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Study protocol for a real-world evaluation of an integrated child and family health hub for migrant and refugee women

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ABSTRACT

Introduction Continuity of child and family healthcare is vital for optimal child health and development for developmentally vulnerable children. Migrant and refugee communities are often at-risk of poor health outcomes, facing barriers to health service attendance including cultural, language, limited health literacy, discrimination and unmet psychosocial needs. 'Integrated health-social care hubs' are physical hubs where health and social services are co-located, with shared referral pathways and care navigation.

Aim Our study will evaluate the impact, implementation and cost-benefit of the First 2000 Days Care Connect (FDCC) integrated hub model for pregnant migrant and refugee women and their infants.

Materials and methods This study has three components. Component 1 is a non-randomised controlled trial to compare the FDCC model of care with usual care. This trial will allocate eligible women to intervention and control groups based on their proximity to the Hub sites. Outcome measures include: the proportion of children attending child and family health (CFH) nurse services and completing their CFH checks to 12 months of age; improved surveillance of growth and development in children up to 12 months, post partum; improved breastfeeding rates; reduced emergency department presentations; and improved maternal well-being. These will be measured using linked medical record data and surveys. Component 2 will involve a mixed-method implementation evaluation to clarify how and why FDCC was implemented within the sites to inform future roll-out. Component 3 is a within-trial economic evaluation from a healthcare perspective to assess the cost-effectiveness of the Hubs relative to usual care and the implementation costs if Hubs were scaled and replicated.

Ethics and dissemination Ethical approval was granted by the South Eastern Sydney Local Health District Human Research Ethics Committee in July 2021 (Project ID: 020/ETH03295). Results will be submitted for publication in peer-reviewed journals and presented at relevant conferences.

Trial registration number ACTRN12621001088831.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study has an embedded implementation evaluation and economic evaluation in addition to the non-randomised trial component of the study.
⇒ A strength of the design of the study is the logic modelling process used to map the implementation context and intervention components to guide data collection methods.
⇒ A strength of the design of the implementation evaluation is a mixed-methods approach that will enable the triangulation of barriers and facilitators to implementing hubs with implementation success across the sites qualitatively and quantitatively.
⇒ The non-randomised design of the trial has some limitations, particularly the inability to guarantee the comparability of the intervention and control groups.

BACKGROUND AND RATIONALE

In New South Wales (NSW), Australia, 25% of children from migrant and refugee families are 'developmentally vulnerable'.[1] Developmental vulnerability is measured by the Australian Early Development Census across five domains including physical health and well-being, social competence, emotional maturity, language and cognitive skills and communication skills and general knowledge. Children who are in the lowest 10% of the national population are classified as developmentally 'vulnerable'.[1] Developmental vulnerability is associated with undetected maternal postnatal depression, the early cessation of breast feeding[2] and parental unmet psychosocial needs (eg, housing, domestic violence).[3 4] Children who are developmentally vulnerable are twice as likely to struggle at school, experience adverse childhood events and have poorer long-term health outcomes and higher healthcare costs.[1 5–12] These adverse childhood events

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can continue into adulthood, contributing up to 44% of adult morbidity.[13 14]

Continuity of care with regular child and family health (CFH) checks by local health district (LHD) employed child and family health nurses (CFHN) are the foundation for optimal child health and development. This is particularly the case for priority populations, including newly arrived migrant and refugee women, children and their families.[5] However, these populations also experience significant barriers to services including cultural, language, limited health literacy, discrimination and unmet psychosocial needs.[15–31] Families with greater disadvantage are at greater risk of developmental vulnerability and poorer maternal mental health and other health problems. These families are less likely to engage with health services, particularly health promotion programmes like CFH checks.[2–4 15 32–36]

Australian policymakers identified service areas that need improvement to optimise outcomes in the first 2000 days of a child's life.[5 37] These include the transition from maternity to CFH services; increasing uptake and length of time families stay connected with CFH services; and supporting priority populations. Unfortunately, in NSW, two-thirds of the children stop attending CFH services by 12 months of age,[15 18–20] further fragmenting care.

