Open access Protocol

BMJ Open

Strengthening Care for Children (SC4C): protocol for a stepped wedge cluster randomised controlled trial of an integrated general practitioner-paediatrician model of primary care

Sonia Khano,[1] Lena Sanci,[2] Susan Woolfenden,[3,4] Yvonne Zurynski ,[5] Kim Dalziel,[6] Siaw-Teng Liaw ,[7] Douglas Boyle,[8] Gary L Freed,[9] Cecilia Moore,[10] Michael Hodgins ,[11] Jane Le,[1] Tammy Meyers Morris,[11] Stephanie Germano,[12] Karen Wheeler,[13] Raghu Lingam,[11,14] Harriet Hiscock [1,15]

To cite: Khano S, Sanci L, Woolfenden S, *et al*. Strengthening Care for Children (SC4C): protocol for a stepped wedge cluster randomised controlled trial of an integrated general practitioner-paediatrician model of primary care. *BMJ Open* 2022;**12**:e063449. doi:10.1136/bmjopen-2022-063449

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2022-063449).

Received 01 April 2022
Accepted 11 August 2022

For numbered affiliations see end of article.

Correspondence to
Dr Harriet Hiscock;
harriet.hiscock@rch.org.au

ABSTRACT

Introduction Australia's current healthcare system for children is neither sustainable nor equitable. As children (0–4 years) comprise the largest proportion of all primary care-type emergency department presentations, general practitioners (GPs) report feeling undervalued as an integral member of a child's care, and lacking in opportunities for support and training in paediatric conditions. This Strengthening Care for Children (SC4C) randomised trial aims to evaluate a novel, integrated GP-paediatrician model of care, that, if effective, will improve GP quality of care, reduce burden to hospital services and ensure children receive the right care, at the right time, closer to home.

Methods and analysis SC4C is a stepped wedge cluster randomised controlled trial (RCT) of 22 general practice clinics in Victoria and New South Wales, Australia. General practice clinics will provide control period data before being exposed to the 12-month intervention which will be rolled out sequentially each month (one clinic per state) until all 22 clinics receive the intervention. The intervention comprises weekly GP-paediatrician co-consultation sessions; monthly case discussions; and phone and email paediatrician support, focusing on common paediatric conditions. The primary outcome of the trial is to assess the impact of the intervention as measured by the proportion of children's (0–<18 years) GP appointments that result in a hospital referral, compared with the control period. Secondary outcomes include GP quality of care; GP experience and confidence in providing paediatric care; family trust in and preference for GP care; and the sustainability of the intervention. An implementation evaluation will assess the model to inform acceptability, adaptability, scalability and sustainability, while a health economic evaluation will measure the cost-effectiveness of the intervention.

Ethics and dissemination Human research ethics committee (HREC) approval was granted by The Royal Children's Hospital Ethics Committee in August 2020 (Project ID: 65955) and site-specific HRECs. The investigators (including Primary Health Network partners) will communicate trial results to stakeholders and participating GPs and general practice clinics via presentations and publications.

Trial registration number Australia New Zealand Clinical Trials Registry 12620001299998.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ First multisite stepped wedge cluster randomised controlled trial to test the effectiveness of a general practitioner (GP)-paediatrician integrated model of care.
⇒ The model could be an exemplar for scaling up nationally and adapting to other paediatric populations and primary care settings.
⇒ The stepped wedge design is susceptible to trends over calendar time (which we will control for in the analysis), and the delay in the implementation of the model in some clusters (practice clinics) may decrease motivation for participation and subsequently increase withdrawal.
⇒ There is potential selection bias of GPs as they may consent knowing when the practice clinic is allocated to receive the intervention model.
⇒ The impact of COVID-19 restrictions and lockdowns, and vaccination programmes in practice clinics may affect practice recruitment and engagement in the intervention model, particularly face-to-face components.

INTRODUCTION

In the last 20 years, Australia's paediatric population (0–17 years) has grown rapidly.[1] Yet, crucially, children represent a diminishing proportion of primary care visits[2] but comprise the largest proportion of low urgency emergency department (ED) presentations, easily outnumbering adults of all ages.[3] In Victoria, children aged 0–4 years

make up 40% of *all* ED attendances, with 90% being low urgency presentations that met criteria for primary care-type conditions.[4 5] While low urgency does not equate with low severity or complexity,[6] there is some evidence that 74% of such presentations could be appropriately managed in primary care.[5] The burden of disease has also been changing for children. There are more children with chronic conditions, including neurodevelopmental and mental health issues, in Australia[7 8] and in other high-income countries.[9] The proportion of children presenting with these conditions has also been increasing in general practice.[10 11] In the face of these compounding factors, general practitioners (GPs) in training currently perceive they lack the skills to manage these paediatric concerns.[12 13]

The current healthcare system is also failing to deliver quality care for children and young people. A study on quality of GP care for Australian children, based on guideline-concordant management of 17 common conditions, found that only 60% of all care for children and young people was adherent to best practice guidelines.[14] Conditions included non-communicable conditions (eg, asthma), mental health (eg, attention deficit hyperactivity disorder), acute infection (eg, tonsillitis) and injury (eg, head injury). GPs being less adherent to guidelines resulted in both overuse of care, for example, prescribing of antibiotics for tonsillitis, and underuse of care, for example, inadequate assessment of dehydration in gastroenteritis, compared with hospital care.[15]

In addition to the growing demand on, and risk to, hospital services, recent research highlights how GPs can feel 'out of the loop' in terms of a lack of communication from hospitals around children's care plans and discharge summaries.[16] GPs also report feeling undervalued as an integral member of a child's care team, and report limited opportunities for support and training for paediatric conditions. In turn, hospital staff report difficulties engaging GPs and significant variation in how GPs manage common child health conditions.[17] Although some GPs report parental influence as a frequent driver of referrals to paediatricians,[18] parents attending paediatric outpatient (OP) clinics report that they would prefer to return to their GP for follow-up care where safe to do so.[19]

