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BC Healthy Connections Project

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BC Healthy Connections Project: Scientific Overview

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BC Healthy Connections Project

A study funded by the BC Ministry of Health with support from the BC Ministry of Children and Family Development and from Fraser Health, Interior Health, Island Health, Northern Health and Vancouver Coastal Health

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Executive Summary

Why Nurse-Family Partnership?

- *Nurse-Family Partnership, or NFP, aims to improve the lives of young first-time mothers and their children*. A nurse home visitation program, it starts early in pregnancy and continues until children reach two years of age. It also focuses on women and children who are experiencing social and economic disadvantage. In US studies, NFP has: 1) reduced prenatal substance use; 2) reduced childhood injuries; 3) improved mental health in early childhood and beyond; 4) improved children's cognitive development; and 5) helped young mothers achieve economic self-sufficiency. In the US, NFP has also proven *highly cost-effective with net returns of over US $18,000 for every family served, even after nursing costs are factored in,* when savings are calculated over 10–15 years, e.g., through reduced healthcare, income assistance and child protection spending.

Why Evaluate Nurse-Family Partnership in BC?

- Beyond a McMaster pilot study in Ontario, *NFP has never been tested in Canada*. So we do not know whether the same benefits will result – given our differing health and social programs, demographics and geography. In 2010, BC therefore decided to evaluate NFP under the auspices of *Healthy Minds, Healthy People*, a 10-year mental health plan featuring promotion and prevention early in life. *BC is demonstrating significant child health and public health leadership* through this NFP evaluation.

What is the BC Healthy Connections Project, or BCHCP?

- *The BCHCP involves a randomized controlled trial (RCT) evaluating NFP's effectiveness in comparison with BC's existing health and social services.* Our main outcome indicators are: prenatal substance use; childhood injuries at age two years; children's mental health and cognitive development at age two years; and mothers' economic self-sufficiency at 24 months post-partum. In addition, we are measuring numerous other indicators such as maternal mental health and exposure to intimate-partner violence. Beyond simply evaluating NFP's effectiveness, the RCT will also provide new data on the characteristics of this high-needs population that has often been underserved, including data on health and social service access and use by mothers and children.

- The BCHCP involves a *BC-wide policy-practice-research collaboration* among: the BC Ministries of Health (MoH) and Children and Family Development (MCFD); the five regional Health Authorities (Fraser Health, Interior Health, Island Health, Northern Health and Vancouver Coastal Health); and a Scientific Team based at the Children's Health Policy Centre at Simon Fraser University (SFU), with collaborators at McMaster University, the University of BC (UBC), the University of Victoria, and the Public Health Agency of Canada. The MoH is covering scientific evaluation costs with support from MCFD. Health Authorities are covering nursing costs and managing referrals.

- We have also garnered *two federally-funded adjunctive projects*: 1) a Process Evaluation funded by the Public Health Agency of Canada (led by Susan Jack); and 2) the Healthy Foundations Study, a biological evaluation of NFP's impact on childhood stress, funded by the Canadian Institutes of Health Research (led by Andrea Gonzalez).

- Collectively, we have made *excellent progress to date*. Over 600 women are now enroled in the RCT – in addition to nearly 300 families who have received NFP as guiding clients, and nearly 150 women who are receiving NFP through the Process Evaluation. We are on track to reach an adequate RCT sample size and to close RCT recruitment by late 2016. We will then follow all RCT families over two-and-a-half years (NFP's duration) taking us to mid-2019. Rich data are being gathered on all the women and children. Young mothers also tell us that they enjoy being part of the project because they feel that their voices are being heard – often for the first time.

- *Interim findings* will be shared – starting with Process Evaluation data, which are already being disseminated, and continuing with baseline reports in mid-2017. Baseline reports will include profiles of the study population, such as social determinants and service access and use. Healthy Foundations data will follow, as will subsequent NFP outcome reports.

1. Why Nurse-Family Partnership?

Developed over 30 years ago by Olds and colleagues in the United States (US), *Nurse-Family Partnership (NFP) aims to improve the lives of young first-time mothers and their children*.[1-4] A home visitation program, NFP starts early in pregnancy and continues until children reach two years of age – in keeping with early interventions being far more cost-effective than public investments later in the lifespan.[5] NFP also focuses on women and children who are experiencing social and economic disadvantage, e.g., low income, limited education or lone parenting. Public health nurses provide the home visits – up to 65 in total over two-and-a-half years. Nurses also receive extensive education, resources to use in the home visits, and ongoing supervision to ensure that they are not only highly skilled in the NFP model but also well supported. Caseloads are limited to 20 clients for a full-time nurse.[1-4]

NFP has been evaluated in three US randomized controlled trials (RCTs) in Elmira, New York; Memphis, Tennessee; and Denver, Colorado. Results from these three RCTs have been reported in numerous articles, as have long-term follow-up findings over more than 20 years.[6-21] NFP has shown several *robust and enduring effects* on maternal and child health outcomes. Table 1 below shows findings that were statistically significant across two or more US RCTs or over two or more time points.[6-21]

Table 1: Benefits of Nurse-Family Partnership According to US Studies[6-21]

Domain	Significant + Replicated Outcomes
Prenatal Health	Reduced prenatal nicotine use
Child Wellbeing	Reduced child injuries → birth to 2 years
	Improved parenting → birth to 2 years
	Improved child behaviour → ages 4 to 15 years
	Improved child cognitive development → ages 2 to 4 years
Maternal Wellbeing	Fewer subsequent pregnancies during follow-up of up to 15 years
	Greater intervals between pregnancies during follow-up of up to 15 years
	Reduced dependence on social assistance during follow-up of up to 15 years
	Reduced substance use during follow-up of up to 15 years
	Reduced arrests, convictions + jail time during follow-up of up to 15 years

Results are also now available from NFP evaluations conducted outside the US. Findings from a trial conducted in the Netherlands indicated that in comparison to existing health and social services, NFP reduced prenatal smoking, increased breastfeeding, reduced child protection reports, and reduced exposure to intimate-partner violence.[22-24] However, an NFP RCT conducted in England demonstrated no additional benefits for children or mothers compared to existing services regarding the four main outcome indicators selected: prenatal smoking; birth weight; child emergency room attendance and hospital admissions (for all causes) by age two years; and subsequent pregnancies at 24 months postpartum (an indicator of maternal economic self-sufficiency).[25] Differing findings across the American, Dutch and English trials underscore the need to evaluate NFP prior to widespread implementation in countries outside the US – as outcomes may differ across contexts, particularly if existing services differ.[26]

Two independent research groups have also conducted comprehensive cost-benefit analyses of NFP in the US. The Rand Corporation estimated net returns of US $2.88 for every dollar invested, with returns for the highest-risk families nearly doubled at US $5.70 for every dollar invested.[27] Similarly, the Washington State Institute for Public Policy estimated a *return on investment of over US $18,000 for every family served, even after nursing costs are factored in*.[28] Both evaluations calculated savings across multiple public sectors over 10–15 years, e.g., from reduced healthcare, income assistance and child protection spending.

