

Aus dem Institut für Sozialmedizin, Epidemiologie und
Gesundheitsökonomie
der Medizinischen Fakultät Charité – Universitätsmedizin Berlin

DISSERTATION

Strategien und Ansätze zur Implementierung komplementär-
und integrativmedizinischer Konsultationen in die
Krebsversorgung von Patientinnen und Patienten

zur Erlangung des akademischen Grades
Doctor rerum medicinalium (Dr. rer. medic.)

vorgelegt der Medizinischen Fakultät
Charité – Universitätsmedizin Berlin

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Datum der Promotion: 04.03.2022

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Abstract Deutsch

Einleitung: Mehr als die Hälfte der Krebspatientinnen und -patienten nutzen komplementärmedizinische Verfahren während ihrer Krebstherapie. Trotz des Wunsches nach komplementärmedizinischen Konsultationen durch onkologisch tätige Ärztinnen und Ärzte berichten Patientinnen und Patienten in Konsultationen oft nicht über ihre Nutzung. Gründe hierfür scheinen vielfältig und umfassen die Befürchtung, mit ihrem Wunsch nicht verstanden zu werden. Andererseits wünschen sich onkologisch tätige Ärztinnen und Ärzte Fortbildungsmöglichkeiten zur Komplementärmedizin.

Zur Verbesserung der Ärztin/Arzt-Patientinnen/Patienten-Kommunikation über dieses Thema sollen Wege zur Implementierung systematisch entwickelter Konzepte für komplementärmedizinische Konsultationen in der Routineversorgung entwickelt werden. Im Einzelnen folgte diese Arbeit vier Zielen in der Entwicklung und Evaluation: (1) von Outcomes und Outcome-Messungen für Kommunikationstrainings in der Onkologie, (2) von Bildungskompetenzen für Gesundheitsberufe in der integrativen Onkologie, (3) von Kriterien zur Identifikation seriöser Anbietender komplementärmedizinischer Verfahren, (4) eines systematisch entwickelten Frameworks für komplementärmedizinische Konsultationen durch onkologisch tätige Ärztinnen und Ärzte.

Methoden und Material: (1) Empfehlungen für Outcomes und Outcome-Messungen wurden in einem drei-stufigen Prozess aus systematischer Literaturrecherche, Expertinnen und Experten-Workshop sowie Konsensusprozess generiert, (2) Bildungskompetenzen wurden anhand einer systematischen Literaturübersicht und einem internationalen, interprofessionellen Konsensusprozess entwickelt, (3) Kriterien zu seriösen Anbietenden wurden in einem Delphi-Konsensusprozess entwickelt und durch Stakeholder evaluiert und (4) unter Anwendung von Mixed-Methods-Verfahren wurde ein Framework für eine komplementärmedizinische Konsultation entwickelt und durch onkologisch tätige Ärztinnen und Ärzte sowie externe Bewertende der Konsultationssituationen evaluiert.

Ergebnisse: (1) Empfehlungen zur Evaluation von Kommunikationstrainings in der Onkologie, (2) Konsens über 37 Bildungskompetenzen (11 aus dem Bereich Wissen, 17 aus dem Bereich Fertigkeiten, neun aus dem Bereich Fähigkeiten) für

Gesundheitsberufe in der integrativen Onkologie, (3) Kriterienliste mit acht obligatorischen und drei fakultativen Kriterien zu seriösen Anbietenden komplementärmedizinischer Verfahren; (4) KOKON-KTO Framework (Konsultationsmanual; Blended Learning Training) zur Führung komplementärmedizinischer Konsultationen in der Onkologie.

Diskussion: Durch Anwendung diverser Implementierungsstrategien und -ansätze können die Ergebnisse dieser Arbeit dazu beitragen, die Kommunikation zwischen Ärztinnen/Ärzten und Patientinnen/Patienten bezüglich komplementärmedizinischer Verfahren in der Onkologie zu verbessern. Zukünftige Studien sollten neben dem Einbezug interkultureller Kompetenzen, diese Strategien auch auf Gesundheitsberufe wie Pflegende anwenden.

Abstract Englisch

Introduction: More than half of cancer patients use complementary medicine therapies (CM) during their cancer treatment. Despite the desire for CM consultations by oncology physicians, many patients do not disclose their use. Reasons for this seem to be multifactorial and often refer to the fear of not being accepted with their wish for CM. On the other hand, oncology physicians would like to be given the opportunity for further training in CM. In order to improve this situation and the physician-patient communication about this topic, strategies for implementing and evaluating systematically developed concepts for CM consultations for cancer patients in routine care become urgent. In detail, this work followed four objectives for the development and evaluation of: (1) recommendations for outcomes and outcome measures for the evaluation of communication training in oncology, (2) educational competencies for health professionals in integrative oncology, (3) criteria for the identification of reputable CM providers, and (4) a systematically developed communication framework (consultation manual, blended learning training) for CM consultations by the treating oncology physician.

Methods and material: (1) Recommendations for outcomes and outcome measures were generated in a three-step developing process consisting of a systematic literature search, expert workshop and a subsequent consensus procedure, (2) educational competencies were developed through a systematic literature search and an international and interprofessional consensus procedure by relevant stakeholder groups, (3) criteria for the identification of reputable CM providers were developed in an interprofessional Delphi-consensus procedure and subsequently evaluated and implemented with the involvement of various stakeholder groups, and (4) using mixed-methods and a leading implementation strategy, a framework for CM consultations was developed and evaluated by oncology physicians and external raters of the consultation situations.

Results: (1) Recommendations for the evaluation of communication training in oncology were recorded, (2) 37 core competencies (11 from the field of knowledge, 17 from the field of skills, 9 from the field of abilities) were developed for health professionals in integrative oncology, (3) a list of 8 mandatory and 3 optional criteria for the identification of reputable complementary medicine providers was developed,

and (4) KOKON-KTO framework (consultation manual, blended learning training) for advising cancer patients on CM was developed.

Discussion: By applying various implementation strategies and approaches, the results of this work can improve the communication between physicians and patients regarding CM in oncology. Future studies should not only include intercultural competencies, but also expand the strategies for health professionals such as nursing care.

1 Einführung

Weniger als der Hälfte aller wissenschaftlicher Erkenntnisse gelingt der Transfer in die allgemeine Routineversorgung von Patientinnen und Patienten (1-3). Diese sogenannte Lücke zwischen Wissenschaft und Praxis („science-practice-gap“) (4) führt neben ethisch-rechtlichen Fragestellungen zur Best Practice in der Gesundheitsversorgung auch zu hohen finanziellen Kosten. Schätzungen zufolge finden über 85% der finanziellen Mittel für klinische Studien keinen Nutzen in der praktischen Anwendung (5). Die Implementationswissenschaften (Implementation Science) machen es sich zum Ziel, evidenzbasierte Interventionen systematisch in die medizinische Praxis zu integrieren und somit die Qualität von Versorgungsleistungen zu verbessern (6). Hierbei ist es entscheidend, von Beginn an adäquate Strategien und Wege zur Implementierung von Forschungsergebnissen in die Studienplanung einzubetten und so folgend Voraussetzungen zur praktischen Umsetzung zu etablieren (7, 8).

Eine solche „Science-Practice-Gap“ kann auch bei der Information zu und Nutzung von komplementärmedizinischen Verfahren in der Onkologie identifiziert werden (9, 10). Als komplementärmedizinische Verfahren werden hierbei verschiedene Therapien wie die Akupunktur oder Phytotherapie bezeichnet, welche zusätzlich zur Krebstherapie angewandt werden können (11). Über 50% der Krebspatientinnen und -patienten nutzen komplementärmedizinische Verfahren während oder nach ihrer Krebsbehandlung (12). Trotz des Nutzungsanstiegs von komplementärmedizinischen Verfahren seitens Patientinnen und Patienten und fortschreitenden wissenschaftlichen Erkenntnissen zu diesen Verfahren, kann von einer routinierten, evidenzbasierten Beratung durch onkologisch tätige Ärztinnen und Ärzte bislang nicht gesprochen werden. Studien zufolge unterrichten bis zu 77% der Krebspatientinnen und -patienten ihre Ärztinnen und Ärzte nicht über die eigene Nutzung komplementärmedizinischer Verfahren (13-15). Die Gründe hierfür sind vielschichtig. So gehen Patientinnen und Patienten oftmals nicht von einer möglichen Interaktionsgefahr dieser Verfahren mit der Krebstherapie aus oder befürchten von ihren behandelnden onkologisch tätigen Ärztinnen und Ärzten in ihrem Anliegen nicht angenommen zu werden (13). Onkologisch tätige Ärztinnen und Ärzte berichten hingegen, neben infrastrukturellen Herausforderungen wie der zeitlichen Integration

solcher Konsultationen über eine unzureichende Kompetenz im Bereich der Komplementärmedizin zu verfügen (16).

Aus diesem Grund finden komplementärmedizinische Konsultationen oftmals nicht durch das onkologische Behandlungsteam statt, was zu erheblichen Folgen führen kann. Johnson und Kolleginnen und Kollegen zeigten in einer kontrovers diskutierten retrospektiven Beobachtungsstudie mit Daten der US-amerikanischen National Cancer Database, dass potentiell kurative Krebspatientinnen und -patienten, welche Alternativmedizin unter Aufsicht nicht-ärztlicher Anbietender anwandten, eine höhere Wahrscheinlichkeit zeigten, zukünftige Krebstherapien abzulehnen oder ihrer Krebserkrankung zu erliegen (17). Dies unterstützt den Bedarf, evidenzbasierte Trainings und folgend Interventionen zur Komplementärmedizin (18-20) in die onkologische Routineversorgung zu implementieren und somit Patientinnen und Patienten sowie Ärztinnen und Ärzten den Zugang zu seriösen Informationsquellen der Komplementärmedizin zu erleichtern (10).

1.2 Zielstellung

Ziel der Arbeit ist, Strategien und Ansätze zu entwickeln, welche die Implementierung evidenzbasierter komplementärmedizinischer Konsultationen für Krebspatientinnen und -patienten durch onkologisch tätige Ärztinnen und Ärzte in der Routineversorgung erleichtern. Vier unterschiedliche aufeinander aufbauende Bereiche wurden hierfür betrachtet:

(1) Empfehlungen zu Outcomes und Outcome-Messungen zur Evaluation von Kommunikationstrainings in der Onkologie sollen systematisch entwickelt und expertinnen- und expertenbasiert überprüft werden (Publikation 1).

(2) Bildungskompetenzen für die integrative Onkologie sollen für komplementärmedizinische Trainings von Gesundheitsberufen systematisch entwickelt und überprüft werden (Publikation 2).

(3) Kriterien zur Identifikation von seriösen Anbietenden komplementärmedizinischer Verfahren für Krebspatientinnen und -patienten in der ambulanten Versorgung sollen entwickelt, evaluiert und implementiert werden (Publikation 3).

(4) Ein systematisch entwickeltes Framework für integrativ-onkologische Konsultationen von Krebspatientinnen und -patienten in der Routineversorgung bestehend aus einem halbstrukturierten Konsultationsmanual und einem Blended Learning Training (e-Learning und Workshop) soll entwickelt, pilotisiert und evaluiert werden (Publikation 4).

2 Material und Methodik

2.1 Publikation 1: Outcomes and outcome measures used in evaluation of communication training in oncology - a systematic literature review, an expert workshop, and recommendations for future research

Zur Entwicklung von Empfehlungen zu Outcomes und Outcome-Messungen in Kommunikationstrainings in der Onkologie wurde eine systematische Literaturrecherche und ein Expertinnen- und Experten-Konsensusprozess durchgeführt. Die Ergebnisse wurden anschließend iterativ mit teilnehmenden Expertinnen und Experten zusammengefasst und in Form von Empfehlungen festgehalten.

Die systematische Literaturrecherche erstreckte sich über sieben Datenbanken (MEDLINE, CENTRAL, CINAHL, EMBASE, PsychINFO, PsychARTICLES, Web of Science) und umfasste jegliche Publikationen, welche die Effekte von Kommunikationstrainings untersuchten. Anschließend wurden 21 Übersichtsartikel hinzugezogen, welche durch Handsuche sowie Literaturhinweise aus recherchierten Publikationen identifiziert werden konnten (21). Der Prozess folgte den Standards der PRISMA-Leitlinie (22) zur Darstellung von Ergebnissen von systematischen Literaturübersichtsarbeiten.

Die Ergebnisse der systematischen Literaturrecherche wurden anschließend in einem zwei-tägigen Expertinnen- und Experten-Workshop (n=16) diskutiert und erweitert. Feinziel des Workshops war es, Herausforderungen in der Evaluation von Kommunikationstrainings festzuhalten und Lösungswege zu entwickeln. Expertinnen und Experten wurden aufgrund ihrer Expertise in den Bereichen Onkologie, Patientinnen- und Patientenvertretung, Kommunikation, Kommunikationstrainings, Outcome-Entwicklung und -Forschung, Public Health und Psycho-Onkologie ausgewählt. Anschließend wurden die gesammelten Ergebnisse aus dem

Expertinnen- und Experten-Workshop iterativ zu Empfehlungen generiert und für zukünftige Kommunikationstrainings in der Onkologie formuliert (23).

2.2 Publikation 2: Education Competencies for Integrative Oncology— Results of a Systematic Review and an International and Interprofessional Consensus Procedure

Zur Entwicklung von Bildungskompetenzen für die integrative Onkologie wurde ein Mixed-Methoden-Ansatz angewandt, der sich aus zwei Phasen zusammensetzte. In der ersten Phase wurde eine systematische Literurrecherche durchgeführt, welche bestehende Bildungskompetenzen für diverse Gesundheitsberufe in der integrativen Onkologie (Ärztinnen/Ärzte, Pflegende, andere Gesundheitsberufe) in sechs Datenbanken (MEDLINE, CENTRAL, CINAHL, EMBASE, PsychINFO, PsychARTICLES, Web of Science) umfasste. Die extrahierten Kompetenzen wurden anschließend in das KSA-Framework (Knowledge-Skills-Abilities (dt. Wissen-Fertigkeiten-Fähigkeiten) eingeordnet.

In der zweiten Phase wurde ein Konsensusprozess durchgeführt, der sich insgesamt aus 3 Stufen zusammensetzte, die jeweils von einer Telefonkonferenz einer internationalen Task Force abgeschlossen wurden. Diese internationale Task Force (n=12) setzte sich aus Ärztinnen/Ärzten sowie naturheilkundlich arbeitenden Ärztinnen/Ärzten, Psychologinnen/Psychologen, Wissenschaftlerin aus dem Bereich Public Health, Patientinnen- und Patientenvertreterinnen und seriöse Anbietende komplementärmedizinischer Verfahren zusammen. In Stufe 1 wurde ein Online Survey implementiert, in dem die in der Literaturübersicht extrahierten Kompetenzen nach ihrer allgemeinen Wichtigkeit (0=nicht wichtig bis 10=absolut wichtig) eingestuft wurden und die Einordnung im KSA-Framework erfolgte. Des Weiteren konnten zusätzliche Kompetenzen vorgeschlagen werden. Hierfür wurde eine internationale Expertinnen- und Expertengruppe (n=25; Australien/Asien, Europa, Nordamerika) über die Task Force rekrutiert und befragt. Im zweiten Online-Survey wurden die Kompetenzen nach ihrer Wichtigkeit für verschiedenen Professionen durch die Task-Force und die Expertinnen-und Expertengruppe differenziert eingestuft.

In der dritten Stufe wurde anschließend Mitglieder eines internationalen Verbunds der integrativen Onkologie (SIO: Society of Integrative Oncology) die Möglichkeit gegeben, ebenfalls über die Kompetenzen abzustimmen und die Kompetenzen

hinsichtlich ihrer Wichtigkeit für verschiedenen Professionen zu bewerten (24). Die Befragung erfolgte in einem Online-Survey (Einladung im Newsletter der Fachgesellschaft als auch auf der jährlichen Fachgesellschaftstagung) sowie als Paper-Pencil-Fragebogen (Auslage auf der Fachgesellschaftstagung).

2.3 Publikation 3: Defining criteria for guiding cancer patients to find a reputable complementary medicine provider: results of a literature review and a consensus procedure

Zur Entwicklung der Kriterien zur Identifikation seriöser Anbietender komplementärmedizinischer Verfahren konnte ein Mixed-Methods-Design bestehend aus einer systematischen Literaturrecherche (Phase I) sowie einem Expertinnen/Experten-Delphi-Konsensusprozess und einer praxisrelevanten Evaluation mit verschiedenen Stakeholdern (Phase II) angewandt werden.

Phase I: In einer systematischen Literaturrecherche wurden existierende Kriterien für seriöse Anbietende komplementärmedizinischer Verfahren aus der Literatur (u.a. wissenschaftliche Fachjournale, Bücher, Webseiten, Kongress- und Abhandlungsschriften) extrahiert. Hierbei wurden mittels einer zuvor festgelegten Suchstrategie unter Verwendung adäquater Schlagworte vor allem wissenschaftliche, elektronische Datenbanken wie Medline, Central, Embase und Web of Science verwendet. Die Selektion der Studien sowie die Daten-Extraktion wurden von zwei Wissenschaftlerinnen durchgeführt, sodass eine intersubjektive Validierung zur Datenreliabilität gewährleistet werden konnte. Die Analyse der Literatur wurde anschließend durch eine qualitative Inhaltsanalyse nach Flick (25) mittels einer induktiven Kodierungsstrategie durchgeführt.

Phase II: Die aus der Literatur extrahierten Kriterien wurden anschließend in einem internationalen und interprofessionellen Delphi-Konsensusprozess innerhalb von drei Runden überprüft und erweitert. Expertinnen und Experten (n=15) wurden anhand ihrer Expertise in den Bereichen Komplementärmedizin, integrative Onkologie, Public Health, Psychologie und Psycho-Onkologie, Pflegewissenschaften, Allgemeinmedizin, Methodik, Epidemiologie, Medizinrecht, Krebselbsthilfegruppen und als Vertretung von Krebspatientinnen und -patienten und deutscher Krankenkassen rekrutiert. Innerhalb der ersten zwei Runden des Delphi-Konsensusprozesses wurden die Resultate der Literaturrecherche iterativ mittels

anonymen Online-Surveys zur Relevanz (Numerische Rating Skala von 0=nicht relevant bis 10=sehr relevant) und Überprüfbarkeit der Kriterien, d.h. wie Patientinnen und Patienten an die Informationen zu den Kriterien gelangen (Open-access (z.B. Internetauftritt); Informationen müssen erfragt werden; Informationen müssen beobachtet werden) sowie in den jeweils darauffolgenden Telefonkonferenzen verfeinert, reduziert und erweitert.

Anschließend wurden die Ergebnisse hinsichtlich ihrer Implementierbarkeit durch verschiedene Stakeholdergruppen (Krebspatientinnen und -patienten, seriöse komplementärmedizinische Anbietende aus Fachgesellschaften sowie integrativ praktizierende onkologisch tätige Ärztinnen und Ärzte) anonymisiert überprüft. Für diesen Zweck wurden die Ergebnisse in Form eines Flyers für Krebspatientinnen und -patienten aufbereitet. Der Flyer beinhaltete außerdem eine Einleitung zu den Kriterien sowie einen Disclaimer. Teilnehmende erhielten den Fragebogen zur Wichtigkeit und Nützlichkeit (Numerische Rating Skala von 0=stimme überhaupt nicht zu bis 10=stimme absolut zu) der Kriterien postalisch oder via E-Mail zugesandt. Sie hatten ebenfalls die Möglichkeit, in einem Freitextfeld weitere Informationen pro Kriterium mitzuteilen. Teilnehmende wurden durch Newsletter von komplementärmedizinischen Verbänden sowie durch Netzwerke teilnehmender Kliniken in Deutschland rekrutiert. Die hieraus resultierenden Ergebnisse wurden anschließend innerhalb einer weiteren Delphi-Runde finalisiert und der Flyer daraufhin für die Implementierung angepasst (26, 27).

2.4 Publikation 4: Training oncology physicians to advise their patients on complementary and integrative medicine: An implementation study for a manual-guided consultation

Unter Anwendung von Mixed-Methods-Forschungsmethoden und einer prozessführenden Implementationsstrategie (basierend auf dem ReAim Framework: Reichweite, Wirksamkeit, Akzeptanz, Umsetzung, Aufrechterhaltung (28)) wurde ein Framework für integrativ-onkologische Konsultationen durch onkologisch tätige Ärztinnen und Ärzte mit ihren Krebspatientinnen und -patienten in einem internationalen und interprofessionellen Verfahren entwickelt, pilotisiert und evaluiert. Das Framework basierte auf dem im selben Projekt entwickelten halbstrukturierten KOKON-KTO Konsultationsmanual (I) sowie dem KOKON-KTO Training (II).

(I) Das KOKON-KTO Konsultationsmanual wurde anhand einer systematischen Literaturrecherche gängiger wissenschaftlicher, elektronischer Datenbanken (MEDLINE, CENTRAL, EMBASE, Web of Science) sowie unter Einbezug internationaler Expertinnen und Experten (n=9) aus den Bereichen Komplementärmedizin, Ärztin/Arzt-Patientin/Patient-Kommunikation, integrative Onkologie, Methodenforschung, Psychologie und Public Health innerhalb eines mehrstufigen, praxisorientierten Expertin/Experten-Delphi-Konsensusprozesses entwickelt und anschließend durch verschiedene Stakeholdergruppen (integrativ onkologisch tätige Ärztinnen und Ärzte (n=3) und Krebspatientinnen und -patienten (n=9) an die Konsultationsbedürfnisse in der integrativen Onkologie angepasst. Der Delphi-Konsensusprozess setzte sich aus anonymisierten Online-Surveys zur Wichtigkeit der Konsultationsbestandteile (Numerische Ratingskala von 0=absolut nicht wichtig bis 10=sehr wichtig) und Anmerkungen zum Aufbau sowie jeweils anschließende Telefonkonferenzen zusammen. Die Ergebnisse der Stakeholder-Befragungen wurden durch semistrukturierte Interviews festgehalten und innerhalb einer Inhaltsanalyse nach Flick (25) deduktiv und induktiv analysiert. Das resultierende KOKON-KTO Konsultationsmanual wurde anschließend durch onkologisch tätige Ärztinnen und Ärzte (n=37) mit Simulationspatientinnen pilotisiert und durch unabhängige externe Bewertende der Konsultationssituationen auf Machbarkeit geprüft (10 Items, Numerische Rating Skala von 1=stimme absolut nicht zu bis 4=stimme absolut zu). Die Bewertenden unterzogen sich zuvor einem Reliabilitätstraining (Eichung), und die Zuverlässigkeit der Beobachtungsergebnisse wurden anhand einer Interclass-Korrelation überprüft. Des Weiteren wurden semistrukturierte Interviews mit den Simulationspatientinnen durchgeführt und anhand einer Inhaltsanalyse nach Flick (25) durch induktive und deduktive Kodierungsstrategien von zwei erfahrenen Wissenschaftlerinnen analysiert.

(II) Das auf dem KOKON-KTO Konsultationsmanual basierende KOKON-KTO Training wurde unter Beachtung international anerkannter Standards zur Entwicklung von Lernzielen nach Bloom (29), Empfehlungen zu Outcomes und Outcome-Messungen von Kommunikationstrainings in der Onkologie (23) sowie internationalen Bildungskompetenzen zur Ausführung von Komplementärmedizin in den Gesundheitsberufen (24) entwickelt. Es besteht aus einem umfassenden evidenzbasierten e-Learning (Erlangung theoretischer Grundlagen zu komplementären und supportiven Verfahren, Kontraindikation und -interaktionen)

sowie einem zwei-tägigen Skills-Training-Workshop zur Erlangung praktischer Fähigkeiten zur Führung einer KOKON-KTO Konsultation. Das KOKON-KTO Training wurde durch 47 onkologisch tätige Ärztinnen und Ärzte (e-Learning und Skills-Training-Workshop: Numerische Rating Skala von 1=stimme absolut nicht zu bis 4=stimme absolut zu) innerhalb eines anonymisierten Online-Surveys evaluiert. Onkologisch tätige Ärztinnen und Ärzte konnten am KOKON-KTO-Training teilnehmen, wenn sie über geringe Erfahrungen in komplementärmedizinischen Beratungen verfügten und eigene Krebspatientinnen und -patienten behandelten (26, 30).

