


BMJ Open Implementation of a nurse-led, multidisciplinary model of care for older adults with cancer: a process evaluation protocol

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ABSTRACT

Introduction Cancer is predominantly a disease of older adults, with an increasing number of cancer diagnoses in individuals aged 65 or older. Multiple geriatric factors have been shown to impact patient outcomes in cancer treatment. However, oncology specialists are not well adapted to incorporate geriatric assessment into practice due to a lack of resources and knowledge of the specialty. The primary aim of this study is to implement and evaluate a nurse-led, multidisciplinary model of care for older adults with cancer at two public tertiary hospitals in Melbourne, Australia.

Methods and analysis This study will aim to assess 200 patients across 2 sites. Both sites will assess individuals with lung cancer; the second site will also include individuals with genitourinary, upper gastrointestinal and colorectal cancers.

This process evaluation will use quantitative and qualitative methods to explore the reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) of the nurse-led, multidisciplinary model of care.

Ethics and dissemination Ethical approval and local governance approvals have been obtained by Austin Health and Monash Health Human Research Ethics committees. Dissemination will occur via publications, conferences, social medical and local engagement with clinicians, consumers and managers.

INTRODUCTION

Cancer is predominantly an age-related disease, with approximately 60% of new cancer diagnoses and 70% of all cancer deaths occurring in individuals aged over 65 years.¹ Despite this, there is a paucity of safety and efficacy data on older adults due to underrepresentation in clinical trials, making treatment decisions in this population challenging. Older adults are highly heterogeneous, and evidence has shown that chronological age is a poor predictor of treatment tolerability and overall survival.² Common performance status measures like the Karnofsky Performance Status Scale³ or Eastern Cooperative Oncology Group Performance Status Scale⁴

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The development of a nurse-led, multidisciplinary model of care for older adults with cancer addresses common barriers to the implementation of geriatric oncology models of care.
- ⇒ The study includes an evaluation of the acceptability of in-home assessments of older individuals with cancer versus those undertaken in the hospital environment.
- ⇒ A limitation of the model is that it does not offer assessment via telehealth.
- ⇒ The model allows for consultation with a geriatrician for all older individuals with cancer following the nurse-led assessment.
- ⇒ The study will implement and evaluate the model of care using the Reach, Effectiveness, Adoption, Implementation and Maintenance framework.

frequently fall short in their ability to predict treatment tolerability and overall survival in older adults with cancer.⁵ However, domains included in a comprehensive geriatric assessment (CGA) such as comorbidities, physical capacity and nutritional status, have consistently been found to predict overall survival.^{6,7}

There is level I evidence that integration of geriatric assessment into oncology care improves patient outcomes. A systematic review concluded that integrating geriatric assessment in the management of older people with cancer resulted in 31% of patients having their cancer treatment plan modified, an increased number of goals of care discussions, lower toxicity/complication rates, improved likelihood of treatment completion and improvements in physical functioning and quality of life.⁸ A more recently published randomised controlled trial also concluded that embedding CGA into routine care for older people with cancer improved functional quality of life, and resulted in fewer unplanned hospital admissions.⁹ Therefore,



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implementing geriatric assessment into routine care for older people with cancer is a priority.

The inclusion of geriatric assessment into routine cancer care is recommended by several peak professional bodies such as the American Society of Clinical Oncology,¹⁰ the International Society of Geriatric Oncology¹¹ and the National Comprehensive Cancer Network.¹² Despite robust evidence of the benefits of geriatric assessment for older people with cancer, it is not routinely incorporated into cancer care. Evidence suggests that physicians lack knowledge about the benefits of geriatric assessment and the resources to undertake a more comprehensive assessment as part of routine care.¹³ Another barrier limiting the inclusion of geriatric assessments is the lack of geriatric specialists available to the volume of patients requiring care.¹⁴ Screening tools allow for selection of patients who would benefit from a geriatric assessment and decrease inappropriate saturation of geriatric services. Common tools such as the Geriatric-8 (G8)¹⁵ or the Vulnerable Elders Survey-13 (VES-13)¹⁶ lack specificity, contributing to the increased need for geriatricians required to embed geriatric assessment into routine care for all older adults with cancer.

