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Effectiveness of nurse-home visiting in improving child and maternal outcomes prenatally to age two years: a randomised controlled trial (British Columbia Healthy Connections Project)

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Background: We investigated the effectiveness of Nurse-Family Partnership (NFP), a prenatal-to-age-two-years home-visiting programme, in British Columbia (BC), Canada. **Methods:** For this randomised controlled trial, we recruited participants from 26 public health settings who were: <25 years, nulliparous, <28 weeks gestation and experiencing socioeconomic disadvantage. We randomly allocated participants (one-to-one; computer-generated) to intervention (NFP plus existing services) or comparison (existing services) groups. Prespecified outcomes were prenatal substance exposure (reported previously); child injuries (primary), language, cognition and mental health (problem behaviour) by age two years; and subsequent pregnancies by 24 months postpartum. Research interviewers were masked. We used intention-to-treat analyses. (ClinicalTrials.gov, NCT01672060.) **Results:** From 2013 to 2016 we enrolled 739 participants (368 NFP, 371 comparison) who had 737 children. Counts for child injury healthcare encounters [rate per 1,000 person-years or RPY] were similar for NFP (223 [RPY 316.17]) and comparison (223 [RPY 305.43]; rate difference 10.74, 95% CI -46.96, 68.44; rate ratio 1.03, 95% CI 0.78, 1.38). Maternal-reported language scores (mean, *M* [*SD*]) were statistically significantly higher for NFP (313.46 [195.96]) than comparison (282.77 [188.15]; mean difference [MD] 31.33, 95% CI 0.96, 61.71). Maternal-reported problem-behaviour scores (*M* [*SD*]) were statistically significantly lower for NFP (52.18 [9.19]) than comparison (54.42 [9.02]; MD -2.19, 95% CI −3.62, −0.75). Subsequent pregnancy counts were similar (NFP 115 [RPY 230.69] and comparison 117 [RPY 227.29]; rate difference 3.40, 95% CI -55.54, 62.34; hazard ratio 1.01, 95% CI 0.79, 1.29). We observed no unanticipated adverse events. **Conclusions:** NFP did not reduce child injuries or subsequent maternal pregnancies but did improve maternal-reported child language and mental health (problem behaviour) at age two years. Follow-up of long-term outcomes is warranted given that further benefits may emerge across childhood and adolescence.
Keywords: Child injuries; child mental health; child problem behaviour; cognitive and language development; subsequent pregnancies; health inequities; nurse-home visiting; randomised controlled trial; public health.

Introduction

Family socioeconomic disadvantage is a serious form of childhood adversity due to its association with child injuries and developmental and mental health difficulties (Brownell et al., 2010; Cooper & Stewart, 2021). In Canada, more than 330,000 children under age 18 years (4.7%) live in families with insufficient economic resources (Statistics Canada, 2022a, 2022c). The rate is tripled for children in female-headed, lone-parent families (16.9%) (Statistics Canada, 2022a). Children of young mothers (<21 years) face additional challenges including suboptimal cognitive and language development and behavioural problems (Cresswell et al., 2022). The adverse effects of family socioeconomic disadvantage are compounded when young mothers' capacities to engage in education and employment are limited by rapid subsequent pregnancies (Ahrens, Nelson, Stidd, Moskosky, & Hutcheon, 2019; Harding, Knab, Zief, Kelly, & McCallum, 2020). Income inequality has grown substantially in Canada, further exacerbating extant disparities (Green, Riddell, & St-Hilaire, 2016). These disparities and their consequences tend to persist throughout the life span, resulting in high costs for both individuals and society (Cooper & Stewart, 2021; Marmot et al., 2010; Rivenbark et al., 2018). Family socioeconomic disadvantage therefore constitutes a potent threat to healthy child development (Cooper & Stewart, 2021; Marmot et al., 2010). Early childhood interventions have the potential to mitigate the negative impact of socioeconomic inequities and improve lifelong outcomes, particularly if these interventions start in pregnancy (Doyle, Harmon, Heckman, &

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Tremblay, 2009). Nurse-Family Partnership (NFP) is one such intervention.

NFP, an intensive home-visiting programme developed in the United States (US), aims to support children and young, first-time mothers who are experiencing socioeconomic disadvantage (Olds, 2008). Evidence from three randomised controlled trials (RCTs) conducted in the United States more than two decades ago demonstrated NFP's benefits by child age two years – including reducing child injuries (Tennessee and New York trials; Kitzman et al., 1997; Olds, Henderson, Chamberlin, & Tatelbaum, 1986), improving child language and cognitive development (in a subgroup experiencing greater disadvantage in the Colorado trial; Olds et al., 2002), and reducing mother's subsequent pregnancies (Tennessee and Colorado trials; Kitzman et al., 1997; Olds et al., 2002). Evidence from follow-up studies in New York (19 years), Tennessee (12 years) and Colorado (4 years) suggested enduring benefits including reduced child and maternal mortality (Olds, 2008; Olds et al., 2014). American economic analyses have also shown that for those experiencing the greatest adversities in early pregnancy, NFP generated net benefits of nearly US $3000 per child when costs of averted services were tabulated across multiple public sectors over approximately 15–20 years (Wu, Dean, Rosen, & Muennig, 2017). Since Canada offers more comprehensive, publicly funded health and social programmes compared with the United States, it was unknown whether comparable benefits would be obtained by early childhood.

