

Kritische Gesundheitsbildung – der Weg zur informierten Entscheidung

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Zielsetzung: Diese Dissertation leistet im Rahmen von drei Projekten (P) einen Beitrag zur Realisierung informierter Entscheidungen mittels kritischer Gesundheitsbildung: P1: Entwicklung und Pilotierung eines Schulungsprogramms für Ersteller*innen von Gesundheitsinformationen. P2: Untersuchung der Machbarkeit und Akzeptanz eines Schulungsprogramms für Ärzt*innen und Medizinstudierende zur Förderung ihrer Kompetenzen in evidenzbasierter Entscheidungsfindung. P3: Anpassung und Validierung der deutschen Version der *Claim Evaluation Tools* zur Messung kritischer Gesundheitskompetenz für Schüler*innen der Sekundarstufe I.

Methoden: P1: Es wurde ein Blended Learning-Schulungsprogramm entwickelt, das die Kompetenzentwicklung zu den Methoden evidenzbasierter Medizin und Kriterien für evidenzbasierte Gesundheitsinformationen beinhaltet. In einer qualitativen Pilotstudie wurden Akzeptanz und Machbarkeit der Schulung durch strukturierte Beobachtungen und Fokusgruppeninterviews getestet. P2: Ein Blended Learning-Schulungsprogramm wurde entwickelt und pilotiert. Die Schulung wurde strukturiert beobachtet, Arbeitsergebnisse wurden dokumentiert und Fokusgruppeninterviews durchgeführt. Kritische Gesundheitskompetenz wurde mit dem *Critical Health Competence-Test* gemessen. P3: Es wurde eine sequentielle Mixed-Method-Studie durchgeführt: 1. Kontextualisierung und Anpassung der Items, 2. Pilotierung der Itemsets mittels qualitativer Interviews mit Sekundarstufenschüler*innen und ihren Lehrenden, 3. Konstruktvalidierung durch Testen der eindimensionalen Rasch-Skalierbarkeit in Deutschland und Österreich.

Wesentliche Ergebnisse: P1: Die Schulung zeigte sich als implementierungsfähig. Aufgrund der Heterogenität der Teilnehmenden war es schwierig, all ihre Anforderungen zu erfüllen. Die Arbeitsaufgaben waren weitestgehend verständlich. Die praktische Relevanz des Inhalts zu evidenzbasierten Gesundheitsinformationen wurde höher bewertet als die zu evidenzbasierter Medizin. Die Umsetzung der Inhalte in die Praxis stellt eine Herausforderung dar. Die Schulung wurde auf Basis der Ergebnisse revidiert. P2: Die Schulung erwies sich als machbar und wurde gut akzeptiert. Die Verständlichkeit der Module wurde als angemessen bewertet. Einige Inhalte wurden weniger gut verstanden und Arbeitsaufgaben waren zum Teil herausfordernd. Die kritische Gesundheitskompetenz war nach der Schulung signifikant höher als vorher. Anhand der Ergebnisse fand eine Optimierung der Schulung statt. P3: Als Ergebnis der qualitativen Interviews wurden geringfügige Modifikationen an den Items vorgenommen. Die Rasch-Analyse ergab eine akzeptable Modellpassung. Eine Distraktorenanalyse gab Hinweise zur Optimierung einzelner Items.

Folgerungen: P1: Die Schulung wird in einer randomisierten kontrollierten Studie untersucht. P2: Um ein Fortbildungsangebot für Mediziner*innen zu etablieren, wird die Evaluation der Schulung in einer randomisierten kontrollierten Studie empfohlen. P3: Nach der Revision einiger Items können die Fragebögen zur Kompetenzmessung eingesetzt werden.

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Abkürzungsverzeichnis

CHC-Test.....	<i>Critical Health Competence-Test</i>
DKFZ	<i>Deutsches Krebsforschungszentrum</i>
DNEbM.....	<i>Deutsches Netzwerk Evidenzbasierte Medizin</i>
EbM.....	<i>Evidenzbasierte Medizin</i>
ePA.....	<i>elektronische Patientenakte</i>
GPGI	<i>Gute Praxis Gesundheitsinformation</i>
HSHC	<i>Halle School of Health Care</i>
IHC.....	<i>Informed Health Choices</i>
IMLEGI.....	<i>Implementierung der Leitlinie evidenzbasierte Gesundheitsinformation</i>
IQWiG.....	<i>Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen</i>
ISDM.....	<i>Informed Shared Decision Making (informierte gemeinsame Entscheidungsfindung)</i>
MAPPinfo.....	<i>Mapping the Quality of Health Information</i>
MRC.....	<i>Medical Research Council</i>
ÖPGK.....	<i>Österreichische Plattform Gesundheitskompetenz</i>
RKI.....	<i>Robert Koch-Institut</i>
UPD.....	<i>Unabhängige Patientenberatung Deutschland</i>

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1 Einleitung und Zielstellung

1.1 Weg zur informierten Entscheidung

Der Weg zur informierten Entscheidung und Partizipation von Bürger*innen an gesundheitsbezogenen Entscheidungsprozessen ist ein langer und zum Teil steiniger, der auch Umwege einschließt. Seit 2013 ist das Recht auf umfassende und verständliche Informationen im Patientenrechtegesetz festgehalten. Vorgesehen ist die Beteiligung von Patient*innen an allen Entscheidungen und damit die Realisierung informierter Entscheidungen [1]. Auch der Nationale Krebsplan definiert für das Handlungsfeld 1 *Weiterentwicklung der Krebsfrüherkennung* explizit das Ziel der informierten Entscheidung [2]. Zum Treffen einer informierten Entscheidung ist adäquates Wissen über den Nutzen und Schaden einer bevorstehenden medizinischen Intervention sowie über Behandlungsalternativen erforderlich. Die jeweilige persönliche Einstellung zu der Intervention sollte mit der Entscheidung und dem letztendlichen Handeln kongruent sein – das heißt der Inanspruchnahme oder Nicht-Inanspruchnahme [3]. Wissenschaftsbasierte (Gesundheits-)Informationen sind die Voraussetzung für informierte Entscheidungen und für die Realisierung des langfristigen Ziels, Unter-, Über- und Fehlversorgung zu reduzieren.

1.2 Barrieren informierter Entscheidungen

Die Gründe dafür, warum der Weg zur informierten Entscheidung steinig ist, sind vielfältig: Ein Grund liegt in der Fülle an existierenden Gesundheitsinformationen, die jedoch nur selten den Qualitätsanforderungen entsprechen [4]. Es besteht nach wie vor ein Mangel an verlässlichen, evidenzbasierten Gesundheitsinformationen, die Risiken und Unsicherheiten transparent kommunizieren. Die Anforderungen an die Qualität von Gesundheitsinformationen wurden bereits vor längerer Zeit definiert. So sollen die *Gute Praxis Gesundheitsinformation* (GPGI) und die Empfehlungen der *Leitlinie evidenzbasierte Gesundheitsinformation* Ersteller*innen bei der Entwicklung von qualitätsgesicherten Gesundheitsinformationen unterstützen [4, 5]. Häufig fehlen den Ersteller*innen allerdings methodische Kenntnisse zu evidenzbasierter Medizin und evidenzbasierten Gesundheitsinformationen, sodass ein Schulungsbedarf vorliegt [6].

Zudem werden Qualitätskriterien wie die Evidenzbasierung von Gesundheitsinformationen bei dem Ranking von Ergebnissen in Suchmaschinen nicht berücksichtigt [7], sodass Bürger*innen die Suche nach verlässlichen Gesundheitsinformationen erschwert wird. In Tiefeninterviews, die im Rahmen einer Studie zu Gesundheitsinformationen im Internet durchgeführt wurden, zeigte sich, dass die wissenschaftliche Fundierung der Angebote für die Teilnehmenden kein Kriterium bei der Online-Suche darstellte. Zudem wurden bekannte Angebote als vertrauenswürdig

bewertet. Dies stellt jedoch einen Trugschluss dar, denn bekannte Informationsangebote sind nicht immer vertrauenswürdig und weisen auch nicht immer eine wissenschaftliche Fundierung auf [8]. Dies zeigt, dass es Bürger*innen häufig schwerfällt, die Qualität und Vertrauenswürdigkeit von Gesundheitsinformationen zu beurteilen. Auch Ärzt*innen sind evidenzbasierte Informationsangebote (z. B. www.gesundheitsinformation.de) häufig entweder nicht bekannt oder sie schätzen sie als nicht vertrauenswürdig ein [9].

Um informierte Entscheidungen treffen zu können, benötigen Bürger*innen zuverlässige Informationen. In den Medien, in Gesundheitsinformationen und in der alltäglichen Kommunikation werden allerdings Behauptungen zum Nutzen und Schaden von Behandlungen aufgestellt, die häufig nicht vertrauenswürdig oder irreführend sind. Bürger*innen einschließlich Angehörige der Gesundheitsprofessionen stehen vor der Herausforderung, die Verlässlichkeit dieser Aussagen kritisch zu bewerten [10]. Vielen Menschen fällt es schwer, die Zuverlässigkeit von Informationen zu beurteilen, sodass sie womöglich anstelle effektiver Behandlungen schädliche oder ineffektive Behandlungen wahrnehmen [11]. Aus diesem Grund ist die Fähigkeit zur kritischen Bewertung von Behauptungen über Behandlungseffekte wichtig [12].

Durch eine selektive Auswahl und Darstellung der Inhalte in Gesundheitsinformationen kann der Nutzen von medizinischen Interventionen überschätzt und der Schaden unterschätzt werden [13]. Weiterhin werden nicht selten irreführende oder schwer verständliche Formate der Risikokommunikation (z. B. relative Risiken) eingesetzt. Darüber hinaus entsprechen Gesundheitsinformationen in ihrem Anspruch häufig nicht der Gesundheitskompetenz der Zielgruppe [14].

Sowohl die (kritische) Gesundheitskompetenz der allgemeinen Bevölkerung [15, 16] als auch die Angehöriger von Gesundheitsprofessionen [17, 18] ist ausbaufähig, denn eine niedrige Gesundheitskompetenz ist mit schlechteren Behandlungserfolgen assoziiert [16].

1.3 Kritische Gesundheitskompetenz

Allen mindestens 17 Definitionen von Gesundheitskompetenz (Health Literacy) ist gemein, dass sie als „[...] die Motivation und die Fähigkeit[en] von Menschen, relevante Gesundheitsinformationen zu finden, zu verstehen, zu beurteilen und anzuwenden, um im Alltag in den Bereichen der Krankheitsbewältigung, Krankheitsprävention und Gesundheitsförderung Urteile fällen und Entscheidungen treffen zu können [...]“ [19, 20] verstanden wird. Diese Definition bezieht sich vor allem auf die Fähigkeit zum kompetenten Umgang mit gesundheitsrelevanten Informationen [19], impliziert jedoch nicht zwangsläufig den Anspruch an die Qualität von Informationen im Sinne evidenzbasierter Gesundheitsinformationen. Nach Nutbeam (2000) gibt es drei Level in der Hierarchie von Gesundheitskompetenz (funktionale, interaktive und kritische), wobei kritische Gesundheitskompetenz auf der höchsten Stufe angesiedelt ist [21]. Kritische Gesundheitskompetenz

beinhaltet die Befähigung dazu, die Qualität der gefundenen Gesundheitsinformationen kritisch zu bewerten und zu hinterfragen [14, 22]. Die Beurteilung von Behauptungen über Behandlungseffekte in (Gesundheits-)Informationen stellt zudem einen Teilaspekt kritischer Gesundheitskompetenz dar [23].

1.4 Informierte gemeinsame Entscheidungsfindung

Bürger*innen wünschen sich die Beteiligung an gesundheitsbezogenen Entscheidungsprozessen und präferieren zu etwa 55 % die gemeinsame Entscheidungsfindung mit der Ärztin oder dem Arzt [24]. Es ist die Aufgabe Angehöriger der Gesundheitsprofessionen, informierte Entscheidungen als ethisch legitimierten Anspruch auf Grundlage der evidenzbasierten Medizin zu ermöglichen [25]. Dazu müssen Bürger*innen – einschließlich Angehöriger der Gesundheitsprofessionen – kritische Gesundheitskompetenz als Voraussetzung für eine evidenzbasierte und informierte gemeinsame Entscheidungsfindung (Informed Shared Decision Making (ISDM)) besitzen. Nur so sind Angehörige der Gesundheitsprofessionen imstande, gemeinsam mit Patient*innen Diagnoseverfahren, Behandlungen, Management oder Unterstützung basierend auf der besten verfügbaren Evidenz und den Werten sowie Präferenzen der Patient*innen auszuwählen [14]. Albarqouni et al. (2018) identifizierten 68 durch ein Expertenpanel konsentiertere Kernkompetenzen für eine evidenzbasierte Praxis, die Curricula für Angehörige der Gesundheitsprofessionen enthalten sollten, um die Qualität der Versorgung und Behandlungsergebnisse zu verbessern [26]. Die meisten dieser Kernkompetenzen konnten nach den klassischen fünf Handlungsschritten nach Sackett (ask, acquire, appraise, apply, assess) klassifiziert werden [26, 27].

Zudem sind evidenzbasierte Gesundheitsinformationen erforderlich, um diese in Konsultationen gezielt einsetzen und empfehlen sowie Risiken transparent kommunizieren zu können. Ersteller*innen von evidenzbasierten Gesundheitsinformationen tragen somit zur Realisierung von informierten Entscheidungen bei.

Patient*innen brauchen die sozialen und kognitiven Fähigkeiten, um ihre persönlichen Werte, Präferenzen und Erfahrungen auszudrücken, effektiv zu kommunizieren und Fragen zu stellen sowie Informationen zu erhalten, zu verstehen und mit Angehörigen der Gesundheitsprofessionen auszutauschen. Dies schließt Informationen zu alternativen Optionen, Risiken und Unsicherheiten ein [14]. Auch die Befähigung zur kritischen Bewertung der Qualität von Gesundheitsinformationen stellt einen wesentlichen Aspekt dar [28]. Besitzen Patient*innen diese Fähigkeiten nicht, ist es erforderlich, dass Angehörige der Gesundheitsprofessionen dies erkennen und entsprechend darauf reagieren (z. B. durch Vorbereitung der Patient*innen auf ein Gespräch mittels einer Checkliste oder Hinzuziehen von Angehörigen).

Um eine optimale Versorgung zu gewährleisten, müssen nach dem erweiterten Modell von Muscat et al. (2021) evidenzbasierte Medizin (EbM), patientenzentrierte Kommunikation und Gesundheitskompetenz im Rahmen der gemeinsamen Entscheidungsfindung zusammenwirken (Abbildung 1):

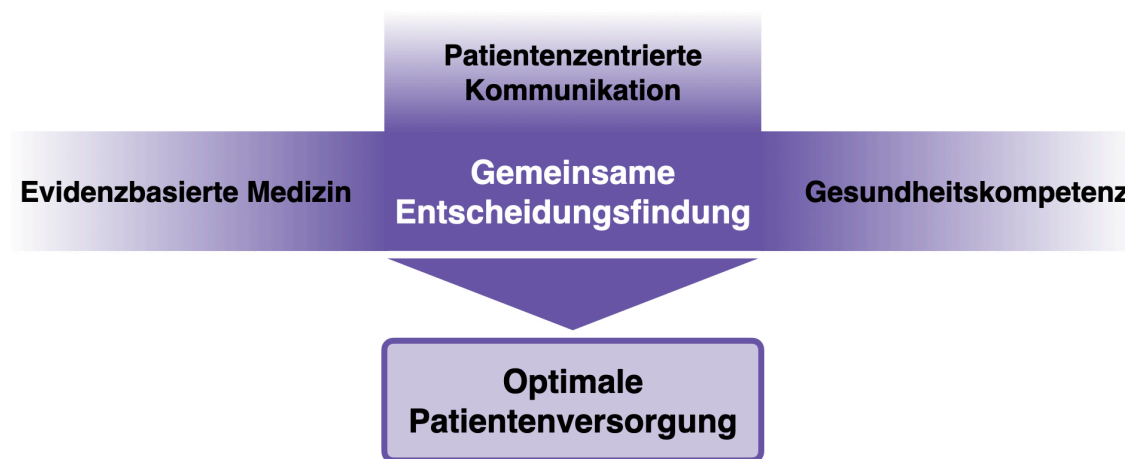


Abbildung 1: Erweitertes Modell der gemeinsamen Entscheidungsfindung unter Berücksichtigung der Gesundheitskompetenz. Eigene Darstellung in Anlehnung an [14].

1.5 Kritische Gesundheitsbildung

Der Schlüssel zu einem Mehr an Gesundheitskompetenz und damit zur informierten Entscheidung ist kritische Gesundheitsbildung, die als geeignetes Instrument zur Verbesserung der Gesundheitskompetenz gilt [29]. Das Konzept der EbM kann dabei als Basis für Interventionen der kritischen Gesundheitsbildung dienen [22, 30]. Das Ziel, die gesundheitliche Kompetenz zu erhöhen, ist u. a. in § 20 des Präventionsgesetzes explizit benannt [31]. Die Förderung der kritischen Gesundheitskompetenz der Bevölkerung (einschließlich Angehöriger der Gesundheitsprofessionen und Ersteller*innen von Gesundheitsinformationen) durch kritische Gesundheitsbildung ist unerlässlich, um das Ziel der informierten Entscheidung zu erreichen.

1.6 Ziele der Dissertation

Diese Dissertation leistet auf drei verschiedenen Wegen einen Beitrag zur Realisierung informierter Entscheidungen mittels kritischer Gesundheitsbildung:

1. durch die Entwicklung und Pilotierung eines Schulungsprogramms für Ersteller*innen von Gesundheitsinformationen zur Entwicklung evidenzbasierter Gesundheitsinformationen (Projekt inkl. Publikation 1 [32]),

2. durch die Entwicklung und Pilotierung eines Schulungsprogramms für Ärzt*innen und Medizinstudierende zur Förderung ihrer Kompetenzen in evidenzbasierter Entscheidungsfindung (Projekt inkl. Publikation 2 [33]) und
3. durch die Mitwirkung an einem Projekt zur Förderung eines Teilbereichs kritischer Gesundheitskompetenz anhand der Validierung eines Instruments zur Kompetenzmessung (Projekt inkl. Publikation 3 [34]).

Für die heterogene Gruppe von Ersteller*innen von Gesundheitsinformationen gab es in Deutschland bisher keine spezielle Fortbildung zur Entwicklung evidenzbasierter Gesundheitsinformationen, um zur Qualitätsentwicklung beizutragen. Projekt 1 versucht dies zu ändern.

Um eine evidenzbasierte Gesundheitsversorgung zu ermöglichen, ist die systematische Integration von ISDM in die Aus-, Weiter- und Fortbildung von Angehörigen der Gesundheitsprofessionen notwendig [26, 35]. Dies impliziert die Förderung der (kritischen) Gesundheitskompetenz. Projekt 2 soll dies realisieren.

Die Förderung der kritischen Gesundheitskompetenz von Schüler*innen sollte möglichst spätestens in der Primarstufe beginnen. Projekt 3 intendiert daher u. a. die kritische Gesundheitskompetenz von Schüler*innen zu fördern, wobei hier zunächst ein Instrument zur Kompetenzmessung validiert wurde.

Alle drei Publikationen wurden jeweils in PubMed-indexierten internationalen Journalen mit Peer-Review-Verfahren veröffentlicht (BMC Medical Education, Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen und BMC Public Health). Die Autorin ist Erstautorin aller Publikationen; bei Publikation 2 handelt es sich um eine geteilte Erstautorenschaft.

1.7 Schulungsprogramme als komplexe Interventionen

Das methodische Vorgehen der Projekte 1 und 2 folgte dem UK Medical Research Council (MRC) Framework für die Entwicklung und Evaluation komplexer Interventionen [36], welches 2021 aktualisiert wurde [37]. Bei Schulungsprogrammen handelt es sich um komplexe Interventionen. Die Komplexität ergibt sich sowohl aus den Komponenten der Intervention als auch aus ihrer Interaktion mit dem Kontext, in dem sie durchgeführt wird. So hat beispielsweise der Kontext einen großen Einfluss auf die Effektivität einer Intervention [37]. Ein Schulungsprogramm besteht stets aus mehreren interdependenten Einzelkomponenten, die für sich allein wirken, sich wechselseitig bedingen und ihrerseits in einen komplexen Kontext implementiert werden, mit dem sie wiederum interagieren [36-38]. Die Komponenten, welche die Wirksamkeit des Schulungsprogrammes beeinflussen können, sind u. a. die Ziele, Inhalte, Methoden und Medien sowie die Qualifikation der Dozierenden.

Forschung zu komplexen Interventionen kann in Phasen betrachtet werden, obwohl diese Phasen nicht unbedingt nacheinander folgen. Bei den Phasen handelt es sich um die Entwicklung oder Identifizierung einer Intervention, die Testung und Bewertung der Machbarkeit und des Evaluationsdesigns, die Evaluation sowie die wirkungsvolle Implementierung. Es ist möglich zur nächsten Phase überzugehen, zu einer vorherigen Phase zurückzukehren, eine Phase zu wiederholen oder aufzuhören. Jede Phase besitzt dabei gemeinsame Kernelemente (Berücksichtigung des Kontexts, Entwicklung und Verfeinerung der Programmtheorie, Einbeziehung der Interessengruppen, Identifizierung der wichtigsten Unsicherheiten, Verfeinerung der Intervention und wirtschaftliche Erwägungen) [37] (Abbildung 2):

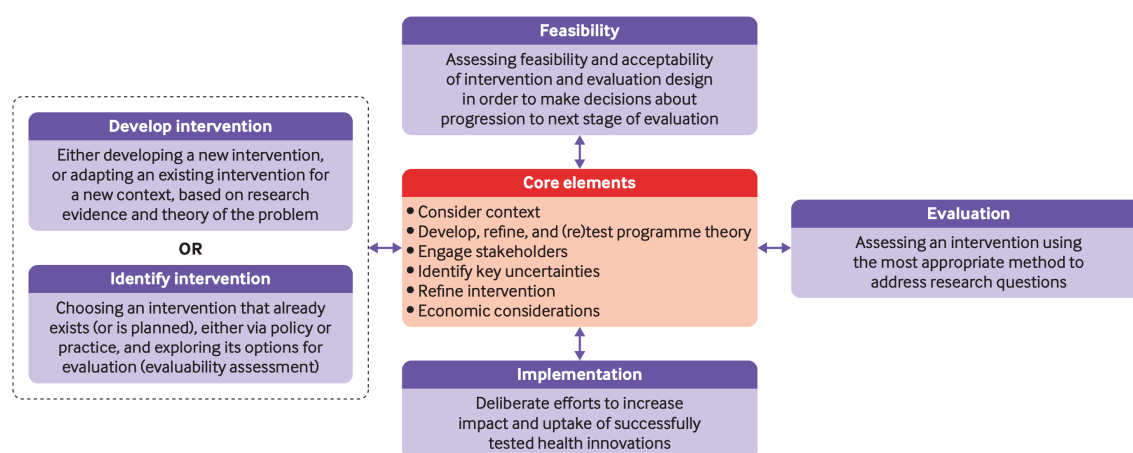


Abbildung 2: Framework für die Entwicklung und Evaluation komplexer Interventionen [37].

