

DR ALICIA JANE SPITTLE (Orcid ID : 0000-0002-6535-661X)

Article type : Original Article

[Original article: 4 tables; 2 figures]

The role of social risk in an early preventative care programme for infants born very preterm: a randomized controlled trial

ALICIA J SPITTLE^{1,2,3}

KARLI TREYVAUD^{2,3,4,5}

KATHERINE J LEE^{2,6}

PETER J ANDERSON^{2,5}

LEX W DOYLE^{2,3,6,7}

1 Department of Physiotherapy, University of Melbourne, Melbourne; **2** Clinical Sciences, Murdoch Children's Research Institute, Melbourne; **3** Newborn Research, Royal Women's Hospital, Melbourne; **4** Department of Psychology and Counselling, La Trobe University, Melbourne; **5** Monash Institute of Cognitive and Clinical Neurosciences, School of Psychological Sciences, Monash University, Melbourne; **6** Department of Paediatrics, University of Melbourne, Melbourne; **7** Department of Obstetrics and Gynaecology, University of Melbourne, Melbourne, Australia.

Correspondence to Alicia Spittle, 7th Floor, Alan Gilbert Building, University of Melbourne
161 Barry Street, Parkville, VIC 3052, Australia. E-mail: aspittle@unimelb.edu.au

PUBLICATION DATA

Accepted for publication 00th Month 2017.

Published online 00th Month 2017.

This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the [Version of Record](#). Please cite this article as [doi: 10.1111/dmcn.13594](https://doi.org/10.1111/dmcn.13594)

This article is protected by copyright. All rights reserved

AIM To examine the differential effects of an early intervention programme for preterm infants on neurodevelopment and parental mental health according to family social risk.

METHOD One hundred and twenty infants born earlier than 30 weeks' gestation were randomized to early intervention ($n=61$) or control groups ($n=59$). Cognitive, language, and motor outcomes were assessed by blinded assessors at 2, 4, and 8 years, and primary caregivers completed questionnaires on their anxiety and depression. Outcomes at each time point were compared between groups using linear regression with an interaction term for social risk (higher/lower).

RESULTS There was evidence of interactions between intervention group and social risk for cognition at 2 and 4 years, motor function at 4 years, and language at 8 years, with a greater intervention effect in children from higher social risk environments. In contrast, the impact of early intervention on parental depressive symptoms was greater for parents of lower social risk than for those of higher social risk.

INTERPRETATION Effects of early intervention on outcomes for preterm children and their caregivers varied according to family social risk. Family social risk should be considered when implementing early intervention programmes for preterm children and their families.

[First page footer]

© 2017 Mac Keith Press

DOI: 10.1111/dmcn.xxxxx

[Left page footer]

Developmental Medicine & Child Neurology 2017, 59: 000–000

[Right page footer]

Early Intervention for Preterm Infants *Alicia J Spittle et al.*

WHAT THIS PAPER ADDS

- Intervention is associated with better early cognitive functioning for children in higher social risk families.
- Positive effects of intervention for the high risk group were not sustained at school-age.
- Intervention has a greater effect on primary caregiver mental health in the lower social risk group compared with higher social risk.

[Main text]

Infants born very preterm (<32 weeks' gestation) are at increased risk of a range of neurodevelopmental impairments, including cognitive, language, and motor difficulties, which are exacerbated for preterm children raised in socially disadvantaged environments.^{1,2} At school age, preterm children are reported to have difficulties with academic skills such as mathematics and spelling, and higher rates of developmental coordination disorder than their term-born peers.^{3,4} Parents of children born preterm are also at risk of poorer mental health, with both mothers and fathers reported to have elevated symptoms of anxiety and depression compared with parents of healthy term-born peers during the newborn period and into early childhood.^{1,5}

Whereas children born very preterm and their families are a heterogeneous group, with variable neurodevelopmental and mental health outcomes, there are several risk factors known to adversely affect child development and parental well-being, including medical, social, and environmental factors.^{6,7} Medical factors such as brain injury and respiratory disease in preterm infants are well-known risk factors for adverse developmental outcomes. However, social and environmental factors, especially post discharge from hospital, also play a pivotal role in child development. Social risk factors such as separated families, low family income, and low caregiver education levels have been associated with poorer neurodevelopmental outcomes for children born very preterm.^{7,8} Previous research by our team has shown that preterm children who are most vulnerable, that is those with both medical and social risk factors, are underserved by early intervention services, yet these are the children who may benefit the most from services.⁹

Early intervention is an umbrella term for multidisciplinary services commenced early in development (0–5 years) provided to children and their families to promote child health and well-being, enhance emerging competencies, minimize developmental delays, remediate existing or emerging disabilities, prevent functional deterioration, and promote adaptive parenting and overall family function.¹⁰ Early intervention appears to be effective in improving the cognitive, motor, and behavioural outcomes for preterm survivors as well as the mental health of their mothers, although to varying extents.^{10–13} While the evidence is not consistent, the strongest evidence appears to be for interventions that target the parent–child relationship.¹⁴ However, it is unclear whether the benefits of early intervention vary according to family social risk.

