


BMJ Open Theory-informed process evaluation protocol to assess a rapid-access outpatient model of care in South East Queensland, Australia

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To cite: Earnshaw A, Carter HE, Wallis S, *et al.* Theory-informed process evaluation protocol to assess a rapid-access outpatient model of care in South East Queensland, Australia. *BMJ Open* 2025;**15**:e089438. doi:10.1136/bmjopen-2024-089438

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<https://doi.org/10.1136/bmjopen-2024-089438>).

Received 30 May 2024

Accepted 13 February 2025



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ABSTRACT

Introduction Chronic diseases place a large burden on health systems globally. While long-term planned care is essential for their management, episodes of deterioration are common. The emergence of rapid access to outpatient care has proliferated in response to increased resource pressures on acute health services. It is anticipated that these new models of care may prevent hospitalisations and reduce the burden on emergency departments. While some evidence supports the clinical effectiveness of these models, little is known about the core components and key attributes of these services. This paper outlines the protocol of a theory-driven, pragmatic process evaluation embedded within a new rapid-access outpatient service for chronic disease in South East Queensland, Australia.

Methods and analysis This mixed-methods process evaluation will be conducted across three phases: (1) context assessment to identify programme characteristics and core components; (2) evaluation of key service processes and development of service improvement strategies and (3) sustainability assessment, with a focus on programme embedding and the resources associated with service evaluation. Each phase will be guided using implementation science frameworks and/or theory. Participants will include service consumers, service delivery staff, implementation leaders and decision-makers and wider system referrers. Professional stakeholders will be recruited through a direct invitation to participate (using purposeful sampling methods) and will be engaged in interviews at 1–3 data collection time points. Service consumers will be recruited through direct advertisement to participate in interviews. Administrative and clinical data collections will be retrospectively analysed with descriptive and inferential methods and triangulated with qualitative data to yield primary and secondary outcomes.

Ethics and dissemination Ethical clearance has been obtained from the West Moreton Hospital and Health Service Human Research Ethics Committee. The planned dissemination of results will occur through conferences, abstracts and publications.

Trial registration number Australia and New Zealand Clinical Trials Registry (ANZCTR Trial ID: ACTRN12624000757516).

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This protocol outlines a theory-informed process to robustly evaluate an implemented model of care in an outpatient setting.
- ⇒ Using a theory-informed process could be generalisable to similar outpatient settings, thereby offering a standard operating procedure for similar evaluations.
- ⇒ This is a single-arm implementation evaluation, and clinical effectiveness cannot be examined.

INTRODUCTION

Chronic diseases (particularly comorbidity and multimorbidity) present a significant burden on individuals,^{1 2} families,³ health systems and broader societies globally.^{4–7} The persistent and progressive nature of chronic diseases has prompted a global call for the reorientation and redesign of healthcare from traditional, episodic care in the hospital and specialist outpatient settings to person-centred, integrated care in the primary and community care settings.^{8 9} While planned long-term care is necessary for chronic condition management, acute exacerbations and deterioration can occur, which can lead to avoidable hospitalisations.^{10–12}

Rapid-access outpatient care models respond to the challenges posed by preventable hospitalisations by offering a middle ground between acute care delivered in hospital settings and specialist outpatient services. This model may promote effective management, thus providing a clinically appropriate alternative to acute hospitalisation.¹³ While such services have demonstrated clinical effectiveness in improving some patient outcomes,^{14–16} reducing health system burden^{17 18} and cost-effectiveness,^{19–21} little is known about the core components²² and implementation determinants²³

associated with optimal service delivery. Identifying core components may aid in determining the minimum set of programme characteristics required to deliver the service as intended. Additionally, characterising the impact of this model of care on patients and their families, as well as the staff to deliver and support it, is essential for programme optimisation, sustainability and future scalability.

However, this can be challenging because health systems are considered complex adaptive systems, as they demonstrate a variable rate of change, unpredictability and emergent characteristics.^{24 25} They are also complicated, as they include multiple components and resourcing elements in addition to an array of behavioural expectations.²⁶ Implementation science seeks to consider these characteristics through the application of theoretically informed methodologies to support the delivery, uptake and sustainment of these complex interventions or programmes into complex adaptive systems.^{27–29} The use of theory-informed process evaluations, while somewhat limited in current literature,³⁰ offers a means to enhance conceptual clarity, contextual planning and transparent methodology.^{30 31}

The Preventative Integrated Care Service is a rapid-access outpatient care model that was recently established in South East Queensland, Australia. It provides a 14–16-day rapid assessment and medical stabilisation service offering intensive specialised medical management of adults living with chronic respiratory diseases, chronic cardiovascular diseases and/or diabetes. Preventative Integrated Care Service is delivered by a specialist-led, multidisciplinary care team and is delivered through multimodalities (eg, in clinics, via telephone, through remote biometric monitoring and during home visits). This programme was established in November 2022, without implementation evaluation planning at its inception. As such, this research is considered pragmatic, as it will evaluate an established service embedded within a local health system with limited additional resourcing.

