

Building evidence to improve maternal and child health



Giving children the best possible start in life is crucial to reduce health disparities.¹ One of the UK Government's efforts to support young children has been to adapt and assess the Family Nurse Partnership (FNP), a programme of prenatal and early childhood home visiting for vulnerable first-time mothers and their children. In *The Lancet*, Michael Robling and colleagues² report on Building Blocks, a multisite trial of the FNP in England. My colleagues and I^{3,4} have developed and tested this programme previously in three randomised trials in the USA. We made independent randomised trials a prerequisite for international expansion when serving large populations, because knowing a programme's added value in new contexts is essential for guiding policy and practice.

In Robling and colleagues' pragmatic, open, individually randomised, controlled trial,² 1645 participants in community midwifery settings at 18 sites in England were randomly assigned to the FNP programme (823 participants received up to 64 structured home visits from early pregnancy until the child's second birthday, delivered by specially recruited and trained family nurses) added to usual care, and 822 received usual care alone. The Building Blocks trial is very well conducted, with objective measures, acceptable rates of completed assessments for most outcomes, and rigorous adherence to its statistical analysis plan; this strengthens the conclusion that FNP had no effects compared with usual care on the study's primary outcomes: prenatal cigarette smoking at the end of pregnancy (304 [56%] of 547 participants with FNP vs 306 [56%] of 545 with usual care), subsequent pregnancies (426 [66%] of 643 with FNP vs 427 [66%] of 646 with usual care), birthweight (mean birthweight 3217.4 g [SD 618.0] for 742 children with FNP vs 3197.5 g [SD 581.5] for 768 children with usual care), or at least one child emergency encounter or hospital admission at an accident and emergency department (587 [81%] of 725 children with FNP vs 577 [77%] of 753 children with usual care).² The study's design would have been strengthened, however, had it been guided more completely by findings from previous trials.³⁻⁵ Moreover, its results need to be understood in the context of usual care after FNP was added to local services. I raise these issues to encourage a deeper conversation within scientific and policy communities about how best

to use scarce research resources aimed at improving the early health and development of vulnerable populations.

As Robling and colleagues note, US trials identified that programme benefits, such as mothers' use of cash-assistance welfare, timing of subsequent pregnancies, verified reports of child maltreatment, injuries and ingestions, and language and cognitive development, were most pronounced in families living in concentrated disadvantage and, for children, those born to mothers who had few psychological resources to cope with adversity.³⁻⁵ The UK FNP has focused on young mothers (<20 years of age) because their children are at risk of compromised development,⁶ and maternal age makes it easy to identify who qualifies.⁷ However, young mothers vary substantially in the extent to which they have overlapping challenges, such as financial difficulties, depression, and substance misuse.⁶ Positive FNP effects identified in a Dutch trial^{8,9} of 460 disadvantaged women on outcomes such as child maltreatment, children's internalising behavioural problems, and intimate partner violence might be attributed, at least partly, to its serving highly vulnerable mothers, irrespective of their age. Robling and colleagues' trial examined a set of possible moderators of FNP effects, but it was not designed to estimate effects with those most vulnerable.

Moreover, we need to consider what usual care was in Robling and colleagues' study.² How did efforts of teenage pregnancy midwives and health visitors affect estimates of FNP's added value? The usual-care group, for instance,

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received a mean of 16.25 (SD 12.15) visits by health visitors—a number probably even higher in those at risk. In view of the fact that health visitors in this trial were informed of mothers' service assignments and directed not to visit families in FNP, the 8.6 (SD 13.74) mean number of health-visitor encounters reported by mothers in FNP must be interpreted with caution. FNP records show a mean of 39.28 (SD 15.19) FNP visits completed during pregnancy through to the age of 2 years; this represents excellent maternal engagement and is probably more than enough to help low-risk mothers.¹⁰

