies.[12] The parents in our study were not particularly disadvantaged in this respect, with IMD scores indicating rather lower levels of economic and social disadvantage than the average population. There did, however, appear to be an excess of mothers with worryingly high levels of parenting stress above the cut-off for concern. This suggests that there was a need for support within this group, particularly because other studies of vulnerable children have suggested that levels of parenting stress increase as difficulties and disabilities become more apparent.[18 32]

Table 1 Maternal characteristics

	Intervention (n = 99)	Control (n = 111)
Median age (interquartile range)	30 (24–34)	29 (25–35)
Marital status, n (%)		
Single/divorced	16 (16)	20 (18)
Parity, n (%)		
First baby	53 (54)	64 (58)
Ethnicity, n (%)		
White European	80 (81)	101 (91)
Educational level, n (%)		
No further education	51 (53)*	49 (47)†
Degree or above	18 (19)	18 (17)
Occupational status, n (%)		
Professional or managerial	35 (37)‡	43 (42)§
Semi routine/ routine	29 (31)	32 (31)

*Three missing values; †seven missing values; ‡five missing values; §eight missing values.

There were other indications of the group's vulnerability. For example, ratings for the HOME responsiveness subscale were indicative of difficulties in the area of communication and emotional reinforcement. The mean scores of 8.8 and 9.1, recorded for the intervention and control groups, respectively, could be considered low and are comparable with the mean of 9.1 found by Armstrong *et al* in a group of disadvantaged parents with history of social or psychological difficulties.[33] The NCATS caregiver scores were also markedly low suggesting that, as a group, mothers did not effectively engage in the teaching activity with their infants. This was particularly evident at discharge when nearly a quarter scored below the cut-off level, indicating cause for concern. These results support previous research findings that premature infants receive less stimulation and physical contact from their mothers than full-term infants[34] and that parental interactions are less sensitive and responsive.[23 35]

One explanation for the failure of PBIP to improve mother and infant outcomes may be that the ''dose'' of intervention was too low to influence the mother's attitudes and behaviour compared with other powerful influences on her during the period her baby was in hospital. Armstrong *et al*'s parenting intervention,[33 36] which did demonstrate an effect on parenting stress and HOME scores, used a more extended programme with weekly visits up to six weeks after birth, fortnightly up to three months and monthly up to six months. The average time given to delivering the intervention was less in our study (about 6 h in total) than in Armstrong's study (12 h).[36]

As brief interventions have been found to be effective,[12] a more important factor may have been the timing of the intervention. We felt that the provision of early support would

Table 2 Infant characteristics

	Intervention (n = 112)	Control (n = 121)
Male infant, n (%)	50 (45)	61 (50)
Median birth weight (IQ range)	1120.5 (900–1408)	1220 (935–1498.5)
Weight less than 1000 g, n (%)	38 (34)	38 (31)
Singleton birth, n (%)	81 (72)	96 (79)
Median weeks' gestation (range)	28.5 (23–31)	29 (23–31)
Born <27 weeks' gestation, n (%)	20 (18)	21 (17)
Median days in hospital (IQ range)	56 (39–85.75)	53 (38.5–77.50)
Median Index of Multiple Deprivation (IQ range)	13.7 (9.5–23.4)	14.0 (8.9–21.8)

Table 3 Intervention effects on outcome variables measured before discharge and at 3 months corrected age*)

