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A non-randomised control trial, implementation evaluation, and economic evaluation of an integrated child and family health hub (FDCC) for migrant and refugee women

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TITLE: A non-randomised control trial, implementation evaluation, and economic evaluation of an integrated child and family health hub (FDCC) 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. 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.

Methods and analysis: 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 geographical proximity to the Hub sites. Impact 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 improve maternal wellbeing. 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 Guided by the Consolidated Framework for Implementation Research and Proctor and colleague's implementation outcomes taxonomy. Component 3 is a within-trial economic evaluation 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: ACTRN12621001088831

ARTICLE SUMMARY

Strength and limitations

- First Australian multi-site non-randomised controlled trial to test the effectiveness of integrated health-social care hubs.
- The model could be an exemplar for scaling up nationally and adapting to other populations who have barriers to accessing child and family health services.
- The non-randomised design of the trial has some limitations, particularly the inability to guarantee the comparability of the intervention and control groups.
- The model, tested in the New South Wales healthcare system, would potentially need further adaptation to be delivered in other health care settings.

BACKGROUND AND RATIONALE

In New South Wales (NSW), Australia, 25% of children from migrant and refugee families are 'developmentally vulnerable'.[1] Developmental vulnerability is associated with undetected maternal postnatal depression, the early cessation of breastfeeding[2], and parental unmet psychosocial needs (e.g., 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 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. These families are less likely to engage with health services, particularly health promotion programs, like CFH checks.[2-4 15 32-35]

Australian policymakers identified service areas that need improvement to optimise outcomes in the

first 2,000 days of a child's life.[5 36] 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 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.[37 38] 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. Yet, individual studies have found Hub models increase access to CFH services and the identification of developmental vulnerability.[39] 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]

Research led by some of the researchers[8 40 41] extended this evidence-base by showing the feasibility and efficacy of integrated CFH hubs and cross-cultural workers (CCW) models in South Eastern Sydney. 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: CFH 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.[40 41] Cross-cultural worker support in pregnancy was also highly rated by staff and pregnant women regarding support for pregnancy and linkage with services.[42 43]

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 (e.g., 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, breastfeeding and maternal wellbeing, 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, SESLHD, SWSLHD, and 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).

Table 1: Inclusion and Exclusion Criteria

Inclusion criteria	Exclusion criteria
Eligible women will be expectant mothers who are:	• Does not comprehend the recruitment invitation (not proficient in English and/or

• Attending antenatal clinics linked to the three study sites • Residing in geographical catchment for the respective antenatal clinic • Expectant mother > 20 weeks gestation • 16 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	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 > 5 years in Australia or self-identified refugee > 10 years in Australia, • From an English speaking background • Not residing in geographical area of study

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 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 clinic 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 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 SPIRIT reporting guidelines.[44] 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 geographic 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 geographic 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 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 postpartum. 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 to 4 weeks postpartum, 6 to 8 weeks postpartum, 6 months postpartum, and 12 months postpartum.

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 learining opportunitites, 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 geographic area will be allocated to a control cohort and receive routine care (e.g., 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).[45] 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'.[45] The CFIR is widely used in diverse healthcare contexts, including primary care.[46] 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.[47]

Table 2: Proctor and colleagues (2011) implementation outcomes mapped to FDCC 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 & 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?

Logic Model

We developed a logic model to inform the FDCC implementation evaluation (**Error! Reference source not found.**). We used a modified version of existing logic model frameworks[48 49] to include the inner context (i.e., individual factors, organisational settings) and the outer context of each site (i.e., 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.[50]

[INSERT FIGURE 1]

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[51] and the elements of the behaviour change wheel that we perceived the model to adhere.[52] 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.[53] 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 3 provides an overview of the planned outcomes and measurement for the implementation evaluation.

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)[54]	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[55] to assess Hub staff buy in to the model	Research survey administered by project officer	NoMAD tool completed by Hub staff	Trial end

Economic Evaluation

The economic evaluation will explore the costs of Hub implementation, including: 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 upon 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 (e.g., vehicles, buildings), governance arrangements to manage the Hubs (e.g., staff meeting time), material costs (e.g., brochures), and in-kind support from staff, including partner agencies. There might be 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 (e.g., salary, on-costs), in-kind costs (e.g., time costs from non-salaried staff), venue costs (e.g., utilities, even if in-kind), and material costs (e.g., 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. Table 2 in Appendix 11.5 provides the list collated for SWSLHD; 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 un-costed. Table 4 provides an overview of the planned outcomes and measurement for the implementation evaluation.

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	Bespoke surveys	Bespoke surveys completed by Hub Staff and Participants in the intervention group	6 and 12 months 6 and 12 months

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 at each site or LHD; surveys administered by a researcher to mothers; and data linkage of participants with administrative datasets (NSW perinatal data collection, NSW emergency department data collection). The primary outcome measure is the proportion of mothers and their respective infant who attend CFH services for early childhood health checks at 1 to 4 weeks postpartum, 6-8 weeks postpartum, 6 months postpartum, and 12 months postpartum. For primary and secondary variables, see Table 5.

Table 5: Overview of the FDCC Study Outcome Variables

FDCC trial			
Outcome measure	**Data Source**	**Methods**	**Data Collection**
Proportion of mothers and their respective infant who attend CFH services for early childhood health 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
Infant identified as at developmental risk by CFHN using the Learnt the Signs Act Early (LtSAE) and Ages and Stages Questionnaire Screening tools	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 & ASQ-SE) given to families by CFHN.	• 6-8 weeks post-partum (LtSAE) • 6 months post-partum (LtSAE and ASQ) • 12 months post-partum (LtSAE and ASQ and ASQ-SE)
Proportion of children monitored for growth parameters and their growth parameters (weight, height, head circumference)	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
Mother identified as at-risk of experiencing depression (Edinburgh Postnatal Depression Scale (EPDS))[58]	Electronic medical record at LHD	Extraction of routine clinical data from electronic medical. • Edinburgh Depression Scale (EPDS) total score • Response to item 10 of EDS	• Baseline (antenatal time of enrolment) • 1-4 weeks post-partum or by 6-8 weeks post-partum • 6 months post-partum

Mother identified as experiencing psychosocial vulnerability/risk factors (Safe Start Psychosocial assessment including Domestic Violence screen)[59]	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
Mother experiencing unmet social need/s (THRIVE We Care questionnaire)[60]	Research survey administered by project officer	Research survey administered by project officer. THRIVE We Care questionnaire.	• Baseline (antenatal time of enrolment) • 6 months post-partum • 12 months post-partum
Mother exclusively breastfeeding /partially breastfeeding/ artificially feeding	Electronic medical record at LHD. Data linkage with NSW Perinatal Data Collection.	Extraction of routine clinical data from electronic medical. • Exclusively breastfed • Predominately breastfed • Partial breastfed • 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.
Mother and infant attendance at emergency departments from recruitment to 12 months post-partum.	Data linkage with NSW-wide Emergency Department Data Collection (EDDC)	NSW-wide EDDC data Linkage	Between baseline and 12 months post-partum

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 (i.e., 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, Chi-square method for categorical outcomes, non-parametric method (e.g., Wilcoxon rank-sum test) and parametric methods (e.g., *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 (e.g., mother's sociodemographic characteristics, geographic area of residence) and community levels at baseline (e.g., neighbourhood socioeconomic factors). Generalised estimating equations method will be used in the regression analysis, considering the potential clustering effect by site. Only deidentified 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 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.[61] 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.[47]

Economic Analysis

We will first assess comparative costs and outcomes between the Hubs. Second, we will estimate the overall cost of Hubs and likely costs and affordability, if Hubs was scaled-up across NSW. 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 routinly collected clinical data from electronic medical records for all participants, per Table 3. Data will be stored within a protected site-based server. Only deidentified 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 postpartum, and 12 months postpartum. 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. Upon completion of data extraction, CHeReL will transfer to UNSW administrative data of the participants who consented to data linkage. The administrative records will be deidentified 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 electronic medical record (eMR) and survey records that belong to the same participant.

ETHICS AND DISSEMINATION

Ethical approval was granted by the South Eastern Sydney LHD (SESLHD) (2020/ETH03295). This trial was registered with the Australian New Zealand Clinical Trials (ACTRN12621001088831).

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 deidentified data will be transferred from each LHD to the UNSW researchers for data analysis. The deidentified data from each LHD to the UNSW team will be securely transferred through a 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 (e.g., 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/ren, the family, and the wider community. These obligations are detailed in the PISCF.

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.[40 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.

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 program at scale. We intend to produce at least two papers (e.g. 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 WH&S 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 HREC. Figure 2 outlines our governance structure.