Addressing these issues requires innovative, integrated models, supported by robust measurement of quality, acceptability, accessibility, appropriateness, sustainability and cost. A 2003 Cochrane systematic review of specialist outreach clinics in primary care and rural hospitals found that colocation of specialists with primary care improved access to specialist care but not necessarily health outcomes.[20] However, integrated services involving collaboration between primary care and specialist services improved access and quality of care and health outcomes.[20] A subsequent systematic review and meta-analysis showed a significant impact of integrated models of care on improved health-related quality of life in children with chronic illness, with weak evidence of a decrease in ED attendance, potentially due to inadequate power.[21]

Two of the four studies in this review identified a decrease in overall hospital delivered care in the integrated model and two showed no change. Common features of models that reduced referrals to hospitals included peer-to-peer training, outreach provision by specialists and feedback on best practice to providers. Similarly, a rapid review of paediatric models of care found that outreach models that provide planned care and up-skilling for local health professionals resulted in fewer hospital attendances and decreased costs compared with standard care.[22] However, these paediatric models have not been evaluated in controlled trials, and almost all were implemented in single sites without robust evaluation of implementation processes or outcomes, limiting generalisability and scalability.

The UK, facing similar issues of overburdened hospital paediatric services that are disconnected from primary care, developed and implemented an integrated GP-paediatrician programme (*Connecting Children for Care*)[23] aiming to upskill GPs in paediatric care and reduce unnecessary referrals to hospital services. Within 12 months of implementation of the model, the programme reduced GP referrals to outpatient hospital services and improved GP-reported knowledge of child health and navigation of the local health system.[23] More so, families reported they preferred to attend an appointment at their general practice clinic and felt more comfortable taking their child to see their GP. Although promising, this model has not been rigorously evaluated and its cost-effectiveness and suitability for translation to other health systems, including the Australian healthcare system, is unknown.

Strengthening Care for Children

The Health Services Research Unit at The Royal Children's Hospital (RCH) codesigned and pilot tested an adapted version of the UK model, developed for the Australian healthcare context. The model—Strengthening Care for Children (SC4C)—consists of regular, shared GP-paediatrician consulting sessions and case discussions held at the general practice clinic, with email/telephone support provided by paediatricians to GPs in between shared consulting sessions. Pilot data from five general practices in Victoria, Australia, showed that GPs found the model acceptable, it improved family trust in and preference for GP care, it improved GP confidence in providing paediatric care and may reduce GP referrals to hospital services.[24]

In response to this successful pilot, the National Medical Research Committee (NHMRC) and Partner Organisations funded a new partnership committed to the evaluation of the SC4C model of care via a multisite, stepped wedge randomised controlled trial in Australian general practice clinics.

This paper reports the research protocol for the SC4C trial. The trial aims to evaluate the effectiveness of the SC4C model of care compared with standard GP care to reduce GP paediatric (0–<18 years) referrals to hospital ED and OP clinics (primary outcome); increase GP

care that is adherent to best practice guidelines and GP confidence in providing paediatric care; and to increase family trust in primary care, while reducing family preference for specialist paediatrician referral (secondary outcomes). It also aims to evaluate the cost-effectiveness and cost-benefit of the SC4C model of care compared with standard GP care. In addition, an implementation evaluation undertaken alongside the trial will identify barriers and enablers associated with implementation of the model to understand factors associated with acceptability, adaptability, scalability and assess the sustainability of the model.

Based on the pilot study,[24] we hypothesise a 4% decrease in GP paediatric referrals to ED and OP clinics; an increased provision of GP care that is adherent to guidelines for four common childhood conditions; a 10% improvement in GP confidence in care and parent confidence in GP care; and a 10% reduction in family preference for paediatrician care (based on GP and family surveys); and that the intervention will be cost-effective and scalable with potential for sustainability.

METHODS AND ANALYSIS

Study design

SC4C is a multisite, stepped wedge cluster randomised controlled trial (RCT) of a GP-paediatrician model of care compared with standard GP care. A stepped wedge design involves the sequential crossover of clusters from control to intervention, thus allowing all participating practices (clusters) to be exposed to the intervention while still comparing with usual care, pre-intervention within and across clusters. This design was selected as our partners required all practices to receive the intervention. Sequentially, one practice from each site per month will switch from control to intervention until all practices receive the intervention from 2021 to 2023 (see figure 1).

During the first month of the intervention for each practice, a 1-month transition period will apply to embed the SC4C model of care into the practice, where data will not contribute to the analysis. The 1-month transition and embedding period will involve orientation with the paediatrician and working with practice staff and GPs to implement the model of care into their practice and resolve any process issues. After the 1-month embedding period, there will be an 11-month intervention period in each practice, followed by sustainability data collection which will continue over an 18-month period to examine the enduring effects of the SC4C model once the paediatrician has left the general practice, compared with control and intervention.

Setting

This is a multisite trial conducted in the states of Victoria and New South Wales, Australia. General practice clinics are recruited within the catchment area of our primary care partnership organisations, North Western Melbourne Primary Health Network (NWMPHN) in Victoria and Central Eastern Sydney Primary Health Network (CESPHN) in New South Wales. The trial regions are selected for their high paediatric referral rates to The Royal Children's Hospital, Melbourne (RCH), and Sydney Children's Hospital Network (SCHN), and interest from the NWMPHN and CESPHN in participating in the trial. In Australia, GP clinics see both children and adults and there are no standalone paediatric clinics. Children can present with acute or chronic illnesses to their GP. Thus, the clinics represent 'usual' primary care in Australia and are not clinics designed to replicate secondary care or to be acute care only clinics.

Participants

Trial participants will be as follows: all eligible and consenting GPs of enrolled general practice clinics within the NWMPHN and CESPHN catchment areas, and all consenting caregivers of patients <18 years seen by participating GPs.

Eligible general practice clinics are those who respond to the expression of interest and meet the inclusion criteria, while GPs and caregivers will also need to meet the inclusion criteria to be enrolled in the study (table 1).