Benefits of integrated health-social care hubs

To address the fragmented CFH services for priority populations, integrated health-social care hubs were established in multiple jurisdictions across Australia. These are physical hubs where health and social services are co-located, supported by care navigators and shared referral pathways.[38 39] Co-location and navigation support aims to remove barriers that hinder engagement between families and CFH services. However, the evidence-base for their effectiveness is limited. Our recent systematic review demonstrated the dearth of experimental trial evidence in Australia regarding physical CFH Hubs.[40] Yet, individual studies have found Hub models increase access to CFH services and the identification of developmental vulnerability.[40] Additionally, a recent scoping review of models of care across the continuum of pregnancy, birth and the postpartum period for women from migrant and refugee backgrounds in high-income countries highlighted an evidence gap for models that improved maternal and child infant health outcomes.[8]

We have extended this evidence-base by showing the feasibility and efficacy of integrated CFH hubs and cross-cultural workers (CCW) models in South Eastern Sydney.[8 41–43] These models support women and families to navigate maternity, CFH and community-based services, providing continuity of care across the continuum of pregnancy and transition to CFH. The pilot interventions demonstrated that for women and families from migrant and refugee populations: CFHN services embedded in integrated hubs increased the completion rate of CFH checks from 30% to 60% at 12 months and facilitated linkage with co-located non-government

organisations.[41 42] CCW support in pregnancy was also highly rated by staff and pregnant women regarding support for pregnancy and linkage with services.[44 45]

Current study: First 2000 Days Care Connect

First 2000 Days Care Connect (FDCC) is an integrated health-social care hub model that builds on these feasible and acceptable pilot interventions. The FDCC model involves co-located CFH services and non-government organisations (NGO), including psychosocial support services (eg, playgroups, domestic violence support, mental health support, early childhood education, family support). These services operate from a physical location to facilitate service collaboration, integration and a community-led approach to local needs. This Hub is supported by care navigation, increasing continuity from maternity to CFH services.

Objectives

The overall aim of the FDCC study is to evaluate: the impact of FDCC (an integrated CFH Hub) on attendance at CFHN services and completion of CFH checks, support of child growth and development, breast feeding and maternal well-being and meeting family psychosocial needs (Component 1); the process of implementing FDCC (Component 2); and the cost-effectiveness of FDCC (Component 3).

Methods and analysis

STUDY SETTING

FDCC is a multisite study, conducted across three metropolitan LHDs in Greater Sydney, NSW—namely, South Eastern Sydney Local Health District (SESLHD), South Western Sydney Local Health District (SWSLHD) and Northern Sydney Local Health District (NSLHD). Participants will be recruited from public and universally available antenatal services at participating public hospitals within the LHDs and receive services from CFHN services within each LHD.

Recruitment and consent

The study will recruit 240 women between November 2021 and April 2022. Eighty participants will be enrolled within SESLHD, NSLHD and SWSLHD, with 40 allocated to the intervention arm (FDCC Hub) and 40 to the control arm (routine care). Potential participants are women attending antenatal clinics at the participating public hospitals within each study site and fulfilling the eligibility criteria (table 1).

Using three processes, midwives and CCWs (where available) will identify eligible women attending antenatal services at the intervention sites during regular consultations. The processes include: midwives and CCW introduce the project to women attending a group model of antenatal care; midwives will promote the study during individual hospital antenatal visits and provide potential participants a flyer; and midwives will identify potential

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Eligible women will be expectant mothers who are: ▸ Attending antenatal clinics linked to the three study sites. ▸ Residing in geographical catchment for the respective antenatal clinic. ▸ Expectant mother >20 weeks gestation. ▸ Sixteen years of age or older at enrolment. ▸ Newly arrived migrant (<10 years in Australia) or self-identified refugee (<10 years in Australia), from a non-English speaking background. ▸ Provide a signed and dated informed consent form.	▸ Does not comprehend the recruitment invitation (not proficient in English and/or declines the offer of an interpreter in their home language). ▸ Have no mechanism for contact (telephone or email). ▸ Already an active client in other targeted support services. ▸ Less than 16 years of age at enrolment. ▸ Migrant >10 years in Australia or self-identified refugee >10 years in Australia. ▸ From an English speaking background. ▸ Not residing in geographical area of study.

participants who meet the eligibility criteria and provide study details during regular antenatal visits. If potential participants provide verbal consent, they will be introduced to the project officer. The project officer will explain the study and provide a participant information sheet and consent form (PISCF) using translated documents and/or interpreter services, if required. They will confirm eligibility at face-to-face clinical visits or via telephone consultation. If the woman is not interested in the study, there will be no further contact regarding the study.

Participants will provide informed consent via completing paper-based consent forms, via email or verbally via phone or via online electronic signature option using the Research Electronic Data Capture (REDCap) database. Participants consenting to the study can opt out of the data linkage component.