3 Ergebnisse

3.1 Publikation 1: Outcomes and outcome measures used in evaluation of communication training in oncology - a systematic literature review, an expert workshop, and recommendations for future research

Es konnten 2181 Referenzen in den Datenbanken und 118 Referenzen aus zusätzlichen Quellen identifiziert werden. Insgesamt wurden 96 Publikationen in einem Voll-Text-Screening durch eine Psychologin und einen Psychologen begutachtet ($\kappa = .56$) und die Ergebnisse in den Konsensusprozess überführt. Es zeigte sich, dass die extrahierten Publikationen in 49,3% der Studien lediglich Outcomes zur Evaluation der Kommunikationstrainings aus einer Perspektive (bspw. der Trainingsteilnehmenden) umfassten (siehe Abbildung 1).

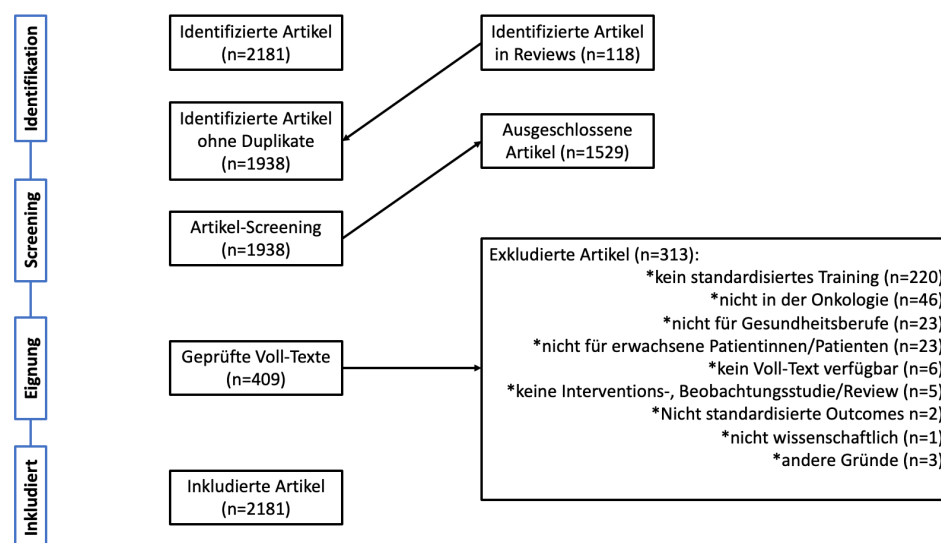


Abbildung 1: Ablauf und Ergebnisse der systematischen Literaturrecherche zu Outcomes in Kommunikationstrainings in der Onkologie (23)

Im Workshop mit Expertinnen und Experten konnten weitere drei Bereiche von Herausforderungen in der Evaluation von Kommunikationstrainings elaboriert werden: (1) Outcomes der Trainingsteilnehmenden (z.B. wie die Kommunikationsfertigkeiten oder Zufriedenheit); (2) Outcomes, welche die Interaktion mit Patientinnen und Patienten messbar machen; und (3) Outcomes, welche durch die Patientinnen und Patienten der Trainingsteilnehmenden erfasst werden (z.B. Zufriedenheit der Patientinnen/Patienten nach Konsultation durch Trainingsteilnehmende).

Es konnte festgehalten werden, dass Outcomes:

- a. spezifisch auf Trainingsinhalte angepasst werden,
- b. Lernziele der Kommunikationstrainings berücksichtigen,
- c. auf drei Ebenen (vor dem Training, während der Ärztin/Arzt-Patientin/Patient-Interaktion, nach der Interaktion) untersucht werden,
- d. durch Stakeholder Engagement entwickelt werden und
- e. mehrere Endpunkte umfassen sollten (23).

3.2 Publikation 2: Education Competencies for Integrative Oncology— Results of a Systematic Review and an International and Interprofessional Consensus Procedure

In der systematischen Literaturrecherche konnten insgesamt 58 Kompetenzen aus 21 Studien generiert werden, welche sich aus 40 Kompetenzen der integrativen Medizin und 18 Kompetenzen aus der Onkologie zusammensetzten.

Im Konsensusprozess wurden die in der Literatur identifizierten Kompetenzen erweitert, adaptiert und diskutiert, sodass letztlich 37 Kernkompetenzen als Bildungskompetenzen in der integrativen Onkologie formuliert werden konnten. Survey-Teilnehmende kamen hauptsächlich aus Nordamerika (1. Survey: 56%; 2. Survey: 68%), aber auch aus Asien/Australien (1. Survey: 24%; 2. Survey: 14%) sowie Europa (1. Survey: 20%; 2. Survey: 18%). Die Gesamtheit der Kompetenzen wurden für alle Gesundheitsberufe entwickelt und konnten in das KSA-Framework überführt werden (Abbildung 2).

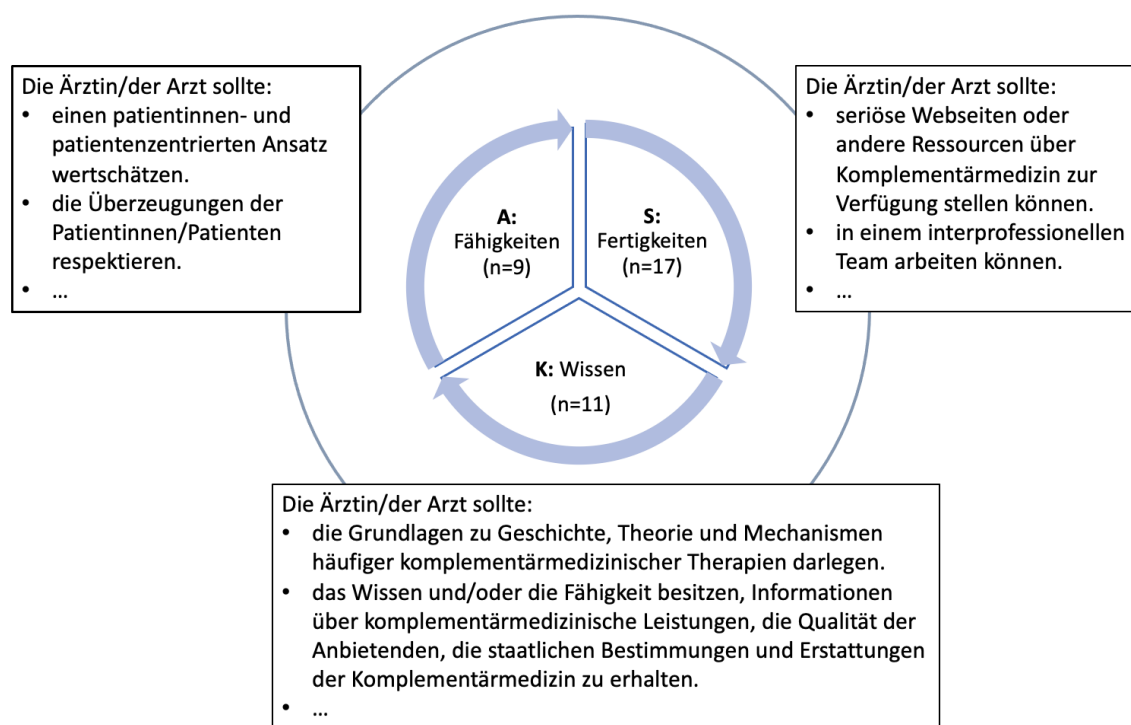


Abbildung 2: Kompetenzen nach dem KSA Frameworks und Beispiele (24)

Anschließend wurden die entwickelten Kernkompetenzen durch SIO-Mitglieder (n=57; 40% Ärztinnen und Ärzte; 14% komplementärmedizinische Anbietende; 9% Pflegende; 36% weitere Gesundheitsberufe) bewertet und mehrheitlich angenommen (Zustimmung: 93-100%) (24).

3.3 Publikation 3: Defining Criteria for Guiding Cancer Patients to Find a Reputable Complementary Medicine Provider: Results of a Literature Review and a Consensus Procedure

Phase I: Der Literatur konnten 13 Artikel/Informationsquellen entnommen werden, welche 30 Kriterien zu seriösen Anbietenden komplementärmedizinischer Verfahren darstellten.

Phase II: Auf Basis der Ergebnisse aus Phase I konnten innerhalb des Delphi-Konsensusprozesses 36 Kriterien entwickelt werden. Bei genauerer Betrachtung der Kriterien konnten diese nach Anwendungsgruppe (Patientinnen/Patienten, Ärztinnen/Ärzte, seriöse Anbietende komplementärmedizinischer Verfahren) eingestuft werden. Insgesamt entstanden so drei spezifisch auf die Adressatinnen und Adressaten zugeschnittene Kriterienlisten zur Identifikation seriöser Anbietender komplementärmedizinischer Verfahren: 23 Kriterien für Patientinnen/Patienten, 28 für Ärztinnen/Ärzte und 14 Kriterien, welche als notwendig für ein mögliches

Zusatzzertifikat „Komplementärmedizin“ für seriöse Anbietende dieser Verfahren gelten könnten.

Die entwickelten 23 Kriterien für Krebspatientinnen und -patienten wurden daraufhin in Form eines Flyers auf eine Anzahl von zehn Kriterien zusammengefügt, um einen vereinfachten Zugang für Patientinnen und Patienten zu ermöglichen. Zur besseren Anwendbarkeit durch Patientinnen und Patienten wurde dem Flyer ebenfalls eine Einleitung in die Kriterien als auch ein Disclaimer angefügt. Zur weiteren Überprüfung der Implementierbarkeit wurde der Flyer an Krebspatientinnen und -patienten (n=18), onkologisch tätige Ärztinnen und Ärzte (n=20) und Anbietende komplementärmedizinischer Verfahren (Yoga n=10, Mind-and-Body-Stressreduction n=7, Anbietender naturheilkundlicher Verfahren n=6 und in Akupunktur ausgebildete Ärztinnen/Ärzte n=3) versandt und durch diese evaluiert.

Die Mehrzahl der Teilnehmenden (88,5%) wandten regelmäßig komplementärmedizinische Verfahren an, und zwei Drittel (65,4%) behandelten regelmäßig Krebspatientinnen/-patienten. Die Kriterien wurden mehrheitlich als wichtig und nützlich eingestuft. Drei Kriterien wurden als schwer durch Patientinnen und Patienten überprüfbar eingeschätzt: adäquate Ausbildung im angebotenen komplementärmedizinischen Verfahren, Behandlungserfahrung und Teilnahme an Fortbildungen. In der finalen sich darauf anschließenden Delphi-Konsensusrunde wurden die Kriterien hinsichtlich ihrer Überprüfbarkeit angepasst. Der endgültige Flyer beinhaltete acht obligatorische und drei fakultative Kriterien zur Identifikation seriöser Anbietender komplementärmedizinischer Verfahren (Abbildung 3) (27).

Die Anbieterin/der Anbieter sollte:

- 1 Ihre Diagnose und die bisherige Behandlung erfragen.
- 2 Bereit sein, mit Ihnen über mögliche Wechselwirkungen zwischen der komplementärmedizinischen Behandlung und Ihrer Krebstherapie zu sprechen.
- 3 Ihnen erklären, warum speziell diese komplementärmedizinische Behandlung für Sie empfehlenswert ist.
- 4 Ihnen die Möglichkeiten und Grenzen dieser Behandlung realistisch und verständlich darstellen und bereit sein, bisherige Erfahrungen mit diesem Verfahren darzulegen sowie gesicherte Daten zu vermitteln.
- 5 Mit Ihnen Ziele, Inhalte, Dauer und Kosten der geplanten Behandlung und Änderungen im Verlauf sowie Wege zur möglichen Erstattung besprechen.
- 6 Ihnen eine angemessene Bedenkzeit einräumen und Ihnen ermöglichen, sich frei für oder gegen die vorgeschlagene Behandlung zu entscheiden.
- 7 Ihre Entscheidung für oder gegen eine komplementärmedizinische Behandlung respektieren.
- 8 Ihnen eine nachvollziehbare Rechnung für die Behandlung vorlegen.

Es sind noch andere Aspekte wichtig, jedoch sind diese schwieriger zu überprüfen. Falls Sie dies über die Anbieterin/den Anbieter wissen möchten, müssten Sie es erfragen:

1. Es wurde eine Fachausbildung (oder ein spezielles Studium) mit regulierter Länge abgeschlossen und es werden nur Behandlungsmethoden angewendet, die erlernt wurden und aktuell beherrscht werden.
2. Es werden regelmäßig Fort- und Weiterbildungen besucht.
3. Es bestehen mind. 2 Jahre Erfahrung in der Behandlung von Krebspatientinnen und -patienten bzw. mit an Krebs erkrankten Kindern.

Abbildung 3: Auszug des Flyers zur Identifikation seriöser Anbietender komplementärmedizinischer Verfahren (27)

3.4 Publikation 4: Training oncology physicians to advise their patients on complementary and integrative medicine: An implementation study for a manual-guided consultation

(I) Das KOKON-KTO-Konsultationsmanual: Nach der systematischen Literaturrecherche wurden acht Publikationen identifiziert, welche die Struktur und den Ablauf des zu entwickelnden Konsultationsmanuals formten (Runde 1). In der zweiten Delphi-Befragung konnten weitere Empfehlungen zur Durchführung von komplementärmedizinischen Konsultationen in der Onkologie entwickelt werden. Mittels des Online-Surveys (n=11) wurden die Empfehlungen und die Struktur als adäquat eingestuft und ein weiterer Schritt im Konsultationsablauf (*Informieren*) eingefügt. Auf Wunsch der Survey-Teilnehmenden wurden flexible Schritte im Ablauf der Konsultation entwickelt, um einen individuellen Konsultationsstil der Ärztinnen und Ärzte zu ermöglichen. In der anschließenden Testung des Konsultationsleitfadens mit Krebspatientinnen und -patienten (n=3) konnten hohe Werte in der Zufriedenheit erreicht werden. In der 3. Delphi-Befragung wurde die Einteilung der Konsultation in a) Einführung in den Konsultationskontext, b) Konsultationsschritte: Informieren, Erfassen, Priorisieren, Empfehlen, Besprechen, Empfehlungen konkretisieren und c) Monitoring durchgeführt. Es konnte ein 8-

schrittiges halbstrukturiertes Konsultationsmanual für onkologisch tätige Ärztinnen und Ärzte zu komplementärmedizinischen Konsultationen in der Onkologie entwickelt werden (Abbildung 4). Die KOKON-KTO Konsultation kann an den individuellen ärztlichen Konsultationsstil sowie an Bedingungen der onkologisch-praktischen Tätigkeit (max. Zeitrahmen von 20 Minuten) angepasst werden (30). In der anschließenden Evaluation des KOKON-KTO Konsultationsmanuals konnten onkologisch-tätige Ärztinnen (n=37) mit Simulationspatientinnen die Konsultation testen. Externe Bewertende (n=4) konnten die KOKON-KTO Konsultation mit hoher Übereinstimmung ($R^2=0,58 \pm 0,29$) als gut umsetzbar in einem Zeitrahmen von 20 Minuten einstufen (30).



Abbildung 4: Struktur und Ablauf der KOKON-KTO Konsultation (30)

(II) Das KOKON-KTO Training: Basierend auf dem KOKON-KTO Konsultationsmanual wurde das KOKON-KTO Training entwickelt, welches onkologisch tätigen Ärztinnen und Ärzten theoretische und praktische Fähigkeiten zu komplementärmedizinischen Konsultationen in der Onkologie zur Verfügung stellte. Das KOKON-KTO Training wurde in Form eines Blended Learnings entwickelt, in

welchem ein e-Learning sowie ein 2-tägiger Workshop miteinander kombiniert wurden (Abbildung 5) (30).

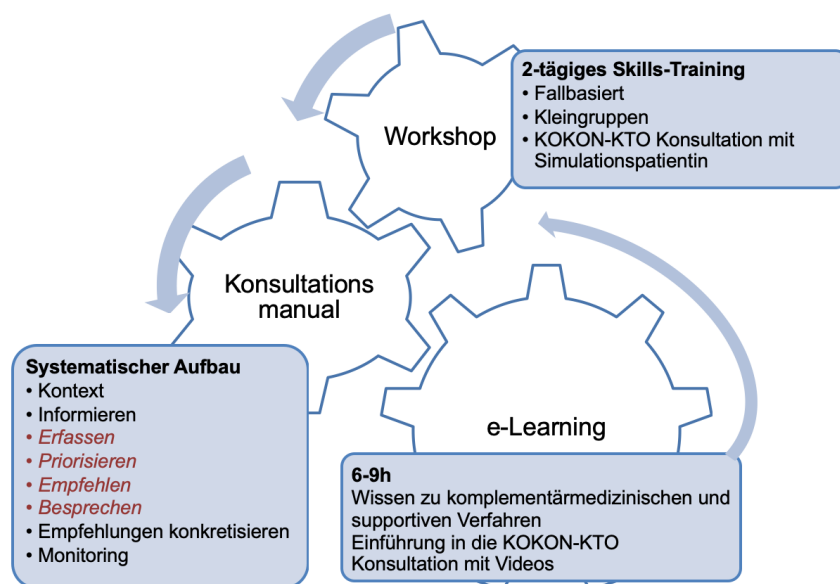


Abbildung 5: KOKON-KTO-Konzept bestehend aus Konsultationsmanual und Training (30)

Das e-Learning resultierte in drei obligatorischen Kursen (Gesamtlänge: 9x45 Minuten) mit Themenblöcken zu Einführungen in die Komplementärmedizin in der Onkologie, spezifischen komplementären und supportiven Therapien sowie dem Erlernen der KOKON-KTO Konsultation. Der darauffolgende Skills-Training-Workshop (Gesamtlänge: 16x45 Minuten) konnte praxisrelevante Themen zu komplementärmedizinischen Konsultationen vertiefen und Teilnehmende die KOKON-KTO Konsultation praktisch erlernen lassen. Da die KOKON-KTO Konsultation zur Anwendung bei eigenen Krebspatientinnen und -patienten konzipiert wurde, basierten die Übungsaufgaben während des Workshops auf einer Fallvignette zu einer Patientin. Das KOKON-KTO Training wurde von teilnehmenden Ärztinnen und Ärzten (n=37) mit hohen Werten in der Relevanz für die praktische Tätigkeit und Zufriedenheit evaluiert (Abbildung 6 zur e-Learning Bewertung) (30).

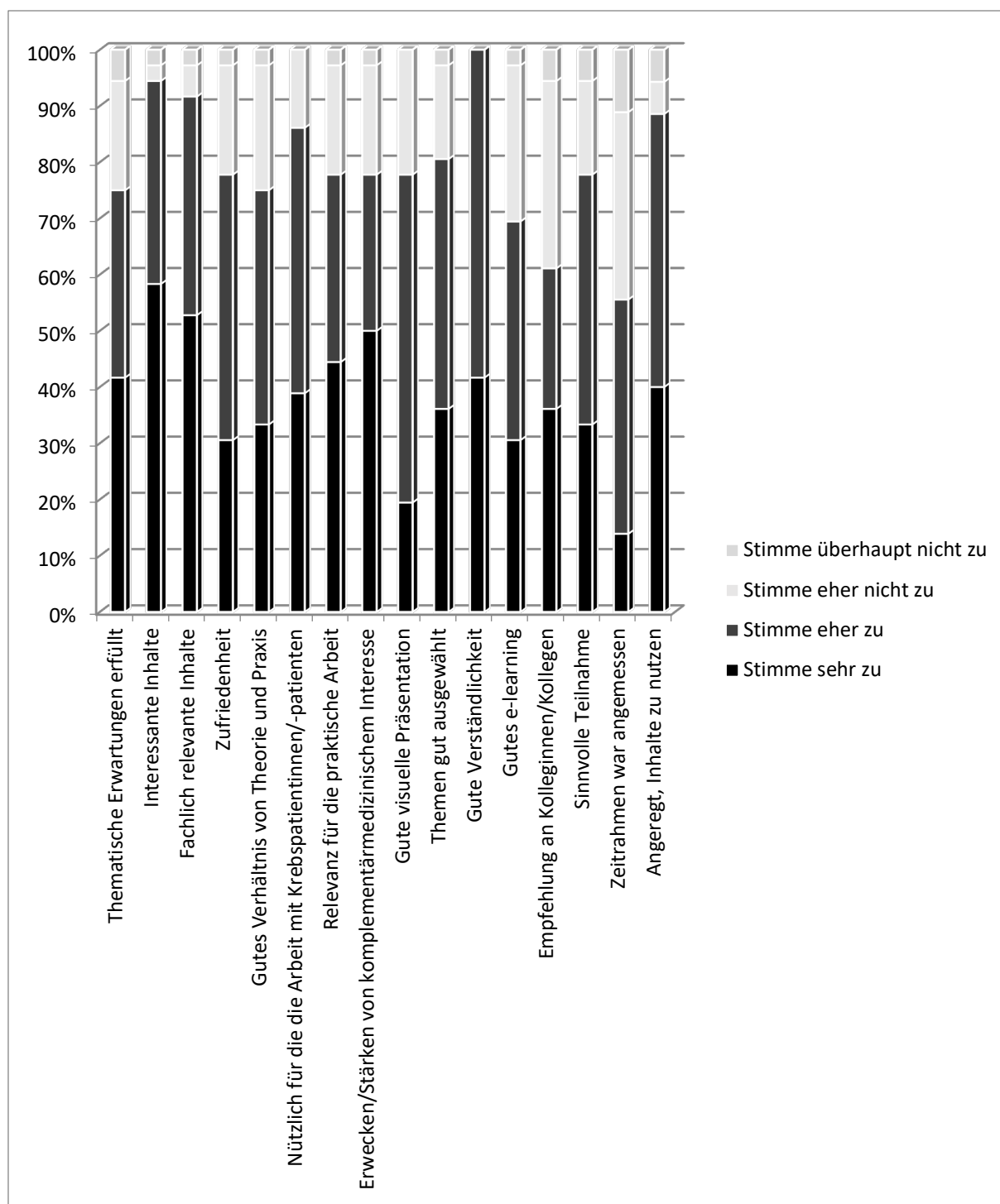


Abbildung 6: Evaluation des e-Learnings vom KOKON-KTO Training (30)

4 Diskussion

In der vorliegenden Arbeit wurden vier Strategien und Ansätze zur Implementierung und Evaluation systematisch entwickelter Konzepte für komplementärmedizinische und integrative Konsultationen für Krebspatientinnen und -patienten in der

Routineversorgung entwickelt, implementiert und evaluiert. Im Einzelnen umfassten die vier Projekte (Outcomes und Outcome-Messungen zur Evaluation von Kommunikationstrainings in der Onkologie (23), Bildungskompetenzen für die integrative Onkologie (24), Kriterien zur Identifikation seriöser Anbietender komplementärmedizinischer Verfahren (27), KOKON-KTO Framework zur Führung komplementärmedizinischer Konsultation durch onkologisch tätige Ärztinnen und Ärzte (30)) verschiedene Strategien wie der Determinantenbestimmung erfolgreicher Implementierungen in die praktisch-onkologische Tätigkeit (z.B. zeitliche Rahmenbedingungen; Adaptation an den individuellen Kommunikationsstil; geringe Schwelle zu Trainingszugängen) oder den Einbezug verschiedener Stakeholdergruppen (31) in Studiendesign und -ausführung zur Implementierung komplementärmedizinischer Konsultationen in die Routineversorgung der Onkologie.

