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Effects of training oncology physicians advising patients on complementary and integrative therapies on patient-reported outcomes: A multicenter, cluster-randomized trial

Rogge, Alizé A ; Helmer, Stefanie M ; King, Ryan ; Canella, Claudia ; Icke, Katja ; Pach, Daniel ; Witt, Claudia M

Abstract: **BACKGROUND:** Many patients with cancer do not disclose complementary medicine use but want their physician's advice on this matter. This study evaluated whether using blended learning (e-learning plus a workshop) to train oncology physicians in providing advice on complementary and integrative medicine (CIM) therapies to their patients with cancer, in addition to distributing an information leaflet on reputable CIM websites, had different effects on patient-reported outcomes for the consultation than only distributing the leaflet. **METHODS:** In this multicenter, cluster-randomized trial, patients from private practices/hospital departments, recruited by 48 oncology physicians randomly allocated to an intervention group (CIM consultation plus information leaflet) or a control group (information leaflet), received CIM information. Patient-reported outcomes included satisfaction (Patient Satisfaction With Information on Cancer Treatment), readiness to make a decision (Preparation for Decision Making), and physician-patient communication (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire and Communication 26 [EORTC QLQ-COMU26]) for the consultation. Qualitative interviews were conducted with a physician subsample. **RESULTS:** A total of 291 patients (128 in the intervention group and 169 in the control group) advised by 41 physicians participated. Patients in the intervention group rated physician-patient communication higher on all EORTC QLQ-COMU26 scales (mean total score, 84.3 [95% CI, 79.5-89.2] vs 73.6 [95% CI, 69.3- 78.0]; $P=.002$), were more satisfied with the advice (mean, 4.2 [95% CI, 4.0-4.4] vs 3.7 [95% CI, 3.5-3.8]; $P<.001$), and were readier to make a decision (mean, 63.5 [95% CI, 57.4-69.6] vs 53.2 [95% CI, 47.8-58.7]; $P=.016$) than the control group. Physicians who reported patients in both settings seemed satisfied with the advice given. **CONCLUSIONS:** This study evaluated a novel education intervention for training oncology physicians in providing CIM advice in routine care. Providing structured CIM consultations had positive effects on patient satisfaction, readiness to make decisions, and physician-patient communication.

DOI: <https://doi.org/10.1002/cncr.33562>

Posted at the Zurich Open Repository and Archive, University of Zurich

ZORA URL: <https://doi.org/10.5167/uzh-203842>

Journal Article

Published Version





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Originally published at:

Rogge, Alizé A; Helmer, Stefanie M; King, Ryan; Canella, Claudia; Icke, Katja; Pach, Daniel; Witt, Claudia M (2021). Effects of training oncology physicians advising patients on complementary and integrative therapies on patient-reported outcomes: A multicenter, cluster-randomized trial. *Cancer*, 127(15):2683-2692.

DOI: <https://doi.org/10.1002/cncr.33562>

Effects of Training Oncology Physicians Advising Patients on Complementary and Integrative Therapies on Patient-Reported Outcomes: A Multicenter, Cluster-Randomized Trial

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BACKGROUND: Many patients with cancer do not disclose complementary medicine use but want their physician's advice on this matter. This study evaluated whether using blended learning (e-learning plus a workshop) to train oncology physicians in providing advice on complementary and integrative medicine (CIM) therapies to their patients with cancer, in addition to distributing an information leaflet on reputable CIM websites, had different effects on patient-reported outcomes for the consultation than only distributing the leaflet. **METHODS:** In this multicenter, cluster-randomized trial, patients from private practices/hospital departments, recruited by 48 oncology physicians randomly allocated to an intervention group (CIM consultation plus information leaflet) or a control group (information leaflet), received CIM information. Patient-reported outcomes included satisfaction (Patient Satisfaction With Information on Cancer Treatment), readiness to make a decision (Preparation for Decision Making), and physician-patient communication (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire and Communication 26 [EORTC QLQ-COMU26]) for the consultation. Qualitative interviews were conducted with a physician subsample. **RESULTS:** A total of 291 patients (128 in the intervention group and 169 in the control group) advised by 41 physicians participated. Patients in the intervention group rated physician-patient communication higher on all EORTC QLQ-COMU26 scales (mean total score, 84.3 [95% CI, 79.5-89.2] vs 73.6 [95% CI, 69.3-78.0]; $P = .002$), were more satisfied with the advice (mean, 4.2 [95% CI, 4.0-4.4] vs 3.7 [95% CI, 3.5-3.8]; $P < .001$), and were readier to make a decision (mean, 63.5 [95% CI, 57.4-69.6] vs 53.2 [95% CI, 47.8-58.7]; $P = .016$) than the control group. Physicians who reported patients in both settings seemed satisfied with the advice given. **CONCLUSIONS:** This study evaluated a novel education intervention for training oncology physicians in providing CIM advice in routine care. Providing structured CIM consultations had positive effects on patient satisfaction, readiness to make decisions, and physician-patient communication. *Cancer* 2021;0:1-10. © 2021 American Cancer Society.

KEYWORDS: cancer, clinical trials, complementary medicine, integrative oncology, physician-patient communication.

