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A targeted literature review on the impact of tailored interventions on patient outcomes in oncology

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Non-pharmacological approaches to managing symptoms and side effects of cancer treatments are not always aligned with true needs and characteristics of patients. Without proactive patient-tailored interventions to anticipate, prevent, and manage side effects, risk of patients experiencing treatment interruption or discontinuation increases. A targeted literature review identified published studies evaluating the impact of tailored (customized based on individual patient characteristics) non-pharmacological interventions on patient outcomes in oncology versus routine care (usual clinical practice), enhanced care (support beyond routine care, including additional patient education, psychological support, and medication tracking), or uniform engagement (non-tailored support offered in a uniform manner). Thirty completed clinical studies were included. Approximately 50% of interventions across studies were remote health education/self-management programs, and the remaining provided clinical follow-up for symptom management. All types of tailored intervention led to positive patient outcomes versus routine care. Significant improvements were seen in favor of self-efficacy for self-management (patient's belief in their ability to manage own symptoms and treatment; $p < 0.05$) and symptom burden (overall as well as specific symptoms including anxiety, nausea, vomiting; all $p < 0.05$), although there were inconsistent effects on health-related quality of life (HRQoL), healthcare resource utilization (HCRU), and adherence. Compared with enhanced care, most studies showed no consistent improvement for tailored interventions in symptom burden, self-efficacy, HRQoL, HCRU or adherence, although benefits were slightly more common in larger/longer studies. Tailored interventions were not consistently better than uniform engagement in improving outcomes, although the number of studies was limited, with small sample sizes/short follow-ups. In summary, tailored interventions showed positive benefits versus routine or enhanced care (the latter only in larger and longer studies). No consistent benefit was observed compared with uniform engagement. Clinical outcomes were most sensitive to type of intervention. Tools to both enhance and measure the process should be routinely incorporated in clinical trials.

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INTRODUCTION

Cancer patients receiving therapy often experience treatment-related side effects in addition to continued symptoms of the cancer [1, 2]. Without proactive and effective interventions to anticipate, prevent, and manage symptoms and side effects, patients are at risk of interrupting or even discontinuing their therapy [3–6]. Premature treatment discontinuation can lead to poorer outcomes, resulting in disease progression and a reduction in quality of life [7, 8], while long-term and/or latent side effects have been shown to contribute to increased morbidity and mortality and poorer quality of life among cancer survivors [9].

Because symptoms and adverse effects of cancer treatment are typically discovered only on an ad hoc basis during hospital visits or doctor rounds, their management is often reactive and non-systematic, and may not be optimal [10, 11]. Recent research has suggested that certain biomarkers or clinical indicators may be able to identify those patients with a greater risk of side effects, for example to checkpoint inhibitors [12–14], providing an opportunity for clinicians to intervene early and mitigate the effects of toxicity. However, there is also evidence demonstrating that a higher rate of immune-related adverse events can be associated with a greater therapeutic efficacy of anti-PD-1 antibodies, suggesting that a careful clinical balance is required between optimizing therapeutic efficacy and managing side effects [15].

Non-pharmacological approaches to managing the side effects of cancer treatment are designed to improve patient engagement and quality of life, increase knowledge about the treatment, encourage self-efficacy, and enable more consistent reporting of symptoms and adverse events [16, 17]. However, despite considerable differences between patients in terms of beliefs and attitudes toward treatment, health status, comorbidities, type and duration of therapy, regimen complexity, and treatment-associated toxicity, such interventions tend to adopt a "one-size-

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fits-all" approach, without accommodating the distinct needs of individual patients.

It is also important to note that the perceived severity of side effects, as well as the willingness to tolerate adverse effects, may be impacted by the treatment setting (adjuvant, neoadjuvant, or metastatic treatment), duration of treatment, and the overall prognosis for the patient [18, 19]. In the case of poor prognosis, improving survival outcomes may be of greatest importance to patients, whereas outcomes beyond survival (including HRQoL and participation in activities of daily living) may have more value if the prognosis is more favorable [19, 20]. It is therefore important to consider the trade-off between the side effects of treatment and overall survival benefits when managing treatment toxicities [21]. The degree to which side effects may be tolerated also depends to a substantial extent on belief systems, support available and personal values [18, 19]. In addition, there may be a substantial cost associated with the alleviation of side effects, which also needs to be considered when devising targeted strategies to help patients manage the adverse effects of treatment [22–24].

A number of individual studies have suggested that customizing non-pharmacological interventions to suit the characteristics of individual patients may improve patient engagement and outcomes [25–31]. However, we have not been able to identify any literature reviews that consolidate the underlying evidence on tailored interventions in oncology, determine their overall effectiveness, or distill key learnings for future clinical research and practice.

Given the absence of any published synthesis of evidence, we undertook a targeted literature review to assess the use of tailored interventions and evaluate their impact on patient outcomes in oncology. To structure this review, we defined six initial research questions, as follows: (1) What types of tailored approaches have been tested? (2) How do these tailored interventions perform in improving patient outcomes? (3) What factors are associated with success/failure across the types of interventions? (4) What outcome measures have been used most often? (5) Has the testing of these interventions been carried out to methodologically robust standards (i.e. with how much confidence can we draw conclusions from the evidence?) (6). What are the learnings from the literature for the design of a new tailored intervention for evaluation in clinical studies, and translation and adoption into clinical practice?

For the purpose of this review, tailored interventions are defined as non-pharmacological procedures or measures that aim to enhance the outcomes of patients undergoing medical cancer therapy, which may be customized according to certain patient characteristics. Dynamic tailoring may also be introduced, whereby an adjustment to care is made in real-time in response to patient feedback, clinical signs or symptoms, or another stimulus.

METHODOLOGY

Search strategy

In this targeted literature review, extensive keyword-based searches using PubMed, Google, and Google Scholar were conducted to identify relevant publications. The key search terms listed in Supplementary Table 1 were used individually and in different combinations. In addition to keyword-based searches, bibliographic searches of relevant recent publications were also carried out. All searches were conducted between August 2023 and October 2023.

Selection criteria

Both clinical trials and observational studies were included during the initial selection process if they assessed tailored interventions in oncology within the last 5 years. Searches were limited to papers published in English, but no restrictions were included with respect to age, ethnicity, outcome, geography, or treatment setting (neoadjuvant, adjuvant, or metastatic).

Abstracts and titles were then screened by a single reviewer who examined the full text in detail in order to determine the final list for inclusion. As this study is a targeted and not a systematic literature review, a single reviewer only was used for screening and data extraction. Formal quality assessment of all included RCTs was performed using the National Institute for Health and Care Excellence (NICE) checklist (quality rating: low risk of bias, unclear risk of bias, or high risk of bias) [32].