This protocol aims to outline a theory-informed, pragmatic approach to evaluating a novel, rapid-access outpatient model of care for people living with one or more chronic conditions. This will involve addressing the following objectives:

1. Describe the context in which the service operates, identifying determinants and core components, as well as barriers and enablers to service delivery and implementation effectiveness.
2. Describe implementation processes, measure implementation outcomes and identify opportunities for service iteration and adaptation.
3. Conduct a sustainability assessment, identifying resources associated with service evaluation and factors influencing long-term service spread, scale-up and sustainability.

It is hypothesised that this theory-informed process evaluation will lead to a set of contextually appropriate and acceptable strategies for service improvement.

METHODS

Study design

This is a mixed-methods, pragmatic process evaluation employing an adapted, theoretically informed design³² that will be conducted in three phases. Phase 1 will involve a framework-informed context assessment to identify programme determinants and core components. Phase 2 will involve a theory-informed process evaluation of overall service delivery and the identification of related service improvement strategies. Phase 3 will examine programme sustainability, which will incorporate the resources associated with conducting the service evaluation. The study duration will be approximately 18 months (June 2024–December 2025). The Standard Protocol Items: Recommendations for Interventional Trials checklist³³ was used to inform the development of this protocol.

Theoretical rationale

This research has been developed with an underlying epistemology of complex systems theory. As such, this research will employ three Implementation Science frameworks to address the three study objectives. The use of multiple Implementation Science theories, models and frameworks is commonplace, yet each should be used parsimoniously and thoroughly.³⁴

The context assessment will use two deterministic frameworks to systematically investigate the characteristics in which the service is being delivered. Deterministic frameworks enable a hierarchical and systematic understanding of complex interventions, such as health services. This context assessment will be informed by the Consolidated Framework for Implementation Research (CFIR).³⁵ The CFIR categorises 48 contextual determinants that influence implementation activities across five domains, offering insights into the services' organisational and policy environment, barriers and enablers. The CFIR has been used to identify common contextual influencers across a range of health settings and similar human social systems worldwide.³⁶ The second framework to be employed for the context assessment is the Non-Adoption, Abandonment, Scale-up, Spread and Sustainability (NASSS) framework. The NASSS framework was specifically developed for the study of the implementation of digital innovations in healthcare. It describes seven domains—health condition, technology, value proposition, adopters, organisation(s), wider system and embedding and adaptation over time.³⁷ This framework will be included due to the use of several aspects of digitally enabled care in the Preventative Integrated Care Service model and the ubiquitous use of electronic medical records and scheduling.

The final two phases of research will be informed by the Theoretical Domains Framework (TDF). The TDF is a validated behaviour change model that seeks to identify factors influencing implementation outcomes within a range of behavioural contexts. The TDF has been selected to address the behavioural influences of actors within complex systems and has been successfully used

in conjunction with the CFIR.³⁸ The TDF comprises 14 domains, including beliefs about capabilities, social influences and social/professional roles and identities that facilitate the assessment of behavioural contributions to implementation efforts,³⁹ and it has been used to identify, modify and inform solutions for a range of healthcare problems.^{40–42} The TDF will be used to identify behaviourally specific barriers and enablers to service delivery and related behavioural influences. These findings will then be used in facilitated service improvement workshops to develop and identify key improvement factors and related strategies.

Study setting

There are three main study settings. The first study setting involves recruiting participants who work within and receive care from the Preventative Integrated Care Service delivery model. The Preventative Integrated Care Service operates from an outpatient clinic located a short distance from a major acute teaching hospital in metropolitan South East Queensland. The service operates with a multidisciplinary staff of approximately 30 clinicians constituted of medical, nursing and allied health (eg, physiotherapy, dietetics, pharmacy and social work) professionals. It offers multimodal delivery via face-to-face clinic, home visits, telehealth and remote biometric monitoring.⁴³ Within the first 6 months of operation, the Preventative Integrated Care Service provided over 4000 occasions of service and received 710 referrals.⁴⁴