In Canada, NFP evaluations began in 2008 with a successful acceptability and feasibility pilot study conducted in Ontario (Jack, Catherine, et al., 2015). In 2011, the Government of British Columbia (BC) then funded a RCT evaluation of NFP, the BC Healthy Connections Project (BCHCP). Prespecified outcomes were: (1) prenatal substance exposure (reported previously); (2) child injuries (primary), (3) language/cognition and (4) mental health (problem behaviour) by age two years; and (5) subsequent pregnancies by 24 months postpartum (Catherine et al., 2016; Catherine, Boyle, et al., 2020). We report here on the four child and maternal outcomes. The aim was to evaluate NFP's effectiveness in improving child and maternal outcomes by child age two years compared with existing services in BC.

Methods

Trial design and setting

We conducted a pragmatic, single-blinded, RCT in 26 urban–suburban local health areas (LHAs) across four of five regional health authorities (HAs; Appendix S1). The LHAs were selected based on anticipated birth rates and feasibility of conducting in-person research interviews across wide geographic areas. We registered the trial at ClinicalTrials.gov (NCT01672060) and have published detailed trial methods (Catherine et al., 2016).

Participants

Eligible participants were preparing to parent for the first time, less than 28 weeks gestation, less than 25 years of age, experiencing indicators of socioeconomic disadvantage and residing in an NFP catchment area (Box 1). Based on age alone, girls 19 years or younger were considered to meet socioeconomic disadvantage criteria given the likelihood of interrupted education, limited income and lone parenting at a young age. Recruitment was embedded within existing services. NFP nurses were responsible for informing primary care providers, such as physicians or midwives, to refer potential participants to public health prenatal registries; pregnant individuals could also self-register. Public health nurses in the 26 LHAs then screened for eligibility and referred potential participants to the study team at Simon Fraser University (SFU). The study

Box 1 Eligibility criteria*

Inclusion criteria

- Less than 25 years of age
- Preparing to parent for the first time†
- Less than 28 weeks gestation
- Competent to provide informed consent‡
- Experiencing socioeconomic disadvantage
  - Age 19 years or younger§
  - Age 20–24 years and having two or more of the following indicators
    - Preparing to parent while single (not married or not living common law) ¶
    - Having limited access to education (less than grade 12)
    - Having limited income (one or more of the following): Receiving income assistance; 'finding it difficult to live on total household income regarding food or rent'; and/or being homeless#

Exclusion criteria

- Planning to have their child adopted
- Planning to leave the BCHCP catchment area for three months or longer

*Adapted from Catherine et al. (2016). †Eligible if any previous pregnancy ended in termination, pregnancy loss or stillbirth, or if previous parenting was step-parenting. ‡Competence included ability to converse in English. §Based on age alone, girls age 19 years or younger met socioeconomic disadvantage criteria given the likelihood of interrupted education, limited income and lone parenting. ¶Common law was defined as living with the same person for more than one year. #Homelessness was defined as living on the streets, staying in a place not meant for long-term habitation (e.g. car or tent), staying in a shelter, or staying somewhere temporarily with no permanent address (e.g. 'couch surfing').

team confirmed participants' eligibility by telephone using the same criteria and scheduled in-person meetings to obtain consent and conduct baseline research interviews.

Ethical considerations

We obtained research ethics approvals from all participating HAs (Fraser, Interior, Island and Vancouver Coastal Health), universities (SFU, University of BC, University of Victoria, and McMaster University) and the Public Health Agency of Canada. We obtained informed written consent prior to gathering data at the baseline interview. The consent form was read aloud to ensure comprehension; mature minors were deemed competent to provide informed consent. An independent Data and Safety Monitoring Committee tracked participant safety and protocol compliance.

Randomisation and masking

An independent statistician developed separate schedules for each of the 26 LHAs using constrained randomisation wherein a smaller block size was used in areas where fewer than 18 participants per year were expected. Following the baseline interview, a study team member not involved in data management performed computer-generated random allocation to intervention (NFP plus existing services) or comparison (existing services) groups (1:1), then informed NFP nurses (unmasked) and participants (unmasked) of their group allocation. Field interviewers and trial analysts were masked. Before each follow-up research interview, field interviewers reminded participants not to disclose group assignment during the interviews.

Intervention

NFP involves regular public health nursing home visits starting in early pregnancy and continuing until the child's second birthday. NFP entails up to 64 structured visits (approximately 14 prenatal and 50 postpartum) (Olds, 2008). The aims are to develop a close, trusting partnership to improve: (1) pregnancy outcomes through positive maternal health behaviours; (2) child health and developmental outcomes through sensitive and competent parenting; and (3) maternal economic self-sufficiency through pregnancy spacing and encouragement of education and employment opportunities. Injury prevention aligns with NFP goals over the life course (Olds et al., 2014). NFP is designed to enhance mothers' motivation to protect their children, buffering them from the impact of early toxic stress during a sensitive period of development, with long-term implications for healthy neurodevelopment and behaviours (Gee & Cohodes, 2021; Olds et al., 2014; Sheridan et al., 2022).

For the BC trial, nurses used home-visit content guidelines and programme fidelity model elements that were adapted for the Canadian context (Jack, Catherine, et al., 2015). Participating HAs recruited public health nurses – registered nurses with a bachelor's degree in nursing at a minimum – who received 140 hr of NFP education and ongoing supervision and support. Nurses provided informed written consent to participate in the trial and attended research orientations delivered by the study team. Nurses contacted those allocated to the intervention arm to schedule the first home visit before 29 weeks gestation, an NFP fidelity element. Throughout the trial, nurses entered programme data via their established HA electronic health systems for ongoing fidelity monitoring.

Existing services

All participants were eligible to receive BC's existing health and social services, typically at no cost. Services for expectant and new mothers and young children varied across the province and could include: primary and specialist health care; emergency room (ER) and hospital care; mental health services including for substance use; public health services including prenatal classes and brief telephone or home encounters by non-NFP nurses and other providers; child immunizations; social and community programmes; and parenting and early child development programmes. Other social services through federal, provincial, municipal and non-profit organisations could include employment and income assistance, child benefits, housing supports and food banks.