Study characteristics

Each study selected for inclusion in this review was analyzed with respect to the type of tailored intervention, timing of the intervention, type of comparator group, and assessment of patient outcomes.

Tailored interventions. Tailored interventions are defined as non-pharmacological measures or procedures that aim to enhance outcomes of patients undergoing medical cancer therapy, which may be customized according to certain patient characteristics. Examples of tailored interventions include provision of patient education, advice on symptom management, questionnaires on patient symptoms, and patient reminders. Tailored interventions may be customized according to patient-specific factors, including patient health status, patient goals, symptom severity, adverse events, and treatment adherence (Supplementary Table 2).

The timing of a tailored intervention was characterized as *pre-treatment* (prior to the initiation of the intervention) or *on-treatment* (while the intervention was ongoing) (Supplementary Table 2).

Comparator groups. A set of three standardized comparator groups was defined in this review based on the control groups used in individual studies. The comparators provide a measure of control against which the effectiveness of the tailored interventions may be assessed. The comparator groups were defined as ***routine care*** (standard of care as per routine clinical practice, with no additional tailored intervention), ***enhanced care*** (additional support beyond routine care; including additional information about the disease/treatment/side effects, psychological support from nurses and physicians, or medication tracking), or ***uniform engagement*** (non-tailored support offered in a uniform manner), as described in Table 1 and Supplementary Table 2.

Table 1. Definitions of types of non-pharmacological intervention described in this study.

	Type of intervention	Definition
Tailored intervention		Individualized intervention according to individual patient characteristics May include element of dynamic tailoring
Comparator interventions	Routine care	Standard of care as per routine clinical practice, with no additional tailored intervention
	Enhanced care	Additional support beyond routine care
	Uniform engagement	Non-tailored support offered in a uniform manner

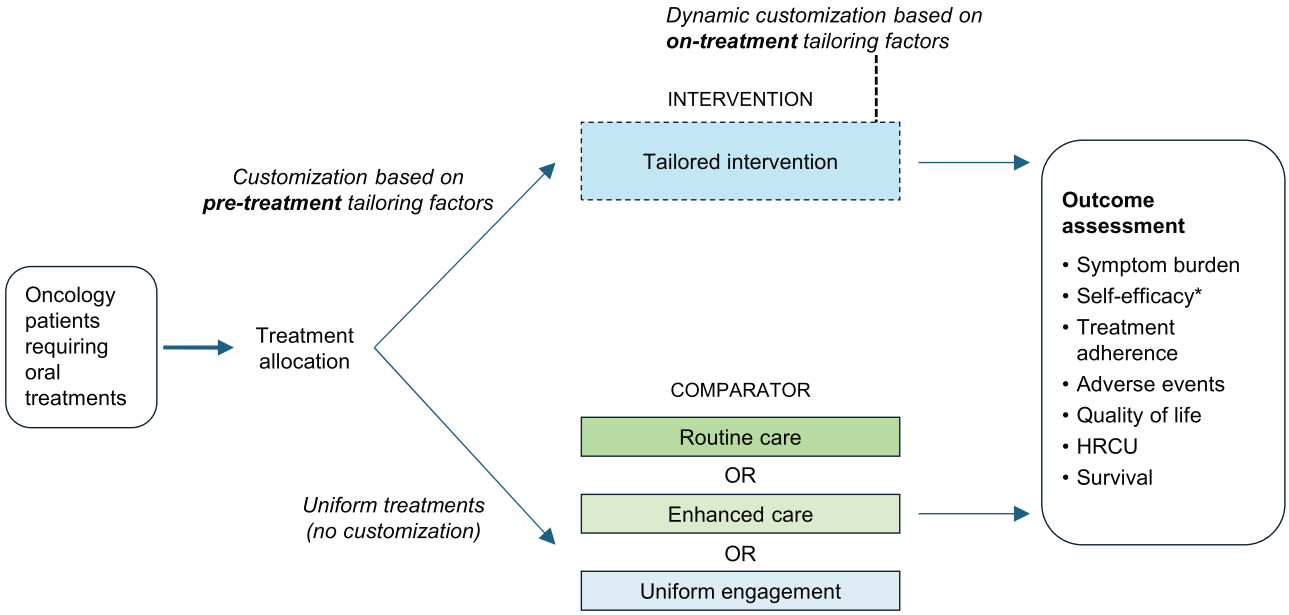

Fig. 1 Design elements of studies exploring tailored approaches in oncology patient management. HCRU Healthcare resource utilization. *Patient's belief in their ability to manage their symptoms and treatment. **Routine care:** Standard of care as per routine clinical practice, with no additional tailored intervention; **Enhanced care:** Additional support beyond routine care; including additional information about the disease/treatment/side effects, psychological support from nurses and physicians, or medication tracking; **Uniform engagement:** Non-tailored support offered in a uniform manner.

Outcomes. The impact of an intervention was assessed against a number of study outcomes, including symptom/adverse event burden, treatment adherence, health-related quality of life (HRQoL), healthcare resource utilization (HCRU), and self-efficacy for self-management (a patient's belief in their ability to manage their own symptoms and treatment) (Supplementary Table 2). Assessment of study outcomes provides a measure of the success of the intervention. Most studies assessed several outcomes simultaneously.

Overall, the key elements of the interventions that were considered as part of this review can be summarized as shown in Fig. 1.

RESULTS

Characteristics of included studies

Using the strategy described, approximately 750 publications were identified from the initial searches. Following full-text review of 250 publications, 31 primary studies (including one ongoing study at time of review) evaluating 28 tailored interventions in oncology were included, based on reviewer judgment regarding alignment with the objectives of this review **(**Fig. 2**)**. The key characteristics of the 30 completed studies are summarized in Supplementary Table 3.

Most studies (26/30) were randomized controlled trials (RCTs), with one non-randomized controlled trial and three single-arm pilot studies (Supplementary Table 3). No real-world observational studies were identified. Of the 26 RCTs, six were rater-blinded while the rest were open-label. Across the 26 RCTs assessed using the NICE quality assurance (QA) checklist, a low risk of bias was observed in all or almost all studies for selective reporting (100%), declaration of conflicts of interest (100%), random sequence generation (92%) and comparability of groups (88%), and in a majority of the studies for imbalance in dropouts (73%), allocation concealment (65%), and incomplete reporting (62%). An unclear risk of bias was observed in 31% of studies for allocation concealment and 12% of studies for blinding and comparability of groups, while a high risk of bias was observed in 69% of studies for blinding. A risk map by NICE checklist parameter is presented in Supplementary Figure 1, and a detailed assessment by trial is presented in Supplementary Table 4.