The second study setting involves participants who serve as executive decision-makers within the larger West Moreton Hospital and Health Service under which the Preventative Integrated Care Service operates. West Moreton Hospital and Health Service serves the aforementioned catchment area and operates one major acute teaching hospital (231 beds), four rural hospitals (approximately 20 beds each) and one minor injury and illness clinic.⁴⁵

The third study setting involves referrers to the Preventative Integrated Care Service operating within the West Moreton catchment area. This includes a population of approximately 330 000 persons served by 91 general practitioner clinics. The population is characterised by 5.2% identifying as First Nations and 10.6% as persons born overseas in a non-English-speaking country. The median age of this catchment area is 35.2 years, with approximately 13.1% of the population aged over 65 years.

Additionally, 51% of the population live in geographical areas of high relative socioeconomic disadvantage, as defined by the Index of Relative Socioeconomic Advantage and Disadvantage.⁴⁶

Participants and recruitment

There are four categories of participants in this study, which have been classified in alignment with the NASSS Framework. Table 1 summarises the four participant categories, the study setting from which each participant category will be recruited and the target sample sizes at each qualitative data collection time point throughout the research period. Sample sizes are both pragmatic and sufficient to achieve thematic saturation.⁴⁶

Adopters: consumers receiving the Preventative Integrated Care Service

Consumer participants who meet the following inclusion criteria will be invited to participate: they must meet the Preventative Integrated Care Service eligibility criteria (see online supplemental appendix A), have received services in the past 6 months and be aged 18 years or older at the time of programme enrolment. Participants may wish to attend interviews with a carer or support person. Participants who require an interpreter will be supported through the use of translating and interpreting services. Exclusion criteria include consumers who do not meet the Preventative Integrated Care Service eligibility criteria and/or have not been engaged with the Preventative Integrated Care Service within the past 6 months.

These participants will be recruited through posters and leaflet advertisements placed in the Preventative Integrated Care Service clinic spaces. Preventative Integrated Care Service consumers will be made aware of the research project by the staff at the completion of their appointments. Posters and leaflets will display a brief overview of the research project, a QR code that will take participants through to an online platform (where a digital copy of the participant information and consent form is available) and contact details of the principal investigator. Participants will be asked to contribute to an initial interview and a 6-month follow-up interview. Reciprocity will be provided to consumer participants for their time in the form of \$A60 grocery vouchers for each completed interview.

All consumer interviews will be conducted via telephone, following the return of completed consent forms.

Table 1 Participants, study setting and sample sizes throughout the research period

Participant category	Study setting			Sample size at data collection time points		
	Preventative Integrated Care Service	Hospital and health service	Wider system	t1	t2	t3
Adopters (consumers)	✓			n=30		
Adopters and implementers (service delivery staff)	✓			n=15	n=15	n=3–5
Implementation decision-makers		✓		n=5	n=5	
Wider system referrers		✓	✓			n=10

The researchers will schedule a time that is most convenient for each consumer. Each interview will run for approximately 45 min.

Adopters and implementers: Preventative Integrated Care Service staff who are delivering the service protocol

Participants within this group will be West Moreton Hospital and Health Service employees who are involved in delivering the Preventative Integrated Care Service protocol. This will include clinicians and support staff (eg, administration) delivering the Preventative Integrated Care Service and professionals who are responsible for financial, informatics and technological support to the Preventative Integrated Care Service. Snowball purposeful sampling strategies⁴⁷ will be employed. This will be facilitated by the West Moreton Hospital and Health Service research team members to ensure an even distribution of participants across disciplines (ie, medical, nursing, allied health, administrative and informatics) via a stratified recruitment process. The authors, AE and SW, who are embedded within the health service, will identify prospective participants who are likely to meet the inclusion criteria. Recruitment will be monitored by a member of the research team and iterated accordingly to ensure representation. Initial contact will be made by the research team via email, where a copy of the participant information and consent form (professional) will be available. At least one member of the research team will attend a regular, scheduled Preventative Integrated Care Service team meeting to introduce the research prior to initial contact being made.

Inclusion criteria for these participants include any current team member within the Preventative Integrated Care Service or individuals contributing subject matter expertise to service delivery components of the Preventative Integrated Care Service throughout the study period. Exclusion criteria include staff members who have not worked within the Preventative Integrated Care Service during the study period and staff external to the West Moreton Hospital and Health Service.

Participant interviews will be conducted face-to-face via telephone or virtual meeting for approximately 45 min. Interviews will be scheduled during usual working hours (07:00–17:00). Participants recruited to fulfil study objective 1 will be contacted for their participation in study objective 2. Informed consent will be sought prior to each interview.

