Results of the First Steps study: a randomised controlled trial and economic evaluation of the Group Family Nurse Partnership (gFNP) programme compared with usual care in improving outcomes for high-risk mothers and their children and preventing abuse

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Declared competing interests of authors: Elizabeth Allen, Joanna Sturgess and Diana Elbourne report grants from the NHS National Institute for Health Research Public Health Programme to the London School of Hygiene and Tropical Medicine during the conduct of the study. Geraldine Macdonald is in the process of completing a Cochrane Review of home-visiting programmes that will include studies of nurse–family partnership. Two predecessor reviews were withdrawn in response to a criticism by David Olds. The criticism did not materially affect the results or conclusions of the reviews, but it was deemed appropriate to correct these and republish. This work is in progress, but the results are not yet available.

Published November 2017
DOI: 10.3310/phr05090

Scientific summary

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Public Health Research 2017; Vol. 5: No. 9
DOI: 10.3310/phr05090

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Background

Recent estimates show that the suboptimal parenting of infants is a major public health issue. Early intervention during pregnancy and infancy is highlighted in UK policy documents, but there is limited evidence available about 'what works'. Randomised controlled trials (RCTs) in the USA and the Netherlands have shown that the home-based one-to-one Nurse Family Partnership programme is effective in decreasing child maltreatment and improving parenting practices. Delivered by specially trained family nurses (FNs), home visits are made approximately fortnightly from early pregnancy until children are aged 2 years, with a curriculum covering maternal health, maternal role, family and friends, environmental health, life course and referrals to health and human services. Renamed Family Nurse Partnership (FNP) in the UK, it has been offered to first-time teenage mothers since 2007, although recent (2015) RCT evidence failed to replicate the US findings in the UK in terms of FNP's impact on reducing risks for child abuse. In 2009, a new programme, Group Family Nurse Partnership (gFNP), was developed by the Family Nurse Partnership National Unit, offering similar content but over a shorter time frame (early pregnancy to 12 months post partum), delivered by two FNs (one also a midwife) to a group of between 8 and 10 women with similar expected delivery dates (EDDs). The eligibility criteria were designed to exclude women eligible for FNP, intending to allow other potentially vulnerable mothers to be offered a programme based on the FNP approach. Routine antenatal and infant checks were incorporated into the gFNP programme, with the aim of encouraging mothers to assess and record the relevant information themselves, with guidance from the FNs. The feasibility of offering gFNP had been established with two implementation studies. It was acceptable to clients and FNs and both clients and FNs perceived positive impacts. The next stage for evaluation was a RCT. In response to a National Institute for Health Research call for studies of programmes with the potential to reduce the likelihood of child abuse and neglect, the First Steps RCT was designed.

Objectives

The study objectives were:

1. to determine whether or not gFNP, compared with usual care, could reduce risk factors for maltreatment in a vulnerable group (namely expectant mothers aged < 20 years who already had a child and expectant mothers aged 20–24 years with no previous live births and low/no educational qualifications).

To answer the following questions:

1. Would provision of the gFNP programme, compared with usual care, enhance maternal physical and mental health in pregnancy and the experience of pregnancy and delivery?
2. Would provision of gFNP, compared with usual care, enhance infant birth status and health status in infancy, breastfeeding in the first 2 months and immunisation uptake during the first year?
3. How feasible and acceptable would gFNP be as part of routine ante- and postnatal services?
4. How cost-effective was gFNP as part of routine antenatal and postnatal services?

Methods

The study comprised a multisite randomised controlled parallel-group trial in which eligible women were allocated (minimised by site and maternal age group) to one of two arms: (1) gFNP delivered via 44 sessions over 76 weeks or (2) usual care.

Participants

Women eligible for the trial had EDDs within approximately 10 weeks of each other and were 16–20 weeks pregnant when the programme commenced. In addition, they were either aged < 20 years at their last menstrual period (LMP) with one or more previous live births or aged 20–24 years at their LMP with no previous live births and low educational qualifications, defined as having General Certificate of Secondary Education (GCSE) at grade C or higher in neither mathematics nor English language or, if they had both, no more than four GCSEs at grade C or higher. Exclusions were expectant mothers aged < 20 years who had previously received home-based FNP; mothers in either age group with psychotic mental illness (defined as bipolar disorder or schizophrenia); and mothers who were not able to communicate orally in English.

Study setting and intervention

Seven FNP teams based around England delivered gFNP. The programme started in the first trimester of pregnancy, designed to last until infants were aged 12 months, with 44 sessions in the curriculum (14 pregnancy and 30 infancy). Meetings, held in a children's centre or health centre in the local area, were planned to last around 2 hours. Two experienced FNP FNs, one of whom had given notification of her intention to practise as a midwife, facilitated the groups. Following National Institute for Health and Care Excellence guidelines, the FN midwife provided routine antenatal care, taking an approach based on the Centring Pregnancy Programme, which encourages women to monitor their own health. After infants were born, both FNs were involved in routine infant checks, conducted in accordance with the Healthy Child Programme.