For component 2, once the FDCC trial is underway, the project implementation scientist will contact participating CFHNs, NGO staff and Hub administrative staff via telephone and/or email to invite them to an interview or focus group. Prior to the interviews and focus groups, the implementation researcher will describe the study to participants and its rationale, providing a PISCF, and obtain informed consent. Hub staff and service leaders, including LHD partners and policymakers, will be invited to complete a 32-item online survey at the completion of Component 1. The online survey will include a detailed description of the study, rationale and an opportunity to indicate informed consent before survey completion. Hub staff and managers who do not complete the survey will receive a reminder thrice via email.

Study procedures

This protocol has used the Standard Protocol Items: Recommendations for Interventional Trials (online supplemental spirit checklist) reporting guidelines.[46] Following the identification of potential participants, project officers will confirm participant eligibility as part of the consent process. This is a non-randomised study whereby eligible participants will be allocated to a study arm (FDCC intervention or control group) based on their residential postcode at the time of enrolment (see below). Participation will be 12 months, including: intervention allocation; intervention delivery (12 months); and data collection (baseline, 6 months post partum, 12-month post partum). In addition to English, the study materials will be translated in the six most common community languages (Arabic, Bengali, Simplified Chinese, Korean, Hindi and Vietnamese).

Allocation, concealment and implementation

Women attending antenatal services from the participating hospitals who live in a defined geographical area (postcode) served by an established CFH Hub in their LHD will be allocated to the FDCC intervention group. Women attending antenatal services from the participating hospitals but do not live in the defined geographical area above will be in the control group.

Blinding

Given the nature of the study, blinding to group allocation is impractical. However, as the intervention is dependent on participant postcode of residence, there is expected to be minimal treatment contamination between the intervention and control groups. To assess for intervention contamination, women in all groups will be asked at the 12 months postpartum assessment regarding the use of any Hub and CFHN service. While the site project officers collecting survey data at each site will not be blinded to allocation, the researcher analysing data will be blinded to group allocation.

Intervention

After recruitment, the Hub navigator or key worker (ie, an individual based at the hub responsible for linking participants with services, usually the CFHN) will contact participants to introduce Hub services and support engagement with identified services, if needed. This will be followed by another contact between birth and 8 weeks post partum. Following mothers' and infants' discharge from birthing services, women will access CFH services via the Hub, as well as psychosocial support services suited to maternal needs and preferences. Per routine care, all women and their babies will be offered an appointment (approximately 1 hour) with a CFHN at 1–4 weeks post partum, 6–8 weeks post partum, 6 months post partum and 12 months post partum.

Hub services will be face-to-face, online and one-to-one. Some services, such as playgroup or mothers' groups, might be in a group setting. Mothers and their babies will have access to the Hub for 12 months. Further contacts with the Hub navigator or keyworker as participants require.

The integrated FDCC Hubs are a physical building and a way of working, facilitating service collaboration, integration and a community-led approach to local needs. Hubs most commonly operate from a host building from which partner community-based or public services are delivered. In our Hub model, CFH services are co-located with NGOs. Families are linked with psychosocial support services, including playgroups, early childhood learning opportunities and family support. Within the Hub services, existing CFH and NGO services support families to navigate systems and engage with other health services. These include general practitioners, early childhood, education and psychosocial support to address their needs.

Control arm: routine care

Pregnant women attending the participating hospitals who meet eligibility criteria but do not live in the geographical area will be allocated to a control cohort and receive routine care (eg, receive information on CFHN services at discharge and follow-up as per current pathways).

Implementation evaluation

Our mixed-methods implementation evaluation will assess the barriers and facilitators to implementing the FDCC Hubs at the three sites, as guided by the consolidated framework for implementation research (CFIR).[47] The CFIR is a comprehensive framework designed to 'offer an overarching typology to promote implementation theory development and verification about what works where and why across multiple contexts'.[47] The CFIR is widely used in diverse healthcare contexts, including primary care.[48] The CFIR identifies five major domains and guides the consideration and assessment of factors that can impact intervention implementation and effectiveness. Additionally, the researchers will evaluate specific implementation outcomes of acceptability, appropriateness, fidelity to the implementation strategy, coverage, sustainability and cost

(table 2) as guided by the taxonomy proposed by Proctor and colleagues.[49]

Logic model

We developed a logic model to inform the FDCC implementation evaluation (figure 1). We used a modified version of existing logic model frameworks[50 51] to include the inner context (ie, individual factors, organisational settings) and the outer context of each site (ie, area demographics, policy climate, relevant geographically adjacent clinical services). These contextual factors were incorporated within the logic modelling to enable implementation researchers to better describe the determinants of successful implementation in clinical practice.[52]