Die Projekte 1 und 2 bilden jeweils die Phase der Entwicklung und Testung der Machbarkeit ab. Dabei sollten u. a. Unsicherheiten im Hinblick auf das Evaluationsdesign (z. B. in Bezug auf die Rekrutierung) oder die Intervention (z. B. in Bezug auf Inhalte, Durchführung, Akzeptanz der Teilnehmenden, Kapazität der Anbieter zur Durchführung der Schulungsprogramme) reduziert werden [37].

1.8 Zu Projekt und Publikation 1

Das Projekt zur *Implementierung der Leitlinie evidenzbasierte Gesundheitsinformation* (IMLEGI) intendiert die Verbesserung der Qualität von Gesundheitsinformationen im deutschen Sprachraum durch die Schulung von Ersteller*innen. Die Leitlinie definiert Qualitätskriterien für die Erstellung von evidenzbasierten Gesundheitsinformationen. Das Projekt beinhaltete zunächst die wissenschaftliche Entwicklung und Pilotierung eines Schulungsprogramms für die Ersteller*innen von Gesundheitsinformationen, da Schulungen die Implementierung von Leitlinien verbessern können [39]. Im Rahmen einer qualitativen Pilotstudie sollte die Machbarkeit und

Akzeptanz eines Blended Learning-Schulungsprogramms getestet und die Schulung iterativ optimiert werden, um sie anschließend in einer randomisierten kontrollierten Studie zu evaluieren.

Das Schulungsprogramm besteht aus zwei Modulen. Das erste Modul umfasst Inhalte zu EbM und soll Kompetenzen zur systematischen Recherche, Auswahl, kritischen Bewertung und Extraktion von relevanter Literatur vermitteln. Das zweite Modul befasst sich mit der Anwendung der Leitlinie und umfasst die Qualitätskriterien für evidenzbasierte Gesundheitsinformationen, die kritische Bewertung von Gesundheitsinformationen und die Reflexion von Prozessen zur Entwicklung von Gesundheitsinformationen [32].

1.9 Zu Projekt und Publikation 2

Es wurde ein Blended Learning-Schulungsprogramm zum Kerncurriculum Basismodul *Evidenzbasierte Entscheidungsfindung* des Deutschen Netzwerks Evidenzbasierte Medizin (DNEbM) in einem Projekt des Fachbereichs EbM in Aus-, Weiter- und Fortbildung im Rahmen der ärztlichen Fortbildung entwickelt und pilotiert. Das Curriculum *Evidenzbasierte Entscheidungsfindung* intendiert die Evidenzbasierung klinischer Entscheidungen im Sinne einer wissenschaftlich fundierten und kritisch reflektierten klinischen Praxis zu fördern [40]. Das Schulungsprogramm wurde für Ärzt*innen und Medizinstudierende zur Förderung ihrer Kompetenzen in evidenzbasierter Entscheidungsfindung entwickelt. Partner im durchgeführten Projekt waren die Halle School of Health Care (HSHC) und die Ärztekammer Berlin.

Die Schulung setzt sich aus insgesamt sechs Modulen zusammen. Die Module 1 bis 5 zielen darauf ab, Kompetenzen für die systematische Recherche, Auswahl, kritische Bewertung und Extraktion relevanter Literatur nach den Methoden der evidenzbasierten Medizin zu vermitteln. Modul 6 beabsichtigt Ärzt*innen und Medizinstudierende dazu zu befähigen, Patient*innen die beste verfügbare Evidenz zur Verfügung zu stellen, Behandlungsoptionen mit ihnen zu diskutieren und dabei evidenzbasierte Gesundheitsinformationen und individuelle Patientenpräferenzen zu berücksichtigen [33].

1.10 Zu Projekt und Publikation 3

Die internationale Arbeitsgruppe des *Informed Health Choices* (IHC)-Projekts hat sich zum Ziel gesetzt, Menschen unter anderem durch Schulungen zu befähigen, Behauptungen über Behandlungseffekte (oder Effekte zu gesundheitsbezogenen Handlungen) bewerten und informierte Entscheidungen treffen zu können [41]. Die Arbeitsgruppe hat 2013 begonnen Schlüsselkonzepte zu entwickeln, die Lehrenden, Journalist*innen oder anderen Vermittler*innen als Rahmenkonzept zur Entwicklung von Lehr-/Lernmaterialien dienen sollen, damit Menschen befähigt werden, die Konzepte zu verstehen und anzuwenden. Mittlerweile handelt es sich um 49 Schlüsselkonzepte

(ursprünglich 32), die drei Oberkategorien mit 10 Unterkategorien zugewiesen sind und zwischen 2015 und 2019 jährlich literatur-, experten- und erfahrungsbasiert weiterentwickelt wurden [42, 43] (Abbildung 3):

1. Claims <i>Claims about effects that are not supported by evidence from fair comparisons are not necessarily wrong, but there is an insufficient basis for believing them.</i>	2. Comparisons <i>Studies should make fair comparisons, designed to minimise the risk of systematic errors (biases) and random errors (the play of chance).</i>	3. Choices <i>What to do depends on judgements about a problem, the relevance of the available evidence, and the balance of expected benefits, harms, and costs.</i>
1.1 Assumptions that treatments are safe or effective can be misleading. 1.2 Seemingly logical assumptions about <i>research</i> can be misleading. 1.3 Seemingly logical assumptions about <i>treatments</i> can be misleading. 1.4 Trust based on the source of a claim alone can be misleading.	2.1 Comparisons of treatments should be fair. 2.2 Reviews of the effects of treatments should be fair. 2.3 Descriptions of effects should clearly reflect <i>the size of the effects</i>. 2.4 Descriptions of effects should reflect <i>the risk of being misled by the play of chance</i>.	3.1 Evidence should be relevant. 3.2 Expected advantages should outweigh expected disadvantages.

Abbildung 3: Drei Oberkategorien und Unterkategorien der Schlüsselkonzepte [43].

Die erste Oberkategorie (Claims) sagt aus, dass Behauptungen über Effekte, die nicht durch Evidenz aus fairen Vergleichen gestützt werden, nicht unbedingt falsch sind, aber es keine ausreichende Grundlage gibt, um ihnen zu vertrauen. Die zweite Oberkategorie (Comparisons) meint, dass Studien zur Identifizierung von Behandlungseffekten faire Vergleiche anstellen sollten, um das Risiko von systematischen und zufälligen Fehlern zu minimieren. Die dritte Oberkategorie (Choices) bedeutet, dass die Entscheidung, was zu tun ist, von der Beurteilung eines Problems, der Relevanz der verfügbaren Evidenz und dem Gleichgewicht zwischen erwartetem Nutzen, Schaden und erwarteten Kosten abhängt [43].

Um Schulungen evaluieren zu können, wurden die *Claim Evaluation Tools* entwickelt, die einen Teilaspekt kritischer Gesundheitskompetenz messen. Es handelt sich um einen Pool aus Multiple-Choice-Fragen bestehenden Items. Die Items messen die Fähigkeit, Behauptungen über Behandlungseffekte beurteilen zu können. Die Entwicklung und Pilotierung erfolgten über drei Jahre iterativ mittels qualitativer und quantitativer Methoden. Die Items des Instruments sind den Schlüsselkonzepten zugeordnet und messen die Fähigkeit diese anzuwenden. Aktuell findet eine Übersetzung, Pilotierung und Validierung in verschiedenen Ländern statt [34, 44].

Ziel des Vorhabens dieser Dissertation war die Anpassung und Validierung der deutschen Items der *Claim Evaluation Tools* für die Zielgruppe der Schüler*innen der Sekundarstufe I (6.-10. Klasse, 11-16 Jahre). Die Reliabilität und Validität der Skala wurden anhand der probabilistischen Testtheorie von Rasch bestimmt [34].

2 Diskussion

2.1 Zusammenfassung wesentlicher Ergebnisse

Diese kumulative Dissertation leistet auf drei verschiedene Weisen einen Beitrag zur Realisierung informierter Entscheidungen mittels kritischer Gesundheitsbildung. Erstens wurde durch die Entwicklung und Pilotierung eines Schulungsprogramms für Ersteller*innen die Verbesserung der Qualität von Gesundheitsinformationen im deutschen Sprachraum angestrebt [32]. Zweitens wurde durch die Untersuchung der Machbarkeit und Akzeptanz eines Schulungsprogramms für Ärzt*innen und Medizinstudierende zur Förderung ihrer Kompetenzen in evidenzbasierter Entscheidungsfindung ein wichtiges Bildungsangebot auf den Weg gebracht [33]. Drittens fand die Anpassung und Validierung von Items der *Claim Evaluation Tools* statt, die einen Teilaspekt von kritischer Gesundheitskompetenz messen und zur Evaluation von Schulungen zur Förderung kritischer Gesundheitskompetenz eingesetzt werden können [34].

Sowohl das entwickelte Schulungsprogramm zur Förderung von Kompetenzen in evidenzbasierter Entscheidungsfindung als auch das Schulungsprogramm für Ersteller*innen von Gesundheitsinformationen erwies sich als machbar und wurde von den Teilnehmenden gut akzeptiert [32, 33]. Die Ergebnisse des *Critical Health Competence-Tests* (CHC-Test), der das Konstrukt der kritischen Gesundheitskompetenz in Verbindung mit dem Konzept der EbM operationalisiert, zeigten eine Steigerung der kritischen Gesundheitskompetenz der Teilnehmenden des Schulungsprogrammes zu evidenzbasierter Entscheidungsfindung [33].

Die deutschen Items der *Claim Evaluation Tools* wurden für die Zielgruppe der Sekundarschüler*innen kontextualisiert, adaptiert und validiert. Die Validierungsstudie zeigte, dass die meisten Items zur Messung der Fähigkeit von Sekundarschüler*innen zur Beurteilung von Behauptungen über Behandlungseffekte verwendet werden können, da sie eine akzeptable Modellpassung aufweisen. Einige Items mussten jedoch revidiert werden, indem die Texte der Szenarien vereinfacht, Antwortoptionen entfernt oder überarbeitet wurden [34].

2.2 Stärken und Schwächen

Eine Stärke beider Schulungsprogramme ist deren systematische Entwicklung auf Grundlage des problemorientierten Lernens [45] durch berufspädagogisch qualifiziertes Personal. Die Schulung von Ersteller*innen zur Entwicklung von evidenzbasierten Gesundheitsinformationen ist zudem nach Wissen der Autorin bisher einmalig. Die Datenanalyse wurde jeweils von zwei Forschenden durchgeführt und verschiedene Daten (Feldnotizen der Unterrichtsbeobachtungen und Ergebnisse der Fokusgruppeninterviews) wurden trianguliert. Der Kodierungsvorgang wurde transparent

dokumentiert, damit er reproduzierbar ist. Eine Limitation beider Pilotstudien stellt allerdings die Tatsache dar, dass die Forschenden, welche die Schulung entwickelt und durchgeführt haben, auch die Daten sammelten und analysierten [32, 33].

Beim Schulungsprogramm für Entwickler*innen von Gesundheitsinformationen stuften sich nicht alle Teilnehmenden tatsächlich als Entwickler*innen ein (z. B. Medien- und Kommunikationswissenschaftler*innen). Demzufolge gaben sie an, den Praxisbezug der Schulung schlechter einschätzen zu können als beispielweise Methodiker*innen [32]. Ähnlich war es in der Pilotstudie zur Förderung von Kompetenzen in evidenzbasierter Entscheidungsfindung. Auch dort waren nicht alle Teilnehmenden praktisch als Ärzt*innen tätig und konnten damit den Praxisbezug der Schulung weniger gut einschätzen. Zudem zeigte sich, dass eine klare Zielgruppendefinition entscheidend ist, da einige der Teilnehmenden (z. B. Wissenschaftler*innen) angaben, dass die Schulung nicht optimal auf sie zugeschnitten sei [33].

Dennoch wurde in beiden Pilotstudien deutlich, dass eine multiprofessionelle Schulung eine Chance darstellen könnte, da verschiedene Gesundheitsprofessionen und Berufsgruppen von den Perspektiven und Meinungen anderer zu profitieren schienen. Bei der Pilotstudie zur Förderung von Kompetenzen in evidenzbasierter Entscheidungsfindung war dies insbesondere während der Rollenspiele zu gemeinsamer Entscheidungsfindung der Fall. Hauptsächlich bedingt durch die Heterogenität der Zielgruppe kam es teilweise zu gegensätzlichen Meinungen bei den Fokusgruppeninterviews. Daher lässt sich nicht ausschließen, dass eine Datensättigung nicht vollständig erreicht wurde [32, 33].

Die Ergebnisse des CHC-Tests bei der Schulung zu evidenzbasierter Entscheidungsfindung sind mit Vorsicht zu interpretieren, u. a. da zu Beginn des ersten Moduls und am Ende der Schulung nur 22 Teilnehmende den Test absolvierten. Darüber hinaus wurde das Instrument bei geschulten und ungeschulten Schüler*innen und Studierenden validiert und nicht bei Ärzt*innen [33].

Eine wichtige Stärke der Studie zu den *Claim Evaluation Tools* besteht darin, dass die Rasch-Analyse verwendet wurde, die es ermöglicht, das gemessene Kompetenzniveau zu untersuchen und Variabilität in der Messgenauigkeit zu identifizieren [46]. Die Itemsets sind einfach zu handhaben und zeitsparend einsetzbar. Es braucht nur eines der drei Itemsets verwendet werden, um die Fähigkeit zur Beurteilung von Behauptungen über Behandlungseffekte zu messen. Darüber hinaus basieren die *Claim Evaluation Tools* auf den Schlüsselkonzepten, die als Definition der zu erwerbenden Kompetenzen dienen. Die Einbeziehung der Zielgruppe in die Entwicklung von Messinstrumenten zur Erhebung der Gesundheitskompetenz hat sich als sinnvolle Methode zur Verbesserung der Instrumentenqualität erwiesen [47]. Daher wurden qualitative Interviews durchgeführt, um mögliche Barrieren, Lesbarkeit, Verständlichkeit und Akzeptanz der Itemsets

durch die Schüler*innen zu eruieren und eine fachliche Einschätzung in Bezug auf die Zielgruppe durch die Lehrenden zu erhalten [34].

Eine Schwäche der Studie zu den *Claim Evaluation Tools* stellt die Tatsache dar, dass die Itemsets nur in zwei deutschsprachigen Ländern und nicht in der Schweiz getestet wurden. Da es sich um ein Convenience Sample handelte, sind die Ergebnisse insbesondere aufgrund der durch das föderale Bildungssystem in Deutschland bedingten Heterogenität nicht repräsentativ für alle Schüler*innen der Sekundarstufe I. Die begrenzte Zahl der teilnehmenden Schulen und die Tatsache, dass keine Gymnasien, sondern eine Oberschule (Kombination von Haupt- und Realschule) und zwei Neue Mittelschulen (entsprechen Hauptschulen) eingeschlossen wurden, schränken die Verallgemeinerbarkeit der Ergebnisse ein. Unklar bleibt außerdem, wie die Items in anderen Settings funktionieren (z. B. bei vorliegenden kulturellen Unterschieden). Das Geschlecht und der Migrationshintergrund wurden zudem nicht in die Analyse einbezogen [34].

Darüber hinaus könnte der Pool an übersetzten und getesteten Items vergrößert werden, da die Liste der Schlüsselkonzepte und der entsprechenden Items in den letzten Jahren erweitert wurde. Einige Schlüsselkonzepte könnten jedoch von jüngeren Sekundarschüler*innen zu schwer verständlich sein. Da die Datenbank der Items im Jahr 2020 aufgrund der letzten Änderungen der Schlüsselkonzepte aktualisiert wurde, müssen die übersetzten Items neu angeordnet werden, damit sie mit der neuesten Version übereinstimmen [48]. Die Tatsache, dass die Schlüsselkonzepte kontinuierlich weiterentwickelt werden, erschwert die Durchführung internationaler Validierungsstudien. Das Update hat allerdings keine Auswirkungen auf die verwendeten Methoden oder die Ergebnisse dieser Validierungsstudie [34].

2.3 Bedeutung der Dissertation: Implikationen und Handlungsfelder

Das Thema kritische Gesundheitsbildung wurde aus drei verschiedenen Perspektiven bzw. mittels drei verschiedener Herangehensweisen betrachtet. Die Dissertation fokussierte die vier Zielgruppen Ersteller*innen von Gesundheitsinformationen, Ärzt*innen und Medizinstudierende sowie Sekundarstufenschüler*innen. Die Projekte 1 und 2 befassten sich mit den Phasen der Entwicklung und Pilotierung von Schulungsprogrammen. Projekt 3 befasste sich mit der Anpassung und Validierung eines Erhebungsinstrumentes, das u. a. zur Evaluation von Schulungen eingesetzt werden kann. Die Projekte weisen zahlreiche Synergien auf (insbesondere Projekt 1 und 2) und es ergeben sich verschiedene Handlungsfelder und folgende Herausforderungen:

Eingeschränkte Umsetzung evidenzbasierter Praxis

Eine wichtige Herausforderung besteht darin, dass EbM und die Versorgung gemeinsam gedacht werden und nicht als Dichotomie wahrgenommen werden. Gleiches gilt für medizinische Curricula, in denen EbM als Kernelement betrachtet werden sollte [49]. Auch wenn EbM mittlerweile

in viele medizinische Curricula integriert wurde, zeigt die Evidenz eine unzureichende Nutzung wissenschaftlicher Erkenntnisse in der täglichen Praxis. Als Gründe für die eingeschränkte Umsetzung evidenzbasierter Praxis wurden häufig mangelnde Ressourcen und Zeit, ein unzureichender Zugang sowie finanzielle Barrieren identifiziert [50, 51], was sich mit den Ergebnissen der Pilotstudie deckt [33]. Nur elf der 29 Teilnehmenden hatten Zugang zur Cochrane Library. Zeitmangel wurde als großes Hindernis für die Umsetzung evidenzbasierter Praxis und gemeinsamer Entscheidungsfindung angesehen. Mangelnde Kompetenzen sind allerdings das am häufigsten genannte Hindernis für die Integration von wissenschaftlichen Erkenntnissen in die tägliche Versorgung [50, 52].

Insbesondere ISDM war in der Vergangenheit häufig nicht Bestandteil von Curricula [26, 53, 54]. Das Schulungsprogramm legt hingegen einen Fokus auf den Prozess der gemeinsamen Entscheidungsfindung. Kommunikationsfähigkeiten sind dabei essentiell [55, 56].

Rekrutierungsprobleme bei den Schulungen

Trotz intensiver Werbung (u. a. über Verteiler, Flyer, Facebook-Ankündigungen) traten in Halle Rekrutierungsprobleme für die Schulung zu evidenzbasierter Entscheidungsfindung auf. Daher musste die Zielgruppe auf andere Gesundheitsprofessionen ausgeweitet werden. Außerdem war es aufgrund wiederholter Rekrutierungsprobleme nicht möglich, in Leipzig eine geplante Schulung zu realisieren. Der Standort scheint ein wichtiger Faktor zu sein, da es in Berlin keine Rekrutierungsprobleme gab. Darüber hinaus kann die Art der Institution, welche die Fortbildung anbietet, eine Rolle spielen, da die Ärztekammer Berlin beispielsweise für ihr Angebot an medizinischer Fortbildung bekannt ist [33].

Auch die Rekrutierungserfahrungen aus der Pilotstudie mit Ersteller*innen von Gesundheitsinformationen weisen darauf hin, dass die Rekrutierung von Organisationen für die Schulung eine Herausforderung darstellt. Organisationen sehen die Notwendigkeit einer Schulung möglicherweise nicht, da Führungskräfte ihre Mitarbeiter*innen bereits für gut qualifiziert halten. Derzeit gibt es zudem kaum Anreize für die Entwicklung von evidenzbasierten Gesundheitsinformationen (z. B. seitens der Politik), sodass der Mehrwert nicht unbedingt gesehen wird. Darüber hinaus könnte der mit dem Schulungsprogramm verbundene Aufwand ein Hindernis sein, da es von den teilnehmenden Einrichtungen einen relativ hohen Zeit- und Personalaufwand erfordert. Es ist daher wichtig, eine Strategie zu entwickeln, um Anreize für Anbieter von Gesundheitsinformationen zu schaffen, eine Kompetenzentwicklung der Mitarbeiter*innen anzustreben und evidenzbasierte Gesundheitsinformationen zu entwickeln [32]. Auch zur finanziellen und nicht-finanziellen Intensivierung gemeinsamer Entscheidungsfindung gibt es Überlegungen (z. B. Bereitstellung von Entscheidungshilfen, Vergütung). In diesem Zusammenhang stellen sich jedoch mehrere Fragen.

So wäre beispielsweise zu überlegen, ob nur incentiviert werden soll, wenn auch Entscheidungshilfen vorliegen und wie genau zu beurteilen ist, ob ISDM tatsächlich umgesetzt wurde [57].

Aneignung von EbM-Inhalten

Im Hinblick auf die EbM-Inhalte ähneln einige der Ergebnisse der Pilotstudie mit Ersteller*innen von Gesundheitsinformationen denen der Pilotstudie mit Ärzt*innen und Medizinstudierenden zur Kompetenzentwicklung in evidenzbasierter Entscheidungsfindung. Bei beiden Schulungen baten die Teilnehmenden um eine theoretische Einführung in statistische und methodische Begriffe anhand von Praxisbeispielen [32, 33]. So kommen u. a. auch Jenny et al. (2018) in einer prospektiven Beobachtungsstudie zu dem Schluss, dass Medizinstudierende und Professionelle eine vertiefte Schulung in der Interpretation risikobezogener medizinischer Statistiken erhalten sollten, um deren statistische Kompetenz zu fördern [58-61]. Dies ist Teil beider Schulungsprogramme.

