Effects of shared decision making on distress and healthcare utilization among patients with lung cancer: a systematic review


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Effects of shared decision making on distress and healthcare utilization among patients with lung cancer: a systematic review

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Abstract

Context Lung cancer is associated with significant distress, poor quality of life, and a median prognosis of less than one year. Benefits of shared decision making (SDM) have been described for multiple diseases, either by the use of decisions aids or as part of supportive care interventions.

Objectives To summarize the effects of interventions facilitating SDM on distress and healthcare utilization among patients with lung cancer.

Methods We performed a systematic literature search in the CINAHL, Cochrane, EMBASE, MEDLINE, and PsychINFO databases. Studies were eligible when conducted in a population of patients with lung cancer, evaluated the effects of an intervention that facilitated SDM, and measured distress and/or health care utilization as outcomes.

Results A total of 12 studies, detailed in 13 publications, were included: nine randomized trials and three retrospective cohort studies. All studies reported on a supportive care intervention facilitating SDM as part of their intervention. Eight studies described effects on distress and eight studies measured effects on healthcare utilization. No effect was found in studies measuring generic distress. Positive effects, in favor of the intervention groups, were observed in studies using anxiety-specific measures (n=1) or depression-specific measures (n=3). Evidence for reductions in healthcare utilization was found in five studies.

Conclusion Although not supported by all studies, our findings suggest that facilitating SDM in the context of lung cancer may lead to improved emotional outcomes and less aggressive therapies. Future studies, explicitly studying the effects of SDM by using decision aids, are needed to better elucidate potential benefits.

Keywords: Lung Neoplasm, Decision Making, Decision Aid(s), Shared Decision Making, Supportive Care
Introduction

Lung cancer represents 13% of all cancer diagnoses and remains one of the most frequently diagnosed cancers worldwide. It is the leading cause of cancer deaths with a median prognosis of less than one year.\textsuperscript{1} Patients with lung cancer experience high levels of distress throughout and after treatment, especially when compared to patients with other types of cancer.\textsuperscript{2,3} Also, the overuse of aggressive therapies (e.g. chemotherapy) near the end of life is increasingly regarded as disadvantageous.\textsuperscript{4–7} Patient-centred conversations earlier in the disease course may lead to improved emotional well-being and to care that is aligned with patients’ personal preferences.\textsuperscript{8,9}

To better achieve such conversations, especially when patients are faced with difficult treatment trade-offs, an increased emphasis is put on the concept of shared decision making (SDM).\textsuperscript{10,11} Especially in preference-sensitive decisions, such as the decision on whether or not to pursue a new course of treatment when faced with a life-limiting illness, SDM is of critical relevance.\textsuperscript{10,12–15} To date however, patient values and personal preferences are not routinely integrated in clinical care mainly due to time constraints, unawareness, or uncertainty on part of the clinician.\textsuperscript{13,16,17} In contrast to this, a majority of patients do express a desire to have a role in SDM, emphasizing the need to further develop evidence on how to facilitate such a process.\textsuperscript{18–23}

Facilitation of SDM has been shown to improve a patients’ emotional state of well-being, increase patient or caregiver involvement, increase decision satisfaction, and possibly reduce overly aggressive therapies near the end of life.\textsuperscript{24,25} In other settings, tools have been developed to specifically facilitate SDM in clinical practice.\textsuperscript{26,27} Such tools, hereafter referred to as decision aids, usually inform patients about benefits and disadvantages of different (treatment) alternatives. To date however, no study has summarized the effects of SDM in patients with lung cancer. We therefore conducted a systematic review to summarize the
available evidence on the effects of SDM in patients with lung cancer and focused on the effects on distress and healthcare utilization.
Methods

Design and data sources

The review protocol was registered in PROSPERO (CRD42015026954). We systematically searched the CINAHL, Cochrane, EMBASE, MEDLINE, and PsycINFO databases. Two search updates were performed; the latest update was conducted on 2 May 2018. Terms used in our electronic search strategy were shared decision-making, lung cancer, distress and healthcare utilization. We decided to use a broad search strategy since no MESH heading for “shared decision making” is available. This search strategy included both subject headings and free text terms and was adjusted for the use of synonyms and alternative spellings (Supplement A). A librarian assisted this process. All references were exported to RefWorks, ProQuest LCC, 2017 and duplicates were removed. We adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist throughout the reporting of our study.²⁸

Eligible studies

Two investigators (MES and OPG) independently performed an initial screening based on title and abstract. The same investigators performed a full-text appraisal of the remaining studies to determine final inclusion. Reference lists of all included studies were hand searched for additional studies. Disagreements were resolved through a consensus discussion with a third independent investigator (AJB). Studies were eligible for inclusion if all of the following criteria were met:

1) The study contained original data;
2) The study included ≥100 patients with a confirmed diagnosis of lung cancer; authors of studies which included a sample of different cancer populations without reporting
separately on the subsample of lung cancer patients were approached for data on the lung cancer patients;

3) The study explicitly detailed on the facilitation of SDM, either as part of a supportive care intervention or by use of a decision aid;

4) SDM had to be facilitated throughout treatment-related decisions: studies reporting on decision rules for clinicians, decisions on lifestyle changes only, clinical trial entry, or education programs not geared towards a specific decision were excluded;

5) The study had a control group in which patients received usual care, we accepted both randomized and non-randomized studies;

6) At least one outcome measure of distress and/or healthcare utilization was used.

We used the definition as provided by Towle et al.\textsuperscript{11} to delineate SDM: A process to make decisions that are shared by both doctor and patient by informing patients using best evidence about risks and benefits including patient-specific characteristics and values. Distress was defined as: “emotional and/or physical distress measured by a generic distress scale and/or a scale measuring symptoms of depression or anxiety”.\textsuperscript{29} Questionnaires measuring distress were considered to quantify generic distress if two or more of the following domains were covered: physical problems, spiritual problems, social problems, or symptoms of anxiety or depression. We defined healthcare utilization as “any measure quantifying the amount of care a patient may have received” (e.g. the number of hospitalizations throughout the study period or whether a patient received chemotherapy in the last 30 days of life). The time period as defined by the study was used. Since healthcare utilization may be expressed in many different ways, we decided to summarize the effects on the three most frequently used outcomes of healthcare utilization
across all included studies. All other outcomes and results related to healthcare utilization are provided in Supplement B.

