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Review

Effects of routine collection of patient-reported outcomes on patient health outcomes in oncology settings: A systematic review

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ABSTRACT

Objective: This study aims to investigate the potential benefits of integrating patient-reported outcomes (PROs) into routine clinical practice for patients undergoing active anticancer treatment.

Methods: We conducted a comprehensive systematic review of randomized controlled trials involving cancer patients undergoing active anticancer treatment, spanning various cancer types and stages. The review covered four electronic databases (Medline, EMBASE, Cochrane Library, and CINAHL) up to September 2022. Key inclusion criteria focused on the incorporation of PROs as a routine intervention. Bias assessment followed the Cochrane collaboration's criteria, while the synthesis of results utilized effect size measurements (Cohen's d). The study adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.

Results: Out of 1549 initially screened records, 16 published randomized controlled trials encompassing 5300 patients met the inclusion criteria. The interventions involved 18 different PROs measurements, with prominent tools being EORTC QLQ-C30 (utilized in four trials) and PRO-CTCAE (utilized in four trials). Measured endpoints included overall quality of life (12 trials), physical health (11 trials), mental health (7 trials), and social health (5 trials). Overall, the study revealed a limited number of statistically significant findings, with predominantly small to moderate effect sizes associated with the interventions.

Conclusions: The findings suggest that the routine integration of PROs into clinical practice does not yield definitive advantages in terms of PROs. It is apparent that further efforts are necessary to ascertain the impact of these interventions on patient health.

Systematic review registration: The review protocol was registered on PROSPERO (ID: CRD42022365456).

Introduction

Cancer caused nearly 10 million deaths in 2020 and continues to be a major public health concern.[1] Appropriate and effective treatments may cure the cancer or prolong life. However, cancer patients receiving treatment commonly suffer from symptoms that often are overlooked or underestimated.[2,3] This implies a need for patient-reported outcomes (PROs) to assist with symptom detection. To date, many PRO measurements have been developed; there is a rapidly growing interest in integrating PROs into routine clinical practice for compiling patient status reports.[4]

The introduction of PROs into the clinical context brings considerable benefits for disease monitoring and treatment adherence.[5–9] PRO measures may also improve patient health when used in daily oncologic clinical practice.[10–17] However, the evidence supporting the positive health-related effects of PROs is equivocal.

Kotronoulas et al suggest that PRO assessment effects on health outcomes, physical symptoms, quality of life (QoL), and psychological symptoms are clinically meaningful but not always statistically significant.[18] Jack et al included 27 articles citing potentially positive impacts on symptoms, side effects, toxicity, and emotional well-being.[19] Nonetheless, the evidence for social well-being and improved QoL is inadequate.

Thus, given the advances in cancer treatment over the last decade,[20] the effect of regular collection of PROs in oncologic settings requires further exploration, as evidenced by the substantial number and quality of randomized controlled trials (RCTs) in this field.[14–17,21,22] Here, we performed a systematic review to identify RCTs of interventions that involved the routine collection of PROs related to cancer or its treatment.

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Methods

The review was conducted according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses criteria.[23] The review protocol was registered on PROSPERO (ID: CRD42022365456). Eligibility evaluation, data extraction, and risk of bias assessment were performed independently by two reviewers (DY and FL). Any disagreements were discussed with the third reviewer (QM).

Search strategy

We searched Medline, EMBASE, Cochrane Library, and CINAHL from database inception to September 2022, using a systematic strategy that was devised and refined by researchers and a professional medical librarian via an interactive process. The following medical subject heading terms and text words were used: ("neoplasms" OR "cancer" or "tumor") AND ("patient-reported outcome measures") AND ("Randomized Controlled Trial"). More details were presented in Tables 1–4. The reference lists of the articles were searched for any missed studies.

Eligibility criteria

The literature selection in this present study was based on the following inclusion criteria: patients were of 18 years or older; the patient must be diagnosed with cancer (all cancer types, grades, stages, and prognoses) and under anticancer treatment. The intervention of patients was asked or positive to fill out PRO measurements on a regular basis (daily/weekly/monthly/every clinical appointment) and subsequently with or without timely feedback to healthcare professionals. There were no restrictions on the types, forms, or content of PRO measurements and no limits on the setting of PRO measurements administration. Outcomes included patient health outcomes; articles were available electronically. More details about the inclusion and exclusion criteria are summarized in Table 5.

Table 1
The design characteristics and public years of included studies.

Total	*n* (%)	
	n = 16	Percentage (%)
Publication year		
1996	1	(6)
2004	1	(6)
2006	1	(6)
2009	2	(13)
2016	2	(13)
2017	1	(6)
2020	3	(19)
2021	3	(19)
2022	2	(13)
Study location		
USA	4	(25)
UK	4	(25)
France	2	(13)
Switzerland	1	(6)
Dutch	1	(6)
Sweden	1	(6)
Demark	1	(6)
Canada	1	(6)
Multi countries	1	(6)
Study center		
Multicenters	9	(56)
Single-center	6	(38)
Not reported	1	(6)
Study setting		
Home	11	(69)
Outpatient clinic	3	(19)
Two centers	2	(13)
Cancer type		
Mixed population	10	(63)
Breast cancer	3	(19)
Lung cancer	1	(6)
Head and neck cancer	1	(6)
Melanoma	1	(6)

Data extraction procedures

From each included study, we extracted data according to well-designed data extraction table.

Risk of bias

The risk of bias was assessed according to the Cochrane collaboration's risk-of-bias tool 2.0 (ROB 2.0).[24] The reviewers were not blinded to any journal information.

Synthesis of results and determination of effect size

A meta-analysis was not feasible due to the variability among studies. Individual outcomes were classified into outcome categories, which were determined according to the World Health Organization's three dimensions of health. When enough data were available, effect sizes (ESs; Cohen's d) and 95% confidence intervals were estimated. ESs with $d \geq 0.2$, $d \geq 0.5$, and $d \geq 0.8$ were considered small, moderate, and large, respectively.[25]

Results

Search results and study characteristics

The initial search retrieved 1539 references from electronic databases and 10 from reference lists.[11,13,15,17,21,26–30] Sixteen articles reporting 16 unique RCTs fulfilled the eligibility criteria and were included in a qualitative synthesis (Figure 1).

The demographic characteristics of the included studies are, respectively, shown in Table 1. While we searched the literature from database inception, 11 trials (69%) were published between 2012 and 2022, indicating a marked increase in the volume of studies published over the last decade in this area. Forty (25%) studies were conducted in the USA; forty (25%) studies were conducted in the UK. Nine trials (56%) were multicenter studies. Most studies were conducted in home settings (n = 11, 69%), and only 3 trials (19%) were in outpatient clinics. Ten studies were conducted among a mixed population with a variety of cancer types. The most measured population was that of patients having breast cancer (n = 4). All patients were receiving active anticancer treatments during study participation, and these treatments were most frequently chemotherapy or surgery.

The summary of intervention details of the included studies is shown in Table 2. The number of study patients varied (median, 194.5; range, 50–1191 individuals; total, 5300 individuals). The quality of studies published since 2012 has also improved demonstrably, with much larger sample sizes, including six trials with sample sizes exceeding 200 and four trials with sample sizes exceeding 500. The PRO measurements were completed by all patients in the intervention group. In seven studies, the clinician asked or recommended contacting the patient if the PRO measures score reached the alert threshold,[26–28,30–33] two studies sent knowledge support materials,[17,21] and seven studies placed PROM summaries in the medical records or sent them to health providers before the clinical visit as a reference.[11,13,15,29,34–36] Three studies (19%) adopted a comprehensive theoretical model and framework or had clinicians follow specific guidelines for PROs feedback.[11,15,21] Nine trials (56%) implemented PROs intervention every week, two trials (13%) daily, and two trials (13%) monthly. Thirteen trials (81%) evaluated the intervention effects long-term (3 months).

