Study protocol: primary healthcare transformation through patient-centred medical homes—improving access, relational care and outcomes in an urban Aboriginal and Torres Strait Islander population, a mixed methods prospective cohort study

Danielle Butler, Anton Clifford-Motopi, Saira Mathew, Carmel Nelson, Renee Brown, Karen Gardner, Lyle Turner, Leanne Coombe, Yvette Roe, Yu Gao, James Ward, ISoC2 Study Team members

ABSTRACT

Introduction For over 40 years, Aboriginal and Torres Strait Islander Community-Controlled Health Services (ACCHS) in Australia have led strategic responses to address the specific needs of Aboriginal and Torres Strait Islander populations. Globally, there has been rapid growth in urban Indigenous populations requiring an adaptive primary healthcare response. Patient-centred medical homes (PCMH) are an evidenced-based model of primary healthcare suited to this challenge, underpinned by principles aligned with the ACCHS sector—relational care responsive to patient identified healthcare priorities. Evidence is lacking on the implementation and effectiveness of the PCMH model of care governed by, and delivered for, Aboriginal and Torres Strait Islander populations in large urban settings.

Method and analysis Our multiphased mixed-methods prospective cohort study will compare standard care provided by a network of ACCHS to an adapted PCMH model of care. Phase 1 using qualitative interviews with staff and patients and quantitative analysis of routine primary care health record data will examine the implementation, feasibility and acceptability of the PCMH. Phase 2 using linked survey, primary care and hospitalisation data will examine the impact of our adapted PCMH on access to care, relational and quality of care, health and wellbeing outcomes and economic costs. Phase 3 will synthesise evidence on mechanisms for change and discuss their implications for sustainability and transferability of PCMHs to the broader primary healthcare system

Ethics and dissemination This study has received approval from the University of Queensland Human Research Ethics Committee (2021/HE00529). This research represents an Aboriginal led and governed partnership in response to identified community priorities. The findings will contribute new knowledge on how key mechanisms underpinning the success and implementation of the model can be introduced into policy and practice. Study findings will be disseminated to service providers, researchers, policymakers and, most importantly, the communities themselves.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Prospective cohort design support data collection from intervention and standard care sites to determine the impact of the patient-centred medical homes (PCMH) on access, quality of care and health outcomes.
⇒ Triangulation of quantitative and qualitative data will enable examination of implementation, feasibility and acceptability of the PCMH from the perspective of health providers and patients.
⇒ Participatory action research which privileges Aboriginal and Torres Strait Islander worldviews, knowledge, realities and terms of reference will guide the conduct of the study.
⇒ Randomisation was not feasible in this real world, primary healthcare context, where the priority for implementation of a significant system reform was site readiness, and randomisation may also be negatively perceived by the community as restricting access to the new model of care.
⇒ Specific measures of patient’s self-reported experience were developed for the study as validated culturally modified measures of self-reported patient experiences are limited.

INTRODUCTION

Health-promoting and resilience factors—such as, connection to culture, country and community and agency—are fundamental for Aboriginal and Torres Strait Islander
health and wellbeing. However, these protective factors have been undermined by ongoing colonisation and resultant intergenerational trauma. Consequently, Aboriginal and Torres Strait Islander peoples experience high levels of both non-communicable and communicable diseases. Added to this, improvements in healthcare over the last 50 years have resulted in an increase in the number of Aboriginal and Torres Strait Islander people reaching older age as well as a booming younger population, with trends projected to increase significantly over the coming decades. Furthermore, recent global trends towards urbanisation of Indigenous peoples are also reflected in the Australian context, with rapid population growth most evident in urban settings. This population growth, change in the age distribution and overall health levels, has required an adaptive approach to healthcare—particularly, primary healthcare (PHC).

Aboriginal and Torres Strait Islander Community-Controlled Health Services (ACCHS) are holistic PHC services, delivered and governed by Indigenous peoples for Indigenous peoples. Established in the 1970s, the formation of ACCHS across Australia was a political and strategic response to the health and social inequities experienced by Aboriginal and Torres Strait Islander peoples. In 2009, in response to significant growth and geographic dispersal of Aboriginal and Torres Strait Islander peoples in the South-East region of Queensland, the Institute for Urban Indigenous Health (IUIH) was established to drive innovation in delivery of health and family wellbeing services. The region is one of the most populous—being home to more than 11% of Aboriginal and Torres Strait Islander peoples—and fastest population growth areas in Australia. Over a 10-year period, IUIH and its member services (the ‘IUIH network’) have increased service coverage to the Aboriginal and Torres Strait Islander population in the region from 16% to 45%, with the number of regular patients now just under 40 000. Through this and the consequent improved relational care delivered, substantial gains in health outcomes have been observed.

However, for the IUIH to continue to respond to identified community needs, and build on these health gains, further redesign of the current system of PHC was necessary. The patient-centred medical home (PCMH) is a model of healthcare delivery that has been implemented to address the challenge of growing urban populations with complex care needs, internationally and in Australia. Defining features of PCMH models include multidisciplinary team-based care, voluntary enrolment of patients with a team of providers, patient education and self-management, the use of technology to support patient care (including data-driven improvements in care) and service planning and coordination. Conceptually, PCMHs operationalise the core functions of PHC (universal access, comprehensive care provided within people’s community, coordination, relational continuity of care and intersectoral collaboration) with an explicit focus on—and responsiveness to—patient needs.

International evidence has established that PCMH models contribute to reductions in hospital admissions and improved clinical outcomes in diabetes, asthma and preventative care and patient satisfaction. Similar findings were observed for the Southcentral Foundation’s model of PCMH in Alaska, the only published example of a PCMH implemented for, and by, Indigenous peoples. There are few published Australian studies examining the implementation of the PCMH model and none examining the effectiveness of the model for improving quality of care or health outcomes, including in urban Indigenous communities.