Implementation decision-makers: health service directors and executive leaders

Participants within this group will consist of West Moreton Hospital and Health Service staff who have professional and/or operational leadership delegation over one or more components of the Preventative Integrated Care Service (eg, Executive, Team Leader, Allied Health Directors and Informatics Managers) within the study period. Purposeful sampling methods will be employed by the research team and facilitated by West Moreton Hospital

and Health Service research team members to ensure an even distribution of participants across organisational seniority and discipline via a stratified recruitment process. Identification of prospective participants, initial contact, informed consent and interview scheduling will follow the same processes noted above for adopters and implementers.

Wider system referrers: general practitioners and other specialists within the catchment area

Primary care providers and referring West Moreton Hospital and Health Service staff will be invited to participate in a semistructured interview. An invitation to participate will be made via an introductory phone call or email by authors SW or AE. A follow-up letter to participate and participant information and consent form will be sent by email.

The research team will schedule these 30 min interviews during regular working hours (07:00–17:00). Exclusion criteria include general practitioners practising in the catchment area and secondary referrers who have never referred to any West Moreton Hospital and Health Service programme or service. Sampling rates for each participant group will be described further below.

Study phases and outcomes

Phase 1: context assessment

The initial phase of this research will conduct a context assessment to identify contextual determinants and core components. The context assessment will enable the development and baseline audit of current workflows within the service. The primary outcomes for phase 1 (context assessment) of this research are the identification and definition of core components, programme determinants and qualitative exploration of consumer experiences of the Preventative Integrated Care Service. Secondary outcomes are the identification of barriers and enablers to service delivery. 9 domains of inquiry for the context assessment will be triangulated from two determinant frameworks (CFIR and NASSS) and agreed to by consensus of the research team. The triangulation of CFIR and NASSS will provide a taxonomy for a consistent description of context at two time points (t1 and t2). The preliminary hierarchical view of this research has been defined through multilevel inner and outer settings, as noted in [figure 1](#).

CFIR-informed and NASSS-informed semistructured interviews will be conducted with service delivery staff (n=15) and implementation decision-makers (n=5) to generate qualitative data. Key service delivery actions and associated barriers and enablers will be generated from the triangulation of interview and document content data. Two process maps will be developed from these key actions to reflect both levels of adopters—the consumer (ie, patient journey) and service delivery staff (ie, clinical and administrative workflow) perspectives.

A facilitated focus group discussion will be conducted at the end of this phase with a subsample of service delivery

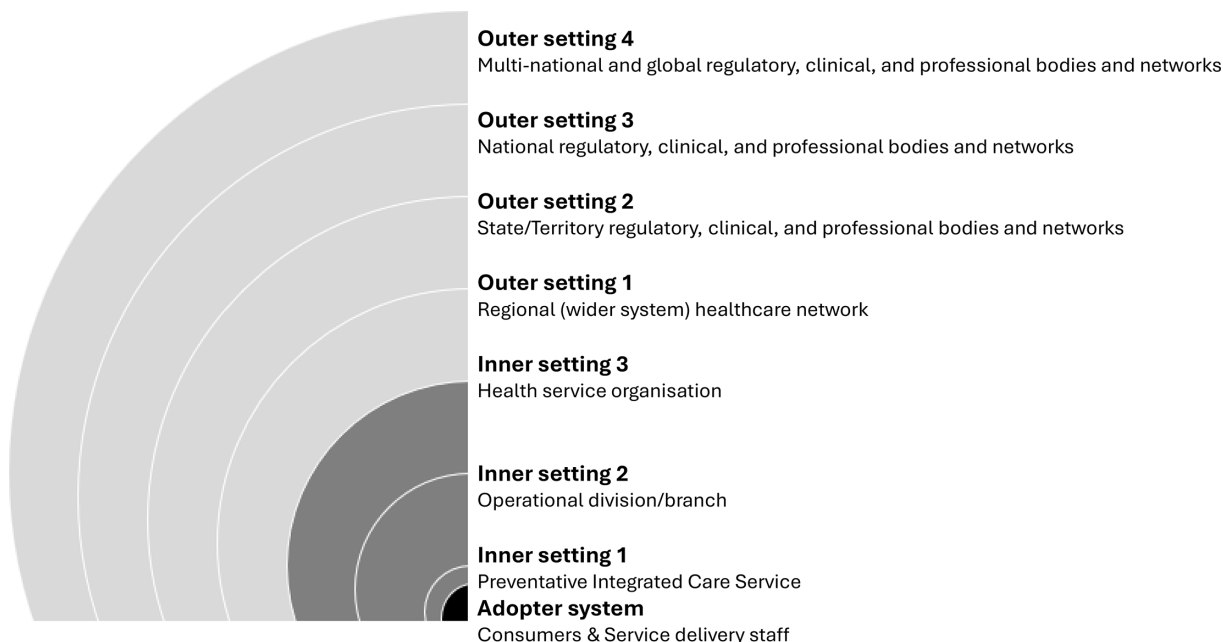


Figure 1 Hierarchical ecosystem.