Eighteen PRO measures were administered in the reviewed trials to deliver the interventions (Table 3). Ten RCTs relied on only one intervention PRO measure, three RCTs two PRO measures,[34–36] and two RCTs

Table 2
The summary of intervention details of included studies.

Author and Year of study	Sample size	Intervention/Control	Timepoint and time length of PRO measures administration	Feedback to PRO measures outcomes	Guidelines were used to guide clinician response	Health outcomes assessed	Timepoint of outcomes assessed
Maunsell et al, 1996	130(I); 131(C)	***Intervention***: Brief psychosocial intervention from social worker post-surgery and screening for psychological distress with PROM; further intervention for highly distressed patients. ***Control:*** Brief psychosocial intervention by social worker post-surgery but no screening.	***Begins***: 21 days after randomization; ***Frequency:*** Monthly ***Time length:*** For approximately 360 days	Social workers telephone all patients with scores $\geq$ 5 as quickly as possible within the 2-week.	No	***Primary outcome:*** Psychologic distress; ***Other outcomes:*** Physical health; functional status; performance of Social and leisure activities; return to work; Marital satisfaction	***3 times:*** Baseline; 3 months after initial surgical treatment; 12 months after initial surgical treatment
Velikova et al, 2004	144(I); 70(C); 72(C)	***Intervention:*** Completion of touch-screen intervention PROMs before clinic visit and feedback available to physicians. ***Attention control:*** Completion of intervention PROMs before clinic visit, but feedback unavailable to physicians. ***Control:*** Standard care.	**Begins:** NR ***Frequency:*** Before every clinic encounter ***Time length:*** For approximately 180 days	Physicians discuss the outcomes during every clinic appointment.	No	***Primary outcome:*** Quality of life	***4 times:*** Baseline, After three on-study encounters (approximately 2–3 months); After 4 months, At study end (approximately 6 months).
Kornblith et al, 2006	96(I); 93(C)	***Intervention:*** Completion of intervention PROMs at home monthly for 6 months through telephone in addition to educational materials; Feedback available to oncology nurse if levels of distress above preset cut-off scores; Individualized discussion and treatment recommendation during follow-up calls. ***Control:*** Standard care and educational materials only.	***Begins:*** NR; ***Frequency:*** Monthly ***Time length:*** For approximately 180 days	Oncology nurse call patients who scored above these cut-off levels to discuss these findings and, if warranted, made a treatment recommendation.	NO	***Primary outcome:*** Psychologic distress; ***Other outcomes:*** Physical distress; Social support	***3 times:*** Baseline; 6 months after entry (at the completion of intervention); 9 months after entry (3 months after the completion of intervention)
Kearney et al, 2009	56(I); 56(C)	***Intervention:*** Completion of intervention PROM on mobile phone at home on days 1–14 post chemotherapy administration; Symptom information available to clinicians in real-time in the form of alerts (amber: mild/moderate severity; red: severe or life-threatening); Clinicians contacted the patient within 1 h (red). ***Control:*** Standard care.	***Begins:*** 1–14 days after chemotherapy ***Frequency:*** Twice daily ***Time length:*** Four cycles of chemotherapy (for approximately 84–112 days)	Clinicians were advised to contact patients within 1 h of receipt of a red alert.	No	***Primary outcome:*** Incidence, severity and distress of six chemotherapy-related symptoms (nausea, vomiting, fatigue, mucositis, hand–foot syndrome and diarrhea)	***5 times:*** Baseline; Pre-cycle 2; Pre-cycle 3; Pre-cycle 4; Pre-cycle 5
Mills et al, 2009	57(I); 58(C)	***Intervention:*** Weekly completion of intervention PROM at home; Patients were asked to share information with any health care professionals involved in their care. ***Control:*** Usual care.	***Begins:*** NR ***Frequency:*** Weekly ***Time length:*** For approximately 112 days	Health care professionals can use the PROs data during patient consultation.	No	***Primary outcome:*** Change in health-related quality life from Trial Outcome Index subscale summary score; ***Other outcomes:*** Change in health-related quality life from other indices	***3 times:*** Baseline; 2nd month; 4th month
Basch et al, 2016	441(I); 325(C)	***Intervention:*** Weekly completion of intervention PROM at home for computer-experienced participants and patients were	***Begins***: NR ***Frequency***: Weekly for computer-experienced participants; every clinic visits for	Treating oncologist can refer to a report tracking participants' symptoms at clinic visit; Nurses received e-mail alerts when participants	No	***Primary outcome:*** Health-related quality of Life; ***Other outcomes:*** Emergency room visits; Hospitalizations;	***4 times:*** Baseline; every 12 $\pm$ 4 weeks until 6 months; 1 year

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Table 2 (*continued*)

Author and Year of study	Sample size	Intervention/Control	Timepoint and time length of PRO measures administration	Feedback to PRO measures outcomes	Guidelines were used to guide clinician response	Health outcomes assessed	Timepoint of outcomes assessed
		encouraged to call the hospital office for medical help; completed during every clinic visit for computer-inexperienced participants; oncologist can refer to the printed report during clinic visit. ***Control***: Usual care.	computer-inexperience participants ***Time length***: For approximately 180 days	reported severe or worsening symptoms and initiated clinical actions in response to the alerts, including telephone counseling about symptom management, supportive medication initiation/change, referral to the ER/ hospital, chemotherapy dose modification, and imaging/test orders.		Survival; quality-adjusted survival	
Strasser et al, 2016	145(I); 119(C)	***Interventions:*** Weekly completion of intervention PROM immediately before every clinic visit; a printed colored comprehensive longitudinal monitoring sheet (LoMoS) was immediately given to the oncologists for reference. ***Control:*** Usual care.	***Begins:*** NR ***Frequency:*** Before weekly oncologists' visit ***Time length:*** For approximately 180 days	Oncologists can refer to the PROs data at clinic visit.	No	***Primary outcome:*** Change of quality of life; ***Other outcomes:*** Symptom distress; symptom complexity; function; nutrition	***2 times*** for quality of life: Baseline, 6 weeks (after last study visit) ***Several times*** for symptoms and functions and nutrition: Baseline and weekly
Denis et al, 2017	60(I); 61(C)	***Interventions:*** Weekly completion of intervention PROM; add spontaneous comments to report other symptoms or incidents in a free text window; web-mediated prompting of follow-up CT scans; alert email was automatically sent to the oncologist when self-scored symptoms matched predefined criteria. ***Control*:** Usual care (routine follow-up with CT scans scheduled every three to six months).	***Begins***: NR ***Frequency***: Before weekly oncologists' visit ***Time length***: for approximately 180 days	After algorithm notification, a nurse of the institution called the patient to check whether the web reporting symptom was accurate; if so, the oncologist was asked to contact the patient by phone. If a relapse or some dangerous condition was suggested, a clinical visit (and, if needed, CT scans) was performed within 8 days after the oncologists 'phone call. Additional comment automatically triggered a web-alert to the oncologist but provider judgment was used whether to follow-up by phone call.	No	***Primary outcome:*** Overall Survival; ***Other outcomes:*** Performance status (the total score of 5 symptoms); progression-free survival (duration from randomization to the first radiologic observation of disease progression or to last follow-up when the patient is censored); change of quality of life	***4 times:*** Baseline; 3rd month; 6th month; 12th month
Fjell et al, 2020	74(I); 75(C)	***Interventions***: Daily completion of intervention PROM; system generated the alerts to inform nurse; if an alert is triggered, a notification suggests to the patient to read related self-care advice; patient has continuous access to evidence-based self-care advice and relevant websites. ***Control***: Standard care.	***Begins:*** First day of Neoadjuvant chemotherapy ***Frequency:*** Daily on weekdays ***Time length:*** For approximately 126 days (until two weeks after end of Neoadjuvant chemotherapy)	Nurses will contact the patients when score generate an alarm to discuss the symptom and how it should be managed. The patients were instructed to contact the clinic according to standard procedure if emergency health care attention outside these hours was needed.	No	***Primary outcome:*** Symptom burden; other outcomes: quality of life	***2 times***: Baseline; 2 weeks after the end of chemotherapy
Lugtenberg et al, 2020	60(I); 53(C)	***Interventions***: Completion of intervention assessment consisting of QoL, distress, and care needs before every chemotherapy cycle visit; patients and their health care providers received a copy of the QoL overview and results were shown in patients' medical files. ***Control***: Standard care.	***Begins***: First chemotherapy cycle clinic visits ***Frequency***: Before every chemotherapy cycle visit ***Time length***: Until the first follow-up visits after chemotherapy	Health care providers can refer to and discuss the outcomes every medical visits.	Yes	***Other outcomes***: Quality of life; Illness perceptions; Distress	***4 times:*** Baseline; Before the start of the second chemotherapy; 2 months after the second chemotherapy; 4 months later, the second chemotherapy