We have previously developed and assessed, in a randomized controlled trial, a preventative care programme to improve child developmental outcomes, the parent–infant relationship, and parental well-being for infants born very preterm and their families over the first year of life compared with standard care.¹⁵ The preventative care programme involved nine visits at home with a physiotherapist and psychologist, whereas the control group received standard care. We have

previously published the outcomes of this trial at 2, 4, and 8 years corrected age.^{11–13} The children in the intervention group had better behavioural outcomes at 2 and 4 years than standard care, but this was not sustained at 8 years. There were minimal effects on cognitive and motor outcomes at any time point. Importantly, primary caregivers in the intervention group reported better mental health outcomes at all time points than primary caregivers in the standard care group, with fewer anxiety symptoms at 2 and 4 years, and fewer depressive symptoms at 8 years. The objective of the current study was to explore how the effects of the early-preventative care programme on child cognitive, motor, and language outcomes, and primary caregiver anxiety and depression at 2, 4 and 8 years, varied in relation to social risk of the family.

METHOD

The trial has been registered with the Australian New Zealand Clinical Trials Registry (identifier ACTRN12606000252516).

Participants

One hundred and twenty infants born at less than 30 weeks' gestation between January 2005 and December 2007 were recruited at term-equivalent age from two tertiary neonatal intensive care units in Melbourne, Australia. Ethical approval was obtained from the Human Research Ethics Committees at the Royal Women's Hospital and The Royal Children's Hospital, and parents provided written informed consent to participate. Infants were included in the study if they were born earlier than 30 weeks' gestational age, lived within a 100 km radius of the hospital, and had a parent who could read and speak English. Infants were excluded if they had a congenital abnormality that was likely to have an adverse effect on neurodevelopment. Infants were randomized to the preventative care programme (intervention) or standard care (control) group after informed consent by the primary caregiver and completion of baseline data. Full details of the protocol have been published previously.¹⁵

Baseline data

Comprehensive perinatal data were collected at term-equivalent age. In addition, parents were asked to complete a socio-demographic questionnaire, which included items for the 'Social Risk Index', a tool widely used for measuring family social risk that has been related to developmental outcomes.⁶ Families were classified as being lower (score 0–1) or higher social risk (score ≥ 2), dichotomized around the median score of 1 based upon the sum of six factors that were each assigned a score of 0, 1, or 2: family structure (two caregivers, separated parents, single caregiver), education of primary caregiver (tertiary, 11–12y, <11y), occupation of primary income earner

(skilled, semi-skilled, unskilled), employment status of primary income earner (full time, part time, unemployed/government pension), language spoken at home (English, some English, no English), and maternal age at birth (>21, 18–21, <18y).

Intervention

Infants in the intervention group received a preventative care programme over the first 12 months of life delivered by a physiotherapist and psychologist over nine sessions in the home. The intervention had two key components: (1) generic content that was provided to all families, including strategies for promoting an enriched environment, positive play, general developmental milestones, feeding, sleeping, and parental well-being; and (2) specific content that was targeted to the infant and family based upon goals and/or concerns identified by the parent. Both the control group and intervention group received standard care, which included access to a maternal child health nurse as part of government-funded early-developmental surveillance and access to additional early intervention childhood services if a referral was deemed appropriate from the child's health care team. In the state of Victoria at the time of the trial, access to early intervention services varied greatly; no routine early intervention services were available and families often faced long waiting lists.⁶ It was not ethical to restrict families (control or intervention) from accessing other early intervention services. All families were asked to record access to other early intervention services in the first 12 months, including (but not limited to) physiotherapy, occupational therapy, and speech pathology.

Outcome measures

Children and their parents were invited to participate in follow-up at 2, 4, and 8 years of corrected age at the Royal Children's Hospital, Melbourne. If the family was not able to attend the follow-up, a home visit was offered. Direct assessment of child development was completed by assessors who were blinded to group allocation and perinatal history. Assessment of mental health in parents and behaviour in children was necessarily done using parent report and thus could not be blinded.

Child measures

At 2 years corrected age (range 23–29mo), toddlers were assessed with the Bayley Scales of Infant and Toddler Development (3rd edition), a criterion standard measure of cognitive, language, and motor development.¹⁶ The Bayley Scales of Infant and Toddler Development (3rd edition) is norm-referenced, with a mean of 100 and standard deviation (SD) of 15. Social–emotional functioning was assessed using the Infant Toddler Social and Emotional Assessment, a norm-referenced, parent-report questionnaire.¹⁷ The Infant Toddler Social and Emotional Assessment generates

standard scores (mean 50, SD 10) and clinically significant cut-off scores for four domains (internalizing behaviour, externalizing behaviour, dysregulation, social–emotional competence). Higher scores on dysregulation, internalizing and externalizing, and lower scores on competence indicate more difficulties.