Additionally, we included a detailed description of the intervention to identify feasibility elements to measure during the study. These include features of the physical location of services, how services are integrated, the availability of culturally sensitive support materials and services and the navigator or keyworker. To supplement the practical elements of the intervention, we described the underlying theoretical principles of the model. These include the collective impact framework[53] and the elements of the behaviour change wheel that we perceived the model to adhere.[54] Collective impact is designed to inform change on complex social issues, and draws on five conditions: common agenda; continuous communication; mutually reinforcing activities; backbone support; and shared measurement.[55] Collective impact and the behavioural change wheel mechanisms of change within the logic model will inform the qualitative interview schedule. Finally, we drew connections from these underlying theories of change to the specific intermediate and long-term outcomes that we hypothesised the model will produce. Principally, we hypothesise that the intervention components will work on the core principles of environmental restructure, enablement, modelling and training within the Hub sites, underpinned by the collective impact principles to support migrant and refugee parents to engage with health and social support services. This engagement will provide better outcomes for children and families. It will also create opportunities for shared knowledge between health and non-health services, as part of an acceptable and cost-effective model delivery.

Table 2 Proctor and colleagues implementation outcomes mapped to First 2000 Days Care Connect evaluation

|	Questions addressed by each implementation factor
Acceptability	Do Hub staff and families view the Hub model as acceptable?
Adoption	Do Hub staff intend to apply the Hub model as described in the study protocol?
Appropriateness	Do Hub staff perceive the Hub model as relevant and useful for their services?
Fidelity	Is the Hub model applied as intended?
Coverage	How many eligible families are reached through the Hub model and keyworker?
Cost	How much does it cost to implement Hubs?
Sustainability	What are the factors that will allow the Hubs to be sustained/scaled-up further?
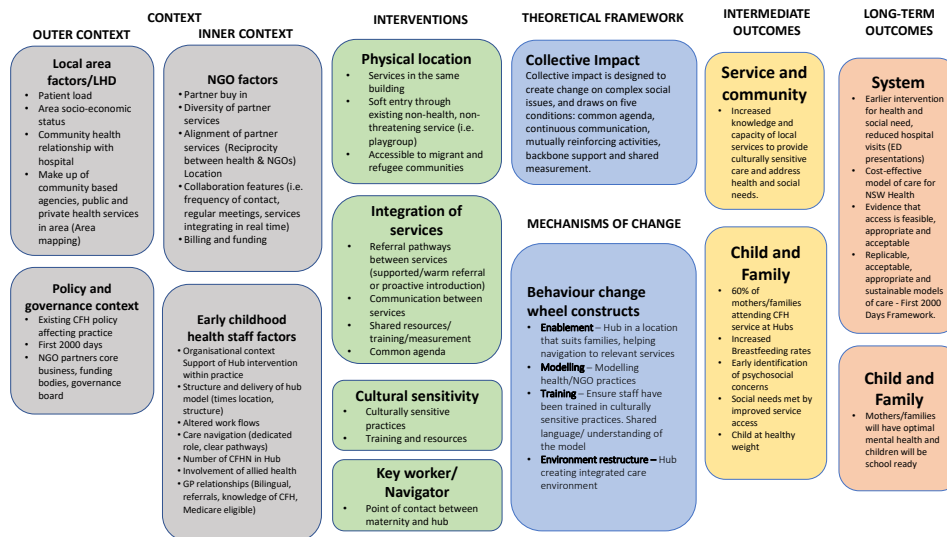
Figure 1 First 2000 Days Care Connect implementation evaluation logic model. CFH, child and family health; CFHN, child and family health nurses; ED, emergency department; LHD, local health district; NGO, non-government organisations; NSW, New South Wales.

Table 3 provides an overview of the planned outcomes and measurement for the implementation evaluation.

Economic evaluation

The economic evaluation will adopt a healthcare perspective beginning with a cost consequence analysis to describe the costs and all main study outcome measures (tables 4 and 5) and then generate a cost-utility analysis. The costs of Hub implementation will include: the establishment and operation of Hubs; and the flow-on cost from service use from Hub referrals. Hubs are likely to be implemented in different ways relative to local context and, as such, costs might differ. Two bespoke costing templates will be

shared with Hub managers on trial commencement to be completed at 6 and 12 months, with researcher support to ensure accuracy. The templates will allow for standardisation and between-site comparison.