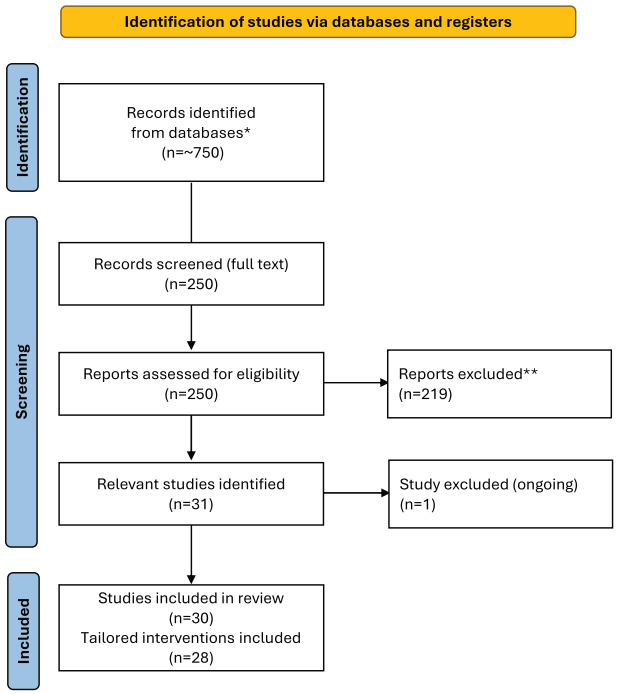

Fig. 2 Simplified flow diagram illustrating study selection. *Databases searched were PubMed, Google, and Google Scholar. Bibliographic searches of relevant recent publications were also carried out. **Subjective exclusion was performed by a single reviewer. Studies were selected for inclusion based on the agreed objectives of the current review, with emphasis on those publications that addressed the research questions.

Six studies were exclusively conducted in breast cancer, three in prostate cancer, two each in lung and hematological cancers, and one each in bladder, intestinal and neuroendocrine cancer. Fourteen studies covered cancer across multiple sites (including breast, lung, prostate, head and neck, lymphoma, digestive system, genitourinary, or gynecological cancers). The stage of cancer was not reported in 50% of the studies (15/30). Ten studies categorized patients into different stages, with wide variability in the distribution of patients into different stages across studies (10% to 88% were in stage 0–I, 6% to 55% in stage II, 6% to 27% in stage III, and 12% to 47% were in stage IV). Five studies reported cancer stage in terms of locally advanced (20% to 62% of patients) or metastatic (30% to 80%) tumors (Supplementary Tables 5–7).

Approximately 50% of studies were conducted in North America, while 30% were in Europe and 20% were in Asia. Sample sizes ranged from 39 to 829 patients, and follow-up for the longitudinal studies ranged from one to 24 months (Supplementary Tables 5–7).

Across studies, mean age ranged from 51.9–70.7 years and median age ranged from 54.0–70.0 years. Age ranges were similar in the intervention and control groups. Across 22 mixed-gender studies, the proportion of females ranged from 24.0% to 81.9%, with similar proportions in the intervention and control groups. Six studies included only females with breast cancer, while three included only males with prostate cancer. Among the 12 studies (all from the US) that reported race/ethnicity distribution, the majority of participants were White or Caucasian (72.8–92.3%), followed by Black/African American (1.0–22.7%), Asian (1.0–5.5%), and other/mixed/unknown race (0.0–5.4%). Hispanic or Latino ethnicity was reported by 1.7–6.7% of participants (Supplementary Tables 5–7).

In 18 studies, the entire sample of eligible participants received a specific type of cancer treatment, including chemotherapy (11 studies), surgery (two studies), immunotherapy (two studies), targeted therapy (one study), or radiation therapy (one study); or adjuvant hormone therapy in the case of female breast cancer (three studies). In other studies, the most common cancer treatments received at baseline or planned during the study were surgery (5.0–97.5%), chemotherapy (3.9–63.9%), radiation therapy (0.9–91.2%), and various combinations of the above (0.4–64.3%). Additionally, hormone therapy was received or planned by 28–73.3% of breast cancer patients, 32.2-44.9% of prostate cancer patients, and 71% of patients with neuroendocrine tumors (Supplementary Tables 5–7).

In most studies, the control group consisted of routine care (10/27) or enhanced care (10/27), with only seven studies using uniform engagement as the control. Approximately 50% of the interventions provided remote health education and self-management programs, with the remaining interventions being clinical follow-up by a healthcare professional (HCP) in an oncology practice for symptom management. In most studies (25/30), the intervention was tailored while it was ongoing ("on-treatment"), while the intervention was customized prior to its delivery ("pre-treatment") in five studies. Interventions were delivered primarily via web-based interfaces, often a mobile/tablet app, and were implemented for a duration ranging from 4 weeks to 96 weeks (Supplementary Tables 5–7).

Symptom burden and HRQoL were the most commonly evaluated outcomes (21 studies each), followed by adherence (13 studies), HCRU, and self-efficacy for self-management (10 studies each) (Supplementary Tables 5–7).

Tailored intervention vs routine care

Key findings from the 10 studies that directly compared tailored interventions versus routine care are summarized in Table 2, with full study details provided in Supplementary Table 5.

Seventy-percent (7/10) of the studies in this analysis had a sample size of more than 100 patients, with four studies including more than 500 patients. The follow-up duration was ≥6 months in 50% of the studies. The large studies (>500 patients) had robust power calculations and used multivariate analyses controlling for key confounders.

All types of tailored interventions were associated with positive outcomes compared with routine care. Both pre-treatment and on-treatment timings showed positive outcomes across a range of tailoring factors, including patient health status, patient needs, skills and goals, and symptom severity.

There was evidence that tailored interventions significantly improved self-efficacy for self-management compared with routine care ($p < 0.05$) [26–30]. Significant improvements were also seen for symptom burden (overall as well as specific symptoms such as anxiety, nausea, vomiting; all $p < 0.05$) [27, 29–31], although there were inconsistent effects on HRQoL, HCRU and adherence.

Improvements in HRQoL were mostly seen when the interventions were tailored by symptom severity, while improvements in HCRU were seen when the interventions were tailored by medication adherence or symptom severity. This suggests that the choice of tailoring factor is important when these outcomes are evaluated.

Tailored intervention vs enhanced care

Key findings from the 10 studies that directly compared tailored interventions against enhanced care are summarized in Table 3, with full study details provided in Supplementary Table 6. As noted earlier, in studies with enhanced care, patients in the control group received some additional support or care beyond routine care (for example, additional information about the disease, treatment, and side effects, as well as psychological support from nurses and physicians, or medication tracking). However, this care was different from that received by patients in the tailored intervention group, and was applied in a uniform manner across all patients in the group.

