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Symptom Management and Supportive Care

Effect of a Skills Training for Oncologists and a Patient Communication Aid on Shared Decision Making About Palliative Systemic Treatment: A Randomized Clinical Trial

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Disclosures of potential conflicts of interest may be found at the end of this article.

Key Words. Shared decision making • Advanced cancer • Palliative medicine • Systemic treatment • Doctor-patient communication • Patient participation • Patient education • Communication skills training

Abstract

Background. Palliative systematic treatment offers uncertain and often limited benefits, and the burden can be high. Hence, treatment decisions require shared decision making (SDM). This trial examined the independent and combined effect of an oncologist training and a patient communication aid on SDM.

Methods. In this multicenter randomized controlled trial with four parallel arms (2016–2018), oncologists (n = 31) were randomized to receive SDM communication skills training or not. The training consisted of a reader, two group sessions, a booster session, and a consultation room tool (10 hours). Patients (n = 194) with advanced cancer were randomized to receive a patient communication aid or not. The aid consisted of education on SDM, a question prompt list, and a value clarification exercise. The primary outcome was observed SDM as rated by blinded observers from audio-recorded consultations. Secondary outcomes included patient-reported SDM, patient and oncologist satisfaction, patients' decisional conflict, patient quality of life 3 months after consultation, consultation duration, and the decision made.

Results. The oncologist training had a large positive effect on observed SDM (Cohen's d = 1.12) and on patient-reported SDM (d = 0.73). The patient communication aid did not improve SDM. The combination of interventions did not add to the effect of training oncologists only. The interventions affected neither patient nor oncologist satisfaction with the consultation nor patients' decisional conflict, quality of life, consultation duration, or the decision made.

Conclusion. Training medical oncologists in SDM about palliative systemic treatment improves both observed and patient-reported SDM. A patient communication aid does not. The incorporation of skills training in (continuing) educational programs for medical oncologists is likely to stimulate the widely advocated uptake of shared decision making in clinical practice. *Trial registration*. Netherlands Trial Registry NTR 5489. ***The Oncologist*** 2020;25:e578–e588

Implications for Practice: Treatment for advanced cancer offers uncertain and often small benefits, and the burden can be high. Hence, treatment decisions require shared decision making (SDM). SDM is increasingly advocated for ethical reasons and for its beneficial effect on patient outcomes. Few initiatives to stimulate SDM are evaluated in robust designs. This randomized controlled trial shows that training medical oncologists improves both observed and patient-reported SDM in

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clinical encounters (n = 194). A preconsultation communication aid for patients did not add to the effect of training oncologists. SDM training effectively changes oncologists' practice and should be implemented in (continuing) educational programs.

Introduction

Treatment for advanced cancer offers uncertain and often small survival benefits, and the burden can be high. The recent advances in targeted and immunotherapy, with significant survival benefits for a minority of patients, complicate the tradeoff even more [1]. Hence, to allow for patient-centered care and respect patients' autonomy [2], treatment decisions require shared decision making (SDM). SDM implies that physician and patient discuss the benefits and harms of the available options as well as the patient's values and preferences to come to an agreed-upon decision [3, 4]. SDM advocated for ethical reasons [2]; furthermore, a majority of patients also want to be involved in decision making [5]. Although stronger evidence is needed, studies show beneficial effects on patient outcomes such as patient satisfaction, well-being, and quality of life [6–8]. Moreover, SDM is considered, albeit tentatively, to enhance attention to symptom control rather than aggressive medical interventions at the end of life [9–12].

Nevertheless, observational studies consistently show that decision making about systemic treatment for advanced cancer does not meet the standards of SDM [13–17]. Oncologists infrequently inform patients about the expected survival benefit or the option to refrain from systemic treatment [13, 16, 17]. Moreover, discussing patients' values and preferences is not standard practice [14], particularly not once systemic treatment has started. Both oncologists and patients have been shown to prefer to focus on the short term and on controlling the cancer, rather than anticipating what is to come [15, 18, 19]. Such focus may hinder careful consideration of patients' wishes and priorities in the last phase of life.

Communication skills programs in oncology vary widely in format and components with, thus far, little high-quality research to draw robust conclusions about effectiveness [20]. The same holds for training specifically focused on SDM [21–23]. Besides physician training, there is growing interest in patient-targeted communication interventions [24, 25], such as prompt lists [26–30] and decision aids to increase patient participation [31–34]. Few studies have examined the combination of physician training with patient-targeted interventions on SDM in palliative cancer care [35].

The CHOICE (Choosing Treatment Together in Cancer at the End of Life) trial [36] aims to add high-quality evidence on the effectiveness of communication interventions by examining both the separate and combined effect of an SDM training for medical oncologists and a patient communication aid (PCA) on observed SDM about palliative systemic treatment. We hypothesize that both interventions will independently improve observed SDM in recorded consultations and that the combination will be more effective than targeting only one party. Secondary outcomes include observed SDM per step, patient-reported SDM, patient and oncologist satisfaction with communication, patients' decisional conflict, consultation duration, and the decision made.

Materials and Methods

This paper is written in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement [37]. Detailed information can be found in the trial protocol [36].