Recruitment

General practice clinics and GPs

To recruit general practice clinics, a first round of expression of interest invitations is sent to the top 50 high

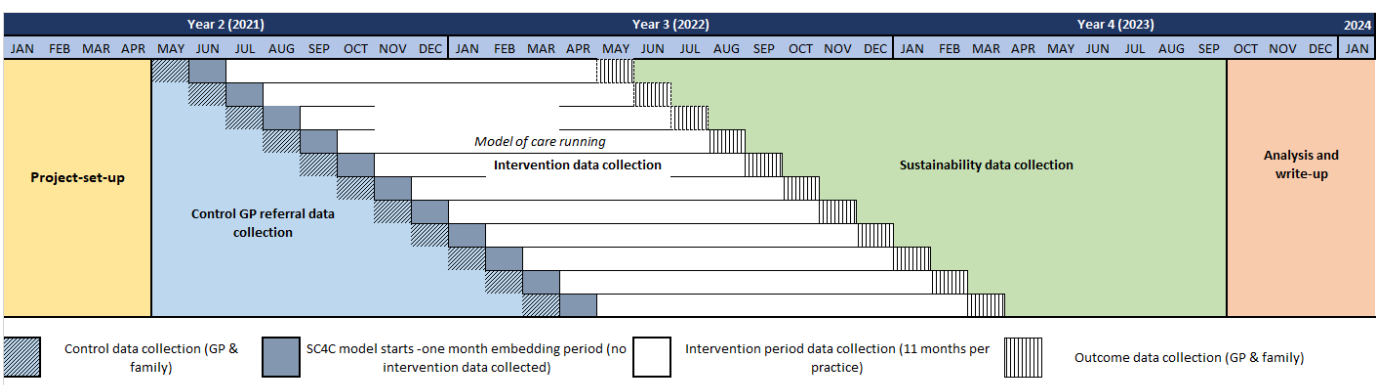

Figure 1 Timeline of stepped wedge design of SC4C (Strengthening Care for Children) model of care. GP, general practitioner.

Table 1 Trial population inclusion and exclusion criteria applied during recruitment

Inclusion	Exclusion
General practice clinics	
► Be located within either the NWMPHN or CESPHN catchment	► Less than 3 GPs working in the practice are willing to participate in the study, unless they met the threshold for *active patients (<900 active patients)
► Have Best Practice or Medical Director V.3 as their electronic medical record software	
► Be formally accredited by an independent accreditation agency against the Royal Australian College of General Practice standards[32]	
► Have a minimum 900 *active patients <18 years attending their clinic in the past 12 months (to ensure sufficient numbers of active paediatric patients to ensure GP uptake of the model, based on pilot acceptability)[24]	
► Have a minimum of 3 GPs working in the practice who consent to take part in the study	
GPs	
► Work a minimum of 2 clinical sessions per week in the practice	
► See paediatric patients <18 years of age	
► Can provide a minimum of 2 weeks of control referral data	
Families	
► Caregivers of paediatric patients seen by a participating GP during the trial	► Children or young people who present to the GP practice without a parent/guardian
► Caregivers with sufficient English to complete survey	► Insufficient English

*An 'active patient' is a patient who has attended the practice/service three or more times in the past 2 years, as defined by the Royal Australian College of General Practitioners (RACGP) standards for general practices.[32]
CESPHN, Central Eastern Sydney Primary Health Network; GP, general practitioner; NWMPHN, North Western Melbourne Primary Health Network.

referring practices within the NWMPHN and CESPHN catchment. A second round of expression of interest invitations is then followed if the required sample size is not met. In NSW, in the absence of reliable data of high referring practices, a second round of expression of interest invitations was sent to all general practice clinics within the CESPHN region. In Victoria, a further targeted approach to recruit high referring practices is being conducted in partnership with the Victorian primary care practice-based research and education network (VicREN). VicREN is led by the Department of General Practice at the University of Melbourne.

Interested general practice clinics are visited by the lead project investigator (HH, RL), the project manager and the Primary Health Network (PHN) project officer in each state to present the model of care and invite GPs to formally consent to the project. General practice clinics are required to sign a memorandum of understanding with the research team adhering to the requirements of their participation, as well as a licence agreement to instal the software clinical data extraction tool (GRHANITE) in their practice. GPs are required to sign a participant information statement adhering to the requirements of the model of care, to be formally consented into the project. GPs who join the general practice clinic during the intervention phase who cannot provide 2 weeks of control referral data are excluded from participating in the study. Practice incentive payments of $7000 per practice and Royal Australian College of General Practitioners' Continuing Professional Development points are provided to support practice participation in the trial.

Families

Eligible caregivers of patients <18 years who present to a participating practice during the control and intervention periods of the trial (consecutively each month) are invited to complete a family survey about their experience of the GP consultation. Trained researchers approach families in the waiting rooms of practices to screen for eligibility and gain informed consent to complete the anonymous online survey. During busy practice days, researchers verbally screen for eligibility before offering the survey. Families are alerted to the study through posters and flyers at reception and in the waiting room of their general practice clinic.

In the event that COVID-19 restrictions impact our face-to-face data collection of family surveys, we will engage with practices to send a broadcast SMS on behalf of the study to paediatric patients of participating GPs via their booking system. On agreement with the practice, the

study team will provide an SMS script with a link to the online family survey to be sent to all caregivers of paediatric patients seen in the last 2 months (to limit recall bias).

During the model of care (intervention period), in addition to completing the family survey, caregivers will be invited to take part in a qualitative interview either in person or via telephone/online video, led by the implementation evaluation team of the study. These interviews will only be available to families who have participated in a SC4C co-consultation during the intervention period.

Outcomes

Randomisation and blinding

General practice clinics (clusters) are randomly assigned by the independent project statistician to sequentially start the SC4C intervention from month 1 through to month 11, using a computer-generated randomisation schedule stratified by site (Victoria, New South Wales). Although each practice will be treated as one cluster, two clusters (one from each state) will be randomised to cross from control to intervention each month.

To avoid recruitment bias in clusters, randomisation will occur once all general practice clinics have been recruited and enrolled; that is, after all inclusion and exclusion criteria are addressed, and all general practice clinics sign the relevant project agreements. Following randomisation, practices will be unblinded to their allocation status/model of care start date. It is necessary for general practice clinics to know their randomisation position to prepare their clinic, particularly due to the concurrent burden of executing COVID-19 vaccination programmes. The study team are also unblinded to the allocation status to allow them to effectively prepare and coordinate the implementation schedule.