**Data extraction and statistical analysis**

A standardized data extraction form following the CONSORT criteria\textsuperscript{30,31} was developed to synthesize the data of selected studies. The extraction form consisted of nine items assessing study methodology (e.g. study design and the follow-up period) and six items evaluating the study’s results (e.g. flow of participants throughout the study and numbers of participants analyzed). Whenever multiple measures of one outcome (e.g. different questionnaires to quantify distress) were used, we extracted data from all measures. Different publications detailing on the same study population were analyzed as one study. We expected that pooling of results in a meta-analysis would not be feasible due to intervention- and outcome measures heterogeneity. When the number of studies included was considered too small to perform subgroup analyses, the ‘best evidence’ approach was performed including an analysis of the strength of evidence.\textsuperscript{32}

Clinical relevance was assessed based on available literature regarding the “Minimally Clinical Important Difference” (MCID). The following MCID’s and cutoff scores were used: +3 for the Edmonton Symptom Assessment System (ESAS),\textsuperscript{33,34} +1.5 for the Hospital Anxiety and Depression Scale (HADS) or a subscale cutoff of >7 with a minimal 5% difference between study groups,\textsuperscript{35} a cutoff of >4 for the Brief Distress Thermometer (BDT) with a minimal 5% difference between study groups,\textsuperscript{36} and a minimal change of 50% from baseline score for the Patient Health Questionnaire-9.\textsuperscript{37} An MCID or cutoff score for the Symptom Distress Scale (SDS) was not found. Therefore, we applied the rule of half a standard deviation\textsuperscript{38,39} as a best proxy leading to an estimated MCID of +3.5.\textsuperscript{40}
Risk of bias assessment

The Cochrane Collaborations’ Risk of bias tool was used to assess risk of bias. Using this tool, seven aspects that may be subject to bias were assessed: 1) random sequence generation, 2) allocation concealment, 3) blinding of participants or personnel, 4) blinding of outcome assessors, 5) incomplete outcome data, 6) selective outcome reporting, and 7) other potential sources of bias including unbalanced groups at baseline. This tool is primarily designed to assess risk of bias in RCTs. For uniformity, we decided to also use this tool in other studies and score RCT-specific aspects as non-applicable.

Risk of bias of included studies was assessed and reported in a standardized spreadsheet by two independent investigators (MES and OPG or MES and AJB). For each category, the risk of bias was assessed as low, high, or unclear. Discrepancies were resolved by consensus and settled through discussion with a third independent investigator (AJB or MYB).
Results

Search results

The search yielded 4929 titles and was reduced to 3633 titles after removing duplicates. Of these, 92 titles met the criteria for a full text review. A total of 12 eligible studies, reported in 13 publications, were included: nine randomized controlled trials (RCTs) and three retrospective cohort studies (Figure 1). Three of the RCTs were performed in mixed cancer populations. Comparison of the subsamples of patients with lung cancer vs. the total study samples showed that patients with lung cancer suffered from more distress when compared to the total sample (data not shown). Pooling of results in a meta-analysis was not performed due to intervention- and outcome measures heterogeneity.

Description of interventions

All included studies detailed on a supportive care intervention facilitating SDM as part of the intervention. None of the included studies described the effects of a decision aid. Overall, the goal of such multi-component interventions was to provide earlier and systematic access to palliative care services through either specially trained advanced practice nurses, a registered nurse case manager, or members of a palliative care team. Interventions were primarily aimed at improving emotional well-being and QoL by encouraging self-management, addressing symptom burden, and discussing unmet needs. Table 1 provides further details on the characteristics of the included studies (13 publications).

Measures of distress

Effects on distress are summarized in Table 2 and the data below are displayed as intervention group (group for which SDM was facilitated) vs. control group. Eight RCTs, comprising 1294 patients with lung cancer, evaluated effects on distress.
studies measured generic distress using either the ESAS,\textsuperscript{42,50} the HADS total score,\textsuperscript{44,47} the BDT,\textsuperscript{47} or the SDS.\textsuperscript{48} Four studies measured anxiety, all using the HADS-A subscale.\textsuperscript{25,44,46,49} Five studies measured depression and used either the Center for Epidemiologic studies Depression Scale (CES-D),\textsuperscript{42} the Patient Health Questionnaire (PHQ-9),\textsuperscript{25,46,49} or the HADS-D subscale.\textsuperscript{25,44,46,49} Only statistically significant differences are detailed below. Based on the previously described MCID’s, clinically relevant differences are displayed in Table 2.

Effects on distress

Generic distress

None of the five studies measuring generic distress showed statistically significant differences between the intervention group and the usual care group at any time point.\textsuperscript{42,44,47,48,50}

Anxiety

Of the four studies measuring anxiety, one study (n=150) showed a significantly lower percentage of patients with symptoms of anxiety after 12 weeks in the intervention group (17\% vs. 27\%; p<0.05).\textsuperscript{49} Another study (n=151) showed the same trend but there was no significant difference (25\% vs. 30\%; p=0.66).\textsuperscript{25} The other two studies showed no significant differences in mean anxiety scores.\textsuperscript{44,46}

Depression

Three out of five studies measuring depression observed beneficial effects favoring the intervention group. Two studies (n=151 and n=150) showed a significantly lower proportion of patients with high levels of depression as measured with the HADS-D (16\% vs. 38\%; p<0.001 and 19\% vs. 32\%; p<0.001, respectively).\textsuperscript{25,49} These two studies found similar effects
in the PHQ-9 scores (data not shown) as did the third study (n=191): mean depression scores on the PHQ-9 at both 12 weeks (5.61 vs. 7.21; \( p=0.04 \)) and 24 weeks (5.54 vs. 6.71; \( p=0.05 \)).  The latter study showed no effect in the HADS-D.  The two other studies compared mean depression scores and observed no significant differences.  

Measures of healthcare utilization

Effects on healthcare utilization are summarized in Table 3 and the data below are displayed as intervention group (group for which SDM was facilitated) vs. control group. Eight studies, reported in nine publications and detailing on data from 2914 patients, described effects on healthcare utilization: five RCT’s and three retrospective cohort studies. Across these studies, effects on hospitalizations (n=7), emergency department (ED) visits (n=5), and the use of chemotherapy (n=5) were the three most frequently used outcomes and are summarized in detail below. All other outcomes and results related to healthcare utilization are provided in Supplement B.

