

SCORE: a randomised controlled trial evaluating shared care (general practitioner and oncologist) follow-up compared to usual oncologist follow-up for survivors of colorectal cancer



Michael Jefford,^{a,b,c,*} Jon D. Emery,^d Andrew James Martin,^e Richard De Abreu Lourenco,^f Karolina Lisy,^{a,b,c} Eva Grunfeld,^g Mustafa Abdi Mohamed,^a Dorothy King,^a Niall C. Tebbutt,^h Margaret Lee,ⁱ Ashkan Mehrnejad,^a Adele Burgess,^h Julie Marker,^j Renee Eggins,^e Joseph Carrello,^e Hayley Thomas,^e and Penelope Schofield^{a,c,k}



^aDepartment of Health Services Research, Peter MacCallum Cancer Centre, Melbourne, VIC, Australia

^bAustralian Cancer Survivorship Centre, Peter MacCallum Cancer Centre, Melbourne, VIC, Australia

^cSir Peter MacCallum Department of Oncology, University of Melbourne, Parkville, VIC, Australia

^dCentre for Cancer Research and Department of General Practice and Primary Care, University of Melbourne, Melbourne, VIC, Australia

^eNHMRC Clinical Trials Centre, University of Sydney, Sydney, NSW, Australia

^fCentre for Health Economics Research and Evaluation, University of Technology Sydney, Ultimo, NSW, Australia

^gDepartment of Community and Family Medicine and Ontario Institute for Cancer Research, University of Toronto, Canada

^hOlivia Newton John Cancer Centre, Heidelberg, VIC, Australia

ⁱDepartment of Medical Oncology, Western Health, Melbourne, VIC, Australia

^jPrimary Care Collaborative Cancer Clinical Trials Group, Centre for Cancer Research and Department of General Practice and Primary Care, University of Melbourne, Melbourne, VIC, Australia

^kDepartment of Psychology and Iverson Health Innovation Research Institute, Swinburne University, Melbourne, VIC, Australia

Summary

Background SCORE is the first randomised controlled trial (RCT) to examine shared oncologist and general practitioner (GP) follow-up for survivors of colorectal cancer (CRC). SCORE aimed to show that shared care (SC) was non-inferior to usual care (UC) on the EORTC QLQ-C30 Global Health Status/Quality of Life (GHQ-QoL) scale to 12 months.

Methods The study recruited patients from five public hospitals in Melbourne, Australia between February 2017 and May 2021. Patients post curative intent treatment for stage I–III CRC underwent 1:1 randomisation to SC and UC. SC replaced two oncologist visits with GP visits and included a survivorship care plan and primary care management guidelines. Assessments were at baseline, 6 and 12 months. Difference between groups on GHQ-QoL to 12 months was estimated from a mixed model for repeated measures (MMRM), with a non-inferiority margin (NIM) of –10 points. Secondary endpoints included quality of life (QoL); patient perceptions of care; costs and clinical care processes (CEA tests, recurrences). Registration ACTRN12617000004369p.

Findings 150 consenting patients were randomised to SC (N = 74) or UC (N = 76); 11 GPs declined. The mean (SD) GHQ-QoL scores at 12 months were 72 (20.2) for SC versus 73 (17.2) for UC. The MMRM mean estimate of GHQ-QoL across the 6 month and 12 month follow-up was 69 for SC and 73 for UC, mean difference –4.0 (95% CI: –9.0 to 0.9). The lower limit of the 95% CI did not cross the NIM. There was no clear evidence of differences on other QoL, unmet needs or satisfaction scales. At 12 months, the majority preferred SC (40/63; 63%) in the SC group, with equal preference for SC (22/62; 35%) and specialist care (22/62; 35%) in UC group. CEA completion was higher in SC. Recurrences similar between arms. Patients in SC on average incurred USD314 less in health costs versus UC patients.

Interpretation SC seems to be an appropriate and cost-effective model of follow-up for CRC survivors.

Funding Victorian Cancer Agency and Cancer Australia.

Copyright © 2023 The Author(s). Published by Elsevier Ltd. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

eClinicalMedicine
2023;66: 102346
Published Online 30
November 2023
<https://doi.org/10.1016/j.eclim.2023.102346>

*Corresponding author. Department of Health Services Research, Peter MacCallum Cancer Centre, 305 Grattan Street, Melbourne, VIC 3000, Australia.

E-mail address: Michael.Jefford@petermac.org (M. Jefford).

Keywords: Colorectal neoplasms; Survivors; Shared care; Model of care; General practice; Randomised controlled trial

Research in context

Evidence before this study

The SCORE study was initiated in 2016 in recognition that existing models of survivorship care were suboptimal and unsustainable given the limited specialist oncology workforce and the large and growing numbers of survivors. A Cochrane review and meta-analysis in 2019 included several studies of general practitioner-led (GP) care, finding that GP-led care appears safe, is associated with high patient satisfaction and is more cost effective than specialist-led hospital-based care. The same review included just one published study of shared care (combined GP and specialist follow up care) for survivors of prostate cancer, showing similar disease-specific quality of life in men exposed to shared care compared to usual hospital-based care, lower costs with shared care, and patient preference for shared care.

Added value of this study

The SCORE study found that shared care for survivors of colorectal cancer is acceptable, feasible and results in similar patient-reported outcomes including general and disease-specific quality of life, satisfaction, and unmet needs. Patients who experienced shared care indicated a strong preference for this model of follow up care. GPs were more adherent to recommended carcinoembryonic antigen (CEA) surveillance testing, when compared to hospital-based oncologist-led follow up. Overall health care costs were lower in the shared care arm.

Implications of all the available evidence

Follow up care that is shared between hospital-based oncologists and GPs can be considered an acceptable and less expensive alternative to usual hospital-based follow up care for survivors of colorectal cancer.