Ethics Approval and Consent to Participate

The study was conducted according to the principles of the Declaration of Helsinki (64th World Medical Association General Assembly, Fortaleza, Brazil, October 2013) and in accordance with the Medical Research Involving Human Subjects Act. The study protocol has been reviewed and approved by the Medical Ethical Committee of the coordinating center (Academic Medical Center, University of Amsterdam; NL 48722.018.15; METC-2015-149). In line with the External Review Directive 2015 issued by the Central Committee of Research Involving Human Subjects, all participating centers have reviewed and approved local feasibility.

Design and Timeline

The study has a randomized controlled trial design with four parallel arms. Oncologists were allocated (1:1) to either the training or the control arm (standard practice). Their patients were randomized (1:1) to receive the patient communication aid or care as usual. Patients and oncologists filled out a questionnaire on baseline characteristics at inclusion. Consultations were audio-recorded. Oncologists filled out a questionnaire after the consultation. This paper reports on the outcomes reported by patients in paper questionnaires filled out at home in the week after and at 3 months after the consultation. Clinical data were collected from patients' medical files by a research associate or nurse.

Setting and Participants

Medical oncologists treating patients with metastatic or inoperable tumors were eligible. When using the term oncologists, we refer to both senior staff and medical oncologists in training (fellows). Dutch fellows work under supervision but communicate with patients independently. Patients were eligible when diagnosed with metastatic or inoperable tumors for which survival curves indicate a median life expectancy of <12 months without disease targeted treatment and for which systemic palliative treatment does not offer a median survival benefit >6 months. Patients could be included before an *initial* consultation to discuss either the start of (a new line) of (experimental) treatment or an *evaluative* consultation about the (dis)continuation or adjustment of current treatment on the basis of computed tomography (CT) or positron emission tomography (PET)–CT evaluation (complete eligibility criteria are in supplemental online File 1).

Sample Size

Based on previous studies, the trial is powered to detect a large independent intervention effect (Cohen's d = 0.8) on observed SDM, as assessed with the 12-item Observing Patient Involvement scale (OPTION12) [38, 39]. Sample size calculation was based on the effect of the oncologist training (two-sided Student's t test; intraclass correlation, 0.20; power > 80%, α = .05), as the between-oncologist comparison required the most subjects. This resulted in a required sample size of 24 oncologists and 192 patients (12 oncologists per arm and 8 patients per oncologist; power = 0.84).

Recruitment

Oncologists

The medical oncology departments of both academic and nonacademic hospitals were approached through existing networks until at least 30 oncologists were recruited, considering a possible dropout of 25%. Oncologists were informed about the study by the local and the principal investigator, received an information letter, and were asked for written informed consent.

Patients

Eligible patients were identified from the outpatient clinic agendas >1 week in advance by the oncologist (in the coordinating hospital supported by the research team) or by a designated oncologist or nurse. Either the treating oncologist, a nurse, or a trial officer contacted the patient by telephone to ask for permission to provide patient information to the research team. The research team then informed the patient by telephone. Because time between initial contact and consultation was often short, patients were randomized after providing oral consent by phone. Patients subsequently received a paper information letter covering the condition they were assigned to (and, depending on condition, the PCA) and a paper informed consent form to be signed before the consultation.

Randomization

Oncologists

Oncologists were randomized to receive training or continue their standard practice in blocks of two, stratifying for working experience through separate randomization lists for staff and fellows. Oncologists were randomized per hospital to ensure that in each hospital about half of the participants would receive training. Randomization always occurred in groups of at least two oncologists (either staff members or fellows) to prevent predictable allocation. As randomization did not result in a sufficiently large training group for the last hospital (more than two), one additional participant was recruited and assigned to the training. Randomization lists were created by an independent methodologist. Randomization was performed by an independent researcher.

Patients

Patients were randomized to receive the communication aid or "usual care." Randomization in ALEA software (ALEA Clinical, Abcoude, The Netherlands) stratified for (A) the condition of the oncologist (trained vs. untrained), (B) working experience of the oncologist (staff vs. in training), and (C) the type of consultation (initial treatment planning consultation vs. evaluative consultation). Stratification occurred through minimization. Stratification factor 1 received a weight of 3; factors 2 and 3 a weight of 1. A biased coin of 5 started to work in case of a contrast of >3 between the two conditions. Data in ALEA were adjusted by an independent methodologist when (A) patients switched oncologists after randomization, (B) patients did not provide written informed consent, and (C) patients turned out to be ineligible during the consultation.

Blinding

Oncologists were not blinded for their personal allocation, but they were not informed about their patient's allocation. Patients were not blinded for their personal allocation, but they were not informed about their oncologist's allocation. Outcomes assessors were blinded for the allocation of oncologists and patients, but the PCA or training may have come up in the audio-recorded consultation.

Interventions

The SDM training and the PCA are described in Figure 1. The effect of the training was previously evaluated in simulated consultations with standardized patients [40]. In this simulated context, the training had a significant and large effect on observed SDM and improved observed SDM behavior in all four SDM stages.

Measures

Oncologist Characteristics

Oncologists reported their age, years of experience in medical oncology, and earlier experience with communication skills training (yes vs. no).