Most studies with enhanced care as a comparator demonstrated no consistent improvement across most outcomes such as symptom burden, self-efficacy, HRQoL, HCRU and adherence. Statistically significant improvements in at least one of the outcomes were observed slightly more frequently in larger studies, in which sample sizes were based on robust power calculations. Only the second largest study in the sample ($n = 300$ patients), with a 6-month follow-up period, showed a positive improvement in most outcomes [33]. The three studies with a sample size less than 100 patients did not provide any details on sample size estimation. Multivariate analyses controlling for key confounders were performed in only four studies.

Interventions involving health education, self-management (skills and strategies patients use to control and cope with their cancer symptoms), and clinical follow-up demonstrated significant improvement in some of the outcomes such as symptom burden, self-efficacy, HRQoL, and adherence, although the findings were inconsistent. The very limited data available suggested that a significant improvement in outcome was more likely with interventions that were tailored dynamically while on treatment, with the tailoring factor being severity of ongoing patient symptoms or adverse events.

There was significant benefit on adverse event severity as measured by the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 5.0 (49% reduced risk of severe immune-related adverse events) as an outcome when the intervention was tailored based on the CTCAE v5.0 [33]. In addition, there was a significant benefit on adherence (~32% higher adherence to aromatase inhibitors) as an outcome, when the intervention (a web-based app that provided patients with the ability to report symptoms and medication use) was tailored based on adherence rates [34, 35].

Table 2. Summary results from studies comparing tailored intervention vs routine care.

Author, year & country	Study details	Tailored intervention	Timing of the tailoring	Specific patient factor(s) used for tailoring	Alerts sent to	Symptom burden	Adherence	HRQoL	HCRU	Self-efficacy[a]
Feng, 2023 [26] China	RCT $N = 82$; F/P = NR	Health education & self-management program	Pre-treatment	Health status	NA	NA	✓	NA	NA	✓
Lambert, 2022 [27] Canada	RCT (rater-blinded) $N = 49$; F/P = 3 m	Health education & self-management program	Pre-treatment	Patient needs, skills & goals	NA	✓	NA	✓	NA	✓
Willems, 2017 [43] The Netherlands	RCT $N = 462$; F/P = 12 m	Health education & self-management program	Pre-treatment	Patient needs, skills & goals	NA	NA	NA	X	NA	NA
Mir, 2022 [57] France	RCT $N = 559$; F/P = 6 m	Clinical follow-up	On-treatment	Ongoing symptom severity	Both	NA	X	X	✓	NA
Park, 2022 [28] South Korea	RCT $N = 61$; F/P = 1 m	Counseling to improve adherence	On-treatment	Ongoing medication adherence	Patients	X	✓	NA	NA	✓
Basch 2016, [11] US	RCT $N = 766$; F/P = 12 m	Clinical follow-up	On-treatment	Ongoing symptom severity	Both	NA	✓	✓	✓	NA
Holch, 2023 [58] UK	RCT $N = 167$; F/P = 6 m	Clinical follow-up	On-treatment	Ongoing symptom severity	Both	NA	NA	✓	NA	NA
Absolom, 2021 [29] UK	RCT $N = 508$; F/P = 4 m	Clinical follow-up	On-treatment	Ongoing symptom severity	Both	✓	X	✓	X	✓
Maguire, 2021 [30] Multicountry	RCT (rater-blinded) $N = 829$; F/P = NR	Clinical follow-up	On-treatment	Ongoing symptom severity	HCPs	✓	NA	✓	NA	✓
Fjell, 2020 [31] Sweden	RCT $N = 149$; F/P = 4 m	Clinical follow-up	On-treatment	Ongoing symptom severity	HCPs	✓	NA	✓	NA	NA

✓ = Improvement in outcomes; X = No improvement in outcomes.

[a]Patient's belief in their ability to manage their symptoms and treatment.

Routine care: Standard of care as per routine clinical practice, with no additional tailored intervention.

F/P follow-up period, *HCP* Healthcare professional, *HCRU* Healthcare resource utilization, *HRQoL* Health-related quality of life, *m* months, *NA* not assessed/not applicable, *NR* Not reported, *RCT* randomized controlled trial, *UK* United Kingdom, *US* United States.

Table 3. Summary results from studies comparing tailored interventions vs enhanced care.

Author, year & country	Study details	Tailored intervention	Timing of the tailoring	Specific patient factor(s) used for tailoring	Alerts sent to	Symptom burden	AE	Adherence	HRQoL	HCRU	Self-efficacy[a]	Survival
LeBlanc, 2023 [59] US	RCT $N = 89$; F/P = 2 m	Health education & self-management program	On-treatment	Ongoing symptom severity	NA	X	NA		X	NA	NA	NA
Lee, 2023 [60] China	RCT (rater-blinded) $N = 222$; F/P = 2 m	Health education & self-management program	On-treatment	Ongoing symptom severity	NA	NA	NA	NA	X	X	✓	NA
Verweij, 2023 [61] The Netherlands	Non-RCT $N = 108$; F/P = 6 m	Clinical follow-up	On-treatment	Adverse event severity	HCP	X	NA	X	X	NA	✓	NA
Jacobs, 2022 [62] US	RCT N = 100; F/P = 6 m	Health education & self-management program	On-treatment	Ongoing patient needs, skills & goals	NA	✓	NA	X	✓	NA	X	NA
Zhang, 2022 [33] China	RCT $N = 300$; F/P = 6 m	Clinical follow-up	On-treatment	Adverse event severity	HCP	NA	✓	✓	✓	✓	NA	X
Tagai, 2021 [63] US	RCT $N = 431$; F/P = 6 m	Health education & self-management program	On-treatment	Patient needs, skills & goals	NA	✓	NA	NA	X	NA	NA	NA
Greer, 2020 [64] US	RCT $N = 181$; F/P = 3 m	Clinical follow-up	On-treatment	Ongoing symptom severity & medication adherence	HCP	X	NA	X	X	X	NA	NA
Handa, 2020 [65] Japan	RCT $N = 95$; F/P = 3 m	Health education & self-management program	On-treatment	Ongoing symptom severity	NA	X	NA	NA	NA	NA	NA	NA
Hauffman, 2020 [66] Sweden	RCT (rater-blinded) $N = 245$; F/P = 10 m	Health education & self-management program	On-treatment	Ongoing symptom severity	NA	✓	NA	NA	X	NA	NA	NA
Graetz, 2018 [35] US	RCT $N = 48$; F/P = 2 m	Clinical follow-up	On-treatment	Ongoing symptom severity & medication adherence	HCP	X	NA	✓	NA	NA	NA	NA

✓ = Improvement in outcomes; X = No improvement in outcomes.