Establishment and operational costs

A micro-costing approach will be adopted to account for funded and in-kind expenditures.[56 57] A simple template will have major generic expenditure categories, including upfront capital costs (eg, vehicles, buildings), governance arrangements to manage the Hubs (eg, staff meeting time), material costs (eg, brochures) and in-kind support from staff, including partner agencies. There might be

Table 3	Overview of the implementation evaluation outcomes		
Implementation evaluation outcomes			
Outcome measure	**Data source**	**Methods**	**Data collection**
Description of local context and Hub	SEIFA data, search of grey literature, informal contact with Hub service leaders.	SEIFA data, search of grey literature, informal contact with Hub service leaders.	Trial commencement.
Fidelity of Hub model	Hub intervention log.	A bespoke log completed by site project officers.	Ongoing during the trial.
Acceptability of intervention measure (AIM), intervention appropriateness measure (IAM), and feasibility of intervention measure (FIM)[63]	Research survey administered by project officer.	AIM, IAM and FIM measures completed by Hub staff, service leaders, participants in the intervention group.	Trial end (included in the 12-month postpartum parent survey for parents and separate staff survey).
Barriers and facilitators to running the FDCC Hubs	Interviews with Hub staff, service leaders, participants in the intervention group.	Qualitative interviews and focus groups, guided by the CFIR.	Pre-trial (with Hub staff and service leaders). Ongoing during and end of the trial for all participants.
The NoMAD tool[64] to assess Hub staff buy in to the model	Research survey administered by project officer.	NoMAD tool completed by Hub staff.	Trial end.
CFIR, consolidated framework for implementation research ; FDCC, First 2000 Days Care Connect; NoMAD, NOrmalization MeAsure Development; SEIFA, Socio-Economic Indexes for Areas.			

Table 4 Overview of the economic evaluation outcomes

Economic evaluation outcomes			
Outcome measure	Data source	Methods	Data collection
Mother quality of life (EQ-5D quality of life)	Research survey administered by project officer.	Research survey administered by project officer. EQ-5D quality of life questionnaire.	Baseline (antenatal time of enrolment) 6 months post partum 12 months post partum
Cost of implementing Hubs and referral services	Bespoke surveys.	Bespoke surveys completed by Hub staff and participants in the intervention group.	6 and 12 months 6 and 12 months

EQ-5D, EuroQol five-dimension scale questionnaire.

expenditures against these categories. At this stage, there is no plan for capital expenditures. This is included for completeness. Operational costs pertain to daily Hub operation, including new staff hired (eg, salary, on-costs), in-kind costs (eg, time costs from non-salaried staff), venue costs (eg, utilities, even if in-kind) and material costs (eg, brochures).

Referral costs
Prior to Hub commencement, Hub personnel will be asked for a list of service partners to create a template where clients will be asked the services accessed and frequency; clients will be surveyed using this. Other sites will follow suit. Full client recall is not anticipated. However, it is important that the study clarifies the impact on referral services, if possible. A top-down costing estimate will then be made.[56 57] Each partner service will then be contacted to generate an estimate of the average client service cost. Providers typically adopt an activity-based costing approach in accounting and funding proposals. No specific client data will be accessed. Rather, the researchers will guide service providers to generate average costs, which typically only involves dividing total funding for service(s) by total occasions of service. Researchers will only be privy to the overall average costs. Where costs are unavailable, an approximation will be made if public and research data are available. Otherwise, a list of service counts only will be made and remain uncosted. Table 4 provides an overview of the planned outcomes and measurement for the implementation evaluation.

Primary and secondary outcome measures
Outcomes will be measured from enrolment (baseline) until and including 12 months post partum (table 5). Outcomes will be gathered via: the extraction of routinely collected clinical data from electronic medical records (eMRs) at each site or LHD; surveys administered by a researcher to mothers; and data linkage of participants with administrative data sets (NSW perinatal data collection, NSW emergency department data collection). The primary outcome measure is the proportion of mothers and their respective infant who attend CFHN services for early childhood health checks at 1–4 weeks post partum,

6–8 weeks post partum, 6 months post partum and 12 months post partum. For primary and secondary variables, see table 5.

Data analysis plan
Sample size estimation
Based on pilot data, we anticipate the percentage of children to have their CFH check done by a CFHN will be 60% in the intervention group and 30% in the control group. Therefore, 72 children will be needed for each arm to provide 80% of power to detect the magnitude of such an increase with a p value<0.05. Allowing for a 40% attrition rate (ie, loss-to-follow-up) as this is a vulnerable community,[15] we aim to recruit 120 children in each arm or 240 children in total across the three sites.