Patient and Consultation Characteristics

Patients reported their age, educational level, and religious affiliation (Christianity, Islam, or other). The type of consultation (initial or evaluative) and the patient's tumor location were noted on the local case report forms (CRF). From the medical records, we registered results of the (PET)CT scan in case of an evaluative consultation, the patient's World Health Organization (WHO) performance status at the time of the consultation (0–4), and the line of therapy that was discussed during the consultation.

Primary Outcome

The primary outcome was observed SDM as assessed from the audio-recorded consultations using OPTION12 (supplemental online File 2) [38, 39, 41]. OPTION12 aims to assess the extent to which health care providers involve patients in the decision-making process. The 12 items represent key patient-involving behaviors such as listing options and explaining pros and cons. Items were rated on a five-point scale (0: "behavior not observed" to 4: "very high standard"), and the sum score was transformed to reflect a total out of 100. Observed SDM was also assessed with the 4SDM, a newly developed instrument based on the four-step SDM model [4], which provides a score for each of the steps: set the SDM agenda, inform about options, explore patient values and preferences, make or defer decision. The 4SDM has eight items (two for each step), which are coded

Oncologist SDM training

The training (10 hours) was based on a model with four essential SDM steps [4]: (A) set the SDM agenda, (B) inform about the options and pros and cons, (C) explore patients values and support preference construction, (D) make or defer a decision in agreement. The training aimed to address oncologists' knowledge, attitude, and skills and was provided in small groups (three to six participants) by an experienced trainer in two sessions, both 3.5 hours, with preferably 2 weeks in between. Staff members and fellows were trained separately. The training adopted behavior change [65] and known communication skills training techniques [66, 67], such as modelling (tailor made videos) and practice (role play with professional actors). Moreover, the training explicitly addressed the transfer to clinical practice in an individual booster session of 1 to 1.5 hours with personal feedback on a videotaped consultation, preferably 6 weeks after training. Additionally, participants received a pocket-size card presenting the four SDM steps with example phrases. The training was accredited by the Netherlands Association of Internal Medicine (12 CME credits).

Patient communication aid

The patient communication aid (PCA) was developed based on examples [29, 68–73], interviews with patients and (bereaved) relatives, and a pilot [54]. It encompasses a paper brochure containing education about SDM, a question prompt list (QPL), and value clarification methods (VCMs). The brochure presents the treatment options: disease-targeted treatment and best supportive care. The subsequent QPL is a structured list of example questions patients can ask their physician. QPLs have been shown to stimulate question asking and putting difficult issues, such as prognosis, on the agenda [26–29]. The last part contains VCMs, which are often used in decision aids to help patients in constructing a treatment preference [71, 72]. The VCM included open-ended questions about values, narratives of fictive patients expressing their values, and scaling items requiring the weighing of opposing values. Patients were encouraged to share their answers with their oncologist.

Figure 1. Description of the interventions.
Abbreviations: CME, continuing medical education; PCA, patient communication aid; QPL, question prompt list; SDM, shared decision making; VCM, value clarification method.

on a four-point scale (0: "not observed" to 3: "observed and of high quality").

Two blinded assessors independently rated the consultations after training and calibration (procedure and details on interrater reliability are in supplemental online File 3). The intraclass correlation was strong (>0.80) for both scales. The average weighted κ was sufficient (>0.60) for OPTION12 (0.62) and almost sufficient for 4SDM (0.57).

Secondary Outcomes

Patient-reported shared decision making was assessed with the validated nine-item Shared Decision Making Questionnaire [42, 43]. The five-item Patient Satisfaction Questionnaire [44] was used to assess oncologists' and patients' postconsultation satisfaction with communication (in an adjusted version for oncologists [45]). One item about satisfaction with patient involvement in decision making was added. Responses were given on a visual analog scale (0–100). Patients' decisional conflict was assessed with the 16-item Decisional Conflict Scale [46, 47], a widely used scale to assess patient's uncertainty about medical decisions. The formulation of the last three items was slightly adapted (from "my" into "this" decision). Quality of life was assessed at 3 months after the consultation with the Global Health Status subscale of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire [48], which is composed of two items on overall health and quality of life in the past week with response categories ranging from 1 ("very poor") to 7 ("excellent"). The mean score was transformed to reflect a total out of 1. The decision made (best supportive care or watchful waiting or systemic treatment, either within the target consultation or < 1 month thereafter) was registered from the medical record. Consultation duration was registered from the audiotape. Lastly, patients reported on the perceived helpfulness of the PCA using seven purposefully designed items with responses on a five-point Likert scale (with anchor points labeled as "not at all helpful" to "very helpful"). The median perceived helpfulness will be presented.

Statistical Methods

Mixed linear models were constructed in IBM SPSS Statistics 24 (IBM Corporation, Armonk, NY) for all continuous outcomes, taking into account the clustered nature of the data (patients within oncologists). These models can handle missing measurements on patient outcomes without the need for imputation using maximum likelihood estimation [49]. Besides condition (the four arms), the two stratification variables as well as the characteristics that significantly differed across arms were entered in the model one by one. These covariates were kept in the model if they improved model fit as determined by a significant decrease in −2 log-likelihood ($p < .05$). Models with a random intercept and random slopes were systemically examined for all outcomes.