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Table 2 (*continued*)

Author and Year of study	Sample size	Intervention/Control	Timepoint and time length of PRO measures administration	Feedback to PRO measures outcomes	Guidelines were used to guide clinician response	Health outcomes assessed	Timepoint of outcomes assessed
Tolstrup et al, 2020	73(I); 73(C)	***Interventions***: Weekly completion of intervention PROM; as soon as the patients reported a mild or higher adverse event, an alert was triggered telling the patient to contact the hospital. ***Control***: Standard care (assessment of adverse events by a clinician before each treatment cycle).	***Begins***: First immunotherapy clinic visits ***Frequency***: Weekly ***Time length:*** For approximately 168 days	When the patients came for their scheduled appointment in the outpatient clinic, the physician would log into the system to see the patient reporting and discuss it with the patient.	No	***Primary outcome:*** Number of severe adverse events (grades 3 and 4); ***Other outcomes:*** Number of telephone consultations; extra outpatient visits; number of days in the hospital; days in steroid treatment; The time patients experienced grade 2 or higher toxicity	***25 times:*** Baseline; Every week until 24 weeks
Absolom et al, 2021	256(I); 252(C)	***Interventions***: Weekly completion of intervention PROM; participants received immediate severity-dependent advice on symptom management or a prompt to contact the hospital; alerts for severe symptom reports were sent to each clinical team, monitored by nurses. ***Control***: Standard care.	***Begins***: NR ***Frequency***: Weekly plus when having symptoms ***Time length***: For approximately 126 days	Clinicians will discuss the PROs when reviewing patients	Yes	***Primary outcome:*** Symptom control; ***Other outcomes:*** Patient self-efficacy; global quality of life; acute admissions	***4 times:*** Baseline; 6 weeks; 12 weeks; 18 weeks (end of chemotherapy); 12 months
Billa et al, 2021	100(I); 100(C)	***Interventions***: Completion of intervention PROM; a duplicate of their self-report questionnaires, with the corresponding scores generated, was made available to the physician prior to the corresponding medical appointment. ***Control***: Standard care.	***Begins***: NR ***Frequency***: Weekly during radiotherapy for 7 weeks; at 3, 6, and 9 months after radiotherapy ***Time length***: For approximately 319 days	Physicians can use the outcomes every medical appointment.	NR	***Primary outcome:*** Health-related quality of life; ***Other outcomes:*** Patient self-efficacy; Global quality of life; Acute admissions	***3 times:*** Baseline; 1 year after radiotherapy; 2 years after radiotherapy
Maguire et al, 2021	415(I); 414(C)	***Interventions***: Daily completion of intervention PROM; alerts may be generated: amber (for persistent mild-moderate symptoms for which early intervention could prevent progression) and red (for chemotherapy emergencies such as neutropenic sepsis). ***Control***: Standard care.	***Begins***: NR ***Frequency***: Daily and whenever they felt unwell ***Time length***: Over six cycles of chemotherapy	Clinicians would response in 8 h for amber alerts and 30 min for red alerts by calls. During calls with patients, clinicians worked through evidence based clinical decision support systems embedded within system to inform symptom management interventions	NR	***Primary outcome***: Symptom burden; ***Other outcomes***: Quality of life; supportive care needs; anxiety; self-efficacy; work limitations	***7 times***: Baseline; At the end of 1st, 2nd, 3rd, 4th, 5th, 6th chemotherapy circle
Bash et al, 2022	593(I); 598(C)	***Interventions*:** Weekly completion of intervention PROM; patient received educational materials or care team was alerted to give interventions ***Control***: Standard care.	***Begins***: NR ***Frequency***: Weekly ***Time length:*** For up to 1 year until or discontinued all cancer treatment	Whenever score reached a pre-specified level worsening compared with the prior survey, the patient received an email with a link to patient-level educational materials about their self-management of that symptom.	Yes	***Primary outcome***: Overall survival; ***Other outcomes***: Physical function; Symptom control; Health-related quality of life; Emergency department visits; Duration of chemotherapy	***3 times:*** Baseline; 1st month; 3rd month; 6th month; 9th month; 12th month
Merz et al, 2022	25(I); 25(C)	***Interventions***: Weekly completion of intervention PROM; Based on the responses received, the app delivered relevant supportive care service and content recommendations. ***Control***: Standard care.	***Begins***: NR ***Frequency***: Weekly ***Time length***: For 84 days	Based on the responses received, the app delivered relevant supportive care service and content recommendations.	No	***Other outcomes:*** Awareness/use of supportive care resources; patient activation (knowledge and confidence in self-management of illnesses); quality of life;	***2 times:*** Baseline; 12th weeks

NR, not reported; PROM, patient-reported outcome measurements; CT, computed tomography.

Table 3
Intervention and outcome assessment PRO measurements used in the included studies.

