

The Family Nurse Partnership to reduce maltreatment and improve child health and development in young children: the BB:2–6 routine data-linkage follow-up to earlier RCT

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Personal dedication: Our work aims to improve the life chances of babies. All babies are precious. Their wonderful potential, their joy and their sorrows can sometimes get lost when quantified statistically. It is often our personal knowledge that brings meaning to such numbers. I dedicate this report to my own grand-daughter, Luna Alice Atkins, who left us this year aged only three days old. She will forever remain precious to us and her life will always have meaning. *Michael Robling, 2020*

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Scientific summary

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Scientific summary

Background

Protecting children from maltreatment and promoting their healthy development are UK policy priorities, and there has been increasing emphasis on primary prevention. One such intervention is the Family Nurse Partnership, developed in the USA as the Nurse–Family Partnership. The Family Nurse Partnership is a home-visiting programme for women expecting their first child. Three US trials have demonstrated that the programme results in improvements in prenatal health behaviours and birth outcomes, sensitive child care, maternal life course and child functioning. A subgroup analysis of poor unmarried teenage mothers in the first Nurse–Family Partnership trial (Olds DL, Henderson CR, Chamberlin R, Tatelbaum R. Preventing child abuse and neglect: a randomized trial of nurse home visitation. *Pediatrics* 1986;**78**:65–78) found verified maltreatment by the age of 2 years in 19% of control children and in 4% of children in the group in receipt of the Nurse–Family Partnership during both pregnancy and infancy (mean percentage difference: 0.15, 95% confidence interval –0.01 to 0.31). There was also a 56% relative reduction in emergency department encounters for injuries and ingestions during the second year of life. For children with state-verified maltreatment reported by the age of 4 years, children in the Nurse–Family Partnership group had fewer risks for harm than the control group at between 25 and 50 months of life.

The Family Nurse Partnership was adapted for implementation in England in 2007, primarily for teenage mothers. The Building Blocks (BB:0–2) trial of the Family Nurse Partnership in England (ISRCTN23019866) [Robling M, Bekkers MJ, Bell K, Butler CC, Cannings-John R, Channon S, *et al.* Effectiveness of a nurse-led intensive home-visitation programme for first-time teenage mothers (Building Blocks): a pragmatic randomised controlled trial. *Lancet* 2016;**387**:146–55] evaluated short-term outcomes to age 2 years. The trial found no difference for four primary outcomes: maternal tobacco use in late pregnancy, birthweight of the baby, proportion of women with a second pregnancy within 24 months post partum, and emergency attendances and hospital admissions for the child within 24 months post partum. We observed some differences in favour of the Family Nurse Partnership for secondary child development outcomes, including maternal-reported cognitive function and language at 24 months. Although the trial evidence did not support programme continuation in England, the previous US trials demonstrated benefit over the longer term. For maltreatment outcomes, this benefit became increasingly evident after the age of 4 years. The current study sought to establish whether or not the Family Nurse Partnership moderates maltreatment outcomes over a medium-term period and the impacts on programme-relevant developmental and maternal outcomes.

Objectives

Primary objective

The primary objective was to determine the Family Nurse Partnership programme effectiveness in reducing objectively measured maltreatment outcomes, when compared with usually provided health and social care alone.

Secondary objectives

The secondary objectives were to determine:

- programme effectiveness in reducing maltreatment, as measured by injuries and ingestions, and non-attendance rates for hospital appointments, when compared with usually provided health and social care alone

- the programme's impact on other medium-term outcomes, notably subsequent pregnancies, school readiness and educational outcomes
- the impact of theoretical moderators of programme effect, including domestic abuse and baseline maternal characteristics
- the costs and consequences of the programme over the full follow-up period.

Methods

Study design

We followed up participant mothers and children from the BB:0-2 trial for a further 5 years using routine data only. We retrieved data from public sector providers, which we linked to the trial data set. This enabled us to track children and mothers until the children reached Key Stage 1, by which time most children would be 7 years of age.

Study participants

Building Blocks:2-6 (BB:2-6) study participants were women and their first child (or twins, if relevant) who were not mandatorily withdrawn from the BB:0-2 trial or did not electively withdraw.

BB:0-2 trial participants were eligible if at recruitment they were nulliparous women aged ≤ 19 years, living in one of 18 local authority Family Nurse Partnership catchment areas, were at < 25 weeks' gestation, were able to provide consent and were able to converse in English. Women with a previous pregnancy ending in miscarriage, stillbirth or termination were eligible. Women planning to have their child adopted or to move outside the Family Nurse Partnership catchment area for > 3 months were not eligible.

Intervention

The Family Nurse Partnership is a programme of up to 64 home visits delivered by specially trained family nurses from early pregnancy until the child is 2 years of age that address personal and environmental health, life course development, the maternal role, family and friends, and access to health and social services.

All study participants received usually provided health and social care services for pregnancy and new mothers. Participants in the usual-care arm received these services alone.

Outcomes

Primary

The primary outcome was the recording of a child-in-need status (i.e. child is unlikely to achieve or maintain a reasonable level of health or development, or whose health and development is likely to be significantly or further impaired without provision of services, or a child who is disabled) at any time during the follow-up period.