At 4 and 8 years corrected age participants were assessed with the Differential Abilities Scale (2nd edition)¹⁸ and the Movement Assessment Battery for Children (2nd edition).¹⁹ The General Conceptual Ability score of the Differential Abilities Scale (2nd edition) was used to assess general cognitive outcomes and the Verbal Composite score was used to assess language outcomes. The Differential Abilities Scale (2nd edition) is norm-referenced, with both indices having a mean of 100 and SD of 15. The Movement Assessment Battery for Children (2nd edition) is a norm-referenced motor assessment, with the total standard score used to assess motor outcomes (mean 10, SD 3). Social-emotional functioning was assessed at 4 years using the Child Behaviour Checklist,²⁰ and at 8 years with either the Problem Behaviour Index from the Social Skills Improvements Rating Scales or the Total Problem Score from the Strengths and Difficulties Questionnaire.^{21,22} As two different assessment tools were used to assess social–emotional functioning at 8 years, raw scores were used to classify children as having a ‘social–emotional impairment’ if raw scores on either measure were greater than 1 SD above the mean raw scores of a term reference group.¹¹

Primary caregiver well-being

At each time point the primary caregiver’s mental health was assessed using the self-report Hospital Anxiety and Depression Scale.²³ The questionnaire was completed at the follow-up assessment of the child or, if the primary caregiver was unable to attend, the questionnaire was sent via post. Higher scores on the anxiety and depression scales indicate more severe symptoms.

Power calculations

The sample size of the original randomized controlled trial was 120 infants, which provided 80% power to detect a difference of 0.54 SD on the Bayley Scales of Infant and Toddler Development (3rd edition) cognitive scale at 2 years. The analyses in the current paper are post hoc exploratory analyses. Given the original study was not powered for subgroup analyses, trends in the data were explored rather than just using arbitrary *p*-values of 0.05.

Statistical analysis

Data were analysed using Stata 14 (StataCorp, College Station, TX, USA). Child outcomes at each follow-up (2, 4, and 8 years corrected age) were compared between intervention and control groups for children with lower and higher social risk at term-equivalent age using linear regression. Models

were fitted using generalized estimating equations to allow for correlations between twins, with an interaction between group and social risk. Results are represented as means and 95% confidence intervals (CIs) for the intervention and control group for each outcome presented separately for lower and higher social risk, with evidence for the differential effect of the intervention between social risk groups assessed via the interaction term. Parental mental health outcomes from one parent per family were also compared between the groups in those with lower and higher social risk at baseline using simple linear regression, again including an interaction between group and social risk.

RESULTS

Of the 120 infants initially enrolled in the study, 61 were randomized to the intervention, with 21 (34%) classified as higher social risk, and 59 were randomized to the control group, with 26 (44%) classified as higher social risk (Fig. 1). Baseline characteristics were similar in the two groups (Table I). Two infants in the intervention group died before 2 years. Of the 92 (78%) surviving infants who provided information regarding access to other early intervention services at 2 years (Table I), a similar proportion accessed early intervention services in the control and intervention groups. Follow-up rates at 2, 4, and 8 years were similar between the groups (higher risk 94%, 87%, and 75% respectively; lower risk 93%, 89%, and 89% respectively). There was no difference in perinatal characteristics (gestational age, birthweight, sex) for those children who did and did not attend follow-up between groups at each time point.

There was evidence for differential intervention effects according to social risk for cognitive outcomes at 2 and 4 years (Table II). At 2 years, within the higher social risk stratum the intervention group scored approximately two-thirds of a SD higher on the Bayley Scales of Infant and Toddler Development (3rd edition) cognitive scale compared with the control group (Table II, Fig. 2), whereas there was little difference in cognitive scores between intervention and control groups within the lower social risk stratum. At 4 and 8 years, within the higher social risk stratum, the infants in the intervention group were still performing better than controls with regard to cognitive scores, although the evidence for differences was weaker than at 2 years (Table II), with similar scores in the intervention and control groups in those with lower social risk.

For language outcomes, there was evidence of differential intervention effects according to social risk at 8 years (Table II, Fig. 2), with a stronger intervention effect in participants with higher social risk. There was weak evidence for a similar effect at 2 and 4 years.

For motor outcomes, there was some evidence of differential intervention effects according to social risk at 4 years (Table II), with only weak evidence for an intervention effect in participants with higher social risk.

There was little evidence for differential intervention effects according to social risk for social–emotional outcomes (Table II). However, at 2 years there was evidence that children in the intervention group had fewer externalizing behaviours than the control group in those with higher social risk but little difference between the intervention groups in participants with lower risk. The intervention was associated with fewer dysregulation behaviours at 2 years in all participants.

In general, the intervention group reported better parental mental health outcomes than the control group regardless of social risk stratum (Table IV); however, a differential effect was observed for depression at 4 years with the intervention effect being more prominent in the lower social risk group.