Procedure

Field interviewers collected computer-assisted survey data using standardised measures and survey items, verbally administering questionnaires at baseline (in-person at study entry), at 34-to-36 weeks gestation, and when children were two, 10, 18 and 24 months of age (in-person or by telephone; Catherine et al., 2016). We report on the items administered at baseline and 24 months of age that informed the main outcome analyses (Appendix S2). Field interviewers had post-secondary degrees and received intensive training on trial procedures such as interview skills, participant retention, data management and risk mitigation (Catherine et al., 2016). They conducted in-person interviews in homes or community settings such as private rooms in public libraries when necessary for confidentiality (e.g. due to shared housing). Participants received gift cards (CAD$75–100 after each 2.5-hr interview) to recognise their time and contribution.

Participants could withdraw at any time. As per the informed consent protocol, their own and their child's data were included in the analyses up to the withdrawal date. To support participant inclusion and sustained engagement, we developed and implemented a theory- and evidence-based retention protocol (Catherine, Lever, et al., 2020). We also followed an intention-to-treat protocol, inviting individuals to continue with research interviews if they withdrew from NFP, missed an interview or experienced pregnancy loss or adoption. NFP nurses and field interviewers recorded adverse events. A senior study team member monitored these events in accordance with the trial protocol.

Outcomes

The prespecified primary outcome was counts of healthcare encounters for child injuries (including ingestions) from birth to the second birthday, based on both community/outpatient and hospitalisation events. Complete ER data were not available earlier in the trial to inform the sample size estimation and are therefore not a component of the primary outcome indicator. Nevertheless, exploratory outcomes included ER and hospital encounters (including hospital length-of-stay [LOS] defined as the total number of days of injury-related hospital care per episode). We counted one hospital episode if a previous discharge date and next admission date were within one day (Appendices S2, S3).

For the secondary outcomes, we assessed maternal-reported language using vocabulary production scores from the MacArthur-Bates Communicative Development Inventories (CDI) (Fenson, Dale, Reznick, & Bates, 1993), and maternal-reported mental health (problem behaviour) using the externalising subscale of the Child Behaviour Checklist for Ages 1.5-to-5-year-olds (CBCL; Achenbach & Rescorla, 2000). We administered the CDI and CBCL during telephone or in-person interviews with participants in all four HAs. We also directly assessed cognition and language for a subgroup of children in their homes using the Bayley Scales of Infant and Toddler Development, Third Edition, or Bayley (Bayley, 2006). This subgroup resided in communities in two local HAs within

driving distance for field interviewers. For Bayley administration, field interviewers and the trial manager received training from an external academic psychology consultant. The trial manager then provided weekly supervision to field interviewers to ensure consistency in administration and coding. We also examined the count of subsequent maternal pregnancies and the timing of the first subsequent pregnancy up to 24 months postpartum (Appendices S2, S3).

Sample size

We estimated the sample size based on available provincial administrative data for child injury healthcare encounters for a similar cohort – informed by both community/outpatient injury events and hospitalisations. In summary, the injury base rate was estimated to be 239 per 1,000 person-years (PYs). For a type I error rate of 0.05 and a power of at least 80%, we determined that 732 participants (349 individuals per study arm plus 5% attrition) were required to detect a 30% reduction in the injury rate due to the intervention (relative ratio 0.70). (See Appendix S4 for details on original sample size estimation.)

Statistical analysis

All analyses were by intention-to-treat, analysing participants (and children) according to the treatment groups to which they were randomly assigned. We report group means (standard deviation, *SD*) for continuous outcomes, and event numbers (and days) and incident rates for count outcomes (and hospitalisation length of stay). The incident rate is the ratio of the total number of events to the total person-years accumulated during the follow-up, reported as the number of events per 1,000 person-years. We also report the rate differences (RD) between the NFP and comparison groups with their 95% confidence intervals (CIs) for these differences. The main statistical models for evaluating intervention effects included: individual child's outcome evaluated at age two years as the response variable; an indicator for intervention group assignment as the fixed effect; and random-effects for LHA clusters (maternal participants nested in 26 LHAs across four health authorities). These models belong to the class of generalised linear mixed-effects models (GLMMs) that are efficient and recommended statistical methods for analysing RCT data and are applicable for a wide variety of types of clustered outcomes, including continuous, binary and count data (Diggle, Heagerty, Liang, & Zeger, 2013). Specifically, we analysed the primary outcome (informed by both community/outpatient injury events and hospitalisations) using mixed-effects quasi-Poisson regression models with log link (a special case of GLMMs) for clustered/overdispersed count data. We reported intervention effects as the model-adjusted rate ratio (ratio of NFP to comparison regarding injury rates), computed as the exponential of the coefficient estimate of intervention group indicator in the model. To deal with overdispersion issues, we used robust sandwich estimators for GLMMs to compute empirical standard errors to calculate 95% CIs and *p*-values that are robust to model specification. We conducted further exploratory analyses on community/outpatient (only) visits as well as ER visits using the same mix-effects quasi-Poisson regression models. We estimated hospitalisation counts and hospital LOS (days) using an exact Poisson model to address low frequency.

For the secondary child outcomes – cognition/language and problem behaviour – we used linear mixed models (LMM), a special case of GLMM, reporting the intervention effects as model-adjusted mean difference (MD) in scores of these indicators between groups estimated from the model, obtained as the coefficient estimate of intervention group indicator in the LMM model. CBCL data were analysed as continuous and categorical variables. We estimated the proportion of children rated in the CBCL borderline-to-clinical range for externalising problem behaviours using a GLMM with the logit link function for binary outcomes (an exploratory outcome). We reported the model-adjusted odds ratio as the intervention effect estimate, computed as the exponential of the coefficient estimate of intervention group indicator in the model.