Hospitalizations

Two of the retrospective studies found evidence for changes with regard to hospitalizations. One of these studies (n=286) compared the percentage of patients that were hospitalized in the last three months before death, across patients receiving early palliative care, late palliative care, or no palliative care (73% vs. 97% vs. 88%; \( p=0.03 \)). The other study (n=1476) observed that patients who had received a palliative care consultation had a longer mean length of stay (16.3 days vs. 8.3 days; \( p<0.001 \)). The five RCTs detailing on this showed no significant differences for hospitalizations between intervention and control group. In two of these studies (n=151 and n=223), a trend towards significance,
favoring the intervention groups, was observed in the percentage of hospitalized patients in the last 30 days of life: 37% vs. 54%; no p-value provided, and 47% vs. 56%; p=0.23.\textsuperscript{25,44}

\textit{Emergency department visits}

One RCT (n=201) found that the cumulative incidence of patients admitted to the ED was lower in the intervention group (39% vs. 53%; p=0.02).\textsuperscript{43} Similar trends, although not significant, were observed in two other RCTs (ED-visits in last 30 days of life: 22% vs. 30%; no p-value provided, and 25% vs. 38%; p=0.09).\textsuperscript{25,44} The remaining two studies did not find differences between the mean number of ED-visits in both study groups.\textsuperscript{42,48}

\textit{Use of chemotherapy}

One RCT (n=223) and one retrospective cohort study (n=286, analyzing early palliative care vs. late palliative care vs. no palliative care) reported a significantly lower proportion of patients in the intervention group who received chemotherapy in the last 30 days of life: 12% vs. 26%; p=0.03 and 14% vs. 40% vs. 28%; p=0.003, respectively.\textsuperscript{44,52} Another RCT (n=151) found similar effects when analyzing the use of chemotherapy in the last 60 days of life (53% vs. 70%; p=0.05) and a trend in the last 30 days of life 30% vs 43%; p=0.14.\textsuperscript{25,45} The other two studies did not observe significant differences in the use of chemotherapy, either as measured by the mean duration of chemotherapy or by the number of chemotherapy treatments.\textsuperscript{43,51}

\textbf{Risk of bias}

Assessment of the risk of bias of individual studies is shown in Figure 2. Overall, the risk of selection bias and attrition bias was perceived as low in most RCT’s. A high risk of bias was found regarding blinding of participants or personnel, which was not performed in most
studies due to the nature of the interventions. Reporting bias was unclear in some studies since not all study protocols were made publicly available online prior to publication. In two retrospective studies, the study groups were not comparable thereby making selection bias highly likely.\textsuperscript{52,53} In the third retrospective study this was unclear due to scarce information.\textsuperscript{51}
Discussion

To our knowledge, this is the first systematic review synthesizing evidence on the effects of SDM on distress and healthcare utilization in patients with lung cancer. We identified 12 studies, detailed in 13 publications, describing the effects of supportive care interventions that facilitated SDM as part of their intervention. We found no statistically significant differences in distress in studies using a generic measure. However, mixed effects, in favor of patients for which SDM was facilitated, were found in studies specifically measuring depression or anxiety. Regarding reductions in healthcare utilization, we observed some evidence that SDM leads to reductions in healthcare use.

A number of observations are of importance. As the incorporation of SDM is increasingly propagated for different diseases in order to truly provide patient-centered care,\textsuperscript{54–56} we found evidence that it may lead to less depression and anxiety and reductions in healthcare use. This suggests that involving patients in treatment decisions earlier in the disease course may lead to care that is better aligned with patients’ personal preferences and consequently to improved patient-reported outcomes. Yet, since all included studies described multicomponent supportive care interventions, we are not able to deduce whether SDM or other components of these interventions (e.g. earlier referrals or improved symptom management) account for the observed effects. Clearly, palliative care may also improve outcomes related to distress and healthcare utilization without the explicit facilitation of SDM. This is especially relevant since we were unable to measure exactly how and, more importantly, to what extent SDM was provided throughout the included studies.
Unfortunately, we did not identify any studies solely describing the effects of the use of a decision aid for patients with lung cancer. Several relevant pilot studies described the design and pilot testing of such tools.\textsuperscript{57–60} These studies all conclude that facilitating SDM in clinical practice is feasible. Moreover, two of these studies provided preliminary evidence for reductions in distress, enhanced patient satisfaction, better symptom control, and improved disease knowledge and understanding.\textsuperscript{59,60} Such tools have yet to be tested in larger cohorts of patients with (lung) cancer.

We found several research protocols describing interventions aimed at testing the effects of decision aids in patients with different types of (advanced) cancer.\textsuperscript{61–64} Additionally, two recent systematic reviews concluded that the evidence base for SDM is at a relatively early stage.\textsuperscript{26,27} These studies summarized the use of decision aids for patients facing health treatment or screening decisions\textsuperscript{26} and patients with a life-limiting illness.\textsuperscript{27} Both reviews do provide strong evidence on improved health-literacy and some evidence for reductions in decisional conflict.\textsuperscript{26,27}

Strengths of the current review include the use of an extensive, systematic search strategy in five widely used databases from founding date through May 2018. We therefore believe the chance of having missed relevant studies is small. In addition, by limiting our inclusion of eligible studies to patients having received a diagnosis of lung cancer, our results provide important information on a relatively homogeneous patient population. Lastly, we adhered to the evidence-based PRISMA guidelines, thereby improving our study’s reporting structure.\textsuperscript{28} Several limitations of this review deserve consideration. A number of studies in this review were powered to detect effects for a larger sample with different types of cancer being included. This might have resulted in insufficient power to detect effects in the subsample of lung cancer patients. A meta-analysis would have increased statistical power but was not
possible due to heterogeneity of interventions and outcomes. Clinical relevance, however, is not affected by sample size and was clearly defined for most questionnaires in our study.

Furthermore, we decided to focus on effects of SDM on distress and healthcare utilization. We specifically opted for these outcomes since patients with lung cancer are faced with a poor prognosis, are highly distressed, and face difficult treatment choices when approaching the end of life.\textsuperscript{65,66} The observation that subsamples of patients with lung cancer experienced higher levels of distress further supports this notion. Evidently, other outcomes such as quality of life, patient knowledge or patients’ decisional satisfaction are also of relevance in this setting. Such outcomes were not included in the current study but should be a target of future studies, especially when SDM is explicitly facilitated through the use of a decision aid.