Introduction

Colorectal cancer (CRC) is the third most common cancer globally and is responsible for the second largest number of cancer deaths.¹ However, the majority of those diagnosed will become long-term survivors.^{1,2} Survivors of CRC represent the third-largest group of long-term survivors in the Western world (after survivors of breast and prostate cancer).^{1,3}

In the US, an estimated 1.4 million people have a personal history of CRC.³

Survivors may experience varied consequences from CRC and its treatments^{4,5} which include physical issues such as fatigue and bowel disturbance,^{6–9} emotional and psychological issues, including fear of cancer recurrence^{10–12} and practical issues, such as financial stress and difficulty returning to work.^{13–15} Compared to those without a CRC experience, survivors may experience poor quality of life (QoL) and persistent unmet needs.^{12,16–20}

Guidelines recommend follow-up care after treatment for CRC, though these tend to emphasise surveillance for cancer recurrence or possible new cancer(s), rather than incorporating more holistic survivorship care including consideration of comorbid illness and opportunities for health promotion.^{21,22}

Current models of specialist-led follow-up care leave survivors with significant unmet needs and missed opportunities for health promotion.^{5,23,24} Further, specialist-led care is expensive and unsustainable given the growing numbers of survivors and the limited health workforce.^{5,23,24} Alternative models of follow-up care have been trialled, including those which are led by the patient's general practitioner (GP, also referred to as

primary care provider).^{24–27} Several studies have been undertaken, including an Australian-based randomised controlled trial (RCT) evaluating GP versus specialist follow-up care for survivors of CRC.²⁸ No compelling evidence for difference in efficacy was found. Despite these studies, GP-led follow-up care has not been widely adopted.^{29–31} Our own work with survivors, GPs, surgeons and oncologists reported strong support for GPs to be involved in the ongoing care of CRC survivors and that GPs should be provided with information to facilitate care.³²

The vast majority of CRC survivors have coexisting illness.^{33,34} Models of post-treatment survivorship care should address the holistic health care needs of survivors with optimal cancer-specific follow up, management of comorbid illness, and general preventive care.^{5,23,24} An alternative to oncology-led follow-up is a shared care model, combining the expertise of both primary care generalists, with cancer specialists. International recommendations support shared care models.^{35,36} Shared care is widely used in antenatal care and in the management of chronic conditions such as diabetes, asthma and ischaemic heart disease.

Few studies have examined shared care in the post-treatment survivorship phase.^{23,24,26,27,37} We undertook the first study of shared care with patients treated for prostate cancer.³⁸ This randomised phase II study included 88 men, 45 randomised to usual care and 43 to shared care.³⁹ There were no significant differences between groups with respect to prostate cancer specific QoL, distress or satisfaction. Men exposed to shared care preferred this model, and shared care was also less expensive than usual care.

Here we report results from SCORE (shared care of colorectal cancer survivors), a randomised trial evaluating a model of shared follow-up care which combined care provided by the treating hospital with that from the patient's own GP, for people treated with curative intent for CRC.⁴⁰ The primary objective of SCORE was to determine the effect of shared care versus usual care on overall health-related QoL. Distinct from other studies, SCORE was designed as a non-inferiority study. Secondary objectives included comparing shared care with usual care on QoL; unmet needs; satisfaction; patient perceptions of continuity of care; patient preferences regarding preferred follow up model; clinical care processes (carcinoembryonic antigen (CEA) tests, recurrences) and health system costs.

Methods

Study design

A non-inferiority, parallel individually randomised controlled trial, conducted in two stages, with stage 1 involving an assessment of feasibility and harm in the first N = 100 patients and stage 2 of the trial planned to expand recruitment to a total of 200 patients, should the first stage confirm appropriateness to continue.⁴⁰ Five public hospitals in Victoria, Australia participated.

Ethics statement

Central ethics approval was obtained from Peter MacCallum Cancer Centre (HREC/16/PMCC/89). All sites completed necessary governance approvals. All patients provided written informed consent.

Participants

Patients were eligible if they: had histologically confirmed diagnosis of colon or rectal cancer; had stage I–III disease; completed treatment with curative intent with surgery, with or without radiation, and with or without chemotherapy, within two months; were over the age of 18 years; were able to understand English, and had a GP willing to participate in the study. Exclusion criteria were: cognitive or psychological difficulties that would preclude participation; too unwell to participate; prior cancer, other than non-melanoma skin cancer, and if the person's GP was already participating in the study (to avoid contamination). Data regarding sex was obtained from the patient's medical record, which was supplied on registration to the individual hospital. All participants provided written informed consent.

Randomisation and masking

After providing written informed consent and completing baseline measures, participants were randomised to receive either shared care or usual care using a 1:1 ratio. Randomisation was based on a minimisation scheme with stratification for site. Randomisation sequence was computer-generated using a centralised

randomisation database. Allocation sequence was concealed within a database (Microsoft Access, Microsoft, Redmond, WA, USA) managed by a data manager independent of the day-to-day study operations.

Procedures

Research staff at each recruiting site identified and screened potentially eligible patients from outpatient clinic lists, and chemotherapy, surgery and radiotherapy lists. Eligibility was confirmed with the treating clinician. Research staff approached eligible patients and invited their participation. Eligible and consenting patients completed baseline measures prior to randomisation. The patient's preferred GP was contacted to confirm willingness to be involved. An opt-out approach was used for GPs. If the form was not returned within a week, consent to participate was implied. Outcome measures were collected at end of treatment (baseline) and at 6 and 12 months. Recurrences were collected at 6 and 12 months. Research staff contacted GP practices and hospitals to determine whether CEA blood tests had been ordered. If there were two missing tests in a row (in either study arm), research staff alerted clinical teams.

Usual care

Following treatment completion, patients received standard hospital-based, specialist-led follow up care. This involved 3-monthly specialist visits which included history taking, physical examination and a blood test for CEA, with a computed tomography (CT) scan at 12 months if recommended by the patient's treating specialist.

Shared care

Following treatment completion, follow-up care was shared between the hospital-based specialist and the person's GP for a period of 12 months. The shared care intervention followed the same model as usual care but replaced the specialist appointments at 3 and 9 months with a GP appointment and added an additional GP appointment at 2–6 weeks following the end of treatment to re-establish contact and discuss follow-up care. At baseline, shared care participants also received a tailored survivorship care plan, the 'Living Well after Cancer' booklet produced by Cancer Council (a national cancer charity) and a DVD titled 'Just Take It Day to Day',⁴¹ which was later provided as a weblink. A 'common issues and concerns' checklist was administered prior to GP clinic attendance to assist with identification of individual needs. A survivorship care plan was prepared by the research team, approved by the treating specialist and provided to both the patient and their GP. It included diagnosis, treatment history, details about additional hospital services received and information about common issues experienced by CRC survivors, advice about staying well and available community

services. The patient's GP also received management guidelines detailing common issues experienced by CRC survivors and how to manage these, as well as details on how best to contact the specialist treating team for advice or if recurrence was suspected. Both patients and GPs received a reminder letter about upcoming follow-up appointments, with GPs further reminded to provide information on patient progress and to copy pathology results to the hospital-based team.