The trial conducted in Denver also included an evaluation of NFP's delivery by paraprofessionals compared with nurses with baccalaureate nursing degrees.[10,12] Overall, *nurse delivery led to a broader range of stronger and more enduring positive outcomes, especially for children*. Olds and colleagues therefore concluded that *nurse* home visitors were essential for NFP to be effective.[3,10,12]

Independent reviews have also examined the evidence for NFP's effectiveness compared with other early childhood programs, particularly for preventing child maltreatment and child antisocial behaviour in disadvantaged populations. These reviews have concluded that *NFP is the most effective program, supported by the strongest evidence base, particularly when cost-effectiveness is also factored in*.[29-33] NFP also has strong potential for improving children's mental health more generally, including preventing anxiety, substance use and depressive disorders.[2,5] Mental disorders are now estimated to affect 12.6% of children at any given time – or nearly 84,000 in BC and nearly 700,000 in Canada.[5] Anxiety, substance use, conduct and depressive disorders are among the most common. Being able to prevent these four disorders could therefore significantly improve children's mental health in Canada.[5] NFP is also entirely consistent with longstanding calls for greater public investments starting very early in childhood.[34]

2. Why Evaluate Nurse-Family Partnership in BC?

Despite the benefits shown in the US and the Netherlands, *NFP has never been tested in Canada*. So we do not know whether the same benefits will result – given our differing health and social programs, demographics and geography.[35] Compared to the US, for example, Canada offers more generous public programs including healthcare, income support and child benefits. There are also no evaluations of NFP's effectiveness in ethnically-diverse communities or in rural communities with small populations, as is found in BC.[35] Work began in Canada in 2008 with a Hamilton, Ontario pilot study assessing NFP's feasibility and acceptability with approximately 100 mothers and children. *NFP was well received by mothers, nurses, family members and community partners in the Ontario pilot study*, laying the foundation for conducting an RCT in BC.[36]

Children's mental health has long been a priority for the BC Government, starting in 2003 with BC's unique five-year *Child and Youth Mental Health Plan,* sponsored by the Ministry of Children and Family Development (MCFD).[37] In 2010, BC then announced *Healthy Minds, Healthy People*, a new 10-year mental health plan led by the Ministry of Health (MoH) together with MCFD.[38] This plan made promotion and prevention high priorities, featuring nurse home visitation for disadvantaged first-time families as a central initiative. Under the auspices of *Healthy Minds, Healthy People*, in 2010, MoH and MCFD invited the Children's Health Policy Centre in the Faculty of Health Sciences at SFU to explore the options for evaluating NFP, in collaboration with McMaster's NFP pilot study team. MoH and MCFD also convened an initial Provincial Advisory Committee (PAC) comprising senior representatives from Health Authorities, MCFD regions, First Nations organizations, the Public Health Agency of Canada and others. Committee meetings provided a forum for seeking consensus on proceeding with the NFP evaluation. Subsequent working groups and committees were also developed. The BC Healthy Connections Project (BCHCP) was then launched in early 2012. *BC is demonstrating significant national child health and public health leadership* through this NFP evaluation.

3. The BC Healthy Connections Project

The BCHCP involves an RCT comparing *NFP with BC's existing health and social services. The overarching goals are to improve children's mental health and development and to improve mothers' life circumstances.* We are therefore evaluating NFP's effectiveness across the domains of pregnancy, child wellbeing and maternal wellbeing – beginning in early pregnancy and continuing until the children reach age two years – in a population of disadvantaged young first-time mothers and their children. The BCHCP trial outcome indicators and measures were explicitly chosen to enable replication of some of the more robust US trial findings, while also addressing potential explanatory factors and indicators of salience for BC policymaking. The main outcome indicators are: 1) prenatal substance use; 2) childhood injuries by age two years; 3) children's mental health at age two years; 4) children's cognitive development at age two years; and 5) mothers' economic self-sufficiency at 24 months post-partum. In addition, we are measuring the impact of other crucial indicators of NFP program effects such as maternal mental health (including self-efficacy) and exposure to intimate-partner violence. Table 2 below provides more information on the outcome indicators.

Table 2: Overview of BC Healthy Connections Project measures at each assessment point*