staff and implementation decision-makers (n=3–5) using context assessment findings to identify core components and determinants of the Preventative Integrated Care Service programme. Consumer perspectives on the acceptability and appropriateness of core components and service attributes will be examined through semi-structured interviews (n=30).

Phase 2: process evaluation

The process evaluation (phase 2) will examine two primary outcomes—fidelity and adoption. This research will consider fidelity in the context of the fidelity/adaptation dilemma—the degree to which contextually appropriate changes to a programme are made from the original design while maintaining its effectiveness.^{48 49} As such, fidelity will examine how the service is delivered compared with its initial intent, perceptions of and participation in the service and the interaction between these factors.⁵⁰ Adherence to the service protocol will be qualitatively examined through semistructured interviews with service delivery staff (n=10–15) and implementation

decision-makers (n=3–5) at two time points (t1 and t2). Quantitative investigation of fidelity will use administrative data collections to assess attributes of the Preventative Integrated Care Service model, such as the length of time from referral to assessment and length of stay in the service. Preventative Integrated Care Service consumers' perceptions of the appropriateness of Preventative Integrated Care Service core components will be qualitatively explored through semistructured interviews informed by CFIR and NASSS. Service delivery staff's and implementation decision-makers' perceptions of core components' appropriateness will be explored with semistructured interviews across two time points (t2 and t3; refer to [figure 2](#)) informed by TDF. Wider system referrer (n=10) appropriateness will be measured through semistructured interviews (at t3) informed by the TDF.

Phase 2a: theory-informed mapping of processes

Key attributes, characteristics and determinants identified during the context assessment will be mapped to the TDF domains by the research team. Moore *et al*⁸¹

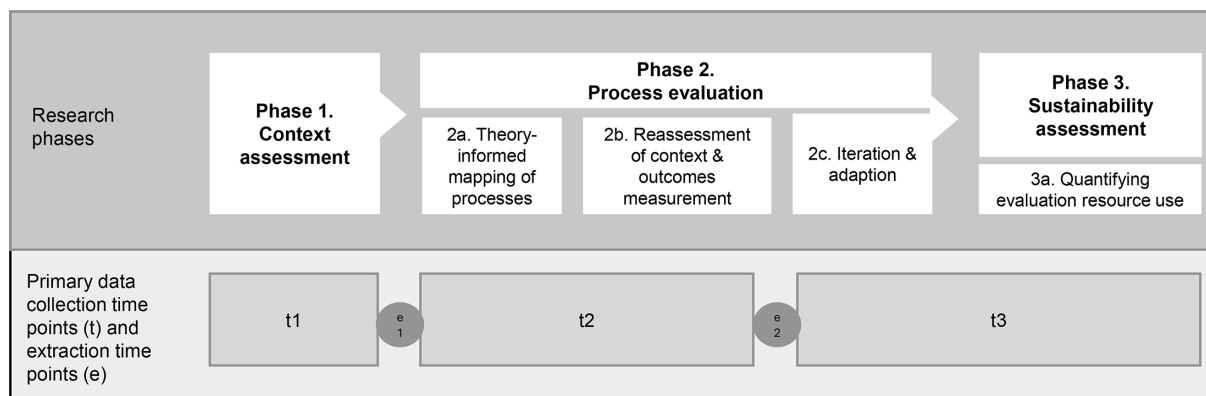


Figure 2 Outline of theory-informed process evaluation across three time points.

showed that an important role for process evaluations for complex interventions is to understand actual implementation—understanding the quantity and quality of what was implemented in practice and why. As such, service delivery processes will be examined through more than one technique (eg, interviews, document analysis and descriptive analyses of retrospective data) and triangulated. Semistructured interview guides will be developed to examine behavioural influencers on service delivery processes. These interview guides will be developed in alignment with the TDF domains, constructs and processes identified in phase 1. Semistructured interviews will be conducted with adopters and implementers (ie, service delivery staff, n=15) and implementation decision-makers (n=5).