Outcome measures

The primary outcome was overall health-related QoL to 12 months assessed by the European Organisation for Research and Treatment of Cancer core questionnaire (EORTC QLQ-C30) Global Health Status/Quality of Life (GHQ-QoL) scale.⁴² Secondary objectives included comparing shared care with usual care on QoL; unmet needs; satisfaction; patient perceptions of continuity of care; patient preferences regarding preferred follow up model; clinical care processes (CEA tests, recurrences) and health system costs.

Individual aspects of QoL

The EORTC QLQ-C30 functional and symptom scales and the CRC module (EORTC QLQ-CR29)⁴³ collectively assess specific symptoms such as fatigue, anxiety and pain as well as function on several domains, including physical, role, emotional, cognitive, social, sexual, urinary and bowel function.

Survivors' unmet needs

The Short-Form Survivor Unmet Needs Survey⁴⁴ provides a measure of cancer survivors' unmet needs, using 30 items across 5 domains: emotional health, access and continuity of care, relationships, financial concerns and information.

Continuity of care

The Picker Ambulatory Oncology survey (AOPSS) comprises eight items that assess patient experience of oncology care.⁴⁵

Satisfaction

The Patient Satisfaction Questionnaire short form, comprises 18 items assessing satisfaction.⁴⁶ All items are scored such that higher scores reflect satisfaction with medical care.

Health care resource use

Patients provided consent to access data on medical service use through Medicare (Australia's publicly funded universal health care system) from the Commonwealth Department of Human Services. This provided information on the type, frequency and costs associated with outpatient and general practice medical service use by participants, as subsidised via the public Medicare Benefits Scheme (MBS).

Recurrence

To determine recurrence, participants are asked to provide an indication that disease recurrence is suspected.

Fidelity

There were two components to the fidelity section. First, participants were asked to respond whether additional specialist/GP appointments were scheduled during the follow-up period. Second, there were eight questions pertaining to what participants remembered receiving (e.g., survivorship care plan, DVD) as part of the intervention.

Economic evaluation

Based on the non-inferiority design, a within-trial cost minimisation analysis was undertaken using a health system perspective.⁴⁷ Health care use was categorised as: (i) follow-up care (protocol specified specialist and GP visits); (ii) CRC investigations (CEA tests, colonoscopies and scans [CT and PET]); (iii) medical services (GP and specialist services [other than for follow up care]), and (iv) other services (all other outpatient services).

In Australia, services provided by public hospital specialists are typically funded via hospital budgets, not MBS. Thus, if a patient had no evidence of MBS data for specialist appointments, it was assumed they were treated as a public hospital patient and attended all their protocol specified specialist appointments. Costs were allocated to these public hospital specialist appointments using the relevant MBS item number (105, specialist attendance at consulting rooms or hospital).⁴⁸ Unit costs were inflated to 2022 Australian dollars (AUD) using a health consumer price index,⁴⁹ converted to 2022 US dollars (USD) using the mean exchange rate for that financial year.⁵⁰

To explore uncertainty around cost minimisation estimates, two sensitivity analyses were conducted, firstly, excluding patients who were withdrawn from the clinical trial (either through cancer recurrence or patient decision), and second, removing assumptions about patients attending specialist appointments as public hospital patients. Statistical significance of the difference in mean total costs was assessed using a generalised linear model with treatment group as the variable of interest.

Statistical analysis

A statistical analysis plan was prepared prior to analysis that provides further detail on the approaches used. The target sample size of 200 was calculated to provide over 80% power at the 2.5% one-sided level of significance to conclude that shared care is non-inferior to usual care on the primary endpoint of GHQ-QoL (EORTC QLQ-C30) to 12 months given a non-inferiority margin of 0.45 SD, a true difference of 0, that 95% of patients will adhere to their assigned

treatment, and that 90% of patients will be followed-up to 12 months. The non-inferiority margin chosen, of 0.45 SDs, was within the minimal clinically important difference proposed for health-related QoL measures,⁵¹ and assumed an SD at month 12 of 22 (based on reference values published by the EORTC). A margin of 0.45 SDs corresponds to a clinically meaningful difference of 10 points on a 0–100 scale.⁵² To compensate for the reduced precision of estimates of effect due to the lower than planned sample size achieved, the primary endpoint was changed to GHQ-QoL (EORTC QLQ-C30) to 12 months, rather than at 12 months. This modification to the research plan was made without knowledge of how this would affect the study conclusions and the principals of the CONSERVE statement were followed.⁵³

The full analysis comprised all randomised patients (intention-to-treat (ITT) population). The Per-Protocol (PP) population comprised all randomised patients who attended at least the 3-month and/or 9-month visits and supplied at least one post-baseline questionnaire (at 6-months and/or 12-months). All endpoints were analysed for the ITT population. For the primary endpoint, sensitivity of non-inferiority conclusions to adherence to the protocol was explored by comparing the results from the ITT and the PP populations.

The primary comparison was based on the overall estimate of treatment effect size, and interpretation focussed on the evaluation of the lower limit of the two-sided 95% confidence interval for the estimated difference (shared care—usual care) against a non-inferiority margin of –10 points. A mixed model for repeated measures (MMRM) was applied to the longitudinal patient-reported scale scores. These models included fixed effect terms for: treatment allocation; time point; baseline assessment; and epoch (pre- and post-covid restrictions); and a random effect for patient. Chi-square tests were used to compare the number of participants experiencing a recurrence in each group, and Fisher's Exact test was used to compare preferences for model of care between groups at each time point. The analyses were performed using SAS version 9.4 and R version 4.2.1.

The study was monitored centrally by the steering committee, see protocol for more details. The trial was registered on the Australian New Zealand Clinical Trials Registry ACTRN1261700004369p. Registered on 3 January 2017; protocol version 4 approved 24 February 2017.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, writing of the report, or in the decision to submit the paper for publication. All authors agreed on the decision to publish. Prof Jefford should be contacted regarding access to the dataset.

Results

Between February 24 2017 and August 27 2018 (stage 1) and October 18 2019 and May 28 2021 (stage 2), a total of 3803 patients were screened and 604 patients were eligible. The majority of those ineligible had metastatic cancer. Principle reasons for not participating included conflicting studies; the impact of COVID-19 on recruitment; patients being too busy or not interested in research; concerns regarding questionnaires; pre-existing preference for either hospital-based, or GP-led care; or lack of confidence in their GP. Some special-ists recommended that patients not be approached, most commonly because of concern of high risk of recurrence; 11 GPs declined participation. 151 patients were randomised, 75 to shared care and 76 to usual care. The vast majority of participants completed 6 and 12 month measures. Fig. 1 shows the Trial profile.