There are varying models to embed geriatric assessment into routine care for older people with cancer, including screening and referral, shared care, multidisciplinary consultative model, geriatric driven/consultative model, geriatric oncologist as a primary provider and self-administered geriatric assessment.¹⁷ Currently, most programmes use a screening-based model of care whereby eligible patients are screened using the G8 or VES-13. Patients who reach screening criteria then undergo a CGA. However, these models of care require substantial resources, with between 61% and 84% of older people with cancer reaching the criteria for a CGA.^{7 18} As the success of these models relies on their ability to reach all eligible individuals, as well as their effectiveness, there is a need for a sustainable and scalable model of care that can be implemented into routine care for all older people diagnosed with cancer. To address common barriers associated with embedding geriatric oncology assessment into routine cancer care such as additional resources required and access to geriatricians for individuals who met specified criteria for further assessment, we developed a nurse-led, multidisciplinary model of care for older people newly diagnosed with cancer.

There is limited literature that specifically reports on nurse-led models of care for older people with cancer.¹⁹ However, while several models of care cited in the literature do not identify as nurse-led, nurses commonly play a key role in the multidisciplinary team (MDT) and in caring for older people with cancer.^{17 20 21} Existing literature on nurse-led models of care for older adults with cancer has shown that these models are feasible and acceptable,^{22 23} and resulted in lower rates of treatment-related complications and fewer days spent in hospital.²⁴ Nurse-led models of care fill an important gap in current practice by increasing access to geriatric assessment and

ensuring all older people with cancer receive geriatric assessment prior to their initial oncology consultation, where evidence has identified there is most benefit.⁸

The main feature of our model is the interdisciplinary collaboration of geriatric medicine, medical oncology, nursing and other specialties, where available, such as palliative care. Within the model of care, individual needs and goals of the patient are discussed, and the need for a geriatrician-led CGA determined based on the results of the nurse-led assessment at an MDT meeting. Our model of care also includes follow-up of patients post the MDT meeting to ensure recommendations from the MDT meetings have been actioned.

Understanding factors that influence successful implementation of a nurse-led MDT model of care is needed. Process evaluation is a common tool used in pragmatic studies to assess the impact of intervention delivery and access within the study, as well as provide an understanding of how and why the intervention did or did not have its desired impact.²⁵ This process evaluation aims to implement and evaluate a nurse-led, MDT model of care for older adults with cancer using the Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) framework.²⁶

METHODS AND ANALYSIS

This is a multi-site process evaluation using quantitative and qualitative research methods being undertaken at two public tertiary hospitals in Melbourne, Victoria, Australia. The study is being conducted from September 2021 to April 2024. Data collection methods include a retrospective audit of patient's medical records, an audit of study activity logs, longitudinal surveys and semi-structured interviews with patients and healthcare professionals.

The study team consists of advanced practice nurses with expertise in cancer (PHD, ET, KM and JR), medical oncologists (SP and SA), geriatricians (KL and PY) and a patient representative (RK). The model of care was developed based on existing literature,^{8 9} a retrospective audit of current practice, and discussion among key stakeholders, including a patient representative, oncologists, specialist cancer nurses and geriatricians. A retrospective audit of frailty and geriatric domains (functional status, comorbidity, cognition, mental health, social support, nutrition and geriatric syndromes) documented by treating oncologists at outpatient consultation for consideration of anticancer therapy for individuals newly diagnosed with solid organ malignancies was undertaken at one of the study sites prior to the development of this model of care. Findings from this audit identified gaps in current practice, specifically in relation to the documentation of cognition, mood, nutrition and polypharmacy and contributed to the design of this model of care.

Patient and public involvement

RK, as a patient representative, has an active role in the team and has been involved since the project's inception,

including evaluating the assessment tools, interpreting study findings and developing the dissemination plan. The nurse-led assessment, including the assessment tools and how they are administered and communicated, was initially piloted with the patient representative (RK) and refined by the study team.

Setting

This study is being conducted at two large public tertiary hospitals in Melbourne, Australia (Austin Health and Monash Health) that provide comprehensive cancer care services for all solid and haematological malignancies, including the provision of cancer clinical trials. Prior to the implementation of this model of care, older individuals with cancer did not receive any specific geriatric assessment as part of routine cancer care. Across the two sites, approximately 52% of patients newly diagnosed with a solid organ malignancy are aged 65 years and older.