We analysed time to maternal-reported subsequent pregnancies (and subsequent births, an exploratory outcome) using a Cox proportional hazards model. We followed all participants with a subsequent pregnancy (or birth) from the index child's birth month to the month of their first subsequent pregnancy (or birth). All other participants were followed until they were lost to follow-up, moved out of BC or completed the study. We report the hazard ratio of subsequent pregnancies for the NFP versus comparison groups.

We conducted sensitivity analyses to evaluate the robustness of our analysis to missing data in secondary outcomes. We first performed a multiple imputation that incorporated select baseline covariates (from Table 1) that were potentially predictive of the secondary outcomes and were associated with the probability of missingness – in order to impute missing values using chained equations under the missing at random (MAR) assumption. We combined the intervention effects estimates from imputed data sets using Rubin's rule (van Buuren & Groothuis-Oudshoorn, 2011). In a second sensitivity analysis, we used selection models and calculated the index of local sensitivity to nonignorability (ISNI) to assess the potential impact of data missing not at random on intervention effect estimates (Xie et al., 2018). We performed a sensitivity analysis for handling twin children whose outcome measures were likely correlated. We replicated the statistical analyses on the primary and secondary child outcomes including data for one of the twin children in the analyses. Finally, we conducted robust analysis that winsorises (i.e. censors) the extreme LOS values to reduce the influence of potential LOS outliers.

All p-values were two-sided and were not adjusted for multiple comparisons as the study had only one primary outcome for confirmatory analysis. Analyses were conducted using R version 4.1 and Stata 17.1.

Results

Between October 2013 and December 2016, 2,503 potential participants were screened and 1,177 were then referred to the study team. Of these, 739 expectant mothers were enrolled. They and their 737 children were included in the analyses (Figure 1). Randomisation was implemented and baseline characteristics were balanced between groups (Table 1). Research interview data were collected by 30 November 2019 (80.4–90.3% retention across the five follow-up interviews). Administrative injury data (primary outcome) were received by 20 January 2021 with <1% missing data. (No administrative injury data were available for five children born outside BC. Three children were also withdrawn after birth therefore had injury data for less than the two-year observation time.) For the Bayley, among the 490 children whose mothers lived in the two local HAs at baseline interview, 377 (186 NFP; 191 comparison) were assessed in the home; baseline characteristics were also balanced between groups (Appendices S5, S6).

For the primary outcome, we found no difference in mean injury counts [rate per 1,000 person-years]

Table 1 Participant maternal baseline and child characteristics[a]

	NFP	Comparison
Participant/maternal baseline characteristics		
	N = 368	*N* = 371
Sociodemographic characteristics		
Age (years)	19.8/368 (2.4)	19.7/371 (2.3)
Age (19 years or younger)	186/368 (51%)	175/371 (47%)
Single (not married or common law)	333/367 (91%)	337/369 (91%)
English as first language	335/368 (91%)	351/370 (95%)
Racial/ethnic identity[b]		
White	201/368 (55%)	217/371 (58%)
Indigenous including First Nations, Métis and Inuit	35/368 (10%)	44/371 (12%)
Indigenous including First Nations, Métis or Inuit and other ancestries (including white or other non-Indigenous)	65/368 (18%)	56/371 (15%)
Mixed ancestries (≥2 excluding Indigenous)	32/368 (9%)	23/371 (6%)
Asian (Chinese, South Asian, or Other)	16/368 (4%)	16/371 (4%)
Other (including 'Latin-American', Black)	19/368 (5%)	15/371 (4%)
Highest educational qualification		
Less than high school	186/367 (51%)	188/371 (51%)
High school diploma or equivalent	117/367 (32%)	126/371 (34%)
College or other non-university degree	19/367 (5%)	18/371 (5%)
University or higher degree	45/367 (12%)	39/371 (11%)
Income from employment (CAD)	9368.5/363 (9963.6)	10,489.9/362 (11,139.7)
Income from employment (CAD)		
Less than $5,000	162/364 (45%)	146/362 (40%)
$5000–9,999	54/364 (15%)	64/362 (18%)
$10,000–19,999	93/364 (26%)	87/362 (24%)
$20,000–29,999	37/364 (10%)	38/362 (10%)
$30,000 or more	18/364 (5%)	27/362 (7%)
Unstable housing		
Moved 3 or more times (past year) or ever homeless	198/365 (54%)	187/366 (51%)
Psychological distress		
Moderate-to-severe psychological distress (past month)	114/368 (31%)	122/371 (33%)
Experiences of violence		
Child maltreatment at age 16 years or younger	204/361 (57%)	206/367 (56%)
Exposure to intimate partner violence, IPV (past year)[c]	138/365 (38%)	138/369 (37%)
Child characteristics		
	N = 364	*N* = 373
Sex (female)	171/364 (47%)	170/373 (46%)
Twin	8/364 (2%)	14/373 (4%)

Data are *n*/*N* (%) or mean/*N* (standard deviation, *SD*). CAD, Canadian dollars; NFP, Nurse-Family Partnership.
[a]Table adapted from previous papers (Catherine, Boyle, et al., 2020; Catherine, Lever, et al., 2020; Catherine et al., 2019).
[b]Categories based on outdated Statistics Canada 2006 Census (Statistics Canada, 2010); participants could give more than one answer.
[c]IPV was classified using a criterion cut-off score of ≥7 compared to cut-off of ≥3 used in previous papers (Appendix S2) (Catherine, Boyle, et al., 2020; Catherine, Lever, et al., 2020; Catherine et al., 2019).