[INSERT FIGURE 2]

Author contributions

The original trial design was conceived by SW and TR. All authors contributed to refinement of, and approved, the final manuscript.

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Competing interests

The views expressed are those of the author(s) and not necessarily those of the funding partners. NSW Health has no direct role in study design; data collection, analysis, and interpretation, or writing of final reports, presentations, or publications.

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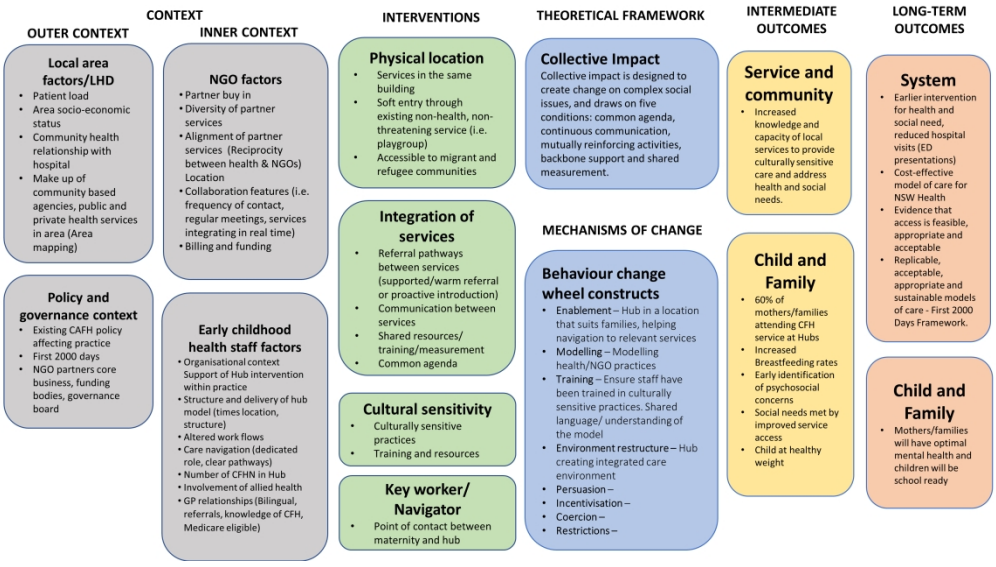
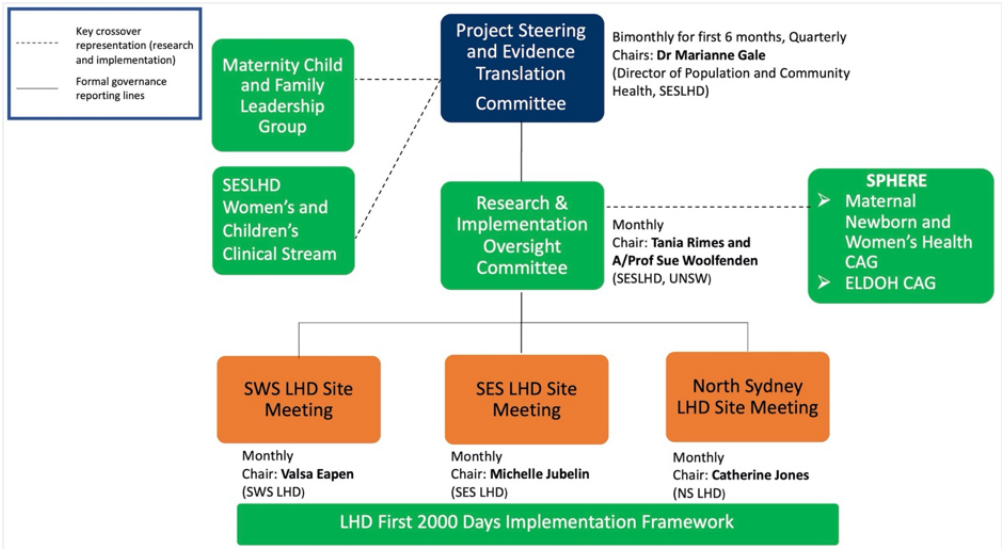


FDCC implementation evaluation logic model

861x484mm (118 x 118 DPI)



FDCC governance structure

626x342mm (38 x 38 DPI)

APPENDICES

Appendix 1: Participant Information Sheet and Consent Form

Primary and Community Health Directorate

PARTICIPANT INFORMATION SHEET AND CONSENT FORM
Participant

***Family Care Connect* – a holistic first 2000 days model of care for women and families from migrant and refugee communities.**

Invitation

You are invited to take part in the Family Care Connect project. Family Care Connect involves child and family Hubs, where health and other agencies work together and you are supported to navigate these services. Our research is seeing whether these Hubs support the health and development of children, mothers and families from migrant and refugee communities.

Who is doing the research?

Tania Rimes
Children and Communities Program Coordinator
Primary and Community Health Directorate| South Eastern Sydney Local Health District (SESLHD).

Associate Professor Sue Woolfenden (Research lead)
NHMRC Senior Research Fellow, Population Child Health Group | The University of New South Wales (UNSW). Senior Staff Specialist, Community Child Health | Sydney Children's Hospitals Network.

Before you decide if you want to take part in this research, we would like to explain what we are doing and why we are doing it. . Please take the time to read the following information carefully. You can talk about it with a relative or a friend if you wish before deciding.

What is the purpose of this research?

We want to see if child and family Hubs help women and families from migrant and refugee communities move from pregnancy to Child and Family Health services. Also, we want to see if these Hubs support children's health and development in the first 12 months of life.

We will also look at how easy and cost-effective the Hub is for you and other women and families.

Why have I been invited to participate in this research?

You are eligible to participate in this research because you:

- are having your baby or recently given birth to your baby at [INSERT HOSPITAL SITES]
- live in the postcode of [INSERT POSTCODE/S]

- are at least 20 weeks pregnant, OR have recently given birth to your baby and have not been discharged home from postnatal ward
- are a newly arrived migrant (within the last 10 years) from a non-English speaking background; or a refugee (living in Australia for less than 10 years) from a non-English speaking background
- are 16 years of age or older.

If I say yes, what will it involve?

If you decide to take part in the research and live in [INSERT SITE AREA] you will be in the **'FDCC Group'**. You will receive information about the child and family services in your area you can access after the birth of your baby. This information is given to all women, regardless of whether or not they participate in the study.
If you take part in the **"FDCC Group",** you will also be contacted by a worker from the local child and family Hub who will give you more information on the services offered and assist you with accessing these services if you choose.

If you agree to take part, we will ask you to sign the Participant Information and Consent form below; OR sign the online consent found here [INSERT ONLINE CONSENT URL]; OR provide verbal consent over the telephone to the contact person for the research.

After you provide consent to take part in this research, we will ask you to:

- Complete a survey about you, your family, your support needs, and your wellbeing. This will take about 30 minutes. You can choose to do it online, by paper, over the phone, or in-person. ***We can provide an interpreter to assist.***
- Complete another survey when your baby is 6 months and 12 months old. This will ask questions about you, what your needs are, and what services you have used. ***We can provide an interpreter to assist.***
- We will also collect data from your local and state-wide hospital/s about you and your baby. This reduces the number of questions we need to ask you.

The data we collect from local hospitals includes:

- Information about you and your child such as country of birth, date of birth, gender, language spoken at home
- Information from routine questions asked to all women when they come to hospital about their health and wellbeing and their child's
- Information about the services you or your child has seen, for example the child and family health nurse.

The data we collect from state-wide hospitals includes:

- Information that is collected on all new mothers and babies in NSW
- Emergency Department presentations for you and your baby

If you don't want us to collect data about you and your baby from state-wide hospitals, then we won't. Please let us know by checking the box.

I DO NOT want my state-wide hospital data included as part of this research ☐

If you only provide verbal consent, we will not collect data about you and your baby from state-wide hospitals.
As part of this research, we may also invite you to be interviewed. We will contact you at another time to discuss this process before the research is complete.

Any information we collect that can identify you or your child will remain confidential.

The total time you are involved with this project will be for 12 to 18 months, but you can choose to withdraw at any time.

What if I don't want to take part in this research, or if I want to withdraw later?
It is completely up to you whether or not you decide to take part. Saying yes or no will not affect your relationship with the care you receive, the services you access, or your visa status now or in the future.

If you wish to leave the research once it has started, you can do so verbally or in writing at any time without giving a reason. However, it may not be possible to withdraw your data from the research results once we have collected it and removed your identifying details. This is due to be done from March 2023.