DISCUSSION

This exploratory study has found evidence of differential effectiveness of an early preventative care programme for preterm infants in the first year of life according to social risk, although this varied depending on the outcome assessed. While we have previously reported that there was little evidence for the effectiveness of our preventative care programme on cognitive, language, and motor outcomes,^{11–13} in our social risk subgroup analysis we found evidence that the programme was associated with better cognitive outcomes at 2 years in children from higher social risk environments but not in those with lower social risk, with weaker evidence for a similar pattern at 4 and 8 years. Further, there was evidence that the intervention was associated with improved language outcomes at 8 years in children with higher social risk but not in those with lower social risk, and some evidence of a differential intervention effect in motor outcomes at 4 years, although the effectiveness of the intervention in motor outcomes was not clear. The reasons for the different effects of intervention in the higher social risk group, especially on early cognitive outcomes, are unknown. However, mechanisms are likely to include the intervention’s focus on enhancement of the parent–infant relationship and enrichment of the home environment, both of which can be negatively affected by socio-economic disadvantage.²⁴

We have previously reported that the preventative care group (i.e. both higher and lower social risk groups combined), had better social–emotional outcomes at 2 years, including fewer dysregulation and externalizing difficulties and better competence, whereas at 4 years the intervention children had fewer internalizing difficulties than standard care.^{12,13} In the current study, there was a trend for a greater intervention effects at 2 years in those with higher social risk, but at 4 years the magnitude of treatment benefit on internalizing behaviours was similar in those with higher and lower social risk, with the effect of intervention diminishing on the other social–emotional outcomes at this time point for all participants.

Improvements in parental mental health from our early intervention trial have previously been reported.¹¹⁻¹³ There was evidence of an interaction between social risk and the intervention effectiveness for depression at 4 years; however, for this outcome there was a stronger intervention effect in participants with lower social risk. This pattern was in the opposite direction to the child outcomes, and suggests that the intervention may have been less effective in supporting mental health for parents with higher versus lower social risk. Low socio-economic status is a risk factor for postpartum depression,²⁵ and the mean scores for depression and anxiety across most of the time points in the current study were higher in participants with higher compared with lower social risk. It is possible that parents from higher risk social backgrounds who may be experiencing potential life stressors, including financial hardship, unemployment, marital separation, or language barriers in accessing health services, might benefit from a more intensive, personalized, and more frequent psychological intervention than that included in our intervention to support their well-being more effectively.

We acknowledge that the findings of our study warrant further investigation and support future studies on interventions targeted towards the social risk of families. In particular, there are several limitations that should be noted regarding the current study. This study was a post hoc analysis and the initial sample size was not powered to investigate subgroup differences based upon social risk; thus, these findings should be treated as exploratory. Moreover, we only explored social risk status established at term, as we wanted to determine the relationship with intervention over the first year of life. However, social risk is likely to change over time and, clinically, it is important to consider for an individual family how this may influence outcomes throughout development. As is the case for most parameters of social risk, the social risk index used in this study has not been fully validated as there are no criterion standards. But it has been used extensively by our group and has been found to be sensitive to differences in change between groups in socio-demographics, and associated with child cognition and behaviour.^{26, 27}

Despite having excellent follow-up rates, the rate of follow-up decreased over time, especially in those with higher social risk, which further diminished the power to detect differences between subgroups. Studies have shown that those children who do not attend follow-up have poorer neurodevelopmental outcomes and thus the magnitude of the effect of intervention between the higher risk groups maybe even larger.²⁸ Further, a challenge of conducting early intervention trials of therapy is families accessing other intervention services that could potentially reduce the treatment effect if families choose to seek additional therapy.²⁹ We collected data on access to other early intervention services at 2 years, and of the 75% who had complete data, there were more families in the control group with lower social risk who received other early intervention than the higher social risk control group. Infants from families with lower social risk may have been more

able to access private services, as children who are of higher social risk are known to access early intervention services less.⁶ This may not only be owing to the financial cost of the actual service, but also owing to other factors, such as fewer support networks, practical issues such as reduced access to transport, lower levels of parental education, and possible language or cultural barriers. A further consideration in understanding the effects of early intervention is to consider dosage, or the amount and type of early intervention received. We did not document dosage of other early interventions and further research studies would benefit from investigating a relationship between intervention dose and outcomes.

CONCLUSION

A preventative care programme over the first year of life for very preterm children and their families tends to result in improved cognitive, language, and motor outcomes for those in higher social risk home environments. In contrast, the programme benefited parental mental health more so for lower social risk mothers. Social risk appears to have an important role in the response to early intervention on a range of child and parental outcomes. Further randomized controlled trials of interventions to improve cognitive outcomes at preschool and school age in the child, and parental mental health outcomes should account for family social risk.

ACKNOWLEDGEMENTS

This study was funded by grants from the National Health and Medical Council (Project Grant ID 284512; Senior Research Fellowship [PJA] ID1081288; Career Development Fellowship [AJS] ID 1108714; Centre of Research Excellence ID 1060733); The Cerebral Palsy Alliance Project Grant; Murdoch Childrens Research Institute, Myer Foundation, Allens Arthur Robinson Foundation, Thyne Reid Foundation, and the Victorian Government's Operational Infrastructure Support Program. The authors have stated that they had no interests that might be perceived as posing a conflict or bias.