Statistical analysis
Statistical analysis will include descriptive analysis of participating mother and child outcomes at each assessment. We will compare outcomes between the intervention and control groups using the Fisher's test for binary outcomes, χ^2 method for categorical outcomes, non-parametric method (eg, Wilcoxon rank-sum test) and parametric methods (eg, t-test) for continuous and ordinal variables. As outcomes will be measured repeatedly, multilevel regression analysis will be undertaken to examine intervention impact on outcomes, controlling for the plausible confounders at the individual (eg, mother's socio-demographic characteristics, geographical area of residence) and community levels at baseline (eg, neighbourhood socioeconomic factors). Generalised estimating equations method will be used in the regression analysis considering the potential clustering effect by site. Only de-identified data will be analysed. No data safety monitoring committee is needed for this study due to the known minimal risks. No interim analyses or stopping rules will be applied.

Implementation evaluation analysis
Implementation effectiveness will be evaluated using the validated scoring system of −2 to +2 with score descriptions as follows: −2 indicates the construct has negatively influenced the practice and examples of negative manifestations are indicated; −1 indicates the construct

Table 5 Overview of the FDCC study outcome variables

FDCC trial

Outcome measure	Data source	Methods	Data collection
Proportion of mothers, children and families who attend CFHN at FDCC Hub for checks. (*Primary Outcome*)	Electronic medical record at LHD.	Extraction of routine clinical data from electronic medical record at LHD.	▲ 1–4 weeks post partum. ▲ 6–8 weeks post partum. ▲ 6 months post partum. ▲ 12 months post partum.
Proportion of mothers, children and families who are up to date with age appropriate health checks, either via CFHN services or GP. (*Primary Outcome*)	Electronic medical record at LHD.	Extraction of routine clinical data from electronic medical record at LHD.	▲ 1–4 weeks post partum. ▲ 6–8 weeks post partum. ▲ 6 months post partum. ▲ 12 months post partum.
Proportion of women identified as at risk of experiencing depression on the EPDS.[65] (*Secondary Outcome*)	Electronic medical record at LHD.	Extraction of routine clinical data from electronic medical. ▲ EPDS total score. Response to item 10 of EPDS.	▲ Baseline (antenatal time of enrolment). ▲ 1–4 weeks post partum or by 6–8 weeks post partum. ▲ 6 months post partum.
Proportion of women identified as having more than one unmet social need on the We Care questionnaire.[66] (*Secondary Outcome*)	Research survey administered by project officer.	Research survey administered by project officer. We Care questionnaire.	▲ Baseline (antenatal time of enrolment). ▲ 6 months post partum. ▲ 12 months post partum.
Proportion of women identified as experiencing psychosocial vulnerability on NSW Health psychosocial screening tools (Safe Start Psychosocial assessment including Domestic Violence screen).[67] (*Secondary Outcome*)	Electronic medical record at LHD.	Extraction of routine clinical data from electronic medical. Presence/absence of psychosocial risk factors on Safe Start Psychosocial assessment including the Domestic Violence screen.	▲ Baseline (antenatal time of enrolment). ▲ 1–4 weeks post partum or by 6–8 weeks post partum. ▲ 6 months post partum.
Proportion of mothers reporting poor quality of life on EQ-5D quality of life questionnaire. (*Secondary Outcome*)	Research survey administered by project officer.	Research survey administered by project officer. EQ-5D quality of life questionnaire.	▲ Baseline (antenatal time of enrolment). ▲ 6 months post partum. ▲ 12 months post partum.
Proportion of children monitored for growth parameters and their growth parameters (weight, height, head circumference). (*Secondary Outcome*)	Electronic medical record at LHD.	Extraction of routine clinical data from electronic medical. ▲ Height (cm). ▲ Weight (kg) head circumference (cm).	▲ 1–4 weeks post partum. ▲ 6–8 weeks post partum. ▲ 6 months post partum. ▲ 12 months post partum.
Proportion of women exclusively breast feeding / predominately breast feeding/partially breast feeding/ artificially feeding. (*Secondary Outcome*)	Electronic medical record at LHD. Data linkage with NSW Perinatal Data Collection.	Extraction of routine clinical data from electronic medical. ▲ Exclusively breast fed. ▲ Predominately breast fed. ▲ Partial breast fed. ▲ Artificial feeding.	Electronic medical record at LHD: ▲ 1–4 weeks post partum. ▲ 6–8 weeks post partum. ▲ 6 months post partum. Data linkage with NSW Perinatal Data Collection ▲ Breast feeding initiated at discharge postnatally.
Proportion of children identified by CFHN as at developmental risk on the Learn the Signs Act Early (LtSAE) and Ages and Stages Questionnaire Screening tools. (*Secondary Outcome*)	Electronic medical record at LHD.	Extraction of routine clinical data from electronic medical record at LHD. ▲ LtSAE screening completed, and the concerns/no concerns identified on LtSAE screening domains. Ages and Stages Questionnaire (ASQ and ASQ-SE) secondary screener given to families by CFHN as clinically required .	▲ 6–8 weeks post partum (LtSAE). ▲ 6 months post partum (LtSAE and ASQ). 12 months post partum (LtSAE and ASQ and ASQ-SE).
Mother and infant attendance at emergency departments from recruitment at 6-month post partum and 12-month post partum. (*Secondary Outcome*)	Data linkage with NSW-wide Emergency Department Data Collection (EDDC).	NSW-wide EDDC data Linkage.	At 6-month post partum and 12-month post partum.