Only main effects were examined. Bootstrapped fixed effects with two-sided $p < .05$ were considered significant; bootstrapped 95% confidence intervals are provided. All analyses were intention-to-treat. Cohen's *d* was calculated based on model estimates [50] (0.2, small; 0.5, medium; 0.8, large [51]). For the only categorical outcome, that is, the treatment decision made, the effect of condition was estimated using generalized estimating equations.

In all models, the effect of the oncologist training was established by comparing care as usual with consultations

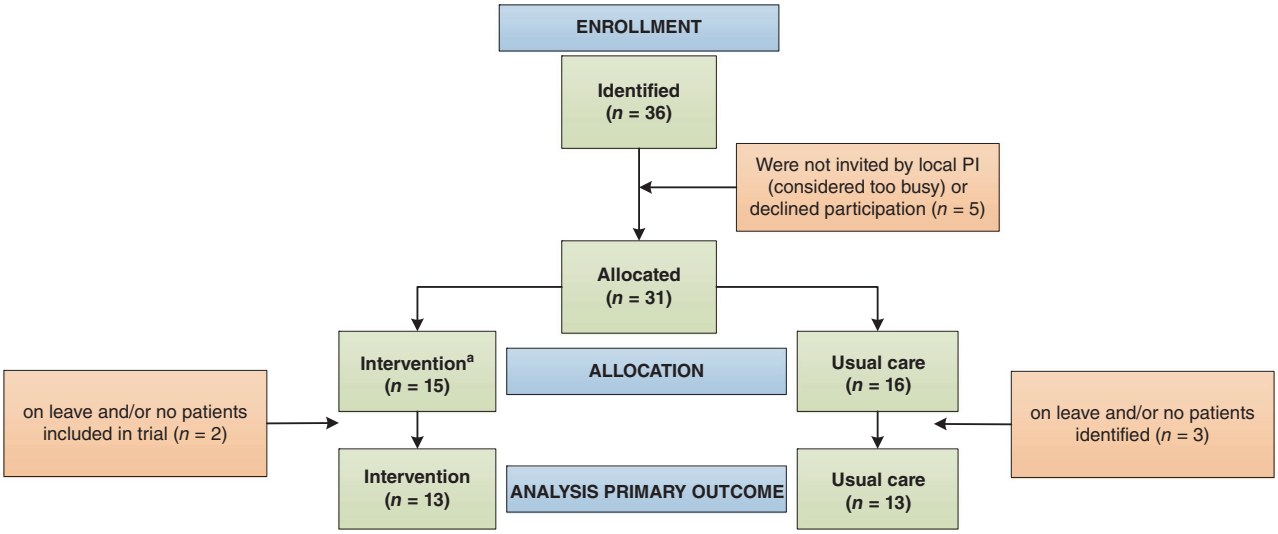

Figure 2. Flow chart of oncologist inclusion.
[a]As randomization did not result in sufficiently large training groups (>2), one additional participant was recruited and assigned to the training. This final participant did not include patients in the trial because of a leave of absence in the inclusion period after training.