Die umfangreichen EbM-Inhalte in der Schulung für Ersteller*innen von Gesundheitsinformationen förderten ein tieferes Verständnis des komplexen Entwicklungsprozesses von evidenzbasierten Gesundheitsinformationen, der umfassende Fähigkeiten erfordert sowie zeit- und personalintensiv ist. Dies führte jedoch dazu, dass sich einige Teilnehmende überfordert fühlten und die Notwendigkeit der Aneignung umfangreicher EbM-Kenntnisse nicht sahen, da sie diese in der Praxis nicht anwenden würden [32].

Heterogenität der Ersteller*innen von Gesundheitsinformationen

Eine weitere Herausforderung besteht darin, dass Mitarbeitende mit unterschiedlichen Qualifikationen und Professionen in die Entwicklung von Gesundheitsinformationen eingebunden werden und sie während ihrer Ausbildung nicht unbedingt mit dem Thema in Berührung gekommen sind. Sowohl EbM als auch die Entwicklung von evidenzbasierten Gesundheitsinformationen sollten in die Curricula der gesundheitswissenschaftlichen Studiengänge integriert werden, da dies ein relevantes Berufsfeld für Gesundheitswissenschaftler*innen darstellt [32].

Angemessenheit der Schulungsprogramme für die Zielgruppe

Die Angemessenheit des Schulungsprogrammes für die Zielgruppe scheint ein wichtiges Thema zu sein, da die Teilnehmenden hinsichtlich ihres Vorwissens und ihrer Beteiligung an der Entwicklung von Gesundheitsinformationen innerhalb ihrer Einrichtungen heterogen waren, sodass der Praxistransfer in unterschiedlichem Ausmaß stattfindet. Die Angemessenheit für die Zielgruppe wird voraussichtlich eine Herausforderung bleiben, da es keine definierte Qualifikation zur Entwicklung von evidenzbasierten Gesundheitsinformationen gibt [32]. Auch in der Schulung zu evidenzbasierter Entscheidungsfindung wünschten sich die Teilnehmenden eine klarere Zielgruppendefinition. Hier musste die Zielgruppendefinition aufgrund von Rekrutierungsproblemen

ausgeweitet werden, sodass auch andere Gesundheitsprofessionen eingeschlossen wurden [33]. Dennoch zeigten beide Pilotstudien, dass eine multiprofessionelle Schulung eine Chance offenbart, da die Teilnehmenden von den Perspektiven und Meinungen anderer zu profitieren schienen [32, 33]. In der Schulung zu evidenzbasierter Entscheidungsfindung wurde angeregt, dass die Zielgruppe der Schulung anhand von Vorwissen und Erfahrungen anstatt der Profession definiert werden könnte [33].

Mangel an Englischkenntnissen

Ein Mangel an Englischkenntnissen kann ein Problem bei der Entwicklung von evidenzbasierten Gesundheitsinformationen darstellen. Englischkenntnisse sind notwendig, um eine systematische Literaturrecherche durchführen, Studien kritisch bewerten und Daten extrahieren zu können. In der Pilotstudie wurde den Teilnehmenden die übersetzten Studie angeboten, was in der Praxis nicht der Fall sein wird [32]. Auch Ärzt*innen müssen hierfür über ausreichende Englischkenntnisse verfügen. Angebote wie *Cochrane kompakt* ermöglichen es jedoch, Kurzzusammenfassungen von Cochrane Reviews auf Deutsch zu erhalten [62]. Dieses Angebot wird auch in dem Schulungsprogramm vorgestellt.

Messung kritischer Gesundheitskompetenz

Ein Ziel des IHC-Projekts ist es, Schüler*innen zu befähigen, kritisch über Gesundheitsbehauptungen und -entscheidungen als einen wichtigen Aspekt der (kritischen) Gesundheitskompetenz nachzudenken. Perspektivisch kann der Einsatz des validierten Instruments dazu beitragen, die Entwicklung und Evaluation von Schulungen zu unterstützen, insbesondere im Hinblick auf Schlüsselkonzepte, die eher schwierig zu verstehen sind.

Der Nachweis der Rasch-Skalierbarkeit des Instruments bietet u. a. die Chance, die Messung kritischer Gesundheitskompetenz studien- und zielgruppenübergreifend zu standardisieren, indem Items aus einer Itembank verwendet werden [63]. Dies kommt der Tatsache zugute, dass aktuell mindestens 217 validierte Instrumente zur Messung von Gesundheitskompetenz zur Verfügung stehen. Diese unterscheiden sich in den Messdomänen (z. B. Rechnen, Verständnis), dem Kontext (z. B. generisch, krankheitsspezifisch), dem Ansatz zur Instrumentenentwicklung (z. B. Rasch), der Durchführungszeit, der Art der Validierungsstudie (z. B. Stichprobe, Durchführung), der Sprache und Bewertung (objektiv/leistungsbasiert oder subjektiv/selbstberichtet) [64]. Die meisten Instrumente orientieren sich an der klassischen Testtheorie und nur wenige an modernen Messtheorien wie der Item-Response-Theorie [63]. Die Items der *Claim Evaluation Tools* sind das einzige im deutschsprachigen Raum verfügbare Rasch-skalierte Instrument für diese Altersgruppe, das hinreichend zuverlässig ist und als objektives Maß kritischer Gesundheitskompetenz herangezogen werden kann [34].

Evaluation von Schulungen

Eine Herausforderung bleibt die Evaluation von Schulungen, die bisher nur selten in Bezug auf (kritische) Gesundheitskompetenz und ISDM stattfindet. Es besteht allerdings die Notwendigkeit, Interventionen sowohl für Angehörige der Gesundheitsprofessionen als auch für die breite Öffentlichkeit zu evaluieren, um sicherzustellen, dass sie Behauptungen über Behandlungseffekte und Entscheidungen kritisch hinterfragen können. Angehörige der Gesundheitsprofessionen und Personen, die Gesundheitsinformationen weitergeben, sollten sich darüber im Klaren sein, dass Patient*innen möglicherweise nicht in der Lage sind, kritisch über Behauptungen zu Behandlungseffekten nachzudenken. Daher haben sie eventuell Schwierigkeiten, Informationen zu verarbeiten, die für informierte Entscheidungen erforderlich sind [65].

Steckelberg et al. untersuchten bereits 2013 die Evidenzbasierung edukativer Interventionen im Bereich Aus-, Weiter- und Fortbildung. Es wurden 259 randomisierte kontrollierte Studien eingeschlossen. Die Evaluationsstudien waren etwa zur Hälfte in der Medizin angesiedelt, wobei lediglich 16 von 259 Studien in Deutschland durchgeführt wurden. Nur bei 85 Studien wurde eine Stichprobenberechnung berichtet. Die Autorinnen kommen zu dem Schluss, dass ein dringender Bedarf an randomisierten kontrollierten Studien zu edukativen Interventionen besteht. Demnach ist eine öffentliche Förderung von Wirksamkeitsstudien für den Bildungsbereich essentiell [66]. Die Evaluation der Wirksamkeit von Schulungsprogrammen als komplexe Interventionen ist methodisch anspruchsvoll, aber möglich. Es handelt sich um einen wichtigen Schritt vor der Implementierung in die Praxis.

In einer systematischen Übersichtsarbeit wurde die Effektivität von EbM-Schulungen untersucht. EbM-Schulungen scheinen einen Einfluss auf das Wissen und die Fähigkeiten zu haben, jedoch bleibt die praktische Anwendung von EbM unklar. Die eingeschlossenen Studien wiesen zudem eine schlechte Berichtsqualität auf und es wurde häufig nicht berücksichtigt, dass es sich um komplexe Interventionen handelt. Die Autor*innen empfehlen, dass die Auswirkungen auf Versorgungsprozesse und patientenrelevante Endpunkte untersucht werden sollten [67].

Theorie-Praxis-Transfer

Der Theorie-Praxis-Transfer bleibt eine große Herausforderung von evidenzbasierter Entscheidungsfindung. Daher erscheinen Folgeinterviews zur Überprüfung der Anwendung der erworbenen Kenntnisse in der Praxis als Teil der Evaluation sinnvoll [33]. Der Praxistransfer ließe sich ebenfalls mittels eines Simulationspatientengesprächs untersuchen [68]. Selbst wenn entsprechende Kompetenzen erworben wurden, müssen sie z. B. in Konsultationen zum Einsatz kommen, um ISDM zu realisieren. Gemäß des zentralen Schulungsziels wären bei EbM-Schulungen ISDM und kritische Gesundheitskompetenz, die für evidenzbasierte Entscheidungsfindung erforderlich ist, geeignete Endpunkte. Zur Messung gemeinsamer Entscheidungsfindung liegen

zahlreiche Instrumente vor. Hinsichtlich ihrer psychometrischen Eigenschaften fehlt es allerdings an Evidenz, entweder weil die Eigenschaften nicht evaluiert wurden oder weil eine unzureichende Methodik Anwendung fand [69].

2.4 Schlussfolgerung und Ausblick

Im deutschen Gesundheitssystem steckt noch viel Entwicklungspotential, um die Gesundheitskompetenz der Bevölkerung und ISDM zu fördern [70] sowie zu einer evidenzbasierten Gesundheitsversorgung zu gelangen. Es ist eine strukturelle Integration von (kritischer) Gesundheitsbildung notwendig, um eine langfristige Förderung sicherzustellen. Dies umfasst die entsprechende Gestaltung der Rahmenlehrpläne der allgemeinbildenden Schulen und Curricula der beruflichen Aus-, Weiter- und Fortbildung zur gezielten Qualifizierung von Angehörigen der Gesundheitsprofessionen [70]. Hierbei sind die spezifischen Bedürfnisse der Zielgruppen zu berücksichtigen. Wesentlich scheint auch nach wie vor ein Wandel zu sein, der eine positive Kultur hinsichtlich evidenzbasierter Praxis bewirkt [51]. Es müssen weiterhin Strategien entwickelt werden, wie die Umsetzung von ISDM und evidenzbasierter Praxis gelingen kann. Das durch den Innovationsfonds geförderte Projekt *Making SDM a Reality* hat sich beispielsweise zum Ziel gesetzt, gemeinsam mit Patient*innen und medizinischem Fachpersonal ISDM in den Klinik- und Praxisalltag sowie in die Regelversorgung zu integrieren. Derzeit wird beraten, ob das Programm in die Regelversorgung überführt werden kann [71].

So existieren in Deutschland mehrere Bestrebungen, um zu informierten Entscheidungen von Bürger*innen zu gelangen. Ein wesentliches Problem besteht jedoch in dem „Flickenteppich“ aus Einzelbestrebungen. Es sollte die Entwicklung und dauerhafte Moderation eines Netzwerks angestrebt werden, das gemeinsam an einem Strang zieht und Aktivitäten bündelt. In Österreich wurde beispielsweise zur Förderung der Gesundheitskompetenz der österreichischen Bevölkerung die Österreichische Plattform Gesundheitskompetenz (ÖPGK) gebildet, auf der wesentliche Akteure vernetzt sind [72]. Über ein gemeinsames Portal könnten alle deutschlandweiten Aktivitäten (u. a. Nationaler Aktionsplan Gesundheitskompetenz [19]) transparent gemacht werden, um Synergien zu nutzen.

Die Ergebnisse der Pilotstudie mit Ersteller*innen von Gesundheitsinformationen wurden bei der Durchführung der randomisierten kontrollierten Studie zur Implementierung der *Leitlinie evidenzbasierte Gesundheitsinformation* berücksichtigt [73]. Aufgrund der SARS-CoV-2-Pandemie musste das Schulungsprogramm in ein reines Online-Format überführt werden. Dies erhöhte die Flexibilität hinsichtlich der Durchführung. Das Schulungsprogramm könnte nach einer erfolgreichen Evaluation z. B. auf dem Nationalen Gesundheitsportal, das seit September 2020 online und dessen Träger das Bundesministerium für Gesundheit ist [74], als Fortbildung angeboten werden.

Im Konzept des Instituts für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG) zum Nationalen Gesundheitsportal wurde festgehalten, dass die Content-Partner des Portals perspektivisch bestimmte Qualitätsanforderungen erfüllen sollten. Dabei soll der Träger des Portals die Content-Partner durch ein Qualifizierungsprogramm unterstützen [75]. Das Portal intendiert die Suche nach Gesundheitsinformationen zu optimieren und qualitativ hochwertige Gesundheitsinformationen bereitzustellen. Langfristiges Ziel ist es, die Gesundheitskompetenz der Bevölkerung zu verbessern [75]. Aktuell liefern vier Content-Partner die Inhalte für die Gesundheitsinformationen auf der Webseite oder unterstützen bei der Erstellung des Inhalts: das IQWiG, der Krebsinformationsdienst des Deutschen Krebsforschungszentrums (DKFZ), das Robert Koch-Institut (RKI) und die Unabhängige Patientenberatung Deutschland (UPD) [76]. Es sind unter Umständen weitere Content-Partner erforderlich, u. a. um eine inhaltliche Fülle zu gewährleisten.

Damit qualitativ hochwertige Gesundheitsinformationen langfristig zur Verfügung stehen, sollten zudem Strukturen zur Entwicklung geschaffen werden, beispielsweise im Rahmen der Erstellung medizinischer Leitlinien [32]. Sinnvoll erscheint eine zentrale Koordination der Aktivitäten. So könnte mittels eines nationalen Themenkataloges eine Kartierung vorgenommen werden, die transparent macht, welche Einrichtung welche Themen bearbeitet. In jedem Fall sollten Einrichtungen, die Gesundheitsinformationen erstellen, mit erfahrenen Methodiker*innen der evidenzbasierten Medizin zusammenarbeiten. Durch eine systematische Bewertung der Gesundheitsinformationen mittels der validierten Checkliste *Mapping the Quality of Health Information* (MAPP info) [77] könnte eine Qualitätsbeurteilung vorgenommen, nicht erfüllte Qualitätskriterien identifiziert und eine Qualitätsverbesserung forciert werden. Die zunehmende Digitalisierung bietet zudem die Chance, qualitativ hochwertige Gesundheitsinformationen besser zu disseminieren, z. B. über die Integration in eine Praxissoftware oder die elektronische Patientenakte (ePA).

Im DNEbM wurde eine Projektgruppe aus dem Fachbereich EbM in Aus-, Weiter- und Fortbildung zur Entwicklung eines Evaluationskonzept für Lernangebote für Angehörige von Gesundheitsprofessionen basierend auf dem DNEbM Kerncurriculum Basismodul *Evidenzbasierte Entscheidungsfindung* gegründet [78]. Eine Herausforderung stellt die Entwicklung eines validen Evaluationsinstrumentes dar, das einfach, flexibel und schnell einsetzbar ist und zur Qualitätssicherung, Effektivitätsbeurteilung und als Feedbackfunktion für Lernende und Lehrende dient [79]. Dies ist u. a. durch die eingeschränkte Vergleichbarkeit der unterschiedlichen EbM-Kursangebote im deutschsprachigen Raum mit heterogenen Zielgruppen in verschiedenen Settings begründet, aus der unterschiedliche Anforderungen resultieren. Unter Berücksichtigung internationaler Literatur wurden für die sechs curricularen Module kompetenzorientierte Lehr-/Lernziele formuliert, die an zwei Zielgruppen (nicht-akademische und akademische Angehörige von Gesundheitsprofessionen) angepasst wurden. Die Lehr-/Lernziele wurden anschließend in einem Delphi-Verfahren durch ein Expertenpanel konsentiert. Sie sollen als Basis für die Entwicklung

eines Item-Pools zur Evaluation der jeweiligen Module des Curriculums dienen. Das Instrument soll bedarfsgerecht an verschiedene Zielgruppen und Formate anpassbar sein. Langfristig ist es geplant, das bestehende Curriculum in ein *Living Curriculum* weiterzuentwickeln [80].

Nach einer erfolgreichen Evaluation in einer randomisierten kontrollierten Studie kann das EbM-Schulungsprogramm als Fortbildungsprogramm etabliert und institutionalisiert werden. Das Schulungsprogramm könnte ebenfalls an eine interprofessionelle Fortbildung angepasst werden. Auch die Entwicklung einer Schulung für interessierte Bürger*innen, beispielsweise in Form eines Kurses an der Volkshochschule oder für Patient*innen im Rahmen der Patientenuniversität [81], erscheint sinnvoll, um die kritische Gesundheitskompetenz zu fördern.

Ein zukünftiges Ziel der deutschen Projektgruppe bezüglich der *Claim Evaluation Tools* ist es, den Pool der übersetzten und getesteten Items zu vergrößern. Ein weiterer Schritt ist die Übersetzung der Lehr-/Lernressourcen ins Deutsche, sodass die Itemsets als Instrument in einer randomisierten kontrollierten Studie verwendet werden könnten, um die Wirksamkeit von Schulungen bezogen auf die Fähigkeit von Sekundarschüler*innen, Behauptungen über Behandlungseffekte zu bewerten, zu messen. Außerdem könnten sie zur objektiven Kompetenzmessung in Querschnittsstudien eingesetzt werden. Derzeit messen die *Claim Evaluation Tools* nur einen Teil der kritischen Gesundheitskompetenz. Die Schlüsselkonzepte und folglich die *Claim Evaluation Tools* könnten beispielsweise auf Behauptungen zur diagnostischen Genauigkeit ausgeweitet werden. Zusätzlich könnten Items zur Messung der funktionalen und interaktiven Gesundheitskompetenz aufgenommen werden [34].

Im Rahmen des IHC-Projekts wurden bereits Lehr-/Lernmaterialien für Grund- und weiterführende Schulen entwickelt, die beginnend im Jahr 2022 in randomisierten Studien in Kenia, Ruanda und Uganda evaluiert werden sollen [48]. Eine verbleibende Herausforderung ist die Aus- und Fortbildung von Lehrenden, die möglicherweise nicht über die erforderlichen Kompetenzen zum Unterrichten der Schlüsselkonzepte verfügen. So sollten beispielsweise Teach the teacher-Kurse etabliert werden, damit Lehrende auf diese Aufgabe bestmöglich vorbereitet werden. Kritische Gesundheitskompetenz muss fächerübergreifend vermittelt werden, da sie Fächer wie Mathematik, Biologie und Englisch umfasst. Daher müssen Konzepte und Ressourcen für fächerübergreifenden Unterricht wie Teamteaching organisiert werden. Darüber hinaus wäre es sinnvoll, die Schlüsselkonzepte anhand eines Spiralcurriculums zu lehren und zu lernen, das zuvor erlernte Inhalte festigt und gleichzeitig neue Konzepte einführt [11]. Viele Schulen in Deutschland und Österreich haben immer noch wissensbasierte anstatt kompetenzbasierte Curricula, was den Erwerb von Gesundheitskompetenz erschwert [34]. Mittels Unterstützung und gezielter Beratung bei der kompetenzorientierten Curriculumentwicklung könnte dies verbessert werden.

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Thesen

1. Die Entwicklung und Pilotierung eines Blended Learning-Schulungsprogramms für Ersteller*innen von Gesundheitsinformationen kann entscheidend zur Verbesserung der Qualität der Gesundheitsinformationen im deutschen Sprachraum beitragen.
2. Da die teilnehmenden Ersteller*innen von Gesundheitsinformationen heterogene Qualifikationen, Professionen und Aufgabenbereiche aufwiesen, kamen sie insbesondere zu unterschiedlichen Bewertungen der Relevanz der umfangreichen EbM-Inhalte und sahen teilweise nicht die Notwendigkeit diese zu erlernen.
3. Das entwickelte Blended Learning-Schulungsprogramm für Ärzt*innen und Medizinstudierende auf Basis von problembasiertem Lernen zur Förderung ihrer Kompetenzen in evidenzbasierter Entscheidungsfindung hielt der Machbarkeitsprüfung stand und wurde von den Teilnehmenden gut akzeptiert.
4. Die Teilnehmer*innen der Schulung zur Förderung der Kompetenzen in evidenzbasierter Entscheidungsfindung wiesen im Prä-Post-Vergleich eine signifikant höhere kritische Gesundheitskompetenz auf.
5. Die Teilnehmer*innen der Schulung zur Förderung der Kompetenzen in evidenzbasierter Entscheidungsfindung empfanden die praktische Umsetzung der Methoden evidenzbasierter Medizin zum Teil als zu umfangreich, sodass der Theorie-Praxis-Transfer von evidenzbasierter Entscheidungsfindung eine bleibende Herausforderung darstellt und in Evaluationsstudien fokussiert werden sollte.
6. Sowohl beim Schulungsprogramm für Ersteller*innen von Gesundheitsinformationen als auch beim Schulungsprogramm für Ärzt*innen und Medizinstudierende wurden durch die Pilotierung die Unsicherheiten im Hinblick auf das Evaluationsdesign (z. B. in Bezug auf die Rekrutierung) und die Intervention (z. B. in Bezug auf Inhalte, Durchführung, Akzeptanz der Teilnehmenden, Kapazität der Anbieter zur Durchführung der Schulungsprogramme) reduziert. Die Wirksamkeit sollte in randomisierten kontrollierten Studien überprüft werden.
7. In beiden Pilotstudien zu den Schulungsprogrammen wurde deutlich, dass eine multiprofessionelle Schulung eine Chance darstellt, da verschiedene Gesundheitsprofessionen und Berufsgruppen von den Perspektiven und Meinungen anderer zu profitieren schienen.

8. Durch die Kontextualisierung, Adaption und Validierung der deutschen Items der *Claim Evaluation Tools* liegt nun das einzige im deutschsprachigen Raum verfügbare Rasch-skalierte Instrument für Sekundarschüler*innen vor, das hinreichend zuverlässig ist und als objektives Maß kritischer Gesundheitskompetenz zur Evaluation von Schulungen und in Querschnittsstudien herangezogen werden kann.

9. Der Nachweis der Rasch-Skalierbarkeit der deutschen Items der *Claim Evaluation Tools* bietet u. a. die Chance, die Messung kritischer Gesundheitskompetenz studien- und zielgruppenübergreifend zu standardisieren, indem Items aus einer Itembank verwendet werden.

Publikationsteil

Die vorliegende Dissertation beinhaltet folgende Publikationen:

1. Hinneburg J, Lühnen J, Steckelberg A, Berger-Höger B. A blended learning training programme for health information providers to enhance implementation of the Guideline Evidence-based Health Information: development and qualitative pilot study. *BMC Med Educ.* 2020;20(1):77. Epub 2020/03/19. doi: 10.1186/s12909-020-1966-3.
2. Hinneburg J, Hecht L, Berger-Höger B, Buhse S, Lühnen J, Steckelberg A. Development and piloting of a blended learning training programme for physicians and medical students to enhance their competences in evidence-based decision-making. *Z Evid Fortbild Qual Gesundheitswes.* 2020;150-152:104-11. Epub 2020/05/23. doi: 10.1016/j.zefq.2020.02.004.
3. Hinneburg J, Gasteiger-Klicpera B, Kasper J, Lühnen J, Maitz K, Martens T, et al. Evaluating student's ability to assess treatment claims: validating a German version of the Claim Evaluation Tools. *BMC Public Health.* 2023;23(1). doi: 10.1186/s12889-022-14700-w.