Intervention

The SC4C model of care comprises three components offered to all randomised general practices clinics and their participating GPs (figure 2). The intervention will be delivered face-to-face and or via telehealth (telephone or video) by experienced paediatricians. Study paediatricians will be co-located at each general practice clinic for a total of 12 months (including 1 month embedding period), for one half-day per week for the first 6 months, then reducing to fortnightly (fade out model). Each state has a dedicated project manager and PHN representative officer to provide ongoing support to practices and ensure practical elements of the implementation are agreed on prior to the intervention (eg, roles and responsibilities, scheduling of co-consultations and case discussions, technological capabilities for telehealth and COVID-19 safety guidelines). Following the 12-month intervention at each general practice clinic, the study paediatricians will no longer be colocated at the practice and will cease all support components of the model of care (co-consultations, case discussions and telephone/email support). However, GPs will be able to access paediatric support via their local hospitals (usual care practice).

Paediatricians will complete a data log of the number and nature of co-consultations (eg, patient age/gender, presenting problem, diagnosis and outcome), case discussions and telephone/email consultations. Paediatricians will be supported by monthly supervision with lead investigators from each state (HH and RL, both experienced specialist paediatricians) to discuss any process or clinical issues. As per our pilot, this monthly peer mentoring facilitates support for relatively junior paediatricians to work in a primary care environment with shorter consultation times and fewer resources than paediatric secondary care settings.

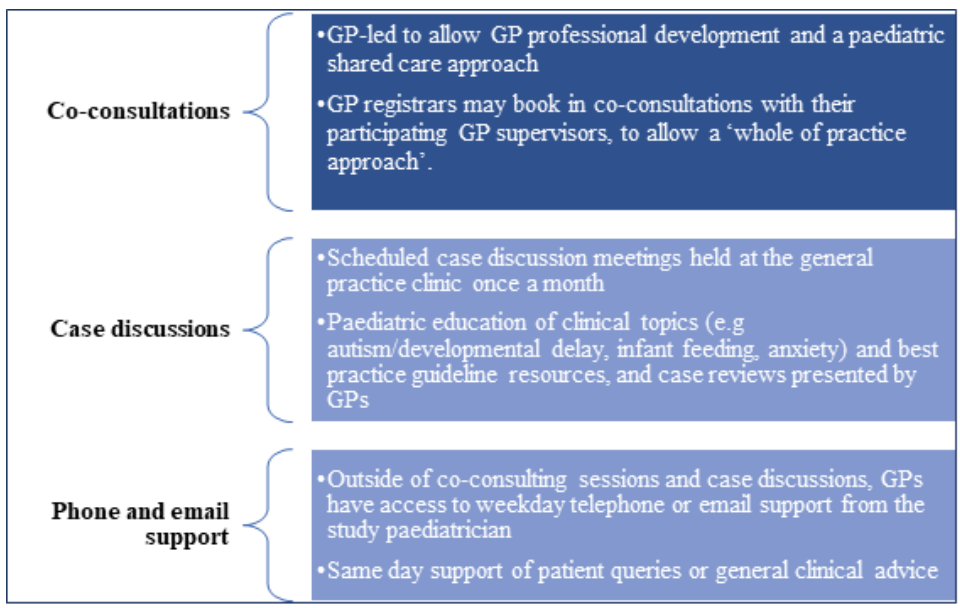

Figure 2 SC4C model of care intervention components. GPs, general practitioners; SC4C, Strengthening Care for Children.

Table 2 Description of outcomes

Primary and secondary objectives	Data sources	Methods of collection	Period of data collection	Outcomes of interest
1. What is the impact of SC4C on GP referral to hospital outpatient clinics and EDs? (Primary outcome)	GP medical records	GRHANITE data extraction of referral destination (including no referral made) for each paediatric visit to participating GPs	Collected as part of paediatric GP consults at the beginning of the control data period and throughout the intervention period	Whether or not the GP referred the child to hospital outpatient clinics or EDs
2. What is the impact of SC4C on GP quality of care for common childhood conditions?	GP medical records	GRHANITE data extraction of care quality based on the measurement of the CareTrack Kids[14] indicators	Collected as part of paediatric GP consults at the beginning of the control data period and throughout the intervention period	Whether or not the GP followed clinical guidelines (ie, did not request unnecessary tests or prescriptions) for five common childhood conditions (ie, asthma/wheeze, bronchiolitis, constipation/abdominal pain, upper respiratory infections, infant crying and reflux)
3. What is the impact of SC4C on GPs? (eg, confidence and skills in paediatric care, use of clinical guidelines, feasibility/acceptability)	GP online survey	Control and intervention surveys completed online via REDCap[27]	Control surveys are collected in the month prior to the implementation commencing in each practice. Intervention surveys are collected in the last month of the implementation at each practice.	Changes in the level of confidence in paediatric care; level of knowledge and skill in navigating the health system for children; reported use of clinical guidelines; reported feasibility/acceptability of the model
4. What is the impact of SC4C on patients and family experience?	Family survey	Control and intervention surveys completed with families in waiting room of GP clinics	Control surveys are collected in the month prior to the implementation commencing in each practice. Intervention surveys are collected in the last month of the implementation at each practice.	Level of confidence in GP care, level of satisfaction with GP care, desire for referral to specialist care, preference for GP or specialist review
Health economic evaluation				
5. What is the cost of implementing the model of care? What is the cost effectiveness?	Trial data and supplementary unit costings	Trial data on the model of care, health service costs, health service use and patient costs and outcomes will be combined with relevant unit costs to produce a cost-effectiveness analysis	Data will be collected throughout the model of care	Costs of conducting the model of care compared with usual care; costs/savings of change in OP/ED referrals; costs/savings to families compared with accessing usual care
Implementation Evaluation (see also Hodgins *et al* (2022)				
6. What are the aspects of the model of care that make it effective or ineffective at producing system change?	Paediatrician collected data, qualitative interviews and online surveys with GPs, Practice managers and administration staff, study Paediatricians, families and children and project team members	Consolidated Framework for Implementation Research; qualitative interviews with families, children and practitioners; online surveys. Paediatricians will collect unidentifiable data on the patient characteristics (eg, age, sex) and nature of paediatric support provided (eg, reason for visit, topic of case study discussion).	Qualitative and online survey data will be collected on completion of the model of care in each Practice; paediatrician data will be collected as part of the co-consultations, case study discussions and phone/email support throughout the model of care	Identify strategies for successful implementation as well as practical difficulties and facilitators in adoption, delivery and maintenance to inform future scaling. Describe the model of care, including number of children seen in GP-Paediatrician co-consultations, reasons for co-consultations, number of phone and emails to the paediatrician support, number and topic of case study discussions
Sustainability				
7. Explore the sustainability and enduring effects of SC4C post-implementation on proportion of GP paediatric referrals to OP clinics or EDs and GP quality of care compared with pre-intervention GP care	GP medical records	GRHANITE data extraction of referral destination (including no referral made) for each paediatric visit to participating GPs and of care quality based on the measurement of care provided for the five common childhood conditions	Data will be collected on paediatric GP consults following completion of the model of care in each practice (ie, once the paediatrician has left the practice) until the end of the study	(1) Whether or not the GP refers the child to a hospital OP or ED; (2) whether or not the GP followed clinical guidelines for five common childhood conditions (as above); (3) how GP paediatric referrals (1) and quality of care (2) in the sustainability period compare to the intervention period (when the paediatrician was in the clinic); (4) economic evaluation results reflecting national roll out in real world sustainable setting along with budget impact