CFHN, child and family health nurses ; EPDS, Edinburgh Postnatal Depression Scale; EQ-5D, EuroQol five-dimension scale questionnaire; FDCC, First 2000 Days Care Connect; GP, General Practitioner; LHD, local health district ; NSW, New South Wales .
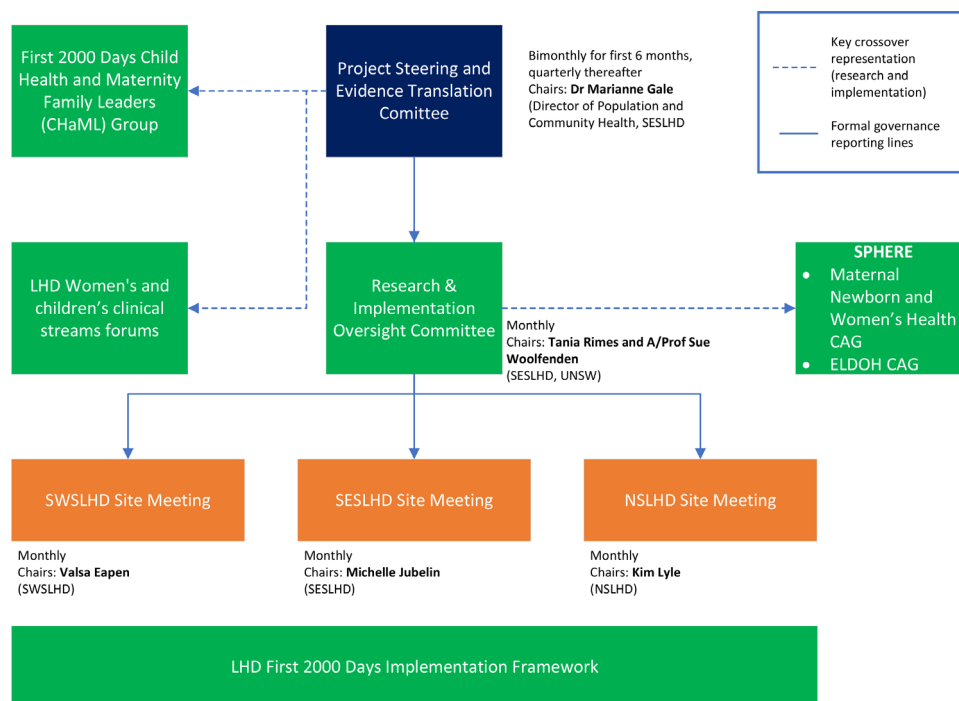
Figure 2 First 2000 Days Care Connect governance structure. CAG, Clinical Academic Group; ELDOH, Early Life Determinants of Health; LHD, local health district; NSLHD, Northern Sydney Local Health District; SESLHD, South Eastern Sydney Local Health District; SWSLHD, South Western Sydney Local Health District. UNSW, University of New South Wales.

has negatively influenced the practice and general statements of negative manifestations are made; 0 indicates the construct neutrally influenced the practice; +1 indicates the construct positively influenced the practice and general statements of positive manifestations are made; and +2 indicates the construct positively influenced the practice and explicit examples of positive manifestations are described.[58] Using these scores, construct scores can range from a low of −80 to a high of +80, demonstrating the key barriers and facilitators to uptake and sustain the FDCC hubs. This method of quantifying implementation effectiveness will be supplemented with an inductive analysis of qualitative data to ensure openness to emerging themes not readily captured by the CFIR and Proctor and colleague's outcome measures.[49]