More work in this context is clearly needed. Development of a MESH term specifically detailing on SDM would be useful in the future. We had to perform a relatively broad search, including 49 terms to fully cover the concept of shared decision making and to ensure that all eligible studies were identified. Further, randomized studies may not be the most optimal mode to study potential benefits of SDM. This could especially be true for patients with lung cancer since the disease course is unpredictable and patients are faced with a poor prognosis. Yet, despite the relatively small differences, we did find positive effects on emotional outcomes (e.g. anxiety and depression) and healthcare use. In light of the overuse of aggressive therapies near the end of life,\textsuperscript{65,67,68} facilitating SDM in the context of lung cancer may lead to improved well-being and better alignment of care to patients’ personal preferences. Future studies should attempt to establish such associations and explicitly focus on measuring the effects of a decision aid, possibly by measuring the achievement of personalized goals. Ultimately, such studies could further elucidate mechanisms on how to facilitate SDM and provide patient-centered care for patients with lung cancer.
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Conflict of interest

The authors declare no conflicts of interest.
References

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Figure legends

Figure 1: Flow chart reporting on selection of articles based on the Flow Diagram by the PRISMA Statement

Figure 2: Risk of bias assessment

Other bias included design specific bias, baseline imbalances, differential diagnostic activity and contamination.
Table 1: Characteristics of included studies

<table>
<thead>
<tr>
<th>Source</th>
<th>Study design</th>
<th>Study population</th>
<th>Setting</th>
<th>Follow-up</th>
<th>SDM intervention</th>
<th>Control group</th>
<th>Primary outcome(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bakitas et al. (2009)†</td>
<td>RCT</td>
<td>117 patients with advanced lung cancer</td>
<td>Dartmouth-Hitchcock Norris Cotton Cancer Center, affiliated outreach clinics and VA Medical Center</td>
<td>13 months or until death</td>
<td>Telephone based case management, educational approach to encourage patient activation, self-management, and empowerment</td>
<td>Allowed to use all oncology and supportive services without restriction</td>
<td>Quality of life: FACT-L, Symptom intensity: ESAS, Resource use</td>
</tr>
<tr>
<td>Basch et al. (2016)†</td>
<td>RCT</td>
<td>201 patients starting with chemotherapy for metastatic lung cancer</td>
<td>Memorial Sloan Kettering Cancer Center</td>
<td>Median 3 months (range: 0.25 to 49 months)</td>
<td>Web-based self-report of symptom burden, email alerts to nurses, symptom report printed at each clinical visit for both nurse and oncologist</td>
<td>Standard procedure for monitoring and documenting symptoms: discussed and documented in the medical record during clinical encounters between patients and oncologists</td>
<td>Health related quality of life: EuroQoL EQ-5D</td>
</tr>
<tr>
<td>Geerse et al. (2016)</td>
<td>RCT</td>
<td>223 patients with newly diagnosed or recurrent lung cancer starting systemic therapy</td>
<td>University Medical Center Groningen Groningen, Groningen, The Netherlands</td>
<td>25 weeks</td>
<td>Distress thermometer and problem list before outpatient visit, followed by face-to-face meeting with psychosocial nurse and referral if appropriate</td>
<td>Medical and psychosocial care as offered by treating physician every 3 weeks</td>
<td>Quality of life: EORTC-QLQ-C30</td>
</tr>
<tr>
<td>Temel et al. (2010) and Greer et al. (2012)</td>
<td>RCT</td>
<td>151 patients with newly diagnosed, metastatic non-small cell lung cancer</td>
<td>Massachusetts General Hospital Boston, Massachusetts, USA</td>
<td>12 weeks 18 months</td>
<td>Attention to physical and psychosocial symptoms, establishing goals of care, assisting with decision making regarding treatment, coordinating care</td>
<td>Not scheduled to meet with the palliative care service unless a meeting was requested by the patient, the family, or the oncologist</td>
<td>Quality of life: Trial Outcome Index</td>
</tr>
<tr>
<td>Source</td>
<td>Study design</td>
<td>Study population</td>
<td>Setting</td>
<td>Follow-up</td>
<td>Intervention group</td>
<td>Control group</td>
<td>Primary outcome(s)</td>
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<tr>
<td>Temel et al. (2017)†</td>
<td>RCT</td>
<td>191 patients with newly diagnoses incurable lung cancer</td>
<td>Massachusetts General Hospital Boston, Massachusetts, USA</td>
<td>12 weeks and 24 weeks</td>
<td>Outpatient palliative care at visit at least once a month</td>
<td>Usual oncology care, able to meet PC clinician only upon request.</td>
<td>Quality of life: FACT-G after 12 weeks</td>
</tr>
<tr>
<td>Schofield et al. (2013)</td>
<td>RCT</td>
<td>108 patients with inoperable lung or pleural cancer</td>
<td>Peter MacCallum Cancer Center, Melbourne, Victoria, Australia</td>
<td>12 weeks</td>
<td>Meeting individualized unmet needs of patients by providing information and support</td>
<td>Standard care as per hospital protocol</td>
<td>Unmet needs: Needs Assessment for Advanced Lung Cancer Patients</td>
</tr>
<tr>
<td>Yount et al. (2014)</td>
<td>RCT</td>
<td>253 patients with stage III or IV non-small cell lung cancer or small-cell lung cancer</td>
<td>Northwestern University, Rush University Medical Center, John. H. Stroger Jr. Hospital</td>
<td>12 weeks</td>
<td>Weekly monitoring of symptoms with reporting to the clinical team</td>
<td>Weekly symptom monitoring alone</td>
<td>Overall symptom burden: Symptom Distress Scale</td>
</tr>
<tr>
<td>Zhuang et al. (2018)</td>
<td>RCT</td>
<td>150 patients with diagnosed non-small cell lung cancer</td>
<td>First People’s Hospital of Xianyang City Xi’an, Shaanxi, China</td>
<td>12 weeks</td>
<td>Early palliative care by board-certified palliative care physicians and advanced-practice nurses</td>
<td>Treated only with conventional tumor management</td>
<td>Not specified</td>
</tr>
<tr>
<td>Zimmermann et al. (2014)†</td>
<td>Cluster-RCT</td>
<td>101 patients with advanced lung cancer</td>
<td>Princess Margaret Cancer Center, Toronto, Ontario, Canada</td>
<td>4 months</td>
<td>(1) Multidisciplinary assessment of symptoms, distress, and support (2) Telephone contact with palliative care nurse (3) Palliative care follow-up (4) A 24 on-call telephone service</td>
<td>No formal intervention, but palliative care referral was not denied, if requested</td>
<td>Quality of life: FACIT-Sp</td>
</tr>
<tr>
<td>King et al. (2016)</td>
<td>Retrospective cohort study</td>
<td>207 patients with advanced lung cancer</td>
<td>Carbone Cancer Center Madison, Wisconsin, USA</td>
<td>-</td>
<td>Early palliative care provided by one oncologist</td>
<td>Standard oncology care by any other oncologist</td>
<td>Survival</td>
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<tr>
<td>Source</td>
<td>Study design</td>
<td>Study population</td>
<td>Setting</td>
<td>Follow-up</td>
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<tr>
<td>Nieder et al. (2016)†</td>
<td>Retrospective cohort study</td>
<td>286 patients with histologically confirmed non-small cell lung cancer</td>
<td>Nordland Hospital Trust Bodo Center Bodo, Salten, Norway</td>
<td>-</td>
<td>Received either early or late palliative care throughout the study period</td>
<td>Did not receive palliative care, standard oncology care</td>
<td>Not specified</td>
</tr>
<tr>
<td>Reville et al. (2010)</td>
<td>Retrospective cohort study</td>
<td>1476 patients with primary or secondary diagnosis of lung cancer</td>
<td>Thomas Jefferson University Hospital Philadelphia, Pennsylvania, USA</td>
<td>-</td>
<td>Received a palliative care consultation</td>
<td>Did not receive a palliative care consultation</td>
<td>Not specified</td>
</tr>
</tbody>
</table>