INTRODUCTION

Up to 70% of patients with cancer do not spontaneously disclose the use of complementary medicine (CM) therapies to their oncology physicians.¹⁻³ The reasons could include a perceived lack of knowledge and approval from the treating physician or the assumption that CM therapies are harmless and do not interfere with cancer treatment.⁴⁻⁶ Clinical practice guidelines show that there is an emerging body of evidence for both beneficial and harmful interventions.⁷ Nevertheless, patients want to gain information from their oncology physicians on CM therapies⁸ and to receive support for decision-making.^{9,10} Because CM is not always part of cancer treatment, oncology physicians often do not give advice regarding

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The trial registration number of the Competence Network for Complementary Medicine–Consultation Training for Oncology Physicians study is DRKS00012704 at the German Clinical Trials Register (date of registration: August 28, 2017).

Independent medical ethics committees approved the Competence Network for Complementary Medicine–Consultation Training for Oncology Physicians study (ethics committee of Charité–Universitätsmedizin Berlin [EA1/127/17], Hamburg Medical Association [MC-368/17], Baden-Wuerttemberg Medical Association [B-F-2017-10], Nord Rhine Medical Association [2417337], ethics committee of the Medical Association of Westphalia-Lippe [2017-624-b-S], ethics committee of the Medical Faculty of Würzburg [274/17_z-me], ethics committee of the Medical Faculty of Heidelberg [S-550/2017], and ethics commission of the Albert Ludwigs University of Freiburg [531/17]). Informed consent was obtained from all of the participants.

We thank Iris Bartsch, Beatrice Eden, Felix Fischer, Markus Horneber, Anita Thomae, and the scientists at the Institute for Social Medicine, Epidemiology, and Health Economics (Charité–Universitätsmedizin Berlin) for their helpful comments on the study as well as all of the members of the Competence Network for Complementary Medicine in Oncology collaborative research project.

Correction added 24 May 2021: The degrees and ORCID iD for Claudia Canella and Claudia M. Witt have been corrected.

Additional supporting information may be found in the online version of this article.

DOI: 10.1002/cncr.33562, **Received:** December 21, 2020; **Revised:** February 19, 2021; **Accepted:** March 12, 2021, **Published online** Month 00, 2021 in Wiley Online Library (wileyonlinelibrary.com)

these therapies.¹¹ Instead, patients might consult with nonmedical CM practitioners; hence, safety issues, such as adverse effects from CM¹² or even the refusal of cancer treatment,¹³ can occur.

Integrating CM into cancer treatments could at its best result in an integrative oncology approach described as a “patient-centered, evidence-informed field of cancer care that utilizes mind and body practices, natural products, and/or lifestyle modifications from different traditions alongside conventional cancer treatments.”¹⁴

For this project, we used the term *complementary and integrative medicine* (CIM) because the training aims to enable oncology physicians to provide evidence-based advice but does not train them in the full set of competencies needed for an integrative oncology provider.¹⁵

Previous research has shown that patient-centered communication can influence patient satisfaction, decision-making, well-being, compliance with cancer therapy, and malpractice litigation.^{16,17} Numerous training programs for oncology physicians focusing on communication^{18,19} or CIM²⁰ coexist; however, the key to targeting the communication gap for CIM use in oncology might be training that focuses on both communication and CIM.

The systematically developed Competence Network for Complementary Medicine–Consultation Training for Oncology Physicians (KOKON-KTO) training²¹ supports oncology physicians in providing evidence-based advice on CIM to their patients with cancer on the basis of a consultation manual that can be applied in routine care.

In clinical practice, the time that can be spent with a patient with cancer is limited. Therefore, it would be important to know whether a consultation that takes 20 minutes and requires training is more beneficial than addressing the topic in 5 minutes on the basis of a leaflet about CIM websites. In the KOKON-KTO study, we evaluated whether training oncology physicians to give advice on CIM to their patients with cancer, in addition to distributing an information leaflet about reputable websites, had different effects on outcomes at the patient, physician, and physician-patient levels in comparison with only distributing the information leaflet.²² This article focuses on the patient-reported outcomes.

MATERIALS AND METHODS

Design

In this prospective, multicenter, cluster-randomized, controlled study, 48 oncology physicians were randomized by clusters (at the hospital department or private practice

level) into an intervention group or a control group. The intervention group received the KOKON-KTO training²¹ (nine 45-minute e-learning modules and a 2-day onsite skill-training workshop), and the control group received only a short e-learning module (45 minutes) on how to distribute the KOKON-KTO information leaflet for reputable CIM websites.²² Oncology physicians in both groups were asked to provide advice for up to 10 of their patients with cancer (1 consultation per patient and a maximum of 10 patients per oncology physician). Both oncology physicians and patients with cancer completed standardized questionnaires. Then, the oncology physicians in the control group also received KOKON-KTO training and were asked to conduct consultations on the basis of the KOKON-KTO framework²¹ with up to 5 patients with cancer.

Patients completed baseline questionnaires before consultation with the oncology physician. Two weeks after their consultations, the patients received a second questionnaire.