Leveraging from findings of a pilot study within the IUIH network, this study will undertake an evaluation of a PCMH adapted by, and for, the South-East Queensland Aboriginal and Torres Strait Islander community (IUIH PCMH System of Care – ISoC2). Conducted over 5 years, our study will extend the pilot study and expand the research programme to a second, larger health hub. This Indigenous led and governed study will generate evidence on implementing a PCMH for a large urban Aboriginal and Torres Strait Islander population in Australia. Furthermore, it will contribute new knowledge on: the effectiveness of such a model for improving access, relational care and health outcomes; the impact on economic costs; and the transferability and scalability of the model for the broader PHC sector.

Objectives
The overall aim of this study is to undertake a process and outcome evaluation of an adapted model of a PCMH (ISoC2) at two ACCHS in South-East Queensland. Specifically, this study aims to:

1. Examine the process of implementing ISoC2, including how model elements are operationalised and the extent to which the model is delivered as planned (fidelity).
2. Identify barriers and enablers to implementation and delivery (feasibility) of ISoC2 and explore its acceptability to staff and patients.
3. Evaluate the effectiveness and economic impact of ISoC2 by quantifying changes in access, quality of care (with a specific focus on relational qualities of that care) and health outcomes, following implementation compared with baseline and standard care.

METHODS AND ANALYSIS
Study setting
The IUIH network is the largest provider of PHC to the South-East Queensland Aboriginal and Torres Strait Islander population. The standard model of care offered at each of the IUIH network’s 20 clinics supports universal primary care, with a blended payment model and provided at no cost to the patient. A range of comprehensive services and programmes are made available as a one-stop shop for patients. The study will evaluate two IUIH ACCHS located in the greater Brisbane region of
Intervention
Adapted from an Alaskan Native community-controlled health service, ISoC2 builds on the strengths of the existing IUIH model of care through adaptations intended to: strengthen access, relationship-based care, patient engagement and agency; improve health outcomes; increase efficiency by directing resources within the service to deliver greatest impact and to scale the service model to cater for growing demand.

Table 1  Comparison of care components for models of care

| Care components | PCMH16 17 | IUIH standard care | ISoC2 |
|-----------------|-----------|-------------------|------|
| Leadership*     | Leaders fully engaged with the process of change at all levels of the organisation | Community governance and accountability structure | Community governance and accountability structure Distinct operational working group to support model transformation |
| Patient enrolment† | Assigned to a clinic or ‘teamlet’ of PCP/PCP assistants | Administration staff or patients assign to preferred GP provider | Voluntary patient-initiated enrolment with a core multidisciplinary care team, a ‘Pod’ |
| Team-based care | Provider working with a team of other providers; may have 2–3 PCP/PCP assistants in a ‘teamlet’ | Providers working together with teams but work independently | Pod members working collaboratively |
| Care pathways‡ | Various, in Australia mostly from GP to other services | First contact with administration staff and then to RN/AHW, followed by the GP. GP then refers to other allied or specialist services | Dynamic pathway where Pod members work collaboratively to customise a pathway to meet patient needs |
| Scope of practice | Various, specific and expanded roles | Traditional discipline and specific roles | Expanded, intersecting scope of practice particularly of non-GP providers |
| Relationship-based care and continuity of care | Primarily between PCP/‘teamlet’ and patient | Primarily between GP and patient | Patient and Pod |
| Use of technology for data-driven care coordination and quality improvement | Supports shared decision-making | Usually supports shared decision-making | Routine use of goal setting and patient-led decision-making tools |
| Use of technology for data-driven care coordination and quality improvement | Shared electronic health record | Shared electronic health record. Data-driven continuous quality improvement in care | Shared electronic health record Data-driven continuous quality improvement in care Data-driven stratification of healthcare resources according to patient needs (cultural, emotional, social and physical) |
| Access and availability | Use of multiple modalities with extended hours | Use of multiple modalities but mostly face to face | Use of multiple modalities: face to face, telephone and home visits with extended hours |
| Funding sources¶ | Multiple often blended payments | Blended payments | Blended payments |

*ACCHS has a specific governance structure, see section on public involvement for further details. The operational working group overseeing ISoC2 includes clinicians and managers from participating sites, personnel responsible for workforce development and service implementation, and research and evaluation partners.
†In ISoC2, a ‘pod’ comprises an administrative coordinator, AHW, RN and GP working together throughout the patient’s care journey.
‡In most circumstances in Australia, including in Health Care Homes18 (the PCMH implemented in some services in Australia over the last 5 years), most patients will see a GP prior to other providers. GP then refers to other allied or specialist services.
¶PHC in Australia is funded predominantly through fee-for-service, while PCMH models often have a blended payment (capitation, pay for performance and fee-for-service), while ACCHS have blended payment as the standard funding model.
AHW, Aboriginal and Torres Strait Islander health worker; GP, general practitioner; IUIH, Institute for Urban Indigenous Health; PCMH, patient-centred medical home; PCP, primary care physician; RN, registered nurse.

Queensland, Australia. Collectively, the clinics provide services to almost 4000 Aboriginal and Torres Strait Islander patients. These services were the first sites to have their premises redesigned and workforce reconfigured to support the ISoC2 model, the first beginning 2019, and the second in early 2020. The study evaluation began in June 2020 and will conclude in June 2025 (6-year and 5-year post-implementation of ISoC2 at site one and two respectively).
Table 1 outlines the differences in the care components between the PCMH model, IUIH’s current model of care and ISoC2. Figure 1 summarises the key changes in the care pathways that will result from implementation of ISoC2. In the ISoC2 model, team-based care comprises an Aboriginal or Torres Strait Islander health worker, administrative coordinator, registered nurse and general practitioner (GP, Australia’s primary care physicians) (operationally referred to as a ‘Pod’) working collectively to lead and coordinate care based on the patient’s identified health and wellbeing priorities. All staff in these roles were assembled into Pods, with approximately 3–4 Pods per intervention site. During implementation of ISoC2, all clients attending the service were assigned to their preferred Pod, with new clients similarly assigned throughout the evaluation study.