† The complete study included a larger sample of patients with different types of cancer. Data of the subsample of patients with lung cancer is displayed in this table
‡ Data were analyzed and displayed as three groups: early palliative care (>3 months before death), late palliative care (<3 months before death), or no palliative care
<table>
<thead>
<tr>
<th>Source</th>
<th>General distress</th>
<th>Anxiety</th>
<th>Depression</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bakitas et al. (2009)†</td>
<td>ESAS linear mixed model analysis</td>
<td>ESAS mean score after 4 months 3.16 vs. 2.80, p=0.49</td>
<td>CES-D Linear mixed model analysis p=0.39  CES-D mean score after 4 months 11.1 vs. 11.6 p=0.92</td>
</tr>
<tr>
<td></td>
<td>HADS-Total mean change score at 25 weeks -2.1 vs. -2.4, p=0.85</td>
<td>HADS-A mean change score at 25 weeks -1.3 vs. -1.3, p=0.98</td>
<td>HADS-D mean change score at 25 weeks -0.6 vs. -0.9, p=0.77</td>
</tr>
<tr>
<td>Temel et al. (2010)</td>
<td>-</td>
<td>HADS-A percentage above cutoff score at 12 weeks 25% vs. 30%*, p=0.66</td>
<td>HADS-D percentage above cutoff score at 12 weeks 16% vs. 38%*, p&lt;0.01</td>
</tr>
<tr>
<td>Temel et al. (2017)†</td>
<td>-</td>
<td>HADS-A mean score after 12 weeks 4.47 vs. 5.23‡</td>
<td>PHQ-9 adjusted mean score at 12 weeks 5.61 vs. 7.21, p=0.04</td>
</tr>
<tr>
<td></td>
<td>HADS-A mean score after 24 weeks 4.63 vs. 5.24‡</td>
<td>PHQ-9 adjusted mean score at 24 weeks 5.54 vs. 6.71, p=0.05</td>
<td>HADS-D mean score after 12 weeks 4.90 vs. 5.26‡</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>-</td>
<td>HADS-D mean score after 24 weeks 4.44 vs. 5.03‡</td>
</tr>
<tr>
<td>Schofield et al. (2013)</td>
<td>HADS-total mean score 12 weeks post-treatment 11.52 vs. 10.34, p=0.48</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>BDT mean score 12 weeks post-treatment 2. 85 vs. 2.99, p=0.81</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Yount et al. (2014)</td>
<td>SDS mean score at 12 weeks adjusted for baseline 25.3 vs. 25.5, p=0.51</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
Data on group for which SDM was facilitated vs. control group are displayed. Abbreviations: BDT: Brief Distress Thermometer. CES-D: Center for Epidemiological Studies Depression Scale. ESAS: Edmonton Symptom Assessment Scale. HADS-A: Hospital Anxiety and Depression Scale – Anxiety. HADS-D: Hospital Anxiety and Depression Scale – Depression. PHQ-9: Patient Health Questionnaire. SDS: Symptom Distress Scale
† The complete study included a larger sample of patients with different types of cancer. Data of the subsample of patients with lung cancer is displayed in this table.
‡ No p-value provided, but according to authors no significant difference
* Clinically relevant outcome.

<table>
<thead>
<tr>
<th>Zhuang et al. (2018)</th>
<th>HADS-A percentage above cutoff at 12 weeks</th>
<th>HADS-D percentage above cutoff at 12 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>17% vs. 27%*, p&lt;0.05</td>
<td>19% vs. 32%*, p&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>PHQ-9 percentage above cutoff at 12 weeks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>9% vs. 16%*, p&lt;0.001</td>
<td></td>
</tr>
</tbody>
</table>

| Zimmermann et al. (2014)† | ESAS change from baseline score 3 months: -0.62 vs. 0.42, adjusted difference 1.01, p=0.81 | - |
|                          | ESAS change from baseline score 4 months: -1.97 vs. 0.91, adjusted difference 3.67*, p=0.38 | - |
Table 3: Effects on hospitalizations, emergency department visits, and use of chemotherapy