ED, emergency department; GPs, general practitioners; OP, outpatient; SC4C, Strengthening Care for Children.

In the event of COVID-19 restrictions impacting our intervention, a tailored approach will be used for each practice due to their respective COVID-19 policies and telehealth capabilities. However, we will preference the delivery of the model of care in the following order:

1. Face to face co-consultations and case discussions.
2. Face to face co-consultations, online case discussions.
3. Telehealth two-way via telephone or video: GP and paediatrician together in the practice-patient joins online remotely.
4. Telehealth three-way via telephone or video: GP, paediatrician and patient all join online remotely.

Medicare is Australia's publicly funded universal health insurance scheme. A comprehensive range of services, diagnostic tests and procedures are itemised as the Medicare Benefits Schedule (MBS). Every public or private patient receives a reimbursement via Medicare for services provided by GPs or specialists. As no Medicare items exists for the GP-paediatrician co-consultations sessions, GPs will bill Medicare using standard Medicare item numbers.

The SC4C model of care will be delivered by four specialist (consultant level) paediatricians (two per state), funded by The Royal Children's Hospital and Sydney Children's Hospital Network.

Data collection

Table 3 outlines the primary and secondary outcome data collection timepoints of the trial.

GP electronic medical record data collection

The primary outcome will capture routinely collected paediatric referral data from GP electronic medical records (EMR) via GRHANITE technologies, a secure and ethical acquisition of data for research purposes, developed and managed at the University of Melbourne. GRHANITE software will be remotely embedded into all participating GP medical software computers (compatible with Best Practice or Medical Director EMR software) to extract deidentified routinely collected data of all paediatric patients seen throughout the trial. Deidentified paediatric patient data will include but not limited to patient demographics, reason for visit, diagnoses, referrals, prescriptions, ordered imaging and pathology testing, and Medicare item billing. This extraction will include data that will inform the analysis of GP quality of care, based on the CareTrack Kids indicators (see table 2).[14]

GP referrals are not consistently recorded in EMR. Therefore, the GRAHNITE team will develop a tailored pop-up window of referral outcomes (specific to each state) to completed by GPs following each paediatric consultation. This pop-up window will feature the most common referral options for consultations (eg, no referral, hospital OP or ED, private psychologist, or allied health, etc). Collection of GP EMR referral data will commence for all practices following randomisation and be collected throughout the trial. A natural language processing (NLP) algorithm, developed by the Computing and Information Systems at the University of Melbourne, will be used to automatically transform GP EMR clinical free text of 'reason for visit' or diagnosis into structured clinical data, based on SNOMED CT (Systematised Nomenclature of Medicine Clinical Terminology).[25]

GP and family survey data collection

GP and family survey data collection will occur during the control period (1 month prior to the intervention) and in the last month of the intervention for each practice. GP experience and confidence in paediatric care will be measured using the SC4C GP online survey which will be sent to all participating GPs via email or in hardcopy if preferred. The GP online survey (online supplemental appendix A) collects demographic information about the GP sample, items relating to factors that impact their decision to refer a paediatric patient, knowledge and confidence of paediatric care and services, and reported use of HealthPathways, an online information portal for primary healthcare providers The family online survey (online supplemental appendix B) will be used to measure confidence in GP paediatric care, preference for paediatrician referrals, and experience of the model of care in general practice. The GP and family surveys have been developed specifically for SC4C and are comprised of items generated by the SC4C investigators and drawn from our previously published literature and pilot study.[18 19 24] In addition, the GP survey will include validated measures of working culture and learning climate of the practice; pragmatic measure of perceived fit of the intervention, and assessment of how well the intervention was incorporated into standard work practice—NOMAD tool, based on the Normalisation Process Theory[26] (see table 3).

Data management and storage

All participants (GPs, caregivers) will be assigned a unique numerical identifier (an ID code) for use throughout the study. A single electronic, password protected, database in REDCap[27] will record all practice and GP details and questionnaire data. The project database will be accessed by the study team and hosted on the Murdoch Children's Research Institute (MCRI) server, which meets security and ethical confidentiality requirements. Paediatrician recorded data on co-consultations and case discussions will be stored in the REDCap database and paper versions scanned and stored on the secure Murdoch Children's Research Institute's sharepoint drive.