In dieser Arbeit konnten Kriterien zur Identifikation seriöser Anbietender komplementärmedizinischer Verfahren in einem interprofessionellen und internationalen Konsensusprozess unter Einbezug relevanter Stakeholdergruppen entwickelt werden und so eine praktische Implementierung der Kriterien eingeleitet werden. Die Ergebnisse dieses Projekts wurden an onkologisch tätige Ärztinnen und Ärzte sowie Kliniken distribuiert und Kooperationen mit Krebsselfhilfegruppen wurden etabliert. Durch die Involvierung einer großen deutschen Krankenkasse wurden die Ergebnisse über diverse Plattformen Patientinnen und Patienten zur Verfügung gestellt. Die umfassende Liste von acht obligatorischen Kriterien kann nicht nur als unterstützende Maßnahme in Patientinnen und Patienten-Navigationssystemen in der integrativen Onkologie dienen, sondern auch Ärztinnen und Ärzte unterstützen, welche nicht direkt auf komplementärmedizinische Anbietende verweisen können. Somit unterstützt die Liste, qualitätsrelevante Faktoren in der komplementärmedizinischen Versorgung Patientinnen und Patienten näherzubringen und kann als praktisches Material auch Selbsthilfegruppen und Informationsdiensten zur Verfügung gestellt werden (27).

Die entwickelten Empfehlungen zur Evaluation von Outcomes und Outcome-Messungen (23) sowie der Bildungskompetenzen für die integrative Onkologie (24) konnten in die Entwicklung des KOKON-KTO-Trainings (30) überführt werden. Als weiteres Ergebnis dieser Arbeit entspricht das entwickelte KOKON-KTO-Konsultationsmanual nicht nur evidenzbasierten Empfehlungen aus dem Bereich der

integrativen Onkologie (19), sondern auch den aus der Literatur entnommenen Bedürfnissen (32-34) von onkologisch tätigen Ärztinnen und Ärzten, sodass von einer guten Implementierbarkeit auf Ärztinnen/Ärzte-Level ausgegangen werden kann. Auch die Evaluation des KOKON-KTO Trainings durch Simulationspatientinnen und externe Bewertende zeigte positive Ergebnisse, sodass auch von einer guten Implementierbarkeit auf Patientinnen/Patienten-Level ausgegangen werden kann.

Als deutliche Stärke dieser Arbeit kann der systematische, evidenzbasierte Forschungsansatz hervorgehoben werden. Neben dem Einbezug der Bedürfnisse und Präferenzen von Patientinnen und Patienten wurden ebenfalls die klinische Expertise als auch die aus der Literatur entnommene Evidenz komplementärmedizinischer Konsultationen in der Onkologie für die Entwicklung, Implementierung und Evaluation der vorgestellten Studien betrachtet. Neben klaren Implementierungsstrategien und -ansätzen, die von Beginn jedes Projekts federführend für das Vorgehen galten, konnten des Weiteren systematische Entwicklungsprozesse unter Einbezug interprofessioneller und internationaler Expertinnen und Experten verfolgt werden. Aus einer systematischen Literaturübersicht geht hervor, dass über zwei Drittel der Trainingsprogramme in der integrativen Onkologie lediglich zu Forschungs- oder Evaluationszwecken dienen (35). Die in dieser Arbeit gezeigten Forschungsergebnisse konnten bereits unter anderem in das KOKON-KTO Training (30) implementiert, Fachgesellschaften zur Verfügung gestellt (36) und in der randomisiert kontrollierten, prospektiven, multizentrischen KOKON-KTO Studie (26) ausgeführt werden.

Die in dieser Arbeit vorgestellten Studien haben auch Schwächen. Während Implementierungsprojekte die Frage nach dem „Wie“ (z.B. Umsetzbarkeit, Machbarkeit) untersuchen, fokussieren klassische klinische Studien die Frage nach dem „Was“ (Wirksamkeit, Innovationsentwicklung) (37). In dieser Arbeit wurden beide Aspekte zusammengeführt, was oftmals zu Kompromissen in der Studienaufführung führte. Zum einen führte die Neuartigkeit der einzelnen Projekte dazu, nicht auf bestehende evidenzbasierte Standards von Trainings in der integrativen Onkologie zurückgreifen zu können, sodass beispielsweise der Fokus auf onkologisch tätige Ärztinnen und Ärzte in der Entwicklung des KOKON-KTO Konsultationsmanuals gelegt wurde (Wirksamkeit), jedoch andere Gesundheitsberufe wie die Pflege zunächst außen vor gelassen wurden, welche in der onkologischen Versorgung eine

tragende Rolle einnehmen (Umsetzbarkeit). Die praktische Umsetzung des KOKON-KTO Frameworks außerhalb der ärztlichen Profession gilt es daher zukünftig zu untersuchen. Dennoch konnten auch hier Aspekte der Implementationswissenschaften eingefügt werden, sodass auf die spezifischen Rahmenbedingungen der onkologischen Praxis eingegangen werden konnte (z.B. Zeitrahmen einer Konsultation). Die leitfadengetreue Durchführung des KOKON-KTO Konsultationsmanuals wurde zwar im KOKON-KTO Training untersucht und evaluiert, jedoch nicht in weiteren Konsultationen durch die onkologisch tätigen Ärztinnen und Ärzte in ihren individuellen beruflichen Umgebungen (30). Um dies zu prüfen, wurden die Ergebnisse dieser Arbeit in eine randomisiert kontrollierte, multizentrische Studie implementiert (26) und das Anliegen dieser Arbeit, nämlich die Überbrückung der vorliegenden Science-Practice-Gap in der integrativen Onkologie, fortgesetzt.

Auch die in dieser Arbeit entwickelten Kriterien wurden zwar zur Implementierung vorbereitet, von einer klinischen Anwendung kann wohlmöglich erst bei erfolgreicher Implementierung der Kriterien in gängige Leitlinien gesprochen werden (38). Selbiges gilt für die Arbeiten zu den entwickelten Outcomes und Outcome-Messungen (23) sowie den Bildungskompetenzen in der integrativen Medizin (24). Es handelt sich hierbei um relevante Forschungsfragen, welche die Implementierbarkeit zwar stets im Sinn hatten, diese Strategien jedoch außerhalb dieser Arbeit bislang nur bedingt überprüfen konnten und somit eher als Ansätze zu betrachten sind. Für einen evidenzbasierten Fortschritt im Bereich der integrativen Onkologie ist es zukünftig wichtig, die Ergebnisse dieser Arbeiten im wissenschaftlichen Netzwerk (scientific community) zu verbreiten und in weitere Studien zu implementieren (10). Im Sinne des Ziels dieser Arbeit wurden die Ergebnisse der Projekte anschließend open-access verschiedenen Anbietendengruppen frei zur Verfügung gestellt (39) sowie in das integrative Training der Arbeitsgemeinschaft Gynäkologische Onkologie (Kommission integrative Medizin) zum Zertifizierungskurs integrative Medizin eingebettet (36).

Im Rahmen dieser Arbeit wurden jeweils erstmalig Empfehlungen zur Evaluation von Outcomes und Outcome-Messungen in Kommunikationstrainings in der Onkologie (23), relevante Bildungskompetenzen in der integrativen Onkologie (24), Kriterien zu seriösen Anbietenden komplementärmedizinischer Verfahren (27), ein ärztliches

Training zur Führung komplementärmedizinischer Konsultationen (30), entwickelt. Durch Anwendung diverser Implementierungsstrategien können die Ergebnisse dieser Arbeit dazu beitragen, eine Brücke in der Kommunikation zwischen Ärztinnen/Ärzten und Patientinnen/Patienten bezüglich komplementärmedizinischer Verfahren zu schlagen und ärztliche sowie patientenzentrierte Kompetenzen in diesem Bereich zu erweitern. Zukünftige Studien sollten das KOKON-KTO Framework um interkulturelle Kompetenzen und weitere Gesundheitsberufe wie Pflegende oder die Psychoonkologie erweitern, um die multidimensionale Kommunikationsachse der Onkologie praxis-relevant abzeichnen zu können (30).

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6 Eidesstaatliche Versicherung/Anteilserklärung

„Ich, Alizé A. Rogge, versichere an Eides statt durch meine eigenhändige Unterschrift, dass ich die vorgelegte Dissertation mit dem Thema: „Strategien und Ansätze zur Implementierung komplementär- und integrativmedizinischer Konsultationen in die Krebsversorgung von Patientinnen und Patienten“ selbstständig und ohne nicht offengelegte Hilfe Dritter verfasst und keine anderen als die angegebenen Quellen und Hilfsmittel genutzt habe. Alle Stellen, die wörtlich oder dem Sinne nach auf Publikationen oder Vorträgen anderer Autoren/innen beruhen, sind als solche in korrekter Zitierung kenntlich gemacht. Die Abschnitte zu Methodik (insbesondere praktische Arbeiten, Laborbestimmungen, statistische Aufarbeitung) und Resultaten (insbesondere Abbildungen, Graphiken und Tabellen) werden von mir verantwortet. Ich versichere ferner, dass ich die in Zusammenarbeit mit anderen Personen generierten Daten, Datenauswertungen und Schlussfolgerungen korrekt gekennzeichnet und meinen eigenen Beitrag sowie die Beiträge anderer Personen korrekt kenntlich gemacht habe (siehe Anteilserklärung). Texte oder Textteile, die gemeinsam mit anderen erstellt oder verwendet wurden, habe ich korrekt kenntlich gemacht.

Meine Anteile an etwaigen Publikationen zu dieser Dissertation entsprechen denen, die in der untenstehenden gemeinsamen Erklärung mit dem/der Erstbetreuer/in, angegeben sind. Für sämtliche im Rahmen der Dissertation entstandenen Publikationen wurden die Richtlinien des ICMJE (International Committee of Medical Journal Editors; www.icmje.org) zur Autorenschaft eingehalten. Ich erkläre ferner, dass ich mich zur Einhaltung der Satzung der Charité – Universitätsmedizin Berlin zur Sicherung Guter Wissenschaftlicher Praxis verpflichte.

Weiterhin versichere ich, dass ich diese Dissertation weder in gleicher noch in ähnlicher Form bereits an einer anderen Fakultät eingereicht habe.

Die Bedeutung dieser eidesstattlichen Versicherung und die strafrechtlichen Folgen einer unwahren eidesstattlichen Versicherung (§§156, 161 des Strafgesetzbuches) sind mir bekannt und bewusst.“

Datum:

Unterschrift: _____
Alizé A. Rogge

Alizé A. Rogge hatte folgenden Anteil an den aufgelisteten Publikationen:

Publikation 1: Fischer F, Helmer SM, **Rogge AA**, Arras JI, Buchholz A, Hannawa A, Horneber M, Kiss A, Rose M, Söllner W, Stein B, Weis J, Schofield P, Witt CM. Outcomes and outcome measures used in evaluation of communication training in oncology – a systematic literature review, an expert workshop, and recommendations for future research. *BMC Cancer*, 2019; 19(1): 808. doi: 10.1186/s12885-019-6022-5

Beitrag im Einzelnen

Konzeption der Studie: Die Promovendin unterstützte in der Konzeption der Studie, indem sie basierend auf dem KOKON-Projektantrag gemeinsam mit den Ko-Autorinnen und -Autoren den Aufbau der Studie (Literaturrecherche – Workshop - Konsensusprozess) strukturierte und Zeitpläne setzte.

Literaturrecherche: Die Promovendin unterstützte in der Literaturrecherche, in dem sie selbstständig (s. Abbildung 1 der Dissertation) die einzelnen Arbeitsschritte einer Literaturrecherche durchführte und gemeinsam mit dem Erst-Autor des Manuskripts die Ergebnisse diskutierte und für den folgenden Workshop aufbereitete.

Datenauswertung und Methodik: Die Promovendin diskutierte gemeinsam mit den Ko-Autorinnen und -Autoren des Manuskripts die Ergebnisse des Workshops sowie die daraus resultierenden Empfehlungen.

Erstellung des Manuskripts: Die Promovendin diskutierte kritisch gemeinsam mit den Ko-Autorinnen und -Autoren des Manuskripts die Erstversion und fügte Anmerkungen in das Manuskript ein.

Überarbeitung des Manuskripts im Rahmen des Peer-Review Prozess: Die Promovendin begutachtete kritisch die Erstversion der Antworten an die Reviewenden sowie die Änderungen in der Erstversion des Manuskripts und machte hierzu Anmerkungen, welche an den Erstautor gesendet wurden.

Publikation 2: Witt CM, Balneaves LG, Carlson LE, Cohen, M, Deng G, Fouladbakhsh JM, Kinney AY, Mehta A, Mailman J, Pole L, **Rogge AA**, O'Toole C, Zick SM, Helmer SM. Education Competencies for Integrative Oncology-Results of a Systematic Review

and an International and Interprofessional Consensus Procedure [published online ahead of print, 2020 Aug 11]. J Cancer Educ. 2020;10.1007/s13187-020-01829-8.doi:10.1007/s13187-020-01829-8

Beitrag im Einzelnen

Literaturrecherche: Die Promovendin unterstützte in der Literaturrecherche und führte ab den Volltext-Versionen die Datenextraktion eigenständig und parallel zur Ko-Autorin durch. Anschließend verglich sie die Ergebnisse mit denen der Ko-Autorin und diskutierte diese kritisch.

Datenauswertung und Methodik: Die Promovendin unterstützte in der Datenauswertung des Delphi-Konsensus-Prozesses, in dem sie die Schwellenwerte (Threshold) gemeinsam mit den Ko-Autorinnen und -Autoren diskutierte und festlegte.

Erstellung des Manuskripts: Die Promovendin diskutierte kritisch gemeinsam mit den Ko-Autorinnen und Autoren des Manuskripts die Erstversion und fügte Anmerkungen in das Manuskript ein. Sie übernahm die administrative Einreichung beim wissenschaftlichen Journal eigenständig und verfasste den ersten Entwurf des Anschreibens zum Einreichen des Manuskripts.

Überarbeitung des Manuskripts im Rahmen des Peer-Review Prozess: Die Promovendin erstellte einen Entwurf des Antwortschreibens an die Reviewenden und diskutierte diesen mit der Betreuerin dieser Arbeit. Nach Einfügen der Anmerkungen durch die Ko-Autorinnen und -Autoren reichte sie die überarbeitete Version des Manuskripts ein.

Publikation 3: Rogge AA, Baur I, Blettner G, Holtkamp U, Horneber M, Jahn P, Joos S, Keberle S, Kettelgerdes A, Klemperer D, Längler A, Voiß P, Weis J, Witt CM. Defining Criteria for Guiding Cancer Patients to Find a Reputable Complementary Medicine Provider: Results of a Literature Review and a Consensus Procedure. Patient Preference Adherence. 2020;14:747-755. doi:10.2147/PPA.S230705

Beitrag im Einzelnen

Konzeption der Studie: Die Promovendin koordinierte die Studie in Zusammenarbeit mit den weiteren Teammitgliedern. Sie kontaktierte die Ko-Autorinnen und -Autoren zur Mitarbeit an dieser Studie sowie die Teilnehmenden der Evaluationsphase selbstständig.

Literaturrecherche: Die Promovendin hat eine systematische Literaturrecherche zur Identifikation bereits bestehender Kriterien zur Vorbereitung des Delphi-Konsensus-Prozess eigenständig durchgeführt. Sie erfragte ergänzende Literatur bei den Ko-Autorinnen und -Autoren an und fügte diese der Literaturrecherche bei. Sie bereitete die Ergebnisse für den darauffolgenden Delphi-Konsensusprozess nach Diskussion und Begutachtung durch die Betreuerin vor.

Datenauswertung und Methodik: Die Promovendin entwickelte in Diskussion mit der Betreuerin das methodische Vorgehen. Die Promovendin koordinierte den Delphi-Konsensus-Prozess in jeder Phase und bereitete die Ergebnisse aus den Diskussionsrunden und anonymen Surveys auf. Sie kontaktierte entsprechende Stakeholder für den Evaluationsprozess und bereitete die Ergebnisse zur finalen Darstellung vor. Sie führte hierbei eigenständig die Datenanalyse sowohl qualitativ als auch quantitativ durch, hierbei harmonisierte sie die verschiedenen Datensets aus dem Delphi-Konsensus-Prozess und der Evaluation mit dem Statistikprogramm SPSS bzw. durch eine Inhaltsanalyse nach Flick.

Ergebnisdarstellung: Die Darstellung der Ergebnisse wurde von der Promovendin vorgeschlagen und in Abstimmung mit den Ko-Autorinnen und -Autoren für die Publikation aufbereitet. Alle Tabellen und Graphiken wurden hierbei eigenständig von der Promovendin erstellt. Des Weiteren hat die Promovendin in Abstimmung mit den Ko-Autorinnen und -Autoren alle Ergebnisse interpretiert und mit der Betreuerin dieser Arbeit sowie den Ko-Autorinnen und -Autoren diskutiert.

Diskussion und Schlussfolgerung: Die Ergebnisse, Stärken und Schwächen dieser Studie wurden von der Promovendin nach wissenschaftlichen Standards diskutiert und kritisch begutachtet sowie in Zusammenarbeit mit der Betreuerin und den Ko-Autorinnen und -Autoren in den allgemeinen wissenschaftlichen Kontext eingeordnet.

Erstellung des Manuskripts: Ein erster vollständiger Entwurf des Manuskripts wurde von der Promovendin eigenständig verfasst und nach Diskussion mit der Betreuerin an die Ko-Autorinnen und -Autoren zur kritischen Durchsicht versendet. Die anschließend eingehenden Vorschläge wurden von der Promovendin selbstständig bearbeitet und mit der Betreuerin sowie den Ko-Autorinnen und Autoren in das Manuskript eingefügt. Sie führte die administrative Einreichung beim wissenschaftlichen Journal eigenständig durch und verfasste das Anschreiben zum Manuskript für das wissenschaftliche Journal.

Überarbeitung des Manuskripts im Rahmen des Peer-Review Prozesses: Die Promovendin erstellte eigenständig einen Entwurf der Antworten an die Reviewenden und fügte die Anmerkungen der Ko-Autorinnen und -Autoren nach Absprache mit der Betreuerin in die überarbeitete Fassung des Manuskripts ein. Anschließend reichte sie die überarbeitete Version des Manuskripts erneut eigenständig ein.

Publikation 4: Witt CM, Helmer SM, Schofield P, Wastell M, Canella C, Thomae AV, **Rogge AA**. Training oncology physicians to advise their patients on complementary and integrative medicine: An implementation study for a manual-guided consultation. *Cancer*. 2020;126(13):3031-3041. doi:10.1002/cncr.32823

Beitrag im Einzelnen

Konzeption der Studie: Die Promovendin beteiligte sich seit Beginn der Studie und unterstützte bei der Auswahl der Methoden. Die Koordination der Simulationspatientinneninterviews führte sie eigenständig durch.

Literaturrecherche: Die Promovendin supervidierte die systematische Literaturrecherche und diskutierte kritisch die Ergebnisse dieser. Sie war an der Aufbereitung der Ergebnisse maßgeblich beteiligt. Sie entwickelte hierbei in Absprache mit den Ko-Autorinnen die methodische Vorgehensweise.

Methodik und Datenanalyse: Die Promovendin erstellte mit den Ko-Autorinnen projektspezifische Fragebögen zur Evaluation des KOKON-KTO Frameworks. Sie entwickelte Teile des e-Learnings und programmierte diese für die Teilnehmenden des KOKON-KTO Trainings. Sie unterstützte in der Entwicklung des Skills-Training-Workshops und entwickelte hierzu mit der Betreuerin und den Ko-Autorinnen dieser

Arbeit alle Trainingsmaterialien. Sie führte die qualitativen Interviews und deren Analyse durch.

Ergebnisdarstellung: Die Promovendin bereitete die Ergebnisse der Studie mit den Ko-Autorinnen für das Manuskript vor. Die Abbildungen, Grafiken und Tabellen wurden von der Promovendin eigenständig erstellt.

Erstellung des Manuskripts: Ein erster vollständiger Entwurf des Manuskripts wurde von der Promovendin eigenständig verfasst und nach Überarbeitung durch die Betreuerin an die Ko-Autorinnen und -Autoren zur Durchsicht versendet. Die eingehenden Vorschläge wurden von der Promovendin selbstständig bearbeitet und mit der Betreuerin sowie den Ko-Autorinnen in das Manuskript eingefügt. Sie führte die administrative Einreichung beim wissenschaftlichen Journal eigenständig durch, verfasste das Anschreiben zum Einreichen des Manuskripts bei dem wissenschaftlichen Journal eigenständig unter Supervision der Betreuerin.

Überarbeitung des Manuskripts im Rahmen des Peer-Review-Prozess: Die Promovendin verfasste eigenständig die erste Version der Antworten an die Reviewenden und diskutierte diese kritisch mit der Betreuerin. Die anschließenden Anmerkungen durch die Ko-Autorinnen fügte die Promovendin in das überarbeitete Manuskript ein und reichte dies nach Überarbeitung durch die Betreuerin erneut ein.

Unterschrift, Datum und Stempel der betreuenden Hochschullehrerin

Unterschrift der Doktorandin

7 Druckexemplare der ausgewählten Publikationen

7.1 Publikation 1

Fischer *et al.* *BMC Cancer* (2019) 19:808
<https://doi.org/10.1186/s12885-019-6022-5>

BMC Cancer

RESEARCH ARTICLE

Open Access

Outcomes and outcome measures used in evaluation of communication training in oncology – a systematic literature review, an expert workshop, and recommendations for future research



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Abstract

Background: Communication between health care provider and patients in oncology presents challenges. Communication skills training have been frequently developed to address those. Given the complexity of communication training, the choice of outcomes and outcome measures to assess its effectiveness is important. The aim of this paper is to 1) perform a systematic review on outcomes and outcome measures used in evaluations of communication training, 2) discuss specific challenges and 3) provide recommendations for the selection of outcomes in future studies.

Methods: To identify studies and reviews reporting on the evaluation of communication training for health care professionals in oncology, we searched seven databases (Ovid MEDLINE, CENTRAL, CINAHL, EMBASE, PsychINFO, PsychARTICLES and Web of Science). We extracted outcomes assessed and the respective assessment methods. We held a two-day workshop with experts ($n = 16$) in communication theory, development and evaluation of generic or cancer-specific communication training and/or outcome measure development to identify and address challenges in the evaluation of communication training in oncology. After the workshop, participants contributed to the development of recommendations addressing those challenges.

Results: Out of 2181 references, we included 96 publications (33 RCTs, 2 RCT protocols, 4 controlled trials, 36 uncontrolled studies, 21 reviews) in the review. Most frequently used outcomes were participants' training evaluation, their communication confidence, observed communication skills and patients' overall satisfaction and anxiety. Outcomes were assessed using questionnaires for participants (57.3%), patients (36.0%) and observations of real (34.7%) and simulated (30.7%) patient encounters. Outcomes and outcome measures varied widely across studies. Experts agreed that outcomes need to be precisely defined and linked with explicit learning objectives of the training. Furthermore, outcomes should be assessed as broadly as possible on different levels (health care professional, patient and interaction level).

(Continued on next page)

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(Continued from previous page)

Conclusions: Measuring the effects of training programmes aimed at improving health care professionals' communication skills presents considerable challenges. Outcomes as well as outcome measures differ widely across studies. We recommended to link outcome assessment to specific learning objectives and to assess outcomes as broadly as possible.

Keywords: Communication training, Evaluation, Oncology, Outcome

Background

Communicating with cancer patients, for example disclosing the diagnosis, discussing treatment and providing emotional support in discussions about end of life, can be challenging [1]. Hence, effective communication skills are considered vital to high quality cancer care [2]. Programmes have been developed and conducted to train physicians and other health care professionals (HCPs) to communicate more effectively with cancer patients [3, 4]. Although intuitively appealing, a recent review of randomized controlled trials investigating the benefit of communication skill training (CST) showed mixed results. While an improvement in HCPs' communication skills was reported for some programmes, effects on patient-reported outcomes, such as psychological distress or quality of life, have not been established yet [5]. This was also reported in earlier reviews [6, 7]. Nonetheless, experts agree that the ultimate objective of clinician-patient communication training is to improve patient outcomes, such as adherence, self-efficacy health-related quality of life [6].