[a]Patient's belief in their ability to manage their symptoms and treatment.

Enhanced care: Additional support beyond routine care; including additional information about the disease/treatment/side effects, psychological support from nurses and physicians, or medication tracking.

AE Adverse event. *F/P* follow-up period, *HCP* healthcare professional, *HCRU* Healthcare resource utilization, *HRQoL* health-related quality of life, *m* month, *NA* not assessed/not applicable, *RCT* randomized controlled trial, *US* United States.

Tailored intervention vs uniform engagement

Key findings from the seven studies that directly compared tailored interventions versus uniform engagement are summarized in Table 4, with full study details provided in Supplementary Table 7.

Not all studies provided details on sample size estimation, with robust power calculations described in only five studies. Furthermore, multivariate analyses adjusting for key confounders were conducted in only four studies. Very limited insights could be drawn from study design characteristics such as sample size and follow-up duration, as the findings were inconsistent. The two studies that demonstrated an improvement (both on symptom burden) had the largest (n = 358; [36]) and the smallest sample size (n = 83; [10]). One of the studies also had a short follow-up period of just 1 month [10]. No clear geographical trends were observed across the studies.

Almost all studies implemented tailoring based on severity of ongoing symptoms after treatment was initiated ("on-treatment") and involved automated alerts to either the HCP (in most cases) or the patient themselves when the symptom severity met preset thresholds; for example, a score ≥4 or 5 on a 0–10 scale for symptoms [10, 37, 38]. It should be noted that none of the studies reported the duration of symptoms or severity using the CTCAE at baseline, though all studies did use a study-specific numeric rating scale (ranging from 0 to 10/20) for measuring the severity of the symptoms. As might be expected, the interventions tailored to symptom severity demonstrated a significant impact on symptom burden, although this positive effect was seen in only three of five studies evaluating this outcome. Importantly, the improvement in symptom burden failed to translate to improved HRQoL or HCRU in all three studies. The nature of HCP involvement may be a key factor, as automated alerts were sent to HCPs and not to patients in all three studies that demonstrated improvement in symptom burden. The response by the HCPs was within 24 h of receiving the alert (within 4 h in one study). In addition to HCP involvement, these studies also involved more frequent patient engagement, including daily self-management coaching via recorded calls in response to high symptom severity [36, 39]. This may be an important factor in achieving symptom reduction.

None of the three studies involving health education and self-management programs demonstrated significant improvement in any outcome measure [8, 40, 41]. This suggests that merely providing tailored healthcare education and self-management support without any corresponding clinical follow-up may be insufficient to improve outcomes.

Symptom burden was the only outcome on which benefit was demonstrated, albeit inconsistently. This was also the most 'proximal' outcome, as these studies were tailored to patient symptom severity and the intervention was focused directly on symptom management.

More 'distal' outcomes such HRQoL were not seen to be sufficiently sensitive to demonstrate the impact of a tailored intervention. A randomized study with an electronic patient-reported outcome (ePRO) intervention in a population of metastatic melanoma patients showed no difference in HRQoL between the two arms until months after the applied ePRO intervention [42]. This implies that a longer duration of follow-up is required to demonstrate improvement in HRQoL. The follow-up period for the three studies that evaluated HRQoL ranged from 4 to 18 weeks.

In terms of HCRU, paradoxical findings may be expected as the enhanced focus on symptom handling and toxicity may lead to an increase in hospitalizations [8]. This may perhaps explain the negative finding of HCRU despite the benefit on symptom reduction in two studies [10, 39].

While evaluating treatment adherence, Sikorskii and colleagues noted that adherence is dependent on the stage of the disease [41], with patients who are further into their course of treatment being less likely to adhere to their regimen compared with patients who are initiating treatment. It is therefore more likely that an improvement in adherence would be seen among patients in the early stages of a disease or those who are initiating treatment.

Subgroup analysis

There were limited data on the effect of tailored intervention in different subgroups. Improvement in social functioning was seen with tailored interventions in men but not in women [43]. In the same study, a decrease in fatigue was seen in participants aged 56 or younger, but not for participants aged 57 or older [43]. Additionally, a decrease in depression was seen in participants who received chemotherapy with or without surgery, but not in participants who received surgery only, radiotherapy with or without surgery, or chemotherapy and radiotherapy with or without surgery [43]. Participants with a medium educational level reported higher social functioning with tailored interventions, while participants with a low educational level reported lower social functioning [43]. The benefits of tailored intervention in reducing symptom burden were greater in participants with Hodgkin's disease or non-Hodgkin's lymphoma compared with breast or colorectal cancer [30]. No effect of tailored intervention in improving physical well-being was observed in the metastatic subgroup, while positive effect was seen in the early-stage subgroup [29].

DISCUSSION

This analysis of 30 completed and published studies identified through a targeted literature search shows that the use of tailored non-pharmacological interventions in oncology achieved generally favorable results compared with routine care (standard of care as per routine clinical practice, with no additional tailored intervention). Tailored interventions significantly improved self-efficacy for self-management compared with routine care; significant improvements were also seen for symptom burden. When enhanced care (additional support beyond routine care) was used as a comparator, no consistent improvement were seen across most outcomes such as symptom burden, self-efficacy, HRQoL, HCRU and adherence. Positive results were seen slightly more frequently in larger and longer studies, highlighting the fact that study design in terms of sample size and follow-up period needs to be optimized to demonstrate benefit. Compared with uniform engagement, the interventions tailored to symptom severity demonstrated a significant impact on symptom burden; however, this positive effect was inconsistent (Fig. 3). The lack of any consistent superiority for tailored interventions over uniform engagement may be due to the presence of compounding factors, which were not adjusted for in most studies included, as well as inconsistencies in sample size and follow-up duration. In addition, HCP involvement and clinical follow-up was variable across studies, while the enhanced focus on symptom handling and toxicity associated with tailored interventions may paradoxically lead to more hospitalizations and an increase in HCRU.

Across the studies, the key aspects that pointed toward a successful outcome were interventions in the form of HCP responses and automated self-management coaching customized after treatment initiation, on the basis of severity of ongoing symptoms, suggesting that patients responded well to ongoing support. Both pre-treatment and on-treatment customization showed positive outcomes, across a range of tailoring factors, including patient health status, patient needs, skills and goals, and symptom severity, indicating that the presence rather than the timing of the intervention was significant. In general, clinical outcomes (especially symptom burden) seemed to be most sensitive to change. HRQoL, HCRU, and treatment adherence were not generally associated with positive study outcomes.

Table 4. Summary results from studies comparing tailored intervention vs uniform engagement.