<table>
<thead>
<tr>
<th>Source</th>
<th>Hospitalizations</th>
<th>Emergency department visits</th>
<th>Use of chemotherapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bakitas et al. (2009)†</td>
<td>Number of days in hospital between randomization and reference date‡ 3.1 days vs. 2.2 days, p=0.66</td>
<td>Mean number of ED visits between randomization and reference date‡ 0.5 vs. 0.4, p=0.81</td>
<td>-</td>
</tr>
<tr>
<td>Basch et al. (2016)†</td>
<td>Hospitalizations (cumulative incidence at one year) 52% vs. 56% p=0.40</td>
<td>ED visits (cumulative incidence at one year) 39% vs. 53%, p=0.02</td>
<td>Mean duration of chemotherapy 7.49 vs. 5.64 months vs 7.49, p=0.10</td>
</tr>
<tr>
<td>Geerse et al. (2016)</td>
<td>Hospitalizations between randomization and death: 73% vs. 76%, p=0.61</td>
<td>ED visit(s) between randomization and death 58% vs. 69%, p=0.15</td>
<td>Chemotherapy in last 14 days of life 4% vs. 11%, p=0.10</td>
</tr>
<tr>
<td></td>
<td>Hospitalizations in last 14 days of life 33% vs. 43%, p=0.22</td>
<td>ED visit(s) in last 14 days of life 18% vs. 25%, p=0.28</td>
<td>Chemotherapy in last 30 days 12% vs. 26%, p=0.03</td>
</tr>
<tr>
<td></td>
<td>Hospitalizations in last 30 days of life 47% vs. 56%, p=0.23</td>
<td>ED visit(s) in last 30 days of life 25% vs. 38%, p=0.09</td>
<td>-</td>
</tr>
<tr>
<td>King et al. (2016)</td>
<td>-</td>
<td>-</td>
<td>Chemotherapy ≥ 2 lines 48% vs. 52%, adjusted OR 1.12, p=0.71</td>
</tr>
<tr>
<td>Nieder et al. (2016)φ</td>
<td>Hospitalized in the last 3 months of life 73% vs. 97% vs. 88%, p=0.03</td>
<td>-</td>
<td>Chemotherapy in last 14 days of life 4% vs 4%, adjusted OR 0.94, p=0.93</td>
</tr>
<tr>
<td>Reville et al. (2010)</td>
<td>Mean length of stay: 16.3 days vs. 8.3 days, p&lt;0.001</td>
<td>-</td>
<td>Chemotherapy in last 30 days of life 11% vs. 17%, adjusted OR 0.66, p=0.38</td>
</tr>
<tr>
<td></td>
<td>Median length of stay 12.5 days vs. 6 days§</td>
<td>-</td>
<td>Receipt of active anticancer treatment in the last month of life 14% vs. 40% vs. 28%, p=0.003</td>
</tr>
</tbody>
</table>

† Source for this study is no longer available. § Median length of stay.
<table>
<thead>
<tr>
<th>Source</th>
<th>Hospitalizations</th>
<th>Emergency department visits</th>
<th>Use of chemotherapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temel et al. (2010) and Greer et al. (2012)‡</td>
<td>Hospitalizations between randomization and death 74% vs. 77%§</td>
<td>ED visit(s) between randomization and death 53% vs. 57%§</td>
<td>Chemotherapy in last 14 days of life 14% vs. 24%, p=0.18</td>
</tr>
<tr>
<td></td>
<td>Hospitalizations in last 30 days of life 37% vs. 54%§</td>
<td>ED visit(s) in last 30 days of life 22% vs. 30%§</td>
<td>Chemotherapy in last 30 days of life 30% vs. 43%, p=0.14</td>
</tr>
<tr>
<td></td>
<td>Median length of hospitalization between randomization and death 5.0 days (range 0-50) vs. 7.0 days (range 0-45)§</td>
<td></td>
<td>Chemotherapy in last 60 days of life 53% vs. 70%, p=0.05, adjusted OR 0.47 (0.23-0.99), p=0.05</td>
</tr>
<tr>
<td>Yount et al. (2014)</td>
<td>Mean number of hospital admissions during 12 weeks: 0.62 vs. 0.67, p=0.88</td>
<td>Mean number of ED visits during 12 weeks 0.69 vs. 0.58 , p=0.85</td>
<td>-</td>
</tr>
</tbody>
</table>

Data on group for which SDM was facilitated vs. control group are displayed. Abbreviations: ED: Emergency Department. OR: Odds Ratio, provided with 97% confidence interval.

† The complete study included a larger sample of patients with different types of cancer. Data of the subsample of patients with lung cancer is displayed in this table.

§ Data were analyzed and displayed as three groups: early palliative care (>3 months before death), late palliative care (<3 months before death), or no palliative care.


§ No p-value provided.
Figure 1: Flow chart reporting on selection of articles based on the Flow Diagram by the PRISMA Statement
Figure 2: Risk of bias assessment

Other bias included: design specific bias, baseline imbalances, differential diagnostic activity and contamination.
Supplement A: PICO and Search Strategy

Participants/population

Adult patients with lung cancer

Intervention(s), exposure(s)

Inclusions:

• Implementation of shared decision making: intervention designed to help people make specific and deliberative choices among options (including the status quo, symptom relief, treatment etc.)

• Use by patients or caregiver

• Content is relevant with regards to treatment decisions

Comparator(s)/control

Inclusions:

• Patient group which received usual care

Exclusions:

• Studies describing a comparison of SDM tools without a usual care arm

Outcomes

1) Distress with symptoms of either:

   - Distress (as separate scale or validated domain within a scale)
   - Anxiety
   - Depression
- Quantified by a validated screening instrument (for example the Hospital Anxiety and Depression Scale)

2) Healthcare utilization

- Chemotherapy administration
- Hospital and GP visits
- Hospitalizations
- Emergency department visits
- Hospice services
- Location of death
- Documentation of resuscitation preference

Search
# 1 Shared decision making
# 2 Lung cancer
# 3 Distress
# 4 Healthcare utilization

# 1 AND #2 AND (#3 OR #4)

Search strings (Medline via EBSCO)

# 1 Shared decision making
((MH "Decision Making+") OR (MH "Decision Support Techniques+") OR (MH "Decision Support Systems, Clinical") OR (MH "Patient Preference") OR (MH "Patient Care Planning+") OR (MH "Needs Assessment") OR (MH "Patient Participation") OR (MH "Patient-Centered Care+") OR (MH "Advance Care Planning+") OR TI "Treatment decision*" OR TI "decision aid*" OR TI "decision tool*" OR TI "communication aid*" OR TI "decision making" OR TI "decision support" OR TI preference* OR TI "goal* of care" OR TI "patient care planning" OR TI "need* assessment*" OR TI "care need*" OR TI "patient need*" OR TI "patient participation" OR TI "patient centered care" OR TI "patient centered care" OR TI "advance care planning" OR TI "early palliative care" OR TI "integrated care" OR TI "supportive care" OR TI "integrated palliative care"

OR

AB "Treatment decision*" OR AB "decision aid*" OR AB "decision tool*" OR AB "communication aid*" OR AB "decision making" OR AB "decision support" OR AB preference* OR AB "goal* of care" OR AB "patient care planning" OR AB "need* assessment*" OR AB "care need*" OR AB "patient need*" OR AB "patient participation" OR AB "patient centered care" OR AB "patient centered care" OR AB "advance care planning" OR AB "early palliative care" OR AB "integrated care" OR AB "supportive care" OR AB "integrated palliative care"
# 2 Lung cancer
((MH "Lung Neoplasms+")
OR
TI “Lung Neoplasm*” OR TI “Lung Cancer” OR (TI Lung AND TI Cancer) OR TI SCLC OR TI NSCLC OR TI “Lung carcinoma”
OR
AB “Lung Neoplasm*” OR AB “Lung Cancer” OR (AB Lung AND AB Cancer) OR AB SCLC OR AB NSCLC OR AB “Lung carcinoma”)