The choice of appropriate outcomes and the instrument to measure these (outcome measures) is critical to accurately assess the effectiveness of CST [8, 9]. It has been demanded to closely link outcomes with the content of the CST, to use only validated scales as outcome measures and to assess long-term effects of the intervention [10]. This can be challenging as outcomes directly linked to an intervention (proximal outcomes) might be considered less relevant as distal outcomes, particularly for long-term follow-up [11], and validated scales are sparse for narrowly defined outcomes. Eventually, many different outcome measures have been developed and used in the past, and as a result, there are no standards for appropriate evaluation (i.e., methodology and measurement) of clinician-patient communication training in oncology.

Therefore, this paper aims to

1. Provide an overview of the outcomes and outcome measures as well as the respective assessment methods used for CST in oncology,
2. Identify challenges that have been encountered in the evaluation of CST in oncology,
3. Provide recommendations to address these challenges in future research.

To achieve these aims, we 1) performed a systematic review of the literature and identified outcomes and outcome measures that have been used to evaluate the effects of CST, 2) convened a workshop involving international experts to discuss challenges in assessing outcomes of CSTs to complement the review and 3) developed recommendations to address these challenges in future evaluations of CSTs.

Methods

Systematic review

We conducted a systematic review to identify outcomes assessed as well as the respective outcome measures used in the field. We specified a protocol, which is available at <https://tinyurl.com/yd5hyggt>. We searched seven electronic databases (Ovid MEDLINE, CENTRAL, CINAHL, EMBASE, PsychINFO, PsychARTICLES and Web of Science) in December 2016 for publications reporting on the effects of standardized CST in oncology. In addition, we hand-searched reference lists of the 21 identified reviews for relevant studies missed by our search.

We combined search terms describing aspects of physician-patient relations that are common goals of CST (communication, empathy, interaction, ...) with terms describing structured programmes (course, curriculum, training, ...). Search terms were informed by previous reviews [4, 5, 8, 9, 12], which mainly investigated the effects of standardized communication trainings. We used MeSH terms and limits to restrict the results to trials and observational studies in adult cancer patients, depending on the respective database. Explicit search terms are listed in Table 1.

Inclusion criteria were interventional or observational studies or reviews, which assessed the effects or evaluated standardized CST tailored to physicians and/or other health care professionals focusing on communication with adult cancer patients. In addition, these needed to be published in a scientific outlet or as publicly available reports, working papers or theses. Publications were excluded if the outcome assessment was not standardized in the specific study, e.g., not all participants were evaluated using the same method, or if the publication was available in neither English nor German.

One reviewer (FF) checked all references found in the literature search and excluded clearly irrelevant articles based on titles and abstracts. We obtained full text

Table 1 Search terms for MEDLINE search

Search terms	Limiters
((AB (communicat* OR empath* OR 'interaction' OR 'interpersonal' OR 'interview' OR 'patient relation' OR 'shared decision making') OR TI (communicat* OR empath* OR 'interaction' OR 'interpersonal' OR 'interview' OR 'patient relation' OR 'shared decision making'))AND (AB (teach* OR session OR educat* OR program* OR instruction OR curriculum OR course OR training OR workshop OR skills) OR TI (teach* OR session OR educat* OR program* OR instruction OR curriculum OR course OR training OR workshop OR skills)) AND (AB (evaluation OR assessment OR effects OR study OR trial OR investigation) OR TI (evaluation OR assessment OR effects OR study OR trial OR investigation)))) AND MM "Neoplasms"	Abstract Available; Human; Age Related: Young Adult: 19–24 years, Adult: 19–44 years, Middle Aged: 45–64 years, Middle Aged + Aged: 45 + years, Aged: 65+ years, Aged, 80 and over, All Adult: 19+ years; Subject Subset: Cancer; Publication Type: Clinical Trial, Clinical Trial, Phase I, Clinical Trial, Phase II, Clinical Trial, Phase III, Clinical Trial, Phase IV, Comparative Study, Controlled Clinical Trial, Evaluation Studies, Meta-Analysis, Multicenter Study, Randomized Controlled Trial, Review, Validation Studies; Language: English, German

copies from all remaining articles and two reviewers (FF, AR) assessed those independently for eligibility. We assessed the agreement of their selections by calculating the kappa statistic. We excluded publications when both reviewers agreed. We documented reasons for exclusion and resolved disagreements by discussion. If several reports for a single study were identified, all publications were reviewed for eligibility.

We grouped outcome measures in original research into the respective underlying constructs, and counted the frequency of their use. Along with information about the outcomes assessed, we extracted the study design, sample size, target group and intervention characteristics. As the results of the included studies were not of interest, we did not assess the risk of bias.

As reviews on the efficacy of CST potentially contained relevant information about challenges in outcome choice and outcome measurement, we included them in our review. We extracted and qualitatively synthesized arguments regarding outcomes and the respective outcome measures. To avoid redundancy, we did not extract information about outcomes and outcome measures used in primary data from the reviews.

In general, we followed the PRISMA reporting guidelines [13], although some items were not applicable given the scope of the review.

Expert workshop

We held a two-day workshop in Berlin, Germany in February 2017. The aim of the workshop was to complement the systematic review by identifying challenges in the evaluation of communication training in oncology and to discuss ways to address those challenges in future research.

We invited researchers from the "Kompetenznetzwerk Komplementärmedizin in der Onkologie" KOKON, who investigate communication about complementary medicine, to the workshop. We also defined fields for which we sought additional expertise. These fields were communication theory, development and evaluation of generic or cancer-specific communication training and/or outcome measure development. Experts in these fields

were identified based on their occurrence in the review as well as through suggestions by other invited researchers. Overall, 16 experts, including a patient representative, took part in the workshop (see Table 2).

We organised the workshop into four parts:

1. Participants shared their perspectives and experiences regarding development and evaluation of communication trainings. In this part, we posed four broad questions: (a) what are good practices when communicating with oncology patients, (b) what are the desirable effects of good communication, (c) how one can generally assess quality of communication, and (d) what are experiences from evaluations of CST. Additionally, we presented preliminary results of the review. Participants wrote Issues elicited that were important for a valid assessment/evaluation of CST on cards.
2. The participants then clustered those cards on a board into broader topics to identify areas that needed to be considered when measuring the effects of CST. Then, we identified three main topics for further discussion.
3. The members participated in structured, small group discussions focusing on the three topics. We assigned participants to one of the three groups. Each group discussed one of the three topics for 20 min prior to rotating to the next group. Three 'discussion leaders' were each assigned to one of the three topics to guide the small group discussion.
4. Discussion leaders presented the results obtained in step 3 to the entire group, and we discussed these results in a plenary session.

Development of expert recommendations

After the workshop, we drafted recommendations for future evaluations of communication training in oncology based on the results of the systematic review as well as the experts' discussions. We invited workshop participants to comment on the recommendations during

Table 2 Participants in the expert workshop

Participant	Affiliation	Country
Juan Ignacio Arraras	Complejo Hospitalario de Navarra, Radiotherapeutic Oncology Department & Medical Oncology Department, Pamplona	Spain
Angela Buchholz	Department of Medical Psychology, University Medical Center Hamburg-Eppendorf	Germany
Felix Fischer	Department of Psychosomatic Medicine, Center for Internal Medicine and Dermatology, Charité – Universitätsmedizin Berlin	Germany
Corina Güthlin	Institute of General Practice, Johann Wolfgang Goethe University, Frankfurt/Main	Germany
Stefanie Helmer	Institute for Social Medicine, Epidemiology and Health Economics, Charité – Universitätsmedizin Berlin	Germany
Annegret Hannawa	Center for the Advancement of Healthcare Quality and Patient Safety (CAHQS), Faculty of Communication Sciences, Università della Svizzera Italiana, Lugano	Switzerland
Markus Horneber	Department of Internal Medicine, Divisions of Pneumology and Oncology/Hematology, Paracelsus Medical University, Klinikum Nuernberg	Germany
Ulrike Holtkamp	German Leukemia & Lymphoma Patients' Association	Germany
Alexander Kiss	Department of Psychosomatic Medicine, University Hospital Basel	Switzerland
Christin Kohrs	Department of Internal Medicine, Division of Oncology and Hematology, Paracelsus Medical University, Klinikum Nuernberg	Germany
Darius Razavi	Psychosomatic and Psycho-Oncology Resarch Unit, Université Libre de Bruxelles, Brussels	Belgium
Matthias Rose	Department of Psychosomatic Medicine, Center for Internal Medicine and Dermatology, Charité – Universitätsmedizin Berlin	Germany
Jan Schildmann	Institute for History and Ethics of Medicine, Martin Luther University Halle-Wittenberg	Germany
Penelope Schofield	Department of Psychology, Swinburne University, Melbourne	Australia
Barbara Stein	Department of Internal Medicine, Division of Oncology and Hematology, Paracelsus Medical University, Klinikum Nuernberg	Germany
Claudia Witt	Institute for Complementary and Integrative Medicine, University Hospital Zurich and University of Zurich	Switzerland

manuscript preparation, and the recommendations were adapted until no further comments were made.

Results

Systematic review

Search results

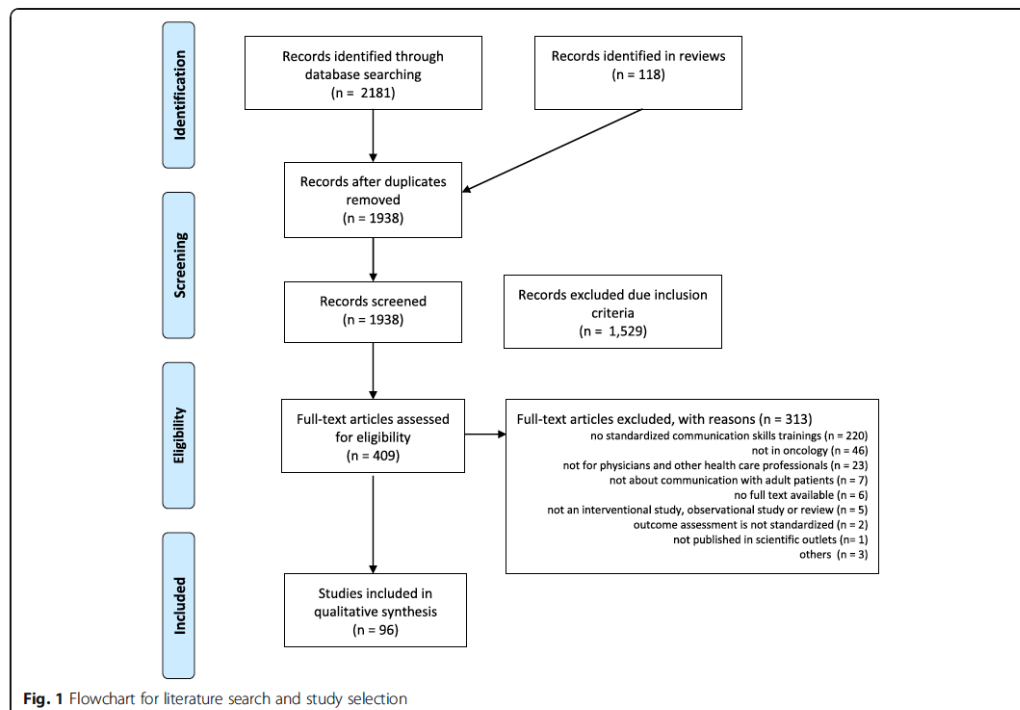
Overall, our search retrieved 2181 references. We identified an additional 118 references by examining reference lists in identified reviews on communication training. After removing duplicates, we screened 1938 abstracts and excluded 1529 because they did not fulfill inclusion criteria, leaving 409 references for full text analysis. Of these, 313 publications did not fulfill inclusion criteria and were therefore excluded, leaving 96 publications for inclusion in the review. The agreement on exclusion between reviewers was moderate ($\kappa = 0.56$), with consistent decisions on 351 articles. All conflicts were resolved through discussion. We give the detailed reasons for the exclusion of references in Fig. 1.

Included studies

Of the 96 publications found eligible for synthesis, 33 reported on randomized controlled trials (RCTs), 2

were RCT protocols of so far unpublished trials, 4 were controlled trials (group allocation not randomized), 36 were uncontrolled studies and 21 were reviews.

The number of participants included in studies reporting on primary data ranged from 3 to 515, with 50% of studies reporting sample sizes between 30 and 114. The participants of the CST were physicians in 51% of the studies, nurses in 36%, mixed health care providers (mostly physicians and nurses) in 11% and other health care professionals (e.g., speech therapists) in 3%. Out of 33 RCTs, 19 compared participants of a CST with a waiting list control group, 7 compared different forms of CST, e.g., workshops of varying length or by adding consolidation workshops, 6 compared a CST to a no training condition, and in one RCT, it was unclear whether the control group received any intervention. Two of the four controlled trials compared interventions with a waiting list, whereas 1 compared a basic with an extended intervention, and 1 study compared performance of the same sample before and after completing the intervention. In the uncontrolled studies, 33 of 36 followed a pre-post design, comparing outcomes before



and after the intervention, while 3 assessed outcomes only after the intervention.

Overview of outcomes

The articles reporting primary data and study protocols reported on average 3.2 (sd = 2.2, range = 1–10) distinct outcome measures. 43 (57.3%) articles reported outcome data collected from CST programme participants, 27 (36.0%) from patients of the programme participants, 26 (34.7%) reported on observations of real and 23 (30.7%) on simulated communication encounters, and 9 (12%) reported on other types of outcome measures. Approximately half of the studies (37/49.3%) reported data from one of these sources only, one-third (25/33.3%) two sources, 11 (14.7%) three sources and 2 (2.7%) four sources.

CST participant questionnaires

Overall, 43 studies (11 RCTs, 2 RCT protocols, and 25 trials/observational studies) reported 93 outcomes collected with questionnaires for CST participants. The most frequently reported data were from training evaluation questionnaires, followed by questionnaires obtaining self-ratings on aspects of the respondents'

communication (communication confidence (16), communication self-effectiveness (4), communication skills (3), communication practice (1)) and respondents' distress/burnout (16). The outcomes and the respective instruments are listed in Table 3.

Patient questionnaires

A total of 26 studies (18 RCTs, 2 RCT protocols of so far unpublished trials, and 6 trials/observational studies) reported on 84 (35 unique constructs) outcomes collected with questionnaires for patients of CST participants. Most frequently, patients' overall satisfaction was assessed (12), followed by anxiety (10), generic quality of life (6) and depression (5). All outcomes assessed and the respective instruments are listed in Table 4.

Observations of real patient encounters

A total of 26 articles (14 RCTs, 2 RCT protocols, and 10 trials/observational studies) reported on observations of real patient encounters. Outcomes assessed were communication skills, e.g., supportive utterances or eliciting patients' thoughts [14–16, 52, 54, 55, 83, 87, 90, 91, 101, 104, 110–118], actual content of the interview [41, 42, 104, 116] and shared decision making behaviour [17, 73].

Table 3 Outcomes and respective measures for the assessment of training participants

Outcome construct	Outcome measure	Number of studies	References
Training evaluation	purpose built	25	[14–38]
Communication confidence	Baile's Questionnaire [39]	16	[20, 22, 39, 40]
	Fallowfield's Questionnaire [30]		[30, 41, 42]
	modified Communication Outcomes Questionnaire [43]		[39]
Distress	purpose built	16	[16, 23, 26, 28, 30, 33, 40, 44–46]
	General Health Questionnaire [47]		[21, 22]
	Maslach Burnout Inventory [48]		[17, 19, 20, 22, 35, 49, 50]
	Nursing Stress Scale [51]		[35, 50, 52, 53]
Communication self- effectiveness	purpose built	4	[54, 55]
	modified Communication Outcomes Questionnaire [43]		[56–58]
Attitudes towards cancer	purpose built	3	[50]
	Physician Psychosocial Belief Scale [59]		[46]
Communication skills	purpose built using a semantic differential [60]	3	[52, 53]
	modified Nurses' Basic Communication Skills Scale [61]		[58]
	Perception of the Interview Questionnaire [62]		[52]
Implementation of training elements in practice	purpose built	3	[33]
	purpose built		[28, 29, 46]
Expectations on the consultation	modified Communication Outcomes Questionnaire [43]	3	[39, 58]
	purpose built		[16]
Satisfaction with consultation given	purpose built	3	[16, 52, 56]
Communication practices within the department	purpose built	2	[23, 36]
Anxiety	State-Trait Anxiety Inventory [63]	1	[56]
Attitudes towards caring	Attitudes Towards Caring for Patients Feeling Meaninglessness instrument	1	[34]
Attitudes towards dying	Frommelt Attitude Towards Care of the Dying [64]	1	[34]
Attitudes towards clinician-patient-relationship	Doctor-Patient rating [65]	1	[25]
Confidence in information provision	purpose built [66]	1	[17]
Coping	purpose built	1	[36]
Empathy	Test of Empathic Capacity [67]	1	[25]
Knowledge	purpose built	1	[29]
Patient-centeredness	Words emotionally related to dying test [68] ^a	1	[46]
Perceived support	Nurses' Self-Perceived Support Scale [69]	1	[58]
Clinician-patient relationship	Nurse-Patient Relationship Inventory [70] ^a	1	[50]
Sense of coherence	Sense of Coherence-13 [71]	1	[34]
Shared decision-making behaviour	Mapping-Q [72]	1	[73]
Social support	purpose built	1	[36]
Truth-telling preference	Truth Telling Questionnaire [74]	1	[75]

^areference could not be retrieved

Table 4 Outcomes and respective measures for the assessment of patients

Outcome construct	Outcome measure	Number of studies	Studies
Satisfaction	adapted Client Satisfaction Questionnaire [76]	12	[77]
	adapted from Korsch et al. [78]		[14]
	Cancer Diagnostic Interview Scale [79]		[80]
	EORTC Cancer Outpatient Satisfaction with Care Questionnaire [81]		[54]
	Medical Interview Satisfaction Scale [82]		[77, 83]
	Patient Satisfaction Questionnaire III [84]		[85]
	Patient Satisfaction with Communication Questionnaire [86]		[41]
Anxiety	purpose built	10	[16, 49, 87, 88]
	Hospital Anxiety and Depression Scale [89]		[50, 55, 90–92]
	State-Trait Anxiety Inventory [63]		[14, 41, 49, 77, 91]
Quality of life	EORTC Quality of Life Questionnaire (QLQ)-C-30 [93]	6	[49, 50, 87]
	EORTC Quality of Life Questionnaire (QLQ)-C-15 Pal [94]		[85]
	Perceived Adjustment to Chronic Illness Scale [95]		[49]
	8 Item Short Form Health Survey (SF 8) [96]		[87]
Depression	Beck Depression Inventory [97]	5	[77, 80]
	Hospital Anxiety and Depression Scale [89]		[50, 55, 90]
Distress	Brief Symptom Inventory	5	[80]
	General Health Questionnaire [47]		[41]
	Hospital Anxiety and Depression Scale [89]		[40, 98]
Empathy	purpose built	3	[80]
	Consultation and Relational Empathy Measure [99]		[98, 100]
Knowledge	purpose built	3	[101]
	Ellis Clinical Trials Knowledge [66]		[14]
	purpose built		[49, 73]
Information and control preference	(modified) Information & Control Preference Scale [102]	3	[14, 49]
	Quality of Care Through the Patients' Eyes (QUOTE-gene-CA) [103]		[104]
Satisfaction with decision	Satisfaction with Decision Scale [105]	3	[14, 49, 98]
Communication skills	Perception of the Interview Questionnaire [62]	2	[52]
	purpose built		[85]
Decisional conflict	Decisional Conflict Scale [106]	2	[14, 98]
Clinician-patient relationship	Nurse-Patient Relationship Inventory [107] ^a	2	[50]
	purpose built		[100]
Quality of care	Palliative Care Outcome Scale [108]	2	[85]
	purpose built		[85]
Shared decision-making behaviour	MAPPIN-Q [72]	2	[73]
	Shared Decision Making Questionnaire [109]		[98]
Trust in clinician	purpose built	2	[40, 101]

^areference could not be verified

Encounters were either audio-recorded (17), video-recorded (10) or both (1), partly transcribed and rated using mostly self-developed or adapted coding systems. In general, each coding system defines a number of behaviours or utterances, and observers rate their occurrence subsequently. Those behaviours are usually derived from a clearly defined model of communication.

For example, the coding system employed by Wilkinson et al. [117] reflects key areas of a nurse interview, and Fukui et al. [55, 87, 90] connects behaviour to the 6 steps of the SPIKES protocol. Only in one paper [113], authors used an established coding scheme without adaptation (MIPS [119]). Publications using the same coding systems were mostly from the same research group.

Several measures were usually taken to ensure the quality of the rating process. These included blinding of the raters, rater training and assessment of inter-rater reliability in the full or a subsample of recorded observations or rater supervision by an experienced rater. In two studies, transcripts were automatically coded using specialized software along with context-specific dictionaries [54, 110].

Observations of simulated patient encounters

A total of 23 references ([13] RCTs, 10 trials/observational studies) reported on observations of simulated patient encounters. Most studies assessed communication skills [15, 18–21, 40, 44, 52, 53, 56, 57, 80, 88, 110, 120–127]. In two studies, the content of the interview was explicitly assessed as the number of elicited concerns specified in the actors role [19] and observed key aspects from guidelines [44]. The reaction to scripted cues [21] and the working alliance [127] were each assessed in one study.

In 10 cases, encounters were video-taped, whereas in 11 they were audio-taped; in 2, it was unclear whether encounters had been recorded. Similar to observations of real patient encounters, in most cases, (20) self-developed or adapted ratings of communication behaviour were assessed [18–20, 57, 75, 80, 120–122, 126]. The most frequently used rating system was an adaption of the Cancer Research Campaign Workshop Evaluation Manual (CRCWEM) [52, 53, 88, 110, 125, 128]. All these studies were conducted by the same research group. Three studies [40, 123, 127] used adapted versions of the Roter Interaction Inventory, and one study [124] assessed communication behaviour using the Medical Interaction Process System MIPS [119].

Other outcomes

A total of 10 outcome measures in 9 studies were assessed using other methods than direct observations of a communication situation or questionnaires for health care professionals or patients. In one case, objective measures (HCPs' heart rate and cortisol level) were used to measure stress [56]. Another strategy was to use open questions on either case vignettes or actual communication encounters to test knowledge on communication models [21, 22, 129] or interview either patients or programme participants [23, 115]. Additionally, observable patient behaviour, such as uptake of a treatment or screening participation [73] or as feedback from simulated patients [24, 44], served as outcome.

Outcome assessments in reviews on the efficacy of CSTs

A total of 21 reviews assessed the efficacy of CST. In 7 of these 21 reviews, the choice of outcome measures in the included studies was not discussed [3, 130–135].

One review commented that the term “communication” was used vaguely and inconsistently across studies [136], and another concluded that studies often did not clearly define which specific communication competencies were addressed by the respective CST [6]. Consequently, these problems hampered the comparability of studies [137]. Hence, it has been suggested that core communication competencies should be defined to guide future research [138], preferably in terms of an overall score with some key dimensions [6]. Such a communication model for a specific domain can be developed, for example, within a meta-synthesis [139]. For example, researchers could identify critical internal and external factors in the domain of breaking bad news that could be used to inform the development of the CST as well as the desired outcome [139]. A key challenge is that it may be impossible to define communication behaviours that are appropriate in all given situations [140].

Outcome assessment must be aligned to the specific aim of the CST [7, 10] with a formal definition of the communication behaviour that is being taught. Some authors argued that a change in patient outcomes is the ultimate goal of communication training [6, 137], but communication training can also be seen as a vital resource for HCPs to reduce work-induced stress [141]. It has been proposed to employ an outcome measurement framework – such as Kirkpatrick's triangle [137], which differentiates different levels of impact of the training, or a more specific framework detailing the possible effects of a communication training in the context of oncology [142].

