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**Physical therapy for older people with dizziness:
Development and piloting of evidence-based care pathways
to improve mobility and participation**

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Affidavit



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Affidavit

Regauer, Verena Magdalena

Surname, first name

I hereby declare, that the submitted thesis entitled

Physical therapy for older people with dizziness: Development and piloting of evidence-based care pathways to improve mobility and participation

is my own work. I have only used the sources indicated and have not made unauthorised use of services of a third party. Where the work of others has been quoted or reproduced, the source is always given.

I further declare that the dissertation presented here has not been submitted in the same or similar form to any other institution for the purpose of obtaining an academic degree.

Rosenheim, 06.02.2025

Place, Date

Verena Magdalena Regauer

Signature doctoral candidate

Abkürzungsverzeichnis

BayWISS	Bayerisches Wissenschaftsforum
BCW	Behaviour Change Wheel
CFIR	Consolidated Framework for Implementation Research
ERIC	Expert Recommendations for Implementing Change
ICF	International Classification of Functioning, Disability and Health
LMU	Ludwig-Maximilians-Universität
MobileE-PHY	Physiotherapeutische Interventionen für ältere Menschen mit Schwindel und Gleichgewichtsstörungen
MRC	Medical Research Council
PROSPERO	International Prospective Register of Systematic Reviews
VAP	Vertigo Activities and Participation Questionnaire
VR	Vestibuläre Rehabilitation
WHO	Weltgesundheitsorganisation

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Zusammenfassung

Hintergrund:

Schwindel und Gleichgewichtsstörungen sind mit einer Prävalenz von bis zu 50% häufige Probleme älterer Menschen über 65 Jahren und beeinträchtigen deren Mobilität und soziale Teilhabe. Betroffene profitieren von einer mobilitätsfördernden Physiotherapie. Trotz bekannter Wirksamkeitsnachweise werden physiotherapeutische Interventionen bei Schwindel und Gleichgewichtsstörungen im Alter eher selten von Hausärzt*innen verordnet. Wie eine optimierte Implementierung von Physiotherapie in die Primärversorgung in Deutschland gelingen kann, wurde noch nicht untersucht. Ein Weg, um Evidenz in die lokale Versorgungspraxis zu bringen, ist der Einsatz von Versorgungspfaden. Durch einen Versorgungspfad kann die Versorgung einer Zielgruppe standardisiert und optimiert werden, indem Entscheidungshilfen für alle relevanten diagnostischen und therapeutischen Schritte für seine Anwender*innen bereitgestellt werden. Neben der Aufbereitung von Evidenz wird empfohlen, die Bedarfe involvierter Interessensgruppen in den Pfad zu integrieren, ihn für seine Anwender*innen maßzuschneidern und Lösungsstrategien für potentielle Barrieren und Förderfaktoren vorzuschlagen. Bei der systematischen Identifikation von Barrieren und Förderfaktoren auf verschiedenen Ebenen und der Auswahl geeigneter Lösungsstrategien unterstützen Instrumente der Implementierungsforschung wie das *Consolidated Framework of Implementation Research (CFIR)* und die *Expert Recommendations for Implementing Change (ERIC)*. Obwohl beide englischsprachigen Instrumente bereits im deutschsprachigen Raum Anwendung finden, liegen bisher keine standardisierten und validierten Übersetzungen in die deutsche Sprache vor.

Ziel der vorliegenden Dissertation ist es (1) zu untersuchen, welche physiotherapeutischen Interventionen wirksam für ältere Menschen mit Schwindel und Gleichgewichtsstörungen sind und (2) basierend darauf einen Versorgungspfad zu entwickeln, mit welchem diese in die Primärversorgung integriert werden können. Um die optimale Integration in die lokale Versorgungspraxis vorzubereiten, sollen (3) zwei englischsprachige Instrumente der Implementierungsforschung für deutsche Anwender*innen bereitgestellt und auf ihre Verständlichkeit getestet werden.

Methoden:

(Ziel 1) Gemäß den Empfehlungen des *UK Medical Research Councils* stellt die Aufarbeitung vorhandener Evidenz den ersten Schritt zur Entwicklung eines Versorgungspfades dar. Ein systematischer Review wurde angefertigt, um die Qualität der Evidenz physiotherapeutischer Interventionen für ältere Menschen mit Schwindel und Gleichgewichtsstörungen zu identifizieren. Eine Literaturrecherche über MEDLINE via PubMed, Cochrane Library CINAHL und PEDro wurde durchgeführt. Methodisch folgten wir dem *Cochrane Handbook for Systematic Reviews of Interventions* und schlossen mit einer narrativen Datensynthese.

