BMJ Open

Factors that influence clinical trial participation for oncology patients in Australia: a scoping review

Kyung Ha You ,[1,2] Zarnie Lwin,[1,2] Elizabeth Ahern,[3,4] David Wyld,[1,2] Natasha Roberts [5,6]

To cite: You KH, Lwin Z, Ahern E, *et al*. Factors that influence clinical trial participation for oncology patients in Australia: a scoping review. *BMJ Open* 2025;**15**:e095355. doi:10.1136/bmjopen-2024-095355

► 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-2024-095355).

Received 21 October 2024
Accepted 11 April 2025

[1]Cancer Care Services, Royal Brisbane and Women's Hospital, Herston, Queensland, Australia
[2]Faculty of Medicine, The University of Queensland, Herston, Queensland, Australia
[3]Monash Medical Centre Clayton, Clayton, Victoria, Australia
[4]Monash University School of Clinical Sciences at Monash Health, Clayton, Victoria, Australia
[5]Metro North Hospital and Health Service, Herston, Queensland, Australia
[6]School of Public Health and Social Work, The University of Queensland Centre for Clinical Research, Herston, Queensland, Australia

Correspondence to
Dr Kyung Ha You;
kyung.you@health.qld.gov.au

ABSTRACT

Objectives Ensuring equity in clinical trials has been declared a global priority. Australia is competitive in the international clinical trial sphere. We aimed to explore factors that influence oncology clinical trial participation in Australia.

Design Scoping review.

Data sources On 27 May 2024, a systematic search using a predefined strategy was conducted across four electronic databases (Medline, CINAHL, EMBASE and Scopus), grey literature and hand searches.

Eligibility criteria All cancer (haematological and non-haematological) clinical trials that discussed factors influencing participation in Australia were included. There were no language or age restrictions.

Data extraction and synthesis Data were extracted using a predesigned extraction tool. Quantitative results were analysed using descriptive statistics. Qualitative data were synthesised using a framework method into four domains (1) patients, (2) healthcare professionals, (3) clinical trials and (4) health services.

Results Of 1084 citations identified, 393 duplicates were removed. Of the 691 titles and abstracts screened, 54 articles underwent full-text review, and 42 articles were included in the final analysis. Key factors that influence clinical trial participation were identified across all domains, many consistent with the international literature. For example, while self-reported willingness emerged as a key facilitator across diverse patient groups, cohort studies revealed lower participation rates for migrant populations, older patients and those residing in regional areas. Importantly, we were also able to identify the foundations of an evidence base of interventions that directly support increased clinical trial participation.

Conclusion This scoping review contributes new findings to a body of international literature, while contributing a unique Australian perspective. These findings establish the foundations of an evidence base that supports inclusive clinical trial participation.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This scoping review outlines a transparent and rigorous study design which follows an established scoping review methodology.
⇒ An extensive search strategy was developed in consultation with an experienced medical librarian with validation from content experts.
⇒ The scoping review is limited to the Australian health context and may be limited in its application to other health contexts.

INTRODUCTION

Clinical trials are integral to routine oncology patient care.[1 2] Over the past two decades, the treatment landscape for cancer care has undergone rapid transformations driven by the development of targeted molecular agents, immunotherapy and combination therapies. These advances have significantly improved survival and quality of life.[3] In addition, clinical trial designs have also evolved, introducing innovations such as combined phase II-III trials, Sequential Multiple Assignment Randomized Trial and platform designs and teletrials. Participation in cancer clinical trials offers patients' early access to potentially life-saving treatments, as well as comprehensive healthcare services encompassing regular examinations and investigations. Due to these well-documented benefits, clinical trial participation for cancer patients is endorsed by international guidelines.[4 5]

Despite this, the participation rate in cancer clinical trials has remained stagnant at 5% over two decades.[3 6] Studies conducted from the '90s have indicated that patient willingness and physician-related factors were key barriers to trial participation, with 70–80% of non-participation attributed to the treating physician's reluctance.[7 8] In recent years, emerging international research indicates that limited availability of trials and restrictive eligibility criteria contribute to the non-participation of 75% of cancer patients in clinical trials.[9] Reports identify that there is a clear need to understand the impact of major barriers such as trial availability, study designs and eligibility criteria.

The COVID-19 pandemic played a pivotal role in highlighting the low enrolment and under-representation of minority populations

in COVID-19 vaccine trials, which posed a threat to the generalisability and validity of trial findings.[10] Moreover, the pandemic shed light on health disparities and their subsequent negative downstream effects, serving as a pertinent reminder of the importance of generating timely and reliable clinical evidence. As a result, ensuring diversity and inclusion in clinical trial participation has become a key priority for the healthcare ecosystem and research community.[11]

Australia is diverse and has unique demographics, such as having one of the lowest population densities in the world and being considered one of the world's most culturally diverse countries.[12 13] Similar to the UK and Canada, Australia has a binary healthcare system, encompassing both public and private sector healthcare providers. In contrast to the USA, Australia's universal healthcare system covers the cost of care in public (state-run) hospitals, with most clinical trials being conducted within the public health system. Approximately one-third (30%) of the population was born overseas and one-fifth (19%) speaks a language other than English at home.[13] Furthermore, it is noteworthy that one-third of the Australian population resides outside of major cities, and among them, over 3% are First Nations people, with more than two-thirds living in areas away from major metropolitan cities.[12 14] Despite its diversity, Australia is a competitive clinical trials destination, contributing 5% of clinical trial activity globally.[15] Irrespective of the global decline in clinical trial activity during the pandemic, Australia experienced successful growth in cancer trials activity throughout the pandemic.[15 16] The unique attributes of Australia offer insights and understanding to augment the current evidence base.[9] While the factors influencing clinical trial participation by cancer patients have been explored in the international literature, the Australian landscape has not been well represented. Moreover, while scoping reviews serve as valuable tools for systematically assessing the breadth of available literature,[17] they also provide a comprehensive overview and identify research gaps in the literature.[18] Differing from a systematic review which typically focuses on a well-defined question with well-defined study designs identified in advance for inclusion, a scoping review addresses broader topics where various different study designs are applicable.[19] Our scoping review aimed to explore what factors influence cancer clinical trial participation in Australia. The findings from this study aim to provide foundational knowledge for key players in the clinical trials sphere, while also identifying initiatives and future directions that will improve equity in trial participation.

METHODS

Protocol development and framework

The scoping review methods followed Joanna Briggs Institute (JBI) methodology and Preferred Reporting Items for Systematic Reviews and Meta-Analyses for Scoping Reviews (PRISMA-ScR) guidelines for reporting.[20 21] The protocol has been published in BMJ Open.[22]

Search strategy and source of evidence

First, we conducted a preliminary search guided by an expert health science librarian in Medline using OVID. Keywords and index terms used to describe articles were searched in titles and abstracts and were used to develop a full strategy for Medline via OVID. Ensuring the comprehensive capture of the relevant literature, we subsequently formulated a final search strategy tailored for each database (see online supplemental appendix 1).