Although self-reports of the participants have been frequently obtained, these are more prone to bias compared to more objective measurements, e.g., through observation of communication behaviour [136]. Consequently, the latest, most comprehensive Cochrane review on the effects of communication trainings in oncology specifically excludes self-reported outcomes on knowledge and attitudes as those are prone to optimistic bias [5]. Furthermore, generic outcomes, such as overall satisfaction of patients, have been found to be sensitive to ceiling effects, making it difficult to measure improvement through CST [7]. On the other hand, it has been argued that direct observations of clinical encounters can also be biased as this might be intrusive [143]. Arguably, there is a need to assess patient outcomes more frequently [6, 144] and to investigate the impact of an intervention on the whole medical team [144]. However, existing reviews indicated that the effect of CST on patients is small [5, 7]. It is unclear whether this is because of competing influences on patient outcomes or an inappropriate choice of outcome measures.

The reviews agree that it would be desirable to concentrate on a single pre-specified outcome measure [5, 7, 145] and to use validated scales for outcome assessment [5, 10].

Results of the workshop

We identified additional challenges in the evaluation of CST during the workshop, which are presented in Table 5.

Participants identified three main domains of outcomes for further discussion:

1. Outcomes related to the HCP taking part in the CST, such as their communication skills or satisfaction with the training,

2. Outcomes related to a specific interaction between HCPs and patients,
3. Outcomes related to the patients who communicate with the trained HCP.

Overall, experts agreed that a “one size fits all approach” is not appropriate in defining outcomes for CST evaluations; thus, we cannot give recommendation on specific constructs. Rather, outcomes need to be dependent on the specific learning objectives of the CST under evaluation. For each of the levels mentioned above, investigators need to define realistic and achievable outcomes for a specific CST. The group favoured measurement of direct behavioural observation of the targeted communication skills either with simulated or

Table 5 Challenges in the choice of outcomes and outcome measures for CSTs in oncology

Challenge	Description
Communication skills and the outcomes of communication encounters between health care professionals and their patients are related to many internal and external variables.	HCPs communication is influenced by trait factors such as extraversion, state variables such as current stress level and work satisfaction as well as personal knowledge. The same is true for patients, who also have different personality factors and information bases as well as emotional needs and may be at different stages in the illness trajectory. A specific communication encounter will be additionally influenced by external factors that shape the communication situation, such as availability of time and its implementation in clinical routine.
It is hard to define ‘correct’ communication behaviour.	HCPs communication styles and patients’ needs addressable by communication differ widely, both across patients and during the course of disease. Communication often takes unpredictable turns and miscommunication is frequent; this does not necessarily imply that the outcome of a miscommunication is bad.
Targeting of CST can be improved.	Highly motivated HCPs with good communication skills are more likely to take part in CSTs than HCPs with bad communication styles. Therefore, ceiling effects, both in actual effects and their measurement, have been frequently observed. Patients’ needs must be adequately addressed in the conceptualization of the training.
Learning objectives of CST vary widely.	CSTs differ widely in their specificity (generic communication training, such as active listening and expressing empathy vs. training tailored to specific communication tasks such as breaking bad news). If a CST is focused on a specific communication task, consideration needs to be given to all the skills required to satisfactorily deal with the situation.
Communication affects many different outcomes.	CSTs target many different outcome parameters. Some of them are closely connected to the content of the CST (proximal outcomes), others are influenced by many other factors as well (distal outcomes). While proximal outcomes are more likely to reflect changes after a CST, there are known problems. For example, measures of satisfaction of CST participants have frequently exhibited ceiling effects. Additionally, empathy was considered an important construct by experts but difficult to measure in an objective way. It seems to be difficult to define the appropriate measurement to capture proximal outcomes, such as clinician skill in expression of empathy. Distal outcomes such as Anxiety, Distress and Quality of Life are influenced by many other factors besides communication and the effect of a communication training on such distal outcomes has often been limited.
Validated measures are not available for specific outcomes of interest.	The limited availability of validated scales for proximal outcomes was identified by experts as a considerable barrier. This also implies that it is unclear what minimal important differences are on such scales. Scales measuring generic, broadly applicable outcomes are more likely to be used and validated. Most outcomes for which validated measures exist are distal. The imperative in research to employ validated scales might influence researchers to select generic outcomes, which may not be optimally aligned with the goals of a particular CST.

real patients. For example, situational judgement tests where participants are asked how they would react in a given situation [146] could be an interesting way to measure the effect of CST.

Recommendations for future research

Based on the results from the systematic review and the discussion during the workshop, we make the following recommendations:

1. The choice of outcomes must be closely linked to the scope of communication training. Achieving a change in distal, generic outcomes requires the use of more intense interventions and larger evaluation studies compared to assessment of proximal, specific outcomes. Minimal clinically important differences should be defined beforehand.
2. Learning objectives must be adequately defined and targeted in the training. Proximal outcomes must be closely aligned with these objectives. Theoretical models or concepts of how these proximal outcomes will affect more distal outcomes should be made explicit.
3. Researchers should distinguish between three different levels for the evaluation of communication training: I) during the actual training process, II) during the interaction between patient and HCP, and III) after the interaction between patient and HCP. The intended impact of the training on these different settings and the respective proximal and distal outcomes should be explicitly defined, preferably derived from theoretical communication models.
4. Both experts and stakeholders, in particular patient representatives, should be involved in the definition of learning objectives, the development of the actual training, and the choice of outcomes.
5. A single outcome measure cannot cover all relevant outcomes to measure the effects of CST in oncology. Therefore, we recommend
 - a. Considering multiple potential outcomes. We suggest measuring the effects of communication training on all three domains identified: HCP, patient and interaction. Assessing the interaction is particularly relevant as concordance of judgements between patient and HCP should be investigated.
 - b. Avoiding measuring outcomes with known problems. For example, global ratings from patients on empathy or satisfaction have frequently exhibited ceiling effects and might be prone to social desirability.
 - c. Complementing quantitative assessments with qualitative assessments when possible as

quantitative assessments seem unable to completely represent the communication process. These qualitative assessments could be an analysis of the communication encounter as well as qualitative interviews with CST participants or patients. Less common outcome measures, such as physiological stress reactions or situational judgement testing using case vignettes, might help to fill a gap.

- d. Ensuring that the development and selection of outcome measures is transparent, clearly described and reproducible for other researchers as purpose-built outcome measures still have a central role in the evaluation of communication training programmes to reflect the content of the specific training.

Discussion

This paper gives an overview of outcomes and the respective outcome measures previously used in the evaluation of communication training in oncology. It further discusses challenges experienced with outcome measurement in such studies and gives recommendations for future research. Many CSTs have been developed, implemented and evaluated to support health care professionals addressing specific communication challenges in cancer care. Our systematic review showed that outcomes and the respective outcome measures differ widely. The complementing workshop clearly described the challenges experienced in the evaluation of CSTs. To date, neither a specific outcome nor a specific outcome measure is a widely accepted standard tool. The large differences in content, extent and target populations of communication training in oncology can explain this. The lack of standardization, however, hampers building systematic and more conclusive evidence. Specific models of communication and theories how communication affects HCPs as well as patients in oncology can inform selection of appropriate outcomes.

An interesting finding is that outcomes and the respective outcome measures, as well as the challenges identified, are in most cases not specific to oncology. This suggests that generic communication processes can hardly be broken down to be disease specific. Exceptions are the outcome measures provided by the EORTC and the Cancer Research Campaign Workshop Evaluation Manual (CRCWEM), which have been specifically developed to assess the experiences of cancer patients.

The strengths of this study include its comprehensiveness as a descriptive review of outcome measures used in the evaluation of CSTs. The inclusion of systematic literature reviews on the effects of CSTs in this review revealed additional challenges, which are particularly

relevant when study results need to be synthesized in meta-analysis.

Nonetheless, limitations of this work need to be taken into account when interpreting its findings. First, we could not register the review protocol, as its scope did not fulfil eligibility criteria for PROSPERO. Nonetheless, we wrote a protocol before we conducted the review. Furthermore, the syntheses of the specific outcomes in categories was difficult to standardize, since most primary studies made no specific distinction between outcome and the respective outcome measure. Although we grouped similar outcomes into categories, category borders are somewhat blurry, as often there are no clear definitions of the outcomes available. A further limitation is that a detailed analysis of psychometric quality in terms of reliability and validity of all outcome measures identified in the review has not been feasible. Hence, we cannot advise for or against the use of specific instruments, but we encourage the assessment of psychometric quality when one chooses an outcome measure. For this purpose, standardized tools can be used (e.g., EMPRO [147]). Another limitation is that the recruitment of the participants for the workshop did not follow a pre-specified protocol, but we selected potential participants based on their appearance as authors in the review as well as by recommendation by other participants. Furthermore, not all participants participated in the development of the recommendations after the workshop. Hence, these recommendations may not necessarily reflect the opinions of all participants in the workshop.

Conclusion

Our review of the literature and the expert workshop made it clear that measuring the impact of CST in oncology is challenging. As human communication is complex, the heterogeneity of outcome assessment in studies is large. The complexity of the interventions and their potential effects hampers establishment of standard outcomes and outcome measures. Definition of a single core outcome suitable for each CST in oncology is unrealistic – there is a lack of consensus on what a core outcome could be and how it could be reliably assessed. Hence, we suggest a broad, reproducible assessment of communication on different levels derived from explicit learning objectives. Future research should emphasize the associations between these different perspectives on communication and develop theoretical frameworks that can guide the choice of relevant outcomes and meaningful effects of CSTs.

Acknowledgements

The authors like to thank Corinna Güthlin, Ulrike Holtkamp, Christin Kohrs, Darius Razavi, and Jan Schildmann for their valuable contributions in the workshop.

Authors' contributions

The systematic review was planned by FF and CMW and conducted by FF, SH, and AR. FF, SH, AR and CMW planned the workshop, and JIA, AB, AH, MH, AK, MR, WS, BS and PS contributed to the workshop. FF wrote a first draft of the manuscript. SH, AR, JIA, AB, AH, MH, AK, MR, WS, BS, JW, PS and CW revised this draft, and all authors approved the final manuscript.

Funding

This project was funded by the Deutsche Krebshilfe (Kompetenznetzwerk Komplementärmedizin in der Onkologie - KOKON, grant number 70112369). The funder had no role in the planning of the study or the preparation of the manuscript.

Availability of data and materials

Not applicable.

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Received: 7 January 2019 Accepted: 6 August 2019

Published online: 14 August 2019

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7.2 Publikation 2

Journal of Cancer Education
<https://doi.org/10.1007/s13187-020-01829-8>



Education Competencies for Integrative Oncology—Results of a Systematic Review and an International and Interprofessional Consensus Procedure

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Abstract

Integrative oncology is a burgeoning field and typically provided by a multiprofessional team. To ensure cancer patients receive effective, appropriate, and safe care, health professionals providing integrative cancer care should have a certain set of competencies. The aim of this project was to define core competencies for different health professions involved in integrative oncology. The project consisted of two phases. A systematic literature review on published competencies was performed, and the results informed an international and interprofessional consensus procedure. The second phase consisted of three rounds of consensus procedure and included 28 experts representing 7 different professions (medical doctors, psychologists, nurses, naturopathic doctors, traditional Chinese medicine practitioners, yoga practitioners, patient navigators) as well as patient advocates, public health experts, and members of the Society for Integrative Oncology. A total of 40 integrative medicine competencies were identified in the literature review. These were further complemented by 18 core oncology competencies. The final round of the consensus procedure yielded 37 core competencies in the following categories: knowledge ($n = 11$), skills ($n = 17$), and abilities ($n = 9$). There was an agreement that these competencies are relevant for all participating professions. The integrative oncology core competencies combine both fundamental oncology knowledge and integrative medicine competencies that are necessary to provide effective and safe integrative oncology care for cancer patients. They can be used as a starting point for developing profession-specific learning objectives and to establish integrative oncology education and training programs to meet the needs of cancer patients and health professionals.

Keywords Cancer · Core competencies · Integrative oncology · Interprofessional collaboration · Consensus procedure

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Published online: 11 August 2020

Springer

Introduction

The use of complementary and integrative medicine (CIM) by cancer patients [1] and cancer survivors [2] is widespread with meta-analytic evidence showing that more than 40% of cancer patients use CIM [3]. The term “integrative oncology” has been defined [4] using a consensus process, by the Society for Integrative Oncology (SIO [5]), 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. Integrative oncology aims to optimize health, quality of life, and clinical outcomes across the cancer care continuum and to empower people to prevent cancer and become active participants before, during, and beyond cancer treatment” [6].

Founded in 2003, SIO is an interprofessional non-profit organization whose mission is to advanced evidence-based, comprehensive integrative healthcare to improve the lives of people affected by cancer. Through education, research, and knowledge transfer initiatives, such as an annual international conference and the development of clinical practice guidelines, SIO’s vision is to have research inform the integration of complementary modalities into oncology care so that evidence-based integrative oncology care is accessible and standard for all patients across the cancer continuum. SIO provides much needed, evidence-informed leadership and collaborative opportunities to the interdisciplinary integrative oncology research and clinical practice communities around the world.

As integrative oncology involves various healthcare professionals [7], its implementation into clinical practice requires a divergent set of competencies [8]. Although integrative oncology content exists in courses, curricula, syllabi, and trainings, information about the required core competencies is incomplete and not yet standardized [8, 9]. To date, no core set of education competencies for integrative oncology that reflects different professions and countries has been developed. This may be due to heterogeneous education systems and activities across countries as well as different legal, ethical, regulatory, and political influences on the practice of integrative oncology. As such, the primary aim of this project was to systematically develop a set of core education competencies for integrative oncology that would be applicable to a wide range of healthcare providers from different educational backgrounds and countries.

Methods

The absence of clearly defined core competencies for integrative oncology was seen by the SIO Board at its retreat in 2016 as a quality-related problem in integrative healthcare. To close the gap between what is and what is desired, a model that has

been used by the Institute for Health Care Improvement in the USA called the “Collaborative Model for Achieving Breakthrough Improvement” has been adapted to the needs of the project [10]. After the topic of the core competencies was identified, the SIO Board members representing different professions were recruited for the project. The project consisted of two phases, and the teams for the phases were selected based on their expertise. Phase I included a systematic review of the literature, the identification of relevant competencies, as well as categorizing them. In Phase II, building on the results of the systematic review, an international and interprofessional consensus procedure was conducted to develop a set of core competencies for healthcare professions who deliver integrative oncology care.

Systematic Literature Review

Literature Inclusion and Exclusion Criteria

Publications focused on education integrative oncology competencies for physicians, nurses, integrative oncology practitioners, and other healthcare professionals that were published in scientific journals or as reports, consensus papers, and working papers or theses were included. Publications were excluded if the education competencies or activities did not include CIM in the context of cancer, if the reporting of the education activity did not include competencies or details about the curricula, or if the publication was not available in English or German.

Search Strategy

Scientific literature about integrative oncology education and information about education activities, such as curricula, syllabi, and course objectives, were searched and analyzed to get an overview about required core competencies. The search strategy was conducted using an explicit and reproducible methodology in the following electronic databases from inception until February 6, 2017: Ovid MEDLINE, CENTRAL, CINAHL, EMBASE, PsychINFO, PsychARTICLES, and Web of Science. The search included all types of papers published related to competencies in integrative oncology by using the following keywords or free text words in combination with subject headings, where available: disciplines possibly related to integrative oncology (integrative oncology OR complementary medicine OR alternative medicine OR integrative care OR integrative nursing OR integrative medicine) AND educational element (course OR curriculum OR education or program* OR session or teaching OR training OR workshop OR competencies OR value OR knowledge OR attitude OR skill* OR mission* OR vision* OR syllab*) AND type of publication (evaluation OR investigation OR study or trial OR proposal OR examination OR research OR

survey). MeSH terms were used to restrict the results to literature specific to oncology, depending on the respective database. In addition, the SIO members were asked to provide gray and/or unpublished literature on education competencies.

Selection of Studies

All items identified by the literature search were entered into a bibliographic database. One reviewer thoroughly checked all searched items by assessing titles and abstracts, excluding clearly ineligible articles based on the search criteria and aim of the project. Full text copies were obtained of all remaining articles and assessed by two reviewers independently for eligibility. Publications were excluded only with the agreement of both reviewers. Reasons for exclusion were documented and any disagreements resolved by discussion. If several publications for a single study were published, all publications were reviewed if they met the eligibility criteria.

Data Extraction

Two reviewers extracted data from selected publications using a standardized form. The results of the data extraction were collated into the categories, “knowledge,” “skills,” and “abilities” (KSA), to structure the results and to summarize findings. The KSA classification was drawn from the basic core competency model used by the Association of American Medical Colleges for Entering Medical Students [11]. In this classification, knowledge was defined as a body of information applied directly to the performance of a function; skills as observable competence to perform a learned psychomotor act; and ability as a competence to perform an observable behavior or a behavior that results in an observable product. Any uncertainties regarding data extraction and classification for specific publications were discussed by the reviewers, with disagreements resolved by consensus and the final decisions resolved by a third reviewer.

Consensus Procedure

In Phase II, a consensus procedure was performed involving a task force, an extended expert group, and knowledgeable SIO members. The initial set of competencies developed from the literature review and additional core oncology competencies was further refined through a multistep process that was guided by the task force. The task force consisted of 12 experts representing seven different professions (medical doctors (MDs), psychologists, nurses, naturopathic doctors (NDs), traditional Chinese medicine (TCM) practitioners, yoga practitioners, patient navigators) and additional relevant perspectives (public health and patient advocates). Each task force member identified further experts from a similar professional background representing three different regional areas

(Asia/Australia, Europe, North America). The extended expert group helped broaden the expertise represented in the consensus procedure and allowed perspectives from different international regions to be included. The consensus process involved three online surveys and an onsite survey at an international integrative oncology conference (SIO conference in 2017) as well as direct feedback from the task force members. Each survey was followed by a task force conference call and emails to revise the competencies.

In the first online survey, the importance of each competency found in the literature was rated by the task force and extended experts on a scale from 0 (not important) to 10 (very important). In addition, the task force indicated their agreement with the placement of the competencies in one of the KSA categories, and new core competencies that were not listed could be suggested.

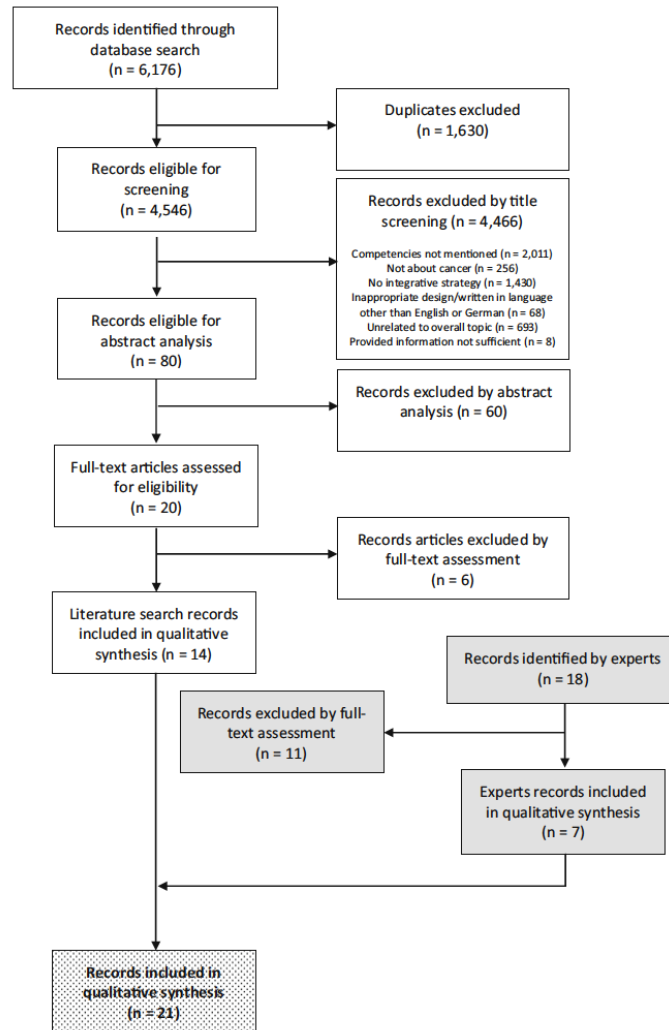
The second online survey was again forwarded to the task force and extended experts for review. The revised list of competencies was then prioritized based on how important each competency was for a given healthcare profession (low, moderate, high priority, or not applicable for my profession). The final set of competencies was included in a survey that was sent to all SIO members using a link in a newsletter and was also provided as a hardcopy version at the annual SIO conference in November 2017. Respondents were asked to prioritize and comment on the competencies with respect to the importance for their respective profession. During each conference call, the task force consented agreed upon a threshold that needed to be met to keep a competency on the list. Competencies reaching the threshold were only discussed if at least one task force member wanted to discuss optional changes. All competencies not reaching the threshold were discussed in detail. All decisions during the conference calls were based on full consensus among the group.

Results

Systematic Literature Review

The literature review yielded 21 eligible studies (see Fig. 1). The vast majority were from North America ($n = 10$ from the USA, $n = 2$ from Canada) and Europe ($n = 7$). Most publications ($n = 18$) mentioned competencies that could be classified into the three KSA categories. Nearly all publications ($n = 19$) reported competencies for the broader field of integrative medicine, but 2 publications [12, 13] defined competencies that were of special interest for health professionals working in the field of breast cancer oncology. Most publications addressed several professions; 5 publications focused on nurses only [13–17], 3 publications on physicians [18–20], and 1 on medical students [21].

Fig. 1 Flowchart for literature search and study selection



A total of 28 competencies were identified from the literature review, summarized and classified into the KSA categories (see Table 1). Some of these 28 competencies had elaborate descriptions that had to be summarized, and several of the competencies needed to be broken up into single competencies. Following this process, a total of 40 single competencies were developed. In addition, 18 other competencies that are known to be core competencies for medical oncology were added by one task force member (GD) to the list [22]. This resulted in a total of 58 competencies as a starting point for the consensus procedure.

Consensus Procedure

A total of 25 experts from 7 different healthcare professions and 3 international regions completed the initial web-based survey (24% from Asia/Australia, 20% from Europe, 56% from North America).

The majority ($n = 20$, 80%) of the participants agreed with the suggested KSA competency categories. The task force decided that all competencies with a level of importance rating specified by median and/or mean of least 9 on the 0–10 (10 being a very important competency) scale would remain on the list. All other competencies were discussed in detail and

Table 1 Overview of competency categories identified in the systematic literature review

Knowledge	Skill	Ability
General knowledge about evidence-based medicine [7, 17, 20, 21, 24–26]	Provide evidence-based, balanced, resource-oriented, up-to-date complementary and integrative medicine (CIM) information that assists patients to make a decision [7, 9, 15, 16, 18–20, 27–31]	Respect individual differences in the understanding and implementation of integrative oncology [17, 19–21, 24, 26]
Knowledge on how to access and appraise scientific literature on integrative oncology [19, 20, 31]	Identify, understand, and contextualize relevant information on CIM [7, 12, 15–19, 21]	Respect cultural and ethnic differences in the understanding and implementation of integrative oncology [7, 21, 29]
Knowledge about cancer [18, 26, 28]	Understand patients, the problems patients face, and their needs [14, 19, 29, 31, 32]	Appreciate a whole person and patient-centered approach [16, 25]
Knowledge about common complementary medicine (CM) therapies, including their history, theory, proposed mechanisms, safety/efficacy profile, contraindications, prevalence, and patterns of use [7, 12–15, 17–20, 26, 27, 29, 31–33]	Engage with patients (and caregivers) to build resilience and resources to best empower patients during cancer treatments [12, 18, 19, 21, 26, 28–30]	Be empathic [12, 19, 29]
Knowledge about services/providers' quality assurance and reimbursement [19, 21]	Master the principles and practices of communication [12, 18, 19, 21, 26, 28–30]	Respect of patient's beliefs [7, 12, 17–20]
Knowledge about the principles of a healing environment [14, 17, 21]	Inquire about patients' use of CIM and their motives [7, 12, 14, 15, 17, 19, 20, 29]	Be open-minded [7, 12, 18–20, 28, 29]
Knowledge about communication theories and strategies [9, 28]	Work in an interprofessional team [14–16, 19, 21, 24, 28]	Be attentive [19]
Knowledge about conventional medical language [15, 24, 30]	Have an adequate training in one or more CIM modalities and be able to apply it to cancer patients [14, 17, 19, 26, 28, 30, 34]	Be self-aware [15, 19, 20, 24, 29, 31]
	Identify suitable CIM providers for a respective patient [15, 16, 19, 20, 25, 29]	Be able to accept that CIM use is often based on no/unclear evidence [29]
	Adequate documentation of interventions and patients' response to them [14, 15, 21, 24, 29]	
	Use adequate medical terminology [15, 29]	

either rephrased, merged, or deleted. This process led to a total of 38 competencies: 10 knowledge, 15 skill, and 7 ability competencies and an additional 2 knowledge, 2 skill, and 2 ability competencies that were newly developed or extensively modified by the task force.