(Ziel 2) Um die Entwicklung des Versorgungspfades mit den Bedarfen potentieller Anwender*innen und Empfänger*innen zu informieren, fanden Einzel- und Fokusgruppeninterviews mit Betroffenen, Physiotherapeut*innen, Hausärzt*innen und ambulanten Pflegepersonen statt. Die Forschungsergebnisse mündeten in einen multidisziplinären Expertenworkshop, in welchem ein erster Entwurf eines Versorgungspfades

mit adäquater Implementierungsstrategie modelliert wurde. Der Interventionsansatz zur Verhaltensänderung folgte dem *Behaviour Change Wheel*. Die einzelnen Resultate wurden in einem *Logic Model* hinsichtlich ihrer angestrebten Ergebnisse, des geplanten Arbeitsaufwands und zugrundeliegende Änderungsmechanismen, welche mit einer Anwendung des Versorgungspfades verbunden sind, systematisch dargestellt.

(Ziel 3) In einem mehrstufigen Prozess gemäß Empfehlungen der *World Health Organization* wurden zwei im Modellierungsprozess verwendete Instrumente der Implementationsforschung *CFIR* und *ERIC* aus dem englischen Original ins Deutsche übersetzt. Diese Übersetzung wurde nachfolgend in einem bilingualen Gremium diskutiert, von einer Muttersprachlerin rückübersetzt und mit 12 potentiellen Anwender*innen in kognitiven Interviews auf ihre Validität überprüft.

Ergebnisse:

(Ziel 1) Die systematische Übersichtsarbeit schloss 18 randomisierte und 2 nicht-randomisierte kontrollierte Studien zu vestibulärer Rehabilitation in ihrer klassischen Form, mit zusätzlichen virtuellen Elementen, sowie in Verbindung mit Tai Chi ein. Zudem wurde je eine randomisierte kontrollierte Studie zu Lagerungsmanövern und zu manueller Therapie inkludiert. Die eingeschlossenen Studien unterschieden sich in der Komplexität ihrer Interventionen, ihren gemessenen Ergebnisparametern und ihrer methodischen Qualität voneinander. In der Zusammenschau lässt sich feststellen, dass moderate Evidenz dazu vorliegt, die vestibuläre Rehabilitation den Vergleichsbehandlungen überlegen darstellt, um Mobilität und insbesondere das funktionelle Gleichgewicht zu verbessern.

(Ziel 2) Insgesamt 17 Einzel- und 2 Gruppeninterviews mit potentiellen Anwender*innen des Versorgungspfades verdeutlichten den Bedarf an einer konkreten Handlungsempfehlung bei Diagnosestellung und Therapieplanung, ein standardisiertes Überweisungsregime, spezifische Fortbildungsmöglichkeiten und ein gemeinsames Dokumentationssystem. 11 Einzelinterviews mit Patient*innen zeigten eine vorherrschende Bagatellisierung von Schwindel- und Gleichgewichtsproblemen im Alter und Interpretation als physiologische Alterungserscheinung. Kontinuierliche Physiotherapie und altersspezifische Behandlungsangebote wurden gewünscht. Der Expertenworkshop resultierte in eine erste Version eines Versorgungspfades mit seinen Interventionskomponenten und ausgewählten Implementierungsstrategien. Zusammenfassend entstand ein *Logic Model*, welches Informationen zu angenommenen Ursache-Folge-Ketten gibt.

(Ziel 3) Die Instrumente *CFIR* und *ERIC* wurden standardisiert übersetzt und erprobt. Dieser Prozess ergab Unterschiede in den vorläufigen Versionen, die durch Diskussion mit allen Teilnehmenden gelöst werden konnten. Die Verständlichkeit der deutschen Übersetzungen wurden in 69% / 64% der Items (*CFIR* / *ERIC*) bestätigt, bei 28% / 36% wurden kleine Modifikationen vorgeschlagen und bei 3% / 0% eine komplette Überarbeitung. Die finalen Versionen wurden von allen involvierten Personen bestätigt.