On 27 May 2024, we systematically searched four electronic databases—Medline (Ovid), CINAHL (EBSCOHost), EMBASE (Elsevier) and Scopus (Elsevier) (see online supplemental appendix 2). All identified citations from these databases were collected and managed using the reference manager, EndNote V.X9 (Clarivate Analytics). The reference lists of included full-text articles were manually searched for additional relevant articles. To capture all the relevant literature, there was no limitation on the year of publication, language and study design. Unpublished articles and grey literature were searched across four different grey literature platforms—Google Scholar, Grey Literature Report and Web of Science Proceedings. Key search terms were developed with the support of an expert librarian. For Google Scholar, the search was also filtered to only portable document format (PDF files) and those originated from Australian websites. Additionally, we conducted a targeted search of the grey literature in local, state and national organisations' websites, clinical trial organisations and collaborative groups within Australia.

Inclusion criteria

We revised the inclusion and exclusion criteria from the original scoping review protocol.[22] Initially, our protocol defined clinical trials, excluding other forms of clinical research like database registries, tumour banks, translation studies and supportive care. However, no studies met these exclusion criteria, so we omitted them. The updated criteria were finalised before the screening process (see table 1).

Table 1 Inclusion criteria

Participant	All patients with cancer including haematological and non-haematological cancers. No age restrictions.
Concept	Factors that influence clinical trial participation by cancer patients
Context	Any literature that involved patients participating in cancer clinical trials in Australia.
Type of sources	All study designs and articles were included with no limitation in year/time frames and language.

Screening process

All citations were imported into the reference manager, EndNote V.X9 (Clarivate Analytics).[23 24] After removing duplicates, two independent reviewers (KHY and NR) conducted title and abstract screening using the inclusion criteria in the JBI System for the Unified Management, Assessment and Review of Information (JBI SUMARI; Adelaide, Australia) platform.[23] Ten citations were piloted screened to assess accuracy and consistency between two researchers before commencing the formal title and abstract screening. Relevant citations identified from title and abstract screening phase were retrieved in full-text. Prior to formal full-text screening, another pilot test was conducted by two researchers on 10 full-text articles. During formal full-text screening, reasons for exclusions of relevant articles were recorded. Any disagreements that arose during both title/abstract screening and full-text screening were resolved through discussions between the two reviewers (KHY and NR). A third reviewer was not required to resolve discrepancies.

Data extraction tool and extraction process

The data extraction tool (see online supplemental appendix 2) was designed using the research question, then using JBI SUMARI resources, further detail was added. It was pilot tested independently by two researchers (KHY and NR) on five fulltext articles to assess reliability. No further changes were made after this step. Data extraction commenced with fortnightly meetings between KHY and NR and meetings with the broader team taking place every 1–2 months.

Data analysis and presentation

All extracted data from the final articles were collated, grouped and summarised. The descriptive characteristics of included articles and key relevant findings to our research question were presented in tabular form. Two reviewers (KHY and NR) worked collaboratively to collate all findings into tables to identify overarching key themes. Using themes from the international literature,[6] framework methodology was used to deductively synthesise qualitative findings.[25] This conceptual process was independently reviewed by another investigator (ZL) to ensure accuracy. Descriptive statistics using Microsoft Excel V.2022 (Microsoft Corporation, Satan Rosa, California, USA) was used to describe included articles.[26]

To build on the existing international evidence base,[3 6 27] we summarised the factors of influence into four defined categories with factors relating to: (1) patients, (2) healthcare professionals (HCPs), (3) clinical trials and (4) health services.

Patient and public involvement

There was no patient and public involvement in the conduct of this scoping review. However, input was sought in the development of the scoping review protocol from a consumer advisor.[22]

RESULTS

Results of search

A total of 1084 citations were identified from electronic databases and grey literature repositories. After the removal of the duplicates, 691 citations underwent title and abstract screening. 54 potential studies were included for full text screening, and 42 studies were included in the final analysis.

The final review did not identify any articles from the grey literature with factors related to Australia involving cancer patients. The PRISMA-ScR flow diagram is shown in figure 1.

Characteristics of included articles

Tables 2 and 3 present an overview of the included studies. Forty-two unique articles were identified across 20 different journals. Of these, 21 studies (50%) were

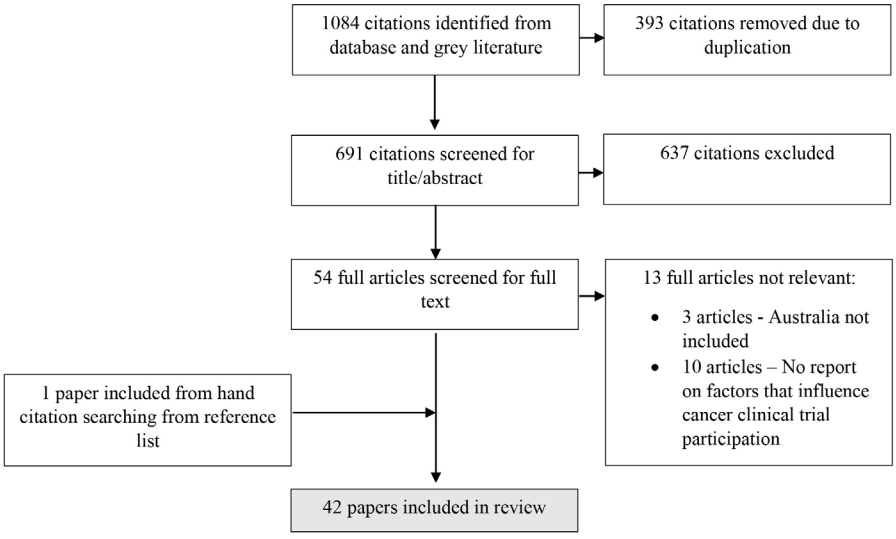

Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses for Scoping Reviews flow chart for selection of articles.

Table 2 Descriptive characteristics of included articles

Characteristics	N (%)
Location*	
State based†	22 (52.3)
New South Wales	16 (36.3)
Victoria	7 (15.9)
Queensland	3 (6.8)
South Australia	1 (2.3)
National	20 (47.6)
Year	
2015–2024	23 (59.1)
2008–2014	10 (22.7)
2001–2007	8 (18.2)
1994–2000	1 (2.2)
Article type	
Original research article	37 (91.7)
Expert opinion	5 (8.3)
Total studies included	42 (100)

*Location of study conducted or location of corresponding author address when recorded.
†Studies may have occurred in multiple states.

cross-sectional surveys, 9 studies (21.4%) were quantitative studies (5 randomised control trials (RCT) and 4 retrospective audits), 4 studies (9.5%) were qualitative studies and 3 studies (7.1%) were mixed methods studies. Within 21 cross-sectional surveys, 10 studies (23.8%) were HCPs surveys, 6 studies (14.3%) were patient surveys and 5 studies (11.9%) were surveys that included both patient and HCP. Seven of 42 (16.7%) studies were reviewing and optimising shared decision-making process for clinical trial discussions between clinicians and patients. All RCTs were assessing the impact of various decision aids (video, booklet, website) on trial participation. From 2001–2007 to 2015–2024, the number of publications has almost tripled from 8 articles to 23 articles, which reflects the substantial increasing interest in this field post the COVID-19 pandemic.