Author and Year of study	Intervention PRO measurements	Method of Administration of PRO measurements	Outcomes assessment PRO measurements
Maunsell et al, 1996	General Health Questionnaire	Telephone interview	Social support questionnaire; Life experiences surgery; Locke-Wallace Marital Adjustment Test; Diagnostic interview schedule; Psychiatric symptom index; One question assessment on general health perception; One question assessment on health worried or preoccupied level; 11 questions on performance of home, social, leisure, and physical activities.
Velikova et al, 2004	European Organization for Research and Treatment of Cancer–Core Quality of Life Questionnaire; Hospital Anxiety and Depression Scale	Electronic platform	Functional Assessment of Cancer Therapy–General
Kornblith et al, 2006	Hospital Anxiety and Depression Scale; European Organization for Research and Treatment of Cancer (EORTC)-QLQ-C30 quality-of-life questionnaire; Medical Outcomes Study (MOS) Social Support Survey	Telephone interview	EORTC QLQ-C30 questionnaire; The Geriatric Depression Scale (short form); Hospital Anxiety and Depression Scale; Medical Outcomes Study (MOS) Social Support Survey; Physical Health subscale of the Older American Resources and Services Questionnaire; Utilization of Mental Health and Psychosocial Services instrument; Geriatric Schedule of Recent Experience (GSRE) instrument; Patient Satisfaction with the Research Program BOMC test
Kearney et al, 2009	Self-developed PROM integrating Common Toxicity Criteria Adverse Events (CTCAE) grading system and Chemotherapy Symptom Assessment Scale	Electronic platform	Self-developed PROM integrating Common Toxicity Criteria Adverse Events (CTCAE) grading system and Chemotherapy Symptom Assessment Scale (paper-based version)
Mills et al, 2009	European Organization for Research and Treatment of Cancer Quality of Life Questionnaire C30; European Organization for Research and Treatment of Cancer Quality of Life Questionnaire related lung cancer module LC13	Take-home logbook	Functional Assessment of Cancer Therapy–Lung questionnaire Trial Outcome Index subscale; Palliative Care Quality of Life Index
Basch et al, 2016	National Cancer Institute's Common Terminology Criteria for Adverse Events (12 symptoms)	Electronic platform	EuroQol EQ-5D Index
Strasser et al, 2016	Edmonton Symptom Assessment Scale	Electronic platform	Global Quality of Life (Composite of questions 29 and 30 of the EORTC-QLQ-C30); Edmonton symptom assessment score; Karnofsky performance scale; Physical and emotional function scores from EORTC-QLQ-C30
Denis et al, 2017	Self-symptom score (assessing 12 symptoms: weight loss, appetite loss, fatigue, pain, cough, depression, breathlessness, fever, sudden face swelling, occurrence of lump under the skin, voice changing, appearance or increase of blood in sputum); Free text additional comment window	Electronic platform	Self-symptom score; Functional Assessment of Cancer Therapy–Lung (FACT-L) scale
Fjell et al, 2020	Self-symptom report (assessing 14 symptoms: fever, breathing difficulties, pain, numbness/tingling in hands and feet, nausea, vomiting, diarrhea, constipation, oral problems, depression, anxiety/worry, fatigue, insomnia, and swelling/pain/redness in the arm);	Electronic platform	Memorial Symptom Assessment Scale; European Organization for Research and Treatment of Cancer Quality of Life Questionnaire C30
Lugtenberg et al, 2020	European Organization for Research and Treatment of Cancer BR-23 breast cancer questionnaire; Care Notebook; National Comprehensive Cancer Network; Distress Thermometer; One free text dialog box; One question assessing additional supportive care needs	Electronic platform; Paper-and-pencil tool	European Organization for Research and Treatment of Cancer-Core Quality of Life Questionnaire (EORTC-QLQ C30); Brief Illness Perception Questionnaire; Distress Thermometer; Hospital Anxiety and Depression scale
Tolstrup et al, 2020	Self-developed 29-items PROM based on Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE)	Electronic platform	Self-developed 29-items PROM based on Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE)
Absolom et al, 2021	Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE)	Electronic platform	Self–efficacy scale; Cancer Behavior Inventory; Patient activation measure; Functional Assessment of Cancer Therapy-General; Functional Assessment of Cancer Therapy-Physical Well-Being subscale; EQ5D -visual analog scale; EORTC QLQ-C30 summary score
Billa et al, 2021	EORTC QLQ-C30; EORTC QLQ-H&N35	Paper-and-pencil tool in clinic	EORTC QLQ-C30; EORTC QLQ-H&N35; Euro Qol questionnaire (EQ-5D)
Maguire et al, 2021	Daily Chemotherapy Toxicity Self-Assessment Questionnaire (DCTAQ)	Electronic platform	Memorial Symptom Assessment Scale (MSAS); Functional Assessment of Cancer Therapy—General (FACT-G);

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Table 3 (*continued*)

Author and Year of study	Intervention PRO measurements	Method of Administration of PRO measurements	Outcomes assessment PRO measurements
			Supportive Care Needs Survey Short-Form (SCNS-SF34); State-Trait Anxiety Inventory—Revised (STAI-R); Communication and Attitudinal Self–Efficacy scale for cancer (CASE-Cancer); Work Limitations Questionnaire (WLQ)
Bash et al, 2022	Self-developed PROM integrating Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE), Eastern Cooperative Oncology Group (ECOG) performance status, and Comprehensive Score for Financial Toxicity–Functional Assessment of Chronic Illness Therapy (COST-FACIT) questionnaire.	Electronic platform	European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (QLQ-C30)
Merz et al, 2022	The revised Edmonton Symptom Assessment Survey (ESAS-r)	Electronic platform	Supportive Care Services Awareness/Utilization Survey; Patient Activation Measure (PAM-13); Functional Assessment of Cancer Therapy-General (FACT-G);

Table 4
Risk of bias assessment of included studies.

Author and Year of study	Randomization process	Timing of identification or recruitment of participants	Deviations from intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported result	Overall
Maunsell et al, 1996	Low	–	Some concerns	Low	High	Some concerns	High
Velikova et al, 2004	Low	–	Some concerns	Low	High	Some concerns	High
Kornblith et al, 2006	High	–	Low	Low	High	Some concerns	High
Kearney et al, 2009	Low	–	Low	Low	High	Some concerns	High
Mills et al, 2009	Some concerns	–	High	Low	High	Some concerns	High
Basch et al, 2016	Low	–	High	Low	High	Low	High
Strasser et al, 2016	Low	Low	Low	Low	High	Low	High
Denis et al, 2017	Some concerns	–	Low	Low	Low	Low	Some concerns
Fjell et al, 2020	High	–	Low	Low	High	Low	High
Lugtenberg et al, 2020	Some concerns	–	High	Low	High	Some concerns	High
Tolstrup et al, 2020	High	–	High	Low	High	Low	High
Absolom et al, 2021	Low	–	Low	Low	High	Low	High
Billa et al, 2021	Low	–	Low	Low	High	Low	High
Maguire et al, 2021	Some concerns	–	Some concerns	Low	High	Low	High
Bash et al, 2022	Low	Low	High	Low	Low	Low	High
Merz et al, 2022	Low	–	High	Low	High	Low	High

-, no information available.

three or more PRO measures.[11,27] The most frequently used PRO measures were the European Organization for Research and Treatment of Cancer series questionnaire C30 ($n = 4$)[27,34–36] and the PROs version of the Common Terminology Criteria for Adverse Events ($n = 4$).[13,15,21,28] Twelve trials (75%) administrated PRO measures via electronic platforms and two (13%) via telephone.

Risk of bias within and across studies

All trials adopted a longitudinal study design; only two used a cluster randomized controlled design,[21,29] which is a sampling technique to overcome simple RCT limitations.[37] Fourteen RCTs were reviewed by ROB 2.0 for randomized trials, and two were reviewed by ROB 2.0 for cluster-randomized trials.[21,29]

The risk of bias is shown in Table 4. Nine trials (56%) were rated low for the randomization process, two (100%) for the timing of identification or participant recruitment, seven (44%) for deviations from the intended interventions, sixteen (100%) for missing outcome data, two (13%) for measurement of the outcome (given that it is not possible to blind the participants, and most of the outcomes are not objective but also come from patients), and ten (63%) for selection of the reported result. Overall, 9 trials (56%) were rated as low-risk in three or more bias categories[15,17,21,28,29,31–33,36] and 15 trials (94%) were rated as high for overall risk due to large bias in the outcome measurements.