REFERENCES

1. Saigal S, Doyle LW. An overview of mortality and sequelae of preterm birth from infancy to adulthood. *Lancet* 2008; **371**: 261–9.
2. Treyvaud K. Parent and family outcomes following very preterm or very low birth weight birth: a review. *Semin Fetal Neonatal Med* 2014; **19**:131-5.

3. Bhutta AT, Cleves MA, Casey PH, Cradock MM, Anand KJ. Cognitive and behavioral outcomes of school-aged children who were born preterm: a meta-analysis. *JAMA* 2002; **288**: 728–37.
4. de Kieviet JF, Piek JP, Aarnoudse-Moens CS, Oosterlaan J. Motor development in very preterm and very low-birth-weight children from birth to adolescence: a meta-analysis. *JAMA* 2009; **302**: 2235–42.
5. Pace CC, Spittle AJ, Molesworth CM, et al. Evolution of depression and anxiety symptoms in parents of very preterm infants during the newborn period. *JAMA Pediatr* 2016; **170**: 863–70.
6. Roberts G, Howard K, Spittle AJ, Brown NC, Anderson PJ, Doyle LW. Rates of early intervention services in very preterm children with developmental disabilities at age 2 years. *J Paediatr Child Health* 2008; **44**: 276–80.
7. Doyle LW, Cheong JL, Burnett A, Roberts G, Lee KJ, Anderson PJ, Victorian Infant Collaborative Study Group. Biological and social influences on outcomes of extreme-preterm/low-birth weight adolescents. *Pediatrics* 2015; **136**: e1513–20.
8. Howard K, Roberts G, Lim J, et al. Biological and environmental factors as predictors of language skills in very preterm children at 5 years of age. *J Dev Behav Pediatrics* 2011; **32**: 239–49.
9. Shonkoff JP, Meidels SJ. Handbook of early childhood intervention (2nd edition). Cambridge: Cambridge University Press, 2000.
10. Spittle A, Orton J, Anderson PJ, Boyd R, Doyle LW. Early developmental intervention programmes provided post hospital discharge to prevent motor and cognitive impairment in preterm infants. *Cochrane Database Syst Rev* 2015; **11**: CD005495.
11. Spittle AJ, Barton S, Treyvaud K, Molloy CS, Doyle LW, Anderson PJ. School-age outcomes of early intervention for preterm infants and their parents: a randomized trial. *Pediatrics* 2016; **138**: e20161363.
12. Spencer-Smith MM, Spittle AJ, Doyle LW, et al. Long-term benefits of home-based preventive care for preterm infants: a randomized trial. *Pediatrics* 2012; **130**: 1094–101.
13. Spittle AJ, Anderson PJ, Lee KJ, et al. Preventive care at home for very preterm infants improves infant and caregiver outcomes at 2 years. *Pediatrics* 2010; **126**: e171–8.
14. Van Wassenaer-Leemhuis AG, Jeukens-Visser M, van Hus JW, et al. Rethinking preventative post-discharge intervention programmes for very preterm infants and their parents. *Dev Med Child Neurol* 2016; **58**(Suppl. 4): 67–73.

15. Spittle AJ, Ferretti C, Anderson PJ, et al. Improving the outcome of infants born at <30 weeks' gestation - a randomized controlled trial of preventative care at home. *BMC Pediatr* 2009; **9**: 73.
16. Bayley N. Bayley scales of infant and toddler development (3rd edition). San Antonio, TX: The Psychological Corporation, 2005.
17. Carter AS, Briggs-Gowan MJ. Infant-toddler social and emotional assessment: examiner's manual. San Antonio, TX: Pearson, 2006.
18. Elliot CD. The differential abilities scales (2nd edition). San Antonio, TX: Pearson Education, 2007.
19. Henderson SE, Sugden DA, Barnett AL. Movement assessment battery for children (Movement ABC-2) (2nd edition). London: The Psychological Corporation, 2007.
20. Achenbach TM, Rescorla LA. Manual for the ASEBA preschool forms and profiles. Burlington, VT: University of Vermont Department of Psychiatry, 2000.
21. Gresham F, Elliott SN. Social Skills Improvement System (SSIS) rating scales. New York: Pearson, 2008
22. Goodman R. The Strengths and Difficulties Questionnaire: a research note. *J Child Psychol Psychiatry* 1997; **38**: 581–6.
23. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983; **67**: 361–70.
24. Hilferty F, Redmond G, Katz I. The implications of poverty on children's readiness to learn. *Aust J Early Child* 2010; **35**: 63–71.
25. O'Hara MW, McCabe JE. Postpartum depression: current status and future directions. *Annu Rev Clin Psychol* 2013; **9**: 379–407.
26. Reidy N, Morgan A, Thompson DK, Inder TE, Doyle LW, Anderson PJ. Impaired language abilities and white matter abnormalities in children born very preterm and/or very low birth weight. *J Pediatr* 2013; **162**: 719–24.
27. Anderson PJ, Treyvaud K, Neil JJ, et al. Associations of newborn brain magnetic resonance imaging with long-term neurodevelopmental impairments in very preterm children. *J Pediatr* 2017; **187**: 58–65.
28. L Orton J, McGinley JL, Fox LM, Spittle AJ. Challenges of neurodevelopmental follow-up for extremely preterm infants at two years. *Early Hum Dev* 2017; **9**: 689–94.
29. Hadders-Algra M. Challenges and limitations in early intervention. *Dev Med Child Neurol* 2011; **53**(Suppl. 4): 52–5.