Main study outcomes

Primary

(1) The Adult Adolescent Parenting Inventory Version 2 (AAPI-2) is a 40-item self-report measure able to discriminate between abusive and non-abusive parents. The total raw score converts to a standard 10 score, with lower scores indicating a higher risk for abusive parenting practices. Responses are on a five-point Likert-type scale, ranging from strongly agree to strongly disagree. (2) The observational CARE-Index, scored from a video recording of 3–5 minutes of mother–child play, measures three aspects of maternal behaviour (sensitivity, covert and overt hostility, and unresponsiveness) and four aspects of infant behaviour (co-operativeness, compulsive compliance, difficultness and passivity). For this study, only maternal sensitivity was considered as the co-primary outcome, a lower score indicating less sensitivity.

Secondary

Eight secondary outcomes were used to assess socioemotional aspects of parenting and family life and service use: CARE-Index infant co-operativeness (12 months); maternal depression (Edinburgh Postnatal Depression Scale at baseline, 2, 6 and 12 months); maternal stress (Abidin Parenting Stress Index, Short Form, at 2 and 12 months); parenting sense of competence (Parenting Sense of Competence, at 2 and 12 months); social support (Medical Outcomes Study, Social Support Survey, at baseline and 12 months); maternal smoking, alcohol and drug use (at baseline, 2 and 12 months); relationship violence (at baseline, 2 and 12 months); and infant feeding (at baseline, 2, 6 and 12 months).

Information, other than that for the primary and secondary outcome at different time points, was collected and is shown but was not formally tested (e.g. baby demographics, immunisations, and maternal smoking, alcohol and drug use).

Economic evaluation outcomes

Maternal health-related quality of life (HRQoL) was assessed using the EuroQol-5 Dimensions, five-level version measure (at baseline and at 2, 6 and 12 months), and potentially abusive parenting was assessed by the child's attendance at hospital accident and emergency departments (at 2, 6 and 12 months). The service use of mother and infant was reported at 2, 6 and 12 months, with unit costs derived from local and national sources and estimated in line with best practice.

Process study

The uptake of the programme and the extent and nature of delivery were calculated based on data from standardised gFNP forms completed by FNs. A parallel appraisal informed by qualitative interviews was concerned with the experiences of families offered gFNP and of the practitioners delivering the programme.

Nested 'looked-after children' study

Interviews were sought with participants who had reported that they spent time away from their parent(s) during childhood, in the care of social services. Interviews were also conducted with FNs who were involved in delivering gFNP in sites that had self-identified, 'looked-after' participants, and with other professionals involved in providing support to young parents who had been 'looked after'.

Recruitment, data collection and analysis

The trial commenced in February 2013; recruitment and baseline data collection commenced in July 2013, continuing to September 2014. Data collection was completed in March 2016; it was conducted by researchers making four visits to participants' homes (at baseline and when infants were aged 2, 6 and 12 months), when they administered structured questionnaires, and at 12 months they also made a 3- to 5-minute video of the mother and infant together. The data collection team and those scoring the videos were blind to treatment allocation.

Randomisation at baseline was overseen by the London School of Hygiene and Tropical Medicine (LSHTM) Clinical Trials Unit (CTU) and conducted by the central randomisation service at Health Services Research Unit, Aberdeen, using an automated telephone procedure. Allocation to one of two arms, minimised by site and age group (< 20 years or 20–24 years), was computer generated and delivered by e-mail to the LSHTM CTU, which conveyed the allocation by post to the participants, and to each gFNP team giving the names and contact details of women allocated to the intervention arm.

Statistical analyses

Primary analyses were by intention to treat (ITT), and included adjustment for baseline measure of the outcomes when possible (analysis of covariance). When outcomes were collected at multiple time points to gain power, random-effects models, using a likelihood-based approach, were fitted simultaneously to the outcomes at all time points they were measured at.

For the primary outcomes a linear regression model was used to estimate a mean difference in scores between the two arms of the trial. A complier average causal effect (CACE) analysis was also carried out, which estimates a measure of the effect of the intervention on participants who received it as intended by the original allocation.

For the secondary outcomes, appropriate generalised linear models were used to examine the effect of the intervention. Odds ratios (ORs) and mean differences are reported with 95% confidence intervals (CIs). When continuous measures were available at baseline, they were adjusted for in the analysis.

Economic evaluation

Two main analyses of incremental cost-effectiveness were conducted. First, a cost–utility analysis calculated the incremental cost per quality-adjusted life-year (QALY) gained attributable to the gFNP programme, based on maternal HRQoL outcomes. Second, a cost-effectiveness analysis calculated the incremental cost per unit change in each of the primary outcomes [i.e. incremental cost per unit change in the AAPI-2 or incremental cost per unit change in the CARE-Index (maternal sensitivity)]. The results were primarily expressed as an incremental cost-effectiveness ratio (ICER) calculated as the difference in mean costs divided by the difference in mean outcomes (QALYs or maltreatment outcome measure) between the trial comparators. Non-parametric bootstrapping was used to determine the level of sampling uncertainty surrounding the mean ICER by generating 10,000 estimates of incremental costs and benefits, represented graphically on

four-quadrant cost-effectiveness planes. Cost-effectiveness acceptability curves illustrated the probability that the gFNP programme was cost-effective relative to usual care.