How is this research being paid for?
The research is being paid for by NSW Health as part of the Translational Research Grant Scheme. More information about this scheme can be found here: https://www.medicalresearch.nsw.gov.au/translational-research-grants-scheme/

Are there risks to me in taking part in this research?
There is very little risk to you, however if you become upset or distressed because of taking part in the research, the research team will arrange for counselling or other help. Any counselling or help will be provided by qualified staff who are not members of the research team. This will be provided free of charge.

Another risk in taking part in this research is the risk to your privacy as part of collecting data about you, your child, and your family. While this is a risk, we will take all the steps to ensure your information remains private and confidential. We do not collect you or your baby's name, or anything else that could identify you or your family. Instead, your name will be replaced with a number. Only people involved with this research will be able to tell that the information is about you.

What happens if I suffer injury or complications as a result of the research?
It is very unlikely that you will suffer any injury as we are only asking you to complete questionnaires. However, if you require treatment or suffer loss as a result of the wrongdoing of any of the parties involved in the research, you can seek compensation. The cost of your treatment must be paid by the compensation you receive.

Will I benefit from the research?
This research aims to determine how best to provide child health services for families and to improve how parents in the future access child and family health services, however it may or may not directly benefit you or your baby.

Will taking part in this research cost me anything, and will I be paid?
Taking part in this research will not cost you anything, nor will you be paid.

How will my confidentiality be protected?
Any information that is collected about you as part of this research will remain private and confidential and will be discussed only with your permission, except as required by law. This means the research team are Mandatory Reporters and may need to speak with NSW Department of Communities and Justice if they are told or are concerned that a child is being hurt or is at risk of being hurt e.g. if there is abuse or violence in the home.

If such a situation happens, we would discuss this with you in private and arrange for you to speak with another professional if required.

Only the researchers named above will have access to your details. All information will be stored on a secure drive within [INSERT LHD SITES] and UNSW. We will keep the information for 5 years after the research ends. After this time, it will be destroyed.

In line with Australian, New South Wales, and other relevant laws, you have the right to access and correct the information we collect and store about you. Please contact us if you would like to access the information.

What happens with the results?
If you give us your permission by providing your consent in written form, online, or verbally, we plan to publish the results in a report and in peer reviewed journals. We may also present results at professional forums and conferences to inform better ways of working and providing services.

We will also give a report on the research to the South Eastern Sydney Local Health District Human Research Ethics Committee.
In any report, publication, or presentation, information will be provided in such a way that you or your family cannot be identified.

What should I do if I want to discuss this research further before I decide?
When you have read this information, the researcher interviewer/project officer will discuss it with you and answer any queries you may have. If you would like to know more at any stage, please do not hesitate to contact Tania Rimes, Principal Investigator on (02) 9382 8696 or email her at tania.rimes@health.nsw.gov.au. If you need an interpreter, you can contact Tania through the Translating and Interpreting Service (TIS) on 131 450.

Who should I contact if I have concerns about the conduct of this research?
This research has been approved by the South Eastern Sydney Local Health District Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this research should contact the Research Support Office which is nominated to receive complaints from research participants. You should contact them on 02 9382 3587, or email SESLHD-RSO@health.nsw.gov.au and quote HREC reference number: 2020/ETH03295.

The conduct of this research is at the [INSERT SITE NAMES]. Any person with concerns or complaints about the conduct of this research may also contact the [*details of the Research Governance Officer of the health district will be provided following SSA application*]

Thank you for taking the time to consider this research.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

Primary and Community Health Directorate

CONSENT FORM

***Family Care Connect* – a holistic first 2000 days model of care for women and families from migrant and refugee communities.**

1. I,.....
of.....
agree to take part in the research described in the participant information statement set out above and to have my data linked as outlined in the information sheet.

2. I have read the participant information statement, which explains why I have been asked to take part, the aims of the research and the possible risks of the research, and the statement has been explained to me to my satisfaction.

3. Before signing this consent form, I have been able to ask any questions relating to any possible physical and mental harm I might suffer as a result of taking part and I have received satisfactory answers.

4. I understand that I can withdraw from the research at any time without affecting my relationship with South Eastern Sydney Local Health District or service at the child and family hub.

5. I agree that research information collected from the results of the research may be published and presented, provided that I cannot be identified.

6. I understand that if I have any questions relating to my participation in this research, I may contact Tania Rimes on telephone (02) 9382 8696, who will be happy to answer them. I can call 131450 (TIS) for language support.

7. I have been given a copy of this Consent Form and the Participant Information Statement.

Complaints may be directed to the Research Support Office, South Eastern Sydney Local Health District, Prince of Wales Hospital, Randwick NSW 2031 Australia (phone 02-9382 3587, fax 02-9382 2813, email SESLHD-RSO@health.nsw.gov.au .

Signature of participant	**Please PRINT name**	**Date**
_____	_____	_____
Signature of witness	**Please PRINT name**	**Date**
_____	_____	_____

Signature of investigator	Please PRINT name	Date
_____	_____	_____

Investigator/officer taking consent to complete:

Check box if participant DOES NOT want their state-wide hospital data included as part of this research ☐

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet	17

		registered, name of intended registry	
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	#3	Date and version identifier	2
Funding	#4	Sources and types of financial, material, and other support	19
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	19
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	19
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	19
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the	19

		trial, if applicable (see Item 21a for data monitoring committee)	
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	4
Objectives	#7	Specific objectives or hypotheses	5-6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	7
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries	6

		where data will be collected. Reference to where list of study sites can be obtained	
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	5,8
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a There are no plans to discontinue or modify the interventions.
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	7
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg,	12-15

		change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	7
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	15
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	6-7
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce	7

		predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	8
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome,	12-15

		baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	15-16
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	16

Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	16
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	16
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	16
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	16-17
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	19

Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	16
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	19
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	6
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a No ancillary studies are planned for this data.
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	16
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	17

Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	16
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a This is a low-risk trial with minimal foreseen harms to participants.
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	17
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	17
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	17
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and	Supp. file

		authorised surrogates	
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a No biological specimens will be collected as part of this trial.

BMJ Open

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

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TITLE: 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 improve maternal wellbeing. 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: ACTRN12621001088831

ARTICLE SUMMARY

Strength and limitations

- First Australian multi-site non-randomised controlled trial to test the effectiveness of integrated health-social care hubs.
- The study is novel as it has an embedded implementation evaluation and economic evaluation in addition to the non-randomised trial component of the study.
- The non-randomised design of the trial has some limitations, particularly the inability to guarantee the comparability of the intervention and control groups.

EBACKGROUND 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 wellbeing, social competence, emotional maturity, language and cognitive skills, and communication skills and general knowledge. Children who are in the lowest 10 per cent of the national population are classified as developmentally 'vulnerable'.[1] Developmental vulnerability is associated with undetected maternal postnatal depression, the early cessation of breastfeeding[2], and parental unmet psychosocial needs (e.g., 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 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 programs, like

CFH checks.[2-4 15 32-36]

Australian policymakers identified service areas that need improvement to optimise outcomes in the first 2,000 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 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] Cross-cultural worker 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 (e.g., 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, breastfeeding and maternal wellbeing, 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, SESLHD, SWSLHD, and 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).

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 • 16 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

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 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 clinic 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 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 SPIRIT 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 geographic 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 geographic 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 (i.e. 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 postpartum. 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 to 4 weeks postpartum, 6 to 8 weeks postpartum, 6 months postpartum, and 12 months postpartum.

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 learining opportunitites, 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 geographic area will be allocated to a control cohort and receive routine care (e.g., 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]

Table 2: Proctor and colleagues (2011) implementation outcomes mapped to FDCC 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 & 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?

Logic Model

We developed a logic model to inform the FDCC implementation evaluation (**Error! Reference source not found.**). We used a modified version of existing logic model frameworks[50 51] to include the inner context (i.e., individual factors, organisational settings) and the outer context of each site (i.e., 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]

[INSERT FIGURE 1]

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

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)[56]	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[57] to assess Hub staff buy in to the model	Research survey administered by project officer	NoMAD tool completed by Hub staff	Trial end

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 upon 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.[58 59] A simple template will have major generic expenditure categories, including upfront capital costs (e.g., vehicles, buildings), governance arrangements to manage the Hubs (e.g., staff meeting time), material costs (e.g., brochures), and in-kind support from staff, including partner agencies. There might be 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 (e.g., salary, on-costs), in-kind costs (e.g., time costs from non-salaried staff), venue costs (e.g., utilities, even if in-kind), and material costs (e.g., 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.[58 59] 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 un-costed. Table 4 provides an overview of the planned outcomes and measurement for the implementation evaluation.