RESEARCH ARTICLE

Open Access



A blended learning training programme for health information providers to enhance implementation of the *Guideline Evidence-based Health Information*: development and qualitative pilot study

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Abstract

Background: The *Guideline Evidence-based Health Information* was published in 2017 and addresses health information providers. The long-term goal of the guideline is to improve the quality of health information. Evidence-based health information represents a prerequisite for informed decision-making. Health information providers lack competences in evidence-based medicine. Therefore, our aim was to develop and pilot-test a blended learning training programme for health information providers to enhance application of the guideline.

Methods:

1. Development:

We developed the training programme according to the Medical Research Council guidance for developing and evaluating complex interventions. The training programme was planned on the basis of problem-based learning. It aims to impart competences in evidence-based medicine. Furthermore, it comprises the application of criteria for evidence-based health information.

2. Pilot testing:

We conducted a qualitative pilot study focusing on the acceptability and feasibility of the training programme. Health information providers were recruited and in-house training sessions were offered. Feasibility and acceptability were explored by structured class observations and in semi-structured focus group interviews with the participants after the training sessions. The transcripts and documentations were analysed using qualitative content analysis according to Mayring. The training was revised iteratively according to the results.

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Results: We conducted two training courses with 17 participants between November 2018 and March 2019. The adequacy of the training for the target group was identified as a major issue. There was significant heterogeneity concerning previous knowledge. Some wished to delve deeper while others seemed to be overwhelmed. In general, the work tasks were understandable. However, the participants asked for a more detailed theoretical introduction in advance. The practical relevance of the evidence-based medicine contents was rated rather low compared to the content about evidence-based health information. Based on these results, we revised the programme.

Conclusions: Overall, the training proved to be feasible for implementation. Meeting the needs of all the participants was a challenge, since they were heterogeneous. Not all of them will be able or intend to implement the training contents into their working routine to the full extent. The implementation will be evaluated in a randomised controlled trial.

Keywords: Training, Health information, Evidence-based medicine, Guideline implementation, Guideline adherence

Background

Evidence-based health information (EBHI) is a prerequisite for informed decision-making, which is based on adequate knowledge and implies decisions which are congruent with peoples' preferences and values [1]. Most German citizens prefer shared decision-making [2]. The German Patients' Rights Act underlines the right to comprehensive and comprehensible information and implies patient participation in medical decisions [3]. Furthermore, the German National Cancer Plan defined shared decision-making as one of the planned goals [4].

There is a flood of health information available on the internet, but most of the information does not fulfil the quality criteria for good health information. Unfortunately, quality criteria are not considered in the ranking algorithms of the search engines so that the search for high-quality health information is challenging. In addition, people often rate familiar and commercial online information sources as being trustworthy [5].

In Germany, good practice guidelines for health information have been published by a working group in the German Network for Evidence-based Medicine. They provide support for authors and publishers of EBHI by offering quality criteria [6]. Even though the criteria for EBHI have long been defined [7, 8], implementation into practice is lacking [9, 10]. Interviews with providers of health information revealed shortcomings regarding their competences in evidence-based medicine (EBM) [11].

In 2017, the *Guideline Evidence-based Health Information* was published by the German Network for Evidence-based Medicine [12]. It addresses providers of health information and aims to improve the quality of health information by giving 21 recommendations on EBHI based on systematic evidence syntheses. The guideline includes evidence-based recommendations for the development, content and presentation of EBHI (e.g. numerical and graphical representation). Moreover, it comprises methodological and ethical requirements like

the development process, contents of EBHI and target group involvement.

Several strategies for implementing guidelines have been discussed. There is comprehensive evidence that the implementation of guidelines in combination with a training programme can improve implementation [13]. In contrast to medical guidelines, the *Guideline Evidence-based Health Information* requires methodological competence to systematically search and appraise the evidence before it can be presented according to the guideline recommendations. Therefore, this implementation strategy seemed to be essential for the guideline.

This qualitative study describes the development and piloting of a blended learning training programme for health information providers to enhance implementation of the *Guideline Evidence-based Health Information*. It is part of a project on the implementation of the guideline in combination with a training programme which will be evaluated in a randomised controlled trial registered on the ISRCTN registry (ISRCTN96941060). The study protocol of the randomised controlled trial has been submitted to *Trials*. The aim of this study was to explore the feasibility and acceptability of the programme. The study protocol is available online [14].

Methods

We followed the Medical Research Council guidance for developing and evaluating complex interventions with focus on acceptability and feasibility (phase I and II) [15]. The results are reported according to the revised *Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare* (CReDECI 2) [16] and *COnsolidated criteria for REporting Qualitative research* (COREQ) (see Additional file 1) [17].

Development of the training programme

We developed the training programme following Kern's six-step approach for curriculum development for medical education [18]:

- *Step 1: Problem identification and general needs assessment*

The paucity of EBHI as a prerequisite for participation and informed decision-making has repeatedly been described. The *Guideline Evidence-based Health Information* summarised this background and was therefore used as the main source to derive the general needs.

- *Step 2: Targeted needs assessment*

Health information providers, who develop and publish health information, have been defined as the target group, which is not limited to a special profession or level of education. However, we expected that most of the participants would be health professionals with an academic background. Competences required for developing EBHI were defined and squared with the results of exploratory interviews previously conducted with the target group in order to set the scope of the training [11].

- *Step 3: Goals and objectives*

The teaching goals were inspired by the basic curriculum for evidence-based decision-making of the German Network for Evidence-based Medicine [19] and formulated accordingly. They are broadly defined in Table 1.

- *Step 4: Educational strategies*

The educational strategies were developed using information gained in steps 1–3. The training programme

was planned on the basis of problem-based learning to foster active learning. Problem-based learning was chosen since it complies with the paradigm of EBM such as critical thinking. A case example about smoking cessation was set up as a practical challenge. Problem-based learning is intended to increase knowledge and understanding by using appropriate problems that serve as a stimulus for learning [20]. Due to the limited amount of time, the format of problem-based learning was shortened: The problem and teaching goals were formulated by the teachers instead of offering a complete open setting. The problem of smoking cessation was chosen to enable providers to understand the relevance of scientific knowledge [20] in the development process of health information and also to promote intrinsic interest and motivation. The topic comprises evidence-based methods for smoking cessation, for instance counselling, medications (e.g. bupropion) and nicotine replacement therapy.

- *Step 5: Implementation*

This step corresponds to the piloting of the training programme.

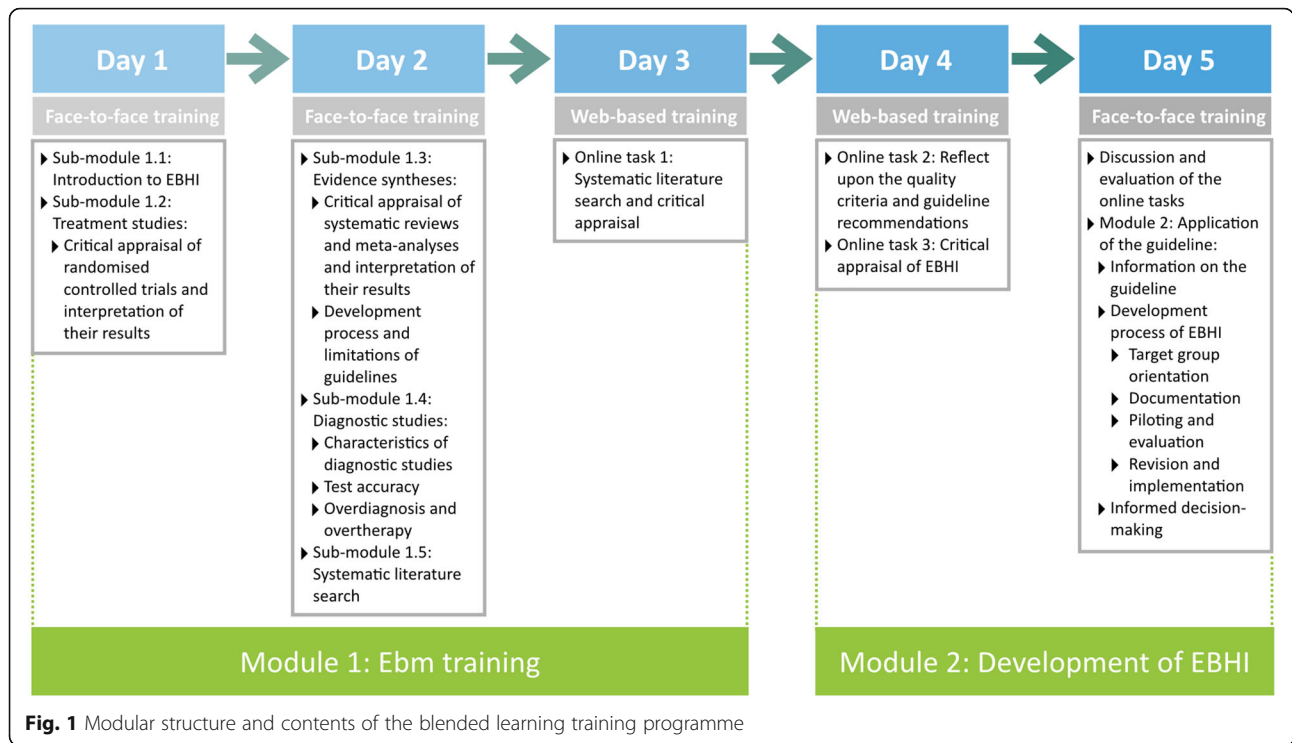
- *Step 6: Evaluation and feedback*

The training programme was revised according to the results of this qualitative pilot study and the implementation will be evaluated in a randomised controlled trial.

The training programme consists of two modules (Fig. 1). The first module comprises EBM training (submodule 1.1–1.5) and aims to impart competences in

Table 1 Teaching goals

Module	Goals
Module 1: EBM training	
1.1 Introduction to EBHI	<ul style="list-style-type: none"> • Participants gain an overview of the development process of EBHI and reflect on their own practice. • Participants start to consider EBHI as the prerequisite for informed decision-making.
1.2 Treatment studies	<ul style="list-style-type: none"> • Participants understand the difference between association and causality and that randomised controlled trials (RCTs) are designed to establish a causal relationship. • Participants know the characteristics of RCTs. • Participants are able to interpret the results of RCTs and critically appraise them.
1.3 Evidence syntheses	<ul style="list-style-type: none"> • Participants are able to interpret the results and critically appraise systematic reviews and meta-analyses. • Participants describe the development process of guidelines and are aware of their limitations.
1.4 Diagnostic studies	<ul style="list-style-type: none"> • Participants are able to identify the major study designs for diagnostic studies. • Participants are able to calculate and interpret test accuracy. • Participants recognise the problem of overdiagnosis and overtherapy.
1.5 Systematic literature search	<ul style="list-style-type: none"> • Participants are able to conduct systematic literature searches to identify literature appropriate to their research question.
Module 2: Application of the guideline	
	<ul style="list-style-type: none"> • Participants are able to develop EBHI and document the development process. • Participants know about and apply strategies for piloting EBHI. • Participants consider EBHI as the prerequisite for informed decision-making.



searching for, critically appraising and extracting relevant literature according to the principles of EBM. The second module is about the application of the guideline and comprises the criteria for EBHI, critical appraisal of health information and the reflection of providers' processes for developing health information. A folder containing the training materials, sorted according to the modules, was provided for the participants.

The training programme was designed in a blended learning format. The first module comprises 2 days of face-to-face training followed by 1 day of web-based training (approximately 8 h per day). The second module is designed as an inverted (or flipped) classroom scenario (participants deal with the learning material prior to the face-to-face training) [21]: 1 day of web-based training followed by 1 day of face-to-face training.

The length of the online phase was coordinated with the participating institutions. A two-week online phase was recommended so that the participants would have enough time to complete the tasks. For the web-based training, the learning management system ILIAS was used. ILIAS included slideshows and text resources combined with online tasks and video tutorials. In addition, further information on the course contents was provided so that the participants could deepen the contents of the face-to-face phase. They were encouraged to upload the results of their online tasks and to receive feedback during the face-to-face training.

Piloting and feasibility of the training programme

We conducted a qualitative pilot study with focus on acceptability and feasibility of the training programme.

Setting and sample

The recruitment of health information providers was performed on an institutional level. Participating institutions were recruited via already existing contacts with the institutions. The directors of the institutions were contacted directly by telephone and asked if they were interested. We offered in-house training sessions for those employees involved in the development process of health information. There were no further requirements for participation. The teaching programme was designed for a maximum of 15 participants per course.

Data collection and procedure

Health information providers participated voluntarily in the training programme. An information sheet was sent out to the participants via email prior to the training. Written informed consent was obtained at the beginning of the training and data collection was conducted during the training sessions. Training and data collection were carried out by BBH and JH, who gave a brief introduction to their research. Baseline characteristics of the participants, including sex, age, education status, self-estimated English skills, self-estimated EBM knowledge and their qualifications for the development of health information, were assessed.

Feasibility and acceptability of the training programme were investigated from the perspectives of both learners and teachers. Acceptability was defined as the acceptance of teaching methods at classroom level and the relevance of contents at the practical level. Feasibility was defined as the practicability and usability of the training programme and its contents. At classroom level the focus was on the following aspects: comprehensibility of the learning and teaching materials and contents, structure of the training, scheduling, usability of the web-based learning environment and target group orientation. Potential application barriers, framework conditions and motivation were assessed at the practical level.

Furthermore, structured class observations were carried out by at least one silent observer taking field notes. Main foci of the observations were the reactions of the participants to teaching methods, the comprehensibility of materials and content, the interaction between teachers and participants (e.g. questions from the participants), problem-solving in the classroom situation as well as scheduling. The teachers also took field notes, which were discussed with observers afterwards. Work products such as flip charts, processes and interactions were documented.

After module 1 and module 2, feasibility and acceptability were explored from the personal perspective of the participants in semi-structured focus group interviews. The participants and three researchers (BBH, JH and AS), who led the focus groups, were present. At least one of these researchers had advanced experience in conducting focus groups. The researchers followed an adapted semi-structured interview guide which had been developed in a prior pilot study [22] to cover pre-defined categories but also allowed new categories to come up for discussion (see Additional file 2). Field notes were taken additionally during the focus group interviews which were also audio-recorded and transcribed verbatim. A short feedback (flash light) by the participants followed the online phase. The transcripts and findings were not returned to the participants for comment and/or correction because this would have involved a considerable additional organisational expense.

Data analysis

Analyses of the baseline characteristics were descriptive. The transcripts and documentations were analysed using qualitative content analysis according to Mayring [23]. The data were combined using between-methods triangulation [24]. BBH and JH coded the transcripts applying a coding guideline (see Additional file 3) and using the software QCAmap [25]. Initially, a category system was deductively derived from the research

questions. Despite the already existing category system, categories could be adapted flexibly via feedback loops during data analysis. During the coding process, categories were adapted and subcategories were inductively derived from the data. Afterwards, two researchers discussed the results. Theoretical data saturation was intended by an iterative process of testing, analysing and revising the training programme.

Results

Participants

We performed two pilot courses with employees from a health insurance company ($n = 5$) and a health information provider ($n = 12$) between November 2018 and March 2019. All the participants completed the training programme. The mean age of the participants was 41 years (range 28–51) and nine of 17 participants were female. Fifteen of 17 participants had a university degree (one in medicine) and two had a general education school-leaving certificate. The participants rated their English skills as being elementary (A2) ($n = 2$), intermediate (B1) ($n = 2$), upper intermediate (B2) ($n = 10$) or as being advanced (C1) ($n = 3$). They perceived their EBM knowledge as little ($n = 2$), moderate ($n = 11$), good ($n = 3$) and very good ($n = 1$). They all reported that they had acquired their qualification for the development of health information through their occupational activity (“learning by doing”) and by individual study using literature. The participants stated that they used the following sources for the development of health information: medical databases ($n = 9$), journals ($n = 10$), guidelines ($n = 12$), experts ($n = 11$) and others such as diverse online sources and conferences ($n = 7$).

Feasibility and acceptability

After the second training course, theoretical data saturation was assumed since few or no new insights were revealed. The focus groups lasted approximately 30 min. All the participants had the opportunity to express themselves and contributed to the focus group. Seven categories were established via qualitative content analysis: 1. expectations and motivation, 2. framework conditions of the training, 3. interaction and teaching methods, 4. planning of the training programme, 5. value and design of the learning and teaching materials, 6. comprehensibility of the contents and 7. practical relevance and feasibility. The field notes of the class observations and the results of the focus group interviews were triangulated. Most of the results from the class observations were congruent with those of the focus groups. Additionally, usage data (number and duration of accesses) from the learning management system ILIAS were considered. Quotes were translated verbatim.

1. Expectations and motivation

This category describes the participants' main motives for taking part in the training and what they expected of it.

In the first pilot course, the participants regarded the potential competitive advantage, unique selling point and their strategic development as the motivation for the training. Moreover, they saw it as an opportunity to have an improved argumentation basis for patients demanding services which are not covered by their health insurance, for example individual health services.

The participants' expectations of the second pilot course differed somewhat from those of the first pilot course. This was mainly due to the fact that the participating institution's main purpose is to develop health information. They mentioned that they wanted to get an overview of the complex market of health information. Concerning health information, they were interested in learning about do's and don'ts and how to translate evidence into plain language. Furthermore, they wanted to acquire EBM knowledge as well as statistical literacy, because they were afraid of making mistakes.

The participants described an area of tension between the criteria of EBHI and practice in both pilot courses. One participant was concerned that patients could be overwhelmed by EBHI, perhaps because they might not want to make a decision on their own.

2. Framework conditions of the training

This category includes the adequacy of the training for the target group, the adequacy of the time frame and the technical realisation of the online phase.

The adequacy of the training for the target group seemed to be a major topic in the focus group interviews. The participants were not sure about the definition of the target group and whether or not they belonged to it. On the one hand, this was the case because some participants did not identify or classify themselves as developers of health information since it was not their main task at work. On the other hand, there was significant heterogeneity among participants. Some were already trained in EBM and others were novices. One participant stated:

"I think it was bit by bit, actually. One was gradually introduced. I'm a beginner. Not from the EBM department. Therefore, I found it to be a good introduction to the topic." (Focus group 2)

But then again, one participant expressed her concern since she was not able to follow the contents:

"You expect previous knowledge that I don't have. And if you are always lagging behind a bit, it becomes difficult." (Focus group 1)

This implied that novices would not attain a deeper understanding. Other participants explained that they could follow quite well. It became clear that some participants with previous knowledge would have wished to delve deeper into a few of the topics and for others the contents seemed to be overwhelming:

"Surprisingly, lots of things weren't new for me. Therefore, I could follow quite well. I've done an EBM training before and I'm working in this field. Nevertheless, there were some new aspects and things one starts to see differently. I wasn't bored. Of course, I would have delved deeper into some aspects in another group. But it was clear that those who had just started absolutely could not... That's of course the challenge in such a diverse group." (Focus group 2)

The class observations coincided with the results of the focus groups. Especially in the second pilot course during the sub-module *Treatment studies* it became obvious that some participants already had knowledge of statistical terms, whereas others needed extensive explanations with the help of practical examples.

The participants explained that the heterogeneity of the target group fostered mutual understanding of the different departments within one institution. One participant said:

"I liked the fact that so many out of different departments participated. Because sometimes I've the feeling that they don't really know what we're doing and smile about it. Why we need so much time and come forward with quality and this and that. Insofar, I think it's good for the whole team. [...] Although it was heterogenic, it was productive." (Focus group 2)

Nevertheless, some participants suggested dividing up the training into different smaller modules or different courses depending on the prior knowledge:

"I sometimes asked myself the question, who the target group is. One would have to break up the training into smaller modules. [...] For different target groups so that it is possible to focus on different levels of knowledge." (Focus group 2)

However, one participant mentioned that it would not be possible to disentangle the target group.

Some participants appreciated the compact format of the training, but it was discussed whether the scope of

the training should be modified, depending on the previous knowledge of the target group. It was mentioned that the training programme requires quite a large amount of time and staff resources by the participating institutions.

Moreover, the participants gave feedback on the learning management system ILIAS. They said that it could not be operated intuitively. In addition, minor navigation problems in ILIAS were reported (e.g. locating download material). The usage data of ILIAS showed that all of the participants visited the platform. The duration of use differed significantly, partly because the participants organised themselves in groups to complete the online tasks. Additionally, some of the participants used the platform only for up- and downloading the online tasks.

3. Interaction and teaching methods

This category characterises the exchange between the involved people as well as the adequacy, realisation and acceptance of the teaching methods.

The participants described the learning atmosphere as pleasant and open for questions. The interactive instructional design, feedback and explanations were appreciated. Some participants said that the exercises and work tasks enhanced the learning effect:

“The practical exercises were very helpful to get a deeper understanding.” (Focus group 1)

Some of the working phases were perceived as too long as they required increased attention. Group work was judged to be well suited for the work task on systematic literature search (e.g. development of the PICO scheme).

4. Planning of the training programme

This category describes the adequacy of the planning of the training programme.

Some of the participants found it difficult to integrate the online phase into their working routine. One participant described the online phase and work task on systematic literature search as follows:

“I think I’ve done everything. But I’m much faster than my colleagues who’ve never done that before. And some of us had completed the first work task in a large group. [...] Self-organisation isn’t as easy sometimes. But we did a quite good job.” (Focus group 2)

Furthermore, it was mentioned that the online task on systematic literature search requires more time, especially for beginners. Implementing comprehensive

literature searches into the working routine seemed to be challenging.

Sometimes, a common thread was missing and the training concept was not transparent for some participants:

“What was missing... The big picture of the whole training concept. What are we doing how, and what is building on what and where can I expect what. Because some things will be part of the third attendance day, and I don’t know, will they be a topic or do I have to ask.” (Focus group 2)

Moreover, especially the participants of the first course wished for a longer input phase before performing the work tasks. This was particularly the case for the sub-module *Treatment studies*:

“It would have been easier for me if we had dealt with the terminology and the question ‘where do I have to look’ first and then with the tasks. Because those are fun and interesting, and I really want to know it. And then it’s frustrating to do the task like chewing a hard piece of meat and afterwards you get the tenderiser.” (Focus group 1)

The class observation also revealed that a common thread was missing in this sub-module and that several topics seemed to arise at random.