In addition, a separate discrete choice experiment (DCE) was conducted among a representative sample of the general population and a sample of expectant mothers with the view to quantifying preferences for the disparate outcome measures collected in evaluating the gFNP programme.

Results

Main study

A total of 166 women were enrolled (99 to the intervention group and 67 to the control group). There was no suggestion of an important effect of gFNP on either primary outcome in the ITT analyses based on outcomes available within the agreed time frame: the AAPI-2 total was 7.5/10 [standard error (SE) 0.1] in both arms [difference adjusted for baseline, site and maternal age group 0.08 (95% CI –0.15 to 0.28; $p = 0.50$)]; and mother's sensitivity on the CARE-Index was 4.0 in the intervention arm (SE 0.3) and 4.7 in the control arm (SE 0.4) [difference adjusted for site and maternal age group –0.76 (95% CI –1.67 to 0.13; $p = 0.21$)]. Three sensitivity analyses were carried out: the first included all participants irrespective of whether or not they were within the pre-specified time window; the second explored the effect of including a random effect for the group the intervention was delivered in; and the third explored the effect of premature births. All three supported the primary analyses.

Using a CACE analysis to take account of compliance made little difference to the ITT results for the AAPI-2, with compliance defined as attending at least one session (difference 0.14, 95% CI –0.41 to 0.69; $p = 0.64$); and with compliance defined as attending at least 17 sessions (difference 0.17, 95% CI –0.91 to 1.24; $p = 0.76$). The corresponding results for mother's sensitivity on the CARE-Index are difference –1.29 (95% CI –2.78 to 0.19; $p = 0.09$) when compliance was defined as attending at least one session, and difference –2.61 (95% CI –5.57 to 0.35; $p = 0.8$) when compliance was defined as attending at least 17 sessions.

There was no evidence of any effect of the intervention on all but one of the eight secondary outcomes, the only exception being that the proportion of women still breastfeeding at 6 months was higher in the intervention arm (adjusted OR 3.2, 95% CI 0.99 to 10.6; $p = 0.05$). The sensitivity analyses supported the primary analyses.

Economic evaluation

The average total cost was £8179 in the gFNP intervention group, compared with £6107 in the usual-care group, generating a mean incremental cost of £2072. The mean incremental cost-effectiveness of the gFNP intervention was estimated at –£247,485 per QALY gained (i.e. on average the intervention was associated with a net positive cost and a net negative effect). Regardless of the value of the cost-effectiveness threshold, the probability that the gFNP intervention was cost-effective did not exceed 3%. This pattern was broadly replicated when using the CARE-Index (maternal sensitivity). When outcomes were measured in terms of *change* in AAPI-2 score (baseline to 12 months), the probability that the gFNP intervention was cost-effective was estimated at 25.1% at a notional £20,000 cost-effectiveness threshold. The sensitivity analyses had little notable effect on the overall pattern of results. The DCE highlighted the value placed by both pregnant women and members of the general population on non-health outcomes that were not included in the QALY metric.

Process evaluation

This identified substantial variability in both the number of sessions offered by sites and the dosage for individual clients, although the content was delivered in sessions as the programme developers planned. Participants allocated to gFNP were generally positive and described perceived benefits, but also discussed a range of barriers to attendance. FNs delivering the programme reported on its perceived strengths, on issues that arose for them delivering gFNP and on changes that might be required for sustainability.

Conclusions

The meaning of the main study findings is that gFNP in its present form did not represent a clinically effective or cost-effective way to reduce the risk of child abuse or neglect in a potentially vulnerable population. However, the study faced challenges in recruiting sufficient women for the groups to be of adequate size, which may have affected the results.

Future research could . . .

- Compare the impact of two different models of gFNP, one incorporating the antenatal care based on the 'Centring Pregnancy' model and another offering the FNP curriculum, but in a group context and focusing in particular on role play of enjoyable and sensitive mother–child interactions with a primary outcome focusing on parent confidence and infant care practices, with the possibility of examining longer-term child outcomes.
- Vary the target client group in a large enough sample so that any impact can be compared for women with varying levels of vulnerability.

Trial registration

This trial is registered as ISRCTN78814904.

Funding

Funding for this study was provided by the Public Health Research programme of the National Institute for Health Research.

Public Health Research

ISSN 2050-4381 (Print)

ISSN 2050-439X (Online)

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This report

The research reported in this issue of the journal was funded by the PHR programme as project number 11/3002/02. The contractual start date was in February 2013. The final report began editorial review in August 2016 and was accepted for publication in January 2017. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PHR editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the PHR programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the PHR programme or the Department of Health.

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