Study design

The study is a mixed-methods prospective cohort study, using a hybrid implementation and clinical effectiveness design (type 1) where the effect of an intervention on outcomes is tested while gathering information on implementation. The study will evaluate the model of care over three sequential phases, from June 2020 to June 2025 (figure 2). Phase 1 will examine the implementation of ISoC2 (how it is operationalised, and its feasibility and acceptability from the perspective of patients and health staff). Phase 2 will examine the effectiveness of ISoC2 on access to care, quality of care, economic costs and health and wellbeing outcomes. Phase 3 will bring the findings together to synthesise evidence on the process of implementing ISoC2 and mechanisms for change, sustainability and the translation of PCMHs and their key elements into the broader PHC system. Randomisation was not feasible in this real-world context, where the priority for implementation of a significant system reform was site readiness. Further, randomisation may also be negatively perceived by the community as restricting access to the new model of care.

Participatory action research was used to codesign a programme logic to guide the research process, ensuring that the IUIH Cultural Integrity Framework underpins the evaluation and Aboriginal and Torres Strait Islander worldviews, knowledge, realities and terms of reference are privileged throughout the research process. Participatory action research will also be used to feedback research findings to health and management staff in real time to inform a continuous process of service refinement as well as the conduct and interpretation of the research itself. A steering committee, representing potential knowledge brokers and knowledge users, including Aboriginal and Torres Strait Islander and non-Indigenous researchers, clinicians, managers and community liaison officers, will oversee the project. A clinical reference group will also meet to provide advice on long-term outcomes, including those related to linked emergency department admissions and potentially preventable hospitalisations. Both the steering committee and clinical reference group will provide oversight with respect to data sovereignty ensuring that what is measured is meaningful, culturally and clinically.

Study participants

Study participants include staff and regular patients (defined as at least three visits in the preceding 24 months). Patients are eligible to participate if they are registered with the intervention clinic, identify as Aboriginal and/or Torres Strait Islander, and, for qualitative and survey data, are at least 18 years of age. Eligible patients can choose to consent to participate in qualitative
interviews or complete a survey. Those completing the survey can also consent to having their data linked to deidentified electronic health records (at intervention clinics and hospital administrative data). Eligible staff are those currently employed at intervention clinics, or who were employed at the clinics during implementation of ISoC2 and consent to participate.

In addition, for quantitative analysis using routinely collected electronic clinic health record data, study participants will also include regular clients at standard care clinics located within the IUIH network and matched for clinic characteristics.

**Data collection**

Routinely collected health data will be extracted from electronic clinic health records for client attendance numbers, service access relative to the estimated resident population and specific health outcomes for all eligible participants. Data will be extracted retrospectively for a period of 3 years prior to implementation of ISoC2 at intervention sites, with updated extracts approximately every 12 months until the study end date. All data will be deidentified; individual participants will be given a unique identifier to enable follow-up, multi-level modelling (random effects) and for linking survey and hospital administrative data (secondary care data). Information relating to sociodemographics, long-term health conditions, medications, clinical measures (eg, blood pressure, weight and other investigation results), consultations and Medicare Benefit Schedule service item claims (for medical services funded through Medicare, Australia’s universal health insurance scheme) will be collected from routinely collected health record data.

Survey data will be collected using an adapted survey questionnaire currently used in a national study of Aboriginal and Torres Strait Islander Wellbeing (the Mayi Kuwayu (MK) study), which was developed in consultation with communities across Australia. Survey questions will inquire about clients’ sense of connection to service and care providers, relational continuity of care, adapted from standard instruments specifically for this study, and health and wellbeing outcomes from the original survey instrument (see online supplemental file for further details). Health and wellbeing outcomes are related to cultural practice and expression, health and wellbeing, health behaviours and family support and connection, which are not captured through routinely collected health record data. A random sample based on the age and sex distribution of intervention clinics will be invited to participate in the survey until final sample sizes are achieved. Two waves of survey data collection will occur—baseline survey (completed during implementation at each intervention site) and follow-up survey (completed 3 years post the baseline survey at each intervention site) (figure 2).

For controls, routinely collected clinic health data will be extracted from comparable standard care clinics based on location, clinic size and composition, history of clinic...
establishment and demographics, with at least two randomly selected controls for every intervention participant. For outcomes derived from survey data, intervention participants will be matched to at least two randomly selected controls within the MK study cohort (as these survey data are unavailable from standard care sites). Subject to MK data custodian approval, matching will be performed by the data custodians and be minimally based on age, gender, remoteness/geography of residence and other relevant sociodemographic and health characteristics.

Qualitative data will be collected from patients and healthcare providers using individual interviews. Semi-structured individual interviews with staff will explore their experiences and perceptions of ISoC2 related to coherence, strengths and limitations of the model, barriers and enablers to its implementation and the nature and extent to which providers collaborate to implement the model and embed it into everyday practice for routine delivery. Interview data will be analysed thematically to identify, characterise and explain mechanisms that promote and inhibit the implementation and embedding of ISoC2 in everyday work for routine delivery. Yarning interviews, culturally respectful conversation that is relaxed, narrative-based and emphasises the value of story telling, will be undertaken with patients from each intervention site to explore their experiences and perceptions of ISoC2. Interviews will be conducted using a yarning guide, developed by the lead for IUIH’s Cultural Integrity Investment Framework (RB), comprising domains used in patient satisfaction surveys at IUIH: Community and Belonging, Country and Culture, Health and Wellbeing, Connection, Your Clinic and One Time. Yarns will be analysed using thematic analysis, privileging interpretations by Aboriginal and Torres Strait Islander researchers and healthcare providers. Interviews with staff and clients are expected to take between 30 min and 60 min and will be audio recorded and stored in MP3 or MP4 format.