In the second online survey, 28 experts from 7 different healthcare professions (14% from Asia/Australia, 18% from Europe, 68% from North America) prioritized the competencies according to the importance for their profession and gave feedback on the new or modified competencies. As all competencies met the overall threshold of importance (rated at least moderate or high priority, using the categories low/moderate/high), the task force decided to examine the feedback from the different professions and to retain all competencies that were of high priority for at least 80% of the participants of each profession. All other competencies were again discussed by the task force group and either rephrased ($n = 1$) or omitted ($n = 1$). The final list with 37 competencies included 11 knowledge, 17 skill, and 9 ability competencies.

There was a full agreement among task force members that all 37 competencies were relevant for all participating healthcare professions.

A total of 57 SIO members answered the online or the hard copy survey ((40% MD, 14% TCM specialist, 9% nurses/

nurse practitioners) and 36 others (i.e., researcher, students, administrator, yoga practitioners, patient navigators)) and overall agreed about the relevance of the core competency set as shown in their ratings. The findings of the second survey (task force and extended expert group) and third survey (SIO members) are summarized in Table 2.

Discussion

This study is among the first to identify core competencies for integrative oncology healthcare providers. Based on an iterative process including a comprehensive literature review by an expert task force and multi-disciplinary oncology providers and by a survey of members of SIO, a final set of 37 core competencies for integrative oncology was identified. These 37 competencies were further categorized into knowledge, skills, and abilities and agreed on by representatives from seven different professions from Asia, Europe, and North America.

Searching the literature on integrative oncology competencies and complementing it with current fundamental knowledge in oncology will ensure that future healthcare providers who develop these competencies are competent and able to take a safe and knowledgeable approach to integrative oncology care. The

Table 2 Results of the extended expert group and SIO member surveys

Knowledge competencies	Rated as priority (%)		Skill competencies		Rated as priority (%)		Ability competencies		Rated as priority (%)	
	Experts	SIO members	Health professionals working in integrative oncology should	Health professionals working in integrative oncology should	Experts	SIO members	Health professionals working in integrative oncology should	Experts	SIO members	
Have general knowledge about evidence-based medicine	96.4	100	Provide evidence-based and balanced CM information	96.7	100	Respect individual, cultural, and ethnic differences in the understanding and implementation of integrative oncology	96.4	100		
Know how to access and appraise the scientific literature on complementary medicine (CM)	100	96.5	Stay up-to-date with CM information	100	98.2	Appreciate a patient-centered, whole person approach	100	100		
Demonstrate the understanding of the basics of history, theory, and mechanisms of common CM therapies	96.4	93.0	Provide reputable websites and other information or resources on CM	100	100	Be empathic, non-judgmental, open minded attentive, and self-aware and respect patients' beliefs	100	100		
demonstrate the understanding of safety/effectiveness, interaction profiles, and contraindications of common CM therapies	100	98.2	Assist patients to make a decision	92.9	93	Establish rapport and form a therapeutic partnership with patient	100	100		
Understand the major cancer treatment modalities (surgery, chemotherapy, radiotherapy, endocrine, and biological therapy)	100	91.2	Identify, understand, and contextualize relevant information on CM	96.4	98.2	Identify one's own knowledge deficiency and know where to find help	100	98.2		
List common symptoms associated with cancer	100	94.7	Master the principles and practices of communication, which means an empathic, open, trustful communication that follows common recommendations of communication with cancer patients	100	96.5	Pursue lifelong learning and continuous self-improvement	100	96.5		
List common side effects of cancer treatment	100	94.7	Engage with patients (and caregivers) to build resilience and resources to best empower patients during cancer treatment	100	96.5	Respect the strengths and limitations of applying evidence-based medicine principles to the circumstances of an individual patient	100	100		
Describe the cancer care continuum	100	94.7	Inquire about patients' use of CM and their motives	100	93.0	Be able to obtain key information regarding the patient's cancer history: type of cancer, types of previous treatments (surgery, chemotherapy, radiation, endocrine, targeted therapy), current disease stage, and current treatment	92.9	92.9		
Discuss the psycho-social-cultural context of cancer care	100	96.5	Work in an interprofessional team	100	96.5	Help patient understand the risks and benefits of evidence-based CM approaches so that they may choose care that aligns with their values and goals	96.4	98.2		

Table 2 (continued)

Knowledge competencies	Rated as priority (%)		Skill competencies		Rated as priority (%)		Ability competencies		Rated as priority (%)	
	Experts	SIO members	Health professionals working in integrative oncology should	Health professionals working in integrative oncology should	Experts	SIO members	Health professionals working in integrative oncology should	Health professionals working in integrative oncology should	Experts	SIO members
Discuss the distinction between the terms "healing" and "curing"	96.4	96.5	Understand patients, the problems patients face, and their needs	100	98.2	adequately document interventions and patients' response to them	100	94.7		
Have knowledge and or ability to obtain information about services/providers' quality assurance, licensing government regulation, and reimbursement of CM	100	91.2	Identify CM providers for a patient	89.3	94.7	Use appropriate medical terminology	96.4	94.7		
						Assess patients' psychosocial-cultural environment and identify barriers to proper care	100	95.7		
						Implement a personal self-care strategy (may include nutrition awareness, self-regulatory techniques, exercise, journaling, creative arts, spirituality, mind body skills, etc.)	100	96.5		
						Discuss CIM in the context of different types of cancer	92.8	93.0		
						Be able to obtain information about cancer pathogenesis, the general course of the disease, and treatment outcomes of common cancers	92.8	93.0		

Percentage of respondents that rated competencies as moderate or high priority for their profession

consensus procedure incorporated practical experiences and perspectives from different professions and international regions to be embedded in the competencies. In addition, we partially utilized a model that has been used by the Institute for Health Care Improvement for breakthrough advancement in health care [10]. However, we adapted this model to our needs. The so-called action periods that typically take place between the “learning sessions” (exchange between experts) were used for discussions within each profession because implementing the changes (competencies) and measuring the outcomes as typically done within this model would have taken too long for the scope of this project. An alternative result of the project would have been developing different core competencies for each healthcare profession, which would have been supported by the general approach called for in the Collaborative Model for Achieving Breakthrough Improvement. Interestingly, there was full consensus on having the same competencies for all professions, which will make it much easier to inform about the results and measure the impact in the future.

Validation by an even broader international group was also possible by giving SIO members the opportunity to provide feedback on the competency list. However, the study also had limitations. We only included papers in English and German in the systematic review. In addition, surveys typically do not reach all stakeholders, and only those SIO members who have a strong educational interest might have completed the member survey. In addition, SIO members might reflect a unique group of healthcare providers in integrative oncology, resulting in a response bias. They might be more drawn to a scientific, evidence-based, and interprofessional approach and see fundamental oncology knowledge as a basis for integrative oncology. Nevertheless, a strong advantage of SIO is that it is an interprofessional organization with integrative oncology experts from world-leading cancer centers. As such, integrative oncology as represented by this set of core competencies would reflect an approach that can be integrated in cancer centers globally and aims for best outcomes and to provide best care.

The development of a core set of competencies for integrative oncology that encompasses seven professions highlights the interprofessional nature of the field and the potential for future development of interprofessional trainings to benefit cancer patients and improve outcomes.

The 37 core competencies defined in this study are an important starting point and inform future integrative oncology education and training programs for different healthcare professions.

It is important to distinguish between the different sectors of health care when applying education competencies for integrative oncology. In acute care situations, such as brief hospital stays (e.g., fever during chemotherapy) or emergency room visits, an integrative oncology approach will play a less important role. In contrast, in outpatient care situations (e.g., ambulatory chemotherapy or radiation therapy), lengthier hospital stays, or during palliative care, it is of higher importance given the potential role

of integrative oncology therapies. For those professions who are part of the cancer care team and are engaged in the integrative oncology care, the core competencies will play a more substantive role. Nevertheless, each profession will have to determine which of the defined integrative oncology competencies are already part of their undergraduate curricula (e.g., MD or nursing degrees) and which will need to be embedded in graduate and continuing education courses and programs. Furthermore, profession-specific and perhaps even country-specific competencies may require development and detailed learning objectives, and didactical approaches would have to be defined.

Competencies are of high relevance because the evidence for selected CIM interventions is growing. If patients decide, based on the advice of their oncology healthcare provider, to pursue a CIM treatment, it would be of limited help if the provider does not have relevant core competencies for integrative cancer care [23]. This core set of integrative oncology competencies will help to have more competent providers in the future, who provide evidence-based care for symptom reduction and quality of life improvement of cancer patients and are able to avoid negative aspects of those interventions such as time herb-drug interactions.

Acknowledgments Open access funding provided by University of Zurich. This work was partially funded by the National Cancer Institute (NCI grant R25CA203651 to Suzie Zick) and the German Cancer Aid (Deutsche Krebshilfe grant 70112369 to Claudia Witt). We like to thank the SIO membership and further international experts that provided feedback during the development of the core competencies.

Data Availability The raw data supporting the conclusion of this manuscript will be made available by the corresponding author on reasonable request.

Compliance with Ethical Standards

Conflict of Interest The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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7.3 Publikation 3

Patient Preference and Adherence

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ORIGINAL RESEARCH

Defining Criteria for Guiding Cancer Patients to Find a Reputable Complementary Medicine Provider: Results of a Literature Review and a Consensus Procedure

This article was published in the following Dove Press journal:
Patient Preference and Adherence

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Purpose: Even in cases of positive evidence for complementary medicine (CM) therapies, it is still difficult for cancer patients to identify reputable providers. The aim of this study was to develop and evaluate a criteria list to provide guidance to cancer patients seeking a reputable CM provider.

Methods: The design combined a literature review, an expert consensus procedure (n=15) and an assessment from three stakeholder perspectives (patients (n=18), CM providers (n=26) and oncology physicians (n=20)).

Results: A total of 30 existing CM criteria were extracted from the literature, and 12 more were added by the experts. The main challenge was to define criteria that could easily be applied by the patients. A final comprehensive list of 8 criteria guiding cancer patients to find a reputable CM provider was developed.

Conclusion: Health professionals and cancer information services might find the criteria list helpful when aiming to strengthen patients' awareness of quality-related factors associated with CM providers. The criteria developed might be helpful when standards are established for quality assurance in CM in oncology.

Keywords: neoplasms, complementary medicine, patient-centered care, standards, healthcare quality assurance

Background


Approximately half of cancer patients use complementary medicine (CM) during their cancer treatment,¹ and that percentage has appeared to increase over time.² The term CM summarizes a broad range of heterogeneous therapies such as yoga, relaxation techniques, herbal medicine or whole traditional systems such as traditional Chinese medicine, many of which lack sufficient data or clinical evidence. A recent retrospective observational study using data from the American National Cancer Database³ suggested that CM provided by nonmedical personnel was associated with a higher risk of death due to declined cancer treatments. These findings have been vigorously challenged for the validity of its conclusion due to sampling and data issues.⁴ Nevertheless, the publication highlights the need to involve medical personnel to guide patients when they want to use CM. In particular, there is an increasing body of positive evidence for some therapies, such as yoga to reduce fatigue and sleep disturbances⁵ or mindfulness-based stress

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<https://doi.org/10.2147/PPA.S230705>

Patient Preference and Adherence 2020:14 747–755

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reduction (MBSR)⁶ to improve quality of life and mood symptoms which is reflected in existing medical guidelines.^{7,8}

The evidence for the quality of CM offers is often difficult to judge for patients and physicians without experience in CM. The lack of standards and regulations for nonmedical CM providers (providers without a medical license) in some countries and the fact that they are usually not part of the oncology care team make this process even more difficult. Some hospitals and private practices offer in-house CM programs to ensure the quality of their interventions; however, this approach is not considered standard. Therefore, patients may sometimes feel alone when searching for reputable non-medical providers for CM therapies. Even when patients try to follow their oncology physicians' evidence-based CM recommendations, they are still unsure which providers offer both safety and high quality. Therefore, a need exists to discriminate between more and less "safe" nonmedical CM providers.

As part of the Competence Network Complementary Medicine in Oncology (KOKON),⁹ a collaborative research project in Germany funded by the German Cancer Aid (grant 70112369), this project aims to develop CM criteria as indicators of reputable CM providers in oncology.

Method

The design (see [Figure 1](#): Flowchart of the criteria list development process) included a systematic literature review (Phase I) to identify existing criteria for reputable CM providers. This process was followed by an international and interprofessional expert consensus procedure (Phase II) and a practice evaluation with relevant stakeholder groups (cancer patients, CM providers and oncology physicians). Experts recruited for this study were based in Germany and Switzerland, and from diverse backgrounds (medical oncology, primary care, psychology, psycho-oncology, nursing, pediatric oncology, law, statutory health insurance, patient advocacy/patient representation, research methodology, public health, and epidemiology). Oral informed consent was provided by the participating experts, patients provided written informed consent and the other survey participants were informed about the aim of the project and that if they completed the survey, their answers were anonymous.

Phase I – Literature Review

Literature Inclusion and Exclusion Criteria

Publications were included from scientific journals, working papers, and theses. Additionally, information materials,

websites and other types of publications addressing criteria and standards for reputable CM providers for cancer patients, physicians, CM providers and leaders of cancer support groups were included. Publications were excluded if the stated criteria were in the context of neither oncology nor CM, or the publication was not available in the English or German language. Publications were not restricted by year of publication.

Search Strategy

Electronic databases (Ovid MEDLINE, CENTRAL, EMBASE and Web of Science) were searched from June until August 31, 2017. We linked the following keywords and text words and, if possible, combined them with subject headings: professional field related to complementary and integrative oncology (integrative oncology, OR oncology AND complementary medicine OR integrative medicine) AND elements of quality assurance (criteria OR standard OR quality OR safety) AND/OR profession (provider* OR health professional OR physician). Our search strategy included all types of publications and research designs. In addition, members of the expert consensus procedure were asked to provide additional literature, especially gray and/or unpublished literature. Moreover, we searched the web using the same terms for websites and materials that provide information on how to choose reputable CM providers.

Selection of Studies and Data Extraction

One reviewer (AAR) searched the literature reviewing the results thoroughly by assessing titles and abstracts (if possible depending on the type of publication). Publications were excluded if they did not mention any criteria. Full text copies were generated from the resulting literature, assessed and data extracted by one reviewer (AAR). The study selection and data extraction were supervised by a methodologist (CMW). Criteria were then derived from qualitative analysis. Therefore, a qualitative content analysis according to Flick¹⁰ was performed. Two independent reviewers (AAR, CMW) extracted criteria. Content units were identified to cluster the selected criteria using inductive coding strategies. Moreover, an intersubjective validation of the coding by the two reviewers to verify the reliability of the data was conducted. Based on this, criteria themes were developed and discussed within the team (education and training, medical approach, attitude, cost and reimbursement). Criteria were categorized by both reviewers independently,

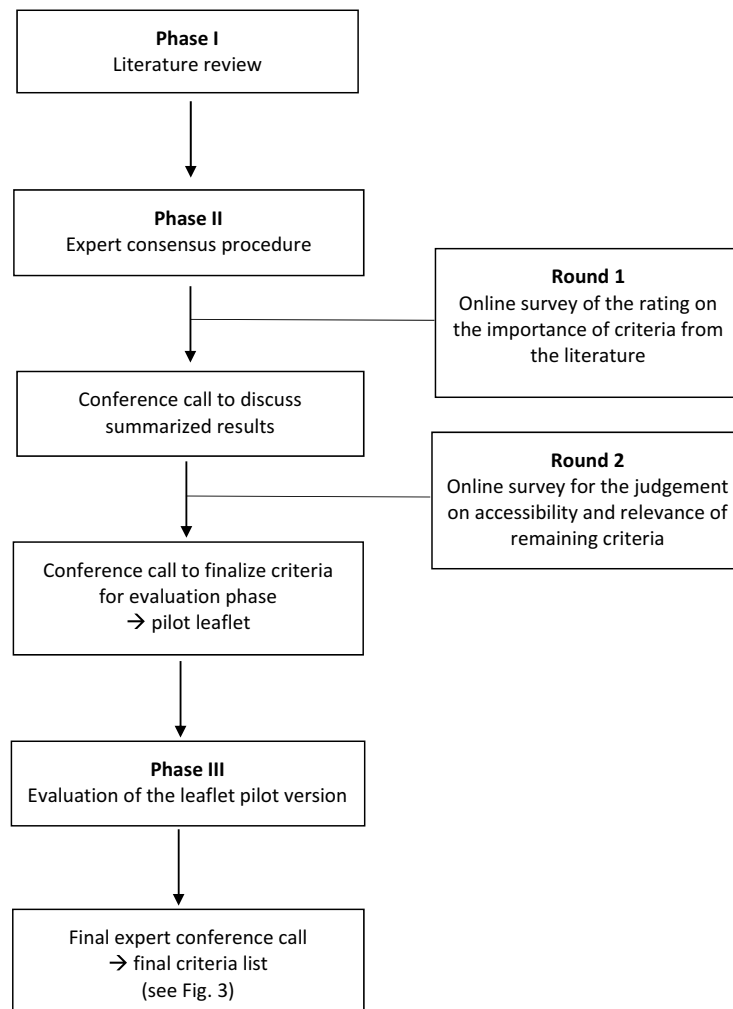


Figure 1 Flowchart of the criteria list development process.

and any discrepancies considering categorization were documented and resolved via discussion.

Phase II – Expert Consensus Procedure Including an Evaluation on Three Different Levels

A three-round expert consensus procedure was performed. Experts (n=15) were invited to participate in this study by email explaining the aim of this project. This group of experts

discussed, developed and redefined existing criteria from the literature search in multiple rounds. In the first two rounds, online surveys were completed, followed by conference calls and written exchange to find consensus.

In a first survey, the experts indicated the importance of the criteria found in the literature on a 0–10 Numeric Rating Scale (NRS, 0 = “not important at all” to 10 = “fully important”). The summarized results were discussed in a conference call, and the criteria were revised accordingly. In the second survey, the remaining criteria were judged regarding their accessibility

(open access = the information is easily accessible eg during consultation the patient can ask the provider, provider has to be asked, provider has to be observed) and relevance (NRS 0–10; 0 = “not relevant at all” to 10 = “very relevant”). Furthermore, experts indicated the necessity (mandatory, optional or unnecessary) of each criterion for patients, physicians and an optional future registry (as an obligation tool for CM providers). This registry could serve as a quality assurance system in order to identify reputable CM providers. As a predefined threshold, 50% of the experts had to find a criterion relevant to a certain group (patient, physician, registry level) to keep it on the list, and two-thirds had to indicate that the criterion was mandatory to make it necessary for the resulting criteria list. This multilayer process was followed by a second conference call finalizing the criteria for the practice evaluation.

Furthermore, an introductory text and a disclaimer were prepared to provide context to cancer patients when they read the final leaflet. This approach was approved by the expert group.

For the practice evaluation, the developed leaflet was sent to cancer patients, oncology physicians and CM providers based in Germany. Cancer patients and oncology physicians were recruited within the ongoing KOKON-KTO study (Trial registration number: DRKS00012704). CM providers were recruited by newsletters of professional associations in the field of yoga, naturopathy, acupuncture and MBSR.

Using an online survey or hard copies, 24 questions (NRS 0–10 Likert scale: 0 = “don’t agree at all” to 10 = “fully agree”) on the importance and usefulness of the criteria were asked. Open-ended fields allowed survey participants to provide additional feedback.

The evaluation results were discussed during two more conference calls with the expert group, and a final criteria list, including the introductory text and a disclaimer for cancer patients, was agreed upon.

Data from the online surveys were analyzed using descriptive statistics. The best practices in consensus methods were informed by Murphy et al.¹¹ The study was approved by the relevant local ethics board (Ethics Committee of Charité – Universitätsmedizin Berlin (EA1/127/17)).

Results

Literature Review

From the literature search (Phase I), 13 articles from databases and the internet describing criteria for reputable CM providers in oncology were revealed, and two more articles

from the experts were included (see [Figure 2](#): Flowchart for literature search and study selection). A total of 30 existing CM criteria were extracted. The criteria (see [Table 1](#): criteria for reputable providers from the literature) were categorized into four dominant themes, namely, education and training,^{12–22} medical approach,^{12,13,15–17,19–21,23–26} attitude^{12–15,20–23} and cost and reimbursement,^{12–16,21,22} which were used as the basis for the subsequent expert consensus procedure. Most articles were developed for patient use, and only one-third of the articles addressed physicians, CM providers and others. The only detailed criteria lists addressed the training of CM providers. Criteria lists were usually developed from an insurance perspective or for memberships of professional associations. No criteria list purely supported health professionals and/or consulting services in recommending nonmedical CM providers.

Phase II – Expert Consensus Procedure and Evaluation

The 30 criteria resulting from the literature search were merged into 27 after the elimination of duplicate criteria. The first survey provided feedback from all experts, and 26 criteria (with the exception of one criterion, namely, membership in a professional association) were rated as highly important (median: 9–10 on the NRS; mean: 7.4–10). In the following conference call, when discussing the survey results, participants agreed upon the criteria as necessary and applicable to a German-speaking target group. Additionally, two criteria were deleted for reasons of redundancy, but 12 new criteria were added to the list.

In the second survey from the available 36 criteria, 23 were seen as mandatory for informing patients, 28 seemed relevant for physicians, and 14 were viewed as necessary for a possible registry (see [Appendix 1](#): Results of the 2nd survey of the expert consensus procedure). Furthermore, it was decided to focus on the criteria list for guiding patients in this project. In the following conference call, the criteria were merged, rephrased and brought into an order, resulting in a list of 10 criteria. During the discussion, experts agreed that although some of the criteria are important, they are difficult to verify by patients. Furthermore, the introductory text and the disclaimer for the patient leaflet were discussed and revised, and a consented pilot version of the leaflet was developed.