Table 3 Methodology of included articles

Characteristics	N (%)
Study design	
Cross-sectional survey	21 (50)
Healthcare professional only	10 (23.8)
Patient only	6 (14.3)
Healthcare professional and patient	5 (11.9)
Randomised control trial	5 (11.9)
Retrospective study	4 (9.5)
Qualitative study	4 (9.5)
Expert opinion	5 (11.9)
Mixed-methods study*	3 (7.1)
Did the study state a factor that influenced clinical trial participation?	
No	36 (85.7)
Yes	6 (14.3)
Total number of studies included	42 (100)

*Other mixed methods studies that included both qualitative and quantitative studies.

Key factors that influence cancer trial participation in Australia

All relevant data were extracted from the 42 included studies. Figure 2 presents an overview of the key findings under the predetermined factors related to the four key themes.

Synthesis of factors relating to the four key categories influencing clinical trial participation

Factors related to patients/parents/caregivers

Engagement with decision-making

The most investigated factor identified was understanding and improving shared decision-making (SDM) processes between patients and doctors during clinical trial discussions (26.1% of articles, n=11/42). Much of the research available was built on earlier studies of clinical trial discussions associated with low recruitment.[28–33]

One study investigated patient-doctor agreement on recall of clinical trial discussions to better understand SDM. Discrepancies between doctor and patient recall did not impact the patient's decision to participate in a clinical trial.[30] Three articles reported on communication education about clinical trial participation.[31 34 35] These studies did not have a statistical impact on clinical trial participation.[35 36]

Six articles (14.3%, n=6/42) evaluated decision aids. The use of a universal serial bus (USB) with a video invitation led to increased participation in patient-related outcome research compared with routine written information.[37] The implementation of other patient decision supports, such as education booklets, clinical trials website and clinical trial question prompt list, did not directly assess their impact on trial participation rates.[33 38–40] Implementation of a clinical trials website was associated with improvement in patient knowledge and increased discussion on the possibility to participate.[39] However, this website was unable to demonstrate increased recruitment in clinical trials.[38 39]

Willingness

Five articles (11.9%, n=5/42) reported patient willingness as a facilitator for cancer clinical trial participation. Three surveys conducted among rural and remote patients each reported patient willingness to travel for clinical trial participation.[41 42] In two studies, investigators invited survey participants to take part in the clinical trial, and over 70% and 90% enrolled in the studies.[43 44] Participants from lower socioeconomic postcodes showed

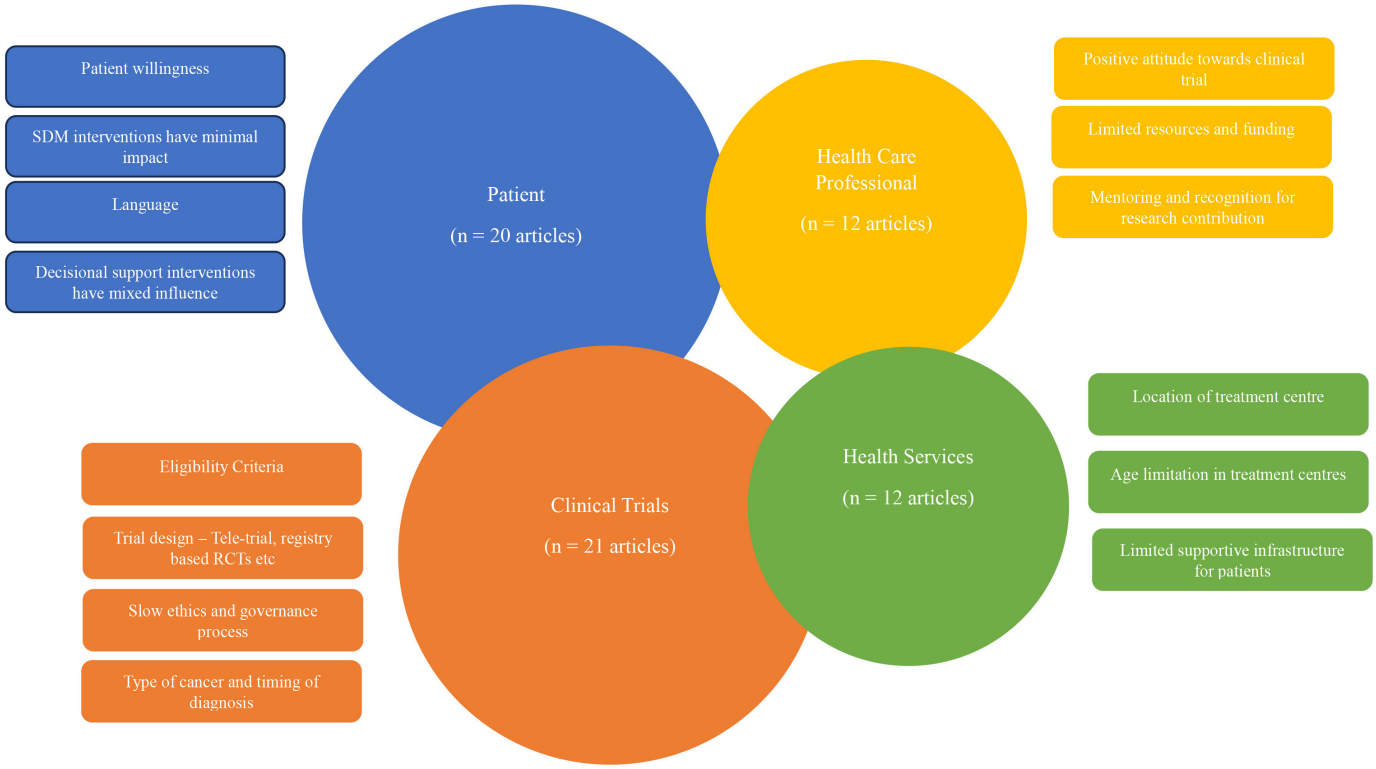

Figure 2 Overview of factors that influence participation. SDM, shared decision-making; RCT, randomised control trial.

greater willingness to travel compared with those residing in metropolitan areas and higher socioeconomic regions[42] and were more likely to take part if there were no changes in their oncologist and if there were no additional financial costs.[42] Trust in their treating clinician was identified as an important influencing factor for patient willingness to participate.[45]