Schlussfolgerung:

Die aktuelle Evidenzlage zeigt, dass zur physiotherapeutischen Behandlung älterer Menschen mit Schwindel und Gleichgewichtsstörungen eine vestibuläre Rehabilitation unabhängig ihrer

Variation empfehlenswert ist, wobei weitere methodisch hochwertige Studien mit patientenrelevanten Ergebnisparametern durchgeführt werden sollen, um klinische Entscheidungen zu fundieren. Um in die Entwicklung eines Versorgungspfades und seiner Implementierungsstrategie neben dem Qualitätskriterium der Evidenzbasierung auch die Perspektive der Stakeholder*innen zu integrieren und ein Mitgestalten von potentiellen Anwender*innen und Empfänger*innen zu ermöglichen, ist der Methodenmix aus Interviews und Expertenrunden ein adäquates und machbares Studiendesign. Der entwickelte Versorgungspfad wird nun auf seine Machbarkeit und Akzeptanz getestet und von einer Prozessevaluation begleitet, um letztendlich eine Effektivitätsstudie zu informieren. Die bei der Entwicklung verwendeten deutschen Versionen der beiden Rahmenkonstrukte zur Implementierung *CFIR* und *ERIC* liegen vor und können nun im deutschsprachigen Raum genutzt werden können. Dadurch könnte die Anwendung evidenzbasierter Implementierungsinstrumente verbessert werden.

Abstract

Background:

With a prevalence of up to 50%, vertigo, dizziness and balance disorders are common problems in older adults over 65 years of age and impair their mobility and social participation. Affected people benefit from mobility-enhancing physical therapy. Despite known evidence of effectiveness, physical therapy interventions for vertigo, dizziness and balance disorders in older adults are rarely used by general practitioners. So far, a successful implementation of an optimized use of physical therapy in primary care has not been investigated in Germany. A possibility to bring evidence into local care structures is the use of care pathways. A care pathway standardizes and optimizes the care of a target group by providing decision-making aids for all relevant diagnostic and therapeutic steps for its users. In addition to the evidence base of a care pathway, it is recommended to integrate the needs of stakeholders involved into the pathway, tailor it for its users and recommend strategies for potential barriers and facilitators. Implementation research instruments like the *Consolidated Framework of Implementation Research (CFIR)* and the *Expert Recommendations for Implementing Change (ERIC)* support a systematic identification of barriers and facilitators and the selection of implementation strategies. Although both instruments are used in German-speaking countries, no standardized and validated translation in German language is available yet.

The aim of this dissertation is (1) to investigate which physical therapy interventions are effective for older adults with vertigo, dizziness and balance disorders and (2) based on this, to develop a care pathway with which these can be integrated into primary care. In order to enable optimal integration into local care practice, (3) two English-language implementation research instruments should be made available for German users and tested for their comprehensibility.

Methods:

(Objective 1) As recommended by the *UK Medical Research Council*, reviewing existing evidence is the first step in developing a care pathway. A systematic review was conducted to identify the quality of evidence on physical therapy interventions for older adults with vertigo, dizziness and balance disorders. A literature search on MEDLINE via PubMed, Cochrane Library, CINAHL and PEDro was conducted. Methodologically, we followed the *Cochrane Handbook for Systematic Reviews of Interventions* and concluded with a narrative synthesis.

(Objective 2) In order to inform the development of the care pathway with the needs of the potential users and recipients, individual and focus group interviews were conducted with patients, physical therapists, general practitioners and outpatient nurses. The results guided to a multidisciplinary expert workshop and a first draft of a care pathway with an adequate implementation strategy was modeled. The behaviour change intervention approach followed the *Behaviour Change Wheel*. In summary, the individual results were combined in a *logic model* and the intended results, the planned work and the underlying mechanisms of change associated with the use of the care pathway were systematically presented.

(Objective 3) In a multi-stage process according to recommendations of the *World Health Organization*, two instruments of implementation research *CFIR* and *ERIC* used in the modeling process were translated from the English original into German language. This

translation was discussed in a bilingual committee, re-translated by a native speaker and checked for its validity with 12 potential users in cognitive interviews.

Results:

(Objective1) The systematic review included 18 randomized and 2 non-randomized controlled trials on vestibular rehabilitation in its classic form, with additional virtual elements, and in connection with tai chi. In addition, one randomized controlled study on positioning maneuvers and one on manual therapy was included. The included studies varied in complexity of their interventions, measured outcome parameters and their methodological quality. In summary, there is moderate quality evidence showing that vestibular rehabilitation is superior to comparative treatments in order to improve mobility and, in particular, functional balance.

(Objective 2) A total of 17 individual and 2 focus group interviews with potential users of the care pathway emphasized the need for a concrete recommendation when making a diagnosis and planning therapy, a standardized referral regime, specific training opportunities and a common documentation system. 11 individual interviews with potential recipients showed a prevailing trivialization of vertigo, dizziness and balance problems in older adults and interpretation as a physiological sign of aging. Continuous physical therapy and age-specific treatment options were desired. The expert workshop resulted in a first version of a care pathway with its intervention components and implementation strategies. In summary, a *logic model* was created that provides information on assumed causal chains.