	Assessment Points						
	Prenatal		Birth through 24 Months Postpartum				
Measures	**Baseline**	**34–36 Weeks**	**Birth**	**2 Months**	**10 Months**	**18 Months**	**24 Months**
Maternal Demographics and Socioeconomic Status							
Age, racial/cultural group, language	✔						
Education + employment	✔	✔		✔	✔	✔	✔
Income + financial supports	✔	✔		✔	✔	✔	✔
Housing/residential stability	✔	✔		✔	✔	✔	✔
Relationship status + demographics	✔	✔		✔	✔	✔	✔
Maternal Health and Functioning							
Obstetric history	✔	✔	✔				
History of abuse or neglect	✔						
General health + long-term illness	✔						✔
Self efficacy + mastery	✔	✔		✔	✔	✔	✔
Anxiety + depression	✔	✔		✔	✔	✔	✔
Prenatal nicotine + alcohol use**	✔	✔					
Prenatal illicit drug use	✔	✔					
Intimate-partner violence (IPV)	✔	✔		✔	✔	✔	✔
Executive functioning	✔						
Cognitive ability	✔						
Substance misuse				✔	✔	✔	✔
Antisocial behaviour				✔	✔	✔	✔
Contraceptive use				✔	✔	✔	✔
Subsequent pregnancies**				✔	✔	✔	✔
Neonatal Health							
Gestation at delivery			✔				
Birth weight			✔				
Apgar scores (1 + 5 minutes)			✔				
Intensive care admission(s)			✔				
Parenting Behaviours and Beliefs							
Breastfeeding initiation + duration				✔	✔		
Provision of safe + nurturing home				✔	✔	✔	✔
Child exposure to 2nd hand smoke				✔	✔	✔	✔
Parenting attitudes/beliefs						✔	
Child Health and Development							
General health + long-term illness							✔
Immunizations				✔	✔	✔	✔
Language + cognition**							✔
Mental health (behaviour)**							✔
Physician encounters for injuries**				✔	✔	✔	✔
Substantiated abuse or neglect				✔	✔	✔	✔
Maternal and Child Service Access + Use							
Prenatal programs	✔	✔					
Primary + secondary healthcare	✔	✔		✔	✔	✔	✔
Specialist care, e.g., mental health	✔	✔		✔	✔	✔	✔
Financial/education assistance	✔	✔		✔	✔	✔	✔
Other services, e.g., housing	✔	✔		✔	✔	✔	✔
Parenting programs	✔	✔		✔	✔	✔	✔
Early child development programs				✔	✔	✔	✔
Other services	✔	✔		✔	✔	✔	✔
Barriers to essential services	✔	✔		✔	✔	✔	✔

* All data are being gathered on both NFP and control children and mothers (those not receiving NFP), yielding rich information about this under-served population's characteristics and needs across pregnancy and very early childhood

** Main outcome indicators

Starting in 2012, Health Authorities recruited a cadre of public health nurses and sponsored *comprehensive education to prepare nurses and supervisors for delivering NFP as part of the RCT*. Nurses then took on "guiding clients" – consolidating and honing their skills by delivering the full NFP program to a small number of women, preparing them to assume a full caseload of 20 participants (per full time nurse). Approximately 300 families were enrolled and have received NFP as guiding clients, with most graduating by 2016.

Following the RCT launch in late 2013, women are being enrolled and randomly assigned to either existing services or NFP plus existing services. Outcome data are being collected at regular intervals until the children turn two years of age. Data are being collected using maternal self-report questionnaires and maternal and child observational and cognitive testing, as well as through MoH data sharing agreements. Particularly for assessing development, child observational testing (rather than maternal report) is considered the "gold standard" and is comparable to the methodology used in the US NFP trials in Denver, Colorado. Throughout the study, women who are randomized to the intervention group receive the NFP program as well as existing services within their Health Authority, while women in the comparison group receive existing services (but not NFP). Existing services vary across BC but may include: primary healthcare; public health programs including prenatal classes, pregnancy outreach and home visiting by (non-NFP) nurses or paraprofessionals; and a variety of targeted and universal parenting and early child development programs. Appendix 1 outlines the study pathways for participants in both the intervention and comparison groups (please see page 10).

Referrals for the BCHCP come through the participating Health Authorities. Table 3 outlines the *eligibility criteria, consistent with NFP's focus on young, disadvantaged, first-time mothers and their children*.

Table 3: BC Healthy Connections Project Eligibility Criteria

Women are eligible if they meet *all* inclusion criteria at time of baseline interviews
1. Aged 24 years or younger
2. First birth[a]
3. Less than 28 weeks gestation[b]
4. Competent to provide informed consent, including conversational competence in English[c]
5. Experiencing socioeconomic disadvantage[d]
• Age 19 or younger
• Age 20–24: Meets 2 of 3 indicators: *Lone parent*; *less than grade 12*; or *low income*
Women are ineligible if they meet *any* exclusion criteria at time of referral
1. Planning to have the child adopted
2. Planning to leave the BCHCP catchment area for three months or longer[e]

a. Women are eligible if a previous pregnancy ended in termination, miscarriage or stillbirth, or if previous parenting involved step-parenting only; individual circumstances may also be considered on a case-by-case basis
b. Women must receive their first home visit by 28th week of gestation, according to NFP fidelity requirements
c. Women must be able to participate without requiring an interpreter
d. Research shows that these indicators of socioeconomic disadvantage are associated with increased risk of child injuries
e. Catchment area comprises designated Local Health Areas within BC and surrounding areas; individual circumstances may also be considered on a case-by-case basis

We welcome all eligible First Nations and Indigenous women who are living "off reserve" and who wish to participate in the BCHCP. The First Nations Health Authority (FNHA) holds responsibility for all "on reserve" public health programs in BC, and is currently exploring a variety of child and maternal health options – NFP being one of many programs under consideration. Following consultations with FNHA representatives, the BCHCP is not being offered to First Nations and Indigenous women who are living "on reserve" at the time of referral or baseline interviews. However, permission is being obtained from the pertinent local First Nations to continue the study for all enroled women who move back "on reserve" and who wish to continue with NFP and data collection.

Collectively, we have made *excellent progress to date*. Over 600 women are now enroled in the RCT – in addition to nearly 300 families who have received NFP as guiding clients, and nearly 150 women who are receiving NFP through the adjunctive Process Evaluation, described on the next page. We are on track to reach our planned

RCT sample size and to close RCT recruitment by late 2016. We will then follow all the RCT families over two-and-a-half years (NFP's duration) taking us to mid-2019. Rich data are being gathered on all the women and children. Young mothers also tell us that they enjoy being part of the project because they feel that their voices are being heard – often for the first time. Appendix 2 provides a timeline for the study (please see page 11).

To ensure that findings are adopted in policy and practice, a "real world" effectiveness trial such as the BCHCP RCT requires reciprocal and sustained collaborations among researchers, policymakers, practitioners and community agencies. Considerable care and commitment have gone into developing and sustaining this collaborative process, reflected in a governance structure that guides our work. Appendix 3 describes this governance structure (please see page 12). Appendix 4 describes the Scientific Team members and their roles (please see page 13).