In a paediatric population, a survey of HCPs from the Australian and New Zealand Children's Haematology/Oncology Group revealed that the main barrier in obtaining consent in early-phase clinical trials was HCP perceptions of parents' eagerness to 'try anything'.[45] A study involving cancer caregivers found that a lack of interest in participating in clinical trials was a major challenge to recruitment; male caregivers were less likely to participate.[46]

Perceived understanding of the health system was significantly associated with more patients agreeing to participate in clinical trials.[44] Limited knowledge about cancer treatment was also identified as a barrier to trial participation.[47] In the paediatric population, inadequate information provided to parents about clinical trials was found to influence their decision to participate.[45] Parents reported that having sufficient and comprehensive information resources regarding clinical trials was helpful.[45 48] Regardless of cultural background, both Vietnamese Australian and Anglo-Australian cancer populations with higher knowledge and more positive attitudes were more inclined to express their intention to participate in future trials.[49]

Language

The lack of routine data collection for culturally and linguistically diverse (CALD) patient enrolment was identified as a barrier.[50] Three articles (7.1%, n=3/42) identified lower English proficiency as a factor influencing trial participation. Two studies with CALD cancer patients identified that English proficiency, rather than culture, influenced their clinical trial participation, and those with a primary language other than English were less likely to participate.[44 51] Specifically, individuals with lower confidence in speaking, understanding and communicating in English were less likely to take part in clinical trials.[44] As a result, a cross-sectional survey of HCP has identified limited consultation time and difficulties accessing interpreters as barriers to participation.[50] One cohort study found that migrants were less likely to consent to participate in clinical trials when invited, compared with English-speaking Australian-born cancer patients.[44] Due to these identified barriers, trial navigators and a generic cancer trial pamphlet available in multiple languages have been recommended to engage trial participation.[50]

A commentary highlighted the significant impact of pre-existing language barriers on the recruitment of patients with brain cancer. Given the baseline vulnerability associated with this disease, brain cancer patients are already prone to a decline in cognitive function. The additional challenge of limited language proficiency can further complicate the processes of obtaining informed consent and participation in cognitive assessments within trials.[47] A survey of HCP found that language or cultural

diversity did not act as barriers to neuro-oncology trial participation.[52]

Other sociodemographic factors

Four articles (9.5%, n=4/42) presented mixed findings regarding the influence of other socioeconomic and demographic factors on clinical trial participation. Two patient surveys indicated that neither age nor country of birth was associated with the likelihood of being invited to participate in a trial.[43 44] These findings contrasted with the findings of two quantitative cohort studies which reported lower participation rates among patients with different sociodemographic attributes. Factors such as age (those 75 years or older), gender (male), cancer stage and absence of case discussion in multidisciplinary team meetings were statistically significant predictors of lower trial participation in another population study.[51]

Age limitations at treatment centres have been identified as barriers for adolescent and young adults (AYA) with cancer.[48 53] Although 50% of paediatric trials have an upper age eligibility of 18 years or older,[53] enrolment in these trials is hindered by paediatric hospital access policies that mandate treatment for patients aged 18 years and younger. On the other hand, although adult hospitals usually accept patients older than 16 years, there are very few trials available for this age group.[48] Due to these limitations, a retrospective analysis of AYA cancer patients has shown that enrolment in paediatric hospitals was significantly higher than in adult hospitals.[53] The lack of reciprocal relationships between paediatric and adult oncology in terms of awareness of open trials has also been identified as a barrier to trial participation and future research collaborations.[48]

Factors related to HCPs

Attitudes

Five articles (11.9%, n=5/42) described HCP attitudes towards research. HCP groups included allied health members—radiation therapists,[54] social workers, nurses,[45] surgeons, radiation oncologists and medical oncologists.[55 56] Additionally, organisations such as state cancer council, specialist college and national bodies endorse participation in well-designed RCTs.[57] HCPs support patients' decisions to participate, irrespective of their own personal attitude.[56]

A survey of general practitioners (GPs) revealed that 47% would refer breast cancer patients to a specialist for enrolment in a clinical trial.[29] Although GPs recognised the benefits of RCTs in advancing scientific knowledge in cancer research, 50% expressed concerns about treatment equipoise in RCTs. The processes for obtaining consent for paediatric patients within the AYA population are a reported barrier for HCPs of clinical trials.[48]

Mentoring and support of clinician engagement with research

Clinician engagement and participation within clinical trial networks were all recognised as facilitators. This involved collaborating with other clinicians, colleges or cooperative trials groups.[57 58] Opportunities to access mentoring by experienced HCPs were reported as an important factor to support engagement within clinical teams and healthcare facilities. Acknowledgement of their contributions to research activity has been reported as a positive enabler.[54]

Factors related to clinical trial

Disease characteristics

Four articles (9.5%, n=4/42) reported that the type of cancer and time of diagnosis are an influence on trial participation. Relevant articles reported generally that Australia has a lack of available cancer trials that reflect the burden of disease in the country.[59] This concern is particularly relevant for the AYA population and First Nations people.[54 60] It has also been highlighted that those with cancers at advanced stages were more likely to have a trial available than those with early stage cancers.[59]

Timing of diagnosis appears to be an influence on whether a patient is offered a clinical trial. A cohort study had shown that those diagnosed with cancer over 12 months ago were significantly less likely to be invited to participate in a clinical trial.[43]

Clinical trial design

Six articles (14.3%, n=6/42) identified that clinical trial design is a key influencing factor to trial participation. Examples included surgical and radiation oncology RCTs[32 56 61] with the risk of cancer recurrence or progression and the aversion to randomisation as key drivers.[32 61] Patient and surgeon preference for one form of surgery was highlighted as the most common reason for no enrolment.[61] A cross-sectional survey of patients showed that study designs such as randomised open-label, randomised placebo-controlled or single arm are not influencing factors.[42]

A survey of breast cancer specialists which included medical oncologists, surgeons and radiation oncologists identified that the choice of treatment in study design or complexity of study design influenced participation in RCTs for early-stage breast cancer.[62] Clinical relevance and equipoise in treatment arms influenced engagement by clinical trial organisations to support a clinical trial.[56] Onerous visit schedules which required additional appointments to hospital for participants were also identified as a top barrier from a national survey.[9]

Innovative trial designs such as registry-based clinical trials have also been identified as effective for appropriate investigation questions.[63]

Eligibility criteria

Two articles (4.7%, n=2/42) identified restrictive eligibility criteria as a factor influencing clinical trial participation, with other articles identifying this as an area for future research. For example, an analysis of cancer trials registered in the Australian and New Zealand Cancer Trials registry (ANZCTR) estimated that First Nations peoples face potential exclusion due to pre-existing

comorbidities, mental illness and/or inadequate organ function, which are mandated in many clinical trial inclusion and exclusion criteria.[60]