(Objective 3) The instruments *CFIR* and *ERIC* were translated and tested in a standardized way. This process resulted in differences in the preliminary versions that could be resolved through discussion with all participants. The comprehensibility of the German translations was confirmed in 69% / 64% of the items (*CFIR* / *ERIC*), minor modifications were suggested in 28% / 36% and a complete revision in 3% / 0%. The final versions have been confirmed by everyone involved.

Conclusion:

The current quality of the evidence shows that vestibular rehabilitation can be recommended for the physical therapy treatment of older adults with vertigo, dizziness and balance disorders, regardless of its variation. Further methodologically high-quality studies with patient-relevant outcome parameters need to be carried out in order to substantiate clinical decisions. In order to integrate the perspective of the stakeholders into the development of a care pathway and its implementation strategy in addition to the quality criterion of evidence-based knowledge and to enable potential users and recipients to help shape it, the method mix of interviews and expert panels is an adequate and feasible study design. The developed care pathway is now being tested for its feasibility and acceptance and accompanied by a process evaluation in order to inform an effectiveness study. The German versions of the two frameworks for implementation *CFIR* and *ERIC* used during development are available and can now be used in German-speaking countries. This could improve the use of evidence-based implementation tools.

Einleitung

Hintergrund und Forschungsvorhaben

Schwindel und Gleichgewichtsstörungen im Alter

Mit einer Prävalenz von bis zu 50% [1 – 4] sind Schwindel und Gleichgewichtsstörungen nach Gelenkerkrankungen die häufigste Ursache für Behinderung im Alter [5]. Schwindel und Gleichgewichtsstörungen sind mit einer erhöhten Sturzrisiko [6], Mobilitätseinschränkungen im Alltag und einer verringerten sozialen Partizipation Betroffener verbunden [7, 8]. Je älter Betroffene sind, desto größer wird die subjektive Behinderung und die Minderung der gesundheitsbezogenen Lebensqualität wahrgenommen [5, 7]. Die Symptombelastung durch Schwindel und Gleichgewichtsstörungen steht linear in Beziehung zum psychischen Wohlbefinden und ist mit einer höheren Fünf-Jahres-Mortalität verbunden [9]. Besonders im Alter sind die Ursachen für Schwindel und Gleichgewichtsstörungen multifaktorieller Natur und auf degenerative Prozesse im vestibulären, visuellen und propriozeptiven System zurückzuführen [10], was versorgende Gesundheitsberufe vor Herausforderungen stellt. Hausärzt*innen fühlen sich oft nicht kompetent genug Schwindel und Gleichgewichtsstörungen zu diagnostizieren und zu behandeln [11] und tragen durch wiederholte und nicht zielführende Konsultationen, Überweisungen zu Spezialisten und dem Einsatz bildgebender Diagnostik zu steigenden Kosten für das Gesundheitssystem bei [12]. Die Wirksamkeit einer mobilitätsfördernden Physiotherapie wurde in Reviews für eine nach unten geöffnete Altersgruppe bereits bestätigt [13, 14]. Physiotherapeutische Interventionen stellen bisher allerdings keine zentrale Option im Behandlungsrepertoire für Schwindel und Gleichgewichtsstörungen im Alter von primärversorgenden Hausärzt*innen dar [15]. Somit wird ein effektiver Therapiebaustein nicht genutzt [16]. Altersgruppenunabhängig werden physiotherapeutische Schlüsselinterventionen wie Lagerungsmanöver, Gleichgewichtsübungen und edukative Komponenten für Schwindel und Gleichgewichtsstörungen empfohlen, wobei eine Physiotherapie bei multifaktoriellem Altersschwindel besonders ein individuelles und problemorientiertes Vorgehen zur Mobilitätsförderung erfordert [17 - 19].