Secondary

- Additional objective measures of maltreatment: referral to social services (overall, child protection referral, child-in-need referral), child protection registration, child-in-need categorisation, looked-after status (mother, child)
- Associated measures of maltreatment: recorded injuries and ingestions, non-attendance rates for hospital appointments
- Maternal outcomes: subsequent pregnancies
- Child health and developmental and educational outcomes: special educational needs, early educational attendance and assessments (Early Years Foundation Stage profile, Key Stage 1).
- Costs: health resource use.

Data linkage

Maternal and child identifiers were sent to NHS Digital and the National Pupil Database for matching with their databases. Matching with NHS Digital used NHS number, date of birth, postcode and sex. NHS Digital also used NHS number to obtain mortality data from the Office for National Statistics. Matching with the National Pupil Database used exact matching on first name and surname, date of birth and postcode (of both mother and child for social care data, and of just the child for all other data sets). Matching to child-in-need and child-looked-after data sets involved first matching to the National Pupil Database, adding the unique pupil number and then using the unique pupil number to identify records. All matched data were sent to a third-party data safe haven, linked by project identifiers to trial data and analysed via remote access.

Analysis

We conducted all analyses on a modified intention-to-treat basis. First, we examined binary outcomes in twins, with the aim of examining the correlation between them. If outcomes tended to always apply to both twins, then we aimed to reduce the multilevel nature of the data (children within mother) to one child as opposed to adjusting for twins.

We used three-level multilevel modelling to allow for clustering of effect within a site and family nurse when both were fitted as random effects. When there was little impact of clustering at the family nurse level, then we aimed to present the results from the two-level model (i.e. site and participant). We present all parameter estimates alongside a 95% confidence interval and *p*-value. We adjusted for variables used in randomisation such as smoking status, gestational age and language.

For binary outcomes, comparative analysis used logistic multilevel modelling with results presented as odds ratios. For categorical variables, comparative analyses used multinomial multilevel regression and presented odds ratios. For continuous data (e.g. Early Years Foundation Stage profile total point score), we used linear multilevel regression and present mean differences. For count data (e.g. number of child-in-need referrals), we used Poisson multilevel regression modelling. When event distribution displayed signs of overdispersion, a negative binomial multilevel regression model was used (or a zero-inflated model, in which there was an excess of zero events). Results are presented as incidence rate ratios. Time-to-event data (e.g. interbirth interval) used Cox regression multilevel modelling, presented with hazard ratios.

Sensitivity analyses for the primary outcome included adjusting for hypothesised confounders at baseline, dosage effects (i.e. number of visits) using complier-average causal effects modelling and subgroup analysis of potential effect moderators and mediators (maternal deprivation; adaptive functioning; not in employment, education or training at recruitment; maternal age at recruitment; child sex; maternal care status; duration of maternal care; and domestic abuse self-reported at 24 months) as interaction terms in the main comparative models. Sensitivity analyses for selected secondary outcomes (Early Years Foundation Stage profile, Key Stage 1, referral to social services) included complier-average causal effects, imputation for missing data and subgroups.

A cost-consequences analysis of the Family Nurse Partnership over the full follow-up period (BB:0-2 and BB:2-6) took, primarily, a health-care (UK NHS) perspective. The principal data source was Hospital Episode Statistics records (inpatient, outpatient, accident and emergency), which were matched to appropriate NHS reference costs. Maternal and child resource use were costed separately and valued in Great British pounds. When data were absent in Hospital Episode Statistics records, it was assumed that no resource use was incurred. No primary care data were available beyond the 18-month follow-up point in BB:0-2. Costs were discounted back from year of event to baseline at an annual rate of 3.5%.

Results

Data for 1537 mothers and 1547 children (1517 singletons, 15 sets of twins) were sent to NHS Digital and the National Pupil Database for matching, forming the BB:2-6 study population. Match rates for children were 98.3% (NHS Digital) and 97.4% (National Pupil Database).

Maltreatment

Of all the children, 27% were referred at least once to children's social services, with no difference in referral rates between study arms. More children in the usual-care arm were referred on multiple occasions than children in the Family Nurse Partnership arm. Children in the Family Nurse Partnership arm were, on average, 90 days younger than children in the usual care arm at referral. This difference was not statistically significant. A total of 323 referred children (21.5%) were assessed as in need at some point by age 6 years, but there was no difference in proportions between children in the Family Nurse Partnership arm (21.1%) and children in the usual-care arm (21.7%), even when adjusting for the number of Family Nurse Partnership visits. There was no difference between study arms in the timing of the first referral for children subsequently assessed as in need. Adjusting for baseline maternal characteristics and child sex made no difference to the overall picture for child-in-need status. The duration for which children were assessed as in need was similar in the two study arms among those whose period of additional support had concluded. The proportion of all children in need with a primary need of abuse or neglect was similar across study arms (Family Nurse Partnership, 57.1%; usual care, 63.0%). The rates of children with a child protection plan (Family Nurse Partnership, 6.8%; usual care, 6.6%) and who were looked after (Family Nurse Partnership, 3.3%; usual care, 3.6%) were the same in both study arms.