5. Value and design of the learning and teaching materials

This category explains how the participants rated the learning and teaching materials with regard to their practical relevance and design.

The training folder and printed presentations were appreciated for making notes and repeating the contents. Some participants would have liked digital slides as well. In general, the learning material was rated as clear and readily understandable. The authenticity of the studies used in the work tasks was emphasised positively:

“I liked the real texts. The use of real studies. That’s very concrete. That’s the real work and the right material to work on. It’s irritating if it [the studies in the work tasks] looks completely different.” (Focus group 2)

Additionally, the checklist for appraising health information was judged to be very helpful:

“I found the checklist for appraising health information very helpful for reflecting upon my own work.” (Focus group 2)

6. Comprehensibility of the contents

This category means the comprehensibility of the work tasks, terminology, criteria of EBHI and includes suggestions for additional contents.

The work tasks were judged to be understandable but some of them were also extensive and challenging. On the one hand, some participants considered the translated studies as too long for reading. On the other hand, some of the more experienced participants suggested that they could be offered the original English language studies. Critical appraisal of the studies was regarded as too demanding in the first pilot study. Some wished for a better explanation of the procedure of a study and a short guideline on how to read a study.

Furthermore, the calculation of absolute numbers from a meta-analysis was perceived as difficult. Many of the participants asked for definitions of (statistical) terms (e.g. *p* value and confidence interval) combined with practical examples before attempting the work tasks.

The participants gave some suggestions for additional contents. Since different departments of the institutions participated in the second pilot study, they had different perspectives on the development of health information. Therefore, they wanted to work on the interface between EBM and communication:

"I think it's important to discuss the interface between communication topics and EBM." (Focus group 2)

One participant suggested that it could be helpful to appraise health information from the participating institutions:

"I would have found it exciting to take a piece of our information and discuss what is already good and what isn't so that we are able to test the results concretely." (Focus group 2)

Moreover, some participants missed a further explanation of the evidence behind the guideline recommendations as well as the evidence concerning pictures, comics and multimedia formats. Regarding the criteria of EBHI, some participants wanted to intensify the practical application of the criteria.

"Of course, I would have liked more about how to apply it since I already know a lot of it from EBM. Extend this process of reflection, which we've worked on today." (Focus group 2)

They found it interesting that there might not be a clear answer to some questions concerning the development of EBHI due to insufficient evidence. The

definition of the target group and goal of an EBHI were identified as crucial criteria:

"Especially the goal and target group, that has to be focused very clearly before developing information or it has to be taken into consideration. Those are aspects that weren't clear to me before. Even if I've read it. I completely lost sight of it. Because it's logical that we do it to...? But why are we doing it? I found it quite interesting." (Focus group 2)

Furthermore, it was discussed whether it is ethical to leave out information that, for instance, does not have a good evidence base.

7. Practical relevance and feasibility

This category describes the practical relevance and applicability in practice.

Systematic literature search was regarded as interesting and informative. The sub-module *Diagnostic studies* was described as exciting as well. Reading the studies promoted critical thinking. Especially the explanation of different features of a meta-analysis seemed to be very helpful.

The case example about smoking cessation was considered to be relevant and helpful.

"The example and the topic were well chosen because it's a topic everyone is interested in and that everyone knows." (Focus group 1)

One participant described the case example as too abstract. The continuity of the example was considered as positive as was the fact that it caused empathy and structured the training:

"I liked Ms Lemke because one can put oneself in the position of a real person. She was present all the time and structured it for me. I liked this approach." (Focus group 2)

Moreover, the case example induced the reflection of the target group definition. In this case, the case example (Ms Lemke) suggested a need for information.

The practical relevance of the EBM module was rated rather low compared to the second module. The second module was described as more comprehensible and practical:

"It was much more comprehensible today than the two days before. This was mainly because of the practical examples, which are more familiar to me from daily business. I liked it really a lot." (Focus group 1)

In general, the participants saw the training as a good opportunity to deepen specific topics and many of them affirmed that they profited from it. However, the scientific character required a comprehensive training. Furthermore, it encouraged respect concerning the development of EBHI:

“Would I dare to develop an EBHI based on those three days of training? No way. I have to say so. I’ve great respect. But I think one sees those things with different eyes. And details are revealed, critical aspects, and that helps.” (Focus group 1)

Regarding the necessary resources in the workplace, it was mentioned that it is an advantage if there are several departments developing health information together. Additionally, the participants named time as the most relevant resource.

Revision

The training programme was revised iteratively based on our results. However, most of the changes were minor ones on slides or in the work tasks in order to improve clarity. Table 2 shows the identified need for revision and the revision conducted.

Discussion

Overall, the training was well accepted and it proved to be feasible for implementation. The extensive EBM knowledge encouraged a deeper understanding of the

complex development process of EBHI. However, it led to the fact that some participants felt overwhelmed by the contents and did not see the necessity of learning the extensive EBM contents.

The adequacy of the training for the target group seems to be a major issue since the participants in the pilot training sessions were heterogeneous regarding their prior knowledge and their involvement in the process of developing health information within their institutions. Not all of them will be able to or intend to implement the training contents into their working routine. Nevertheless, the training encouraged respect concerning the development of EBHI because the participants realised that developing EBHI is a complex process which requires comprehensive skills, is time-consuming and staff-intensive. The adequacy of the training for the target group will probably remain a challenge since there is no defined qualification for developing EBHI. Nevertheless, the pilot study showed that an interprofessional training seems to be an opportunity since different professions appeared to profit from the perspectives and opinions of others. A lack of English skills might be a problem in the process of developing EBHI. English skills are necessary to search for, critically appraise and extract relevant literature according to the principles of EBM. We offered the participants the translated studies but in practice this will not be the case.

To our knowledge, until now this training of health information providers for developing EBHI is unique. With regard to the EBM contents, some of the results of

Table 2 Results of the focus groups, class observations and revision process

Identified need for revision	Revision conducted
Focus groups and class observations: Whole training programme: A common thread was missing sometimes and the training concept was not transparent for some of the participants.	The explanation of the training programme’s structure had already been included in the sub-module 1.1 <i>Introduction to EBHI</i> and in the training folders. The structure will be made permanently visible in following training sessions (e.g. by using a poster).
Focus groups and class observations: Sub-module 1.2 <i>Treatment studies</i> : The participants asked for a theoretical introduction to statistical and methodological terms on the basis of practical examples in preparation for the work tasks.	The module was better structured and an input phase including practical examples was planned before the work tasks after the first pilot study. Additional practical examples were added after the second pilot course.
Focus groups and class observations: Sub-module 1.3 <i>Evidence syntheses</i> : Critical appraisal of the studies was regarded as too demanding in the first pilot study.	The work task on critical appraisal of a systematic review was divided up and planned as a group task.
Focus groups and class observations: Sub-module 1.2 <i>Treatment studies</i> and 1.3 <i>Evidence syntheses</i> : Reading the translated studies was considered as very challenging and time-consuming by the participants of the first pilot study.	The study texts were shortened by deleting less meaningful passages.
Focus groups: Online phase: Some participants mentioned that the online task on a systematic literature search requires more time, especially for beginners. The implementation of comprehensive literature searches into the working routine seemed to be challenging.	The work task was defined as optional for participants who are not involved in the methodical development of health information.
Focus groups and class observations: Module 2 <i>Application of the guideline</i> : Some participants requested further explanation of the evidence behind the guideline recommendations as well as the evidence concerning pictures, comics and multimedia formats.	Some slides containing the evidence behind relevant recommendations were added.

this pilot study are similar to those of another training course conducted for physicians and medical students to enhance their competences in evidence-based decision-making [26]. Here too, the participants asked for a theoretical introduction to statistical and methodological terms on the basis of practical examples. Studies revealed shortcomings regarding medical professionals' statistical literacy [27–30]. For instance, Jenny et al. (2018) conclude that medical students and professionals should receive enhanced training in how to interpret risk-related medical statistics [27], which is part of this training.

One of the strengths of this study is the systematic development of the training programme on the basis of problem-based learning by staff trained in vocational education and training. Additionally, the data analysis was performed by two researchers and different data were triangulated. We documented the coding procedure transparently so that it is reproducible. However, it is important to mention some limitations of this study. First of all, not all the participants actually classified themselves as developers of health information who were able to judge the practical relevance of the training. Furthermore, the researchers who developed and conducted the training also collected and analysed the data.

Conclusions

The results of this study will be taken into account when conducting the randomised controlled trial evaluating the implementation of the *Guideline Evidence-based Health Information*. Recruitment experiences from this pilot study indicate that recruiting institutions for the subsequent randomised controlled trial as well as corresponding training programmes might, in general, be challenging. Several aspects need to be considered: Institutions might not see the necessity for training since they consider themselves already well-trained. Currently, there are almost no incentives (e.g. from politics) for developing EBHI. On the contrary, it seems as if it is much easier to distribute health information which is not evidence-based, and the general public perceives familiar and commercial health information as being trustworthy [5]. This is problematic because well-known information is often not trustworthy and does not have a scientific basis. Moreover, the length of the training programme could be a barrier because it requires quite a large amount of time and staff resources from the participating institutions.

Training programmes and their curricula have a key role for acquiring EBM knowledge as well as the competences for developing EBHI. Theory-practice transfer and behaviour change seem to remain a major issue. It is important to develop a strategy to create incentives for health information providers to develop EBHI and

improve their competences in the long term. Another challenge is that different professions are involved in developing health information, a topic which has not necessarily been addressed in their original training. It appears to be important to integrate EBM as well as the development of EBHI into the curricula of degree programmes in health sciences, since this could be a crucial occupational field for health scientists. Furthermore, structures for developing health information should be established, for instance in the context of medical guideline processes where competence and expertise is being pooled.

In addition, in Germany, a national health portal is being planned [31]. The portal is intended to optimise the search for health information and provide quality assured health information. The long-term goal is to improve the general public's health literacy. The concept includes training opportunities for the portal's content partners concerning the development of high-quality health information [32]. It is conceivable that the developed training programme could be offered as a continuing education opportunity in the context of the health portal in order to reach the long-term goal of improving the quality of health information.

Supplementary information

Supplementary information accompanies this paper at <https://doi.org/10.1186/s12909-020-1966-3>.

Additional file 1. COREQ Checklist.

Additional file 2. Interview guide for the focus group interviews.

Additional file 3. Coding guideline.

Abbreviations

COREQ: COnsolidated criteria for REporting Qualitative research; CReDECI: Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare; EBHI: Evidence-Based Health Information; EBM: Evidence-Based Medicine; RCT: Randomised Controlled Trial

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Authors' contributions

JH wrote the first draft of the paper. BBH and JH developed the training concept and materials. JL and AS reviewed the drafts of the training materials. BBH and JH conducted the training courses. BBH and JH performed the analysis and revised the training. BBH, JL and AS reviewed and edited the manuscript. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets generated and analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

Ethical approval was obtained from the ethics committee of the Martin Luther University Halle-Wittenberg (No. 2018–139). At the beginning of the courses, all the employees gave written informed consent to participate.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Additional file 1

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

Manuscript: A blended learning training programme for health information providers to enhance implementation of the *Guideline Evidence-based Health Information: development and qualitative pilot study*

No. Item	Guide questions/description	Reported on page No.
Domain 1: Research team and reflexivity		
<i>Personal Characteristics</i>		
1. Interviewer/facilitator	Which author/s conducted the interview or focus group?	5
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	–
3. Occupation	What was their occupation at the time of the study?	1
4. Gender	Was the researcher male or female?	1
5. Experience and training	What experience or training did the researcher have?	5
<i>Relationship with participants</i>		
6. Relationship established	Was a relationship established prior to study commencement?	4
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	4
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	4
Domain 2: study design		
<i>Theoretical framework</i>		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	5
<i>Participant selection</i>		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	4
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	4
12. Sample size	How many participants were in the study?	5
13. Non-participation	How many people refused to participate or dropped out? Reasons?	5
<i>Setting</i>		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	4
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	5
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	5

<i>Data collection</i>		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	5
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	5
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	5
20. Field notes	Were field notes made during and/or after the interview or focus group?	5
21. Duration	What was the duration of the interviews or focus group?	5
22. Data saturation	Was data saturation discussed?	5
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	5
Domain 3: analysis and findings		
<i>Data analysis</i>		
24. Number of data coders	How many data coders coded the data?	5
25. Description of the coding tree	Did authors provide a description of the coding tree?	5
26. Derivation of themes	Were themes identified in advance or derived from the data?	5
27. Software	What software, if applicable, was used to manage the data?	5
28. Participant checking	Did participants provide feedback on the findings?	5
<i>Reporting</i>		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	6-9
30. Data and findings consistent	Was there consistency between the data presented and the findings?	6-9
31. Clarity of major themes	Were major themes clearly presented in the findings?	6-9
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	6-9

Developed from:

Tong A, Sainsbury P, Craig J: Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Health Care* 2007, 19(6):349-357.

Interview guide: focus group interviews

After the first training block:

- 1. First thoughts on the training days**
 - What did you like and what did you like less?
 - What suggestions for improvement do you have?
 - Did you miss something? If yes, what?
- 2. Feedback on concrete teaching elements/methods**
 - Do you like the topic of the case example and do you think that it is realistic?
 - How comprehensible were the contents for you?
 - Were there any difficulties in understanding? If so, what? (e.g. terminology, work tasks, contents of the studies)
- 3. How did you experience the relationship between lecture and work phases?**
- 4. What expectations do you have for the online phase?**

Short feedback (flash light) before the second training block:

- **How did you cope with the online phase?**
 - How did you cope with the learning platform?
 - How did you get along with the work tasks?
 - How satisfied were you with the support during the online phase?

After the second training block:

- 1. First thoughts on the training days**
 - What did you like and what did you like less?
 - What suggestions for improvement do you have?
 - Did you miss something? If yes, what?
 - 2. Feedback on concrete teaching elements/methods**
 - How comprehensible were the contents for you?
 - Were there any difficulties in understanding? If so, what? (e.g. terminology, work tasks, contents of the studies)
- Case example:**
- To what extent did the smoking cessation case example help you transfer the content to your own professional practice?
 - To what extent has the case example caught your interest in dealing with the topic?
- 5. How did you experience the relationship between lecture and work phases?**
 - 6. How did you perceive the heterogeneity of the participants (e.g. different professions) within the group?**
 - 7. To what extent can you imagine applying what you have learned in your professional practice after this training?**
 - If yes, what and how?
 - If not, why?

Coding guideline: qualitative content analysis

Category	Definition	Coding rules	Anchor examples
Framework conditions of the training	Contextual factors	Coding unit: Clear meaning component (seme) in the text	
Heterogeneity of the target group and adequacy of the training for the target group	Heterogeneity of the target group regarding their skills and prior knowledge, adequacy of the training for the target group		<p><i>"I think it was bit by bit...actually. One was gradually introduced. I'm a beginner. Not from the EBM department. Therefore, I found it to be a good introduction to the topic."</i></p> <p><i>"Concerning the target group, I was in-between. I had some previous knowledge but not really EBM knowledge. I could follow very well. Statistical basics are present. I didn't have to think much, but the stumbling block of EBM became clear."</i></p>
Time frame	Adequacy of the time frame (timing and duration of the training)		<i>"The time was going by fast. It was very compact."</i>
Online phase: learning management system ILIAS	Technical realisation of the online phase		<i>"Concerning the learning management system. I think it couldn't be operated intuitively. A clear layout would be better. Also a bit better structured."</i>
Interaction	Exchange between the involved people	Coding unit: Clear meaning component (seme) in the text	
Interaction between learners and teachers	Mutual interaction of learners and teachers regarding their actions and communication		<i>"Overall, I found the atmosphere to be very pleasant. I got the impression that everyone can ask questions."</i>
Team teaching	Teacher cooperation, simultaneous teaching by two teachers		<i>"How you communicate, so enthusiastically. You want it. Without rebuke. Excellent. That's very appealing."</i>

Category	Definition	Coding rules	Anchor examples
Relationship between lecture and work phases	Balance between lecture and work phases		<i>"The relationship between lecture and work phases turned out well."</i>
Methods	Use of teaching methods	Coding unit: Clear meaning component (seme) in the text	
Adequacy of methods regarding teaching and learning goals	Contribution to achieving the teaching and learning goals		<i>"The practical exercises were very helpful to get a deeper understanding."</i>
Realisation of the teaching methods	Successful implementation of the teaching methods (e.g. group work)		<i>"Towards the end, [the work task on] user testing... I think there was a bit too much switching. Group building could be simplified."</i>
Acceptance of the teaching methods	Acceptance of the teaching methods by the learners		<i>"75 minutes is quite long. It was inconvenient doing it [the work task] as the first thing in the morning. In the morning, listening is more convenient."</i>
Planning of the training programme	Smooth running of teaching/adequacy of the training programme	Coding unit: Clear meaning component (seme) in the text	
Schedule	Time constraints in planning and their feasibility	Were the planned time slots realistic? Time frame (under framework conditions) refers to the timing and duration of the whole training.	<i>"I think I've done everything. But I'm much faster than my colleagues who've never done that before. And some of us had completed the first work task in a large group. [...] Self-organisation isn't as easy sometimes. But we did a quite good job."</i>
Common thread	Structuring of the lessons, transparency of the teaching process		<i>"What was missing... The big picture of the whole training concept. What are we doing how, and what is building on what and where can I expect what. Because some things will be part of the third attendance day, and I don't know, will they be a topic or do I have to ask."</i>

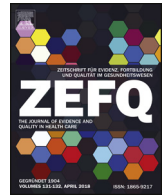
Category	Definition	Coding rules	Anchor examples
Transparency of teaching and learning goals	Clarity/transparency of teaching and learning goals for the learners		<i>"One should think about the goal, what should be remembered? What's the teaching goal? And then think about the question 'How to teach different groups with different previous knowledge?'"</i>
Value and design of the learning and teaching materials	Usability of the materials	Coding unit: Clear meaning component (seme) in the text	
Practical relevance and value	Feedback on the learning and teaching materials: use of the materials in practice (e.g. folders, printed presentations)		<i>"I liked the real texts. The use of real studies. That's very concrete. That's the real work and the right material to work on. It's irritating if it [the studies in the work tasks] looks completely different." "I'm glad to have this folder, because I've the feeling that I have got to look up quite a lot."</i>
Design	Comprehensibility, design and logical structure of the learning and teaching materials		<i>"If the pages had been numbered consecutively, it would have been helpful."</i>
Adequacy for the target group	Adequacy of the learning and teaching materials for the target group		<i>"The real texts. One could offer the studies in original language depending on who is attending the training."</i>
Comprehensibility	Comprehensibility of the contents of the training	Coding unit: Clear meaning component (seme) in the text	
Studies	Comprehensibility of the study characteristics and contents		<i>"I was sometimes overwhelmed by the work tasks. [...] Especially, the critical appraisal of the review. That overwhelmed me a bit."</i>
Online tasks	Comprehensibility of the online tasks		<i>"If you had left me alone with this work task [on systematic literature search], I would have failed."</i>
Terminology	Comprehensibility of terms		<i>"[...] about the comprehensibility of terms or deeper understanding. Further explanations would be necessary. It could be a good thing for the handout. A glossary."</i>

Category	Definition	Coding rules	Anchor examples
Criteria of evidence-based health information (EBHI)	Comprehensibility of the EBHI criteria		<i>"Especially the goal and target group, that has to be focused very clearly before developing information or it has to be taken into consideration. Those are aspects that weren't clear to me before. Even if I've read it. I completely lost sight of it. Because it's logical that we do it to...? But why are we doing it? I found it quite interesting."</i>
Missing contents and examples	Lack of input, missing examples that contribute to comprehension		<i>"I think it's important to discuss the interface between communication topics and EBM."</i>
Practical relevance and feasibility	Applicability in practice	Coding unit: Clear meaning component (seme) in the text	
Acceptance of the contents	To what extent can the participants accept the contents of the training?		<i>"It was much more comprehensible today than the two days before. This was mainly because of the practical examples, which are more familiar to me from daily business. I liked it really a lot."</i>
Case example	Did the case example arouse interest?, realism of the case example, assistance for transfer to own practice		<i>"The example and the topic were well chosen because it's a topic everyone is interested in and that everyone knows."</i>
Theory-practice transfer	Transfer/application of the acquired knowledge/competencies in practice		<i>"Would I dare to develop an EBHI based on those three days of training? No way. I have to say so. I've great respect. But I think one sees those things with different eyes. And details are revealed, critical aspects, and that helps."</i>
Required institutional resources	Resources that must be available in the institutions to implement the guideline		<i>"We have the luxury to have a department for everything. There are no barriers."</i>
Chances	Reasons that underline the implementation of the learning content in practice		<i>"The training definitely confirmed the methods of our institution and it showed that the way we work complies with the suggested gold standard."</i>



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Development and piloting of a blended learning training programme for physicians and medical students to enhance their competences in evidence-based decision-making



Entwicklung und Pilotierung eines Blended Learning-Schulungsprogramms für Ärztinnen, Ärzte und Medizinstudierende zur Förderung ihrer Kompetenzen in evidenzbasierter Entscheidungsfindung

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SUMMARY

Introduction: In 2016, the German Network for Evidence-based Medicine revised its basic curriculum for competences in evidence-based medicine. A curriculum-based training programme for physicians and medical students to enhance their competences in evidence-based decision-making was developed. The training programme was planned on the basis of problem-based learning. The aim of this qualitative pilot study was to explore the feasibility and acceptability of the training programme. Hypotheses concerning its influence on critical health literacy and the attitude toward evidence-based decision-making were to be generated.

Methods: Participating healthcare professionals received a structured training in a blended learning format. Data collection was conducted during the training sessions. The lessons were observed and protocolled and the working results were documented. Two focus group interviews were conducted after the training blocks with focus on acceptability and feasibility of the training programme. Interview transcripts and protocols were analysed using qualitative content analysis according to Mayring. Data saturation was intended by an iterative process of testing, analysing and revising the training programme. In addition, critical health literacy was assessed using the validated Critical Health Competence test. Levels of competence were calculated to measure the effect of the training on critical health competences.