Factors related to health services

Geography

Five articles (11.9%, n=5/42) have identified location of treatment centre as an influencing factor. A cross-sectional survey conducted in New South Wales found a significant association between the treatment centre and the likelihood of being invited to participate.[43] This survey revealed that individuals from regional centres were more likely to receive invitations compared with those in larger metropolitan centres. [43]Other articles identified geography as a barrier to trial participation,[58] with examples of low participation rates of 6.7% in metropolitan Melbourne and 1.2% in regional Victoria.[58] Implementation of a regional trials network and teletrials has resulted in a 49% increase in patient recruitment between 2017 and 2019.[58] Following the COVID-19 pandemic, four articles (9.5%, n=4/424) discussed innovative designs such as teletrials to combat these identified barriers.[41 58 64 65]

A survey conducted among medical oncology patients at Townsville Hospital, a regional metropolitan hospital, revealed that for rural or remote patients, cost and support from family or friends for trials were important considerations when participating in clinical trials compared with regional metropolitan patients.[41]

The availability of clinical trials for First Nations people was identified as a potential barrier to participation. With 39% of First Nations people residing outside major cities/inner regional areas and 89% of registered cancer trials being conducted in these areas, it is anticipated that First Nations people will have limited opportunities to participate.[60 66 67]

Infrastructure

The allocation of healthcare resources that support research was identified as a key facilitator. Providing non-clinical time for clinicians to engage in research has been reported to ensure sustainable engagement.[52 54] Other health services measures such as accessible regulatory support,[68] education and promotional information[57] and fostering relationships with external partners such as universities and cancer cooperative groups to facilitate resource sharing have shown to be supportive.[52 58 68] The need for clinical trial expertise was not identified as a barrier by the Cooperative Trials Group for Neuro-Oncology (COGNO) group when collaborating in international neuro-oncology clinical trials.[52] Two surveys conducted among various other HCPs identified insufficient staffing of physicians and clinical research associates as a barrier to trial participation.[9 55]

Five cross-sectional surveys (11.9%, n=5/42) of various individual HCPs and collaborative groups such as COGNO and Australian and New Zealand Cancer Trials groups have reported limited funding and resources as a significant barrier to clinical trial participation.[52 62] Surveys from allied health HCPs including radiation therapists and other clinical research associates (such as data managers, nurses, trial coordinators and trial support staff) identified limited resources and a lack of time during working hours as perceived obstacles to participating in trials.[54 68] The challenges of limited resources were also reported within the clinical trials sector for AYA and paediatric populations.[48 68]

To further support this finding, a prospective study demonstrated that recruitment rates were positively associated with an onsite data manager and negatively associated with increased case load.[32]

Streamlining ethics/governance

Among the reviewed articles, four articles (9.5%, n=4/42) reported barriers associated with the ethics and governance processes for clinical trials.[55 68]

Known barriers, such as staffing, data sharing regulations, establishing transparent and user-friendly trials processes and fostering relationships with pharmaceutical companies were reported to effectively facilitate clinical trial ethics and governance approvals.[58]

DISCUSSION

This scoping review represents the first systematic comprehensive exploration of the factors influencing cancer clinical trial participation in Australia. The pursuit of equity in clinical trials has been recognised as an international priority, with 42 Australian studies responding to this call identified in our search. Findings from analyses demonstrated that there are key factors relating to patients, HCPs, clinical trials and health services that influence participation in clinical trials in Australia. While shared decision-making has established a strong evidence base, we identified that patient-related and HCP-related engagement with clinical trials may also be influenced by clinical trial-related factors (such as clinical trial design and eligibility criteria) and health service factors (such as geography and infrastructure). Across many of these factors, included studies also identified opportunities to directly address factors that influence clinical trial participation. Successful interventions are now in large-scale development.

The most commonly studied factor, accounting for 30% of the included studies, focused on understanding and improving trial discussions between patients and clinicians. Several interventions were trialled in this body of work, but evidence to demonstrate that improvements in access and engagement in clinical trials were not identified. This research is also aligned with international research aiming to address concerns of low patient accrual attributed to eligible patients declining participation due to inadequate understanding about the trials.[31 34 35]

The findings from this scoping review have identified that patients are willing to participate in clinical trials. Four out of five articles were cross-sectional surveys that assessed hypothetical willingness to participate in clinical

trials. Studies with Australian patient surveys included participants from diverse backgrounds such as rural/remote areas and CALD communities, demonstrating that over 70% of patients expressed an interest in clinical trial participation.[41 44] International literature has identified that approximately 55% of patients who were invited to participate were successfully enrolled in clinical trials.[27 69 70] Similar to the international literature, our scoping review identified a variation in general participation rates ranging from 5% to 10%.[51 58 68] Further research is needed to characterise the patient population enrolled in Australia, enabling the development of interventions that align with the needs of those currently seeking treatment.

Actual clinical trial participation rates within Australia of any patient group remain unknown. For example, this review has highlighted that ethnicity data are not routinely collected in Australian clinical trials.[49 50] Although guidelines recommend collecting minimum data points to capture diversity in healthcare services, this is not mandated and there is no consensus in Australia on which specific data points should be included in cancer clinical trial demographic data collection.[50] At present, only the collection of identified Aboriginal and Torres Strait Islander status is advised for reporting, but guidance as to how clinical trial sites can do this is unavailable. As a result, capturing equity in cancer clinical trials remains a challenge in Australia. Without robust data, developing strategies that can respond to the needs of patients and communities, HCPs, clinical trials communities and health services to optimise equitable participation in clinical trials is a challenge.

Financial support for clinical trial participation appears to play a role for both individual patients, clinical teams and health services. In contrast to the international literature, the financial burden on patients was not reported as a barrier in the Australian context,[27] yet financial toxicity research in cancer care is an area of growing concern.[6] The provision of public healthcare is made available to the Australian population, with the majority of clinical trials still predominantly available within the public system.[9] This differs from countries like the USA, where State Medicaid programmes may not uniformly cover the costs of clinical trials.[27] Limited information is available regarding the Australian private healthcare system in the clinical trials sphere.