Author, year & country	Study details	Tailored intervention	Timing of the tailoring	Specific patient factor(s) used for tailoring	Alerts sent to	Symptom burden	Adherence	HRQoL	HCRU
De Hosson, 2019 [40] The Netherlands	RCT *N* = 91; F/P = 3 m	Health education & self-management program	Pre-treatment	Patient needs, skills & goals	NA	NA	NA	X	NA
Taarnhøj, 2023 [8] Denmark	RCT *N* = 228; F/P = 4.5 m	Health education & self-management program	On-treatment	Ongoing symptom severity	Patients	NA	X	X	X
Sikorskii, 2018 [37] US	RCT (rater-blinded) *N* = 272; F/P = 3 m	Health education & self-management program	On-treatment	Ongoing symptom severity	Patients	X	X	NA	NA
Dai, 2022 [10] China	RCT (rater-blinded) *N* = 83; F/P = 1 m	Clinical follow-up	On-treatment	Ongoing symptom severity	HCPs	✓	NA	X	X
Rha, 2020 [38] South Korea	RCT *N* = 324; F/P = 24 m	Clinical follow-up	On-treatment	Ongoing symptom severity	HCPs	X	NA	NA	NA
Mooney, 2017 [36] Kolb, 2018 [39] US[a]	RCT *N* = 358; F/P = 6m *N* = 252; F/P = 3 m	Clinical follow-up	On-treatment	Ongoing symptom severity	HCPs	✓	NA	NA	X

✓ = Improvement in outcomes; X = No improvement in outcomes.
[a][36] and [39] are different analyses of the same dataset.
Uniform engagement: Non-tailored support offered in a uniform manner.
F/P follow-up period, *HCP* healthcare professional, *HCRU* healthcare resource utilization, *HRQoL* health-related quality of life, *m* months, *NA* not assessed/not applicable, *RCT* randomized controlled trial, *US* United States.

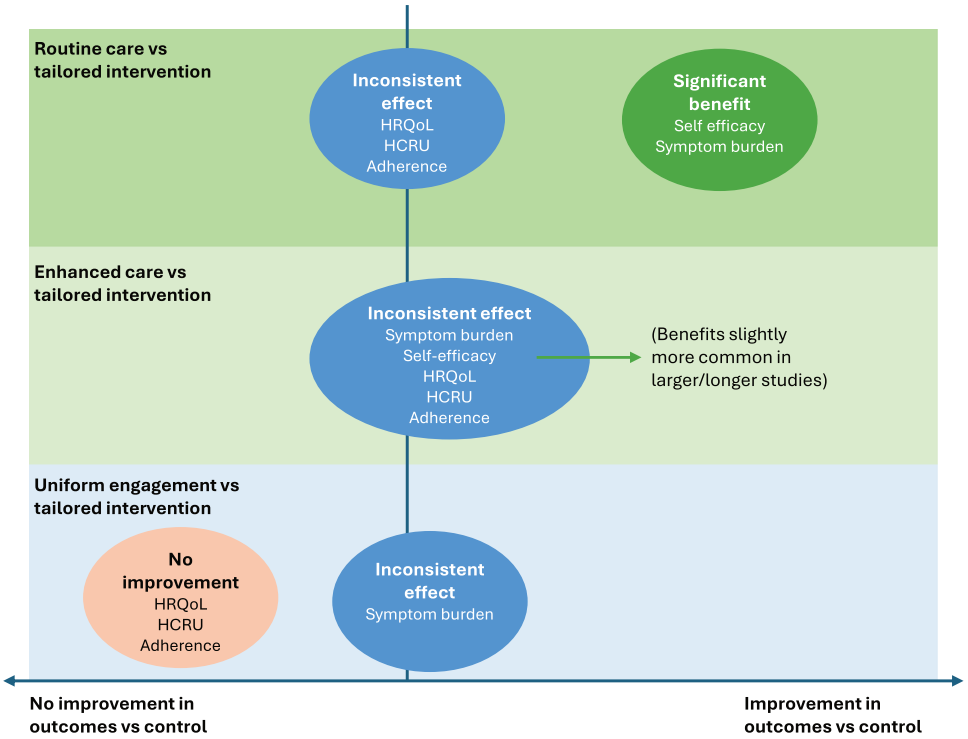

Fig. 3 Qualitative summary of the impact of tailored interventions versus comparators on patient outcomes among patients receiving medical treatment for cancer. HCRU healthcare resource utilization, HRQoL healthcare-related quality of life. **Routine care:** Standard of care as per routine clinical practice, with no additional tailored intervention; **Enhanced care:** Additional support beyond routine care; including additional information about the disease/treatment/side effects, psychological support from nurses and physicians, or medication tracking; **Uniform engagement:** Non-tailored support offered in a uniform manner.

Improvements in HRQoL were mostly seen when the interventions were tailored by symptom severity, and improvements in HCRU were seen when the interventions were tailored by medication adherence or symptom severity. This suggests that the choice of tailoring factor is important when these outcomes are evaluated.

Although tailored interventions have not been shown to be consistently better than uniform (non-tailored support offered in a uniform manner) engagement in improving outcomes, this does not imply that tailoring per se is ineffective. These studies were few in number, and generally had smaller samples and shorter follow-up periods than studies involving routine care comparators. This may point toward practical challenges in conducting large studies with a robust design. However, in the absence of such high-quality studies, the question regarding the potential benefit of tailoring remains unanswered. Even in other indications (for example, heart failure), there were no studies comparing tailored interventions directly with uniform engagement, and therefore no learnings can be drawn from these studies.

Although we have not shown conclusive evidence of the benefit of tailoring in this analysis, definitive conclusions regarding the effectiveness of this approach are not possible due to the identified deficiencies in the data. Suggestions for future well-designed studies to address this knowledge gap are recommended in the next section.

A number of other interesting observations emerge from this research. For example, as well as considering the level of investment of time and resource that is appropriate to achieve a meaningful impact on patient symptoms and side effects, it is also important to consider which functions within the healthcare system are in the best position to offer the required engagement. It is possible that interventions should be initiated and pursued by behavioral psychologists or other HCPs rather than doctors or nurses whose time may be used more effectively in other capacities. In addition, it is likely that much of the tailoring and initial engagement may be performed using automated programs, and that only the final engagement (such as direct management of patient symptoms and side effects) would need to be carried out by an HCP [44, 45]. Although there were insufficient data available from the publications identified to allow firm conclusions to be reached on the most appropriate professional to administer the intervention, this is an interesting and important avenue for further research with clear implications for clinical practice and health policy, as it would help healthcare managers direct the most appropriate resources to optimize the management of symptoms and side effects.