Results: Two pilot courses with 29 physicians and other healthcare professionals were conducted between January and March 2019. Overall, the training programme proved to be feasible. The participants rated the comprehensibility of the learning modules as high. However, the practical exercises (e.g. role plays in shared decision-making) revealed that relevant subjects were insufficiently understood (e.g. the difference between the benefits and harms of a diagnostic test and its test accuracy). The interactive instructional design was appreciated. The participants appraised the work tasks as comprehensible but also challenging and requested a theoretical introduction to statistical terms in preparation for work tasks. The programme was revised iteratively according to the results. Critical health competences increased significantly after the training. Mean values (\pm SD) of levels of competence were 571.21 (\pm 82.87) before training and 671.90 (\pm 51.38) after training ($p < 0.0001$) (levels of competence with a range from 0 to 1,000).

Abbreviations: CHC test, Critical Health Competence test; COREQ, Consolidated criteria for REporting Qualitative research; CReDECI, Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare; EBM, Evidence-Based Medicine; HSHC, Halle School of Health Care; RCT, Randomised Controlled Trial.

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Conclusion: The training programme is feasible and was well accepted by the participants. It should be established as a continuing medical education opportunity for practitioners. Evaluation in a randomised controlled trial is recommended. Furthermore, the training can easily be adapted for interprofessional training. A concept for long-term implementation is needed.

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ZUSAMMENFASSUNG

Hintergrund: 2016 überarbeitete das Deutsche Netzwerk Evidenzbasierte Medizin das Curriculum *Evidenzbasierte Medizin*. Basierend auf dem Curriculum wurde ein Schulungsprogramm für Ärztinnen, Ärzte und Medizinstudierende zur Förderung ihrer Kompetenzen in evidenzbasierter Entscheidungsfindung entwickelt. Das Schulungsprogramm wurde mithilfe von problembasiertem Lernen geplant. Ziel dieser qualitativen Pilotstudie war es, die Machbarkeit und Akzeptanz des Schulungsprogramms zu explorieren. Es sollten Hypothesen bezüglich des Einflusses auf die kritische Gesundheitskompetenz und die Einstellung zu evidenzbasierter Entscheidungsfindung generiert werden.

Methode: Die teilnehmenden Angehörigen der Gesundheitsprofessionen erhielten eine strukturierte Schulung im Blended Learning-Format. Die Datenerhebung wurde im Rahmen der Schulung durchgeführt. Der Unterricht wurde strukturiert beobachtet und protokolliert sowie die Arbeitsergebnisse dokumentiert. Im Anschluss an die Schulungsböcke wurden zwei Fokusgruppeninterviews mit dem Fokus auf der Akzeptanz und Machbarkeit der Schulung durchgeführt. Die Interviewtranskripte und Unterrichtsprotokolle wurden mittels qualitativer Inhaltsanalyse nach Mayring ausgewertet. Angestrebt wurde eine Datensättigung durch einen iterativen Prozess des Testens, Analysierens und Revidierens der Schulung. Zusätzlich wurde die kritische Gesundheitskompetenz mithilfe des validierten Critical Health Competence Tests erhoben. Zur Beurteilung des Effekts der Schulung auf die kritische Gesundheitskompetenz wurden Kompetenzlevel berechnet.

Ergebnisse: Zwischen Januar und März 2019 wurden zwei Pilotkurse mit insgesamt 29 Ärztinnen und Ärzten sowie anderen Angehörigen von Gesundheitsprofessionen durchgeführt. Insgesamt war die Schulung gut machbar. Die Verständlichkeit der Module wurde als gut bewertet. Allerdings ergaben die praktischen Übungen wie Rollenspiele zur gemeinsamen Entscheidungsfindung, dass relevante Inhalte unzureichend verstanden wurden (z. B. der Unterschied zwischen dem Nutzen und Schaden und der Testgüte eines diagnostischen Tests). Die interaktive Gestaltung der Schulung wurde als gelungen empfunden. Die Teilnehmenden stufen die Arbeitsaufgaben sowohl als verständlich als auch als herausfordernd ein. Daher bestand z. B. der Wunsch nach einer theoretischen Einführung in statistische Begriffe in Vorbereitung auf die Arbeitsaufgaben. Die Schulung wurde auf Basis der Ergebnisse in einem iterativen Prozess optimiert. Die kritische Gesundheitskompetenz steigerte sich signifikant durch die Teilnahme an der Schulung. Die Mittelwerte (\pm SD) der Kompetenzlevel betragen 571,21 (\pm 82,87) vor der Schulung und 671,90 (\pm 51,38) nach der Schulung ($p < 0,0001$) (Kompetenzlevel mit einer Spanne von 0 bis 1.000).

Schlussfolgerungen: Die Schulung ist machbar und wurde von den Teilnehmenden gut akzeptiert. Das Schulungsprogramm sollte zur Fortbildung von Ärztinnen und Ärzten etabliert werden. Eine Evaluation im Rahmen einer randomisierten kontrollierten Studie wird empfohlen. Zudem könnte das Konzept an eine interprofessionelle Schulung adaptiert werden. Weiterhin bedarf es eines Konzepts zur Langzeitimplementierung.

Introduction

In 2009, the Institute of Medicine's (now National Academy of Medicine) roundtable on evidence-based medicine (EBM) set the "goal that, by the year 2020, 90 percent of clinical decisions will be supported by accurate, timely, and up-to-date clinical information, and will reflect the best available evidence" [1]. Ten years later, this goal remains a major challenge, although evidence-based practice is a prerequisite for high-quality healthcare and best patient outcomes.

A German survey showed that approximately 55% of citizens prefer shared decision-making [2]. In 2013, the Patients' Rights Act came into force, which includes the right to comprehensive and comprehensible information and implies patient participation in medical decisions [3]. Additionally, shared decision-making is one of the goals set by the German National Cancer Plan [4]. Informed choice as a result of shared decision-making is considered as a patient-relevant outcome [5]. Thus, the paternalistic model has run its course and informed shared decisions should replace it. Healthcare professionals therefore need to be equipped for shared decision-making. Evidence-based decision-making and practice is required as a core element of healthcare professional education.

Therefore, the German Network for Evidence-based Medicine developed a basic curriculum for *evidence-based decision-making*. It is multi- as well as interdisciplinary and is thought to serve as a framework for shaping initial and continuing vocational education and training for both healthcare professionals and citizens. The aim is to promote evidence-based clinical decisions [6].

Based on this curriculum, a blended learning training programme for physicians and medical students was developed to enhance their competences in evidence-based decision-making. The aim was to explore the feasibility and acceptability of the programme. Moreover, hypotheses concerning its influence on critical health literacy and the attitude toward evidence-based decision-making were to be generated.

Material and methods

We followed the UK Medical Research Council Framework for developing and evaluating complex interventions with focus on acceptability and feasibility [7]. Our results are reported in accordance with the revised *Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare* (CREDECI 2) and *Consolidated criteria for Reporting Qualitative research* (COREQ)

[8,9]. The ethics committee of the Martin Luther University Halle-Wittenberg reported back that an ethical approval was not necessary, since no personal data were obtained from the participants (no. 2019-101). The study protocol is available online [10].

Development of the training programme

We developed the training programme according to Kern's six-step approach for curriculum development for medical education [11]. The training programme consists of six modules: introduction, treatment studies, systematic literature search, systematic reviews and guidelines, diagnostic studies and application of evidence-based decision-making. The modules 1 to 5 aim to impart competences in searching for, selecting, critically appraising and extracting relevant literature according to the principles of evidence-based medicine. The goal of module 6 is to supply the patient with the best available evidence by training physicians and medical students to discuss treatment options with patients taking evidence-based health information and patients' individual preferences into account. Overall, the modules follow the five steps of evidence-based practice according to Sackett [12]. We embedded work tasks that were supposed to facilitate the transfer and reflection of the learning content with regard to the physicians' own practice. A training folder was provided.

The training programme was designed in a blended learning format with a web-based learning phase between the two face-to-face training blocks (Fig. 1). The face-to-face trainings lasted 18 hours distributed over four days. The web-based training phase comprised two weeks with a work-load of three hours. The length of the online phase was coordinated with the responsible institution. A two-week online phase was recommended so that the participants would have enough time to complete the tasks.

The learning management system ILIAS was used for the web-based learning phase. ILIAS included slideshows and text resources combined with online tasks and video tutorials. In addition, further information on the course content was provided so that the participants could deepen the content of the face-to-face training. They were encouraged to upload their results of the online tasks and to receive feedback during the face-to-face training.

The training programme was planned on the basis of problem-based learning to foster active learning. Within the training, a case example about smoking cessation provided a clinical problem. Problem-based learning intends increasing knowledge and understanding by using appropriate problems which serve as a stimulus for learning [13]. The problem of smoking cessation was thought to enable healthcare professionals to understand the relevance of scientific knowledge and evidence-based decision-making. The topic smoking cessation was chosen in order to address the heterogeneity of the target group. It has relevance for several medical specialities and should therefore promote intrinsic interest and motivation. It comprises evidence-based methods for smoking cessation, for instance counselling, medications (e.g. bupropion) and nicotine replacement therapy. The teaching goals are broadly defined in Table 1.

Piloting and feasibility of the training programme

Setting and sample

Two pilot courses were scheduled at the Berlin Chamber of Physicians (Ärztchamber Berlin) and the Halle School of Health Care (HSHC), Germany. The participants were recruited via mailing lists and newsletters, flyers, Facebook, event calendars and institution websites. The teaching programme was designed for a maximum of 25 participants per course. The primary target groups were physicians and medical students.

Table 1
Teaching goals of the modules.

Module	Goals
1. Introduction	<ul style="list-style-type: none"> • Participants gain an overview of evidence-based decision-making and reflect on their own practice. • Participants start to consider evidence-based health information as the prerequisite for informed decision-making.
2. Treatment studies	<ul style="list-style-type: none"> • Participants understand the difference between association and causality and that randomised controlled trials (RCTs) are designed to establish a causal relationship. • Participants know the characteristics of RCTs. • Participants are able to interpret the results of RCTs and critically appraise them.
3. Systematic literature search	<ul style="list-style-type: none"> • Participants are able to conduct systematic literature searches to identify appropriate literature matching their clinical question.
4. Systematic reviews and guidelines	<ul style="list-style-type: none"> • Participants are able to interpret the results and critically appraise systematic reviews and meta-analyses. • Participants describe the development process of guidelines and are aware of their limitations.
5. Diagnostic studies	<ul style="list-style-type: none"> • Participants are able to identify the major study designs for diagnostic studies. • Participants are able to calculate and interpret test accuracy. • Participants recognise the problem of overdiagnosis and overtherapy.
6. Application of evidence-based decision-making	<ul style="list-style-type: none"> • Participants consider evidence-based health information as the prerequisite for informed decision-making. • Participants are enabled to perform evidence-based decision-making in practice.

Data collection and procedure

Attendees participated voluntarily in the training programme. During registration they were informed about the pilot study. The Berlin Chamber of Physicians offered a reduced registration fee due to piloting. An information sheet was sent out to the participants via email prior to the training. Written informed consent was obtained at the beginning of the training. Six teachers conducted the courses (SB, LH, JH, CL, JL and AS). Module coordinators were specified in advance. Data collection was integrated in the training sessions and carried out by both teachers and observers. The participants generated a personal code as an anonymous identifier. Baseline characteristics of the participants, including sex, age, occupation, work experience, self-estimated English skills and EBM knowledge were assessed anonymously.

Feasibility and acceptability of the training programme were investigated from the perspective of both learners and teachers. Furthermore, hypotheses concerning its influence on critical health literacy and the attitude toward evidence-based decision-making were generated.

Acceptability was defined as the acceptance of teaching methods on the classroom level and the relevance of contents on the practical level. Feasibility was defined as the practicability and usability of the training programme and its contents. On classroom level, the following aspects were focused: comprehensibility of teaching material and contents, structure of the training, scheduling, usability of the web-based learning environment and target

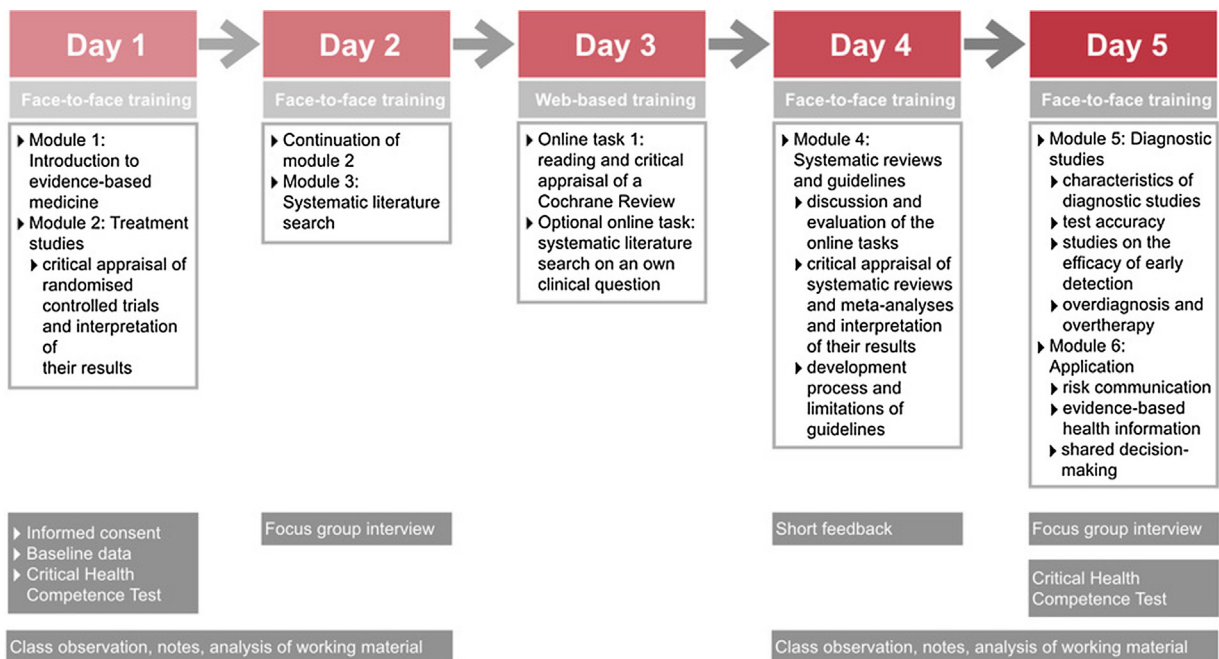


Figure 1. Modular structure and contents of the blended learning training programme.

group orientation. Potential application barriers, framework conditions and motivation were assessed on the practical level.

After the two face-to-face training blocks, feasibility, acceptability and attitude were explored from the participants' perspective in semi-structured focus group interviews with maximum ten people and led by LH and SB. SB has notable experience in conducting focus groups. The researchers followed an adapted semi-structured interview guide which had been developed in a prior pilot study [14] (Appendix A). The influence on the attitude toward evidence-based decision-making was explored by asking questions concerning the value of evidence-based decision-making for their work, patients and the healthcare system and how far their attitude changed through the training. Field notes were also taken during the focus groups. They were audio recorded and transcribed anonymously. A short feedback took place after the online phase (Fig. 1).

Moreover, structured class observations were carried out by at least one silent observer, who took field notes. Main foci of the observation were reactions of the participants to teaching methods, the interaction between teacher and participants (e.g. questions from the participants), problem-solving in the classroom situation as well as scheduling. The teachers also took field notes, which were discussed with the observers afterwards. Working results like flip charts, processes and interactions were documented.

Critical health literacy is a core competence for evidence-based decision-making. We assessed critical health literacy using the Critical Health Competence test (CHC test) [15], which is based on four medical scenarios forming the context for 72 items. The items assess basic core competences of the concept of critical health literacy. Within the validation trial the overall reliability of the test for the Rasch model (ANOVA) was 0.91 and for the single scenarios 0.71 (scenario 1), 0.78 (scenario 2), 0.75 (scenario 3) and 0.80 (scenario 4). Two of the scenarios were used in the pilot study – scenario 1 with 17 items before training and scenario 3 with 17 items after training.

Data analysis

Baseline characteristics were analysed descriptively. Interview transcripts and documentations were analysed using qualitative content analysis according to Mayring [16]. Two researchers (LH

and JH) coded the transcripts using the software QCAmap [17]. The coding guideline is available on request. A category system was pre-defined by the research questions as well as previous knowledge. Despite the already existing category system, categories could be adapted flexibly via feedback loops. Categories were adapted during data analysis and subcategories were inductively derived from the data. Afterwards the results were discussed by two researchers. Theoretical data saturation was intended by an iterative process of testing, analysing and revising the training programme.

CHC tests were coded according to the coding guideline. Levels of competence were assessed by calculating mean person parameters with a range from 0 to 1,000 in order to explore the effects of the training on critical health competences. We used the Shapiro-Wilk test for testing the normality of the data. To compare differences in critical health competences before and after the training we used the Wilcoxon test. All data analyses were performed using IBM SPSS Statistic version 22. The data were combined using between-methods triangulation [18].

Results

Participants

Two pilot courses were conducted at the Berlin Chamber of Physicians and the HSHC between January and March 2019. 20 physicians participated who were working as resident doctors (n = 8), researchers (n = 6), clinicians (n = 4) or in other fields of the healthcare system (n = 2) (Table 2). Most of them were general practitioners (n = 8). Additionally, nine healthcare professionals from other fields (e.g. pharmacists) attended. The target group definition had to be modified because of recruiting problems. No medical students participated. The average professional experience of the participants was 14.4 (± 10.6) years and they all completed the programme.

Feasibility, acceptability and attitude

After the second training course, theoretical data saturation was assumed since few or no new insights were revealed from

Table 2
Baseline characteristics.

Sex (n = 29)	Female	18 (62%)*
	Male	11 (38%)
Age (n = 29)		44.4 (26–67) ± 11.8
English skills: Read and comprehend	Very good	10 (35%)
	Good	10 (35%)
English in everyday life (n = 29)	Satisfactory	4 (14%)
	Sufficient	4 (14%)
	Poor	1 (3%)
English skills: Comprehend medical literature (n = 29)	Very good	5 (17%)
	Good	10 (35%)
	Satisfactory	10 (35%)
	Sufficient	1 (3%)
Occupation (n = 29)	Poor	3 (10%)
	Research scientist	5 (17%)
	Assistant physician	6 (21%)
	Medical specialist	11 (38%)
	Senior physician	1 (4%)
	Pharmacist	1 (3%)
	Nutrition scientist	1 (3%)
	Natural scientist	1 (3%)
Continuing medical education in EBM (n = 29)	Other	3 (10%)
	Yes	11 (38%)
	No	18 (62%)
	EBM knowledge (n = 28)	Little
	Moderate	15 (54%)
	Good	7 (25%)
	Very good	–
Access to the Cochrane Library (n = 29)	Yes	11 (38%)
	No	13 (45%)
	I don't know	5 (17%)

* Percentages may not total 100 due to rounding.

the participants. The duration of each focus group interview was approximately 20 minutes. Eight categories were established inductively via qualitative content analysis: 1. expectations, 2. framework conditions of the training, 3. interaction and teaching methods, 4. schedule, 5. value of the teaching material, 6. comprehensibility of the contents, 7. practical relevance and feasibility, 8. attitude toward evidence-based decision-making. The field notes of the class observations and the results of the analysis of the focus group interviews were triangulated. Quotes were translated verbatim.

1. Expectations

Participants' expectations were similar regarding the contents and goals of the training programme. They wished to learn how to search for and appraise evidence, transfer it into practice as well as translate it for their patients. Some participants desired to acquire statistical competences and some wanted to be able to have evidence-based discussions with their colleagues and pharmaceutical representatives. Concerning literature search, some of the participants were looking for efficient ways to find good and reliable information. Some of them saw the training programme as an opportunity to refresh the already acquired knowledge.

2. Framework conditions of the training

Some participants remarked that a clearer target group definition could be helpful. They referred to the fact that other healthcare professionals were included in the training although physicians and medical students were defined as the target group originally. In the second training course, one research scientist stated: *"Since we work in research, we do have other experiences. The curriculum doesn't fit 100% to us as a target group. I think it's for doctors, especially registered doctors."* Nevertheless, they negated the question about whether the heterogeneity was disturbing. *"I think it's also very interesting for us and therefore it's a pity that the flyer doesn't address us as nursing or health scientists. One profits from it [the training programme]."*

One participant said that the training could be enriched by an interdisciplinary approach. *"I think it makes discussions more interesting. If there were 20 people in the course from different disciplines, I think it would be much more stimulating."* It was suggested that the target group should be defined by previous knowledge and experience rather than the profession.

The learning management system ILIAS caused some technical problems (e.g. during log-in). Therefore, some participants preferred to do the work task paper-based.

3. Interaction and teaching methods

The interactive instructional design was appreciated since it promoted exchange and discussions:

"[...] and the proportion of hands-on activities is what brings the crucial advantage in the end. I mean this frontal teaching, one knows that it's no use and you go home and it's gone. It's of no use then."

"I found the discussions about different points very fruitful. I liked the anecdotes as well."

Some participants said that the exercises and work tasks enhanced the learning effect: *"You work on something and apply it directly. That's a great learning effect."*

However, some participants wished for more input phases. All in all, the ratio between input phases and work tasks was judged to be good.

4. Schedule

The duration of the various training modules depended on the group size and discussions. In the first pilot study, the participants wanted the structure of the training course to be communicated more clearly. In the second pilot study, the structure was judged to be good and transparent.

Some participants wished to have more time for the module *Treatment studies*. Two participants suggested that they would have preferred to receive the randomised controlled trial in advance to read it more intensively.

5. Value of the teaching material

The training folder was appreciated for making notes. Nevertheless, some participants wished for digital presentations as well, in order to be able to work on the material on their own laptops.

6. Comprehensibility of the contents

In general, the participants rated the comprehensibility of the learning modules as high. For example, the module *Systematic literature search* was rated as very understandable. Working on studies (a randomised controlled trial and a systematic review) was described as very complex, difficult and challenging but helpful for learning statistical terms. The participants asked for a theoretical introduction to statistical and methodological terms on the basis of practical examples in preparation for the work tasks (e.g. number needed to treat and randomisation). Furthermore, they wanted to improve their statistical literacy and therefore asked for a tutorial on how to interpret data presented by others. It was suggested practicing this in a role play with a visiting pharmaceutical representative.

There was a discussion about the difference between prevention and early detection in the module *Diagnostic studies*. Some participants had difficulties in understanding the clear differentiation. Additionally, some practical exercises (e.g. role plays on informed shared decision-making) revealed that relevant subjects had been insufficiently understood (e.g. the difference between the benefits and harms of a diagnostic test and its test accuracy).

Table 3
Results of the focus groups, class observations and revision process.