Health outcomes

Among the 16 RCTs, 15 used more than one outcome related to health, indicating a more holistic health assessment and effect (Table 5). Overall health outcomes were the endpoints of 13 studies, and physical and mental health outcomes were explored in 11 and 7 studies, respectively. Only five studies assessed social health. Other outcomes such as adverse events or overall survival were the most frequently evaluated endpoints.

Overall QoL

Among the 13 studies that reported an impact on overall QoL, 7 well-designed large RCTs reported a positive statistical or clinical effect,[15,21,30–32,34,36] and 2 RCTs reported a negative effect[33,35] (Table 5). The other four trials[11,17,27,29] reported no statistically significant effect, of which one reported no significant improvement in overall health possibly due to the high self-efficacy in all participating patients at baseline, leaving little room for improvement.[11] In terms of overall QoL improvement, the ESs ranged from 0.28 to 0.36 but were mainly small in magnitude (Table 6). Nevertheless, the ES of a declining QoL in inoperable lung cancer patients was larger in the intervention group than the control group ($d = 0.59$).[35] Velikova et al reported improvements in patient QoL scores at treatment initiation, which were influenced by whether QoL was actually discussed during consultation.[34]

Table 5
Main finding of included studies.

Author and Year of study	Overall QoL	Physical health	Mental health	Social health	Other health outcomes
Maunsell et al, 1996	-	No IG/CG differences in physical health, functional status, frequency of arm problems, social and leisure activities, return to work or hours worked.	IG participants' psychological distress levels decreased over the study period ($P = 0.001$), but no IG/CG differences were observed ($P = 0.065$). No statistically significant or consistent IG/CG differences were observed for worry about health.	No IG/CG differences in marital satisfaction.	-
Velikova et al, 2004	Participants in IG and attention control had better QoL than the CG participants ($P = 0.006$ and $P = 0.01$, respectively). IG and attention-control groups were not significantly different ($P = 0.80$). A larger proportion of intervention patients showed clinically meaningful improvement in HRQL.	Participants in IG and attention control had better physical well-being than the CG participants ($P = 0.006$ and $P = 0.003$, respectively)	Participants in IG and had better emotional well-being than the CG participants ($P = 0.008$)	No IG/CG differences in social or family well-being.	-
Kornblith et al, 2006	No IG/CG differences in EORTC overall QoL ($P = 0.24$).	No IG/CG differences in EORTC physical symptoms ($P = 0.25$) and physical functioning ($P = 0.28$).	Patients in the IG reported significantly less anxiety ($P < 0.0001$), depression ($P = 0.004$), and overall distress ($P < 0.0001$) compared with patients in the CG.	–	
Kearney et al, 2009	–	For the symptom incidence, there were significantly more reports of fatigue in the CG compared to the IG (odds ratio = 2.29, 95% CI = 1.04 to 5.05, $P = 0.040$) and reports of hand–foot syndrome were on average less in the CG (odds ratio CG/IG = 0.39, 95% CI = 0.17 to 0.92, $P = 0.031$), but no IG/CG differences in reports of vomiting, nausea, diarrhea, or sore mouth/throat. For the symptom severity, there were significantly higher hand-foot syndrome severity in the IG compared to the CG ($P = 0.033$), but no IG/CG differences in vomiting, nausea, diarrhea, sore mouth/throat, fatigue. For the symptom distress, there were significantly higher hand-foot syndrome distress in the IG compared to the CG ($P = 0.028$), but no IG/CG differences in vomiting, nausea, diarrhea, sore mouth/throat, fatigue.	–	–	–
Mills et al, 2009	Only a small but consistent difference in QoL was found between IG and CG. The IG had a poorer QoL in many domains. Two different QoL summary scores (total and overall QOL) indicated a statistically significant between-group difference.	No IG/CG differences in physical and functional well-being	–	–	–
Basch et al, 2016	HRQL improved among more participants in the IG than CG (34% vs 18%) and worsened among fewer (38% vs 53%; $P <$ 0.001) HRQL of IG by the previously established clinically meaningful score change threshold of ≥ 6 points compared with CG (21% vs 11%), and fewer experienced a ≥ 6-point worsening (28% vs 37%; $P = 0.001$) Mean HRQL declined by less in	At 6 months, IG patients experience significantly better mobility ($P = 0.02$). At 6 months, no between groups difference in pain/discomfort ($P = 0.05$) or usual activity ($P = 0.09$).	At 6 months, IG patients experience significantly better anxiety/depression ($P = 0.01$).	–	At 6 months, IG patients experience significantly better self-care ($P = 0.01$). IG patients were less frequently admitted to the emergency room at 1 year (34% vs 41%; $P = 0.02$). No between groups difference in hospitalized at 1 year ($P = 0.08$). IG patient were remained on chemotherapy longer (mean, 8.2 vs 6.3 months; $P = 0.002$) a median of 4.1 months versus 3.5 months, respectively ($P = 0.002$).

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Table 5 (*continued*)

Author and Year of study	Overall QoL	Physical health	Mental health	Social health	Other health outcomes
	IG than CG (1.4- vs 7.1-point drop; $P < 0.001$).				More IG patients survived at 1 year with 75% of IG patients was alive at 1 year and only 69% of CG patients survived ($P = 0.05$). IG had longer quality-adjusted survival (mean of 8.7 vs 8.0 months; $P = 0.004$).
Strasser et al, 2016	No between groups difference in global QoL ($P = 0.11$).	–	–	–	IG patients had less symptom distress ($P = 0.003$).
Denis et al, 2017	At 6th month, the change of QoL favored the IG because 80.6% of patients in the IG had stable or improved scores, 58.6% in CG ($P = 0.04$)	–	–	–	IG patients had longer median overall survival. The median overall survival was 19.0 months (95% CI = 12.5 to non-calculable) in IG and 12.0 months (95% CI = 8.6 to 16.4) in CG (one-sided $P = 0.001$) (hazard ratio = 0.32, 95% CI = 0.15 to 0.67, one-sided $P = 0.002$). IG patients had higher one year overall survival. The one-year overall survival was 78.2% (95% CI = 67.7 to 88.6) in IG (CG overall survival = 58.2%, 95% CI = 45.8 to 70.5, $P = 0.008$). The performance status at first detected relapse was 0–1 for 75.9% of the patients in IG and for 32.5% of those in the CG (two-sided $P < 0.001$). More patients attended unscheduled visits in IG (58.3%) than in CG (24.6%, $P = 0.008$).
Fjell et al, 2020	There were no between groups differences in global health status/QoL.	The IG rated statistically significant less symptom prevalence in nausea ($P = 0.041$), vomiting ($P = 0.037$), appetite loss ($P = 0.027$) and constipation ($P = 0.007$). The IG rated statistically significant lower levels of physical symptom distress ($P = 0.031$).	The IG rated statistically significant less symptom prevalence in feeling sad ($P = 0.003$). The IG rated statistically significant higher emotional functioning ($P = 0.008$).	No IG/CG differences in social functioning.	IG rated statistically significant less overall symptom distress than the CG ($P = 0.004$).
Lugtenberg et al, 2020	No IG/CG groups differences in QoL.	No IG/CG differences in physical functioning, role functioning, cognitive functioning, fatigue, nausea, pain, dyspnea, insomnia, appetite loss, constipation, diarrhea.	No IG/CG groups difference in anxiety and depression.	No IG/CG differences in social functioning.	No IG/CG differences in illness perceptions.
Tolstrup et al, 2020		–	–	–	No between group difference in the number of grade 3 or 4 adverse events ($P = 0.983$). No between group difference in the time the patients experienced grade 2 or higher toxicity ($P = 0.516$). There was a tendency towards patients in the IG having more extra visits ($P = 0.156$). There was a tendency that patients in IG had more days in the hospital compared to patients in CG ($P = 0.101$).
Absolom et al, 2021	At 12 weeks and 18 weeks, patients reported better health on EQ5D-VAS ($P = 0.0302$, $P = 0.0095$, respectively), but no difference at 6 weeks ($P = 0.3773$). At 12 weeks, IG patients showed an increase in symptom control in EORTC QLQ-C30 summary score ($P = 0.0111$) and no difference at 6 and 18 weeks ($P = 0.4420$, $P = 0.2255$, respectively).	IG showed improved physical well-being at 6 ($P = 0.028$) and 12 ($P = 0.039$) weeks and no between difference at 18 weeks ($P = 0.6992$). At 6 and 12 weeks a smaller proportion of IG patients had physical well-being deterioration.	–	–	There were no between-group differences for acute admissions ($P = 0.4003$) or chemotherapy delivery. At 18 weeks, IG patients reported better self-efficacy ($P = 0.0073$).