BCHCP Scientific Team members have also garnered *two federally-funded adjunctive projects*: 1) a *Process Evaluation* funded by the Public Health Agency of Canada; and 2) the *Healthy Foundations Study*, a biological evaluation of NFP's impact on childhood stress and subsequent mental and physical health outcomes, funded by the Canadian Institutes of Health Research. *Susan Jack*, BCHCP Co-Principal Investigator, is leading the Process Evaluation, a mixed methods evaluation of NFP's implementation across BC. The goals are to explore the factors that influence NFP implementation and to identify the adaptations required for successful long-term delivery. This evaluation is being conducted in all five Health Authorities. Meanwhile, *Andrea Gonzalez*, BCHCP Co-investigator, is leading the Healthy Foundations Study, the first biological evaluation of NFP. Saliva and cheek cell swabs are being collected from children and hair samples are being collected from mothers. Samples are then being tested for markers of stress (such as cortisol) that may influence brain development and child mental and physical health over the long term. This study has the potential to demonstrate that NFP can improve biological development starting very early in life – setting the course for multiple positive health and learning outcomes over the life span. The Healthy Foundations Study is being conducted in Fraser and Vancouver Coastal Health Authorities. (Please see Appendices 5 and 6 on pages 14 and 15 for more information on these two adjunctive studies.)

Regarding ethics, the *BCHCP RCT follows Canadian and international standards* for study design as well as data analysis and interpretation.[39] *We have received research ethics board (REB) approvals from all 10 participating organizations*: SFU, UBC, the University of Victoria, McMaster University, the Public Health Agency of Canada, and the five regional Health Authorities. We have also prepared detailed protocols for monitoring participant safety and reporting any adverse events. Annual reports are submitted to all 10 REBs. An independent Data and Safety Monitoring Committee also monitors recruitment, participant safety, protocol compliance and data quality. Due to the highly sensitive nature of the data being received from the MoH, e.g., on child injuries, the Scientific Team has also made detailed data security provisions that *exceed* REB requirements – to protect all participants.

Notably, many of NFP's most compelling US findings have been demonstrated 10–20 years after the program ended, including decreased child and maternal mortality.[1,20,40] The Scientific Team is therefore *setting the stage for long-term follow-up,* for example, evaluating NFP's impact on children's mental health, school readiness, and general resilience and vulnerability upon kindergarten entry.

In other countries where NFP is being provided – including the US, the Netherlands, England, Scotland, Northern Ireland and Australia, following completion of RCTs or as part of ongoing pilot studies – steps have also been taken to ensure integration of the program within existing universal health service systems. This integration is crucial for NFP to be a sustainable component of comprehensive public health services in BC and in Canada.

The BCHCP is providing new information for policy formulation and service planning – by highlighting NFP's potential role not only in improving child health and public health outcomes, but also in reducing the need for services across many different sectors over the long term including emergency healthcare, the justice system, special education, income support and child protection services. In essence, the BCHCP will provide pragmatic evidence for those who need to act – to improve children's mental health and development by addressing the inequities that some BC children face. By generating new evidence through the BCHCP, we hope that we may encourage British Columbians – and all Canadians – to take *new steps in bringing about a proportionate universalism that truly addresses extremes of disadvantage* starting very early in the lifespan.[5,41,42]

Citing This Overview

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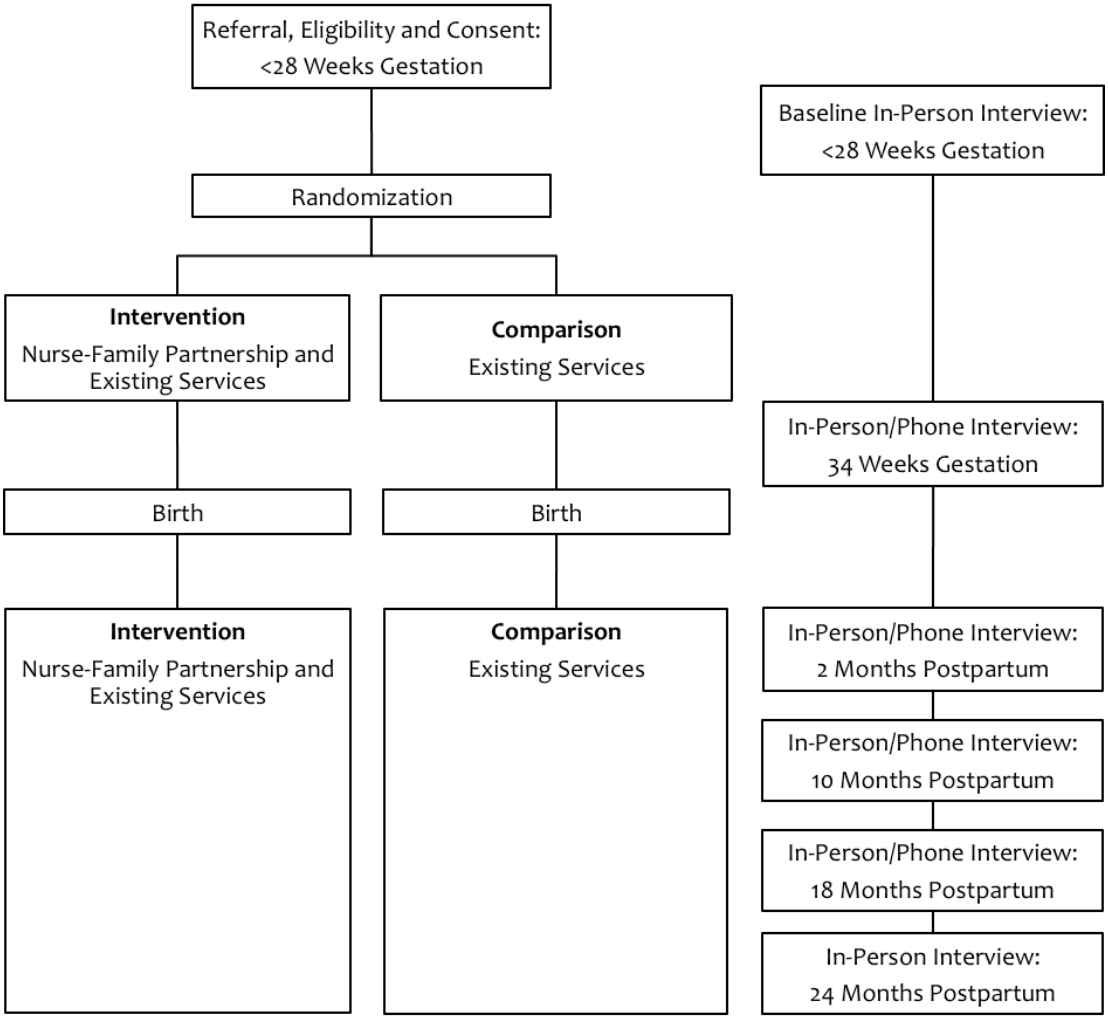
References