Table I: Characteristics of participants at baseline and age at follow-up assessments according to intervention group and social risk

	Higher social risk		Lower social risk	
	Intervention (<i>n</i> =21)	Control (<i>n</i> =26)	Intervention (<i>n</i> =40)	Control (<i>n</i> =33)
Mean(SD) gestational age (wk)	27.0(1.6)	27.5(1.4)	27.4(26.8)	27.4(1.6)
Mean(SD) birthweight (g)	985(291)	981(220)	1052(285)	999(265)
Males	9(43)	13(50)	25 (63)	14 (42)
Antenatal corticosteroids	1(5)	4(15)	7(18)	7(21)
Postnatal corticosteroids	1(5)	1(4)	1(3)	2(6)
Primary caregiver with tertiary education	3(14)	3(13)	24(60)	22(67)
Maternal age >21y	21(100)	22(96)	40(100)	33(100)
English only at home	12(57)	13(50)	39(98)	29(88)
Primary income earner professional	5(24)	3(12)	34(85)	27(82)
Primary income earner full-time employed	16(76)	22(85)	40(100)	33(100)
Two-caregiver family	17(81)	25(96)	40(100)	33(100)
Moderate-to-severe white-matter injury	1(5)	3(12)	4(10)	2(6)
Mean(SD) age at 2y assessment (y)	24.3(0.63)	24.3(0.90)	24.3(24.60)	24.6(1.20)
Mean(SD) age at 4y assessment (y)	4.5(0.23)	4.6(0.35)	4.40(0.20)	4.4(0.20)
Mean(SD)age at 8y	8.1(0.8)	8.0(0.6)	8.2(0.7)	7.7(0.5)

assessment (y)				
Accessed other early intervention ^a	5(33)	7(39)	12(41)	19(63)

Data are $n(\%)$ unless otherwise indicated. ^aData missing for 25% of sample with data collected at 2 years. SD, standard deviation.

Author Manuscript

TABLE II: Comparison of outcomes between intervention and control groups by social risk

Child		Higher social risk						Lower social risk						Interaction			
		Intervention			Control			Group difference			Intervention				Control		
Outcome		<i>n</i>	Mean(SD)	<i>n</i>	Mean(SD)	Mean difference(95% CI) ^a	<i>p</i>	<i>n</i>	Mean(SD)	<i>n</i>	Mean(SD)	Mean difference ^a (95% CI)	<i>p</i>	<i>p</i>			
Cognitive	2y Bayley-III	19	101.8(11.0)	25	92.2(12.5)	9.7(2.7–16.6)	0.006	39	97.6(13.6)	32	98.3(12.2)	-1.4(-7.8 to 5.0)	0.664	0.022			
	4y DAS-GCA	17	100.2(3.8)	21	90.7(16.5)	8.9(-1.6 to 19.4)	0.097	35	98.7(15.5)	30	102.7(13.2)	-3.8(-11.1 to 3.5)	0.310	0.047			
	8y DAS-GCA	16	103.0(11.5)	16	95.9(17.1)	6.7(-3.8 to 17.2)	0.212	35	101.3(13.2)	27	102.2(8.0)	-1.2(-6.5 to 4.2)	0.671	0.164			
Language	2y Bayley-III	18	96.4(10.1)	22	91.6(14.8)	4.2(-3.7 to 12.2)	0.299	39	96.5(18.4)	32	102.2(15.6)	-6.0(-14.4 to 2.3)	0.156	0.082			
	4y DAS-Verbal	17	96.4(14.0)	22	84.6(22.0)	9.4(-2.5 to 21.4)	0.123	35	100.6(9.3)	30	101.8(10.5)	-1.00(-6.2 to 4.2)	0.710	0.100			
	8y DAS-Verbal	16	103.4(12.4)	16	94.2(15.6)	9.0(-0.1 to 18.1)	0.052	35	100.5(1.9)	27	104.0(12.6)	-3.1(-9.4 to 3.2)	0.337	0.032			
Motor	2y Bayley-III	19	103.8(11.3)	25	97.4(18.8)	7.2(-2.1 to 16.8)	0.129	39	98.0(16.0)	32	99.7(15.5)	-1.7(-8.2 to 6.1)	0.768	0.210			

	4y MABC-2	17	8.9(3.9)	22	7.0(4.9)	2.0(-1.0 to 5.0)	0.185	35	7.1(3.4)	30	8.6(3.5)	-1.5(-3.0 to 0.0)	0.059	0.039
	8y MABC-2	15	9.2(3.8)	15	8.7(4.2)	0.5(-2.7 to 3.9)	0.736	35	8.1(3.5)	28	8.5(3.5)	-0.2(-1.9 to 1.5)	0.738	0.591

All outcome measures have a mean of 100 and SD of 15, except for Movement Assessment Battery for Children-2 (MABC-2), which has a mean of 10 and SD of 3. ^aAnalyses adjusted for multiple births. SD, standard deviation; CI, confidence interval; Bayley-III, Bayley Scales of Infant and Toddler Development (3rd edition); DAS, Differential Ability Scale; GCA, General Conceptual Ability.