Additionally, FNP and usual-care effects on prenatal smoking should be placed in the context of other smoking interventions. As noted in the supplementary materials,² women in FNP identified as smokers at registration quit at a rate of 17% (49 of 293) compared with 17% (49 of 297) of those in usual care. Although smoking cessation as an outcome overlooks women identified as smokers at the end of pregnancy who were not classified as smokers at registration, it allows us to put the prenatal smoking effects in the trial into context.¹¹ These cessation rates are much larger than those identified for most prenatal counselling and education interventions for women who smoked at baseline, and in which cessation is biochemically validated (ie, 9–11%, calculated from studies reported in a review of the scientific literature).¹¹ Thus, both usual care and FNP were comparatively successful, notwithstanding how much more needs to be done to reduce prenatal cigarette smoking. By contrast, neither FNP nor usual care prevented subsequent pregnancy within 24 months after delivery of the first child (66% in both groups). These high rates make me wonder whether this outcome has the same functional meaning in this sample as it does elsewhere.¹²

The two primary child outcomes selected for Robling and colleagues' trial² are not outcomes that FNP claims to affect. There were no previous replicated effects on birthweight or children's accident and emergency department encounters as operationalised in this trial. It is noteworthy that this accident and emergency outcome combines all emergency encounters and hospital admissions into a single yes or no variable. This categorisation does not distinguish, for example, between a concerned parent taking a child with a possible ear infection to accident and emergency when GP care is unavailable, and a comatose child admitted for abusive head trauma. The higher rate of an accident and

emergency outcome encounter in the FNP group (81% vs 77%) might represent heightened parental concern and raises questions about this variable's meaning.

Two child outcomes of clear public health importance affected in previous trials were not selected as primary outcomes. The first is language or cognitive development, which was measured objectively in earlier trials.^{3–5} Robling and colleagues' study² would have been strengthened had its designers identified language as a primary outcome and measured it directly. In view of previous replicated effects, the significant intervention–control differences in maternally reported language development (and language and cognitive development concerns) in this trial are promising: at the age of 24 months, children in the FNP group had mean Early Language Milestone percentile values of 60.8 (SD 31.4) versus 55.7 (SD 31.4) for children in the usual-care group; at age 18 months, language development concerns (children not meeting milestones) were present for 84 (17%) of 490 in the FNP group versus 110 (24%) of 455 for those in usual care; and at 24 months, cognitive development concerns were present for 46 (8%) of 569 children in the FNP group versus 66 (13%) of 522 for those in usual care. Both children in FNP and usual care exceeded the median normative values for age-matched children assessed with the Early Language Milestone; both groups were faring better than most children of their age.

The second outcome of importance is serious injury, often an indication of maltreatment in young children. Although more safeguarding was reported in FNP than in usual-care families, this is consistent with previous findings,¹³ and probably represents FNP nurses' efforts to ensure children's protection. In view of previous programme impact on maltreatment and length of hospital stay for injuries,³ a case can be made for examining serious injuries in such trials—an outcome much more consistent with previous effects.

Those responsible for delivering FNP in the UK must now determine next steps. Continued assessment is essential as increased effort is focused on mothers who need FNP the most, and intensified support is given to nurses tackling challenging behaviour, such as maternal smoking and pregnancy planning. The results of Robling and colleagues' trial² underscore why we cannot simply disseminate programmes without assessing them, and why, to accelerate construction of a solid early-intervention evidence base, we need to

ensure that results and insights from previous studies are integrated thoroughly into the designs of new ones.

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I, with colleagues, founded the Nurse-Family Partnership (NFP; also known as FNP). The Prevention Research Center for Family and Child Health (PRC), which I direct at the University of Colorado School of Medicine, USA, receives licensing fees and travel expenses from governments and entities outside the USA linked to its implementation. My institution has received fees from the UK Department of Health; the British Columbia Department of Health, Canada; Simon Fraser University, Canada; the City of Hamilton, Canada; and agencies in Australia, Norway, Bulgaria, the Netherlands, Scotland, and Northern Ireland. I also have received research funding from National Institute of Justice (public funding), the National Institute on Drug Abuse (public funding), the John and Marcie Fox Foundation, and Pyramid Peak Foundation. In the USA, NFP is replicated by the NFP National Service Office, which provides funding to the PRC for research on improving NFP and its implementation. I have received compensation for consulting with the following organisations: the Coalition for Evidence-Based Policy, the Urban-Child Institute, and the Department of Psychiatry and Behavioral Sciences, Northwestern University.

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