The triangulation process will use a triangulation matrix that will denote key activities identified in process maps developed in phase 1 and TDF domains. Key insights from the semistructured interviews and document content analysis will be placed in this matrix alongside quantitative measures of processes. The latter will be defined through consideration of existing data sources, such as referral information and routine administrative data collections, as noted in [table 2](#).

Phase 2b: reassessment of context and implementation outcomes measurement

Reassessment of context and measurement of implementation outcomes will be conducted at two intervals, 6 months apart (t1 and t2). Reassessment of context will be concurrently undertaken using the domains of inquiry noted in phase 1, with a subsample of service delivery staff (n=3–5). The subsample of service delivery staff will review the determinants (including barriers and enablers) and workflow process maps with the research team. The research team will record any changes and produce new versions of these documents.

Implementation outcomes will be triangulated from qualitative data generated from interviews, document content analysis and quantitative measures sourced from routine administrative and clinical data collections (see [table 2](#)). Key insights will be entered into a triangulation matrix developed with the outcome of interest and data source.

Phase 2c: iteration and adaptation

Behavioural influencers (such as skills, optimism and social influences) will be identified in phase 2a. In phase 2c, these will be mapped to intervention functions³⁹ by the research team. These intervention functions are promoted through the application of one or more policy categories, including fiscal measures and legislation.²⁶ This will produce an initial set of recommended strategies to iterate and adapt the Preventative Integrated Care Service. A full-day workshop will be held with a subsample (n=5–10) of adopters and implementers (ie, service delivery staff) and implementation decision-makers to discuss initial strategies, generate further

solutions to barriers and optimise enablers. These will be refined following the completion of the workshop by assessing alignment to TDF intervention functions. The research team will synthesise workshop results and present the potential service improvement strategies to the same cohort of participants in a follow-up workshop. The research team will not participate in any decisions regarding proposed changes, but will document the outcomes of these decisions as part of the process evaluation.

Phase 3: sustainability assessment

In phase 3, we will undertake a sustainability assessment informed by findings from phase 2. Sustainability as an outcome will be investigated by mapping the number and types of iterations and related adaptations for service delivery to sustainability components as defined by Lennox *et al*,⁵¹ as noted in [table 3](#).

Wider system referrers (n=10) will participate in TDF-informed semistructured interviews to examine behavioural influencers on referrals to the Preventative Integrated Care Service and care continuity for consumers. Key findings from the process evaluation and data generated from wider system referrer interviews will be assessed and mapped to sustainability constructs ([table 3](#)) by the research team. A triangulation matrix will be developed using Lennox *et al*'s⁵¹ sustainability constructs and participant categories (eg, service delivery staff and implementation decision-makers). Key qualitative findings and quantitative measures reflecting other primary and secondary outcomes will be entered into this triangulation matrix. This triangulation matrix will enable the synthesis and identification of factors that promote or inhibit the sustainability of the Preventative Integrated Care Service.

Phase 3a: quantifying evaluation resource use

An important and often overlooked factor in healthcare programme sustainability is the use of long-term evaluations, which may be related to short-term funding cycles in the healthcare sector.⁵² While there is limited past literature on the role of evaluation in programme sustainability, costing methods from similar papers will be applied. Cost categories, as informed by extant literature, will include personnel and on-costs (medical, nursing, allied health, administrative and research), equipment and overheads.^{53–55} Resource consumption will be prospectively collected throughout the lifetime of the research using project log spreadsheets. This resource information may be used in subsequent cost analysis studies, which are outside the scope of the current protocol.

Patient and public involvement

Patients and the public were not involved in the conceptualisation of this research protocol.

Table 2 Primary and secondary outcomes

Outcome type			Research phase					Participant category			
Primary	Secondary	Outcome	Quantitative measures	Quantitative measures	1: context assessment	2: process evaluation	3: sustainability assessment	Consumers	Service delivery staff	Decision-makers	Wider system referrers
✓		Core components	CFIR-informed and NASSS-informed semistructured interviews.		✓			✓	✓	✓	
✓		Programme determinants	CFIR-informed and NASSS-informed semistructured interviews.		✓			✓	✓	✓	
	✓	Barriers and enablers	CFIR-informed and NASSS-informed semistructured interviews.	Service performance data audit.	✓	✓					
✓		Consumer experiences	CFIR-informed and NASSS-informed semistructured interviews.		✓			✓			
✓		Fidelity	TDF-informed semistructured interviews.	Length of time from referral to assessment (days). Length of stay in service (days). Adherence to remote biometric monitoring protocol (proportion do/do not adhere)		✓			✓	✓	
✓		Adoption	CFIR-informed and NASSS-informed semistructured interviews TDF-informed semistructured interviews.	Number of unique consumers. Number of referrals by source. Service utilisation rate, disaggregated by demographic characteristics (e.g., First Nations status, gender). Consumer failure to attend rate (number of completed appointments as a proportion of scheduled appointments)	✓	✓	✓	✓	✓		✓
	✓	Service iteration and adaptation	TDF-informed workshop.			✓	✓		✓	✓	