Table 1 shows the number of patients randomised, the number with data available for the primary analysis (i.e., a baseline and at least one post-baseline EORTC QLQ-C30 QoL/GHQ score at 6 months and/or 12 months), and the number in the per protocol population.

Table 2 shows baseline characteristics of all randomised participants. Recruitment continued to stage 2 as the protocol-specified requirements for stopping early due to futility/safety at stage 1 were not met.

Fig. 2 shows results for the primary outcome. There was no statistical evidence that shared care was inferior to usual care on the main study outcome of global QoL. Scale scores on the EORTC QLQ-C30 were similar in patients assigned to shared care or to usual care (Fig. 2). There was no evidence that treatment effect differed across time points (Supplementary Figure S1). Results for the per protocol population were very similar (Supplementary Figure S2).

There were no between-group differences regarding general (EORTC QLQ-C30) or colorectal cancer specific QoL (EORTC QLQ-CR29). Unmet needs (Supplementary Figure S3) and satisfaction (Supplementary Figure S4) were similar in both groups.

With respect to patients' perceptions of continuity of care, results were similar between groups (Table 3), however more people in the shared care arm responded positively at 12 months to the item 'if you had a visit with your family doctor in the past 6 months, did you feel your family doctor knew enough?' (40/62, 65% versus 24/58, 41%). At 12 months, patients in the shared care arm indicated a preference for this model of care (40/63, 63%, Fig. 3). Patients in usual care had the same preference for shared care (22/62, 35%) as for 'follow up care at the hospital, by the doctors who treated my cancer' (22/62, 35%).

Adherence to recommended CEA blood testing was higher in the shared care arm, compared to usual care: 89% (65/73) at 3 months and 83% (58/70) at 9 months in the shared care arm, versus the usual care arm 63%

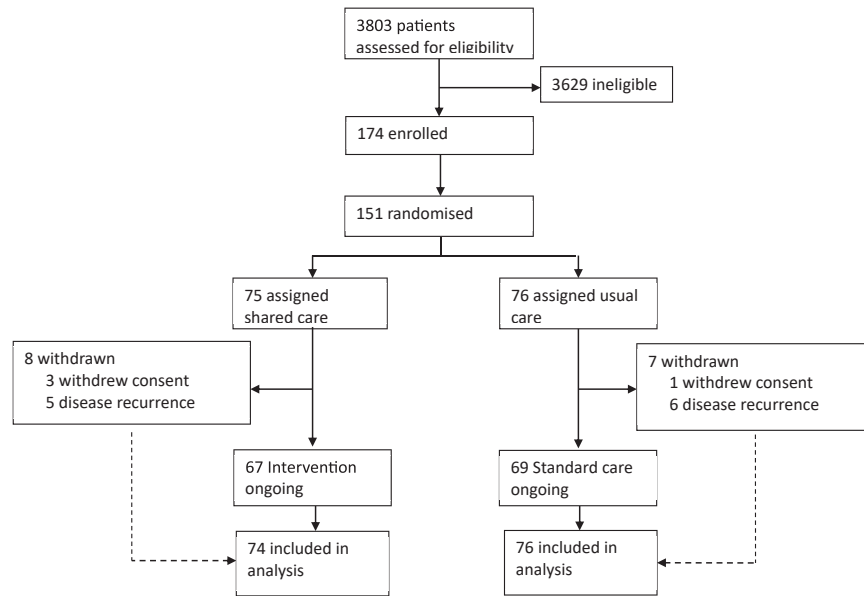


Fig. 1: Trial profile.

(47/75) at 3 months and 68% (49/72) at 9 months. There were 5 recurrences in the shared care arm and 6 in usual care. Median months to recurrence were 5.72 (1.74–9.66) in shared care, and 9.81 (6.77–11.33) in the usual care condition.

Medicare data were available for 144 (95%) patients; 71 in the shared care group and 73 in usual care. Compared to usual care, mean health system costs were approximately USD314 lower in the shared care group, indicating the shared care intervention was cost minimising (Table 4). This was driven by reduced ‘other services’ costs. The results were robust to the sensitivity analyses; the shared care intervention remained cost-minimising.

In accordance with the adherence data, the shared care group had a greater number of CEA tests during the trial (218 at an average of 3.1 tests per patient, compared to 181 [2.8 tests per patient] in usual care). Colonoscopies were similar between groups (three patients had a total of five procedures in usual care, compared to two patients [three procedures] in shared care). While the total number of scans was similar between groups (100 scans [86 CT and 14 PET scans] in usual care and 99 scans [89 CT and 10 PET scans] in shared care), this was spread over a greater number of patients in usual care (66 patients requiring a scan compared to 60 patients in shared care).

Characteristic ^b	Shared care, N = 74 ^a	Usual care, N = 76 ^a	Overall, N = 150 ^a
ITT (randomised)			
Yes	74 (100%)	76 (100%)	150 (100%)
Has a baseline and at least one post-baseline QLQC-30 QoL/GHQ score			
No	5 (6.8%)	7 (9.2%)	12 (8.0%)
Yes	69 (93.2%)	69 (90.8%)	138 (92.0%)
Attendance of 3-month and/or 9-month appointment			
No	6 (8.5%)	25 (34.2%)	31 (21.5%)
Yes	65 (91.5%)	48 (65.8%)	113 (78.5%)
Unknown	3	3	6
PP			
No	13 (17.6%)	7 (9.2%)	20 (13.3%)
Yes	61 (82.4%)	69 (90.8%)	130 (86.7%)

^an (%). ^bAdherence is considered for deriving PP population in Shared Care arm only.

Table 1: Analysis sets.

Characteristic	Shared care, N = 74 ^a	Usual care, N = 76 ^a	Overall, N = 150 ^a
Stage 1 or 2 of trial?			
1	47 (64%)	47 (62%)	94 (63%)
2	27 (36%)	29 (38%)	56 (37%)
Study epoch			
Post covid-19	21 (28%)	23 (30%)	44 (29%)
Pre covid-19	53 (72%)	53 (70%)	106 (71%)
Sex			
Female	28 (38%)	31 (41%)	59 (39%)
Male	46 (62%)	45 (59%)	91 (61%)
Age	64 (51, 73)	63 (54, 72)	63 (53, 73)
Radiotherapy			
Did not receive radiotherapy	57 (77%)	57 (75%)	114 (76%)
Received radiotherapy	17 (23%)	19 (25%)	36 (24%)
Type of colorectal cancer			
Colon	44 (59%)	44 (58%)	88 (59%)
Rectum	24 (32%)	24 (32%)	48 (32%)
Overlapping	6 (8.1%)	8 (11%)	14 (9.3%)

^an (%); Median (IQR).