GRHANITE extraction tool will be managed by the developer (DB) at Health and Biomedical Informatics Centre at the University of Melbourne (UoM). GRHANITE is designed to work in any environment where data are being routinely collected, and addresses the many legal, ethical, organisational and technical barriers that prevent or hinder such vital activities in

Table 3 Description of measures and data collection timepoints

	Time point		
	Control period	Embedding period	Intervention period
Measure			
GP demographics	X	–	X
Family demographics	X	–	X
Paediatrician co-consultation data logs	X	X*	X
Paediatrician case discussion data logs	X	X*	X
Primary outcome			
GP referral outcomes GRAHNITE extracted from routinely collected GP EMR data	X	X*	X
Secondary outcomes			
GPs			
Quality of care GRHANITE EMR data extraction on care quality based on measurement of the CareTrack Kids indicators[8]: Asthma Bronchiolitis Constipation Upper respiratory infections Infant crying and gastro-oesophageal reflux	X	X*	X
Confidence in paediatric care and access to paediatric services. Study designed based on pilot study.	X	–	X
Skills to manage child health. Study designed based on pilot study	X	–	X
Awareness and use of HealthPathways. Study designed based on pilot study	X	–	X
9-item implementation culture (Consolidated Framework Implementation Research—CFIR)[33]	X	–	–
5-item learning climate (CFIR)	X	–	–
4-item measure of perceived intervention appropriateness Intervention Appropriateness Measure (IAM)	X	–	–
18-item intervention buy-in Adapted NoMAD tool based on Normalisation Process Theory[26]	–	–	X
Model feasibility, acceptability, feedback and patient benefit Study designed based on pilot study	–	–	X
Families			
Confidence in GP care Study designed based on pilot study	X	–	X
Quality of care and interactions with the GP Study designed based on pilot study	X	–	X
Preference for paediatrician referral and GP review Study designed based on pilot study	X	–	X

*Data collected during the embedding period month will not be analysed
EMR, electronic medical records; GP, general practitioner.

Australia. Data extracted by GRHANITE will be stored in a Research Databank on the UoM Research Cloud, physically located within UoM Secure Data Centre. GRHANITE data will be made available to the study team from this databank via a UoM secure virtual research environment that gives researchers access to the data in a controlled manner. This data management process was adopted for our pilot with GRHANITE data on over 8000 paediatric GP consultations. Data collected by REDCap will be combined into the secure research environment for analysis whereby only designated study team members (investigators, statistician and project managers) will have access to the data.

Sample size calculation

Based on a stepped wedge design with all practices randomised to sequentially initiate the intervention, two each month, a 1-month transition period after initiation of the intervention, and 11 months of intervention data collection per clinic, a sample size of 22 practices (11 per

state) was calculated. This calculation is based on mixed effects models to estimate treatment effect and allows for a homogeneous temporal trend across clusters. Twenty practices with an average of 40 observations (paediatric patient visits) per practice per month will provide 90% power to detect a 4% reduction in the percentage of children who are referred to ED or OP clinics from 10% to 6% (primary outcome), based on an intracluster correlation of 0.06 (derived from our pilot data) and two-sided alpha of 0.05. Recruiting 22 practices (11 in each state) will allow for the potential drop out of 1 practice per state. In our pilot study, we found a 7% reduction in GP referrals (primary outcome) to hospital EDs and OPs but have powered our study using a conservative 4% reduction.

Statistical methods

All available data from each recruited GP and family will be analysed according to an intention-to-treat principle. We will treat the primary outcome as a binary variable: for each paediatric visit, the child will be deemed either to have been referred or not referred to an OP clinic or ED. The primary outcome will be analysed using mixed effects logistic regression fitted at the child level. To investigate the differences between the control and intervention periods, our model will include a fixed effect of group (intervention period vs control period). It will also allow changes in referral practices over time by including fixed effect for calendar time (as a continuous variable) and will allow for variability in referral practices by clinic by including a random effect for clinic. We will also consider whether the effect of time and clinic vary by group (control vs intervention period) by the inclusion of interaction terms. Secondary outcomes collected at the child level will be analysed similarly, with separate models for the four common conditions to measure quality of care. GP survey outcomes will be analysed using mixed effects linear regression, again including a fixed effect for group and calendar time, and a random effect for clinic exploring the presence of interactions.

Handling of missing data

Prior to analysis, missing data in the primary and secondary outcomes will be explored. The frequency and patterns of missing data will be examined and sensitivity analyses will be performed to compare the results of analyses restricted to GP and family surveys with complete data and analyses accounting for the missing data. If there is little missing data (<5%), complete case analysis will be presented as the primary analysis.

Data monitoring

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.

Economic evaluation

Using a standard economic evaluation framework,[28] we will determine the costs of conducting SC4C (paediatrician time and supervision, GP training, practice administrative support, co-consultations and case-study discussions) relative to standard GP care. Within the Australian public healthcare financing system there is no ability of GP's to be paid to co-consult with paediatricians. The cost of the paediatricians will be funded by the trial and GPs will continue to bill as per their usual arrangement for individual patient consultations.

Combined with the SC4C outcomes (GP referral outcomes and guideline adherent care), the economic evaluation will be presented from both a health system and a societal perspective, with the latter including impacts on parental time, productivity, travel and child school attendance. Cost-benefit analysis will be presented as a unit cost per ED presentation and OP attendance, and per additional child receiving care adherent to guidelines, to produce an estimate of *net present value* and a benefit-cost ratio. Data will be sourced from the trial database, GRHANITE software and the trial hospitals (cost of ED and OP visits).

The uncertainty of cost and outcome data will be tested in a sensitivity analysis. The costs of implementing the model will be scaled to national level along with a budget impact analysis from the perspective of potential payers (Medicare, PHNs, hospitals) to guide translation of findings and the design of sustainable implementation.

Implementation evaluation

A mixed methods evaluation will be carried out and is detailed in our companion paper.[29]

Ethics, consent and dissemination

This study is approved by the Human Research Ethics Committees of The Royal Children's Hospital (HREC 65955) and The Sydney Children's Hospital Network (STE03927), New South Wales, Australia.

Consent

At recruitment, each GP signs a consent form (online supplemental appendix C) before the model of care commences in their general practice clinic. The consent form describes the roles and responsibilities of the GP in this trial (record referral outcomes for paediatric consultations, schedule co-consultations with study paediatrician and attend case study discussions). GP's consent to the study is documented in their record on the study's electronic database. GPs will continue to be followed with the research data collection, unless they request to withdraw from the trial, in which case all research aspects will cease.

During the family survey data collection periods, caregiver survey consent will be obtained electronically (online supplemental appendix D). Trained researchers will explain to caregivers the purpose of the study, risks and benefits of participation and answer any questions about the study. Consent is voluntary and free from coercion. At all times it is made clear that non-participation in the study does not affect their GP care or care from any partner hospitals.