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

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 at each site or LHD; surveys administered by a researcher to mothers; and data linkage of participants with administrative datasets (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 to 4 weeks postpartum, 6-8 weeks postpartum, 6 months postpartum, and 12 months postpartum. For primary and secondary variables, see Table 5.

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 *(Secondary 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 Edinburgh Depression Scale (EPDS)[60] *(Secondary Outcome)*	Electronic medical record at LHD	Extraction of routine clinical data from electronic medical. • Edinburgh Depression Scale (EPDS) total score Response to item 10 of EDS	• 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[61] *(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)[62] *(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 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 breastfeeding /predominately breastfeeding/partially breastfeeding/ 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 breastfed • Predominately breastfed • Partial breastfed • 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 & 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 postpartum and 12-month postpartum. *(Secondary Outcome)*	Data linkage with NSW-wide Emergency Department Data Collection (EDDC)	NSW-wide EDDC data Linkage	At 6-month postpartum and 12-month postpartum.

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 (i.e., 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, Chi-square method for categorical outcomes, non-parametric method (e.g., Wilcoxon rank-sum test) and parametric methods (e.g., *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 (e.g., mother's sociodemographic characteristics, geographic area of residence) and community levels at baseline (e.g., neighbourhood socioeconomic factors). Generalised estimating equations method will be used in the regression analysis, considering the potential clustering effect by site. Only deidentified 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 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.[63] 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 (table 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 health utility (derived from the EQ5D) simulated using a decision tree, and where the threshold willingness to pay is varied between

$42,000-$67,000.[64] Third, a probability sensitivity analysis (PSA) and value of information analysis (VOI) 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.[65] Finally, a budget impact analysis (BIA) 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 routinly collected clinical data from electronic medical records for all participants, per Table 3. Data will be stored within a protected site-based server. Only deidentified 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 postpartum, and 12 months postpartum. 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. Upon completion of data extraction, CHeReL will transfer to UNSW

administrative data of the participants who consented to data linkage. The administrative records will be deidentified 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 electronic medical record (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 66] 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 South Eastern Sydney LHD (SESLHD) (2020/ETH03295). This trial was registered with the Australian New Zealand Clinical Trials (ACTRN12621001088831).

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 deidentified data will be transferred from each LHD to the UNSW researchers for data analysis. The deidentified data from each LHD to the UNSW team will be securely transferred through a 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 (e.g., 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/ren, the family, and the wider community. These obligations are detailed in the PISCF (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 program at scale. We intend to produce at least two papers (e.g. 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 WH&S 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 HREC. Figure 2 outlines our governance structure.

[INSERT FIGURE 2]

Author contributions

The original trial design was conceived by SW, TR, AW, RL, VE and HR. The implementation evaluation design was conceived by MH and RL. The economic evaluation design was conceived by KL. The statistical analysis methods were initially designed by NH. MH developed the intial draft of the protocol, which was refined by SW, TR, AW RL, VE, HR, KO, NH, KL, NS, AH, EM, SR, AMD, and AD. All authors approved, the final manuscript.

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Competing interests

The views expressed are those of the author(s) and not necessarily those of the funding partners. NSW Health has no direct role in study design; data collection, analysis, and interpretation, or writing of final reports, presentations, or publications.

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FIGURE 1: FDCC IMPLEMENTATION EVALUATION LOGIC MODEL

FIGURE 2: FDCC GOVERNANCE STRUCTURE

CONTEXT

OUTER CONTEXT

Local area factors/LHD

- Patient load
- Area socio-economic status
- Community health relationship with hospital
- Make up of community based agencies, public and private health services in area (Area mapping)

Policy and governance context

- Existing CAFH policy affecting practice
- First 2000 days
- NGO partners core business, funding bodies, governance board

INNER CONTEXT

NGO factors

- Partner buy in
- Diversity of partner services
- Alignment of partner services (Reciprocity between health & NGOs) Location
- Collaboration features (i.e. frequency of contact, regular meetings, services integrating in real time)
- Billing and funding

Early childhood health staff factors

- Organisational context Support of Hub intervention within practice
- Structure and delivery of hub model (times location, structure)
- Altered work flows
- Care navigation (dedicated role, clear pathways)
- Number of CFHN in Hub
- Involvement of allied health
- GP relationships (Bilingual, referrals, knowledge of CFH, Medicare eligible)

INTERVENTIONS

Physical location

- Services in the same building
- Soft entry through existing non-health, non-threatening service (i.e. playgroup)
- Accessible to migrant and refugee communities

Integration of services

- Referral pathways between services (supported/warm referral or proactive introduction)
- Communication between services
- Shared resources/ training/measurement
- Common agenda

Cultural sensitivity

- Culturally sensitive practices
- Training and resources

Key worker/ Navigator

- Point of contact between maternity and hub

THEORETICAL FRAMEWORK

Collective Impact

Collective impact is designed to create change on complex social issues, and draws on five conditions: common agenda, continuous communication, mutually reinforcing activities, backbone support and shared measurement.

MECHANISMS OF CHANGE

Behaviour change wheel constructs

- **Enablement** – Hub in a location that suits families, helping navigation to relevant services
- **Modelling** – Modelling health/NGO practices
- **Training** – Ensure staff have been trained in culturally sensitive practices. Shared language/ understanding of the model
- **Environment restructure –** Hub creating integrated care environment

INTERMEDIATE OUTCOMES

Service and community

- Increased knowledge and capacity of local services to provide culturally sensitive care and address health and social needs.

Child and Family

- 60% of mothers/families attending CFH service at Hubs
- Increased Breastfeeding rates
- Early identification of psychosocial concerns
- Social needs met by improved service access
- Child at healthy weight

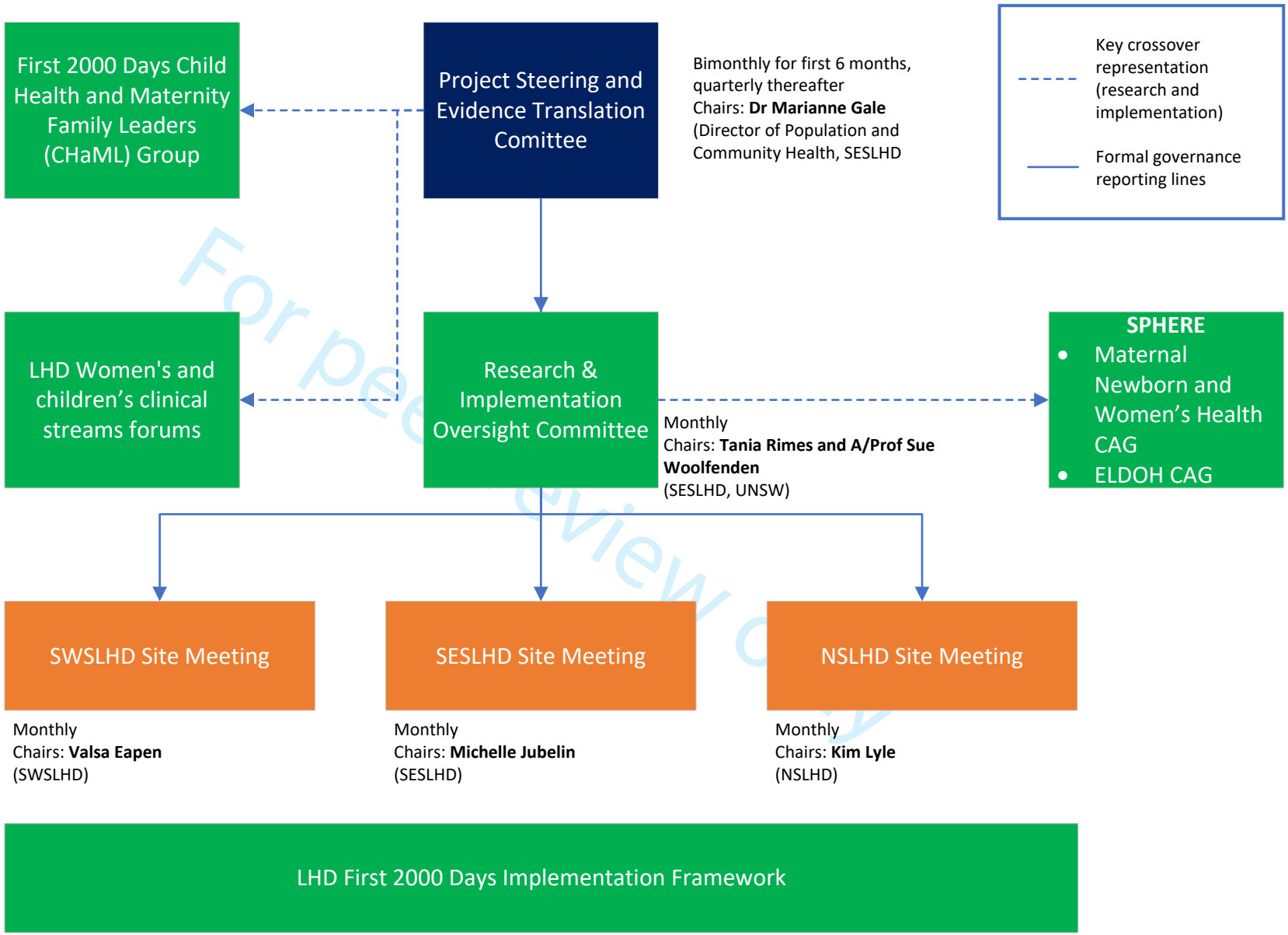
LONG-TERM OUTCOMES

System

- Earlier intervention for health and social need, reduced hospital visits (ED presentations)
- Cost-effective model of care for NSW Health
- Evidence that access is feasible, appropriate and acceptable
- Replicable, acceptable, appropriate and sustainable models of care - First 2000 Days Framework.