Another interesting area for further research would be to investigate any relationship between patient or disease characteristics and response to tailored intervention. It is possible that differences in factors such as tumor type (solid versus hematologic), patient age, treatment setting (neoadjuvant, adjuvant, or metastatic), as well as geographical or cultural characteristics may have an impact on the response to a non-pharmacological intervention introduced to manage symptoms and side effects. For example, there is some evidence that patients from different cultures may respond differently to side effects of cancer treatments, with Asian patients appearing to have a greater reluctance to report pain and use prescribed analgesics than Western patients [46], while patients in some African countries may have less opportunity to report side effects due to poor infrastructure, low awareness, and lack of a reporting culture [47]. In this review, approximately 50% of the studies were conducted in North America, 30% in Europe, and 20% in Asia, which means that the small number of studies included from certain regions precludes a detailed analysis of this issue. In addition, as all of the included studies were carried out in adult patients, the vast majority of whom were treated for solid tumors, it is not possible to assess the impact of age or tumor type on response to tailored intervention. Although this review was extensive and wide-

ranging, little data were identified to allow a fuller investigation of the impact of patient and disease characteristics on patient response to a given non-pharmacological intervention. This highlights another potential area for future research.

It is not possible to consider the future directions of healthcare strategies and resource use without considering the growing and increasingly essential role played by machine learning and artificial intelligence (AI) tools in all fields of medicine. Early research has suggested that novel data visualization techniques and unsupervised machine learning may help predict the safety profile of cancer treatments, allowing greater anticipation and management of side effects, including side effects which may frequently cluster both in terms of severity and temporally [48]. In addition, AI tools may be able to predict those patients most likely to experience adverse events, allowing targeting of resources to those patients who are more likely to gain the most benefit from a given intervention [49–51]. Furthermore, AI techniques could be used to dynamically adapt the level of engagement for each patient based initially on baseline patient characteristics, and then subsequently on dynamic patient information following treatment initiation. This approach may allow for real-time tailoring of the non-pharmacological interventions according to patient needs, without considerable investment of HCP time, and further highlights the potential for adaptive personalization of tailored interventions in clinical practice. The use of AI in the ways described would be likely to have a substantial impact on health system efficiency and the practical management of clinical practice.

Other technological advances are likely to assist healthcare professionals in managing side effects according to individual patient needs and characteristics. The emergence of apps such as "Patient knows best" [52] allows patients to see their own medical records and care plans, and provides patients with greater autonomy over their own data. However, reports suggest that providing this level of information without further context or support can lead to confusion and anxiety among patients who may not fully understand the data available to them [53–55]. Combining this approach with tailored interventions in the form of one-to-one nurse reviews or plain language summaries may increase the effectiveness of apps such as "Patient knows best", allowing patients to benefit from increased data transparency in a positive and constructive way while avoiding any unnecessary anxiety due to a lack of understanding.

Recommendations for future study design

The results of this review reveal many gaps in the literature regarding the value and impact of tailored interventions on patient outcomes in oncology. In order to fill these gaps, future clinical studies are required that take into consideration the type of tailored intervention and the outcome of interest, as well as the choice of comparator.

In terms of type of tailored intervention, a number of aspects need to be considered. For example, tailored interventions involving clinical follow-up of patients by HCPs have shown the most benefit. With regard to timing, the strongest data support dynamically tailoring the intervention based on the status of the patient (with respect to symptom severity, adherence or adverse events) after the treatment has been initiated. Lower quality data support the customization of interventions prior to their initiation. Finally, the strongest evidence is seen for tailoring based on clinical factors such as symptom severity and adverse events, while lower quality evidence supports tailoring based on other factors such as adherence, health status, needs, and goals.

With regard to outcomes, most robust data support improvement in symptoms and adverse events while lower quality data support improvement in adherence. In addition, limited data show improvement in HRQoL and HCRU.

There is also significant interplay within the elements of the tailored interventions and between the tailored interventions and the outcomes. For example, tailored interventions focused on improving symptoms (outcome) include customized HCP follow-up (intervention) that is tailored according to symptom severity (tailoring factor) and is most effective after the treatment has been initiated (timing of tailoring).

For other outcomes, self-efficacy may be included as an outcome if the tailored intervention is directly focused on improving this measure through imparting health information, coaching, and other techniques. Furthermore, HRQoL may be included as an outcome to demonstrate the humanistic benefit of the intervention, with the caveat that demonstrating benefit on this outcome is difficult in these studies. When studying HCRU, it is important to keep in mind that HCRU may show paradoxical results, i.e., a successful non-pharmacological intervention focused on patient symptoms and adverse events may result in *increased* HCRU.

In order to definitively address the question of whether tailoring is effective, a three-arm study design is recommended to compare a tailored intervention (arm 1), uniform engagement (arm 2), and routine care (arm 3). An analysis of arm 1 vs arm 2 would demonstrate the benefit of tailoring itself, while analysis of arm 1 vs arm 3 would demonstrate the actual expected benefit of this tailored intervention beyond the current standard of care.

In terms of other study design considerations, raters/researchers involved in assessing outcomes and analysis may be blinded, even though full blinding would be challenging due to differences in the interventions. Data generally suggests that longer studies are better, with 6 months being the minimum duration. This may be especially true for demonstrating benefit on outcomes such as HRQoL. The study would need to be adequately powered to demonstrate what may be a small, albeit significant, difference between tailored and uniform engagements. The minimal clinically important difference for a patient-reported outcome should be taken into consideration for sample size calculation when symptom is a primary outcome. Given the heterogeneity in effect size demonstrated in the literature, a medium effect size for mean comparison between the groups should be considered. A large proportion of participants are expected to drop out especially in internet/mobile-based studies, and therefore the sample size calculation should allow for a reasonable attrition rate. Finally, there is likely to be a role for tools based on AI, especially for real-time dynamic customization based on patient-reported symptoms and to identify patients who would derive a benefit from the dynamic customization. This may reduce the logistic complexity of these trials, and thus facilitate larger, longer trials.

These recommendations are summarized in Fig. 4.

Once the efficacy of a tailored intervention has been demonstrated in clinical trials, we recommend evaluation of its clinical utility/effectiveness through real-world prospective studies before implementation in routine clinical practice is planned.