1. Olds DL, Hill PL, O'Brien R, et al. Taking preventive intervention to scale: The nurse-family partnership. *Cognitive and Behavioral Practice* 2003; 10: 278-290.
2. Olds DL. The nurse-family partnership: An evidence-based preventive intervention. *Infant Mental Health Journal* 2006; 27: 5-25.
3. Olds DL, Sadler L, Kitzman H. Programs for parents of infants and toddlers: Recent evidence from randomized trials. *Journal of Child Psycholology and Psychiatry* 2007; 48: 355-391.
4. Olds DL. Preventing child maltreatment and crime with prenatal and infancy support of parents: The nurse-family partnership. *Journal of Scandinavian Studies in Criminology and Crime Prevention* 2008; 9: 2-24.
5. Waddell C, Shepherd C, Schwartz C, Barican J. *Child and youth mental disorders: Prevalence and evidence-based interventions*. Vancouver, BC: Children's Health Policy Centre, Simon Fraser University, 2014.
6. Olds DL, Eckenrode J, Henderson CR, et al. Long-term effects of home visitation on maternal life course and child abuse and neglect. Fifteen-year follow-up of a randomized trial. *Journal of the American Medical Association* 1997; 278: 637-643.
7. Olds D, Henderson CR, Jr., Cole R, et al. Long-term effects of nurse home visitation on children's criminal and antisocial behavior: 15-year follow-up of a randomized controlled trial. *Journal of the American Medical Association* 1998; 280: 1238-1244.
8. Kitzman H, Olds DL, Henderson CR, et al. Effect of prenatal and infancy home visitation by nurses on pregnancy outcomes, childhood injuries, and repeated childbearing. A randomized controlled trial. *Journal of the American Medical Association* 1997; 278: 644-652.
9. Kitzman H, Olds DL, Sidora K, et al. Enduring effects of nurse home visitation on maternal life course: A 3-year follow-up of a randomized trial. *Journal of the American Medical Association* 2000; 283: 1983-1989.
10. Olds DL, Robinson J, Pettitt L, et al. Effects of home visits by paraprofessionals and by nurses: Age 4 follow-up results of a randomized trial. *Pediatrics* 2004; 114: 1560-1568.
11. Olds DL, Kitzman H, Cole R, et al. Effects of nurse home-visiting on maternal life course and child development: Age 6 follow-up results of a randomized trial. *Pediatrics* 2004; 114: 1550-1559.
12. Olds DL, Robinson J, O'Brien R, et al. Home visiting by paraprofessionals and by nurses: A randomized, controlled trial. *Pediatrics* 2002; 110: 486-496.
13. Olds DL, Kitzman H, Hanks C, et al. Effects of nurse home visiting on maternal and child functioning: Age 9 follow-up of a randomized trial. *Pediatrics* 2007; 120: 832-845.
14. Olds DL, Kitzman HJ, Cole RE, et al. Enduring effects of prenatal and infancy home visiting by nurses on maternal life course and government spending: Follow-up of a randomized trial among children at age 12 years. *Archives of Pediatric and Adolescent Medicine* 2010; 164: 419-24.
15. Olds DL, Henderson CR, Jr., Chamberlin R, Tatelbaum R. Preventing child abuse and neglect: A randomized trial of nurse home visitation. *Pediatrics* 1986; 78: 65-78.
16. Olds DL, Henderson CR, Jr., Kitzman H. Does prenatal and infancy nurse home visitation have enduring effects on qualities of parental caregiving and child health at 25 to 50 months of life? *Pediatrics* 1994; 93: 89-98.
17. Eckenrode J, Ganzel B, Henderson CR, Jr., et al. Preventing child abuse and neglect with a program of nurse home visitation: The limiting effects of domestic violence. *Journal of the American Medical Association* 2000; 284: 1385-1391.