Child and Family

- Mothers/families will have optimal mental health and children will be school ready



APPENDICES

Appendix 1: Participant Information Sheet and Consent Form

Primary and Community Health Directorate

PARTICIPANT INFORMATION SHEET AND CONSENT FORM
Participant

***Family Care Connect* – a holistic first 2000 days model of care for women and families from migrant and refugee communities.**

Invitation

You are invited to take part in the Family Care Connect project. Family Care Connect involves child and family Hubs, where health and other agencies work together and you are supported to navigate these services. Our research is seeing whether these Hubs support the health and development of children, mothers and families from migrant and refugee communities.

Who is doing the research?

Tania Rimes
Children and Communities Program Coordinator
Primary and Community Health Directorate| South Eastern Sydney Local Health District (SESLHD).

Associate Professor Sue Woolfenden (Research lead)
NHMRC Senior Research Fellow, Population Child Health Group | The University of New South Wales (UNSW). Senior Staff Specialist, Community Child Health | Sydney Children's Hospitals Network.

Before you decide if you want to take part in this research, we would like to explain what we are doing and why we are doing it. . Please take the time to read the following information carefully. You can talk about it with a relative or a friend if you wish before deciding.

What is the purpose of this research?

We want to see if child and family Hubs help women and families from migrant and refugee communities move from pregnancy to Child and Family Health services. Also, we want to see if these Hubs support children's health and development in the first 12 months of life.

We will also look at how easy and cost-effective the Hub is for you and other women and families.

Why have I been invited to participate in this research?

You are eligible to participate in this research because you:

- are having your baby or recently given birth to your baby at [INSERT HOSPITAL SITES]
- live in the postcode of [INSERT POSTCODE/S]

- are at least 20 weeks pregnant, OR have recently given birth to your baby and have not been discharged home from postnatal ward
- are a newly arrived migrant (within the last 10 years) from a non-English speaking background; or a refugee (living in Australia for less than 10 years) from a non-English speaking background
- are 16 years of age or older.

If I say yes, what will it involve?

If you decide to take part in the research and live in [INSERT SITE AREA] you will be in the **'FDCC Group'**. You will receive information about the child and family services in your area you can access after the birth of your baby. This information is given to all women, regardless of whether or not they participate in the study.
If you take part in the **"FDCC Group",** you will also be contacted by a worker from the local child and family Hub who will give you more information on the services offered and assist you with accessing these services if you choose.

If you agree to take part, we will ask you to sign the Participant Information and Consent form below; OR sign the online consent found here [INSERT ONLINE CONSENT URL]; OR provide verbal consent over the telephone to the contact person for the research.

After you provide consent to take part in this research, we will ask you to:

- Complete a survey about you, your family, your support needs, and your wellbeing. This will take about 30 minutes. You can choose to do it online, by paper, over the phone, or in-person. ***We can provide an interpreter to assist.***
- Complete another survey when your baby is 6 months and 12 months old. This will ask questions about you, what your needs are, and what services you have used. ***We can provide an interpreter to assist.***
- We will also collect data from your local and state-wide hospital/s about you and your baby. This reduces the number of questions we need to ask you.

The data we collect from local hospitals includes:

- Information about you and your child such as country of birth, date of birth, gender, language spoken at home
- Information from routine questions asked to all women when they come to hospital about their health and wellbeing and their child's
- Information about the services you or your child has seen, for example the child and family health nurse.

The data we collect from state-wide hospitals includes:

- Information that is collected on all new mothers and babies in NSW
- Emergency Department presentations for you and your baby

If you don't want us to collect data about you and your baby from state-wide hospitals, then we won't. Please let us know by checking the box.

I DO NOT want my state-wide hospital data included as part of this research ☐

If you only provide verbal consent, we will not collect data about you and your baby from state-wide hospitals.
As part of this research, we may also invite you to be interviewed. We will contact you at another time to discuss this process before the research is complete.

Any information we collect that can identify you or your child will remain confidential.

The total time you are involved with this project will be for 12 to 18 months, but you can choose to withdraw at any time.

What if I don't want to take part in this research, or if I want to withdraw later?
It is completely up to you whether or not you decide to take part. Saying yes or no will not affect your relationship with the care you receive, the services you access, or your visa status now or in the future.

If you wish to leave the research once it has started, you can do so verbally or in writing at any time without giving a reason. However, it may not be possible to withdraw your data from the research results once we have collected it and removed your identifying details. This is due to be done from March 2023.

How is this research being paid for?
The research is being paid for by NSW Health as part of the Translational Research Grant Scheme. More information about this scheme can be found here: https://www.medicalresearch.nsw.gov.au/translational-research-grants-scheme/

Are there risks to me in taking part in this research?
There is very little risk to you, however if you become upset or distressed because of taking part in the research, the research team will arrange for counselling or other help. Any counselling or help will be provided by qualified staff who are not members of the research team. This will be provided free of charge.

Another risk in taking part in this research is the risk to your privacy as part of collecting data about you, your child, and your family. While this is a risk, we will take all the steps to ensure your information remains private and confidential. We do not collect you or your baby's name, or anything else that could identify you or your family. Instead, your name will be replaced with a number. Only people involved with this research will be able to tell that the information is about you.

What happens if I suffer injury or complications as a result of the research?
It is very unlikely that you will suffer any injury as we are only asking you to complete questionnaires. However, if you require treatment or suffer loss as a result of the wrongdoing of any of the parties involved in the research, you can seek compensation. The cost of your treatment must be paid by the compensation you receive.

Will I benefit from the research?
This research aims to determine how best to provide child health services for families and to improve how parents in the future access child and family health services, however it may or may not directly benefit you or your baby.

Will taking part in this research cost me anything, and will I be paid?
Taking part in this research will not cost you anything, nor will you be paid.

How will my confidentiality be protected?
Any information that is collected about you as part of this research will remain private and confidential and will be discussed only with your permission, except as required by law. This means the research team are Mandatory Reporters and may need to speak with NSW Department of Communities and Justice if they are told or are concerned that a child is being hurt or is at risk of being hurt e.g. if there is abuse or violence in the home.

If such a situation happens, we would discuss this with you in private and arrange for you to speak with another professional if required.

Only the researchers named above will have access to your details. All information will be stored on a secure drive within [INSERT LHD SITES] and UNSW. We will keep the information for 5 years after the research ends. After this time, it will be destroyed.

In line with Australian, New South Wales, and other relevant laws, you have the right to access and correct the information we collect and store about you. Please contact us if you would like to access the information.

What happens with the results?
If you give us your permission by providing your consent in written form, online, or verbally, we plan to publish the results in a report and in peer reviewed journals. We may also present results at professional forums and conferences to inform better ways of working and providing services.

We will also give a report on the research to the South Eastern Sydney Local Health District Human Research Ethics Committee.
In any report, publication, or presentation, information will be provided in such a way that you or your family cannot be identified.

What should I do if I want to discuss this research further before I decide?
When you have read this information, the researcher interviewer/project officer will discuss it with you and answer any queries you may have. If you would like to know more at any stage, please do not hesitate to contact Tania Rimes, Principal Investigator on (02) 9382 8696 or email her at tania.rimes@health.nsw.gov.au. If you need an interpreter, you can contact Tania through the Translating and Interpreting Service (TIS) on 131 450.