Table 2: Baseline characteristics.

Discussion

The SCORE study sought to determine whether shared care might be an appropriate model of post-treatment follow up care for survivors of CRC.⁴⁰ Shared care has potential advantages including continuity of care with providers who often have a long-established relationship with the patient, care closer to home, and more optimal oncologic and general and preventive health care.^{24,30,40,54} We found that patients allocated to shared care had non inferior global QoL, compared to those patients who

were followed according to usual care—that is oncologist-led, hospital-based follow up. Patients in both follow up arms experienced similar disease-specific QoL, satisfaction, unmet needs and perception of care coordination. People who had experienced shared care had a strong preference for this model of care. Even those who had not experienced shared care were equally happy to support this model, or the usual care approach. GPs in the shared care arm were more likely to perform recommended surveillance tests, compared with clinicians

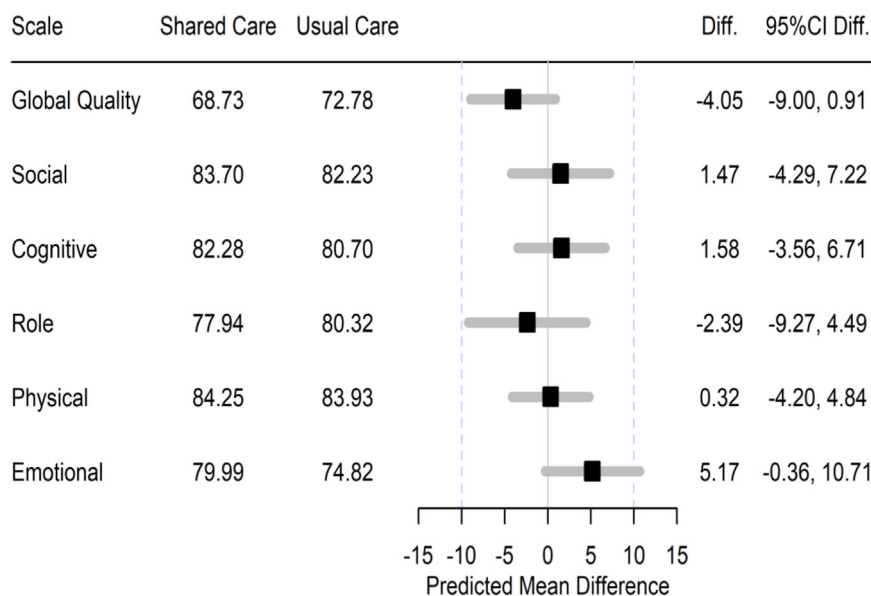


Fig. 2: EORTC QLQ GHQ/QoL and functional scale predicted means (model without a time-by-treatment interaction).

Question	Shared care						Usual care					
	Baseline ^a	N	6 months	N	12 months	N	Baseline ^a	N	6 months	N	12 months	N
Do you think the care providers knew enough about treatments appropriate for you?	62 (84%)	74	52 (79%)	66	45 (73%)	62	63 (85%)	74	51 (77%)	66	43 (70%)	61
Did you know who was in charge of different aspects of your care?	43 (58%)	74	42 (65%)	65	35 (56%)	62	42 (57%)	74	37 (56%)	66	32 (53%)	60
How often were your care providers familiar with your medical history?	34 (46%)	74	33 (51%)	65	31 (49%)	63	35 (47%)	75	27 (41%)	66	28 (47%)	60
How often were your care providers aware of your test results?	41 (55%)	74	35 (54%)	65	32 (52%)	62	37 (49%)	75	38 (58%)	66	32 (53%)	60
How often were you given confusing or contradictory information about your health or treatment?	43 (58%)	74	45 (68%)	66	44 (70%)	63	56 (75%)	75	50 (77%)	65	44 (72%)	61
How often did you know who to ask when you had questions about your health problems?	33 (45%)	73	25 (38%)	65	24 (38%)	63	31 (41%)	75	27 (41%)	66	22 (37%)	60
How often did you know what the next step in your care would be?	29 (40%)	73	25 (38%)	66	22 (35%)	63	32 (42%)	76	29 (44%)	66	23 (38%)	60
If you had a visit with your family doctor in the past 6 months, did you feel your family doctor knew enough?	38 (60%)	63	42 (67%)	63	40 (65%)	62	40 (58%)	69	44 (69%)	64	24 (41%)	58

^an (%).

Table 3: AOPSS frequency and percentage of positive experiences.

in usual care. There was no apparent difference between groups regarding the number of recurrences, or time to detection of cancer recurrence. Finally, shared care was cheaper for the health care system, with patients averaging USD314 less in costs compared to those in usual care.

Our findings are similar to those from our previous study, ProCare, that examined shared care follow up for

survivors of prostate cancer.^{38,39} In ProCare, we found similar QoL scores for those in shared care, as compared to usual care, though this was designed as a superiority trial so there was greater uncertainty about whether QoL scores were truly equivalent. GPs were more adherent to recommended PSA testing, compared to usual practice. Patients exposed to shared care strongly preferred this model of care and, again,

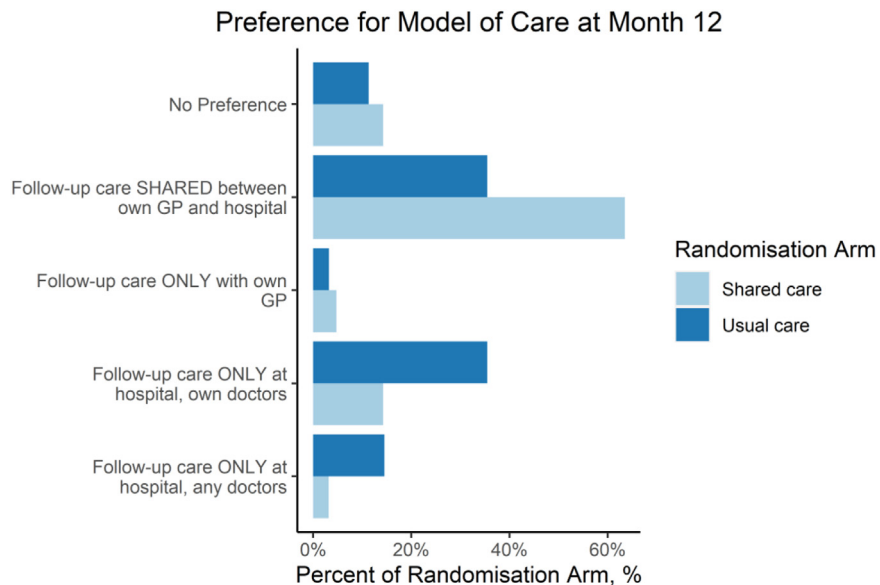


Fig. 3: Patient preference for model of care at month 12.