**Outcomes measures**

Primary and secondary outcomes were selected on the basis that they aligned with the study objectives, were considered a priority from the services’ perspective and reflected current guidelines. Measures will be calculated according to standard methods where available. Due to the lack of a validated culturally modified measure of self-reported patient experiences and outcomes for our population of interest, standard instruments have been adapted for this study (see online supplemental file for further details).

**Effectiveness-access, quality of care and health outcomes**

**Primary outcomes**

1. Proportion of clinic catchment population that will be active patients.
2. Proportion of regular patients with a continuity of care score of ≥75% by care team.
3. Proportion of patients with type 2 diabetes with glycated haemoglobin A1C (HbA1C) <7% (or if >7%, decreased by at least 2% from baseline).
4. Proportion of patients at high absolute cardiovascular disease risk.
5. Rates of potentially preventable hospitalisations and emergency department presentations.

**Secondary outcomes**

1. Regularity score for clients with asthma or diabetes.
2. Self-reported relational continuity of care score (collected in patient surveys).
3. Self-reported shared decision-making and reciprocity in care planning (collected in patient surveys).
4. Proportion of regular patients who have participated in a health assessment.
5. Ratio of care plan reviews to chronic disease management plans/team care arrangements.
6. Proportion of those at high absolute risk of cardiovascular disease on guideline-recommended medications (lipid-lowering and blood pressure-lowering medication).
7. Self-reported agency regarding healthcare access and engagement (collected in patient surveys).
8. Self-reported community cohesion (collected in patient surveys).

**Process outcomes related to the implementation of ISoC2 and its core components**

1. Staff perceptions and experiences of barriers and enablers (feasibility) to delivering ISoC2 (qualitative data).
2. Staff and patient perceptions and experiences of the acceptability of ISoC2 (qualitative data).
3. Patient enrolment: % of total visits with assigned pod team.
4. Distribution of care between providers: per cent of total visits with each pod team member (quantitative data).
5. Accommodation/modalities of care (quantitative data).
   - Proportions of patient consultations delivered by modality.
   - Third next available appointment by pod team and by GP (number of days).

**Power and sample size**

This study has been powered to detect changes in clinical outcomes of patients accessing care at both intervention sites pre-implementation and post-implementation of ISoC2. To be able to detect a minimum difference of 5% in the proportion of people attending the clinic from baseline (38.5%) to after implementation (43.5%) with 80% power and at a 5% level of significance using an independent $\chi^2$ test requires at least 1520 people in the catchment area (table 2). Remaining sample size calculations above are derived assuming zero correlation, thus these are conservative sample size estimates. For example, a sample size of about 250 clients with diabetes in each of the pre-time and post-time periods will have 80% power to detect a minimum difference of 0.25 SD in
continuous HbA1c (eg, from 7.4 baseline to 6.9 at post-implementation, at a 5% level of significance) using an independent samples’ t test. The sample size required to detect the same difference will be smaller with a paired sample t test, for example, assuming a precoefficient and postcoefficient of correlation of 0.2, the sample size goes down to 200 clients per time point.

The sample size for qualitative interviews with patients will be determined through the course of data collection. Recruitment will cease when sufficient numbers of participants have been interviewed to reach data saturation.

Data linkage
For linkage of survey data to clinic health record data, deidentified survey data with a unique code and linkage key will be sent as a secure encrypted file to IUIH data custodians. Linkage of clinic health record data to secondary care data (hospital admission and emergency department data) and death registration data will be performed by the Statistical Services Branch, Queensland Health, subject to data custodian approval (in progress).38

Linkage is performed by deterministic and probabilistic methods and/or the Master Linkage File, as appropriate to the in-scope cohort.

The data sets which will be linked for this study include the following:

Queensland hospital-admitted patient data collection: data for all admitted patients from public and private hospitals, and day surgery units within the state, including their date of admission and separation, primary diagnosis/other diagnoses (International Classification of Diseases [ICD] 10 codes), procedures, discharge destination, facility type as well as basic demographic and geographical information.

Emergency department minimum data collection: data for all patients presenting to emergency departments in Public Hospitals in Queensland, including their presentation/atriage/discharge date and time, triage category, arrival transport mode, visit type, principle diagnosis/other diagnoses (ICD 10 codes) and other basic demographic and geographical information.

Death Registration Data (for censoring only): includes all death registrations in Queensland.

Patient and public involvement statement
This research represents an Aboriginal led and governed partnership between community, service providers and researchers, seeking to respond to identified community priorities. The project has been initiated by and is embedded in IUIH, a community-controlled health service. Community governance and ownership of IUIH have practical expression through a board of directors that combines community-elected and independent skill-based directors, underpinned by a community accountability framework, centred on the principle that decision-making should occur at the closest level possible to clients, families and communities.

Statistical analysis
Health record and survey data will be analysed at the individual patient level. Primary, secondary and quantitative process outcomes derived from electronic health record data and linked hospital data will be summarised using descriptive statistics at 3 years prior to implementation (baseline), following the implementation phase, then at 12 monthly intervals for the follow-up period. Bivariate and regression analyses will be used to examine differences between cohorts for baseline characteristics and to quantify changes in primary and secondary outcome from pre-implementation to post-implementation of ISOc2, between intervention and standard care sites. Data allowing, multilevel (random-effects) or interrupted time series analysis will be used to quantify changes in outcomes over time (at minimum baseline and post-implementation) and to compare outcomes

| Table 2 | Power calculations for primary outcomes |
|---------|---------------------------------------|
| Outcome | From  | To     | Sample size required (regular client or relevant subgroup) | Power |
|---------|-------|--------|-------------------------------------------------------------|-------|
| Proportion of clinic catchment population that will be active patients has an absolute increase of 5% from baseline. | 38.5% | 43.5% | 1520 | 80% |
| Proportion of regular patients with a continuity of care score of ≥75% by care team increased by 10% from baseline | 41.8% | 51.8% | 392 | 80% |
| Proportion of patients with type 2 diabetes with HbA1c <7% has an absolute increase of 10% from baseline | 46% | 56% | 394 | 80% |
| Mean HbA1c difference equal to 0.5% | 7.4% | 6.9% | 253 | 80% |
| Proportion of patients at high absolute risk of cardiovascular disease decreased by 10% and 5% from baseline* | 25.3% | 15.3% | 20.3% | 1107 | 80% |
| Rates of potentially preventable hospitalisations and emergency department presentations† | 3.8% | 1.8% | 1070 | 80% |