18. Kitzman HJ, Olds DL, Cole RE, et al. Enduring effects of prenatal and infancy home visiting by nurses on children: Follow-up of a randomized trial among children at age 12 years. *Archives of Pediatric and Adolescent Medicine* 2010; 164: 412-418.
19. Eckenrode J, Campa M, Luckey DW, et al. Long-term effects of prenatal and infancy nurse home visitation on the life course of youths: 19-year follow-up of a randomized trial. *Archives of Pediatric and Adolescent Medicine* 2010; 164: 9-15.
20. Olds DL, Kitzman H, Knudtson MD, et al. Effect of Home Visiting by Nurses on Maternal and Child Mortality: Results of a 2-Decade Follow-up of a Randomized Clinical Trial. *Journal of the American Medical Association Pediatrics* 2014; 168: 800-806.
21. Zielinski DS, Eckenrode J, Olds DL. Nurse home visitation and the prevention of child maltreatment: Impact on the timing of official reports. *Development and Psychopathology* 2009; 21: 441-453.
22. Mejdoubi J, van den Heijkant S, van Leerdam FJM, et al. Effects of nurse home visitation on cigarette smoking, pregnancy outcomes and breastfeeding: A randomized controlled trial. *Midwifery*, 2013; 30: 688-695.
23. Mejdoubi J, van den Heijkant S, van Leerdam FJM, et al. Effect of nurse home visits versus usual care on reducing intimate partner violence in young high-risk pregnant women: A randomized controlled trial. *PLOS ONE*, published online October 21, 2013.
24. Mejdoubi J, van den Heijkant S, van Leerdam FJM, et al. The effect of VoorZorg, the Dutch Nurse-Family Partnership, on child maltreatment and development: A randomized controlled trial. *PLOS ONE*, published online April 1, 2015.
25. Robling M, Bekkers MJ, Bell K, et al. Effectiveness of a nurse-led intensive home-visitation programme for first-time teenage mothers (Buliding Blocks): A pragmatic randomised controlled trial. *Lancet*, 2015; 387: 146-155.
26. Olds D. Building evidence to improve maternal and child health. *Lancet*, 2015; 387: 105-107.
27. Karoly LA, Kilburn MR, Cannon JS. *Early childhood interventions: Proven results, future promise*. Santa Monica, CA: RAND Corporation, 2005.
28. Lee S, Aos S, Miller M. *Evidence-based programs to prevent children from entering and remaining in the child welfare system: Benefits and costs for Washington.* Olympia, WA: Washington State Institute for Public Policy, 2008.
29. Waddell C, Hua JM, Garland O, et al. Preventing mental disorders in children: A systematic review to inform policy-making in Canada. *Canadian Journal of Public Health* 2007; 98: 166-173.
30. MacMillan HL. Preventive health care, 2000 update: Prevention of child maltreatment. *Canadian Medical Association Journal* 2000; 163: 1451-1458.
31. MacMillan HL, Wathen CN, Barlow J, et al. Interventions to prevent child maltreatment and associated impairment. *Lancet* 2009; 373: 250-266.
32. Mikton C, Butchart A. Child maltreatment prevention: A systematic review of reviews. *Bulletin of the World Health Organization* 2009; 87: 353-361.
33. National Collaborating Centre for Determinants of Health. *Preventive home visiting for pregnant women and mothers of young children: A review of reviews*. Antigonish, NS: National Collaborating Centre for Determinants of Health, 2010.
34. Heckman JJ. Skill formation and the economics of investing in disadvantaged children. *Science* 2006; 312: 1900-1902.
35. Durlak JA, DuPre EP. Implementation matters: A review of research on the influence of implementation on program outcomes and the factors affecting implementation. *American Journal of Community Psychology* 2008; 41: 327-350.
36. Jack S, Busser D, Sheehan D, et al. Adaptation and implementation of the Nurse-Family Partnership in Canada. *Canadian Journal of Public Health* 2012; 103: S42-S48.
37. Ministry of Children and Family Development. *Child and youth mental health plan for British Columbia.* Victoria, BC: Government of British Columbia, 2003.
38. Ministry of Health and Ministry of Children and Family Development. *Healthy minds, healthy people: A 10-year plan to address mental health and substance use in British Columbia.* Victoria, BC: Government of British Columbia, 2010.
39. Moher D, Schulz KF, Altman DG. The CONSORT statement: Revised recommendations for improving the quality of reports of parallel-group randomised trials. *Lancet* 2001; 357: 1191-94.
40. Olds DL, Kitzman H, Knudtson MD, et al. Effect of home visiting by nurses on maternal and child mortality: Results of a 2-decade follow-up of a randomized clinical trial. *Journal of the American Medical Association Pediatrics* 2014; 168: 800-806.
41. Marmot M, Allen J, Goldblatt et al. *Fair Society, Healthy Lives*. London, UK: University College London, 2010.
42. Reading R, Bissell S, Goldhagen J, et al. Promotion of children's rights and prevention of child maltreatment. *Lancet* 2009; 373: 332-343.

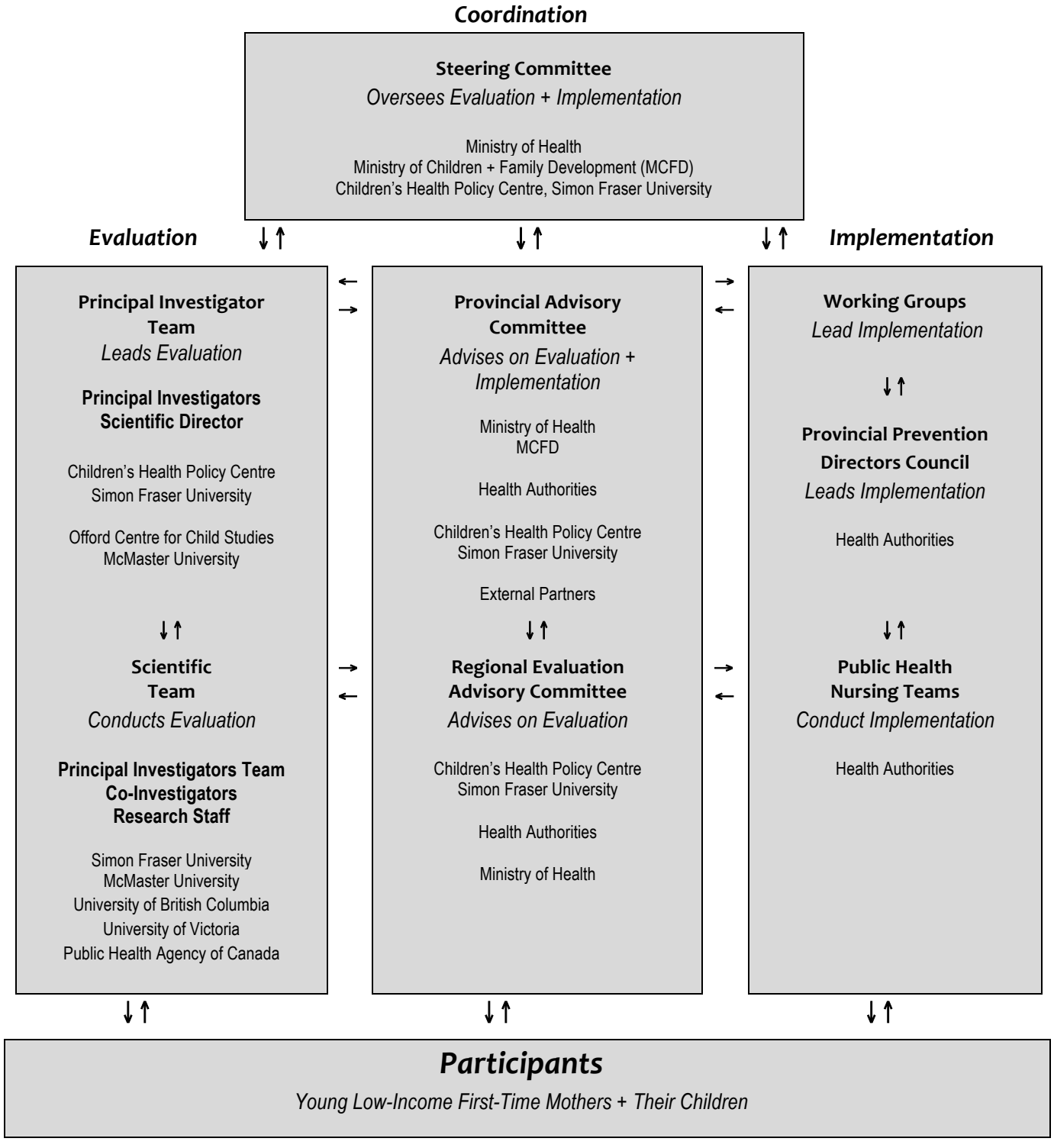
Appendix 1:
Randomized Controlled Trial Participant Pathway