Subsequently, qualitative interviews were conducted with a subsample of oncology physicians who gave advice in both consultation settings. The study followed the usual guidelines for clinical trials (Declaration of Helsinki and International Conference on Harmonisation Good Clinical Practice where appropriate) and was approved by the respective ethics committees. The heads of the participating hospitals, oncology physicians, and patients with cancer provided written informed consent to participate in the study. For further information on the study design, see the published study protocol.²² The whole project, including the development of the KOKON-KTO framework,²¹ the trial, and the maintenance, was guided by the RE-AIM implementation research framework.²³

KOKON-KTO Training

KOKON-KTO training is an evidence-based, blended-learning program training oncology physicians to conduct CIM consultations with their patients with cancer in a practice-relevant timeframe of approximately 20 minutes.²¹ The KOKON-KTO framework has been systematically developed and has been positively evaluated with an implementation research framework,²¹ and it addresses the core competencies for integrative oncology providers.¹⁵ It is based on the semistandardized consultation manual, and the training consists of 9 units, each 45 minutes in length, of e-learning content and 16 units of the skill-training workshop over 2 days.²¹

Eligibility Criteria

Oncology physicians

Oncology physicians (50% oncology gynecologists treating female malignancies, including breast cancer only, and 50% oncologists) were recruited from hospital departments (in each case, 2 oncology physicians as clusters) and private practices (in each case, 1 oncology physician) specializing in oncology as part of the KOKON-KTO study.²² Physicians were eligible if they fulfilled the following selection criteria: self-reported little knowledge of CIM, no previous structured training in CIM in the field of oncology, minimal experience in advising patients with cancer on CIM, the ability to participate in the onsite skill-training workshop, and good German language skills. Eligibility criteria were determined in a standardized telephone interview with oncology physicians (self-disclosure). The included oncology physicians either were board-certified oncology residents or were in residency training for oncology as a medical specialty and were treating their own patients with cancer in Germany.²²

Patients

Patients were eligible if they met the following criteria: they were interested in receiving advice on CIM, they were 18 years old or older, they were diagnosed with cancer, they were being treated at a participating hospital department or private practice, cancer treatment was planned or ongoing, and they had good German language skills. Patients with severe cognitive impairments were excluded by the participating oncology physicians.²²

Randomization and Masking

Cluster randomization occurred at the physician level (level I, hospital department [2 oncology physicians per hospital] or private practice [1 oncology physician per private practice]; level II, specialization in oncology gynecology or oncology) with an allocation ratio of 1:1 according to a first-come, first-served principle for both strata. The randomization list was generated by a statistician not otherwise involved in the study with SAS software (version 9.4; SAS Institute, Cary, North Carolina). Patients were blinded to group assignments and recruited by participating oncology physicians. All of the patients were in treatment by the consulting oncology physician and hence knew the cancer treatment team and private practice/hospital department. However, because of the different training settings in both groups, the participating oncology physicians were not blinded.

Procedures

Intervention procedures

Patients with cancer in the intervention group received a 20-minute KOKON-KTO consultation by their treating oncology physician in addition to the KOKON-KTO information leaflet describing 4 reputable CIM websites.²² The KOKON-KTO consultation was developed to train oncology physicians in giving advice on CIM to their patients with cancer.²¹

Control procedures

Patients with cancer in the control group received a 5-minute consultation introducing the KOKON-KTO information leaflet by their treating oncology physician. No additional advice on CIM therapies was provided.

Physicians in both groups received the same e-learning (including an example sentence and example video) for distributing the information leaflet. While handing out the flyer, physicians were trained to introduce only the websites and not to go into specifics about CIM therapies. More detailed information on the flyer is described in the KOKON-KTO study protocol.²²

Patients with cancer in both groups were asked to complete the baseline assessments before the consultation with the oncology physician and further questionnaires 2 weeks after the consultation. CIM consultations or the distribution of the information leaflet was included in the routine care visits.

Information about the KOKON-KTO study was displayed via flyers in hospital departments or in the reception areas of private practices. Patients with cancer interested in receiving information about CIM then indicated their interest in participating and were recruited according to a first-come, first-served principle.

Quantitative Outcomes and Outcome Measures

Outcomes and outcome measurements were based on a literature search and an expert consensus procedure.²⁴ Patients completed questionnaires on the quality of communication (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire and Communication 26 [EORTC QLQ-COMU26]²⁵), their satisfaction with the CIM information provided during the consultation (Patient Satisfaction With Information on Cancer Treatment [PS-CaTE]²⁶), and their preparation to make a decision about CIM (Preparation for Decision Making [PrepDM]²⁷) 2 weeks after the consultation with the oncology physician.

Baseline Characteristics and Other Variables

At the baseline, patients documented sociodemographic data (eg, age, sex, and education), previous use of CIM therapies, and assumptions about their effectiveness (positive, neutral, or negative). Moreover, patients were asked to answer questions on their level of knowledge about CIM (multiple-choice questions based on 3 case vignettes; see the supporting information for CIM questions). Patients also rated their treating oncology physician's empathy (Consultation and Relation Empathy Scale²⁸) and their physician's attitude toward CIM (self-developed instrument).

In addition, disease-specific information was documented by the oncology physician directly after the consultation.