Confidentiality

Participant confidentiality is strictly held in trust by the investigators, research staff, and the sponsoring institutions and their agents, and is extended to cover clinical information relating to participants. The study protocol, documentation, data and all other information generated are held in strict confidence and in password protected electronic files. No information concerning the study or the data is released to any unauthorised third party, without prior written approval of the sponsoring institutions. Investigators and authorised representatives of the sponsoring institutions have access to the final dataset via permissions maintained by the data managers.

Dissemination

Principal investigator HH holds the primary responsibility for publication of the results of the study in accordance with the study publication and dissemination plan. The findings from this trial will be reported according to the CONSORT (Consolidated Standards of Reporting Trials) statement guidelines.[30]

Patient and public involvement

Patients and public were not involved in the study design or conduct, or reporting or dissemination plans of this research. A lay summary of findings will be provided to participants and posted on the study website.

DISCUSSION

Australia's current healthcare services for children are neither sustainable nor equitable. Hospitals face issues of limited resources leading to long wait times which the COVID-19 pandemic has exacerbated. As paediatric populations grow,[1] models evaluating whether the rise in paediatric attendances to ED and OPs might be counterbalanced by better support for guideline-concordant primary care are urgently required. Building on a promising UK model of integrated GP-paediatrician care[23] and our own pilot study confirming feasibility and acceptability of a similar approach,[24] we will conduct what we believe to be a world-first, stepped wedge trial of an integrated GP-paediatrician model of care for children, designed to reduce referrals to the hospital system. The Strengthening Care for Children trial is designed to improve clinical care closer to home. Hospital services are often used, especially for families from lower socioeconomic groups, as a default primary care service.[31] By improving access to improved paediatric services in primary care, we hope to improve access to high-quality paediatric care delivered by GPs closer to home. We will conduct a rigorous evaluation of the model's effectiveness, cost-effectiveness and implementation. If effective, and widely scalable, it will improve access to care, reduce costs to the healthcare system and society, and ensure children sustainably receive the right care, at the right time, and in the right place.

Limitations of our trial include inclusion of practices that use Best Practice or Medical Director EMR software and an incentive payment of $7000 per practice so our results may not generalise to practices that use other software or who would not take up this incentive payment. Further, we have not included children or young people or those with insufficient English to complete caregiver surveys, limiting generalisability of our findings to these groups. Regardless, results will be of significance to countries with primary care led healthcare systems facing similar challenges.

Author affiliations
[1]Health Services, Murdoch Children's Research Institute, Parkville, Victoria, Australia
[2]Department of General Practice, University of Melbourne, Melbourne, Victoria, Australia
[3]Community Paediatrics, Sydney Local Health District, Sydney, New South Wales, Australia
[4]Department of Paediatrics, University of New South Wales, Sydney, New South Wales, Australia
[5]Australian Institute of Health Innnovation, Macquarie University, Sydney, New South Wales, Australia
[6]School of Population and Global Health, The University of Melbourne, Carlton, Victoria, Australia
[7]School of Public Health and Community Medicine, UNSW Australia, Fairfield, New South Wales, Australia
[8]Department of General Practice, University of Melbourne, Carlton, Victoria, Australia
[9]Department of Pediatrics, University of Michigan, Ann Arbor, Michigan, USA
[10]Clinical Sciences and Biostatistics Unit, Murdoch Children's Research Institute, Parkville, Victoria, Australia
[11]University of New South Wales, Sydney, New South Wales, Australia
[12]North Western Melbourne Primary Health Network, Melbourne, Victoria, Australia
[13]Central and Eastern Sydney Primary Health Network, Sydney, New South Wales, Australia
[14]Sydney Children's Hospitals Network, Sydney, New South Wales, Australia
[15]Health Services Research Unit, The Royal Children's Hospital, Parkville, Victoria, Australia

Twitter Yvonne Zurynski @YvonneZurynski

Acknowledgements SC4C is a research collaboration between the Health Services Group, Murdoch Children's Research Institute; The Royal Children's Hospital (RCH, Melbourne, Victoria); Population Health, The University of New South Wales; Sydney Childrens Hospital Network; the University of Melbourne; North Western Primary Health Network (NWMPHN) and Central and Eastern Sydney Primary Health Network (CESPHN), Agency for Clinical Innovation New South Wales Health (ACI), and the Sydney Partnership for Health, Education, Research & Enterprise (SPHERE). We thank all the general practice clinics, GPs, paediatricians and families who participated in the trial.

Contributors The original study design was conceived by HH, RL, LS, SW, YZ, KD, SL, KL, DB and GF. KL and CM provided statistical expertise in the trial design; SK, CM and MH conducted the data cleaning; and CM conducted the statistical analysis. JL, TMM, SG and KW have contributed to the data processes of the study and reviewed the final draft of the protocol. HH and RL are the overall guarantors.

Funding The study is funded through a 4-year National Health and Medical Research Council (NHMRC) Partnership Grant (APP1179176). This includes direct funding from the NHMRC, as well as cash and in-kind support from the following Partner Organisations: RCH, SCHN, NWMPHN, CESPHN, ACI NSW Health. The NHMRC has no direct role in study design; data collection, analysis, and interpretation; or writing of final reports, presentations, or publications. Murdoch Children's Research Institute research is supported by the Victorian Government's Operational Infrastructure Support Program. Professor Harriet Hiscock is supported by an NHMRC Practitioner Fellowship (1136222). Professor Sue Woolfenden is supported by an NHMRC Fellowship (1158954). Representatives from each Partner Organisation will form the Advisory Committee for the project; and will therefore have a role in the study and may influence the activities above.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iDs
Yvonne Zurynski http://orcid.org/0000-0001-7744-8717
Siaw-Teng Liaw http://orcid.org/0000-0001-5989-3614
Michael Hodgins http://orcid.org/0000-0001-9177-3428
Harriet Hiscock http://orcid.org/0000-0003-3017-2770

