Informierte Entscheidungen in der zahnmedizinischen Versorgung fördern – Gesundheitsinformationen und Schulungsprogramme

Dissertation

zur Erlangung des Doktorgrades der Philosophie

Universität Hamburg

Fakultät für Mathematik, Informatik und Naturwissenschaften

Fachbereich Chemie

Institut für Pharmazie

Gesundheitswissenschaften

Vorgelegt von

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Berlin 2016

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Disputation: 03. Februar 2017

Druckfreigabe: 03. Februar 2017

Die vorliegende Dissertation entstand in der Zeit vom 01.09.2008 bis 20.12.2016 an der Universität Hamburg, MIN Fakultät, Fachbereich Chemie, Institut für Pharmazie, Gesundheitswissenschaften.

„Des Menschen größtes Verdienst bleibt wohl,
wenn er die Umstände soviel als möglich bestimmt
und sich so wenig als möglich von ihnen bestimmen läßt."

Johann Wolfgang von Goethe
(Wilhelm Meisters Lehrjahre, 1795)

Danksagung

Zum Gelingen dieser Arbeit haben eine Vielzahl von Menschen beigetragen, bei denen ich mich an dieser Stelle ganz herzlich bedanken möchte.
An erster Stelle gilt mein Dank Frau Univ.-Prof. Dr. med. Ingrid Mühlhauser. Von ihr als Doktormutter und Chefin habe ich gelernt einen kritischen Blick zu entwickeln, Haltungen einzunehmen und diese auch zu vertreten.
Ich möchte mich auch bei Frau Univ.-Prof. Dr. phil. Anke Steckelberg und Herrn Univ.-Prof. Dr. phil. Sascha Köpke für die fachliche Unterstützung und das offene Ohr in hektischen Zeiten bedanken. Sie haben mich in den gemeinsamen Projekten gefordert, gefördert und kritisch konstruktiv unterstützt.
Außerdem danke ich meinen anderen Kolleginnen und Kollegen für ihr Engagement in gemeinsamen Projekten.
Weiterhin danke ich Frau Univ.-Prof. Dr. phil. Gabriele Meyer herzlich für die Begutachtung meiner Arbeit.

Publikationen der Dissertation

- **Bunge M**, Mühlhauser I, Steckelberg A (2010): What constitutes evidence-based patient information? Overview of discussed criteria. Patient Educ Couns 78(3): 316-28.
- **Albrecht M**, Isenbeck F, Kasper, Mühlhauser I, Steckelberg A (2016): The foundation in evidence of medical and dental telephone consultations. Dtsch Arztebl Int 113(22-23): 389-95.
- Steckelberg A, **Albrecht M**, Kezle A, Kasper J, Mühlhauser I (2013): Impact of numerical information on risk knowledge regarding human papillomavirus (HPV) vaccination among schoolgirls: a randomised controlled trial. GMS Ger Med Sci 11: Doc15. DOI: 10.3205/000183.
- Lühnen J, **Albrecht M**, Hanßen K, Hildebrandt J, Steckelberg A (2015): Leitlinie evidenzbasierte Gesundheitsinformation: Einblick in die Methodik der Entwicklung und Implementierung. Z Evid Fortbild Qual Gesundh wesen 109(2): 159-65.
- Steckelberg A, Mühlhauser I, **Albrecht M** (2013): Wollen wir wissen, was wir tun? Evidenzbasierung edukativer Interventionen. Z Evid Fortbild Qual Gesundh wesen 107(1): 13-8.
- **Albrecht (nee Bunge) M**, Kupfer R, Reissmann DR, Haastert B, Mühlhauser I, Köpke S (2016): Oral health educational interventions for nursing home staff and residents. (Protocol) Cochrane Database of Systematic Reviews 2013, Issue 5. Art. No.: CD010535. DOI:10.1002/14651858.CD010535.
- **Albrecht M**, Kupfer R, Reissmann DR, Mühlhauser I, Köpke S (2016): Oral health educational interventions for nursing home staff and residents. Cochrane Database of Systematic Reviews 2016, Issue 9. Art. No.: CD010535. DOI: 10.1002/14651858.CD010535.pub2.

I. Inhaltsverzeichnis

II. Abkürzungsverzeichnis

CReDECI	Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare
EBGI	Evidenzbasierte Gesundheitsinformation
EbM	Evidenzbasierte Medizin
RCT	Randomised controlled trial (randomisiert-kontrollierte Studie)
UK MRC	United Kingdom Medical Research Council

1. Zusammenfassung

Diese Dissertation beinhaltet die Forschungsergebnisse mehrerer Studien, die die methodischen Grundlagen und Voraussetzungen für informierte Entscheidungen definieren und komplexe Interventionen, wie z.B. evidenzbasierte Gesundheitsinformationen (EBGI) und Schulungsprogramme, in der zahnmedizinischen Versorgung überprüfen. Alle Studien sind in begutachteten Zeitschriften veröffentlicht.

Das Ziel der ersten Arbeit ist es, die Kriterien für EBGI aus der internationalen Literatur zu erfassen und die Evidenz für die identifizierten Kriterien darzustellen. Insgesamt wurden 13 Kriterien identifiziert.

Die zweite Arbeit präsentiert eine Erhebung zur Qualität von Telefonberatungen zu ausgewählten Gesundheitsthemen durch verdeckte Klienten. Die Analyse zeigt, dass die derzeit vermittelten Informationen nicht den Kriterien für EBGI entsprechen.

Die dritte Arbeit stellt die Ergebnisse einer randomisiert-kontrollierten Studie (RCT) dar, die die Effekte eines Informationsflyers zur HPV-Impfung, der mit Risikoinformationen ergänzt wurde, mit einem Standardflyer hinsichtlich des Risikowissens vergleicht. Die Teilnehmerinnen, die den Flyer mit Risikoinformationen erhielten, gaben häufiger korrekte Antworten im Vergleich zu Teilnehmerinnen mit der Standardinformation.

Der vierte Artikel gibt Einblick in die Methodik der Entwicklung einer evidenzbasierten Leitlinie für EBGI. Außerdem werden die Ergebnisse einer qualitativen Studie, die die Kompetenzen von Gesundheitsinformationserstellern explorierte, berichtet. Die Ergebnisse weisen auf einen Schulungsbedarf hin, da die Kompetenzen zu den Methoden der Evidenzbasierten Medizin (EbM) und EBGI sehr unterschiedlich ausgeprägt sind.

Das Ziel der fünften Arbeit ist es aufzuzeigen, welche edukativen Interventionen in einem definierten Zeitraum von drei Jahren in RCTs untersucht wurden. Die Ergebnisse zeigen, dass nur wenige RCTs zu edukativen Interventionen,

insbesondere in Deutschland, durchgeführt wurden und weisen auf den dringenden Bedarf an methodisch hochwertigen Studien mit ausreichender Power hin.

Der sechste Artikel stellt das Studienprotokoll für eine systematische Übersichtsarbeit zur Wirksamkeit von Schulungsprogrammen für Pflegende oder Bewohner von Alten- und Pflegeheimen zur Erhaltung der Mundgesundheit der Bewohner dar. Die Methodik folgt dem Handbuch für systematische Übersichtsarbeiten der Cochrane Collaboration und nutzt die Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare (CReDECI).

Der letzte Artikel präsentiert die Ergebnisse der systematischen Übersichtsarbeit. Wichtige bewohnerbezogene Endpunkte, wie mundgesundheitsbezogene Lebensqualität oder unerwünschte Ereignisse, wurden nicht untersucht. Die identifizierten Studien zeigen keinen Nutzen der Schulungen hinsichtlich der untersuchten Parameter zur Zahngesundheit. Angaben zur Entwicklung und Evaluation der komplexen Interventionen wurden unzureichend berichtet. Die Ergebnisse erlauben daher keine Schlussfolgerungen hinsichtlich der Implementierung der Schulungsprogramme.

Zusammenfassend lässt sich sagen, dass diese Dissertation wesentlich zur Implementierung von informierten Entscheidungen sowohl auf der Ebene der Patienten als auch der Ebene des Gesundheitssystems beiträgt.

2. Abstract

This dissertation comprises the research results of several original studies, which define the methodological principles and requirements for informed choices, and assesses complex interventions such as evidence-based health information and educational programmes in dental care. All studies have been published in peer-reviewed journals.

The objective of the first article is to survey criteria for evidence-based health information from the international literature and to compile the evidence for the identified criteria. In total 13 criteria have been identified.

The second article presents a survey on the quality of telephone consultations on selected health topics using inquiries by hidden clients. The analysis shows that currently provided information does not meet the criteria for evidence-based health information.

The third article shows the results of a randomised controlled trial (RCT) comparing the effects of an information leaflet on HPV vaccination supplemented with risk information with a standard leaflet on risk knowledge. Risk information recipients were more likely to give correct answers compared to standard information recipients.

The fourth article highlights the methodology of the development process of an evidence-based guideline on evidence-based health information. Furthermore, the results of a qualitative study exploring the competences of health information developers are reported. The results indicate a need for training as the levels of competences regarding the methods of evidence-based medicine and health information vary substantially.

The objective of the fifth article is to survey which educational interventions have been evaluated in RCTs during a defined period of three years. The results show that only very few RCTs have been conducted, especially in Germany, and highlight an urgent need for adequately powered high-quality studies.

The sixth article comprises the study protocol for a systematic review on the effects of oral health educational interventions for nursing home staff or residents to maintain oral health of nursing home residents. The methodology follows the Cochrane Handbook for Systematic Reviews of Interventions and the Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare (CReDECI).

The last article shows the results of the systematic review. Important resident-related outcomes such as oral health-related quality of life or adverse events have not been assessed. Eligible studies do not provide evidence on the effectiveness of educational interventions on any measure of residents' oral health. Details of the development and evaluation of the complex interventions have been insufficiently reported. Therefore, results do not allow to draw conclusions regarding the implementation of such interventions.

In sum, this dissertation substantially contributes to the implementation of informed choices on the patient level as well as on the level of the health care system.

3. Einleitung

Informierte Entscheidungen sind spätestens mit dem 2013 in Kraft getretenen Patientenrechtegesetz [1] verbürgtes Recht. Das Modell der informierten Entscheidung sieht vor, dass der Entscheidungsträger (Patient/Bürger) über adäquates Wissen verfügt und seine Entscheidung bzw. sein Handeln in Übereinstimmung mit seinen Werten und Präferenzen steht [2]. Zur Erreichung dieses Zieles gelten evidenzbasierte Informationen als Voraussetzung und der gemeinsame Entscheidungsprozess (shared decision-making [3]) zwischen Arzt und Patient in der zahnärztlichen Praxis seit Jahren als Grundpfeiler [4]. Die Grundlage für Entscheidungen auf anderen Systemebenen sollte auch evidenzbasiert sein, um eine gute Versorgung zu gewährleisten. Es bedarf daher sowohl einer qualitativ hochwertigen Methodik zur Generierung der Inhalte als auch evidenzbasierter Formate, um diese Inhalte für unterschiedliche Zielgruppen nutzbar zu machen. So könnte evidenzbasiertes Entscheiden und Handeln in der (zahn-)medizinischen Versorgung langfristig befördert und etabliert werden.

Gesundheitsinformationen und Schulungsprogramme, die als komplexe Interventionen gelten, gehören zu diesen Formaten und werden mit unterschiedlichen Zielsetzungen in der Gesundheitsversorgung eingesetzt. Sie vermitteln zumeist gesundheits- bzw. krankheitsrelevantes (Fakten-)Wissen, das in Handlung umgesetzt werden soll. Für die Entwicklung und Evaluation komplexer Interventionen definiert der Leitfaden des United Kingdom Medical Research Council (UK MRC) das methodische Vorgehen [5].

4. Zielsetzung und Problemstellung der Arbeit

Die vorliegende Arbeit zeigt auf, wie wissenschaftliche Evidenz generiert und präsentiert werden sollte, um evidenzbasierte und informierte Entscheidungen auf unterschiedlichen Ebenen des Gesundheitssystems zu fördern. An Beispielen versorgungsrelevanter Themen der Zahnmedizin wird die Methodik zur Erstellung der komplexen Interventionen Gesundheitsinformation und Schulungsprogramm kritisch reflektiert und vorhandene Angebote werden auf Einhaltung der definierten wissenschaftlichen Standards und Evidenzbasierung überprüft.

5. Synopsis

Im Rahmen der ersten Arbeit wurde ein bestehender Katalog zur Beschreibung der Kriterien evidenzbasierter Patienten-/Gesundheitsinformationen auf Grundlage systematischer Literaturrecherchen erweitert und die vorhandene Evidenz zu den jeweiligen Kriterien in Form einer Übersichtsarbeit zusammengefasst [6]. Sie kann die Ersteller von EBGI-Angeboten im Entwicklungsprozess unterstützen bzw. ermöglicht die Überprüfung von Informationen.

Die Definition der relevanten inhaltlichen Komponenten, Darstellungsformate und methodischen Anforderungen an den Erstellungsprozess einer EBGI sind ein erster notwendiger Schritt, wenn informierte Entscheidungen der Patienten[1] und Bürger ermöglicht werden sollen. Die ethisch und wissenschaftlich begründeten Kriterien müssen allerdings auch Eingang in die Praxis finden und der Nachweis erbracht werden, dass die Einhaltung sich positiv auf die Versorgungsqualität auswirkt. Diese beiden Punkte wurden in zwei weiteren Arbeiten fokussiert [7, 8]. So wurde die Qualität von Telefonberatungen in einem nationalen Survey mit verdeckten Klienten zu den zahnmedizinischen Themen Fissurenversiegelung, Professionelle Zahnreinigung, Quecksilberausleitung und drei weiteren medizinischen Fragestellungen überprüft [7]. In einer randomisiert-kontrollierten Studie (RCT) wurde ein Flyer zur HPV-Impfung, der um numerische Informationen

[1] Zur besseren Lesbarkeit dieser Arbeit schließt der Plural die feminine und maskuline Form gleichermaßen ein.

zur Nutzen-Schaden-Bewertung ergänzt wurde, gegen eine Standardinformation im Hinblick auf ein verbessertes Risikowissen bei Schülerinnen getestet [8].

Da die Kriterien für EBGI trotz Bestrebungen und Initiativen der Politik und der Wissenschaft [9-14] in der Praxis kaum genutzt werden oder wenig bekannt sind, wurde die Entwicklung einer evidenzbasierten Leitlinie zur Erstellung von EBGI initiiert [15]. Leitlinien sind mit ihren klaren Handlungsempfehlungen wesentliche Instrumente zur Förderung von Qualität in der (zahn-)medizinischen Versorgung. Die vierte Arbeit gibt anhand zweier exemplarischer Fragestellungen zur graphischen Darstellung von Gesundheitsinformationen Einblick in die Methodik der Entwicklung der Leitlinie. Sie präsentiert zudem die Ergebnisse einer explorativen Studie zu den Kompetenzen von Erstellern, die die Entwicklung eines Schulungsprogrammes für Leitliniennutzer informiert [16].

In der Versorgung werden Schulungsprogramme auf den verschiedenen Systemebenen für diverse Zielgruppen eingesetzt. Schulungsprogramme und andere edukative Interventionen werden als komplexe Interventionen betrachtet, bei denen die Überprüfung der Wirksamkeit methodisch anspruchsvoll, aber möglich ist. Um evidenzbasiert über die Implementierung dieser Interventionen entscheiden zu können, sind sowohl Informationen über den Entwicklungsprozess als auch den Evaluationsstand relevant.

Die fünfte Arbeit untersucht, welche edukativen Interventionen international in der Aus-, Fort- und Weiterbildung in RCTs auf ihre Wirksamkeit evaluiert wurden. Die systematischen Literaturrecherchen schlossen als Zielgruppen Kinder, Schüler, Studierende und Berufstätige ein, während Patientenschulungen ausgeschlossen wurden [17].

An dem versorgungsrelevanten Thema Mundgesundheit von Alten- und Pflegeheimbewohnern sollte exemplarisch gezeigt werden, ob Schulungsprogramme für Pflegende und Bewohner wirksam sind und die relevanten Informationen für eine Implementierungsentscheidung vorliegen [18]. Die etablierte Methodik der Cochrane Collaboration wurde daher um die Anwendung der Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare (CReDECI) ergänzt [19].

In einer abschließenden Betrachtung gilt es, die Ergebnisse der einzelnen Arbeiten in Hinblick auf deren Bedeutung für die informierte Entscheidung zu diskutieren.

6. Publikationen

6.1 Bunge M, Mühlhauser I, Steckelberg A (2010): What constitutes evidence-based patient information? Overview of discussed criteria. Patient Educ Couns 78(3): 316-28.

Patient Education and Counseling 78 (2010) 316–328

Contents lists available at ScienceDirect

Patient Education and Counseling

journal homepage: www.elsevier.com/locate/pateducou

What constitutes evidence-based patient information? Overview of discussed criteria

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ARTICLE INFO

Article history:
Received 30 April 2009
Received in revised form 7 October 2009
Accepted 23 October 2009

Keywords:
Evidence-based patient information
Informed choice
Framing of data
Patient involvement
Risk communication

ABSTRACT

Objective: To survey quality criteria for evidence-based patient information (EBPI) and to compile the evidence for the identified criteria.
Methods: Databases PubMed, Cochrane Library, PsycINFO, PSYNDEX and Education Research Information Center (ERIC) were searched to update the pool of criteria for EBPI. A subsequent search aimed to identify evidence for each criterion. Only studies on health issues with cognitive outcome measures were included. Evidence for each criterion is presented using descriptive methods.
Results: 3 systematic reviews, 24 randomized-controlled studies and 1 non-systematic review were included. *Presentation of numerical data, verbal presentation of risks* and *diagrams, graphics and charts are based on good evidence. Content of information and meta-information, loss- and gain-framing* and *patient-oriented outcome measures* are based on ethical guidelines. There is a lack of studies on *quality of evidence, pictures and drawings, patient narratives, cultural aspects, layout, language* and *development process*.
Conclusion: The results of this review allow specification of EBPI and may help to advance the discourse among related disciplines. Research gaps are highlighted.
Practice implications: Findings outline the type and extent of content of EBPI, guide the presentation of information and describe the development process.

1. Introduction

Evidence-based patient information (EBPI) can play an important part in supplementing and reinforcing information provided by clinicians within consultations. EBPI can also be used outside consultations especially for subjects where consultations do not necessarily occur, e.g. information on screening procedures.

Most patients want more information and a greater share in decision-making, though, proportion of people wanting active involvement varies within and between countries [1,2] or medical conditions [3]. In a survey in eight European countries 51% of the sample opted for the shared decision-making model, whereas 23% said that the patient should decide and 26% assigned the role of main decision-maker to the doctor [4].

Evidence-based patient information is a prerequisite for informed choice. Evidence-based patient choice intends to incorporate science and rigour of evidence-based medicine with the personal values of consumers and patients. The information has to be easy to understand and should give information on the benefits and harms of treatment options, diagnostic or screening procedures. Patients and consumers have the (ethical) right to get such information.

Decision aids facilitate patient involvement in decision-making and improve decision quality. Furthermore, decision aids show promise to prevent over- or underuse of medical interventions [5].

Despite various initiatives to improve the quality and availability of health information, the information needs of patients and the public are not adequately met yet. Health professionals tend to overestimate the amount of provided information [6]. In addition, there are concerns about the quality and usefulness of much printed and electronic consumer health information [7,8]. Recent studies have shown that decision aids are frequently not evidence-based even though they might be labelled as evidence-based [9].

There is as yet little discussion as to what can be expected of EBPI. It is important to define what basically comprises EBPI and how the information should be presented. In addition, the special needs of the target groups have to be considered in the development process of EBPI.

Steckelberg et al. [10] provided an overview of criteria for EBPI, which is available in German language only. Trevena et al. conducted a systematic review on communicating with patients about evidence [11].

This article provides an update and extension of our previous work [10]. It intends to support developers of EBPI, and might be helpful for consumers who want to judge the quality of existing EBPI.

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0738-3991/$ – see front matter © 2009 Elsevier Ireland Ltd. All rights reserved.
doi:10.1016/j.pec.2009.10.029

The main objectives of this overview were to identify categories for EBPI and to survey the underlying evidence for each criterion.

2. Methods

The methods consist of two predefined phases: phase 1: update of the pool of categories for EBPI and phase 2: identification of the evidence of categories and criteria.

2.1. Phase 1

A primary systematic search was conducted to identify all criteria for EBPI to revise the pool of categories. The search in the Cochrane database of systematic reviews, PubMed, PsycINFO, PSYNDEX and the Education Research Information Center (ERIC) was limited to systematic reviews and reviews published in English or German for the period from November 1, 2004 to February 28, 2009.

2.2. Phase 2

Criteria are described for considering studies to identify the evidence of categories and criteria.

2.2.1. Types of studies

Systematic reviews and randomized-controlled trials (RCTs) published in English or German.

Studies with less than 40 participants were excluded. Sample sizes of studies on categories of EBPI are often rather small. Since validity of such studies is limited, we decided to only include studies with at least 40 participants in order to not exclude too many studies.

2.2.2. Types of interventions

The interventions consist of the different categories. Categories with examples are: content of information and meta-information (e.g. benefit and harm of the intervention), quality of evidence (QOE) (e.g. symbols for presentation of QOE), patient-oriented outcome measures (e.g. mortality, quality of life), presentation of numerical data (e.g. absolute risk reduction (ARR), number needed to treat (NNT)), verbal presentation of risks (e.g. verbal descriptors, i.e. common or rare risk of side effects), diagrams, graphics and charts (e.g. bar chart, pie chart), loss- and gain-framing, pictures and drawings (e.g. line-drawings, cartoons), patient narratives (e.g. use of personal stories to present evidence, symptoms or diseases), cultural aspects (e.g. content of pictures), layout (e.g. font style and size, bolded headings), language (e.g. plain language, mother-tongue), development process (e.g. involvement of patients, consumers in EBPI development process).

We considered studies which tested the interventions in printed, web-based and audiovisual information material, excluding verbal only communication and educational programs.

2.2.3. Types of outcome measures

Outcome measures focusing on cognition were included: knowledge, comprehension, understanding, recall, risk perception, and readability.

Studies that only measured affective, behavioral, economic, or health status outcomes were excluded. If studies assessed different outcomes, only the cognitive ones were considered. The development process was not restricted to the defined outcome measures.

2.2.4. Search methods for identification of studies

A systematic literature search was undertaken to identify evidence for each category. Two authors (MB and AS) searched the Cochrane database of systematic reviews, PubMed, PsycINFO, PSYNDEX and ERIC (from November 1, 2004 to February 28, 2009). The search strategies were developed from the first publication of this review [10]. Search terms for the new categories were added without limits of dates of publication.

Box 1. Search terms.

Symbols; numbers; letters; visual display; graph*; chart*; pictogr*; ARR; RRR; NNT; diagram; Patient Participation [MeSH]; Probability Theory [MeSH]; Risk Assessment [MeSH]; Data Display [MeSH]; Sensitivity and Specificity [MeSH]; Communication [MeSH]; Communication Barriers [MeSH]; Persuasive Communication [MeSH]; Comprehension [MeSH]; Language Tests [MeSH]; Health Knowledge, Attitudes, Practice [MeSH]; Information Services/standards [MeSH]; Information Services/statistics and numerical data [MeSH]; Quality Assurance, Health Care/standards [MeSH]; Biomedical Research/standards [MeSH]; Cultural Competency [MeSH]; Cultural Characteristics [MeSH]; Consumer Participation [MeSH]; Personal Narratives [Publication Type]; Anecdotes as Topic [MeSH]; patient participation; risk assessment; sensitivity; specificity; communication AND barriers; persuasive communication; comprehension; plain language; non patronizing AND language; language AND measurement; language AND assessment; readability; cultural characteristics; cultur* AND compet*; consumer participation; personal narratives; narratives; testimonial*; narration; framing AND data; risk communication; involve*; Patient Education as Topic [MeSH]; Patient Education Handout [Publication Type]; Health Education/methods [MeSH]; Communications Media [MeSH]; Teaching Materials [MeSH]; Information Dissemination [MeSH]; Consumer Health Information [MeSH]; Decision Support Systems, Clinical [MeSH]; Evidence-Based Medicine [MeSH]; patient education; health education; teaching materials; consumer health information; decision support systems; evidence-based medicine.

Search strategies were tailored to the relevant databases using medical subject headings (MeSH) and keywords (Box 1).

The titles and abstracts of all articles were screened by two investigators (MB and AS). Full articles were examined if the abstract met the inclusion criteria. Reference lists were screened. Disagreements were solved by discussion (Box 1).

2.2.5. Critical appraisal, data extraction and analysis

We extracted key information from all included publications. Extracted data included sample size, participants, interventions, controls and outcome measures. The quality of the included studies was assessed using the SIGN-checklist for systematic reviews [12] and the EPOC-checklist for RCTs [13].

Two authors (MB and AS) assessed the quality and analyzed all papers. Differences in assessment of publications were solved by discussion.

Due to heterogeneity of interventions, study participants and healthcare settings descriptive data analysis was carried out.

3. Results

3.1. Phase 1: Pool of categories

The existing pool of categories was enlarged and specified. The final pool contains the following categories:

1. Content of information and meta-information.
2. Quality of evidence.
3. Patient-oriented outcome measures.
4. Presentation of numerical data.
5. Verbal presentation of risks.
6. Diagrams, graphics and charts.
7. Loss- and gain-framing.
8. Pictures and drawings.
9. Patient narratives.
10. Cultural aspects.
11. Layout.
12. Language.
13. Development process.

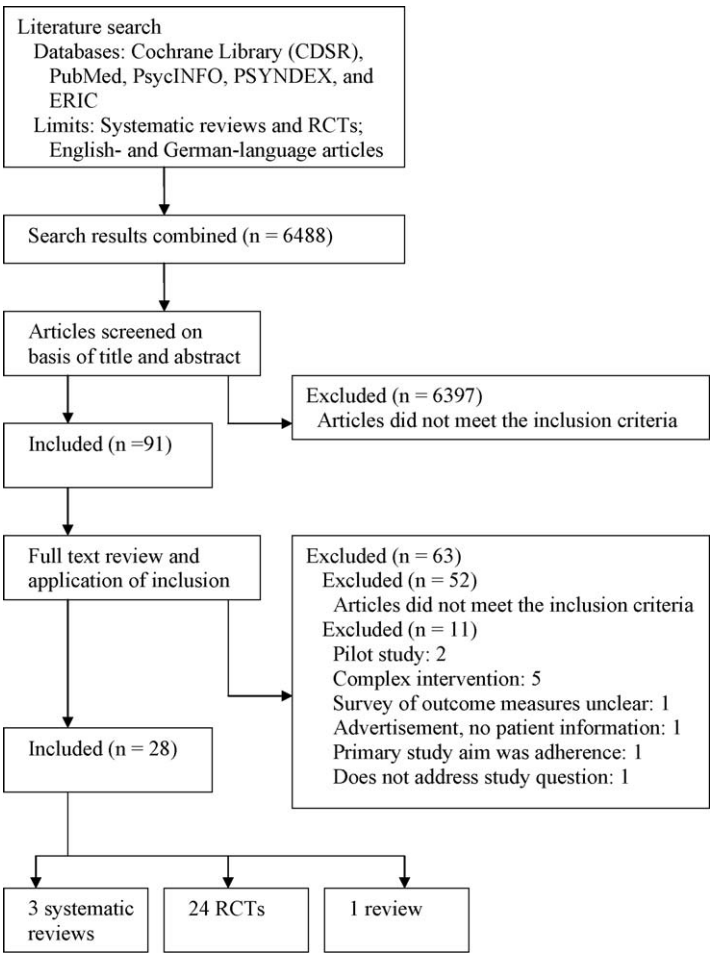


Fig. 1. Flow diagram of study selection (phase 2).

3.2. Phase 2: Study selection

Three systematic reviews and 24 randomized-controlled studies met the inclusion criteria and were included. One additional review was included after reference tracking. See flow diagram Fig. 1.

3.3. Descriptions of studies

The characteristics and outcomes of included studies are shown in Table 1. Excluded studies with reasons for exclusion are shown in Table 2.

Table 1
Characteristics of included studies.

Study	Methods	Participants	Intervention	Outcome
Akl et al. [27]	Randomized-controlled trial	84 participants of a community health education program (mean age: 59.6 years), USA	Symbols compared to numbers and letters for the representation of strength of recommendation (SOR) and quality of evidence (QOE)	Understanding
Almashat et al. [30]	Randomized-controlled trial	102 students (mean age: 19.7 years), USA	Vignettes and a debiasing questionnaire compared to vignettes with control questionnaire	Framing effect
Austin et al. [49]	Randomized-controlled trial	101 emergency department patients with lacerations (mean age: not reported), USA	Comparison of discharge instructions with or without illustrations	Comprehension
Braun et al. [66]	Randomized-controlled trial	86 students and non-students (mean age: 32.7 years), Germany	3 versions of package inserts that varied with regard to the personal nouns used (a generic masculine version and two gender-neutral ones)	Recall
Brotherstone et al. [52]	Randomized-controlled trial	318 participants (aged 60–64), United Kingdom	Written information leaflet with illustrations compared to a written (standard) information on bowel cancer and screening procedure	Understanding
Delp and Jones [50]	Randomized-controlled trial	234 emergency department patients with lacerations or parents/guardians of children with lacerations (mean age: 20.6 years), Michigan/USA	Wound care instruction sheet with cartoon illustrations compared to wound care instruction sheet without cartoon illustrations	Comprehension
Edwards et al. [29]	Systematic review	People facing real life decisions about whether to undergo screening	Personalised risk information (oral, written, video or electronic media) compared to generalised risk communication interventions	Knowledge of risk, accurate risk perception
Edwards et al. [28]	Systematic review	People attending consultations for themselves or their children or using materials communicating risk	Risk communication interventions	Knowledge, risk perception

Table 1 (*Continued*)

Study	Methods	Participants	Intervention	Outcome
Ghosh et al. [44]	Randomized-controlled trial	150 women at increased risk for breast cancer (mean age: 60.2 years), 88% white, 70% some college education, Minnesota/USA	Risk presentation (probability) with a bar graph alone compared to a bar graph with frequency format diagram. Each patient's 5-year risk estimate of invasive breast cancer was calculated using the Gail model	Risk perception
Hawley et al. [45]	Randomized-controlled trial	2412 internet user (mean age: 49 years), 82% white, well educated, USA	Comparison between different graphs (pie chart, bar graph, pictograph, sparkplug, clock graph, table) for presentation of treatment risk and benefit information	Verbatim and gist knowledge
Knapp et al. [53]	Randomized-controlled trial	67 primary care patients (mean age: 79.3 years), United Kingdom	Full-sized pictograms (9×9 cm) compared to smaller pictograms (3×3 cm)	Interpretation of pictograms
Kools et al. [54]	Randomized-controlled trial	99 participants (aged 20–60 years), Netherlands	Instructions for asthma devices with line-drawings and captions compared to original instructions	Recall
Kools et al. [68]	Randomized-controlled trial	46 students (mean age: 19 years) (1st-year undergraduates), Netherlands	12-pages text with graphic organizers (on the top of each page) compared to a standard text about asthma	Comprehension
Leiner et al. [55]	Randomized-controlled trial	206 parents/caretakers of paediatric patients receiving polio vaccines (mean age: not reported), Texas/USA	Vaccine information video (animated cartoon) compared to a printed vaccine information sheet (VIS)	Knowledge
Mansoor and Dowse [51]	Randomized-controlled trial	120 HIV-positive out-patients (aged 26-40), English or isiXhosa-speaking, black, no antiretroviral therapy on chronic co-trimoxazole therapy, South Africa	A simple, shorter patient information leaflet incorporating pictograms and text compared to a standard PIL (longer, more complex, no pictures) on co-trimoxazole therapy	Knowledge
Mazor et al. [57]	Randomized-controlled trial	600 (317) patients with anticoagulant therapy (mean age: not reported), Massachusetts/USA	3 video versions (narrative evidence, statistical evidence and combination of narrative and statistical evidence) compared to usual-care (control)	Knowledge
McDonald et al. [58]	Randomized-controlled trial	113 community-dwelling adult women (mean age: 42.6 years), English or Spanish-speaking, Connecticut/USA	Pamphlets with educational format (storytelling/narrative vs. factual). All versions use pictures	Knowledge
Murphy et al. [56]	Randomized-controlled trial	187 adolescents at risk of HIV/AIDS (aged 15–19 years), USA	Simplification of the HIVNET prototype (simplified text with illustrations) compared to the standard version. Reading grade level was simplified from 8.4 to 5.1	Comprehension, recall
Muscatello et al. [46]	Randomized-controlled trial	543 participants (mean age: not reported), New South Wales/Australia	12 modified (one or more changes) graphs compared to the original graphs	Comprehension
Nilsen et al. [70]	Systematic review	Healthcare consumers (or professionals) involved in decisions about health care	Ways of involving consumers to participate in patient information material (printed, audio-visual and electronic information that is intended to help patients to make informed decisions about healthcare) compared to no consumer involvement or different methods of involvement	Knowledge
Sansgiry et al. [67]	Randomized-controlled trial	225 Spanish-speaking consumers of over-the-counter (OCT) medications (mean age: 38.9 years), Texas/USA	A bilingual (English and Spanish) OCT-patient information leaflet compared to the old label version and the new FDA label format	Knowledge
Sudore et al. [65]	Randomized-controlled trial	205 English and Spanish-speaking people (aged >50), California/USA	A redesigned advance directive (5th grade reading level, >14 point font, graphics) compared to a standard advance directive (12th grade reading level, 12 point font)	Knowledge
Trevena et al. [11]	Review	Patients making healthcare decisions	Different presentation formats/methods (numeric, absolute risk reduction, relative risk reduction, graphical, pictures and text words) compared to no method or each other	Understanding, knowledge, comprehension
Walker et al. [69]	Randomized-controlled trial	363 participants with rheumatoid arthritis (mean age: 62 years)	Arthritis Research Campaign (ARC) booklet with a mind map compared to the standard ARC booklet	Knowledge
Yates and Pena [64]	Randomized-controlled trial	200 adult emergency medicine patients with head injuries (aged: 38–48 years), New Zealand	A short, simplified head injury advice sheet compared to a standard sheet	Comprehension
Zikmund-Fisher et al. [43]	Randomized-controlled trial	1704 internet users (mean age: 50 years), USA	Survival curves (5 or 15 years) compared to mortality curves (5 or 15 years)	Comprehension
Zikmund-Fisher et al. [31]	Randomized-controlled trial	1393 internet users (mean age: 49 years)	Comparison of different communication formats: risk presentation with text alone, text with pictograph, total risk and incremental risk	Perceived likelihood
Zikmund-Fisher et al. [32]	Randomized-controlled trial	659 women with risk of breast cancer >1.66% estimated by the Gail model (mean age: 59 years), USA	Comparison of different presentation formats for risks of side effects: pictograph vs. numeric text, total vs. incremental risk, 100 vs. 1000 persons as denominators	Risk perception, gist knowledge

Table 2
Excluded studies.

Study	Reason for exclusion
Boer et al. [14]	Advertising of health products
Braun et al. [15]	Intervention: complex intervention
Dowse and Ehlers [16]	Primary study aim adherence
Fagerlin et al. [17]	Does not address study question
Fuchs and Hippius [18]	Intervention: complex intervention
Hinshaw et al. [19]	Pilot study
Hoffmann et al. [20]	Intervention: tailored complex intervention
James et al. [21]	Survey of outcome measures unclear
Lipkus and Klein [22]	Intervention: tailored complex intervention
Schwartz et al. [23]	Intervention: complex intervention
Wilson et al. [24]	Pilot study

3.4. Risk of bias in included studies

Critical appraisal of systematic reviews showed high quality. Results of critical appraisal of RCTs are shown in Table 3.

3.5. Evidence of categories

3.5.1. Category: Content of information and meta-information

The ethical guidelines of the General Medical Council (GMC) define principles for the content of EBPI [25]. The guidelines describe how patients have to be informed before therapeutic, diagnostic or screening interventions.

Patients have to be informed about the purpose of the intervention, uncertainties about diagnosis and prognosis, and the options for treating or managing the condition, including the option not to treat. Furthermore, they must be given the probabilities of potential benefits, risks, likelihood of success or failure, side effects, and false-positive/false-negative results.

In addition, it is demanded to consider criteria of transparency, so-called meta-information [7], which supplemented the GMC criteria. Information should be given about the authors, sponsoring, financial dependencies, aim of the publication, sources of information, publication date of the information itself and also about the background information, references for further information and additional support or patient organizations.

3.5.2. Category: Quality of evidence

Patients prefer information which is given with an honest assessment of whether or not interventions are known to be effective [26].

A large number of taxonomies are used to rate quality of an individual study and the strength of recommendation if based on a body of evidence. However, the diversity of these scales rather confuses than enhances perception.

One randomized-controlled study was included [27]. Akl et al. [27] evaluated health care consumers' understanding and preferences for symbols vs. numbers and letters for the representation of strength of recommendation (SOR) and QOE. Understanding was measured with correct interpretations of the used grading formats. In addition, they evaluated health care consumers interest in receiving information about the SOR and the QOE using a seven-point Likert scale (−3 "strongly disagree" to +3 "strongly agree"). Participants expressed a strong preference to be informed about the QOE (mean Likert scale rating = +2.50; 95% CI, 2.26–2.73).

Symbols were superior to numbers for the presentation of the SOR (understanding: 74% vs. 14%), but were not preferred by the participants due to the grading system which is well known by American students. Understanding was high for symbols and letters for the presentation of the QOE (91% vs. 95%).

The standardization of systems of grading the QOE and SOR should be supported. There is a need to balance simplicity and clarity. However, the meaning of the presentation type must possibly be learned by the intended audience.

Until then developers of EBPI should ensure that a clear explanation is readily available for the presentation which is used.

3.5.3. Category: Patient-oriented outcome measures

Patients should be informed about two key factors when weighing new information about the effectiveness of a treatment: the quality of the evidence supporting its use and whether the evidence focuses on patient-oriented outcomes or disease-oriented outcomes.

No study was found which evaluated the impact of patient-oriented outcomes in patient information material.

Missing evidence for patient-oriented outcomes should be communicated, if patient-oriented outcomes were not considered.

3.5.4. Category: Presentation of numerical data

The way numerical data is presented, the framing of data, affects understanding and decision-making. This category comprises various aspects like presentation of risks, results and diagnostic tests.

Two systematic reviews [28,29], three randomized-controlled trials [30–32] and one review [11] were included.

Edwards et al. [28] reviewed existing literature on risk communication in genetics and described the effects on key outcomes for clients. As a result risk communication interventions achieve some benefits for consumers on cognitive outcomes, e.g. knowledge and risk perception, but counselling and psychosocial interventions appeared to be more effective.

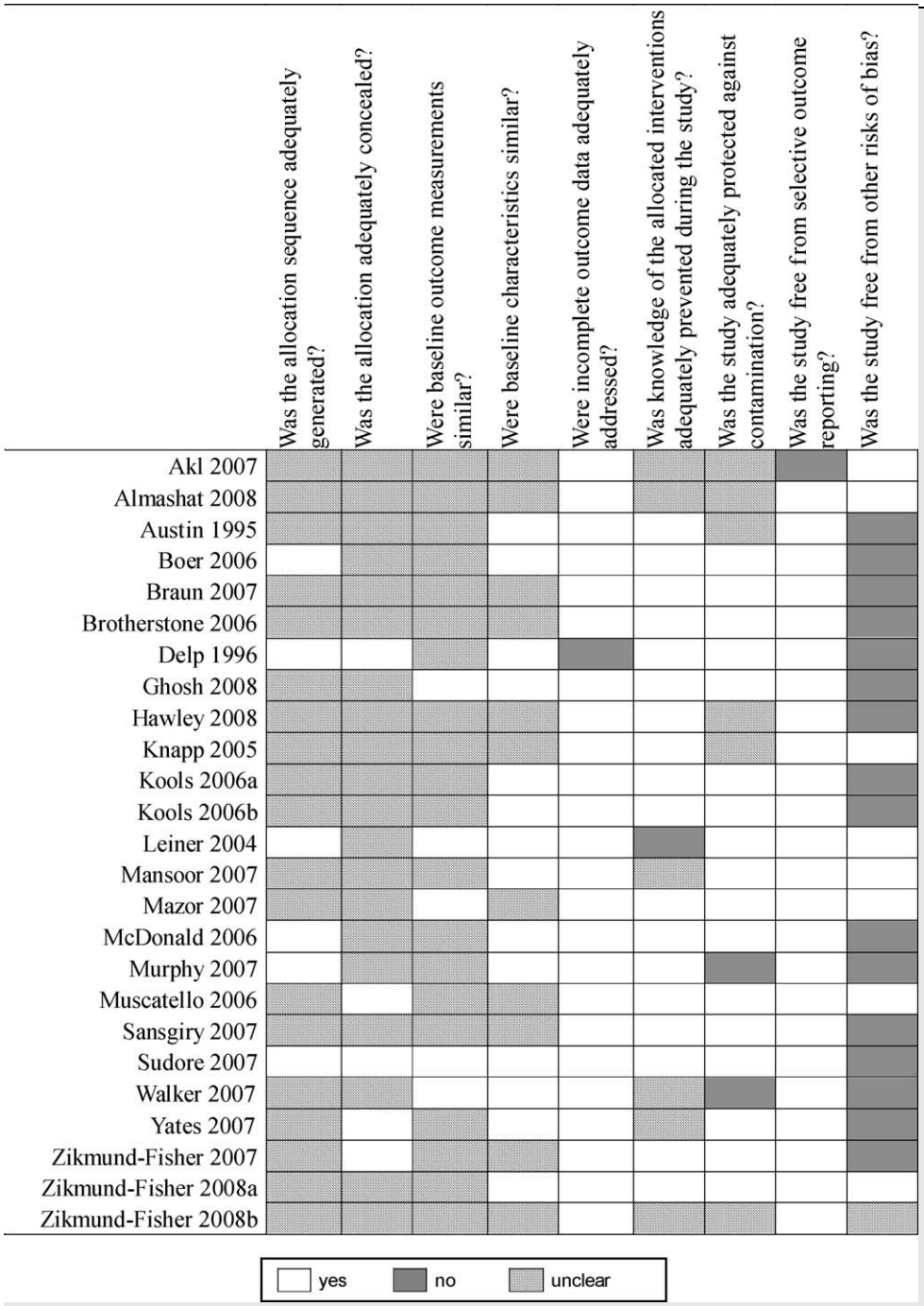
Edwards et al. [29] reviewed the literature to assess the effects of different types of personalised risk communication about screening tests. In three studies the interventions showed a trend towards more accurate risk perception (fixed effects OR 1.46 (95% CI, 1.13–1.88)). Three other trials with heterogeneous outcome measures showed improvements in knowledge with personalised interventions. But there was insufficient data from the included studies to report odds ratios on knowledge. There is little evidence that personalised risk communication (whether written, spoken or visually presented) promotes or achieves their effects by enhancing informed decision-making in consumers.

Almashat et al. [30] studied the use of a debiasing questionnaire to prevent the framing effect for young adults on hypothetical decisions. The participants read a set of three medical treatment vignettes that presented information (i.e. mortality vs. survival frame) in terms of different outcome probabilities (i.e. cumulative probability, interval probability, life expectancy) under either debiasing or control conditions. The debiasing technique involved participants listing advantages and disadvantages of each treatment prior to decision-making. The control group was given a questionnaire with questions regarding stress, dental hygiene, and physical fitness. The participants had to choose a treatment option after answering one of the questionnaires.

The framing effect was demonstrated in the control group in two of the three vignettes. The debiasing group successfully avoided the framing effect for both vignettes; e.g. the cumulative probability vignette, control participants were more likely to select the risky choice in the survival frame (OR 7.64) and less likely to select the risky choice in the mortality frame (OR 0.30). In the intervention group, the odds ratio for selecting the risky choice was 0.60 (95% CI, 0.34–1.08) for the mortality frame, and 1.69 (95% CI, 0.90–3.18) for the survival frame.

A debiasing questionnaire may be a helpful aid for patients and consumers to concentrate on given information. On the other hand

Table 3
Risk of bias.



presentation styles, that affect patients' decisions, should not be used in EBPI.

Zikmund-Fisher et al. [31] assessed participants subjective reactions to different communication formats for medication side effects, using a 2×2 factorial design to independently vary risk framing (total risk vs. incremental risk) and number of graphs (single graph vs. a sequence of two graphs). Participants indicated their perceived likelihood of experiencing each side effect using an 11-point (0–10) scale. Incremental risk framing had a significant effect on perception of likelihood of experiencing side effects. Effect sizes ranged from $d = 0.15$ for judgements of the likelihood of strokes to $d = 0.39$ for perceived likelihood of experiencing more colds. No effect was shown for using a two-graph sequence compared to a single pictograph. Participants with higher numeracy scores perceived significantly less risk.

Zikmund-Fisher et al. [32] examined whether using pictographs, incremental risk formats, and varied risk denominators influence perceptions and gist (general impression) knowledge of side effects in an online decision aid. Tailored estimates of the risks of five side effects were presented in a three factor design: risk

Table 4
Examples of presentation of numerical data.

1. Presentation of numbers	
Natural frequencies: 5 out of 100.	5 out of 100 correspond to 5%. Percentages are often misunderstood [33].
Comparability of numbers: 1 out of 100; 5 out of 100; etc.	Comparisons between two likelihoods will be more accurate if they are presented as 5 out of 100 vs. 25 out of 100, rather than the formally equivalent representation of 1 out of 20 vs. 1 out of 4 [34].
2. Presentation of risks	
Comparison of health-risks with everyday risks: 150 out of 1000 male smokers, who just turned 50, will die within the next 10 years: thereof 2 will die from colorectal cancer, 1 from prostate cancer, 30 from lung cancer, 35 from cardiovascular diseases and 4 from accidents [35].	The additional presentation of everyday risks allows comparing risks [35].
3. Presentation of results	
Absolute risk reduction (*ARR*): Uptake of colorectal screening reduces colorectal cancer mortality by 0.1 percent points.	The presentation of absolute risk reduction leads to better understanding compared to relative risk reduction [33].
Relative risk reduction (*RRR*): Uptake of colorectal screening reduces colorectal cancer mortality by 20%.	The presentation of relative risk reduction leads to an overestimation of intervention effects [36,37].
Number needed to be screened (*NNS*): About 1000 people would have to take part in colorectal cancer screening with occult blood test every 2 years for 10 years, to prevent 1 death caused by colorectal cancer.	The presentation of number needed to treat (NNT), NNS and number needed to harm (NNH) is comparable to ARR regarding comprehensibility [36].
Confidence intervals: About 1000 people would have to take part in colorectal cancer screening with occult blood test every 2 years for 10 years, to prevent 1 death caused by colorectal cancer. It might as well be about 700 or else 3000, who would have to take part in screening [38].	Confidence intervals communicate uncertainty of data [39].
4. Presentation of diagnostic tests	
Test results: Of 1000 pregnant women who are 40 years of age, 10 will have children with Down syndrome. If all 1000 women were tested, 9 of the women with Down syndrome babies would test positive for the condition, and 1 would test negative. Of the 990 women whose babies do not have Down syndrome, 394 would test positive, and 596 would test negative.	When the information on diagnostic tests is presented as frequencies rather than single event probabilities (e.g. 0.01), it is immediately obvious, that a positive test result carries much less diagnostic certainty [34].

information displayed either in pictographs or numeric text, risk reported either total or incremental risk with or without tamoxifen, and risk estimates used 100 or 1000 person as denominators. Incremental risk formats consistently lowered perceived risk of side effects but resulted in low knowledge when displayed by numeric text only. Adding pictographs, however, produced significantly higher comprehension levels.

Trevena et al. [11] reviewed studies which examined different formats of presentation of probabilistic information in order to improve patients' understanding of evidence. Based on one study it is suggested that natural frequencies or event rates are better understood than probability formats with varying denominators. Two other studies indicated that changes in risk are better understood if absolute risk reduction or relative reductions with baseline risk formats are used.

Cognitive psychology provides insight into the best ways to present risks and benefits to promote understanding and minimize interpretation bias.

Table 4 gives examples and practical recommendations.

3.5.5. Category: Verbal presentation of risks

The use of verbal descriptors is an effort to facilitate communication about risks with consumers. A guideline of the European Commission established five verbal descriptors for the probabilities of medication side effects (very common, common, uncommon, rare, very rare) with assigned frequencies [40].

One review [11] was identified, that included two relevant studies.

Patients have a more accurate perception of risk if probabilistic information is presented as numbers rather than words [11].

As already shown in the previous review, consumers significantly overestimate the risk of side effects when interpreting verbal descriptors [41,42]. Table 5 shows consumers' perception of verbal descriptors. Consumers were asked to estimate the probability (as a percentage) of having a side effect from a prescribed drug from one of the five qualitative descriptions.

Therefore risks should be presented numerically or else numerically and verbally.

3.5.6. Category: Diagrams, graphics and charts

Diagrams, graphics and charts are commonly used to visually display numerical information, e.g. bar graph, pie chart, table.

Four randomized-controlled trials [43–46] and one review [11] were included.

In an internet-administered survey Zikmund-Fisher et al. [43] assessed participants' comprehension of four graphs showing data of treatment outcomes. Participants received either a survival curve showing 15 years worth of data, an abbreviated survival graph showing only 5 years worth of data, or one of two analogous mortality graphs. Comprehension was surveyed. They observed a significant difference in people's ability to correctly identify the most effective treatment. While 94% of participants viewing the survival graphs accurately interpreted the graphs, this percentage dropped to 85% among those viewing the mortality curves. In addition, comprehension of mortality graphs was generally at least as good as, and often better, than comprehension of survival

Table 5
Example of verbal descriptors [42].

Qualitative descriptors	EU assigned frequency	Mean frequency estimated by participants ($n = 200$)
Very common	>10%	65% (24.2)
Common	1–10%	45% (22.3)
Uncommon	0.1–1%	18% (13.3)
Rare	0.01–0.1%	8% (7.5)
Very rare	<0.01%	4% (6.7)

Values are mean (SD).

graphs. The number of years of data in the survival curve can change beliefs about treatment effectiveness.

Ghosh et al. [44] evaluated whether patient education regarding breast cancer risk using a bar graph, with or without a frequency format diagram, improved the accuracy of risk perception. Overall, 72% of women overestimated their risk of breast cancer in the pre-visit questionnaire. Accuracy of risk perception improved after the intervention (bar graph group, 19 to 61%; bar graph with frequency format group, 13 to 67%). Results were not significant. But the difference was significant for women who inaccurately perceived very high risk (≥50% risk), inaccurate risk perception decreased significantly in the frequency format group (22 to 3%) compared with the bar graph only group (28 to 19%).

Hawley et al. [45] evaluated the ability of six graph formats to impart knowledge about treatment risks and benefits in a hypothetical medical decision-making scenario (bar graph, pictograph, modified pictograph (sparkplug), pie chart, modified pie chart (clock graph) and table). Perception of the graph formats and two different types of knowledge were assessed: verbatim (specific numerical) knowledge and gist (general impression) knowledge. Participants who saw the table were most likely to have adequate verbatim knowledge (67% vs. 18–62% for other formats, $p < 0.001$), whereas those who viewed the pie chart more often had adequate gist knowledge (68% vs. 57–65% for other formats, $p < 0.05$). Among participants with lower numeracy, tables and pie graphs produced the most correct answers for verbatim and gist knowledge, followed by pictographs in both cases.

Muscatello et al. [46] tested modified statistical graphs compared to the original graphs to improve comprehension by non-experts. Comprehension rate (CR) was defined as the prevalence of correct answers to the tasks and categorized according to the following scale: 0% to <20%, very low; 20% to <40%, low; 40% to <60%, moderate; 60% to <80%, high; and 80–100%, very high. One or more modifications were made to improve comprehension of the statistical information depicted in the graph. Different categories of changes were made and combined, e.g. changing graph type, including a footnote or removing independent variables. The modifications with the most benefit for a single task were: changing a pie chart to a bar graph (changed CR from low to very high), changing the *y* axis of a graph so that the upward direction represented an increase rather than a decrease (changed CR from low to high), including a footnote to explain an acronym (changed CR from very low to low), and making the *y* axis of two adjacent graphs match (changed CR from moderate to very high). The modification of removing a layer from a stacked layer graph and adding a footnote reduced the comprehension rate from very high to high.

Trevena et al. [11] reported that patients can understand survival curves, when given more than one opportunity to do so. This result was based on one study. There is also some evidence in two studies that vertical bar graphs with numeric estimates may be the best way to graphically represent probabilities.

There is only little consensus regarding which methods for conveying information to patients are most likely to achieve the necessary level of understanding.

Table 6 gives examples and practical recommendations.

3.5.7. Category: Loss- and gain-framing

The presentation of information is either framed focusing on gain or on loss or on both.

No study was found that assessed the defined outcome measures. But some studies tested the persuasiveness of gain- and loss-framing regarding a desired behavior, e.g. uptake of screening.

The ethical guidelines explicate that the information given to the patients should presented in a balanced way [25].

3.5.8. Category: Pictures and drawings

The utilization of written text in combination with pictures in health communication is thought to be helpful for patients, especially for those with limited literacy. The category pictures and drawings comprises cartoons, pictures, pictograms, drawings and photographs.

Eight randomized-controlled trials [49–56] were included.

Austin et al. [49] examined comprehension of patients given written discharge instructions with or without pictures. The median number of correct responses was 5 out of 10. Patients who received text plus pictures were 1.5 times more likely to give five or more correct responses compared to the control group (65% vs. 43%, $p = 0.033$). In addition, they found that this was especially pronounced among nonwhites, patients with no more than high school education, and women.

Delp and Jones [50] evaluated printed instructions for caring wounds at home for patient with lacerations. The control group were given just text and the intervention group received the same text plus pictures (like comic drawings). The pictures illustrated the textual information. Participants were interviewed by telephone a series of questions about information in the handout 3 days later. The percentage of people who correctly answered all wound care questions when comparing patients who were given the illustrated version and the text version differed significantly (46% vs. 6%). A subset analysis of those patients who had less than high school education demonstrated a more pronounced difference between the groups.

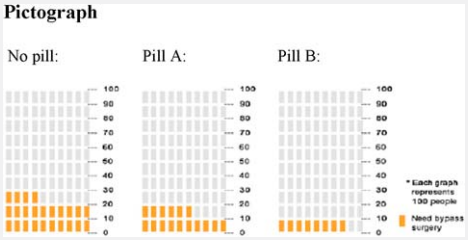
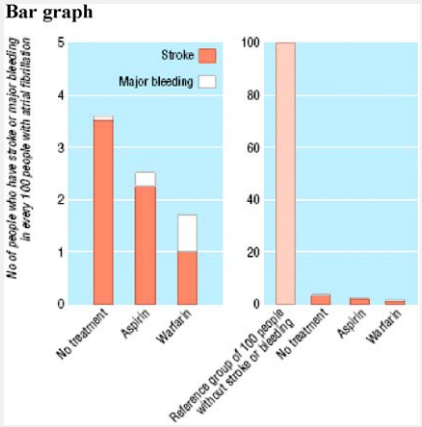
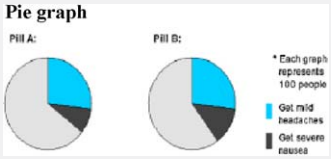
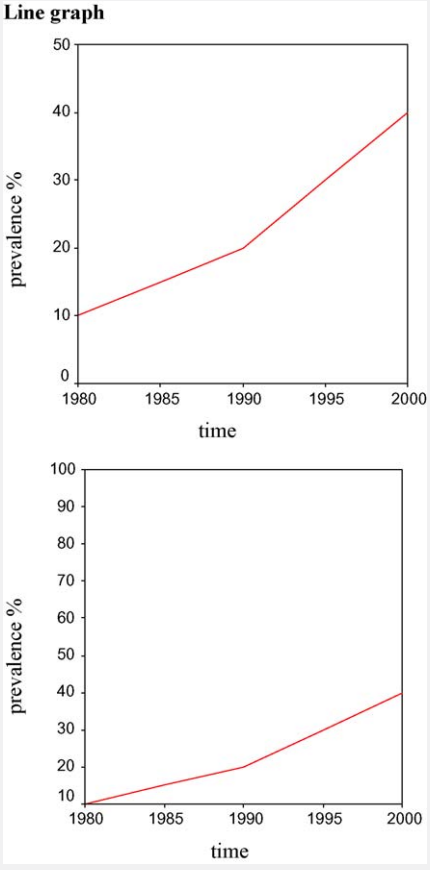
Mansoor and Dowse [51] evaluated two different patient information leaflets on co-trimoxazole therapy compared to standard care with any printed information. The interventions consisted of a short, simple version with pictures and a more complex version. A significant higher mean percentage of correct answers for medical knowledge were assessed for the patient information with pictures compared to the others (76% vs. 43% and 50.9%). This may be an indicator that pictures enhance knowledge. However, some important information was unknown by all participants.

Brotherstone et al. [52] studied the effectiveness of visual illustrations in improving peoples' understanding of the preventive aim of flexible sigmoidoscopy screening. The illustrations represented the removal of polyps and the polyp-cancer process. Three hundred and eighteen people were invited to participate and got information material with illustrations or the control information material. Only 65 out of these were interviewed. The illustration group had 84% good understanding compared to the only-written group with 57% good understanding. Therefore the results suggest that only the meaning contained within the illustrations has an advantage regarding recall.

Knapp et al. [53] examined the correct interpretation of medication pictograms and the effects of pictogram size on understandability among older people. The participants had to interpret the pictograms at two times. They were told the correct meaning after their first interpretation. Participants were more likely to correctly interpret pictograms that were larger (9×9 cm vs. 3×3 cm) at both times. Participants viewing the large pictograms correctly interpreted at mean 3.1 pictograms at the first interview and 5.0 at the second interview. The control group received scores of 2.0 and 3.6, respectively. However, in the second interview only 5 out of 10 pictograms were correctly interpreted.

Kools et al. [54] evaluated the additional presentation of seven line-drawings (visualizing the instructions) with textual instructions for two medical devices (11 instructions for the inhaler chamber and 26 instructions for the peak flow meter). Some

Table 6
Examples of diagrams, graphics and charts.

Pictograph 	Hawley et al. compared different formats which showed the effect of different drug interventions on bypass surgery. Pictographs achieved adequate levels of verbatim and gist knowledge across numeracy levels [45]. Pictographs are also used with faces or stick-figures. A drawback of pictographs is that they require more space than numerical presentations [34].
Bar graph 	Different representations of the same benefits of treatment: the reduction after treatment in the number of people who have a stroke or major bleeding looks much larger on the left, where the reference class of 100 patients who have not had a stroke or bleeding is not shown [47]. Bar graphs are well understood by patients and consumers. In addition, bar graphs are perceived to be helpful [48].
Pie graph 	Pie graphs are used to show the increased risk of headaches and nausea caused by taking pills. People who viewed a pie graph achieved more gist knowledge, especially those with low numeracy levels. However, the effect on verbatim knowledge was much smaller [45].
Line graph 	Line graphs are used to display, e.g. cumulative risk. Scaling of line graphs influences risk perception. The larger the area under the curve the higher the risk is estimated. Line graphs are effective for communicating trends in data [48].

textual instructions served as captions below the line-drawings. It was expected that the line-drawings improve understanding of the instructions and the effect would be stronger for the inhaler chamber. Regarding the number of correctly recalled propositions of the inhaler chamber instruction the text with picture group outperformed the text-only group (6.04 vs. 4.81 correct propositions).

Leiner et al. [55] compared a four-page non-illustrated leaflet with a video-tape of animated cartoons explaining the need for a polio vaccine. Both versions were available in English and Spanish and contained the same information. Results showed statistically significant higher post-knowledge scores for the animated cartoon group. Furthermore, 30% of this group responded to all questions correctly while none of the printed group did so.

Murphy et al. [56] examined two versions of consent a form for a HIV vaccine trial. A simplified, picture-based version was compared to the HIVNET prototype with adolescents at risk of HIV. The simplified version contained modification in vocabulary, grammar and sentence structure and added illustrations. A comprehension test and interview with recall questions were conducted. The simplified consent group scored (significantly) higher on comprehension with mean scores of 15.29 (out of 19) compared to 13.62. 63% of the participants of the intervention group answered at least 16 items correctly; in the standard group only 32% answered at least 16 items. Participants of the simplified consent form were also able to recall more items than the control group. However, it is unclear which factor, the illustrations or the simplifications, lead to the better scoring. Six of the seven items for which the simplified group scored significant better had pictures to illustrate the concept.

There is some indication that pictures enhance knowledge und comprehension, especially for instructional advices (medication pictograms). But there are differences for the various types of pictures. Clear and simple drawings which support textual information should be preferred. More research is needed to examine which kinds of pictures are most beneficial regarding different target groups.

3.5.9. Category: Patient narratives

Patient narratives (also called testimonials or described as using a narrative or storytelling format) are used to educate (education programs) and to support patients (DA).

In contrast to a statistical message patient narratives present a definite experience not a probability of an experience. Patient narratives are typically considered as more concrete, familiar and vivid. They are expected to make information more memorable, realistic and comprehensible.

Two randomized-controlled studies were identified [57,58].

Mazor et al. [57] designed three versions of an educational video depicting a physician talking with a patient about anticoagulant medication management (with warfarin). The versions differed in the presentation of the key points. The physician used anecdotes about patient experiences, referred to scientific evidence using lay language or used a combination of both. These video interventions were compared to usual-care. The relevant outcome knowledge was measured by a baseline and post-intervention questionnaire. The participants who watched any video showed greater gains compared to those in the control group ($p < .001$). None of the video versions were superior compared to the others.

McDonald et al. [58] evaluated a storytelling format compared to a factual format to teach women about myocardial infarction symptoms. Four groups used different pamphlets in English and Spanish. No differences were found regarding the primary outcome. Women in both groups identified significantly more symptoms after reading the pamphlet compared to baseline data. However, the English-speaking women reported more symptoms than the Spanish-speaking women ($p < .007$).

Regarding cognitive outcomes no beneficial effects for the use of a storytelling format or additional narratives were found.

3.5.10. Category: Cultural aspects

Health information tries to get the attention of a broad audience. Up to now little attention has been given to cultural differences. These differences are observably in cultural aspects (e.g. religiosity) and dimensions (e.g. uncertainty avoidance, masculinity vs. femininity) [59].

No study was found. Studies that examined language related aspects were considered in the category Language.

Following ethical responsibility it is supposed that cultural aspects should be considered by developing patient information material.

3.5.11. Category: Layout

The layout of EBPI can facilitate reading and supports comprehension. Many recommendations and instructions exist to design written patient information.

Nevertheless no study was identified comparing information materials which only vary in layout and design.

The Harvard School of Public Health offers a concise compilation (including aspects of type, spacing, lines and design) [60].

It is recommended to use a readable type style (generally a serif type in 12 point size) and an appropriate space between lines (1.2–1.5 spacing) printed on paper that provides contrast between the paper and the text (no words on shaded or patterned background). The lines should be left-aligned with an appropriate length (maximum of five inches) and splitting of words across two lines should be avoided. Relevant aspects and recommendations for the overall design are:

- be consistent,
- provide a guide for finding key information,
- clearly label all illustrations and charts,
- offer explanations and make legends clear,
- place charts as close as possible to explanatory text,
- avoid wrapping text around illustrations,
- use consistent and easily recognized headings, and
- signal main points with bold or highlights.

3.5.12. Category: Language

Language means a system of spoken sounds or conventional symbols for communicating thoughts or ideas. Language facilitates the exchange of information, but people differ in their abilities to admit and process information. Language may a be barrier for people in search of information and knowledge. Therefore, the intended audience, including their use and handling of language, must be considered. Several aspects describe this category and build the following criteria.

Six randomized-controlled studies [64–69] for different criteria were included.

3.5.12.1. Criterion: Plain language and readability. Explicit communication is recommended to enhance health literacy and understanding of medical issues. A key communication strategy is to use plain language [61]. Plain language is a way of organizing and presenting information so that it makes sense and is easy to read. Plain language is defined as a simple, clear, conservational style and one that presents information in a logical order [62]. The consideration of using everyday words and examples, explanation of technical terms, avoidance of long and complex sentences, avoidance of gender-specific terminology, and writing in active voice is recommended.

The NIH Plain Language Coordinating Committee recommends a 4th–8th grade reading level for public information materials [62]. Written materials for people with limited literacy skills should generally be at 5th grade level or lower [63].

Yates and Pena [64] investigated understanding of medical information in emergency medicine patients to assess differences in comprehension between a standard head injury advice sheet (750 words, 4th grade Flesch Reading Grade Level) and a more structured, simplified one (371 words, 4th grade Flesch Reading Grade Level). 84.5% of the participants had a reading level of high school or above. Lower literacy groups were hardly represented. Median comprehension score for the standard form was 9 (out of 10), and for the simplified form 10 (out of 10).

Sudore et al. [65] evaluated a redesigned advance directive (5th grade reading level with redesigned layout and graphics) compared to a standard form (12th grade reading level). Pre- and post-knowledge was assessed as a secondary outcome. English and Spanish versions of both forms were provided. The participants had a mean literacy score of 24.6 that implied an adequate literacy (>9th grade reading level). The knowledge was improved in both groups, but the redesigned form did not result in greater knowledge gains. Participants answered a similar number of knowledge items correctly (71.2%, redesigned vs. 70.8%, standard form). However, more participants preferred and wanted to take home the redesigned advance directive.

Braun et al. [66] examined fictitious package leaflets that varied with regard to the personal nouns used. A generic masculine version and two gender-neutral ones were compared to assess recall. Female and male participants recalled a similar amount of details in all three text versions. However, male participants rated the generic masculine version as more comprehensive compared to the gender-neutral versions.

Plain language is recommended, but studies showed only marginal effects. One reason may be that the included participants did not present the target audience.

3.5.12.2. Criterion: First language. The first language (also mother-tongue) is the language a human being acquires in early childhood. But one can have two or more languages, being a native bilingual or multilingual. The proficiency of a language has an impact on comprehension and understanding of information.

Sansgiry et al. [67] evaluated bilingual Product Information Labels (PILs) compared to currently available label formats in a sample of Spanish-speaking consumers. Mean scores for product knowledge from PILs among Spanish-only speakers differed significantly from mean scores of old (CI, 4.50-8.63, $p < 0.05$) and new label formats (CI, 4.17-8.25, $p < 0.05$).

Bilingual materials provide an opportunity to receive information and may foster knowledge gain for a broader audience.

3.5.12.3. Criterion: Comprehension enhancing tools. To comprehend a text, the text information should become part of the reader's personal knowledge base. Readers need to cognitively encode the incoming information by maintaining coherence in their mental representation of the content. Graphical organizers such as network maps, hierarchical tree diagrams or matrices try to clarify or highlight relations among the macro level concepts in the text. They may foster the comprehension of the thematic structure and the organization of information in the memory of the reader.

Kools et al. [68] examined the effect of graphic organizers on the comprehension of a health education brochure text. The graphic organizers were graphically depictions of relations among concepts in a text. Participants read a text about asthma with or without graphical organizers. A questionnaire with open-ended questions was developed to measure objective comprehension. Individual scores were transformed into percentages of the maximum possible score. The graphic organizer group had better comprehension (57.2% vs. 43.8%, $p < 0.01$). The findings suggest that systematic placement of graphic organizers encourages readers to learn the whole picture rather than only facts.

Walker et al. [69] determined the knowledge gain of a booklet compared to a booklet with a pictorial mind map. Both groups showed a significant increase in knowledge (mean increase 6.56 vs. 6.45), but there was no significant difference between these groups. Mind maps seem to be a helpful method, but were not superior. However, mind maps should be a support for people with low literacy skills, but only a few of these people participated in the study.

The beneficial effect depends on the used tool. Graphic organizers highlighting hierarchical relations seem to improve comprehension, but this effect was not shown for mind maps.

3.5.12.4. Criterion: Non-alarmist and non-patronizing. A non-alarmist [26] and non-patronizing [10] use of language is discussed and recommended. However, no study was found that examined these aspects.

3.5.13. Category: Development process

It is expected that the involvement of consumers in the development process has beneficial effects, since patients' and consumers' ideas and information needs are incorporated.

One systematic review was identified [70].

Nilsen et al. [70] assessed the effects of consumer involvement and compared different methods in the health care domain. One aspect is consumer involvement in the development process of patient information material. Two studies were included which compared patient information material with consumer consultation to those without consumer consultation. The involvement or consultation of consumers resulted in patient information material that had more illustrations and was more readable. Based on one study there is moderate quality evidence that consultation of consumers before developing patient information material can improve knowledge of the patients.