Two weeks after the consultation, patients answered questions on the usefulness of the CIM websites provided by the KOKON-KTO information leaflet, answered the same multiple-choice questions on CIM knowledge that were asked at the baseline, and responded to questions about current and planned CIM use (and, in the case of current use, its effectiveness).

Statistical Analysis

Continuous variables are presented as means and standard deviations, and categorical variables are presented as absolute and relative frequencies. The outcomes of the study were analyzed across all consultations (from a maximum of 10 consultations per oncology physician) via a linear mixed model with fixed effects: a control group effect, an intervention group effect, and the variables with which the randomization was stratified (hospital department/private practice and oncology/gynecology). The clustering of patients within 1 oncology physician was included as a random effect. Patients who completed the follow-up questionnaires were analyzed for study purposes. Because all of the statistical analyses are considered exploratory, linear mixed model adjusted group means and 95% confidence intervals (CIs) are displayed, and no sample size was calculated.²² Statistical analyses were conducted with RStudio software.²⁹

Qualitative Data Collection and Analysis

The oncology physicians in the control group received KOKON-KTO training after the intervention phase. After the KOKON-KTO skill-training workshop, oncology physicians were invited to conduct up to 5 KOKON-KTO consultations with their patients on a voluntary basis because doing so was not part of the initial study agreement. In addition, to know more about

their experiences with both settings, these physicians were invited for a qualitative telephone interview. After 9 interviews, we seemed to have reached a saturated spectrum of expressed topics and experiences by the physicians and subsequently stopped recruiting for more interview partners. In the qualitative interviews (see the supporting information for interview guidelines), oncology physicians were asked about potential differences between the 2 consultation settings (KOKON-KTO consultation vs KOKON-KTO information leaflet only) in general and about differences in patient satisfaction with the advice given. Interviews occurred 8 to 10 weeks after the KOKON-KTO training. The interviews were audiotaped and transcribed verbatim. A qualitative content analysis was performed according to Flick³⁰ and was supported by MAXQDA qualitative data analysis software.³¹ The transcripts were coded in content units combining deductive and inductive coding strategies. The research team predefined deductive codes according to the KOKON-KTO consultation manual.²¹ Other subcategories were created in a continuous process of inductively building and verifying codes from the data; this was accompanied by an intersubjective validation of the coding by 2 independent researchers (A.A.R. and C.C.) to verify the reliability and robustness of the data analysis. In this article, concerning qualitative data, we focus on the reporting physicians' perceptions of patients' satisfaction with both settings.

RESULTS

Patients with cancer received consultations between February 15, 2018, and November 30, 2018 (see Fig. 1 for the Consolidated Standards of Reporting Trials study flow). In total, 291 patients (128 in the intervention group and 169 in the control group) received advice from 41 of the 48 randomized oncology physicians. Two-thirds of the patients were diagnosed with breast cancer or gynecological cancers. Oncology physicians in the control group treated patients with more severe tumors (see Table 1 for patients' baseline data and Table 2 for physicians' baseline data).

Oncology physicians in the control group were slightly older, and there was a higher prevalence of women. They were also slightly more experienced working with patients with cancer than those in the intervention group.

Patients with cancer (124 from the intervention group and 157 from the control group) answered follow-up questionnaires 2 weeks after consultation with their oncology physician. No significant differences