Positive attitudes towards clinical trials by HCPs at both individual level and organisational level were identified as a positive factor, largely because of the additional resources. This included the addition of available treatment pathways for patients, guidelines to treatment management, access to streamlined imaging and nursing support.[45 54–57] This value was shared across different players including clinicians and clinical research associates. Similar positive attitudes were found in US surveys among cancer physicians and allied health specialists.[71 72] However, limited funding and resources to support investigator-led clinical trial activities emerged as the top perceived barrier from HCPs.[32 52 54 62 68] International HCP surveys have also identified logistical barriers, such as competing demands on time and resources, as well as lack of awareness about available trials due to a lack of infrastructure that supports clinical trials delivery.[73] Australian research has identified that HCP engagement in clinical trials appears to be clinician dependent, with clinical trials collaborative groups acting as an important positive factor for providing resources, mentoring and established national networks.[74]

The findings in this review identified that there may be more than one factor that can determine whether a patient can access an available clinical trial. It has been well established in the international literature that over 50% of patients are not enrolled into clinical trials due to limited trial availability at their healthcare institution.[6] In Australia, some health services provide cancer care. As a result, there is variation in clinical trials activity across Australia, with some attracting more clinical trials than others.[75] Decentralising clinical trials is an important strategy that not only improves access for those that live in regional and remote areas, but also those that live in large metropolitan areas with a hospital that is closer to their home.[58 64 65] There have been significant efforts in cancer centres across Australia to improve the accessibility of clinical trials through ‘teletrials’, and this work is ongoing.[64 65 74]

Another significant finding in this review is that the available clinical trials do not accurately reflect the true burden of disease in Australia. For example, multiple studies have reported concerns about clinical trial availability among patient cohorts such as AYA and First Nations people.[48 59 60] The influence of age on clinical trial participation has been investigated in the international literature. Less than 10% of patients aged 70 years and older participate in National Cancer Institute-sponsored clinical trials in the USA.[76 77] Some of these discrepancies may be attributed to selection biases in cross-sectional surveys. The patient population included in these surveys predominantly consisted of individuals with a median age under 70 years,[35 41–44 49 78] female gender[35 38 41 44 78 79] and breast cancer.[30 34 35 38 78 80] Another possible explanation is that once a trial becomes available and patients are invited to participate, other barriers such as eligibility criteria based on comorbidities and cancer characteristics may prevent their enrolment in clinical trials. Internationally, restrictive eligibility criteria have been identified as a significant barrier, with approximately 20% of consented patients being ineligible on screening.[6] As 60% of clinical trials in Australia are globally sponsored by the industry, it is anticipated that eligibility criteria will have a similar impact.[60] However, gaining a better understanding of these criteria may be beneficial.

The research conducted in this scoping review provides new insights into trial participation in Australia. Collaborative efforts are essential to ensure diversity, inclusion and equity in cancer research. Through united efforts, we can build strong foundations and make significant

strides towards ensuring that all individuals have equitable opportunities to participate in cancer clinical trials.

Strengths and limitations

This was the first scoping review to systematically investigate factors that influence cancer clinical trial participation in Australia. Barriers to clinical trial participation have been extensively investigated in the broader international literature. Despite this, enrolment remains static and disparities exist. The findings from this scoping review build on this global knowledge, bring a fresh perspective and further understanding while consolidating the evidence base for strategies that can improve equitable access to clinical trials.

Our review employed a comprehensive search strategy and broad inclusion criteria, which has resulted in an extensive summary of all the available literature. Inequity in clinical trials has been an area of growing interest for some time now, and it is acknowledged that any records published after this search would not be included. Articles included in this review adopted a wide range of designs, approaches and methodologies which result in differences in data and reporting. The heterogeneity in study designs has meant that synthesis of findings is limited, and the findings presented are only descriptive in nature. Nonetheless, we applied a consistent approach to data extraction for all records. The included articles often lacked demographic details such as sociodemographic, gender and ethnicity of participants, making it difficult to assess diversity across the records.

Around half of the included studies were cross-sectional surveys targeting either HCPs or patients which were aimed at identifying perceived factors to trial participation. Many of these surveys set eligibility criteria for patient participants that potentially introduced biases related to language proficiency, cognitive function and age (median age of participants ranged from 30 to 46 years). This raises concerns of selection bias and misrepresentation of certain minority groups. Notably, HCP surveys and commentary pieces were commonly from academic centres in Metropolitan areas which may limit broader relevance.

Acknowledgements The authors wish to thank Lars Eriksson for his expertise in developing the search strategy.

Contributors KHY: validation, investigation, data curation, writing-original draft, writing-review and editing. NR and ZL: conceptualisation, methodology, writing- original draft, writing-review and editing, investigation, visualisation and supervision. EA: conceptualisation, methodology, writing-review and editing, investigation and supervision. DW: conceptualisation, methodology, writing-review and editing and supervision. KHY is the guarantor.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

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.

Ethics approval Research ethics approval was not required as this study did not involve participants.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as supplementary information. This is a literature review. Screening process of eligible article is attached to supplementary information.

ORCID iDs

Kyung Ha You http://orcid.org/0000-0001-7583-5502
Natasha Roberts http://orcid.org/0000-0003-0534-8084

REFERENCES

1 Howard-Jones AR, Webb SA. Embedding clinical trials within routine health-care delivery: Challenges and opportunities. *J Paediatr Child Health* 2021;57:474–6.
2 Australian Commission on Safety and Quality in Health Care. National Clinical trials Governance Framework, 2023. Available: https://www.safetyandquality.gov.au/standards/national-clinical-trials-governance-framework/resources-national-clinical-trials-governance-framework#overview
3 Unger JM, Cook E, Tai E, *et al*. The Role of Clinical Trial Participation in Cancer Research: Barriers, Evidence, and Strategies. *Am Soc Clin Oncol Educ Book* 2016;35:185–98.
4 Gilligan T, Coyle N, Frankel RM, *et al*. Patient-Clinician Communication: American Society of Clinical Oncology Consensus Guideline. *J Clin Oncol* 2017;35:3618–32.
5 National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology: Biliary Tract Cancers, 2025. Available: https://www.nccn.org/professionals/physician_gls/pdf/btc.pdf
6 Unger JM, Vaidya R, Hershman DL, *et al*. Systematic Review and Meta-Analysis of the Magnitude of Structural, Clinical, and Physician and Patient Barriers to Cancer Clinical Trial Participation. *J Natl Cancer Inst* 2019;111:245–55.
7 Gotay CC. Accrual to cancer clinical trials: Directions from the research literature. *Soc Sci Med* 1991;33:569–77.
8 Schain WS. Barriers to clinical trials. Part II: Knowledge and attitudes of potential participants. *Cancer* 1994;74:2666–71.
9 You KH, Ahern E, Wyld D, *et al*. Scoping to analyze oncology trial participation in Australia. *Semin Oncol* 2022;49:178–81.
10 Khalil L, Leary M, Rouphael N, *et al*. Racial and Ethnic Diversity in SARS-CoV-2 Vaccine Clinical Trials Conducted in the United States. *Vaccines (Basel)* 2022;10:290.
11 Pierce IJ. 2021 Presidential Adress: Equity: Every Patient. Every Day. Everywhere, 2021. Available: https://connection.asco.org/magazine/features/2021-presidential-address-equity-every-patient-every-day-everywhere
12 Australian Bureau of Statistics. Estimates and Projections, Aboriginal and Torres Strait Islander Australians, 2001 to 2026 (Series B). Canberra: ABS, Available: https://www.abs.gov.au/statistics/people/aboriginal-and-torres-strait-islander-peoples/estimates
13 Australian Bureau of Statistics. Regional population of 2019-2020 financial year, Canberra, Available: https://www.abs.gov.au/statistics/people/population/migration-australia/2019-20
14 Australian Bureau of Statistics. Regional population of 2019-2020 financial year, Available: https://www.abs.gov.au/statistics/people/population/regional-population/2019-20
15 MTPConnect. Australia's Clinical Trial Sector 2021, 2021. Available: https://www.mtpconnect.org.au/images/MTPConnect_Australia's%20Clinical%20Trials%20Sector%20report%202021.pdf
16 McDonald K, Seltzer E, Lu M, *et al*. Quantifying the impact of the COVID-19 pandemic on clinical trial screening rates over time in 37 countries. *Trials* 2023;24:254.