Participants

Eligible patient participants are identified from relevant multidisciplinary meetings and oncology outpatient clinic lists as new consultations and who meet the below eligibility criteria. Individuals diagnosed with lung cancer will be recruited across both sites. In addition, individuals diagnosed with colorectal, upper gastrointestinal and genitourinary cancer will be recruited at the second site (Austin Hospital). Informal caregivers (ie, anyone the patient identifies as a caregiver) will be invited to participate in the semi-structured interviews at the discretion of the patient. Patients can participate in the semi-structured interviews with or without a caregiver.

Eligible healthcare professionals are identified through study teams as those involved in the delivery of care for older people and who are involved in the care of individuals who participated in the model of care described in this protocol.

Inclusion criteria

Our model of care was implemented in a staged approach to minimise potential delays in patients being seen in the oncology clinic. Therefore, the eligibility criteria were pragmatic and included cancer-types commonly seen and most likely to receive anticancer therapies with a higher rate of toxicity. Eligible participants diagnosed with lung (≥ 65 years), colorectal (≥ 75 years), upper gastrointestinal (≥ 70 years) and genitourinary cancers (≥ 70 years) were included. The varied age criteria are based on the average age at diagnosis and the likelihood of having associated comorbidities that may impact treatment-related side effects.

Exclusion criteria

Patients not offered the nurse-led geriatric assessment include those with no confirmed malignancy and who have recently received a CGA from another healthcare provider.

Patients are not eligible to participate in the prospective, longitudinal surveys if they cannot read plain English.

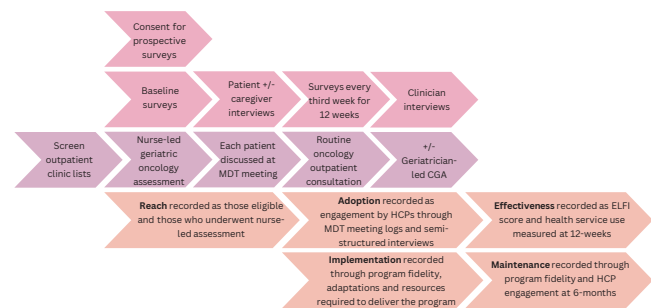


Figure 1 Participant flow through. CGA, comprehensive geriatric assessment; ELFI, Elderly Functional Index; HCP, healthcare professional; MDT, multidisciplinary team.

Similarly, participants are not eligible to participate in the qualitative interviews if they are unable to converse in plain English.

Nurse-led, MDT geriatric oncology model of care

Figure 1 demonstrates participants' flow through the study. Oncology multidisciplinary meetings and oncology outpatient clinics are screened for eligible participants who are reviewed in person or contacted via telephone to arrange a time to undertake the nurse-led geriatric assessment. During the initial stages of implementing this model of care at one site, the availability of physical space to undertake the nurse-led assessment and the subsequent inability to be flexible with appointment times offered to participants impacted their ability to attend the session. To overcome this barrier, existing resources from a hospital in-home programme, which were already established (motor vehicles and relevant infrastructure), were used where possible, to visit patients in their own homes. This service was only available at one site and the incorporation of home visits vs in-hospital visits will be assessed as part of acceptability in this study.

The nurse-led geriatric assessment incorporates a general assessment of physical and psychosocial domains. Validated tools used during the nurse-led assessment are presented in table 1. Through a guided conversation, assessments also incorporate a holistic assessment of the individual's current circumstances including existing family support and social engagement, caregiver strain, community services, whether patients had previously engaged

Table 1 Domains and tools used in nurse-led geriatric oncology assessment

Domain	Validated tool	Description	Abnormal score
General screening	Geriatric-8 ¹⁵	8-item questionnaire—identifies older cancer patients who could benefit from comprehensive geriatric assessment	≤14 score
	Eastern Cooperative Oncology Group ⁴	Score for assessment of level of function and capability of self-care	Higher score indicates worse functioning
Physical function	Timed up and go ³⁸	Walking test to assess balance, gait speed and functional ability related to the performance of basic activities of daily living	>12 s
	Hand grip strength ³⁹	Using a dynamometer—assesses concurrent overall strength, upper limb function, bone mineral density, risk of falls and malnutrition	<15.5 kg female (65–69 years) <14.7 kg female (70–99 years) <28.2 kg male (65–69 years) <21.3 kg male (70–99 years)
Functional status	Elderly Functional Index ²⁹	12-item composite measure of self-reported functioning	Higher score indicates better functioning
Psychological status	Hospital Anxiety and Depression Scale (HADS) ⁴⁰	7-item questionnaire—measures anxiety and depression in a general medical population of patients	0–7 (normal) 8–10 (borderline) 11–21 (abnormal)
	Geriatric depression scale ^{41*}	15-item questionnaire used to screen, diagnose and evaluate depression in elderly individuals	>5 indicative of depression
Cognition	Mini Cog ⁴²	3-item test—used to identify if someone is having difficulty with memory and thinking skills, consisting of a recall test and a clock drawing test	0–2 likely cognitive impairment 3–5 lower likelihood of cognitive impairment but not ruled out
Medication management and polypharmacy	No of medications, medication management	Assessment of knowledge of use, adherence, medication reconciliation	>3 regular medications per day
Social		Guided conversation about social support and level of engagement Guided conversation about potential caregiver strain	
Advance care planning		Advance Care Planning in place (yes/no), If no then discussion to introduce Advance Care Planning where relevant	