Of those with a child protection plan (Family Nurse Partnership, $n = 52$; usual care, $n = 49$), a larger proportion of children in the Family Nurse Partnership arm were assigned a primary code of emotional abuse, and fewer were assigned to neglect, than in the usual-care arm. The proportion of children in care in both study arms was similar (Family Nurse Partnership, $n = 25$; usual care, $n = 27$), with children in the Family Nurse Partnership arm spending, on average, 2 months less in care than children in the usual care arm (adjusted incidence rate ratio 0.75, 95% confidence interval 0.65 to 0.86).

Children in the Family Nurse Partnership arm were as likely to miss a hospital outpatient appointment as children in the usual-care arm. Half of all children had attended an emergency department for an injury or ingestion. The slightly larger proportion attending among children in the Family Nurse Partnership arm was not statistically significant (Family Nurse Partnership, 58.3%; usual care, 54.7%). The rates of children admitted because of an injury or ingestion were comparable (Family Nurse Partnership, 11.7%; usual care, 13.0%).

Children of care-experienced mothers were more frequently defined as in need, but there was no difference in rate between study arms.

Maternal

There was no difference in rates of second pregnancy between mothers in the Family Nurse Partnership arm (590/753, 78.4%) and mothers in the usual-care arm (590/753, 78.4%).

Child health, development and education

There were no differences between the usual-care arm (245/747, 32.8%) and the Family Nurse Partnership arm (219/759, 28.9%) in the proportion of children with special education needs provision. There were no differences in patterns of educational attendance among those aged 2-4 years, or in the type of private, voluntary or independent day care accessed.

Children in the Family Nurse Partnership arm were more likely to reach a good level of development across the combined five areas of learning at school entry (58.0%) than children in the usual-care arm (52.2%) (adjusted odds ratio 1.26, 95% confidence interval 1.03 to 1.55), and also to achieve a good level of development across the combined 17 early-learning goals (Family Nurse Partnership, 55.5%; usual care, 50.1%; adjusted odds ratio 1.24, 95% confidence interval 1.01 to 1.52). In both cases, the effects were strengthened when adjusting for month of birth. Although there was no difference in total point score (i.e. aggregate across 17 learning goals) between study arms, a beneficial impact of the Family Nurse Partnership was observed for younger, rather than older, mothers at study entry, with no other differences by study subgroup found. The number of nurse visits made no difference to effect size.

At Key Stage 1, 65.3% of children in the Family Nurse Partnership arm reached the expected standard for reading, compared with 60.5% of children in the usual-care arm (adjusted odds ratio 1.23, 95% confidence interval 0.99 to 1.53). There were no statistically significant differences in the proportion of children reaching the expected standard for mathematics (Family Nurse Partnership, 62.0%; usual care, 61.3%), science (Family Nurse Partnership, 72.6%; usual care, 71.0%) or writing (Family Nurse Partnership, 48.4%; usual care, 42.9%). Although the difference for reading was of borderline statistical significance, the effect was stronger for children whose families had more visits from a family nurse (adjusted odds ratio 1.38, 95% confidence interval 1.07 to 1.77).

When we adjusted analyses of Key Stage 1 outcomes to account for birth month, children in the Family Nurse Partnership arm were more likely to reach the expected level for reading than children in the usual-care arm (adjusted odds ratio 1.26, 95% confidence interval 1.02 to 1.57); no other group differences were found.

At Key Stage 1, the intervention effect was greater for boys of mothers in the Family Nurse Partnership arm than for girls, particularly for reading and writing (and strengthened after adjusting for birth month); for writing, this difference reached statistical significance (interaction $p = 0.039$). Children with younger mothers at recruitment were less likely to reach the expected standard overall. However, the differences between study arms in favour of children in the Family Nurse Partnership arm were greater for younger women, for mathematics and for writing, an effect that reached statistical significance. In addition, for writing, a programme effect was observed in mothers not in employment, education or training at the time of recruitment; the contrary was seen in mothers who were in employment, education or training. No additional interaction effects were found at Key Stage 1.

Costs

There were negligible resource use and cost differences between study arms. The adjusted incremental cost per woman of programme delivery in BB:0-2 (£1811) remains the key observed cost difference between study arms.

Conclusions

Implications for health care

There are no evident benefits for maltreatment outcomes from the Family Nurse Partnership, but the programme generates higher rates of school readiness and, at Key Stage 1, child attainment of educational goals.

The Family Nurse Partnership remains locally commissioned in England. Local needs and priorities may determine the weight attached to these different sets of outcomes.

Recommendations for research

The benefits of the programme that were observed using routine educational data add to maternally reported developmental benefits seen in the original trial. Determining how these track through to later developmental outcomes will be essential to understanding the value of the programme.

Longer-term routine data from sources used in this study should be supplemented by those from other sectors, and also by prospectively collected data from families, to capture the breadth of potential programme benefit and cost.

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