REFERENCES

1 Australian Bureau of Statistics. Report: 3101.0 – Australian demographic statistics, Jun 2018. Canberra: ABS; 2018.
2 Freed GL, Spike NA, Sewell JR, *et al*. Changes in longer consultations for children in general practice. *J Paediatr Child Health* 2013;49:325–9.
3 Australian Institute of Health and Welfare (AIHW). Use of emergency departments for lower urgency care: 2015–16 to 2018–19, 2020. Available: https://www.aihw.gov.au/reports/primary-health-care/use-of-ed-for-lower-urgency-care-2018-19 [Accessed 09 Dec 2021].
4 Freed GL, Gafforini S, Carson N. Age distribution of emergency department presentations in Victoria. *Emerg Med Australas* 2015;27:102–7.
5 Freed G, Gafforini S, Carson N. Age-related variation in primary care-type presentations to emergency departments. *Aust Fam Physician* 2015;44:584–8.
6 Australian Institute of Health and Welfare. Use of emergency departments for lower urgency care: 2015–16 to 2018–19. cat. No. PHC 3. Canberra; 2020. https://www.aihw.gov.au/reports/primary-health-care/use-of-ed-for-lower-urgency-care2018-19 [Accessed 28 Sep 2021].
7 Australian Bureau of Statistics. Report: 4364.0.55.001 - National Health Survey: First Results, 2014-15. Table 3.1 Long-term health conditions (a), Persons (estimate). Canberra ABS; 2015.
8 Australian Bureau of Statistics. Report: 4364.0.55.001 - National Health Survey: First Results, 2017-18. Table 3.1 Long-term health conditions (a), Persons (estimate). Canberra ABS; 2018.
9 Wolfe I, Mandeville K, Harrison K, *et al*. Child survival in England: strengthening governance for health. *Health Policy* 2017;121:1131–8.
10 Bayram C, Harrison C, Charles J, *et al*. 'The kids are alright' - changes in GP consultations with children 2000-15. *Aust Fam Physician* 2015;44:877–9.
11 Charles J, Harrison CM, Britt H. Management of children's psychological problems in general practice 1970-1971, 1990-1991 and 2008-2009. *Aust N Z J Psychiatry* 2011;45:976–84.
12 Williames S, Temple-Smith M, Chondros P, *et al*. Are we preparing Victorian general practice registrars to be confident in all aspects of primary care paediatrics? *Aust J Gen Pract* 2020;49:759–66.
13 Melville C, Wall D, Anderson J. Paediatric training for family doctors: principals and practice. *Med Educ* 2002;36:449–55.
14 Braithwaite J, Hibbert PD, Jaffe A, *et al*. Quality of health care for children in Australia, 2012-2013. *JAMA* 2018;319:1113–24.
15 Hibbert P, Stephens JH, de Wet C, *et al*. Assessing the quality of the management of tonsillitis among Australian children: a population-based sample survey. *Otolaryngol Head Neck Surg* 2019;160:137–44.
16 Woolfenden S, Short K, Blackmore R, *et al*. How do primary health-care practitioners identify and manage communication impairments in preschool children? *Aust J Prim Health* 2015;21:176–81.
17 Altman L, Breen C, Ging J, *et al*. "Dealing with the Hospital has Become too Difficult for Us to Do Alone" - Developing an Integrated Care Program for Children with Medical Complexity (CMC). *Int J Integr Care* 2018;18:14.
18 Freed GL, Turbitt E, Kunin M, *et al*. General practitioner perspectives on referrals to paediatric public specialty clinics. *Aust Fam Physician* 2016;45:747–53.
19 Freed GL, Turbitt E, Kunin M, *et al*. Children referred for specialty care: parental perspectives and preferences on referral, follow-up and primary care. *J Paediatr Child Health* 2017;53:18–25.
20 Gruen RL, Weeramanthri TS, Knight SE, *et al*. Specialist outreach clinics in primary care and rural hospital settings. *Cochrane Database Syst Rev* 2004;1:CD003798.
21 Wolfe I, Satherley R-M, Scotney E, *et al*. Integrated care models and child health: a meta-analysis. *Pediatrics* 2020;145:e20183747.
22 Zurynski Y, Phu A, Deverell M. Paediatric services capacity: an evidence check rapid review brokered by the Sax Institute for the NSW kids and families 2015, 2015. Available: www.saxinstitute.org.au
23 Montgomery-Taylor S, Watson M, Klaber R. Child health general practice hubs: a service evaluation. *Arch Dis Child* 2016;101:333–7.
24 Hiscock H, O Loughlin R, Pelly R, *et al*. Strengthening care for children: pilot of an integrated general practitioner-paediatrician model of primary care in Victoria, Australia. *Aust Health Rev* 2020;44:569–75.
25 Gaudet-Blavignac C, Foufi V, Bjelogrlic M, *et al*. Use of the systematized nomenclature of medicine clinical terms (SNOMED CT) for processing free text in health care: systematic scoping review. *J Med Internet Res* 2021;23:e24594.
26 May CR, Mair F, Finch T, *et al*. Development of a theory of implementation and integration: normalization process theory. *Implement Sci* 2009;4:29.
27 Harris PA, Taylor R, Thielke R, *et al*. Research electronic data capture (REDCap)-a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42:377–81.
28 Drummond MF, Sculpher MJ, Torrance GW. *Methods for the economic evaluation of health care programmes*. Oxford University Press, 2005.
29 Hodgins H. Protocol for the implementation evaluation of an integrated paediatric and primary care model: Strengthening Care for Children (SC4C). *BMJ Open* 2022.
30 Campbell MK, Piaggio G, Elbourne DR, *et al*. Consort 2010 statement: extension to cluster randomised trials. *BMJ* 2012;345:e5661.
31 Callander EJ, Bull C, Lain S, *et al*. Inequality in early childhood chronic health conditions requiring hospitalisation: a data linkage study of health service utilisation and costs. *Paediatr Perinat Epidemiol* 2022;36:156–66.
32 The Royal Australian College of General Practitioners. *Standards for general practices*. 5th edn. East Melbourne: Vic: RACGP, 2020.
33 Fernandez ME, Walker TJ, Weiner BJ, *et al*. Developing measures to assess constructs from the inner setting domain of the consolidated framework for implementation research. *Implement Sci* 2018;13:52.