*Administered in individuals unable to complete the HADS in English.

with Advance Care Planning and their preferences for anticancer therapy. Assessments are allocated for 1 hour. Domains included in the nurse-led assessment were selected due to their ease of administration (ie, they are not onerous for the patient to complete) and cover key domains relevant for an older individual with cancer (physical, functional, psychosocial, cognition, medication management, social and Advance Care Planning).

Each patient is presented by the geriatric-oncology clinical nurse consultant at the MDT meeting, which is attended by the members outlined above. A quorum is at least one geriatrician, medical oncologist and senior cancer nurse. The MDT meetings are held virtually to maximise attendance by MDT members. Key issues

identified during the nurse-led assessment that may potentially impact oncological treatment adherence and overall disease/treatment trajectory and quality of life are discussed, and a holistic and individualised plan for care and follow-up is determined. The need for a geriatrician-led CGA is discussed and determined at the MDT meeting based on the results of the nurse-led assessment and MDT discussion. Patients are contacted by the nurse after the MDT meeting to discuss the results and ensure any referrals and recommended follow-ups are actioned.

The RE-AIM Framework

RE-AIM is a widely used framework for planning and evaluating health interventions.^{26 27} The RE-AIM framework emphasises the importance of considering all five

dimensions to evaluate the public health impact of an intervention. It encourages researchers and practitioners to go beyond assessing only the effectiveness of an intervention and to also consider its potential for wide-scale adoption, successful implementation and long-term sustainability. By addressing these dimensions, the framework provides a comprehensive approach to evaluating interventions and programmes and supports the translation of research into real-world practice.

Data collection

The process evaluation is guided by the RE-AIM framework²⁶ and will use both qualitative and quantitative methods to evaluate the nurse-led, MDT geriatric oncology model of care to provide guidance for programme expansion with capacity to explore additional assessments and outputs. Process evaluation data will be collected from clinic screening logs, participant electronic medical records, study activity logs, surveys and interviews with patients±caregivers and healthcare professionals. The data collection time points are presented in figure 1. The primary outcome of the study is the reach of the programme over a 12-month implementation period, measured by the proportion of eligible patients who undergo nurse-led geriatric oncology assessment. Evaluation questions, indicators and data sources are described in detail in table 2.

Sociodemographic and disease and treatment characteristics of all patients who meet eligibility criteria are collected from medical records to assess the reach of the model of care and will allow for a comparison of demographics for those who did and did not participate.

For individuals who participated in the geriatric oncology model of care, additional data collected at baseline include results from the geriatric assessment (described in table 1), key issues discussed at the MDT meeting and whether the patient was referred for a geriatrician-led CGA and the reasons. Participants are to complete the Edmonton Symptom Assessment Scale²⁸ and the Elderly Function Index²⁹ every third week for 12 weeks (a total of four times) after their initial nurse-led assessment. Abnormal results are actioned as per routine care. All quantitative data are collected and managed using REDCap electronic data capture tools hosted by Austin Health.^{30 31}

Patient participants are invited to participate in a one-off semistructured interview 4 weeks after participating in the nurse-led geriatric oncology assessment. Caregivers participation in the qualitative interviews will be at the discretion of the patient. The interview schedule was guided by the Theoretical Framework of Acceptability³² and is presented in online supplemental file 1. Interviews will be conducted via telephone or video conferencing and recorded.

Clinician participants (including nurses and medical staff) will be invited to participate in a one-off semistructured interview to explore adoption of the intervention. Interviews will occur between 6 and 12 months after

the model of care has been introduced. The interview schedule was guided by the RE-AIM framework²⁶ and is presented in online supplemental file 1.