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Table 5 (*continued*)

Author and Year of study	Overall QoL	Physical health	Mental health	Social health	Other health outcomes
	No between-group differences were found for Functional Assessment of Cancer Therapy-General (FACT-G) at 6, 12, and 18 weeks. No between-group differences were found for EQ-5D-5L utility scores at 6, 12, and 18 weeks.				
Billa et al, 2021	IG patients were reported to have a statistically significant increase in EQ VAS at 2 years ($P < 0.0001$) and exceeded the minimal clinically important difference (mean change at 2 years from baseline = 10.46). In CG, there was a mean EQ VAS score increase of 4.62 between baseline and 2 years, but it was not statistically significant (mean change = 4.62, $P = 0.0698$). The comparison of mean change scores between groups at 2 years was not statistically significant.	–	–	–	Use of painkillers was comparable between the arms (78.02% vs. 86.02%, $P = 0.1552$). There were no statistically significant differences between groups concerning the use of concomitant medications, such as antidiarrheal agents, antiemetics, psychotropic drugs, and antibiotics ($P > 0.05$).
Maguire et al, 2021	IG rated higher in FACT-G scores across all cycles ($P < 0.001$).	IG patients had lower physical distress ($P < 0.001$). IG rated higher in FACT-G physical domain ($P < 0.001$).	IG patients had lower psychological distress ($P < 0.001$). No IG/CG differences in FACT-G emotional domain. IG patients had lower anxiety distress ($P < 0.05$).	No IG/CG differences in FACT-G social domain.	IG patients had lower symptom burden ($P < 0.001$). IG reported greater self-efficacy ($P = 0.01$) IG patients had lower supportive care needs. No IG/CG differences in work limitations. Adverse events were balanced across IG/CG.
Bash et al, 2022	At 3 months, the mean change from baseline on HRQOL was significantly better for IG than CG ($P = 0.002$) IG patients had significantly greater odds of experiencing clinically meaningful benefits than CG for physical function (8.5% and 4.9%, respectively; OR = 1.41 [95% CI, 1.10–1.81]; $P = 0.006$)	At 3 months, the mean change from baseline on physical function was significantly better for IG than CG ($P = 0.02$). IG patients had significantly greater odds of experiencing clinically meaningful benefits than CG for physical function (7.7% more with improvements of ≥ 5 points and 6.1% fewer with worsening of ≥ 5 points; odds ratio = 1.35 [95% CI, 1.08–1.70]; $P = 0.009$).	–	–	At 3 months, the mean change from baseline on symptom control was significantly better for the IG than CG ($P = 0.002$). IG patients had significantly greater odds of experiencing clinically meaningful benefits than CG for symptom control (8.6% and 7.5%, respectively; OR = 1.50 [95% CI, 1.15–1.95]; $P = 0.003$).
Merz et al, 2022	There was no significant difference between increase in FACT-G score between groups ($P = 0.91$).	–	–	–	No significant difference in awareness of supportive care services across IG/CG groups ($P = 0.27$) There was no significant difference between increase in supportive care service utilization of IG/CG groups ($P = 0.70$) There was no significant change in patient activation (knowledge and confidence in self-management of illnesses) between IG/CG groups ($P = 0.65$)

-, no information available.

Physical health

Overall, fatigue, vomiting, nausea, diarrhea, and physical activity were the most frequently reported physical health endpoints, while other disease/treatment-specific health aspects such as hand–foot syndrome, sore mouth/throat, and constipation were mentioned less frequently. Among the 11 studies that did report effects on reduced symptom prevalence, severity, or distress and improved physical function, 7 reported a positive statistical or clinical effect,[15,21,28,30,31,33,34] and 4 reported no between-group differences[11,26,27,35] (Table 5). In terms of physical health improvement, the ESs ranged from 0.27 to 0.43 but were mainly small in magnitude (Table 6). ESs were larger in terms of intervention effects on constipation (d = 0.43) and nausea and vomiting (d = 0.40).[33]

Mental health

Among the seven studies that reported results related to the impact on patient mental health, four[27,31,33,34] reported a positive effect on improved mental health, including better emotional well-being and fewer negative feelings, and three studies reported no between-group effect[11,26,30] (Table 5). For mental health improvement, the ES ranged from 0.15 to 0.42 but was small in magnitude (Table 6). Of the three