between groups (223 [316.17] for NFP vs. 223 [305.43] for comparison; rate difference [RD] 10.74, 95% CI −46.96, 68.44; model-adjusted rate ratio [RR] of NFP to comparison was 1.03, 95% CI 0.78, 1.38, $p = .8189$; Table 2.) Results from exploratory analyses indicated statistically significant reductions in hospital LOS (count [days per 1,000 person-years]) for NFP (17 [24.10]) vs. comparison (54 [73.96]). The NFP group had a statistically significant lower daily risk of being hospitalised vs. comparison (RD −49.86, 95% CI −72.67, −27.05; RR 0.34, 95% CI 0.14, 0.84, $p = .0197$; Table 2).

For secondary outcomes, mean maternal-reported language – vocabulary production scores [*SD*] – were statistically significantly higher for NFP (313.46 [195.96]) vs. comparison (282.77 [188.15]; model-adjusted mean difference [MD] 31.33, 95% CI 0.96, 61.71; $p = .0432$; Table 3). Mean maternal-reported externalising problem-behaviour scores [SD] were statistically significantly lower for NFP (52.18 [9.19]) vs. comparison (54.42 [9.02]; MD −2.19, 95% CI −3.62, −0.75; $p = .0028$; Table 3). For the subsample assessed in the home, mean observed cognitive scores [*SD*] were similar for NFP (90.35 [12.81]) vs. comparison (91.94 [11.59]; MD −1.59, 95% CI −4.05, 0.87; $p = .2056$; Table 3). Mean observed language scores [*SD*] were similar for NFP (92.12 [16.11]) vs. comparison (91.10 [16.09]; MD 1.02, 95% CI −2.23, 4.27; $p = .5383$; Table 3). We found a positive correlation between maternal-reported language – vocabulary production scores and observed language scores (0.66, 95% CI 0.6, 0.71; $p < .01$). Regarding exploratory analyses of externalising problem behaviour, the odds of