Qualitative interviews were undertaken by PHD, an advanced practice nurse with expertise in cancer, as well as mixed-methods, qualitative and evaluation research, and who is not involved in delivering the nurse-led model of care.

Sample size

The primary analysis will estimate the reach of the model of care. Reach is defined as the extent to which the target audience engages in the health programme and will be measured by the proportion of eligible patients who participate in the nurse-led, MDT model of care.²⁵ Approximately 500 individuals are diagnosed with a solid organ malignancy across both sites in a 12-month period. With an estimated 52% of individuals aged 65 years and older, we anticipate being able to recruit 200 patient participants across both sites for this study. Each site will run the programme for 12 months.

Across both sites, 10 clinicians will be directly involved in caring for participants who will be eligible to participate in this model of care. We estimate approximately eight clinicians will participate in the semistructured interviews.

The sample size for the qualitative interviews will be determined by data saturation, defined as the stage of the research process when no new information is found in data analysis, and this redundancy indicates to researchers that data collection may end.³³

Analysis

Quantitative data will be analysed descriptively, including means and SD, medians and IQRs, and counts and percentages where appropriate.

Audiorecordings will be imported into Otter.ai (Company name) for transcription and checked by a member of the study team. The study team will take a reflexive stance to qualitative data collection and analysis.³⁴ Regular meetings will take place with the study team to reflect on personal biases that may influence data collection and analysis. Qualitative data (interview transcripts) will be analysed using the six-step inductive thematic analysis approach of Braun and Clarke, including (1) familiarising self with data, (2) generating initial codes, (3) searching for themes, (4) reviewing themes, (5) defining themes and (6) producing the report.³⁵ Interview analysis will be conducted by ET, KM and JR with support and training by PHD.

Ethics and dissemination

Ethical approval and local governance approvals have been obtained by Austin Health and Monash Health Human Research Ethics Committees (HREC/76987/Austin-2021). All requests for changes to the study protocol will be submitted to the relevant Human Research Ethics Committees.

Table 2 Evaluation questions, indicators and data sources

RE-AIM component	Evaluation question	Indicator/s and data source
Reach	What percentage of eligible participants participated in the geriatric oncology MOC, and what, if any, were the differences in demographics and disease characteristics?	Percentage and characteristics of individuals who met eligibility criteria and who underwent a geriatric oncology with the nurse Data source: electronic medical records and clinic screening log
	What were the reasons that eligible individuals were not assessed by the nurse?	Reasons that patients were not seen by geriatric oncology nurse Data source: Clinic screening log
	What proportion of individuals were excluded based on exclusion criteria?	Percentage of patients excluded based on eligibility criteria that is, no confirmed cancer diagnosis Data source: Clinic screening log
	Why did patients and their caregivers agree to participate in the geriatric oncology MOC?	Reasons that patients and their caregivers agreed to participate in the geriatric oncology nurse-led assessment Data source: Qualitative interviews with participants±their caregivers
Efficacy	What, if any, unintended outcomes occurred as a result of the geriatric oncology MOC? (positive or negative)	Any adverse events that occurred during nurse-led assessment, or any benefits or consequences expressed by patients/their caregivers Data source: Study documents, electronic medical records, qualitative interviews with patients±their caregivers, clinician interviews, informal conversations that occur (logged in study field notes)
	To what extent does the geriatric oncology MOC impact functional quality of life compared with a physician-led model?	ELFI score at 12-week mark compared with published ELFI score in similar physician-led model Data source: Prospective participant questionnaires, published data
	To what extent does the geriatric oncology MOC impact health service utilisation compared with those who do not participate in the geriatric oncology MOC and to a physician-led model?	No of and frequency of emergency department, inpatient admissions and SURC contacts at 12 weeks from commencing systemic anticancer therapy in individuals who undergo geriatric assessment versus those who do not Data source: electronic medical records, published data
	To what extent does the geriatric oncology MOC impact the incidence of oncological treatment complications?	No and details of changes to oncological treatment plan in individuals who undergo geriatric assessment versus those who do not. Data source: electronic medical records
	What proportion of eligible patients are assessed prior to their initial oncology consult?	No of eligible patients who participate in the geriatric oncology MOC prior to their initial oncology consultation Data source: study screening logs and study activity log
	To what extent is the geriatric oncology MOC acceptable to patients and their caregivers?	The extent to which patients and their caregivers understand the purpose of the geriatric oncology MOC, and feel the content, context and quality of care delivery meets their expectations. Data source: qualitative interviews with patients±their caregivers
Adoption	To what extent did the nurse-led geriatric oncology assessment and MDT meeting inform patient care?	No of referrals made following assessment and MDT; clinician perspectives of whether assessment and MDT discussions informed patient care Data source: electronic medical records and study activity logs; clinician interviews
	To what extent is the geriatric oncology MOC acceptable to relevant clinicians?	The perception of the evidence supporting the MOC; the perceived advantage of the MOC; the perceived complexity of the intervention Data source: Qualitative clinician interviews