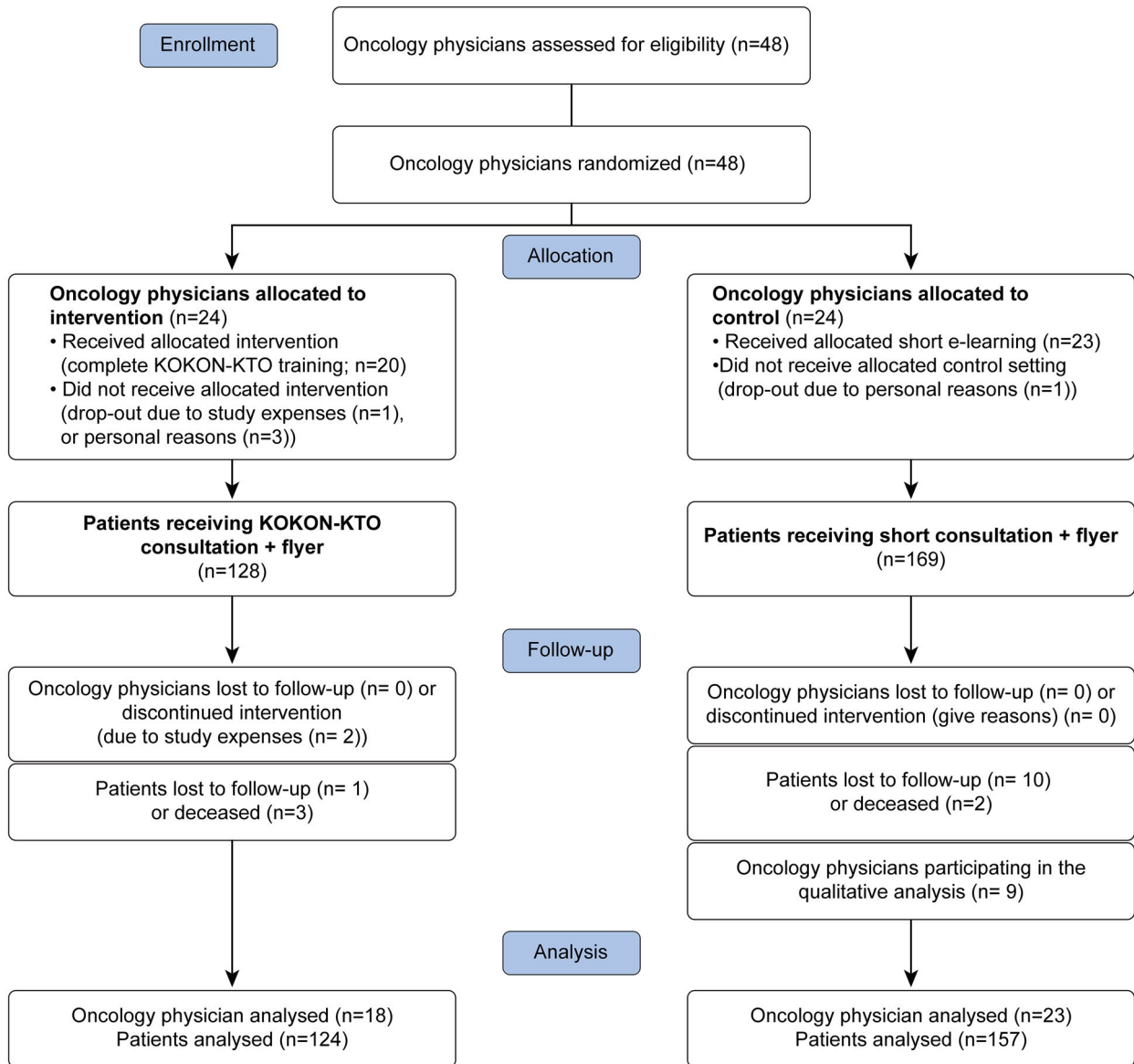


Figure 1. Consolidated Standards of Reporting Trials study flow. KOKON-KTO indicates Competence Network for Complementary Medicine–Consultation Training for Oncology Physicians.

in CIM knowledge or use between the patient groups were observed. However, the intervention group used slightly more CIM websites than the control group. Patients in the intervention group rated the consultation significantly higher on all EORTC QLQ-COMU26²⁵ scales (total score, 84.3 [95% CI, 79.5-89.2] vs 73.6 [95% CI, 69.3-78.0]; $P = .002$). Oncology physicians who received the intervention seemed to be able to communicate better with respect to correcting misunderstandings (mean, 84.8 [95% CI, 79.6-90.0] vs 71.5

[95% CI, 66.9-76.1]; $P < .001$) and showed better skills related to the information given (mean, 73.6 [95% CI, 67.4-79.8] vs 58.3 [95% CI, 52.8-63.8]; $P < .001$). The patients in the intervention group were more satisfied with the advice given (PS-CaTE²⁶; mean, 4.2 [95% CI, 4.0-4.4] vs 3.7 [95% CI, 3.5-3.8]; $P < .001$). They also felt readier to make a decision (PrepDM²⁷; mean, 63.5 [95% CI, 57.4-69.6] vs 53.2 [95% CI, 47.8-58.7]; $P = .016$; see Table 3 for the quantitative results) after the consultation.

TABLE 1. Patients' Baseline Data

Characteristic	Intervention Group (n = 128), Mean ± SD or No. (%)	Control Group (n = 169), Mean ± SD or No. (%)
Sex: female	110 (85.9)	140 (82.8)
Age, y	54.1 ± 10.6	55.6 ± 11.8
Graduation level: A-level or higher	49 (38.3)	71 (42.0)
Cancer entities		
Breast and gynecological	88 (68.8)	107 (63.3)
Gastrointestinal	13 (10.2)	26 (15.4)
Dermatological	2 (1.6)	0 (0)
Hematological	9 (7.0)	12 (7.1)
Ear, nose, and throat	4 (3.1)	2 (1.2)
Pulmonological	5 (3.9)	12 (7.1)
Sarcoma	1 (0.8)	1 (0.6)
Urological	0 (0)	1 (0.6)
Central nervous system	0 (0)	5 (3.0)
Other	6 (2.0)	2 (1.2)
Unknown	3 (1.0)	1 (0.6)
Tumor stage		
T0	8 (8.1)	2 (1.6)
T1	33 (33.3)	37 (29.4)
T2	38 (38.4)	39 (31.0)
T3	15 (15.2)	29 (23.0)
T4	2 (2.0)	16 (12.7)
Tx	3 (3.0)	3 (2.4)
First diagnosis	93 (72.6)	122 (72.2)
Previous therapies		
Surgery	86 (67.2)	101 (59.8)
Chemotherapy	94 (73.4)	114 (67.5)
Hormone therapy	21 (16.4)	29 (17.2)
Radiotherapy	53 (41.4)	49 (29.0)
Others	37 (28.9)	46 (27.2)
None	5 (3.9)	15 (8.9)
Previous CIM therapy: positive experience		
Overall (at least 1 positive experience)	100 (78.1)	123 (72.8)
Acupuncture/acupressure	39 (30.5)	41 (24.3)
Anthroposophical medicine	6 (4.7)	12 (7.1)
Chinese herbs	4 (3.1)	8 (4.7)
Chiropractic	20 (15.6)	23 (13.6)
Homeopathy	54 (42.2)	68 (40.2)
Neural therapy	1 (0.8)	5 (3.0)
Osteopathy	29 (22.7)	34 (20.1)
Mistletoe	6 (4.7)	5 (3.0)
Other plant therapy	9 (7.0)	14 (8.3)
Qigong/tai chi	16 (12.5)	30 (17.8)
Yoga	32 (25.0)	33 (19.5)
Autogenic training	30 (23.4)	42 (24.9)
Progressive muscle relaxation	39 (30.5)	33 (19.5)
Others	17 (13.3)	17 (10.1)
Treatment objective		
Curative/adjunct	88 (68.8)	97 (57.4)
Palliative	34 (26.6)	68 (40.2)
Not clear	6 (4.7)	4 (2.4)
CIM knowledge		
Example 1: correct answer	121 (94.5)	157 (94.6)
Example 2: correct answer	82 (64.6)	110 (65.9)
Example 3: correct answer	98 (77.8)	128 (76.2)
CARE ^a	45.8 ± 5.5	42.5 ± 7.6
Physician is open to CIM ^b	8.2 ± 2.4	7.5 ± 2.7