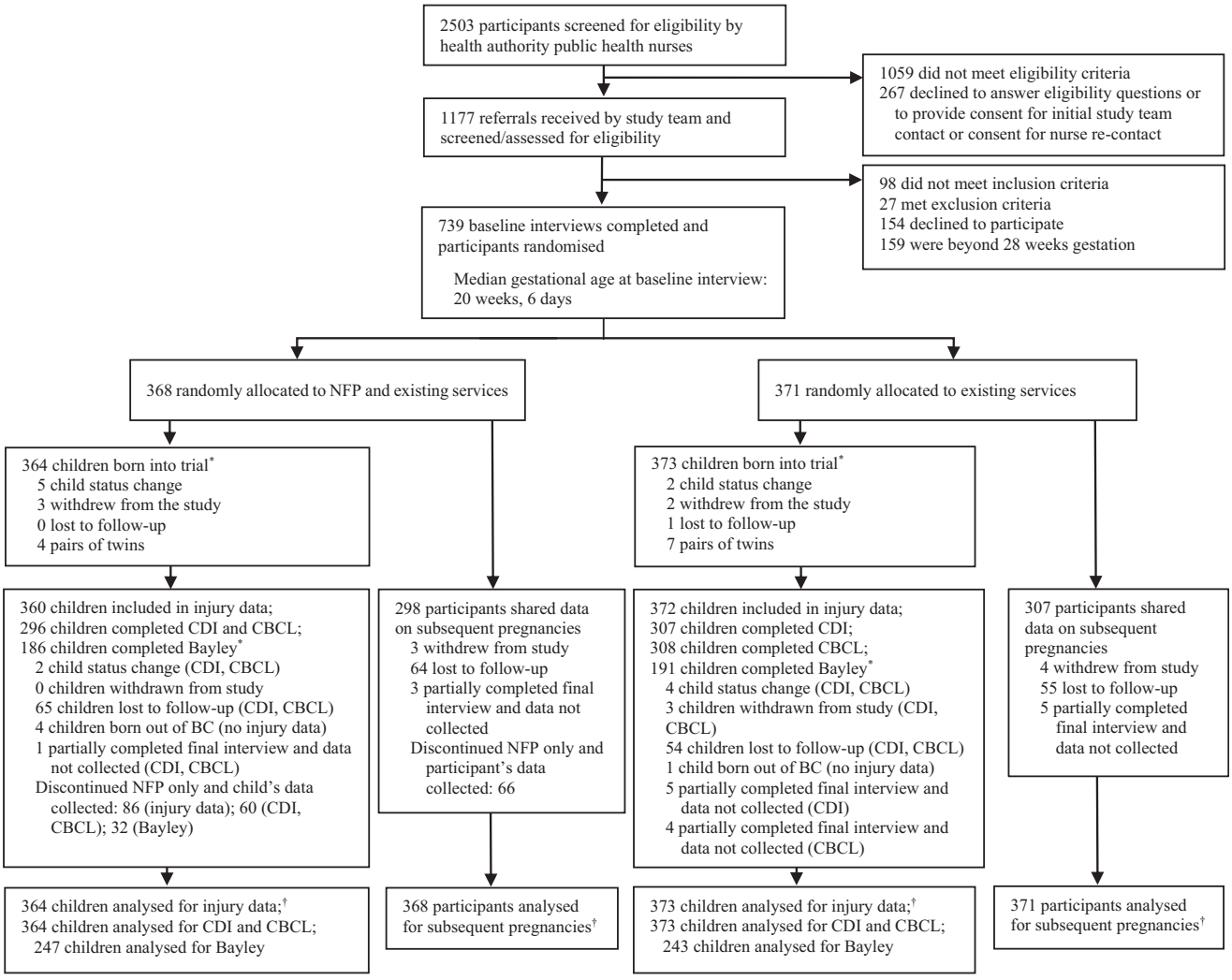

Figure 1 Trial profile. NFP, Nurse-Family Partnership. Child status change = pregnancy loss, stillbirth, abortion, or adoption prenatally or child death or adoption postnatally. CDI = MacArthur-Bates Communicative Development Inventories, vocabulary production score. CBCL = Child-Behaviour Checklist for Ages 1½–5, externalising problem-behaviour score. Bayley = Bayley Scales of Infant and Toddler Development, Third Edition, composite language and cognitive scores. *Trial profile data are available on subgroup who completed the Bayley (Appendix S5). †Shorter observation period for mothers (and children born in BC) who withdrew, or were lost to follow-up, or moved out of province.

Table 2 Primary outcome

	NFP (N = 364) n (rate)	Comparison (N = 373) n (rate)	RD (95% CI)	RR (95% CI)	p-Value
Primary outcome					
Child injuries[a]	223 (316.17)	223 (305.43)	10.74 (−46.96, 68.44)	1.03 (0.78, 1.38)	.8189
Exploratory analysis					
Community/outpatient, event	219 (310.50)	216 (295.84)	14.66 (−42.33, 71.64)	1.05 (0.78, 1.40)	.7500
Hospitalisations, episode	4 (5.67)	7 (9.59)	−3.92 (−12.93, 5.10)	0.59 (0.28, 1.23)	.1589
Emergency room, event	109 (154.54)	102 (139.70)	14.84 (−24.87, 54.54)	1.08 (0.78, 1.51)	.6,336
Length of hospitalisation, days	17 (24.10)	54 (73.96)	−49.86 (−72.67, −27.05)	0.34 (0.14, 0.84)	.0197

n, event counts. N, number of children; NFP, Nurse-Family Partnership. Rate = numbers of injury events (other types of events, episodes, or injury hospitalisation days) per 1,000 person-years, calculated as the ratio of the total count of injury events (other types of events, episodes, or injury hospitalisation days) *1,000 (numerator) to the total person-years accumulated during the follow-up (denominator). RD, rate difference per 1,000 person-years, calculated as the rate in the NFP group minus the rate in the comparison group. RR = model-adjusted rate ratio of injuries, estimated from Quasi-Poisson model with random effect of LHA or exact Poisson models. CI, 95% confidence intervals. p-value for testing null hypothesis of RR = 1.
[a]Community/outpatient and hospital events informed by administrative health data.

Table 3 Child secondary outcomes

	NFP Mean (*SD*); *N* observed	Comparison Mean (*SD*); *N* observed	Observed data only		Observed and imputed data	
			MD (95% CI)	*p*-Value	MD (95% CI)	*p*-Value
Maternal report	*N* = 364	*N* = 373				
Language: CDI	313.46 (195.96); 296	282.77 (188.15); 307	31.33 (0.96, 61.71)	.0432	31.42 (1.91, 60.93)	.0370
Problem-behaviour: CBCL	52.18 (9.19); 296	54.42 (9.02); 308	−2.19 (−3.62, −0.75)	.0028	−2.12 (−3.69, −0.55)	.0086
Child observation[a]	*N* = 247	*N* = 243				
Cognition: Bayley	90.35 (12.81); 186	91.94 (11.59); 191	−1.59 (−4.05, 0.87)	.2056	−1.42 (−3.80, 0.96)	.2401
Language: Bayley	92.12 (16.11); 185	91.10 (16.09); 191	1.02 (−2.23, 4.27)	.5383	1.13 (−1.93, 4.20)	.4679
Exploratory outcome	*n* (%); *N* observed	*n* (%); *N* observed	OR (95% CI)	*p*-Value	OR (95% CI)	*p*-Value
Maternal report	*N* = 364	*N* = 373				
Problem-behaviour, borderline-clinical range: CBCL	58 (38.93%); 296	91 (52.31%); 308	0.58 (0.41, 0.82)	.0018	0.59 (0.40, 0.87)	.0082

NFP, Nurse-Family Partnership. *SD*, standard deviation. *N* observed = number of children where data were collected. CDI = -MacArthur-Bates Communicative Development Inventories, vocabulary production score. CBCL = Child-Behaviour Checklist for Ages 1½–5, externalising problem-behaviour score. Bayley = Bayley Scales of Infant and Toddler Development, Third Edition, composite score. *N*, number of children. *n* (%), number (percentage) of children with externalising problem behaviour in the borderline-to-clinical range. MD = mean difference in scores estimated from the linear mixed models with random effect of LHA. CI, 95% confidence intervals. OR, odds ratio.
[a]Subgroup of children assessed in the home.

children being rated in the borderline-to-clinical range were statistically significantly lower for NFP (*n* = 58, 38.93%) vs. comparison (*n* = 91, 52.31%; model-adjusted odds ratio 0.58, 95% CI 0.41, 0.82, *p* = .0018; Table 3).

The count [rate per 1,000 PYs] of subsequent pregnancies within 24 months postpartum was similar for NFP (115 [230.69]) and comparison (117 [227.29]; rate difference 3.40, 95% CI −55.54, 62.34; hazard ratio 1.01, 95% CI 0.79, 1.29; *p* = .9425; Table 4). The count [rate per 1,000 PYs] of subsequent births was also similar for NFP (43 [73.43]) and comparison (53 [86.73]; rate difference − 13.30, 95% CI −45.35, 18.75; hazard ratio 0.85, 95% CI 0.61, 1.18; *p* = .3235; Table 4).