Who should I contact if I have concerns about the conduct of this research?
This research has been approved by the South Eastern Sydney Local Health District Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this research should contact the Research Support Office which is nominated to receive complaints from research participants. You should contact them on 02 9382 3587, or email SESLHD-RSO@health.nsw.gov.au and quote HREC reference number: 2020/ETH03295.

The conduct of this research is at the [INSERT SITE NAMES]. Any person with concerns or complaints about the conduct of this research may also contact the [*details of the Research Governance Officer of the health district will be provided following SSA application*]

Thank you for taking the time to consider this research.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

Primary and Community Health Directorate

CONSENT FORM

***Family Care Connect* – a holistic first 2000 days model of care for women and families from migrant and refugee communities.**

1. I,.....
of.....
agree to take part in the research described in the participant information statement set out above and to have my data linked as outlined in the information sheet.

2. I have read the participant information statement, which explains why I have been asked to take part, the aims of the research and the possible risks of the research, and the statement has been explained to me to my satisfaction.

3. Before signing this consent form, I have been able to ask any questions relating to any possible physical and mental harm I might suffer as a result of taking part and I have received satisfactory answers.

4. I understand that I can withdraw from the research at any time without affecting my relationship with South Eastern Sydney Local Health District or service at the child and family hub.

5. I agree that research information collected from the results of the research may be published and presented, provided that I cannot be identified.

6. I understand that if I have any questions relating to my participation in this research, I may contact Tania Rimes on telephone (02) 9382 8696, who will be happy to answer them. I can call 131450 (TIS) for language support.

7. I have been given a copy of this Consent Form and the Participant Information Statement.

Complaints may be directed to the Research Support Office, South Eastern Sydney Local Health District, Prince of Wales Hospital, Randwick NSW 2031 Australia (phone 02-9382 3587, fax 02-9382 2813, email SESLHD-RSO@health.nsw.gov.au .

Signature of participant	**Please PRINT name**	**Date**
_____	_____	_____
Signature of witness	**Please PRINT name**	**Date**
_____	_____	_____

Signature of investigator	Please PRINT name	Date
_____	_____	_____

Investigator/officer taking consent to complete:

Check box if participant DOES NOT want their state-wide hospital data included as part of this research ☐

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet	17

		registered, name of intended registry	
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	#3	Date and version identifier	2
Funding	#4	Sources and types of financial, material, and other support	19
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	19
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	19
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	19
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the	19

		trial, if applicable (see Item 21a for data monitoring committee)	
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	4
Objectives	#7	Specific objectives or hypotheses	5-6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	7
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries	6

		where data will be collected. Reference to where list of study sites can be obtained	
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	5,8
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a There are no plans to discontinue or modify the interventions.
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	7
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg,	12-15

		change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	7
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	15
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	6-7
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce	7

		predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	8
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome,	12-15

		baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	15-16
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	16

Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	16
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	16
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	16
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	16-17
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	19

Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	16
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	19
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	6
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a No ancillary studies are planned for this data.
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	16
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	17

Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	16
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a This is a low-risk trial with minimal foreseen harms to participants.
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	17
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	17
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	17
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and	Supp. file

		authorised surrogates	
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a No biological specimens will be collected as part of this trial.

BMJ Open

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

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

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On behalf of the FDCC Collaborative Group

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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 improve maternal wellbeing. 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: ACTRN12621001088831

ARTICLE SUMMARY

Strength and limitations

- 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 wellbeing, social competence, emotional maturity, language and cognitive skills, and communication skills and general knowledge. Children who are in the lowest 10 per cent of the national population are classified as developmentally 'vulnerable'.[1] Developmental vulnerability is associated with undetected maternal postnatal depression, the early cessation of breastfeeding[2], and parental unmet psychosocial needs (e.g., 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 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 programs, like CFH checks.[2-4 15 32-36]

Australian policymakers identified service areas that need improvement to optimise outcomes in the first 2,000 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 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] Cross-cultural worker 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 (e.g., 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, breastfeeding and maternal wellbeing, 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, SESLHD, SWSLHD, and 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).

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 • 16 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

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 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 clinic 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 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 SPIRIT 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 geographic 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 geographic 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 (i.e. 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 postpartum. 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 to 4 weeks postpartum, 6 to 8 weeks postpartum, 6 months postpartum, and 12 months postpartum.

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 learining opportunitites, 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 geographic area will be allocated to a control cohort and receive routine care (e.g., 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]

Table 2: Proctor and colleagues (2011) implementation outcomes mapped to FDCC 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 & 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?

Logic Model

We developed a logic model to inform the FDCC implementation evaluation (**Error! Reference source not found.**). We used a modified version of existing logic model frameworks[50 51] to include the inner context (i.e., individual factors, organisational settings) and the outer context of each site (i.e., 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]

[INSERT FIGURE 1]

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

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)[56]	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[57] to assess Hub staff buy in to the model	Research survey administered by project officer	NoMAD tool completed by Hub staff	Trial end

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 upon 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.[58 59] A simple template will have major generic expenditure categories, including upfront capital costs (e.g., vehicles, buildings), governance arrangements to manage the Hubs (e.g., staff meeting time), material costs (e.g., brochures), and in-kind support from staff, including partner agencies. There

might be 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 (e.g., salary, on-costs), in-kind costs (e.g., time costs from non-salaried staff), venue costs (e.g., utilities, even if in-kind), and material costs (e.g., 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.[58 59] 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 un-costed. Table 4 provides an overview of the planned outcomes and measurement for the implementation evaluation.

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

Primary and Secondary Outcome Measures

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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 at each site or LHD; surveys administered by a researcher to mothers; and data linkage of participants with administrative datasets (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 to 4 weeks postpartum, 6-8 weeks postpartum, 6 months postpartum, and 12 months postpartum. For primary and secondary variables, see Table 5.

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 Edinburgh Depression Scale (EPDS)[60] *(Secondary Outcome)*	Electronic medical record at LHD	Extraction of routine clinical data from electronic medical. • Edinburgh Depression Scale (EPDS) total score Response to item 10 of EDS	• 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[61] *(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)[62] *(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 breastfeeding /predominately breastfeeding/partially breastfeeding/ 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 breastfed • Predominately breastfed • Partial breastfed • 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 & 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 postpartum and 12-month postpartum. *(Secondary Outcome)*	Data linkage with NSW-wide Emergency Department Data Collection (EDDC)	NSW-wide EDDC data Linkage	At 6-month postpartum and 12-month postpartum.

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 (i.e., 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, Chi-square method for categorical outcomes, non-parametric method (e.g., Wilcoxon rank-sum test) and parametric methods (e.g., *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 (e.g., mother's sociodemographic characteristics, geographic area of residence) and community levels at baseline (e.g., neighbourhood socioeconomic factors). Generalised estimating equations method will be used in the regression analysis, considering the potential clustering effect by site. Only deidentified 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 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.[63]

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 (table 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 (QALYs) (with health utilities derived from the EQ5D)[64] simulated using a decision tree, and where the threshold willingness to pay is varied between $42,000-$67,000.[65] Third, a probability sensitivity analysis (PSA) will be undertaken and, where there is statistical uncertainty regarding cost effectiveness, a value of information analysis (VOI) 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.[66] Finally, a budget impact analysis (BIA) will be undertaken where there are positive and attributable impacts regarding primary and/or secondary outcomes (captured in the CCA). 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 deidentified 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 postpartum, and 12 months postpartum. 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. Upon completion of data extraction, CHeReL will transfer to UNSW administrative data of the participants who consented to data linkage. The administrative records will be deidentified 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 electronic medical record (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 67] 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 South Eastern Sydney LHD (SESLHD) (2020/ETH03295). This trial was registered with the Australian New Zealand Clinical Trials (ACTRN12621001088831).[19]

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 deidentified data will be transferred from each LHD to the UNSW researchers for data analysis. The deidentified data from each LHD to the UNSW team will be securely transferred through a 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 (e.g., 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/ren, the family, and the wider community. These obligations are detailed in the PISCF (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 program at scale. We intend to produce at least two papers (e.g. 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 WH&S 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 HREC. Figure 2 outlines our governance structure.

[INSERT FIGURE 2]

Author contributions

The original trial design was conceived by SW, TR, AW, RL, VE and HR. The implementation evaluation design was conceived by MH and RL. The economic evaluation design was conceived by KL. The statistical analysis methods were initially designed by NH. MH developed the intial draft of the protocol, which was refined by SW, TR, AW RL, VE, HR, KO, NH, KL, NS, AH, EM, SR, AMD, and AD. All authors approved, the final manuscript.