In the third phase, the leaflet was evaluated by cancer patients (n = 18), oncology physicians (n = 20) and CM

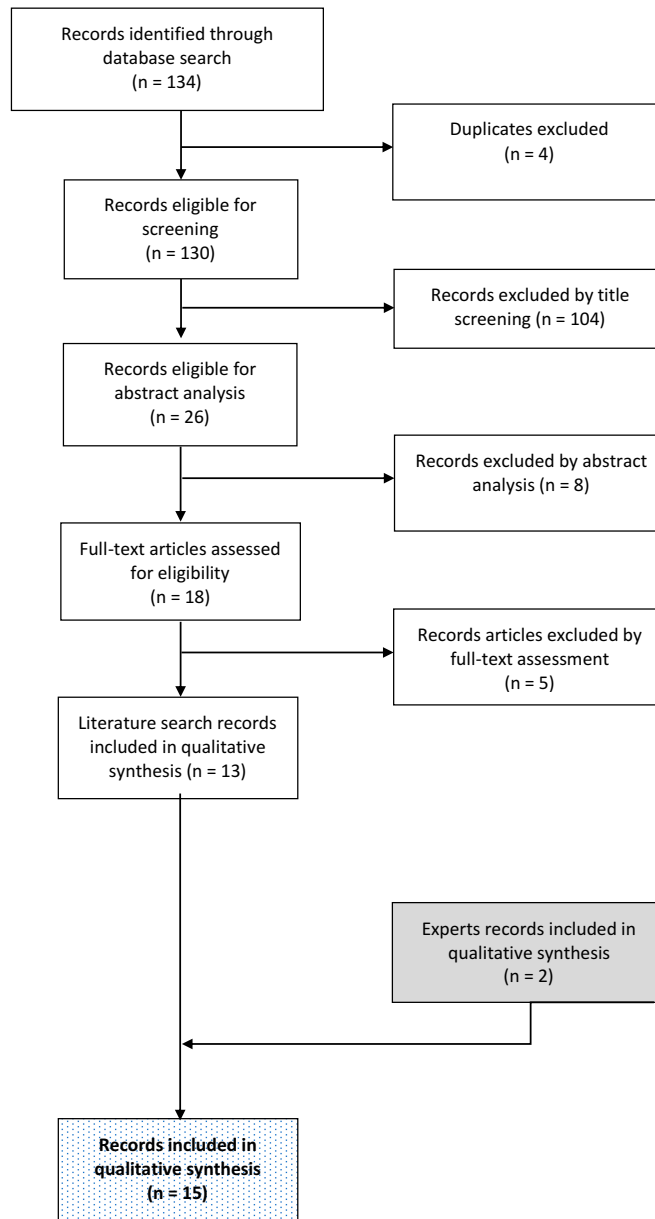


Figure 2 Flowchart for literature search and study selection.

providers (yoga instructors (n = 10), MBSR instructors (n = 7), naturopathic physicians (n = 6), and physicians trained in acupuncture (n = 3)). Most of the CM providers

(88.5%) regularly applied CM treatments, and two-thirds (65.4%) regularly treated cancer patients. In general, and independent of their background, the stakeholders agreed

Table 1 Criteria for Reputable CM Providers from the Literature

Education & Training	Medical Approach	Attitude	Cost & Reimbursement
Further training and education after graduation ^{8,11,13,15,16,19}	Using of medical methods (anamnesis, diagnosis, documentation) ⁸⁻¹¹	No polemical statements against therapeutic alternatives ^{8,18} or further CM therapies [10]	No disproportionate financial demands ⁸
Additional title, if applicable ^{9,12,19}	Diagnosis and treatment plan are set before start of treatment ^{9,10,12,17}	Medically prescribed conventional medicines are taken into account ^{9,10,16}	Treatment costs and possible reimbursement costs are discussed prior to the therapy ^{9,10,12,17,18}
Certificates and quality or association seals ^{9,12,20,21}	Compliance of code of ethics ¹³⁻¹⁵	Acceptance of conventional medical procedures/treatment methods ^{9,10,16,19}	Communication of length/duration of therapy ^{15,18}
Study degree or basic education ^{11,18,20,22} including a specific regulation of the length of education ^{12,13,16,19}	Respect for the individual ^{8,11}	No false pretense of prospects of success ^{8,10}	
Clinical training or experience ^{13,18}	Professionalism ^{11,14}	Possibilities and limitations of CM treatment are shown ^{9,11,16-18}	
Protected title ^{12,13}	Acceptance of patient autonomy ^{16,17}	Willingness to work interdisciplinary ^{18,19}	
Willingness to proof qualifications ¹⁵	Therapy freedom ¹⁶	Commitment to scientific-oriented, empirical medicine ¹⁶	
Knowledge about their own possibilities and limits ^{8,11}	Fixed practice location and times ¹⁰	Rejection of alternative medicine with better evidence of orthodox medicine ¹⁶	
Willingness to name empirical knowledge (evidence) on CM treatment ^{8,12,17,18}			
Practical experience ¹⁶ Special training in specific CM treatment ¹⁶			

that the developed criteria are important. However, three aspects were mentioned: some criteria should be rephrased to be more understandable for patients, some of the criteria were seen as difficult to verify, and views differed on the number of years of experience needed for treating cancer patients. When discussing the evaluation results in the final expert conference call, experts agreed on revising the criteria for better understandability and separating the three criteria that are difficult to verify (having adequate training for the CM therapy, being experienced in treating cancer patients, and participating in continuous training) from the rest of the criteria. One criterion was split into two criteria, which resulted in a final list of 8 mandatory criteria and 3 optional criteria that are more difficult to verify. In addition, the introductory text and the disclaimer

were revised (see [Figure 3](#): Leaflet for patients without the disclaimer).

Discussion

A comprehensive list of 8 criteria guiding cancer patients to find a reputable CM provider was systematically developed in an international and interprofessional consensus procedure. To our knowledge, this is the first consented criteria list to provide helpful guidance to cancer patients when seeking a CM provider.

The developed CM criteria might contribute to better quality control and regulation of CM providers in oncology care, which can help to ensure safe therapies for cancer patients considering CM alongside their cancer treatment. Our approach had the advantage of combining the current

Dear patient,

Did your doctor recommend one or more complementary medicine therapies in addition to your cancer treatment? Are you unsure what to look out for when selecting providers of these therapies?

The following criteria should help you to make a decision about suitable and reputable providers of complementary medicine therapies. However, the fulfilment of the criteria cannot guarantee the reputation of the provider or the safety and effectiveness of the complementary medicine therapies and does not correspond to a certificate. Your own impression should supplement your decision basis.

Reputable providers of complementary medicine can be identified on the basis of the 8 criteria described

The provider should:

1. ask for your diagnosis and previous as well as ongoing treatments.
2. be prepared to talk to you about possible interactions between complementary medicine therapies and your cancer treatment.
3. explain to you why this complementary medicine therapy in particular is recommended for you.
4. present to you the possibilities and limitations of this complementary medicine therapy in a realistic and understandable way, be prepared to present previous experiences with this therapy and to communicate reliable data.
5. discuss with you the goals, contents, duration and costs of the planned therapy and changes in the course as well as ways of possible reimbursement.
6. give you a reasonable period to consider and allow you to freely choose or reject the suggested therapy.
7. respect your decision for or against the complementary medicine therapy.
8. provide you with a comprehensible invoice for the treatment.

There are other important aspects, but they are more difficult to verify. If you would like to know this about the provider, you should ask for:

- A specialist training (or special study curriculum) with a regulated length that has been completed and that only therapies that have been learned and are currently mastered are used
- Regular further and advanced training courses attended
- At least 2 years of experience in the treatment of cancer patients

Figure 3 Leaflet for patients without the disclaimer.

information from the literature with expert knowledge to develop the resulting list of criteria. Engaging international experts from different professions with different perspectives allowed for a comprehensive approach aimed at making the criteria more applicable to all types of cancer patients with different cancer entities, therefore facilitating increased importance and generalizability. The criteria list was tested with different stakeholder groups. Two potential user populations were included (cancer patients and oncology physicians) to ensure understandability and acceptance in the main target groups. In addition, as a third stakeholder group, a range of CM providers (nonmedical CM providers and medical doctors applying CM) provided their feedback.

However, a focus on three stakeholder groups, the experts and participants involved in the evaluation might not

encompass the entire spectrum of perspectives, CM professions and cancer entities and stages. Criteria were selected based on anonymous online surveys but also expert discussions, hence, a detection bias due to the characteristics of the participants or a reader bias in interpreting the results of the online surveys based on the selection of experts might be possible. Moreover, all experts and participants were based in Germany and Switzerland. Adjustments and validations might be necessary for usage in, for example, Asian or African countries. All experts were selected and invited to participate in the study by the study team. Overall they had a broad range of expertise, although, their opinions about CM varied widely in the group, all of them had addressed the topic CM before. Moreover, cancer patients included due to their participation in the KOKON-KTO study might not

represent the whole scope of available patients. The literature review focused on the search terms “integrative oncology” and “complementary medicine” because they are frequently used nowadays, not searching for “alternative medicine” might be seen as a limitation.

Most criteria found in the literature are useful when discussing about the quality assurance of CM providers, but would be very difficult to verify for patients, because the information needed is not freely accessible. In the development of a list with practical implications, only criteria that could be examined by patients were included in the 8 mandatory criteria. However, as a result, all criteria addressing attitudes had to be deleted. Those criteria might be better placed in structures (eg, registries) that include a contract of obligation.^{15,27} Moreover, criteria such as the membership in a professional organization were seen as important. However, in many countries the providers of complementary therapies are not well regulated and because of this, it is not seen as a broadly applicable criterion. In countries, where complementary therapies are well regulated and respective professional organizations are implemented, this can be used as additional criterion. This developed criteria list can be seen as a first step. Future developments might be criteria lists for oncology physicians or health insurance companies for use in their collaborations with CM providers. Moreover, a future registry could be established based on the CM criteria provided. Being listed in this registry could function as a quality certificate for CM providers working with cancer patients. In addition, the impact of the current list for patients on outcomes needs to be evaluated in a prospective study.

This project provides only one tool for a more informed choice of patients. To ensure overall quality of CM use in oncology, oncology physicians should be trained in giving CM advice to cancer patients and to support choosing supportive, evidence-based CM therapies.²⁸ Moreover, other health professionals such as nurses, pharmacologists and psychooncologists should be involved when informing cancer patients on CM therapies.

Trial Registration

This project is part of the KOKON-KTO study registered as DRKS00012704 on the “German Clinical Trials Register” (date of registration: August 28, 2017).

Data Sharing Statement

The datasets analyzed during the current study are available from the corresponding author on reasonable request.

Acknowledgment

We would like to thank Brigitte Blum, Iris Bartsch, Katja Icke, all participants in the evaluation process and the scientists at the Institute for Social Medicine, Epidemiology, and Health Economics, Charité – Universitätsmedizin Berlin, for their helpful comments on the study.

Author Contributions

AAR and CMW performed the systematic review, wrote the manuscript and contributed to the design of the study. AAR coordinated the study and analyzed the data. CMW wrote the grant application and had the overall responsibility for the study. All authors contributed to the development of the criteria list (including data interpretation), drafting and revising of the manuscript, gave final approval of the version to be published, and agreed to be accountable for all aspects of the work.

Funding

This project is part of the collaborative research project KOKON, which was supported by the German Cancer Aid [grant number 109863].

Disclosure

Patrick Jahn reports grants, personal fees from Chugai, personal fees from Bristol-Myers Squibb, non-financial support from Helsinn, non-financial support from Tesaro, outside the submitted work. Petra Voiß reports grants from Carstens-Stiftung, during the conduct of the study. Claudia M. Witt reports personal fees, non-financial support from Several Swiss Hospitals, outside the submitted work. The authors report no other conflicts of interest in this work.

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7.4 Publikation 4:

Original Article



Training Oncology Physicians to Advise Their Patients on Complementary and Integrative Medicine: An Implementation Study for a Manual-Guided Consultation

Claudia M. Witt, MD, MBA ^{1,2}; Stefanie M. Helmer, DrPH²; Penelope Schofield, PhD^{3,4,5}; Marisa Wastell, MPH⁶; Claudia Canella, MA¹; Anita V. Thomae, Dr. sc. ETH¹; and Alizé A. Rogge, BA, MSc ²

BACKGROUND: The unmonitored use of complementary medicine in patients with cancer can be associated with an increased risk of safety-related issues, such as lower adherence to conventional cancer therapies. Training oncology physicians to advise their patients about the effectiveness and safety of these therapies could improve this situation. **METHODS:** The objective of this study was to develop and pretest a consultation framework that has high potential to be widely implemented. The framework comprises: 1) a systematically developed and tested, manualized, guided consultation; and 2) blended learning training (e-learning and communication skills training workshop) to upskill oncology physicians in advising their patients on complementary and integrative medicine (CIM). For this implementation study, mixed methods were used to develop the manual (literature review, consensus procedure, pilot testing) and the training (questionnaires and interviews with oncology physicians and patients with cancer and an examination of the skills in a setting with standardized patients). **RESULTS:** The training was tested with 47 oncology physicians from across Germany. The manual-guided consultation (context: general information on the setting and communication techniques; inform: consultation duration and content; capture: previous CIM use; prioritize: focus on consultation; advise: evidence-based CIM recommendations; discuss, advise, accept, or advise against other CIM; concretize advice: summary and implementation; and monitor: documentation) was considered suitable. The structure and time frame (maximum, 20 minutes) of the consultation as well as the training were feasible and well accepted. **CONCLUSIONS:** The current study demonstrates that the KOKON-KTO framework (a German acronym for Competence Network for Complementary Medicine - Consultation Training for Oncology Physicians) is suitable for training oncology physicians. Its implementation can lead to better physician-patient communication about CIM in cancer. *Cancer* 2020;126:3031-3041. © 2020 The Authors. *Cancer* published by Wiley Periodicals, Inc. on behalf of American Cancer Society This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

KEYWORDS: blended learning, cancer, complementary medicine, integrative oncology, physician-patient communication, practice guidelines as topic, referral and consultation.

INTRODUCTION

Many patients with cancer use complementary medicine (CM). A systematic review has demonstrated that the use of CM has increased over time, and approximately one-half of patients with cancer have used it at least once.¹ Patients who have cancer consider CM therapies for various reasons, including the wish to reduce the side effects of cancer treatment or to gain personal control over their own treatment plan.²⁻⁴ A retrospective analysis of data from a US cancer registry⁵ concluded that the use of these therapies administered by nonmedical personnel in an alternative context was associated with a 2-fold greater risk of death compared with none. This was mainly explained by lower adherence to the recommended cancer treatments. This finding, which is also supported by previous research,^{6,7} highlights the importance of discussing CM during oncology consultations. Because alternative medicine usually refers to therapies that are used as an alternative to conventional cancer treatment in an unmonitored context, it is important to support patients in translating their needs and wishes into a complementary and integrative model of care to reduce possible safety-related risk issues.

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We thank the team of the Competence Network for Complementary Medicine in Oncology (KOKON) for their helpful comments. We would also like to thank Tara von Grebel, University of Zurich, who designed the majority of the graphic elements to be used on the e-learning-platform.

See editorial on pages 2968-70, this issue.

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

DOI: 10.1002/cncr.32823, **Received:** July 31, 2019; **Revised:** November 12, 2019; **Accepted:** November 28, 2019, **Published online** April 14, 2020 in Wiley Online Library (wileyonlinelibrary.com)

Oncology physicians are members of the cancer care team and often are in early contact with the patients. Data show that patients want to be informed by their oncology physicians about complementary and integrative medicine (CIM)^{8,9}, and addressing CIM might increase patients' trust in cancer treatments.^{10,11} Moreover, studies show that physician-led consultations on CIM might have a positive effect on adherence to cancer treatments and overall quality of life in patients with cancer.^{12,13} However, physicians often do not initiate CIM consultations because of low CIM knowledge.¹⁴ There is an urgent need for oncology physicians to feel competent in guiding their patients through the often confusing and heterogeneous field of CIM.¹⁵ Guidelines for CIM consultations in oncology exist,⁷ but consultations based on those guidelines are often difficult to implement for reasons such as a lack of time or the absence of previous evidence-based CIM training.^{7,16} Surveys among physicians indicate a strong interest in evidence-based CIM training for cancer care.¹⁷⁻²⁰ In most countries, training in some type of CIM therapy is available for physicians but consists of training on how to provide CIM (eg, acupuncture or phytotherapy) and not how to advise on available CIM therapies.

With the goal of translating evidence-based knowledge into clinical practice, implementation science addresses these issues by translating scientific findings into practical application.²¹ Our previous cluster-randomized study showed that oncology physicians who had little experience in discussing CIM gained the most benefit from CIM training.²² However, this training used the conceptual approach that patients would receive CIM information from an oncology physician who was not their cancer-treating physician. This resulted in consultations lasting on average 45 minutes, making broad implementation difficult. To meet the needs of patients and physicians and to foster uptake in usual care, training and CIM consultation must fit into the standard cancer care continuum. Hence, it is crucial for the implementation strategy to guide the development of the consultation framework.

In this article, we describe the implementation strategy, the development of the KOKON-KTO (a German acronym for Competence Network for Complementary Medicine - Consultation Training for Oncology Physicians) framework and the associated consultation manual, the corresponding blended learning, and a pilot test of the training and its impact on physician-patient interactions.

Ethics Approval and Consent to Participate

The following independent Medical Ethics committees approved the KOKON-KTO study: Ethics Committee of the Charité - Universitätsmedizin Berlin (EA1/127/17), Medical Association Hamburg (MC-368/17), Medical Association Baden-Wuerttemberg (B-F-2017-10), Medical Association Nord Rhine (2417337), Ethics Committee of the Medical Association of Westphalia-Lippe (2017-624-b-S), Ethics Committee at the Medical Faculty of Wurzburg (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 participants. The trial registration number of the KOKON-KTO study is DRKS00012704 on the German Clinical Trials Register (registered August 28, 2017).

Availability of Data and Materials

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

MATERIALS AND METHODS

Implementation Strategy

The implementation strategy included the following criteria, which were considered crucial for the future dissemination of the framework (manual and training): 1) clinically feasible consultation time that can be implemented in usual care (maximal length of 20 minutes), 2) low threshold for training access (time length, date, location flexibility), 3) teaching of transferable skills that are perceived as useful for other consultation situations, 4) a consultation framework that allows adaptation to the individual consultation style and includes a structured manual and clinical practice materials, and 5) compatibility with relevant standards (eg, competency framework). The implementation strategy was based on the RE-AIM framework (a model for evaluating public health interventions that assesses 5 dimensions: reach, efficacy, adoption, implementation, and maintenance).²³

Development of the KOKON-KTO Framework

The KOKON-KTO framework was developed for oncology physicians' consultations to help to close the gap: patients want to receive CIM advice from their oncology physician, but physicians do not feel competent to provide it. The objective of the KOKON-KTO is to enable oncology physicians to provide advice to their cancer patients about the effectiveness and safety of CIM in

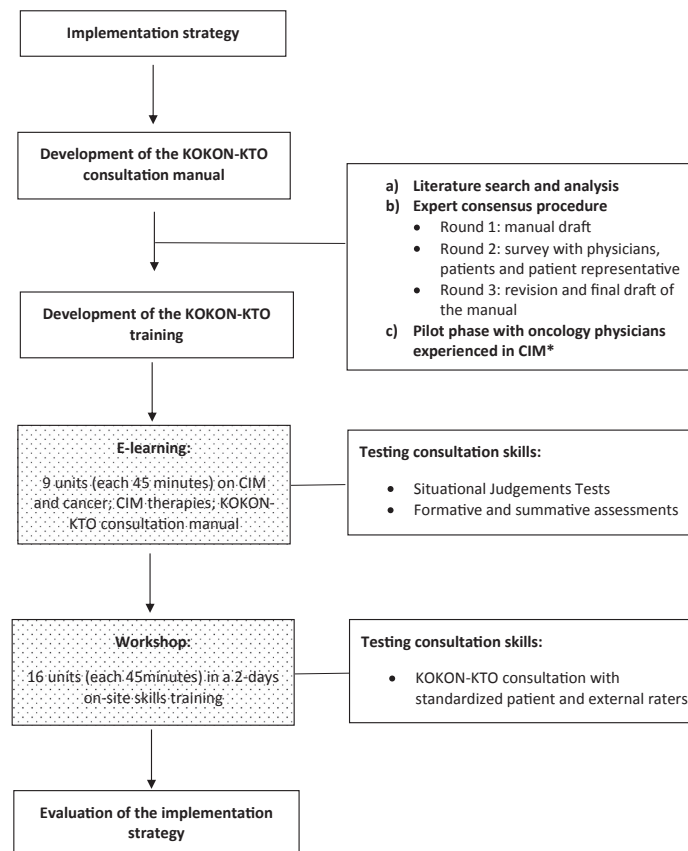


Figure 1. This is a flowchart of the development and evaluation process. Asterisks indicate complementary and integrative medicine (CIM). KOKON-KTO indicates Competence Network for Complementary Medicine - Consultation Training for Oncology Physicians.

a nonjudgmental and empathic consultation. The framework might be adaptable to other health professions in the cancer care team (eg, nurses), but is not intended to train Integrative Medicine Physicians providing CIM. Therefore, the KOKON-KTO framework was developed for its use by oncology physicians working in private practices or cancer clinics to enhance physician-patient communication about CIM as an addition to standard cancer care.

As described in previous medical education initiatives,^{24,25} training oncology physicians in CIM might increase communication skills, improve the oncology physician-patient interaction, and enhance physicians' understanding of CIM use in patients with cancer.

Taking this knowledge into account, the objective of the KOKON-KTO framework, consisting of the KOKON-KTO manual and the blended learning training (e-learning and workshop), is to follow a systematic and evidence-based approach toward teaching oncology physicians how to provide CIM advice to their patients with cancer to enhance patients' and physicians' discussions of CIM as a supportive option during cancer treatment.

KOKON-KTO consultation manual

Development of the manual was based on a systematic literature search and analysis, followed by an international expert consensus procedure (Fig. 1). The manual

was then pilot tested in clinical practice. At each step, the implementation strategy described above was reflected upon and guided the decisions. The expert panel consisted of 9 individuals with knowledge in integrative oncology, communication, psychology, psycho-oncology, oncology, medical ethics, public health, and epidemiology. The literature search was conducted using the MEDLINE, CENTRAL, EMBASE, and Web of Science databases to identify suitable publications. On the basis of the literature analysis, a draft of the KOKON-KTO consultation manual was developed and discussed with the expert panel (first consensus round). Before the second consensus round, 1 patient representative and 23 oncology physicians were invited to complete an online survey (SoSci Survey²⁶ software) with 13 items on the structure and content of the manual (see Supporting Table 1). To determine acceptability, 1 physician (C.M.W.) with experience in CIM consultations conducted face-to-face interviews with 3 patients following a semistructured interview guideline (see Supporting Table 2). The results were discussed with the expert panel, and the manual was revised and finalized (third consensus round). In the subsequent pilot phase (November and December 2017), 3 oncology physicians with CIM expertise used the KOKON-KTO consultation manual in consultations with their patients and were interviewed by 1 interviewer (S.M.H.) following semistructured interview guidelines about their practical experience (see Supporting Table 3). The interview results were shared with the expert panel, and the manual was refined accordingly.

KOKON-KTO training

The learning objectives for the KOKON-KTO training followed the Bloom taxonomy²⁷ and were in line with the core set of educational competencies for integrative oncology that was developed in an international and interprofessional consensus procedure by the Society of Integrative Oncology.²⁸ Blended learning was adopted, in which we combined e-learning modules on the provider platform Moodlerooms/Open LMS²⁹ with a 2-day, on-site skills training workshop. The overall learning objective is as follows: after the KOKON-KTO training, oncology physicians should be able to compare different CIM therapies and other supportive therapies and to lead a context-adapted KOKON-KTO consultation. The specific learning objectives are: 1) after the e-learning session, oncology physicians should be able to a) classify the needs for and challenges of CIM in oncology, b) differentiate between various CIM therapies and other supportive therapies, and c) apply essential elements of a KOKON-KTO

consultation in case studies; and 2) after the on-site skills training workshop, oncology physicians should be able to a) apply knowledge about CIM therapies and other supportive therapies to specific situations, b) implement elements of a KOKON-KTO conversation in role-play exercises, c) deal practically with the challenges of CIM therapies and other supportive therapies in consultations, and d) conduct a KOKON-KTO consultation with a standardized patient.