Missing data for the primary outcome amounted to <1% and estimation results in Table 2 were expected to be robust to so few missing data. For secondary outcome measures, only the following baseline variables were found to have statistically significant associations with data missingness: age, highest educational qualification, income from employment, unstable housing and racial/ethnic identity (data available from authors). Our model for imputation included these baseline variables, together with the intervention group indicator and LHA clusters, to

Table 4 Maternal secondary outcomes

	NFP (*N* = 360) *n* (rate); *N* observed	Comparison (*N* = 366) *n* (rate); *N* observed	RD (95% CI)	Observed data only		Observed and imputed data	
				HR (95% CI)	*p*-Value	HR (95% CI)	*p*-Value
Maternal report							
Subsequent pregnancy	115 (230.69); 298	117 (227.29); 307	3.40 (−55.54, 62.34)	1.01 (0.79, 1.29)	.9425	0.98 (0.76, 1.26)	.8566
Exploratory outcome							
Subsequent birth	43 (73.43); 298	53 (86.73); 307	−13.30 (−45.35, 18.75)	0.85 (0.61, 1.18)	.3235	0.97 (0.66, 1.43)	.8677

NFP, Nurse-Family Partnership; *N*, number of mothers with live births (where 726 mothers had live births with 11 sets of twins). *n*, number of subsequent pregnancies/live births. Rate = number of pregnancies/live births per 1,000 person-years, calculated as the total number of pregnancies/live births * 1000 (numerator) divided by the total person-years accumulated during the follow-up (denominator); RD = rate difference, calculated as the rate in the NFP group minus the rate in the comparison group. HR = hazard ratio of first pregnancy/live birth among NFP to comparison, estimated from the Cox Proportional Hazard model with random effect of LHA. CI, 95% confidence intervals.

impute the missing secondary outcomes. The sensitivity analyses on the secondary outcomes using multiple imputations with chained equations indicated that the NFP intervention effect estimation was robust to imputation of missing values (see 'observed and imputed data' in Tables 3 and 4). Results from the ISNI sensitivity analysis indicated that the intervention effect estimates were robust to the violation of the MAR assumption. The sensitivity analysis including one of the twin's data also confirmed our findings. Finally, our finding on LOS was robust to sensitivity analyses that winsorised one potential outlier in the control group hospital LOS by a half – from the original 30 days to 15 (Appendix S7 outlines the results of these sensitivity analyses).

The intervention group received on average 41.3 (*SD* 28.8) NFP nurse visits. NFP was delivered with adequate fidelity to most programme goals, except for attrition rates during the toddlerhood phase (Appendix S8). No competing intensive nurse-home visiting programmes were offered via existing services for the duration of the trial. Few nurse-home visits (no more than three) were provided to the comparison group using existing services (Appendix S8). Of the 269 adverse events reported during the study, most were related to pregnancy and birth (Appendix S9).

Discussion

Our trial provides new evidence on NFP's effectiveness in a high-income country by age two years. In this BCHCP cohort, we found that NFP resulted in no reductions in child injuries by age two years or for subsequent maternal pregnancies by 24 months postpartum. But we observed benefits for maternal-reported child language and problem behaviour by age two years. We previously published findings showing reduced prenatal cannabis use and modest reduction in number of cigarettes smoked among smokers, although no reduction in rates of prenatal cigarette and alcohol use (Catherine, Lever, et al., 2020). After we launched our trial, findings from NFP trials conducted in Netherlands, England and United States (South Carolina) were published showing mixed results by age two years (McConnell et al., 2022; Mejdoubi et al., 2013, 2015; Robling et al., 2016; Waters et al., 2022). Our trial adds to this body of research. Our main positive findings are based on maternal report which could lead to overestimation in the effects. We did not find benefits of NFP using more objective administrative and observational data.

For child injuries, BC's more comprehensive public health and social services may have muted programme effects compared with findings from the original US trials. Results from exploratory analyses indicated possible benefits regarding hospital LOS for injuries – a reflection of injury severity and consistent with NFP trial results from Tennessee (Olds, 2008). However, the frequency was too low in our trial to ascertain clinical meaningfulness. Follow-up of longer-term injury outcomes via administrative data across childhood and adolescence may provide more information on NFP's potential to influence health longer term.

For child development, our findings suggest that NFP may buffer the adverse effects of socioeconomic disadvantage on early language development, specifically vocabulary production. Language is relatively unstable in the first year of life (Bornstein, Hahn, & Putnick, 2016) and may be amenable to early interventions such as NFP that are designed to improve maternal language environment. However, despite a moderate positive correlation between maternal report and observed assessments of child language, we did not see NFP benefits in a sub-sample using direct child observation, which is a more rigorous measure. Whereas results from exploratory analyses within a sub-sample of the English NFP trial detected improved maternal language (mean length of utterances) by 24 months postpartum, assessed via direct observation, but no improvements in child language (Waters et al., 2022). By child age seven years, benefits were found for child reading achievement assessed via administrative records (Robling et al., 2022). We therefore recommend follow-up and assessment of language, reading and academic ability later in childhood using rigorous assessments such as linked administrative data.