Continued

Table 2 Continued											
Outcome type			Research phase					Participant category			
Primary	Secondary	Outcome	Quantitative measures	Quantitative measures	1: context assessment	2: process evaluation	3: sustainability assessment	Consumers	Service delivery staff	Decision-makers	Wider system referrers
✓		Sustainability	TDF-informed semistructured interviews.			✓	✓		✓	✓	✓
	✓	Evaluation resource use	TDF-informed semistructured interviews.	Prospective collection using project logs.			✓		✓	✓	
CFIR, Consolidated Framework for Implementation Research; NASSS, Non-Adoption, Abandonment, Scale-up, Spread and Sustainability; TDF, Theoretical Domains Framework.											

Table 2 Continued

Data collection and analysis

Interviews and focus groups

Qualitative data analysis has been informed by and will be reported according to the Consolidated Criteria for Reporting Qualitative Studies.⁵⁶ Semistructured interviews and/or focus groups will be conducted across all participant groups (ie, consumers, service delivery staff, decision-makers and wider system referrers). Interviews/focus groups will be led by the primary researcher and informed by interview guides. These will be de-identified, audio recorded and transcribed verbatim. De-identified transcripts will be imported to NVivo V.14 and undergo open coding using reflexive thematic analysis.⁵⁷ Codes will be identified through the domains and constructs of the implementation science frameworks (ie, triangulated CFIR and NASSS constructs) in phase 1 (context assessment) and TDF and study primary outcomes in phases 2 (process evaluation) and 3 (sustainability assessment). Reflexivity will be practised through the maintenance of a reflexive journal, fortnightly supervision and transcript memos. Semistructured interview guides will be iterated in accordance with insights generated from reflexivity, which will also enhance the richness of data. Refer to online supplemental appendices B–D for initial interview guides.

Document analysis

Documents to undergo analyses will be identified by the research team and spontaneously through participant engagement (eg, interviews). Documents will include models of service; policies, protocols and work instructions; meeting agendas and minutes and legislative, policy and regulatory guidance. Documents will be retrieved from relevant websites or shared by the health service-embedded research team members. These will be collated and analysed by the principal investigator. Copies of selected documents will be downloaded, reviewed and annotated. An assessment of each document's authenticity and characteristics will be undertaken. Line-by-line mixed inductive and deductive analyses will be conducted using NVivo V.14. Salient information and insights will be mapped to the domains of inquiry (ie, triangulated CFIR and NASSS constructs) in phase 1 (context assessment) and TDF and study primary outcomes in phase 2 (process evaluation).

Collaborative workshops

At the final data collection time point (t3), collaborative workshops will be facilitated by the research team to identify and refine TDF-informed strategies for service iteration and adaptation. Participants will include at least two members of the research team and a subsample of implementation deliverers and decision-makers. Workshops will be held face-to-face, audio recorded, de-identified and transcribed verbatim by the research team. A written summary of the workshops will be provided to participants within 1 week of its completion. De-identified transcripts will be imported to NVivo V.14 and undergo

Table 3 Sustainability measures

Sustainability construct (Lennox <i>et al</i> ⁵¹)	Measure
Initiative design and delivery	Adaptations to ensure patient safety and quality of care.
Negotiating initiative processes	Adaptations in referral, care coordination and discharge processes.
People involved	Consumer perspective—experience, wait times and attrition. Service delivery staff—experience, burnout and skills.
Resources	Security/longevity of funding—actual and perceived (adopter system—service delivery staff to regional healthcare network). Workforce—retention, succession planning and turnover.
Organisational setting	Degree of normalisation of referrers' use of Preventative Integrated Care Service.
External environment	Referrer's awareness of the Preventative Integrated Care Service and the degree of normalisation of care team's use of Preventative Integrated Care Service. Political intentions—service alignment to State/Territory strategic intent.

reflexive thematic analysis.⁵⁷ Initial analyses will apply codes derived from the TDF domains and constructs, with secondary inductive analyses to generate additional codes as appropriate.