Appendix 2:
BC Healthy Connections Project Anticipated Timelines

2008	• McMaster University pilot project demonstrated NFP's feasibility and acceptability using Canadian NFP curriculum
2010	• Ministry of Health (MoH) invited SFU's Children's Health Policy Centre to explore BC NFP evaluation options • Scientific, policy and practice collaborations established
2011	• MoH announced SFU funding for RCT with support from Ministry of Children and Family Development (MCFD) • Fraser, Interior, Island, Northern and Vancouver Coastal Health Authorities initiate support for the RCT • Scientific, policy and practice collaborations continued and further developed
2012	• Project launched, RCT renamed as BC Healthy Connections Project (BCHCP) • BCHCP RCT protocol developed, research ethics applications submitted, scientific peer review obtained • NFP public health nurses' education initiated with "guiding clients" • Process Evaluation funding obtained from Public Health Agency of Canada (Susan Jack, Principal Investigator ([PI])
2013	• BCHCP RCT protocols finalized, research ethics approvals obtained from 10 boards • RCT launched in Fraser, Vancouver Coastal, Island and Interior Health • Process Evaluation launched in Fraser, Interior, Island, Northern and Vancouver Coastal Health • Healthy Foundations Study funding obtained from Canadian Institutes of Health Research (Andrea Gonzalez, PI)
2014	• BCHCP RCT recruitment continued • Process Evaluation continued, first reports shared • Healthy Foundations Study launched in Fraser and Vancouver Coastal Health
2015	• BCHCP RCT recruitment continued • Process Evaluation continued, ongoing reports shared • Healthy Foundations Study continued
2016	• BCHCP RCT referrals close, followed by enrolment closing; data collection and NFP delivery continue • Process Evaluation continues, ongoing reports shared • Healthy Foundations Study recruitment closes (May 2016); data collection continues
2017	• BCHCP RCT continues; data collection and NFP delivery continue • RCT descriptive reports shared on participants' characteristics in early pregnancy – *Baseline (pre-randomization) data on social determinants of health, e.g., maternal socioeconomic status; housing and residential instability; physical wellbeing; mental health (anxiety, depression, substance use including nicotine, alcohol, street drugs, e-cigarettes); cognitive and executive functioning; self-efficacy; history of child maltreatment; intimate-partner violence; health and social service access and use* • Process Evaluation continues, ongoing reports shared • Healthy Foundations Study continues, preliminary findings shared
2018	• BCHCP RCT continues; data collection and NFP delivery continue • Process Evaluation continues, ongoing reports shared • Healthy Foundations Study data collection continues, continuing reports shared
2019	• BCHCP RCT interviews conclude for all mothers and children • Process Evaluation concludes and final reports shared • Healthy Foundations Study concludes and final reports prepared
2020	• RCT main findings reports prepared on NFP's impact on secondary + other outcome indicators – *Secondary outcome indicators, i.e., prenatal substance use (nicotine and alcohol); child mental health at 24 month; child cognitive development at 24 months; maternal subsequent pregnancies at 24 months* – *Other outcome indicators, e.g., breastfeeding, parenting, maternal mental health including substance misuse, intimate-partner violence; child and maternal health and social service access and use* • Final reports prepared on NFP's impact on primary outcome indicator – *Child injuries by age two years, including all physician community/outpatient, emergency room and hospital encounters and diagnoses, contingent on receiving MoH injury data*
2021	• Plans finalized for long-term follow-up of RCT cohort • BCHCP concludes (March 31, 2021)

Appendix 3:
BC Healthy Connections Project Governance Structure



Appendix 4:
BC Healthy Connections Project Scientific Team

Nominated/Lead Co-Principal Investigators	
Charlotte Waddell, MSc, MD, CCFP, FRCPC Professor Canada Research Chair (CRC) in Children's Health Policy Director, Children's Health Policy Centre Faculty of Health Sciences (FHS), SFU, Vancouver, BC	**Harriet MacMillan, MD, MSc, FRCPC** Professor Chedoke Health Chair in Child Psychiatry Offord Centre for Child Studies FHS, McMaster University, Hamilton, Ontario
Scientific Director and Co-Principal Investigator	
Nicole Catherine, MSc, PhD Mowafaghian University Research Associate and Adjunct Professor Children's Health Policy Centre FHS, SFU, Vancouver, BC	
Co-Principal Investigators	
Susan Jack, RN, BScN, PhD Associate Professor School of Nursing and Offord Centre for Child Studies FHS, McMaster University, Hamilton, Ontario	**Debbie Sheehan, RN, BScN, MSW** Senior Nursing Consultant Children's Health Policy Centre FHS, SFU, Vancouver, BC
Co-Investigators	
Michael Boyle, MSW, MSc, PhD Professor CRC in Social Determinants of Child Health Offord Centre for Child Studies FHS, McMaster University, Hamilton, Ontario	**Ronald Barr, MA, MDCM, FRCPC** Professor Emeritus Department of Pediatrics Centre for Community Child Health Research Faculty of Medicine, UBC, Vancouver, BC
Colleen Varcoe, RN, BSN, MEd, MSN, PhD Professor School of Nursing, UBC, Vancouver, BC	**Lenora Marcellus, RN, BSN, MSN, PhD** Associate Professor School of Nursing, University of Victoria, Victoria, BC
Andrea Gonzalez, MA, PhD Assistant Professor Offord Centre for Child Studies FHS, McMaster University, Hamilton, Ontario	**Amiram Gafni, MSc, DSc** Professor Centre for Health Economics and Policy Analysis FHS, McMaster University, Hamilton, Ontario
Lawrence McCandless MSc, PhD Associate Professor FHS, SFU, Burnaby, BC	**Lil Tonmyr, MSW, PhD** Senior Scientist Public Health Agency of Canada, Ottawa, Ontario
Consultants	
David Olds, PhD Professor Director, Prevention Research Center, School of Public Health University of Colorado, Denver, Colorado	**Harry Shannon, MSc, PhD** Professor Department Clinical Epidemiology and Biostatistics FHS, McMaster University, Hamilton, Ontario
Process Evaluation Principal Investigator	
Susan Jack, RN, BScN, PhD McMaster University	
Healthy Foundations Principal Investigator	
Andrea Gonzalez, MA, PhD McMaster University	