Estimates based on data pooled from both intervention sites.

*Baseline estimates for CVD risk from ref.42
†Age-adjusted potentially preventable hospitalisation rates from ref.36
HbA1c, glycosylated haemoglobin.

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BMJ Open: first published as 10.1136/bmjopen-2022-061037 on 29 September 2022. Downloaded from http://bmjopen.bmj.com on December 14, 2022 by guest. Protected by copyright.
between intervention and randomly matched control (standard care) participants. Models adjusted for covariates (minimally age and sex, additional other sociodemographic and health characteristics) will be used to determine ORs and CIs for the association of IsoC2 with outcomes. Similar analyses will be conducted for self-reported data collected through surveys, comparing differences between intervention and matched MK survey controls, and changes between baseline and follow-up responses. Qualitative interviews with staff will be analysed using The Framework Analysis, a method of qualitative data analysis that begins deductively from predefined objectives and is explicit and informed by a priori reasoning. Interviews with patients will be analysed using Interpretative Phenomenological Analysis, a method that describes how a person experiences their world.

Economic analysis
The economic component of the study will include two types of economic analysis: cost consequence analysis and cost-effectiveness analysis (CEA). Both analyses will take a perspective from the Australian Government Department of Health, and the time horizon used in this study will be 2 years to capture the changes of chronic conditions. All the direct costs related to the management of a patient’s condition will be included: consultations with GPs or other health workers, diagnostic tests, pharmaceuticals, hospital inpatient admissions and emergency department admissions. The consultation costs will be estimated using the Medicare Benefits Schedule and the Pharmaceutical Benefit Scheme (for medications funded under Medicare) will be used to estimate the pharmaceutical costs. All the costs for hospital admissions will be estimated using Australian Refined Diagnosis Related Groups. Costs will be measured in 2025 Australian dollars and 3.5% discounting rate will be applied. Clinical outcomes in the CEA will be outcome measures that demonstrate a clinically significant improvement in the intervention group. The cost difference per patient and proportion of per achieved outcome will be calculated with a 95% CI between the standard care and intervention (IsoC2). The incremental cost-effectiveness ratio with a 95% CI will be estimated using non-parametric bootstrap (1000 replications) methods and the simulation results will be graphed on a cost-effectiveness plane. The cost-effectiveness acceptability curve will be drawn to summarise the impact of uncertainty on the results.

ETHICS AND DISSEMINATION
Consent
Prior, free and informed written consent will be enacted throughout the study. All materials for the conduct of the study (staff interview and yarning guides, surveys, client information and consent forms) have been co-designed with the steering committee providing cultural and clinical oversight of the study. Participants for survey (clients) and interviews (clients and staff) will be provided with a plain-language information sheet about the study along with a consent form. Participants may choose to withdraw at any time during the study. Survey participants have specifically consented for linkage of survey data to routinely collected health data and for health and wellbeing research (subject to approvals by the MK Aboriginal and Torres Strait Islander governance committee). A waiver of the requirement for consent has been obtained for secondary use of routinely collected deidentified health data (electronic health record and linked hospitalisation data) for intervention and standard care sites. Ethical approval for the study was obtained from the University of Queensland Human Research Ethics Committee (2021/HE000529).

DISCUSSION AND IMPLICATIONS
This study reflects the aspirations and obligation of ACCHS in South-East Queensland to build the evidence base for high-quality PHC able to meet the needs of rapidly growing urban Aboriginal and Torres Strait Islander populations. Building from the foundations of a pilot study, this research incorporates a process, outcome and economic evaluation of a model of PCMH in an ACCHS setting in Australia derived from international best evidence and adapted to local context to optimise its acceptability, feasibility and effectiveness. The study has been powered to detect a difference in clinical outcomes shown to improve with successful implementation of a PCMH.

This study is anticipated to be of direct benefit to Aboriginal and Torres Strait Islander people living in South-East Queensland through strengthened relational care and improved access to high-quality, comprehensive and culturally responsive PHC. The knowledge, learnings and evidence from this study are likely to be of public benefit through contributing new knowledge to inform policy and service delivery in the broader Australian PHC sector. If IsoC2 can be successfully implemented and demonstrates a good return on investment, this will represent an Indigenous designed and implemented, culturally safe and cost-effective model of PCMH transferable for trialling in settings in the broader context–within Australia and globally.

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Acknowledgements We acknowledge the clients of the Moreton Aboriginal and Torres Strait Islander Community Health Service (MATSICHS) Caboolture who contributed their valuable time to participate in the pilot study. We acknowledge the staff of MATSICHS Caboolture for their immense support and participation in the pilot study which informed the current study, and the IsoC2 working group who provided clinical and cultural oversight for the development of this project.

Collaborators IsoC2 Study Team members not listed as authors on this manuscript include (listed alphabetically): Adrian Carson (Institute for Urban Indigenous Health) and Raymond Lovett (The Australian National University).