4. Discussion and conclusion

4.1. Discussion

The evidence for the categories for EBPI is quite heterogeneous. Some are supported by good evidence, e.g. presentation of numerical data or graphical presentations. Others, like content of information, derive from ethical guidelines. Some categories have not yet been studied, e.g. cultural aspects. This review is the first which summarizes the evidence of categories and criteria for EBPI.

Our review has limitations. Many studies evaluated various outcomes. Because understanding and comprehension of information are prerequisites for informed patient choice, we only included cognitive outcomes. Our search was limited to RCTs and systematic reviews, as we searched for efficacy trials. Therefore, we did not consider formats which showed positive effects within qualitative studies. In addition, we focused on the context of health information. Therefore, findings from cultural studies and the like were not considered. The quality of included studies was heterogeneous, sometimes poor. Further systematic reviews should be performed on single categories to allow inclusion of multitude of outcomes in RCTs and also studies beyond RCTs.

The development of EBPI requires consideration of the target audiences and their special needs, e.g. those deriving from the

cultural background. Culturally relevant tailoring is discussed, but has not yet been tested within the context of patient information. It remains unclear which cultural aspects are relevant and should therefore be considered. Culturally competent approaches have been examined in educational programs for diabetes. Anderson-Loftin et al. included ethnic beliefs, values, customs, food preferences, language, learning methods and health care practices in the development of their program [71]. Study results showed significant positive changes in BMI and dietary behaviors, whereas metabolic parameters were not affected. Therefore, relevance of effects is questionable. Furthermore, Nollen et al. tested culturally sensitive patient information and found no differences in smoking cessation [72]. According to the authors this might be due to the heterogeneity of the addressed ethnic group.

In the rapidly growing field of health communication, narrative approaches are emerging as a promising set of tools [73]. Sometimes the use of narrative approaches is expected to persuade consumers in order to achieve health-behavior changes. This is in contrast to the aims of EBPI.

Fagerlin et al. studied the influence of anecdotes in patient information on decision-making [74]. When the content and number of the narratives were adapted to the statistical data (e.g. bypass surgery cures angina in 75%, three anecdotes describing success and one describing failure of treatment) the effect on treatment choices was significant. Participants receiving anecdotes which were representative of the statistical information were more likely to choose bypass surgery compared to those who received one anecdote about successful and one about unsuccessful experiences (41% vs. 20%). In addition, the latter study showed that the presentation of statistical information using a pictograph reduced the undue influence of anecdotal reasoning in hypothetical treatment choices on balloon angioplasty and bypass surgery.

Framing of information in either gain or loss is also used to support health-behavior. The persuasiveness of gain- and loss-framed messages for encouraging disease prevention behavior was assessed [75]. Gain-framed messages were significantly more persuasive than the loss-framed ones. However, a balanced presentation of benefit and harm is required for EBPI [25]. In the context of patient information Almashat et al. studied the effect of mortality vs. survival framing regarding treatment choice. Participants were more likely to select the risky choice in the survival frame than in the mortality frame [30]. Trevena et al. also reported that the framing of information in terms of either benefit or harms can affect patient preferences [11].

4.2. Conclusion

The results of this review allow specification of EBPI and may help to advance the discourse among related disciplines. Research gaps are highlighted.

4.3. Practice implications

The results of this review are useful for developers of EBPI. Findings outline the type and extent of content of EBPI, guide the presentation of information and describe the development process. However, depending on the qualification of the developers of EBPI, additional guidance may be needed. A manual that contains detailed guidance on the complex process of developing EBPI is still lacking. Further research should address this gap. The Medical Research Council proposed a framework for the development and evaluation of complex interventions [76]. Since so far, no instruments have been developed to evaluate EBPI, the categories may be helpful to guide evaluation of EBPI.

Conflicts of interest

We have no conflicts of interest to declare.

Role of funding

There was no funding of this work.

References

[1] Schoen C, Osborn R, Doty MM, Bishop M, Peugh J, Murukutla N. Toward higher-performance health systems: adults' health care experiences in seven countries, 2007. Health Aff 2007;26:w717–34.
[2] Grol R, Wensing M, Mainz J, Jung HP, Ferreira P, Hearnshaw H, et al. Patients in Europe evaluate general practice care: an international comparison. Brit J Gen Pract 2000;50:882–7.
[3] Coulter A, Jenkinson C. European patients' views on the responsiveness of health systems and healthcare providers. Eur J Public Health 2005;15:355–60.
[4] Hamann J, Neuner B, Kasper J, Vodermaier A, Loh A, Deinzer A, et al. Participation preferences of patients with acute and chronic conditions. Health Expect 2007;10:358–63.
[5] Stacey D, Bennett C, Saarimaki A, Khangura S, Eden K, Col N. How effective are patient decision aids? In: Edwards A, Elwyn G, editors. Shared decision making in health care. Achieving evidence-based patient choice. Oxford: University Press; 2009. p. 201–7.
[6] Coulter A, Ellins J. Patient-focused interventions: a review of the evidence. Oxford: The Health Foundation; 2006.
[7] Coulter A, Entwistle V, Gilbert D. Informing patients: an assessment of the quality of patient information materials. London: King's Fund; 1998.
[8] Eysenbach G, Powell J, Kuss O, Sa ER. Empirical studies assessing the quality of health information for consumers on the world wide web: a systematic review. J Amer Med Assoc 2002;287:2691–700.
[9] Feldman-Stewart D, Brennenstuhl S, McIssac K, Austoker J, Charvet A, Hewitson P, et al. A systematic review of information in decision aids. Health Expect 2007;10:46–61.
[10] Steckelberg A, Berger B, Kopke S, Heesen C, Muhlhauser I. Criteria for evidence-based patient information. Z Arztl Fortbild Qualitatssich 2005;99:343–51.
[11] Trevena LJ, Davey HM, Barratt A, Butow P, Caldwell P. A systematic review on communicating with patients about evidence. J Eval Clin Pract 2006;12:13–23.
[12] Scottish Intercollegiate Guidelines Network. Methodology Checklist 1: systematic reviews and meta-analyses, http://www.sign.ac.uk/guidelines/fulltext/50/checklist1.html [accessed 20.01.2009].
[13] Cochrane Effective Practice and Organisation of Care Group. Risk of bias tool. Draft, http://www.epoc.cochrane.org/en/handsearchers.html [accessed 28.04.2009].
[14] Boer H, Ter Huurne E, Taal E. Effects of pictures and textual arguments in sun protection public service announcements. Cancer Detect Prev 2006;30:432–8.
[15] Braun KL, Fong M, Kaanoi ME, Kamaka ML, Gotay CC. Testing a culturally appropriate, theory-based intervention to improve colorectal cancer screening among Native Hawaiians. Prev Med 2005;40:619–27.
[16] Dowse R, Ehlers M. Medicine labels incorporating pictograms: do they influence understanding and adherence? Patient Educ Couns 2005;58:63–70.
[17] Fagerlin A, Zikmund-Fisher BJ, Ubel PA. If I'm better than average, then I'm ok?": comparative information influences beliefs about risk and benefits. Patient Educ Couns 2007;69:140–4.
[18] Fuchs J, Hippius M. Inappropriate dosage instructions in package inserts. Patient Educ Couns 2007;67:157–68.
[19] Hinshaw K, El-Bishry G, Davison S, Hildreth AJ, Cooper A. Randomised controlled trial comparing three methods of presenting risk of Down's syndrome. Eur J Obstet Gyn R B 2007;133:40–6.
[20] Hoffmann T, McKenna K, Worrall L, Read SJ. Randomised trial of a computer-generated tailored written education package for patients following stroke. Age Ageing 2007;36:280–6.
[21] James S, Reddy PS, Ruiter R, Taylor M, Jinabhai CC, Van Empelen P, et al. The effects of a systematically developed photo-novella on knowledge, attitudes, communication and behavioural intentions with respect to sexually transmitted infections among secondary school learners in South Africa. Health Promot Int 2005;20:157–65.
[22] Lipkus IM, Klein WM. Effects of communicating social comparison information on risk perceptions for colorectal cancer. J Health Commun 2006;11:391–407.
[23] Schwartz LM, Woloshin S, Welch HG. Using a drug facts box to communicate drug benefits and harms: two randomized trials. Ann Intern Med 2009;150:516–27.
[24] Wilson FL, Brown DL, Stephens-Ferris M. Can easy-to-read immunization information increase knowledge in urban low-income mothers? J Pediatr Nurs 2006;21:4–12.
[25] General Medical Council. Consent: patients and doctors making decisions together, http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance/Consent_guidance.pdf [accessed 22.04.2009].
[26] Coulter A, Entwistle V, Gilbert D. Sharing decisions with patients: is the information good enough? Brit Med J 1999;318:318–22.
[27] Akl EA, Maroun N, Guyatt G, Oxman AD, Alonso-Coello P, Vist GE, et al. Symbols were superior to numbers for presenting strength of recommendations to

health care consumers: a randomized trial. J Clin Epidemiol 2007;60:1298–305.
[28] Edwards A, Gray J, Clarke A, Dundon J, Elwyn G, Gaff C, et al. Interventions to improve risk communication in clinical genetics: systematic review. Patient Educ Couns 2008;71:4–25.
[29] Edwards A, Thomas R, Williams R, Ellner AL, Brown P, Elwyn G. Presenting risk information to people with diabetes: evaluating effects and preferences for different formats by a web-based randomised controlled trial. Patient Educ Couns 2006;63:336–49.
[30] Almashat S, Ayotte B, Edelstein B, Margrett J. Framing effect debiasing in medical decision making. Patient Educ Couns 2008;71:102–7.
[31] Zikmund-Fisher BJ, Fagerlin A, Roberts TR, Derry HA, Ubel PA. Alternate methods of framing information about medication side effects: incremental risk versus total risk of occurrence. J Health Commun 2008;13:107–24.
[32] Zikmund-Fisher BJ, Ubel PA, Smith DM, Derry HA, McClure JB, Stark A, et al. Communicating side effect risks in a tamoxifen prophylaxis decision aid: the debiasing influence of pictographs. Patient Educ Couns 2008;73:209–14.
[33] Hoffrage U, Lindsey S, Hertwig R, Gigerenzer G. Medicine. Communicating statistical information. Science 2000;290:2261–2.
[34] Burkell J. What are the chances? Evaluating risk and benefit information in consumer health materials. J Med Libr Assoc 2004;92:200–8.
[35] Woloshin S, Schwartz LM, Welch HG. Risk charts: putting cancer in context. J Natl Cancer I 2002;94:799–804.
[36] Edwards A, Elwyn G, Mulley A. Explaining risks: turning numerical data into meaningful pictures. Brit Med J 2002;324:827–30.
[37] Slovic P, Fischhoff B, Lichtenstein S. Facts versus fears: understanding perceived risks. In: Kahnemann D, Slovic P, Tversky A, editors. Judgement under uncertainty: heuristics and biases. Cambridge: Cambridge University Press; 1982. p. 463–89.
[38] Towler B, Irwig L, Glasziou P, Kewenter J, Weller D, Silagy C. A systematic review of the effects of screening for colorectal cancer using the faecal occult blood test, hemoccult. Brit Med J 1998;317:559–65.
[39] Schwartz LM, Woloshin S, Welch HG. Risk communication in clinical practice: putting cancer in context. J Natl Cancer I Monogr 1999;124–33.
[40] European Commission. A guideline on the readability of the label and package leaflet of medicinal products for human use, http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-2/c/gl981002.pdf [accessed 21.04.2009].
[41] Berry D, Raynor T, Knapp P, Bersellini E. Over the counter medicines and the need for immediate action: a further evaluation of European Commission recommended wordings for communicating risk. Patient Educ Couns 2004;53:129–34.
[42] Berry DC, Knapp P, Raynor DK. Provision of information about drug side-effects to patients. Lancet 2002;359:853–4.
[43] Zikmund-Fisher BJ, Fagerlin A, Ubel PA. Mortality versus survival graphs: improving temporal consistency in perceptions of treatment effectiveness. Patient Educ Couns 2007;66:100–7.
[44] Ghosh K, Crawford BJ, Pruthi S, Williams CI, Neal L, Sandhu NP, et al. Frequency format diagram and probability chart for breast cancer risk communication: a prospective, randomized trial. BMC Womens Health 2008;8:18.
[45] Hawley St, Zikmund-Fisher B, Ubel P, Jancovic A, Lucas T, Fagerlin A. The impact of the format of graphical presentation on health-related knowledge and treatment choices. Patient Educ Couns 2008;73:448–55.
[46] Muscatello DJ, Searles A, MacDonald R, Jorm L. Communicating population health statistics through graphs: a randomised controlled trial of graph design interventions. BMC Med 2006;4:33.
[47] Gigerenzer G, Edwards A. Simple tools for understanding risks: from innumeracy to insight. Brit Med J 2003;327:741–4.
[48] Lipkus IM, Hollands JG. The visual communication of risk. J Natl Cancer I Monogr 1999;149–63.
[49] Austin PE, Matlack R, Dunn KA, Kesler C, Brown CK. Discharge instructions: do illustrations help our patients understand them? Ann Emerg Med 1995;25:317–20.
[50] Delp C, Jones J. Communicating information to patients: the use of cartoon illustrations to improve comprehension of instructions. Acad Emerg Med 1996;3:264–70.
[51] Mansoor L, Dowse R. Written medicines information for South African HIV/AIDS patients: does it enhance understanding of co-trimoxazole therapy? Health Educ Res 2007;22:37–48.
[52] Brotherstone H, Miles A, Robb KA, Atkin W, Wardle J. The impact of illustrations on public understanding of the aim of cancer screening. Patient Educ Couns 2006;63:328–35.
[53] Knapp P, Raynor DK, Jebar AH, Price SJ. Interpretation of medication pictograms by adults in the UK. Ann Pharmacother 2005;39:1227–33.
[54] Kools M, Van De Wiel MW, Ruiter RA, Kok G. Pictures and text in instructions for medical devices: effects on recall and actual performance. Patient Educ Couns 2006;64:104–11.
[55] Leiner M, Handal G, Williams D. Patient communication: a multidisciplinary approach using animated cartoons. Health Educ Res 2004;19:591–5.
[56] Murphy DA, Hoffman D, Seage GR, Belzer M, Xu J, Durako SJ, et al. Improving comprehension for HIV vaccine trial information among adolescents at risk of HIV. AIDS Care 2007;19:42–51.
[57] Mazor KM, Baril J, Dugan E, Spencer F, Burgwinkle P, Gurwitz JH. Patient education about anticoagulant medication: is narrative evidence or statistical evidence more effective? Patient Educ Couns 2007;69:145–57.
[58] McDonald DD, Goncalves PH, Almario VE, Krajewski AL, Cervera PL, Kaeser DM, et al. Assisting women to learn myocardial infarction symptoms. Public Health Nurs 2006;23:216–23.
[59] Hofstede G. Culture's consequences. Comparing values, behaviors, institutions and organizations across nations. Thousand Oaks, London, New Delhi: Sage; 2001.
[60] Rudd R. How to create and assess print materials, http://www.hsph.harvard.edu/healthliteracy/materials.html [accessed 22.04.2009].
[61] Nagel K, Wizowski L, Duckworth J, Cassano J, Hahn SA, Neal M. Using plain language skills to create an educational brochure about sperm banking for adolescent and young adult males with cancer. J Pediatr Oncol Nurs 2008;25:220–6.
[62] Harvard School of Public Health. Clear and to the Point: guidelines for using plain language at NIH, http://www.hsph.harvard.edu/healthliteracy/how_to/clear.html [accessed 22.04.2009].
[63] National Work Group of Literacy and Health. Communicating with patients who have limited literacy skills. Report of the National Work Group on Literacy and Health. J Fam Practice 1998;46:168–76.
[64] Yates K, Pena A. Comprehension of discharge information for minor head injury: a randomised controlled trial in New Zealand. New Zeal Med J 2006;119:U2101.
[65] Sudore RL, Landefeld CS, Barnes DE, Lindquist K, Williams BA, Brody R, et al. An advance directive redesigned to meet the literacy level of most adults: a randomized trial. Patient Educ Couns 2007;69:165–95.
[66] Braun F, Oelkers S, Rogalski K, Bosak J, Sczesny S. "For reasons of intelligibility ...": how masculine generics and alternative forms affect the cognitive processing of a text. Psychologische Rundschau 2007;58:183–9.
[67] Sansgiry SS, Chanda S, Shringarpure GS. Impact of bilingual product information labels on Spanish-speaking adults' ability to comprehend OTC information. Res Social Adm Pharm 2007;3:410–25.
[68] Kools M, Van De Wiel MW, Ruiter RA, Cruts A, Kok G. The effect of graphic organizers on subjective and objective comprehension of a health education text. Health Educ Behav 2006;33:760–72.
[69] Walker D, Adebajo A, Heslop P, Hill J, Firth J, Bishop P, et al. Patient education in rheumatoid arthritis: the effectiveness of the ARC booklet and the mind map. Rheumatology 2007;46:1593–6.
[70] Nilsen ES, Myrhaug HT, Johansen M, Oliver S, Oxman AD. Methods of consumer involvement in developing healthcare policy and research, clinical practice guidelines and patient information material. Cochrane Database Syst Rev 2006;3:CD004563.
[71] Anderson-Loftin W, Barnett S, Bunn P, Sullivan P, Hussey J, Tavakoli A. Soul food light: culturally competent diabetes education. Diabetes Educator 2005;31:555–63.
[72] Nollen N, Ahluwalia JS, Mayo MS, Richter K, Choi WS, Okuyemi KS, et al. A randomized trial of targeted educational materials for smoking cessation in African Americans using transdermal nicotine. Health Educ Behav 2007;34:911–27.
[73] Hinyard LJ, Kreuter MW. Using narrative communication as a tool for health behavior change: a conceptual, theoretical, and empirical overview. Health Educ Behav 2007;34:777–92.
[74] Fagerlin A, Wang C, Ubel PA. Reducing the influence of anecdotal reasoning on people's health care decisions: is a picture worth a thousand statistics? Med Decis Making 2005;25:398–405.
[75] O'Keefe DJ, Jensen JD. The relative persuasiveness of gain-framed and loss-framed messages for encouraging disease prevention behaviors: a meta-analytic review. J Health Commun 2007;12:623–44.
[76] Craig P, Dieppe P, MacIntyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. Brit Med J 2008;337:a1655.

6.2 Albrecht M, Isenbeck F, Kasper, Mühlhauser I, Steckelberg A (2016): The Foundation in Evidence of Medical and Dental Telephone Consultations. Dtsch Arztebl Int 113(22-23): 389-95.

ORIGINAL ARTICLE

The Foundation in Evidence of Medical and Dental Telephone Consultations

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SUMMARY

Background: Patients can only make well-informed decisions if the information they are given by health professionals is based on scientific evidence. In this study, we assessed the foundation in evidence of free, publicly available telephone consultations in Germany.

Methods: From March 2013 to January 2014, four hidden clients seeking information asked standardized questions about three medical topics (screening for colorectal cancer, for glaucoma, and for trisomy 21) and three dental ones (the sealing of dental fissures, professional dental cleaning, and mercury detoxification). Depending on the topic, the questions addressed such issues as the risk of disease and the purpose, content, validity, benefits, and risks of potential diagnostic and therapeutic measures. All identifiable telephone consultation services that provided counselling on the above topics were included in the study (23 government-sponsored institutions, 31 institutions independently run by physicians, 521 institutions under religious auspices, 25 dental counselling services).

Results: Of the 599 telephone consultation services that were identified, 567 were contacted; 404 did not offer any relevant counselling. A total of 293 conversations were held with the remaining 163 consultation services. Six of these conversations fully met predefined criteria for evidence-based counselling. The percentage of appropriate answers to the key questions on each topic was 5% for colorectal cancer screening (7/140), 23.8% for glaucoma screening (25/105), 33.9% for trisomy 21 screening (121/357), 27.5% for the sealing of dental fissures (28/102), 16.2% for professional dental cleaning (19/117), and 12.9% for mercury detoxification (12/93). The percentage of appropriate answers also varied depending on the type of institution: 26.8% for government-sponsored institutions (67/250), 4.5% for institutions independently run by physicians (4/88), and 31.1% for institutions under religious auspices (82/264).

Conclusion: The medical and dental counselling now offered over the telephone by the types of institutions included in this study does not satisfy the criteria for evidence-based health information.

▶ Cite this as:
Albrecht M, Isenbeck F, Kasper J, Mühlhauser I, Steckelberg A:
The foundation in evidence of medical and dental telephone consultations.
Dtsch Arztebl Int 2016; 113: 389–95. DOI: 10.3238/arztebl.2016.0389

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Patients in Germany want to receive detailed information and be involved in medical decision processes (1, 2). According to the German law on patients' rights they are entitled to evidence-based health information (3).

National and international working groups have defined criteria for evidence-based health information with the aim of enabling informed decision making (4–7). The same standards apply to telephone consultations (5). Information enabling the patient to evaluate the potential benefit and adverse effects of a diagnostic or therapeutic intervention is particularly relevant in this context.

The number of persons contacting the Independent Patient Counselling Service Germany (*Unabhängige Patientenberatung Deutschland*, UPD) is increasing year on year and reached around 80 500 consultations in 2015 (8). The proportion of telephone inquiries was around 80% (8). Telephone calls also represent the majority of inquiries to the Cancer Information Service (*Krebsinformationsdienst*, KID) of the German Cancer Research Center (82% of 32 774 contacts in 2010) (9). Clarimedis, the information service of the large statutory health insurance provider AOK, receives around half a million telephone calls each year (10).

There are many other sources of free counselling on health-related topics in Germany that can be contacted by telephone.

Previous analyses of these services by means of user surveys and the use of "hidden clients" have served primarily to ascertain demand and have focused mainly on the availability of the counsellors, the target groups reached, and the subjective satisfaction of those seeking advice (11–14).

While doctor–patient communication and information materials for patients have been researched in depth, there are only isolated publications investigating to what extent the content and communication of health-related information provided to patients and consumers is founded on evidence (15–17). Studies from the Max Planck Institute for Human Development in Berlin report considerable deficiencies in the advice given personally to patients. In a 1998 study on the quality of information given by Aids consultation services to clients at low risk of infection, half of the 20 advisors who were questioned falsely stated that a

positive test result definitely indicated HIV infection even in the case of low risk (15). A recent study by the same investigators shows that the quality of information has not improved (17). Moreover, physicians' understanding of health statistics is poor (18, 19).

The consumer protection center of the city of Hamburg sent sham patients to a number of medical specialists and reported that deficient information was given in a high proportion of consultations (20–22).

In contrast to these investigations of the personal advice given by physicians, we were unable to identify any studies on the foundation in evidence of telephone consultations.

We therefore set out to evaluate the quality of telephone consultations on selected health topics by means of inquiries by hidden clients. We investigated whether the information they were given fulfilled the criteria for evidence-based health information.

Methods

Study design

The study took the form of a telephone survey in which male and female hidden clients asked standardized questions.

Sample and setting

Our goal was to include as wide a spectrum as possible of the groups offering telephone consultation on medical and dental topics in Germany. To this end, we strove to identify, by means of internet searches, all telephone counselling services available to the general public free of charge *(eBox 1)*.

The following were excluded from the outset:

- Advice hotlines of medical or dental companies and organizations with commercial interests
- Websites where written questions can be submitted to experts
- Services offered by statutory health insurance providers, because these are generally open only to those insured by the respective provider
- Second opinion hotlines on the subject of dental prostheses, because the standardized inquiries in our study all related to preventive measures

The contact details (telephone number, times available) of all eligible consultation services were documented.

The sample for medical topics embraced consultation services (n = 574) offered by the UPD, the KID, the medical associations (MA), the associations of statutory health insurance physicians (ASHIP), and denominational groups (Donum Vitae and the *Diakonie* [the social welfare organization of Germany's Protestant churches]) *(eFigure)*. For dental topics we included consultation services (n = 25) of the federal state dental associations (DA), the associations of statutory health insurance dentists (ASHIP), and the Dental Consumers' and Patients' Advisory Service of the Working Group on Dental Health (*Zahnärztliche Verbraucher- und Patientenberatung der Arbeitsgemeinschaft Zahngesundheit*).

Following initial contact and determination of the principal topics covered by each telephone service, denominational facilities that confined themselves to counselling on pregnancy options or offered only face-to-face consultation were excluded (n = 404) *(eFigure)*.

Topics

Topics were selected for which evidence was available and which were of wide interest or had been the subject of recent media coverage. We aimed to include a wide range of consultation facilities. The chosen topics included both interventions covered by the statutory health insurance providers and services for which the clients would have to pay out of their own pocket.

The medical topics were bowel cancer screening with colonoscopy, glaucoma screening with measurement of internal ocular pressure, and screening for trisomy 21 with amniocentesis. The dental topics were fissure sealing, professional cleaning, and mercury detoxification.

The content of the inquiries varied depending on the topic. For the medical consultations the following aspects were included: risk of illness, test quality, benefit and harm, underlying evidence, and further sources of information. For dental topics, the areas addressed were: aim of intervention, elements and course of intervention, benefits and adverse effects, and further sources of information.

Development of standardized inquiries and survey instruments

Regarding the content of the inquiries, three or four so-called central queries were formulated. The correct answers were determined using the methods of evidence-based medicine (for details see *eBox 2*). Next, standards for counselling were drawn up according to the criteria for evidence-based health information (4). Each standard response contained the required information (23) presented in such a way as to be readily understandable to the lay person (4, 5). For risk of illness and other numerical data, we defined ranges within which the answers should lie *(Table)*. All responses outside these ranges were defined as under- or over-estimates.

Pilot phase and training

In a pilot phase, two of us (M.A. and F.I.) tested the standardized inquiries and documentation forms by making telephone calls to experts (qualified dental assistants n = 5, dentists n = 2, midwives n = 2, ophthalmologist n = 1, primary care physician n = 1, gastroenterologist n = 1) under realistic conditions. The aim was to ensure that the inquiries were expressed in a natural-sounding way and in lay language. In an iterative process, they were revised until information saturation was achieved. Supplementary questions were asked to make the conversation appear authentic, but these were not included in later analysis.

The hidden clients were students of health sciences (age 24–35 years) who were learning to become teachers at vocational schools. A female bachelor's

TABLE 1

Rate of adequate answers and correct content per central query

Central query (abbreviated)	Adequate answer according to consultation standard (abbreviated)	Question asked (n)	Adequate*1 answer (n)	Correct content (n)
Bowel cancer screening (colonoscopy)				
How common is bowel cancer at my age? (woman, 56 years old)	Ten-year risk: <1%	35	3	14
If the examination doesn't show anything, do I definitely not have bowel cancer? How accurate is the examination?	At least one quality criterion is stated: sensitivity: 90–99%; specificity: 95 to <100%; PPV: 8–14%; NPV: 95 to <100%	35	3	3
Is it clear that people benefit from having this done? Does it reduce the number of people who die of bowel cancer?	The benefit cannot be quantified, because no randomized controlled trials have yet been published. This uncertainty is mentioned.	35	1	1
Are there also risks involved with colonoscopy? How often do things like that happen?	Death and at least one further major risk factor (perforation, bleeding) are mentioned and the probability of at least one complication occurring is specified. Bleeding (0.2–0.3%); perforation (0.01–0.1%)	35	0	3*2
Glaucoma screening (tonometry)				
Is glaucoma common at my age? How common? (woman, 42 years old)	Age-specific prevalence (42 years): <1%	35	9	9
Does the examination show that for sure? How accurate is it?	At least one quality criterion is stated: sensitivity: 40–60%; specificity: 89–97%; PPV: 1–15%; NPV: 99–99.9%; false-positive rate: 3–11%	35	3	3
Is it clear that the measurement (internal ocular pressure) helps people at all?	Reference is made to the lack of certainty on this issue (no conclusive studies have yet been published).	35	13	13
Trisomy 21 screening (amniocentesis)				
At my age (34 years), how high is the risk that my baby will have Down syndrome?	The risk of 0.1–0.4% is stated.	119	38	38
Are the results of amniocentesis reliable?	The test accuracy of 99–99.95% is stated.	119	10	54*3
Could amniocentesis lead to me losing my baby?	The intervention-related rate of loss (0.3–1.5%) is stated.	119	73	73
Fissure sealing				
Why is fissure sealing done?	Prevention of tooth decay on the chewing surfaces	34	27	27
And there would never be a cavity in that tooth?	Risk reduction of 40–60% is stated. (Without sealing, the risk of tooth decay on the chewing surfaces of molars within 9 years is 77%.)	34	0	0
How is the sealing done?	Reference is made to the elementary importance of dryness of the area concerned and to the equivalence of absolute and relative dryness.	34	1	1
Professional dental cleaning				
What does professional cleaning consist of?	Training/practice in oral hygiene and/or use of oral hygiene aids are specified as a component of professional dental cleaning.	39	15	15
Is the cleaning a good thing? Would it help me?	Reference is made to the lack of certainty on this issue, or it is pointed out that benefit is achieved only if the patient receives training and takes care of his/her oral hygiene at home.	39	3	3
Are there any reasons not to have the cleaning done? In the long term?	Reference is made to the lack of studies or to suspected adverse effects.	39	1	1
Mercury detoxification				
What is mercury detoxification? What does it aim to achieve?	Increased elimination of mercury from the body or reduction of the mercury concentration in the body	31	11	11
Will the detoxification help me? How well does it work?	Studies have been published only for chelate formers (dimercaptosuccinic acid and dimercaptopropanesulfonic acid), whose efficacy has not been confirmed.]	31	1	1
Are there any adverse effects?	Adverse effects are described in numerical terms (depending on the substance used).	31	0	0

PPV, positive predictive value; NPV, negative predictive value

*1 Content correct according to current state of knowledge and expressed in a way intelligible to the lay person

*2 Correct statement of adverse effects (death, bleeding, or perforation)

*3 Communication of almost 100% accuracy

BOX 1

Example of a central query: prevalence of bowel cancer

Question: Is that important at my age (I'm 56 years old)?
How common is bowel cancer at my age?
(General population, no risk factors. If prompted, specify:
" there's never been anyone in my family with [...]" or similar)

- Numerical data (possibly stating age group: _):
  - X of Y get bowel cancer (_ of 100/1000/10 000/ _)
    (note any time period mentioned _)
  - percentage: _%
  - absolute value: _
  - annual incidence: _
- Verbal description (free text): _

Supplementary question: What do you mean by… (e.g., rare, common)?

student, two female master's students, and a male with a master's degree were trained individually for all inquiries. Their training comprised an introduction to the standardized inquiries, pseudonymization, and documentation of the consultations. The telephone conversations were then practiced in the form of role-play under realistic conditions.

Data acquisition

For the medical topics, we set out to put the three inquiries to at least two counsellors at each local branch of each consultation service. The only exceptions were the KID (bowel cancer screening only) and the denominational organizations (trisomy 21 only).

For the dental topics, our aim was to pose all three inquiries to all (at least two) of the counsellors at every branch of each consultation service. Each part of the survey was ended at the conclusion of the predefined period (dental topics: March to June 2013; medical topics: July 2013 to January 2014).

The hidden client's telephone number was always withheld. The conversation began with the reason for calling. In cases where the caller's age or sex did not match the topic, the explanation was that the inquiry was being made on behalf of someone else, e.g., a female relative. After asking whether the counsellor could give information as a doctor, the hidden client followed up with the central queries (see *Box 1* for an example) and supplementary questions, some of which were predefined. The central queries are reproduced in *eBox 3*. Finally, the hidden client requested information material about the content of the consultation and asked about further sources of information or the addresses of relevant institutions.

During and immediately after the conversation, the hidden client noted on the documentation form the information given. Audio recording was prohibited because it would have contravened the German law on data protection. To avoid duplication, the pseudonymization codes contained information on the organization and on the individual counsellor consulted. Because the consultation services are partly staffed by non-medical personnel who are neither qualified nor authorized to dispense medical advice, e.g., lawyers, it was decided in advance that conversations with such counsellors could be terminated prematurely and not be included in later analysis.

Outcome parameters

The primary outcome parameter was evidence-based counselling. A consultation was considered to be founded on evidence if the information regarding all central queries (three or four per topic) was correct and understandable for lay persons (consultation standards). The secondary outcome parameters were adequate answers to the individual central queries and information on further sources.

Answers to the central queries were coded as adequate if they were both correct (i.e., reflected the current state of knowledge) and intelligible to lay persons. Answers about test quality were coded as correct when one criterion of test quality (sensitivity, specificity, positive predictive value, negative predictive value) was communicated with a correct numerical value. By intelligible to lay persons, we mean expression of numerical data as percentages or X out of Y (e.g., 1 out of every 100 people). An example of coding is given in *eBox 4*.

A consultation was classified as being founded on evidence if all central queries were answered adequately according to the consultation standard.

Analysis

Two of us (M.A. and A.S.) analyzed the documented contents of the consultations separately in a blinded fashion. Codes were assigned according to the defined consultation standards and coding discrepancies were resolved by discussion.

To ensure anonymity of the consultation services, those providing information on medical topics were grouped into publicly funded organizations (UPD, KID), services offered autonomously by physicians (MA, ASHIP), and denominational organizations (Donum Vitae, *Diakonie*). The organizations supplying counselling on dental topics were not divided into subgroups.

For the primary outcome parameter, the results are presented as frequency of evidence-based consultations. For the secondary outcome parameters, the results are expressed as proportions of adequate answers in relation to the individual topics and the provider groups. The statistical software PASW version 22 was used for all calculations.

Ethics and data protection

The study protocol was presented to the data protection authority responsible for all universities and colleges in Hamburg and to the ethics committee of the Hamburg

Medical Association. The data protection officer approved the study. Audio recordings of the consultations were prohibited by the German law on data protection. To protect the anonymity of the individual counsellors, the results of individual consultation services cannot be presented. In order to avoid distortion of the results, the consultation services were not informed of our study in advance.

The ethics committee stated that its approval was not required because the study contained no scientific research on humans.

Results

The survey of medical telephone consultations took place between July 2013 and January 2014. Contact was established with 542 of the 574 identified local branches of the consultation services, and of these 542, 138 were included. Altogether, 189 of 211 documented consultations were analyzed. The remaining 22 conversations were ended prematurely after the counsellors stated they were unable to give medical information.

In the dental survey, from March to June 2013, all 25 identified branches of the consultation services were contacted. Altogether, 104 consultations were included in the analysis. Five consultations were excluded because the counsellors could not provide information on dental topics *(eFigure)*. The qualifications of all counsellors are summarized in *eTable 1*.

Primary outcome parameter

Six of the 189 completed consultations on medical topics and none of the 104 consultations on dental concerns fulfilled the defined standard for foundation in evidence. Five of the six evidence-based consultations were with counsellors from publicly funded organizations on the topics of glaucoma screening (n = 4) and trisomy 21 screening (n = 1). The sixth evidence-based consultation was with a denominational organization on the subject of trisomy 21 screening.

Secondary outcome parameters

The rate of adequate answers to the central queries was 5% (7 of 140) for bowel cancer screening, 23.8% (25 of 105) for glaucoma screening, 33.9% (121 of 357) for trisomy 21 screening, 27.5% (28 of 102) for fissure sealing, 16.2% (19 of 117) for professional dental cleaning, and 12.9% (12 of 93) for mercury detoxification.

The rate of adequate answers to the central queries on medical topics was 26.8% (67 of 250) for publicly funded organizations, 31.1% (82 of 264) for denominational organizations, and 4.5% (4 of 88) for services offered autonomously by physicians.

The *Table* gives an overview of the adequately and correctly answered central queries on all six topics. The incidence of under- or overestimation and the frequency of false or missing responses are shown in *eTable 2*.

The answers to the question "Where does this information come from?" revealed a broad spectrum of sources. These included, among others, personal experience or opinion, the internet, patient information leaflets, specialist media, training courses, and scientific studies/investigations. The numbers of counsellors who provided inaccurate information despite claiming scientific findings were 15 of 31 (professional dental cleaning), 2 of 5 (mercury detoxification), 10 of 23 (bowel cancer screening), 2 of 14 (glaucoma screening) und 5 of 46 (amniocentesis).

Information sources

In 278 of the 293 telephone consultations analyzed, when prompted the counsellor provided details of persons, institutions, or other sources where further information on the topic in question could be obtained (*eTable 3*).

Discussion

The telephone consultations on medical and dental topics provided by the organizations we included in this study do not currently meet the criteria for evidence-based health information. With regard to both content and presentation, the findings of recent research are largely ignored.

Strengths and limitations

For the test inquiries we selected topics for which evaluated evidence-based health information (24, 25) and other sources of syntheses of evidence (26–30) were freely accessible. All counsellors therefore had access to these data or could call the client back to complete the consultation.

The inclusion of a large and representative number of local branches of the telephone consultation services we covered means that our results have high validity for these organizations.

Although a telephone consultation differs from other ways of furnishing information, it is subject to the same criteria for evidence-based risk communication (5).

Health insurance providers could not be included among the organizations covered, because their consultation services are open only to their members. For some of the organizations we were unable to complete the planned number of consultations. Moreover, no valid comparison of individual organizations is possible. On the one hand, the content and scope of the inquiries were not directly comparable; on the other, the impact of the respective organizations' internal arrangements could not be quantified.

The conversations could not be recorded without contravening the German law on data protection. However, the pilot phase showed that our documentation procedure entailed no relevant loss of information. Nevertheless, from the point of view of ethics it needs to be discussed how future investigations of this nature can protect workers' rights but also prevent patients from receiving substandard counselling.

The significance of the results

This study complements and supports the findings of previous research into the quality of personal consultations on Aids and mammography, which has revealed grave

KEY MESSAGES

- The criteria for evidence-based health information apply also in the context of consultation.
- Telephone consultations on medical and dental topics currently fail to meet the criteria for evidence-based health information.
- The information conveyed fails to provide an adequate basis for informed decisions.
- The providers of telephone consultation services must give their counsellors access to the health information and data syntheses they need to do their job.
- There is a lack of proper training courses for counsellors; such courses should be oriented on the recognized standards of evidence-based medicine and observe the defined criteria for health information.

deficiencies (15, 17, 31) despite the existence of defined obligations and clear concepts. For instance, the professional bodies representing dentists in Germany have defined principles to be observed in dental consultations (32). These target both the expertise of the counsellors, who should be in a position to provide a "consultation commensurate with the latest findings in dental science," (first principle) and the intelligibility of the information for the patient (eighth principle).

However, differing findings regarding the UPD were presented in a recently published evaluation report. In each of the four phases of the survey one or two scenarios were employed for the test topic medicine and health. The rates of correct answers in the four phases were 90%, 76%, 59%, and 78% (12). To what extent the queries were geared towards evidence-based information—and thus yielded results comparable with our findings—is unclear.

Implications for practice

The results point to room for improvement in the provision of medical and dental telephone consultations. The counsellors seem not to be taking specific advantage of the evidence-based information and data syntheses that are available and do not always possess the expertise required. The methods of evidence-based medicine, including the compilation and use of health data, must be systematically integrated into the counsellors' training plans.

In Germany, the German Evidence-Based Medicine Network (*Deutsches Netzwerk Evidenzbasierte Medizin*) has recently published a revised and extended version of its "Good Practice Guidelines for Health Information" (5). This document explicitly demands transparency of the procedures for compilation and communication of health information. Providers of telephone consultation services for patients should fulfill these criteria.

Acknowledgments
The authors thank Birgit Müller, Raphaela Wiedemann, Anna Geiling, and Anto Cetina (M. Ed.) for their help with acquisition of data in the context of telephone consultations.

Conflict of interest statement
Mrs Albrecht, Dr. Steckelberg, Prof. Mühlhauser, and Prof. Kasper have, in the course of their work on evidence-based medicine and evidence-based health information, carried out a number of research projects in cooperation with statutory health insurance providers, communal organizations, and public sponsors. The funds provided went to the university. In connection with these studies honoraria were paid and/or travel costs were reimbursed.
In connection with private activity for his institute for communication, Prof. Kasper has received honoraria from public funds for designing training in evidence-based counselling to patients and for scientific services.
Mr. Isenbeck declares that no conflict of interest exists.

Translated from the original German by David Roseveare

Manuscript submitted on 15 July 2015, revised version accepted on 9 February 2016

REFERENCES

1. Hamann J, Neuner B, Kasper J, et al.: Participation preferences of patients with acute and chronic conditions. Health Expect 2007; 10: 358–63.
2. Braun B, Marstedt G: Partizipative Entscheidungsfindung beim Arzt: Anspruch und Wirklichkeit. In: Böcken J, Braun B, Meierjürgen R (eds.): Gesundheitsmonitor 2014. Bürgerorientierung im Gesundheitswesen. Gütersloh: Verlag Bertelsmann Stiftung 2014; 107–31.
3. Gesetz zur Verbesserung der Rechte von Patientinnen und Patienten, vom 20. Februar 2013. In: Bundesgesetzblatt (BGBl.) 2013; 277.
4. Bunge M, Mühlhauser I, Steckelberg A: What constitutes evidence-based patient information? Overview of discussed criteria. Pat Educ Couns 2010; 78: 316–28.
5. Deutsches Netzwerk Evidenzbasierte Medizin e. V., Arbeitsgruppe Gute Praxis Gesundheitsinformation: Gute Praxis Gesundheitsinformation. Z Evid Fortbild Qual Gesundhwes 2016; 110: 85–92.
6. Trevena LJ, Davey HM, Barratt A, Butow P, Caldwell P: A systematic review on communicating with patients about evidence. J Eval Clin Pract 2006; 12: 13–23.
7. International Patient Decision Aids Standards (IPDAS) Collaboration. http://ipdas.ohri.ca/ (last accessed on 28 January 2016).
8. Unabhängige Patientenberatung Deutschland: Monitor Patientenberatung 2015. www.patientenbeauftragter.de/images/pdf/Monitor_Patientenberatung_2015bf.pdf (last accessed on 28 January 2016).
9. Krebsinformationsdienst: Nutzerstatistik 01.01.2010–31.12.2010. www.krebsinformationsdienst.de/aufbewahrung/statistik-2010.pdf (last accessed on 28 January 2016).
10. AOK-Clarimedis: Nutzerzahlen. www.aok.de/niedersachsen/gesundheit/behandlung-aok-clarimedis-frage-der-woche-210871.php (last accessed on 26 January 2016).
11. Niekusch U, Wagner C, Klett M: Unabhängige zahnärztliche Patientenberatung – Erfahrungen aus der Beratungsstelle für den Rhein-Neckar-Kreis. Gesundheitswesen 2006; 68: 18–25.
12. IGES Institut GmbH (ed.)/Deckenbach B, Rellecke J, Stöppler C: Externe Evaluation der neutralen und unabhängigen Verbraucher- und Patientenberatung nach § 65b SGB V. www.gkv-spitzenverband.de/media/dokumente/krankenversicherung_1/praevention__selbsthilfe__beratung/beratung/Evaluation_der_NUVP_Abschlussbericht_IGES_10–2015.pdf (last accessed on 28 January 2016).
13. Dierks ML, Haverkamp A, Hofmann W, Kurtz V, Seidel G: Evaluation der Modellprojekte zur unabhängigen Patienten- und Verbraucherberatung nach §65b SGB V. Hannover: Medizinische Hochschule Hannover 2006.

14. Kurtz V: Qualität telefonischer Patientenberatung zu präventiven Gesundheitsthemen. Ergebnisse einer Hidden Client-Untersuchung (Masterarbeit). München: GRIN-Verlag 2006.
15. Gigerenzer G, Hoffrage U, Ebert A: AIDS counselling for low-risk clients. AIDS Care 1998; 10: 197–211.
16. Bryant AG, Levi EE: Abortion misinformation from crisis pregnancy centers in North Carolina. Contraception 2012; 86: 752–6.
17. Prinz R, Feufel MA, Gigerenzer G, Wegwarth O: What counselors tell low-risk clients about HIV test performance. Curr HIV Res 2015; 13: 369–80.
18. Wegwarth O, Gigerenzer G: Mangelnde Statistikkompetenz bei Ärzten. In: Gigerenzer G, Muir Gray JA (eds.): Bessere Ärzte, bessere Patienten, bessere Medizin: Aufbruch in ein transparentes Gesundheitswesen (Strüngmann Forum Reports). Berlin: Medizinisch Wissenschaftliche Verlagsgesellschaft 2013; 137–51.
19. Wegwarth O, Schwartz LM, Woloshin S, Gaissmaier W, Gigerenzer G: Do physicians understand cancer screening statistics? A national survey of primary care physicians. Ann Int Med 2012; 156: 340–9.
20. Verbraucherzentrale Hamburg: „Sie haben eine sehr schöne Brust. Da kann man alles machen." www.vzhh.de/gesundheit/96503/2010–11–15_Schoenheitsprojekt.pdf (last accessed on 28 January 2016).
21. Verbraucherzentrale Hamburg: Beratung bei Hamburger Orthopäden: Note 3,9. www.vzhh.de/gesundheit/335196/Orthop%C3%A4dentest_vzhh_2014.pdf (last accessed on 28 January 2016).
22. Verbraucherzentrale Hamburg: „Wenn Sie diese Zahnlücke nicht behandeln lassen, fallen Ihnen bald alle Zähne aus!" www.vzhh.de/gesundheit/293166/2013–01–17_-Zahn%C3%A4rztetest.pdf (last accessed on 28 January 2016).
23. General Medical Council: Consent: patients and doctors making decisions together. www.gmc-uk.org/static/documents/content/Consent_-_English_1015.pdf (last accessed on 28 January 2016).
24. Steckelberg A, Hülfenhaus C, Haastert B, Mühlhauser I: Effect of evidence-based risk information on „informed choice" in colorectal cancer screening: a randomised controlled trial. BMJ 2011; 342: d3193.
25. Steckelberg A , Mühlhauser I: Darmkrebs Früherkennung. www.gesundheit.uni-hamburg.de/upload/Barmer_Darmkrebsbroschuere.pdf (last accessed on 8 April 2016).
26. IGeL-Monitor: Professionelle Zahnreinigung. www.igel-monitor.de/IGeL_A_Z.php?action=abstract&id=74 (last accessed on 28 January 2016).
27. IGeL-Monitor: Messung des Augeninnendrucks zur Glaukom-Früherkennung. www.igel-monitor.de/pdf_bewertungen/Messung%20 des%20Augeninnendrucks_Evidenzsynthese.pdf (last accessed on 28 January 2016).
28. Deutsche Gesellschaft für Zahn-, Mund- und Kieferheilkunde: S3-Leitlinie Fissuren- und Grübchenversiegelung. 2010. www.awmf.org/uploads/tx_szleitlinien/083–002l_S3_Fissuren-Gruebchenversiegelung-2010-abgelaufen.pdf (last accessed on 28 January 2016).
29. Bundesinstitut für Qualität im Gesundheitswesen: Professionelle Zahnhygiene. Quick Assessment. www.goeg.at/cxdata/media/download/berichte/Professionelle_Dentalhygiene.pdf (last accessed on 28 January 2016).
30. Alfirevic Z, Mujezinovic F, Sundberg K: Amniocentesis and chorionic villus sampling for prenatal diagnosis. Cochrane Database Syst Rev 2003; 3: CD003252.
31. Wegwarth O, Gigerenzer G: „There is nothing to worry about": Gynecologists' counseling on mammography. Pat Educ Couns 2011; 84: 251–56.
32. Bundeszahnärztekammer/Kassenzahnärztliche Bundesvereinigung: Patienten im Mittelpunkt: Die Patientenberatung der Zahnärzteschaft in Deutschland. www.bzaek.de/fileadmin/PDFs/pati/patientenberatung_zahnaerzte.pdf (last accessed on 28 January 2016).

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Supplementary material
For eReferences please refer to:
www.aerzteblatt-international.de/ref2216

eTables, eBoxes:
www.aerzteblatt-international.de/16m0389

Erratum

In the article "Health and Disease at Age 100: Findings From the Second Heidelberg Centenarian Study" by Daniela S Jopp et al. (Dtsch Arztebl Int 2016; 113: 203–10, issue 12), the paragraph on pain severity on page 208 requires additional information. The sentence should be completed as follows (bold type): "Of those reporting pain **and of whom information on pain severity was available (n=58)**, most said that their pain was "bearable" (57%); four (7%) had mild pain." MWR

Supplementary material to:

The Foundation in Evidence of Medical and Dental Telephone Consultations

by Martina Albrecht, Florian Isenbeck, Jürgen Kasper, Ingrid Mühlhauser, and Anke Steckelberg

Dtsch Arztebl Int 2016; 113: 389–95. DOI: 10.3238/arztebl.2016.0389

eREFERENCES

e1. Scottish Intercollegiate Guidelines Network (SIGN) (2015): Critical appraisal: Notes and checklists. www.sign.ac.uk/methodology/checklists.html (last accessed on 28 January 2016).

e2. Higgins JPT, Altman DG, Sterne JAC: Assessing risk of bias in included studies. In: Higgins JPT, Green S (eds.): Cochrane handbook for systematic reviews of interventions. Version 5.1.0 (updated March 2011). The Cochrane Collaboration 2011; www. cochrane-handbook.org (last accessed on 28 January 2016).

e3. Robert Koch-Institut, Gesellschaft der epidemiologischen Krebsregister in Deutschland e. V.: Beiträge zur Gesundheitsberichterstattung des Bundes: Krebs in Deutschland 2007/2008. 2012. www.rki.de/DE/Content/Gesundheitsmonitoring/Gesundheitsberichterstattung/GBEDownloadsB/KID2012.pdf?__blob=publicationFile (last accessed on 7 July 2015).

e4. Pickhardt PJ, Hassan C, Halligan S, Marmo R: Colorectal cancer: CT colonography and colonoscopy for detection: systematic review and meta-analysis. Radiology 2011; 259: 393–405.

e5. Ludwig Boltzmann Institut: Screening for colorectal cancer, part 1: screening tests and program design. HTA 41a 2012. http://eprints.hta.lbg.ac.at/981/1/HTA-Projektbericht_Nr.41a_Update_2012.pdf (last accessed on 7 July 2015).

e6. Bretthauer M: Colorectal cancer screening. J Intern Med 2011; 270: 87–98.

e7. Crispin A, Birkner B, Munte A: Process quality and incidence of acute complications in a series of more than 230,000 outpatient colonoscopies. Endoscopy 2009; 41: 1018–25.

e8. Warren JL, Klabunde CN, Mariotto AB, et al.: Adverse events after outpatient colonoscopy in the medicare population. Ann Intern Med 2009; 150: 849–57.

e9. Burr JM, Mowatt G, Hernandez R: The clinical effectiveness and cost-effectiveness of screening for open angle glaucoma: a systematic review and economic evaluation. 2007. www.hta.ac.uk/fullmono/mon1141.pdf (last accessed on 22 February 2013).

e10. Ervin AM, Boland MV, Myrowitz EH, et al.: Screening for glaucoma: comparitive effec-tiveness review 59. 2012. /www.effectivehealthcare.ahrq.gov/ehc/products/182/1026/CER59_Glaucoma-Screening_Final-Report_20120524.pdf (last accessed on 22 April 2015).

e11. Fleming C, Whitlock E, Beil T, et al.: Primary care screening for ocular hypertension and primary open-angel glaucoma: evidence syntheses 34. 2005. www.ncbi.nlm.nih.gov/books/NBK42905/ (last accessed on 22 April 2015).

e12. Hatt SR, Wormald R, Burr J: Screening for prevention of optic nerve damage due to chronic open angle glaucoma. Cochrane Database Syst Rev 2006; 4: CD006129.

e13. Moyer V: Screening for glaucoma, U.S. Preventive Services Task Force recommendation statement. Ann Intern Med 2013; 159; 484–9.

e14. Bray I, Wright DE, Davies C, Hook EB: Joint estimation of down syndrome risk and ascertain-ment rates: a meta-analysis of nine published data-sets. Prenat Diagn 1998; 18: 9–20.

e15. Morris JK, Mutton DE, Alberman E: Revised estimates of the maternal age specific live birth prevalence of Down´s syndrome. J Med Screen 2002; 9: 2–6.

e16. Snijders RJM, Holzgreve W, Chuckle H, Nicolaides KH: Maternal age-specific risks for trisomies at 9–14 weeks gestation. Prenat Diagn 1994; 14: 543–52.

e17. Loft A, Tabor A: Discordance between prenatal cytogenetic diagnosis and outcome of pregnancy. Prenat Diagnosis 1984; 4: 51–9.

e18. Tabor A, Philip J, Madsen M: Randomised controlled trial of genetic amniocentesis in 4606 low-risk women. Lancet 1986; 1: 1287–93.

e19. Ahovuo-Saloranta A, Forss H, Walsh T, Hiiri A, et al.: Sealants for preventing dental decay in the permanent teeth. Cochrane Database Syst Rev 2013; 3: CD001830.

e20. Bravo M, Montero J, Bravo JJ, Baca P, Llodra JC: Sealant and fluoride varnish in caries: a randomized trial. J Dent Res 2005; 84: 1138–43.

e21. Albani F, Ballesio I, Campanella V, Marzo V, Marzo G: Pit and fissure sealants: results at five and ten years. Eur J Paediatr Dent 2005; 6: 61–5.

e22. Eidelman E, Fuks AB, Chosack A: The retention of fissure sealants: rubber dam or cotton rolls in a private practice. ASDC J Dent Child 1983; 50: 259–61.

e23. Ganss C, Klimek J, Gleim A: One year clinical evaluation of the retention and quality of two fluoride releasing sealants. Clin Oral Investig 1999; 4: 188–93.

e24. Griffin SO, Oong E, Kohn W, et al.: The effectiveness of sealants in managing caries lesions. J Dent Res 2008; 87: 169–74.

e25. Lygidakis NA, Oulis KI, Christodoulidis A: Evaluation of fissure sealants retention following four different isolation and surface preparation techniques: four years clinical trial. J Clin Pediatr Dent 1994; 19: 23–5.

e26. McConnachie I: The preventive resin restoration: A conservative alternative. J Can Dent Assoc 1992; 58: 197–200.

e27. Straffon LH, Dennison JB, More FG: Three-year evaluation of sealant: effect of isolation on efficacy. J Am Dent Assoc 1985; 110: 714–7.

e28. Wood AJ, Saravia ME, Farrington FH: Cotton roll isolation versus Vac-Ejector isolation. ASDC J Dent Child 1989; 56: 438–41.

e29. Wright GZ, Friedman CS, Plotzke O, Feasby WH: A comparison between autopolymerizing and visible-light-activated sealants. Clin Prev Dent 1988; 10: 14–7.

e30. Worthington HV, Clarkson JE, Bryan G, Beirne PV: Routine scale and polish for periodontal health in adults. Cochrane Database Syst Rev 2013; 11: CD004625.

e31. Needleman I, Suvan J, Moles DR, Pimlott J: A systematic review of professional mechanical plaque removal for prevention of periodontal diseases. J Clin Periodontol 2005; 32 (Suppl 6): 229–82.

e32. Bernhoft RA: Mercury toxicity and treatment: a review of the literature. J Environ Public Health 2012; Article ID 460508; doi: 10.1155/2012/460508.

e33. Adams JB, Baral M, Geis E, et al.: Safety and efficacy of oral DMSA therapy for children with autism spectrum disorders: Part A—medical results. BMC Clin Pharmacol 2009; 9: 16.

e34. Cao Y, Chen A, Jones RL, et al.: Efficacy of succimer chelation of mercury at background exposures in toddlers: a randomized trial. J Pediatr 2011; 158: 480–5.e1.

e35. Grandjean P, Guldager B, Larsen IB, Jørgensen PJ, Holmstrup P: Placebo response in environmental disease. Chelation therapy of patients with symptoms attributed to amalgam fillings. J Occup Environ Med 1997; 39: 707–14.

e36. Sandborgh Englund G, Dahlqvist R, Lindelöf B, et al.: DMSA administration to patients with alleged mercury poisoning from dental amalgams: a placebo-controlled study. J Dent Res 1994; 73: 620–8.

e37. Schuurs A, Exterkate R, ten Cate JM: Biological mercury measurements before and after administration of a chelator (DMPS) and subjective symptoms allegedly due to amalgam. Eur J Oral Sci. 2000; 108: 511–22.

e38. Kaminski MF, Bretthauer M, Zauber AG, et al.: The NordICC Study: rationale and design of a randomized trial on colonoscopy screening for colorectal cancer. Endoscopy 2012; 44: 695–702.

e39. Day LW, Kwon A, Inadomi JM: Adverse events in older patients undergoing colonoscopy: a systematic review and meta-analysis. Gastrointest Endosc 2011; 74: 885–96.

e40. Pox CP, Altenhofen L, Brenner H, Theilmeier A, von Stillfried D, Schmiegel W: Efficacy of a nationwide screening colonoscopy program for colorectal cancer. Gastroenterology 2012; 142: 1460–7.

e41. Schmiegel W, Pox C, Reinacher-Schick A, et al. S3-Leitlinie kolorektales Karzinom 2004/2008. Zeitschrift für Gastroenterologie 2008; 46: 1–73.

e42. Sillars-Hardebol AH, Carvalho B, van Engeland M, Fijneman RJ, Meijer GA: The adenoma hunt in colorectal cancer screening: defining the target. J Pathol 2012; 226: 1–6.

e43. Whitlock EP, Lin J, Liles E, et al.: Screening for colorectal cancer: an updated systematic review, evidence syntheses 65.1. 3, key questions & results. 2008. www.ncbi.nlm.nih.gov/books/NBK35186/ (last accessed on 7 July 2015).

e44. Antony K, Genser D, Fröschl B: Erkenntnisgüte und Kosteneffektivität von Screeningverfahren zur Erfassung von primären Offenwinkel-Glaukomen. DIMDI-HTA 50 2007. http://portal.dimdi.de/de/hta/hta_berichte/hta144_bericht_de.pdf (last accessed on 8 July 2015).

e45. Bahrami H. Causal inference in primary open angle glaucoma: specific discussion on intra-ocular pressure. Ophthalmic Epidemiol 2006; 13: 283–9.

e46. Berufsverband der Augenärzte Deutschlands e. V., Deutsche Ophthalmologische Gesellschaft e.V.: Leitlinie Nr. 15 c: Detektion des primären Offenwinkelglaukoms (POWG): Glaukom-Screening von Risikogruppen, Glaukomverdacht, Glaukomdiagnose. 2006. www.augeninfo.de/leit/leit15c.pdf (last accessed on 28 April 2015).

e47. Burr JM, Botello-Pinzon P, Takwoingi Y: Surveillance for ocular hypertension: an evidence synthesis and economic evaluation. 2012. www.ncbi.nlm.nih.gov/books/NBK100061/pdf/TOC.pdf (last accessed on 22 February 2013).

e48. Claessen H, Genz J, Bertram B: Evidence for a considerable decrease in total and cause-specific incidences of blindness in Germany. Eur Journal Epidemiol 2012; 27: 519–24.

e49. Foster PJ, Buhrmann R, Quigley HA, et al.: The definition and classification of glaucoma in prevalence surveys. Br J Ophthalmol 2002; 86: 238–42.

e50. National Institute for Health and Clinical Excellence: Glaucoma: diagnosis and management of chronic open angle glaucoma and ocular hypertension. 2009. www.nice.org.uk/nicemedia/live/12145/43887/43887.pdf (last accessed on 22 April 2015).

e51. Quigely HA: Glaucoma. Lancet 2011; 377: 1367–77.

e52. Vass C, Hirn C, Sycha T, et al.: Medical interventions for primary open angle glaucoma and ocular hypertension. Cochrane Database Syst Rev 2007; 4: CD003167.

e53. Wolfram C, Pfeiffer N: Glaukomerkrankungen in Rheinland-Pfalz 2010: Epidemiologie und Inanspruchnahme der Versorgung. Ophthalmologe 2012; 109: 271–6.

e54. European Surveillance of Congenital Anomalies: EUROCAT-Prävalenz, -Daten ,-Tabellen: Trisomie-21, Lebendgeburtenrate. 2010. www.eurocat-network.eu/accessprevalencedata/prevalencetables (last accessed on 8 April 2016).

e55. Loane M, Morris JK, Addor MC, et al.: Twenty-year trends in the prevalence of Down syndrome and other trisomies in Europe: impact of maternal age and prenatal screening. Eur J Hum Genet 2013; 21: 27–33.

e56. Los FJ, van Den Berg C, Wildschut HI, et al: The diagnostic performance of cytogenetic investigation in amniotic fluid cells and chorionic villi. Prenat Diagn 2001; 21: 1150–8.

e57. Morris JK, Alberman E: Trends in Down´s syndrome live births and antenatal diagnoses in England and Wales from 1989 to 2008: analysis of data from the National Down Syndrome Cytogenetic Register. BMJ 2009; 339: b3794.

e58. Tabor A, Alfirevic Z: Update on procedure-related risks for prenatal diagnosis techniques. Fetal Diagn Ther 2010; 27: 1–7.

e59. Waters JJ, Waters KS: Trends in cytogenetic prenatal diagnosis in the UK: results from UKNEQAS external audit 1987–1998. Prenat Diagn 1999; 19: 1023–6.

e60. Brothwell DJ, Jutai DK, Hawkins RJ: An update of mechanical oral hygiene practices: evidence-based recommendations for disease prevention. J Can Dent Assoc 1998; 64: 295–306.

eBOX 1

Research strategies for identification of the organizations offering telephone consultation

The potential providers of free and publicly available consultations on dental and medical topics were known to the authors before commencement of the project: publicly funded organizations (the Independent Patient Counselling Service Germany [*Unabhängige Patientenberatung Deutschland*, UPD] and the Cancer Information Service of the German Cancer Research Center [*Krebsinformationsdienst*, KID]), medical/dental associations and associations of statutory health insurance physicians/dentists, denominational organizations, health insurance providers.
The individual branches of the various services and their contact details (telephone number, hours) were identified by means of an internet search.
With regard to the consultation providers, the research strategies were as follows:

- **1. Publicly funded providers**
  - The home page of the UPD (www.patientenberatung.de) was accessed to identify the UPD branches nationwide (listed on www.patientenberatung.de/beratung-vor-ort/).
  - The contact details for the KID were retrieved from the home page (www.krebsinformationsdienst.de).

- **2. Dental associations and associations of statutory health insurance dentists**
  - The home page of the German Dental Association (*Bundeszahnärztekammer*, BZAEK; www.bzaek.de) was accessed.
    On the pull-down menu "Patientenberatungsstellen" (www.bzaek.de/nc/fuer-patienten/patientenberatungsstellen.html) the individual federal states were selected and the branches of the consultation service offered by each state's dental association were identified.
  - Next, the home page of the Association of Statutory Health Insurance Dentists (*Kassenzahnärztlichen Bundesvereinigung*,KZBV) was accessed (www.kzbv.de).
    Via a link on the pull-down menu "Patienten," the list of branches of the consultation service was found (www.kzbv.de/beratungsstellen-fuer-patienten.759.de.html).
  - The branches of the BZAEK und KZBV were compared and merged into one combined list .

- **3. Medical associations and associations of statutory health insurance physicians**
  - The home pages of the German Medical Association (*Bundesärztekammer*, BÄK; www.bundesaerztekammer.de) and the Association of Statutory Health Insurance Physicians (*Kassenärztlichen Bundesvereinigung*, KVB; www.kbv.de) were accessed. However, no reference to or list of nationwide patient consultation services could be identified.
  - Next, therefore, the home pages of the medical associations and associations of statutory health insurance physicians of all federal states were accessed and searched.
  - Finally, a Google search for the term "Patientenberatung" was conducted. Inspection of the first 300 items listed revealed no further hits.

- **4. Denominational organizations**
  - The branches of the consultation service offered by the organization "donum vitae: zur Förderung des Schutzes des menschlichen Lebens" (Donum Vitae) were identified via the home page www.donumvitae.org/beratung_fuer_schwangere_frauen.
  - Via the home page of the social welfare organisation of Germany's Protestant churches (*Diakonie Deutschland*; www.diakonie.de/index.html), all branches offering telephone consultation on the topic of pregnancy were identified (list at: www.diakonie.de/service-navigator.html?action=map&consulting=1&l=0).

- **5. Health insurance providers**
  - The statutory health insurance providers were identified via the home page of the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband).
    The link www.gkv-spitzenverband.de/service/versicherten_service/krankenkassenliste/krankenkassen.jsp leads to an up-to-date listing of all statutory health insurance providers. Direct links to the websites of the individual health insurance funds are provided.
  - As part of the preparation for the survey, one of the authors (FI) contacted by telephone many of the then roughly 140 health insurance funds listed (if possible via an advice hotline). He was asked for either his health insurance number or his name and date of birth.
    He was then given no further information because he was not insured by the respective provider. As witnessed by various home pages, the health insurance funds advertise the fact that their consultation services are available exclusively to members.
  - For this reason, it would have been necessary to either invent fictive insured persons in cooperation with the health insurance providers or to select the hidden clients according to their membership thereof. Therefore, statutory health insurance funds were excluded from the survey.

- **6. Free internet search for other services:**
  - Google searches for the terms "Patientenberatung" ("patient counselling") and "Zahn" ("tooth") were conducted, identifying the consultation service of the Dental Consumers' and Patients' Advisory Service of the Working Group on Dental Health (*Zahnärztliche Verbraucher- und Patientenberatung der Arbeitsgemeinschaft Zahngesundheit*; www.agz-rnk.de).

eBOX 2

Methods used to establish the underlying evidence regarding the inquiries

The methods of evidence-based medicine were used to define the correct answers to the central queries for each of the six selected topics,

First, a search strategy for each individual central query was developed. This facilitated the subsequent surveys of the medical databases Cochrane Library und PubMed. Both MeSH terms and free text were used in these searches, which were restricted to the relevant types of studies. The searches were limited to publications in German or English with no restriction on year of publication.

Furthermore, searches were carried out in databases of guidelines and health technology assessment documents (Association of the Scientific Medical Societies in Germany, National Institute for Health and Care Excellence, Agency for Healthcare Research and Quality, German Agency for Health Technology Assessment, Ludwig Boltzmann Institute–Health Technology Assessment) and in the resources of institutions that publish epidemiological data for Germany (federal government health reports, Robert Koch Institute, Association of Population-based Cancer Registries in Germany).

Each of the searches above was conducted independently by two of three authors (A.S., M.A., F.I.).

For questions regarding test quality we searched for validation studies; for benefit and harm, randomized controlled studies (RCTs) and meta-analyses (of RCTs). If the identified RCTs did not document harm, cohort studies were sought. Prevalence data were obtained or calculated from epidemiological studies or other sources of epidemiological information.

The identified studies were critically evaluated on the basis of established checklists (e1, e2) by two persons independently. Only studies with high-quality methodology were used for synthesis.

All of the sources used are listed in the eReferences. The principal sources for the central queries on each topic were as follows:

- Bowel cancer screening (colonoscopy): prevalence (e3), test quality (e4), benefit (e5, e6; no RCTs yet available), adverse effects (e7, e8)
- Glaucoma screening (tonometry): prevalence (e9), test quality (e9), benefit (e10–e13)
- Trisomy 21 screening (amniocentesis): prevalence (e14–e16), test accuracy (e17), adverse effects (30, e18)
- Fissure sealing: goal (28, e19), benefit (e19, e20), elements/procedure (e21–e29)
- Professional dental cleaning: elements (29), benefit (29, e30, e31), adverse effects (29, e30, e31)
- Mercury detoxification: goal (e32), benefit with DMPS/DMSA (e33–e37), benefit with EDTA and natural substances such as ramsons and coriander (no RCTs yet available), adverse effects (e33, e34, e36).

eBOX 3

Standardized inquiries

- **Bowel cancer screening (with colonoscopy)** (25, e3–e8, e38–e43)
  - Introduction:
    Hello, my name is … . My doctor has recommended me to have a colonoscopy to check for bowel cancer. I'm not sure I really want a colonoscopy and have a few questions...
  - Question 1 on disease risk:
    Is it really important at my age? I'm 56. How common is bowel cancer at that age?
    Supplementary question: What do you mean by… (e.g., rare, common ...)?
  - Question 2 on test quality (colonoscopy):
    If the examination doesn't show anything, do I definitely not have bowel cancer? (How accurate is the examination?)
    Supplementary question: What do you mean by… (e.g., quite safe, almost always reliable ...)?
  - Question 3 on benefit: Is it clear that people benefit from having this done?
    Supplementary question: Is that your opinion, or where are you getting the information from?
  - Question 4 on adverse effects: That can't be very pleasant. Can anything go wrong?
    Supplementary question: How often do things like that happen?
  - Question 5 on information material, further sources:
    That was a lot all at once. Can you recommend me anything to read, so I can think about it in peace and quiet?