Continued

Table 2 Continued

RE-AIM component	Evaluation question	Indicator/s and data source
	To what extent do relevant clinicians engage in the MDT meeting?	No of MDT meetings where required disciplines are present (cancer, geriatric medicine, palliative care, nursing) Data source: study activity logs
	To what extent do patients accept and engage in referrals and recommendations made following the geriatric oncology assessment and MDT meeting?	No of patients who uptake referrals offered based on assessment and MDT; reasons patients accepted or declined referrals Data source: electronic medical records, study activity logs; qualitative patient interviews
Implementation	To what extent has the geriatric oncology MOC been implemented as intended?	Adherence with guidelines to conduct geriatric oncology assessment; no of follow-up calls missed or not conducted Data source: documentation of nurse-led geriatric oncology assessment and assessment fields recorded; study activity logs
	To what extent was the geriatric oncology MOC adapted during its implementation?	Adaptations made the MOC and reasons for during evaluation period Data source: Study activity logs
	What resources are required to deliver the geriatric oncology MOC?	No of and time taken to undertake nurse-led geriatric oncology assessment; number and length of time taken for MDT meetings Data source: Study activity logs
Maintenance	To what extent is fidelity of the geriatric oncology MOC maintained at 6 months?	Adherence with guidelines to conduct geriatric oncology assessment Data source: Occurrence of geriatric oncology assessment and MDT meetings at 6 months and documentation of geriatric assessment and MDT outcomes
	To what extent is clinician engagement maintained at 6 months?	No of MDT meetings where required disciplines are present (cancer, geriatric medicine, nursing) at 6 months; clinician's perceived benefits and challenges of the MOC at 6 months Data source: study activity logs; qualitative clinician interviews and 6 months

ELFI, Elderly Function Index; MDT, multidisciplinary team; MOC, model of care; SURC, symptom and urgent review clinic.

Eligible participants (patients±caregivers) will be asked to provide written consent to participate in the longitudinal surveys and qualitative interviews. A waiver of consent has been approved to access demographic, disease and treatment-related data and health service use from the electronic medical records of eligible patients to participate in the programme. Health professionals will be invited to participate in a semistructured interview through an email invitation with verbal consent obtained prior to the interview.

Participant confidentiality and privacy will always be maintained, and all data will be stored securely. Data access will only be provided to study staff and investigators.

The results of the study will be disseminated through publications, conferences and local presentations. The International Committee of Medical Journal Editors recommended criteria for authorship on publications will be followed.

Strengths and limitations

The implementation of a nurse-led, MDT model of care for older adults with cancer addresses common barriers to implementation of geriatric oncology models of care and allows for greater equity of access to geriatrician-led CGA. Incorporating an MDT meeting where all patients are discussed allows for a holistic plan of care to be developed and for consultation and prioritisation with members of the MDT prior to formal referral, which is often accompanied by waiting periods.

Delivering care in patients' own homes is a key initiative introduced by the Victorian government in 2020. The Better at Home initiative encourages care to be delivered in the convenience of patients' own homes and aims to free up in-hospital services delivered by the health services.^{36 37} However, this approach requires additional resources and may limit the ability to scale this intervention to other health services, particularly those in regional

and rural areas that service a larger geographic region. Future research is needed to develop and pilot a similar model that can be delivered via telehealth.

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Contributors PHD, SP and RK conceived the study and provided domain knowledge and expertise. PHD and SP designed the final study protocol and secured funding. PHD wrote the initial manuscript draft. ET, KM and JR helped in the design of the protocol and coordination and research activities and revised the initial manuscript draft. PY and KL provided domain knowledge and expertise and revised the initial manuscript draft. SA provided domain knowledge, is a site investigator and revised the initial manuscript draft.

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

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