Identified need for revision	Revision conducted
Module 2 <i>Treatment studies</i> : The participants asked for a theoretical introduction to statistical and methodological terms on the basis of practical examples in preparation for the work tasks.	An input phase including practical examples was included before the work tasks.
Module 6 <i>Application of evidence-based decision-making</i> : The participants could not clearly distinguish between test accuracy and the benefits and harms of a diagnostic test. Therefore, they did not communicate this information to laypersons correctly.	Additional partner exercises were developed to train the communication of the benefits and harms, test accuracy and their probabilities to laypersons.
Module 6 <i>Application of evidence-based decision-making</i> : Some groups did not focus on the criteria of shared decision-making during the role plays.	The role plays were optimised by adding questions from the patient's point of view.
Web-based learning: The participants asked for further information.	A folder with further information was provided via the learning management system ILIAS.

7. Practical relevance and feasibility

Reading and working on the randomised controlled trial was well accepted. It was mentioned that it aroused interest in working further on the study. A participant said that *"The nice thing is that it was a study with limitations. At first sight it was well done, but the conclusions are borderline. [...] One has to be critical. Insofar it was well chosen."*

The module *Treatment studies* was judged to be helpful: *"Those statistical things were good to go through, because I forget it very fast. Especially because I don't need it that often in working life."*

Systematic literature search was seen as relevant for working life by some participants:

"[...] PICO. I haven't done it as systematically as here before."

"For me the systematic literature search was in fact the most relevant."

Others were of the opinion that they would not search via PubMed since it is too time-consuming in practice. They wanted faster methods for finding relevant literature.

The case example about smoking cessation was judged as relevant and helpful. Various participants said they had already been confronted with a similar situation in practice: *"Definitely [relevant]. Probably more in general practice or pneumology. Where it's really relevant. And I think it's missed out in most studies."*

The continuity of the case example was also judged positively: *"It's in any case reasonable to extend it through the whole training programme, because you stay with this topic and don't have to deal with something else all the time."*

Regarding theory-practice transfer, the steps of shared decision-making were seen as helpful structuring consultations: *"What's quite good is that the model shows, OK, you have the option not to do it."*

It was mentioned that the training encouraged reflection on the process of shared decision-making and doing it more intensively in the future. In addition, participants learned to appraise health information critically: *"[...] And perhaps check the health information you hand over. What is written there and does it make sense to hand it over or does it need further explanation."* The participants made it clear that it could be problematic to offer a patient every option since it might, for example, be possible that an option is not available in this area.

Moreover, it was seen as a barrier that shared decision-making would be time-consuming and that good information material is quite often missing: *"If you want to do that with every medication, it would be very, very complicated. If I want to give a patient so much information so that he can make a decision, I don't know, that's difficult. If it's a topic like colon cancer screening and screening in general, there is enough information material. Then I can hand it over and work with*

it. But if I think about which pill to use for blood pressure adjustment. [...] Information material is missing."

It became apparent that the participants did not know where to find necessary numbers to communicate in the consultation. The specific material should already be available, since it is a prerequisite for theory-practice transfer and to search for it would be difficult.

Communicating risks through role plays was considered a challenge. It would require good preparation, especially concerning dealing with the numbers and developing a concept for the consultation. One participant admitted that he had never communicated risks to his patient before and that the numbers communicated in the training caused doubts to be raised.

8. Attitude toward evidence-based decision-making

Some participants were of the opinion that they already practice evidence-based decision-making: *"I think to a large extent I do it already, since it is effectively our job to present different options."*

The participants explained that evidence-based decision-making has a great significance, especially for their personal decision-making. Patient participation was considered as an important factor for adherence. Some feared that patients would be overwhelmed with study data (e.g. risk communication), especially less educated patients. Moreover, some were of the opinion that patients want their doctor to decide.

The patients' wishes were seen as being most important. Even if an intervention has not shown to be effective, some doctors would not discourage their patients. Furthermore, some participants were afraid that the information about a lack of efficacy or evidence could destroy a trustful relationship between doctor and patient.

Revision

The training programme was revised iteratively based on our results. An input phase was planned at the beginning of every module. Most changes were minor changes on slides or work tasks to improve clarity. [Table 3](#) shows the identified need for revision and the revision conducted:

Critical health competence

In order to measure effects of the training on participants' level of critical health competences, person parameters were calculated for all healthcare professionals (n = 22) who completed both scenarios of the CHC test. Higher person parameters after the training reflect an increase in critical health competences ([Table 4](#)).

Table 4
Results of the CHC test.

	Mean (\pm SD) before training	Mean (\pm SD) after training	P value
Person parameters	571.21 (\pm 82.87)	671.90 (\pm 51.38)	<0.0001

Discussion

The training programme was performed successfully at two institutions. It was well accepted by the participants and seemed to increase their critical health competences.

Ideally, evidence-based practice integrates research evidence and patients' values and preferences into healthcare. It should be a basic element of healthcare professional education and is seen as a core competence for improving the safety and quality of healthcare [19]. An important challenge is that evidence-based practice and actual care require integration and should not be perceived as a dichotomy. The same applies to medical curricula where EBM should be considered as a core element [20].

Even if the implementation of evidence-based practice into many curricula and teaching programmes for healthcare professionals is beginning to spread, the evidence clearly shows an insufficient use of evidence and implementation of evidence-based practice in daily practice. A lack of resources and time, inadequate access and financial barriers were often found to hinder the implementation of evidence-based practice [18]. This covers findings from our pilot study. Just 40% of the participants have access to the Cochrane Library and a lack of time was seen as a big obstacle for implementing evidence-based practice and shared decision-making. However, poor knowledge and skills are the most commonly reported barriers for integrating research knowledge into daily patient care [21,22].

To recognize the rationale for evidence-based practice, the ability to conduct a systematic literature search and critically appraise the results in order to understand and practice shared decision-making are the core competences that should be covered in evidence-based practice training programmes. In particular, shared decision-making has often not been part of evidence-based practice curricula in the past [23]. Our programme aims at training all of the required skills mentioned and setting a focus on the process of shared decision-making. The goal of module 6 is for the participants to be able to supply the individual patient with evidence and to perform shared decision-making in their daily practice. Current reviews pointed out that communication skills are key to realising shared decision-making between healthcare professionals and patients [24,25].

The pilot study revealed that a clear target group definition seems to be crucial since some participants (e.g. researchers) expressed the opinion that the training programme did not suit them as a target group very well. Nevertheless, the pilot study showed that an interprofessional training could be an opportunity since different health professionals seemed to profit from the perspectives and opinions of others, especially during the role plays practicing evidence-based decision-making.

The results of the CHC test showed increased critical health competences of participants at the end of the pilot trial. The CHC test has significant strengths as it operationalises the construct of critical health literacy linked to the concept of EBM. Of course, the results should be interpreted with caution, as only 22 participants completed the test at the beginning of the first module and at the end of the training. Furthermore, the instrument has been validated with trained and untrained secondary school and university students and not with physicians.

A further limitation of this study is that not all the participants were practitioners who were able to judge the practical relevance of the training. It is not entirely clear whether data saturation was achieved since there were some contrary opinions mainly caused by the heterogeneity of the target group. Furthermore, the researchers who developed and conducted the training also collected and analysed the data. However, a strength of this study is the systematic development of the training programme on the basis of problem-based learning by staff trained in vocational education and training.

It is also important to mention recruitment problems encountered in Halle, despite intensive advertising. The target group had to be extended to other healthcare professionals because of recruitment problems. Besides, it was not possible to realise a planned training course in Leipzig because of repeated recruitment problems. The location seems to be an important factor since there were no recruitment problems in Berlin. Moreover, the hosting organisation might be a factor since the Berlin Chamber of Physicians is well known for offering continuing medical education, for example.

Conclusions

Education programmes and their curricula have a key role in shaping healthcare professionals' competences and skills to deliver evidence-based practice. The training programme tested in this pilot study was feasible and might increase critical health competences. Theory-practice transfer remains a major challenge. Therefore, follow-up interviews to investigate the application into practice seem to be reasonable and a cluster randomised controlled trial should be the next step in the process. According to our key training objective, shared decision-making and informed choice as well as the increase of critical health competences would be the ideal outcome measures. After a successful evaluation in a cluster randomised controlled trial, the course should be established as a continuing medical education opportunity for practitioners. The training could also be easily adapted to interprofessional training. A concept for long-term implementation needs to be derived in order to reach the goal of facilitating evidence-based practice.

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Conflict of interest

None declared.

CRedit author statement

JH and LH wrote the first draft of the paper. BBH, SB, LH, JH and JL developed the training concept and materials. SB, LH, JH, CL, JL and AS conducted the training courses. JH and LH performed the analysis. BBH, SB, JL and AS reviewed and edited the manuscript. AS approved the final version of the manuscript.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at [doi:10.1016/j.zefq.2020.02.004](https://doi.org/10.1016/j.zefq.2020.02.004).

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After the first training block:

- 1. First thoughts on the training days**
 - What did you like and what did you like less?
 - What suggestions for improvement do you have?
 - Did you miss something? If yes, what?
- 2. Feedback on concrete teaching elements/methods**
 - Do you like the topic of the case example and do you think that it is realistic?
 - How comprehensible were the contents for you?
 - Were there any difficulties in understanding? If so, what? (e.g. terminology, work tasks, contents of the trials)
- 3. How did you experience the relationship between lecture and work phases?**

Flash light before the second training block:

- **How did you cope with the online phase?**
 - How did you cope with the learning platform?
 - How did you get along with the work tasks?
 - How satisfied were you with the support during the online phase?

After the second training block:

- 1. My expectations for the training were fulfilled/not fulfilled because...**
 - 2. First thoughts on the training days**
 - What did you like and what did you like less?
 - What suggestions for improvement do you have?
 - Did you miss something? If yes, what?
 - 3. Feedback on concrete teaching elements/methods**
 - How comprehensible were the contents for you?
 - Were there any difficulties in understanding? If so, what? (e.g. terminology, work tasks, contents of the trials)
- Case example:
- To what extent did the smoking cessation case example help you transfer the content to your own clinical decision-making process?
 - To what extent has the case example caught your interest in dealing with the topic?
- 4. How did you experience the relationship between lecture and work phases?**
 - 5. How did you perceive the heterogeneity of the participants (e.g. different disciplines) within the group?**
 - 6. How do you assess the value of evidence-based decision-making for your work, patients and the healthcare system?**
 - 7. How has your attitude to evidence-based decision-making changed after the training?**
 - 8. To what extent can you imagine applying what you have learned in your professional practice after this training?**
 - If not, why?
 - If yes, what and how?

RESEARCH

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Evaluating student's ability to assess treatment claims: validating a German version of the Claim Evaluation Tools

Jana Hinneburg¹, Barbara Gasteiger-Klicpera², Jürgen Kasper³, Julia Lühnen¹, Katharina Maitz², Thomas Martens⁴ and Anke Steckelberg^{1,5*}

Abstract

Background The Claim Evaluation Tools measure the ability to assess claims about treatment effects. The aim of this study was to adapt the German item sets to the target group of secondary school students (aged 11 to 16 years, grade 6 to 10) and to validate them accordingly. The scale's reliability and validity using Rasch's probabilistic test theory should be determined.

Methods We conducted a sequential mixed-method study comprising three stages: contextualisation and adaption of the items (stage 1), piloting of the item sets using qualitative interviews (stage 2) and a construct validation by testing the unidimensional Rasch scalability for each item set after data collection in one secondary school in Germany and two secondary schools in Austria. We explored summary and individual fit statistics and performed a distractor analysis (stage 3).

Results Secondary school students ($n = 6$) and their teachers ($n = 5$) participated in qualitative interviews in Germany. The qualitative interviews identified the need for minor modifications (e.g. reducing thematic repetitions, changing the order of the items). The data of 598 German and Austrian secondary school students were included to test for Rasch scalability. Rasch analyses showed acceptable overall model fit. Distractor analyses suggested that model fit could be improved by simplifying the text in the scenarios, removing and editing response options of some items.

Conclusion After the revision of some items, the questionnaires are suitable to evaluate secondary school students' ability to assess health claims. A future goal is to increase the pool of items being translated and tested.

Keywords Evidence-based medicine, Health education, Health literacy, Critical thinking, Treatment claims, Informed choices, Rasch analysis, Validation, Probabilistic test theory

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Background

Nowadays, people are confronted with a flood of information, which is sometimes conflicting, misleading and questionable – especially in the current SARS-CoV-2 pandemic. Claims about treatment effects can be found in the media, advertisements, health information and through communication with physicians, friends and family. Claims about the benefits and harms of treatments (or a health-related action) describe what outcomes are caused by the treatment [1], e.g. “Not smoking can make you happy!” [2]. Despite the flood of health information available, most information does not fulfil the quality criteria for evidence-based health information [3–5]. Citizens need to be able to assess the reliability of these claims by thinking critically and making decisions whether to believe them or not [6, 7]. Therefore, people need good health literacy in order to be prepared to think critically, assess the evidence, critically appraise information and consequently to be able to make good choices. Otherwise, they might suffer unnecessarily and waste resources by getting therapies (or other interventions) that are sometimes harmful or ineffective, and might thus miss helpful, effective treatments [1].

To meet this challenge, the international, multidisciplinary working group of the Informed Health Choices (IHC) project aims to enable people to recognise reliable claims about treatment effects and make informed health choices by developing, evaluating and disseminating resources [8, 9]. To date, the IHC Network includes over 120 people from over 30 countries [9].

The ability to assess treatment claims is one aspect of critical health literacy [10]. A comprehensive definition of health literacy is as follows: “*Health literacy is linked to literacy and entails people’s knowledge, motivation and competences to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course.*” [11]. According to this definition, the competent management of health-related information is a major aspect of health literacy [12]. Nutbeam (2000) distinguished a three-level hierarchy of health literacy (functional, interactive and critical health literacy), where critical health literacy is the highest level [13]. Critical health literacy implies that citizens are enabled to critically appraise the quality of identified health information [10] and to engage in informed decision-making. Unfortunately, the search for high-quality health information is challenging, e.g. because quality criteria are not considered in the ranking algorithms of the internet search engines [14]. Furthermore, familiar and commercial online information sources are often rated as being trustworthy [15].

The promotion of (critical) health literacy should start at the latest in primary school [16–19]. Therefore, the members of the IHC project developed 49 plain language Key Concepts based on the concept of evidence-based medicine [20] (originally 32 [21]), which can be embedded in education for citizens of all ages and which are thought to evaluate the trustworthiness of claims. The Key Concepts, first published in 2015, are considered as evolving and were therefore revised over the years according to feedback, suggestions and a systematic review [7, 22]. In 2022, the most current version was published [20]. The Key Concepts can help people to beware of untrustworthy treatment claims, check the evidence from treatment comparisons and make well-informed health choices [17]. This means, for example, that personal experiences or anecdotes are an unreliable basis for most claims (e.g. “the drug helped me”). Moreover, fair comparisons are necessary to estimate a treatment effect. Furthermore, it is important to weigh up the expected benefits and harms of an intervention.

The Key Concepts are not a learning resource itself but can inform the development of learning resources, curricula and evaluation tools [7, 17, 23]. The IHC working group developed, pilot tested and evaluated teaching materials for primary as well as secondary schools in different languages [1, 9, 17]. Moreover, a database for learning and teaching resources on evidence-based health care was provided, which includes the IHC learning resources [24, 25]. Further pilot testing and evaluation studies are underway [9]. Currently, the Key Concepts are not taught in a structured manner in German or Austrian secondary schools, because they are not integrated into the curricula.

Furthermore, the Claim Evaluation Tools were developed iteratively based on the Key Concepts using qualitative and quantitative methods, providing an objective generic instrument to measure the ability to assess claims about treatment effects [26] (as one important aspect of critical health literacy). They are freely available for non-commercial use via the Testing Treatments interactive website [27]. This is a pool of multiple-choice questions which are assigned to the Key Concepts and can be used as outcome measures in trials [17], to evaluate trainings and for competence measurement in cross-sectional studies [28].

The first validation study using Rasch analysis applied to the Claim Evaluation Tools was published in 2017 [17]. In recent years, the items have been translated, contextualised, pilot tested and validated in different countries like Uganda, Norway, China, Mexico, Croatia and Germany [17, 26, 28–32]. In addition, the Claim Evaluation Tools have been used in trials to assess outcomes. In Uganda, 24 multiple-choice questions from the Claim

Evaluation Tools item bank were used as an outcome measure in a cluster-randomised trial evaluating an intervention designed to teach primary school children to assess claims about treatment effects [33].

In 2016, the German working group translated 68 items addressing 22 of the original Key Concepts [21, 26] from the Claim Evaluation Tools item bank and conducted a validation study. The data collection was carried out online as well as paper-based at schools and universities in Germany. The sample of 805 people included students from vocational grammar schools, trainees in health care occupations, nursing students, students in health sciences and citizens between 16 and 52 years (mean 22.4). The study showed that some of the items were too easy to solve so that item difficulty needed to be increased by adjusting task difficulty or distractors. Furthermore, distractor analysis revealed that some distractors could be recognised as incorrect too easily [32]. Two items were removed because they showed an underfit.

The aim of the current study was to adapt the German item sets to the target group of secondary school students and to validate them accordingly. The scale's reliability and validity in terms of Rasch's probabilistic test theory should be determined. Rasch's theory and approach to measure a trait is based on the assumption of an underlying dimension representing both item difficulties and individual capacity [34]. In the case that the Rasch model describes the empirical data well, the person's capacity can be determined by the probability of solving items. Items can be randomly selected from an item bank, but items that are located close to the person's position on the underlying dimension will lead to a better estimation of the person's capacity [35]. The Rasch model implies the scale's homogeneity, which means the order of the items with regard to difficulty is stable between persons and groups of persons. The investigation of the validity of the instrument in the current study was done by determining the overall fit of the model to the empirical data and also by investigating the fit of single items. Proving the instrument's Rasch scalability provides, amongst other advantages, chances to standardise the measurement of critical health literacy across studies and groups by using items from the item bank [36].

Methods

Using mixed methods, the study was designed as a sequence of three stages: contextualisation and adaptation of the items (stage 1), piloting of the item sets using qualitative interviews with secondary school students and their teachers (stage 2) and a construct validation by testing the unidimensional Rasch scalability (stage 3). The study was conducted in Austria (November 2018 - February 2019) and in Germany (October 2018 - April 2019)

and approved by the Lower Saxony State Board of Education (Niedersächsische Landesschulbehörde) in Germany and the Provincial School Board for Styria (Bildungsdirektion Steiermark) in Austria.

Stage 1: contextualisation and adaptation

First, we contextualised the German items from the Claim Evaluation Tools item bank in autumn 2018. The items contained examples relating primarily to Sub-Saharan Africa or developing countries in general. The adaptation included changes concerning the language used and item topics to achieve a better fit for the German and Austrian target group as well as the cultural context in order to prevent potential measurement biases. The division into three sets of multiple-choice items from the previous German validation study was retained. The revised version of the item sets for secondary school students comprised 66 items addressing 22 Key Concepts [21]. One item was included in all three item sets (resulting in 68 items in total).

Stage 2: piloting

In this substudy, we piloted the items in qualitative interviews using the think aloud method [37] with secondary school students and their teachers. We carried out interviews with students to explore potential barriers towards responding to the questions, readability, comprehension and acceptance (e.g. terminology, instructions and format). Knowledge about possible barriers could prevent potential measurement biases [9].

The aim of the interviews with teachers was to obtain an expert assessment of the items in relation to the target group of secondary school students. Barriers regarding the reading ability of the target group, possibly unknown or difficult terms and relevant examples for the target group were to be identified. In addition, we checked whether the German gender regulation (e.g. use of alternative forms for masculine and feminine gender) has a negative impact on readability.

Setting and sample

The interviews with secondary school students (aged 11 to 16 years, grade 6 to 10) and their teachers were carried out in a secondary school in Germany. A teacher was asked to choose diverse students regarding age, gender and performance. Students and teachers participated voluntarily in the interviews. The number of interviews was checked consistently with regard to whether data saturation was deemed achieved. In addition, the Austrian working group of the project *Health literacy and diversity for secondary school students (HeLi-D)* [38] (Box 1) and one Austrian teacher checked for needs for adjustment considering the two marginally varying languages.

Box 1: Health literacy and diversity for secondary school students (HeLi-D) project.

HeLi-D is an adaptive digital training programme to promote digital health literacy in students aged 12 to 15 years. It addresses health-related information by means of stories, informational texts, quizzes and research tasks. The programme has an integrated assessment that measures the students' reading skills and adaptively assigns content in four difficulty levels. The programme was developed in participatory workshops with students and evaluated in a controlled longitudinal study with 1,113 students. The results showed an increase in the students' health knowledge and internet-related health literacy [38].

Data collection and procedure

An information sheet was provided for teachers, parents and students prior to the interviews. Data collection was carried out by JH in Germany. Before the interviews, the socio-demographic data sex, age and grade of the students and sex, age and teaching experience of the teachers were surveyed. Data were anonymised for publication. Approximately 30 min were scheduled for each student interview and 2.5 h for each teacher interview. Students were asked to read one of the three item sets and teachers all three item sets. The teacher interviews were conducted prior to the student interviews. We asked the participants to read the items and share their thoughts. In the process, the interviewer could ask questions about the participants' thoughts.

Data analysis

JH made notes on proposed changes directly on the printouts of the items. JH and AS discussed and agreed on the suggested revisions. In the case of disagreement, JL was consulted. Subsequently, the items were revised accordingly. Revisions included a linguistic and content adjustment, and were carried out in an iterative process between the interviews.

Stage 3: construct validation

To test basic assumptions made in the construction of the questionnaires and relevant for application, this substudy aimed at investigating the dimensional structure of data collected with the three revised item sets in Germany and Austria.

Setting and sample

Recruitment of secondary school students (aged 11 to 16 years, grade 6 to 10) was performed in Germany and Austria. Data collection involved a convenient sample and was carried out at a combined general and intermediate

secondary school in Germany and at two general secondary schools in Austria. In Austria, the validation was embedded in the project HeLi-D [38]. The three item sets were assigned to secondary school students who had not received any training related to the Key Concepts in both countries.

There is no established rule for determining the sample size of a survey purposing on performing Rasch analyses. As in other statistical analyses, small samples are associated with less precise estimates, less powerful fit analysis and less robust estimates [39]. We aimed to include approximately 250 completed questionnaires per item set.