- **Glaucoma screening (with measurement of internal ocular pressure)** (e9–e13, e44–e53)
  - Introduction:
    Hello, my name is … . A few days ago I made an appointment with the ophthalmologist. I haven't got any problems with my eyes, but I'm getting to the age where some people need reading glasses. The lady on the telephone said it's important to check your eye pressure. It's to do with glaucoma, which she said a lot of people don't notice. She told me the examination's not covered by health insurance. I'm not sure if I really need it ...
  - Question 1 on disease risk:
    Is glaucoma common at my age? I'm 42.
    Supplementary question: What do you mean by… (e.g., rare, common ...)?
  - Question 2 on test quality :
    And does the examination show that for sure? How accurate is it?
    Supplementary question: Can it happen that there's a false alarm or anything like that?
    Supplementary question: How often does that happen (in my age group)?
  - Question 3 on benefit: Is it clear that people benefit from having this done?
    Supplementary question: Is that your personal opinion, or where are you getting the information from?
  - Question 4 on information material, further sources:
    That was a lot all at once. Can you recommend me anything to read, so I can think about it in peace and quiet?

- **Screening for trisomy 21 (with amniocentesis)** (30, e15–e18, e54–e59)
  - Introduction:
    I'm 14 weeks' pregnant at age 34. It's my first pregnancy, and I'm very anxious because a friend of mine who was 36 was told that she had a risk pregnancy. She decided to have an amniocentesis.
    I'm not sure if I want to do anything like that and I have a few concrete questions …
  - Question 1 on disease risk:
    I've heard that women of my age are at higher risk of having a baby with Down syndrome. How high is the risk for me?
    Supplementary question: What do you mean by… (e.g., rare, low ...)?
  - Question 2 on adverse effects:
    Assuming I have an amniocentesis. I would be worried about something happening to the baby. Could I lose it?
    Supplementary question: What do you mean by… (e.g., rare, low ...)?
  - Question 3 on test accuracy:
    Are the results of amniocentesis reliable?
  - Question 4 on information material, further sources:
    That was a lot all at once. Can you recommend me anything to read, so I can think about it in peace and quiet?

- **Fissure sealing** (28, e19–e29)
  - Introduction:
    Hello, my name is … . I took my 7-year-old daughter to the dentist and he suggested sealing two molars. I 'm calling now because I'd like to hear your opinion (as a dentist).
    (If asked, state that both molars are in the lower jaw.)
  - Question 1 on the goal:
    Why is fissure sealing done?
    Supplementary question: Does that protect the whole tooth?
  - Question 2 on benefit:
    (Sealing protects the tooth) And there would never be a cavity in that tooth?
    Supplementary question: Can you explain that more clearly?, What does … mean? (depending on the answer to question 2, e.g., "there's no guarantee," "it's lower," "there's less decay," "no more decay on the chewing surface")
  - Question 3 on the procedure:
    I didn't have any sealing done, and up to now the dentist has just looked at my daughter's teeth. So how is the sealing done? What happens? (Then I can explain it better to my daughter).
    Supplementary question, if drying is mentioned but the procedure is not described: How is the tooth dried/kept dry?
    Supplementary question, if cotton batting is mentioned: And one person does that alone? It sounds as though more than two hands are needed.
    Supplementary question, if both procedures are mentioned: What's better? Which way is better?
  - Question 4 on information material, further sources:
    Thank you for the information. (That was a lot to take in/I'm not sure I asked all the right questions/got all the details). Is there anything I can read? A brochure or something?

- **Professional dental cleaning** (29, e30, e31, e60)
  - Introduction:
    Hello, my name is … . I had a routine appointment with the dentist last week and he suggested professional cleaning. I said no, but now I'd like to hear your opinion (as a dentist).
  - Question 1 on the procedure:
    What does professional cleaning consist of?
  - Question 2 on benefit:
    Is the cleaning a good thing? Would it help me … I mean, apart from the fact that my teeth would be whiter afterwards?
    Supplementary question: Where do you get that information? What are your sources? Is that your opinion, or how do you know?
  - Question 3 on adverse effects:
    Are there any reasons not to have the cleaning done? In the long term?
    Supplementary question, if only short-term complications are mentioned: (I have to ask again.) Could there be any long-term damage to my teeth or gums?
    Supplementary question, if the counsellor says there are no studies or no findings: Have the long-term consequences (damage/adverse effects) not been studied, or did the studies not find any negative long-term consequences?
  - Question 4 on information material, further sources:
    Thank you for the information. That was a lot to take in. Is there anything I can read? A brochure or something?

- **Mercury detoxification** (e33–e37)
  - Introduction:
    Hello, my name is … . I had a routine appointment with the dentist last week . He told me my old amalgam filling is broken and has to be replaced with a plastic filling. He also advised to have mercury detoxification. As a dentist yourself, can you give me some information about that?
  - Question 1 on the goal:
    What is mercury detoxification? What does it aim to achieve?
  - Question 2 on benefit:
    Will the detoxification help me? How well does it work?
  - Question 3 on adverse effects:
    And are there any negative effects? Or is it well tolerated?
    Supplementary question: Where do you get that information (effect/adverse effect)? What are your sources? Is that your opinion, or how do you know?
  - Question 4 on information material, further sources:
    Thank you for the information. That was a lot to take in. Is there anything I can read? A brochure or something?

eBOX 4

Examples of coding

- **Example 1: Adequate answer**
  - Question: How common is bowel cancer at my age? (woman, 56 years old)
  - Answer: Around 8 out of every 1 000 women are diagnosed with bowel cancer.
  - Coding: correct content + wording readily intelligible = **adequate answer**

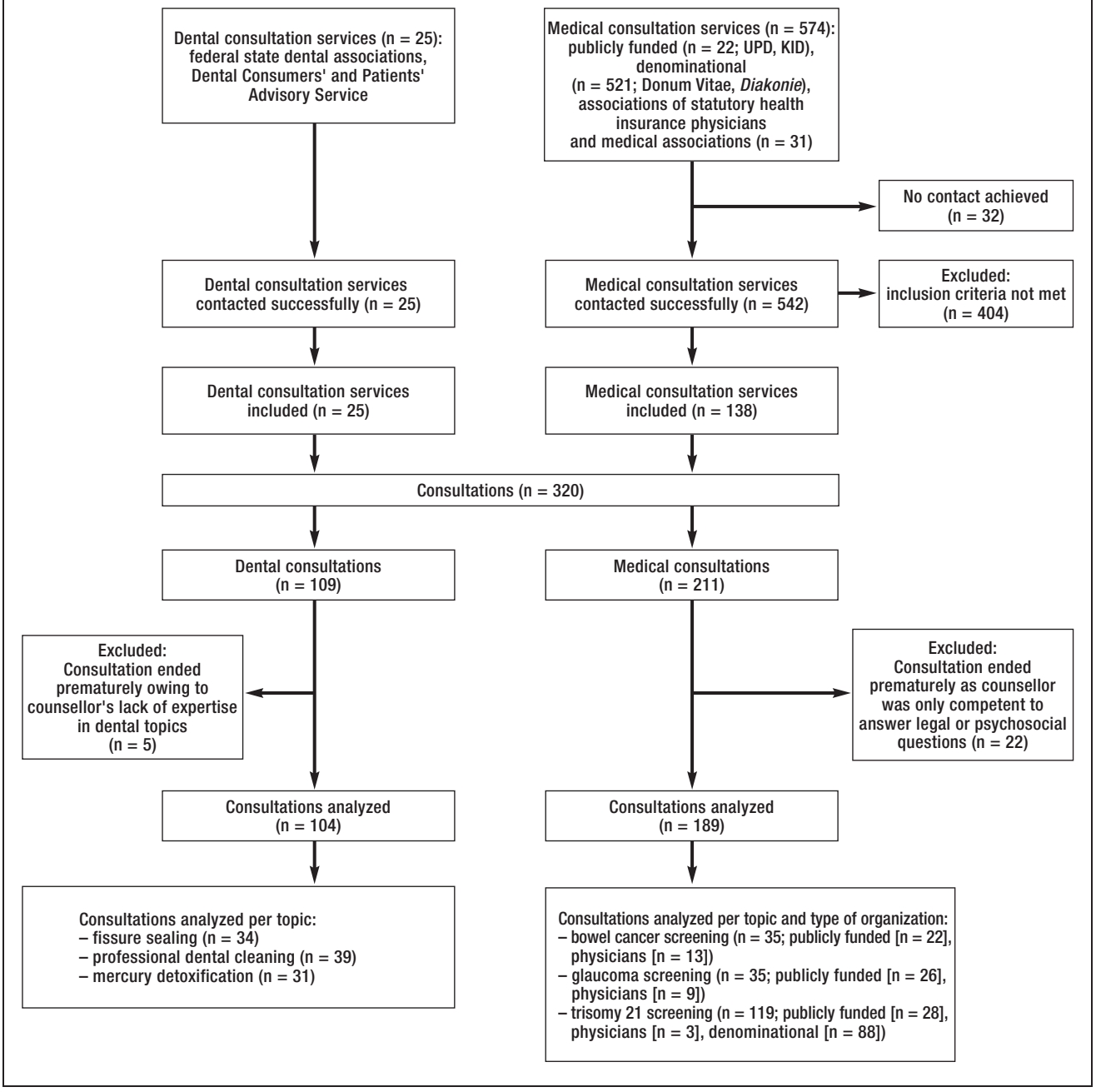
- **Example 2: Adequate answer on further questioning**
  - Question: How common is bowel cancer at my age? (woman, 56 years old)
  - Answer: It's a very rare disease.
  - Supplementary question: What do you mean by very rare?
  - Answer: Around 0.8% of women in your age group are are diagnosed with bowel cancer.
  - Coding: correct content + wording readily intelligible (on further questioning) = **adequate answer**

- **Example 3: Correct answer without readily understandable wording**
  - Question: How common is bowel cancer at my age? (woman, 56 years old)
  - Answer: About 28 000 women get it each year.
  - Coding: correct content + wording not readily intelligible = **correct answer**

- **Example 4: Incorrect answer**
  - Question: How common is bowel cancer at my age? (woman, 56 years old)
  - Answer: It's quite a common disease.
  - Supplementary question: What do you mean by quite common?
  - Answer: Well, that a lot of people get it.
  - Coding: incorrect content + wording not readily intelligible (even on further questioning) = **incorrect answer**

Comment:
Because the existing sources of health information generally communicate the 10-year risk, the counsellors' answers were assessed according to the consultation standard, even if no mention was made of a time period.

eFIGURE 1



Flow chart of consultations

UPD, *Unabhängige Patientenberatung Deutschland* (Independent Patient Counselling Service Germany); KID, *Krebsinformationsdienst* (Cancer Information Service of the German Cancer Research Center)

eTABLE 1

The counsellors' qualifications

Qualification	Dental topics (n = 104)	Medical topics (n = 189)
University education in dentistry, medicine, or health sciences	39	39
University education in non-medical disciplines, e.g., teaching or psychology	0	65
Vocational training, health-related	23	10
Vocational training, other	17	3
Counsellor	0	42
Other	0	2
Not stated	25	28

eTABLE 2

Frequency of under- and overestimation

Central query (abbreviated)	Content correct	Question asked (n)	Correct answers (n)	Incorrect answers			No answer (n)
				Overestimation (n) (values)	Underestimation (n) (values)	Non-numerical answers (n)	
Bowel cancer screening (colonoscopy)							
Prevalence	Ten-year risk: <1% (woman, 56 years old)	35	14	2 (6–15%)	0	10	9
Test quality (colonoscopy)	Sensitivity: 90–99% Specificity: 95–<100%	35	3*[1]	1 (99.9% sensitivity)	0	30	1
				*[1] (100% specificity)			
Risks (colonoscopy)	Bleeding: 0.2–0.3% Perforation: 0.01–0.1%	35	3*[2]	8 (1.3–15% bleeding; 0.2–10% perforation)	*[2] (0.1% bleeding)	22	2
Early detection of glaucoma (tonometry)							
Prevalence	Age-specific prevalence: <1% (woman, 42 years old)	35	9	4 (1–3%)	0	11	11
Test quality (tonometry)	Sensitivity: 40–60% Specificity: 89–97%	35	3	1 (80% sensitivity, 99% specificity)	0	27	4
Trisomy 21 screening (amniocentesis)							
Prevalence	Risk of 0.1–0.4% (pregnant woman, 34 years old)	119	38	14 (0.47–5%)	1 (0.09%)	46	20
Test accuracy (amniocentesis)	Test accuracy: 99–99.95%	119	54	0	0	56	9
Loss rate (amniocentesis)	0.3–1.5%	119	73	8 (1.75–3%)	1 (0.1%)	34	3
Fissure sealing							
Reduction of risk of tooth decay	Risk reduction: 40–60%	34	0	1 (85%)	0	27	6
Professional dental cleaning							
The answers to the three central queries (according to the consultation standard) do not involve numerical values.							
Mercury detoxification							
Adverse effects	Adverse effects (depending on substance used)	31	0	0	0	11	20

*[1] In one consultation the sensitivity was given correctly but the specificity incorrectly (100%).
*[2] In one consultation the risk of perforation was stated correctly but the risk of bleeding was underestimated (0.1%).

eTABLE 3

Stated sources of further information in 278 telephone consultations

Stated sources	Number of times mentioned*1
Medical/dental personnel, institutions, professional associations*2	162
National bodies and publicly financed organizations*2	99
Internet search engines	62
Health insurance providers*2	46
Foundations and groups	14
Online encyclopedias and health portals	10
Information material available from the organization providing the consultation	10
Patient forums	5
Self-help groups	1
Science broadcasts	1
Industry	1
Other	7

*1 Multiple mentions per consultation possible
*2 Including information material (online and/or printed)

6.3 Steckelberg A, Albrecht M, Kezle A, Kasper J, Mühlhauser I (2013): Impact of numerical information on risk knowledge regarding human papillomavirus (HPV) vaccination among schoolgirls: a randomised controlled trial. GMS Ger Med Sci 11: Doc15. DOI: 10.3205/000183.

Impact of numerical information on risk knowledge regarding human papillomavirus (HPV) vaccination among schoolgirls: a randomised controlled trial

Effekt von Zahlenangaben auf das Risikowissen von Schülerinnen zur Humanen Papillomavirus (HPV)-Impfung: eine randomisiert-kontrollierte Studie

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Abstract

Introduction: In Germany the implementation of human papillomavirus (HPV) vaccination for women aged 12–17 years was accompanied by various campaigns. Evidence-based information including numerical data was not provided. However, standard information leads to overestimation of cancer risk and effects of HPV vaccination. Confidence in children's ability to deal with numerical data is low, especially in disadvantaged pupils.
The aim of the present study was to compare the effects of a standard leaflet with an information leaflet supplemented with numerical data on 'risk knowledge' regarding HPV vaccination among schoolgirls.
Methods: Randomised-controlled short-term trial. All 108 schoolgirls of seven school classes were asked to participate and 105 agreed. Participants were vocational schoolgirls who were preparing for grade 10 graduation and who were members of the target group for HPV vaccination. The control group was asked to read a standard leaflet on HPV vaccination of the German Women's Health Network. The intervention group received the same leaflet, but it was supplemented with numerical information on cancer risk and assumed effects of the HPV vaccination on cancer prevention.
As baseline characteristics we surveyed: age, vaccination status, attitude towards HPV vaccination and aspects regarding migration background. The primary end point was 'risk knowledge'. Questionnaire surveys were performed under experimental conditions. Individual randomisation, participants, and intention-to-treat data analyses were blinded. The study was approved by the Ministry of Education and Culture of Schleswig-Holstein and the ethics committee of the Hamburg Chamber of Physicians.
Results: We analysed 'risk knowledge' for all 105 randomised participants. Baseline characteristics of the two groups were comparable. Numerical risk information recipients were more likely to give correct answers compared to standard information recipients: Mean value of risk knowledge score (0–5 points): 4.6±1.0 vs. 2.6±1.2 (mean difference 2.0 (95% CI 1.6–2.4)); ($P<0.001$). Post hoc distractor analysis of single items was performed. Incorrect answers of control participants indicated that cervical cancer risk was highly overestimated whereas total cancer risk was mostly underestimated, and possible impact of HPV vaccination on cancer prevention was overestimated.
Conclusion: Supplementing health information on HPV vaccination with numerical data improves 'risk knowledge' among schoolgirls.

Keywords: consumer health information, human papillomavirus vaccination, risk knowledge, evidence-based medicine

Zusammenfassung

Einführung: In Deutschland wurde die Implementierung der Humanen Papillomavirus (HPV)-Impfung für 12–17-jährige Mädchen von diversen Kampagnen begleitet. Evidenz-basierte Informationen, die Zahlenangaben beinhalten, wurden nicht zur Verfügung gestellt. Stattdessen führten die Standardinformationen zu einer Überschätzung des Krebsrisikos und den Effekten der HPV-Impfung. Das Vertrauen in die Fähigkeit von Kindern mit Risiken umzugehen ist gering, insbesondere wenn es sich um sozial benachteiligte Schüler handelt.
Das Ziel dieser Studie ist ein Vergleich der Effekte eines Standard-Flyers mit einem Informationsflyer, der Zahlenangaben beinhaltet, hinsichtlich des Risikowissens über die HPV-Impfung bei Schülerinnen.
Methoden: Randomisiert-kontrollierte Kurzzeitstudie. Es wurden alle 108 Schülerinnen aus sieben Schulklassen auf die Teilnahme angesprochen und 105 stimmten zu. Die Teilnehmerinnen waren Berufsfachschülerinnen, die den Abschluss der 10. Klasse anstrebten und zur Zielgruppe für eine HPV-Impfung gehörten. Die Kontrollgruppe wurde gebeten, den Standardflyer des Nationalen Netzwerks Frauen und Gesundheit zu lesen. Die Interventionsgruppe erhielt den gleichen Flyer, der jedoch mit numerischen Informationen zum Krebsrisiko und zu den angenommenen Effekten der HPV-Impfung auf die Krebsprävention ergänzt worden war. Als Basischarakteristika wurden Alter, Impfstatus, Einstellung zur HPV-Impfung und Aspekte bezüglich des Migrationshintergrunds erhoben. Der primäre Endpunkt war Risikowissen. Die Fragebogenerhebungen erfolgten unter experimentellen Bedingungen. Die individuelle Randomisierung, die Teilnehmerinnen und die intention-to-treat Datenanalyse waren verblindet. Die Studie wurde vom Ministerium für Bildung und Kultur des Landes Schleswig-Holstein und der Ethikkommission der Hamburger Ärztekammer genehmigt.
Ergebnisse: Risikowissen wurde für alle 105 randomisierten Teilnehmerinnen analysiert. Die Basischarakteristika der beiden Gruppen waren vergleichbar. Die Schülerinnen, die den Flyer mit Zahlenangaben erhielten, gaben häufiger korrekte Antworten im Vergleich zur Kontrollgruppe mit der Standardinformation: Mittelwert des Risikowissens (0–5 Punkte): 4,6±1,0 vs. 2,6±1,2 (Differenz 2,0 (95% CI 1,6–2,4)); (P<0,001). Post hoc wurde eine Distraktorenanalyse der einzelnen Items durchgeführt. Die inkorrekten Antworten der Teilnehmerinnen der Kontrollgruppe zeigten, dass das Zervixkarzinom-Risiko stark überschätzt wurde, das Risiko für Krebserkrankungen im Allgemeinen meist unterschätzt wurde und der mögliche Einfluss der HPV-Impfung auf die Krebsprävention überschätzt wurde.
Schlussfolgerung: Die Ergänzung eines Informationsflyers zur HPV-Impfung mit Zahlenangaben verbesserte das Risikowissen von Schülerinnen.

Schlüsselwörter: Gesundheitsinformationen, Humane Papillomviren-Impfung, Risikowissen, Evidenz-basierte Medizin

Introduction

In Germany HPV vaccination for young women 12–17 years of age started in 2007. The implementation was accompanied by various campaigns. Pharmaceutical industry was strongly involved including presentations in school classes [6]. Neumeyer-Gromen et al. have analysed German media reports and public brochures from 2007–2009 to study whether available information facilitates informed choice in HPV vaccination. They found that only 41% of the identified sources provided numbers on effectiveness and 2% on absolute risk reductions for the cancer surrogate dysplasia. Also, none of the numbers was correct [14].
Adolescents' participation in decision making lacks essential prerequisites for informed choice including availability of evidence-based patient information. This means information that is unbiased, complete and understandable [2]. Incomplete and biased information may lead to wor-

rying misconceptions as reported in a number of recent publications.

About one year after the introduction of the UK vaccination programme, Hilton et al. explored schoolgirls' knowledge and understanding about HPV infection and its link to cervical cancer, beliefs about safer sex, and personal risk in relation to HPV, understandings and concerns about HPV vaccination, vaccination experiences, and understanding of the importance of cervical cancer screening. Participants (n=87) of this focus group study were between 12–18 years old. Typically girls referred to the HPV vaccination as the cancer jab. Results showed that knowledge on HPV was low and partly incorrect [9].

Schmeink et al. interviewed 698 female and male students aged 18–25 years. After implementation of the national HPV vaccination programme in the Netherlands, more than 50% had never heard of HPV [15]. In a web-based survey with 396 female American college students, Dillard et al. explored general knowledge on HPV vaccination. Results showed that HPV related knowledge averaged only 65% overall [5]. In addition, an Australian focus group and interview study found lack of knowledge about HPV vaccination (HPV infection, transmission, cervical cancer connection, HPV vaccine, recommendations) among parents and girls [4].

In preparing the protocol of the present study, few studies were identified which explored children's perception of risk information. In fact, confidence in children's ability to deal with numerical data is low, especially in disadvantaged pupils. Ulph et al. studied children's perception of different presentations of probability information. In principal, children between 7 and 11 years of age can understand probability information. Pie charts were helpful to support understanding of presentations [20].

In 2008, the British General Medical Council explicitly demanded the participation of adolescents in decision making, which requires evidence-based information [7]. In the UK the Gillick guidelines provide a legal framework for professionals who have to judge on adolescents' ability to consent to medical treatment [8]. However, in practice, the interpretation of the guideline varies [21]. Based on an interview study with stakeholders, Wood et al. suggest to allow "Gillick competent" adolescents to consent or to refuse, even if this contradicts their parents' opinion [21].

The target group of HPV vaccination demands and urgently needs numerical information on disease risk [19]. Stöckli et al. analysed three HPV information brochures for adolescents and conducted focus groups with Swiss pupils aged 14–19 years. One of the analysed HPV information was the leaflet of the German Women's Health Network which was used in the control group of the present study [13]. They reported that none of the information provided numerical data on cervical cancer risk. However, the information drew certain pictures on the disease risks. Pupils highly overestimated cervical cancer risk with overall ratings between 24% and 35%, and estimates up to 90%. One information leaflet induced another serious confusion. Participants equalised the cervical cancer risk to the risk of HPV infection, which was stated to be 70%. In fact, lifetime cervical cancer risk is approximately 1%. The authors concluded that those developing information should beware of these communication pitfalls. Their study shows that standard information without numerical data causes harm by evoking misconceptions of disease risks [19]. Communicating numbers could prevent false conclusions [19].

Therefore, the aim of the present study was to compare the effects of an information leaflet including numerical data to standard information without numerical data on 'risk knowledge' regarding HPV vaccination in disadvantaged schoolgirls of full-time vocational schools.

Methods

In 2009, 3 vocational schools, in Schleswig Holstein, Germany, were asked to participate in the project and facilitate access to the target group of HPV vaccination in full-time vocational classes. All schools agreed and facilitated access to eligible classes. Classes were recruited until sample size was reached.

Participants

All 108 schoolgirls of seven classes were asked to participate and 105 gave informed consent. Participants were full-time vocational schoolgirls who were preparing for grade 10 graduation and who were members of the target group for HPV vaccination in Germany (age 15–17).

We randomly assigned the 105 schoolgirls to receive either one of the two information formats on HPV vaccination. Individual randomisation was done for all participants by an external person. Allocation was concealed. ID numbers were either even or odd numbers representing either one study group and leading to an even distribution in each class. Students, trial staff and also the statistician, were unaware of the study arm to which participants had been assigned.

Intervention and comparison

The intervention consisted of the modified standard leaflet of the German Women's Health Network, which is part of the European Women's Health Network and aims to enhance women's health. This standard leaflet comprised one A4 size paper, printed on both sides, and did not include numerical risk information (Attachment 1). For the intervention group the standard leaflet was supplemented with numerical information on cancer risk and on benefit of the HPV vaccination in terms of cervical cancer prevention [13] (Attachment 2). The control group was asked to read the standard leaflet on HPV vaccination. The modified leaflet was pilot tested with members of the target group (n=5) for comprehensibility, readability, and acceptability.

Procedure

In Germany, any studies performed within public schools require approval from the federal state government. In contrast to other federal states, Hamburg always requires informed consent given by parents. According to the German data protection act, the target group is judged to be mature enough to give informed consent regarding the present study. Therefore, in September 2009 we addressed the three vocational schools in Schleswig Holstein that offered full-time vocational classes in the field of health and were situated close to Hamburg. The schools were addressed and information on the project was provided. Seven classes were consecutively included until the sample size was reached.

Schoolgirls who were present at school the day of the study were addressed. Male students were offered the intervention but they were not included.

After a short introduction of the project by one of the authors (AS or MA), envelopes were consecutively distributed. According to IDs, participants were then seated either in the window section or the non-window section of the classroom to avoid contamination among the groups. The time frame comprised 90 minutes. After the schoolgirls exhaustively worked through the flyer, they completed the knowledge questionnaire.

After completion of the study, participants had the chance to ask questions and discuss relevant issues on HPV vaccination.

Outcome measure

The primary outcome measure was 'risk knowledge'. Age, vaccination status, attitude towards HPV vaccination, information accessed for HPV, native language and parents' countries of birth were surveyed as baseline characteristics.

The knowledge questionnaire was based on the 'informed choice' knowledge questionnaire developed by Marteau et al. and adapted to HPV vaccination [11]. It comprised 6 items (Table 1). The first 2 items referred to general knowledge and were assumed to be easy to answer. They were intended to motivate adolescents to work on the questionnaire.

Items were coded according to a predefined coding sheet. Each correct response scored either 0.5 points (2 items on general knowledge) or 1.0 point (4 items on 'risk knowledge') leading to a maximum score of 5 points. Missing responses were counted as wrong answers.

Attitudes were surveyed applying the attitude item of the 'informed choice' instrument by Marteau et al. (scale: 1 (positive) – 4 (negative)) [11].

We had decided not to survey components of the outcome measure at baseline, before distribution of the information leaflets, for methodological reasons. Applying the same questionnaires twice within one session would have biased results.

Hypothesis

We expected risk knowledge to be poor with standard information and that the intervention would improve 'risk knowledge' by 30% of the scale range among schoolgirls.

Statistical analysis

The primary analysis was performed by intention-to-treat. Baseline variables are presented as means and standard deviation (SD) or frequency distributions. Fisher's exact tests for categorical variables and unpaired t-tests for continuous variables were used to explore comparability of the study groups at baseline.

The data columns considering 'risk knowledge' did not contain any missing values because only correct answers were counted as 'risk knowledge'. Knowledge scores were analysed as continuous variables and analysed based on mean-scores (SD). Groups were compared using unpaired t-test.

The software package SPSS 16.0 was used for statistical calculations.

Sample size

Sample size calculation: We assumed that the control group would achieve 10% (0.5 points) of the maximum score. We considered an increase of 30% (1.5 points) in 'risk knowledge' as an important improvement. Aiming for a power of 90% at an alpha error of 5% each study group should therefore include 47 participants.

Results

Baseline characteristics of the two groups were comparable (Table 2). Attitudes towards HPV vaccination showed no significant differences between intervention and control group. Mean values (SD) were 1.7 (0.8) and 1.7 (0.6) respectively, p=0.95 (scale 1 (positive) – 4 (negative)) (Table 1). We analysed 'risk knowledge' for all 105 randomised participants (Figure 1). Numerical information recipients were much more likely to give correct answers compared to standard information recipients: mean value of 'risk knowledge' score (scale 0–5 points): 4.6±1.0 vs. 2.6±1.2; difference 2.0 (95% CI 1.6–2.4; p<0.001) (Table 3).

Post hoc analyses of single items were performed. Incorrect answers of control participants indicated that cervical cancer risk was highly overestimated whereas total cancer risk was mostly underestimated, and possible impact of HPV vaccination on cancer prevention was overestimated. Results of the multiple choice knowledge items are shown in Table 1. 89% of adolescents of the intervention group correctly estimated their lifetime risk to get cervical cancer versus 29% in the control group. Only 12% of the participants in the intervention group overestimated their risk, compared to 50% in the control group. Comparable results are shown for the risk of dying from cervical cancer.

Table 1: Distractor analyses of multiple choice items of the knowledge questionnaire (correct answers in bold). Values are numbers (percentages)* of participants

	Intervention group (n=53)	Control group (n=52)	p-value
Questions regarding general knowledge of HPV:			
1. What is the HPV vaccine supposed to prevent?			p=1.000
Hepatitis	0 (0)	0 (0)	
Human-Papilloma-Virus	**52 (98)**	**52 (100)**	
AIDS	0 (0)	0 (0)	
All sexually transmitted diseases	0 (0)	0 (0)	
2. How can I get infected with HPV?			p=1.000
Drinking from the same glass	0 (0)	0 (0)	
Visiting a swimming pool	0 (0)	0 (0)	
Having sex	**53 (100)**	**52 (100)**	
Sharing a lipstick	0 (0)	0 (0)	
Questions regarding cervical cancer risk without vaccination:			
3. How many out of 1000 women will get cervical cancer in their lifetime?			p<0.001
4	0 (0)	4 (8)	
10	**47 (89)**	**15 (29)**	
140	4 (8)	21 (40)	
800	2 (4)	5 (10)	
4. How many out of 1000 women will die from cervical cancer?			p<0.001
3	**48 (91)**	**21 (40)**	
10	0 (0)	12 (23)	
100	5 (9)	12 (23)	
750	0 (0)	1 (2)	
Questions regarding cervical cancer risk with vaccination:			
5. How many out of 1000 women will die from cervical cancer if they were vaccinated before they first had sex (in consideration of the present screening conditions in Germany)?			p<0.001
0	3 (6)	16 (31)	
1	**47 (89)**	**27 (52)**	
60	2 (4)	4 (8)	
280	0 (0)	0 (0)	
6. How many out of 1000 women will die from other cancer diseases?			p<0.01
80	3 (6)	18 (35)	
230	**48 (91)**	**19 (37)**	
570	1 (2)	9 (17)	
800	1 (2)	1 (2)	

* values may not sum up to 100% due to missing values

Table 2: Baseline characteristics of participants (n=105)

	Intervention group (n=53)	Control group (n=52)	p-value
Age			
Mean (SD) years	16.6 (1.3)	17.0 (1.5)	.158
Range	15–21	15–22	
First language			
German	45	41	.607
Other	6	10	
Parents' countries of birth			
Fathers			.329
Germany	42	33	
Russia	2	5	
Turkey	4	6	
Other	2	7	
Mothers			.401
Germany	36	34	
Russia	2	5	
Turkey	5	6	
Other	8	6	
HPV vaccination status			.020
Completely vaccinated	29	21	
Incompletely vaccinated	7	2	
Not vaccinated	14	17	
Attitude towards HPV vaccination*			
Mean (SD)	1.7 (0.8)	1.7 (0.6)	.947
Information accessed on HPV vaccination before the study			
Yes	39	33	.064

* scale 1 (positive) – 4 (negative)

Table 3: Primary outcome 'risk knowledge' (scale 0–5 points)

	Intervention group (n=53)	Control group (n=52)	Mean difference
Risk Knowledge Mean (SD)	4.6 (1.1)	2.6 (1.2)	2.0 (95% CI 1.6 to 2.4) p<0.001

9% vs. 48% of adolescents overestimated their risk in the intervention and control group, respectively. Finally, 6% (intervention group) vs. 31% (control group) stated that no woman out of 1,000 vaccinated women will die from cervical cancer, which indicates overestimation of HPV vaccination efficacy.

In addition, we surveyed the sources used by adolescents to find health information on HPV vaccination. The sources most frequently accessed were doctors (33 vs. 29), parents (23 vs. 15) and friends (16 vs. 11) for intervention and control group, respectively. Journals (4 vs. 9), television (7 vs. 9), internet (6 vs. 5), and school (8 vs. 5) were less frequently mentioned as a source of information by intervention and control group participants.

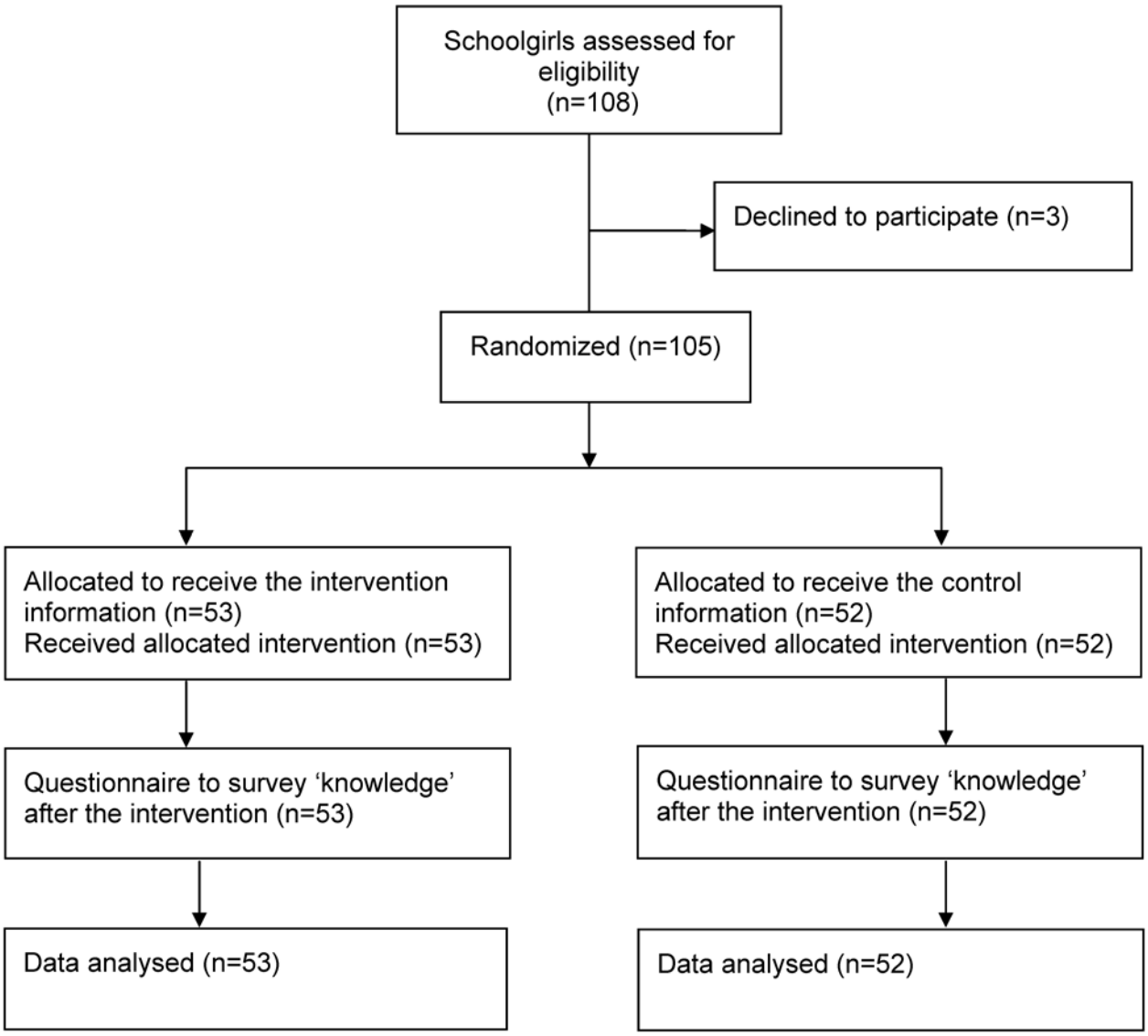

Figure 1: Flow of participants through trial

Discussion

Our study shows that risk knowledge is low and misconceptions about cervical cancer risk and HPV vaccination are high among schoolgirls when using standard patient information. Numerical information on HPV vaccination improved risk knowledge.

Strengths and limitations

Primary analysis was on intention-to-treat and pupils were blinded to group affiliation. The study participants were disadvantaged students who were preparing for their first graduation in vocational full-time schools.

The trial also has limitations. Outcome measures had to be surveyed right after the intervention for data privacy protection reasons. The knowledge test had not been validated. Hence, lack of discrimination of single items might have obscured existing differences. In this study however, we detected a difference in risk knowledge. Furthermore, surveying adverse effects is an important issue. In this study follow up data collection was neither feasible nor intended. However, as demonstrated in the present and previous studies standard information on HPV vaccination rather than risk communication with numerical data appears to evoke adverse effects in adolescents' risk perception [19]. Overestimation of personal cancer risk and unrealistic expectations of medical intervention are clearly undesired outcomes of health information. Finally, the numerical information flyer was not rigorously developed according to defined criteria for evidence-based patient information and was also limited by the leaflet format [2]. Participants of the intervention group reported a slightly higher access to information on HPV. As evidence-based consumer information including numerical data was not available at the time of our study, this imbalance could have hardly influenced the results on risk knowledge.

Meaning of the study results

Our results extend the findings of other trials. Few studies addressed adolescents regarding risk knowledge on HPV vaccination. It is of note, that none of these studies surveyed risk knowledge on cervical cancer risk and effects of HPV vaccination on cancer prevention. In contrast to these recent international studies, schoolgirls in our study showed good knowledge regarding general aspects of HPV in both study groups as the first two items of the questionnaire were correctly answered by all except one participants [4], [5], [9].

Risk knowledge is an important component in decision making, but there are some other aspects of relevance. Connolly et al. emphasized that in case of vaccination decisions accurate and credible information on risks and benefits alone is not enough [3]. Decision makers need help to structure and transfer the relevant information into a well-reasoned decision. The authors suggest internet-based decision aids to face this issue [3]. They discuss a hierarchy of decision aids to offer health information of different levels of complexity in order to meet the individuals' needs, and suggest 3 different levels: simple recommendation; supported recommendation; interactive and assisted personal decision model [3].

On the other hand, Web 2.0 information has been shown to be influenced by anti-vaccination movements. Kata has outlined the rhetorical tactics of these movements [10]. Betsch et al. also discussed opportunities and challenges of Web 2.0 related to vaccination information. They identified users who are particularly vulnerable to finding and using misleading information [1]. This group especially comprises persons with low numeracy and low health literacy [1]. Therefore, improving risk literacy in young people is a prerequisite to informed decision making.

Conclusion

Those designing and implementing vaccination programmes must respect the ethical right to evidence-based information for the target groups including adolescents. Results support the ethical guidelines' demand for evidence-based, reliable and easy to understand information on benefit and harm of medical interventions. Campaigns, using incomplete and misleading presentations of information are delusive and should be abandoned. In the meantime, the HPV flyer used in the intervention group is available on the internet [13]. Finally, as emphasized by various authors, adolescents need health literacy to be prepared for the critical appraisal of health information. Various projects have addressed this important issue [12], [17], [18].

Notes

Data

Data for this article are available from the Dryad Repository: http://dx.doi.org/10.5061/dryad.2pm60 [16]

Competing interests

The authors declare that they have no competing interests.

Funding

University of Hamburg

Ethical approval

The study was approved by the Ministry of Education and Culture, Schleswig Holstein, and by the local ethics committee of the Hamburg Chamber of Physicians (PV3344).

Trial registration

Current Controlled Trials ISRCTN86240771

Attachments

Available from
http://www.egms.de/en/journals/gms/2013-11/000183.shtml

1. 000183_leaflet control group.pdf (706 KB)
   Standard leaflet without numerical risk information
2. 000183_leaflet intervention group.pdf (713 KB)
   Leaflet for the intervention group supplemented with numerical risk information

References

1. Betsch C, Brewer NT, Brocard P, Davies P, Gaissmaier W, Haase N, Leask J, Renkewitz F, Renner B, Reyna VF, Rossmann C, Sachse K, Schachinger A, Siegrist M, Stryk M. Opportunities and challenges of Web 2.0 for vaccination decisions. Vaccine. 2012 May 28;30(25):3727-33. DOI: 10.1016/j.vaccine.2012.02.025
2. Bunge M, Mühlhauser I, Steckelberg A. What constitutes evidence-based patient information? Overview of discussed criteria. Patient Educ Couns. 2010 Mar;78(3):316-28. DOI: 10.1016/j.pec.2009.10.029
3. Connolly T, Reb J. Toward interactive, Internet-based decision aid for vaccination decisions: better information alone is not enough. Vaccine. 2012 May 28;30(25):3813-8. DOI: 10.1016/j.vaccine.2011.12.094
4. Cooper Robbins SC, Bernard D, McCaffery K, Brotherton J, Garland S, Skinner SR. "Is cancer contagious?": Australian adolescent girls and their parents: making the most of limited information about HPV and HPV vaccination. Vaccine. 2010 Apr 26;28(19):3398-408. DOI: 10.1016/j.vaccine.2010.02.078

5. Dillard JP, Spear ME. Knowledge of human papillomavirus and perceived barriers to vaccination in a sample of US female college students. J Am Coll Health. 2011;59(3):186-90. DOI: 10.1080/07448481.2010.493189

6. Dören M, Gerhardus A, Gerlach FM, Hornberg C, Kochen MM, Kolip P, Ludwig WD, Mühlhauser I, Razum O, Rosenbrock R, Schach C, Schmacke N, Windeler J. Wissenschaftler/innen fordern Neubewertung der HPV-Impfung und ein Ende der irreführenden Informationen [Scientists call for a reevaluation of HPV vaccination and an end to the misleading information]. Pharm Unserer Zeit. 2009;38(2):186-7. DOI: 10.1002/pauz.200990010

7. General Medical Council. Consent guidance: patients and doctors making decisions together. 2008. Available from: http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp

8. Gillick (A.P.) v. West Norfolk and Wisbech Area Health Authority and the Department of Health and Social Security (England). Judgment. 1985 3 All ER 402. Available from: http://www.bailii.org/uk/cases/UKHL/1985/7.html

9. Hilton S, Smith E. "I thought cancer was one of those random things. I didn't know cancer could be caught...": adolescent girls' understandings and experiences of the HPV programme in the UK. Vaccine. 2011 Jun 10;29(26):4409-15. DOI: 10.1016/j.vaccine.2011.03.101

10. Kata A. Anti-vaccine activists, Web 2.0, and the postmodern paradigm – an overview of tactics and tropes used online by the anti-vaccination movement. Vaccine. 2012 May 28;30(25):3778-89. DOI: 10.1016/j.vaccine.2011.11.112

11. Marteau TM, Dormandy E, Michie S. A measure of informed choice. Health Expect. 2001 Jun;4(2):99-108. DOI: 10.1046/j.1369-6513.2001.00140.x

12. Miron Shatz T, Mühlhauser I, Bower B, Diefenbach M, Goldacre B, Smith RSW, Spiegelhalter D, Wegwarth Odette. Barriers to health informationand building solutions. In: Gigerenzer G, Gray JAM, eds. Better doctors, better patients, better decisions: envisioning health care 2020. Cambridge, MA: MIT Press; 2011. p. 192-212.

13. Nationales Netzwerk Frauen und Gesundheit. Informationsflyer zum Thema HPV-Impfung. 2011. Available from: http://www.nationales-netzwerk-frauengesundheit.de/downloads/hpv.flyer.pdf

14. Neumeyer-Gromen A, Bodemer N, Müller SM, Gigerenzer G. Ermöglichen Medienberichte und Broschüren informierte Entscheidungen zur Gebärmutterhalskrebsprävention? [Do media reports and public brochures facilitate informed decision making about cervical cancer prevention?]. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz. 2011 Nov;54(11):1197-210. DOI: 10.1007/s00103-011-1347-5

15. Schmeink CE, Gosens KC, Melchers WJ, Massuger LF, Bekkers RL. Young adults awareness of HPV and vaccine acceptance after introduction of the HPV vaccine in the Dutch national vaccination program. Eur J Gynaecol Oncol. 2011;32(5):481-6.

16. Steckelberg A, Albrecht M, Kezle A, Kasper J, Mühlhauser I. Data from: Impact of numerical information on risk knowledge regarding human papillomavirus (HPV) vaccination among schoolgirls: a randomised controlled trial. Dryad Digital Repository. 2013. DOI: 10.5061/dryad.2pm60

17. Steckelberg A, Hülfenhaus C, Kasper J, Mühlhauser I. Ebm@school – a curriculum of critical health literacy for secondary school students: results of a pilot study. Int J Public Health. 2009;54(3):158-65. DOI: 10.1007/s00038-008-7033-1

18. Steckelberg A, Hülfenhaus C, Kasper J, Rost J, Mühlhauser I. How to measure critical health competences: development and validation of the Critical Health Competence Test (CHC Test). Adv Health Sci Educ Theory Pract. 2009 Mar;14(1):11-22. DOI: 10.1007/s10459-007-9083-1

19. Stöckli N, Traub A, Eggler M. Medizinische Aufklärungstexte für Jugendliche [unpublished Bachelor Thesis]. Bachelorthesis 2009/2010 J-Z. Zürcher Hochschule für Angewandte Wissenschaften; 2010.

20. Ulph F, Townsend E, Glazebrook C. How should risk be communicated to children: a cross-sectional study comparing different formats of probability information. BMC Med Inform Decis Mak. 2009 Jun 5;9:26. DOI: 10.1186/1472-6947-9-26

21. Wood F, Morris L, Davies M, Elwyn G. What constitutes consent when parents and daughters have different views about having the HPV vaccine: qualitative interviews with stakeholders. J Med Ethics. 2011 Aug;37(8):466-71. DOI: 10.1136/jme.2010.038562

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Please cite as

Steckelberg A, Albrecht M, Kezle A, Kasper J, Mühlhauser I. Impact of numerical information on risk knowledge regarding human papillomavirus (HPV) vaccination among schoolgirls: a randomised controlled trial. GMS Ger Med Sci. 2013;11:Doc15. DOI: 10.3205/000183, URN: urn:nbn:de:0183-0001830

This article is freely available from

http://www.egms.de/en/journals/gms/2013-11/000183.shtml

Received: *2013-07-09*
Revised: *2013-09-12*
Published: *2013-10-17*

6.4 Lühnen J, Albrecht M, Hanßen K, Hildebrandt J, Steckelberg A (2015): Leitlinie evidenzbasierte Gesundheitsinformation: Einblick in die Methodik der Entwicklung und Implementierung. Z Evid Fortbild Qual Gesundh wesen 109(2): 159-65.

Z. Evid. Fortbild. Qual. Gesundh. wesen (ZEFQ) (2015) 109, 159—165

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SCHWERPUNKT

Leitlinie evidenzbasierte Gesundheitsinformation: Einblick in die Methodik der Entwicklung und Implementierung

Guideline for the Development of Evidence-based Patient Information: insights into the methods and implementation of evidence-based health information

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Eingegangen/submitted 19. November 2014; überarbeitet/revised 25. März 2015; akzeptiert/accepted 30. März 2015

SCHLÜSSELWÖRTER
Evidenzbasierte Gesundheitsinformation;
Leitlinie;
grafische Darstellungen;
Kompetenzen

Zusammenfassung Das Projekt Entwicklung einer Leitlinie zur Erstellung von evidenzbasierten Gesundheitsinformationen stellt ein Novum dar. Es zielt auf eine Verbesserung der Qualität von Gesundheitsinformationen. Der Entwicklungsprozess und die Implementierung orientieren sich an nationalen und internationalen Standards. Insbesondere die Einbeziehung der Ersteller von Gesundheitsinformationen in diesen Prozess hat einen hohen Stellenwert.

Der Artikel gibt am Exempel Grafiken einen Einblick in den Leitlinienentwicklungsprozess. Zudem werden die Ergebnisse einer explorativen Studie zur Ermittlung der Kompetenzen von Erstellern von Gesundheitsinformationen vorgestellt, die handlungsleitend für die Vorbereitung der Leitlinienimplementierung sind.

Zu zwei exemplarischen Fragestellungen nach dem Effekt von Grafiken in Gesundheitsinformationen wurden systematische Literaturrecherchen (bis Juni 2014), eine kritische Bewertung der Literatur und eine deskriptive Datensynthese nach GRADE durchgeführt. Aus 3287 Treffern wurden 11 RCTs in die Analyse eingeschlossen. Die Qualität der Evidenz wurde nach GRADE zwischen niedrig und mittel bewertet. Ergänzende Grafiken können einen positiven Effekt auf kognitive Endpunkte haben. Die Relevanz der Ergebnisse ist allerdings fraglich. Sollen Grafiken verwendet werden, so gibt es Anhaltspunkte, dass insbesondere Piktogramme, aber auch Balkendiagramme einen positiven Effekt auf kognitive Endpunkte haben und den Präferenzen der Nutzer entsprechen.

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http://dx.doi.org/10.1016/j.zefq.2015.03.004
1865-9217/

In der Vorstudie zur Implementierung der Leitlinie wurden mittels Experteninterviews die Kompetenzen der Ersteller von Gesundheitsinformationen exploriert. Es wurden vier leitfadengestützte Telefoninterviews geführt, aufgezeichnet, transkribiert und in Anlehnung an die Grounded Theory analysiert. Es wurden sechs Kategorien gebildet: *Literaturrecherche, Erstellung von Gesundheitsinformationen, Partizipation der Zielgruppe, Fort- und Weiterbildung der Ersteller, Kooperation mit anderen Institutionen, Notwendige Kompetenzen*. Die Kompetenzen zu den Methoden der evidenzbasierten Medizin und evidenzbasierten Gesundheitsinformationen sind sehr unterschiedlich ausgeprägt und weisen auf einen Schulungsbedarf hin. Diese Ergebnisse sind in die Entwicklung des Schulungsprogramms, welches die Implementierung unterstützen soll, eingeflossen.

KEYWORDS
Evidence-based health information; guideline; graphical representation; competencies

Summary The "Guideline for the Development of Evidence-based Patient Information" project is a novelty. The aim of this project is to enhance the quality of health information. The development and implementation process is guided by national and international standards. Involvement of health information developers plays an essential role.

This article provides an insight into the guideline's underlying methodology, using graphics as an example. In addition, the results of a qualitative study exploring the competencies of health information developers are presented. These results will guide the implementation of the guideline.

We conducted systematic literature searches (until June 2014), critical appraisal and descriptive analyses applying GRADE for two selected guideline questions. Out of 3,287 hits 11 RCTs were included in the analysis. The evidence has been rated to be of low to moderate quality. Additional graphics may have a positive effect on cognitive outcomes. However, the relevance of the results is questionable. For graphics, we found some indication that especially pictograms but also bar graphs have a positive effect on cognitive outcomes and meet patients' preferences.

In order to prepare for the implementation of the guideline, we conducted a qualitative study to explore the competencies of health information developers using expert interviews. Four telephone interviews were conducted, audio recorded, transcribed and analysed according to Grounded Theory. Six categories were identified: *literature search, development of health information, participation of target groups, continuing education and further training of health information developers, cooperation with different institutions, essential competencies*. Levels of competencies regarding the methods of evidence-based medicine and evidence-based health information vary considerably and indicate a need for training. These results have informed the development of a training programme that will support the implementation.

Einleitung

Das Projekt Entwicklung einer Leitlinie zur Erstellung von evidenzbasierten Gesundheitsinformationen will einen Beitrag zur Verbesserung der Qualität von Gesundheitsinformationen leisten [1]. Leitlinien sind wesentliche Instrumente zur Förderung von Qualität in der medizinischen Versorgung. Sie beinhalten klare Handlungsempfehlungen und stellen somit Entscheidungshilfen für die Anwender dar [2]. Auch evidenzbasierte Gesundheitsinformationen zielen auf die Verbesserung der Versorgung ab. Die Entwicklung einer Leitlinie zu dem Thema ist ein Novum. Eine systematische Recherche in der medizinischen Datenbank Pubmed konnte keine relevanten Leitlinien zur Erstellung von Gesundheitsinformationen identifizieren. Darüber hinaus konnten auch über Internetrecherchen und gezieltes Aufsuchen von Internetseiten keine entsprechenden Leitlinien ermittelt werden. Allerdings konnten national und international Manuale identifiziert werden, die das Thema adressieren: Die australischen *„General Guidelines for Medical Practitioners on Providing Information to Patients"* [3], der französische Methodenleitfaden *„How to produce an information brochure for patients and users of the healthcare system"* [4] und die *Toolkits* des National Health Services [5] sollen den Entwicklungsprozess unterstützen. Das Deutsche Netzwerk Evidenzbasierte Medizin [DNEbM], Fachbereich Patienteninformation, hat bereits 2010 die *Gute Praxis Gesundheitsinformationen* publiziert, die auf die Notwendigkeit von Standards hinweist [6]. Zudem liegen mit dem *„Manual Patienteninformation"* des Ärztlichen Zentrums für Qualität in der Medizin [7], den Methoden des Instituts für Qualität und Wirtschaftlichkeit im Gesundheitswesen [8] und den Übersichtsarbeiten von Steckelberg et al. [9] und Bunge et al. [10] umfangreiche Vorarbeiten vor.

Die Struktur der Leitlinienentwicklung folgt dem Leitfaden zur Erstellung des Leitlinienreports der Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF) und des Ärztlichen Zentrums für Qualität in der Medizin (ÄZQ) [2]. Für die Bewertung der Evidenz und der Einstufung der Empfehlungen wird das Grading of Recommendations Assessment, Development and Evaluation Verfahren (GRADE) zugrunde gelegt[11]. Da diese Leitlinie keine medizinische Indikation adressiert, werden im

Entwicklungsprozess die Ersteller von Patienteninformationen die bisherige Rolle der klinischen Experten einnehmen. Das Studienprotokoll und erste Ergebnisse sind über die Internetseite Leitlinie-Gesundheitsinformation.de abrufbar [1].

Die vorliegende Arbeit stellt beispielhaft zwei Fragestellungen aus dem Leitlinienentwicklungsprozess zum Thema Grafiken in Gesundheitsinformationen vor. Zudem werden die Ergebnisse einer explorativen Studie zur Ermittlung der Kompetenzen der Ersteller von Gesundheitsinformationen präsentiert und ein Ausblick auf die Implementierung der Leitlinie mit einem Schulungsprogramm gegeben.

Grafiken in Gesundheitsinformationen

Grundlage für eine informierte Entscheidung ist die Kommunikation quantitativer Daten [12]. Die Forschung zeigt, dass sowohl Professionelle als auch Laien Schwierigkeiten mit dem Verständnis von Statistiken und Zahlen haben und so beispielsweise Risiken falsch eingeschätzt werden [13]. Grafiken sollen diese Daten in einer leicht verständlichen Form präsentieren und die realistische Einschätzung von Nutzen und Schaden präventiver, diagnostischer und therapeutischer Maßnahmen verbessern [13,14]. Im Bereich Gesundheitsinformationen werden insbesondere Piktogramme, Balkendiagramme und Tortendiagramme genutzt. Piktogramme können sortiert oder unsortiert gestaltet sein und unterschiedliche Icons nutzen, z.B. Smileys, geometrische Formen oder anthropomorphische Symbole. Häufig werden sie als 100er oder auch 1000er Piktogramme eingesetzt. Balkendiagramme können horizontal oder vertikal ausgerichtet sein. Durch die Auswahl der Skalen kann die Perzeption der Information verzerrt werden. Daher ist besonders auf die Darstellung der Bezugsgröße und eine präzise Beschriftung zu achten. Ein bewusst eingesetztes Framing, welches die Leser irreführt und manipuliert wird für evidenzbasierte Gesundheitsinformationen prinzipiell ausgeschlossen [13]. Sehr gut gestaltete Grafiken, mit vollständiger Legende und angemessener Skalenbeschriftung, können den Aufwand an benötigter Denkleistung reduzieren, weil diese durch die visuelle Wahrnehmung ersetzt wird [14]. Dennoch werden Grafiken nicht immer wie vom Ersteller der Information intendiert interpretiert [14].

In diesem Artikel werden zwei der insgesamt sieben Fragestellungen zum Thema Grafiken aus dem Leitlinienentwicklungsprozess vorgestellt.

1. Welche Effekte haben ergänzende grafische Darstellungen in Gesundheitsinformationen im Vergleich zu alleinigen numerischen Darstellungen im Text oder in Tabellen auf die definierten kognitiven und affektiven Endpunkte?
2. Welche Effekte haben verschiedenen Grafiktypen im Vergleich miteinander (z.B. Balkendiagramm vs. Piktogramm) auf die definierten kognitiven und affektiven Endpunkte?

Methoden

Literaturrecherche

Zu den Fragestellungen wurden bis Juni 2014 systematische Literaturrecherchen in den Datenbanken PubMed, Cochrane Library, PSYNDEX, PsycINFO, CINAHL, Campbell Collaboration und DIMDI durchgeführt. Verknüpft wurden Suchbegriffe zu Gesundheitsinformationen und grafischen Darstellungen (Abb. 1). Limitiert wurde auf randomisiert-kontrollierte Studien (RCTs), systematische Übersichtsarbeiten und Metaanalysen in deutscher und englischer Sprache. Zusätzlich wurden die Referenzlisten relevanter Übersichtsarbeiten gesichtet. Eingeschlossen wurden RCTs, die grafische Darstellungen von gesundheitsbezogenen Risiken und Häufigkeiten gegeneinander oder gegen numerische Darstellungen in Text oder Tabelle hinsichtlich der definierten Endpunkte untersucht haben. Dabei sind die kognitiven Endpunkte Wissen, Risikowahrnehmung und Verstehen entscheidende Parameter, Verständlichkeit und Lesbarkeit sind wichtig, aber nicht entscheidend. Den affektiven Endpunkten Akzeptanz, Attraktivität und Glaub- bzw. Vertrauenswürdigkeit kommt eine geringe Bedeutung zu. Das Screening der Titel, Abstracts und Volltexte erfolgte unabhängig durch zwei Personen (AS, JL). Nichtübereinstimmungen wurden diskursiv gelöst.

Kritische Bewertung und Datensynthesen

Die methodische Qualität der RCTs wurde mit dem *Risk of Bias Instrument* [15] bewertet. Zu allen eingeschlossenen Arbeiten wurden *study fact sheets* erstellt und die Ergebnisse in Evidenztabellen zusammengefasst und bewertet. Die Bewertung der Evidenz erfolgte nach *GRADE* [11]. Die Datensynthese erfolgte deskriptiv. Aus der Qualität der Evidenz, dem Ausmaß der Effekte sowie der Relevanz der Ergebnisparameter leiten sich die Empfehlungen der Leitlinie ab. Es werden Entwürfe formuliert, welche durch die Leitlinienentwicklungsgruppe diskutiert und konsentiert werden.

Ergebnisse

Die initiale Suche bis März 2014 ergab insgesamt 3287 Treffer. Nach den definierten Kriterien wurden 87 Volltexte ausgewählt und nach weiterer Beurteilung 11 RCTs in die Analysen eingeschlossen. Es wurden die Referenzlisten von sechs Übersichtsarbeiten gesichtet und daraufhin 14 Arbeiten im Volltext eingesehen, von denen keine den

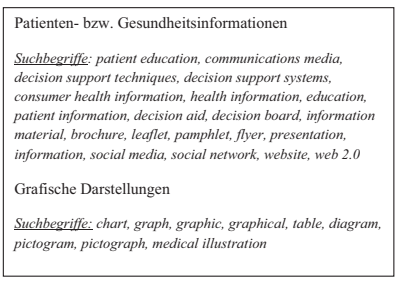

Abbildung 1 Suchbegriffe

Tabelle 1 Vergleich von ergänzenden grafischen Darstellungen mit alleinigen numerischen Darstellungen im Text oder in Tabellen.

Endpunkte	Ergebnisse
Verstehen und Risikowahrnehmung (6 Studien, N = 7831) Brewer, 2012 [21] Hawley, 2008 [24] Ruiz, 2013 [16] Sprague, 2011 [17] Tait, 2010a [18] Tait, 2010b [19]	2 Studien [17,18] zeigen einen Effekt für Grafiken im Vergleich zu Text (65% vs. 39%, p = 0,02; 66,5% vs. 49,1%, p<0,05) und Tabelle (66,5% vs. 44,6%, p < 0,05). 1 Studie [24] zeigt einen Effekt für die tabellarische Darstellung im Vergleich zu verschiedenen Grafiken (67% vs. Grafiken 18-62%, p < 0,001). 3 Studien [16,19,21] zeigen keinen Effekt. *Erhebung anhand von Fragen nach konkreten numerischen Angaben zu Nutzen und Risiken. Berichtet wird jeweils der Anteil der Probanden mit adäquatem Verstehen. Nicht berücksichtigt wurden subjektive Risikoeinschätzungen ohne Bezug zu dem realen Risiko.*
Wissen (7 Studien, N = 8642) Brewer, 2012 [21] Hawley, 2008 [24] Lee, 2003 [22] Tait 2010a [18] Tait, 2010b [19] Tait, 2012 [25] Zikmund-Fischer, 2008 [20]	2 Studien [18,19] zeigen einen Effekt für Grafiken im Vergleich zu Tabelle (66,4% vs. 62,9%, p < 0,05) und Text (66,4% vs. 61,3%, p < 0,05), wobei ein Unterschied [19] fraglich relevant ist (Median 4 vs. 3 richtige Antworten von möglichen 5, p < 0,025). 1 Studie [24] zeigt einen Effekt für Tortendiagramme im Vergleich zur Tabelle und weiteren Grafiken (68% vs. 57-65%, p < 0,05). 4 Studien [20—22,25] zeigen keinen Effekt. *Erhebung anhand von Fragen nach der Einschätzung von Unterschieden und Größenordnungen der dargestellten Werte sowie deren Bedeutung. Wenn nicht anders angegeben, wird jeweils der Anteil der Probanden mit adäquatem Wissen berichtet.*
Verständlichkeit und Lesbarkeit (5 Studien, N = 7403) Brewer, 2012 [21] Hawley, 2008 [24] Tait 2010a [18] Tait, 2010b [19] Tait 2012 [25]	5 Studien [18,19,21,24,25] zeigen keine bzw. keine relevanten Unterschiede. *Erhebung anhand der Selbsteinschätzung der Probanden oder Ermittlung der Fehlerraten und Antwortzeiten.*
Attraktivität und Akzeptanz (1 Studie, N = 200) Tait, 2012 [25]	1 Studie [25] zeigt einen Effekt für Grafiken im Vergleich zu Text (82% vs. 17,5%; p < 0,001). *Erhebung anhand der subjektiven Einschätzung der Probanden. Angegeben ist der Anteil der Probanden, die das jeweilige Format präferieren.*
Glaubwürdigkeit (2 Studien, N = 7097) Hawley, 2008 [24] Tait, 2010a [18]	2 Studien [18,24] zeigen signifikante aber fraglich relevante Effekte. *Erhebung anhand der subjektiven Einschätzung der Probanden.*

Einschlusskriterien entsprach. Updates wurden bis Juni 2014 berücksichtigt, wobei keine weiteren relevanten Treffer erzielt wurden.

Die eingeschlossenen RCTs weisen überwiegend schwerwiegende Risiken für Bias auf. Insgesamt wurde die Qualität der Evidenz zwischen niedrig und mittel bewertet. In fünf der eingeschlossenen RCTs wurde der Effekt von ergänzenden Piktogrammen im Vergleich zur alleinigen numerischen Darstellungen in Text und /oder Tabelle untersucht [16—20]. Eine Studie überprüfte die Verwendung von Balkendiagrammen [21], eine weitere den Nutzen einer vergleichenden Risikodarstellung mit Alltagsrisiken (Paling perspective scale) [22]. In vier Studien [23—26] wurden unterschiedliche Grafiktypen (Piktogramme, Balken- und Tortendiagramme) miteinander verglichen, wobei in zwei auch numerische Angaben einbezogen wurden [24,25]. Die Ergebnisse der Datensynthese werden in Tab. 1 und 2 dargestellt. Zusammenfassend zeigt sich, dass ergänzende grafische Darstellungen in Gesundheitsinformationen im Vergleich zu alleinigen numerischen Darstellungen im Text oder in Tabellen einen positiven Effekt auf Wissen, Verstehen und die Risikoeinschätzung haben können. Die Relevanz der Ergebnisse ist allerdings fraglich. Auch die Vermutung, dass insbesondere Personen mit geringer Rechenfähigkeit von der grafischen Darstellung quantitativer Daten profitieren, lässt sich mit den vorliegenden Daten nicht belegen. In einer Studie ist der Effekt von Piktogrammen auf das Wissen und Verstehen in dieser Personengruppe deutlicher als in der Vergleichsgruppe mit hoher Rechenfähigkeit [18]. Weitere Studien bestätigen dieses Ergebnis allerdings nicht [16,17,19,20,24,25]. Möchte man Grafiken in einer Gesundheitsinformation verwenden, so gibt es Anhaltspunkte, dass insbesondere Piktogramme, aber auch Balkendiagramme einen positiven Effekt auf kognitive Endpunkte haben und auch den Präferenzen der Nutzer entsprechen.

Kompetenzen der Ersteller von Gesundheitsinformationen

Um eine hohe Akzeptanz der Leitlinie zu erreichen, werden die Ersteller von Gesundheitsinformationen in den Erstellungsprozess einbezogen und die Implementierung von

Tabelle 2 Vergleich verschiedener Grafiken miteinander.

Endpunkte	Ergebnisse
Verstehen und Risikowahrnehmung (2 Studien, N = 2562) Ghosh 2008 [26] Hawley, 2008 [24]	1 Studie [24] zeigt einen Effekt für Balkendiagramme (62%) und Piktogramme im Vergleich zu anderen Grafiken (58% vs. 18-49%, p < 0,001). 1 Studie [26] zeigt keinen Effekt. *Erhebung anhand von Fragen nach konkreten numerischen Angaben zu Nutzen und Risiken. Berichtet wird jeweils der Anteil der Probanden mit adäquatem Verstehen. Nicht berücksichtigt wurden subjektive Risikoeinschätzungen ohne Bezug zu dem realen Risiko.*
Wissen (2 Studien, N = 2612) Hawley, 2008 [24] Tait, 2012 [25]	1 Studie [24] zeigt einen Effekt für Tortendiagramme im Vergleich zu anderen Grafiken (68% vs. 57-65%, p < 0,05) und für Piktogramme (65% vs. 57-64%, p < 0,05). 1 Studie [25] zeigt keinen Effekt. *Erhebung anhand von Fragen nach der Einschätzung von Unterschieden und Größenordnungen der dargestellten Werte sowie deren Bedeutung. Berichtet wird jeweils der Anteil der Probanden mit adäquatem Wissen.*
Verständlichkeit und Lesbarkeit (2 Studien, N = 2628) Feldman-Stewart, 2007 [23] Hawley 2008 [24]	In 2 Studien [23,24] zeigt sich eine Tendenz für Piktogramme und Balkendiagramme im Vergleich zu anderen Grafiken (Fehlerrate in Prozent: vertikale Balken 0,87% vs. Tortendiagramme 1,6%, p = 0,0000; Antwortzeit in Sekunden: vertikale Balken 1,42s vs. Tortendiagramme 1,51s, p = 0,0075; unsortierte Häufigkeitspiktogramme vs. Tortendiagramme; p = 0,04) *Erhebung anhand der Selbsteinschätzung der Probanden oder Ermittlung der Fehlerraten und Antwortzeiten.*
Attraktivität und Akzeptanz (2 Studie, N = 350) Ghosh, 2008 [26] Tait, 2012 [25]	In 2 Studien [25,26] zeigt sich eine Tendenz für Piktogramme und Balkendiagramme, ohne dass Effekte durch statistische Tests gezeigt wurden (32% Piktogramme, 31% Balken- und 19,5% Tortendiagramme [25]; Vergleich Balkendiagramme vs. Piktogramme: ca. 50% gleichwertig, ca. 50% Piktogramme [26]). *Erhebung anhand der subjektiven Einschätzung der Probanden. Angegeben ist der Anteil der Probanden, die das jeweilige Format präferieren.*

einem Schulungsangebot für die Leitlinien Nutzer begleitet. Im Folgenden wird dargestellt, welche Kompetenzen die Ersteller von Gesundheitsinformationen mitbringen und wie diese in Vorstudien exploriert wurden.

Es wurden Experteninterviews mit Erstellern von Gesundheitsinformationen durchgeführt. Grundlage des Interviewleitfadens waren die Methoden der evidenzbasierten Medizin [27] und die Kriterien für evidenzbasierte Gesundheitsinformationen [10,28].