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Competing interests

The views expressed are those of the author(s) and not necessarily those of the funding partners. NSW Health has no direct role in study design; data collection, analysis, and interpretation, or writing of final reports, presentations, or publications.

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FIGURE 1: FDCC IMPLEMENTATION EVALUATION LOGIC MODEL

FIGURE 2: FDCC GOVERNANCE STRUCTURE

CONTEXT

OUTER CONTEXT

Local area factors/LHD

- Patient load
- Area socio-economic status
- Community health relationship with hospital
- Make up of community based agencies, public and private health services in area (Area mapping)

Policy and governance context

- Existing CAFH policy affecting practice
- First 2000 days
- NGO partners core business, funding bodies, governance board

INNER CONTEXT

NGO factors

- Partner buy in
- Diversity of partner services
- Alignment of partner services (Reciprocity between health & NGOs) Location
- Collaboration features (i.e. frequency of contact, regular meetings, services integrating in real time)
- Billing and funding

Early childhood health staff factors

- Organisational context Support of Hub intervention within practice
- Structure and delivery of hub model (times location, structure)
- Altered work flows
- Care navigation (dedicated role, clear pathways)
- Number of CFHN in Hub
- Involvement of allied health
- GP relationships (Bilingual, referrals, knowledge of CFH, Medicare eligible)

INTERVENTIONS

Physical location

- Services in the same building
- Soft entry through existing non-health, non-threatening service (i.e. playgroup)
- Accessible to migrant and refugee communities

Integration of services

- Referral pathways between services (supported/warm referral or proactive introduction)
- Communication between services
- Shared resources/ training/measurement
- Common agenda

Cultural sensitivity

- Culturally sensitive practices
- Training and resources

Key worker/ Navigator

- Point of contact between maternity and hub

THEORETICAL FRAMEWORK

Collective Impact

Collective impact is designed to create change on complex social issues, and draws on five conditions: common agenda, continuous communication, mutually reinforcing activities, backbone support and shared measurement.

MECHANISMS OF CHANGE

Behaviour change wheel constructs

- **Enablement** – Hub in a location that suits families, helping navigation to relevant services
- **Modelling** – Modelling health/NGO practices
- **Training** – Ensure staff have been trained in culturally sensitive practices. Shared language/ understanding of the model
- **Environment restructure –** Hub creating integrated care environment

INTERMEDIATE OUTCOMES

Service and community

- Increased knowledge and capacity of local services to provide culturally sensitive care and address health and social needs.

Child and Family

- 60% of mothers/families attending CFH service at Hubs
- Increased Breastfeeding rates
- Early identification of psychosocial concerns
- Social needs met by improved service access
- Child at healthy weight

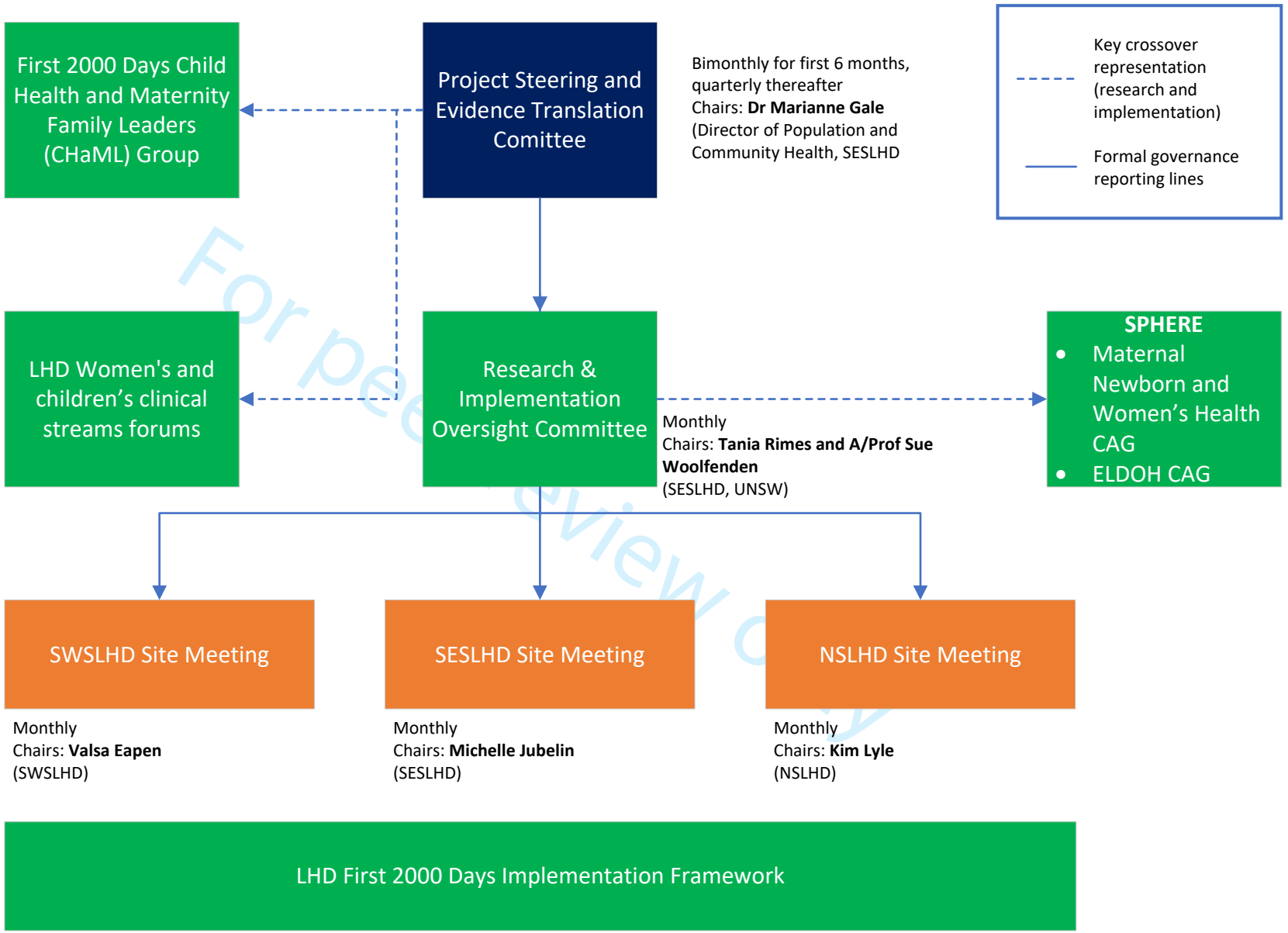
LONG-TERM OUTCOMES

System

- Earlier intervention for health and social need, reduced hospital visits (ED presentations)
- Cost-effective model of care for NSW Health
- Evidence that access is feasible, appropriate and acceptable
- Replicable, acceptable, appropriate and sustainable models of care - First 2000 Days Framework.

Child and Family

- Mothers/families will have optimal mental health and children will be school ready



APPENDICES

Appendix 1: Participant Information Sheet and Consent Form

Primary and Community Health Directorate

PARTICIPANT INFORMATION SHEET AND CONSENT FORM
Participant

***Family Care Connect* – a holistic first 2000 days model of care for women and families from migrant and refugee communities.**

Invitation

You are invited to take part in the Family Care Connect project. Family Care Connect involves child and family Hubs, where health and other agencies work together and you are supported to navigate these services. Our research is seeing whether these Hubs support the health and development of children, mothers and families from migrant and refugee communities.

Who is doing the research?

Tania Rimes
Children and Communities Program Coordinator
Primary and Community Health Directorate| South Eastern Sydney Local Health District (SESLHD).

Associate Professor Sue Woolfenden (Research lead)
NHMRC Senior Research Fellow, Population Child Health Group | The University of New South Wales (UNSW). Senior Staff Specialist, Community Child Health | Sydney Children's Hospitals Network.

Before you decide if you want to take part in this research, we would like to explain what we are doing and why we are doing it. . Please take the time to read the following information carefully. You can talk about it with a relative or a friend if you wish before deciding.

What is the purpose of this research?

We want to see if child and family Hubs help women and families from migrant and refugee communities move from pregnancy to Child and Family Health services. Also, we want to see if these Hubs support children's health and development in the first 12 months of life.

We will also look at how easy and cost-effective the Hub is for you and other women and families.

Why have I been invited to participate in this research?

You are eligible to participate in this research because you:

- are having your baby or recently given birth to your baby at [INSERT HOSPITAL SITES]
- live in the postcode of [INSERT POSTCODE/S]

- are at least 20 weeks pregnant, OR have recently given birth to your baby and have not been discharged home from postnatal ward
- are a newly arrived migrant (within the last 10 years) from a non-English speaking background; or a refugee (living in Australia for less than 10 years) from a non-English speaking background
- are 16 years of age or older.