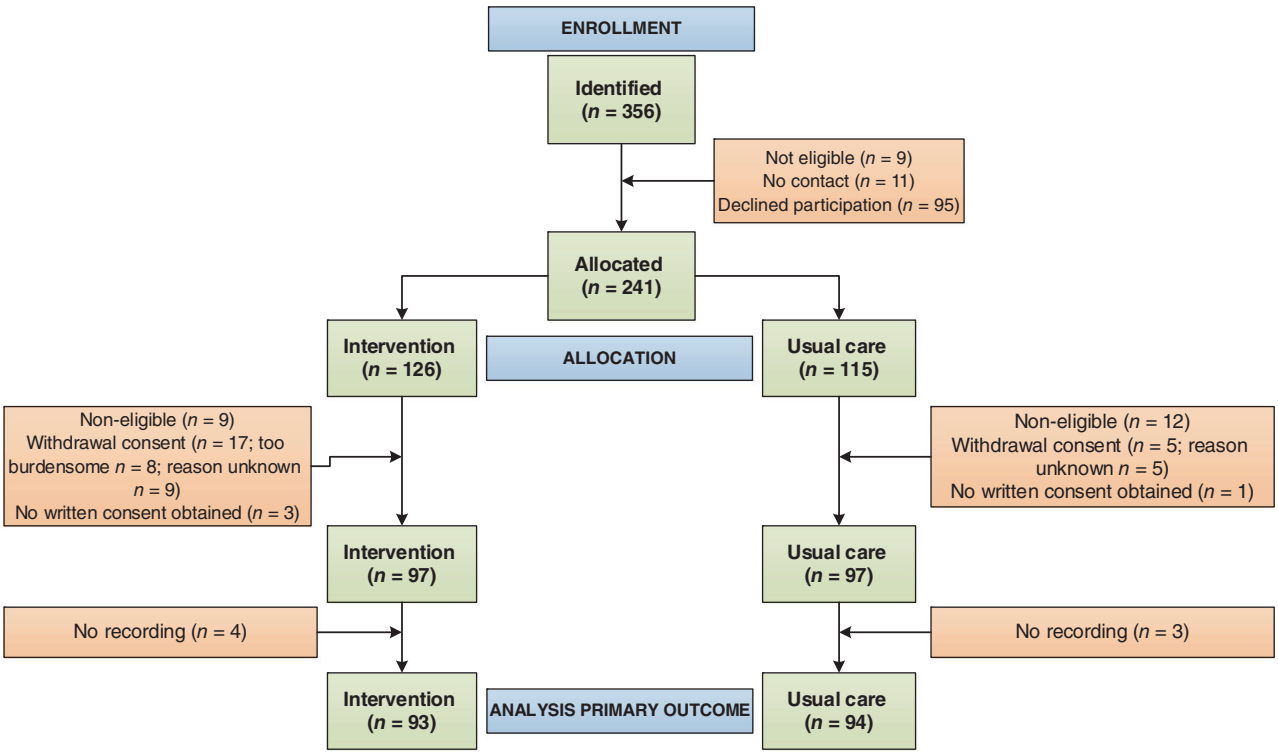

Figure 3. Flow chart of patient inclusion.

of trained oncologists with patients who did not receive the aid. The effect of the communication aid was established by comparing care as usual with consultations of untrained oncologists with patients who received the aid. Combining the two interventions was hypothesized to increase but not to double the effect of the single interventions. The study was not powered to statistically test this added value of the combination. Hence, the combination was considered more effective than either or both single interventions if (A) the effect size of the combination compared with care as usual was statistically significant and (B) was at least 150% of the (simple) effect size of either or both single interventions.

Results

Sample Characteristics

Of the 19 departments contacted, 6 agreed to participate. Of the 36 oncologists invited from these departments, 31 consented (86%), of whom 15 were allocated to the intervention

Table 1. Consultation and patient characteristics for the total sample and per condition

		Conditions			
		No physician training		Physician training	
Characteristics	**Total sample**	**No patient aid**	**Patient aid**	**No patient aid**	**Patient aid**
Consultation characteristics					
Type of consultation, % (*n*)					
Initial[a]	38.7 (75)	24.5 (12)	40.0 (20)	47.9 (23)	42.6 (20)
Evaluative[b]	61.3 (119)	75.5 (37)	60.0 (30)	52.1 (25)	57.4 (27)
Consulting physician, % (*n*)					
Staff oncologist	64.4 (125)	59.2 (29)	68.0 (34)	66.7 (32)	63.8 (30)
Fellow	35.6 (69)	40.8 (20)	32.0 (16)	33.3 (16)	36.2 (17)
Patient characteristics					
Age, mean ± SD[c]	63.6 ± 11.2	62.1 ± 12.7	63.6 ± 9.4	67.4 ± 9.5	61.3 ± 12.2
Gender male, % (*n*)	51.0 (99)	49.0 (24)	48.0 (24)	52.2 (25)	55.3 (26)
Educational level,[d] % (*n*)					
Low	35.5 (61)	28.9 (13)	37.8 (17)	29.3 (12)	46.3 (19)
Medium	25.6 (44)	35.6 (16)	20.0 (9)	19.5 (8)	26.8 (11)
High	39.0 (67)	35.6 (16)	42.2 (19)	51.2 (21)	26.8 (11)
Affiliation with Christianity, % (*n*)[e]	43.4 (75)	37.8 (17)	33.3 (15)	54.8 (23)	48.8 (20)
Tumor type,[f] % (*n*)					
Pancreatic	20.6 (40)	12.2 (6)	24.0 (12)	27.1 (13)	19.1 (9)
Esophagogastric	20.6 (40)	6.1 (3)	14.0 (7)	37.5 (18)	25.5 (12)
Gynecological	10.8 (21)	16.3 (8)	10.0 (5)	6.3 (3)	10.6 (5)
Other gastrointestinal	10.8 (21)	10.2 (5)	4.0 (2)	10.4 (5)	19.1 (9)
Colorectal	9.8 (19)	12.2 (6)	4.0 (2)	6.3 (3)	17.0 (8)
Urogenital	7.2 (14)	12.2 (6)	16.0 (8)	0 (0)	0 (0)
Mamma	5.7 (11)	10.2 (5)	12.0 (6)	0 (0)	0 (0)
Melanoma	5.2 (10)	10.2 (5)	6.0 (3)	4.2 (2)	0 (0)
Other (each type $n < 10$)[g]	9.3 (18)	10.2 (5)	10.0 (5)	8.3 (4)	8.5 (4)
Results (PET) CT,[h] % (*n*)					
Stable or response	68.6 (81)	75.7 (28)	73.3 (22)	68.0 (17)	53.8 (14)
Progression	28.0 (33)	21.6 (8)	23.3 (7)	32.0 (8)	38.5 (10)
No CT made[i]	3.4 (4)	2.7 (1)	3.3 (1)	0 (0)	7.7 (2)
WHO status,[j] % (*n*)					
0–1	81.5 (145)	78.6 (33)	76.1 (35)	87.2 (36)	83.7 (36)
2–4	8.5 (33)	21.4 (9)	23.9 (11)	12.8 (7)	16.3 (7)
Line of treatment discussed,[c] % (*n*)					
First line	56.0 (108)	36.7 (18)	60.0 (30)	68.8 (33)	58.7 (27)
Second line or higher	44.0 (85)	63.3 (31)	40.0 (20)	31.3 (48)	41.3 (19)