17 Pollock D, Tricco AC, Peters MDJ, *et al*. Methodological quality, guidance, and tools in scoping reviews: a scoping review protocol. *JBI Evid Synth* 2021.
18 Munn Z, Peters MDJ, Stern C, *et al*. Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. *BMC Med Res Methodol* 2018;18:143.
19 Arksey H, O'Malley L. Scoping studies: towards a methodological framework. *Int J Soc Res Methodol* 2005;8:19–32.
20 Joanna Briggs Institute. Joanna Briggs Institute Reviewers' Manual: 2015. 2015.
21 Tricco AC, Lillie E, Zarin W, *et al*. PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. *Ann Intern Med* 2018;169:467–73.
22 You KH, Lwin Z, Ahern E, *et al*. Factors that influence clinical trial participation by patients with cancer in Australia: a scoping review protocol. *BMJ Open* 2022;12:e057675.
23 Munn Z, Aromataris E, Tufanaru C, *et al*. The development of software to support multiple systematic review types: the Joanna Briggs Institute System for the Unified Management. *Assessment and Review* 2019;17:36–43.
24 Rider JV, Longhurst JK. Fear-of-falling activity-avoidance behavior in people with Parkinson's disease: a scoping review protocol. *JBI Evid Synth* 2021;19:1698–704.
25 Gale NK, Heath G, Cameron E, *et al*. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Methodol* 2013;13:117.
26 Microsoft Corporation. Microsoft excel, Available: https://office.microsoft.com/excel
27 Unger JM, Hershman DL, Till C, *et al*. "When Offered to Participate": A Systematic Review and Meta-Analysis of Patient Agreement to Participate in Cancer Clinical Trials. *J Natl Cancer Inst* 2021;113:244–57.
28 Signorelli C, Wakefield CE, Fardell JE, *et al*. The Role of Primary Care Physicians in Childhood Cancer Survivorship Care: Multiperspective Interviews. *Oncologist* 2019;24:710–9.
29 Ellis PM, Butow PN. Focus group interviews examining attitudes to randomised trials among breast cancer patients and the general community. *Aust N Z J Public Health* 1998;22:528–31.
30 Bernhard J, Aldridge J, Butow PN, *et al*. Patient-doctor agreement on recall of clinical trial discussion across cultures. *Ann Oncol* 2013;24:391–7.
31 Brown RF, Butow PN, Ellis P, *et al*. Seeking informed consent to cancer clinical trials: describing current practice. *Soc Sci Med* 1982;58:2445–57.
32 Abraham NS, Hewett P, Young JM, *et al*. Non-entry of eligible patients into the Australasian laparoscopic colon cancer study. *ANZ J Surg* 2006;76:825–9.
33 Juraskova I, Butow P, Bonner C, *et al*. Improving decision making about clinical trial participation - a randomised controlled trial of a decision aid for women considering participation in the IBIS-II breast cancer prevention trial. *Br J Cancer* 2014;111:1–7.
34 Brown RF, Butow PN, Butt DG, *et al*. Developing ethical strategies to assist oncologists in seeking informed consent to cancer clinical trials. *Soc Sci Med* 2004;58:379–90.
35 Brown RF, Butow PN, Boyle F, *et al*. Seeking informed consent to cancer clinical trials; evaluating the efficacy of doctor communication skills training. *Psychooncology* 2007;16:507–16.
36 Bernhard J, Butow P, Aldridge J, *et al*. Communication about standard treatment options and clinical trials: can we teach doctors new skills to improve patient outcomes? *Psychooncology* 2012;21:1265–74.
37 Signorelli C, Wakefield CE, McLoone JK, *et al*. A cost-effective approach to increasing participation in patient-reported outcomes research in cancer: A randomized trial of video invitations. *Int J Cancer* 2021;148:971–80.
38 Dear RF, Barratt AL, Askie LM, *et al*. Impact of a cancer clinical trials web site on discussions about trial participation: a cluster randomized trial. *Ann Oncol* 2012;23:1912–8.
39 Dear RF, Barratt AL, Crossing S, *et al*. Consumer input into research: the Australian Cancer Trials website. *Health Res Policy Syst* 2011;9:30.
40 Tattersall MHN, Jefford M, Martin A, *et al*. Parallel multicentre randomised trial of a clinical trial question prompt list in patients considering participation in phase 3 cancer treatment trials. *BMJ Open* 2017;7:e012666.
41 Sabesan S, Burgher B, Buettner P, *et al*. Attitudes, knowledge and barriers to participation in cancer clinical trials among rural and remote patients. *Asia Pac J Clin Oncol* 2011;7:27–33.
42 Zdenkowski N, Lynam J, Sproule V, *et al*. Results of a survey of cancer patients' willingness to travel to participate in a clinical trial. *Intern Med J* 2019;49:1321–5.
43 Carey M, Boyes AW, Smits R, *et al*. Access to clinical trials among oncology patients: results of a cross sectional survey. *BMC Cancer* 2017;17:653.
44 Lim BT, Butow P, Sze ML, *et al*. Impact of migrancy on cancer clinical trial participation: Factors associated with approach and consent in Australian-born versus migrant groups. *Asia Pac J Clin Oncol* 2020;16:115–22.
45 Robertson EG, Mitchell R, Wakefield CE, *et al*. Enrolment in paediatric oncology early-phase clinical trials: The health-care professionals' perspective. *J Paediatr Child Health* 2019;55:561–6.
46 Heckel L, Gunn KM, Livingston PM. The challenges of recruiting cancer patient/caregiver dyads: informing randomized controlled trials. *BMC Med Res Methodol* 2018;18:146.
47 Lwin Z, Broom A, Cosman R, *et al*. Culturally and linguistically diverse patient participation in glioma research. *Neurooncol Pract* 2014;1:101–5.
48 Ellis JA, Malalasekera VS, Allan C, *et al*. Systems-Level Change to Alleviate Barriers to Cancer Clinical Trial Access for Adolescents and Young Adults in Australia. *J Adolesc Young Adult Oncol* 2022;11:173–80.
49 Smith AB, Niu AY, Descallar J, *et al*. Clinical trials knowledge and attitudes of Vietnamese- and Anglo-Australian cancer patients: A cross-sectional study. *Asia Pac J Clin Oncol* 2020;16:e242–51.
50 Pal A, Smith B, Allan C, *et al*. Improving Access to Cancer Clinical Trials for Patients From Culturally and Linguistically Diverse Backgrounds in Australia: A Survey of Clinical and Research Professionals. *JCO Oncol Pract* 2023;19:1039–47.
51 SmithAAgar M, Delaney G, *et al*. Lower trial participation by culturally and linguistically diverse (CALD) cancer patients is largely due to language barriers. *Asia Pac J Clin Oncol* 2018;14:52–60.
52 Kong BY, Carter C, Nowak AK, *et al*. Barriers and potential solutions to international collaboration in neuro-oncology clinical trials: Challenges from the Australian perspective. *Asia Pac J Clin Oncol* 2022;18:259–66.
53 White V, Skaczkowski G, Anazodo A, *et al*. Clinical trial participation by adolescents and young adults with cancer: A continued cause for concern? *Semin Oncol* 2018;45:275–83.
54 Agustin C, Grand M, Gebski V, *et al*. Radiation therapists' perspective on barriers to clinical trials research. *J Med Imaging Radiat Oncol* 2008;52:178–82.
55 Dear RF, Barratt AL, Tattersall MHN. Barriers to recruitment in cancer trials: no longer medical oncologists' attitudes. *Med J Aust* 2012;196:112–3.
56 Laba JM, Senan S, Schellenberg D, *et al*. Identifying Barriers to Accrual in Radiation Oncology Randomized Trials. *Curr Oncol* 2017;24:524–30.
57 Ellis PM, Tattersall MH. Advocacy for clinical trials: do the Royal Colleges and State cancer councils play an appropriate role? *Aust N Z J Public Health* 2001;25:9–11.
58 Muthusamy A, Long D, Underhill CR. Improving recruitment to clinical trials for regional and rural cancer patients through a regionally based clinical trials network. *Med J Aust* 2021;214:453–4.
59 Dear RF, Barratt AL, McGeechan K, *et al*. Landscape of cancer clinical trials in Australia: using trial registries to guide future research. *Med J Aust* 2011;194:387–91.
60 Cunningham J, Garvey G. Are there systematic barriers to participation in cancer treatment trials by Aboriginal and Torres Strait Islander cancer patients in Australia? *Aust N Z J Public Health* 2021;45:39–45.
61 Solomon MJ, Pager CK, Young JM, *et al*. Patient entry into randomized controlled trials of colorectal cancer treatment: factors influencing participation. *Surgery* 2003;133:608–13.
62 Ellis PM, Butow PN, Simes RJ, *et al*. Barriers to participation in randomized clinical trials for early breast cancer among Australian cancer specialists. *Aust N Z J Surg* 1999;69:486–91.
63 Yan MK, Adler NR, Heriot N, *et al*. Opportunities and barriers for the use of Australian cancer registries as platforms for randomized clinical trials. *Asia Pac J Clin Oncol* 2022;18:344–52.
64 Sabesan S, Malica M, Gebbie C, *et al*. Implementation of the Australasian Teletrial Model: Translating ideas into action using implementation science frameworks. *J Telemed Telecare* 2023;29:641–7.
65 Underhill C, Freeman J, Dixon J, *et al*. Decentralized Clinical Trials as a New Paradigm of Trial Delivery to Improve Equity of Access. *JAMA Oncol* 2024;10:526–30.
66 Cancer Council Australia. Inequalities in cancer outcomes by Indigenous status and socioeconomic quintile: An integrative review. 2020.
67 Rural & Remote Health. Australian Institute of Health and Welfare, 2023. Available: https://www.aihw.gov.au/reports/rural-remote-australians/rural-and-remote-health