Der dem Interviewleitfaden zugrunde gelegte Kompetenzbegriff orientiert sich an den Konzepten der *Kommission der Europäischen Gemeinschaft* sowie an dem Konzept von *Erpenbeck und Rosenstiel* [29]. Die Kommission der Europäischen Gemeinschaft definiert Kompetenzen „als Ausdruck der Fähigkeit des Einzelnen, die verschiedenen Elemente seines Wissens und seiner Fertigkeiten selbstgesteuert, implizit oder explizit und in einem bestimmten Kontext zu bündeln“ [30]. Im Zuge dessen kommt der Selbststeuerung eine elementare Bedeutung zu. Das Maß der Selbststeuerung entscheidet darüber, inwieweit Personen dazu befähigt sind, unbekannte komplexe Situationen oder Problemstellungen durch selbstorganisiertes Handeln zu bewältigen [30]. Beide Konzepte beinhalten die vier Kompetenzklassen personale, aktivitäts- und umsetzungsorientierte, fachlich-methodische sowie sozial-kommunikative Kompetenzen.

Methoden

Für die systematische Auswahl der Interviewpartner wurde die Strategie des „Theoretical sampling“ von Glaser und Strauss herangezogen [31]. Es wurde eine heterogene Stichprobe bewusst und kriterienorientiert rekrutiert, um die für die zu untersuchende Fragestellung relevanten Fälle einzubeziehen und das Risiko einer verzerrten Stichprobe zu minimieren [31]. Eingeschlossen wurden Personen, die Gesundheitsinformationen erstellen oder die an der Erstellung beteiligt sind. Die Interviewpartner wurden aus den Bereichen öffentliche Institutionen, Krankenkassen, Selbsthilfegruppen, Verbraucherzentralen, Patienteninitiativen und kommerzielle Anbieter ausgewählt. Pharmafirmen wurden nicht berücksichtigt. Im Verlauf der ersten Interviews wurden die theoretischen Kategorien entwickelt. Die Telefon Interviews wurden audio aufgezeichnet und transkribiert. Anschließend erfolgte die Analyse unter Verwendung von MAXQDA. Dabei wurde berücksichtigt, dass nach der Grounded Theory die Kategorien auf der Grundlage des empirischen Datenmaterials induktiv gebildet wurden [32]. Zudem fanden deduktiv abgeleitete Kategorien Berücksichtigung.

Ergebnisse

Es wurden 4 Interviews durchgeführt. Insgesamt wurden 6 Kategorien mit bis zu 5 Subkategorien identifiziert:

Kategorie: Literaturrecherche (5 Subkategorien)

Suchstrategie: Die Herangehensweise der Ersteller bei der Suche nach geeigneter Literatur reicht von einem unsystematischen „*jede Mitarbeiterin [. . .] hat da ‚ne eigene Herangehensweise*“ bis zu einem sehr systematischen Vorgehen unter Einbeziehung des PIKE-Schemas.

Datenbanken: Das Spektrum der Quellen, die die Ersteller heranziehen, reicht von der Nutzung der Suchmaschine

Google, der Recherche in der Enzyklopädie Wikipedia, Interviews mit Experten, der Sichtung von Publikationen anderer Institutionen bis zur Recherche in medizinischen Datenbanken.

Studientypen: Auch diese Subkategorie zeigt eine große Vielfalt. Sie reicht von Meta-Analysen über qualitative Studientypen bis hin zur Nutzung von Abstracts wissenschaftlicher Publikationen.

Auswahl der Literatur: Bei der Auswahl der Literatur wurde sowohl der Aspekt des unabhängigen Abstract Screenings durch zwei Personen als auch die Auswahl anhand patientenrelevanter Endpunkte angesprochen.

Bewertung der Literatur: In dieser Subkategorie reicht das Spektrum von einer erfahrungsbasierten Beurteilung bis hin zur Verwendung etablierter Bewertungsinstrumente.

Kategorie: Erstellung von Gesundheitsinformationen (3 Subkategorien)

Probleme bei der Erstellung des Entwurfs: Es konnten folgende Problemfelder identifiziert werden: Es besteht ein Konflikt zwischen der Erwartung der Nutzer nach Informationen und dem Anspruch der evidenzbasierten Informationen, die eine informierte Entscheidung befördern möchte. Zudem stellt die Kommunikation von Fachtermini eine Herausforderung dar. Eine Übersetzung in laienverständliche Sprache, ohne Präzision einzubüßen, ist schwierig. Auch die Kommunikation von Unsicherheiten ist anspruchsvoll und wird oft nicht verstanden. Nicht zuletzt stellt der Umfang der Gesundheitsinformationen ein Problem dar.

Ziele der EBPI: Die Zielsetzungen decken das Spektrum von dem Ziel, die Patienten in einer leicht verständlichen Sprache zu informieren, sie bestenfalls zu befähigen, „*auf Augenhöhe mit ihrem Arzt [. . .] kommunizieren zu können* " bis zu Entscheidungen unter Einbeziehung persönlicher Präferenzen. Zudem sollen sie emotional unterstützt werden.

Wissenschaftlicher Diskurs: Auch hier reicht das Spektrum von keinem Austausch, über die Diskussion in den Arbeitsgruppen bis hin zur Einbeziehung externer Experten in den Erstellungsprozess.

Kategorie: Partizipation der Zielgruppe (3 Subkategorien)

Befragung der Zielgruppe: Es werden mehrere Möglichkeiten der Einbeziehung angesprochen wie Telefonbefragungen, Einzel- als auch Gruppeninterviews. Dabei wurde auch auf die Limitierungen dieser Methoden verwiesen: es wird Klientel einbezogen *„was sowieso Informationen sucht und vielleicht nicht ganz repräsentativ ist für Patienten in Deutschland*".

Literaturrecherche der Patientenbedürfnisse: Literaturrecherchen zur Identifikation von Studien, die die Patientenbedürfnisse untersuchen, werden nur von einzelnen durchgeführt.

Evaluation der EBPI: In dieser Subkategorie reicht das Spektrum von keiner Evaluation *„ich hab keine Evaluation, die irgendwas Wissenschaftliches trägt*" bis hin zu Nutzertestungen.

Kategorie: Fort- und Weiterbildung der Ersteller

Einzelne Interview Partner nutzen das Fortbildungsangebot von Fachorganisationen. Eine bedeutsame Rolle spielt auch der Austausch mit anderen Erstellern.

Kategorie: Kooperation mit anderen Institutionen

Die Interviewpartner gaben eine Vielzahl von nationalen und internationalen Kooperationen wie Krankenkassen, Universitäten, Stiftung Warentest etc. an.

Kategorie: Notwendige Voraussetzungen und Kompetenzen

Es wurden eine Vielzahl von Voraussetzungen und Kompetenzen genannt: Zeit, technisches Equipment, finanzielle Mittel, eine zielgruppengerechte Schreibkompetenz, Kenntnisse zu Layout und Grafik, sozialwissenschaftliche Kenntnisse, Fachwissen und die Unabhängigkeit der Ersteller: „*Gerade in der Pharmaindustrie oder im Gesundheitswesen spielen so viele Interessen eine Rolle*". Einmal wird auch explizit der Bedarf an Methodentrainings geäußert.

Zusammenfassend kann festgehalten werden, dass die Kompetenzen zu den Methoden der evidenzbasierten Medizin und evidenzbasierten Gesundheitsinformation sehr unterschiedlich ausgeprägt sind und insgesamt auf einen Schulungsbedarf hinweisen.

Implikationen /Ausblick

Leitlinien können dann wirksam werden, wenn ihre Empfehlungen im Alltag Anwendung finden und umgesetzt werden. Erst dann kann entschieden werden, welchen Nutzen sie für ihre Anwender, wie z. B. Patienten oder Ärzte haben und welche Rolle sie insgesamt für das Gesundheitswesen aufzeigen. Die Implementierung der Leitlinien sollte daher aktiv durch den Einsatz verschiedener Strategien wie zum Beispiel Schulungsmaterialien und -programme, Audit und Feedback oder Reminder erfolgen. [33—35].

Für das aktuelle Leitlinienprojekt ist ein Schulungsprogramm für die Implementierung vorgesehen. Für die Erarbeitung wurde das Perspektivenschema der kritisch-konstruktiven Didaktik von Wolfgang Klafki zugrunde gelegt [36]. Die Ergebnisse der Experteninterviews sind dabei in die Bedingungsfeldanalyse eingeflossen, die eine Erhebung der personellen (Lehr- und Lernvoraussetzungen) sowie der curricularen und institutionellen Bedingungen vorsieht. Insbesondere haben die Interviews zur Aufnahme des EbM Trainingsmoduls geführt. Dieses Modul umfasst 5 Teilmodule (Kohortenstudien und randomisiert-kontrollierte Studien, Fragestellung und Literaturrecherche, systematische Übersichtsarbeiten, Diagnostische Tests und evidenzbasierte Gesundheitsinformation), die an 4 Tagen unterrichtet werden.Das zweite Modul, welches die Nutzung der Leitlinie beinhaltet wird in Kürze bereitgestellt. Das Modul 1 wurde bereits pilotiert und wird nach Revision erneut zusammen mit dem Modul 2 überprüft werden. Anschließend ist die Evaluation der Leitlinie in einer randomisiert-kontrollierten Studie geplant.

Interessenkonflikt

JL, MA und AS haben in den letzten Jahren finanzielle Förderungen von Krankenkassen für Auftragsforschungen erhalten. Darüber hinaus und für JH und KH liegen keine Interessenkonflikte vor.

Literatur

[1] Leitlinie Gesundheitsinformation 2014 [cited 30.09.2014]; Available from: www.leitlinie-gesundheitsinformation.de

[2] Die Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF). Regelwerk für die Erstellung von

Leitlinien. 2001 [cited 10.10.2014]; Available from: http://www.awmf.org/leitlinien/awmf-regelwerk.html
[3] Australian Government National Health and Medical Research Council. General Guidelines for Medical Practitioners on Providing Information to Patients. 2004 [cited 30.09.2014]; Available from: http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e57.pdf
[4] Haute Autorité de santé. How to produce an information brochure for patients and users of the healthcare system. 2008 [cited 30.09.2014]; Available from: http://www.has-sante.fr/portail/upload/docs/application/pdf/2009-10/how_to_produce_an_information_brochure_-_methodology_guide.pdf
[5] National Health Service Brand Guidelines. Patient information introduction. 2010 [cited 15.10.2014]; Available from: http://www.nhsidentity.nhs.uk/tools-and-resources/patient-information/presentation%2c-print-and-production-general-guidance
[6] Klemperer D, Lang B, Koch K, Bastian H, Brunsmann F, Burkhardt M, et al. Gute Praxis Gesundheitsinformation. Z Evid Fortbild Qual Gesundheitswes 2010;104:66—8.
[7] Sänger S, Lang B, Klemperer D, Thomeczek C, Dierks M-L. Manual Gesundheitsinformation Empfehlungen zur Erstellung evidenzbasierter Patienteninformationen. ÄZQ Schriftenreihe Band 25; [cited 15.10.2014]; Available from: http://www.aezq.de/mdb/edocs/pdf/schriftenreihe/schriftenreihe25.pdf
[8] Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG). Allgemeine Methoden. 2014 [cited 15.10.2014]; Available from: https://www.iqwig.de/de/methoden/methodenpapiere/allgemeine-methoden.3020.html
[9] Steckelberg A, Berger B, Kopke S, Heesen C, Muhlhauser I. Kriterien fur evidenzbasierte Patienteninformationen. Z Arztl Fortbild Qualitatssich 2005;99(6):343—51. Epub 2005/08/27.
[10] Bunge M, Muhlhauser I, Steckelberg A. What constitutes evidence-based patient information? Overview of discussed criteria. Patient Educ Couns 2010;78(3):316—28.
[11] The Grading of Recommendations Assessment Development and Evaluation (GRADE) Working Group. Guidelines - best practices using the GRADE framework. 2014 [cited 15.10.2014]; Available from: http://www.gradeworkinggroup.org/publications/JCE_series.htm
[12] Akl EA, Oxman AD, Herrin J, Vist GE, Terrenato I, Sperati F, et al. Using alternative statistical formats for presenting risks and risk reductions. The Cochrane database of systematic reviews 2011;(3):CD006776. Epub 2011/03/18.
[13] Gigerenzer G, Edwards A. Simple tools for understanding risks: from innumeracy to insight. BMJ 2003;327(7417):741—4. Epub 2003/09/27.
[14] Ancker JS, Senathirajah Y, Kukafka R, Starren JB. Design features of graphs in health risk communication: a systematic review. JAMIA 2006;13(6):608—18. Epub 2006/08/25.
[15] Higgins J, Altman D, Sterne J. Assessing risk of bias in included studies. Cochrane Handbook for Systematic Reviews of Interventions. Version 5.1.02011. Available from: www.cochrane-handbook.org
[16] Ruiz JG, Andrade AD, Garcia-Retamero R, Anam R, Rodriguez R, Sharit J. Communicating global cardiovascular risk: Are icon arrays better than numerical estimates in improving understanding, recall and perception of risk? Patient Educ Couns 2013;93(3):394—402.
[17] Sprague D, LaVallie DL, Wolf FM, Jacobsen C, Sayson K, Buchwald D. Influence of graphic format on comprehension of risk information among American Indians. Med Decis Making 2011;31(3):437—43.
[18] Tait AR, Voepel-Lewis T, Zikmund-Fisher BJ, Fagerlin A. The effect of format on parents' understanding of the risks and benefits of clinical research: a comparison between text, tables, and graphics. J Health Commun 2010;5:487—501.
[19] Tait AR, Voepel-Lewis T, Zikmund-Fisher BJ, Fagerlin A. Presenting research risks and benefits to parents: does format matter? Anesth Analg 2010;3:718—23.
[20] Zikmund-Fisher BJ, Ubel PA, Smith DM, Derry HA, McClure JB, Stark A, et al. Communicating side effect risks in a tamoxifen prophylaxis decision aid: the debiasing influence of pictographs. Patient Educ Couns 2008;73(2):209—14. Epub 2008/07/08.
[21] Brewer NT, Gilkey MB, Lillie SE, Hesse BW, Sheridan SL. Tables or bar graphs? Presenting test results in electronic medical records. Med Decis Making 2012;32(4):545—53.
[22] Lee DH, Mehta MD. Evaluation of a visual risk communication tool: effects on knowledge and perception of blood transfusion risk. Transfusion 2003;43(6):779—87. Epub 2003/05/22.
[23] Feldman-Stewart D, Brundage MD, Zotov V. Further insight into the perception of quantitative information: judgments of gist in treatment decisions. Med Decis Making 2007;27(1):34—43. Epub 2007/01/24.
[24] Hawley ST, Zikmund-Fisher B, Ubel P, Jancovic A, Lucas T, Fagerlin A. The impact of the format of graphical presentation on health-related knowledge and treatment choices. Patient Educ Couns 2008;73(3):448—55. Epub 2008/08/30.
[25] Tait AR, Voepel-Lewis T, Brennan-Martinez C, McGonegal M, Levine R. Using animated computer-generated text and graphics to depict the risks and benefits of medical treatment. Am J Med 2012;125(11):1103—10. Epub 2012/09/04.
[26] Ghosh K, Crawford BJ, Pruthi S, Williams CI, Neal L, Sandhu NP, et al. Frequency format diagram and probability chart for breast cancer risk communication: a prospective, randomized trial. BMC women's health 2008;8:18. Epub 2008/10/22.
[27] Sackett DL, Straus SE, Richardson WS, Rosenberg W, Haynes RB. Evidence-based Medicine: How to Practice and Teach EBM. Edinburgh:. Churchill Livingstone; 2000.
[28] Trevena LJ, Davey HM, Barratt A, Butow P, Caldwell P. A systematic review on communicating with patients about evidence. J Eval Clin Pract 2006;12(1):13—23. Epub 2006/01/21.
[29] Erpenbeck J, Rosenstiel Lv. Handbuch Kompetenzmessung. Erkennen, verstehen und bewerten von Kompetenzen in der betrieblichen, pädagogischen und psychologischen Praxis. Stuttgart: Schäffer-Poeschel Verlag; 2007.
[30] Europäische Komission Bildung und Kultur. Der europäische Qualifikationsrahmen für lebenslanges Lernen. 2008 [cited 30.09.2014]; Available from: https://ec.europa.eu/ploteus/sites/eac-eqf/files/brochexp_de.pdf. in press.
[31] Kelle U, Kluge S. Vom Einzelfall zum Typus. Fallvergleich und Fallkontrastierung in der qualitativen Sozialforschung. Wiesbaden: VS Verlag für Sozialwissenschaften, Springer Fachmedien; 2010.
[32] Glaser G, Strauss A. Grounded Theory. Strategien qualitativer Forschung. Bern: Hans Huber Hogrefe AG; 2005.
[33] Grimshaw JM, Thomas RE, MacLennan G, Fraser C, Ramsay CR, Vale L, et al. Effectiveness and efficiency of guideline dissemination and implementation strategies. Health Technol Assess 2004;8(6):1—72, iii—iv. Epub 2004/02/13.
[34] Scottish Intercollegiate Guidelines Network. A guideline developer's handbook 2014 [cited 15.10.2014]; Available from: http://www.sign.ac.uk/pdf/sign50.pdf
[35] Guidelines International Network (GIN). Implementation Tools and Guidance. 2014 [cited 30.10.2014]; Available from: http://www.g-i-n.net/working-groups/implementation/implementation-resources-tools
[36] Klafki W. Neue Studien zur Bildungstheorie und Didaktik. Zeitgemäße Allgemeinbildung und kritisch-konstruktive Didaktik. Beltz Verlag: Weinheim und Basel; 1993.

6.5 Steckelberg A, Mühlhauser I, Albrecht M (2013): Wollen wir wissen, was wir tun? Evidenzbasierung edukativer Interventionen. Z Evid Fortbild Qual Gesundh wesen 107(1): 13-8.

Z. Evid. Fortbild. Qual. Gesundh. wesen (ZEFQ) (2013) **107**, 13—18

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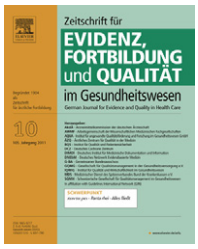

SCHWERPUNKT

Wollen wir wissen, was wir tun? Evidenzbasierung edukativer Interventionen☆

Do we want to know what we are doing? The evidence-basedness of educational interventions

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SCHLÜSSELWÖRTER
Evidenz-basierte Edukation;
medizinische Aus-, Fort- und Weiterbildung;
Forschungsdesign;
Methoden

Zusammenfassung

Hintergrund: Die edukative Praxis ist geprägt von Moden, Mythen und Traditionen. Studien, die die Wirksamkeit edukativer Interventionen untersuchen, sind rar.

Ziel: Wir haben untersucht, welche edukativen Interventionen im Bereich der Aus-, Fort- und Weiterbildung in den letzten 3 Jahren in randomisiert-kontrollierten Studien (RCT) evaluiert wurden.

Methoden: Es wurden systematische Literaturrecherchen in den Datenbanken PubMed, Psyndex, Psychinfo und Education Research Information Center (ERIC) durchgeführt. Die Recherchen wurden auf den Zeitraum 01.2009-02.2012, die Sprachen Deutsch und Englisch und das Studiendesign RCT limitiert.

Eingeschlossen wurden Studien mit Zielgruppen: Kinder, Schüler, Studenten und Berufstätige; Settings: Krippen, Kindergärten, Vorschulen, Schulen, Universitäten und Fachhochschulen und Settings der beruflichen Aus- und Weiterbildung; Interventionen: edukative Interventionen in vorschulischen Institutionen, Schulen, Universitäten, Fachhochschulen und Einrichtungen der beruflichen Aus- und Weiterbildung sowie Präventionsmaßnahmen in den Settings Schule und vorschulische Einrichtungen. Studien zu Patientenschulungen wurden ausgeschlossen. Die Datenerhebung erfolgte anhand eines Datenextraktionsbogens. Für die Interventionen wurden prädefinierte Kategorien verwendet; für die anderen Bereiche wurden nach der Datenextraktion in einem zweiten Schritt Kategorien gebildet. Erhoben wurden die folgenden Merkmale: Zielgruppe, Setting, Art der Intervention, Land, Institutionen, die Studien durchgeführt haben, und Förderung. Als Kriterium der Qualitätsbewertung wurde dokumentiert, ob eine Abschätzung der Stichprobe berichtet wurde. Für die Kategorien wurden Häufigkeiten berechnet.

Ergebnisse: Es wurden 259 RCT eingeschlossen, die in insgesamt 36 Ländern durchgeführt wurden. Etwa die Hälfte der edukativen Studien (n=154) wurde im Bereich der Medizin initiiert. Die Mehrzahl der 95 Studien, die Vorschüler und Schüler adressierten, untersuchten

☆ Dieser Beitrag wurde anlässlich der 13. Jahrestagung des Deutschen Netzwerks Evidenzbasierte Medizin, 2012 in Hamburg vorgestellt.

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1865-9217/$ - see front matter
http://dx.doi.org/10.1016/j.zefq.2012.12.004

Präventionsprogramme (n=75). Nur 16 der 259 Studien wurden in Deutschland durchgeführt. Stichprobenberechnungen wurden in 85 Studien berichtet.
Fazit: Zu edukativen Interventionen gibt es aktuell kaum RCT. Insbesondere in Deutschland fehlen solche Untersuchungen. Die Qualität der Studien scheint fraglich.
Es besteht ein dringender Bedarf an RCT zu edukativen Interventionen.

KEYWORDS
Evidence-based education;
medical education;
experimental research;
research design;
methods

Summary
Background: Educational practice is characterised by fashion, myths und traditions. Studies examining the efficacy of educational interventions are rare.
Objective: We studied which educational interventions in the field of education and training have been evaluated in randomised controlled trials (RCTs) during the past three years.
Methods: Systematic searches were conducted in PubMed, Psyndex, Psychinfo, and Education Research Information Center (ERIC). The database searches were limited to the RCT study design and trials published in German or English language for the period from January 2009 to February 2012. Studies with the following target groups were included: children, pupils, students, and employed persons; settings: pre-school institutions, schools, universities and universities of applied sciences, and settings of vocational or occupational education and training; interventions: educational interventions in pre-school institutions, schools, universities, universities of applied sciences and institutions of vocational or occupational education and training, as well as prevention programmes in schools and pre-school institutions. We excluded studies on patient education. The data collection was carried out using a data extraction sheet. Only predefined categories were used for the interventions. Further categories were developed in a second step. The following data were surveyed: target group, setting, type of intervention, country, institutions conducting the studies, and funding. Sample size calculations were documented to survey the quality of studies. Frequencies were calculated for the categories.
Results: 259 RCTs carried out in 36 countries were included. About half of the educational studies (n = 154) were initiated in the medical field. The majority of the 95 studies, which addressed pre-schoolers and pupils, studied prevention programmes (n = 75). Only 16 out of 259 studies were conducted in Germany. Sample size calculations were reported in 85 studies.
Conclusion: As yet only very few RCTs of educational interventions have been conducted. In particular, this kind of study is lacking in Germany. The quality of the studies seems questionable. There is an urgent need for RCTs on educational interventions.

Hintergrund

Die edukative Praxis ist geprägt von Moden, Mythen und Traditionen. Erkenntnisse der Wissenschaft fließen zu wenig in die Praxis ein und zudem sind Studien, die die Wirksamkeit edukativer Interventionen untersuchen, rar [1,2].

Kürzlich berichtete die Süddeutsche Zeitung über den immer häufigeren Einsatz zweifelhafter esoterischer Methoden wie Duftöl und Gehirngymnastik in den Schulen [3]. Viele dieser „Brain Gym“ Ansätze werben damit, dass Sie auf neurowissenschaftlichen Erkenntnissen basieren. Studien, die die Wirksamkeit dieser Ansätze überprüft haben, konnten für kein Verfahren einen Nutzen für die Schüler zeigen [1].

Auch auf Systemebene werden Entscheidungen wider vorhandene Evidenz getroffen. In Bremen wurde 2005 ein Präventionsprogramm initiiert, welches die Straftaten gefährdeter Jugendlicher reduzieren sollte. Die unmittelbare Konfrontation mit Inhaftierten war Teil dieses Programms [4]. Gleichwohl lag zu dem Zeitpunkt bereits ein Cochrane Review vor, welches zeigte, dass diese Programme keinen Nutzen haben, sondern im Gegenteil Hinweise auf Schaden berichtet wurden [5].

Der Goldstandard für den Wirksamkeitsnachweis von Interventionen ist die randomisiert-kontrollierte Studie. In der Medizin hat die Einführung der Evidenz-basierten Medizin sowohl die Forschung als auch die Praxis revolutioniert und stellt auch Jahrzehnte später noch eine Herausforderung dar [6]. Diese wissenschaftliche Revolution zu Beginn des 20. Jahrhunderts hat den Forschungsbereich der Edukation umgangen [7]. Obwohl in der Edukation randomisiert-kontrollierte Studien bereits zu Beginn des 20. Jahrhunderts durchgeführt wurden und erst später in die Medizin übertragen wurden [8], wird dieses Design bisher kaum durchgeführt [9]. Der Mangel an Forschungsförderung für Wirksamkeitsnachweise trägt zusätzlich dazu bei, dass kaum Evidenz generiert wird. Es liegen überwiegend Vorher-Nachher Studien vor, die kostengünstiger sind, statt Untersuchungen mit Kontrollgruppendesigns [9].

In den USA wurde 2001 begonnen, einen Schwerpunkt der Forschungsförderung auf experimentelle Studien im Bildungsbereich zu legen. So werden Anträge mit experimentellen Studien im Auswahlverfahren höher bewertet [10,11]. Damit wird auch bei den Antragstellern der methodologische Diskurs befördert. In Deutschland werden experimentelle Studien vom Bundesministerium für Bildung und Forschung, unter anderem mit der Begründung der Länderhoheit im Bildungsbereich nicht gefördert.

In der folgenden Arbeit soll systematisch erhoben werden, welche edukativen Interventionen im Bereich der Aus-, Fort- und Weiterbildung in den letzten 3 Jahren in randomisiert-kontrollierten Studien evaluiert wurden.

Tabelle 1 Häufigkeit edukativer Interventionen nach Institutionen.

	Anzahl der Studien (n=259)	
	Deutschland (n=16)	Länder ohne Deutschland (n=243)
Universität - Medizin	12	142
Universität - Psychologie	0	12
Universität - Edukation	0	12
Universität - Pharmazie	0	3
Universität - Grafik und Design	0	1
Universität interdisziplinär (mit Medizin)	1	29
Universität interdisziplinär (ohne Medizin)	0	13
Universität (mit Medizin) und außeruniversitäre Forschungseinrichtungen	1	16
Universität (ohne Medizin) und außeruniversitäre Forschungseinrichtungen	0	12
Außeruniversitäre Forschungseinrichtungen	2	1
Nicht spezifiziert	0	2

Methoden

Systematische Literaturrecherchen

Es wurden systematische Literaturrecherchen in den Datenbanken PubMed, Psyndex, Psychinfo und Education Research Information Center (ERIC) durchgeführt. Die Recherchen mit den Suchbegriffen *education, teach** und *instruct** wurden auf den Zeitraum 01.2009-02.2012, die Sprachen deutsch und englisch und das Studiendesign *randomised-controlled trial* limitiert. Zwei Autorinnen (AS und MA) führten die Recherchen durch. Es wurden die Titel und Abstracts gescreent. Es wurden sowohl Artikel in Fachzeitschriften als auch die in Erziehungswissenschaften üblicheren Buchbeiträge eingeschlossen. Nicht-Übereinstimmungen wurden diskutiert bis zum Erreichen eines Konsenses.

Ein- und Ausschlusskriterien

Zielgruppen: Eingeschlossen wurden Kinder, Schüler, Studenten und Berufstätige.

Settings: Krippen, Kindergärten, Vorschulen, Schulen, Universitäten und Fachhochschulen und Settings der beruflichen Aus- und Weiterbildung.

Interventionen: Edukative Interventionen in vorschulischen Institutionen, Schulen, Universitäten, Fachhochschulen und Einrichtungen der beruflichen Aus- und Weiterbildung. In den vorschulischen Institutionen und Schulen wurden zudem Präventionsmaßnahmen eingeschlossen. Ausgeschlossen wurden Patientenschulungen.

Datenerhebung, Datenextraktion und Analysen

Die Datenerhebung erfolgte anhand eines Datenextraktionsbogens. Für die Interventionen wurden prädefinierte Kategorien verwendet. Für die anderen Bereiche wurden nach der Datenextraktion in einem zweiten Schritt Kategorien gebildet. Erhoben wurden die folgenden Merkmale:

- Zielgruppen: Vorschüler, Schüler, Studenten (mit Angabe der Fachdisziplin), Berufsgruppen (mit Angabe des Berufsfeldes)
- Interventionen: Methodenvergleiche, fachbezogene Interventionen und Präventionsprogramme
- Land, in dem die Studie durchgeführt wurde
- Studiendurchführende Institutionen (Universitäten Angabe der Fachdisziplin)
- Finanzierung: keine Angaben, keine Förderung, öffentliche Förderung, Stiftungen/Fachgesellschaften, (Pharma-) Industrie, Kombination (nur öffentlich), Kombination (öffentlich und Industrie)
- Stichprobenberechnung (vorhanden, nicht vorhanden, in Vorpublikationen veröffentlicht, post hoc Stichprobenberechnungen, keine Stichprobenberechnungen (Pilotstudien, Follow-up)

Für die Kategorien wurden Häufigkeiten berechnet. Die Analysen erfolgten mit PASW Statistics 18.

Ergebnisse

Die Datenbankrecherchen ergaben 8839 Treffer. Eingeschlossen wurden 259 randomisiert-kontrollierte Studien (Literatur beim Verfasser).

Die 259 Studien wurden in den folgenden Ländern durchgeführt: USA (n=104), Deutschland (n=16), UK (n=26), Australien (n=12), Kanada (n=13), Niederlande (n=8), Taiwan (n=8), Schweden (n=8), Spanien (n=6), Belgien (n=6), Iran (n=5), Finnland (n=4), Norwegen (n=4), China (n=4), mehrere Länder (n=4), Japan (n=3), Schweiz (n=3), Italien (n=3), Indien (n=2), Südafrika (n=2), Brasilien (n=2), Türkei (n=2), Neuseeland (n=1), Nigeria (n=1), Dänemark (n=1), Saudi Arabien (n=1), Korea (n=1), Singapur (n=1), Mexico (n=1), Trinidad & Tobago (n=1), Ägypten (n=1), Mauritius (n=1), Thailand (n=1), Island (n=1), Pakistan (n=1), Hong Kong (n=1)

Tabellen 1 und 2 zeigen die Häufigkeiten von RCT nach Institutionen und Zielgruppen. Tabellen 3 und 4

Tabelle 2 Häufigkeit edukativer Interventionen nach Zielgruppen.

	Anzahl der Studien (n=259)
Kindergartenkinder	**3**
Vorschüler	**2**
Schüler	**90**
Studenten	**72**
Medizin	47
Zahnmedizin	2
Pflege	6
Lehramt	1
Psychologie	1
Medizin + Pflege	2
Tiermedizin	1
Rettungsdienst	1
Pharmazie	5
Physiotherapie	1
Kinesiologie	1
Science	1
Sprachtherapie	1
Nicht spezifiziert	3
Berufsgruppen	**91**
Mediziner	38
Gesundheitsfachberufe	34
Lehrer	8
Forscher/Wissenschaftler	1
Sozialarbeiter	1
Mediziner + Gesundheitsfachberufe	4
Apotheker	2
Erzieher	2
Mediziner + Pharmazeuten	1

Tabelle 3 Häufigkeit edukativer Interventionen nach Interventionen.

	Anzahl der Studien (n=259)
Methodenvergleich	**104**
Kindergarten	0
Vorschule	0
Schule	13
Universität/Fachhochschule	57
Betriebliche Aus- und Weiterbildung	34
Fachbezogene Intervention	**80**
Kindergarten	1
Vorschule	0
Schule	5
Universität/Fachhochschule	19
Betriebliche Aus- und Weiterbildung	55
Präventionsprogramm	**75**
Ernährung	7
Adipositas	12
Rauchen	2
HIV/AIDS	1
Gewalt	5
Mundgesundheit/Karies	5
"Life skills/social capital"	3
Selbstmord	1
"Kombi-Prävention"	5
Alkohol	4
Multiple Substanzen	3
Bewegung/Fitness	10
Psychische Gesundheit	6
Leseschwäche/Literacy	2
Mobbing	2
Essstörungen	1
Rückenschule	1
Parasiten	1
Verletzungen	1
Lernbereitschaft	1
Drogen	2

zeigen die Häufigkeiten nach Interventionen und Förderung.

Stichprobenberechnungen waren in 85 Studien vorhanden. Es fehlten Stichprobenkalkulationen (n=163) bzw. es wurden post hoc Berechnungen durchgeführt (n=4) oder aber aufgrund von Pilotphasen (n=1) keine Berechnungen vorgenommen. In 6 Studien wurde auf Vorpublikationen verwiesen.

Diskussion

Insgesamt wurde eine vergleichsweise geringe Anzahl an randomisiert-kontrollierten Studien identifiziert. Die

Tabelle 4 Häufigkeit von edukativen Interventionen nach Förderung.

	Anzahl der Studien (n=259)	
	Deutschland (n=16)	Länder ohne Deutschland (n=243)
Keine Angabe	6	67
Keine Förderung	2	11
Öffentliche Förderung	3	107
Stiftungen/Fachgesellschaften	1	23
Industrie	0	5
Mischfinanzierung (mit Industrie)	4	11
Mischfinazierung (ohne Industrie)	0	19

Mehrzahl der randomisiert-kontrollierten Studien zu edukativen Interventionen wurde im Bereich Medizin und Gesundheit publiziert.

Die Stärken unserer Analyse liegen in den umfassenden Literaturrecherchen, die auch die im Forschungsfeld Edukation üblichen Buchpublikationen berücksichtigt haben.

Zu den Limitierungen zählt die Eingrenzung bei der Literaturauswahl auf randomisiert-kontrollierte Studien. Eine Aufnahme der kontrollierten Studien wäre sinnvoll, würde jedoch den Rahmen der vorliegenden Arbeit sprengen. Zudem fand keine systematische kritische Bewertung der Studien, z.B. in Bezug auf Verblindung von Randomisierung oder andere Bias Faktoren statt. Zur groben Abschätzung der Qualität der RCT haben wir jedoch analysiert, ob eine Schätzung der Stichprobengröße berichtet wurde.

Torgerson et al. haben in einer Analyse medizinscher RCTs gezeigt, dass zwischen 1975 und 1990 nur 32% der Studien die Stichprobenkalkulationen berichteten [12]. Die vorliegende Arbeit zeigt ein vergleichbares Ergebnis. Zudem konnten Torgerson et al. 2006 zeigen, dass die Qualität der medizinischen Studien kontinuierlich angestiegen ist. Die Qualität der edukativen Studien hingegen hat in der Qualität abgenommen [13]. In einer aktuellen systematischen Übersichtsarbeit wurde gezeigt, dass edukative Forschungsarbeiten selten Stichprobenkalkulationen berichten und wenn diese berichtet werden, werden unrealistisch hohe Effekte antizipiert [14]. Es muss daher davon ausgegangen werden, dass auch andere Qualitätskriterien für vertrauenswürdige RCT in einem signifikanten Ausmaß nicht erfüllt werden.

Cook hat die Ergebnisse von vier Meta-Analysen, die insgesamt 750 Studien zu edukativen Interventionen einbezogen haben, zusammengefasst. Zwei Drittel der Studien wurden mit einer einzigen Untersuchungsgruppe in einem Vorher-Nachher Design durchgeführt [14].

Das Fehlen von qualitativ hochwertigen experimentellen Studien im erziehungswissenschaftlichen Bereich wurde mehrfach beklagt. Rudd et al. weisen darauf hin, dass eine Ausrichtung der Forschungsförderung auf die Anwendung von randomisiert-kontrollierten Studien dazu beitragen würde, die Methoden edukativer Forschung weiterzuentwickeln [10].

Mit der Gründung der Campbell Collaboration [15] im Jahr 2000 werden vergleichbar mit der Cochrane Collaboration [16] für den medizinischen Bereich unter Anwendung stringenter methodischer Verfahren systematische Literaturanalysen und Übersichten von Interventionen (systematic reviews) für den erziehungswissenschaftlichen Bereich erstellt. Zudem wird eine Datenbank mit randomisiert-kontrollierten Studien zur Wirksamkeit pädagogischer Maßnahmen aufgebaut [15]. Insgesamt gibt es bisher nur zu sehr wenigen edukativen Bereichen aussagekräftige RCTs und folglich auch einen Mangel an systematischen Übersichten.

Systematische Übersichtsarbeiten stellen jedoch eine wichtige Grundlage für informierte Entscheidungen sowohl auf der Systemebene als auch für einzelne Lehrkräfte dar. Voraussetzung für die Erstellung dieser Übersichtsarbeiten sind randomisiert-kontrollierte Studien [15].

Die methodischen Herausforderungen der Durchführung von RCTs in der Edukation ergeben sich aus der Besonderheit, dass es sich um komplexe Interventionen handelt, die aus mehreren Komponenten bestehen, die sich wiederum gegenseitig bedingen können. Diese Besonderheit trifft auf beide Forschungsbereiche zu. In der Edukation werden als komplexe Intervention z.B. Curricula und Unterrichtsmethoden evaluiert. In der Medizin zählen z.B. stroke units und Patientenschulungsprogramme zu den komplexen Interventionen. Das UK MRC hat dazu 2008 einen Leitfaden für die Entwicklung und Evaluation komplexer Interventionen herausgegeben [17]. Zudem wurde kürzlich das CONSORT Statement für das Berichten von RCTs um die Cluster-Randomisierung erweitert, die auch für die Evaluation komplexer Inrterventionen eine höchst relevante Methode darstellt [18].

Fazit

Evidenz-basierte Edukation setzt randomisiert-kontrollierte Studien voraus, die eine Bewertung und einen Vergleich edukativer Interventionen ermöglichen. Dieser Veränderungsprozess stellt eine Herausforderung für die Erziehungswissenschaften und verwandte Fächer dar. In der Medizin hat sich der Paradigmenwechsel von der Eminenz-basierten zur Evidenz-basierten Medizin in einem Zeitraum mehrerer Jahrzehnte vollzogen, auch wenn die Umsetzung nach wie vor eine Herausforderung darstellt [19]. Es gibt sehr viele Gemeinsamkeiten in den Methoden der Medizin und Edukation. Der Bereich Edukation könnte von der Methodenentwicklung der Medizin profitieren [12]. Die Methode des RCT zielt in beiden Bereichen auf das gleiche Ziel: „. . .what randomised controlled trials offer in the social domain is exactly what they promise to medicine: protection of the public from potentially damaging uncontrolled experimentation and a more rational knowledge about the benefits to be derived from professional intervention [8].” Cook konstatiert zudem “The future is bright for medical education research” [14]. Warum nicht auch für die edukative Forschung insgesamt?

Interessenkonflikte

Die Autoren erklären, dass keine Interessenkonflikte vorliegen.

Förderung

Keine Förderung.

Referenzen

[1] Geake J. Neuromythologies in education. Educational Research 2008;50:123—33.
[2] Norcini JJ, Banda SS. Increasing the quality and capacity of education: the challenge for the 21st century. Med Educ 2011;45:81—6.
[3] Höhl A. Aroma-Dusche im Klassenzimmer. Süddeutsche Zeitung vom 24.09.2012.
[4] Bomeier S. Die wahre Knast-Geschichte. Süddeutsche Zeitung vom 23.07.2005.
[5] Petrosino A, Turpin-Petrosino C, Buehler J. “Scared Straight” and other juvenile awareness programs for preventing juvenile delinquency. Cochrane Database Syst Rev 2002;(2):CD002796, http://dx.doi.org/10.1002/14651858.CD002796.

[6] Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. BMJ 1996;312:71—2.
[7] Slavin RE. Evidence-based education policies: Transforming educational practice and research. Educational Research 2002;31:15—21.
[8] Oakley A. Experimentation and social interventions: a forgotten but important history. BMJ 1998;317:1239—42.
[9] Cook DA. If you teach them, they will learn: why medical education needs comparative effectiveness research. Adv Health Sci Educ Theory Pract 2012;17:305—10.
[10] Rudd A, Burke Johnson R. Lessons learned from the use of randomized and quasi-experimental field designs for the evaluation of educational programs. Studies in Educational Evaluation 2008;34:180—8.
[11] What Works Clearinghouse. National registry of effective programs and practices. http://ies.ed.gov/ncee/wwc/ (Zugriff am 30.09.2012).
[12] Torgerson CJ, Torgerson DJ. The design and conduct of randomised controlled trials in education: lessons from health care. Oxford Rev Educ 2003;29(1):67—80.
[13] Torgerson CJ, Torgerson DJ, Birks YF, Porthouse J. A comparison of randomised controlled trials in health and education. Brit Educ Res J 2005;3186:761—85.
[14] Cook DA, Levinson AJ, Garside S. Method and reporting quality in health professions education research: a systematic review. Med Educ 2011;45:227—38.
[15] The Campbell Collaboration. http://www.campbellcollaboration.org (Zugriff am 30.09.2012).
[16] The Cochrane Collaboration. http://www.cochrane.org (Zugriff: 30.09.2012).
[17] UK Medical Research Council. Developing and evaluating complex interventions: new guidance. 2008 www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC004871 (Zugriff: 30.09.2012).
[18] Campbell MK, Piaggio G, Elbourne DR, Altman DG, Consort 2010 statement: extension to cluster randomised trials. CONSORT Group. BMJ 2012;345:e5661, http://dx.doi.org/10.1136/bmj.e5661.
[19] Takeshima K. Advances in evidence-based education: a roadmap to evidence-based education. Educ Treat Children 2009;32:178—83.

Informationen über Klinische Studien werden transparent

Im Portal PharmNet.Bund (www.pharmnet-bund.de) finden Sie ab sofort Informationen über in Deutschland genehmigte klinische Arzneimittelprüfungen. „Jeder kann die Daten über klinische Studien kostenfrei einsehen", begrüßte Bundesgesundheitsminister Daniel Bahr die neue Datenbank Klinische Prüfungen. „Damit stellen wir Transparenz her für Ärzte, Patienten und andere interessierte Bürger."

Die Datenbank enthält umfangreiche Datensätze zu klinischen Prüfungen ab August 2004. Dazu gehören u.a. Informationen über:

- Sponsor (für die Prüfung verantwortliche natürliche oder juristische Person)
- Design (Aufbau, Aufteilung auf Prüfzentren, Dauer etc.)
- zu prüfende/geprüfte Arzneimittel
- Anwendungsgebiete, Ziele und Prüfungsphasen
- Personen, die in die Prüfung eingeschlossen werden sollen

Mit einer komfortablen Suchfunktion kann die Datenbank gezielt nach bestimmten Aspekten, Studienphasen, Diagnostik oder Arzneimitteln durchsucht werden.
Im Portal PharmNet.Bund sind alle in der Datenbank genutzten Begriffe ausführlich beschrieben. Die neuen Webseiten zu klinischen Prüfungen informieren zudem über die Herkunft der Daten und nach welchen Regeln diese veröffentlicht werden.
Voraussichtlich Anfang 2013 finden Sie auch die Ergebnisberichte von vielen klinischen Prüfungen in der Datenbank.
Mit PharmNet.Bund entsteht ein integriertes Arzneimittel-Informationssystem, das die bundesweit vorliegenden amtlichen Daten über zugelassene Arzneimittel in Deutschland zentral zur Verfügung stellt. PharmNet.Bund wird als zentrale Plattform Patienten,

MAGAZIN

Ärzten und Apothekern Gelegenheit zur zuverlässigen Recherche bieten, den Behörden effiziente Bearbeitungsmöglichkeiten und der pharmazeutischen Industrie komfortable Vorlagemöglichkeiten, z.B. in Zulassungsverfahren. Hinweis: Die Benutzung des Namensteils PharmNet erfolgt mit freundlicher Genehmigung der Cerner Deutschland GmbH, die als Anbieter von IT-Lösungen für das Gesundheitswesen unter dieser Marke eine Software-Anwendung für die Verwaltung von Arzneimitteln in Krankenhäusern anbietet. Das DIMDI und Cerner stehen in keiner geschäftlichen Verbindung.

Gemeinsame Pressemitteilung des Bundesministeriums für Gesundheit und des DIMDI.

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6.6 Albrecht (nee Bunge) M, Kupfer R, Reissmann DR, Haastert B, Mühlhauser I, Köpke S (2016): Oral health educational interventions for nursing home staff and residents. (Protocol) Cochrane Database of Systematic Reviews 2013, Issue 5. Art. No.: CD010535. DOI:10.1002/14651858.CD010535.

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Oral health educational interventions for nursing home staff and residents (Protocol)

Albrecht (nee Bunge) M, Kupfer R, Reissmann D, Haastert B, Mühlhauser I, Köpke S

Albrecht (nee Bunge) M, Kupfer R, Reissmann D, Haastert B, Mühlhauser I, Köpke S.
Oral health educational interventions for nursing home staff and residents.
Cochrane Database of Systematic Reviews 2013, Issue 5. Art. No.: CD010535.
DOI: 10.1002/14651858.CD010535.

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[Intervention Protocol]

Oral health educational interventions for nursing home staff and residents

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Editorial group: Cochrane Oral Health Group.
Publication status and date: New, published in Issue 5, 2013.

Citation: Albrecht (nee Bunge) M, Kupfer R, Reissmann D, Haastert B, Mühlhauser I, Köpke S. Oral health educational interventions for nursing home staff and residents. *Cochrane Database of Systematic Reviews* 2013, Issue 5. Art. No.: CD010535. DOI: 10.1002/14651858.CD010535.

ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To assess the effects of oral health educational interventions for nursing home staff and residents to maintain or improve the oral health of nursing home residents.

To describe the components of the complex interventions used in the included studies.

BACKGROUND

Description of the condition

The demographic shift in developed countries has important implications for healthcare services as there will be more (frail) elderly people with morbidity and care dependency (Branca 2009), and an increasing number of nursing home residents. Whereas until recently most nursing home residents were provided with dentures, nowadays increasingly more residents retain a considerable number of natural teeth (Hopcraft 2012; Samson 2008). Declining rates of edentulism have important implications for oral health and management of these residents because a greater proportion will have more teeth at risk of dental caries and periodontal disease. Additionally, high-quality and complex dental prostheses have to be maintained (i.e. implants, bridges, and removable dental prostheses). Nursing home residents are often unable to carry out adequate oral care such as optimal removal of dental plaque. Therefore, continuous preventive and curative oral health care provided by trained staff seems increasingly important. In nursing homes, nursing staff and other carers play a crucial role in the provision of daily oral health care. This also applies to the organisation of routine prophylaxis and treatment provided by dental professionals (Nitschke 2010).

In the past, it has been reported that nursing staff frequently would not acknowledge the importance of oral health or would lack knowledge of how to achieve it (Glassman 1994). The attitude has changed, but knowledge about oral hygiene is still inadequate among nursing staff (Jablonski 2009; Wardh 2012). There is a large discrepancy between the proposed need for assistance with

daily oral hygiene among nursing home residents and the actual assistance provided by nursing staff (Forsell 2009). Elderly who need assistance with oral care most are most likely to resist helping behaviours (Jablonski 2011). This so-called 'care-resistant behaviour' is a common phenomenon encountered by nursing staff during the provision of oral care (Frenkel 1999; Jablonski 2011). Measures of poor oral health (e.g. gingivitis, caries, and chewing difficulties), along with discomfort and pain, have been reported for nursing home residents in different countries (De Visschere 2006; Gluhak 2010; Hopcraft 2012; Simunković 2005; Wyatt 2002). Dental plaque generally leads to an increased risk for dental caries, gingivitis, and periodontitis as well as other infections in the oral cavity. Also, the accumulation of microorganisms on teeth and denture surfaces, caused by lack of oral hygiene, may influence residents' general health by causing pneumonia, arteriosclerosis and infection-related disorders (Azarpazhooh 2006; Desvarieux 2003; Scannapieco 2003; Shay 2002). Evidence from randomised controlled trials (RCTs) suggests positive preventive effects of oral care on respiratory tract infection and pneumonia in nursing home residents (Sjögren 2008). In addition, a Cochrane review protocol on this topic is under preparation (Shi 2013).

Furthermore, involuntary weight loss has been associated with poor oral health (Mojon 1999; Sheiham 2001). Institutionalised elderly people who suffer from mouth discomfort, problems with chewing or swallowing, compromised dentition, or poorly fitted dentures have a higher incidence of nutritional deficiency (Saunders 2007).

In addition, poor oral hygiene and poor dental status among elderly people is associated with reduced quality of life (Walker 2007). Elderly people in adult day health centres have shown considerably higher levels of oral health problems compared to community-dwelling elderly people (Walker 2007). The reasons are difficulties in maintaining a sufficient level of oral hygiene and difficulties in accessing professional dental care (Forsell 2009). Two-thirds of elderly people living in residential facilities use dental services only in case of dental problems and on demand (De Baat 1993; Isaksson 2007). In a British study, 70% of residents had not seen a dentist for more than 5 years (Frenkel 2000).

Consequently, interventions to improve oral health seem warranted as they possibly yield a number of positive effects including improved nutritional status and health-related quality of life (Naito 2010).

Description of the intervention

Oral health-related educational interventions are programmes that facilitate knowledge and skills acquisition in nursing home staff and residents to maintain or improve oral health, using a variety of formats. They may target nursing home residents or staff and they may be provided to individuals or groups. A number of RCTs investigating educational interventions aiming to improve oral health in nursing home residents have been published (Budtz-Jørgensen 2000; Frenkel 2001; Frenkel 2002; MacEntee 2007; Quagliarello 2009).

These interventions are usually designed as complex interventions, consisting of different components. Three components commonly included are:

1. educational sessions for staff or residents or both, aiming at changing knowledge of oral health and oral health care;
2. staff training on how to examine and clean the mouth/dentures of residents; and
3. oral hygiene skills training for residents.

How the intervention might work

The goal of the educational interventions is to improve oral and dental health of residents by increasing knowledge and skill levels of nursing home staff and nursing home residents.

Interventions targeting nursing home staff aim to strengthen the staff expertise in oral care for residents. Increased knowledge about oral health, association between oral health and general health, and oral health care may lead to changes in attitudes, oral health-related behaviour and improved health outcomes for residents.

Interventions targeting nursing home residents, especially oral hygiene skills training, may foster the ability to self perform dental care and thus decrease the need for assistance. There may also be direct effects of education on residents' attitudes as well as quality of life.

Why it is important to do this review

Despite a growing number of RCTs, so far there has been no systematic review of interventions for improvement of oral health in nursing home residents. Considering the different complex interventions addressing various outcome measures, it seems highly warranted to describe the components of interventions and to identify effective intervention strategies. A systematic review will impact the implementation of different approaches and trigger the development of new interventions on the basis of current best evidence. A systematic review on this topic is also urgently needed since interventions of questionable effectiveness and unclear consequences might be in use.

OBJECTIVES

To assess the effects of oral health educational interventions for nursing home staff and residents to maintain or improve the oral health of nursing home residents.

To describe the components of the complex interventions used in the included studies.

METHODS

Criteria for considering studies for this review

Types of studies

We will include all individual randomised controlled trials (RCTs) or cluster-RCTs including groups of nursing home staff or residents or both, allocated either:

- to a programme aiming to maintain/improve oral health of nursing home residents by one or more oral health educational/ oral hygiene promotion interventions (the intervention group), or
- to (optimised) regular dental care or any other oral health care intervention (the control group).

We will not apply any language restrictions. We will exclude trials with a follow-up period of less than 2 weeks.

Types of participants

Participants will be:

- male or female residents living in facilities which provide supervision or (nursing) care for the elderly (e.g. nursing homes or long-term care facilities). We will include studies if the majority of residents were over the age of 64 years or the mean age was at least 65 years;
- nursing staff working in those facilities; or
- a combination of the above.

We aim to include all participants included in the primary studies (i.e. irrespective of residents' oral health status or staff profession).

Types of interventions

Any intervention or group of interventions where subjects or clusters are allocated to receive an oral health education programme versus (optimised) usual oral health care, or any other oral health-care intervention.

Oral health education programmes include either direct-to-staff programmes, direct-to-resident-programmes (e.g. oral hygiene promotion or skills training) or any combination of both. We expect a range of different approaches varying for example in terms of frequency, length and content. Contents are likely to include all or some of the following: oral health, oral diseases and impact on general health, diet, oral hygiene measures, best oral care practices for elderly people with natural dentition and dentures, oral hygiene promotion, and skills training.

Following the 'framework for design and evaluation of complex interventions', it will not be possible to extract the effective or ineffective components of educational programmes (Campbell 2000; Craig 2008), but components of included programmes will be collected and described in detail as suggested by Lenz 2007.

We will exclude interventions that do not include educational or oral hygiene promotion components from the intervention group, but we will consider including them as controls. Also, sole organisational interventions aiming to change organisational policies, for example through introduction of practice guidelines, oral health co-ordinators, regular visits by a dentist or dental hygienist for professional oral care and examination, or regular visits of residents in dental surgeries, will only be considered as controls. The same applies to exclusive oral hygiene interventions (e.g. the provision of chemical topical interventions and mechanical auxiliaries).

Types of outcome measures

Primary outcomes

1. Oral health-related quality of life: measured by instruments such as Oral Health Impact Profile (OHIP) (Slade 1994) or (OHIP-14) (Slade 1997), Geriatric/General Oral Health Assessment Index (GOHAI) (Atchison 1990), Dental Impact Profile (DIP) (Strauss 1993).
2. Oral health: measured by instruments such as Brief Oral Health Status Examination (BOHSE) or Oral Health Assessment (OHAT) (Chalmers 2005; Kayser-Jones 1995).
3. Dental health measures such as:

- caries, incidence of new caries;
- dental or denture plaque or both: measured by plaque scores and denture cleanliness scores (scales) such as Plaque Index (Silness 1964), Mucosal-Plaque Index (Henriksen 1999), or Denture Plaque Index (Wefers 1999); or
- gingivitis: measured by instruments such as Gingival Bleeding Index (Ainamo 1975), Gingival-Index (Löe 1967), or Community Periodontal Index (Benigeri 2000).

Secondary outcomes

- Nutritional status (e.g. body weight, Body Mass Index - BMI).
- Incidence of respiratory diseases and pneumonia.
- Adverse effects of the interventions.

Intermediate Outcomes

- Oral health-related knowledge of staff or residents or both: measured by any instruments used in the included studies (e.g. questionnaire or interview).
- Oral health-related attitude and behaviour of staff or residents or both: measured by any instruments used in the included studies (e.g. questionnaire or interview).

As the oral health-related outcomes listed above might only be achieved along with considerable impediment of residents' autonomy (e.g. by applying measures against residents' wills), we will put special consideration on potentially interdependent outcomes (e.g. residents' quality of life and oral health status). We expect these data to be only rarely available which then will be stated.

Search methods for identification of studies

For identification of studies to be included or considered for this review, detailed search strategies will be developed for each database searched. These will be based on the search strategy developed for MEDLINE (Appendix 1) but revised appropriately for each database to take account of differences in controlled vocabulary and syntax rules.

The search strategy will combine the subject search with the Cochrane Highly Sensitive Search Strategy for identifying reports of randomised controlled trials (2008 revision) (as published in box 6.4.c in the *Cochrane Handbook for Systematic Reviews of Interventions* version 5.1.0, updated March 2011) (Higgins 2011).

Electronic searches

We will search the following databases.

- The Cochrane Oral Health Group Trials Register (to present).
- The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*, current issue).
- MEDLINE via OVID (1946 to present) (see Appendix 1).
- EMBASE via OVID (1980 to present).
- CINAHL via EBSCO (1980 to present).

We will attempt to identify all relevant studies irrespective of language. Non-English language papers will be translated.

Searching other resources

We will search the National Institutes of Health Trials Register for ongoing trials (ClinicalTrials.gov). We will check reference lists of published reviews and retrieved articles for additional trials, and forward citation tracking will be performed by using Google Scholar, Web of Science and Scopus.

We will contact experts in the field to identify unpublished or ongoing studies.

Data collection and analysis

Selection of studies

Two review authors will independently screen titles and abstracts of identified studies, rejecting any which are obviously irrelevant. Full text copies of all eligible and potentially eligible studies will be obtained and evaluated in detail by two review authors to identify those studies which actually meet all inclusion criteria. From this group, those studies which do not meet the inclusion criteria will be recorded in the excluded studies section of the review and the reason for exclusion will be noted in the 'Characteristics of excluded studies' table. We will resolve any disagreement by discussion or, if necessary, by consulting a third review author.

Data extraction and management

Two review authors will independently extract data using a standardised data collection sheet and data will be entered in the current version of RevMan (RevMan 2012). The review authors will not be blinded to the authors of the included studies. Disagreement will be resolved by discussion between the two review authors or, if necessary, a third review author will be consulted in order to reach consensus. Data will be sought per participant or randomised cluster (nursing home) on all of the outcome measures of interest from all assessment times (including baseline). we will extract data for: characteristics of participants, baseline data, interventions, duration of intervention, length of follow-up, outcome measures, and adverse events. For cluster-RCTs, we will extract estimates of the intracluster correlation coefficient if possible.

We will retrieve data on process evaluation of the complex interventions on the basis of a criteria list for reporting the development and evaluation of complex interventions in health care (CReDECI) (Möhler 2012). The process evaluation comprises developmental details like the description and intensity of the components, feasibility and piloting, as well as evaluation of the complex intervention. In addition, data on the fidelity of the intervention implementation will be extracted. If, as is frequently the case, information about the intervention and the development process have not been reported sufficiently in the publication, we will try to acquire detailed information about the interventions used by contacting authors of the primary study (e.g. by asking about related publications). Also, following earlier suggestions (Lenz 2007), we will perform extra searches for publications related to included studies.

Required data for each trial and each outcome for continuous data are the mean change from baseline, the standard error of the mean change, and the number of residents for each cluster at each assessment. Where changes from baseline were not reported, we will use the mean standard deviation and the number of residents in each cluster at each time point, if available.

Assessment of risk of bias in included studies

Assessment of risk of bias will follow the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). Two review authors will independently assess studies using a two-part tool, addressing six domains (sequence generation, allocation conceal-

ment, blinding, incomplete outcome data, selective outcome reporting, and other issues). The first part of the tool describes what has been reported in the study. In the second part, a judgement concerning the related risk of bias is assigned for each domain, either 'Low risk', 'High risk' or where insufficient information is available on which to make a judgement, the risk of bias will be assessed as 'Unclear risk'. The domains of sequence generation, allocation concealment (selection bias) and selective outcome reporting (reporting bias) will be addressed in the tool by a single entry for each study. Blinding of participants, staff and outcome assessors (performance bias and detection bias) will be considered separately for objective outcomes and subjective outcomes. Incomplete outcome data (attrition bias) will be considered separately for different lengths of follow-up (shorter and longer follow-up). We will summarise the risk of bias as follows.

Risk of bias	Interpretation	In outcome	In included studies
Low risk of bias	Plausible bias unlikely to seriously alter the results	Low risk of bias for all key domains	Most information is from studies at low risk of bias
Unclear risk of bias	Plausible bias that raises some doubt about the results	Unclear risk of bias for one or more key domains	Most information is from studies at low or unclear risk of bias
High risk of bias	Plausible bias that seriously weakens confidence in the results	High risk of bias for one or more key domains	The proportion of information from studies at high risk of bias is sufficient to affect the interpretation of results

A risk of bias table will be completed for each included study and the results will also be presented graphically.

Measures of treatment effect

For dichotomous data (e.g. incidence of respiratory disease) the effect measure will be risk ratio (RR). The absolute numbers in each group and the numbers experiencing the outcome of interest will be sought and recorded. For continuous data (e.g. plaque indices) the effect measure will be the mean difference if the same instrument is used, or the standardised mean difference (SMD) if different instruments are used for the same outcome measure. The mean change from baseline, the standard deviation of the mean change, and the number of patients for each treatment group at each assessment will be extracted. Where changes from baseline are not reported, we will extract the mean standard deviation and the number of participants for each group at each time point, if available.

Unit of analysis issues

We will consider for each study whether groups of individuals were randomised in clusters or individually, whether individuals underwent more than one intervention, or whether there were multiple observation times for the same outcome. As results from more than one time point per study cannot be combined in the meta-analysis, depending on the reported follow-up periods of included studies, we will perform separate analyses to reflect short-term and long-term follow-up (Higgins 2011).

If individual and cluster-RCTs are analysed together, 'effective sample sizes' for cluster-RCTs will be estimated as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (sections 16.3.4 to 16.3.7) (Higgins 2011).

Dealing with missing data

We will contact trial authors to retrieve missing data where necessary. We will describe the amounts and types of missing data related to participant withdrawal in the 'Characteristics of included studies' table. We will discuss the impact of these missing data. Their

potential impact on the results will depend on the extent of missing data, the pooled estimate of the treatment effect, and the variability of the outcomes. Variation between studies in the amount of missing data may also be considered as a potential source of heterogeneity. Where possible, intention-to-treat (ITT) analyses will be performed. We will seek data on whether or not clusters were subsequently deemed ineligible, or otherwise excluded from treatment or follow-up.

We will only use imputation to calculate missing standard deviations as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (section 16.1.3.) (Higgins 2011). Recognising that statistical analyses cannot reliably compensate for missing data (Unnebrink 2001), we will assess the impact of any assumption by trying more than one method for a sensitivity analysis. For example, for dichotomous data, it will first be assumed that all missing participants in the first group incurred the event and those in the second group did not, after which the opposite will be assumed. If ITT data are not available in the publications, 'on-treatment' data or the data of those who completed the trial will be sought and indicated as such. Data from non-randomised follow-on periods will not be used.

Assessment of heterogeneity

We will only undertake meta-analyses when studies are sufficiently homogeneous in terms of participants, interventions and outcomes. We will consider both clinical heterogeneity and statistical heterogeneity. We will investigate statistical heterogeneity between trials included in each analysis using the I^2 statistic. A rough guide to interpreting the I^2 statistic is given in section 9.5.2 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011): 0% to 40% might not be important; 30% to 60% may represent moderate heterogeneity; 50% to 90% may represent substantial heterogeneity; and 75% to 100% may represent considerable heterogeneity.

Assessment of reporting biases

In order to minimise the risk of publication bias, we will undertake a comprehensive search in multiple databases, including searching for unpublished studies in trials registries. Providing there are a minimum of 10 included studies, we will construct a funnel plot to assess the likelihood of publication bias.

Data synthesis

It has been discussed that there are specific difficulties in defining, developing, documenting, and reproducing complex interventions (Craig 2008; Lenz 2007). These difficulties may lead to important methodological challenges when aiming to synthesise results from the studies (e.g. in meta-analyses requiring new approaches for synthesis) (Pawson 2005; Shepperd 2009), or they may even make meta-analyses inappropriate (Lenz 2007). In this context, it has also been claimed that education programmes should not be allocated into categories referring to interdependent components (Lenz 2007), and decisions concerning what should and should not be combined are inevitably subjective, and are not amenable to statistical solutions but require discussion and clinical judgement (Higgins 2011). Therefore, meta-analysis will only be conducted for the same intervention (main trial and replication trials). Two review authors will carry out categorisation of replication trials. We will contact the authors of the included studies to ask whether they feel that their intervention has been categorised appropriately.

We will only conduct meta-analysis for studies with comparable analyses reporting similar outcome measures. We will combine risk ratios for dichotomous data (e.g. number of people in each arm with gingivitis), and mean differences for continuous data (e.g. mean plaque scores in each trial arm), using random-effects models, assuming that the identified studies allow this procedure. Where there are few studies, or the studies are small, it may be impossible to estimate between-study variance with any precision. In that case a random-effects analysis would provide poor estimates of the distribution of intervention effects, so we would use a fixed-effect model instead (Higgins 2011).

We will analyse cluster-RCTs at the level of individuals. Results from appropriately analysed cluster-RCTs will be meta-analysed using the generic inverse variance method in RevMan. If original analyses do not account for clustering, we will conduct an adjusted analysis, provided that the necessary information (e.g. mean cluster size, proportion of individuals with events, intracluster correlation coefficient) can be extracted (Higgins 2011).

We will present meta-analyses using forest plots. If it is not possible to pool the data, we will present results in a descriptive review.

Subgroup analysis and investigation of heterogeneity

We will conduct subgroup analyses for relevant and clinically meaningful subgroups if sufficient data are available.

Possible subgroup analyses will be carried out for:

- study design (cluster randomised versus individual randomised participants);
- target group of interventions (educational interventions delivered to nursing home staff, to residents, or to both); and
- type of control intervention (usual care versus active control).

Sensitivity analysis

Providing that there are sufficient included studies, we will undertake sensitivity analysis based on risk of bias (Higgins 2011).

Presentation of main results

A summary of findings table will be developed for the primary outcomes, using GRADEPro software, following the methods outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (section 11.5) (Higgins 2011). The quality of evidence will be assessed with reference to the overall risk of bias of the included studies, the directness of the evidence, the consistency of the results, the precision of the estimates, the risk of publication bias, the magnitude of the effect, and whether or not there is evidence of a dose response. The quality of evidence for each of the primary outcomes will be categorised as high, moderate, low, or very low.

ACKNOWLEDGEMENTS

We wish to acknowledge the contribution of consumer reviewer Johannes van Dijk (gerontopsychiatric nurse and trainer in dementia care mapping, Hamburg, Germany). We would also like to thank the following peer referees for their helpful comments on the protocol: Ina Nitschke, Ivor G Chestnutt, Aubrey Sheiham, Toru Naito, and Rita A Jablonski.

REFERENCES

Additional references

Ainamo 1975
Ainamo J, Bay I. Problems and proposals for recording gingivitis and plaque. *International Dental Journal* 1975;**25**(4):229–35.

Atchison 1990
Atchison KA, Dolan TA. Development of the Geriatric Oral Health Assessment Index. *Journal of Dental Education* 1990;**54**(11):680–7.

Azarpazhooh 2006
Azarpazhooh A, Leake JL. Systematic review of the association between respiratory diseases and oral health. *Journal of Periodontology* 2006;**77**(9):1465–82.

Benigeri 2000
Benigeri M, Brodeur JM, Payette M, Charbonneau A, Ismail AI. Community periodontal index of treatment needs and prevalence of periodontal conditions. *Journal of Clinical Periodontology* 2000;**27**(5):308–12.

Branca 2009
Branca S, Bennati E, Ferlito L, Spallina G, Cardillo E, Malaguarnera M, et al.The health-care in the extreme longevity. *Archives of Gerontology and Geriatrics* 2009;**49**(1):32–4.

Budtz-Jørgensen 2000
Budtz-Jørgensen E, Mojon P, Rentsch A, Deslauriers N. Effects of an oral health program on the occurrence of oral candidosis in a long-term care facility. *Community Dentistry and Oral Epidemiology* 2000;**28**(2):141–9.

Campbell 2000
Campbell M, Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D, et al.Framework for design and evaluation of complex interventions to improve health. *BMJ* 2000;**321**(7262):694–6.

Chalmers 2005
Chalmers JM, King PL, Spencer AJ, Wright FA, Carter KD. The oral health assessment tool - validity and reliability. *Australian Dental Journal* 2005;**50**(3):191–9.

Craig 2008
Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;**337**:a1655.

De Baat 1993
De Baat C, Bruins H, van Rossum G, Kalk W. Oral health care for nursing home residents in The Netherlands - a national survey. *Community Dentistry and Oral Epidemiology* 1993;**21**(4):240–2.

De Visschere 2006
De Visschere LM, Grooten L, Theuniers G, Vanobbergen JN. Oral hygiene of elderly people in long-term care institutions - a cross-sectional study. *Gerodontology* 2006;**23**(4):195–204.

Desvarieux 2003
Desvarieux M, Demmer RT, Rundek T, Boden-Albala B, Jacobs DR Jr, Papapanou PN, et al.Relationship between periodontal disease, tooth loss, and carotid artery plaque: the Oral Infections and Vascular Disease Epidemiology Study (INVEST). *Stroke* 2003;**34**(9):2120–5.

Forsell 2009
Forsell M, Sjögren P, Johansson O. Need of assistance with daily oral hygiene measures among nursing home resident elderly versus the actual assistance received from the staff. *The Open Dentistry Journal* 2009;**3**:241–4.

Frenkel 1999
Frenkel HF. Behind the screens: care staff observations on delivery of oral health care in nursing homes. *Gerodontology* 1999;**16**(2):75–80.

Frenkel 2000
Frenkel H, Harvey I, Newcombe RG. Oral health care among nursing home residents in Avon. *Gerodontology* 2000;**17**(1):33–8.