[a]Consultations about the start of first-line palliative systemic treatment or the start of a new line of (experimental) treatment.
[b]Consultations that included an evaluation of current treatment on the basis of (PET)CT results or patient symptoms, including evaluations after a therapy-free period.
[c]Significant difference across conditions, $p < .05$.
[d]$n = 172$, $n = 22$ missing. Low, low-level vocational education, ≤9 years; medium, medium level vocational education, ≤12 years; high, higher vocational or academic education, >15 years.
[e]$n = 173$, 21 missing; as none of the respondents reported an affiliation with Islam and only 3% reported another type of religion, we present affiliation with Christianity only.
[f]Significant difference across conditions, $p < .01$.
[g]Including carcinoid tumor, sarcoma, glioblastoma, head-neck cancer, mediastinal tumor.
[h]$n = 118$ of the total of 119 evaluative consultations, 1 missing.
[i]These concerned three evaluative consultations after therapy-free periods and one evaluative consultation based on side effects.
[j]$n = 178$, 16 missing.
Abbreviations: CT, computed tomography; PET, positron emission tomography; WHO, World Health Organization performance status.

Table 2. Raw means ± SDs for continuous outcomes and relative frequencies for the binary outcome for total sample and each condition

		Raw means ± SDs				
			No physician training		Physician training	
Outcomes	*n*	Full sample	No patient aid	Patient aid	No patient aid	Patient aid
SDM (OPTION12, 0–100)	187	36.62 ± 16.86	29.50 ± 14.40	29.88 ± 13.19	49.49 ± 14.19	49.83 ± 12.8
SDM (4SDM, 0–24)	187	15.11 ± 6.12	11.00 ± 5.36	12.09 ± 5.27	18.28 ± 4.87	19.15 ± 4.29
SDM step 1 (0–6): Setting SDM agenda	187	3.89 ± 1.79	2.72 ± 1.65	2.98 ± 1.58	4.77 ± 1.37	5.13 ± 1.13
SDM step 2 (0–6): Informing	187	3.53 ± 1.95	2.19 ± 1.56	2.51 ± 1.54	4.66 ± 1.66	4.78 ± 1.43
SDM step 3 (0–6): Exploring	187	3.47 ± 1.72	2.62 ± 1.52	2.83 ± 1.58	4.15 ± 1.59	4.26 ± 1.56
SDM step 4 (0–6): Deciding	187	4.22 ± 1.81	3.45 ± 2.03	3.77 ± 1.71	4.70 ± 1.69	4.98 ± 1.32
Patient-reported SDM (0–45)	163	33.40 ± 9.15	29.42 ± 10.14	31.73 ± 9.99	35.71 ± 7.00	36.63 ± 7.43
Patient satisfaction (0–100)	164	77.65 ± 17.68	79.13 ± 15.67	76.40 ± 17.68	77.51 ± 18.46	77.56 ± 19.32
Oncologist satisfaction (0–100)	191	70.02 ± 12.73	70.90 ± 10.81	73.15 ± 12.00	69.13 ± 12.39	66.64 ± 14.96
Patient decisional conflict (0–100)[a]	145	37.63 ± 9.12	37.99 ± 8.07	40.33 ± 10.40	36.31 ± 8.13	36.01 ± 9.17
Patient quality of life at 3 months (0–100)	125	62.5 ± 19.3	60.5 ± 19.2	62.9 ± 18.8	62.9 ± 20.8	63.8 ± 19.2
Consultation duration, min:sec	187	31:22 ± 14:35	27:51 ± 12:06	30:08 ± 16:03	36:27 ± 14:32	31:01 ± 14:27
Decision to start or continue systemic treatment,[b] %	188	71.6	78.7	77.6	62.5	77.3

[a]Patients were instructed to skip the items of the Decisional Conflict Scale if, in their view, a decision was not or not yet made (*n* = 23 patients skipped all or more than two items of the scale).
[b]For two patients we could not collect information on the decision made, and for four patients the decision was not yet made after 1 month. These were excluded from the analysis.
Abbreviations: 4SDM, four-step SDM instrument; OPTION12, 12-item Observing Patient Involvement scale; SDM, shared decision making.

and 16 to the control condition (Fig. 2). One oncologist moved to a different hospital during the study. Hence, eventually patients from seven hospitals participated. Out of these, 26 included patients in the trial (mean, 7.5 patients; range, 3–14). The oncologist participants were aged a mean ± SD of 41.5 ± 9.5 years and had 7.7 ± 9.0 years of experience in oncology. Approximately two-thirds were staff members (61.5%), and a quarter were male (26.9%). Most received communication skills training during medical school (84.6%), half during (current) residency (53.8%), and some after training (18.8% of post-training staff). Untrained and trained oncologists did not differ on any of these characteristics. Intervention fidelity is described in supplemental online File 4.

A total of 356 patients were identified, of whom 336 could be contacted, of whom 241 provided oral consent (response rate 72%; Fig. 3). More patients in the intervention than in the control condition withdrew oral informed consent after randomization (17 vs. 5; $p = .01$). A total of 194 patients were eligible and provided written informed consent. There were statistically significant differences across the conditions on age, type of tumor, and line of treatment discussed (Table 1).