TABLE III: Comparison of behavioural outcomes between intervention and control groups by social risk

Child	Outcome	Higher social risk						Lower social risk						Interaction
		Intervention		Control		Group difference		Intervention		Control		Group difference		
		<i>n</i>	Mean(SD)	<i>n</i>	Mean(SD)	Mean difference(95% CI) ^a	<i>p</i>	<i>n</i>	Mean(SD)	<i>n</i>	Mean(SD)	Mean difference(95% CI)	<i>p</i>	<i>p</i>
2y	Internalizing	14	48.5(10.5)	23	50.9(12.1)	0.45(-3.9 to 4.8)	0.852	35	44.9(9.0)	28	44.5(7.7)	0.3 (-3.9 to 4.6)	0.877	0.899
	Externalizing	14	46.9(7.8)	23	55.6(12.6)	-8.7(-16.4 to -1.1)	0.027	35	48.9(9.1)	28	49.9(7.0)	-0.9(-4.6 to 2.8)	0.627	0.077
	Dysregulation	14	45.4(8.3)	23	56.9(11)	-10.8(-17.3 to -4.3)	0.001	35	41.9(7.2)	28	47.2(12)	-5.4 (-10.7 to 0)	0.045	0.185

	Competence	13	48.9(13.0)	21	40.5(14.5)	8.4(-1.1 to 17.9)	0.084	35	48.8(11.1)	28	44.1(12.6)	4.6(-2.5 to 11.8)	0.201	0.528
4y	Internalizing	14	48.4(9.5)	14	53.6(12.4)	-5.1(-13.2 to 2.9)	0.210	32	48.3(10.4)	28	53.4(9.8)	-5.1(-10.2 to 0.1)	0.047	0.995
	Externalizing	15	50.9(10.9)	14	52.7(10.3)	-2.2(-9.9 to 5.5)	0.571	32	52.4(10.1)	28	52.5(7.4)	0.00(-4.5 to 4.5)	1.000	0.668
	Adaptive skills	15	42.3(10.8)	14	44.4(9.8)	-1.9(-9.4 to 5.6)	0.623	32	48.5(9.6)	28	44.7(8.0)	3.7(-0.9 to 8.2)	0.114	0.204
	Behavioural symptoms index	15	54.5(11.2)	14	56.5(9.85)	-2.03(-9.9 to 5.5)	0.625	32	53.5(8.3)	28	53.5(8.3)	-1.4(-6.6 to 3.9)	0.607	0.890
	Outcome	<i>n</i>	<i>n</i> (%)	<i>n</i>	<i>n</i> (%)	OR(95% CI)	<i>p</i>	<i>n</i>	<i>n</i> (%)	<i>n</i>	<i>n</i> (%)	OR(95% CI)	<i>p</i>	Interaction
8y	Any social problems	15	9(60.0)	17	7(41.2)	1.18(0.3-5.3)	0.828	36	13(36.1)	29	13(44.8)	0.99(0.33-2.94)	0.49	0.894

All outcome measures have a mean of 50 and SD of 10. ^aAnalyses adjusted for multiple births. SD, standard deviation; CI, confidence interval; OR, odds ratio.

TABLE IV: Comparison of primary caregiver anxiety and depression between intervention and control groups by social risk

Primary caregiver	Higher social risk		Lower social risk		Interaction
	Intervention	control	Group difference	Intervention	