Cost category	Mean cost shared care (95% CI)	Mean cost usual care (95% CI)	Mean difference (95% CI)
Follow-up care	\$120.62 (\$112.85, \$128.40)	\$93.20 (\$83.76, \$102.64)	\$27.42 (\$25.75, \$29.09)
CRC investigations	\$618.23 (\$479.93, \$756.52)	\$622.37 (\$498.14, \$746.59)	-\$4.14 (-\$18.21, \$9.94)
Medical services	\$460.48 (\$435.56, \$485.40)	\$437.95 (\$396.96, \$478.94)	\$22.53 (\$6.46, \$38.60)
Other services	\$1115.83 (\$790.56, \$1441.11)	\$1455.58 (\$1031.03, \$1880.13)	-\$339.75 (-\$240.48, -\$439.02)
Total costs	\$2349.20 (\$1895.21, \$2803.18)	\$2663.10 (\$2131.12, \$3195.09)	-\$313.91 (-\$235.90, -\$391.91)
Sensitivity analyses			
Excluding patients withdrawn from study	\$2117.67 (\$1678.16, \$2557.18)	\$2452.63 (\$1946.49, \$2958.78)	-\$334.96 (-\$268.33, -\$401.59)
Removing assumption about specialist appointments for public patients	\$2315.17 (\$1859.31, \$2771.03)	\$2609.10 (\$2011.40, \$3146.66)	-\$293.94 (-\$152.10, -\$375.63)

Abbreviations: CI, confidence interval; CRC, colorectal cancer. Results of the generalised linear model for mean total cost showed shared cost USD\$296.82 (95% CI -\$156.99, -\$436.64, p-value <0.001) less than standard of care; consistent with the result of the arithmetic difference of means reported in Table 4.

Table 4: Mean health system costs by treatment arm (valued in 2022 USD).

shared care was cheaper for the health care system (with average cost savings of USD237 per patient in 2022). SCORE and ProCare are amongst few published randomised controlled studies that have examined shared post-treatment follow up care for cancer survivors.

We had hypothesised that shared care might result in improved focus on the issues that survivors can commonly experience after cancer treatment. We anticipated that this might then translate to improved general and disease-specific QoL, fewer unmet needs and higher satisfaction. This was not observed. We hypothesise that this may be because the SCORE study did not place sufficient focus on eliciting and responding to these issues. Future studies might encourage patients and GPs to more deliberately identify issues and needs, using patient-reported outcomes or question prompt lists, and place greater emphasis on the delivery, receipt and use of such tools to identify and address survivorship concerns.^{30,55,56} GPs could also be provided with advice and support to manage common survivorship concerns, including details regarding care pathways and services that patients may be referred to.^{55,56} It is also possible that the measures used to assess these secondary outcomes (QoL, needs, etc) may not be sensitive to improvements that are nevertheless meaningful to patients.

There have been multiple studies of GP-led follow up (not shared care).^{24–27} These were not designed as non-inferiority studies. Although they have shown no evidence that either condition is superior and that GP-led care is preferred by patients, and cheaper to the healthcare system, this model has not been widely implemented. Possible reasons for this, supported by several studies, include reluctance of GPs to assume full responsibility for survivorship care, reluctance of oncology specialists to transfer care, and patient preference to maintain contact with oncology providers.^{29–31} Shared care offers potential advantages including that there is no full transfer of care, or this transfer is gradual.

The SCORE study was impacted by the COVID-19 pandemic. In addition to impacting recruitment (all trial recruitment was suspended for several months), the pandemic saw a major shift to telehealth-based, rather than in-person face-to-face visits as part of usual hospital follow-up. One of the potential advantages of shared care is that the patient's GP is often closer to the patient's home or workplace, compared with a cancer hospital. This often makes GP visits more convenient and often cheaper, with fewer travel-associated costs. During the pandemic the experimental arm (shared care) and the usual condition (hospital-based care) became more similar, both providing telehealth follow up. We did not see differences according to study epoch (pre or post COVID) and notably shared care was still the preferred model for those exposed to this condition.

Although more people in the shared care arm endorsed the item 'if you had a visit with your family doctor in the past 6 months, did you feel your family doctor knew enough?' numerous patients reported suboptimal communication and care coordination. Within the SCORE study we also interviewed patients, GPs and oncologists about shared care and about telehealth. This data will be reported separately (manuscript under review), but supports challenges with communication and care coordination. This is a consistent issue in studies of both GP-led care, and in studies of shared care.^{24,29–31,55,56} It is possible that, over time, shared care models might support GPs to feel more knowledgeable and confident in managing patients with cancer.

One strength of this study is high participation and retention of both patients and GPs. Few patients withdrew from shared care, and patients exposed to this model had a strong preference for shared care. Very few GPs declined participation, patients attended GP visits, and almost no GPs withdrew whilst involved with SCORE. This indicates the acceptability of GP participation in the shared follow up of cancer survivors.

SCORE was conducted in the public health care setting in Melbourne, Australia. It is possible that findings may not apply to other settings, including in

the private health care setting in Australia, or to other countries, including in developing countries. Countries differ with respect to the availability of primary care practitioners.^{23,24} Where there is limited availability, a shared care model like SCORE may not be feasible. Also, an important driver within the public health care system is cost containment and an emphasis on high value care. Our results indicate that a shared care approach is likely to result in a reduction in health care costs for this patient group. Also, by reducing the intensity of hospital-based follow up, oncologists are freed to consult new patients in a more timely manner. It may be more difficult to reduce follow up within a fee for service private system. Although shared care may place added burden on GPs, an individual GP is likely to have only a few cancer survivors.

A limitation of SCORE is that the period on study was only 12 months, and evaluations were only conducted up to 12 months. Therefore, we do not know the impact of a shared care model beyond 12 months. However, together with studies that have evaluated GP-led follow up, there does not appear to be any evidence of harm as a consequence of GP involvement (either in GP-led follow up care, or in a shared care model). We did not collect detailed data regarding adherence to all aspects of the protocol. Although we recorded the number of GP visits in each arm (collected by both patient report and through Medicare data), we did not count whether each scheduled visit took place, and on time.