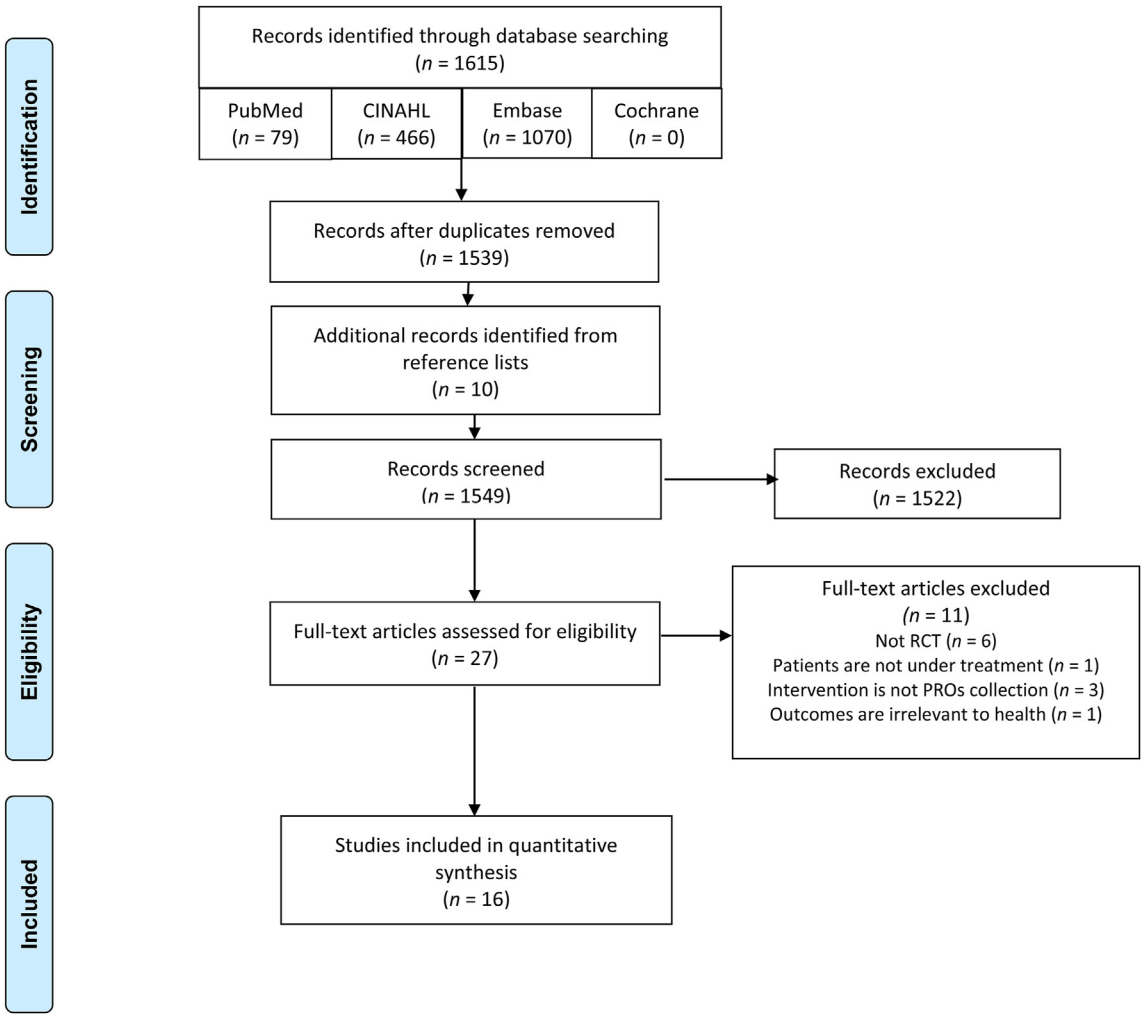

Fig. 1. PRISMA search flow diagram.

Table 6
Evaluation of PRO measurements intervention effects on Patient's health.

Health outcome	ES (d)	95% CI	Effect characterization[a]
Overall QoL			
EORTC overall QoL	−0.04	−0.38 to 0.31[27]	±
Overall QoL	−0.59	−1.16 to −0.01[35]	–
EORTC related lung cancer module LC13	−0.11	−0.65 to 0.43[35]	±
FACT-General	−0.49	−1.06 to 0.09[35]	±
FACT-General	0.04	−0.55 to 0.63[17]	±
FACT-General 6 weeks	0.22	0.03 to 0.41[15]	±
FACT-General 12 weeks	0.31	0.12 to 0.51[15]	±
FACT-General 18 weeks	0.19	−0.01 to 0.39[15]	±
Palliative Care Quality of Life Index (PQLI)	0.0	−0.57 to 0.57[35]	±
Global health status/QoL	0.14[33]	NC	±
EORTC Global health	−0.09	−0.50 to 0.31[11]	±
EQ5D-VAS 6 weeks	0.14	−0.05 to 0.33[15]	±
EQ5D-VAS 12 weeks	0.28	0.08 to 0.47[15]	+
EQ5D-VAS 18 weeks	0.36	0.16 to 0.56[15]	+
EORTC QLQ-C30 6 weeks	0.16	−0.05 to 0.37[15]	±
EORTC QLQ-C30 12 weeks	0.30	0.09 to 0.52[15]	+
EORTC QLQ-C30 18 weeks	0.23	0.01 to 0.46[15]	±
5D5L utility measure 6 weeks	0.20	0.01 to 0.39[15]	±
5D5L utility measure 12 weeks	0.19	−0.00 to 0.39[15]	±
5D5L utility measure 18 weeks	0.19	−0.01 to 0.39[15]	±
EQ-D5 index	0.0	−0.28 to 0.28[36]	±
EQ-D5 index	0.05	−0.23 to 0.32[36]	±
EQ VAS	0.29	0.01 to 0.57[36]	±
EQ VAS	−0.15	−0.43 to 0.13[36]	±

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Table 6 (*continued*)

Health outcome	ES (d)	95% CI	Effect characterization[a]
Physical health			
Number of physical health problems	0.14	−0.11 to 0.39[26]	±
Hours worked per week	0.05	−0.32 to 0.42[26]	±
Household activities performed without help	0.08	−0.17 to 0.33[26]	±
Times per week engaged in social activities	0.23	−0.02 to 0.48[26]	±
Hours per day devoted to leisure activities	−0.14	−0.39 to 0.11[26]	±
Times per week engaged in sports activities	0.02	−0.23 to 0.27[26]	±
EORTC physical symptoms	−0.01	−0.36 to 0.34[27]	±
EORTC physical functioning	−0.20	−0.55 to 0.15[27]	±
Severity of vomiting	0.01	−0.36 to 0.38[28]	±
Severity of nausea	−0.18	−0.55 to 0.20[28]	±
Severity of diarrhea	0.05	−0.32 to 0.43[28]	±
Severity of hand-foot syndrome	0.42	0.05 to 0.80[28]	–
Severity of sore mouth/throat	−0.32	−0.05 to 0.69[28]	±
Severity of fatigue	−0.25	−0.63 to 0.12[28]	±
Distress of vomiting	0.05	−0.32 to 0.42[28]	±
Distress of nausea	−0.15	−0.52 to 0.22[28]	±
Distress of diarrhea	0.0	−0.37 to 0.37[28]	±
Distress of hand-foot syndrome	0.35	−0.02 to 0.72[28]	–
Distress of sore mouth/throat	0.33	−0.05 to 0.70[28]	±
Distress of fatigue	−0.31	−0.69 to 0.06[28]	±
physical and functional well-being	−0.41	−0.95 to 0.14[35]	±
Physical symptom frequency, severityand distress	0.27[33]	NC	+
Physical functioning	0.23[33]	NC	±
Physical functioning	−0.15	−0.56 to 0.25[11]	±
Role functioning	0.04[33]	NC	±
Role functioning	−0.35	−0.76 to 0.06[11]	±
Cognitive functioning	0.13[33]	NC	±
Cognitive functioning	0.03	−0.38 to 0.43[11]	±
Fatigue	0.27[33]	NC	±
Fatigue	0.10	−0.31 to 0.50[11]	±
Nausea and vomiting	0.40[33]	NC	+
Nausea	0.27	−0.13 to 0.68[11]	±
Pain	0.23[33]	NC	±
Pain	0.10	−0.30 to 0.51[11]	±
Dyspnea	0.24[33]	NC	±
Dyspnea	−0.02	−0.43 to 0.38[11]	±
Insomnia	0.11[33]	NC	±
Insomnia	−0.10	−0.51 to 0.30[11]	±
Appetite loss	0.35[33]	NC	+
Appetite loss	−0.14	−0.55 to 0.26[11]	±
Constipation	0.43[33]	NC	+
Constipation	0.05	−0.36 to 0.45[11]	±
Diarrhea	0.35[33]	NC	±
Diarrhea	−0.11	−0.51 to 0.30[11]	±
Mental health			
Psychological distress	−0.09	−0.34 to 0.16[26]	±
HADS total score	−0.42	−0.76 to −0.07[27]	+
HADS Depression subscale	−0.30	−0.65 to 0.04[27]	+
HADS Depression subscale	−0.13	−0.54 to 0.27[11]	±
HADS Anxiety subscale	−0.15	−0.49 to 0.20[27]	+
HADS Anxiety subscale	0.17	−0.23 to 0.58[11]	±
Geriatric Depression	−0.05	−0.40 to 0.29[27]	±
EORTC emotional functioning	0.10	−0.25 to 0.44[27]	±
EORTC emotional functioning	0.30[33]	NC	+
Emotional functioning	−0.04	−0.44 to 0.37[11]	±
Personal control	0.25	−0.15 to 0.66[11]	±
Treatment control	0.06	−0.34 to 0.47[11]	±
Identity	0.09	−0.32 to 0.49[11]	±
Concern	−0.29	−0.69 to 0.12[11]	±
Emotional response	−0.08	−0.49 to 0.32[11]	±
Social health			
Marital satisfaction	0.0	−0.25 to 0.25[26]	±
Social functioning	0.23[33]	NC	±
Social functioning	0.03	−0.37 to 0.43[11]	±
Other health outcomes			
Global distress	0.34[33]	NC	+
Self-efficacy	0.30	0.10 to 0.50[15]	+
coping efficacy	0.23	0.03 to 0.43[15]	±
Patient Activation	0.09	−0.11 to 0.29[15]	±
Patient Activation	−0.27	−0.85 to 0.32[17]	±
Supportive Care Services Awareness	0.30	−0.29 to 0.89[17]	±
Supportive Care Services Utilization	0.39	−0.20 to 0.98[17]	±