Frenkel 2001
Frenkel H, Harvey I, Newcombe RG. Improving oral health in institutionalised elderly people by educating caregivers: a randomised controlled trial. *Community Dentistry and Oral Epidemiology* 2001;**29**(4):289–97.

Frenkel 2002
Frenkel H, Harvey I, Needs K. Oral health care education and its effect on caregivers' knowledge and attitudes: a

randomised controlled trial. *Community Dentistry and Oral Epidemiology* 2002;**30**(2):91–100.

Glassman 1994
Glassman P, Miller C, Woznick T, Jones C. A preventive dentistry training programme for caretakers of persons with disabilities residing in community residential facilities. *Special Care in Dentistry* 1994;**14**(4):137–43.

Gluhak 2010
Gluhak C, Arnetzl GV, Kirmeier R, Jakse N, Arnetzl G. Oral status among seniors in nine nursing homes in Styria, Austria. *Gerodontology* 2010;**27**(1):47–52.

Henriksen 1999
Henriksen BM, Ambjørnsen E, Axéll TE. Evaluation of a mucosal-plaque index (MPS) designed to assess oral care in groups of elderly. *Special Care in Dentistry* 1999;**19**(4): 154–7.

Higgins 2011
Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Hopcraft 2012
Hopcraft MS, Morgan MV, Satur JG, Wright FA. Edentulism and dental caries in Victorian nursing homes. *Gerodontology* 2012;**29**(2):e512–9.

Isaksson 2007
Isaksson R, Söderfeldt B. Oral status and treatment needs among elderly within municipal long-term care 2002-2004. *Swedish Dental Journal* 2007;**31**(1):45–52.

Jablonski 2009
Jablonski RA, Munro CL, Grap MJ, Schubert CM, Ligon M, Spigelmyer P. Mouth care in nursing homes: knowledge, beliefs, and practices of nursing assistants. *Geriatric Nursing* 2009;**30**(2):99–107.

Jablonski 2011
Jablonski RA, Therrien B, Mahoney EK, Kolanowski A, Gabello M, Brock A. An intervention to reduce care-resistant behavior in persons with dementia during oral hygiene: a pilot study. *Special Care in Dentistry* 2011;**31**(3): 77–87.

Kayser-Jones 1995
Kayser-Jones J, Bird WF, Paul SM, Long L, Schell ES. An instrument to assess the oral health status of nursing home residents. *The Gerontologist* 1995;**35**(6):814–24.

Lenz 2007
Lenz M, Steckelberg A, Richter B, Mühlhauser I. Meta-analysis does not allow appraisal of complex interventions in diabetes and hypertension self-management: a methodological review. *Diabetologia* 2007;**50**(7):1375–83.

Löe 1967
Löe H. The Gingival Index, the Plaque Index and the Retention Index Systems. *Journal of Periodontology* 1967;**38** (6):610–6.

MacEntee 2007
MacEntee MI, Wyatt CC, Beattie BL, Paterson B, Levy-Milne R, McCandless L, et al.Provision of mouth-care in long-term care facilities: an educational trial. *Community Dentistry and Oral Epidemiology* 2007;**35**(1):25–34.

Mojon 1999
Mojon P, Budtz-Jørgensen E, Rapin CH. Relationship between oral health and nutrition in very old people. *Age and Ageing* 1999;**28**(5):463–8.

Möhler 2012
Möhler R, Bartoszek G, Köpke S, Meyer G. Proposed criteria for reporting the development and evaluation of complex interventions in healthcare (CReDECI): guideline development. *International Journal of Nursing Studies* 2012; **49**(1):40–6.

Naito 2010
Naito M, Kato T, Fujii W, Ozeki M, Yokoyama M, Hamajima N, et al.Effects of dental treatment on the quality of life and activities of daily living in institutionalized elderly in Japan. *Archives of Gerontology and Geriatrics* 2010;**50**(1): 65–8.

Nitschke 2010
Nitschke I, Majdani M, Sobotta BA, Reiber T, Hopfenmüller W. Dental care of frail older people and those caring for them. *Journal of Clinical Nursing* 2010;**19**(13-14):1882–90.

Pawson 2005
Pawson R, Greenhalgh T, Harvey G, Walshe K. Realist review - a new method of systematic review designed for complex policy interventions. *Journal of Health Services Research & Policy* 2005;**10 Suppl 1**:21–34.

Quagliarello 2009
Quagliarello V, Juthani-Metha M, Ginter S, Towle V, Allore H, Tinetti M. Pilot testing of intervention protocols to prevent pneumonia in nursing home residents. *Journal of the American Geriatrics Society* 2009;**57**(7):1226–31.

RevMan 2012
Review Manager (RevMan) [Computer program]. Version 5.2. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2012.

Samson 2008
Samson H, Strand GV, Haugejorden O. Change in oral health status among institutionalized Norwegian elderly over a period of 16 years. *Acta Odontologica Scandinavica* 2008;**66**(6):368–73.

Saunders 2007
Saunders MJ, Stattmiller SP, Kirk KM. Oral health issues in the nutrition of institutionalized elders. *Journal of Nutrition for the Elderly* 2007;**26**(3-4):39–58.

Scannapieco 2003
Scannapieco FA, Bush RB, Paju S. Association between periodontal disease and risk for nosocomial bacterial pneumonia and chronic obstructive pulmonary disease. A systematic review. *Annals of Periodontology* 2003;**8**(1): 54–69.

Shay 2002
Shay K. Infectious complications of dental and periodontal diseases in the elderly population. *Clinical Infectious Diseases* 2002;**34**(9):1215-23.

Sheiham 2001
Sheiham A, Steele JG, Marcenes W, Lowe C, Finch S, Bates CJ, et al.The relationship among dental status, nutrient intake, and nutritional status in older people. *Journal of Dental Research* 2001;**80**(2):408–13.

Shepperd 2009
Shepperd S, Lewin S, Straus S, Clarke M, Eccles MP, Fitzpatrick R, et al.Can we systematically review studies that evaluate complex interventions?. *PLoS Medicine* 2009;**6**(8): e1000086.

Shi 2013
Shi Z, Zhang Q, Xie H, Wang P, Li C, Chen E, et al.Oral hygiene for institutionalised patients to prevent community-acquired pneumonia. Cochrane Protocol http://ohg.cochrane.org/reviews (unpublished).

Silness 1964
Silness J, Löe H. Periodontal disease in pregnancy. II. Correlation between oral hygiene and periodontal condition. *Acta Odontologica Scandinavica* 1964;**22**: 121–135.

Simunković 2005
Simunković SK, Boras VV, Panduric J, Zili ć IA. Oral health among institutionalised elderly in Zagreb, Croatia. *Gerodontology* 2005;**22**(4):238–41.

Sjögren 2008
Sjögren P, Nilsson E, Forsell M, Johansson O, Hoogstraate J. A systematic review of the preventive effect of oral hygiene on pneumonia and respiratory tract infection in elderly people in hospitals and nursing homes: effect estimates and methodological quality of randomized controlled trials. *Journal of the American Geriatrics Society* 2008;**56**(11): 2124–30.

Slade 1994
Slade GD, Spencer AJ. Development and evaluation of the Oral Health Impact Profile. *Community Dental Health* 1994;**11**(1):3–11.

Slade 1997
Slade GD. Derivation and validation of a short-form oral health impact profile. *Community Dentistry and Oral Epidemiology* 1997;**25**(4):284–90.

Strauss 1993
Strauss RP, Hunt RJ. Understanding the value of teeth to older adults: influences on the quality of life. *Journal of the American Dental Association* 1993;**124**(1):105–10.

Unnebrink 2001
Unnebrink K, Windeler J. Intention-to-treat: methods for dealing with missing values in clinical trials of progressively deteriorating diseases. *Statistics in Medicine* 2001;**20**(24): 3931–46.

Walker 2007
Walker RJ, Kiyak HA. The impact of providing dental services to frail older adults: perceptions of elders in adult day health centers. *Special Care in Dentistry* 2007;**27**(4): 139–43.

Wardh 2012
Wårdh I, Jonsson M, Wikström M. Attitudes to and knowledge about oral health care among nursing home personnel - an area in need of improvement. *Gerodontology* 2012;**29**(2):e787–92.

Wefers 1999
Wefers KP. The 'Denture Hygiene Index' (DHI). *Dental Forum* 1999;**1**:13–5.

Wyatt 2002
Wyatt CC. Elderly Canadians residing in long-term care hospitals: Part II. Dental caries status. *Journal of the Canadian Dental Association* 2002;**68**(6):359–63.

* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE (OVID) Search Strategy

1. exp Nursing home/
2. Homes for the aged/
3. (home$ adj5 (nurs$ or elder$ or old$ or care or "assisted living" or convalescen$ or rest$ or retir$ or resident$ or "long stay" or longstay or "long term")).mp.
4. (facilit$ adj5 (nurs$ or elder$ or old$ or care or "assisted living" or convalescen$ or rest$ or retir$ or resident$ or "long stay" or longstay or "long term")).mp.
5. (institut$ adj5 (nurs$ or elder$ or old$ or care or "assisted living" or convalescen$ or rest$ or retir$ or resident$ or "long stay" or longstay or "long term")).mp.
6. (residenc$ adj5 (nurs$ or elder$ or old$ or care or "assisted living" or convalescen$ or rest$ or retir$ or "long stay" or longstay or "long term")).mp.
7. or/1-6
8. Oral health/
9. exp Stomatognathic diseases/
10. Halitosis/
11. ((dental or tooth or teeth or enamel or root$) and (decay$ or caries or carious or "white spot$" or plaque or reminerali$ or demineral$ or erosion$ or abrasion$ or wear)).mp.
12. (denture$ and (clean$ or clens$)).mp.
13. (periodont$ or gingivi$ or gingiva$).mp.
14. (stomatitis or "mouth ulcer$" or "oral ulcer$" or (oral adj5 candidi$) or (mouth$ adj5 candidi$) or "aphthous ulcer$" or (aphthae adj3 ulcer$) or (mucositis adj5 mouth$) or (mucositis adj5 oral) or xerostomi$ or "dry mouth$").mp.
15. ((oral adj5 health$) or (mouth adj5 health$) or (dental adj5 health$)).mp.
16. (halitosis or "mouth odour$" or "mouth odor$" or "mouth malodour$" or "mouth malodor$" or "oral malodour$" or "oral malodor$" or (breath adj5 malodour$) or (breath adj5 malodor$) or (breath adj5 odour$) or (breath adj5 odor$)).mp.
17. exp Mouth neoplasms/
18. (("oral cancer$" or (gingiv$or mouth or lip or lips or tongue$ or "salivary gland$" or palat$ or parotid$ or sublingual or submandibular)) and (cancer$ or carcinoma$ or neoplasm$ or tumour$ or tumor$ or lesion$ or malignan$)).mp.
19. leukoplak$.mp.
20. "hairy tongue$".mp.
21. exp Oral hygiene/
22. exp Mouthwashes/
23. exp Dentifrices/
24. ("oral hygiene" or (mouth$ adj3 care) or (dental adj3 care) or (care adj3 teeth) or (mouth$ adj3 hygiene) or (plaque adj3 control$) or (plaque adj3 remov$)).mp.
25. (toothbrush$ or tooth-brush$ or toothpaste$ or dentifrice$ or mouthwash$ or mouth-wash$ or mouthrinse$ or mouth-rinse$ or fluoride$).mp.
26. (floss$ or "interdental brush$" or "inter-dental brush$" or (tooth adj5 clean$) or (teeth adj5 clean$) or (denture$ adj5 hygien$) or (denture$ adj5 clean$) or (tongue$ adj5 scrap$) or (tongue$ adj5 brush$) or (chewing adj5 stick$) or (chewing adj5 gum$)).mp.
27. ((oral adj3 care) or (oral adj3 "self care")).mp.
28. or/8-27
29. Health education, dental/
30. exp Health promotion/
31. (instruct$ or advis$ or advice or educat$ or promot$ or teach$ or train$).mp.
32. ((demonstrat$ adj5 toothbrush$) or (demonstrat$ adj5 "tooth brush$") or (demonstrat$ adj5 tooth-brush$) or (demonstrat$ adj5 floss$) or (demonstrat$ adj5 "interdental brush$") or (demonstrat$ adj5 "inter-dental brush$") or (demonstrat$ adj5 "interdental clean$") or (demonstrat$ adj5 "inter-dental clean$") or (demonstrat$ adj5 wood-stick$) or (demonstrat$ adj5 woodstick$) or (demonstrat$ adj5 "wood stick$")).mp.
33. (demonstrat$ adj5 (denture$ adj3 (clean$ or clens$))).mp.
34. (supervis$ adj5 (denture$ adj3 (clean$ or clens$))).mp.

35. ((supervis$ adj5 toothbrush$) or (supervis$ adj5 "tooth brush$") or (supervis$ adj5 tooth-brush$) or (supervis$ adj5 floss$) or (supervis$ adj5 "interdental brush$") or (supervis$ adj5 "inter-dental brush$") or (supervis$ adj5 "interdental clean$") or (supervis$ adj5 "inter-dental clean$") or (supervis$ adj5 wood-stick$) or (supervis$ adj5 woodstick$) or (supervis$ adj5 "wood stick$")).mp.
36. (lecture$ or seminar$ or presentation$ or session$ or tutorial$ or video or audio or DVD or online or podcast$ or vodcast$).mp.
37. (leaflet$ or manual$ or book$ or pamphlet$ or brochure$).mp.
38. or/29-37
39. 7 and 28 and 38

The search will be linked with the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomised trials in MEDLINE: sensitivity maximising version (2008 revision) as referenced in Chapter 6.4.11.1 and detailed in box 6.4.c of the *Cochrane Handbook for Systematic Reviews of Interventions* version 5.1.0, updated March 2011 (Higgins 2011).
1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab.
5. drug therapy.fs.
6. randomly.ab.
7. trial.ab.
8. groups.ab.
9. or/1-8
10. exp animals/ not humans.sh.
11. 9 not 10

CONTRIBUTIONS OF AUTHORS

For the protocol:

- Martina Albrecht (MA) initially planned the review and has written the protocol with important contribution from Sascha Köpke (SK).
- Ramona Kupfer (RK), Daniel Reissmann (DR), Burkhard Haastert (BH), Ingrid Mühlhauser (IM) and SK commented on and approved the protocol.

For the review:

- MA and RK will contribute to all aspects.
- DR will provide specialist dental expertise.
- BH will provide statistical expertise.
- SK will provide methodological and specialist nursing expertise.
- IM will provide methodological expertise.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- Unit of Health Sciences and Education, University of Hamburg, Germany.
- Nursing Research Group, Institute for Social Medicine, University of Lübeck, Germany.

External sources

- Ministry of Education and Research, Germany.
- National Institute for Health Research (NIHR), UK.

CRG funding acknowledgement:
The NIHR is the largest single funder of the Cochrane Oral Health Group.
Disclaimer:
The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NIHR, NHS or the Department of Health.

- Cochrane Oral Health Group Global Alliance, UK.

All reviews in the Cochrane Oral Health Group are supported by Global Alliance member organizations (British Orthodontic Society, UK; British Society of Paediatric Dentistry, UK; Canadian Dental Hygienists Association, Canada; National Center for Dental Hygiene Research & Practice, USA; and New York University College of Dentistry, USA) providing funding for the editorial process (http://ohg.cochrane.org).

6.7 Albrecht M, Kupfer R, Reissmann DR, Mühlhauser I, Köpke S (2016): Oral health educational interventions for nursing home staff and residents. Cochrane Database of Systematic Reviews 2016, Issue 9. Art. No.: CD010535. DOI: 10.1002/14651858.CD010535.pub2.

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Oral health educational interventions for nursing home staff and residents.
Cochrane Database of Systematic Reviews 2016, Issue 9. Art. No.: CD010535.
DOI: 10.1002/14651858.CD010535.pub2.

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[Intervention Review]

Oral health educational interventions for nursing home staff and residents

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Editorial group: Cochrane Oral Health Group.
Publication status and date: New, published in Issue 9, 2016.
Review content assessed as up-to-date: 18 January 2016.

Citation: Albrecht M, Kupfer R, Reissmann DR, Mühlhauser I, Köpke S. Oral health educational interventions for nursing home staff and residents. *Cochrane Database of Systematic Reviews* 2016, Issue 9. Art. No.: CD010535. DOI: 10.1002/14651858.CD010535.pub2.

ABSTRACT

Background

Associations between nursing home residents' oral health status and quality of life, respiratory tract infections, and nutritional status have been reported. Educational interventions for nurses or residents, or both, focusing on knowledge and skills related to oral health management may have the potential to improve residents' oral health.

Objectives

To assess the effects of oral health educational interventions for nursing home staff or residents, or both, to maintain or improve the oral health of nursing home residents.

Search methods

We searched the Cochrane Oral Health Trials Register (to 18 January 2016), the Cochrane Central Register of Controlled Trials (CENTRAL) (the Cochrane Library, 2015, Issue 12), MEDLINE Ovid (1946 to 18 January 2016), Embase Ovid (1980 to 18 January 2016), CINAHL EBSCO (1937 to 18 January 2016), and Web of Science Conference Proceedings (1990 to 18 January 2016). We searched ClinicalTrials.gov and the World Health Organization International Clinical Trials Registry Platform for ongoing trials to 18 January 2016. In addition, we searched reference lists of identified articles and contacted experts in the field. We placed no restrictions on language or date of publication when searching the electronic databases.

Selection criteria

Randomised controlled trials (RCTs) and cluster-RCTs comparing oral health educational programmes for nursing staff or residents, or both with usual care or any other oral healthcare intervention.

Data collection and analysis

Two review authors independently screened articles retrieved from the searches for relevance, extracted data from included studies, assessed risk of bias for each included study, and evaluated the overall quality of the evidence. We retrieved data about the development and evaluation processes of complex interventions on the basis of the Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare: revised guideline (CReDECI 2). We contacted authors of relevant studies for additional information.

Main results

We included nine RCTs involving 3253 nursing home residents in this review; seven of these trials used cluster randomisation. The mean resident age ranged from 78 to 86 years across studies, and most participants were women (more than 66% in all studies). The proportion of residents with dental protheses ranged from 62% to 87%, and the proportion of edentulous residents ranged from 32% to 90% across studies.

Eight studies compared educational interventions with information and practical components versus (optimised) usual care, while the ninth study compared educational interventions with information only versus usual care. All interventions included educational sessions on oral health for nursing staff (five trials) or for both staff and residents (four trials), and used more than one active component. Follow-up of included studies ranged from three months to five years.

No study showed overall low risk of bias. Four studies had a high risk of bias, and the other five studies were at unclear risk of bias.

None of the trials assessed our predefined primary outcomes 'oral health' and 'oral health-related quality of life'. All trials assessed our third primary outcome, 'dental or denture plaque'. Meta-analyses showed no evidence of a difference between interventions and usual care for dental plaque (mean difference -0.04, 95% confidence interval (CI) -0.26 to 0.17; six trials; 437 participants; low quality evidence) or denture plaque (standardised mean difference -0.60, 95% CI -1.25 to 0.05; five trials; 816 participants; low quality evidence). None of the studies assessed adverse events of the intervention.

Authors' conclusions

We found insufficient evidence to draw robust conclusions about the effects of oral health educational interventions for nursing home staff and residents. We did not find evidence of meaningful effects of educational interventions on any measure of residents' oral health; however, the quality of the available evidence is low. More adequately powered and high-quality studies using relevant outcome measures are needed.

PLAIN LANGUAGE SUMMARY

Education for nursing home staff and/or residents to improve residents' oral health

Review question

We reviewed the evidence about the effectiveness of oral health education for nursing staff or nursing home residents compared to usual care for improving residents' oral health.

Background

Nursing home residents are often unable to carry out proper oral care, which is an important factor in maintaining the health of the mouth, teeth, and gums. Nursing home staff may not be prepared to provide adequate care. Therefore, oral health care education for residents and/or nursing staff may be one strategy to improve this situation.

Study characteristics

We searched for relevant studies that had been conducted up until January 2016 and identified nine trials involving a total of 3253 nursing home residents. The average age of residents across the studies ranged from 78 to 86 years. In all of the studies most of the people taking part had dentures (between 62% and 87%).

The trials evaluated a variety of approaches including educational programmes, skills training, and written information material. Topics included dental issues that were particularly relevant for older people such as care of dentures and covered dental and oral diseases, prevention of oral diseases, dental hygiene tools, and oral health care guidelines. The length of the trials ranged from three months to five years.

Key results

We could not identify a clear benefit of training of nurses and/or residents on residents' dental health as assessed by dental and denture plaque. No study assessed oral health, oral health-related quality of life or adverse events. As education programmes were not fully described, results do not allow for clear conclusions about the effectiveness or potential harm of specific oral health education interventions in nursing homes.

Quality of the evidence

Overall, there was a low quality of information from the studies regarding all of the results. We conclude that there is a need for clinical trials to investigate the advantages and harms of oral health educational programmes in nursing homes.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

Oral health education for nursing home staff and residents (with information and practical components) compared to usual care

Patient or population: nursing home residents
Settings: nursing homes
Intervention: oral health education (with information and practical components)
Comparison: usual care

Outcomes	Illustrative comparative risks (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Usual care	Oral health education (with information and practical components)				
Oral health-related quality of life	-	-	-	-	-	Outcome not reported
Oral health	-	-	-	-	-	Outcome not reported
Dental plaque Plaque Index, Oral Hygiene Index, Geriatric Simplified Debris Index (all scales scoring 0 to 3) Follow-up: 3 to 60 months	Mean dental plaque scores in control groups ranged from 0.29 to 2.18 (0 to 3 scale)	Mean difference **0.04 lower** (95% CI 0.26 lower to 0.17 higher)	See comment	437 (6 RCTs)	⊕⊕◯◯ **low**[1,2]	Information from 2 further studies was not available for meta-analysis A lower score indicates less plaque.
Denture plaque Denture Plaque Index (scoring 0 to 3) and method of Augsburger (scoring 0 to 4) Follow-up: 3 to 60	See comment	Standardised mean difference **0.60 lower** (95% CI 1.25 lower to 0.05 higher)	See comment	816 (5 RCTs)	⊕⊕◯◯ **low**[1,2]	Different outcome scales used Information from another study was not available for meta-anal-

months					ysis
Gingivitis Gingival Bleeding Index and method of Suomi Follow-up: 3 to 6 months			245 (3 RCTs)	⊕⊕◯◯ **low**[1,3]	No meta-analysis (data not comparable). 3 studies at unclear risk of bias showed inconsistent results
Denture-induced stomatitis Method of Budtz-Jørgensen Follow-up: 6 to 18 months			417 (2 RCTs)	⊕⊕◯◯ **low**[1,3]	No meta-analysis (data not comparable). 2 studies at unclear, in Frenkel 2001, or high risk of bias, in Mojon 1998, showed no apparent differences at short-term, in Frenkel 2001, or long-term follow-up (Mojon 1998).
Caries/root caries Follow-up: 6 to 18 months			178 (2 RCTs)	⊕⊕◯◯ **low**[1,3]	2 studies at unclear, in Frenkel 2001, or high risk of bias, in Mojon 1998, showed no apparent differences at short-term, in Frenkel 2001, or long-term follow-up (Mojon 1998).

CI: confidence interval; **RCT:** randomised controlled trial

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1]Downgraded one level due to serious risk of bias.
[2]Downgraded one level due to inconsistency (heterogeneity): I^2= 66% and 92%.

[3]Downgraded one level due to inconsistency (clinical heterogeneity).

BACKGROUND

Description of the condition

The demographic shift in high-income countries as people live longer has important implications for healthcare services. There are and will be more elderly people with important morbidity and care dependency (Branca 2009), and an increasing number of nursing home residents. Whereas, until recently, most nursing home residents were provided with dentures, now a larger number of residents retain a considerable number of natural teeth (Hopcraft 2012; Porter 2015; Samson 2008). Declining rates of edentulism (having no teeth) have important implications for oral health and oral health management of these residents, as a greater proportion will have teeth at risk of dental caries and periodontal disease. Additionally, high-quality and complex dental prostheses (i.e. implants, bridges, and removable dental prostheses) must be maintained. Nursing home residents are often unable to carry out adequate oral care, such as optimal removal of dental plaque. Continuous preventive and curative oral health care provided by trained staff therefore seems increasingly important. In nursing homes, nursing staff and other caregivers play a crucial role in the provision of daily oral health care (Porter 2015), as well as in initiating and organising routine prophylaxis and treatment by dental professionals (Nitschke 2010).

In the past, it was reported that nursing staff frequently do not acknowledge the importance of oral health and lack knowledge about how to achieve it (Glassman 1994). Some more recent studies have suggested knowledge about oral hygiene is still inadequate among nursing staff (Jablonski 2009; Wardh 2012), and that there is a large discrepancy between the proposed need for assistance with daily oral hygiene among nursing home residents and the actual assistance provided by nursing staff (Forsell 2009). In addition to dependence, some people with dementia exhibit unco-operative or disruptive behaviour during helping interactions. These behaviours range from mild (e.g. turning the head away) to extreme resistance (e.g. hitting the nursing staff) (Jablonski 2009). This so-called care-resistant behaviour is a common phenomenon encountered by nursing staff during the provision of oral care (Frenkel 1999; Jablonski 2011).

Measures of poor oral health (e.g. gingivitis, caries, and chewing difficulties), along with discomfort and pain, have been reported for nursing home residents in different countries (De Visschere 2006; Gluhak 2010; Hopcraft 2012; Simunković 2005; Wyatt 2002). Dental plaque generally leads to an increased risk for dental caries, gingivitis, and periodontitis, as well as other infections in the oral cavity.

In addition, poor oral hygiene and poor dental status among elderly people are associated with reduced quality of life (Porter 2015; Walker 2007). Elderly people in day care have shown considerably higher levels of oral health problems compared to community-dwelling elderly (Walker 2007), due to difficulties in maintaining a sufficient level of oral hygiene and in accessing professional dental care (Forsell 2009). Two-thirds of elderly people living in residential facilities use dental services only in the case of dental problems and on demand (De Baat 1993; Isaksson 2007). In a British study, 70% of residents had not seen a dentist for more than five years (Frenkel 2000).

The accumulation of micro-organisms on teeth and denture surfaces, caused by lack of oral hygiene, may influence residents' general health by causing pneumonia, arteriosclerosis, and infection-related disorders (Azarpazhooh 2006; Desvarieux 2003; Scannapieco 2003; Shay 2002). Evidence from randomised controlled trials (RCTs) suggests positive preventive effects of oral care on respiratory tract infection and pneumonia in nursing home residents (El-Rabbany 2015; Sjögren 2008).

Furthermore, poor oral health has been associated with involuntary weight loss (Mojon 1999; Sheiham 2001). Institutionalised elderly people who suffer from oral discomfort, problems with chewing or swallowing, compromised dentition, or poorly fitted dentures have a higher incidence of nutritional deficiency (Saarela 2014; Saunders 2007).

Consequently, interventions to improve oral health seem warranted, as they possibly yield a number of positive effects including improved nutritional status and health-related quality of life (Naito 2010).

Description of the intervention

In the context of this review, we have defined oral health-related educational interventions as programmes that facilitate knowledge and skills acquisition in nursing home staff and/or residents to maintain or improve oral health, using a variety of formats (e.g. lectures, demonstrations, practical education). Programmes may target nursing home residents, staff, or both and may be provided to individuals or groups.

Interventions are usually complex, consisting of several different components. Three commonly included components included are:

1. theoretical education for staff or residents, or both aiming at improving knowledge of oral health and oral health care;
2. staff training (practical education) on examination and cleansing of the mouth or dentures, or both of residents; and
3. oral hygiene skills training for residents.

How the intervention might work

In general, the goal of educational interventions is to improve oral and dental health of residents by increasing knowledge and skill levels of nursing home staff or nursing home residents, or both. Interventions targeting nursing home residents, especially oral hygiene skills training, may foster the ability to self perform dental care and thus decrease the need for assistance. There may also

be direct effects of education on residents' attitudes as well as on quality of life.

Interventions targeting nursing home staff will strengthen staff expertise in oral care for residents. Furthermore, staff attitude and self efficacy will be influenced, leading (together with improved knowledge and skills) to improved oral health-related behaviour and, as a consequence, improved oral health outcomes for residents.

Why it is important to do this review

The Cochrane Oral Health Group undertook an extensive prioritisation exercise in 2014 to identify a core portfolio of titles that were the most clinically important ones to maintain on the Cochrane Library (Worthington 2015). This review was identified as a priority title by the dental public health expert panel (Cochrane OHG priority review portfolio).

At the time of protocol preparation, there were no systematic reviews available summarising the effects of providing oral healthcare education to nursing home staff and/or residents. In 2014, a systematic review on oral healthcare education was published, which included two RCTs, one non-randomised study, and three cross-sectional studies (De Lugt-Lustig 2014). The authors concluded that oral healthcare education for nursing staff may have a positive effect on attitudes and oral healthcare knowledge of nurses in nursing homes and on oral hygiene of residents. Meta-analyses by Wang 2015 including one RCT and four before-and-after studies also found limited evidence that education for caregivers is effective in improving oral health. However, both reviews only focused on educational interventions for nursing staff or caregivers. De Lugt-Lustig 2014 disregarded any educational interventions considering nursing home residents as recipients, whereas Wang 2015 excluded education for residents only. In addition, a further systematic review, Weening-Verbree 2013, which included a broad range of study designs, concluded that knowledge, self efficacy, and facilitation of behaviour are determinants that are used in successful implementation strategies. Taking into account the heterogeneity of studies, the authors were not able to recommend a single strategy or combination of strategies for improving oral health in institutionalised elderly. Furthermore, they highlighted the importance of considering contextual factors (e.g. setting) when choosing implementation strategies. A high-quality systematic review considering the growing number of RCTs published in recent years and describing the components of interventions was therefore warranted. This systematic review may impact the implementation of different approaches and trigger the development of new interventions on the basis of current best evidence.

OBJECTIVES

To assess the effects of oral health educational interventions for nursing home staff or residents, or both, to maintain or improve residents' oral health.

To describe the components of the complex interventions used in the included studies.

METHODS

Criteria for considering studies for this review

Types of studies

We included individually randomised controlled trials (RCTs) or cluster-RCTs with a follow-up period of at least two weeks including groups of nursing home staff or residents, or both allocated either to:

- a programme aiming to maintain or improve oral health of nursing home residents by one or more oral health educational and/or oral hygiene promotion interventions (the intervention group); or
- (optimised) regular dental care or any other oral healthcare intervention (the control group). Optimised care means that the control group receives an additional component in addition to usual standardised care, e.g. provision of dental care auxiliaries or informative presentations.

We considered additional publications on development and piloting of complex interventions as well as process evaluations, without focusing on specific study designs, in order to capture single components of the complex interventions and contextual factors.

Types of participants

We considered male and female residents living in facilities providing supervision or nursing care for the elderly (e.g. nursing homes or long-term care facilities) for inclusion. The majority of residents in a study had to be over the age of 64 years, or the mean age had to be at least 65 years. We also included nursing staff working in these facilities or a combination of residents and nursing staff. We included all participants involved in the primary studies (i.e. irrespective of residents' oral health status or qualifications of the nursing staff).

Types of interventions

We included any trial of an intervention or group of interventions where participants or clusters were allocated to receive an oral health education programme versus (optimised) usual oral health care, or any other oral healthcare intervention.

Oral health education programmes include either direct-to-staff programmes, direct-to-resident programmes (e.g. oral hygiene

promotion or skills training), or a combination of both. We expected approaches to vary, for example in terms of frequency, length, and content, with the educational content likely to include some or all of the following: oral health, oral diseases and impact on general health, diet, oral hygiene measures, best oral care practices for elderly people with natural dentition and dentures, oral hygiene promotion, and skills training.

We expected some interventions to be designed as complex interventions comprising more than one of the components outlined above. Following the 'framework for design and evaluation of complex interventions', it may not be possible to extract the effective or ineffective components of the interventions (Campbell 2000; Craig 2008), but components of included programmes were collected and described in detail as suggested by Lenz 2007.

We considered interventions without educational or oral hygiene promotion components only as controls. In addition, we considered sole organisational interventions aiming to change organisational policies, for example through introduction of practice guidelines, oral health co-ordinators, regular visits by a dentist or dental hygienist for professional oral care and examination, or regular visits of residents in dental surgeries, only as controls. The same applied to exclusive oral hygiene interventions (e.g. the provision of chemical topical interventions and mechanical auxiliaries).

Types of outcome measures

Primary outcomes

1. Oral health-related quality of life: measured by instruments such as Oral Health Impact Profile (OHIP) or OHIP-14 (Slade 1994; Slade 1997), Geriatric/General Oral Health Assessment Index (GOHAI) (Atchison 1990), Dental Impact Profile (DIP) (Strauss 1993).
2. Oral health: oral health was defined as a functional, structural, aesthetic, physiologic, and psychosocial state of well-being assessed by an instrument such as Brief Oral Health Status Examination (BOHSE) or Oral Health Assessment Tool (OHAT) that covers different oral hygiene categories (Chalmers 2005; Kayser-Jones 1995).
3. Dental health: dental health comprises only one aspect of oral health, such as:

i) dental or denture plaque, or both: measured by plaque scores and denture cleanliness scores (scales) such as Plaque Index (Silness 1964), Mucosal-Plaque Index (MPS) (Henriksen 1999), or Denture Plaque Index (Wefers 1999);

ii) gingivitis or denture-induced stomatitis: measured by instruments such as Gingival Bleeding Index (GBI) (Ainamo 1975), Gingival Index (Löe 1967), or Community Periodontal Index (Benigeri 2000); or

iii) caries, incidence of new caries.

Secondary outcomes

1. Nutritional status (e.g. body weight, Body Mass Index (BMI)).
2. Incidence of respiratory diseases and pneumonia.
3. Adverse effects of the interventions.

Intermediate outcomes

1. Oral health-related knowledge of staff or residents, or both: measured by any instruments used in the included studies (e.g. questionnaire or interview).
2. Oral health-related attitude and behaviour of staff or residents, or both: measured by any instruments used in the included studies (e.g. questionnaire or interview).

Search methods for identification of studies

We developed detailed search strategies for each database to identify studies for inclusion in the review. These were based on the search strategy developed for MEDLINE Ovid but revised appropriately for each database. The search strategy used a combination of controlled vocabulary and free-text terms and was linked with the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying RCTs in MEDLINE: sensitivity-maximising version (2008 revision) as referenced in Section 6.4.11.1 and detailed in box 6.4.c of the *Cochrane Handbook for Systematic Reviews of Interventions* (Lefebvre 2011). Details of the MEDLINE search are provided in Appendix 3. The searches of EMBASE and CINAHL were linked to Cochrane Oral Health's filters for identifying RCTs.

Electronic searches

We searched the following electronic databases:

- Cochrane Oral Health Trials Register (to 18 January 2016) (see Appendix 1);
- Cochrane Central Register of Controlled Trials (CENTRAL; 2015, Issue 12) in the Cochrane Library (searched 18 January 2016) (see Appendix 2);
- MEDLINE Ovid (1946 to 18 January 2016) (see Appendix 3);
- Embase Ovid (1980 to 18 January 2016) (see Appendix 4);
- CINAHL EBSCO (Cumulative Index to Nursing and Allied Health Literature; 1937 to 18 January 2016) (see Appendix 5);
- Web of Science Conference Proceedings (1990 to 18 January 2016) (see Appendix 6).

We placed no restrictions on language or date of publication when searching the electronic databases.

Searching other resources

We searched the following databases for ongoing trials:

- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (clinicaltrials.gov; searched 18 January 2016) (see Appendix 7);
- World Health Organization International Clinical Trials Registry Platform (apps.who.int/trialsearch; searched 18 January 2016) (see Appendix 8).

We examined the reference lists of published reviews and contacted experts in the field to identify unpublished or ongoing studies. We did not perform a separate search for adverse effects of interventions, considering the adverse effects described in included studies only.

Data collection and analysis

Selection of studies

Two review authors (MA and RK) independently screened the titles and abstracts of citations identified by the search and independently assessed articles for inclusion according to the above criteria. We resolved disagreements by discussion.

Data extraction and management

Pairs of review authors (MA, RK, SK) independently extracted data using a piloted standardised data collection sheet. These data were entered into Review Manager 5 software (RevMan 2014). The review authors were not blinded to authors of included studies. The two review authors resolved disagreements by discussion or, if necessary, by consulting a third review author in order to reach consensus. Data were sought per participant or randomised cluster (nursing home) on all outcome measures of interest for all assessment points (including baseline). We extracted data for characteristics of participants, baseline data, interventions, duration of intervention, length of follow-up, outcome measures, and adverse events.

We retrieved data on research processes of the development, piloting, and evaluation of the complex interventions on the basis of Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare: revised guideline (CReDECI 2) (Möhler 2015). Criteria comprise developmental details like the description and intensity of the components, feasibility, and piloting, as well as evaluation of the complex intervention. We also extracted data on the fidelity of the intervention implementation. If, as was frequently the case, no sufficient information on the above-mentioned issues was available from included publications, we attempted to obtain additional information by contacting authors of the primary studies (e.g. by asking about related publications). Following earlier suggestions (Lenz 2007), we performed additional extra searches for publications related to included studies.

Assessment of risk of bias in included studies

Our assessment of risk of bias followed the guidance in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). Two review authors (MA, RK) independently assessed and scored studies in order to identify any potential sources of systematic bias through selection bias, performance bias, attrition bias, or detection bias as recommended in the *Cochrane Handbook* addressing six domains (sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting, and other issues). We assigned a judgement concerning the related risk of bias for each domain, either 'low risk', 'high risk', or where insufficient information was available to make a judgement, 'unclear risk'. In addition, we assessed recruitment bias for cluster-randomised trials, that is whether individuals were recruited after clusters had been randomised. We completed a 'Risk of bias' table for each included study and presented the results graphically.

Measures of treatment effect

For continuous data (e.g. plaque indices), we used the mean difference (MD) and its corresponding 95% confidence interval (CI) if the same instrument was used, or the standardised mean difference (SMD) if different instruments were used for the same outcome measure. For dichotomous data (e.g. incidence of respiratory disease), we used risk ratio (RR). We sought and recorded the absolute numbers in each group and the numbers experiencing the outcome of interest.

Unit of analysis issues

For each study we considered whether groups of individuals were randomised in clusters or individually, whether individuals underwent more than one intervention, and whether there were multiple observation times for the same outcome. As results from more than one time point per study cannot be combined in meta-analysis, depending on the reported follow-up periods of included studies, we performed subgroup analyses for studies with short-term and long-term follow-up (Higgins 2011), only using the longest. For cluster RCTs we checked whether results were cluster-adjusted. For combined meta-analyses of individual and cluster-RCTs, we estimated 'effective sample sizes' for cluster-RCTs as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Sections 16.3.4 to 16.3.7) (Higgins 2011). We aimed to use intraclass correlation coefficients (ICC) as reported in included studies. As no ICCs were reported in included studies, or values seemed unrealistically high, we considered a conservative estimate of ICC = 0.05 based on experience from studies on caries (personal communication with Cochrane Oral Health).

Dealing with missing data

Where data were missing from the published report of a trial, we contacted authors to obtain the data and to clarify any uncertainties. Analyses included only available data (ignoring missing data). However, we used methods for estimating missing standard deviations if necessary (Higgins 2011). Otherwise, we did not undertake any imputation techniques or use statistical methods to account for missing data.

Assessment of heterogeneity

We assessed heterogeneity statistically and quantified it among trials included in each analysis using the I^2 statistic. We followed the guidance of the *Cochrane Handbook* to interpret the I^2 statistic, with I^2 greater than 50% representing substantial heterogeneity and greater than 75% representing considerable heterogeneity (Higgins 2011). To assess clinical heterogeneity, we analysed all studies in terms of interventions, participants, and outcomes.

Assessment of reporting biases

In order to minimise the risk of publication bias, we performed comprehensive searches in multiple databases, including searching for unpublished studies. Due to the small number of included trials, we did not use a funnel plot to assess the likelihood of publication bias.

Data synthesis

We grouped studies according to interventions. For each intervention type, we performed meta-analyses if we considered the studies to be reasonably clinically and methodologically homogeneous. We used random-effects models for all analyses.

Subgroup analysis and investigation of heterogeneity

We conducted the following subgroup analyses for the outcomes dental and denture plaque:

- intervention recipient (nursing staff only versus nursing staff and residents);
- follow-up period (short term versus long term);
- education in the context of guideline implementation versus education without guideline implementation.

Sensitivity analysis

We performed no sensitivity analyses.

Presentation of main results

We have displayed results in a 'Summary of findings' table for the primary outcomes, using GRADEpro software (GRADE 2014), according to the methods outlined in the *Cochrane Handbook* (Section 11.5) (Higgins 2011). We assessed the quality of the evidence with reference to overall risk of bias of included studies, directness of the evidence, consistency of results, and precision of estimates. We categorised the quality of the evidence for each of the primary outcomes as high, moderate, low, or very low.

RESULTS

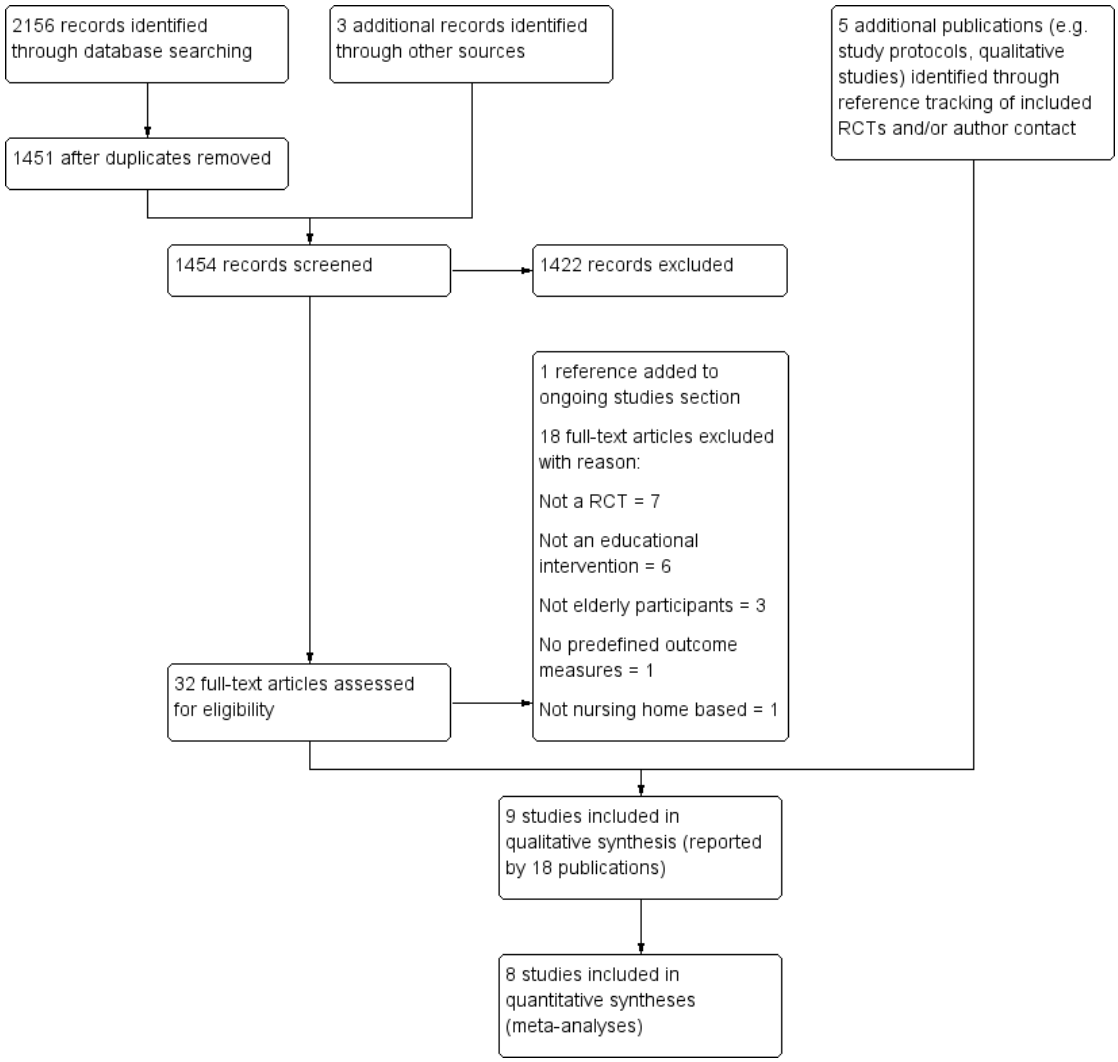
Description of studies

See Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing studies.

Results of the search

We screened a total of 1454 abstracts for inclusion (Table 1; Figure 1), and assessed 37 publications in full text. Eighteen publications reporting nine trials fulfilled the eligibility criteria (Bellomo 2005; De Visschere 2011; De Visschere 2012; Frenkel 2001; MacEntee 2007; Mojon 1998; Schou 1989; Van der Putten 2013; Zenthöfer 2013).

Figure 1. Study flow diagram



Included studies

We included two individual RCTs, Bellomo 2005 and Zenthöfer 2013, and seven cluster-RCTs (De Visschere 2011; De Visschere 2012; Frenkel 2001; MacEntee 2007; Mojon 1998; Schou 1989; Van der Putten 2013), with a total of 3253 nursing home residents as participants.

Funding sources

All but two studies stated information about any kind of funding, for example financial or material support (Bellomo 2005; Schou 1989). One of these studies stated that they received funding for data collection from a commercial source (De Visschere 2011). One study received support from a commercial source in the form of free oral healthcare material (Zenthöfer 2013). Two studies obtained grants from non-commercial sources (Frenkel 2001; MacEntee 2007). The remaining three studies received grants from non-commercial sources as well as free oral hygiene products from commercial sources (De Visschere 2012; Mojon 1998; Van der Putten 2013).

Setting

All studies were based in nursing homes. However, in Schou 1989, the included institutions were described as "institutions for el-

derly". MacEntee 2007 only recruited intermediate-care residents. In Zenthöfer 2013, participants were recruited from institutions for elderly (including assisted accommodation). All of the studies except MacEntee 2007 were conducted in Europe.

Recipients of the educational intervention

In five studies, the target groups of the educational interventions were nursing home staff (De Visschere 2011; De Visschere 2012; Frenkel 2001; MacEntee 2007; Van der Putten 2013). More precisely, two studies aimed to include solely nursing staff (Frenkel 2001; MacEntee 2007), and three studies focused on managerial and nursing staff (De Visschere 2011; De Visschere 2012; Van der Putten 2013). Four studies examined interventions that comprised components for both nursing home staff and residents (Bellomo 2005; Mojon 1998; Schou 1989; Zenthöfer 2013).

The mean resident age ranged from 78.3 to 86.0 years across studies. Most participants were women (more than 66% in all studies). The proportion of residents with dental prostheses ranged from 62.1% to 87.3% across studies. Mean number of natural teeth varied between 4.7 and 17.4 at baseline, and the proportion of edentulous residents had a wide range, from 32.4% to 89.9% (see Characteristics of included studies). Two studies reported information about cognitive status or mental health, or both (De Visschere 2012; Van der Putten 2013). In four studies, cognitive impairment or dementia, or both was an exclusion criterion (Frenkel 2001; MacEntee 2007; Mojon 1998; Zenthöfer 2013). In De Visschere 2012, cognitive impairment tested by the Mini Mental State Examination (MMSE less than 26) was present in 86.5% of the sample. In Van der Putten 2013, 47% of participants in the intervention group and 58% in the control group had a diagnosis of dementia.

Some information on characteristics of participating nursing staff was reported in all studies except Bellomo 2005 and Schou 1989. The two studies examining knowledge and attitudes of nursing staff reported the most detailed description of the characteristics of the employed nursing staff (De Visschere 2012; Frenkel 2001). In both studies, approximately 95% of nursing staff were female. In Frenkel 2001, the median length of work experience was four years, and about 67% reported attending a dentist at least once a year. In De Visschere 2012, nursing staff had been employed for a mean of 13.5 years; 62% were nurses and 38% auxiliary nurses. About 78% reported attending a dentist at least once a year. In addition, this study provided detailed information about the amount and numbers of staff members with previous education or skills training in oral health care. Five studies included nurses as well as nurse assistants (De Visschere 2011; De Visschere 2012; Mojon 1998; Van der Putten 2013; Zenthöfer 2013). Five studies reported the number or proportion of intervention group staff attending the educational sessions. In Frenkel 2001, 65.6% of caregivers attended the educational session. In MacEntee 2007, the proportion of care-aides attending the educational session in the intervention group and control group was 15% and 22%, respectively. De Visschere 2012 reported a 100% response rate (8 to 12 people per home). In Mojon 1998, the education course was attended by 76% of the caregivers. In Zenthöfer 2013, the number ranged from 20 to 40 people per nursing home.

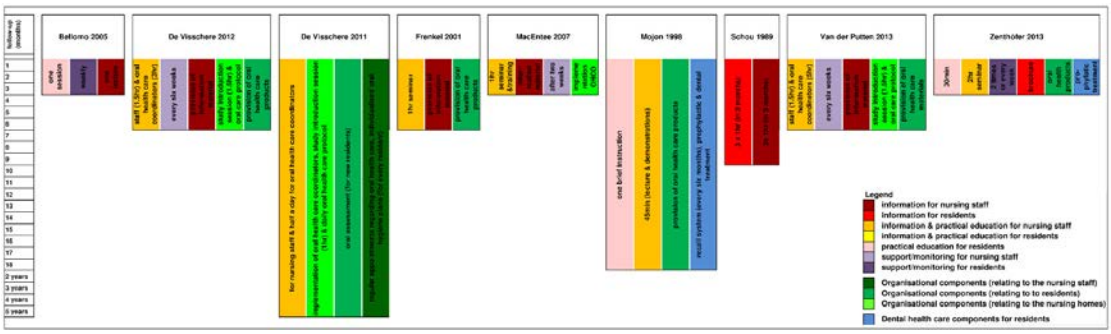
Duration of follow-up

Follow-up for six studies ranged from three months, in Bellomo 2005, MacEntee 2007, and Zenthöfer 2013, to six months (De Visschere 2012; Frenkel 2001; Van der Putten 2013); we categorised this as short term. Follow-up for three studies ranged from nine months, in Schou 1989, to five years (De Visschere 2011); we categorised this as long term.

Description of interventions

Studies differed in terms of intervention components as well as target groups. In all studies, the oral health educational intervention consisted of more than one component (see Figure 2). In all but one study (Bellomo 2005), nursing staff participated in one or more educational sessions. In eight studies, the intervention comprised education including theoretical information and skills training (Bellomo 2005; De Visschere 2011; De Visschere 2012; Frenkel 2001; MacEntee 2007; Mojon 1998; Van der Putten 2013; Zenthöfer 2013). In one study (Schou 1989), the educational intervention focused solely on theoretical information.

Figure 2. Intervention components



Educational interventions with information and practical components (n = 8)

In Bellomo 2005, the long-term care home residents received occupational therapy instruction on tooth and denture brushing. In addition, a subgroup of residents needing assistance were monitored weekly and, if necessary, re-educated by an occupational therapist. De Visschere 2011 implemented a daily oral hygiene protocol. The implementation process included a half-day theoretical and practical educational session for oral health co-ordinators who had to educate the other nursing staff and prepare individualised oral hygiene plans for all residents. In two studies, the supervised implementation of an oral health guideline for older people in long-term care institutions included theoretical and practical education sessions ranging from one to two hours for several groups of nursing home staff, using a train-the-trainer concept, and a daily oral healthcare protocol (De Visschere 2012; Van der Putten 2013). In Frenkel 2001, care assistants were educated by an experienced health promoter in a one-hour session that consisted of a theoretical section on the role of plaque, oral diseases and a practical section with oral hygiene skills training. MacEntee 2007 used a "pyramidal education" approach to train the nursing staff of the intervention homes. Initially, a permanent member of the nursing staff was trained and installed as a nursing educator, who then trained the care-aides in a single one-hour seminar, which included a theoretical section (photographs and texts) and demonstrations of how to examine and clean the mouth. In addition, the nurse educators had to manage the oral health care provided by the care-aides and were supported by the dental hygienist on request. In Mojon 1998, nursing staff took part in an interactive lecture (45 minutes) with slides and demonstration of brushing techniques. Every nurse or nurse aide received personalised oral hygiene instructions for their residents from a dental hygienist. Also, residents received brief (personalised) oral hygiene instructions from a dental hygienist. In addition, for residents, dental or prophylactic treatment including scaling at the start of the study and the implementation of a recall system were applied in the intervention group. In Zenthöfer 2013, the basic intervention for the three intervention groups consisted of a two-hour session (PowerPoint presentation, a film) with dental demonstration models to train nursing staff. Residents received instruction and training on oral hygiene skills according to their specific needs. The residents of two of the three intervention groups were supported either by a dentist (re-instruction and motivation after four and eight weeks) or by caregivers (provision of help twice a week using a standardised procedure). In addition, professional cleaning of dentures and teeth was performed for all intervention groups at the beginning.

Additional informational material on oral health and hygiene was provided to trained staff in four studies (De Visschere 2012; Frenkel 2001; MacEntee 2007; Van der Putten 2013) and to residents in one study (Zenthöfer 2013). Toothbrushes and/or other oral healthcare products were provided for intervention group residents in four studies (De Visschere 2012; Frenkel 2001; Mojon 1998; Van der Putten 2013).

Educational interventions with information only (n = 1)

Schou 1989 only used education without further practical components. Nursing staff and residents took part in a dental health education programme using the "active involvement principle". Each intervention group (one for residents only, one for nursing staff only, and a combined one) met three times for one hour in a monthly interval to talk about dental health and individual experiences with oral health prevention procedures. Sessions were conducted by a dental hygienist who planned the content of the sessions in co-operation with the participants.

Theoretical basis for intervention

Five studies provided at least some information on the interventions' theoretical background. MacEntee 2007 based the intervention on a "pyramidal scheme" that evolved from the "helper principle" (Jones 1977; Riessman 1965). Schou 1989 used the "active involvement principle" for the dental education programme, which

had been examined with positive results in another population (Schou 1985). Frenkel 2001 did not mention underlying theories, but based the intervention on previous research and her own qualitative study (Frenkel 1999). Two studies used a guideline implementation theory (De Visschere 2012; Van der Putten 2013). In four studies, no theoretical basis was mentioned (Bellomo 2005; De Visschere 2011; Mojon 1998; Zenthöfer 2013).

Content

Instructions and training of oral hygiene skills for residents included brushing techniques (tooth and dentures) (Bellomo 2005; Mojon 1998; Zenthöfer 2013), and in some cases also handling of tooth/interdental space brushes, and advice on other auxiliaries, for example mouth rinses (Zenthöfer 2013). Training or demonstrations for nursing staff covered the same aspects (De Visschere 2011; De Visschere 2012; Frenkel 2001; MacEntee 2007; Van der Putten 2013).

The theoretical sessions covered the following topics:

- specifics of gerodontology/geriatric dentistry (e.g. MacEntee 2007; Zenthöfer 2013);
- dental and oral diseases (e.g. Frenkel 2001; MacEntee 2007; Zenthöfer 2013);
- prevention of oral diseases (e.g. Mojon 1998);
- dental hygiene auxiliaries and handling (e.g. Frenkel 2001; MacEntee 2007; Mojon 1998; Zenthöfer 2013);
- handling of removable dentures (e.g. Zenthöfer 2013);
- oral healthcare guideline or daily oral healthcare protocol, or both (De Visschere 2011; De Visschere 2012; Van der Putten 2013).

Educators

The educational sessions for nursing staff were given by dentists (Zenthöfer 2013), dental hygienists (MacEntee 2007; Mojon 1998; Schou 1989), trained nursing staff (so-called oral health co-ordinators, ward oral healthcare organisers, nurse educators) (De Visschere 2011; De Visschere 2012; MacEntee 2007; Van der Putten 2013), and health promoters (Frenkel 2001). In studies that used a pyramidal or train-the-trainer concept, a combination of the aforementioned professions was involved in the educational components (De Visschere 2011; De Visschere 2012; MacEntee 2007; Van der Putten 2013).

Oral hygiene education or skills training for residents was provided by different professions including dental hygienists and occupational therapists (Bellomo 2005; Schou 1989; Zenthöfer 2013). Instructions on oral hygiene to nursing home residents were provided individually (Mojon 1998; Zenthöfer 2013).

Presentation mode

Seven studies made use of more than one presentation mode for educational sessions. Four studies combined theoretical and practical sections for the educational sessions (Frenkel 2001; MacEntee 2007; Mojon 1998; Zenthöfer 2013). Three studies used a combination of oral presentations, lectures, PowerPoint presentations, and practical sessions of differing length (De Visschere 2011; De Visschere 2012; Van der Putten 2013).

Duration and frequency

Not all studies specified the duration and frequency of the educational interventions or their different components.

Zenthöfer 2013 reported the duration of oral health instructions or skills training for nursing home residents as 30 minutes. In Schou 1989, oral health education for residents comprised three one-hour sessions at monthly intervals. Re-instruction or re-education for residents took place weekly in Bellomo 2005. The frequency in Zenthöfer 2013 varied between the two intervention groups: residents received re-instruction twice a week or after four and eight weeks.

The reported session duration for nursing staff ranged from 45 minutes, in Mojon 1998, to three hours (Schou 1989). The length for the training sessions for oral health co-ordinators (train-the-trainer) varied from three to five hours and was not reported in two studies. The oral health co-ordinators were supported by a dental hygienist two weeks after study start, in MacEntee 2007, or every six weeks (De Visschere 2012; Van der Putten 2013).

Control groups

One study included a control intervention that was similar in time and effort to the active intervention (Bellomo 2005). In MacEntee 2007, the control group received the same seminar (with photographs, texts, demonstrations), but education was provided by the dental hygienist. In the other studies (De Visschere 2011; De Visschere 2012; Frenkel 2001; Mojon 1998; Schou 1989; Van der Putten 2013; Zenthöfer 2013), no intervention was offered to the control group. Four studies specified usual care. In two of these studies, usual care implied oral health care according to the unsupervised implementation of a guideline (De Visschere 2012; Van der Putten 2013). De Visschere 2011 used a control group with residents receiving usual oral care in control homes and another group with residents living in intervention homes, but who did not receive the intervention, and in Mojon 1998, usual care meant that prior to the study no oral hygiene care was provided by the caregivers on a regular basis; cleaning of the teeth only took place if requested by the dentist; and oral care was provided by a dentist only at request of the resident, family, or caregivers.

Measured outcomes

Oral health-related quality of life

None of the studies reported this outcome.

Oral health

None of the studies reported this outcome.

Dental health

This includes dental or denture plaque, inflammation of oral mucosa, and caries. The measures assessed and instruments used are shown in Table 2.

All studies except Schou 1989 provided information on assessment of dental plaque. Seven studies used a four-point (0 to 3) plaque scale based on the Plaque Index described by Silness 1964 (Bellomo 2005; De Visschere 2011; De Visschere 2012; Mojon 1998; Van der Putten 2013), or the (simplified) Oral Hygiene Index (OHI-S) by Greene 1964 (Frenkel 2001; MacEntee 2007). Six studies reported mean dental plaque, and one median dental plaque (Mojon 1998). In Zenthöfer 2013, dental plaque was assessed dichotomously using the "plaque-control record". We were able to meta-analyse up to six studies on dental plaque depending on subgroups (Bellomo 2005; De Visschere 2011; De Visschere 2012; Frenkel 2001; MacEntee 2007; Van der Putten 2013).

Seven studies reported on denture plaque (Bellomo 2005; De Visschere 2011; De Visschere 2012; Frenkel 2001; Schou 1989; Van der Putten 2013; Zenthöfer 2013). Denture plaque was assessed in four studies using a five-point scale (0 to 4) described by Augsburger 1982 (De Visschere 2011; De Visschere 2012; Van der Putten 2013), and in two studies using a four-point scale (0 to 3) described by Ambjørnsen 1982 (Bellomo 2005; Schou 1989). A further study used the Denture Hygiene Index to assess presence or absence of denture plaque (Zenthöfer 2013). The authors were unable to provide usable data, so we were unable to include results in meta-analyses (Zenthöfer 2013). We included data from five studies in meta-analyses comparing educational interventions including information and practical components with (optimised) usual care (Bellomo 2005; De Visschere 2011; De Visschere 2012; Frenkel 2001; Van der Putten 2013).

Five studies reported data on inflammation of oral mucosa such as gingivitis, in Frenkel 2001, MacEntee 2007, and Zenthöfer 2013, or denture stomatitis (Frenkel 2001; Mojon 1998; Schou 1989). Two studies assessed gingivitis dichotomously applying the Gingival Bleeding Index (MacEntee 2007; Zenthöfer 2013). Mean gingivitis scores were reported by Frenkel 2001 using the method of Suomi 1968. Denture stomatitis was classified and scored according to the erythema severity (Frenkel 2001; Mojon 1998; Schou 1989). Due to the fact that the studies used different outcomes and measures for inflammation of oral mucosa, we were unable to use the data for meta-analyses.

Two studies reported data on root caries (Frenkel 2001; Mojon 1998). In Frenkel 2001, root caries were assessed on a binary scale as absent/present and reported as median score. Mojon 1998 reported active root caries as percentage of the total number of natural teeth.

Nutritional status

Only one study reported clinical measures of nutritional status (MacEntee 2007). The BMI was determined for every resident and binarily coded, with a score of less than 23 suggesting undernourishment. The Malnutrition Indicator Score (range 0 to 30, higher scores indicate better nourishment) as part of the Mini Nutritional Assessment was assessed, and mean scores were reported.

Incidence of respiratory diseases and pneumonia

None of the studies reported this outcome.

Adverse effects

None of the studies reported this outcome.

Oral health-related knowledge

Two studies reported oral health-related knowledge of nursing staff (De Visschere 2012; Frenkel 2001), assessed by self administered questionnaires reporting true/false responses to 26 statements, in Frenkel 2001, or 15 statements, in De Visschere 2012. The authors of a further study confirmed that this outcome was measured, but data are currently unavailable (Van der Putten 2013). We were able to combine data of two studies on staff knowledge (De Visschere 2012; Frenkel 2001). None of the studies reported oral health-related knowledge of residents.

Oral health-related attitude

Three studies assessed oral health-related attitude of nursing staff (De Visschere 2012; Frenkel 2001; Van der Putten 2013). Self administered questionnaires were applied with four statements using a three-point Likert scale (De Visschere 2012; Van der Putten 2013), or with 25 statements using a five-point Likert scale (Frenkel 2001). We were able to combine the data of two studies (De Visschere 2012; Frenkel 2001), with data from the third study currently unavailable (Van der Putten 2013). No study reported oral health-related attitude of residents.

Oral health-related behaviour

One study assessed oral health-related behaviour of residents (Bellomo 2005). An in-depth structured interview with the residents was taken to obtain information about toothbrushing habits and used dental hygiene auxiliaries.

Excluded studies

We excluded 18 studies: seven were non-randomised; six had no educational component; three included students or adults; one was not nursing home based; and one assessed no predefined outcomes (see Characteristics of excluded studies; Figure 1).

Ongoing studies

We identified one ongoing study assessing the effects of an intervention combining "best mouth care practices" with behavioural techniques (Jablonski 2011). Participants are nursing home residents with any kind of diagnosed dementia. The primary outcome measure is the reduction in care-resistant behaviour. Oral health using the "Oral Health Assessment Tool" is assessed as the secondary outcome.

Risk of bias in included studies

We contacted the first or senior authors of all studies and asked them to provide further information on methodological details not reported in the publications. All authors responded to our requests, with all but one author being able to provide further information.

Allocation

Random sequence generation

Three studies described an adequate method of random sequence generation (De Visschere 2012; Frenkel 2001; Zenthöfer 2013). The authors of two studies responded to our requests for further information (MacEntee 2007; Mojon 1998), which clarified that their methods were adequate. In addition, random sequence generation was probably done in one study since the investigators described an adequate method for another study based on one protocol (Van der Putten 2013). We therefore assessed six studies as being at low risk of bias for this domain. The remaining three studies only stated that participants were randomised but did not describe their methods, and so were assessed as being at unclear risk of bias for this domain (Bellomo 2005; De Visschere 2011; Schou 1989).

Allocation concealment

Two studies provided details of how the random sequence was concealed from those involved in the study (Frenkel 2001; MacEntee 2007). One author stated on request that allocation was not concealed, and so we assessed the study as at high risk of bias for this domain (Bellomo 2005). The remaining six studies did not mention any methods used to conceal the random sequence, and we therefore assessed them as being at unclear risk of bias (De Visschere 2011; De Visschere 2012; Mojon 1998; Schou 1989; Van der Putten 2013; Zenthöfer 2013).

Blinding

Blinding of participants and personnel (performance bias)

In educational interventions, blinding of participants is often not possible, but the relevance of lack of blinding varies according to circumstances. Lack of blinding of study participants or staff, or both, may affect outcomes (Higgins 2011, Chapter 8.4.2), especially if outcomes are self reported, as for example self assessed oral health-related quality of life. Only one study reported blinding of participants (MacEntee 2007). We judged all nine studies to be at low risk of performance bias, given that we considered the influence of residents' and staff awareness on oral health behaviour to be negligible.

Blinding of outcome assessment (detection bias)

Seven studies reported blinded outcome assessment, and we rated them as at low risk of bias for this domain (De Visschere 2011; De Visschere 2012; Frenkel 2001; MacEntee 2007; Schou 1989; Van der Putten 2013; Zenthöfer 2013). We assessed two studies as being at high risk of bias (Bellomo 2005; Mojon 1998): in one study, the author stated on request that the outcome assessor was not blinded (Bellomo 2005), and in the other study, blinding was not possible for practical reasons (Mojon 1998).

Incomplete outcome data

We assessed six studies as being at low risk of bias for this domain because attrition was low considering the special characteristics of the study population (especially high morbidity), and was roughly equal between groups (Bellomo 2005; De Visschere 2012; Frenkel 2001; Mojon 1998; Van der Putten 2013; Zenthöfer 2013). We assessed three studies as at unclear risk (De Visschere 2011; MacEntee 2007; Schou 1989).

Selective reporting

We assessed two studies as being at low risk of selective reporting bias as we could detect no obvious problems (MacEntee 2007; Van der Putten 2013). However, reports of the preplanned outcomes oral health-related knowledge and attitude are still under preparation (Van der Putten 2013). Data reported by De Visschere 2012 differed to some extent from the data in the trial registration (tongue coating was not preplanned), and results of De Visschere 2011 were not available for all preplanned outcome periods. We rated both studies as having a high risk of bias. We rated the remaining five studies as having an unclear risk of bias due to unavailable protocols or trial registrations (Bellomo 2005; Frenkel 2001; Mojon 1998; Schou 1989; Zenthöfer 2013).

Other potential sources of bias

We assessed the trials for other potential sources of bias such as recruitment bias in cluster-randomised trials or contamination. Seven of the included trials were cluster-randomised trials, using nursing homes as the unit of randomisation. In one trial, it was clear that nursing homes residents gave informed consent or were examined at baseline after randomisation (De Visschere 2011), resulting in a high risk of bias. In addition, there was potential contamination between groups in this study (De Visschere 2011). Four trials were at low risk of bias (De Visschere 2012; Frenkel 2001; Mojon 1998; Van der Putten 2013), and the other trials provided insufficient information, resulting in a judgement of unclear risk of bias (MacEntee 2007; Schou 1989).

Overall risk of bias

No study showed overall low risk of bias. Four studies had a high risk of bias (Bellomo 2005; De Visschere 2011; De Visschere 2012; Mojon 1998). The other five studies were at unclear risk of bias (Frenkel 2001; MacEntee 2007; Schou 1989; Van der Putten 2013; Zenthöfer 2013). See Figure 3; Figure 4.

Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies

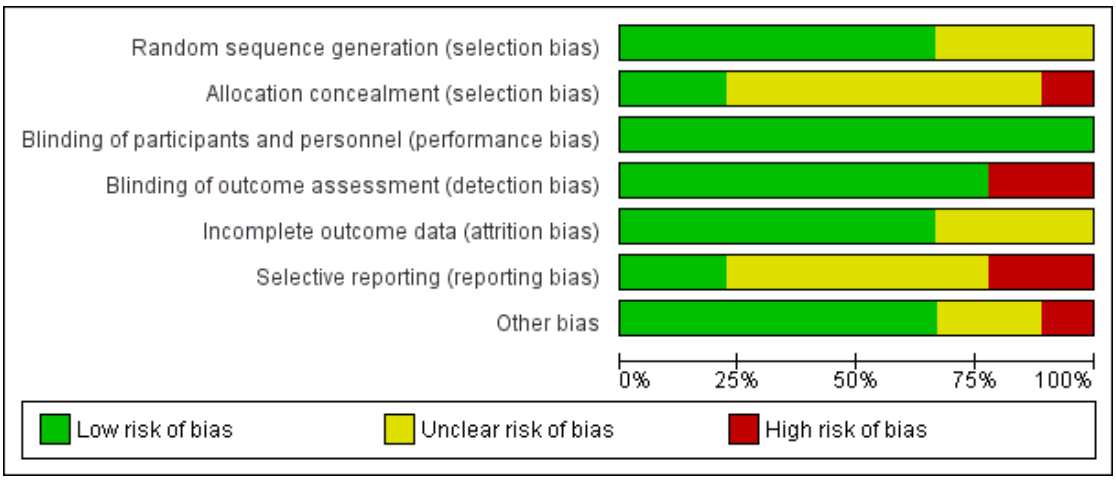
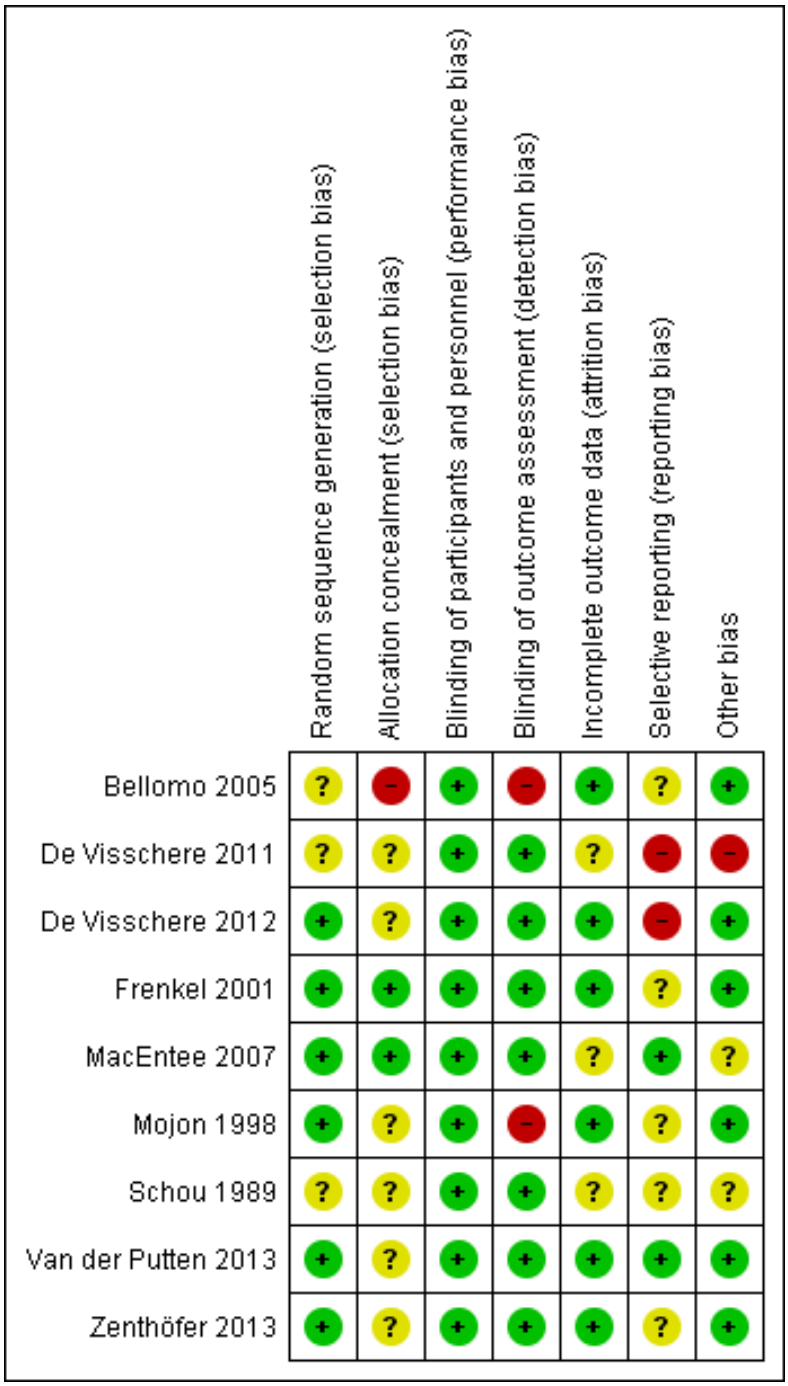


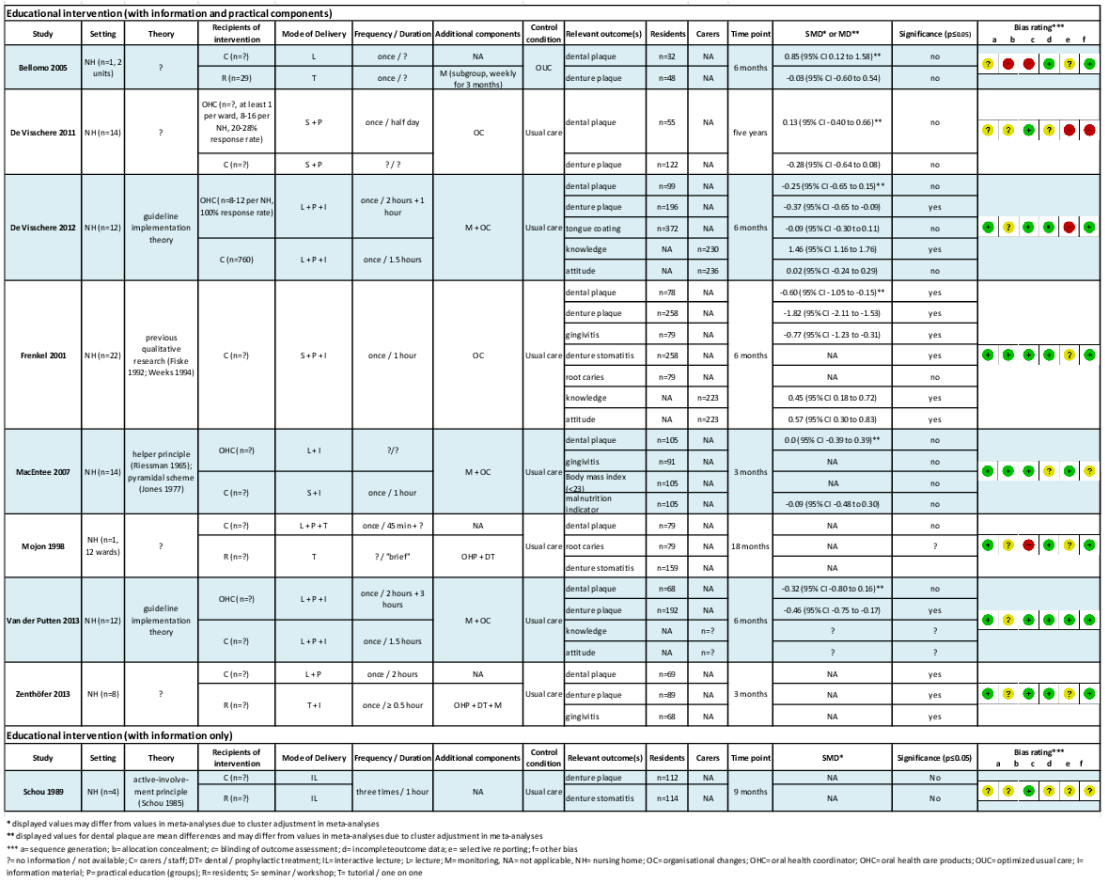
Figure 4. Risk of bias summary: review authors' judgements about each risk of bias item for each included study



Effects of interventions

See: **Summary of findings for the main comparison** Oral health education for nursing home staff and residents (with information and practical components) compared to usual care
See: Summary of findings for the main comparison; Figure 5

Figure 5. Summary of included studies



Educational intervention (with information and practical components)

Study	Setting	Theory	Recipients of intervention	Mode of Delivery	Frequency / Duration	Additional components	Control condition	Relevant outcome(s)	Residents	Carers	Time point	SMD* or MD**	Significance (p≤0.05)	Bias rating*** a b c d e f
Bellomo 2005	NH (n=1, 2 units)	?	C (n=?)	L	once / ?	NA	OUC	dental plaque	n=32	NA	6 months	0.85 (95% CI 0.12 to 1.58)**	no	? - - + ? +
			R (n=29)	T	once / ?	M (subgroup, weekly for 3 months)		denture plaque	n=48	NA		-0.03 (95% CI -0.60 to 0.54)	no	
De Visschere 2011	NH (n=14)	?	OHC (n=?, at least 1 per ward, 8-16 per NH, 20-28% response rate)	S + P	once / half day	OC	Usual care	dental plaque	n=55	NA	five years	0.13 (95% CI -0.40 to 0.66)**	no	? ? + ? - -
			C (n=?)	S + P	? / ?			denture plaque	n=122	NA		-0.28 (95% CI -0.64 to 0.08)	no	
De Visschere 2012	NH (n=12)	guideline implementation theory	OHC (n=8-12 per NH, 100% response rate)	L + P + I	once / 2 hours + 1 hour	M + OC	Usual care	dental plaque	n=99	NA	6 months	-0.25 (95% CI -0.65 to 0.15)**	no	+ ? + + - +
								denture plaque	n=196	NA		-0.37 (95% CI -0.65 to -0.09)	yes	
								tongue coating	n=372	NA		-0.09 (95% CI -0.30 to 0.11)	no	
			C (n=760)	L + P + I	once / 1.5 hours			knowledge	NA	n=230		1.46 (95% CI 1.16 to 1.76)	yes	
								attitude	NA	n=236		0.02 (95% CI -0.24 to 0.29)	no	
Frenkel 2001	NH (n=22)	previous qualitative research (Fiske 1992; Weeks 1994)	C (n=?)	S + P + I	once / 1 hour	OC	Usual care	dental plaque	n=78	NA	6 months	-0.60 (95% CI -1.05 to -0.15)**	yes	+ + + + ? +
								denture plaque	n=258	NA		-1.82 (95% CI -2.11 to -1.53)	yes	
								gingivitis	n=79	NA		-0.77 (95% CI -1.23 to -0.31)	yes	
								denture stomatitis	n=258	NA		NA	yes	
								root caries	n=79	NA		NA	no	
								knowledge	NA	n=223		0.45 (95% CI 0.18 to 0.72)	yes	
								attitude	NA	n=223		0.57 (95% CI 0.30 to 0.83)	yes	
MacEntee 2007	NH (n=14)	helper principle (Riessman 1965); pyramidal scheme (Jones 1977)	OHC (n=?)	L + I	?/?	M + OC	Usual care	dental plaque	n=105	NA	3 months	0.0 (95% CI -0.39 to 0.39)**	no	+ + + ? + ?
								gingivitis	n=91	NA		NA	no	
			C (n=?)	S + I	once / 1 hour			Body mass index (<23)	n=105	NA		NA	no	
								malnutrition indicator	n=105	NA		-0.09 (95% CI -0.48 to 0.30)	no	
Mojon 1998	NH (n=1, 12 wards)	?	C (n=?)	L + P + T	once / 45 min + ?	NA	Usual care	dental plaque	n=79	NA	18 months	NA	no	+ ? - + ? +
			R (n=?)	T	? / "brief"	OHP + DT		root caries	n=79	NA		NA	?	
								denture stomatitis	n=159	NA		NA		
Van der Putten 2013	NH (n=12)	guideline implementation theory	OHC (n=?)	L + P + I	once / 2 hours + 3 hours	M + OC	Usual care	dental plaque	n=68	NA	6 months	-0.32 (95% CI -0.80 to 0.16)**	no	+ ? + + + +
								denture plaque	n=192	NA		-0.46 (95% CI -0.75 to -0.17)	yes	
			C (n=?)	L + P + I	once / 1.5 hours			knowledge	NA	n=?		?	?	
								attitude	NA	n=?		?	?	
Zenthöfer 2013	NH (n=8)	?	C (n=?)	L + P	once / 2 hours	NA	Usual care	dental plaque	n=69	NA	3 months	NA	yes	+ ? + + ? +
			R (n=?)	T + I	once / ≥ 0.5 hour	OHP + DT + M		denture plaque	n=89	NA		NA	yes	
								gingivitis	n=68	NA		NA	yes	

Educational intervention (with information only)

Study	Setting	Theory	Recipients of intervention	Mode of Delivery	Frequency / Duration	Additional components	Control condition	Relevant outcome(s)	Residents	Carers	Time point	SMD*	Significance (p≤0.05)	Bias rating*** a b c d e f
Schou 1989	NH (n=4)	active-involvement principle (Schou 1985)	C (n=?)	IL	three times / 1 hour	NA	Usual care	denture plaque	n=112	NA	9 months	NA	No	? ? + ? ? ?
			R (n=?)	IL				denture stomatitis	n=114	NA		NA	No	

* displayed values may differ from values in meta-analyses due to cluster adjustment in meta-analyses
** displayed values for dental plaque are mean differences and may differ from values in meta-analyses due to cluster adjustment in meta-analyses
*** a= sequence generation; b= allocation concealment; c= blinding of outcome assessment; d= incompleteoutcome data; e= selective reporting; f= other bias
?= no information / not available; C= carers / staff; DT= dental / prophylactic treatment; IL= interactive lecture; L= lecture; M= monitoring, NA= not applicable, NH= nursing home; OC= organisational changes; OHC= oral health coordinator; OHC= oral health care products; OUC= optimized usual care; I= information material; P= practical education (groups); R= residents; S= seminar / workshop; T= tutorial / one on one

Comparison 1: Educational intervention (with information and practical components) versus (optimised) usual care

Six out of eight trials for this comparison presented data suitable for inclusion in meta-analyses. First, we have presented our analysis comprising the primary outcomes dental plaque and denture plaque. We have presented subgroup analysis for:

1. intervention recipient (nursing staff only versus nursing staff and residents);
2. follow-up period (short term versus long term);
3. education in the context of guideline implementation

versus education without guideline implementation (limited to short-term follow-up).
We have presented results for gingivitis, denture-induced stomatitis, caries, secondary outcomes, and oral health-related behaviour in a narrative form.

Primary outcomes

Oral health-related quality of life

Not measured in the included studies.

Oral health

Not masured in the included studies.

Dental plaque

We meta-analysed six studies (Bellomo 2005; De Visschere 2011; De Visschere 2012; Frenkel 2001; MacEntee 2007; Van der Putten 2013), three at high and three at unclear risk of bias, involving 437 nursing home residents. Dental plaque scores did not differ between residents who were cared for by nursing staff educated in oral health and than those receiving usual care (mean difference (MD) -0.04, 95% confidence interval (CI) -0.26 to 0.17; P = 0.71; effective sample size N = 353) (Analysis 1.1). There were no apparent subgroup differences for follow-up periods (Analysis 1.2) or education in context of guideline implementation (Analysis 1.3). The subgroup analysis for educational intervention recipients showed a positive result in favour of interventions providing education for nursing staff only compared to education for staff and residents (P = 0.002), but results should be viewed with caution as there was only one study in the second category (Analysis 1.1).
We were unable to include two studies in this meta-analysis (Mojon 1998; Zenthöfer 2013), which had high and unclear risk of bias, and involved 148 participants. In Mojon 1998, there was an increase in the median dental plaque scores for both groups (0.06 in the intervention group, 0.25 in the control group), a non-significant difference (P = 0.06). In Zenthöfer 2013, dental plaque was assessed dichotomously, demonstrating lower mean percentages of plaque-positive dental sites in three intervention groups compared to usual care (no P values reported).

Denture plaque

We combined five studies, involving 816 nursing home residents, in a meta-analysis. Three of the studies were at high risk of bias (Bellomo 2005; De Visschere 2011; De Visschere 2012), and two were at unclear risk of bias (Frenkel 2001; Van der Putten 2013). Denture plaque scores were not lower for residents who were cared for by nursing staff educated in oral health compared to residents receiving usual care (standardised mean difference (SMD) -0.60, 95% CI -1.25 to 0.05; P = 0.07; effective sample size N = 524) (Analysis 1.4). Subgroup analyses for educational intervention recipient, follow-up period, and education in the context of guideline implementation showed no significant differences (Analysis 1.4; Analysis 1.5; Analysis 1.6).
Zenthöfer 2013, which included 89 participants and was at unclear risk of bias, did not provide adequate data for meta-analysis. Denture plaque was assessed dichotomously, and trial authors reported a lower mean percentage of plaque-positive denture sites in intervention groups compared to usual care (no P values reported).

Gingivitis

Three studies with short-term follow-up (Frenkel 2001; MacEntee 2007; Zenthöfer 2013), all at unclear risk of bias, assessed gingivitis in residents, but we were unable to pool the data. Frenkel 2001 analysed 79 residents and showed a statistically significant difference in mean gingivitis score in favour of the intervention group (adjusted MD -0.28, 95% CI -0.42 to -0.15; P < 0.001). In Zenthöfer 2013, which analysed 68 residents, the mean values for the Gingival Bleeding Index were lower in intervention groups one (8.5, standard deviation (SD) 11.9), two (7.4, SD 8.7), and three (20.7, SD 23.9) compared to the control group (21.8, SD 27.5) (P values not reported/not calculated). MacEntee 2007 analysed 98 residents and showed no significantly different scores for gingivitis between intervention and control (MD -0.2, 95% CI -7.3 to 7.0; P = 0.48).

Denture-induced stomatitis

Frenkel 2001, which involved 258 residents and was at unclear risk of bias, assessed severity of denture-induced stomatitis. Stomatitis was reduced in the intervention group at six months' follow-up compared to the control group (P < 0.0001). Mojon 1998, with 159 residents, assessed the incidence of mucosal and other lesions. There was no significant difference between groups for incidence of denture stomatitis (37% versus 42.2%; P value not reported) or other lesions (18.5% versus 31.6%; P = 0.06), but for incidence of glossitis, the result was in favour of the intervention group (4.9% versus 25%; P = 0.005).

Caries and root caries

Two studies at unclear and high risk of bias assessed caries or root caries (Frenkel 2001; Mojon 1998). The individual studies showed no significant differences between intervention groups and control groups at both short-term and long-term follow-up.

Secondary outcomes

None of the included studies assessed incidence of respiratory diseases, pneumonia, or adverse effects. Only one study assessed nutritional status (BMI and Malnutrition Indicator Score), which had short-term follow-up and an unclear risk of bias (MacEntee 2007). There was no benefit related to BMI scores less than 23 for residents receiving the intervention (odds ratio 1.0, 95% CI 0.3 to 3.1; P = 0.49). The mean difference of Malnutrition Indicator Score (range 0 to 30) was -1.1 (95% CI -2.9 to 0.7; P = 0.11).

Intermediate outcomes

Oral health-related knowledge

We combined two studies at high and unclear risk of bias involving 453 members of nursing staff in a meta-analysis (De Visschere 2012; Frenkel 2001). A non-significant difference in knowledge was reported for nursing staff receiving educational interventions compared to those without education (SMD 0.94, 95% CI -0.04 to 1.92; P = 0.06) (Analysis 1.7).

Oral health-related attitude

We combined two studies involving 459 members of nursing staff in a meta-analysis (De Visschere 2012; Frenkel 2001). A non-significant difference in attitude was reported for nursing staff receiving educational interventions compared to those without education (SMD 0.30, 95% CI -0.23 to 0.83; P = 0.27) (Analysis 1.8).

Oral-health related behaviour

One study assessed oral health-related behaviour of residents (Bellomo 2005). The 60 residents were interviewed about their toothbrushing habits. Use of toothbrushes and the frequency of brushing during the study period were comparable in both groups.

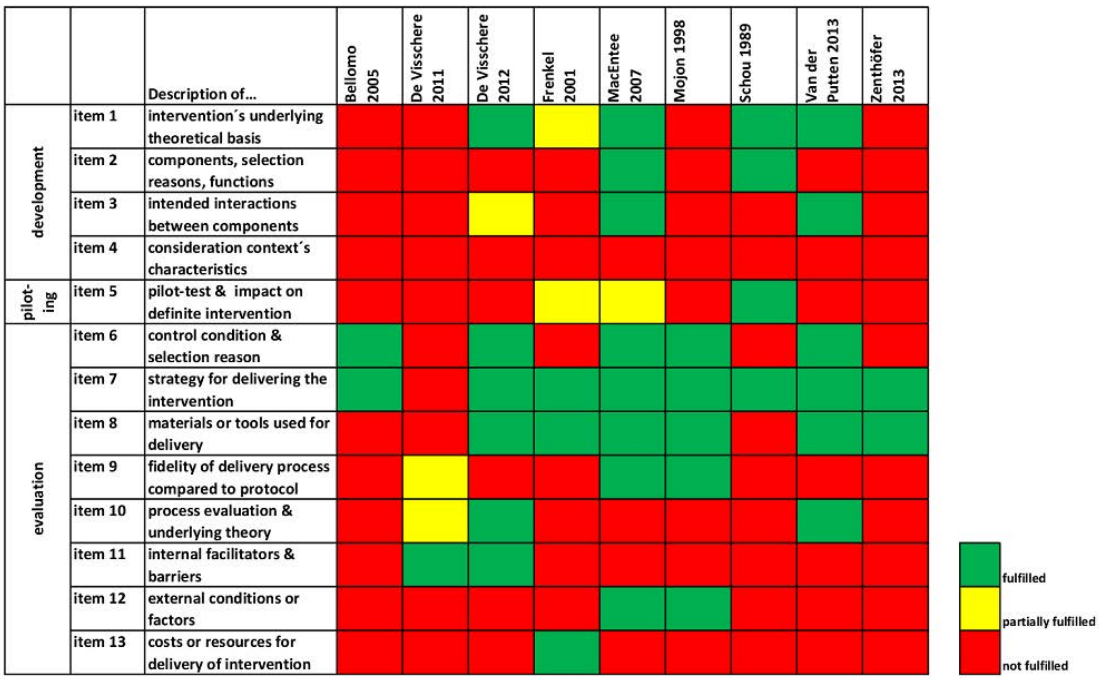
Comparison 2: Educational intervention (information only) versus usual care

One study (Schou 1989), at unclear risk of bias and analysing 114 residents, showed that there is insufficient evidence to determine whether or not denture plaque scores are lower when educating residents or nursing staff without practical training. There was no difference in the prevalence of denture stomatitis between the groups. The number of residents in the intervention groups who reported correct denture cleaning habits increased, but not significantly compared to baseline (baseline N = 28; follow-up N = 38). The study did not assess any other outcomes of this review.

Reporting of complex interventions (CReDECI 2)

Findings for the reporting quality of complex interventions, using the CReDECI 2 checklist (Möhler 2015), are described in Table 3. Information about the development stage (four items) was rarely provided, as most studies failed to report reasons for selection of intervention components/essential function (item 2) or intended interactions between components (item 3). Five studies provided at least some information about the intervention's underlying theoretical basis (item 1) (De Visschere 2012; Frenkel 2001; MacEntee 2007; Schou 1989; Van der Putten 2013). Only MacEntee 2007 and Schou 1989 considered item 2. None of the studies reported consideration of context characteristics in intervention modelling (item 4). Only three studies reported information on the feasibility and piloting stage (item 5) (Frenkel 2001; MacEntee 2007; Schou 1989). A description of the strategy for delivering the intervention (item 7) was reported in all but one study (De Visschere 2011). Six studies described the materials or tools used for the intervention delivery (item 8) (De Visschere 2012; Frenkel 2001; MacEntee 2007; Mojon 1998; Van der Putten 2013; Zenthöfer 2013). In two studies, the process evaluation (item 10) was planned a priori (De Visschere 2012; Van der Putten 2013), and in another two studies qualitative methods for identification of facilitators and barriers were mentioned (De Visschere 2011; MacEntee 2007). A description of costs or required resources for the delivery of the interventions was only provided in Frenkel 2001. Overall, most studies reported insufficient information on processes (Figure 6).

Figure 6. Summary of CReDECI 2: review authors' judgements of fulfilment of CReDECI 2 items for each included study



DISCUSSION

Summary of main results

We have summarised results from nine RCTs, involving 3253 nursing home residents, investigating the effects of oral health educational interventions for nursing staff or nursing home residents, or both. All interventions were complex interventions that used more than one active component. We retrieved process measures and details of the development and evaluation of the complex interventions used, if available, using the CReDECI 2 criteria. The number of intervention components differed markedly between studies (Figure 2), but all interventions included theoretical or practical education sessions, or both, on oral health for nursing staff as one of the main intervention components. We categorised the interventions into two groups: educational intervention with information and practical components or educational intervention with information only. All trials aimed at improving different measures of dental health. Some were additionally concerned with increasing knowledge or improving attitude (De Visschere 2012; Frenkel 2001; Van der Putten 2013). Control interventions differed between studies, ranging from "usual care" to control interventions comparable to the active intervention in terms of time and effort spent.

None of the included studies assessed our primary outcomes oral health-related quality of life and oral health. All studies assessed our third primary outcome dental health, although the outcome measures varied between studies (see Table 2). We found no clear beneficial effect on any dental health measure, and quality of the evidence was generally low.

None of the included studies assessed our secondary outcomes incidence of respiratory diseases, incidence of pneumonia, and adverse effects. Nutritional status (BMI and Malnutrition Indicator Score) was only assessed in MacEntee 2007, which reported no differences between the groups.

In summary, important uncertainties remain. For example, surrogate measures were reported most often, while patient-relevant measures such as quality of life and pneumonia were not assessed. Moreover, there was no information about adverse events and costs. Due to insufficient reporting of interventions, we are unable to reach strong conclusions about the overall effects or the effects of components of the complex interventions used.

Overall completeness and applicability of evidence

This review included nine individual and cluster-RCTs, which were conducted in six high-income countries: the Netherlands, Belgium, Germany, the UK, Switzerland, and Canada. We did not identify any studies conducted in low-income countries. This limits the applicability of our results, since evidence from a small number of countries cannot be directly applied to other countries with different healthcare systems.

Length of treatment effects (sustainability)

The majority of trials (six RCTs) presented data on short-term effects (three or six months). This seems reasonable for outcomes like plaque and oral inflammation. However, it can be considered inadequate for other outcomes such as caries, and possibly knowledge and attitude. Sustainable effects on knowledge and attitudes for nursing staff are probably needed to allow for behavioural changes in oral health care. Studies should therefore measure outcomes in the longer term.

Type of outcomes

We would argue that the most important goal of the investigated interventions was to improve the well-being of nursing home residents, as well as their oral and general health. However, none of the included studies reported data on oral health or oral health-related quality of life. The reported outcomes (e.g. plaque, gingivitis) are important measures of dental health, but may not represent the most important outcomes of interventions to improve oral health in nursing home residents. Still, they can be seen as important surrogate parameters and as adequate indicators for future tooth survival and corresponding well-being (Durham 2013; Mack 2005; Tonetti 2015), especially as in nursing home residents, treatment effects on tooth survival might be hard to establish due to the length of time until tooth loss and limited life expectancy of residents. Apart from directly related outcomes, nutritional status of residents has been related to oral and dental health (Naito 2010), but only one study assessed this outcome, with inconclusive results. None of the included studies assessed care-resistant behaviour, although this has been described as an important factor in oral healthcare delivery (Frenkel 1999). Here, results from ongoing study Jablonski 2011 may provide meaningful data in the future.

Type of participants

The included studies comprised a variety of nursing staff and nursing home residents. Nursing staff varied in terms of qualifications and work experience. Nursing home residents varied in terms of oral health status, care dependency, and cognitive status. Some studies excluded residents with dementia, in Zenthöfer 2013, or cognitive impairment (Frenkel 2001; Mojon 1998). In addition, two studies excluded residents with "care-resistant behaviour" (De Visschere 2012; Van der Putten 2013). Since cognitive impairment is an important factor for nursing home admissions, and rates of residents with dementia regularly exceed 50% (Seitz 2010), this should be considered when judging the generalisability of results. Also, severe cognitive impairment is often a cause of resistance of the residents to oral healthcare activities (Forsell 2011). Excluding these residents may therefore lead to overestimation of treatment effects.

Type of intervention

Oral health education programmes are complex interventions with multiple components that are implemented in complex environments with, for example, different dental and/or organisational conditions and prerequisites. Hence, interpretation of results is difficult. As would be expected for a review of complex educational interventions, outcomes could not be clearly associated with single components since education programmes varied markedly. For example, the duration of interventions has an impact on dental health outcomes, and the same applies to other sources of heterogeneity, for example intensity and components of interventions and mode of delivery. Here, educators delivering the intervention were from a range of professional backgrounds (dentists, dental hygienists, trained nursing staff, health promoters). In most studies, the educators were not members of the established nursing staff, except nurses who were trained as oral healthcare co-ordinators. In general, reporting of the complex interventions as recommended by CReDECI 2 was poor. For example, it was not reported where nurses received training by a trained oral healthcare co-ordinator or numbers of participating nurses and nurse assistants, and there was no information about the direct effects of the education programmes. Control interventions differed markedly with a number of alternative interventions used as controls, which might have masked a possible favourable effect of interventions.

The important role of an underlying theory and a systematic approach to developing behaviour change interventions has been disregarded by most intervention developers, or at least there is little information on this important aspect. In the future, it is crucial to use specified language when reporting content, techniques, and underlying theoretical frameworks of complex interventions, for example applying the suggestions of Michie and colleagues, who have highlighted the important issues concerning behaviour change intervention development and research (Michie 2009), and have suggested approaches for adequately designing such interventions (Michie 2011).

Quality of the evidence

The overall quality of the evidence is reported in Summary of findings for the main comparison.

Educational intervention (with information and practical components) versus usual care

The quality of the evidence included in this comparison limits the confidence with which we can draw conclusions about the efficacy of educational interventions on oral health of nursing home residents. No study included in this comparison was at low risk of bias; we assessed four studies as at unclear risk of bias and four as at high risk of bias. We considered these 'Risk of bias' issues in conjunction with the fact that meta-analyses showed statistically significant heterogeneity (I^2 = 60% and 92%). We downgraded the evidence due to serious risk of bias and inconsistency, which resulted in our rating the evidence as low quality for all assessed outcomes. Low-quality evidence means that future research in these areas is very likely to have an impact on our confidence in the estimate of effect and likely to change the estimate. In addition, it is very concerning that there was no evidence on our primary outcome of oral health-related quality of life and some of the secondary outcomes of this review. These outcomes are likely to be important to nursing home residents and caregivers.

Educational interventions with information only versus usual care

There was insufficient evidence from only one study with unclear risk of bias and low quality evidence on the effects of educational interventions with information only, not allowing any conclusions.

Potential biases in the review process

Due to our comprehensive search strategy, we are confident that publication bias is unlikely. Two review authors independently performed selection of studies and data extraction, and analyses were undertaken and differences were resolved by consensus and by consulting a third review author when necessary.

Agreements and disagreements with other studies or reviews

The results of our meta-analyses (of RCTs) differ from two recent systematic reviews and meta-analyses (De Lugt-Lustig 2014; Wang 2015). Both reviews concluded that oral health education for nurses and informal caregivers may yield positive effects on residents' oral health. However, there are some differences between these reviews and the present review regarding methodological approaches used. Selection criteria differed for study design, time period, and target participants. We only included RCTs and cluster-RCTs, whereas De Lugt-Lustig 2014 and Wang 2015 additionally included before-and-after studies, cross-sectional studies, and non-randomised studies. The literature search was limited to articles since 1990 and disregarded publications like doctoral theses or unpublished studies (De Lugt-Lustig 2014). De Lugt-Lustig 2014 disregarded any educational interventions considering nursing home residents as recipients, whereas Wang 2015 excluded education for residents only. Differing from the other reviews, our review presents data on the fidelity of the intervention implementation (using CReDECI 2), and we contacted the first and/or senior author of included studies to obtain detailed information about the interventions and missing data.

A further systematic review including a broad range of study designs indicated that knowledge, self efficacy, and facilitation of behaviour are determinants that are used in successful implementation strategies (Weening-Verbree 2013). In line with our results, the authors were not able to recommend a single strategy or combination of strategies for improving oral health in institutionalised elderly people.

AUTHORS' CONCLUSIONS

Implications for practice

There is currently insufficient evidence to draw robust conclusions about the effects of oral health educational interventions for nursing home staff and residents in addition to usual care. Eligible studies did not provide evidence of the effectiveness of educational interventions on any measure of residents' oral health or nurses' oral health knowledge and attitude. Moreover, the small number of available studies and important heterogeneity among studies do not allow for clear practice recommendations. Information on many aspects that seem relevant for nursing homes to guide decision making about implementation of such interventions cannot be drawn from the available studies. For example, important resident-related outcomes such as oral health-related quality of life and nutritional status were not or were rarely assessed. Important intermediate measures, for example, staff knowledge and attitude, were also rarely assessed.

Importantly, due to marked clinical heterogeneity of the interventions, it is not possible to reliably determine the effectiveness of specific educational programmes or intervention components. Reporting of the development, piloting, and evaluation processes for the complex interventions was insufficient. Facilitators, barriers, and resources of the different interventions therefore remain unknown, but are clearly relevant for decisions on implementation. Based on the available evidence, it seems impossible to make recommendations about the extent and content of educational programmes as well as favoured educators (e.g. nurses versus dentists) and participants (e.g. nurses versus residents).

It is therefore unclear at present which kind of oral healthcare education programme should be implemented and if nursing homes can expect positive effects from the implementation of such a programme.

Implications for research

There is a need for further RCTs to determine whether oral health

educational interventions for nursing home staff and residents are effective, especially on residents' oral health-related quality of life and oral health, as well as residents' and staff knowledge and attitude. Future trials need to be rigorous in design and delivery with adequate reporting including detailed descriptions of participants, setting, intervention and control conditions.

Nursing home residents differ in terms of personal and medical characteristics, for example, oral health status, care dependency, cognitive status, and medical diagnoses. Nursing homes and/or wards and staff also differ. Nurses mainly taking care of elderly with high levels of care dependency or who are cognitively impaired may need a somewhat different educational content/intervention. Researchers should consider (and describe) these characteristics in future cluster-RCTs. In addition, subgroup analyses, for example of residents with dementia or different levels of cognitive impairment, are needed, as has been planned in an ongoing study (Jablonski 2011).

Most included programmes comprised singular or short-term interventions, and outcomes were usually assessed in the short term. Future studies could therefore implement interventions with a higher frequency of education sessions or continuous provision of oral healthcare education for nursing staff and aim for longer follow-up periods.

Ideally, control interventions should be comparable to experimental interventions in terms of duration and effort for participants to allow for successful blinding and reduce the risk of a Hawthorne effect. As for experimental interventions, control interventions as well as 'usual care' should be described in detail.

Outcome measures should be determined by established and validated measurement methods.

Interventions should be rigorously developed and reported following recommendations for complex interventions (Craig 2008). Michie 2009 has called for better reporting of complex behaviour change interventions, and for authors and reviewers to use reporting guidelines to ensure this. This should include established reporting guidelines that cover different development and evaluation stages, for example the CONSORT statement and, if appropriate, extensions, as well as the whole process of developing and evaluating complex interventions, for example using CReDECI 2 (Möhler 2015). Furthermore, as categorisation of behavioural interventions is problematic due to inconsistent use of descriptive language and may cause problems in replication and implementation (Abraham 2008), interventions should be reported in more detail. for example using the Template for Intervention Description and Replication (TIDieR) criteria (Hoffmann 2014). In addition, Michie 2011 pointed out that behaviour change interventions in particular need to be developed using an underlying theory and systematic and rigorous methods, suggesting methods for characterising and designing behaviour change interventions (e.g. the "behaviour change wheel"), which can be used to design new interventions. However, in our review we showed that although eight of the studies reported at least some information about the strategy of delivering the intervention, and six of nine studies reported information about tools and materials used for delivery, a more detailed description and more easily available curricula and manuals are warranted to ensure transparency, replicability, and integrity of the complex interventions used.

ACKNOWLEDGEMENTS

We wish to acknowledge the contribution to the protocol of consumer reviewer Johannes van Dijk (gerontopsychiatric nurse and trainer in dementia care mapping, Hamburg, Germany) and statistical advice and support of statistician Burkhard Haastert (mediStatistica, Neuenrade, Germany). We wish to thank Anne Littlewood (Cochrane Oral Health Group) for her assistance with literature searching and Helen Worthington, Jan Clarkson, Laura MacDonald, and Phil Riley (Cochrane Oral Health) for their help with the preparation of this review. We also thank Lucy O'Malley, Debbie Bonetti, Catherine Waldron, and Linet Weening for their helpful comments on drafts of this review and Lisa Winer for copy editing the final draft.

REFERENCES

References to studies included in this review

Bellomo 2005 *{published data only}*

Bellomo F. *L ' utilisation de l ' ergothérapie comme technique de guidage pour la prise en charge de l ' hygiène bucco-dentaire des personnes agèes institutionnalisèes. [Thèse de doctorat]*. Univ. Genève, 2006.

* Bellomo F, De Preux F, Chung JP, Julien N, Budtz-Jørgensen E, Müller F. The advantages of occupational therapy in oral hygiene measures for institutionalised elderly adults. *Gerodontology* 2005;**22**:24–31.

Müller F. On article "Advantages of occupational therapy in oral hygiene measures for institutionalised elderly adults" [personal communication]. Email to M Albrecht 1 September 2014.

De Visschere 2011 *{published data only}*

De Visschere L. Information about studies on "oral hygiene protocols in nursing homes" [personal communication]. Email to M Albrecht 28 November 2014.

De Visschere L, De Baat C, De Meyer L, Van der Putten GJ,

Peeters B, Söderfeldt B, et al. The integration of oral health care into day-to-day care in nursing homes: a qualitative study. *Gerodontology* 2015;**32**(2):115–22.
* De Visschere L, De Baat C, Schols JMGA, Deschepper E, Vanobbergen J. Evaluation of the implementation of an 'oral hygiene protocol' in nursing homes: a 5-year longitudinal study. *Community Dentistry and Oral Epidemiology* 2011; **39**:416–25.

De Visschere 2012 ***{published data only}***
De Visschere L. [Information about studies on "oral hygiene protocols in nursing homes" [personal communication]]. Email to M Albrecht 28 November 2014.
De Visschere L, De Baat C, De Meyer L, Van der Putten GJ, Peeters B, Söderfeldt B, et al. The integration of oral health care into day-to-day care in nursing homes: a qualitative study. *Gerodontology* 2015;**32**(2):115–22.
* De Visschere L, Schols J, Van der Putten GJ, De Baat C, Vanobbergen J. Effect evaluation of a supervised versus non-supervised implementation of an oral health care guideline in nursing homes: a cluster randomised controlled clinical trial. *Gerodontology* 2012;**29**:e96–106.
Janssens B, De Visschere L, Van der Putten GJ, De Lugt-Lustig K, Schols J, Vanobbergen J. Effect of an oral healthcare protocol in nursing homes on care staffs' knowledge and attitude towards oral health care: a cluster-randomised controlled trial. *Gerodontology* 2014;**33**(2): 275–86. [DOI: 10.1111/ger.12164]
Van der Putten GJ, de Visschere L, Schols J, de Baat C, Vanobbergen J. Supervised versus non-supervised implementation of an oral health care guideline in (residential) care homes: a cluster randomized controlled trial. *BMC Oral Health* 2010;**10**:17.

Frenkel 2001 ***{published data only}***
Frenkel HF. *A health education intervention to improve oral health among institutionalised elderly people: a randomised controlled trial [Dissertation]*. University of Bristol, 1998.
Frenkel HF, Harvey I, Needs KM. Oral health care education and its effect on caregivers' knowledge and attitudes: a randomised controlled trial. *Community Dentistry and Oral Epidemiology* 2002;**30**:91–100.
* Frenkel HF, Harvey I, Newcombe RG. Improving oral health in institutionalised elderly people by educating caregivers: a randomised controlled trial. *Community Dentistry and Oral Epidemiology* 2001;**29**:289–97.
Newcombe RG. Information about the trial 'Improving oral health in institutionalised elderly people by educating caregivers: a randomised controlled trial' [personal communication]. Email to M Albrecht 3 February 2016.

MacEntee 2007 ***{published data only}***
MacEntee M. Information about the trial 'Provision of mouth care in LTC facilities: an educational trial' and training material [personal communication]. Email to M Albrecht 15 January 2015.
* MacEntee MI, Wyatt CCL, Beattie BL, Paterson B, Levy-Milne R, McCandless L, et al. Provision of mouth-care in long-term care facilities: an educational trial. *Community Dentistry and Oral Epidemiology* 2007;**35**:25–34.
MacEntee MI, Wyatt CCL, Paterson B, Kazanjian A, Milne RL, Beattie L, et al. Impact of in-house education on oral and general health of elders in long-term care facilities - research proposal. 2000.

Mojon 1998 ***{published data only}***
Budtz-Jørgensen E, Mojon E, Rentsch A, Deslauriers N. Effects of an oral health program on the occurrence of oral candidosis in a long-term care facility. *Community Dentistry and Oral Epidemiology* 2000;**28**:141–9.
Mojon P. Randomization - used methods of sequence generation [personal communication]. Email to M Albrecht 7 May 2014.
* Mojon P, Rentsch A, Budtz-Jørgensen E, Baehni PC. Effects of an oral health program on selected clinical parameters and salivary bacteria in a long-term care facility. *European Journal of Oral Sciences* 1998;**106**:827–34.

Schou 1989 ***{published data only}***
Schou L. Active-involvement principle in dental health education. *Community Dentistry and Oral Epidemiology* 1985;**13**:128–32.
Schou L. Article 'Oral health promotion for institutionalised elderly' [personal communication]. Email to: M Albrecht 20 January 2015.
* Schou L, Wight C, Clemson N, Douglas S, Clark C. Oral health promotion for institutionalised elderly. *Dental Health Education* 1989;**17**:2–6.

Van der Putten 2013 ***{published data only}***
Van der Putten GJ. Information about the study 'Effectiveness of supervised implementation of an oral health care guideline in care homes: a single-blinded cluster randomized controlled trial' [personal communication]. Email to M Albrecht 7 January 2015.
* Van der Putten GJ, Mulder J, de Baat C, de Visschere L, Vanobbergen J, Schols J. Effectiveness of supervised implementation of an oral health care guideline in care homes; a single-blinded cluster randomized controlled trial. *Clinical Oral Investigations* 2013;**17**:1143–53.
Van der Putten GJ, de Visschere L, Schols J, de Baat C, Vanobbergen J. Supervised versus non-supervised implementation of an oral health care guideline in (residential) care homes: a cluster randomized controlled trial. *BMC Oral Health* 2010;**10**:17.

Zenthöfer 2013 ***{published data only}***
Zenthöfer A. [Reply to request on article 'Improving oral hygiene in the long–term care of the elderly – a RCT' [personal communication]]. Email to: M Albrecht 27 November 2014.
* Zenthöfer A, Dieke R, Dieke A, Wege KC, Rammelsberg P, Hassel AJ. Improving oral hygiene in the long-term care of the elderly - a RCT. *Community Dentistry and Oral Epidemiology* 2013;**41**:261–8.

References to studies excluded from this review

Avenali 2011 ***{published data only}***
Avenali L, Guerra F, Cipriano L, Corridore D, Ottolenghi L. Diasbled patients and oral health in Rome, Italy: long-term

evaluation of educational initiatives. *Annali di Stomatologia* 2011;**2**:25–30.

Beck 210 ***{published data only}***
Beck AM, Damkjaer K, Sørbye LW. Physical and social functional abilities seem to be maintained by a multifaceted randomized controlled nutritional intervention among old (>65 years) Danish nursing home residents. *Archives of Gerontology and Geriatrics* 2010;**50**:351–5.

Czarkowski 2013 ***{published data only}***
Czarkowski G, Allroggen S, Köster-Schmidt A, Bausback-Schomakers S, Frank M, Heudorf U. Oral health hygiene education programme for nursing personnel to improve oral health of residents in long-term care facilities 2010 in Frankfurt/Main, Germany [Schulung von Pflegepersonal in Altenpflegeheimen zur Verbesserung der Mundhygiene bei den Bewohnern - Interventionsstudie in Frankfurt am Main 2010]. *Gesundheitswesen* 2013;**75**:368–75.

Davies 1990 ***{published data only}***
Davies KW, Whittle JG. Dental health education: training of home carers of mentally handicapped adults. *Community Dental Health* 1990;**7**:193–7.

Gammack 2009 ***{published data only}***
Gammack JK, Pulisetty S. Nursing education and improvement in oral care delivery in long-term care. *Journal of the American Medical Directors Association* 2009;**10**: 658–61.

Jönsson 2012 ***{published data only}***
Jönsson B, Öhrn K, Lindberg P, Oscarson N. Cost-effectiveness of an individually tailored oral health educational programme based on cognitive behavioural strategies in non-surgical periodontal treatment. *Journal of Clinical Periodontology* 2012;**39**:659–65.

Lange 2000 ***{published data only}***
Lange B, Cook C, Dunning D, Froeschle ML, Kent D. Improving the oral hygiene of institutionalized mentally retarded clients. *Journal of Dental Hygiene* 2000;**74**:205–9.

Nicol 2005 ***{published data only}***
Nicol R, Sweeney MP, McHugh S, Bagg J. Effectiveness of health care worker training on the oral health of elderly residents of nursing homes. *Community Dentistry and Oral Epidemiology* 2005;**33**:115–24.

Park 2011 ***{published data only}***
Park MS, Choi-Kwon S. The effects of oral care education on caregivers' knowledge, attitude & behavior towards oral hygiene for elderly residents in a nursing home

[구강간호교육이 노인요양시설 돌봄제공자의

구강간호 지식, 태도 및 행위와 재원노인의

구강위생에 미치는 효과]. *Journal of Korean Academy of Nursing* 2011;**41**:684–93.

Park 2014 ***{published data only}***
Park YH, Chang H. Effect of a health coaching self-management program for older adults with multimorbidity in nursing homes. *Patient Preference and Adherence* 2014;**8**: 959–70.

Paulsson 1998 ***{published data only}***
Paulsson G, Fridlund B, Holmen A, Hyg O, Nederfors T. Evaluation of an oral health education program for nursing personnel in special housing facilities for the elderly. *Special Care in Dentistry* 1998;**18**:234–42.

Quagliarello 2009 ***{published data only}***
Quagliarello V, Juthani-Mehta M, Ginter S, Towle V, Allore H, Tinetti M. Pilot testing of intervention protocols to prevent pneumonia in nursing home residents. *Journal of the American Geriatrics Society* 2009;**57**:1226–31.

Simons 2000 ***{published data only}***
Simons D, Baker P, Jones B, Kidd EAM, Beighton D. An evaluation of an oral health training programme for carers of the elderly in residential homes. *British Dental Journal* 2000;**188**:206–10.

Sniehotta 2007 ***{published data only}***
Sniehotta FF, Araujo Soares V, Dombrowski SU. Randomized controlled trial of a one-minute intervention changing oral self-care behavior. *Journal of Dental Research* 2007;**86**:641–5.

Tan 2010 ***{published data only}***
Tan HP, Lo ECM, Dyson JE, Corbet EF. A randomized trial on root caries prevention in elders. *Journal of Dental Research* 2010;**89**:1086–90.

Vandamme 2006 ***{published data only}***
Vandamme K, Opdebeeck H, Naert I. Pathways in multidisciplinary oral health care as a tool to improve clinical performance. *International Journal of Prosthodontics* 2006;**19**:227–35.

Wyatt 2009 ***{published data only}***
Wyatt CCL. A 5-year follow-up of older adults residing in long-term care facilities: utilisation of a comprehensive dental programme. *Gerodontology* 2009;**26**:282–90.

Yonezawa 2003 ***{published data only}***
Yonezawa H, Takasaki K, Teraoka K, Asaka T, Sata C, Tsuchiya K. Effects of tongue and oral mucosa cleaning on oral Candida species and production of volatile sulfur compounds in the elderly in a nursing home. *Journal of Medical and Dental Sciences* 2003;**50**:1–8.

References to ongoing studies

Jablonski 2011 ***{published data only}***
Jablonski RA, Kolanowski A, Therrien B, Mahoney EK, Kassab C, Lesli DL. Reducing care-resistant behaviors during oral hygiene in persons with dementia. *BMC Oral Health* 2011;**11**:30.

Additional references

Abraham 2008
Abraham C, Michie S. A taxonomy of behavior change techniques used in interventions. *Health Psychology* 2008; **27**(3):379–87.

Ainamo 1975
Ainamo J, Bay I. Problems and proposals for recording gingivitis and plaque. *International Dental Journal* 1975;**25** (4):229–35.

Ambjørnsen 1982
Ambjørnsen E, Valderhaug J, Norheim PW, Fløystrand F. Assessment of an additive index for plaque accumulation on complete maxillary dentures. *Acta Odontologica Scandinavica* 1982;**40**:203–8.

Atchison 1990
Atchison KA, Dolan TA. Development of the Geriatric Oral Health Assessment Index. *Journal of Dental Education* 1990;**54**(11):680–7.

Augsburger 1982
Augsburger RH, Elahi JM. Evaluation of seven proprietary denture cleansers. *Journal of Prosthetic Dentistry* 1982;**47**: 356–9.

Azarpazhooh 2006
Azarpazhooh A, Leake JL. Systematic review of the association between respiratory diseases and oral health. *Journal of Periodontology* 2006;**77**(9):1465–82.

Benigeri 2000
Benigeri M, Brodeur JM, Payette M, Charbonneau A, Ismail AI. Community periodontal index of treatment needs and prevalence of periodontal conditions. *Journal of Clinical Periodontology* 2000;**27**(5):308–12.

Branca 2009
Branca S, Bennati E, Ferlito L, Spallina G, Cardillo E, Malaguarnera M, et al. The health-care in the extreme longevity. *Archives of Gerontology and Geriatrics* 2009;**49**(1): 32–4.

Budtz-Jørgensen 1970
Budtz-Jørgensen E, Bertram U. Denture stomatitis. I. The etiology in relation to trauma and infection. *Acta Odontologica Scandinavica* 1970;**28**:71–92.

Budtz-Jørgensen 1978
Budtz-Jørgensen E. Clinical aspects of Candida infection in denture wearers. *Journal of the American Dental Association* 1978;**96**:474–9.

Campbell 2000
Campbell M, Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D, et al. Framework for design and evaluation of complex interventions to improve health. *BMJ* 2000;**321**(7262):694–6.

Chalmers 2005
Chalmers JM, King PL, Spencer AJ, Wright FA, Carter KD. The oral health assessment tool - validity and reliability. *Australian Dental Journal* 2005;**50**(3):191–9.

Craig 2008
Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;**337**:a1655.

De Baat 1993
De Baat C, Bruins H, van Rossum G, Kalk W. Oral health care for nursing home residents in the Netherlands - a national survey. *Community Dentistry and Oral Epidemiology* 1993;**21**(4):240–2.

De Lugt-Lustig 2014
De Lugt-Lustig KHME, Vanobbergen JNO, van der Putten GJ, de Visschere LMJ, Schols JMGA, de Baat C. Effect of oral healthcare education on knowledge, attitude and skills of care home nurses: a systematic literature review. *Community Dentistry and Oral Epidemiology* 2014;**42**: 88–96.

De Visschere 2006
De Visschere LM, Grooten L, Theuniers G, Vanobbergen JN. Oral hygiene of elderly people in long-term care institutions - a cross-sectional study. *Gerodontology* 2006;**23** (4):195–204.

Desvarieux 2003
Desvarieux M, Demmer RT, Rundek T, Boden-Albala B, Jacobs DR Jr, Papapanou PN, et al. Relationship between periodontal disease, tooth loss, and carotid artery plaque: the Oral Infections and Vascular Disease Epidemiology Study (INVEST). *Stroke* 2003;**34**(9):2120–5.

Durham 2013
Durham J, Fraser HM, McCracken GI, Stone KM, John MT, Preshaw PM. Impact of periodontitis on oral health-related quality of life. *Journal of Dentistry* 2013;**41**:370–6.

El-Rabbany 2015
El-Rabbany M, Zaghlol N, Bhandari M, Azarpazhooh A. Prophylactic oral health procedures to prevent hospital-acquired and ventilator-associated pneumonia: a systematic review. *International Journal of Nursing Studies* 2015;**52**: 452–64.

Forsell 2009
Forsell M, Sjögren P, Johansson O. Need of assistance with daily oral hygiene measures among nursing home resident elderly versus the actual assistance received from the staff. *The Open Dentistry Journal* 2009;**3**:241–4.

Forsell 2011
Forsell M, Sjogren P, Kullberg E, Johansson O, Wedel P, Herbst B, et al. Attitudes and perceptions towards oral hygiene tasks among geriatric nursing home staff. *International Journal of Dental Hygiene* 2011;**9**:199–203.

Frenkel 1999
Frenkel HF. Behind the screens: care staff observations on delivery of oral health care in nursing homes. *Gerodontology* 1999;**16**(2):75–80.

Frenkel 2000
Frenkel H, Harvey I, Newcombe RG. Oral health care among nursing home residents in Avon. *Gerodontology* 2000;**17**(1):33–8.

Glassman 1994
Glassman P, Miller C, Woznick T, Jones C. A preventive dentistry training programme for caretakers of persons with disabilities residing in community residential facilities. *Special Care in Dentistry* 1994;**14**(4):137–43.

Gluhak 2010
Gluhak C, Arnetzl GV, Kirmeier R, Jakse N, Arnetzl G. Oral status among seniors in nine nursing homes in Styria, Austria. *Gerodontology* 2010;**27**(1):47–52.

GRADE 2014 [Computer program]
McMaster University. GRADEpro. www.gradepro.org. McMaster University, 2014.

Greene 1964
Greene JC, Vermillion JR. The simplified oral hygiene index. *Journal of the American Dental Association* 1964;**68**: 25–31.

Greene 1967
Greene JC. The Oral Hygiene Index: development and uses. *Journal of Periodontology* 1967;**38**:625–37.

Henriksen 1999
Henriksen BM, Ambjørnsen E, Axéll TE. Evaluation of a mucosal-plaque index (MPS) designed to assess oral care in groups of elderly. *Special Care in Dentistry* 1999;**19**(4): 154–7.

Higgins 2011
Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from handbook.cochrane.org.

Hoffmann 2014
Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014;**348**:g1687.

Hopcraft 2012
Hopcraft MS, Morgan MV, Satur JG, Wright FA. Edentulism and dental caries in Victorian nursing homes. *Gerodontology* 2012;**29**(2):e512–9.

Isaksson 2007
Isaksson R, Söderfeldt B. Oral status and treatment needs among elderly within municipal long-term care 2002-2004. *Swedish Dental Journal* 2007;**31**(1):45–52.

Jablonski 2009
Jablonski RA, Munro CL, Grap MJ, Schubert CM, Ligon M, Spigelmyer P. Mouth care in nursing homes: knowledge, beliefs, and practices of nursing assistants. *Geriatric Nursing* 2009;**30**(2):99–107.

Jones 1977
Jones F, Fremouw W, Carples S. Pyramid training of elementary school teachers to use classroom management skills package. *Journal of Applied Behavior Analysis* 1977;**10**: 239–53.

Kayser-Jones 1995
Kayser-Jones J, Bird WF, Paul SM, Long L, Schell ES. An instrument to assess the oral health status of nursing home residents. *The Gerontologist* 1995;**35**(6):814–24.

Lefebvre 2011
Lefebvre C, Manheimer E, Glanville J. Chapter 6: Searching for studies. In: Higgins JP, Green S, editor(s). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from handbook.cochrane.org.

Lenz 2007
Lenz M, Steckelberg A, Richter B, Mühlhauser I. Meta-analysis does not allow appraisal of complex interventions in diabetes and hypertension self-management: a methodological review. *Diabetologia* 2007;**50**(7):1375–83.

Löe 1967
Löe H. The Gingival Index, the Plaque Index and the Retention Index Systems. *Journal of Periodontology* 1967;**38** (6):610–6.

Mack 2005
Mack F, Schwahn C, Feine JS, Mundt T, Bernhardt O, John U, et al. The impact of tooth loss on general health related to quality of life among elderly Pomeranians: results from the study of health in Pomerania (SHIP-O). *International Journal of Prosthodontics* 2005;**18**:414–9.

Michie 2009
Michie S, Fixsen D, Grimshaw JM, Eccles MP. Specifying and reporting complex behaviour change interventions: the need for a scientific method. *Implementation Science* 2009; **4**:40.

Michie 2011
Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implementation Science* 2011;**6**:42.

Mojon 1999
Mojon P, Budtz-Jørgensen E, Rapin CH. Relationship between oral health and nutrition in very old people. *Age and Ageing* 1999;**28**(5):463–8.

Möhler 2012
Möhler R, Bartoszek G, Köpke S, Meyer G. Proposed criteria for reporting the development and evaluation of complex interventions in healthcare (CReDECI): guideline development. *International Journal of Nursing Studies* 2012; **49**(1):40–6.

Möhler 2015
Möhler R, Köpke S, Meyer G. Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare - revised guideline (CReDECI 2). *Trials* 2015; **16**:204.

Naito 2010
Naito M, Kato T, Fujii W, Ozeki M, Yokoyama M, Hamajima N, et al. Effects of dental treatment on the quality of life and activities of daily living in institutionalized elderly in Japan. *Archives of Gerontology and Geriatrics* 2010; **50**(1):65–8.

Nitschke 2010
Nitschke I, Majdani M, Sobotta BA, Reiber T, Hopfenmüller W. Dental care of frail older people and those caring for them. *Journal of Clinical Nursing* 2010;**19**(13-14):1882–90.

O'Leary 1972
O'Leary TJ, Drake RB, Naylor JE. The plaque control record. *Journal of Periodontology* 1972;**43**:38.

Porter 2015
Porter J, Ntoula A, Read A, Murdoch M, Ola D, Tsakos G. The impact of oral health on the quality of life of nursing home residents. *Health and Quality of Life Outcomes* 2015; **13**:102.

RevMan 2014
Review Manager (RevMan) [Computer program]. Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014.

Riessman 1965
Riessman F. The helper therapy principle. *Social Work* 1965;**10**:27–32.

Saarela 2014
Saarela RKT, Soini H, Hiltunen K, Muurinen S, Suominen M, Pitkala K. Dentition status, malnutrition and mortality among older service housing residents. *Journal of Nutrition, Health and Aging* 18;**1**:34–8.

Samson 2008
Samson H, Strand GV, Haugejorden O. Change in oral health status among institutionalized Norwegian elderly over a period of 16 years. *Acta Odontologica Scandinavica* 2008;**66**(6):368–73.

Saunders 2007
Saunders MJ, Stattmiller SP, Kirk KM. Oral health issues in the nutrition of institutionalized elders. *Journal of Nutrition for the Elderly* 2007;**26**(3-4):39–58.

Scannapieco 2003
Scannapieco FA, Bush RB, Paju S. Association between periodontal disease and risk for nosocomial bacterial pneumonia and chronic obstructive pulmonary disease. A systematic review. *Annals of Periodontology* 2003;**8**(1): 54–69.

Schou 1985
Schou L. Active-involvement principle in dental health education. *Community Dentistry and Oral Epidemiology* 1985;**13**:128–32.

Seitz 2010
Seitz D, Purandare N, Conn D. Prevalence of psychiatric disorders among older adults in long-term care homes: a systematic review. *International Psychogeriatrics/IPA* 2010; **22**(7):1025–39.

Shay 2002
Shay K. Infectious complications of dental and periodontal diseases in the elderly population. *Clinical Infectious Diseases* 2002;**34**(9):1215-23.

Sheiham 2001
Sheiham A, Steele JG, Marcenes W, Lowe C, Finch S, Bates CJ, et al. The relationship among dental status, nutrient intake, and nutritional status in older people. *Journal of Dental Research* 2001;**80**(2):408–13.

Silness 1964
Silness J, Löe H. Periodontal disease in pregnancy. II. Correlation between oral hygiene and periodontal condition. *Acta Odontologica Scandinavica* 1964;**22**: 121–35.

Simunković 2005
Simunković SK, Boras VV, Pandurić J, Zilić IA. Oral health among institutionalised elderly in Zagreb, Croatia. *Gerodontology* 2005;**22**(4):238–41.

Sjögren 2008
Sjögren P, Nilsson E, Forsell M, Johansson O, Hoogstraate J. A systematic review of the preventive effect of oral hygiene on pneumonia and respiratory tract infection in elderly people in hospitals and nursing homes: effect estimates and methodological quality of randomized controlled trials. *Journal of the American Geriatrics Society* 2008;**56**(11): 2124–30.

Slade 1994
Slade GD, Spencer AJ. Development and evaluation of the Oral Health Impact Profile. *Community Dental Health* 1994;**11**(1):3–11.

Slade 1997
Slade GD. Derivation and validation of a short-form oral health impact profile. *Community Dentistry and Oral Epidemiology* 1997;**25**(4):284–90.

Strauss 1993
Strauss RP, Hunt RJ. Understanding the value of teeth to older adults: influences on the quality of life. *Journal of the American Dental Association* 1993;**124**(1):105–10.

Suomi 1968
Suomi JD, Barbano JP. Patterns of gingivitis. *Journal of Periodontology* 1968;**39**:71–4.

Tonetti 2015
Tonetti MS, Eickholz P, Loos BG, Papapanou P, Van der Velden U, Armitage G, et al. Principles in prevention of periodontal diseases. *Journal of Clinical Periodontology* 2015;**42**(Suppl 16):S5–11. [DOI: 10.1111/jcpe.12368]

Walker 2007
Walker RJ, Kiyak HA. The impact of providing dental services to frail older adults: perceptions of elders in adult day health centers. *Special Care in Dentistry* 2007;**27**(4): 139–43.

Wang 2015
Wang TF, Huang CM, Chou C, Yu S. Effect of oral health education programs for caregivers on oral hygiene of the elderly: A systemic review and meta-analysis. *International Journal of Nursing Studies* 2015;**52**(6):1090–6. [DOI: 10.1016/j.ijnurstu.2015.01.015]

Wardh 2012
Wårdh I, Jonsson M, Wikström M. Attitudes to and knowledge about oral health care among nursing home personnel - an area in need of improvement. *Gerodontology* 2012;**29**(2):e787–92.

Weening-Verbree 2013
Weening-Verbree L, Huisman-de Waal G, van Dusseldorp L, van Acterberg T, Schoonhoven L. Oral health care in older people in long term care facilities: a systematic review of implementation strategies. *International Journal of Nursing Studies* 2013;**50**:569–82.

Wefers 1999

Wefers KP. The 'Denture Hygiene Index' (DHI). *Dental Forum* 1999;**1**:13–5.

Winkel 2003

Winkel EG, Roldán S, Van Winkelhoff AJ, Herrera D, Sanz M. Clinical effects of a new mouthrinse containing chlorhexidine, cetylpyridinium chloride and zinc-lactate on oral halitosis. A dual-center, double-blind placebo-controlled study. *Journal of Clinical Periodontology* 2003;**30**: 300–6.

Worthington 2015

Worthington H, Clarkson J, Weldon J. Priority oral health research identification for clinical decision-making. *Evidence-based Dentistry* 2015;**16**(3):69–71.

Wyatt 2002

Wyatt CC. Elderly Canadians residing in long-term care hospitals: Part II. Dental caries status. *Journal of the Canadian Dental Association* 2002;**68**(6):359–63.

* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Bellomo 2005

Methods	Randomised controlled trial, 2 arms (each with 2 subgroups: independent and assisted) Study period: not reported Planned follow-up period: 6 months
Participants	Country: Switzerland Setting: long-term care home Target audience for intervention: long-term care home residents Number of randomised participants (long-term care home residents): 61 Number of analysed participants (long-term care home residents): 61 Age, mean, years: 85.4 in IG, 86.8 in CG (range for both groups 72 to 97 years) Female: 73.3% in IG, 71% in CG Edentulous: 36.7% in IG, 35.6% in CG Residents with dental prosthesis: 80% (of all participants) Inclusion criteria: residents of the long-term care home (irrespective of state of (oral) health) Exclusion criteria: n/a
Interventions	**Intervention group** 2 subgroups (one with independent residents (IG1) and one with residents who are in need of assistance (IG2)): Instruction/skills training: • IG1: initial occupational therapy instruction on tooth and denture brushing • IG2: initial occupational therapy instructions on tooth and denture brushing followed by weekly monitoring and if necessary re-education. The monitoring consisted of guidance and "gesture/movement education" during the tooth and denture brushing. Education: • Educational lecture for medical/nursing staff of the long-term care home (aiming to raise awareness of dental hygiene needs of the residents, motivation to support the study) **Control group** 2 subgroups (one with independent residents (CG1) and one with residents who are in need of assistance (CG2)) • CG1: usual care • CG2: weekly occupational therapy employing "placebo" interventions, like a manicure carried out by the same occupational therapist Education: • Educational lecture for medical/nursing staff of the long-term care home (aiming to raise awareness of dental hygiene needs of the residents, motivation to support the study) **Co-interventions** n/a

Bellomo 2005 (*Continued*)

Outcomes	**Primary outcomes** Oral hygiene measures, level of autonomy (brushing), and residents' oral health-related behaviour were assessed at baseline, 3 and 6 months after start of the study • Dental plaque: Plaque Index (Silness 1964) • Denture plaque: Denture Plaque Index (Ambjørnsen 1982) • Level of autonomy (ability to brush teeth/dentures): scored by an occupational therapist using a scale from 0 to 3.5 • (Residents') oral health-related behaviour: interview on oral hygiene habits
Funding	Not reported
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information in the paper (correspondence: "randomisation was done by the nursing home via the patient allocation list (availability of rooms) in either one building or the other. no computer sequence generation etc.")
Allocation concealment (selection bias)	High risk	Insufficient information in the paper (correspondence: "no concealment")
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Groups corresponded to 2 separate buildings, which assured blinding of participants to the other study arm
Blinding of outcome assessment (detection bias) All outcomes	High risk	Insufficient information in the paper (correspondence: "outcome assessor was not blinded")
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Two participants passed away during the experimental period and were excluded from analysis." (study group affiliation unclear)
Selective reporting (reporting bias)	Unclear risk	Correspondence: protocol not available, no trial registration
Other bias	Low risk	None apparent

De Visschere 2011

Methods	Cluster-randomised controlled trial, 3 arms Study period: 2003 to 2008 Planned follow-up period: 5 years
Participants	Country: Belgium (Flanders) Setting: 14 nursing homes (selected out of 36 nursing homes using stratified cluster sampling) Target audience of intervention: nursing staff (nurses, nursing assistants, and nurse aides) Number of randomised participants (nursing home residents): 1393 Number of analysed participants (nursing home residents): 70 to 214 depending on outcome and measurement point Age, mean, years (SD): 84.93 (6.97) in IG, 86.0 (7.36) in CG1, 83.18 (8.63) in CG2 Female: 73.9% in IG, 77.6% in CG1, 74.4% in CG2 Edentulous residents: 67.8% in IG, 67.9% in CG1, 68.5% in CG2 Residents with dental prosthesis: 77% (all groups) Inclusion criteria: all residents eligible Exclusion criteria: n/a
Interventions	**Intervention group** Implementation of an oral hygiene protocol including multiple components: Education/skills training: • theoretical and practical training session (half day) for all oral health co-ordinators, who had to educate the other nursing staff (train-the-trainer principle) Additional components: • introduction session (1 hour) with the director of the nursing home • appointment of registered nurses as oral health co-ordinators (responsible for the implementation procedure on their ward) • oral assessment of new residents using newly designed assessment forms • preparation of an "individualized oral hygiene plan" for every resident by the oral health co-ordinators, and integration into daily care by all caregivers involved **Control group** CG1: usual oral hygiene CG2: complex intervention was implemented in the nursing home, but residents did not receive intervention **Co-interventions** n/a
Outcomes	**Primary outcomes** Oral hygiene measures were assessed at baseline, and every year after the start of the study for a period of 5 years • Dental plaque: Plaque Index (Silness 1964) • Denture plaque: method of Augsburger 1982
Funding	GABA International (supported data collection)
Notes	Results/data for primary outcomes only available for baseline, 2 years and 5 years after the start of the study
Risk of bias	

De Visschere 2011 (*Continued*)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "randomly selected" Insufficient information
Allocation concealment (selection bias)	Unclear risk	Insufficient information
Blinding of participants and personnel (performance bias) All outcomes	Low risk	No blinding of participants and personnel or incomplete blinding, but the review authors judge that the assessed outcomes are not likely to be influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "examiners were blind as to which residents were included in the intervention or not"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Correspondence: "every year residents were randomly selected using stratified cluster sampling for outcome assessment (at least 20% residents per nursing home)" Comment: number of residents per assessment period (every year) unclear
Selective reporting (reporting bias)	High risk	No protocol found; results/data for primary outcomes only available for baseline, 2 years and 5 years after the start of the study
Other bias	High risk	Possible contamination between groups, and high risk of recruitment bias (selection/recruitment of participants after randomisation)

De Visschere 2012

Methods	Cluster-randomised controlled trial, 2 arms Study period: spring to winter 2009 Planned follow-up period: 6 months
Participants	Country: Belgium (Flanders) Setting: 12 nursing homes (with somatic and psychogeriatric residents) Target audience for the intervention: nursing home staff Number of randomised participants (nursing home residents; nursing staff): 373; 760 Number of analysed participants (nursing home residents; nursing staff): 297; 259 Age, mean, years (SD): 84.5 (8.5) in IG, 84.9 (7.6) in CG Female: 68.4% in IG, 78.0% in CG Edentulous residents: 55% in IG, 54.3% in CG

	Residents with dental prosthesis: 72.3% in IG, 69.1% in CG Inclusion criteria: having teeth and/or (removable) partial or complete dentures; physically suitable for examination; expected to be residing in the care home during the entire 6-month period Exclusion criteria: residents in day care**,** in short-term residency, in coma, in palliative care or terminally ill, using a denture adhesive, expressing verbal or physical resistiveness before or during an oral examination
Interventions	**Intervention group** Supervised implementation of the "Oral health care Guideline for Older people in Long-term care Institutions (OGOLI)" including multiple components: Education/skills training: • oral presentation (1.5 hours) for the managing director, care home study supervisor, the ward heads, and the ward oral healthcare organiser (WOO) about OGOLI, daily oral healthcare protocol, and the supervised implementation project • lecture (2 hours) for the WOOs including theoretical and practical essentials of OGOLI and the daily oral healthcare protocol • practical education (1 hour) for the WOOs according to the train-the-trainer concept • theoretical and practical education session (1.5 hour) for all nurses and nurse assistants at ward level, presented by the ward's WOO using all education materials. WOOs presented a summary of OGOLI and all executive actions (e.g. tooth brushing) were taught and demonstrated with ward residents on site Information material: • PowerPoint presentation, OGOLI, daily oral healthcare protocol Additional components: • WOO encouraged and assisted nursing staff in the daily delivery of oral health care • monitoring visits of a dental hygienist together with an investigator (every 6 weeks including WOOs support and where necessary repeating educational sessions for (new) nursing staff) • daily oral healthcare protocol **Control group** Usual oral health care according to the no-supervised implemented guideline (since 2007 Dutch guideline OGOLI) The intervention was implemented in the control nursing homes after completion of data collection **Co-interventions** (for the intervention group) • oral healthcare material and products
Outcomes	**Primary outcomes** Oral hygiene measures were assessed at baseline and 6 months after the start of the study • Dental plaque: Plaque Index by Silness 1964 • Denture plaque: method of Augsburger 1982 • Tongue coating: Tongue Coating Index (Winkel 2003) Oral health-related knowledge and attitude were assessed at baseline and 6 months after the start of the study • (nursing staff) knowledge: self administered questionnaire (15 statements assessing knowledge of oral pathology and oral hygiene)

	• (nursing staff) attitude: self administered questionnaire (4 statements)
Funding	Research project is funded by Open Ankh, Soest and Stichting De Opbouw, Utrecht, the Netherlands Oral healthcare products were provided free by GABA International, Eureka Pharma Belgium, Oral-B Belgium, and Johnson & Johnson consumer S.A/N.V
Notes	Questionnaire (included 3 parts: personal items, attitude statements, knowledge statements): The reliability of the attitude part of the questionnaire was measured by a test-retest procedure in a comparable nursing home not involved in the study. Content and construct validity (knowledge part) was assessed by experts in the field of gerodontology including 1 dental hygienist and 3 dentists

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "randomly allocated to the intervention (n = 6) or the control group (n = 6) using computer-aided tools"
Allocation concealment (selection bias)	Unclear risk	Insufficient information
Blinding of participants and personnel (performance bias) All outcomes	Low risk	No blinding of participants and personnel or incomplete blinding, but the review authors judge that the assessed outcomes are not likely to be influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "The examiners were masked, they did not know whether a nursing home was allocated to the intervention or the control group."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote (De Visschere, clinical measures of nursing home residents): "main reasons for loss to follow-up: death (35%), administrative errors (30%), address change, move or absence (15%), hospitalisation or sickness (9%) or refusals (9%). There were no differences in loss to follow-up between those randomised to the intervention group and to the control group." Quote (Janssens, knowledge of nursing staff): baseline N = 760; "259 (34%) respondents were found, 165 belonging to the intervention group and 94 to the con-

		trol group." "All respondents were analysed in the groups to which they were originally allocated (intention to treat analysis). There were no significant differences between the respondents (n = 259) and non-respondents (n = 392) for the explanatory and outcome variables."
Selective reporting (reporting bias)	High risk	Outcomes reported as planned in the study protocol. Tongue coating as outcome not preplanned
Other bias	Low risk	None apparent

Frenkel 2001

Methods	Cluster-randomised controlled trial, 2 arms Study period: not reported Planned follow-up period: 6 months
Participants	Country: UK Setting: 22 nursing homes (with 20 to 40 beds) Target audience for intervention: nursing staff Number of randomised participants (nursing home residents; nursing staff): 412; 322 Number of analysed participants (nursing home residents; nursing staff): 337; 232 Age, mean, years (SD): 84.9 (8.2) in IG, 84.0 (8.3) in CG Female: 81.1% in IG, 75.8% in CG Edentulous: 75.1% in IG, 67.8% in CG Residents with dental prosthesis: 80.6% in IG, 80.1% in CG Inclusion criteria: residents who either wore dentures and/or had one or more natural teeth, and whose general health permitted oral examination to take place Exclusion criteria: residents with significant cognitive impairment
Interventions	**Intervention group** Education/skills training: • oral healthcare education session (1 hour) for the care assistants including a theoretical section (role of plaque in oral diseases, demonstration of cleaning techniques) and a practical section (cleaning techniques for natural teeth and dentures using a manikin head, models, and other teaching aids) Information material: • booklet on oral health care for care assistants who attended the educational session **Control group** Usual care (health education programme was delivered after completion of data collection) **Co-interventions** • toothbrushes (for the IG residents) • course attendance certificate (for care assistants who attended the educational session)

Outcomes	**Primary outcomes** Oral hygiene measures were assessed at baseline, 1 month and 6 months after education • Dental plaque: Simplified Oral Hygiene Index (Greene 1964) • Denture plaque: method of Augsburger 1982 • Gingivitis: method of Suomi 1968 • Denture-induced stomatitis: Budtz-Jørgensen 1978 Caregiver oral health knowledge and attitudes were assessed at baseline, 1 month and 6 months after education • (caregivers) knowledge: self administered questionnaire (26 statements with true/false responses) • (caregivers) attitude: self administered questionnaire (25 statements with responses on a 5-point Likert scale) **Secondary outcomes** The secondary outcome variables were recorded on a binary scale (absent/present) • calculus • root caries • tooth mobility
Funding	Grants from the NHS Executive South West (Research and Development Directorate)
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Block randomisation (block size 4) was performed using a table of random numbers by an independent researcher not involved in data collection or delivery of the intervention."
Allocation concealment (selection bias)	Low risk	Quote: "The allocation was communicated directly and solely to the Health Promoter, and kept by her in a secure location during the trial. Staff in all participating nursing homes were asked to conceal their group allocation from the examiner."
Blinding of participants and personnel (performance bias) All outcomes	Low risk	No blinding of participants and personnel or incomplete blinding, but the review authors judge that the assessed outcomes are not likely to be influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "single-blinded" and "examiner blindness"

Frenkel 2001 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Some indication of completeness of follow-up except for dental plaque measure (some teeth could not be scored)
Selective reporting (reporting bias)	Unclear risk	No protocol available
Other bias	Low risk	None apparent

MacEntee 2007

Methods	Cluster-randomised controlled trial, 2 arms Study period: not reported Planned follow-up: 3 months
Participants	Country: Canada Setting: 14 long-term care facilities Target audience for intervention: care-aides Number of randomised participants (nursing home residents with intermediate care): 127 Number of analysed participants (nursing home residents with intermediate care): 113 Age, mean, years: 78.3 in IG, 79.9 in CG Female: not reported Edentulous: excluded Residents with dental prosthesis: not reported Inclusion criteria: residents receiving intermediate care, with natural teeth, and cognitively and physically suitable for a clinical examination of the mouth Exclusion criteria: not explicitly stated
Interventions	**Intervention group** Pyramidal education consisting of the following. Education/skills training: • nurse educator training (including an annotated series of clinical photographs and texts summarising the appearance and management of oral diseases among frail elderly) for a permanent member of the nursing staff by a dental hygienist • single seminar (1 hour) for care-aides conducted by the nurse educator comprising a theoretical part with photographs and texts, and demonstration with props of how to examine and clean the mouth Information material: • copy of the text for care-aides attending the seminar • access to the photographs for care-aides attending the seminar Additional components: • nurse educator (managing the oral health care provided by the care aides) • nurse educator had direct access to the dental hygienist by telephone for further information/advice as needed • dental hygienist contacted nurse educator within 2 weeks of their meeting to offer additional guidance **Control group** Usual routine (comprises the same 1-hour seminar with photographs, texts, and demon-

	strations but delivered directly to the care-aides by the dental hygienist. No additional information or support.) **Co-interventions** n/a
Outcomes	**Primary outcomes** Oral hygiene measures were assessed at baseline and 3 months after the seminar • Dental plaque: Geriatric Simplified Debris Index (Greene 1967) • Gingivitis: Gingival Bleeding Index (Ainamo 1975) **Secondary outcomes** Clinical measures of dietary nourishment and masticatory potential were assessed at baseline and 3 months after the seminar • body mass index (BMI) • Malnutrition Indicator Score (MIS) • masticatory potential: Eichner index Additional outcomes: psychosocial outcomes were assessed using qualitative research methods (questionnaires, interviews)
Funding	BC Medical Service Foundation Grant
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "randomised block design"; correspondence: "generated from a programme by a research assistant"
Allocation concealment (selection bias)	Low risk	Quote: "A person not involved in the education or analysis of results performed the random selections and assignments, and broke the code when all data were collected. "
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "double-blind.... Neither the examiner nor the residents knew the intervention assignments."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "The examiner or assistant did not know the educational method assigned to the facilities, nor did they know the results from the baseline examinations when examining the residents 3 months later."
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Data for outcomes (gingival bleeding score, tab. 3) were not collected from all participants due to some participants being un-

MacEntee 2007 (*Continued*)

		able or unwilling to co-operate fully Losses to follow-up comparable in intervention (N = 8) and control group (N = 6)
Selective reporting (reporting bias)	Low risk	Insufficient information in published study report, additional data provided on request Results of the psychosocial aspects not published/not available
Other bias	Unclear risk	Possible recruitment bias (insufficient information)

Mojon 1998

Methods	Cluster-randomised controlled trial, 2 arms Study period: not reported Planned follow-up period: 18 months
Participants	Country: Switzerland Setting: 1 long-term care facility (12 wards) Target audience for intervention: nursing staff (nurses and nurse aides) and residents Number of randomised participants (nursing home residents): 237 Number of analysed participants (nursing home residents): 159 Age, mean, years: 83.5 in IG, 84.6 in CG Female: 67% in IG, 69% in CG Edentulous: not reported Residents with dental prosthesis: 62.1% Inclusion criteria: residents Exclusion criteria: residents who could not provide informed consent (cognitive impairment)
Interventions	**Intervention group** Education/skills training: • interactive lecture (45 minutes) with slides on oral health prevention and demonstration on how to brush teeth for nurses and nurse aides • brief oral hygiene instruction for the residents by a dental hygienist • instructions (personalised for every resident) given by a dental hygienist for the accompanying nurse or nurse aide **Control group** Usual care (prior to the study no oral hygiene care was provided by the caregivers on a regular basis) Cleaning of the teeth only took place if requested by the dentist and oral care by a dentist only at request of the resident, family, or caregivers **Co-interventions** • prophylactic treatment including scaling (for the IG residents) • implementation of a recall system with a maximum of 6 months between visits (for the IG residents) • toothbrushes, toothpaste, and further oral care supplies (for the IG residents)

	• dental treatment if needed (for the IG residents)
Outcomes	**Primary outcomes** Oral hygiene measures and infections were assessed at baseline and 18 months later • Dental plaque: Plaque Index (Silness 1964) • Caries and root caries assessed by clinical examination • Salivary bacteria assessed by microbiological sampling • Oral candidosis assessed by oral yeast cultivation • Hyperkeratotic or erythematous lesions (denture stomatitis, glossitis, and diffuse mucositis) assessed by clinical examination
Funding	The research project was supported by the Swiss National Foundation for Research Oral healthcare products were donated by GABA AG, Mibelle AG Cosmetics, and Beecham Markenartikel AG
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Correspondence: "random number table"
Allocation concealment (selection bias)	Unclear risk	Insufficient information
Blinding of participants and personnel (performance bias) All outcomes	Low risk	No blinding of participants and personnel or incomplete blinding, but the review authors judge that the assessed outcomes are not likely to be influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "The dentist who performed the follow-up examination did not have access to the baseline examination form and he was not informed in which ward the resident was living." However, "it was not possible, for practical reasons, to prevent systematically the dentist in charge of the follow-up examinations to know the ward in which the residents were living."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Lost to follow-up (Budtz-Jorgensen): "40 residents in the intervention group and 38 in the control group" (reason: all died) Lost to follow-up (Mojon): "18 died during the study period, 10 became edentulous, and 2 were terminally ill at the time of

		the second examination. Among the 86 remaining residents, 7 refused the oral examination and 23 refused the bacterial sampling." (group allocation unclear)
Selective reporting (reporting bias)	Unclear risk	No protocol found
Other bias	Low risk	None apparent

Schou 1989

Methods	Cluster-randomised controlled trial, 4 arms Study period: January 1985 to September 1985 Planned follow-up period: 9 months
Participants	Country: Scotland, UK Setting: 4 institutions for the elderly Target audience for the intervention: nursing staff or residents, or both Number of randomised participants (residents): 201 Number of analysed participants (residents): 112 to 140 (depending on the outcome measure) Age, mean, years (range): 82 (48 to 99) for all study participants Female: not reported Edentulous: 89.9% of all study participants Residents with dental prosthesis: not reported Inclusion criteria: not reported Exclusion criteria: n/a
Interventions	**Intervention group** 3 groups with a dental health education programme utilising the active involvement principle targeted at different audiences Education: • Sessions on dental health with the active involvement principle (3 times, 1 hour, monthly interval) conducted by dental hygienists for residents only (IG1), staff only (IG2), or staff and residents (IG3) **Control group** Usual care (no educational programme) **Co-interventions** n/a
Outcomes	**Primary outcomes** Oral hygiene measures and oral health-related behaviour were assessed at baseline and 2 months after termination of the programme (9 months after the start) • Denture plaque: Denture Plaque Index (Ambjørnsen 1982), plaque on the fitting surface of dentures using a sickle probe • Prosthetic status according to the WHO criteria • Denture-induced stomatitis using the method by Budtz-Jørgensen 1970 • Oral health-related behaviour (residents) using a questionnaire (interview by a dentist)

Schou 1989 (*Continued*)

Funding	Not reported	
Notes		

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "The four institutions were (...) randomly allocated to a control group or one of the three programmes"
Allocation concealment (selection bias)	Unclear risk	Insufficient information
Blinding of participants and personnel (performance bias) All outcomes	Low risk	No blinding of participants and personnel or incomplete blinding, but the review authors judge that the assessed outcomes are not likely to be influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "dentist who examined all the subjects and who was blind to the individual's affiliation to experimental respective control groups."
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient information
Selective reporting (reporting bias)	Unclear risk	No protocol found
Other bias	Unclear risk	Possible recruitment bias (insufficient information)

Van der Putten 2013

Methods	Cluster-randomised controlled trial, 2 arms Study period: not reported Planned follow-up period: 6 months
Participants	Country: Netherlands Setting: 12 nursing homes Target audience for the intervention: nursing home staff Number of randomised participants (nursing home residents): 343 Number of analysed participants (nursing home residents): 232 Age, mean, years (SD): 80.4 (9.4) in IG, 80.7 (10.9) in CG Female: 66% in IG, 69% in CG Edentulous: 70% in IG, 62% in CG Residents with dental prosthesis: 84% in IG, 75% in CG

	Inclusion criteria: having teeth and/or (removable) partial or complete dentures; physically suitable for examination; expected to be residing in the care home during the entire 6-month period Exclusion criteria: residents in day care**,** in short-term residency (on a rehabilitation ward, residing 2 weeks to 3 months = less than 6 months on this ward), in coma, in palliative care or terminally ill, using a denture adhesive, expressing verbal or physical resistiveness before or during an oral examination
Interventions	**Intervention group** Supervised implementation of the "Oral health care Guideline for Older people in Long-term care Institutions (OGOLI)" including multiple components: Education/skills training: • oral presentation (1.5 hours) for the managing director, care home study supervisor, the ward heads, and the ward oral healthcare organiser (WOO) about OGOLI, daily oral healthcare protocol, and the supervised implementation project • lecture (2 hours) for the WOOs including theoretical and practical essentials of OGOLI and the daily oral healthcare protocol • practical education (3 hours) for the WOOs according to the train-the-trainer concept • theoretical and practical education session (1.5 hours) for all nurses and nurse assistants at ward level, presented by the ward's WOO using all education materials. WOOs presented a summary of OGOLI, and all executive actions (e.g. tooth brushing) were taught and demonstrated with ward residents on site. Information material: • PowerPoint presentation, OGOLI, daily oral healthcare protocol Additional components: • WOO encouraged and assisted nursing staff in the daily delivery of oral health care. • monitoring visits of a dental hygienist together with an investigator (every 6 weeks including WOOs support and where necessary repeating educational sessions for (new) nursing staff) • daily oral healthcare protocol **Control group** Usual oral health care according to the no-supervised implemented guideline (since 2007 Dutch guideline OGOLI) **Co-interventions** (for the intervention group) • oral healthcare material and products
Outcomes	**Primary outcomes** Oral hygiene measures were assessed at baseline and 6 months after the start of the study • Dental plaque: Plaque Index (Silness 1964) • Denture plaque: method of Augsburger 1982 Planned outcomes • oral health-related knowledge (staff) using a self administered questionnaire (15 statements assessing knowledge of oral pathology and oral hygiene) • oral health-related attitude (staff) using a self administered questionnaire (4 statements)

Funding	Research project is funded by Open Ankh Foundation, Utrecht; The Opbouw Foundation, Utrecht; ZonMw, The Hague; Vereniging Zonnehuis, Amstelveen; Stichting Wetenschapsbevordering Verpleeghuiszorg, Amsterdam; MarkTwo Communications, Leusden und Fonds NutsOhra, Amsterdam Oral healthcare products were provided free by GABA International, NoviaCura, and Johnson & Johnson
Notes	Publication of oral health-related knowledge and attitude in preparation

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "allocated randomly" Comment: Probably done, since another report from the same investigators (one study protocol for both trials) described use of "computer-aided tools"
Allocation concealment (selection bias)	Unclear risk	Insufficient information
Blinding of participants and personnel (performance bias) All outcomes	Low risk	No blinding of participants and personnel or incomplete blinding, but the review authors judge that the assessed outcomes are not likely to be influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "examiners were blinded"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "Over the course of the trial, 111 of the residents (32%) were lost to follow-up, 62 (35%) in the intervention group and 49 (29.5%) in the control group. There were no significant differences in loss to follow-up between the intervention and the control group (Chi-square, p=0.18). The main reasons for loss to follow-up were: deceased (66%), administrative error (7%), moved to another care home or otherwise absent (8%), intermediate disease (14%) or refusal (5%). There were also no statistically significant differences in residents' personal and medical characteristics and dental and denture plaque scores at baseline between residents who completed the study and those who did not."

Van der Putten 2013 (*Continued*)

Selective reporting (reporting bias)	Low risk	Additional outcomes planned in the protocol (knowledge and attitude of nursing staff), paper in preparation for knowledge and attitude results (correspondence)
Other bias	Low risk	None apparent

Zenthöfer 2013

Methods	Randomised controlled trial, 4 arms Study period: not reported Planned follow-up period: 12 weeks (re-evaluation after 3 years for IG)
Participants	Country: Germany (South-West Germany) Setting: 8 institutions for elderly people (nursing homes including assisted accommodation) Target audience for intervention: nursing home residents and caregiver staff Number of randomised participants (nursing home residents): 106 Number of analysed participants (nursing home residents): 102 Age, mean, years: 81.5 in IG1, 82.6 in IG2, 79.5 in IG3, 79.4 in CG (mean age (SD), years, range for all study participants: 80.8 (7.45), 49 to 95) Female: 80.8% in IG1, 85.2% in IG2, 80.8% in IG3, 65.2% in CG (78.4% of all participants) Edentulous residents: 32.4% (all groups) Residents with dental prosthesis: 87.3% (all groups) Inclusion criteria: residents at care level 1 or with no care level (Germany has care insurance for financial support of people who need care. Care levels are numbered from 0 to 3, which increase with people's need for care. To receive financial help at care level 1, a person must have a need for care of a minimum of 90 min per day, of which 45 min must be basic care, e.g. personal hygiene and nutrition.) Exclusion criteria: residents with dementia, severe infectious diseases, care level 2, or care level 3
Interventions	**Intervention group(s)** 3 groups with multiple interventions. Basic intervention for all 3 intervention groups: Education/instruction: • individual instructions for every resident in the specifics of his/her oral hygiene including brushing techniques and cleaning auxiliaries (minimum of half an hour) • one 2-hour lesson for caregivers (including a PowerPoint presentation, an oral hygiene film, and dental demonstration models); oral hygiene instructions were given according to a standardised scheme Information material: • brochure for residents regarding oral and denture hygiene Additional interventions: • IG1: no remotivation for residents (over the 12-week study period) • IG2: remotivation for residents by dentist (re-instruction and remotivation after 4 and 8 weeks)

	• IG3: remotivation for residents by caregivers (provision of help twice a week using a standardised procedure) **Control group** Usual oral hygiene **Co-interventions** (for residents in the 3 intervention groups) • provision of oral healthcare utilities (toothbrushes, toothpaste, etc.) • professional cleaning of teeth and dentures
Outcomes	**Primary outcomes** Oral hygiene measures were assessed at baseline and 2 weeks, 6 weeks, 12 weeks, and 3 years after the intervention • Dental plaque: Plaque Control Record (O'Leary 1972) • Gingivitis: Gingival Bleeding Index (Ainamo 1975) • Denture plaque: Denture Hygiene Index (Wefers 1999)
Funding	Mouth rinses and toothpaste were provided free by GABA GmbH, Germany
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The principal investigator assigned group membership by lot"
Allocation concealment (selection bias)	Unclear risk	Quote: "Principal investigator gave the information to the second study clinician"
Blinding of participants and personnel (performance bias) All outcomes	Low risk	No blinding of participants and personnel or incomplete blinding, but the review authors judge that the assessed outcomes are not likely to be influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Baseline and recall examinations (...) were performed without knowledge of the group to which the participant belonged (single-blinded)."
Incomplete outcome data (attrition bias) All outcomes	Low risk	4 participants (3.7%) were lost to follow-up after 12 weeks (1 died, 1 was no longer in the home, 1 had to stay in hospital, and 1 no longer wished to participate)
Selective reporting (reporting bias)	Unclear risk	No protocol found
Other bias	Low risk	None apparent

CG: control group
IG: intervention group
SD: standard deviation
WHO: World Health Organization

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Avenali 2011	Participant age (mean age below 42 years)
Beck 210	Not primarily an educational intervention
Czarkowski 2013	Not a randomised controlled trial
Davies 1990	Not a randomised controlled trial
Gammack 2009	Not a randomised controlled trial
Jönsson 2012	Not nursing home based
Lange 2000	Participant age (ranging from 32 to 64 years)
Nicol 2005	Not a randomised controlled trial
Park 2011	Not a randomised controlled trial
Park 2014	No predefined outcome measures
Paulsson 1998	Not a randomised controlled trial
Quagliarello 2009	No educational intervention
Simons 2000	Not a randomised controlled trial
Sniehotta 2007	Participants were students
Tan 2010	Not primarily an educational intervention
Vandamme 2006	No educational intervention
Wyatt 2009	No educational intervention
Yonezawa 2003	No educational intervention

Characteristics of ongoing studies *[ordered by study ID]*

Jablonski 2011

Trial name or title	Reducing care-resistant behaviors during oral hygiene in persons with dementia
Methods	Randomised controlled trial Estimated study completion date: April 2015 Study completion date: November 2015
Participants	Country: Pennsylvania, USA Inclusion criteria: Nursing home residents (English-speaking, age 65 or older, documented diagnosis of dementia, Alzheimer's disease, vascular dementia, or Lewy body dementia, identified by nursing home staff as resistant to mouth care, at least 2 adjacent teeth and/or daily wearing of at least 1 denture plate, the ability to hold a toothbrush, the ability to move his or her hand to his or her mouth) Estimated enrolment: 80
Interventions	Behavioural: "Managing Oral Hygiene Using Threat Reduction (MOUTh)" The intervention combines best mouth care practices with a constellation of behavioural techniques that reduce threat perception and thereby prevent or de-escalate care-resistant behaviour
Outcomes	Primary outcome measures: Reduction in care-resistant behaviour (time frame: 4 weeks). Care-resistant behavior will be measured using a refinement of the Resistiveness to Care Scale (specifically for use with people with dementia). Secondary outcome measures: Oral health (time frame: 4 weeks) will be measured as the total score obtained from the Oral Health Assessment Tool
Starting date	April 2011
Contact information	Principal Investigator: Rita A Jablonski, Penn State University
Notes	ClinicalTrials.gov identifier: NCT01363258

DATA AND ANALYSES

Comparison 1. Educational intervention (with information and practical components) versus (optimised) usual care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Dental plaque (subgroup analysis intervention recipient)	6	353	Mean Difference (IV, Random, 95% CI)	-0.04 [-0.26, 0.17]
1.1 Education for staff	5	321	Mean Difference (IV, Random, 95% CI)	-0.14 [-0.29, 0.00]
1.2 Education for staff and residents	1	32	Mean Difference (IV, Random, 95% CI)	0.38 [0.08, 0.68]
2 Dental plaque (subgroup analysis follow-up)	6	353	Mean Difference (IV, Random, 95% CI)	-0.04 [-0.26, 0.17]
2.1 Short term (up to six months)	5	306	Mean Difference (IV, Random, 95% CI)	-0.06 [-0.31, 0.18]
2.2 Long term (more than six months)	1	47	Mean Difference (IV, Random, 95% CI)	0.10 [-0.33, 0.53]
3 Dental plaque (subgroup analysis guideline implementation short-term follow-up)	5	306	Mean Difference (IV, Random, 95% CI)	-0.06 [-0.31, 0.18]
3.1 Education in the context of guideline implementation	2	129	Mean Difference (IV, Random, 95% CI)	-0.20 [-0.45, 0.06]
3.2 Education without guideline implementation	3	177	Mean Difference (IV, Random, 95% CI)	0.02 [-0.36, 0.39]
4 Denture plaque (subgroup analysis intervention recipient)	5	524	Std. Mean Difference (IV, Random, 95% CI)	-0.60 [-1.25, 0.05]
4.1 Education for staff	4	476	Std. Mean Difference (IV, Random, 95% CI)	-0.73 [-1.47, 0.00]
4.2 Education for staff and residents	1	48	Std. Mean Difference (IV, Random, 95% CI)	-0.03 [-0.60, 0.54]
5 Denture plaque (subgroup analysis follow-up)	5	524	Std. Mean Difference (IV, Random, 95% CI)	-0.60 [-1.25, 0.05]
5.1 Short term (up to six months)	4	437	Std. Mean Difference (IV, Random, 95% CI)	-0.68 [-1.48, 0.12]
5.2 Long term (more than six months)	1	87	Std. Mean Difference (IV, Random, 95% CI)	-0.28 [-0.70, 0.14]
6 Denture plaque (subgroup analysis guideline implementation short-term follow-up)	4	437	Std. Mean Difference (IV, Random, 95% CI)	-0.68 [-1.48, 0.12]
6.1 Education in the context of guideline implementation	2	221	Std. Mean Difference (IV, Random, 95% CI)	-0.41 [-0.68, -0.14]
6.2 Education without guideline implementation	2	216	Std. Mean Difference (IV, Random, 95% CI)	-0.94 [-2.68, 0.81]
7 Oral health-related knowledge (staff)	2	275	Std. Mean Difference (IV, Random, 95% CI)	0.94 [-0.04, 1.92]
8 Oral health-related attitude (staff)	2	275	Std. Mean Difference (IV, Random, 95% CI)	0.30 [-0.23, 0.83]

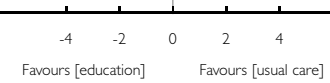
Analysis 1.1. Comparison 1 Educational intervention (with information and practical components) versus (optimised) usual care, Outcome 1 Dental plaque (subgroup analysis intervention recipient).

Review: Oral health educational interventions for nursing home staff and residents

Comparison: 1 Educational intervention (with information and practical components) versus (optimised) usual care

Outcome: 1 Dental plaque (subgroup analysis intervention recipient)

Study or subgroup	Education N	Mean(SD)	usual care N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 Education for staff							
De Visschere 2011	24	1.68 (0.74)	23	1.58 (0.75)		12.9 %	0.10 [-0.33, 0.53]
De Visschere 2012	30	1.58 (0.79)	43	1.77 (0.74)		15.2 %	-0.19 [-0.55, 0.17]
Frenkel 2001	33	1.87 (0.49)	36	2.18 (0.53)		19.7 %	-0.31 [-0.55, -0.07]
MacEntee 2007	31	1.4 (0.5)	45	1.4 (0.6)		19.4 %	0.0 [-0.25, 0.25]
Van der Putten 2013	24	1.58 (0.81)	32	1.78 (0.42)		15.3 %	-0.20 [-0.56, 0.16]
Subtotal (95% CI)	**142**		**179**			**82.5 %**	**-0.14 [-0.29, 0.00]**
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 4.54$, df = 4 (P = 0.34); $I^2 = 12\%$							
Test for overall effect: Z = 1.90 (P = 0.057)							
2 Education for staff and residents							
Bellomo 2005	17	0.67 (0.49)	15	0.29 (0.36)		17.5 %	0.38 [0.08, 0.68]
Subtotal (95% CI)	**17**		**15**			**17.5 %**	**0.38 [0.08, 0.68]**
Heterogeneity: not applicable							
Test for overall effect: Z = 2.52 (P = 0.012)							
Total (95% CI)	**159**		**194**			**100.0 %**	**-0.04 [-0.26, 0.17]**
Heterogeneity: $Tau^2 = 0.05$; $Chi^2 = 14.50$, df = 5 (P = 0.01); $I^2 = 66\%$							
Test for overall effect: Z = 0.37 (P = 0.71)							
Test for subgroup differences: $Chi^2 = 9.61$, df = 1 (P = 0.00), $I^2 = 90\%$							



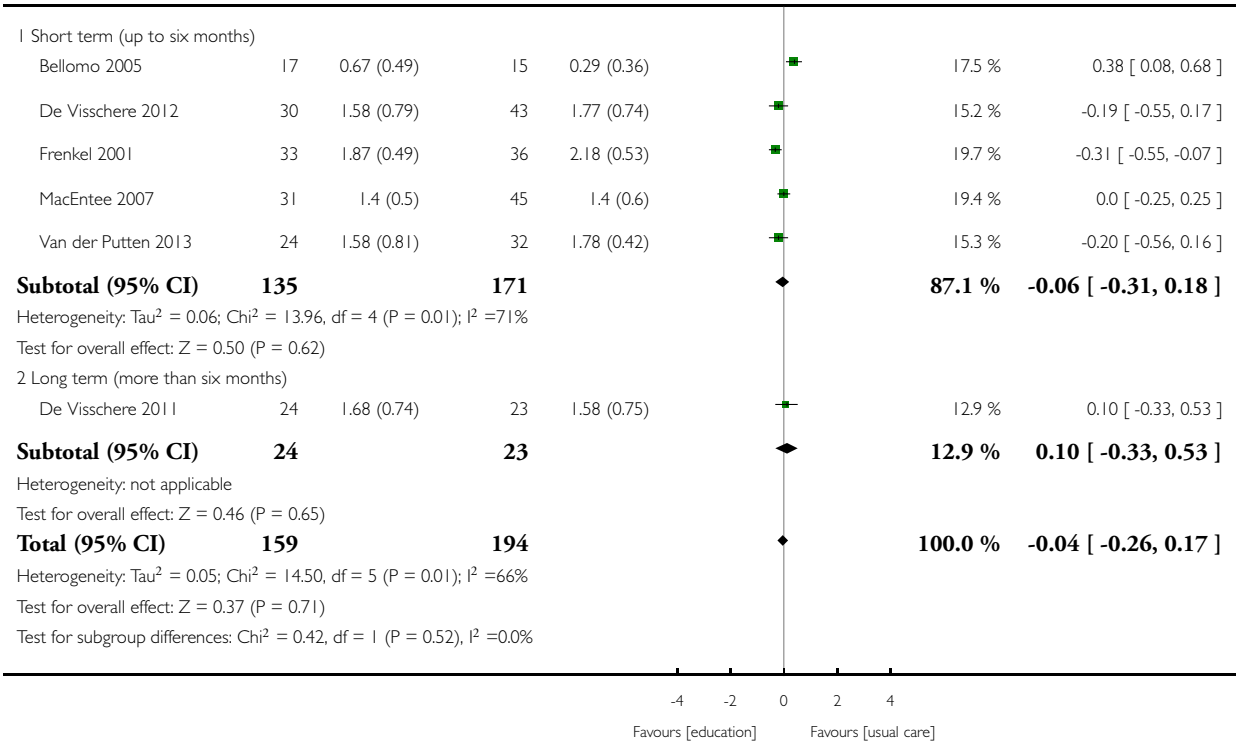
Analysis 1.2. Comparison 1 Educational intervention (with information and practical components) versus (optimised) usual care, Outcome 2 Dental plaque (subgroup analysis follow-up).

Review: Oral health educational interventions for nursing home staff and residents

Comparison: 1 Educational intervention (with information and practical components) versus (optimised) usual care

Outcome: 2 Dental plaque (subgroup analysis follow-up)

Study or subgroup	Education N	Mean(SD)	Usual care N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 Short term (up to six months)							
Bellomo 2005	17	0.67 (0.49)	15	0.29 (0.36)		17.5 %	0.38 [0.08, 0.68]
De Visschere 2012	30	1.58 (0.79)	43	1.77 (0.74)		15.2 %	-0.19 [-0.55, 0.17]
Frenkel 2001	33	1.87 (0.49)	36	2.18 (0.53)		19.7 %	-0.31 [-0.55, -0.07]
MacEntee 2007	31	1.4 (0.5)	45	1.4 (0.6)		19.4 %	0.0 [-0.25, 0.25]
Van der Putten 2013	24	1.58 (0.81)	32	1.78 (0.42)		15.3 %	-0.20 [-0.56, 0.16]
Subtotal (95% CI)	**135**		**171**			**87.1 %**	**-0.06 [-0.31, 0.18]**
Heterogeneity: $Tau^2 = 0.06$; $Chi^2 = 13.96$, df = 4 (P = 0.01); $I^2 = 71\%$							
Test for overall effect: Z = 0.50 (P = 0.62)							
2 Long term (more than six months)							
De Visschere 2011	24	1.68 (0.74)	23	1.58 (0.75)		12.9 %	0.10 [-0.33, 0.53]
Subtotal (95% CI)	**24**		**23**			**12.9 %**	**0.10 [-0.33, 0.53]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.46 (P = 0.65)							
Total (95% CI)	**159**		**194**			**100.0 %**	**-0.04 [-0.26, 0.17]**
Heterogeneity: $Tau^2 = 0.05$; $Chi^2 = 14.50$, df = 5 (P = 0.01); $I^2 = 66\%$							
Test for overall effect: Z = 0.37 (P = 0.71)							
Test for subgroup differences: $Chi^2 = 0.42$, df = 1 (P = 0.52), $I^2 = 0.0\%$							



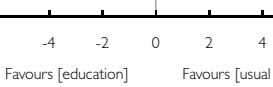
Analysis 1.3. Comparison 1 Educational intervention (with information and practical components) versus (optimised) usual care, Outcome 3 Dental plaque (subgroup analysis guideline implementation short-term follow-up).

Review: Oral health educational interventions for nursing home staff and residents

Comparison: 1 Educational intervention (with information and practical components) versus (optimised) usual care

Outcome: 3 Dental plaque (subgroup analysis guideline implementation short-term follow-up)

Study or subgroup	Education N	Mean(SD)	usual care N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 Education in the context of guideline implementation							
De Visschere 2012	30	1.58 (0.79)	43	1.77 (0.74)		17.7 %	-0.19 [-0.55, 0.17]
Van der Putten 2013	24	1.58 (0.81)	32	1.78 (0.42)		17.8 %	-0.20 [-0.56, 0.16]
Subtotal (95% CI)	**54**		**75**			**35.5 %**	**-0.20 [-0.45, 0.06]**
Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.00$, df = 1 (P = 0.97); $I^2 = 0.0\%$							
Test for overall effect: Z = 1.51 (P = 0.13)							
2 Education without guideline implementation							
Bellomo 2005	17	0.67 (0.49)	15	0.29 (0.36)		20.1 %	0.38 [0.08, 0.68]
Frenkel 2001	33	1.87 (0.49)	36	2.18 (0.53)		22.3 %	-0.31 [-0.55, -0.07]
MacEntee 2007	31	1.4 (0.5)	45	1.4 (0.6)		22.0 %	0.0 [-0.25, 0.25]
Subtotal (95% CI)	**81**		**96**			**64.5 %**	**0.02 [-0.36, 0.39]**
Heterogeneity: $Tau^2 = 0.09$; $Chi^2 = 12.63$, df = 2 (P = 0.002); $I^2 = 84\%$							
Test for overall effect: Z = 0.08 (P = 0.94)							
Total (95% CI)	**135**		**171**			**100.0 %**	**-0.06 [-0.31, 0.18]**
Heterogeneity: $Tau^2 = 0.06$; $Chi^2 = 13.96$, df = 4 (P = 0.01); $I^2 = 71\%$							
Test for overall effect: Z = 0.50 (P = 0.62)							
Test for subgroup differences: $Chi^2 = 0.82$, df = 1 (P = 0.36), $I^2 = 0.0\%$							

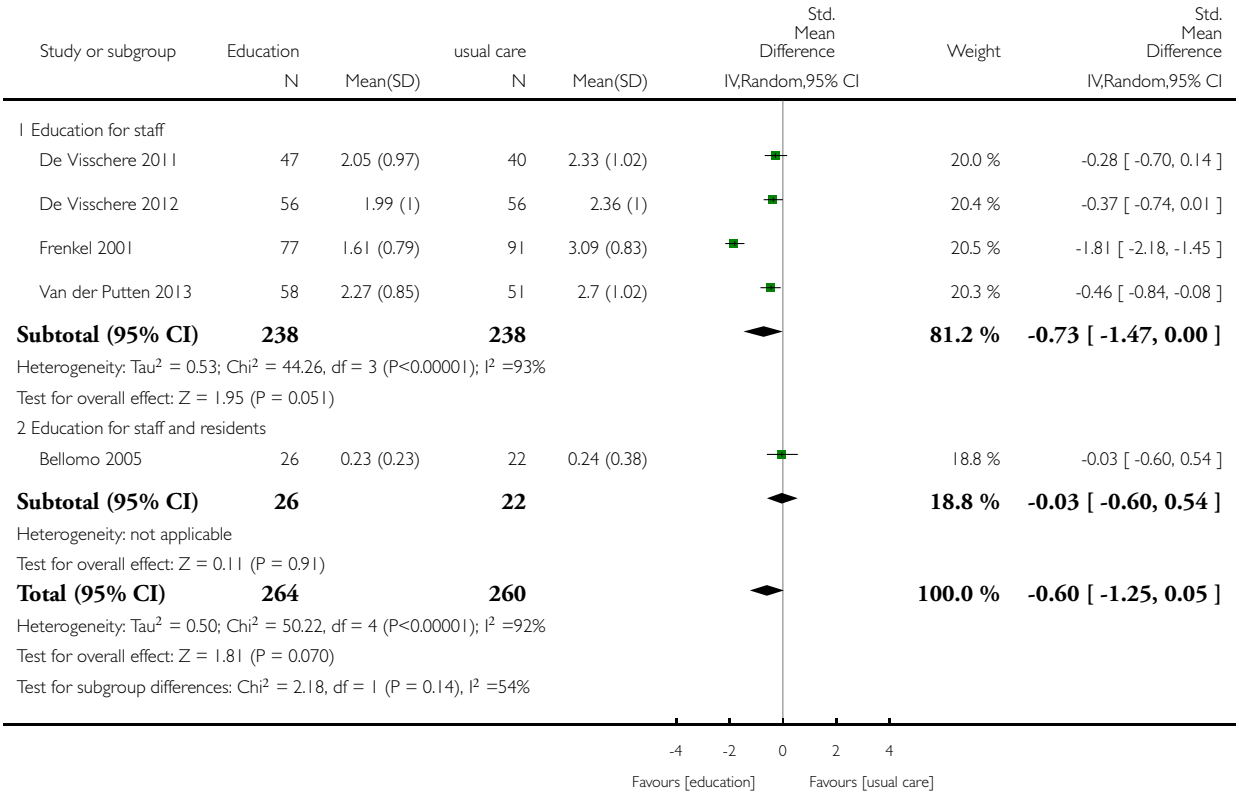


Analysis 1.4. Comparison 1 Educational intervention (with information and practical components) versus (optimised) usual care, Outcome 4 Denture plaque (subgroup analysis intervention recipient).

Review: Oral health educational interventions for nursing home staff and residents

Comparison: 1 Educational intervention (with information and practical components) versus (optimised) usual care

Outcome: 4 Denture plaque (subgroup analysis intervention recipient)

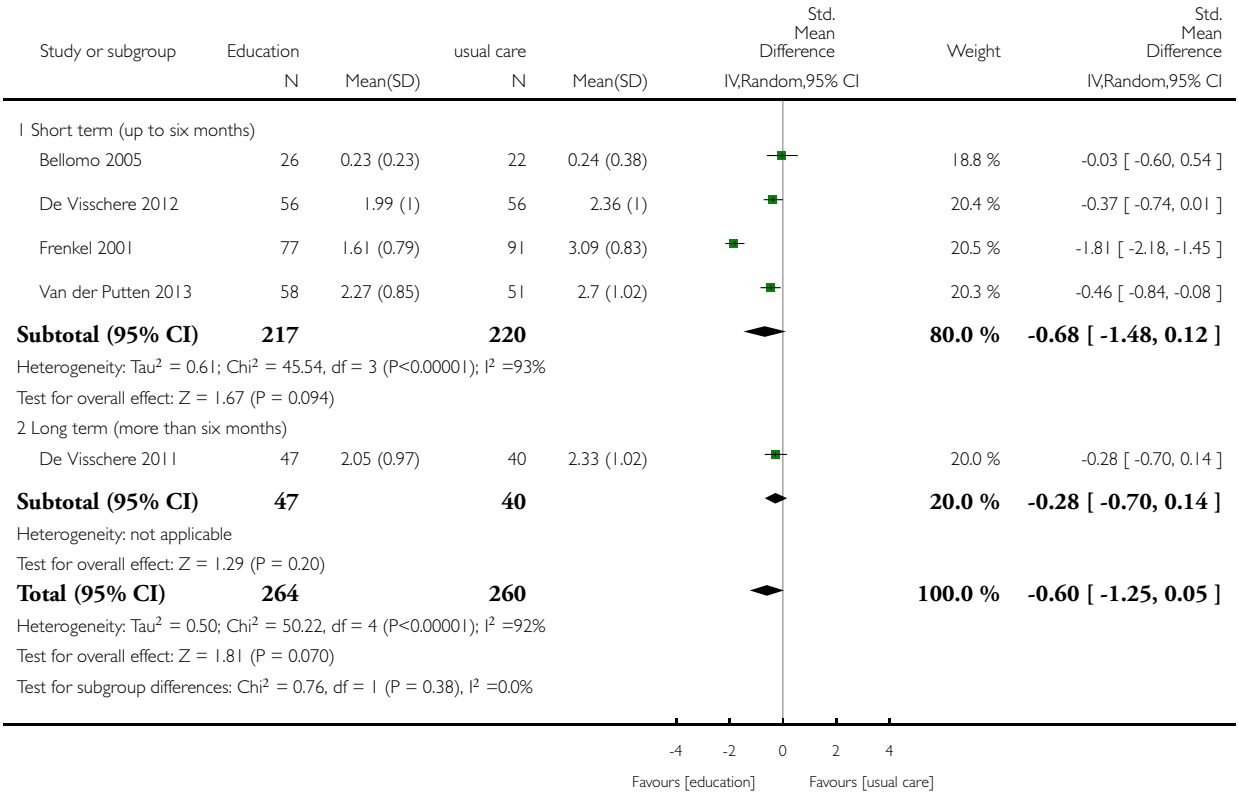


Analysis 1.5. Comparison 1 Educational intervention (with information and practical components) versus (optimised) usual care, Outcome 5 Denture plaque (subgroup analysis follow-up).

Review: Oral health educational interventions for nursing home staff and residents

Comparison: 1 Educational intervention (with information and practical components) versus (optimised) usual care

Outcome: 5 Denture plaque (subgroup analysis follow-up)



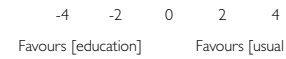
Analysis 1.6. Comparison 1 Educational intervention (with information and practical components) versus (optimised) usual care, Outcome 6 Denture plaque (subgroup analysis guideline implementation short-term follow-up).

Review: Oral health educational interventions for nursing home staff and residents

Comparison: 1 Educational intervention (with information and practical components) versus (optimised) usual care

Outcome: 6 Denture plaque (subgroup analysis guideline implementation short-term follow-up)

Study or subgroup	Education N	Mean(SD)	usual care N	Mean(SD)	Std. Mean Difference IV,Random,95% CI	Weight	Std. Mean Difference IV,Random,95% CI
1 Education in the context of guideline implementation							
De Visschere 2012	56	1.99 (1)	56	2.36 (1)		25.4 %	-0.37 [-0.74, 0.01]
Van der Putten 2013	58	2.27 (0.85)	51	2.7 (1.02)		25.4 %	-0.46 [-0.84, -0.08]
Subtotal (95% CI)	**114**		**107**			**50.8 %**	**-0.41 [-0.68, -0.14]**
Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.11$, df = 1 (P = 0.74); $I^2 = 0.0\%$							
Test for overall effect: Z = 3.02 (P = 0.0025)							
2 Education without guideline implementation							
Bellomo 2005	26	0.23 (0.23)	22	0.24 (0.38)		23.7 %	-0.03 [-0.60, 0.54]
Frenkel 2001	77	1.61 (0.79)	91	3.09 (0.83)		25.5 %	-1.81 [-2.18, -1.45]
Subtotal (95% CI)	**103**		**113**			**49.2 %**	**-0.94 [-2.68, 0.81]**
Heterogeneity: $Tau^2 = 1.53$; $Chi^2 = 26.94$, df = 1 (P<0.00001); $I^2 = 96\%$							
Test for overall effect: Z = 1.05 (P = 0.29)							
Total (95% CI)	**217**		**220**			**100.0 %**	**-0.68 [-1.48, 0.12]**
Heterogeneity: $Tau^2 = 0.61$; $Chi^2 = 45.54$, df = 3 (P<0.00001); $I^2 = 93\%$							
Test for overall effect: Z = 1.67 (P = 0.094)							
Test for subgroup differences: $Chi^2 = 0.34$, df = 1 (P = 0.56), $I^2 = 0.0\%$							

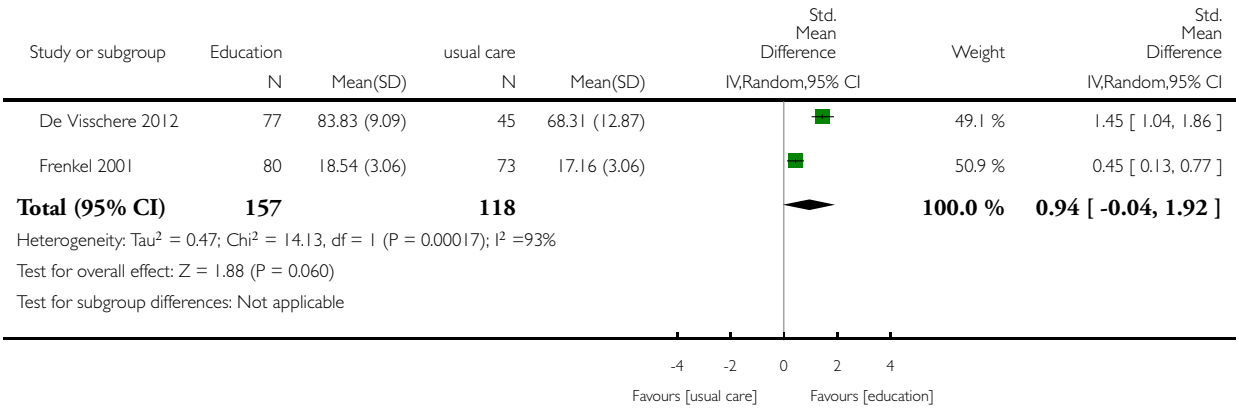


Analysis 1.7. Comparison 1 Educational intervention (with information and practical components) versus (optimised) usual care, Outcome 7 Oral health-related knowledge (staff).

Review: Oral health educational interventions for nursing home staff and residents

Comparison: 1 Educational intervention (with information and practical components) versus (optimised) usual care

Outcome: 7 Oral health-related knowledge (staff)

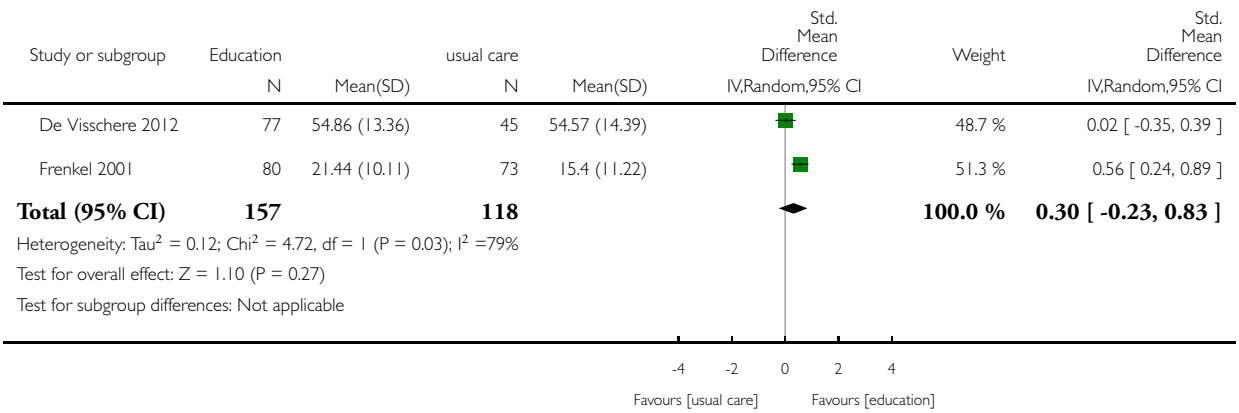


Analysis 1.8. Comparison 1 Educational intervention (with information and practical components) versus (optimised) usual care, Outcome 8 Oral health-related attitude (staff).

Review: Oral health educational interventions for nursing home staff and residents

Comparison: 1 Educational intervention (with information and practical components) versus (optimised) usual care

Outcome: 8 Oral health-related attitude (staff)



ADDITIONAL TABLES

Table 1. Search results

Database	First search date	Records retrieved (excl. duplicates)	Top-up search	Records retrieved (excl. duplicates)	Top-up search	Records retrieved (excl. duplicates)
Cochrane Oral Health Trials' Register	31 July 2013	567	27 January 2015	123	18 January 2016	51
CENTRAL via the Cochrane Library	31 July 2013	164	27 January 2015	29	18 January 2016	10
MEDLINE via OVID	31 July 2013	509 (with RCT filter)	27 January 2015	42 (with RCT filter)	18 January 2016	33 (with filter)
Embase via OVID	31 July 2013	214 (with RCT filter)	27 January 2015	51 (with RCT filter)	18 January 2016	18 (with filter)
CINAHL via EBSCO	31 July 2013	94 (with RCT filter)	27 January 2015	11 (with RCT filter)	18 January 2016	8 (with filter)
Web of Science Conference Proceedings	31 July 2013	151	27 January 2015	6	18 January 2016	3
ClinicalTrials.gov	31 July 2013	22	27 January 2015	23	18 January 2016	24
WHO International Clinical Trials Registry Platform	Not performed	-	27 January 2015	3	18 January 2016	0

RCT: randomised controlled trial
WHO: World Health Organization

Table 2. Summary of dental health outcomes assessed

	Dental plaque	Denture plaque	Gingivitis	Caries
Bellomo 2005	PI	Index for plaque accumulation (Denture Plaque Index) by Ambjørnsen 1982	Not assessed	Not assessed
De Visschere 2011	PI (PO)	Method of Augsburger 1982 (PO)	Not assessed	Not assessed
De Visschere 2012	PI (PO)	Method of Augsburger 1982 (PO)	Not assessed	Not assessed
Frenkel 2001	OHI-S (PO)	Method of Augsburger 1982 (PO)	Gingivitis (Suomi 1968) (PO) Denture-induced stomatitis (Budtz-Jørgensen 1970) (PO)	Root caries* (SO)
MacEntee 2007	GDI-S (PO)	Not assessed	GBI* (PO)	Not assessed
Mojon 1998	PI (PO)	Not assessed	Denture-induced stomatitis (Budtz-Jørgensen 1970) (PO)	Caries* (PO) Root caries* (PO)
Schou 1989	Not assessed	Index for plaque accumulation (Denture Plaque Index) by Ambjørnsen 1982 (PO)	Denture-induced stomatitis (Budtz-Jørgensen 1970) (PO)	Not assessed
Van der Putten 2013	PI (PO)	Method of Augsburger 1982 (PO)	Not assessed	Not assessed
Zenthöfer 2013	Plaque-control record* (PO)	DHI* (PO)	GBI* (PO)	Not assessed

PO: primary outcome measure; SO: secondary outcome measure.
DHI: Denture Hygiene Index; GBI: Gingival Bleeding Index; GDI-S: Geriatric Simplified Debris Index; OHI-S: Simplified Oral Hygiene Index; PI: Plaque Index

*Dichotomously assessed.

Table 3. Evaluation of the included studies using the CReDECI 2 checklist

	Bellomo 2005	De Visschere 2011	De Visschere 2012	Frenkel 2001	MacEntee 2007	Mojon 1998	Schou 1989	Van der Putten 2013	Zenthöfer 2013
Item 1: Description of the intervention's underlying theoretical basis	No	No	Yes, guideline implementation theory; p. e97 & p. 2	(Yes), qualitative data from previous research; p. 92	Yes, pyramidal scheme (Jones 1977); p. 26 (Ref. 30-35)	No	Yes, "active involvement principle"; (Ref. 14)	Yes, guideline implementation theory; p. 1144 & p. 2	No
Item 2: Description of all intervention components, including the reasons for their selection as well as their aims/ essential functions	No	No	No	No	Yes, p. 26	No	Yes, p. 3 (& Ref. 14)	No	No
Item 3: Illustration of any intended interactions between different components	No	No	(Yes, p. e98)	No	Yes, p. 26 & 28	No	No	(Yes), p. 1146	No
Item 4: Description and consideration of the context's characteristics in	No	No	No	No	No	No	No	No	No

Table 3. Evaluation of the included studies using the CReDECI 2 checklist (*Continued*)

intervention modelling									
Item 5: Description of the pilot test and its impact on the definite intervention	No	No	No	(Yes), p. 92	(Yes), research proposal (provided by the author on request)	No	Yes, Ref. 14 (modified intervention)	No	No
Item 6: Description of the control condition (comparator) and reasons for the selection	Yes, p. 26	No	Yes, p. e97	No	Yes, p. 28	Yes, p. 828	No	Yes, p. 1146	No
Item 7: Description of the strategy for delivering the intervention within the study context	Yes, p. 26	No	Yes, p. e98	Yes, p. 290 & 92	Yes, p. 27-28	Yes, p. ??	Yes, p. 3	Yes, p. 1146	Yes, p. 262-263
Item 8: Description of all materials or tools used in the delivery of the intervention	No	No	Yes, p. e98	Yes, p. 92	Yes, p. 27-28 (footnotes 2+3; restructured training material: bcdental.org/YourDentalHealth/	Yes, p. 143	No	Yes, p. 1146	Yes, p. 263 & Ref. 19

Table 3. Evaluation of the included studies using the CReDECI 2 checklist (*Continued*)

					YourDentalHealth.aspx?id=9974)				
Item 9: Description of fidelity of the delivery process compared to the study protocol	No	(Yes), p. 419	No	No	Yes, p. 30	Yes, p. 830	No	No	No
Item 10: Description of a process evaluation and its underlying theoretical basis	No	(Yes), p. 423 qualitative approach/ publication mentioned	Yes, p. 5	No	(Yes), research proposal MacEntee 2007	No	No	Yes, p. 5	No
Item 11: Description of internal facilitators and barriers potentially influencing the delivery of the intervention as revealed by the process evaluation	No	Yes, p. 423 (findings published in an additional publication p. 115-122)	Yes, p. e102 results of process evaluation scantly mentioned (more information in a second publication p. 115-122)	No	No (planned, but unfinished/unpublished)	No	No	No (publication in preparation)	No
Item 12: Description of external condi-	No	No	No	No	Yes, p. 31-32	Yes, p. 147	No	No	No

Table 3. Evaluation of the included studies using the CReDECI 2 checklist (*Continued*)

tions or factors occurring during the study which might have influenced the delivery of the intervention or mode of action (how it works)									
Item 13: Description of costs or required resources for the delivery of the intervention	No	No	No	Yes, tab 4 on p. 294	No	No	No	No	No

APPENDICES

Appendix 1. Cochrane Oral Health Trials Register search strategy

#1 ((home* and (nurs* or elder* or old* or care or "assisted living" or convalescen* or rest* or retir* or resident* or "long stay" or longstay or "long term"))) AND (INREGISTER)
#2 ((facilit* and (nurs* or elder* or old* or care or "assisted living" or convalescen* or rest* or retir* or resident* or "long stay" or longstay or "long term"))) AND (INREGISTER)
#3 ((institut* and (nurs* or elder* or old* or care or "assisted living" or convalescen* or rest* or retir* or resident* or "long stay" or longstay or "long term"))) AND (INREGISTER)
#4 ((residenc* and (nurs* or elder* or old* or care or "assisted living" or convalescen* or rest* or retir* or resident* or "long stay" or longstay or "long term"))) AND (INREGISTER)
#5 (((dental or tooth or teeth or enamel or root*) AND (decay* or caries or carious or "white spot*" or plaque or reminerali* or demineralı* or erosion* or abrasion* or wear))) AND (INREGISTER)
#6 ((denture* and (clean* or clens*))) AND (INREGISTER)
#7 ((periodont* or gingivi* or gingiva*)) AND (INREGISTER)

#8 ((stomatitis or "mouth ulcer*" or "oral ulcer*" or (oral and candidi*) or (mouth* and candidi*) or "aphthous ulcer*" or (aphthae and ulcer*) or (mucositis and mouth*) or (mucositis and oral) or xerostomi* or "dry mouth*")) AND (INREGISTER)
#9 (((oral and health*) or (mouth* and health*) or (dental and health*))) AND (INREGISTER)
#10 ((halitosis or "mouth odour*" or "mouth odor*" or "mouth malodour*" or "mouth malodor*" or "oral odour*" or "oral odor*" or "oral malodour*" or "oral malodor*" or (breath and odour*) or (breath and odor*) or (breath and malodour*) or (breath and malodor*))) AND (INREGISTER)
#11 ((("oral cancer*" or (gingiv* or mouth* or lip or lips or tongue* or "salivary gland*" or palat* or parotid* or sublingual or submandibular)) AND (cancer* or carcinoma* or neoplasm* or tumour* or tumor* or lesion* or malignan*))) AND (INREGISTER)
#12 ((leukoplak* or "hairy tongue*")) AND (INREGISTER)
#13 (("oral hygiene" or (mouth and care) or (dental and care) or (care and teeth) or (mouth and hygiene) or (plaque and control*) or (plaque and remov*))) AND (INREGISTER)
#14 ((toothbrush* or tooth-brush* or toothpaste* or dentifrice* or mouthwash* or mouth-wash* or mouthrinse* or mouth-rinse* or fluoride*)) AND (INREGISTER)
#15 ((floss* or "interdental brush*" or "inter-dental brush*" or (tooth and clean*) or (teeth and clean*) or (denture* and hygien*) or (denture* and clean*) or (tongue* and scrap*) or (tongue* and brush*) or (chewing and stick*) or (chewing and gum*))) AND (INREGISTER)
#16 (((oral and care) or (oral and "self care"))) AND (INREGISTER)
#17 ((instruct* or advis* or advice or educat* or promot* or teach* or train*)) AND (INREGISTER)
#18 (((demonstrat* and toothbrush*) or (demonstrat* and "tooth brush*") or (demonstrat* and tooth-brush*) or (demonstrat* and floss*) or (demonstrat* and "interdental brush*") or (demonstrat* and "inter-dental brush*") or (demonstrat* and "interdental clean*") or (demonstrat* and "inter-dental clean*") or (demonstrat* and woodstick*) or (demonstrat* and wood-stick*) or (demonstrat* and "wood stick*"))) AND (INREGISTER)
#19 (((supervis* and toothbrush*) or (supervis* and "tooth brush*") or (supervis* and tooth-brush*) or (supervis* and floss*) or (supervis* and "interdental brush*") or (supervis* and "inter-dental brush*") or (supervis* and "interdental clean*") or (supervis* and "inter-dental clean*") or (supervis* and woodstick*) or (supervis* and wood-stick*) or (supervis* and "wood stick*"))) AND (INREGISTER)
#20 ((demonstrat* and (dentur* and (clean* or clens*)))) AND (INREGISTER)
#21 ((supervis* and (dentur* and (clean* or clens*)))) AND (INREGISTER)
#22 ((lectur* or seminar* or presentation* or program* or session* or tutorial* or video* or audio* or DVD* or online or podcast* or vodcast*)) AND (INREGISTER)
#23 ((leaflet* or manual* or book* or pamphlet* or brochure*)) AND (INREGISTER)
#24 (#1 or #2 or #3 or #4) AND (INREGISTER)
#25 (#5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16) AND (INREGISTER)
#26 (#17 or #18 or #19 or #20 or #21 or #22 or #23) AND (INREGISTER)
#27 (#24 and #25 and #26) AND (INREGISTER)

Appendix 2. Cochrane Central Register of Controlled Clinical Trials (CENTRAL) search strategy

#1 [mh "Nursing home"]
#2 [mh ^"Homes for the aged"]
#3 (home* and (nurs* or elder* or old* or care or "assisted living" or convalescen* or rest* or retir* or resident* or "long stay" or longstay or "long term")):ti,ab
#4 (facilit* and (nurs* or elder* or old* or care or "assisted living" or convalescen* or rest* or retir* or resident* or "long stay" or longstay or "long term")):ti,ab
#5 (institut* and (nurs* or elder* or old* or care or "assisted living" or convalescen* or rest* or retir* or resident* or "long stay" or longstay or "long term")):ti,ab
#6 (residenc* and (nurs* or elder* or old* or care or "assisted living" or convalescen* or rest* or retir or "long stay" or longstay or "long term")):ti,ab
#7 #1 or #2 or #3 or #4 or #5 or #6
#8 [mh ^"Oral health"]
#9 [mh "Stomatognathic diseases"]
#10 [mh ^Halitosis]

#11 ((dental or tooth or teeth or enamel or root*) and (decay* or caries or carious or "white spot*" or plaque or reminerali* or demineralı* or erosion*
or abrasion* or wear*))
#12 (denture* and (clean* or clens*)):ti,ab
#13 (periodont* or gingivi* or gingiva*):ti,ab
#14 (stomatitis or "mouth ulcer*" or "oral ulcer*" or (oral near/5 candidi*) or (mouth* near/5 candidi*) or "aphthous ulcer*" or (aphthae near/3 ulcer*) or (mucositis near/5 mouth*) or (mucositis near/5 oral) or xerostomi* or "dry mouth*"):ti,ab
#15 ((oral near/5 health*) or (mouth near/5 health*) or (dental near/5 health*)):ti,ab
#16 (halitosis or "mouth odour*" or "mouth odor*" or "mouth malodour*" or "mouth malodor*" or "oral odour*" or "oral odor*" or "oral malodour*" or "oral malodor*" or (breath near/5 odour*) or (breath near/5 odor*) or (breath near/5 malodour*) or (breath near/5 malodor)):ti,ab
#17 [mh "Mouth neoplasms"]
#18 (("oral cancer*" or (gingiv* or mouth* or lip or lips or tongue* or "salivary gland*" or palat* or parotid* or sublingual or submandibular)) and (cancer* or carcinoma* or neoplasm* or tumour* or tumor* or lesion* or malignan*)):ti,ab
#19 leukoplak*:ti,ab
#20 "hairy tongue$":ti,ab
#21 [mh ^"Oral hygiene"]
#22 [mh Mouthwashes]
#23 [mh Dentifrices]
#24 ("oral hygiene" or (mouth* near/3 care) or (dental near/3 care) or (care near/3 teeth) or (mouth* near/3 hygiene) or (plaque near/3 control*) or (plaque near/3 remov*)):ti,ab
#25 (toothbrush* or tooth-brush* or toothpaste* or dentifrice* or mouthwash* or mouth-wash* or mouthrinse* or mouth-rinse* or fluoride*):ti,ab
#26 (floss* or "interdental brush*" or "inter-dental brush*" or (tooth near/5 clean*) or (teeth near/5 clean*) or (denture* near/5 hygien*) or (denture* near/5 clean*) or (tongue* near/5 scrap*) or (tongue* near/5 brush*) or (chewing near/5 stick*) or (chewing near/5 gum)):ti,ab
#27 ((oral near/3 care) or (oral near/3 "self care")):ti,ab
#28 #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27
#29 [mh ^"Health education, dental"]
#30 [mh "Health promotion"]
#31 (instruct* or advis* or advice or educat* or promot* or teach* or train*):ti,ab
#32 ((demonstrat* near/5 toothbrush*) or (demonstrat* near/5 "tooth brush*") or (demonstrat* near/5 tooth-brush*) or (demonstrat* near/5 floss*) or (demonstrat* near/5 "interdental brush*") or (demonstrat* near/5 "inter-dental brush*") or (demonstrat* near/5 "interdental clean*") or (demonstrat* near/5 "inter-dental clean*") or (demonstrat* near/5 woodstick*) or (demonstrat* near/5 wood-stick*) or (demonstrat* near/5 "wood stick*")):ti,ab
#33 ((supervis* near/5 toothbrush*) or (supervis* near/5 "tooth brush*") or (supervis* near/5 tooth-brush*) or (supervis* near/5 floss*) or (supervis* near/5 "interdental brush*") or (supervis* near/5 "inter-dental brush*") or (supervis* near/5 "interdental clean*") or (supervis* near/5 "inter-dental clean*") or (supervis* near/5 woodstick*) or (supervis* near/5 wood-stick*) or (supervis* near/5 "wood stick*")):ti,ab
#34 (demonstrat* near/5 (dentur* near/3 (clean* or clens*))):ti,ab
#35 (supervis* near/5 (dentur* near/3 (clean* or clens*))):ti,ab
#36 (lectur* or seminar* or presentation* or program* or session* or tutorial* or video* or audio* or DVD* or online or podcast* or vodcast*):ti,ab
#37 (leaflet* or manual* or book* or pamphlet* or brochure*):ti,ab
#38 #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37
#39 #7 and #28 and #38

Appendix 3. MEDLINE Ovid search strategy

1. exp Nursing home/
2. Homes for the aged/
3. (home$ adj5 (nurs$ or elder$ or old$ or care or "assisted living" or convalescen$ or rest$ or retir$ or resident$ or "long stay" or longstay or "long term")).mp.
4. (facilit$ adj5 (nurs$ or elder$ or old$ or care or "assisted living" or convalescen$ or rest$ or retir$ or resident$ or "long stay" or longstay or "long term")).mp.
5. (institut$ adj5 (nurs$ or elder$ or old$ or care or "assisted living" or convalescen$ or rest$ or retir$ or resident$ or "long stay" or longstay or "long term")).mp.
6. (residenc$ adj5 (nurs$ or elder$ or old$ or care or "assisted living" or convalescen$ or rest$ or retir$ or "long stay" or longstay or "long term")).mp.
7. or/1-6
8. Oral health/
9. exp Stomatognathic diseases/
10. Halitosis/
11. ((dental or tooth or teeth or enamel or root$) and (decay$ or caries or carious or "white spot$" or plaque or reminerali$ or demineral$ or erosion$ or abrasion$ or wear)).mp.
12. (denture$ and (clean$ or clens$)).mp.
13. (periodont$ or gingivi$ or gingiva$).mp.
14. (stomatitis or "mouth ulcer$" or "oral ulcer$" or (oral adj5 candidi$) or (mouth$ adj5 candidi$) or "aphthous ulcer$" or (aphthae adj3 ulcer$) or (mucositis adj5 mouth$) or (mucositis adj5 oral) or xerostomi$ or "dry mouth$").mp.
15. ((oral adj5 health$) or (mouth adj5 health$) or (dental adj5 health$)).mp.
16. (halitosis or "mouth odour$" or "mouth odor$" or "mouth malodour$" or "mouth malodor$" or "oral malodour$" or "oral malodor$" or (breath adj5 malodour$) or (breath adj5 malodor$) or (breath adj5 odour$) or (breath adj5 odor$)).mp.
17. exp Mouth neoplasms/
18. (("oral cancer$" or (gingiv$or mouth or lip or lips or tongue$ or "salivary gland$" or palat$ or parotid$ or sublingual or submandibular)) and (cancer$ or carcinoma$ or neoplasm$ or tumour$ or tumor$ or lesion$ or malignan$)).mp.
19. leukoplak$.mp.
20. "hairy tongue$".mp.
21. exp Oral hygiene/
22. exp Mouthwashes/
23. exp Dentifrices/
24. ("oral hygiene" or (mouth$ adj3 care) or (dental adj3 care) or (care adj3 teeth) or (mouth$ adj3 hygiene) or (plaque adj3 control$) or (plaque adj3 remov$)).mp.
25. (toothbrush$ or tooth-brush$ or toothpaste$ or dentifrice$ or mouthwash$ or mouth-wash$ or mouthrinse$ or mouth-rinse$ or fluoride$).mp.
26. (floss$ or "interdental brush$" or "inter-dental brush$" or (tooth adj5 clean$) or (teeth adj5 clean$) or (denture$ adj5 hygien$) or (denture$ adj5 clean$) or (tongue$ adj5 scrap$) or (tongue$ adj5 brush$) or (chewing adj5 stick$) or (chewing adj5 gum$)).mp.
27. ((oral adj3 care) or (oral adj3 "self care")).mp.
28. or/8-27
29. Health education, dental/
30. exp Health promotion/
31. (instruct$ or advis$ or advice or educat$ or promot$ or teach$ or train$).mp.
32. ((demonstrat$ adj5 toothbrush$) or (demonstrat$ adj5 "tooth brush$") or (demonstrat$ adj5 tooth-brush$) or (demonstrat$ adj5 floss$) or (demonstrat$ adj5 "interdental brush$") or (demonstrat$ adj5 "inter-dental brush$") or (demonstrat$ adj5 "interdental clean$") or (demonstrat$ adj5 "inter-dental clean$") or (demonstrat$ adj5 wood-stick$) or (demonstrat$ adj5 woodstick$) or (demonstrat$ adj5 "wood stick$")).mp.
33. (demonstrat$ adj5 (denture$ adj3 (clean$ or clens$))).mp.
34. (supervis$ adj5 (denture$ adj3 (clean$ or clens$))).mp.
35. ((supervis$ adj5 toothbrush$) or (supervis$ adj5 "tooth brush$") or (supervis$ adj5 tooth-brush$) or (supervis$ adj5 floss$) or (supervis$ adj5 "interdental brush$") or (supervis$ adj5 "inter-dental brush$") or (supervis$ adj5 "interdental clean$") or (supervis$ adj5 "inter-dental clean$") or (supervis$ adj5 wood-stick$) or (supervis$ adj5 woodstick$) or (supervis$ adj5 "wood stick$")).mp.