Economic analysis

First, a cost consequence analysis will collate and list the main costs and outcomes from the trial (tables 4 and 5) to provide transparency regarding the overall impacts of Hubs. Second, a cost-utility will then report the incremental (net) cost per change in quality adjusted life years (with health utilities derived from the EuroQol five-dimension scale questionnaire (EQ-5D))[59] simulated using a decision tree, and where the threshold willingness to pay is varied between A\$42 000 and \$A67 000.[60] Third, a probability sensitivity analysis will be undertaken and, where there is statistical uncertainty regarding cost-effectiveness a value of information analysis will assess statistical uncertainty and value for further research, including, for example, the value of longer follow-up to assess medium-to-long term impacts.[61] Finally, a budget

impact analysis will be undertaken where there are positive and attributable impacts regarding primary and/or secondary outcomes (captured in the cost consequences analysis). This will estimate the overall financial cost if Hubs were scaled-up across NSW to inform policy affordability considerations. The latter will involve estimating the potential Hubs would be made and an average cost (of the three Hubs) applied, with high and low estimates in a sensitivity analysis.

Data management

All participants will be allocated a randomly generated unique identifier code to be used throughout the study. Project officers will have identified information of the participants enrolled at their site, stored in password protected files. The project officer within each LHD will work with data managers to extract routinely collected clinical data from electronic medical records for all participants, per table 3. Data will be stored within a protected site-based server. Only de-identified data will be transferred from each LHD to the researchers (SW, KO, NH) for data analysis using encrypted transfer.

Project officers with support from CCWs and/or interpreters will collect surveys at baseline, 6 months post partum and 12 months post partum. The survey can be completed in hardcopy (face-to-face or telephone) or online by participants using a secure link to REDCap. Subsequently, project officers who can access the identifying information within each LHD will enter survey data into the REDCap database. REDCap is hosted on the University of NSW (UNSW) infrastructure. Permissions granted to each user within each REDCap project is

controlled by and is the responsibility of the project team. Hardcopy materials will be stored in locked cabinets for the required period, either indefinitely if the participant consents to providing their data for data pooling or for 15 years after the completion of the study. After these periods, hardcopy materials will be destroyed and password-protected electronic archives will be deleted.

The identifying information collected within each LHD will be compiled into a single password-protected file and sent to The Centre for Health Record Linkage (CHeReL) for data linkage. The minimum identifying information for mothers and infants will be used to extract participant records from the administrative data. On completion of data extraction, CHeReL will transfer to UNSW administrative data of the participants who consented to data linkage. The administrative records will be de-identified by CHeReL, which will create the person project number (PPN) for each participant. The PPN will be linked to the participant's unique project identification number to link the administrative records with the eMR and survey records that belong to the same participant.

Patient and public involvement
The research questions were developed based on qualitative research undertaken with Hub participants and community members and service providers in the pilot study.[41 62] The FDCC team have a consumer representative and consultation was undertaken with local Hub partner services. The researchers also consulted multicultural health services, including cultural support workers, to ensure research materials are culturally nuanced. Patients or participants have not directly been involved in the current study design.

ETHICS AND DISSEMINATION
Ethical approval was granted by the SESLHD (2020/ETH03295). This trial was registered with the Australian New Zealand Clinical Trials.

Confidentiality
The researchers acknowledge that ensuring confidentiality is essential. The researchers will exercise due diligence to anonymise participants' responses for reporting, publication and presentation purposes. Only de-identified data will be transferred from each LHD to the UNSW researchers for data analysis. The de-identified data from each LHD to the UNSW team will be securely transferred through an NSW Health-approved e-health platform.

Managing potential harms
If issues are disclosed outside of the study parameters, mandatory NSW Health policy directives will apply (eg, family and domestic violence, child protection matters). These will be managed as per current policies and practices within LHDs. The child protection and domestic violence counselling teams are readily accessible to provide advice and support if issues are identified. As the researchers are all mandatory reporters, they will inform participants that they are not able to maintain confidentiality when it relates to the safety of the participant, the child/children, the family and the wider community. These obligations are detailed in the PISCF (online supplemental appendix 1).

Dissemination
Data obtained for the study will be published in reports, peer-reviewed journals and presented at appropriate conferences. The de-identified data will be available to all investigators. Access by individuals' other than the named investigators will only be permitted after consideration and agreement by all the remaining investigators. An essential element of knowledge translation are the study partners and advisors who will share findings and consider if and how to progress to trialling or implementing the programme at scale. We intend to produce at least two papers (eg, protocol, main findings) for peer-review publication, written by core research and implementation team.

Study governance
The FDCC team will support planning, implementation and governance of the project and ensure that Work Health and Safety requirements and policies are considered and actioned. There are currently no procedures for auditing trial conduct. All protocol modifications will be discussed within all levels of governance and communicated to the SESLHD Human Research Ethics Commitee. Figure 2 outlines our governance structure.

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