Audio recordings of consultations were collected for 187 patients (96%), on average 6 ± 3.64 months since the training of oncologists (range, 0–15 months); 168 patients (87%) returned the postconsultation questionnaire. The oncologists filled out a questionnaire for 191 consultations (98%). Table 2 shows the raw means or relative frequencies of the outcomes per condition.

Primary Outcome: Observed SDM

The interventions had a significant effect on observed SDM as measured with OPTION12 ($F(3,90.97) = 14.53$, $p < .001$; Table 3). The oncologist training improved SDM; the PCA did not. The effect size of the combination was almost equal to the effect of training alone. The interventions had comparable effects on SDM as measured with the 4SDM ($F(3,98.69) = 12.64$, $p < .001$) and each of its four subscales (SDM steps). The effect of training, either separately or in combination with the PCA, was largest for the first two steps: setting the SDM agenda and providing information.

Secondary Outcomes

Condition had a significant effect on SDM as perceived by patients ($F(3,163) = 6.199$, $p < .01$). Training improved patient-reported SDM; the PCA did not; the combination did not add to the effect of training (Table 3). Condition did not affect patients' satisfaction ($F(3,164) = 0.07$, $p = .97$) nor oncologists' satisfaction ($F(3,73.935) = 1.37$, $p = .26$) with communication. Condition did not affect patients' decisional regret ($F(3,145) = 2.08$, $p = .11$) nor patients' quality of life at 3 months after the consultation ($F(3,79.2) = 0.233$, $p = .87$).

Overall, condition did not significantly affect consultation duration ($F(3,88.475) = 1.711$, $p = .17$). Yet, the post hoc comparisons did show a significant effect: consultations lasted about 5 minutes longer for trained oncologists in consultations with patients without an aid ($p = .01$). Condition did not affect the treatment decision made ($\chi^2 = 3.007$, degrees of freedom = 3, $p = .39$; not in Table 3). The likelihood of a decision to start or continue systemic treatment (odds ratio) was 0.52 ($p = .16$) in the training condition, 0.87 ($p = .66$) in the PCA condition, and 1.02 ($p = .98$) the combined condition. The medium perceived helpfulness of the PCA was 3.6 ($n = 81$; range, 1–5).

Table 3. Parameter estimates and bootstrapped significance levels and 95% CIs of the fixed effects in the mixed linear models

	Training		Communication aid		Combination	
Outcomes	***b* (95% CI)**	**Cohen's d[a]**	***b* (95% CI)**	**Cohen's d[a]**	***b* (95% CI)**	**Cohen's d[a]**
SDM (OPTION12, 0–100)[b]	18.06 (12.81 to 23.15)[c]	1.12	0.22 (−4.64 to 5.51)	0.01	19.33 (14.66 to 24.25)[c]	1.21
SDM (4SDM, 0–24)	6.68 (4.52 to 8.74)[c]	1.13	1.62 (−0.24 to 3.49)	0.28	7.17 (5.28 to 9.24)[c]	1.22
SDM step 1 (0–6): Setting SDM agenda	1.87 (1.30 to 2.45)[c]	1.07	0.42 (−0.16 to 1.06)	0.25	2.19 (1.67 to 2.79)[c]	1.24
SDM step 2 (0–6): Informing[d]	2.08 (1.36 to 2.79)[c]	1.19	0.32 (−0.23 to 0.87)	0.19	2.15 (1.44 to 2.86)[c]	1.24
SDM step 3 (0–6): Exploring	1.59 (1.00 to 2.21)[c]	0.90	0.28 (−0.30 to 0.87)	0.16	1.61 (0.98 to 2.22)[c]	0.92
SDM step 4 (0–6): Deciding[d]	1.08 (0.34 to 1.81)[c]	0.60	0.32 (−0.33 to 0.97)	0.19	1.26 (0.52 to 1.99)[c]	0.71
Patient-reported SDM (0–45)	6.29 (2.41 to 10.02)[c]	0.73	2.31 (−2.16 to 6.50)	0.27	7.21 (3.28 to 11.21)[c]	0.83
Patient satisfaction (0–100)	0.10 (−7.04 to 7.39)	0.01	−1.41 (−8.49 to 5.15)	0.08	−0.01 (−8.31 to 7.08)	0.00
Oncologist satisfaction (0–100)	−0.75 (−85.12 to 3.48)	0.04	3.34 (−0.72 to 7.07)	0.18	−2.22 (−6.47 to 2.46)	0.12
Patient decisional conflict (0–100)	−0.26 (−4.01 to 4.45)	0.03	3.44 (−0.68 to 8.16)	0.41	−1.21 (−5.20 to 3.07)	0.14
Patient quality of life at 3 months (0–100)[d]	−1.14 (−10.99 to 8.70)	0.06	−0.48 (−9.42 to 8.47)	0.02	2.74 (−7.17 to 12.65)	0.14
Consultation duration, min	5.43 (1.05 to 9.54)[e]	0.36	1.11 (−3.28 to 5.45)	0.07	0.95 (−3.24 to 5.71)	0.06