36. (lecture$ or seminar$ or presentation$ or session$ or tutorial$ or video or audio or DVD or online or podcast$ or vodcast$).mp.
37. (leaflet$ or manual$ or book$ or pamphlet$ or brochure$).mp.
38. or/29-37
39. 7 and 28 and 38

The search was linked with the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomised trials in MEDLINE: sensitivity maximising version (2008 revision) as referenced in Chapter 6.4.11.1 and detailed in box 6.4.c of the *Cochrane Handbook for Systematic Reviews of Interventions* version 5.1.0, updated March 2011 (Lefebvre 2011).
1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab.
5. drug therapy.fs.
6. randomly.ab.
7. trial.ab.
8. groups.ab.
9. or/1-8
10. exp animals/ not humans.sh.
11. 9 not 10

Appendix 4. Embase Ovid search strategy

1. Nursing home/
2. Home for the aged/
3. (home$ adj5 (nurs$ or elder$ or old$ or care or "assisted living" or convalescen$ or rest$ or retir$ or resident$ or "long stay" or longstay or "long term")).mp.
4. (facilit$ adj5 (nurs$ or elder$ or old$ or care or "assisted living" or convalescen$ or rest$ or retir$ or resident$ or "long stay" or longstay or "long term")).mp.
5. (institut$ adj5 (nurs$ or elder$ or old$ or care or "assisted living" or convalescen$ or rest$ or retir$ or resident$ or "long stay" or longstay or "long term")).mp.
6. (residenc$ adj5 (nurs$ or elder$ or old$ or care or "assisted living" or convalescen$ or rest$ or retir$ or "long stay" or longstay or "long term")).mp.
7. or/1-6
8. exp Mouth disease/
9. Halitosis/
10. ((dental or tooth or teeth or enamel or root$) and (decay$ or caries or carious or "white spot$" or plaque or remineral$ or demineral$ or erosion$ or abrasion$ or wear)).mp.
11. (denture$ and (clean$ or clens$)).mp.
12. (periodont$ or gingivi$ or gingiva$).mp.
13. (stomatitis or "mouth ulcer$" or "oral ulcer$" or (oral adj5 candidi$) or (mouth$ adj5 candidi$) or "aphthous ulcer$" or (aphthae adj3 ulcer$) or (mucositis adj5 mouth$) or (mucositis adj5 oral) or xerostomi$ or "dry mouth$").mp.
14. ((oral adj5 health$) or (mouth adj5 health$) or (dental adj5 health$)).mp.
15. (halitosis or "mouth odour$" or "mouth odor$" or "mouth malodour$" or "mouth malodor$" or "oral odour$" or "oral odor$" or "oral malodour$" or "oral malodor$" or (breath adj5 malodour$) or (breath adj5 malodor$) or (breath adj5 odour$) or (breath adj5 odor$)).mp.
16. exp Mouth tumor/
17. (("oral cancer$" or (gingiv$ or mouth$ or lip or lips or tongue$ or "salivary gland$" or palat$ or parotid$ or sublingual or submandibular)) and (cancer$ or carcinoma$ or neoplasm$ or tumour$ or tumor$ or lesion$ or malignan$)).mp.
18. leukoplak$.mp.
19. "hairy tongue$".mp.
20. exp Mouth hygiene/~
21. Mouthwash/

22. Toothpaste/
23. ("oral hygiene" or (mouth$ adj3 care) or (dental adj3 care) or (care adj3 teeth) or (mouth$ adj3 hygiene) or (plaque adj3 control$) or (plaque adj3 remov$)).mp.
24. (toothbrush$ or tooth-brush$ or toothpaste$ or dentifrice$ or mouthwash$ or mouth-wash$ or mouthrinse$ or mouth-rinse$ or fluoride$).mp.
25. (floss$ or "interdental brush$" or "inter-dental brush$" or (tooth adj5 clean$) or (teeth adj5 clean$) or (denture$ adj5 hygien$) or (denture$ adj5 clean$) or (tongue$ adj5 scrap$) or (tongue$ adj5 brush$) or (chewing adj5 stick$) or (chewing adj5 gum$)).mp.
26. ((oral adj3 care) or (oral adj3 "self care")).mp.
27. or/8-26
28. Dental health education/
29. Health promotion/
30. (instruct$ or advis$ or advice or educat$ or promot$ or teach$ or train$).mp.
31. ((demonstrat$ adj5 toothbrush$) or (demonstrat$ adj5 "tooth brush$") or (demonstrat$ adj5 tooth-brush$) or (demonstrat$ adj5 floss$) or (demonstrat$ adj5 "interdental brush$") or (demonstrat$ adj5 "inter-dental brush$") or (demonstrat$ adj5 "interdental clean$") or (demonstrat$ adj5 "inter-dental clean$") or (demonstrat$ adj5 wood-stick$) or (demonstrat$ adj5 woodstick$) or (demonstrat$ adj5 "wood stick$")).mp.
32. (demonstrat$ adj5 (denture$ adj3 (clean$ or clens$))).mp.
33. (supervis$ adj5 (denture$ adj3 (clean$ or clens$))).mp.
34. ((supervis$ adj5 toothbrush$) or (supervis$ adj5 "tooth brush$") or (supervis$ adj5 tooth-brush$) or (supervis$ adj5 floss$) or (supervis$ adj5 "interdental brush$") or (supervis$ adj5 "inter-dental brush$") or (supervis$ adj5 "interdental clean$") or (supervis$ adj5 "inter-dental clean$") or (supervis$ adj5 wood-stick$) or (supervis$ adj5 woodstick$) or (supervis$ adj5 "wood stick$")).mp.
35. (lecture$ or seminar$ or presentation$ or program$ or session$ or tutorial$ or video or audio or DVD or online or podcast$ or vodcast$).mp.
36. (leaflet$ or manual$ or book$ or pamphlet$ or brochure$).mp.
37. or/28-36
38. 7 and 27 and 37

The above subject search was linked to Cochrane Oral Health's filter for identifying RCTs in Embase Ovid:

1. random$.ti,ab.
2. factorial$.ti,ab.
3. (crossover$ or cross over$ or cross-over$).ti,ab.
4. placebo$.ti,ab.
5. (doubl$ adj blind$).ti,ab.
6. (singl$ adj blind$).ti,ab.
7. assign$.ti,ab.
8. allocat$.ti,ab.
9. volunteer$.ti,ab.
10. CROSSOVER PROCEDURE.sh.
11. DOUBLE-BLIND PROCEDURE.sh.
12. RANDOMIZED CONTROLLED TRIAL.sh.
13. SINGLE BLIND PROCEDURE.sh.
14. or/1-13
15. (exp animal/ or animal.hw. or nonhuman/) not (exp human/ or human cell/ or (human or humans).ti.)
16. 14 NOT 15

Appendix 5. CINAHL EBSCO search strategy

S1 (MH "Nursing Homes+")
S2 (MH "Nursing Home Patients")
S3 (home* N5 nurs*) or (home* N5 elder*) or (home* N5 old*) or (home* N5 care*) or (home* N5 "assisted living") or (home* N5 convalescen*) or (home* N5 rest*) or (home* N5 retir*) or (home* N5 resident*) or (home* N5 "long stay") or (home* N5 longstay) or (home* N5 "long term")
S4 (facilit* N5 nurs*) or (facilit* N5 elder*) or (facilit* N5 old*) or (facilit* N5 care*) or (facilit* N5 "assisted living") or (facilit* N5 convalescen*) or (facilit* N5 rest*) or (facilit* N5 retir*) or (facilit* N5 resident*) or (facilit* N5 "long stay") or (facilit* N5 longstay) or (facilit* N5 "long term")
S5 (institut* N5 nurs*) or (institut* N5 elder*) or (institut* N5 old*) or (institut* N5 care*) or (institut* N5 "assisted living") or (institut* N5 convalescen*) or (institut* N5 rest*) or (institut* N5 retir*) or (institut* N5 resident*) or (institut* N5 "long stay") or (institut* N5 longstay) or (institut* N5 "long term")
S6 (residenc* N5 nurs*) or (residenc* N5 elder*) or (residenc* N5 old*) or (residenc* N5 care*) or (residenc* N5 "assisted living") or (residenc* N5 convalescen*) or (residenc* N5 rest*) or (residenc* N5 retir*) or (residenc* N5 "long stay") or (residenc* N5 longstay) or (residenc* N5 "long term")
S7 S1 or S2 or S3 or S4 or S5 or S6
S8 (MH "Oral health")
S9 (MH "Stomatognathic diseases+")
S10 (MH Halitosis)
S11 ((dental or tooth or enamel or root*) AND (decay* or caries or carious or "white spot*" or plaque or remineral* or demineral* or erosion* or abrasion* or wear))
S12 (denture* and (clean* or clens*))
S13 (periodont* or gingivi* or gingiva*)
S14 (stomatitis or "mouth ulcer*" or "oral ulcer*" or (oral N5 candidi*) or (mouth N5 candidi*) or "aphthous ulcer*" or (aphthae N3 ulcer*) or (mucositis N5 mouth*) or (mucositis N5 oral) or xerostomi* or "dry mouth*")
S15 ((oral N5 health*) or (mouth N5 health*) or (dental N5 health*))
S16 (halitosis or "mouth odour*" or "mouth odor*" or "mouth malodour*" or "mouth malodor*" or "oral odour*" or "oral odor*" or "oral malodour*" or "oral malodor*" or (breath N5 odour*) or (breath N5 odor*) or (breath N5 malodour*) or (breath N5 malodor))
S17 (MH "Mouth neoplasms+")
S18 (("oral cancer*" or (gingiv* or mouth* or lip or lips or tongue* or "salivary gland*" or palat* or parotid* or sublingual or submandibular)) and (cancer* or carcinoma* or neoplasm* or tumour* or tumor* or lesion* or malignan*))
S19 leukoplak*
S20 "hairy tongue*"
S21 (MH "Oral hygiene+")
S22 (MH Mouthwashes+)
S23 (MH Dentifrices+)
S24 ("oral hygiene" or (mouth* N3 care) or (dental N3 care) or (care N3 teeth) or (mouth* N3 hygiene) or (plaque N3 control*) or (plaque N3 remov*))
S25 (toothbrush* or tooth-brush* or toothpaste* or dentifrice* or mouthwash* or mouth-wash* or mouthrinse* or mouth-rinse* or fluoride*)
S26 (floss* or "interdental brush*" or "inter-dental brush*" or (tooth N5 clean*) or (teeth N5 clean*) or (denture* N5 hygien*) or (denture* N5 clean*) or (tongue* N5 scrap*) or (tongue* N5 brush*) or (chewing N5 stick*) or (chewing N5 gum))
S27 ((oral N3 care) or (oral N3 "self care"))
S28 S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23 or S24 or S25 or S26 or S27
S29 (MH "Dental health education")
S30 (MH "Health promotion")
S31 (instruct* or advis* or advice or educat* or promot* or teach* or train*)
S32 ((demonstrat* N5 toothbrush*) or (demonstrat* N5 "tooth brush*") or (demonstrat* N5 tooth-brush*) or (demonstrat* N5 floss*) or (demonstrat* N5 "interdental brush*") or (demonstrat* N5 "inter-dental brush*") or (demonstrat* N5 "interdental clean*") or (demonstrat* N5 "inter-dental clean*") or (demonstrat* N5 woodstick*) or (demonstrat* N5 wood-stick*) or (demonstrat* N5 "wood stick*"))

S33 ((supervis* N5 toothbrush*) or (supervis* N5 "tooth brush*") or (supervis* N5 tooth-brush*) or (supervis* N5 floss*) or (supervis* N5 "interdental brush*") or (supervis* N5 "inter-dental brush*") or (supervis* N5 "interdental clean*") or (supervis* N5 "inter-dental clean*") or (supervis* N5 woodstick*) or (supervis* N5 wood-stick*) or (supervis* N5 "wood stick*"))
S34 (demonstrat* N5 (dentur* N3 (clean* or clens*)))
S35 (supervis* N5 (dentur* N3 (clean* or clens*)))
S36 (lectur* or seminar* or presentation* or program* or session* or tutorial* or video* or audio* or DVD* or online or podcast* or vodcast*)
S37 (leaflet* or manual* or book* or pamphlet* or brochure*)
S38 S29 or S30 or S31 or S32 or S33 or S34 or S35 or S36 or S37
S39 S7 and S28 and S38
The above subject search was linked to Cochrane Oral Health's filter for identifying RCTs in CINAHL EBSCO:
S1 MH Random Assignment or MH Single-blind Studies or MH Double-blind Studies or MH Triple-blind Studies or MH Crossover design or MH Factorial Design
S2 TI ("multicentre study" or "multicenter study" or "multi-centre study" or "multi-center study") or AB ("multicentre study" or "multicenter study" or "multi-centre study" or "multi-center study") or SU ("multicentre study" or "multicenter study" or "multi-centre study" or "multi-center study")
S3 TI random* or AB random*
S4 AB "latin square" or TI "latin square"
S5 TI (crossover or cross-over) or AB (crossover or cross-over) or SU (crossover or cross-over)
S6 MH Placebos
S7 AB (singl* or doubl* or trebl* or tripl*) or TI (singl* or doubl* or trebl* or tripl*)
S8 TI blind* or AB mask* or AB blind* or TI mask*
S9 S7 and S8
S10 TI Placebo* or AB Placebo* or SU Placebo*
S11 MH Clinical Trials
S12 TI (Clinical AND Trial) or AB (Clinical AND Trial) or SU (Clinical AND Trial)
S13 S1 or S2 or S3 or S4 or S5 or S6 or S9 or S10 or S11 or S12

Appendix 6. Web of Science Conference Proceedings search strategy

#1 TS=(home* or facilit* or institut* or residenc*)
#2 TS=(oral and (hygiene or health))
#3 TS=((dental or tooth or teeth or enamel or root) AND (caries or decay* or carious or "white spot*" or plaque or deminerali* or remineral* or erosion* or abrasion* or wear))
#4 TS=(denture* and (clean* or clens*))
#5 TS=(periodont* or gingiva* or gingivi*)
#6 TS=(stomatitis or halitosis)
#7 TS=((oral or mouth or dental) AND (ulcer* or candidi or mucositis or health or odour* or odor* or malodour* or malodor or cancer or carcinoma* or neoplasm* or tumor* or tumour* or lesion* or malignan*))
#8 TS=(xerostomi* or "dry mouth*")
#9 TS=((aphthous or aphthae) and ulcer*)
#10 TS=(breath* AND (odor* or odour* or malodour* or malodor*))
#11 TS=(leukoplak* or "hairy tongue*")
#12 TS=(toothbrush* or tooth-brush* or toothpaste* or dentifrice* or mouthwash* or mouth-wash* or mouthrinse* or mouth-rinse* or fluoride* or floss* or "interdental brush*" or "inter-dental brush*" or "interdental clean*" or "inter-dental clean*" or (tooth and clean*) or (teeth and clean*) or (mouth and health) or (mouth and care) or (mouth and hygiene) or (denture* and hygiene) or (tongue* and scrap*) or (tongue* and brush*) or (chewing and stick*) or (chewing and gum*))
#13 #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12
#14 TS=(instruct* or advis* or advice or educat* or promot* or teach* or train* or demonstrat* or supervis*)
#15 TS=(lecture* or seminar* or presentation* or session* or program* or tutorial* or video* or audio* or DVD* or online or podcast* or vodcast*)
#16 TS=(leaflet* or manual* or book* or pamphlet* or brochure*)

#17 #14 or #15 or #16
#18 #1 and #13 and #17
#19 TS=(random* or trial* or placebo* or group*)
#20 #18 and #19

Appendix 7. US National Institutes of Health Trials Register (ClinicalTrials.gov) search strategy

A series of keyword searches was performed:
home and oral hygiene and education
facility and oral hygiene and education
residence and oral hygiene and education
institution and oral hygiene and education
home and oral hygiene and instruction
facility and oral hygiene and instruction
residence and oral hygiene and instruction
institution and oral hygiene and instruction
home and oral hygiene and advice
facility and oral hygiene and advice
residence and oral hygiene and advice
institution and oral hygiene and advice
home and oral hygiene and teach
facility and oral hygiene and teach
residence and oral hygiene and teach
institution and oral hygiene and teach
home and oral hygiene and train
facility and oral hygiene and train
residence and oral hygiene and train
institution and oral hygiene and train
home and oral hygiene and program
facility and oral hygiene and program
residence and oral hygiene and program
institution and oral hygiene and program
home and oral hygiene and programme
facility and oral hygiene and programme
residence and oral hygiene and programme
institution and oral hygiene and programme

Appendix 8. WHO International Clinical Trials Registry Platform search strategy

A series of keyword searches was performed:
home and “oral hygiene” and education
facility and “oral hygiene” and education
residence and “oral hygiene” and education
institution and “oral hygiene” and education
home and “oral hygiene” and instruction
facility and “oral hygiene” and instruction
residence and “oral hygiene” and instruction
institution and “oral hygiene” and instruction
home and “oral hygiene” and advice
facility and “oral hygiene” and advice
residence and “oral hygiene” and advice
institution and “oral hygiene” and advice

home and “oral hygiene” and teach
facility and “oral hygiene” and teach
residence and “oral hygiene” and teach
institution and “oral hygiene” and teach
home and “oral hygiene” and train
facility and “oral hygiene” and train
residence and “oral hygiene” and train
institution and “oral hygiene” and train
home and “oral hygiene” and program
facility and “oral hygiene” and program
residence and “oral hygiene” and program
institution and “oral hygiene” and program
home and “oral hygiene” and programme
facility and “oral hygiene” and programme
residence and “oral hygiene” and programme
institution and “oral hygiene” and programme

CONTRIBUTIONS OF AUTHORS

Martina Albrecht (MA) initially planned the review and wrote the protocol with important contribution from Sascha Köpke (SK). MA, SK, and Ramona Kupfer (RK) extracted and interpreted the data. MA wrote the review with important contribution from SK. RK, Daniel Reissmann (DR), and Ingrid Mühlhauser (IM) substantially commented on the draft versions.

DECLARATIONS OF INTEREST

Martina Albrecht: none known

Ramona Kupfer: none known

Daniel R Reissmann: none known

Ingrid Mühlhauser: none known

Sascha Köpke: none known

SOURCES OF SUPPORT

Internal sources

- Unit of Health Sciences and Education, University of Hamburg, Germany.
- Nursing Research Group, Institute for Social Medicine, University of Lübeck, Germany.

External sources

- Ministry of Education and Research, Germany.
- National Institute for Health Research (NIHR), UK.

This project was supported by the NIHR, via Cochrane Infrastructure funding to Cochrane Oral Health. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, NHS, or the Department of Health.

- Cochrane Oral Health Global Alliance, UK.

The production of Cochrane Oral Health reviews has been supported financially by our Global Alliance since 2011 (ohg.cochrane.org/partnerships-alliances). Contributors over the last year have been: British Association for the Study of Community Dentistry, UK; British Society of Paediatric Dentistry, UK; Centre for Dental Education and Research at All India Institute of Medical Sciences, India; National Center for Dental Hygiene Research & Practice, USA; New York University College of Dentistry, USA; NHS Education for Scotland, UK

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

- In addition to the resources outlined in the protocol, we also searched Web of Science Conference Proceedings and the World Health Organization Clinical Trials Registry Platform.

- We used the revised reporting guideline CReDECI 2 instead of the original CReDECI criteria to retrieve data on process evaluation of the complex interventions (Möhler 2012).

- In the case of continuous data as measures of treatment effect, we used mean differences or standardised mean differences between study groups at follow-up instead of using differences in mean change from baseline.

- In the Unit of analysis issues section, we planned to use intraclass correlation coefficients from included studies to calculate effective sample sizes. As there were no or unrealistic values, we used a conservative estimate based on Cochrane Oral Health experience of studies on caries in nursing home residents.

- We did not use imputation techniques to account for missing data, as missing data were mostly equally distributed between groups, and numbers seemed reasonable for a population of nursing home residents.

- To account for heterogeneity and apparent problems in synthesising complex interventions, we had originally planned to only conduct meta-analysis for the same intervention (main trial and replication trials). After advice from Cochrane Oral Health, we did not pursue the initial plan and conducted a number of meta-analyses on heterogeneous trials.

- In the Subgroup analysis and investigation of heterogeneity section, we stated in the protocol that we would conduct subgroup analyses for study design (cluster randomised versus individual randomised participants) and type of control intervention (usual care versus active control). Due to the small number of studies, we were unable to conduct all predefined subgroup analyses, but instead conducted two additional subgroup analyses: follow-up period (short term versus long term) and education in the context of guideline implementation versus education without guideline implementation.

- Due to a lack of studies with low risk of bias, we did not perform sensitivity analyses based on risk of bias.

7. Diskussion

Mit dieser Arbeit konnte zum einen aufgezeigt werden, dass sich die komplexe Intervention EBGI wissenschaftsbasiert definieren lässt und welche methodischen Anforderungen im Entwicklungsprozess sowohl für EBGI als auch für Schulungsprogramme erfüllt werden müssen, um informierte Entscheidungen ermöglichen zu können. Zum anderen wurde für exemplarische Fragestellungen aus der zahnmedizinischen Versorgung gezeigt, dass für Entscheidungsprozesse die relevanten Informationen unzureichend vorliegen bzw. vermittelt werden. Damit fehlen die Voraussetzungen für informierte Entscheidungen.

Durch die Synthese der wissenschaftlichen Literatur konnten Kriterien für die Kommunikation von Evidenz abgeleitet werden, die die Inhalte, die Präsentation und den Entwicklungsprozess umfassen [6]. Die zugrundeliegende Evidenz für die einzelnen Kriterien ist dabei heterogen. Während für die Darstellung von Häufigkeiten ausreichende Evidenz von hoher Qualität vorliegt, besteht u.a. Forschungsbedarf zum Einsatz von Patientenerzählungen und zur Nutzerorientierung hinsichtlich Sprache und Kultur.

Der Kriterienkatalog wird national und international in Forschungsprojekten sowohl für die Erstellung von EBGI und Schulungsprogrammen als auch für die Bewertung von vorhandenen Gesundheitsinformationen genutzt [20-24].

Die Ergebnisse der RCT zur Evaluation eines modifizierten Flyers zur HPV-Impfung zeigten, dass laienverständlich vermittelte Nutzen-Schaden-Informationen das Risikowissen von Schülerinnen relevant verbessern können [8]. Die Ergebnisse geben Hinweise darauf, dass numerische Informationen zur Nutzen-Schaden-Abwägung auch bei bildungsbenachteiligten Zielgruppen Überschätzungen des Erkrankungsrisikos und des Nutzens verhindern können und somit informierte Entscheidungen ermöglichen.

Auch für andere Zielgruppen und Gesundheitsthemen haben sich in der Forschung Effekte durch die Bereitstellung von EBGI, die die Kriterien berücksichtigen, gezeigt [25].

Neben Print- und Onlineinformationen werden auch telefonische Beratungen durch verschiedene Anbietergruppen bereitgestellt. Der Survey telefonischer Beratungen zu präventiven zahnärztlichen Leistungen und Früh-erkennungsthemen zeigte, dass derzeit nicht die notwendigen Informationen vermittelt werden, um evidenzbasiert entscheiden zu können [7]. Nur sechs von 293 Gesprächen erfüllten den vorab definierten Standard für eine evidenzbasierte Beratung. Der Anteil korrekt beantworteter Kernfragen lag für die sechs Themen zwischen 5%-33,9%. Das Ergebnis erstaunt insbesondere, weil für die standardisierten Anfragen Themen gewählt wurden, für die Evidenzsynthesen oder (evaluierte) EBGI frei zugängig vorliegen.

Damit können medizinische und zahnärztliche Beratungsstellen mögliche Informationsbedarfe nicht erfüllen. Hinzu kommt, dass aktuell nur für wenige zahnmedizinische Entscheidungssituationen schriftliche (evaluierte) EBGI in deutscher Sprache oder international verfügbar sind [26-29]. Zudem weist eine Untersuchung der Verbraucherzentrale Hamburg mittels einer Schein-Patientin, für die ein Referenzbefund von drei Zahnärzten mit konkreten notwendigen Behandlungen vorlag, auf eine mangelhafte Beratungsqualität bei Zahnärzten hin [30]. Offen bleibt daher, wie die in aktuellen Positionspapieren der deutschen Zahnärzteschaft definierte evidenzbasierte Informationsvermittlung und Versorgung erreicht werden kann [31, 32].

Die Leitlinie zur Erstellung von EBGI zielt darauf ab, langfristig die Versorgung mit qualitativ hochwertigen Gesundheitsinformationen sicherzustellen und damit informierte Entscheidungen zu befördern. Als Ergebnis der im Rahmen der Leitlinienentwicklung durchgeführten Experteninterviews mit Gesundheitsinformationserstellern zur Vorbereitung eines Schulungsprogramms für die Leitlinienimplementierung kann festgehalten werden, dass die Kompetenzen zu den Methoden der EbM und EBGI sehr unterschiedliche Ausprägungen aufweisen und sich insgesamt ein Schulungsbedarf zeigt [16].

Die folgenden drei Arbeiten geben einen Einblick in die Voraussetzungen für evidenzbasierte Entscheidungen auf verschiedenen Systemebenen.

Die Untersuchung vorhandener Wirksamkeitsstudien zu edukativen Interventionen zeigte, dass diese überwiegend im Bereich der Medizin durchgeführt und mehrheitlich keine Stichprobenkalkulationen (163 von 259 Studien) berichtet wurden [17]. Die vergleichsweise geringe Anzahl identifizierter Studien aus Deutschland (16 von 259 Studien), die in der fehlenden öffentlichen Förderung für den Bildungsbereich begründet sein könnte, weist auf einen dringenden Bedarf an RCTs hin. Denn obwohl Curricula, Schulungsprogramme und Lehrmethoden fortlaufend für unterschiedliche Lebenswelten und Zielgruppen entwickelt werden, können die Entscheider auf den jeweiligen Systemebenen die Erkenntnisse zur potentiellen Wirkung – oder auch fehlenden Wirkung – einer (flächendeckenden) Implementierung nicht abschätzen.

Die Analyse der Evidenz zu Schulungsprogrammen zur Förderung der Mundgesundheit hat gezeigt, dass weltweit nur neun evaluiert wurden [18, 19]. Es konnte kein bedeutsamer Nutzen der Schulung von Pflegenden und/oder Bewohnern für einzelne Parameter der Zahngesundheit nachgewiesen werden. Die patientenrelevanten Endpunkte mundgesundheitsbezogene Lebensqualität, Mundgesundheit und potentieller Schaden wurden in keiner Studie erfasst. Zusätzlich liegen weder aus der Literatur noch durch Kontaktaufnahme mit den Entwicklern ausreichend Informationen zu den Interventionskomponenten sowie den kontextuellen Faktoren vor. Die Arbeit zeigt damit prototypisch die Herausforderungen bei der Synthese komplexer Interventionen [33]. Die vorhandenen Daten lassen eine informierte Entscheidung hinsichtlich der Implementierung eines dieser Programme kaum zu.

Auch für Interventionen, die die Informationsvermittlung bei Multipler Sklerose fokussieren, wurden hinsichtlich der Beschreibung kontextueller Faktoren vergleichbare Defizite aufgezeigt [34].

8. Ausblick

Die Erkenntnisse der einzelnen Arbeiten können für die Bereitstellung von evidenzbasierten Informationen und damit für die Förderung informierter Entscheidungen sowohl auf der Ebene der Patienten als auch auf der Systemebene der zahnärztlichen Versorgung genutzt werden.

Für die Leitlinie, die aktiv durch den Einsatz verschiedener Strategien, wie z.B. ein Schulungsprogramm und -materialien, implementiert werden soll, ist die Konsultationsphase abgeschlossen. Ein EbM-Trainingsmodul (fünf Teilmodule) für die Leitlinienimplementierung wurde bereits entwickelt und pilotiert. Die Erarbeitung des zweiten Moduls und die Evaluation der Leitlinienimplementierung stehen aus.

Auch den Forderungen von Vertretungen der Patienteninteressen, wie z.B. der Arbeitsgruppe Brustkrebs des Arbeitskreises Frauengesundheit, nach einer nachhaltigen Bereitstellung von EBGI durch neue Strukturen für die Erstellung von Leitlinien, um die Entwicklung von Entscheidungshilfen nutzen zu können [35], wird durch eine kürzlich durch das Deutsche Netzwerk Evidenzbasierte Medizin e.V. gegründete Arbeitsgruppe Rechnung getragen.

Langfristig förderlich für die Verbesserung der zahnmedizinischen Versorgungsqualität kann die geplante Neuregelung der zahnärztlichen Ausbildung (ZÄPro) sein, deren Entwurf die Hinwendung zu einer wissenschaftlich-evidenzbasierten Ausbildung als grundlegende Zielausrichtung bestimmt. Ob *Wissenschaftliches Arbeiten* mit den Schwerpunkten Medizinische Biometrie, Medizinische Informatik, Literaturrecherche und -bewertung und EbM als Wahlfach, wie es der Entwurf vorsieht, berücksichtigt wird, wird die Abstimmung im Bundesrat im kommenden Jahr zeigen. Denn aus der Wissenschaft wird gefordert eine Pflichtveranstaltung zu etablieren, um den Erwerb von Basisqualifikationen in EbM zu implementieren [36]. Ein Basiscurriculum „Evidenzbasierte Entscheidungsfindung“ liegt bereits vor [37].

9. Literatur

[1] Gesetz zur Verbesserung der Rechte von Patientinnen und Patienten, vom 20. Februar 2013. In: Bundesgesetzblatt (BGBl.) 2013; 277.

[2] Marteau T, Dormandy E, Michi S (2001): A measure of informed choice. Health Expect 4(2): 99-108.

[3] Charles C, Gafni A, Whelan T (1999): Decision-making in the physician-patient encounter: revisiting the shared treatment decision-making model. Soc Sci Med 49(5): 651-61.

[4] Klingenberger D, Kern AO, Micheelis W (2006): Zahnärztliche Kommunikationsmuster bei der Versorgung mit Zahnersatz – Ergebnisse einer bundesweiten Evaluationsstudie zum Festzuschuss-System in der gesetzlichen Krankenversicherung. IDZ-Information 2/2006, Institut der Deutschen Zahnärzte: Köln.

[5] Craig P, Dieppe P, Macintyre S et al. (2008): Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ 337: a1655.

[6] Bunge M, Mühlhauser I, Steckelberg A (2010): What constitutes evidence-based patient information? Overview of discussed criteria. Patient Educ Couns 78(3): 316-28.

[7] Albrecht M, Isenbeck F, Kasper et al. (2016): The Foundation in Evidence of Medical and Dental Telephone Consultations. Dtsch Arztebl Int 113(22-23): 389-95.

[8] Steckelberg A, Albrecht M, Kezle A et al. (2013): Impact of numerical information on risk knowledge regarding human papillomavirus (HPV) vaccination among schoolgirls: a randomised controlled trial. GMS Ger Med Sci 11: Doc15. DOI: 10.3205/000183.

[9] Bundesministeriums für Gesundheit (2000): Bekanntmachung des BMG im Rahmen des Modellprogramms zur Förderung der medizinischen Qualitätssicherung “Der Patient als Partner im medizinischen Entscheidungsprozeß”. Bundesanzeiger Ausgabe Nr. 205 vom 31.10.2000.

[10] Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen / Ressort Gesundheitsinformation. Available from https://www.gesundheitsinformation.de/gesundheitsinformation-de.2169.de.html (last accessed 19 December 2016)

[11] Deutsches Netzwerk Evidenzbasierte Medizin e. V., Arbeitsgruppe Gute Praxis Gesundheitsinformation (2016): Gute Praxis Gesundheitsinformation. Z Evid Fortbild Qual Gesundh wesen 110-111: 85-92.

[12] Klemperer D, Lang B, Koch K et al. (2010): Gute Praxis Gesundheitsinformation. Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen 104(2): 66-8.

[13] Sänger S, Lang B, Klemperer D et al. (2006): Manual Patienteninformation. Empfehlungen zur Erstellung evidenzbasierter Patienteninformationen. Available from http://www.aezq.de/mdb/edocs/pdf/schriftenreihe/schriftenreihe25.pdf (last accessed 19 December 2016)

[14] Deutsches Netzwerk Evidenzbasierte Medizin e.V. Fachbereich Patienteninformation und -beteiligung. Available from http://www.ebm-netzwerk.de/was-wir-tun/fachbereiche/patienteninformation (last accessed 19 December 2016)

[15] Leitlinie evidenzbasierte Gesundheitsinformation [online]. Available from http://www.leitlinie-gesundheitsinformation.de/ (last accessed 19 December 2016)

[16] Lühnen J, Albrecht M, Hanßen K et al. (2015): Leitlinie evidenzbasierte Gesundheitsinformation: Einblick in die Methodik der Entwicklung und Implementierung. Z Evid Fortbild Qual Gesundh wesen 109(2): 159-65.

[17] Steckelberg A, Mühlhauser I, Albrecht M (2013): Wollen wir wissen, was wir tun? Evidenzbasierung edukativer Interventionen. Z Evid Fortbild Qual Gesundh wesen 107(1): 13-8.

[18] Albrecht M, Kupfer R, Reissmann DR et al. (2016): Oral health educational interventions for nursing home staff and residents. Cochrane Database of Systematic Reviews 2016, Issue 9. Art. No.: CD010535. DOI: 10.1002/14651858.CD010535.pub2.

[19] Albrecht (nee Bunge) M, Kupfer R, Reissmann D et al. (2016): Oral health educational interventions for nursing home staff and residents. (Protocol) Cochrane Database of Systematic Reviews 2013, Issue 5. Art. No.: CD010535. DOI:10.1002/14651858.CD010535.

[20] Riemann-Lorenz K, Eilers M, von Geldern G et al. (2016): Dietary interventions in multiple sclerosis: development and pilot-Testing of an evidence based patient education program. PLoS One 11(10):e0165246.

[21] Rahn AC, Backhus I, Fuest F et al. (2016): Comprehension of confidence intervals - development and piloting of patient information materials for people with multiple sclerosis: qualitative study and pilot randomised controlled trial. BMC Med Inform Decis Mak 16: 122. DOI: 10.1186/s12911-016-0362-8.

[22] Steckelberg A, Hülfenhaus C, Haastert B et al. (2011): Effect of evidence-based risk information on "informed choice" in colorectal cancer screening: a randomised controlled trial. BMJ 342:d3193.

[23] Colombo C, Filippini G, Synnot A et al. (2016): Development and assessment of a website presenting evidence-based information for people with multiple sclerosis: the IN-DEEP project. BMC Neurol 16:30. DOI: 10.1186/s12883-016-0552-0.

[24] Lins S, Icks A, Meyer G (2011): Understanding, comprehensibility and acceptance of an evidence-based consumer information brochure on fall prevention in old age: a focus group study. BMC Geriatr 11: 26. DOI: 10.1186/1471-2318-11-26.

[25] Stacey D, Légaré F, Col NF et al. (2014): Decision aids for people facing health treatment or screening decisions. Cochrane Database Systematic Reviews 2014, Issue 1 Art. No.:CD001431. DOI: 10.1002/14651858.CD001431.pub4.

[26] Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen / Gesundheitsinformation.de. Available from https://www.gesundheitsinformation.de/ (last accessed 19 December 2016)

[27] IGeL-Monitor. Available from http://www.igel-monitor.de/ (last accessed 19 December 2016)

[28] Johnson BR, Schwartz A, Goldberg J et al. (2006): A chairside aid for shared decision making in dentistry: a randomized controlled trial. J Dent Educ 70(2): 133-41.

[29] Ottawa Hospital Research Institute: Patient decision aids. Available from https://decisionaid.ohri.ca/index.html (last accessed 19 December 2016)

[30] Verbraucherzentrale Hamburg (2013): „Wenn Sie diese Zahnlücke nicht behandeln lassen, fallen Ihnen bald alle Zähne aus!“ Available from www.vzhh.de/gesundheit/293166/2013–01–17_-Zahn%C3%A4rztetest.pdf (last accessed 19 December 2016)

[31] Bundeszahnärztekammer (2016): Position zum Thema sprechende Zahnmedizin. Available from https://www.bzaek.de/fileadmin/PDFs/b/2016_Position_Sprechende_Zahnmedizin.pdf (last accessed 19 December 2016)

[32] Bundeszahnärztekammer / Kassenzahnärztliche Bundesvereinigung (2015): Patienten im Mittelpunkt: Die Patientenberatung der Zahnärzteschaft in Deutschland. Available from www.bzaek.de/fileadmin/PDFs/pati/patientenberatung_zahnaerzte.pdf (last accessed 19 December 2016)

[33] Mühlhauser I; Lenz M, Meyer G (2011): Entwicklung, Bewertung und Synthese von komplexen Interventionen - eine methodische Herausforderung. Z Evid Fortbild Qual Gesundh wesen 105(10): 751-61.

[34] Köpke S, Solari A, Khan F et al. (2014): Information provision for people with multiple sclerosis. Cochrane Database of Systematic Reviews 2014, Issue 4. Art. No.: CD008757. DOI: 10.1002/14651858.CD008757.pub2.

[35] Arbeitskreis Frauengesundheit (2015): Patientinnenorientiert, evidenzbasiert, modular und digital: Frauengesundheitsnetzwerke fordern S4-Leitlinien für bessere Entscheidungsfindung in der Brustkrebsversorgung. Brief an Bundesgesundheitsminister Gröhe. Available from www.akf-info.de/portal/wp-content/uploads/2016/02/Groehe.pdf (last accessed 19 December 2016)

[36] Deutsches Netzwerk Evidenzbasierte Medizin e.V. (2016): Stellungnahme des DNEbM zu Neuregelung der zahnärztlichen Ausbildung (ZÄPrO). „Evidenzbasierte Medizin muss mehr als ein freiwilliges Angebot in der Neuregelung der zahnärztlichen Ausbildung (ZÄPrO) sein!“ Available from http://www.ebm-netzwerk.de/pdf/stellungnahmen/stellungnahme-zaepro.pdf (last accessed 19 December 2016)

[37] Deutsches Netzwerk Evidenzbasierte Medizin e.V., Arbeitsgruppe Curriculum EbM: Basismodul Evidenzbasierte Entscheidungsfindung (unveröffentlicht). Available from http://www.ebm-netzwerk.de/was-wir-tun/update-curriculum-ebm (last accessed 19 December 2016)

10. Anhang: Formalia

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Publikationen und Vorträge

BEITRÄGE IN FACHZEITSCHRIFTEN

Veröffentlichungen in begutachteten Zeitschriften

Albrecht M, Kupfer R, Reissmann DR, Mühlhauser I, Köpke S (2016): Oral health educational interventions for nursing home staff and residents. Cochrane Database of Systematic Reviews 2016, Issue 9. Art. No.: CD010535. DOI: 10.1002/14651858.CD010535.pub2.

Albrecht M, Isenbeck F, Kasper, Mühlhauser I, Steckelberg A (2016): The Foundation in Evidence of Medical and Dental Telephone Consultations. Dtsch Arztebl Int 113(22-23): 389-95.

Steckelberg A, **Albrecht M**, Mühlhauser I (2015): Evidence-based health information and risk competence. GMS Ger Med Sci 13, Doc11, DOI: 10.3205/000215.

Lühnen J, **Albrecht M**, Hanßen K, Hildebrandt J, Steckelberg A (2015): Leitlinie evidenzbasierte Gesundheitsinformation: Einblick in die Methodik der Entwicklung und Implementierung. Z Evid Fortbild Qual Gesundh wesen 109(2): 159-65.

Steckelberg A, **Albrecht M**, Kezle A, Kasper J, Mühlhauser I (2013): Impact of numerical information on risk knowledge regarding human papillomavirus (HPV) vaccination among schoolgirls: a randomised controlled trial. GMS Ger Med Sci 11: Doc15. DOI: 10.3205/000183.

Albrecht (nee Bunge) M, Kupfer R, Reissmann D, Haastert B, Mühlhauser I, Köpke S. Oral health educational interventions for nursing home staff and residents. (Protocol) Cochrane Database of Systematic Reviews 2013, Issue 5. Art. No.: CD010535. DOI: 10.1002/14651858.CD010535.

Siebolds M, **Albrecht M**, Kahl C, Langer G, Lühmann D, Pralle KH, Schwalbe O, Steckelberg A, Strametz R, Weingart O, Weberschock T (2013): Eckpunktepapier zur Weiterentwicklung des "Curriculums Evidenzbasierte Medizin" der Bundesärztekammer und dem Deutschen Netzwerk Evidenzbasierte Medizin e.V. Z Evid Fortbild Qual Gesundh wesen 107(1): 70-73.

Steckelberg A, Mühlhauser I, **Albrecht M (**2013): Wollen wir wissen, was wir tun? Evidenzbasierung edukativer Interventionen. Z Evid Fortbild Qual Gesundh wesen 107(1): 13-18.

Steckelberg A, **Bunge M** (2012): Informierte Entscheidung bei Darmkrebsfrüherkennung: Ausweg aus der Unmündigkeit. Public Health Forum 20; 74: 23.e1-2.

Bunge M, Mühlhauser I, Steckelberg A (2011): Evidenzbasierte Patienteninformation - Ein Novum in der Chirurgie? Zentralbl Chir 136: 297-301.

Bunge M, Mühlhauser I, Steckelberg A (2010): What constitutes evidence-based patient information? Overview of discussed criteria. Patient Educ Couns 78(3): 316-28.

Schade M, **Bunge M**, Pröpsting K, von Komorowsky S, Wiegand C (2006): Literaturanalyse zur Mangelernährung in Alten- und Pflegeheimen: Lebensqualität in den Mittelpunkt stellen. Pflege Z 59: 772-776.

Weitere Artikel

Mühlhauser I, **Albrecht M**, Steckelberg A (2014): Evidenzbasierte Gesundheitsinformation. Zbl Arbeitsmedizin 64: 334-337.

Steckelberg A, **Bunge M**, Mühlhauser I (2012): Wie komme ich zu einer informierten Entscheidung? Welches Wissen ist dafür notwendig? Impu!se 74/2012 Zeitschrift für Gesundheitsförderung Herausgeberin: Landesvereinigung für Gesundheit und Akademie für Sozialmedizin Niedersachsen e.V.

BUCHBEITRÄGE UND BROSCHÜREN

Albrecht M & Steckelberg A (in press): Prostatakrebs-Früherkennung. Herausgeber: BKK ProVita.

Hinneburg J, **Albrecht M**, Steckelberg A (in press): Gebärmutterhalskrebs-Früherkennung. Herausgeber: BKK ProVita.

Albrecht M (in press): Was sollen/ wollen Beschäftigte wissen? – Gesundheitsinformationen für Beschäftigte. In: Deutschen Gesellschaft für Arbeitsmedizin und Umweltmedizin e.V. (Hrsg.): Dokumentationsband zur 56. Wissenschaftliche Jahrestagung der Deutschen Gesellschaft für Arbeitsmedizin und Umweltmedizin e.V.

Albrecht M, Mühlhauser I, Steckelberg A (2014): Evidenzbasierte Gesundheitsinformation. In: Hurrelmann K & Baumann E (Hrsg.): Handbuch Gesundheitskommunikation. Bern: Hans Huber Verlag, 142-158.

Steckelberg A, **Albrecht M** (2014): Kritische Gesundheitsbildung und Patientenkompetenz. In: Hurrelmann K & Baumann E (Hrsg.): Handbuch Gesundheitskommunikation. Bern: Hans Huber Verlag, 159-169.

Steckelberg A, **Bunge M**, Gerlach A, Mühlhauser I: Evidenzbasierte Patient(inn)en-informationen (2011): Ausweg aus der fremdverschuldeten Unmündigkeit. In: Gesundheitsinformationen in Deutschland, Schriftenreihe der Gesellschaft für Versicherungswissenschaft und -gestaltung e. V. Köln, Band 67

Gerlach A, **Bunge M**, Bohlmann L, Stork J, van Dijk J, Fabian R, Neugebauer E, Mühlhauser I, Laubenthal H (2011): Schmerzbehandlung bei Operationen. Eine Patientenleitlinie. Herausgeber: Deutsche Interdisziplinäre Vereinigung für Schmerztherapie (DIVS) e.V.

MANUALE UND LEITLINIEN

Leitlinie evidenzbasierte Gesundheitsinformation [online]. Available from http://www.leitlinie-gesundheitsinformation.de/ (last accessed 19 December 2016)

Albrecht M, Steckelberg A (2014): Manual für die Erstellung von evidenzbasierten Informationen für Arbeitnehmerinnen und Arbeitnehmer. Dortmund, Berlin, Dresden: Bundesanstalt für Arbeitsschutz und Arbeitsmedizin. ISBN 978-3-88261-022-2.

Steckelberg A, **Bunge M**, Gerlach A, Meyer G, Mühlhauser I (2011): Entwicklung einer S3 Leitlinie zur Erstellung von Patienteninformationen. Studienprotokoll. Available from: http://www.leitlinie-gesundheitsinformation.de/wp-content/uploads/2015/02/Studienprotokoll-LL-EBPI_final_10.6.2011.pdf (last accessed 19 December 2016)

VORTRÄGE UND POSTERPRÄSENTATIONEN

Wissenschaftliche Vorträge

Albrecht M: Was sollen/ wollen Beschäftigte wissen? – Gesundheitsinformationen für Beschäftigte. 56. Wissenschaftliche Jahrestagung der Deutschen Gesellschaft für Arbeitsmedizin und Umweltmedizin e.V. München, 09.-11.03.2016

Albrecht M, Kupfer R, Reißmann D, Mühlhauser I, Köpke S: Schulungsprogramme zur Förderung der Mundgesundheit von Alten- und Pflegeheimbewohnern - Herausforderungen bei der Synthese komplexer Interventionen. 16. Jahrestagung des Deutschen Netzwerks Evidenzbasierte Medizin. Berlin 13.-14.03.2015. Düsseldorf: German Medical Science GMS Publishing House; 2015. DOC15ebmB1d /20150303/.

Albrecht M, Kasper J, Mühlhauser I, Isenbeck F, Steckelberg A: I`ve got a question… Telephone counselling on screening procedures in Germany: is it evidence-based? International Conference on Communication in Healthcare. Amsterdam, The Netherlands, September 28 to October 1, 2014.

Albrecht M, Kasper J, Steckelberg A: Ich habe da mal ´ne Frage… Wie evidenzbasiert sind Telefonberatungen zu zahnmedizinischen Themen? 15. Jahrestagung des Deutschen Netzwerks Evidenzbasierte Medizin. Halle, 13.-

15.03.2014. Düsseldorf: German Medical Science GMS Publishing House; 2014. Doc14ebmE1b. DOI: 10.3205/14ebm020.

Aarabi G**, Bunge M**, Reissmann D: Zahnarzt- und Patientenpräferenzen zur evidenzbasierten Entscheidungshilfe "Zahnverlust – was nun?" Deutscher Zahnärztetag. Frankfurt am Main, 09.-10.11.2012.

Bunge M: Welche Informationen brauchen Patient(inn)en und Bürger(innen) für informierte Entscheidungen? Präkonferenz-Vortrag „Patientenorientierung und Patientenbeteiligung“, 13. Jahrestagung des Deutschen Netzwerks Evidenzbasierte Medizin. Hamburg, 15.-17.03.2012.

Bunge M: Wissenschaftsbasierte Patienteninformation am Beispiel der Gallenblasenoperation. 7. Jahrestagung der Chirurgischen Arbeitsgemeinschaft Akutschmerz (CAAS) und 5. Jahrestagung der Chirurgischen Arbeitsgemeinschaft Perioperative Medizin (CAPM). Köln, 25.-26.11.2011.

Gerlach A, **Bunge M**, Mühlhauser I, Steckelberg A. Entwicklung einer Patientenleitlinie “Schmerzbehandlung nach Operationen” – Methodische Anforderungen an Patientenorientierung und Evidenzbasierung. Forum Medizin 21 der Paracelsus Medizinischen Privatuniversität & 11. EbM-Jahrestagung des Deutschen Netzwerks Evidenzbasierte Medizin. Salzburg, 25.-27.02.2010. Düsseldorf: German Medical Science GMS Publishing House; 2010. Doc10ebm030. DOI: 10.3205/10ebm030

Bunge M, Mühlhauser I, Steckelberg A. Welche Evidenz braucht evidenzbasierte Patienteninformation? Eine systematische Übersichtsarbeit. 10. Jahrestagung des Deutschen Netzwerks Evidenzbasierte Medizin. Berlin, 05.-07.03.2009. Düsseldorf: German Medical Science GMS Publishing House; 2009. Doc09ebmV6.6. DOI: 10.3205/09ebm030.

Poster

Steckelberg A, **Albrecht M**, Lühnen J, Mühlhauser I: Evidenzbasierte Leitlinie zur Erstellung von Gesundheitsinformationen. 17. Jahrestagung des Deutschen Netzwerks Evidenzbasierte Medizin. Köln, 03.-05.03.2016. Düsseldorf: German Medical Science GMS Publishing House; 2016. DOC16ebmP36 /20160223/.

Albrecht M, Kupfer R, Reißmann DR, Mühlhauser I, Köpke S: Methodological strategies for the synthesis of complex interventions – oral health education programmes for nursing staff and residents. 23rd Cochrane Colloquium. Vienna, Austria, 3-7 October.

Lühnen J, **Albrecht M**, Steckelberg A: Verständnis auf den ersten Blick? Grafiken in Gesundheitsinformationen. 16. Jahrestagung des Deutschen Netzwerks

Evidenzbasierte Medizin. Berlin, 13.-14.03.2015. Düsseldorf: German Medical Science GMS Publishing House; 2015. DOC15ebmP2b /20150303/.

Steckelberg A Lühnen J, **Albrecht M**: Risiken effektiv kommunizieren: Darstellung von Zahlen in Gesundheitsinformationen. 15. Jahrestagung des Deutschen Netzwerkes Evidenzbasierte Medizin. Halle, 14.-15.03.2014. Düsseldorf: German Medical Science GMS Publishing House; 2014. DOC14ebmP1e /20140310/.

Lühnen J, **Albrecht M**, Steckelberg A: Informiert oder überredet? Narrative in Gesundheitsinformationen. 15. Jahrestagung des Deutschen Netzwerkes Evidenzbasierte Medizin. Halle, 14.-15.03.2014. Düsseldorf: German Medical Science GMS Publishing House; 2014. DOC14ebmP1a /20140310/.

Bunge M, Aarabi G, Reißmann DR: Entwicklung und Pilotierung einer evidenzbasierten Entscheidungshilfe zur Rehabilitation nach initialem Zahnverlust. 13. Jahrestagung des Deutschen Netzwerks Evidenzbasierte Medizin. Hamburg, 15.-17.03.2012. Düsseldorf: German Medical Science GMS Publishing House; 2012. Doc12ebm060.

Gerlach A, **Bunge M**: Entwicklung und Pilotierung einer evidenzbasierten Patienteninformation – „Schmerzbehandlung bei einer Gallenblasen-Operation“. 13. Jahrestagung des Deutschen Netzwerks Evidenzbasierte Medizin. Hamburg, 15.-17.03.2012. Düsseldorf: German Medical Science GMS Publishing House; 2012. Doc12ebm062.

Steckelberg A, **Bunge M**, Kezle A, Kasper J, Mühlhauser I: Impact of an evidence-based leaflet on ‘risk knowledge’ of human papillomavirus (HPV) vaccination in disadvantaged pupils: a RCT. 6th International Shared Decision Making Conference. Maastricht, Holland, 19.-22.06.2011.

Bunge M, Mühlhauser I, Steckelberg A. What constitutes evidence-based patient information? Overview of discussed criteria. 5th International Shared Decision Making Conference. Abstractband. Boston, 14-17 Juni 2009.

Beiträge zu Wissenschaftlichen Workshops und Seminaren

Albrecht M, Berger-Höger B, Buhse S, Liethmann K, Lühnen J, Rahn A, Richter T, Mühlbauer V, Steckelberg A (Arbeitsgruppe I. Mühlhauser): Evidenzbasierte Gesundheitsinformationen und Entscheidungshilfen zu Themen der Früherkennung und Prävention. Workshop: SDM zum Anfassen: Welche Instrumente der Entscheidungsunterstützung sind bereits im Einsatz? 17. Jahrestagung des Deutschen Netzwerks Evidenzbasierte Medizin. Köln, 03.-05.03.2016. Düsseldorf: German Medical Science GMS Publishing House; 2016. DOC16ebmPRE-WS5 /20160223/.

Bunge M. Entwicklung eines Prototyps für eine evidenzbasierte Patientenleitlinie aus Therapieleitlinien. Workshop: Evidenzbasierte Patientenleitlinien: Geeignete Grundlage der Kommunikation mit Patienten? Forum Medizin 21 der Paracelsus Medizinischen Privatuniversität & 11. EbM-Jahrestagung des Deutschen Netzwerks Evidenzbasierte Medizin. Salzburg, 25.-27.02.2010. Düsseldorf: German Medical Science GMS Publishing House; 2010. Doc10ebm050.

Trainingskurse für Angehörige von Gesundheitsfachberufen

Bunge M, Buhse S, Türp JC. Einführung in die Evidenzbasierte Zahnmedizin. 13. Jahrestagung des Deutschen Netzwerks Evidenzbasierte Medizin. Hamburg, 15.-17.03.2012. Düsseldorf: German Medical Science GMS Publishing House; 2012. Doc12ebm121. DOI: 10.3205/12ebm121.

GUTACHTERTÄTIGKEIT FÜR WISSENSCHAFTLICHE ZEITSCHRIFTEN

- BMC Medical Informatics and Decision Making (2015)
- Canadian Journal of Dental Hygiene (2014)
- Diabetologia (2014)
- European Journal of Integrative Medicine (2014)
- Journal of Clinical Epidemiology (2014)
- Patient Education and Counseling (seit 2011)
- Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen (seit 2009)

LEHRE AN DER UNIVERSITÄT HAMBURG

Studiengang Lehramt Oberstufe – Berufliche Schulen, Teilstudiengang Gesundheitswissenschaften

- Patienteninformation und Beratungsmodule (Bachelor: 3 SWS; Sommersemester 2009 bis Sommersemester 2014)
- Anatomie, Physiologie, Pathologie des Menschen II (Bachelor: Wintersemester 2009/2010)
- Projektseminar I-III (Staatsexamen: Sommersemester 2009 - Sommersemester 2010, Wintersemester 2009/2010 - Wintersemester 2010/2011)
- Praktikumsphase (Bachelor: seit Sommersemester 2010)
- Zahn-Mund-Kieferheilkunde II (Staatsexamen: 2 SWS; Sommersemester 2010)
- Zahn-Mund-Kieferheilkunde IV (Staatsexamen: Sommersemester 2010)

- Wissenschaftsmethoden (Master: Wintersemester 2010/2011)
- Projektseminar I-III (Master: Sommersemester 2011 - Sommersemester 2012, Sommersemester 2012 - Sommersemester 2013, Sommersemester 2014 - Sommersemester 2015)
- Zahnmedizin II (Bachelor: Sommersemester 2011 und Sommersemester 2012)

GUTACHTERTÄTIGKEIT FÜR DIE UNIVERSITÄT HAMBURG

Gutachtertätigkeit für Klausuren und Hausarbeiten im Rahmen der Ersten Staatsexamensprüfung der Hansestadt Hamburg für das Lehramt an der Oberstufe - Berufliche Schulen im Fach Gesundheit seit 2009

Gutachtertätigkeit für Modulprüfungen sowie Bachelor- und Master-Prüfungen im Teilstudiengang Gesundheitswissenschaften, seit 2009

Versicherung und Erklärung des eigenständig geleisteten Anteils an den zur Dissertation eingereichten Publikationen

Die Grundlagen und methodischen Bedingungen (laienverständlicher) Kommunikation wissenschaftlicher Evidenz mit der Zielsetzung Informationsasymmetrien zwischen Gesundheitsinteressierten bzw. Betroffenen und Gesundheitsprofessionellen abzubauen und informierte Entscheidungen zu fördern, bilden den Schwerpunkt der Promotion. Dazu gehört auch die vorhandene Evidenz systematisch aufzubereiten um Ansätze für die Entwicklung evidenzbasierter Interventionen zu identifizieren.
Die Studien im Bereich evidenzbasierte Gesundheitsinformationen wurden von mir (Martina Albrecht) unter der Leitung von Univ.-Prof. Dr. med. Ingrid Mühlhauser und Dr. phil. Anke Steckelberg durchgeführt.
Der von dem Bundesministerium für Bildung und Forschung geförderte Cochrane Review zu Schulungsprogrammen wurde von mir beantragt und durchgeführt.
Ich versichere, dass ich an der Planung, Durchführung, Analyse und Publikation der einzelnen Teilschritte maßgeblich beteiligt war.

Bunge M, Mühlhauser I, Steckelberg A (2010): What constitutes evidence-based patient information? Overview of discussed criteria. Patient Educ Couns 78(3): 316-28.

Die Publikation ist die Aktualisierung einer Übersichtsarbeit zu den Kriterien für evidenzbasierte Patienteninformationen von Anke Steckelberg (AS) aus dem Jahr 2005. Die systematischen Literaturrecherchen, die Auswahl und Analyse der Publikationen erfolgte im Konsensverfahren mit AS.
Die Publikationsvorlage wurde von mir eigenständig verfasst und von AS und Ingrid Mühlhauser (IM) kritisch kommentiert.

Steckelberg A, Mühlhauser I, **Albrecht M** (2013): Wollen wir wissen, was wir tun? Evidenzbasierung edukativer Interventionen. Z Evid Fortbild Qual Gesundh wesen 107(1): 13-8.

Die Grundidee der Publikation experimentelle Studien zu edukativen Interventionen im Bildungsbereich zu analysieren, entstand im Diskurs mit AS und IM. Ich war

maßgeblich verantwortlich für die Entwicklung der Studienskizze, der Recherchestrategien und des Datenextraktionsbogens. Die systematischen Recherchen, die Auswahl und Analyse der Publikationen sowie die Dateneingabe erfolgte im Konsensverfahren mit AS. Die Publikationsvorlage wurde eigenständig von mir verfasst. AS und IM kommentierten die Publikation kritisch.

Steckelberg A, **Albrecht M**, Kezle A, Kasper J, Mühlhauser I (2013): Impact of numerical information on risk knowledge regarding human papillomavirus (HPV) vaccination among schoolgirls: a randomised controlled trial. GMS Ger Med Sci 11: Doc15. DOI: 10.3205/000183.

Der Artikel beschreibt die Evaluation einer evidenzbasierten Gesundheits-information in einer randomisiert-kontrollierten Studie. Ich war an der Planung, Durchführung und Analyse der verblindeten Fragebogenerhebungen in den Schulklassen beteiligt. Den von AS verfassten Artikel habe ich kritisch kommentiert.

Albrecht (nee Bunge) M, Kupfer R, Reissmann DR, Haastert B, Mühlhauser I, Köpke S (2016): Oral health educational interventions for nursing home staff and residents. (Protocol) Cochrane Database of Systematic Reviews 2013, Issue 5. Art. No.: CD010535. DOI:10.1002/14651858.CD010535.

Dieses Studienprotokoll ist die methodische Vorarbeit zu dem von mir beantragten Forschungsprojekt „Schulungsprogramme zur Förderung der Mundgesundheit von Alten- und Pflegeheimbewohnern“ im Rahmen des BMBF/ DFG Programms "Klinische Studien/ Systematische Reviews". Die Entwicklung der wissenschaftlichen Fragestellung und die methodische Planung wurden unter meiner Leitung in enger Zusammenarbeit mit Sascha Köpke (SK) durchgeführt. Die Publikationsvorlage wurde von mir eigenständig verfasst. SK hat den Erstellungsprozess kritisch begleitet und kommentiert. Ramona Kupfer (RK), Daniel Reissmann (DR), Burkhard Haastert (BH) und IM haben die Endversion kritisch kommentiert.

Lühnen J, **Albrecht M**, Hanßen K, Hildebrandt J, Steckelberg A (2015): Leitlinie evidenzbasierte Gesundheitsinformation: Einblick in die Methodik der Entwicklung und Implementierung. Z Evid Fortbild Qual Gesundh wesen 109(2): 159-65.

Die Publikation stellt zwei Teilprojekte aus dem Entwicklungsprozess einer evidenzbasierten Leitlinie für die Erstellung von evidenzbasierten Gesundheitsinformationen dar.
Die explorative Studie zur Ermittlung der Kompetenzen von Erstellern von Gesundheitsinformationen wurde im Rahmen eines studentischen Master-Projektes unter der Leitung von AS und mir durchgeführt. Das von Käthe Hanßen (KH) und Julia Hildebrandt (JH) verfasste Studienprotokoll, der Interviewleitfaden und die Auswertungsmatrix wurden von mir kritisch kommentiert. Die Rekrutierung der Interviewteilnehmer erfolgte unter meiner Beteiligung.
Bei der Bearbeitung der Leitlinienfragen zu grafischen Darstellungen war ich im Falle von Nichtübereinstimmungen bei der Bewertung und Analyse der eingeschlossenen Artikel von Julia Lühnen (JL) und AS als dritte Methodikerin beteiligt.
Den von JL und AS verfassten Artikel habe ich kritisch kommentiert.

Albrecht M, Isenbeck F, Kasper, Mühlhauser I, Steckelberg A (2016): The Foundation in Evidence of Medical and Dental Telephone Consultations. Dtsch Arztebl Int 113(22-23): 389-95.

Die Entwicklung der wissenschaftlichen Fragestellung dieses Telefon-Surveys erfolgte zusammen mit AS und IM. Das Studienprotokoll mit drei zahnmedizinischen Szenarien sowie der Ethikantrag wurden von mir verfasst und von Florian Isenbeck (FI) um drei medizinische Szenarien erweitert. Alle einzelnen Studienphasen wurden von AS kritisch begleitet. Für die zahnmedizinischen Szenarien wurde die Evidenzaufarbeitung, die Entwicklung und Pilotierung der Bögen zur Dokumentation der Beratungsgespräche sowie die Schulung der verdeckten Klientinnen von mir durchgeführt. Unter meiner Leitung wurden diese Schritte für die medizinischen Szenarien von FI durchgeführt. Die Erhebungen erfolgten durch studentische Hilfskräfte. Die Erstellung der Datenmaske, Dateneingabe in die Datenbank sowie die Konzeption der Datenauswertung wurde maßgeblich von mir durchgeführt. Die

statistischen Arbeiten wurden von AS und Jürgen Kasper (JK) unterstützt. Die Auswertung und Interpretation der Ergebnisse habe ich zusammen mit AS, FI, JK und IM vorgenommen.
Die Erstellung der Publikationsvorlage erfolgte eigenständig unter Berücksichtigung kritischer Anmerkungen von AS, FI, JK und IM.

Albrecht M, Kupfer R, Reissmann DR, Mühlhauser I, Köpke S (2016): Oral health educational interventions for nursing home staff and residents. Cochrane Database of Systematic Reviews 2016, Issue 9. Art. No.: CD010535. DOI: 10.1002/14651858.CD010535.pub2.

Diese Publikation ist die von mir beantragte und geplante Metaanalyse aus dem Forschungsprojekt „Schulungsprogramme zur Förderung der Mundgesundheit von Alten- und Pflegeheimbewohnern“ im Rahmen des BMBF/ DFG Programms "Klinische Studien/ Systematische Reviews".
Die methodische Vorgehensweise ist in dem von mir publizierten Studienprotokoll dargestellt. Die Planung der systematischen Literaturrecherche erfolgte zusammen mit SK. Die Auswahl der Publikationen erfolgte im Konsensverfahren mit RK. Die Kontaktaufnahme mit Autoren der ausgewerteten Primärstudien wurde von mir durchgeführt. Die Datenextraktion, Analyse und Interpretation der Ergebnisse habe ich mit RK und SK vorgenommen. Den Austausch und die Absprachen mit der englischen Cochrane Oral Health Gruppe habe ich übernommen. Die Publikationsvorlage wurde von mir unter kritischer Begleitung von SK eigenständig verfasst. RK, DR und IM haben die Endversion kritisch kommentiert.

Hiermit versichere ich an Eides statt, die vorliegende Dissertation selbst verfasst und keine anderen als die angegebenen Hilfsmittel benutzt zu haben. Die eingereichte schriftliche Fassung entspricht der auf dem elektronischen Speichermedium.

Ich versichere, dass diese Dissertation nicht in einem früheren Promotionsverfahren eingereicht wurde.

Martina Albrecht (geb. Bunge) Berlin, 20.12.2016