ES, effect size; NC, non calculable.

[a] Based on *P* value ($P < 0.05$) and direction; + favors the intervention group ($P < 0.05$); - favors the control group ($P < 0.05$); ± represents $P > 0.05$.

studies that did not find such a positive effect, one[26] reported that this type of intervention may be inadequate for those with serious psychological difficulties predating breast cancer diagnosis or that the minimal psychosocial intervention given to all women at the initial treatment may have effectively reduced distress after breast cancer, thus making it difficult to obtain additional benefit from the screening program. Another study stated a possible ceiling effect, meaning that both the intervention and control groups had very good baseline health, potentially impeding obtaining a significant difference between the two arms during the follow-up period.[11]

Social health

Only five RCTs explored the effects of routine PRO measures use on social health, namely, the level of marital satisfaction,[26] social or family well-being,[34] general social health,[30] and social functioning[11,33] (Table 5). All five studies indicated no consistent or significant post-intervention effect on social health.

Other health outcomes

Eleven trials reported other health outcomes, the most common being symptom distress/control ($n = 4$), unscheduled hospital visits ($n = 4$), self-efficacy ($n = 3$), and overall survival rate ($n = 2$) (Table 5). Regardless of the cancer type, significant post-intervention increases over time in the symptom distress/control[21,29,30,33] and overall survival rate[31,32] were recorded. However, among three trials that reported an effect on self-efficacy, two trials[15,30] reported a significant positive effect (d = 0.3), but one trial[17] reported no significant change (Table 6). Of four trials that focused on unscheduled hospital visits, only one[31] indicated that patients in the intervention group were less frequently admitted to the hospital, two[13,15] reported no such between-group difference, but one[32] indicated a tendency toward patients in the intervention group having additional hospital visits. Tolstrup et al stated that the administration of PROs enables patients to assess their symptoms and functions frequently; this helps patients detect their disease condition in advance and pay more attention to their health, leading to an increase in unexpected hospital revisits.[13]

Discussion

A total of 16 studies with routine collection of PROs in cancer patients were included in our systematic review. Unlike previous reviews in this field, this review not only explored the findings from RCTs but also focused on the effects on health outcomes. The results showed that the routine collection of PROs significantly improved physical health and ameliorated mental health symptoms, including perceived stress, anxiety, and depression. However, the current evidence failed to support the efficacy of interventions on social health-related outcomes. The results also showed that PRO collection had potential benefits on other health outcomes that are also important to active anticancer treatment patients, including overall survival rate and unexpected hospital revisit. Nevertheless, the ESs remained small to moderate for all of the mentioned statistically positive effects. For those studies that reported no significant health improvement, possible reasons included adopting PRO measures that were not sufficiently sensitive,[27,29] patients already having a sufficient medical support network,[26] and a high attrition rate.[28] Overall, the positive effect of routine PRO collection has been repeatedly emphasized, eg, early progress and symptom identification,[26,31] increasing attention to disease and health,[13,33] and a longer and stronger relationship with their healthcare provider.[27,28,33,36]

For the PRO measures intervention delivery form, the studies conducted in the early 2000s were implementing intervention via telephone or pencil and paper, whereas most recent studies were more likely to develop specific platforms to administer PROs. Although studies have shown that the results of electronic and paper–pencil measurements are equivalent,[38,39] the electronic methods of collection are safer, easier, more equitable, and acceptable,[13,15,21] especially under the COVID-19 pandemic context.[15,30]

Many studies have focused on how information on PROs is implemented in routine clinical practice; the clinical relevance of this feedback influences its impact on patient management and outcomes.[13,30,34,35,40,41] Therefore, a scientific alert threshold should be established and algorithms refined for communicating alerts with clinical experiences, to avoid alerts being burdensome and to make feedback feasible and acceptable.[13,15,30] Current funding insurance should also be made available to sustain additional costs to clinics related to the addition of technology and/or staff.[21] Future research should work on the frameworks and guidelines for implementing feedback to alerts or other problems. Especially for urgent problems that need to be treated immediately, there is still no clear pathway to guide the respondent.[27]

We conclude that whereas there are some grounds for optimism in the possible impact of PRO collection in clinical practice (specifically in improving diagnosis and recognition of problems and patient–physician communication), considerable work is still required before clinicians can invest resources in the process and rely on consistent evidence of the benefits for their patients. Many methodologically stronger trials successfully implementing feasible interventions with clear positive health effects are required to provide clear direction for clinicians interested in improving their care through the routine use of PRO measures.

Limitations

We acknowledge that this review had several limitations. Only four studies adopted all the health categories reflects the lack of consensus among researchers on the relevance of the indicators and poses yet another challenge to a quantitative summary in this review. Moreover, the choice of representative indicators with three health dimensions supplemented by overall health and other health outcomes and the criteria we relied on may be subject to dispute. Additionally, the RCTs analyzed were heterogeneous in the type of setting, participants (both patients and clinicians), the intensity of the intervention implemented (daily or weekly), diversity of outcomes reported, and treatment of usual care. This represents a major challenge to evaluating the impact of PRO collection and limits the external validity of the study. Further studies are needed to assess which patients benefit the most from this intervention and to identify the most effective strategies for obtaining a positive effect.[11,13,30–32] Also, due to the nature of the study, the subjective outcomes were predominantly obtained from patients, which may introduce a contamination bias; this bias could lead to undesirable effects with respect to the intervention.[27]

Conclusions

This systematic review of the routine collection of PROs on patient health outcomes in oncologic settings found that the intervention is not clearly associated with a better overall QoL and improved physical, mental, and social health. These findings suggest potential areas of patient health improvement for future trials. Finally, more well-reported trials with larger ESs are needed, given the small-to-moderate effect of the included trials.

CRediT author statement

Danyu Li: Conceptualization, Methodology, Data curation, Formal analysis, Writing. **Qingmei Huang**: Methodology, Data curation, Validation **Zhang Wen**: Methodology. **Changrong Yuan**: Conceptualization, Methodology, Supervision. **Fulei Wu**: Conceptualization, Methodology, Data collection, Writing – Review & Editing, Funding acquisition. All authors had full access to all the data in the study, and the corresponding author had final responsibility for the decision to submit for publication. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Declaration of competing interest

All authors have none to declare.

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Ethics statement

Not required.

Data availability statement

Data availability is not applicable to this article as no new data were created or analyzed in this study.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.apjon.2023.100297.

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