Patients in the shared care arm received a package of care comprising not solely the shared hospital and GP visits, but also additional information (survivorship care plan, general information about the post-treatment survivorship phase), which was not routinely provided to patients in the usual care condition. Part of the overall assessment of shared care therefore must consider this. While additional information may increase satisfaction, it is possible too that, for some patients, this might actually cause additional distress.

We conclude that shared care appears to be a safe alternative to hospital-based specialist-led care with evidence of equivalent QoL outcomes. GPs appear to be at least as able as hospital providers to complete recommended surveillance testing. Patients exposed to shared care indicate a preference for this model, and shared care is cheaper for the health care system. Shared care may be appropriate for many survivors of CRC treated with curative intent. This may also free up limited hospital-based oncologist resources, contributing to more sustainable cancer care.

Contributors

MJ, PS, JE, AM, RDAL, KL, and EG designed the study, sought and obtained funding, monitored progress of the study, reviewed data and analysis. AM with RE and HT designed and undertook statistical analysis. RDAL with JC designed and undertook the health economic

analysis. DK and JM are patient partners involved in study design and monitoring and review of data. MAM and AM managed the study including ethics and governance at all study sites. NCT, ML, and AB were site leads involved in all aspects of study participation including supporting ethics and governance approvals and patient recruitment. MJ wrote the first draft of the paper. All authors reviewed the draft manuscript.

Data sharing statement

De-identified aggregate data, the study protocol, participant information and consent forms and statistical analysis plan is available from the corresponding author.

Declaration of interests

We declare no competing interests.

Acknowledgements

We gratefully acknowledge funding from the Victorian Cancer Agency (grant number HSR 15036) and from Cancer Australia (grant number 1158397). JDE is supported by an NHMRC Investigator grant APP1195302.

Appendix A. Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.jeclinm.2023.102346>.

References

- 1 Bray F, Ferlay J, Soerjomataram I, et al. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin.* 2018;68:394–424.
- 2 Siegel RL, Wagle NS, Cercek A, et al. Colorectal cancer statistics, 2023. *CA Cancer J Clin.* 2023;73:233–254.
- 3 Miller KD, Nogueira L, Devasia T, et al. Cancer treatment and survivorship statistics, 2022. *CA Cancer J Clin.* 2022;72:409–436.
- 4 Emery J, Butow P, Lai-Kwon J, et al. Management of common clinical problems experienced by survivors of cancer. *Lancet.* 2022;399:1537–1550.
- 5 Hewitt M, Greenfield S, Stovall E. *From cancer patient to cancer survivor: lost in transition.* Washington, DC: National Academies Press; 2006.
- 6 Eid Y, Bouvier V, Menahem B, et al. Digestive and genitourinary sequelae in rectal cancer survivors and their impact on health-related quality of life: outcome of a high-resolution population-based study. *Surgery.* 2019;166:327–335.
- 7 Jones JM, Olson K, Catton P, et al. Cancer-related fatigue and associated disability in post-treatment cancer survivors. *J Cancer Surviv.* 2016;10:51–61.
- 8 Keane C, O'Grady G, Bissett I, et al. Comparison of bowel dysfunction between colorectal cancer survivors and a non-operative non-cancer control group. *Colorectal Dis.* 2020;22:806–813.
- 9 Yde J, Larsen HM, Laurberg S, et al. Chronic diarrhoea following surgery for colon cancer—frequency, causes and treatment options. *Int J Colorectal Dis.* 2018;33:683–694.
- 10 Custers JAE, Gielissen MFM, Janssen SHV, et al. Fear of cancer recurrence in colorectal cancer survivors. *Support Care Cancer.* 2016;24:555–562.
- 11 Fisher A, Beeken RJ, Heinrich M, et al. Health behaviours and fear of cancer recurrence in 10 969 colorectal cancer (CRC) patients. *Psychooncology.* 2016;25:1434–1440.
- 12 Graca Pereira M, Figueiredo AP, Fincham FD. Anxiety, depression, traumatic stress and quality of life in colorectal cancer after different treatments: a study with Portuguese patients and their partners. *Eur J Oncol Nurs.* 2012;16:227–232.
- 13 den Bakker CM, Anema JR, Huirne JAF, et al. Predicting return to work among patients with colorectal cancer. *Br J Surg.* 2020;107:140–148.
- 14 Mo M, Jia P, Zhu K, et al. Financial toxicity following surgical treatment for colorectal cancer: a cross-sectional study. *Support Care Cancer.* 2023;31:110.
- 15 Yuan CM, Wang CC, Wu WT, et al. Risk factors for return to work in colorectal cancer survivors. *Cancer Med.* 2021;10:3938–3951.