Abbreviations: CARE, Consultation and Relation Empathy Scale; CIM, complementary and integrative medicine; SD, standard deviation.

^aHigher scores indicate higher empathy (10-50).

^bHigher scores indicate higher scores on openness toward CIM (1-10).

A total of 9 oncology physicians in the control group were interviewed after they had provided consultations for patients in both settings (KOKON-KTO consultation vs information leaflet only).

Focusing on what the physicians perceived of the patients' reactions in both settings, we found that the predominant topics identified from the interview data were the patients' satisfaction and the perceived potential and

TABLE 2. Physicians' Baseline Data

Characteristic	Intervention Group (n = 18), Mean ± SD or No. (%)	Control Group (n = 23), Mean ± SD or No. (%)
Age, y	40.5 ± 8.9	42.0 ± 10.6
Years working with cancer patients	11.0 ± 7.6	13.3 ± 10.7
Sex: female	14 (60.9)	19 (79.2)
Gynecology oncologist	11 (47.8)	12 (50.0)
Private practice	8 (34.8)	8 (33.3)

Abbreviation: SD, standard deviation.

challenges of the 2 settings. Supplement 3 of the supporting information shows representative quotes from the interviewees.

From the physicians' perspective, both patients with cancer receiving the information leaflet and patients receiving the KOKON-KTO consultation were satisfied with the information provided. Overall, patients from both groups seemed very grateful for their physicians' dedicating a considerable amount of their consultation time to discussing CIM. Patients receiving the KOKON-KTO consultation seemed to appreciate the opportunity to personally discuss the CIM possibilities with their physician. However, patients with cancer in the control group welcomed the short consultation and seemed interested in exploring CIM websites. Although none of the patients with cancer explicitly expressed dissatisfaction with the short consultation, 2 oncology physicians assumed that some patients might have expected more in-depth information and advice on CIM than only a leaflet. In particular, they agreed to participate in a respective scientific study. Some physicians felt more connected to their patients when providing the KOKON-KTO consultation. However, patients with cancer also seemed satisfied with being referred to the information leaflet. Physicians reported that only a few patients asked for additional information and further support for decision-making in favor of or against CIM for their specific individual conditions.

DISCUSSION

The results show that the structured consultation taught in the KOKON-KTO training had positive effects on physician-patient communication (EORTC QLQ-COMU26), readiness to make a decision about CIM (PrepDM), and patient satisfaction (PS-CaTE) in comparison with a setting in which patients with cancer received only an information leaflet describing reputable CIM websites. To our knowledge, this study is the first evaluating blended learning training for oncology physicians about advising patients with cancer on CIM in routine cancer care.

The research process was guided by an implementation research framework²³ and started with framework development²¹ and the systematic definition of relevant patient-reported outcomes²⁴; this was followed by the implementation of the KOKON-KTO framework and its evaluation in a cluster-randomized trial and an in-depth qualitative analysis.²² Aspects of maintenance are currently being evaluated.

Although our training is scientifically founded and is now prepared for broad implementation, our study still has limitations when we consider the results at the patient level.

According to previous research,²⁴ the definition of a single primary outcome based on the current state of scientific knowledge is not recommended when one is evaluating communication training programs in oncology. Therefore, the main patient-reported outcomes of the KOKON-KTO study were defined on 3 different levels, including the patient level.²² Because of the number of outcomes, the statistical tests were planned and judged in an exploratory manner. Nevertheless, the results across all of the outcomes were homogeneous because they showed the positive effects of KOKON-KTO consultation in comparison with the information leaflet alone. Another limitation is that the "correct" implementation of the KOKON-KTO consultation manual (in accordance with the respective KOKON-KTO framework²¹) was monitored only during the KOKON-KTO training. The ratings showed that all of the trained physicians were able to correctly implement it.²¹ However, there was no video recording of the physicians providing advice in actual routine care settings. The advantages and limitations of video recording were discussed when the study was being designed. On the basis of experience from a previous study³² in which video recording was performed, physicians gave feedback suggesting that video recording negatively influenced the consultation; therefore, for this study, we decided to not use it.