# 3 Distress
((MH "Stress, Psychological+") OR (MH "Mood Disorders+") OR (MH "Anxiety+") OR (MH "Anxiety Disorders+") OR (MH "Depression") OR (MH "Depressive Disorder+")
OR
TI Distress OR TI “Symptom burden” OR TI Mood* OR TI Anxiety OR TI Depression* OR TI
LCSS OR TI “Lung cancer symptom score” OR TI “Lung cancer symptom scale” OR TI “Interest question” OR TI “One-question interview” OR TI BAI OR TI BCD OR TI BDI OR TI BESDS
OR
TI BSI OR TI “Brief Symptom Inventory” OR TI CES D OR TI DI C OR TI DT/PL OR TI ESAS OR TI “Edmonton Symptom Assessment” OR TI GHQ OR TI “General Health Questionnaire” OR TI HADS OR TI HQ OR TI “Hornheide Questionnaire” OR TI IES OR TI “Impact of Event Scale” OR TI “Impact of Event Score” OR TI MEQ OR TI PDI OR TI PHQ
OR
TI “Patient Health Questionnaire” OR TI POMS OR TI PSSCAN OR TI “Psychosocial Screen* for Cancer” OR TI RSCL OR TI “Rotterdam Symptom Checklist” OR TI ZSDS OR TI GDS OR TI HRSD OR TI SAS OR TI SDS OR TI STAI OR TI SD
OR
AB Distress OR AB “Symptom burden” OR AB Mood* OR AB Anxiety OR AB Depression* OR AB LCSS OR AB “Lung cancer symptom score” OR AB “Lung cancer symptom scale” OR AB “Interest question” OR AB “One-question interview” OR AB BAI OR AB BCD OR AB BDI OR AB BEDS OR AB BSI OR AB “Brief Symptom Inventory” OR AB CES D OR AB DI C OR AB DT/PL OR AB ESAS OR AB “Edmonton Symptom Assessment” OR AB GHQ OR AB “General Health Questionnaire” OR AB HADS OR AB HQ OR AB “Hornheide Questionnaire” OR AB IES OR AB “Impact of Event Scale” OR AB “Impact of Event Score” OR AB MEQ OR AB PDI OR AB PHQ OR AB “Patient Health Questionnaire” OR AB POMS OR AB PSSCAN OR AB “Psychosocial Screen* for Cancer” OR AB RSCL OR AB “Rotterdam Symptom Checklist” OR AB ZSDS OR AB GDS OR AB HRSD OR AB SAS OR AB SDS OR AB STAI OR AB SD)

# 4 Health care utilization
((MH "Delivery of Health Care+/UT") OR (MH "Hospitalization+)") OR (MH "Hospice Care/UT") OR (MH "Emergency Medical Services+/UT") OR (MH "After-Hours Care+/UT") OR (MH "Health Services Administration+/UT") OR (MH "Intensive Care Units+/UT") OR (MH "Terminal Care+") OR (MH "Palliative Care")
OR
TI “Healthcare utilization” OR TI “Healthcare utilization” OR TI “Resource* use” OR TI “Chemotherapy administration*” OR TI Hospitalization* OR TI Hospitalisation* OR TI “Hospital visit*” OR TI “Hospital day*” OR TI “Location of Death” OR TI “Death location” OR TI “Emergency Department Visit?” OR TI “ED visit?” OR TI “General Practitioner visit?” OR TI “GP visit?” OR TI “Intensive Care Unit Day*” OR TI “ICU Day*” OR TI “Terminal care” OR TI “Palliative Care” OR TI “End of life care” OR TI “Care at the end of life” OR TI “Care at end of life”
AB “Healthcare utilization” OR AB “Healthcare utilization” OR AB “Resource* use” OR AB “Chemotherapy administration*” OR AB Hospitalization* OR AB Hospitalisation* OR AB “Hospital visit*” OR AB “Hospital day*” OR AB “Location of Death” OR AB “Death location” OR AB “Emergency Department Visit*” OR AB “ED visit*” OR AB “General Practitioner visit*” OR AB “GP visit*” OR AB “Intensive Care Unit Day*” OR AB “ICU Day*” OR AB “Terminal care” OR AB “Palliative Care” OR AB “End of life care” OR AB “Care at the end of life” OR AB “Care at end of life”)
## Supplement B: Other measures of healthcare utilization