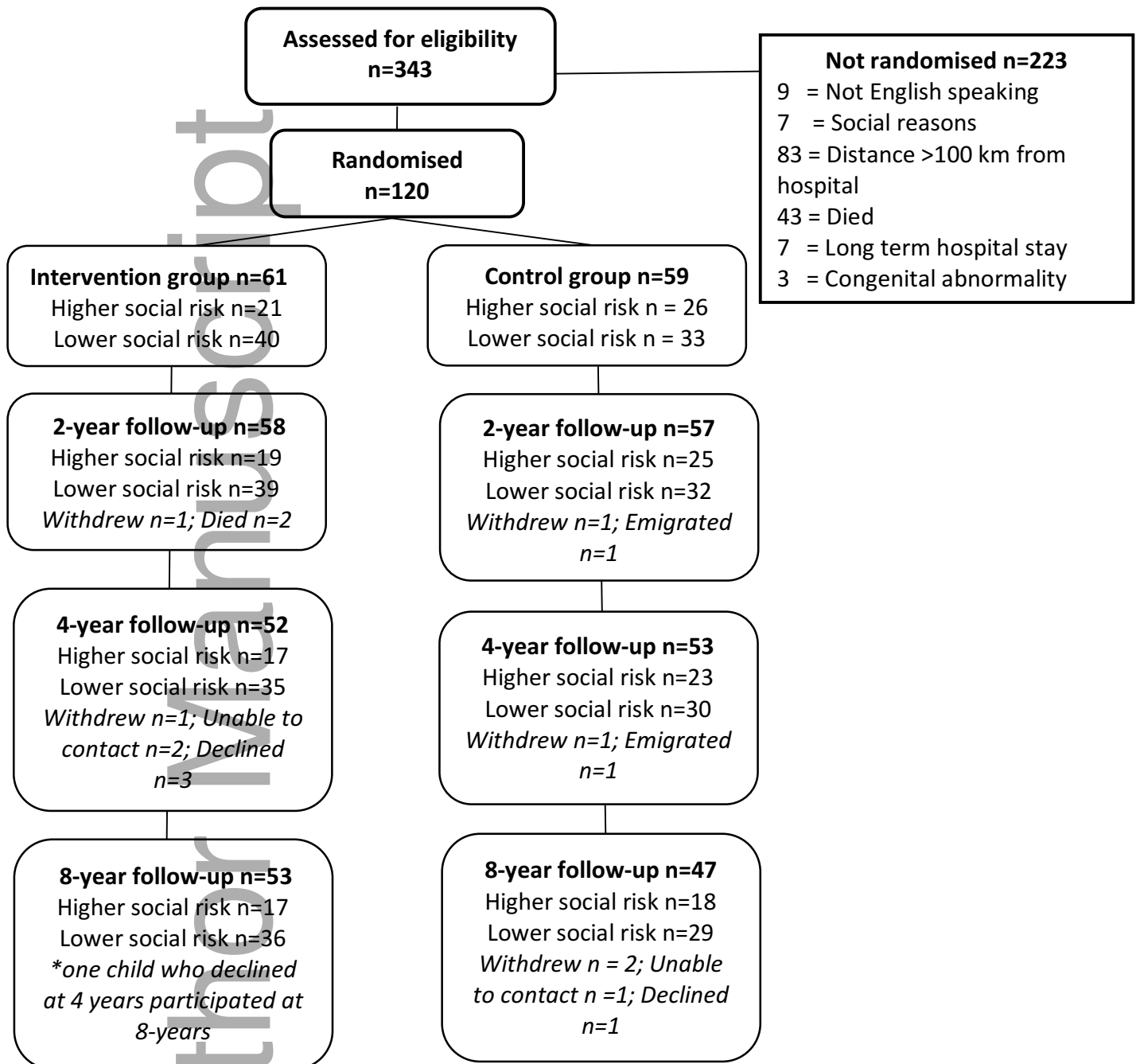
Outcome		<i>n</i>	Mean(S D)	<i>n</i>	Mean(S D)	Mean difference(95 % CI) ^a	<i>p</i>	<i>n</i>	Mean(S D)	<i>n</i>	Mean(S D)	Mean difference(95 % CI) ^a	<i>p</i>	<i>p</i>
Anxiety	2y	18	5.6(3.3)	18	9.2(3.9)	-3.60(-6.0 to - 1.2)	0.005	29	4.6(3.3)	24	7.17(3.2)	-2.6 (-4.4 to - 0.8)	0.006	0.494
	4y	12	7.0(2.4)	14	7.6(2.7)	-0.6(-2.7 to 1.4)	0.523	27	5.3(3.0)	24	7.71(3.7)	-2.4(-4.3 to - 0.5)	0.014	0.199
	8y	13	6.0(3.2)	15	7.7(3.2)	-1.7(-4.6 to 1.3)	0.26	24	4.5(3.7)	23	5.9(4.0)	-1.41(-3.7 to 0.8)	0.212	0.890
Depression	2y	18	3.9(2.7)	19	5.2(3.1)	-1.3(-3.3 to 0.6)	0.176	29	2.9(2.5)	24	5.3(3.7)	-2.5(-4.1 to - 0.6)	0.011	0.431
	4y	12	5.7(4.5)	14	4.6(2.8)	1.02(-2.0 to 4.1)	0.497	27	2.3(2.4)	24	4.5(3.1)	-2.2(-3.8 to - 0.6)	0.007	0.056
	8y	13	3.9(2.4)	15	5.9(3.8)	-1.9(-4.4 to 0.5)	0.115	24	2.5(2.3)	23	5.4(3.1)	-2.9(-4.4 to - 1.3)	0.001	0.527

Hospital Anxiety and Depression Scale score classifications: 0–7 normal range, 8–10 mildly elevated range, 11+ probable clinically significant symptoms. ^aAnalyses adjusted for multiple births. SD, standard deviation; CI, confidence interval.

Figure 1: Flow diagram of participants allocated to intervention and control groups including a breakdown of participants by social risk.

Figure 2: Bayley Cognitive scores at 2 years in the intervention and control groups, presented separately according to social risk.

FIGURE 1. Flow diagram of participants including social risk group allocated to intervention and control groups



Author Manuscript

Bayley Cognitive Score