68 Murray P, Kerridge I, Tiley C, *et al*. Enrollment of patients to clinical trials in haematological cancer in New South Wales: current status, perceived barriers and opportunities for improvement. *Intern Med J* 2010;40:133–8.
69 Hillyer GC, Beauchemin M, Hershman DL, *et al*. Discordant attitudes and beliefs about cancer clinical trial participation between physicians, research staff, and cancer patients. *Clin Trials* 2020;17:184–94.
70 Comis RL, Miller JD, Aldigé CR, *et al*. Public attitudes toward participation in cancer clinical trials. *J Clin Oncol* 2003;21:830–5.
71 Braun-Inglis C, Shvetsov YB, Springer A, *et al*. Understanding Attitudes and Roles of Oncology Advanced Practitioners in the Setting of Cancer Clinical Trials: A Pilot Study. *J Adv Pract Oncol* 2021;12:465–76.
72 Bylund CL, Weiss ES, Michaels M, *et al*. Primary care physicians' attitudes and beliefs about cancer clinical trials. *Clin Trials* 2017;14:518–25.
73 Kumar G, Chaudhary P, Quinn A, *et al*. Barriers for cancer clinical trial enrollment: A qualitative study of the perspectives of healthcare providers. *Contemp Clin Trials Commun* 2022;28:100939.
74 Roberts NA, Cubitt A, Lindsay D, *et al*. Teletrials, the new norm? Expert recommendations for teletrials into the future: Findings from the Clinical Oncology Society of Australia Clinical Trial Research Professionals Group Workshop. *Asia-Pac J Clncl Oncol* 2022;18:650–9.
75 Ives A, Pusztai T, Keller J, *et al*. Resilience and ongoing quality care for cancer clinical trials during COVID-19: Experience from a tertiary hospital in Australia. *Asia Pac J Clin Oncol* 2022;18:e141–7.
76 Trimble EL, Carter CL, Cain D, *et al*. Representation of older patients in cancer treatment trials. *Cancer* 1994;74:2208–14.
77 Hutchins LF, Unger JM, Crowley JJ, *et al*. Underrepresentation of patients 65 years of age or older in cancer-treatment trials. *N Engl J Med* 1999;341:2061–7.
78 Ellis PM, Butow PN, Tattersall MHN. Informing breast cancer patients about clinical trials:a randomized clinical trial of an educational booklet. *Ann Oncol* 2002;13:1414–23.
79 Zdenkowski N, Butow P, Mann GB, *et al*. A survey of Australian and New Zealand clinical practice with neoadjuvant systemic therapy for breast cancer. *Intern Med J* 2016;46:677–83.
80 Juraskova I, Butow P, Lopez A, *et al*. Improving informed consent: pilot of a decision aid for women invited to participate in a breast cancer prevention trial (IBIS-II DCIS). *Health Expect* 2008;11:252–62.