Gaps and limitations

This review has a number of gaps and limitations which should be acknowledged. Perhaps the greatest limitation is that this was a targeted review rather than a systematic review, which could not practicably be completed due to the considerable variability in outcome definitions, durations of follow-up, and intervention modalities. In addition, the large number of studies available in this area makes a systematic review logistically difficult to complete, without necessarily providing additional insights [56]. Furthermore, the studies included in this review were selected carefully based on a thorough understanding of the literature and careful consideration of the defined research questions. However, the fact that this is not a systematic review does introduce a possible source of bias into the review, and means that a degree of caution is required when interpreting the findings. Another potential criticism of this study is that a single reviewer was involved in screening and data extraction. Although this was felt

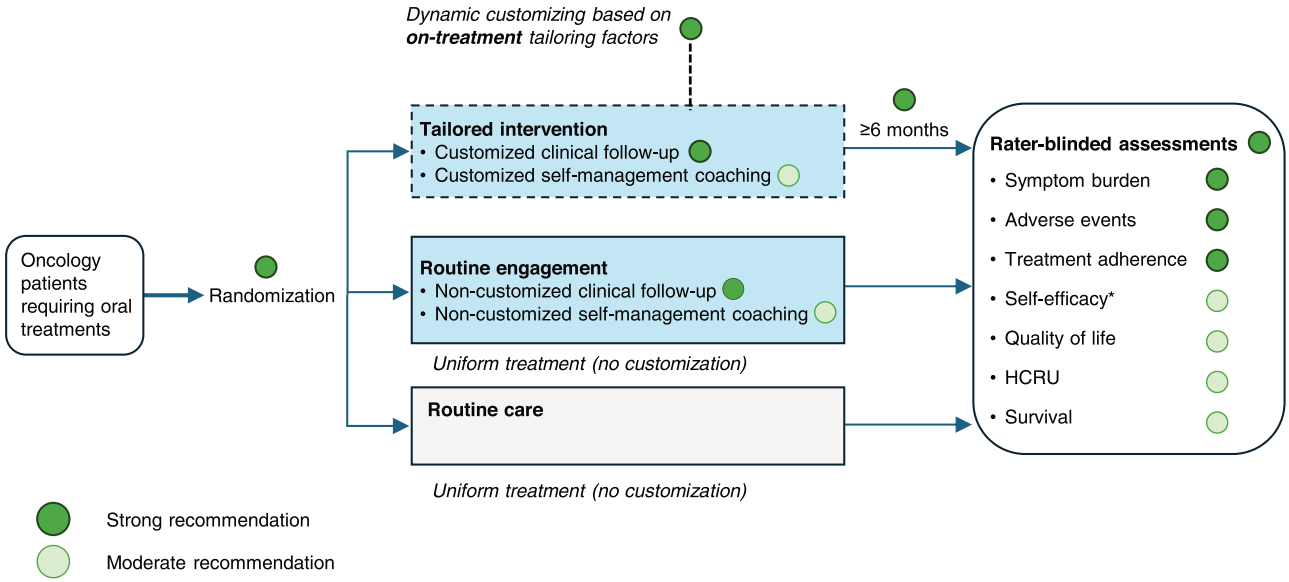

Fig. 4 Design recommendations for a potential study evaluating the impact of a tailored intervention on patient outcomes in oncology. HCRU healthcare resource utilization. *Patient's belief in their ability to manage their symptoms and treatment.

to provide consistency in selection of the studies for inclusion, it should be acknowledged that this is another potential source of bias in our research.

In terms of the studies themselves, there were very limited data on tailored interventions, while almost all of the included studies were RCTs. Only seven studies directly compared tailored interventions with uniform engagement, which limits the conclusions which we are able to draw. In addition, no relevant real-world studies were identified, creating an important gap in our findings.

With regards to study methodology, around 40% of the studies had a sample size below 100 patients, meaning that the insights from some individual studies may not be definitive. Sample sizes were based on robust power calculations in only 50% of the studies, with no details provided in the remaining studies. In addition, very limited long-term data were available, as most studies were less than 6 months in duration.

There was considerable heterogeneity in terms of comparators and patient factors used for tailoring and outcomes. This heterogeneity precludes direct comparisons across studies and quantitative analysis, and also makes it difficult to rank the interventions according to their effectiveness. It is also important to note that multivariate analyses controlling for key confounders was performed in only 40% of the studies.

Notwithstanding these limitations, we feel that this review provides important evidence to meet a clear gap in the literature, and provides valuable insights into the effectiveness of tailored non-pharmacological interventions for patients receiving medical treatment for cancer. Many of these findings could be implemented immediately into clinical practice, with the additional studies suggested undertaken to seek further definitive evidence for the benefit of tailored interventions.

CONCLUSIONS

Use of tailored interventions showed positive benefits over routine care. Positive benefits were shown for tailored interventions compared with enhanced care only in larger and longer studies. Based on limited data, tailored interventions were not shown to be consistently better than uniform engagement in improving outcomes. In general, clinical outcomes (especially symptom burden) appear to be most sensitive to the type of intervention. HRQoL, HCRU, and treatment adherence were not generally associated with positive study outcomes. Future research should focus on leveraging the capacity for machine learning and AI to identify those patients most likely to benefit from tailored interventions.

DATA AVAILABILITY

All data presented in this article are publicly available.

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AUTHOR CONTRIBUTIONS

DM, GK, and SK were responsible for designing the review protocol, writing the protocol, report, and manuscript, conducting the search, screening potentially eligible studies, extracting and analyzing data, interpreting results, updating reference lists and creating 'Summary of findings' tables. GF and FM were responsible for developing the concept, providing feedback on the review protocol and report. GF, AF, HW, AP, and FM were responsible for the development of the manuscript, including inputs at every stage of development, contributions to the discussion section, and approval of the final draft.

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COMPETING INTERESTS

Graham Ferrier and Faisal Mehmud are employed by Pfizer at the time of review and writing of the manuscript. Alessandra di Pietro is employed by Pfizer at the time of review and writing of the manuscript, and also owns stocks as part of her compensation. Deepali Mittal, Geetanjali Kamath, and Saifuddin Kharawala are employees of Bridge Medical Consulting, commissioned by Pfizer to carry out this literature review. Harpreet Wasan has acted on advisory boards or as an invited speaker or has attended meetings for Servier, Pierre Fabre, Incyte, Bayer, Pfizer, Zymeworks, Merck KGaA, Taiho, Seagen, Exact therapeutics, Takeda (Hutchinson Med), Amgen, Roche/Genentech/ FM, SIRTEX Medical, Erytech Pharma, BMS (Celgene), and BTG; has acted in a consultancy or advisory capacity for NICE/BSI expert Takeda, Bayer, Pierre Fabre, ONCOSIL, Incyte, Celgene, Oaktree life sciences; has served on Global Trials committees for Pfizer (Array); Zymeworks, Boehringer Ingelheim (DMC), SIRTEX, Merck KGaA, ARCAD (Pancreas Academic); and has received research funding from MSD, Merck Serono, Pfizer, and Sirtex. Aleksandra Filipovic has no competing interests.

ADDITIONAL INFORMATION

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