BC Healthy Connections Project

PROCESS EVALUATION

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Appendix 5:
Overview on BC Healthy Connections Project Process Evaluation
Susan Jack

The overall aim of the British Columbia Healthy Connections Project (BCHCP) Process Evaluation (PE) is to document how Nurse-Family Partnership (NFP) is being implemented and delivered by regional Health Authorities. The PE is also focused on evaluating different NFP elements including: education, supervision, intersections between public health and child welfare, professional nursing practice, and strategies to respond to families' experiences of mental health, substance misuse, and exposure to intimate partner violence. A central function of the PE is to also examine how this public health nursing intervention is adapted and delivered to families living in rural and remote areas.

To achieve these goals a mixed methods study is being conducted. Five regional Health Authorities are participating in the PE: Northern Health, Island Health, Vancouver Coastal Health, Fraser Health and Interior Health. Within each Health Authority, in-depth interviews to address the study objectives are conducted every six months with all NFP public health nurses, all NFP supervisors and the NFP Provincial Coordinator. At least once a year, an in-depth interview is also conducted with a small group of senior public health decision-makers who are responsible for NFP within each Health Authority. Information about the delivery of NFP is also received from the Ministry of Health and analyzed so we can understand how many families are being reached by NFP and what information is being addressed during the home visits. We are also collecting and analyzing information about the supervisory and team meeting activities occurring within each Health Authority.

Information from the PE will be used to: 1) determine if NFP is being implemented in BC with fidelity to the core model elements; 2) identify individual, team, organizational and geographic factors that influence NFP implementation, uptake, delivery and sustainability; and 3) inform the development and adaptation of Canadian versions of the NFP core model elements, nurse/supervisor education, supervision guidelines, a model for NFP delivery in rural and remote areas, implementation guidelines, and visit-to-visit guidelines and home visit materials.

BC Healthy Connections Project
Core study funding provided by the BC Ministry of Health with support from the BC Ministry of Children and Family Development and from Fraser Health, Interior Health, Island Health, Northern Health and Vancouver Coastal Health

*Additional funding to support the **Process Evaluation** provided by the Public Health Agency of Canada; Principal Investigator: Susan Jack*

SFU
Children's Health Policy Centre
SIMON FRASER UNIVERSITY
FACULTY OF HEALTH SCIENCES

BC Healthy Connections Project

HEALTHY FOUNDATIONS STUDY

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Appendix 6:
Overview on Healthy Foundations Study
Andrea Gonzalez

Healthy Foundation Study (HFS) Objectives

The goal of the HFS is to provide the first biological evaluation of Nurse-Family Partnership's (NFP's) effects in a sample of first-time mothers and their children in BC, embedded within a carefully designed and landmark randomized controlled trial (RCT) on NFP's effectiveness (the BC Healthy Connections Project or BCHCP). More specifically, the HFS has three objectives: 1) to determine whether NFP has an effect on infant biological functions; 2) to investigate whether NFP has an impact on maternal prenatal physiological stress and whether this is associated with alterations in infant's biology; and 3) to examine whether alterations in biological markers explain the association between the impact of NFP and infant health.

Methods Overview

We are enrolling a sub-sample of 340 women participating in the BCHCP RCT from Fraser and Vancouver Coastal Health Authorities. BCHCP field interviewers approach participants during BCHCP baseline interviews to obtain their informed consent to collect hair samples from women and saliva and cheek samples from children, using techniques that have been well established in previous biomarkers studies in similar populations. Specifically, we will collect a hair sample from mothers at baseline and at two months post-partum; saliva samples from infants at two, 10, 18 and 24 months; and cheek swabs from infants at two and 24 months. Samples will then be tested for markers of stress such as cortisol and inflammation markers. Cheek swabs collected from infants will be examined for markers that affect the expression of our genes. To assess aspects of maternal caregiving as a potential mechanism of effect, we are collecting brief videotapes of mother-infant interactions at all postpartum visits. Mothers receive a professional copy of all videos as a memento. HFS samples are collected during scheduled BCHCP interviews with the participants.

Recruitment Targets Met

By May 2016, after two years of recruitment, 355 participants were enroled in the HFS – meeting recruitment targets. (This number also allows for potential attrition over the full duration of the study.) HFS recruitment has therefore now been closed. Of all BCHCP participants approached to participate in the HFS, we have achieved a 91% acceptance rate. Reasons for declining participation include: partner (e.g., baby's father objecting to the study); feeling overwhelmed and stressed (e.g., any additional time is too stressful); and uncertainty regarding samples. Preliminary findings reports will follow in 2017 and beyond.

BC Healthy Connections Project

Core study funding provided by the BC Ministry of Health with support from the BC Ministry of Children and Family Development and from Fraser Health, Interior Health, Island Health, Northern Health and Vancouver Coastal Health

*Additional funding to support the **Healthy Foundations Study** provided by the Canadian Institutes of Health Research; Principal Investigator: Andrea Gonzalez*