[a]Difference in estimated marginal means ("no training, no aid" concerns the comparison group) divided by the pooled standard deviation calculated from the SEs $\sqrt{(((se1 \times \sqrt{n1})^2 \times (n1\text{-}1) + (se2 \times \sqrt{n2})^2 \times (n2\text{-}1)/(n1 + n2\text{-}2))}$ [50].
[b]The intraclass correlation for OPTION12 was 0.49 in the full sample (Wald $Z = 3.1.04$, $p < .01$), 0.37 for the trained oncologists (Wald $Z = 2.104$; $p < .05$), and only 0.03 for the untrained oncologists (Wald $Z = 0.371$; $p = .71$). Hence, training caused consultations within oncologists to become more alike.
[c]Indicates $p < .01$.
[d]Bootstrapping resulted in samples for which the final Hessian matrix was not positive definitive; hence, the estimates from the model without bootstrapping are presented for these outcomes.
[e]Indicates $p < .05$.
Abbreviations: 4SDM, four-step SDM instrument; CI, confidence interval; OPTION12, 12-item Observing Patient Involvement scale; SDM, shared decision making.

Discussion

SDM is increasingly perceived as an ethical imperative, particularly in palliative cancer care. The global curriculum for training of medical oncologists, as endorsed by 50 nations, states that oncologists should master SDM [52]. This is the first randomized study to show that a communication training of 10 hours of mainly experiential learning can significantly improve both observed and patient-reported SDM even months after training. The level of SDM in consultations of trained oncologists was twice as high as the average reported in literature [41]. Hence, this trial provides the evidence needed for more widespread implementation of SDM skills training in educational programs for medical oncologists. Further research needs to examine the most effective and efficient way of training oncologists in advanced communication skills [53].

In contrast to our hypotheses, the PCA did not affect SDM, nor did it add to the effect of training oncologists. In an earlier study [54], patients suggested the PCA could facilitate question asking and deliberation. Others felt they did not need an aid, did not perceive a role for themselves in decision making, or thought that the decision did not require deliberation. In the current trial, about half of the patients seemed to appreciate the PCA. This mixed picture may explain why the aid did not show an effect at a group level. Also, in the current trial, the aid was offered and evaluated at one decisional moment. Yet patients' perspective on decision making changes when their disease progresses [55]. Also, the aid may require advanced competencies, such as the anticipation of future health states, which may be difficult for patients to envision if not supported [56]. An alternative route would be to screen for patients for whom a potentially more difficult tradeoff is at stake. Health professionals could then not only refer to the aid but also safeguard and support shared decision making. This may guarantee the right timing of the aid and also increase its effectiveness.

Apart from the effect of training on patient-reported SDM, the interventions did not significantly affect the secondary outcomes. Post hoc tests showed consultations of trained oncologists did take 5 minutes longer when they communicated with patients who did not receive an aid. Future research should further examine if patient communication

aids can improve SDM efficiency. The interventions did not improve patient satisfaction. Despite the use of visual analog scales to prevent ceiling effects [57], satisfaction was generally high and apparently independent of the oncologist's performance. The interventions also did not prevent decisional conflict. In line with our finding, scholars recently questioned whether SDM interventions should actually aim to decrease uncertainty. They reason that increased thinking about a decision increases rather than decreases decisional conflict [58, 59]. Lastly, the interventions had no significant effect on the treatment decision made. Most patients chose systemic treatment over best supportive care. Our trial was not sufficiently powered to detect differences across the four conditions. Further research is needed to establish whether SDM increases attention to symptom control at the end of life [9–12]. In our trial, the interventions did not affect patients' quality of life 3 months after the consultation in which a treatment decision was made.

Several reviews have called for more robust studies to examine the effect of communication interventions [25, 60, 61]. The current trial meets this call. Strengths are the combination of oncologist- and patient-targeted interventions, the rigorous study design with sufficient power, the concealed and computer-generated allocation, and the blinded outcome assessment. Some limitations have to be acknowledged as well. First of all, the trial has a pragmatic design [62–64], that is, the control condition concerns care as usual instead of a placebo. A pragmatic design was chosen because we were interested in the effect of our interventions in the current routine clinical practice, including both the "real" as well as the possible nonspecific "placebo" effect. Knowing one received an intervention may raise expectations and change behavior. Moreover, patients could have been told the oncologist received a training, and oncologists could have noticed whether the patient received an aid. The outcome assessors did not evaluate for unblinding of training or aid during the audio-recorded consultations. After each consultation, we did ask oncologists whether they thought the patient had received the aid. They did not know in one-third of the consultations, and when they thought they knew, they were right only half of the time. Hence, they seemed blind for the patients' allocation. We randomized individual doctors and patients, thus risking contamination; that is, trained oncologists could influence untrained colleagues, and the interaction with patients with a communication aid could influence interactions with patients without the aid. In addition, 22 patients withdrew informed consent after randomization, of whom 17 received the PCA. This may have resulted in differences in patient characteristics across conditions. Also, our sample of departments and oncologists may be biased, as they voluntarily agreed to take on a study on doctor-patient communication. Lastly, we cannot rule out that the effect of the training depends on an individual trainer's skills.

Conclusion

Training medical oncologists in SDM about palliative systemic treatment can improve observed and patient-reported SDM in clinical encounters. We advocate the implementation of this type of SDM training in (continuing) educational programs for medical oncologists.

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Disclosures

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