In addition, this study measured only short-term outcomes; for future studies, it would be helpful to

TABLE 3. Quantitative Results

	IG (n = 122), Mean (95% CI) or No. (%)	CG (n = 154), Mean (95% CI) or No. (%)	IG-CG Difference, Mean (95% CI) or No. (%)	P
EORTC-QLQ-COMU26^a				
Patient's active role behaviors	85.0 (80.0 to 90.0)	74.3 (70.0 to 78.7)	10.7 (4.0 to 17.3)	.003
Clinician-patient relationship	87.2 (82.1 to 92.4)	76.1 (71.5 to 80.7)	11.2 (4.2 to 18.1)	.003
Professional's qualities creating a relationship	89.6 (85.1 to 94.1)	80.8 (76.8 to 84.8)	8.8 (2.7 to 14.8)	.006
Professional's skills	90.3 (86.4 to 94.1)	84.5 (81.0 to 87.9)	5.8 (0.7 to 11.0)	.029
Professional's management of patient's emotions	85.6 (80.7 to 90.5)	76.9 (72.5 to 81.2)	8.8 (2.2 to 15.3)	.010
Professional takes into account patient's preference	78.8 (71.8 to 85.9)	67.3 (61.1 to 73.5)	11.5 (2.1 to 20.9)	.018
Professional corrects misunderstandings	84.8 (79.6 to 90.0)	71.5 (66.9 to 76.1)	13.3 (6.3 to 20.3)	<.001
Professional's skill related to information	73.6 (67.4 to 79.8)	58.3 (52.8 to 63.8)	15.3 (7.0 to 23.5)	<.001
Enough privacy	85.0 (79.4 to 90.6)	74.0 (69.1 to 78.9)	11 (3.5 to 18.5)	.006
Total score	84.3 (79.5 to 89.2)	73.6 (69.3 to 78.0)	10.7 (4.2 to 17.2)	.002
PS-CaTE ^b	4.2 (4.0 to 4.4)	3.7 (3.5 to 3.8)	0.5 (0.2 to 0.8)	<.001
PrepDM ^c	63.5 (57.4 to 69.6)	53.2 (47.8 to 58.7)	10.3 (2.1 to 18.4)	.016
Usefulness of websites from the KOKON-KTO flyer^d				
Kokoninfo.de	7.1 (6.5 to 7.6)	6.5 (6.1 to 7.0)	0.5 (-0.2 to 1.3)	.143
Krebsinformationsdienst.de	6.9 (6.3 to 7.6)	7.0 (6.4 to 7.5)	0 (-0.9 to 0.8)	.927
Memorial Sloan Kettering	5.5 (4.2 to 6.9)	3.7 (2.6 to 4.8)	1.9 (0.1 to 3.6)	.042
Onkopedia.com	6.8 (6.1 to 7.6)	6.5 (6.0 to 7.1)	0.3 (-0.7 to 1.3)	.522
CIM knowledge				
Example 1: correct answer	120 (97.6)	147 (96.7)		
Example 2: correct answer	90 (74.4)	97 (63.4)		
Example 3: correct answer	98 (79.7)	116 (75.3)		
CIM use (planned or currently used)				
Acupuncture/acupressure	22 (18.0)	24 (15.6)		
Anthroposophical medicine	4 (3.3)	6 (3.9)		
Chinese herbs	4 (3.3)	6 (3.9)		
Chiropractic	3 (2.5)	4 (2.6)		
Homeopathy	28 (23.0)	49 (31.8)		
Neural therapy	1 (1.2)	1 (0.6)		
Osteopathy	9 (7.4)	21 (13.6)		
Mistletoe	14 (11.5)	16 (10.4)		
Other plant therapy	16 (13.1)	24 (15.6)		
Qigong/tai chi	25 (20.5)	24 (15.6)		
Yoga	52 (42.6)	42 (27.3)		
Autogenic training	32 (26.2)	35 (22.7)		
Progressive muscle relaxation	36 (29.5)	23 (14.9)		
Others	34 (27.9)	35 (22.7)		
Positive experience with current CIM therapy				
Acupuncture/acupressure	3 (2.5)	8 (5.2)		
Anthroposophical medicine	2 (1.6)	2 (1.3)		
Chinese herbs	0 (0)	2 (1.3)		
Chiropractic	2 (1.6)	2 (1.3)		
Homeopathy	20 (16.4)	23 (14.9)		
Neural therapy	0 (0)	0 (0)		
Osteopathy	5 (4.1)	14 (9.1)		
Mistletoe	4 (3.3)	2 (1.3)		
Other plant therapy	8 (6.6)	8 (5.2)		
Qigong/tai chi	8 (6.6)	13 (8.4)		
Yoga	11 (9.0)	13 (8.4)		
Autogenic training	9 (7.4)	14 (9.1)		
Progressive muscle relaxation	12 (9.8)	11 (7.1)		
Others	19 (15.6)	20 (13.0)		

Abbreviations: CG, control group; CI, confidence interval; CIM, complementary and integrative medicine; EORTC-QLQ-COMU26, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire and Communication 26; IG, intervention group; KOKON-KTO, Competence Network for Complementary Medicine—Consultation Training for Oncology Physicians; PrepDM, Preparation for Decision Making; PS-CaTE, Patient Satisfaction With Information on Cancer Treatment.