Contributors CN, RB, JW, DB and AC-M led the conception and design of the study. SM, KG, LT, LC, YR and YG contributed to the design of the study. RB developed the cultural integrity framework and led the cultural oversight for this study. All authors reviewed, edited and approved the final manuscript.

Funding The study is funded by the Medical Research Futures Fund Primary Health Care Grant number 1200868.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available.

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ORCID id Danielle Butler http://orcid.org/0000-0003-4870-4544

REFERENCES

1 Thurber KA, Thandrayen J, Banks E, et al. Strengths-based approaches for quantitative data analysis: a case study using the Australian longitudinal study of Indigenous children. SSM Popul Health 2020;12:100637.
2 IUIH. Institute for urban Indigenous health annual report 2017/18. Brisbane Institute of Urban Indigenous Health; 2018.
3 Lowitja Institute. Culture is key: towards cultural determinants-driven health policy-Final report. Melbourne Lowitja Institute; 2020.
4 Paradies Y. Colonisation, racism and indigenous health. J Popul Health 2016;33:63–66.
5 Australian Institute of Health and Welfare. Australian burden of disease study: impact and causes of illness and death in Aboriginal and Torres Strait Islander people 2018. Australian burden of disease study series No. 26. cat. No. BOD 32. Canberra: AIHW, 2022.
6 Markham F, Biddle N. Indigenous population change in the 2016 census., in 2016 census papers. Canberra: ANU, 2016.
7 Temple JB, Wilson T, Taylor A, et al. Ageing of the aboriginal and torres strait islander population: numerical, structural, timing and spatial aspects. Aust N Z J Public Health 2020;44:271–8.
8 Panaretto KS, Wentong M, Button S, et al. Aboriginal community controlled health services: leading the way in primary care. Med J Aust 2014;200:649–52.
9 Turner L, Albers T, Carson A, et al. Building a regional health ecosystem: a case study of the institute for urban indigenous health and its system of care. Aust J Prim Health 2019;25:424–9.
10 Kildea S, Hickey S, Nelson C, et al. Birthing on country (in our community): a case study of engaging stakeholders and developing a best-practice indigenous maternity service in an urban setting. Aust Health Rev 2018;42:230–8.
11 Begg S. Health-adjusted life expectancy (HALE), independent epidemiological study for IUIH. Windsor: IUIH, 2017.
12 Kildea S, Gao Y, Hickey S, et al. Effect of a birthing on country service redesign on maternal and neonatal health outcomes for first nations Australians: a prospective, non-randomised, interventional trial. Lancet Glob Health 2021:9:e651–9.
13 Swerissen H, Duckett SJ, Wright J. Chronic failure in primary medical care. Melbourne: Grattan Institute, 2016.
14 Rosenthal TC. The medical home: growing evidence to support a new approach to primary care. J Am Board Fam Med 2008;21:427–40.
15 Health Policy Analysis. Evaluation of the health care homes program-intervention evaluation report 2020, volume 1: summary report. Canberra Department of health; 2020.
16 Bodenheimer T, Ghorob A, Willard-Grace R, et al. The 10 building blocks of high-performing primary care. Ann Fam Med 2014;12:166–71.
17 Primary Care Collaborative. Defining the medical home. A patient-centered philosophy that drives primary care excellence. Available: https://www.pccpc.org/about/medical-home [Accessed 18 July 2022].
18 Starfield B, Shi L, Macinko J. Contribution of primary care to health systems and health. Milbank Q 2008;83:457–502.
19 Kringos DS, Boerma WGG, Hutchinson A, et al. The breadth of primary care: a systematic literature review of its core dimensions. BMC Health Serv Res 2010;10:65.
20 Jackson GL, Powers BJ, Chattjeee R, et al. The patient-centered medical home. Ann Intern Med 2013;158:169–78.
21 Khanassov V, Piupe Y, Descoteaux S, et al. Organizational interventions improving access to community-based primary health care for vulnerable populations: a scoping review. Int J Equity Health 2016;15:168.
22 Driscoll DL, Hiraetsuka V, Johnston JM, et al. Process and outcomes of patient-centered medical care with Alaska native people at Southcentral Foundation. Ann Fam Med 2013;11 Suppl 1:S41–9.
23 Metusela C, Usherwood T, Lawson K, et al. Patient centred medical home (PCMH) transitions in Western Sydney, Australia: a qualitative study. BMC Health Serv Res 2020;20:282.
24 Lovett R, Dance P, Guthrie J, et al. Walan Girri: developing a culturally mediated case management model for problematic alcohol use among urban indigenous people. Aust Health Rev 2014;38:440–5.
25 Gottlieb K. The Nuka system of care: improving health through ownership and relationships. Int J Circumpolar Health 2013;72:doi:10.3402/iijh.v72i0.21118. [Epub ahead of print: 05 08 2013].
26 Curran GM, Bauer M, Mittman B. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. Med Care 2012;50:217–26.
27 Snijder M, Shakeshaft A, Wagemakers A, et al. A systematic review of studies evaluating Australian Indigenous community development projects: the extent of community participation, their methodological quality and their outcomes. BMC Public Health 2015;15:1154.
28 Kildea S, Hickey S, Barclay L, et al. Implementing birthing on country services for aboriginal and torres strait islander families: rise framework. Women Birth 2019;32:466–75.
29 Cochran PAL, Marshall CA, Garcia-Downing C, et al. Indigenous ways of knowing: implications for participatory research and community. Am J Public Health 2008;98:22–7.
30 Jones R, Thurber KA, Chapman J, et al. Study protocol: our cultures count, the mayi kuwayu study, a national longitudinal study of aboriginal and torres strait islander wellbeing. BMJ Open 2018;8:e023861.
31 Gardner K, Parkinson A, Banfield M, et al. Usability of patient experience surveys in Australian primary health care: a scoping review. *Aust J Prim Health* 2016;22:93–9.