- 16 Chambers SK, Meng X, Youl P, et al. A five-year prospective study of quality of life after colorectal cancer. *Qual Life Res.* 2012;21:1551–1564.
- 17 Downing A, Morris EJ, Richards M, et al. Health-related quality of life after colorectal cancer in England: a patient-reported outcomes study of individuals 12 to 36 months after diagnosis. *J Clin Oncol.* 2015;33:616–624.
- 18 Jansen L, Herrmann A, Stegmaier C, et al. Health-related quality of life during the 10 years after diagnosis of colorectal cancer: a population-based study. *J Clin Oncol.* 2011;29:3263–3269.
- 19 Jansen L, Koch L, Brenner H, et al. Quality of life among long-term (>/=5 years) colorectal cancer survivors—systematic review. *Eur J Cancer.* 2010;46:2879–2888.
- 20 Ramsey SD, Berry K, Moinpour C, et al. Quality of life in long term survivors of colorectal cancer. *Am J Gastroenterol.* 2002;97:1228–1234.
- 21 Argiles G, Taberner J, Labianca R, et al. Localised colon cancer: ESMO clinical practice guidelines for diagnosis, treatment and follow-up. *Ann Oncol.* 2020;31:1291–1305.
- 22 Meyerhardt JA, Mangu PB, Flynn PJ, et al. Follow-up care, surveillance protocol, and secondary prevention measures for survivors of colorectal cancer: American Society of Clinical Oncology clinical practice guideline endorsement. *J Clin Oncol.* 2013;31:4465–4470.
- 23 Alfano CM, Jefford M, Maher J, et al. Building personalized cancer follow-up care pathways in the United States: lessons learned from implementation in England, Northern Ireland, and Australia. *Am Soc Clin Oncol Educ Book.* 2019;39:625–639.
- 24 Jefford M, Howell D, Li Q, et al. Improved models of care for cancer survivors. *Lancet.* 2022;399:1551–1560.
- 25 Chan RJ, Crawford-Williams F, Crichton M, et al. Effectiveness and implementation of models of cancer survivorship care: an overview of systematic reviews. *J Cancer Surviv.* 2023;17:197–221.
- 26 Vos JAM, Duineveld LAM, Wieldraaijer T, et al. Effect of general practitioner-led versus surgeon-led colon cancer survivorship care, with or without eHealth support, on quality of life (I CARE): an interim analysis of 1-year results of a randomised, controlled trial. *Lancet Oncol.* 2021;22:1175–1187.
- 27 Hoeg BL, Bidstrup PE, Karlsen RV, et al. Follow-up strategies following completion of primary cancer treatment in adult cancer survivors. *Cochrane Database Syst Rev.* 2019;2019:CD012425.
- 28 Wattchow DA, Weller DP, Esterman A, et al. General practice vs surgical-based follow-up for patients with colon cancer: randomised controlled trial. *Br J Cancer.* 2006;94:1116–1121.
- 29 Hayes BD, Young HG, Atrchian S, et al. Primary care provider-led cancer survivorship care in the first 5 years following initial cancer treatment: a scoping review of the barriers and solutions to implementation. *J Cancer Surviv.* 2022. <https://doi.org/10.1007/s11764-022-01268-y>.
- 30 Schutze H, Chin M, Weller D, et al. Patient, general practitioner and oncologist views regarding long-term cancer shared care. *Fam Pract.* 2018;35:323–329.
- 31 Vos JAM, de Best R, Duineveld LAM, et al. Delivering colon cancer survivorship care in primary care; a qualitative study on the experiences of general practitioners. *BMC Prim Care.* 2022;23(13).
- 32 Baravelli C, Krishnasamy M, Pezaro C, et al. The views of bowel cancer survivors and health care professionals regarding survivorship care plans and post treatment follow up. *J Cancer Surviv.* 2009;3:99–108.
- 33 Cuthbert CA, Hemmelgarn BR, Xu Y, et al. The effect of comorbidities on outcomes in colorectal cancer survivors: a population-based cohort study. *J Cancer Surviv.* 2018;12:733–743.
- 34 Thong MSY, Boakye D, Jansen L, et al. Comorbidities, rather than older age, are strongly associated with higher utilization of healthcare in colorectal cancer survivors. *J Natl Compr Canc Netw.* 2021;20:468–478.e7.
- 35 McCabe MS, Bhatia S, Oeffinger KC, et al. American Society of Clinical Oncology statement: achieving high-quality cancer survivorship care. *J Clin Oncol.* 2013;31:631–640.
- 36 Vaz-Luis I, Masiero M, Cavaletti G, et al. ESMO Expert Consensus Statements on Cancer Survivorship: promoting high-quality survivorship care and research in Europe. *Ann Oncol.* 2022;33:1119–1133.
- 37 Zhao Y, Brettle A, Qiu L. The effectiveness of shared care in cancer survivors—a systematic review. *Int J Integr Care.* 2018;18:2.
- 38 Emery J, Doorey J, Jefford M, et al. Protocol for the ProCare Trial: a phase II randomised controlled trial of shared care for follow-up of men with prostate cancer. *BMJ Open.* 2014;4:e004972.
- 39 Emery JD, Jefford M, King M, et al. ProCare Trial: a phase II randomized controlled trial of shared care for follow-up of men with prostate cancer. *BJU Int.* 2017;119:381–389.
- 40 Jefford M, Emery J, Grunfeld E, et al. SCORE: shared care of colorectal cancer survivors: protocol for a randomised controlled trial. *Trials.* 2017;18:506.
- 41 Karahalios A, Baravelli C, Carey M, et al. An audiovisual information resource to assist in the transition from completion of potentially curative treatment for cancer through to survivorship: a systematic development process. *J Cancer Surviv.* 2007;1:226–236.
- 42 Aaronson NK, Ahmedzai S, Bergman B, et al. The European Organization for research and treatment of cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. *J Natl Cancer Inst.* 1993;85:365–376.
- 43 Whistance RN, Conroy T, Chie W, et al. Clinical and psychometric validation of the EORTC QLQ-CR29 questionnaire module to assess health-related quality of life in patients with colorectal cancer. *Eur J Cancer.* 2009;45:3017–3026.
- 44 Campbell HS, Hall AE, Sanson-Fisher RW, et al. Development and validation of the short-form survivor unmet needs survey (SF-SUNS). *Support Care Cancer.* 2014;22:1071–1079.
- 45 National Research Corporation. *Development and validation of the Picker Ambulatory Oncology Survey Instrument in Canada: final report.* Markham, ON, Canada: National Research Corporation; 2003.
- 46 Marshall GN, Hays RD. *The patient satisfaction questionnaire short-form (PSQ-18).* Santa Monica, CA, USA: RAND Corporation; 1994.
- 47 Briggs AH, O'Brien BJ. The death of cost-minimization analysis? *Health Econ.* 2001;10:179–184.
- 48 Australian Government Department of Health and Aged Care. *Medicare benefits schedule: item 105.* 2023.
- 49 Australian Institute of Health and Welfare. *Health & welfare expenditure overview.* 2022.
- 50 Australian Government Australian Taxation Office. *Rates for financial year ending 30 June 2022.* 2022.
- 51 Norman GR, Sloan JA, Wyrwich KW. Interpretation of changes in health-related quality of life: the remarkable universality of half a standard deviation. *Med Care.* 2003;41:582–592.
- 52 Osoba D, Rodrigues G, Myles J, et al. Interpreting the significance of changes in health-related quality-of-life scores. *J Clin Oncol.* 1998;16:139–144.
- 53 Orkin AM, Gill PJ, Ghersi D, et al. Guidelines for reporting trial protocols and completed trials modified due to the COVID-19 pandemic and other extenuating circumstances: the CONSERVE 2021 statement. *JAMA.* 2021;326:257–265.
- 54 Rubin G, Berendsen A, Crawford SM, et al. The expanding role of primary care in cancer control. *Lancet Oncol.* 2015;16:1231–1272.
- 55 Lisy K, Kent J, Dumbrell J, et al. Sharing cancer survivorship care between oncology and primary care providers: a qualitative study of health care professionals' experiences. *J Clin Med.* 2020;9:2991.
- 56 Lisy K, Kent J, Piper A, et al. Facilitators and barriers to shared primary and specialist cancer care: a systematic review. *Support Care Cancer.* 2021;29:85–96.