Data collection and procedure

Students participated voluntarily in the study. We provided an information sheet for parents and students prior to the study. Data collection was anonymous and we only surveyed age, sex and grade. It was carried out online in Austria and paper-based in Germany. Decisions about how to assign the questionnaires were made according to what was considered feasible in the local environments. In Germany, the anonymity was ensured by using a box in which questionnaires were put after completion. No written informed consent was required. In Austria, parents gave written informed consent to the students' participation in the HeLi-D project and related research activities. All of the data collected during the project were stored and processed in anonymised form. Withdrawal from the study was possible before or during the study without giving reasons and without any disadvantage for those concerned. Data collection was carried out by JH in Germany and a team of researchers and university students in Austria. The students in each grade level were randomly assigned to one of the three item sets. In Germany, the older students from the 9th and 10th grades filled out two item sets.

Data analysis

Socio-demographic data were analysed descriptively using IBM SPSS Statistics version 27. Validity of the three adjusted item sets was approached by Rasch analyses using WINMIRA 2001 version 1.45 [40]. Measurement using Rasch theory or item response theory is based on the assumption of a latent dimension representing both item difficulty and persons' capacities with regard to the given construct. The analysis determines whether and to what extent the scale properties allow it to be used for reliable assessment of the individual's capacity level. This would also imply the scale's ability to precisely localise a person's level of capacity to a sufficient likelihood. The following properties were calculated to appraise the quality of the scales:

- Item difficulty: Scales designed for Rasch-based assessment use to provide much variability regarding item difficulty. It is important to consider the item difficulty with regard to its distribution over the scale and test feasibility considerations.
- Two estimators of reliability (Anova and Andrich's): Anova reliability works according to Cronbach's alpha in classical test theory. Andrich's reliability is considered more important for appraisal of a scale in terms of the Rasch theory. Andrich's approach to reliability focuses on measurement of persons and not on item statistics, i.e. on the quality of the separation of persons [41]. Therefore, Andrich's reliability is used as the person separation index in this study. Values higher than 0.60 are considered moderate, higher than 0.80 good and higher than 0.90 excellent. In this study, values higher than 0.7 were considered acceptable.
- Q indices display whether an empirical pattern from a single item fits the parameter estimation according to the Rasch model, representing item specific indicators of model fit. Using a p-value, Q indices express empirical deviation from the estimation of single items in one of two directions: an item underfit implies that the item's localisation cannot be interpreted properly, because the chance for solving these items deviates for some people or subgroups, e.g. the order of item difficulties can be different for this subgroup. Indication of overfit for single items is less problematic. It just means that the item characteristic curve, ideally represented as a sigma curve, is seen as a clear step from not being able to solve the items to solving it by 100%. Such an item behaves according to the Guttman model [42], but the order of item difficulties is not disturbed.
- Pearson's coefficients of a bootstrap test: Bootstrap approaches [43, 44] use the model's parameter estimation to generate multiple random data samples. The empirically generated sample is compared to the parameter generated samples. A significant p-value for analysis of model fit by bootstrap approach indicates that the empirical sample does not fit into the range of parameter generated samples, thus implying a poor model fit. As different parameters might contradict each other, appraisal of model fit in terms of homogenous Rasch scalability is not necessarily easy.

In case of misfit, it was planned to perform distractor analyses to inform a discourse about removing or adjusting items or distractors on the basis of distributions of frequencies calculated using SPSS.

Results

Stage 1: contextualisation and adaption

The contextualisation and adaptation included changes like the use of the familiar German form of "you" instead of the formal one, the application of the German gender regulation, the exchange of some unfamiliar names and the deletion of unknown terms like "Kyogero" (herbal bath used in Uganda). Examples used were also changed (e.g. milk with honey instead of water with honey, washing gel instead of soap). In addition, some sentences were simplified.

Stage 2: piloting

Participants

We performed five interviews with teachers and six interviews with students. All the participants completed the interviews that lasted approximately one hour with the teachers and 20 min with the students. The mean age of the teachers was 48.2 years (range 29–65 years), all were female and had 3 to 43 years (on average 18 years) teaching experience. The mean age of the 7th and 9th grade students was 13.5 years (range 12–15 years). Four of the six students were female.

Results of teachers

The teachers in particular named terms (e.g. study, conventional) which they suspected the secondary school students might not be familiar with. In principle, concerns were raised regarding the length of the item sets with regard to the students' ability to concentrate. In addition, the participants made suggestions to improve the readability, e.g. by shortening sentences. On the advice of the teachers, the order of the items was partially modified. Easily readable items were chosen to get started with, followed by text-heavier items to counteract the declining ability to concentrate. Furthermore, thematic repetitions within the item sets were avoided by adjusting the examples. The language check by the Austrian working group and one secondary school teacher revealed the need for two modifications (e.g. the German term for beetroot is not common in Austria).

Results of students

None of the terms classified as critical by the teachers was unknown to the students. All in all, the students rated the instrument as legible and easy to understand. The length of the instrument was also assessed as manageable. As a result of the interviews, which revealed the need for a longer reading time for the students, the required processing time was adapted from 20 to 30 [32] to 30–45 min. Neither teachers nor students criticised the German gender regulation with regard to its impact on readability.

Stage 3: construct validation

Participants

598 students (Germany $n=254$, Austria $n=344$) completed at least one item set. 125 of the German participants completed two sets. The completion of one item set lasted a maximum of 30 min. 49% of the students were female ($n=293$). The mean age of the secondary school students was 13.5 years (range 11–18 years). 150 (25%) students from the 6th, 173 (29%) from the 7th, 150 (25%) from the 8th, 63 (11%) from the 9th and 60 (10%) from the 10th grade participated. There were 3.5% or less missing or incorrect responses per item set.

Results from Rasch analyses

Table 1 shows an overview of fit statistics by item set, separate for each country and in total.

Item difficulties were moderate: 0.53 averaged over item set 1, 0.52 over item set 2 and 0.49 over item set 3. The analysis of how the three item sets fit into the model of homogenous Rasch scales revealed the following results: the person separation indices were 0.70, 0.71 and 0.64 for the item sets 1, 2 and 3 in total. These values indicate moderate reliability. Cronbach's alpha was acceptable (>0.7 for all item sets).

Rasch analyses revealed the need for adjustment of several items to optimise the item fit into the Rasch model. 11 out of 66 items showed an underfit (seven in item set 1, three in item set 2 and one in item set 3). Moreover, seven items indicated overfit (three in item sets 1, three in set 2 and one in item set 3). The bootstrap approach to model fit turned out to be significant ($p=0.03$) for item set 1, indicating lacking goodness of fit to the Rasch model, and unobtrusive for the other two item sets, indicating a sufficient model fit. Distractor analyses and the associated discourse suggested that many items could be improved by simplifying the text in the scenarios, removing and editing response options. One item was removed because it was classified as very difficult for the target group to understand and two other items from this Key Concept were still contained in the item sets. All other items with underfit were adjusted in terms of content.

Discussion

We contextualised, adapted and validated the German items for the target group of secondary school students. The validation study showed that most of the items of the Claim Evaluation Tools can be used for evaluating secondary school students' ability to assess treatment claims since they have acceptable model fit. However, some items needed to be improved by simplifying the text in the scenarios, removing or revising response options.

Strengths and limitations.

An important strength of this study is that we used Rasch analysis for psychometric testing and optimisation which allows to examine the level of skills being measured and to identify variability in measurement precision [45]. The item sets can easily be administered and are time-saving since only one of the three item sets must be used to measure the ability to assess treatment claims. Moreover, the Claim Evaluation Tools directly connect to the Key Concepts which serve as a definition of the skills to be acquired [45]. The inclusion of the target group in the development of health literacy measures has proven to be a sound method to improve the quality of instruments [18]. Therefore, qualitative interviews were conducted to explore potential barriers, readability, comprehension and acceptance of the item sets by the students and to obtain an expert assessment in relation to the target group by the teachers.

This study also has limitations. Although a teacher was asked to choose diverse students for the interviews, we cannot rule out that better-performing students were selected and therefore overrepresented. Since the sample of the construct validation was a convenient one, it is not representative of all secondary school students in Germany and Austria, especially due to the heterogeneity caused by the federal education system in Germany with different types of secondary schools. The limited number of participating schools and the homogeneity regarding school type (general and intermediate secondary schools but no academic secondary schools included) limit the generalisability of the results. Moreover, the item sets were only tested in two German speaking countries. They were not validated in Switzerland. The inclusion of 250 questionnaires per item set was not quite achieved. Therefore, further robust studies should confirm the results. How the items function in other settings (e.g. with existing cultural differences) is unknown. We did not include gender and migration background in the analysis. Furthermore, the pool of items being translated and tested might be increased because the list of Key Concepts and corresponding items has been extended. However, some Key Concepts might be too difficult to be understood and applied by younger secondary school students. Since the item bank was updated, mirroring the last changes to the Key Concept list, the translated items need to be re-arranged so that they match the latest version [9, 20]. However, the update has no impact on the methods used or the results of this validation study.

Comparison with other studies.

So far, items from the Claim Evaluation Tools item bank have been translated and validated in several settings and languages [17, 26, 28–31]. The findings of our study are comparable to those of the other validation

Table 1 Overview of fit statistics by country and in total

Item set	Germany			Austria			Total		
	1	2	3	1	2	3	1	2	3
Items (n)	23	23	22	23	23	22	23	23	22
Persons (n)	121	126	116	115	117	111	236	243	227
Item difficulty	0.58	0.58	0.51	0.46	0.45	0.48	0.53	0.52	0.49
Cronbach's alpha	0.78	0.76	0.72	0.70	0.73	0.75	0.77	0.77	0.74
Person separation index ^a	0.72	0.69	0.62	0.57	0.64	0.66	0.70	0.71	0.64
Items with underfit (overfit)	1 (1)	3 (0)	0 (0)	3 (0)	3 (0)	7 (1)	7 (3)	3 (3)	1 (1)
Overall model fit: p-values for bootstrap estimation ^b	0.03*	0.13	0.43	0.08	0.65	0.53	0.03*	0.18	0.73

^astatistically significant ^aAndrich's reliability ^bPearson parameter

The total number of filled-in item sets was 236 for item set 1, 243 for item set 2 and 227 for item set 3

studies in terms of reliability and confirm the value of the German item sets as a flexible tool for measuring the ability of secondary school students to assess treatment claims objectively. In the validation study with a sample of people from Uganda and Norway, 17 out of 88 items (19%) were identified with a poor model fit [17]. In our study 11 out of 66 items (17%) were identified.

There are at least 202 validated health literacy measures available. They differ concerning measured domains (e.g. numeracy, comprehension), context (e.g. generic, disease-specific), approach for tool development (e.g. Rasch), administration time, validation study (e.g. sample, modes of administration), language and assessment (objective/performance-based or subjective/self-reported) [46]. Most instruments are guided by classical test theory and only a small number by modern measurement theories like the item response theory [36]. A systematic review on generic health literacy measurement instruments for children and adolescents identified fifteen instruments including seven objective (performance-based tests), seven subjective (self-reporting) and one mixed-method measure [18]. Two of these instruments measure critical health literacy – the *Critical Health Competence test (CHC test)* and the *All Aspects of Health Literacy Scale (AAHLS)*. The CHC test is also based on the concept of evidence-based medicine and uses objective measures to assess the actual performance. Likewise, Rasch analysis was used and the test was validated in a sample of secondary school students (grade 10 and 11) and university students [10]. The AAHLS is based on subjective measurement using self-report and covers functional, communicative and critical health literacy [18]. The validity of self-reporting has often been criticised, for instance because of measuring self-efficacy rather than health literacy [18]. The *European Health Literacy Survey (HLS-EU)*, which is also based on self-reporting [47], is often used to report the deficient health literacy of the German population, despite the lack of appropriateness and relevance of its items [48, 49]. Furthermore, the applicability of the HLS-EU is limited for measuring general health literacy among adolescents [50]. In general, there is a lack of evidence regarding child and adolescent health literacy and the varying understanding of health literacy hampers the comparison of different instruments and results [18].

Implications and future research.

The aim of the IHC project is teaching students to think critically about health claims and choices as a major aspect of (critical) health literacy. Learning materials for primary and secondary schools have already been developed and will be evaluated in randomised trials in Kenya, Rwanda and Uganda in 2022 [9]. A remaining challenge is the training of teachers who may not possess the competences

required for teaching the Key Concepts. They probably need support in the form of guidance or teach the teacher courses. Critical health literacy has to be taught across subjects since it includes subjects like Math, Biology and English. Therefore, concepts and resources for cross-subject teaching like team teaching must be organised. Moreover, it would be reasonable to teach and learn the Key Concepts using a spiral curriculum reinforcing previously learned content while introducing new concepts [7]. Many schools in Germany and Austria still have knowledge-based instead of competence-based curricula, which complicates the acquisition of health literacy.

A further step is the translation of the IHC learning resources into German so that the item sets could be used as an outcome measure in a randomised trial, evaluating the effects of training on the ability of secondary school children to assess claims about treatment effects. Especially in the light of the SARS-CoV-2 pandemic, the digitalisation of the learning materials seems to be reasonable. At the moment the Claim Evaluation Tools measure only a part of critical health literacy. Additionally, the Key Concepts and consequently the Claim Evaluation Tools could be expanded covering diagnostic accuracy claims, for example. In principle, items measuring functional and interactive health literacy could be included additionally.

Conclusion

After the revision of some items, the item sets are suitable for being used as an outcome measure to evaluate secondary school students' ability to assess treatment claims and for objective competence measurement in cross-sectional studies. It is the only Rasch-scaled instrument available in the German-speaking countries for this age group, which is sufficiently reliable and can be used as an objective measure of critical health literacy. A future goal is to increase the pool of items being translated and tested.

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Authors' contributions

JH wrote the project outline and first draft of the paper with significant input from JK. BGK and KM performed the data collection in Austria, JH in Germany. JK and TM prepared the data files for the analysis and conducted the Rasch analysis. BGK, JK, JL, KM, TM and AS reviewed and edited the manuscript. All authors approved the final version of the manuscript.

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Data Availability

The datasets generated and analysed during the current study are available from the corresponding author on request. All items from the Claim Evaluation Tools item bank are available upon request for non-commercial use.

Declarations**Ethics approval and consent to participate**

Approval was obtained from the Lower Saxony State Board of Education (Niedersächsische Landesschulbehörde) in Germany (LG 1 R.22-50300) and the Provincial School Board for Styria (Bildungsdirektion Steiermark) in Austria. In Germany, no written informed consent was required due to anonymised data collection. In Austria, parents gave written informed consent to the students' participation in the HeLi-D project and related research activities. All participants were informed of their possibility to terminate their participation at any time.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Anhang 1: Erklärungen

A1.1 Erklärung über frühere Promotionsversuche und Selbstständigkeitserklärung

(1) Ich erkläre, dass ich mich an keiner anderen Hochschule einem Promotionsverfahren unterzogen bzw. eine Promotion begonnen habe.

(2) Ich erkläre, die Angaben wahrheitsgemäß gemacht und die wissenschaftliche Arbeit an keiner anderen wissenschaftlichen Einrichtung zur Erlangung eines akademischen Grades eingereicht zu haben.

(3) Ich erkläre an Eides statt, dass ich die Arbeit selbstständig und ohne fremde Hilfe verfasst habe. Alle Regeln der guten wissenschaftlichen Praxis wurden eingehalten; es wurden keine anderen als die von mir angegebenen Quellen und Hilfsmittel benutzt und die den benutzten Werken wörtlich oder inhaltlich entnommenen Stellen als solche kenntlich gemacht.

Hannover, 28.02.2023

A1.2 Erklärung zum Beitrag aller Autor*innen an den Publikationen dieser Dissertation

Publikation 1:

Hinneburg J, Lühnen J, Steckelberg A, Berger-Höger B. A blended learning training programme for health information providers to enhance implementation of the Guideline Evidence-based Health Information: development and qualitative pilot study. BMC Med Educ. 2020;20(1):77. Epub 2020/03/19. doi: 10.1186/s12909-020-1966-3.

Beiträge der Autor*innen: JH schrieb den ersten Entwurf des Manuskripts. BBH und JH entwickelten das Schulungskonzept und die Materialien. JL und AS überprüften die Entwürfe der Schulungsmaterialien. BBH und JH führten die Schulungen durch. BBH und JH führten die Analyse durch und überarbeiteten das Training. BBH, JL und AS überprüften und bearbeiteten das Manuskript. Alle Autor*innen haben das endgültige Manuskript gelesen und genehmigt.

Publikation 2:

Hinneburg J, Hecht L, Berger-Höger B, Buhse S, Lühnen J, Steckelberg A. Development and piloting of a blended learning training programme for physicians and medical students to enhance their competences in evidence-based decision-making. Z Evid Fortbild Qual Gesundhwes. 2020;150-152:104-11. Epub 2020/05/23. doi: 10.1016/j.zefq.2020.02.004.

Beiträge der Autor*innen: JH und LH schrieben den ersten Entwurf des Manuskripts. BBH, SB, LH, JH und JL entwickelten das Schulungskonzept und die Materialien. SB, LH, JH, Claudia Lucius (CL), JL und AS führten die Schulungen durch. JH und LH führten die Analyse durch. BBH, SB, JL und AS überprüften und bearbeiteten das Manuskript. Alle Autor*innen genehmigten die endgültige Fassung des Manuskripts.

Publikation 3:


Hinneburg J, Gasteiger-Klicpera B, Kasper J, Lühnen J, Maitz K, Martens T, et al. Evaluating student's ability to assess treatment claims: validating a German version of the Claim Evaluation Tools. BMC Public Health. 2023;23(1). doi: 10.1186/s12889-022-14700-w.

Beiträge der Autor*innen: JH schrieb die Projektskizze und den ersten Entwurf des Manuskripts mit maßgeblichem (statistischem) Input von JK. BGK und KM führten die Datenerhebung in Österreich durch, JH in Deutschland. JK und TM bereiteten die Daten für die Analyse vor und führten die Rasch-Analyse durch. BGK, JK, JL, KM, TM und AS überprüften und bearbeiteten das Manuskript. Alle Autor*innen genehmigten die endgültige Fassung des Manuskripts.

Anhang 2: Genehmigungen der Verlage zur Publikation der Artikel innerhalb der Dissertation

Publikation 1:

Hinneburg J, Lühnen J, Steckelberg A, Berger-Höger B. A blended learning training programme for health information providers to enhance implementation of the Guideline Evidence-based Health Information: development and qualitative pilot study. BMC Med Educ. 2020;20(1):77. Epub 2020/03/19. doi: 10.1186/s12909-020-1966-3.



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A blended learning training programme for health information providers to enhance implementation of the Guideline Evidence-based Health Information: development and qualitative pilot study

SPRINGER NATURE

Author: Jana Hinneburg et al
 Publication: BMC Medical Education
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Publikation 2:

Hinneburg J, Hecht L, Berger-Höger B, Buhse S, Lühnen J, Steckelberg A. Development and piloting of a blended learning training programme for physicians and medical students to enhance their competences in evidence-based decision-making. Z Evid Fortbild Qual Gesundheitswes. 2020;150-152:104-11. Epub 2020/05/23. doi: 10.1016/j.zefq.2020.02.004.



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Development and piloting of a blended learning training programme for physicians and medical students to enhance their competences in evidence-based decision-making

ELSEVIER

Author: Jana Hinneburg,Lars Hecht,Birte Berger-Höger,Susanne Buhse,Julia Lühnen,Anke Steckelberg
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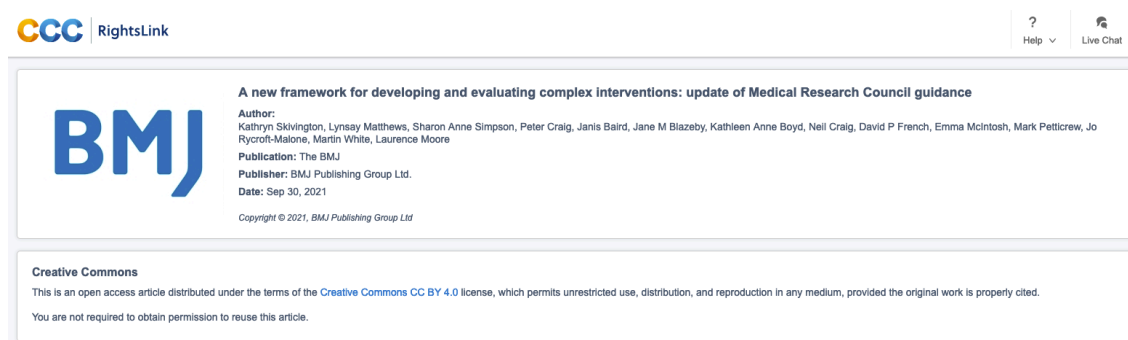
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Anhang 3: Genehmigungen zur Verwendung von Abbildungen

Abbildung 2: Framework für die Entwicklung und Evaluation komplexer Interventionen



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Abbildung 3: Drei Oberkategorien und Unterkategorien der Schlüsselkonzepte

June 3, 2022 Working paper Open Access

Key Concepts for assessing claims about treatment effects and making well-informed treatment choices (Version 2022)

Oxman, Andrew D.; Chalmers, Iain; Dahlgren, Astrid

There are endless claims about treatments in the mass media, advertisements, and everyday personal communication. Some are true and some are false. Many are unsubstantiated: we do not know whether they are true or false. Unsubstantiated claims about the effects of treatments often turn out to be wrong. Consequently, people who believe and act on these claims suffer unnecessarily and waste resources by doing things that do not help and might be harmful, and by not doing things that do help.

In response to these challenges, we developed the Informed Health Choices Key Concepts as the first step in the Informed Health Choices (IHC) project, an initiative supported by the Research Council of Norway. The aim of the IHC project and ongoing work by the IHC Network is to help people make informed health choices.

In this document, we use the term "treatment" to include any intervention (action) intended to improve health, including preventive, therapeutic and rehabilitative interventions, and public health or health system interventions. Although we have developed and framed the Key Concepts to address treatment claims, people in other disciplines may find them relevant; for example, for assessing claims about the effects of educational interventions or environmental measures.

The Informed Health Choices (IHC) Key Concepts serve as the basis for developing learning resources to help people understand and apply the concepts when claims about the effects of treatments (and other interventions) are made, and when they make health choices. They are also the basis for an item bank of multiple-choice questions (the Claim Evaluation Tools item bank) that can be used for assessing people's ability to apply the IHC Key Concepts.

The concepts are principles for evaluating the trustworthiness of treatment claims, comparisons, and choices. The concepts can help people to:

1. Recognise when a claim about the effects of treatments has an untrustworthy basis
2. Recognise when evidence from comparisons of treatments is trustworthy and when it is not

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Keyword(s): concepts, critical thinking, critical appraisal, critical health literacy, causal inference, treatment claims, informed decision making, epistemology

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Anhang 4: Danksagung

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