For child mental health, the beneficial effect for maternal-reported externalising behaviour as early as age two years is a novel finding compared with previous NFP trials that measured this variable (Tennessee, Colorado or England; Olds, 2008; Robling et al., 2016). (The trial in the Netherlands observed programme benefits for internalising but not externalising behaviour at age three years; Mejdoubi et al., 2015.) We prespecified externalising behaviour (only) given higher relevance – insofar as young children living with family socioeconomic disadvantage and displaying externalising problem behaviour, especially in the borderline-to-clinical range, are more likely to experience stability in problem behaviours and to be at risk for later mental disorders (Rivenbark et al., 2018). It is plausible that effects of early interventions may only become evident later in childhood. To illustrate, trial results of a similar home visitation programme, *ProKind*, conducted in Germany, found no benefits for problem behaviour by age two years using the CBCL (Sierau et al., 2016). However, they reported reduced problem behaviour assessed using maternal report (CBCL) by age seven years (Kliem & Sandner, 2021).

For subsequent pregnancies – compared with the original US trials, pregnancy rates were lower in the BCHCP cohort, likely reflecting declining birth rates and better supports and services in BC in recent

years (Statistics Canada, 2022b). It is possible that birth spacing did not reflect the values of participating mothers, including those Indigenous mothers who value children as sacred gifts (First Nations Health Authority [FNHA], 2021). Future qualitative research will generate new knowledge on how NFP works in BC for specific populations in diverse settings.

This trial has several limitations. For the Bayley measure, this may be due to lack of statistical power or error variance introduced by testing in the home rather than the laboratory or clinic. For child language and behaviour, while the CDI and CBCL maternal-report measures are well-established (Appendix S3), they are prone to bias. It is possible that these more positive outcomes in the NFP group, reflect a bias attributable to experiences that come from study participants knowing their intervention status – a challenge for most trials unable to 'blind' participants (Juul et al., 2021). While we achieved an adequate sample size, HA partners reached less than 50% of all potentially eligible participants and many were enrolled later in pregnancy. The median gestational age at study entry was 20 weeks and six days (see Figure 1). The lower HA referral rates were likely due to a newly established public health referral system during trial launch. We recruited from selected urban–suburban areas, not rural or remote communities, where socioeconomic inequalities may be amplified (Daley, Burton, & Phipps, 2015). NFP programme attrition rates were higher than recommended during the toddlerhood phase (Appendix S8). We therefore intend to employ secondary analytical approaches to explore NFP's potential when delivered as intended. Finally, the BCHCP cohort were enrolled based on English language competency and does not reflect BC's population diversity. NFP was not culturally adapted for BC. Tailoring the programme to better reflect BC's diversities – including Indigenous realities (FNHA, 2021) – is therefore an opportunity for future refinement and evaluation.

This trial has several strengths. The trial used an intention-to-treat approach. One primary outcome indicator was prespecified, despite it being a well-established practice for trials of psychosocial interventions to specify multiple outcomes (Grant et al., 2018). Findings on NFP's impact on additional exploratory outcomes – that are of interest to BC mothers, practitioners and policymakers – will follow. We reached a cohort experiencing concentrated socioeconomic disadvantage in early pregnancy, the population that NFP was designed to benefit (Catherine et al., 2019). We implemented a theory- and evidence-based retention protocol (Catherine, Lever, et al., 2020), maintaining high retention rates (80%–99%). Findings from a synthesis of our trial retention strategies are now informing policymakers on better reaching underserved populations (Catherine et al., 2021). The use of administrative data for assessing child injuries is also a strength. This work has laid the foundation for follow-up evaluation of longer-term outcomes across childhood, as per the NFP trials in the United States and England (Olds, 2008; Olds et al., 2014; Robling et al., 2022) and a similar trial in Germany (Kliem & Sandner, 2021). The BCHCP initiative also included two adjunctive studies involving a process evaluation and biological markers, both reported elsewhere (Gonzalez et al., 2018; Jack, Sheehan, et al., 2015).

Ours is the first NFP trial to include a substantial proportion of urban–suburban Indigenous participants – 27.1% of mothers (200 of 739) and 32.2% of children (237 of 737) – despite no specialised referral pathways. Young Indigenous females (age 15–24 years) living off-reserve comprised approximately 4.9% in the general BC population in 2021 (Statistics Canada, 2021). We have therefore demonstrated that NFP programme delivery is feasible with Indigenous populations such as those participating in the BCHCP.

Considering all the available evidence, follow-up of long-term outcomes in the BCHCP sample is warranted – given prenatal and child benefits shown to date and given that further benefits may emerge later in childhood and adolescence, as has occurred with previous NFP trials (US, England; Olds, 2008; Olds et al., 2014; Robling et al., 2022). Future BC findings can in turn continue to inform policy decisions on programme implementation.

Supporting information

Additional supporting information may be found online in the Supporting Information section at the end of the article:

Appendix S1. Participating British Columbia Health Authorities and local health areas.
Appendix S2. Summary of measures.
Appendix S3. Outcome indicators.
Appendix S4. Sample size estimation.
Appendix S5. Trial profile for Bayley subgroup.
Appendix S6. Participant (maternal) baseline characteristics for Bayley subgroup.
Appendix S7. Results of sensitivity analyses.
Appendix S8. Nurse-Family Partnership Programme delivery and fidelity goals.
Appendix S9. Study withdrawals and reported serious adverse events.

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Key points

- Nurse-Family Partnership (NFP) evaluations in the United States (US) have shown enduring programme benefits for mothers and children.
- This pragmatic 'real world' Canadian trial – embedded within the public health system with high retention (80%–99%) – provides new evidence on NFP's effectiveness in a high-income country outside the United States.
- NFP did not reduce child injuries or subsequent pregnancies but did improve maternal-reported child language and mental health (problem behaviour) at age two years; previous published findings showed reduced prenatal substance exposure as well.
- Long-term follow-up is warranted as further benefits may emerge later in childhood.
- To achieve equity goals, new and refined public policies are needed to better reach and support populations experiencing unacceptable levels of avoidable adversity, starting in pregnancy.

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