Retrospective data collection

De-identified, routinely collected administrative data collections (including referral information and hospital admissions) will be accessed retrospectively from data custodians. Descriptive and inferential statistics will be conducted in Jamovi V.2.5 to describe contextual determinants, service processes and costs. Such data includes referral data (eg, demographic information, referral source and primary reason for referral) and Preventative Integrated Care Service utilisation data (eg, length of stay in service, failure to attend, services provided by the healthcare team and discharge information).

Quantifying evaluation resource use

Research project logs will be prospectively developed and maintained. These will note the staff engaged by a professional stream (eg, nursing) and the length of time contributed to the evaluation activity. These will then be assigned a cost category (eg, wages and consumables) and an activity category (eg, data extraction, ethics and governance). Electronic calendars will be used alongside project logs to quantify professional and researcher time allocation. Unit costs will be determined from budget data and publicly available wage data.

DISCUSSION

To the authors' knowledge, this is one of the few theory-informed, pragmatic evaluations of a rapid-access outpatient model of care within a metropolitan health system. This proposed pragmatic methodology has been adapted to meet the situational context and constraints often experienced in health systems, such as lack of prospective evaluation strategies and planned programme roll-out informed by implementation science principles and/or theories, limited fiscal resource allocation to support evaluations, short timeframes associated with clinical service

development to deployment and lack of comparator services. Through documenting this protocol, we seek to provide a rigorous, theoretically informed evaluation for translation into similar contexts and settings. This methodology seeks to add to the implementation science knowledge on applying theory-driven process evaluations, of which there remains a paucity of knowledge.³⁰

This study will contribute to the progression of a minimum standard or guideline for conducting pragmatic, standalone effectiveness-implementation evaluations in real-world settings. Further, this evaluation will demonstrate how the application of process, deterministic and theoretical implementation frameworks and models can inform service iteration and quality improvement in an ongoing and sustainable manner. These approaches may then be adapted to other similar service models in varying contexts. Finally, this is one of the first studies known to the authors to prospectively plan the cost of a theoretically informed evaluation and explore how these costs influence service sustainability. This will inform how healthcare decision-makers identify and prioritise resources when planning for programme evaluations in the future.

LIMITATIONS

This protocol describes a single-arm, pragmatic evaluation and, as such, may be generalisable to health jurisdictions with similar contextual determinants. The ability to conduct a comparative analysis, and thereby establish clinical or cost-effectiveness, is limited for two reasons—there is not a comparator service in an alternative health district, and the short intervention duration of the service restricts the ability for pre-post designs.

ETHICS AND DISSEMINATION

This study has been approved by the human research ethics committee of West Moreton Hospital and Health Service (HREC/2023/QWMS/99335). Each participant in the study will be asked for written informed consent

prior to the commencement of interviews. Qualitative data collection will occur in a de-identified manner. A waiver of consent has been approved for the use of routine administrative data collections and incidental disclosure of personally identifiable information to the research teams during field observations and other qualitative data collections. Data management will occur as described in the Queensland University of Technology Data Management Plan 6704, adhering to Queensland University of Technology and West Moreton Hospital and Health Service data management protocols. This trial is registered with the Australian New Zealand Clinical Trials Registry (ANZCTR Trial ID: ACTRN12624000757516). Information collected through the ANZCTR is aligned with the WHO Trial Registration Data Set.

Committees

This research will be overseen by a project steering committee, including academic staff and student(s) from Queensland University of Technology and clinical advisory staff from West Moreton Hospital and Health Service. This steering committee will oversee study protocol implementation, and amendments to the protocol are communicated, ensuring risk management is in alignment with that outlined in HREC/2023/QWMS/99335 and the data management plan.

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Acknowledgements The authors wish to acknowledge Dr. Mei-Ching Freeman and Therese Hayes for their clinical advice, ongoing support, and advocacy for this research.

Contributors AE, SN, HC, SW, KM and SMM were responsible for study design and protocol and manuscript development. SN and AE were responsible for the conceptualisation of process evaluation, review and feedback on the protocol manuscript. AE drafted the initial manuscript, and all authors were responsible for review, feedback and approval of the protocol document. SN is responsible for the overall content as guarantor.

Funding This study was supported by the Queensland University of Technology and West Moreton Hospital and Health Service. AE is a recipient of an Australian Government Research Training Programme Scholarship and West Moreton Hospital and Health Service stipend top-up.

Competing interests None declared.

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

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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