^aHigher scores indicate better communication (0-100).

^bHigher values indicate higher satisfaction (1-5).

^cHigher scores indicate higher perceived levels of preparation for decision-making (0-100).

^dHigher scores indicate higher ratings on the usefulness of websites (0-10).

evaluate long-term outcomes, such as CIM use, during the course of the disease.

The study compared 2 settings (KOKON-KTO consultation vs an information leaflet on CIM websites); interestingly, the physicians in both groups reported during the interviews that their patients seemed satisfied. However, the self-reported quantitative patient data showed much higher levels of satisfaction in the group that received the KOKON-KTO consultation. One explanation might be that patients are reluctant to provide open feedback directly in consultations; this phenomenon has been shown in other studies.³³ On the basis of this outcome, the patient-reported data of this study might provide a more realistic picture. Adding qualitative data on the physicians' view of patient satisfaction and comparing these data to the quantitative patient-reported outcomes showed an interesting gap, which might be an interesting aspect for future research, but more comparable evaluation tools should be used. Time spent with the oncology physician in the consultation differed between the interventions (5 vs 20 minutes), and a question might arise regarding whether this finding explains the much higher level of satisfaction in the KOKON-KTO group. However, having more time in this context might not always result in better patient-physician interaction because previous research has shown that physicians without CIM training felt uneasy in such situations.³⁴

Moreover, it is uncertain in what way the difference between the 2 groups in the cancer treatment objective (curative vs palliative) might have influenced study outcomes because previous experiences, the type of cancer, expectations, and the social environment can also influence outcomes, and this makes it difficult to judge.

In summary, the results of the KOKON-KTO study at the patient level show that the consultation has a positive influence on patient satisfaction, physician-patient communication, and decision-making. As described in the literature, barriers to physician-patient communication persist and can have a negative influence on cancer treatment; however, physicians' acceptance of patients' interest in CIM and their knowledge of the safety and efficacy of these therapies might help to improve communication about this topic.^{16,17} Oncology physicians addressing CIM with a structured approach could enhance patient satisfaction and improve patient adherence to cancer treatments. A future directive might be to introduce a framework earlier in physicians' medical training on how to advise patients with cancer on CIM (eg, in medical school). Additionally, the KOKON-KTO

framework was developed as an evidence-based, systematic approach tailored to physicians' and cancer patients' needs; hence, in future initiatives, it could be interesting to explore whether this framework could be transferred to other health professions or disease areas.

In conclusion, this is the first study to implement and evaluate an evidence-based CIM consultation in routine cancer treatment. Advising patients with cancer according to a structured, evidence-based consultation manual showed positive effects on patient satisfaction, preparation for decision-making, and physician-patient communication in comparison with only distributing an information leaflet on CIM. The study results emphasize the importance of communication in physician-patient relationships. The implementation and application of the KOKON-KTO manual might lead to greater patient compliance and reporting of CIM use. Future studies should investigate whether the application of the KOKON-KTO consultation leads to changes in behavior (eg, use of CIM) in patients who are later than 4 weeks into the course of cancer treatment.

FUNDING SUPPORT

This project was part of the Competence Network for Complementary Medicine in Oncology, which was established as a collaborative research project funded by German Cancer Aid (Deutsche Krebshilfe; grants 109863 and 70112369) and the Günter und Regine Kelm Stiftung. The funder of the study played no role in the study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all of the data in the study and had final responsibility for the decision to submit the manuscript for publication.

CONFLICT OF INTEREST DISCLOSURES

Alizé A. Rogge reports reimbursements for travel (full or partial). Claudia M. Witt reports fees for scientific presentations from Swiss hospitals; teaching fees from the University of Zurich; reimbursements for travel (full or partial) to several lectures that she gave; participation on advisory boards for the Rugieri Foundation and Vituro der EGK Gesundheitskasse; and leadership or fiduciary roles in the Society of Acupuncture Research, the Society of Integrative Oncology, the European Society for Integrative Medicine, Schweizer Fachverband für Mind Body Medicine, and the Swiss Group for Clinical Cancer Research. The other authors made no disclosures.

AUTHOR CONTRIBUTIONS

Alizé A. Rogge: Writing of the manuscript, performance of the study, and design of the study. **Stefanie M. Helmer:** Writing of the manuscript, performance of the study, and design of the study. **Ryan King:** Statistical analysis. **Claudia Canella:** Qualitative analysis. **Katja Icke:** Quality assurance of data entry and data safety. **Daniel Pach:** Contribution to the study and revision of the manuscript. **Claudia M. Witt:** Writing of the manuscript, performance of the study, and design of the study. All of the authors read and approved the final version of the manuscript.

DATA AVAILABILITY STATEMENT

The data sets analyzed during the current study are available from the corresponding author upon reasonable request.

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