<table>
<thead>
<tr>
<th>Source</th>
<th>ICU admissions</th>
<th>Location of death</th>
<th>Hospice</th>
<th>Composite score for aggressive end of life care</th>
<th>Other measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bakitas et al. (2009)&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Number of days in ICU between randomization and reference date: 0.0 days vs 0.5 days, ( p=0.16 )</td>
<td>-</td>
<td>-</td>
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<td>-</td>
</tr>
<tr>
<td>Basch et al. (2016)&lt;sup&gt;a&lt;/sup&gt;</td>
<td>-</td>
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<td>-</td>
</tr>
<tr>
<td>Geerse et al. (2016)</td>
<td>-</td>
<td>Location of death: home 73% vs 71%; hospital 23% vs 21%, nursing home 2% vs 7%, hospice 2% vs 1%, ( p=0.59 )</td>
<td>-</td>
<td>Aggressive end of life care in last 14 days of life&lt;sup&gt;b&lt;/sup&gt;: 46% vs 37%, ( p=0.25 )</td>
<td>-</td>
</tr>
<tr>
<td>King et al. (2016)</td>
<td>-</td>
<td>-</td>
<td>Hospice enrollment: 84% vs 74%, adjusted OR 1.86, ( p=0.113 )</td>
<td>Median hospice length of stay: 24 days vs 38.5 days, adjusted HR 0.70, ( p=0.041 )</td>
<td>-</td>
</tr>
<tr>
<td>Nieder et al (2016)&lt;sup&gt;f&lt;/sup&gt;</td>
<td>-</td>
<td>Hospital death: 33% vs 47% vs 50%, 0.28</td>
<td>-</td>
<td>-</td>
<td>Documented resuscitation preference: 100% vs 87% vs 76%, ( p=0.007 )</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Documented earlier than in the last 3 months of life: 61% vs 12% vs 18%, ( p=0.0001 )</td>
</tr>
<tr>
<td>Source</td>
<td>ICU</td>
<td>Location of death</td>
<td>Hospice</td>
<td>Composite score</td>
<td>Other measures</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>------------------------------------------</td>
<td>------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Reville et al. (2010)</td>
<td>Receiving ICU-care: 23.3% vs 25.4%</td>
<td>-</td>
<td>-</td>
<td>Discharged to hospice: 6% vs 41%</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Location of death:</td>
<td>Admission to hospice between randomization and death: 65.7% vs 71.0%, p=0.57</td>
<td>Discharged to skilled nursing facility or rehabilitation home 13% vs 8%</td>
<td>Discharged to home 72% vs 17%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>hospital or nursing home or rehabilitation facility: 25.8% vs 19.7%, p=0.53</td>
<td>Admission to hospice ≤ 3 days prior to death: 14.7% vs 3%</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Admission to hospice &gt; 7 days prior to death: 33.3% vs 60.0%, p=0.004</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Median length of stay in hospice: 9.5 days vs 24.0 days, p=0.02</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temel et al. (2010) and Greer et al. (2012)</td>
<td>-</td>
<td>Location of death:</td>
<td>Admission to hospice between randomization and death: 65.7% vs 71.0%, p=0.57</td>
<td>Admission to hospice ≤ 3 days prior to death: 14.7% vs 3%</td>
<td>Aggressive end-of-life-care: 54% vs 33%, p=0.05</td>
</tr>
<tr>
<td></td>
<td></td>
<td>hospital or nursing home or rehabilitation facility: 25.8% vs 19.7%, p=0.53</td>
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<td></td>
<td>Median length of stay in hospice: 9.5 days vs 24.0 days, p=0.02</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yount et al. (2014)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Mean number of unscheduled clinic visits during 12 weeks: 0.25 vs 0.41, p=0.13</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>-</td>
<td>Mean number of phone calls to physicians during 12 weeks: 0.81 vs 0.85, p=0.32</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>-</td>
<td>Mean number of phone calls to nurses during 12 weeks: 1.14 vs 1.79, p=0.02</td>
<td></td>
</tr>
</tbody>
</table>
Data on usual care group versus intervention group are displayed. Abbreviations: OR: Odds Ratio, provided with 97% confidence interval. HR: Hazard Ratio; provided with 95% confidence interval

a The complete study included a larger sample of patients with different types of cancer. Data of the subsample of patients with lung cancer is displayed in this table.

b Patients receiving chemotherapy, being hospitalized, or visiting the ED within either the last 14 or 30 days before death were documented as having received aggressive end-of-life care.

c Median duration of follow up among participants who died 5.7 months.

d Patients receiving chemotherapy within 14 days before death, no hospice care, or admission to hospice 3 days or less before death were documented as having received aggressive end-of-life care.

e No p-value provided.

f Early palliative care vs. late palliative care vs. no palliative care.
# PRISMA 2009 Checklist

<table>
<thead>
<tr>
<th>Section/topic</th>
<th>#</th>
<th>Checklist item</th>
<th>Reported on page #</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TITLE</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>1</td>
<td>Identify the report as a systematic review, meta-analysis, or both.</td>
<td>1</td>
</tr>
<tr>
<td><strong>ABSTRACT</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structured summary</td>
<td>2</td>
<td>Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.</td>
<td>2</td>
</tr>
<tr>
<td><strong>INTRODUCTION</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rationale</td>
<td>3</td>
<td>Describe the rationale for the review in the context of what is already known.</td>
<td>3</td>
</tr>
<tr>
<td>Objectives</td>
<td>4</td>
<td>Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).</td>
<td>4</td>
</tr>
<tr>
<td><strong>METHODS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protocol and registration</td>
<td>5</td>
<td>Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.</td>
<td>5</td>
</tr>
<tr>
<td>Eligibility criteria</td>
<td>6</td>
<td>Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.</td>
<td>5</td>
</tr>
<tr>
<td>Information sources</td>
<td>7</td>
<td>Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.</td>
<td>5</td>
</tr>
<tr>
<td>Search</td>
<td>8</td>
<td>Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.</td>
<td>5</td>
</tr>
<tr>
<td>Study selection</td>
<td>9</td>
<td>State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).</td>
<td>5</td>
</tr>
<tr>
<td>Data collection process</td>
<td>10</td>
<td>Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.</td>
<td>7</td>
</tr>
<tr>
<td>Data items</td>
<td>11</td>
<td>List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.</td>
<td>7</td>
</tr>
<tr>
<td>Risk of bias in individual studies</td>
<td>12</td>
<td>Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.</td>
<td>7</td>
</tr>
<tr>
<td>Summary measures</td>
<td>13</td>
<td>State the principal summary measures (e.g., risk ratio, difference in means).</td>
<td>7</td>
</tr>
<tr>
<td>Synthesis of results</td>
<td>14</td>
<td>Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., $I^2$ for each meta-analysis).</td>
<td>7</td>
</tr>
<tr>
<td>Section/topic</td>
<td>#</td>
<td>Checklist item</td>
<td>Reported on page #</td>
</tr>
<tr>
<td>--------------------------------</td>
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</tr>
<tr>
<td>Risk of bias across studies</td>
<td>15</td>
<td>Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).</td>
<td>7</td>
</tr>
<tr>
<td>Additional analyses</td>
<td>16</td>
<td>Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.</td>
<td>7</td>
</tr>
</tbody>
</table>

**RESULTS**

| Study selection               | 17 | Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram. | 9                  |
| Study characteristics         | 18 | For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations. | 9                  |
| Risk of bias within studies   | 19 | Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12). | 10                 |
| Results of individual studies | 20 | For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot. | 11                 |
| Synthesis of results          | 21 | Present results of each meta-analysis done, including confidence intervals and measures of consistency. | 11                 |
| Risk of bias across studies   | 22 | Present results of any assessment of risk of bias across studies (see Item 15). | 10                 |
| Additional analysis           | 23 | Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]). | 12                 |

**DISCUSSION**

| Summary of evidence           | 24 | Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers). | 14                 |
| Limitations                   | 25 | Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias). | 15                 |
| Conclusions                   | 26 | Provide a general interpretation of the results in the context of other evidence, and implications for future research. | 16                 |

**FUNDING**

| Funding                       | 27 | Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review. | 17                 |

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For more information, visit: [www.prisma-statement.org](http://www.prisma-statement.org).