32 Bessarab D, Ng’andu B. Yarning about yarning as a legitimate method in indigenous research. *IJCIS* 2010;3:37–50.

33 Jee SH, Cabana MD. Indices for continuity of care: a systematic review of the literature. *Med Care Res Rev* 2006;63:158–88.

34 Diabetes Australia. Best practice guidelines, 2018. Available: https://www.diabetesaustralia.com.au/for-health-professionals/best-practice-guidelines/ [Accessed 19 July 2022].

35 Agostino JW, Wong D, Paige E, et al. Cardiovascular disease risk assessment for aboriginal and torres strait islander adults aged under 35 years: a consensus statement. *Med J Aust* 2020;212:422–7.

36 Australian Institute for Health and Welfare. Disparities in potentially preventable hospitalisations across Australia: exploring the data, 2020. Available: https://www.aihw.gov.au/reports/primary-health-care/disparities-in-potentially-preventable-hospitalisations-exploring-the-data/data [Accessed 22 Nov 2021].

37 Moorin RE, Youens D, Preen DB, et al. The association between general practitioner regularity of care and ‘high use’ hospitalisation. *BMC Health Serv Res* 2020;20:915.

38 Statistical Service Branch Queensland Health. Queensland data linkage framework 2017, 2020. Available: http://www.health.qld.gov.au/hsu/pdf/other/qlddatalinkframework.pdf [Accessed 04 Nov 2020].

39 Ritchie J, Spencer L. Qualitative data analysis for applied policy research, in Analysing qualitative data. In: Byrman A, Burgess RG, eds. London: Routledge, 1994: 173–94.

40 Biggerstaff D, Thompson AR. Interpretative phenomenological analysis (ipa): a qualitative methodology of choice in healthcare research. *Qual Res Psychol* 2008;5:214–24.

41 United Nations. Free Prior and Informed Consent – An Indigenous Peoples’ right and a good practice for local communities – FAO, 2016. Available: https://www.un.org/development/desa/indigenouspeoples/publications/2016/10/free-prior-and-informed-consent-an-indigenous-peoples-right-and-a-good-practice-for-local-communities-fao/ [Accessed 25 Mar 2021].

42 Calabria B, Korda RJ, Lovett RW, et al. Absolute cardiovascular disease risk and lipid-lowering therapy among aboriginal and torres strait islander Australians. *Med J Aust* 2018;209:35–41.
Supplementary material-Study Protocol. Primary healthcare transformation through patient centred-medical homes: Improving access, relational care and outcomes in an urban Aboriginal and Torres Strait Islander population, a mixed methods prospective cohort study.

Outcome measures

Primary outcome measures

These were selected on the basis that they aligned with evaluation objectives, were considered a priority for the participating health service, reflect common and important conditions (for example, cardiovascular disease and diabetes which account for a significant burden of disease for the Aboriginal and Torres Strait Islander population[1]) and reflected current guidelines.

Access: The proportion of the catchment population that are regular clients at the service. This is a measure routinely used across the IUIH network in planning services and identifying areas of unmet need.

Continuity of care score (or usual provider index) [2]. This measures the concentration of a patient’s visits to the most common primary care providers among people with at least 4 attendances in a two-year period. A score of 0.75 is defined as good continuity.

Proportion of patients with Type 2 diabetes with glycosylated haemoglobin (HbA1C) <7%: as per guideline recommended targets [3]. A change from baseline was also selected given any improvement in levels will confer a clinically significant benefit in the long term.

Proportion of patients at high absolute cardiovascular disease risk [4]: Based on clinically determined risk as well as according to the Framingham risk equation as per recommended guidelines.

Rates of hospital admissions (total and separately by potentially preventable admissions and non-potentially preventable admissions) and emergency department presentations[5]: Included are hospitalisations which could have potentially been prevented through the provision of appropriate preventative health interventions and early disease management in primary care and community-based care settings (including by general practitioners, medical specialists, dentists, nurses and allied health professionals). They are often used as indicator of the effectiveness of non-hospital care and are currently used for national reporting on the Australian primary healthcare system.

Secondary outcome measures

Regularity of care score: This measures the variation in time intervals between consecutive primary care provider visits for those with 3 or more annual attendances; scores range from 0 to 1 (perfect regularity)[6], and is used as an indicator of quality primary care.

Health assessment and chronic disease care planning: All Australians who identify as Aboriginal or Torres Strait Islander are eligible to access this annual health check, which is funded by the Australian Government via Medicare. A health assessment involves an assessment by a general practitioner (GP) of a patient’s physical, psychological and social wellbeing [7]. GP management plans and team care arrangements, also funded through Medicare for those with at least one long-term condition, includes
chronic disease care planning as well as coordination and referral to other providers to enact that care plan (completed every 12 months) [7]. A review of both services can be claimed through Medicare and is recommended 6 monthly. The ratio of review items to annual care plans/team care arrangements was selected as a secondary outcome as, from the perspective of the service, this is more indicative of proactive management and follow-up than an annual claim alone. This is also consistent with the Commonwealth government approach incorporated into service incentive payments through the PIP IHI program.

Self-reported health and wellbeing: To collect information relating to health and wellbeing as understood from Aboriginal terms of reference, we used an adapted version of the survey questionnaire currently used in a national study of Aboriginal and Torres Strait Islander Wellbeing (the Mayi Kuwayu [MK] Study) [8]. This survey also collects information on cultural determinants of health and wellbeing, such as cultural practice and expression, experiences and environment and family support and connection. The baseline survey was developed through extensive community consultation and in partnership with Aboriginal and Torres Strait Islander organisations across states and territories and is an exemplar of Aboriginal and Torres Strait Islander governance. Several survey items specifically developed or culturally modified for the MK study have been[9, 10] validated or are undergoing validation. Using measures that had been developed by and for Aboriginal and Torres Strait Islander peoples was a priority of the participating services and the ISoC2 study team.