If I say yes, what will it involve?

If you decide to take part in the research and live in [INSERT SITE AREA] you will be in the **'FDCC Group'**. You will receive information about the child and family services in your area you can access after the birth of your baby. This information is given to all women, regardless of whether or not they participate in the study.
If you take part in the **"FDCC Group",** you will also be contacted by a worker from the local child and family Hub who will give you more information on the services offered and assist you with accessing these services if you choose.

If you agree to take part, we will ask you to sign the Participant Information and Consent form below; OR sign the online consent found here [INSERT ONLINE CONSENT URL]; OR provide verbal consent over the telephone to the contact person for the research.

After you provide consent to take part in this research, we will ask you to:

- Complete a survey about you, your family, your support needs, and your wellbeing. This will take about 30 minutes. You can choose to do it online, by paper, over the phone, or in-person. ***We can provide an interpreter to assist.***
- Complete another survey when your baby is 6 months and 12 months old. This will ask questions about you, what your needs are, and what services you have used. ***We can provide an interpreter to assist.***
- We will also collect data from your local and state-wide hospital/s about you and your baby. This reduces the number of questions we need to ask you.

The data we collect from local hospitals includes:

- Information about you and your child such as country of birth, date of birth, gender, language spoken at home
- Information from routine questions asked to all women when they come to hospital about their health and wellbeing and their child's
- Information about the services you or your child has seen, for example the child and family health nurse.

The data we collect from state-wide hospitals includes:

- Information that is collected on all new mothers and babies in NSW
- Emergency Department presentations for you and your baby

If you don't want us to collect data about you and your baby from state-wide hospitals, then we won't. Please let us know by checking the box.

I DO NOT want my state-wide hospital data included as part of this research ☐

If you only provide verbal consent, we will not collect data about you and your baby from state-wide hospitals.
As part of this research, we may also invite you to be interviewed. We will contact you at another time to discuss this process before the research is complete.

Any information we collect that can identify you or your child will remain confidential.

The total time you are involved with this project will be for 12 to 18 months, but you can choose to withdraw at any time.

What if I don't want to take part in this research, or if I want to withdraw later?
It is completely up to you whether or not you decide to take part. Saying yes or no will not affect your relationship with the care you receive, the services you access, or your visa status now or in the future.

If you wish to leave the research once it has started, you can do so verbally or in writing at any time without giving a reason. However, it may not be possible to withdraw your data from the research results once we have collected it and removed your identifying details. This is due to be done from March 2023.

How is this research being paid for?
The research is being paid for by NSW Health as part of the Translational Research Grant Scheme. More information about this scheme can be found here: https://www.medicalresearch.nsw.gov.au/translational-research-grants-scheme/

Are there risks to me in taking part in this research?
There is very little risk to you, however if you become upset or distressed because of taking part in the research, the research team will arrange for counselling or other help. Any counselling or help will be provided by qualified staff who are not members of the research team. This will be provided free of charge.

Another risk in taking part in this research is the risk to your privacy as part of collecting data about you, your child, and your family. While this is a risk, we will take all the steps to ensure your information remains private and confidential. We do not collect you or your baby's name, or anything else that could identify you or your family. Instead, your name will be replaced with a number. Only people involved with this research will be able to tell that the information is about you.

What happens if I suffer injury or complications as a result of the research?
It is very unlikely that you will suffer any injury as we are only asking you to complete questionnaires. However, if you require treatment or suffer loss as a result of the wrongdoing of any of the parties involved in the research, you can seek compensation. The cost of your treatment must be paid by the compensation you receive.

Will I benefit from the research?
This research aims to determine how best to provide child health services for families and to improve how parents in the future access child and family health services, however it may or may not directly benefit you or your baby.

Will taking part in this research cost me anything, and will I be paid?
Taking part in this research will not cost you anything, nor will you be paid.

How will my confidentiality be protected?
Any information that is collected about you as part of this research will remain private and confidential and will be discussed only with your permission, except as required by law. This means the research team are Mandatory Reporters and may need to speak with NSW Department of Communities and Justice if they are told or are concerned that a child is being hurt or is at risk of being hurt e.g. if there is abuse or violence in the home.

If such a situation happens, we would discuss this with you in private and arrange for you to speak with another professional if required.

Only the researchers named above will have access to your details. All information will be stored on a secure drive within [INSERT LHD SITES] and UNSW. We will keep the information for 5 years after the research ends. After this time, it will be destroyed.

In line with Australian, New South Wales, and other relevant laws, you have the right to access and correct the information we collect and store about you. Please contact us if you would like to access the information.

What happens with the results?
If you give us your permission by providing your consent in written form, online, or verbally, we plan to publish the results in a report and in peer reviewed journals. We may also present results at professional forums and conferences to inform better ways of working and providing services.

We will also give a report on the research to the South Eastern Sydney Local Health District Human Research Ethics Committee.
In any report, publication, or presentation, information will be provided in such a way that you or your family cannot be identified.

What should I do if I want to discuss this research further before I decide?
When you have read this information, the researcher interviewer/project officer will discuss it with you and answer any queries you may have. If you would like to know more at any stage, please do not hesitate to contact Tania Rimes, Principal Investigator on (02) 9382 8696 or email her at tania.rimes@health.nsw.gov.au. If you need an interpreter, you can contact Tania through the Translating and Interpreting Service (TIS) on 131 450.

Who should I contact if I have concerns about the conduct of this research?
This research has been approved by the South Eastern Sydney Local Health District Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this research should contact the Research Support Office which is nominated to receive complaints from research participants. You should contact them on 02 9382 3587, or email SESLHD-RSO@health.nsw.gov.au and quote HREC reference number: 2020/ETH03295.

The conduct of this research is at the [INSERT SITE NAMES]. Any person with concerns or complaints about the conduct of this research may also contact the [*details of the Research Governance Officer of the health district will be provided following SSA application*]

Thank you for taking the time to consider this research.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

Primary and Community Health Directorate

CONSENT FORM

***Family Care Connect* – a holistic first 2000 days model of care for women and families from migrant and refugee communities.**

1. I,.....
of.....
agree to take part in the research described in the participant information statement set out above and to have my data linked as outlined in the information sheet.

2. I have read the participant information statement, which explains why I have been asked to take part, the aims of the research and the possible risks of the research, and the statement has been explained to me to my satisfaction.

3. Before signing this consent form, I have been able to ask any questions relating to any possible physical and mental harm I might suffer as a result of taking part and I have received satisfactory answers.

4. I understand that I can withdraw from the research at any time without affecting my relationship with South Eastern Sydney Local Health District or service at the child and family hub.

5. I agree that research information collected from the results of the research may be published and presented, provided that I cannot be identified.

6. I understand that if I have any questions relating to my participation in this research, I may contact Tania Rimes on telephone (02) 9382 8696, who will be happy to answer them. I can call 131450 (TIS) for language support.

7. I have been given a copy of this Consent Form and the Participant Information Statement.

Complaints may be directed to the Research Support Office, South Eastern Sydney Local Health District, Prince of Wales Hospital, Randwick NSW 2031 Australia (phone 02-9382 3587, fax 02-9382 2813, email SESLHD-RSO@health.nsw.gov.au .

Signature of participant	**Please PRINT name**	**Date**
_____	_____	_____
Signature of witness	**Please PRINT name**	**Date**
_____	_____	_____

Signature of investigator	Please PRINT name	Date
_____	_____	_____

Investigator/officer taking consent to complete:

Check box if participant DOES NOT want their state-wide hospital data included as part of this research ☐

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet	17

		registered, name of intended registry	
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	#3	Date and version identifier	2
Funding	#4	Sources and types of financial, material, and other support	19
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	19
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	19
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	19
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the	19

		trial, if applicable (see Item 21a for data monitoring committee)	
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	4
Objectives	#7	Specific objectives or hypotheses	5-6
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	7
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries	6

		where data will be collected. Reference to where list of study sites can be obtained	
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	5,8
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a There are no plans to discontinue or modify the interventions.
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	7
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg,	12-15

		change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	7
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	15
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	6-7
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce	7

		predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	7
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	8
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome,	12-15

		baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	15-16
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	16

Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	16
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	16
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	16
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	16-17
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	19

Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	16
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	19
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	6
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a No ancillary studies are planned for this data.
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	16
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	17

Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	16
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a This is a low-risk trial with minimal foreseen harms to participants.
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	17
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	17
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	17
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and	Supp. file

		authorised surrogates	
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a No biological specimens will be collected as part of this trial.