	Intervention mean (SD)	n	Control mean (SD)	n	Adjusted intervention–control difference (95% CI)†
Before discharge					
NAPI scores at 35 weeks (average of 7 z scores)	*0.40 (0.54)*	*101*	*0.35 (0.65)*	*110*	*0.09 (−0.06 to 0.23), p=0.17*
NCATS cognitive growth fostering	9.5 (3.3)	94	10.1 (3.0)	102	
NCATS maternal sensitivity to cues	9.4 (1.2)	94	9.2 (1.2)	102	
NCATS emotional and social growth fostering	7.9 (1.6)	94	8.1 (1.5)	102	
NCATS maternal response to distress	9.8 (1.6)	94	10.0 (1.6)	102	
NCATS total caregiver score	*36.6 (5.1)*	*94*	*37.4 (4.9)*	*102*	*−0.7 (−2.7 to 1.4)., p=0.43*
3 months corrected age					
NCATS cognitive growth fostering	10.2 (2.9)	93	10.7 (3.2)	106	
NCATS maternal sensitivity to cues	9.6 (1.1)	93	9.5 (1.1)	106	
NCATS emotional and social growth fostering	7.5 (1.5)	93	8.0 (1.6)	106	
NCATS maternal response to distress	10.0 (1.5)	93	10.2 (1.3)	106	
NCATS total caregiver score	37.4 (4.8)	93	38.3 (5.2)	106	−0.8 (−3.6 to 1.9), p=0.45
PSI Difficult child	23.6 (7.1)	91	21.4 (6.8)	108	
PSI Parental distress	27.2 (7.9)	91	26.3 (9.2)	108	
PSI Dysfunctional interaction	21.0 (6.4)	91	19.4 (6.0)	108	
PSI total score	*71.9 (18.9)*	*91*	*67.1 (19.6)*	*108*	*3.8 (−4.7 to 12.4), p=0.28*
HOME responsiveness	*8.8 (1.1)*	*92*	*9.1 (1.5)*	*107*	*−0.2 (−0.9 to 0.5) , p=0.46*

HOME, Home Observation for Measurement of the Environment; NAPI, Neurobehavioral Assessment of the Preterm Infant; NCATS, Nursing Child Assessment Teaching Scale; PBIP, Parent Baby Interaction Programme; PSI, Parenting Stress Index.
*Primary and secondary outcomes in italics.
†Adjusted for cluster-crossover design and for baseline variables (maternal age, maternal education, marital status, parity, gestational age, birth weight, number of fetuses, infant sex and index of multiple deprivation).

be important to promote optimal parenting because more effective maternal coping in the period after birth has been linked to more responsive parenting after discharge.[37] There is emerging evidence, however, that interventions commenced later have greater impact on parent and child outcomes.[12] Indeed in recent studies showing beneficial effects of developmentally focused interventions with mothers of premature infants, the interventions commenced either just before discharge[38] or after discharge.[39] Another issue in the present study may have been the context in which the intervention was delivered. At the time of the study the units in the study did not have resources for developmental care and were limited in their provision of additional contact between mothers and infants (eg, Kangaroo care), which has been shown in non-randomised trials to offer advantages for mothers and babies.[40] Thus the intervention may have conflicted with the ethos of standard nursing care and so had less impact.

Strengths and weaknesses of the study

The study was appropriately powered to detect differences in the primary and secondary outcomes and the groups were extremely well matched in terms of infant and maternal characteristics. There is a possibility of recruitment bias in a cluster-randomised design as recruitment happens after randomisation,[41] but the high recruitment rates, baseline balance and lack of differences in response rates between the two groups are all evidence against such a bias. Measures were chosen to represent valid and reliable indices of the constructs of interest. Excellent reliability was demonstrated for both the NCATS and the HOME parental emotional and verbal responsiveness scale. Researchers were blind to the study allocation of participants.

It may be too early as yet to detect beneficial effects of the programme. A longitudinal study of a supportive parenting intervention with low birthweight infants found that the benefits of early intervention only became apparent after three years of follow up.[42] There was also evidence of a widening advantage for the experimental group in terms of child behaviour and cognitive development by the age of 9 years.

CONCLUSION

This study confirmed the difficulties that mothers of very preterm infants experience in relation to the provision of sensitive and responsive interaction. The intervention we tested

What is already known on this topic

- Very premature infants are vulnerable to cognitive delay.
- Sensitive parenting is associated with improved cognitive outcomes for very premature infants.
- High levels of parenting stress are associated with less sensitive parenting.

What this study adds

- Very premature infants receive less responsive and stimulating care than infants born at term.
- A parenting intervention commenced soon after birth was not effective in enhancing maternal responsiveness or reducing parenting stress in mothers of very premature infants.

made no difference to maternal stress, responsivity or infant neurobehaviour. It is possible that the impact of the intervention becomes apparent later in the study when cognitive function is assessed at 2 years adjusted age.

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AUTHOR CONTRIBUTIONS

CG was involved in preparation of the protocol, trial management, data analysis and drafting of the manuscript. NM and AW were involved in preparation of the protocol, trial management and review of the manuscript. CI was involved in preparation of the protocol, implementation of the trial and data management. TC was involved in preparation of protocol, data monitoring and randomisation. SJ was involved in data collection, data management and review of the manuscript. IW was involved in data analysis and drafting of the manuscript.

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