E-learning

Topics of the e-learning portion were selected by members of the KOKON network³⁰ in light of CIM topics commonly discussed with patients who have cancer. Researchers and clinicians in the field of CIM and oncology were asked to coauthor e-learning lessons and were supported by an e-learning editor. E-learning lessons corresponded to learning objectives following constructive alignment rules.³¹ Lessons, formative assessments, and summative assessments (single and multiple-choice format) were integrated. Texts were reviewed by at least 2 independent reviewers with experience in the respective field. Stakeholders (oncology physicians, medical students) reviewed various aspects, such as the structure of the modules, the diversity of the learning experiences (eg, text, audio, video, infographics), and assessment questions. Tracking of learning success was used to remind participants to complete the e-learning (70% to pass) before attending the workshop.

Workshop

The 2-day, on-site skills training workshop aimed to combine knowledge from the e-learning lessons with clinical practice. By using diverse didactical methods, such as presentations and role-play exercises, oncology physicians were trained to follow the manual. At the end of the workshop, each oncology physician conducted a KOKON-KTO consultation with a standardized patient.³² In total, 4 workshops were performed (2 in March, 1 in November, and 1 in December 2018).

Eligibility Criteria for Participants in the KOKON-KTO Training

Oncology physicians were eligible if they fulfilled the following selection criteria: little knowledge of CIM, no previous structured trainings in CIM in the field of oncology, minimal experience in advising patients with cancer on CIM, ability to take part in the on-site skills training workshop, and good German-language skills. Participants (50% oncology gynecologists treating

malignancies such as breast and ovarian cancer; 50% medical oncologists treating other cancer types) were recruited from hospital departments and private practices specialized in oncology as part of an ongoing randomized controlled trial.³³ In Germany, oncology gynecologists are trained in surgical and pharmacologic treatment principles for the respective cancer entities. The included oncology physicians were either board-certified oncology residents or were in residency training treating their own patients with cancer.

Evaluation of KOKON-KTO Training E-learning

After the e-learning lessons, physicians rated their satisfaction with the training. The web-based assessment (SoSci Survey) consisted of 19 items, which were rated on a numerical rating scale (NRS) from 1 (strongly disagree) to 4 (strongly agree), and 3 open-ended items. To assess whether the learning objectives were reached, situational judgement tests (SJTs) were presented to 2 training groups (November and December 2018) before and after the e-learning.³³ Participants were asked to choose the most suitable answer of 5 options for a given CIM-specific consultation situation. Depending on their specialization, physicians received either 6 gynecologic SJTs (3 breast cancer and 3 ovarian cancer) or 9 nongynecologic SJTs (3 each of lung, pancreatic, and colon cancer).

Workshop

The workshop was evaluated on 2 levels (physician level and physician-patient interaction level). Oncology physicians completed a paper-and-pencil questionnaire (21 items rated on an NRS from 1 [strongly disagree] to 4 [strongly agree]) on their satisfaction. The KOKON-KTO consultations with standardized patients were rated by 2 independent, experienced external raters using a purpose-built questionnaire tailored to the KOKON-KTO consultation manual (10 items rated on an NRS from 1 [strongly disagree] to 10 [strongly agree]). All raters were trained for reliability. Interrater reliability was assessed by calculating the interclass correlation. If medium-to-high agreement was reached, then descriptive statistics were applied.

Semistructured, face-to-face interviews were conducted with each standardized patient, who was asked about their experience and perception in their role. The interviews were audiotaped and transcribed verbatim. A qualitative content analysis according to Flick³⁴ was performed and supported by the qualitative data-analysis software MAXQDA (VERBI Software).³⁵ 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. Other subcategories were created in a continuous process of inductively building codes from the data, and an intersubjective validation of the coding by 2 independent researchers was conducted to verify the reliability and robustness of the data analysis.

RESULTS

Development of the KOKON-KTO Framework KOKON-KTO consultation manual

The literature search revealed 8 publications with relevance for the project. One of these articles⁷ provided the main guidance, which included 5 consecutive steps, whereas the other publications contributed to the topics covered by the manual (Table 1).^{6-7,14,23,36-40} In the first consensus round, relevant aspects of the consultation context, such as the setting and the effect of the physician's attitude, were added.

In the second consensus round, feedback from the survey participants (n = 11) resulted in additional recommendations on how to tackle challenges, such as whether the conversation moved away from the CIM topic, and the addition of *inform* as a first step in the manual to communicate general aspects of the consultation. Three survey participants suggested more individualization in the consultation step order; 6 participants stated that the content of the guideline might exceed the time frame. The semistructured interviews with 3 patients who had cancer showed overall satisfaction. However, 1 patient would have preferred a longer consultation to discuss his previous CIM experience in depth.

In the third round, the manual was divided into 3 sections: section A, providing guidance to the *context*; section B, the steps of the KOKON-KTO consultation (*inform, capture, prioritize, advise, discuss, concretize advice*), and section C, *monitor*. The steps *capture, prioritize, advise, and discuss* could now be applied in flexible order, allowing adaptation to each physicians' communication style. The final KOKON-KTO consultation manual (see Supporting Information) described 8 steps, including example phrases and recommendations on how to deal with the typical challenges that could occur during a KOKON-KTO consultation. To facilitate convenient use of the manual, a pocket card (Fig. 2) was developed. In addition, a questionnaire to capture patients' previous CIM use was provided as part of the training materials.

TABLE 1. Structure and Topics of the First Draft of the Manual

Steps	Topic	Reference(s)
Opening of the consultation	Personal greeting	Trant 2019 ³⁶
	Setting	Schofield 2010, ⁷ Johnston & Beckman 2019, ³⁷ Paladino 2019, ³⁸ Foley 2019, ³⁹ Ben-Arye & Samuels 2019 ⁴⁰
Understand and respect patients' perspective	General reasons for CIM use	Schofield 2010 ⁷
	Risks of interaction and side effects of CIM	Verhoef 2008 ⁶
Asking about CIM use and reasons why	Empathy	Verhoef 2008, ⁶ Schofield 2010 ⁷
	Patients' interest	Verhoef 2008, ⁶ Schofield 2010, ⁷ Lee 2014 ¹⁴
Advise and respond	Previous and present CIM use	Schofield 2010, ⁷ Lee 2014 ¹⁴
	Introduction to nutrition	Schofield 2010 ⁷
Summarize	Introduction to exercise and relaxation	Schofield 2010 ⁷
	Individual recommendations on CIM	Schofield 2010, ⁷ Lee 2014 ¹⁴
	Shared decision making	Verhoef 2008, ⁶ Schofield 2010 ⁷
	Summary	Schofield 2010, ⁷ Johnston & Beckman 2019 ³⁷
Development of therapy plan	Development of therapy plan	Schofield 2010, ⁷ Lee 2014 ¹⁴
	End of consultation and follow-up/documentation	Verhoef 2008, ⁶ Schofield 2010, ⁷ Lee 2014 ¹⁴

Abbreviation: CIM, complementary and integrative medicine.

Pilot testing in clinical practice

Three oncology physicians conducted KOKON-KTO consultations with 9 patients. The manual seemed to be feasible for physicians who had basic CIM knowledge. The flexibility of the steps was received positively, and small design changes for the pocket card were suggested. The physicians agreed that the manual structure met patients' needs and highlighted the necessity of informing patients from the beginning about the aim of the consultation to set expectations.

The KOKON-KTO training

The e-learning consisted of 9 units (45 minutes each) divided into 3 mandatory courses: CIM and cancer (1 unit), CIM therapies (6 units), and KOKON-KTO consultation (2 units) (see Supporting Table 4).

The workshop consisted of 16 units over 2 days (see Supporting Table 4). Because the manual-guided KOKON-KTO consultation was developed to be conducted with the oncology physician's own patients, the participants were introduced to 1 case vignette (a female patient who had cancer with fatigue) before the workshop. All role-play exercises used the same case vignette, but the focus or treatment stage was varied according to the learning objectives of the lecture.

Evaluation of the KOKON-KTO Training

In total, 47 oncology physicians were recruited (see Supporting Table 5). However, only 37 completed the e-learning module and its evaluation (see for e-learning results, see Fig. 3; for workshop results, see Fig. 4). Because oncology physicians were recruited from an

ongoing randomized controlled trial, physicians from the control group³³ received the training after the intervention phase (11 months after recruitment). Reasons for the dropouts included job change, unavailability on the workshop date, and health reasons. Overall, the e-learning and the workshop were rated positively, and the majority of participants were satisfied with the content and its presentation. Moreover, the participants showed good overall results in the SJTs (average proportion of correct group answers: gynecologic SJTs, 83.3%; oncologic SJTs, 77.8%).

The agreement between external raters for the participant observation during the KOKON-KTO consultations with a standardized patient was substantial (average interclass correlation, $R^2 = 0.58 \pm 0.29$). An analysis of the purpose-built rating scale for the role-play exercises during the training showed that participants were able to demonstrate each of the components specified in the KOKON-KTO consultation manual (Table 2) within the time frame.

Interviews with standardized patients

Standardized patients in their role felt positive about the KOKON-KTO consultation. The timeframe for the consultation was found to be appropriate. One standardized patient thought that even less than 20 minutes might be feasible to prevent patients from being overloaded with information. They felt enabled to take up time to speak or to interrupt the physicians if necessary. However, in some situations, they felt that they were not allowed enough time to speak about themselves and their complaints (as the standardized patient

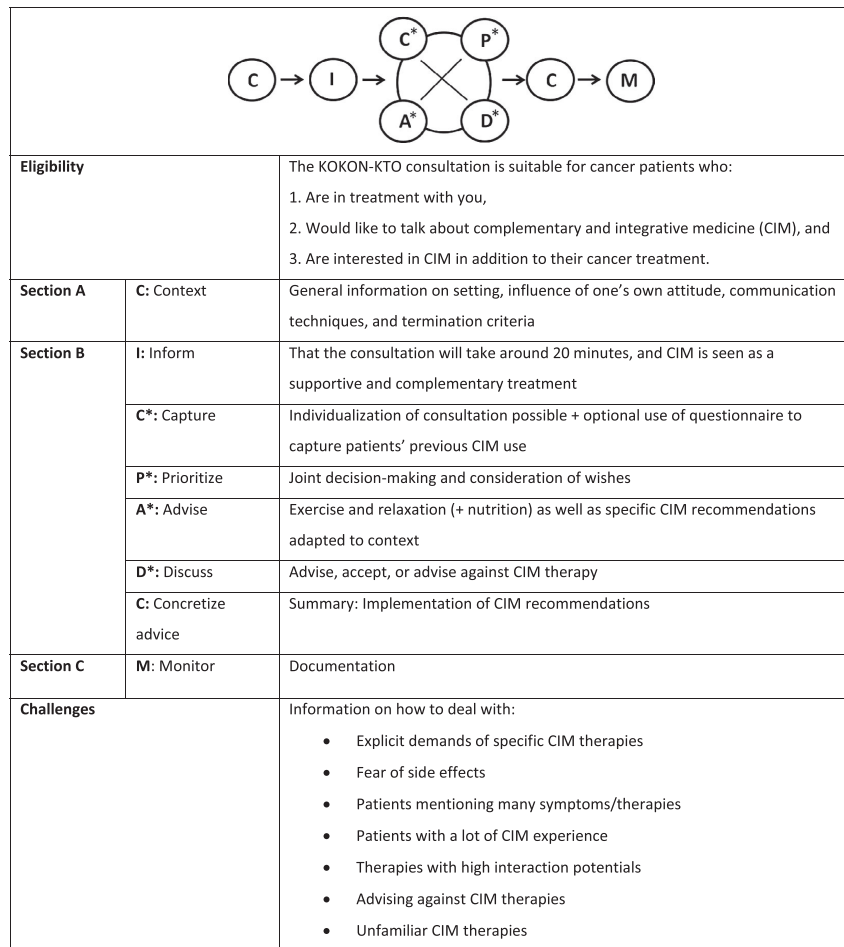


Figure 2. Details of the final training content, as presented in a pocket card that can be used during consultations, are shown. An asterisk indicates complementary and integrative medicine (CIM). KOKON-KTO indicates Competence Network for Complementary Medicine - Consultation Training for Oncology Physicians.

with cancer). The relevant content of the scientific information seemed to be understandable to them. Nevertheless, they did not always understand the scientific explanation or the meaning of the scientific terms (see Supporting Table 6).

Standardized patients especially welcomed individual, resource-oriented CIM recommendations by the physicians. In their opinion, such an approach facilitated implementation of the CIM recommendations into daily practice.

Implementation strategy

The successful realization of the implementation strategy was reflected in fast recruitment and a waiting list for study participation. Of the 37 oncology physicians participating in the e-learning module, 100% completed and 98% participated in its evaluation. After recruitment, physicians had to wait up to 11 months for the workshop; still, 77% participated in the workshop. The KOKON-KTO framework was developed for oncology physicians on the assumption that they are often asked about CIM

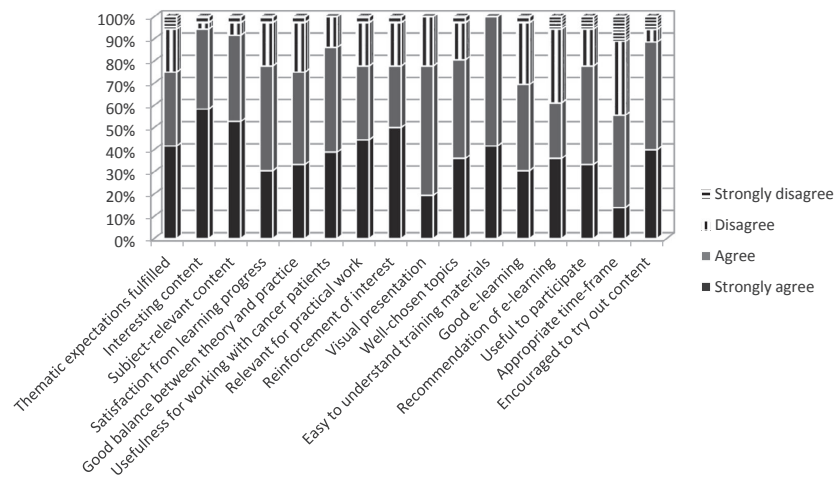


Figure 3. Evaluation results (e-learning) are illustrated. Items were scored on a categorical scale ranging from 1 (strongly disagree) to 4 (strongly agree).

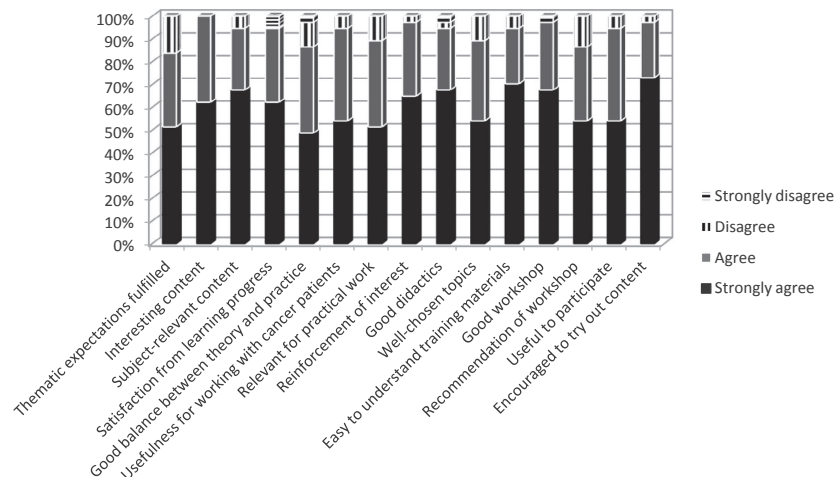


Figure 4. Evaluation results (workshop) are illustrated. Items were scored on a categorical scale ranging from 1 (strongly disagree) to 4 (strongly agree).

by patients with cancer. Given the rapid recruitment of study participants (including a waiting list), the assumption can be considered confirmed, and implementation of the manual can be considered likely. Timeframe and content were implemented as planned and were efficient

in teaching CIM content (see results for SJTs, above); moreover, all physician participants were able to conduct a KOKON-KTO consultation at the end of the training. Because the consultation was developed to be applied during the physicians' daily workflow, implementation

TABLE 2. Rating of Consultation With Standardized Patients at the End of the Workshop, With 2 Raters per Oncology Physician (Mean \pm Standard Deviation Over All Physicians)^a

Participant Was Able To:	Rating: Mean \pm SD		
	Gynecology, n = 17	Oncology, n = 20	Total, n = 37
Explain CIM as a supportive therapy (<i>inform</i>)	8.7 \pm 2.1	9.1 \pm 1.9	8.9 \pm 2.0
Record experiences and current CIM use of the patient according to the situation (<i>capture</i>)	9.5 \pm 1.2	9.9 \pm 0.6	9.7 \pm 0.9
Set priorities internally or with the patient and communicate this process to the patient (<i>prioritize</i>)	8.6 \pm 1.4	9.1 \pm 1.3	8.9 \pm 1.4
Inform about the general potential of movement and relaxation in cancer (<i>advise</i>)	9.7 \pm 0.8	9.5 \pm 1.1	9.6 \pm 1.0
Give information on concrete CIM therapies (depending on the situation and the patient's questions)	9.9 \pm 0.4	9.7 \pm 0.5	9.8 \pm 0.5
Advise, accept, or advise against CIM treatment (<i>discuss</i>)	9.5 \pm 1.0	9.9 \pm 0.4	9.7 \pm 0.8
Give concrete recommendations for an implementation (<i>concretize</i>)	9.4 \pm 0.8	9.2 \pm 0.8	9.3 \pm 0.8
Consider all steps of the KOKON-KTO consultation manual	9.2 \pm 0.9	9.1 \pm 1.1	9.1 \pm 1.0
Always put focus on CIM during conversation	10.0 \pm 0.0	9.9 \pm 0.4	10.0 \pm 0.3
Address the challenge posed by means of a recommendation given in the guideline (<i>advise</i> : explain reason, offer alternative)	8.4 \pm 2.2	9.1 \pm 1.4	8.7 \pm 1.8

Abbreviations: CIM, complementary and integrative medicine; KOKON-KTO, Competence Network for Complementary Medicine - Consultation Training for Oncology Physicians.

^aItems were rated on a numerical rating scale from 1 (strongly disagree) to 10 (strongly agree).

has a low threshold and requires no extra costs for clinics or private practices.

DISCUSSION

The project resulted in a blended learning program for oncology physicians that uses common standards for competencies and learning objectives. The training was based on a consultation manual, and criteria defined as relevant for broad training implementation were reached. The ratings of the KOKON-KTO consultations with standardized patients and the SJTs showed that the learning objectives were fulfilled. However, because this study did not assess the participants in their own clinical activity, the implementation and fidelity of the KOKON-KTO consultation manual needs further investigation in the ongoing KOKON-KTO study.³³ Standardized patients may provide indications but cannot represent patients actually diagnosed with cancer.

As part of the implementation strategy for the KOKON-KTO framework, trained oncology physicians continue to provide feedback within the ongoing KOKON-KTO study. Applying the KOKON-KTO skills in their own clinical environment, oncology physicians will provide information on its clinical feasibility (duration of the consultation and implementation in the daily work practice), patient and physician satisfaction with the consultation, as well as challenges occurring during the KOKON-KTO consultation. Moreover, patients will

answer questionnaires about their satisfaction, preparation for decision making on CIM, physicians' communication skill level, and their CIM use. This will provide results both on feasibility and on the quality of communication and preparation for decision making. Another aspect that must continuously be monitored is its feasibility (eg, reimbursement, time, change of attitudes toward CIM) in health systems.

The KOKON-KTO training, with its evidence-based approach to CIM, fits the needs expressed by physicians.^{17,19,41} The combination of e-learning with an on-site workshop was well received, and these results were in line with previous findings.¹⁷ The evaluation process clearly showed that the continuous adaptation of the framework was useful. However, the e-learning lessons could be adapted more closely to the manual to provide a good knowledge foundation for the on-site workshop. Furthermore, e-learning could allow more individual freedom to deepen CIM knowledge over optional modules, which might have led to higher satisfaction with the learning progress and a reduction in training time.

The on-site workshop included a strong focus on communication skills. The physicians' individual communication style may influence patient satisfaction⁴¹; moreover, the literature suggests that, especially for physicians working in oncology, a patient-centered communication approach may not only enhance shared decision making but also may lead to better therapy outcomes.³⁷⁻³⁹

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Concerns that were expressed in the surveys regarding the timeframe and a possible lack of individualization were not confirmed.

A limitation of the study is that training only 1 profession of the cancer care team does not reflect the multidimensional communication axis that is in place in routine care. Oncology care is applied in an inter-professional context, and this needs to be addressed in the future. However, the literature described a clear gap between patients' needs and physicians' skills, so commencing with oncology physicians (who have early contact with patients during their cancer journey) seemed to be the appropriate starting point. Future research calls for broadening the KOKON-KTO framework to other professions. In addition to interprofessional aspects, the future research should also take into account intercultural aspects.

Finally, oncology physicians who have received KOKON-KTO training cannot replace integrative physicians, who will have far greater training and in-depth knowledge of integrative therapies. The KOKON-KTO framework does not train integrative oncology physicians to whom the cancer team can refer for special treatment. There are other training programs available, including some online,⁴⁰ that focus on those competencies.

The KOKON-KTO framework enables oncology physicians to provide basic evidence-based advice on CIM to their patients with cancer. This may allow an improved standard of care by reducing side effects of CAM use and improving adherence to cancer treatments.

Conclusion

To the best of our knowledge, the KOKON-KTO framework provides a systematically developed, evidence-based and evaluated CIM consultation manual and training for oncology physicians. We have demonstrated that the KOKON-KTO framework is suitable for training oncology physicians to give CIM advice to their patients with cancer, and its implementation could lead to better physician-patient communication about the use of CIM.

FUNDING SUPPORT

This project was part of the Competence Network for Complementary Medicine in Oncology (KOKON) established as a collaborative research project funded by the German Cancer Aid (Deutsche Krebshilfe, grants 109863 and 70112369) and the Günter und Regine Kelm Stiftung.

CONFLICT OF INTEREST DISCLOSURES

The authors made no disclosures.

AUTHOR CONTRIBUTIONS

Claudia M. Witt: Wrote the article and contributed to the design and conduct of the study. **Stefanie M. Helmer:** Wrote the article and contributed to the design and conduct of the study. **Marisa Wastell:** Contributed to the study and revised the article. **Penelope Schofield:** Contributed to the study and revised the article. **Anita V. Thomae:** Developed the majority of the e-learning content. **Claudia Canella:** Supervised the qualitative analysis. **Alizé A. Rogge:** Wrote the article and contributed to the design and conduct of the study. All authors read and approved the final version of the article.

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8 Lebenslauf

Mein Lebenslauf wird aus datenschutzrechtlichen Gründen in der elektronischen Version meiner Arbeit nicht veröffentlicht.

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9 Komplette Publikationsliste

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10 Danksagung

An erster Stelle möchte ich meinen herzlichsten Dank an meine Mentorin und Betreuerin dieser Arbeit richten, Frau Prof. Dr. med. Claudia M. Witt. Danke für die stetige Unterstützung und das Vertrauen in mich. Natürlich danke ich ebenso meinen Kolleginnen und Kollegen des Instituts für Sozialmedizin, Epidemiologie und Gesundheitsökonomie der Charité – Universitätsmedizin Berlin. Insbesondere danke ich für viel Humor, Freude und tatkräftige Unterstützung meinen Kolleginnen und Kollegen: Iris Bartsch, Beatrice Eden, PD Dr. rer. nat. Dipl.-Psych. Felix Fischer, Dr. PH Stefanie Helmer, Katja Icke, Dr. med. Daniel Pach und allen weiteren an den Publikationen beteiligten Wissenschaftlerinnen und Wissenschaftlern, insbesondere den Mitgliedern des Kompetenznetzwerks KOKON.

Für ihre Unterstützung in allen Lebenslagen danke ich meinen Liebsten: Kaspar, Caro, Fabi, Steffi, Sarah, Anna, Hanna, Jana, Danny, Luara, Michi&Clara und all den anderen äußerst liebenswerten Menschen in meinem Leben. Und nicht zuletzt verbeuge ich mich vor meiner Mutter – tout ce que je suis, c'est ce que je suis pour toi.