Self-reported relational continuity of care, shared decision making and agency: Patient-reported experience and outcome measures are commonly used in the literature [11]; however, there are currently limited examples of culturally modified measures that have been validated. Collaborative stakeholder consultation conducted by IUIH identified a need to include additional questions to address gaps in the MK survey around continuity of care and connection to the health service and health care team. Additional questions were developed by the investigators through iterative feedback, piloted for face validity and comprehension [12, 13] and were included in the front-end of the MK study. These questions incorporated key elements of other validated tools [14-18] whilst ensuring the use of Aboriginal and Torres Strait Islander relational language terms and ways [19, 20] and cultural responsiveness to community involved in the study [21].

This relates to the following secondary outcomes:
1. Self-reported relational continuity of care score
2. Self-reported shared decision-making and reciprocity in care planning.
3. Self-reported agency regarding health care access and engagement.

Work is currently in progress validating these self-reported patient experience measures.

Additional measures relating to processes of care (e.g documenting smoking status) and other clinical outcomes (e.g body mass index), as routinely collected for reporting requirements [22] will also be reported.

1. Australian Institute of Health and Welfare, Australian Burden of Disease Study: impact and causes of illness and death in Aboriginal and Torres Strait Islander people 2018. Australian Burden of Disease Study series no. 26. Cat. no. BOD 32. . 2022, AIHW: Canberra.
2. Jee, S.H. and M.D. Cabana, *Indices for continuity of care: a systematic review of the literature*. Med Care Res Rev, 2006. 63(2): p. 158-88.

3. Diabetes Australia. *Best practice guidelines*. 2018 19/07/2022]; Available from: https://www.diabetesaustralia.com.au/for-health-professionals/best-practice-guidelines/.

4. Agostino, J.W., et al., *Cardiovascular disease risk assessment for Aboriginal and Torres Strait Islander adults aged under 35 years: a consensus statement*. Med J Aust, 2020. 212(9): p. 422-427.

5. Australian Institute for Health and Welfare. *Disparities in potentially preventable hospitalisations across Australia: Exploring the data*. 2020 22 Nov 2021]; Available from: https://www.aihw.gov.au/reports/primary-health-care/disparities-in-potentially-preventable-hospitalisations-exploring-the-data/data.

6. Moorin, R.E., et al., *The association between general practitioner regularity of care and ‘high use’ hospitalisation*. BMC Health Services Research, 2020. 20(1): p. 915.

7. Australian Government. *Chronic Disease Management (formerly Enhanced Primary Care or EPC) — GP services*. 2014 18/07/2022]; Available from: https://www1.health.gov.au/internet/main/publishing.nsf/Content/mbprimarycare-chronicdiseaseamangement.

8. Jones, R., et al., *Study protocol: Our Cultures Count, the Mayi Kuwayu Study, a national longitudinal study of Aboriginal and Torres Strait Islander wellbeing*. BMJ Open, 2018. 8(6): p. e023861.

9. Thurber, K.A., et al., *Developing and validating measures of self-reported everyday and healthcare discrimination for Aboriginal and Torres Strait Islander adults*. International Journal for Equity in Health, 2021. 20(1): p. 14.

10. Brinkley, M.-M., et al., *Reliability, validity, and clinical utility of a culturally modified Kessler scale (MK-K5) in the Aboriginal and Torres Strait Islander population*. BMC Public Health, 2021. 21(1): p. 1111.

11. Gardner, K., et al., *Usability of patient experience surveys in Australian primary health care: a scoping review*. Aust J Prim Health, 2016. 22(2): p. 93-99.

12. Dronavalli, M., Thompson, S. C., *A systematic review of measurement tools of health and wellbeing for evaluating community-based interventions*. J Epidemiol Community Health, 2015: p. 1-11.

13. Bolarinwa, O.A., *Principles and Methods of Validity and Reliability Testing of Questionnaires Used in Social and Health Science Researches*. Nigerian Postgraduate Medical Journal, 2015: p. 195-201.

14. Desborough J, B.N., Banfield M, Mills J, Phillips C, Korda R., *The impact of general practice nursing care on patient satisfaction and enablement in Australia: A mixed methods study*. International Journal of Nursing, 2016: p. 108-19.

15. Jatrana, S., P. Crampton, and K. Richardson, *Continuity of care with general practitioners in New Zealand: results from SoFIE-Primary Care*. N Z Med J, 2011. 124(1329): p. 16-25.

16. Kristjansson, E., et al., *Predictors of relational continuity in primary care: patient, provider and practice factors*. BMC Fam Pract, 2013. 14: p. 72.

17. Haggerty JL, R.R., Freeman GK, Starfield BH, Adair CE, McKendry R, *Continuity of care: a multidisciplinary review*. BMJ, 2003: p. 1219-21.

18. Schafer WL, B.W., Kringos DS, De Maeseneer J, Gress S, Heinemann S, et al., *QUALICOPC, a multi-country study evaluating quality, costs and equity in primary care*. BMC Fam Pract, 2011: p. 115.

19. Martin, K., Mirraboopa, B, *Ways of knowing, being and doing: A theoretical framework and methods for indigenous and indigenist re-search*. Journal of Australian Studies, 2003: p. 203-214.
20. Institute for urban indigenous health annual report 2017/18. 2018, Institute of Urban Indigenous Health: Brisbane.
21. Freshtling Westat, J., A Guide to Conducting Culturally Responsive Evaluations, in The 2010 User-Friendly Handbook for Project Evaluation. 2010, National Science Foundation: Virginia. p. 75-93.
22. Australian Government. National Key Performance Indicators for Aboriginal and Torres Strait Islander primary health care. 2022 18/07/22]; Available from: https://www.health.gov.au/health-topics/aboriginal-and-torres-strait-islander-health/reporting/nkpis.