Versorgungspfade zur Optimierung von Versorgung

Um die Primärversorgung von Schwindel und Gleichgewichtsstörungen bei älteren Menschen zu optimieren und letztendlich die Behinderung der Betroffenen zu verringern, zielt das Projekt *Mobile-PHY* darauf ab, Versorgungspfade zu entwickeln, welche auf Mobilität und soziale Teilhabe ausgerichtet sind [16]. Versorgungspfade sind multidisziplinäre Ablaufpläne, welche alle wesentlichen diagnostischen und therapeutischen Schritte in der Versorgung einer spezifischen Zielgruppe strukturiert und in chronologischer Reihenfolge beschreiben unter Orientierung an der aktuellen Evidenzlage [20]. Durch ihren Einsatz kann die Versorgung einer Zielgruppe standardisiert und optimiert werden, indem beispielsweise Behandlungsfehler vermieden werden und Ressourcen effizient eingesetzt werden [20, 21]. Die Dissertation befasst sich mit der optimalen Integration wirksamer physiotherapeutischer Interventionen in die Primärversorgung Betroffener. Dazu entwickelt und pilotiert *Mobile-PHY* einen evidenzbasierten, multidisziplinären Versorgungspfad zur Verbesserung von Mobilität und Partizipation älterer Menschen mit Schwindel und Gleichgewichtsstörungen. Ein Versorgungspfad wird dabei als komplexe Intervention im Sinne des *UK Medical Research*

Councils (MRC) verstanden. Eine Intervention gilt als komplex, wenn sie sich durch mehrere, miteinander interagierende Komponenten auszeichnet, gleichzeitig verschiedene Adressat*innen anspricht, mehrere Outcomes misst, in ihrer Anwendung eine gewissen Flexibilität erfordert oder verschiedene Verhaltensweisen bei Durchführenden oder Empfängern impliziert [22]. Dabei unterstützt der *Framework* des *MRC*, eine geeignete Forschungsmethodik anzuwenden [22]. Das vorgestellte Projekt umfasst die ersten beiden Schritte des *MRC Framework*: die Entwicklung und Pilotierung eines Versorgungspfades.

Instrumente der Implementierungsforschung

Die Identifikation potentieller Barrieren und Förderfaktoren bei einer Implementierung und die Auswahl adäquater Implementierungsstrategien gelten als entscheidend für eine erfolgreiche Implementierung [22]. Zudem ist bekannt, dass maßgeschneiderte Interventionen eher zu einer Weiterentwicklung der professionellen Praxis beitragen [23]. Um Strategien theoretisch zu untermauern und maßzuschneidern, unterstützen Rahmenkonstrukte zur Implementierung. Der *Consolidated Framework for Implementation Research (CFIR)* katalogisiert verschiedene Barrieren und Förderfaktoren auf Ebenen der Intervention selbst, der Anwender*innen, des Implementierungsprozesses sowie des inneren und äußeren Umfeldes [24]. Das Rahmenkonstrukt der *Expert Recommendations for Implementing Change (ERIC)* listet verschiedene Implementierungsstrategien auf [25] und erleichtert deren Auswahl durch ein *Matching Tool* (verfügbar unter: www.cfirguide.org). Beide Instrumente liegen im englischen Original vor, werden aber im deutschsprachigen Raum bereits verwendet [26]. Dennoch existiert keine standardisierte deutsche Version.

Gegenstand der Dissertation

Aufgrund der aufgeführten Relevanz einer wissenschaftlichen Auseinandersetzung mit der Thematik, ist das Ziel der vorliegenden Dissertation die Entwicklung eines evidenzbasierten Versorgungspfades für ältere Menschen mit Schwindel und Gleichgewichtsstörungen über 65 Jahren, um deren Primärversorgung zu optimieren und somit deren Mobilität und soziale Teilhabe zu fördern. Der Schwerpunkt der Arbeit liegt auf

1. Sichtung und systematischen Aufarbeitung der momentan besten verfügbaren Evidenz, welche physiotherapeutischen Interventionen bei älteren Menschen mit Schwindel und Gleichgewichtsstörungen effektiv sind. Die Ergebnisse daraus geben einen Überblick, welche physiotherapeutischen Behandlungsansätze aus der aktuellen wissenschaftlichen Literatur empfohlen werden können, um die darauffolgende Studienphase zu informieren (→ **Publikation I** [27]: Systematischer Review; Erstautorenschaft).
2. Analyse von Bedürfnissen der involvierten Interessensgruppen, um die Entwicklung des Versorgungspfades weiter zu informieren und diesen mit seinen Implementierungsstrategien zu entwickeln (→ **Publikation II** [28]: Mixed-Methods-Studie; Erstautorenschaft).
3. Übersetzung mit Pre-Testing der Instrumente zur Implementierung *CFIR* und *ERIC*, welche bei der Entwicklungsphase des Versorgungspfades beispielhaft in deutscher Sprache genutzt wurden, um deren Gebrauch in deutschsprachigen Ländern zu erleichtern und auszudehnen. (→ s. **Anhang: Publikation III** [29]: Kognitive Interviews; Erstautorenschaft).

Mit der Identifikation der verfügbaren Evidenz (→ **Publikation I** [27]), der Entwicklung und Modellierung des Versorgungspfades mit seinen Interventionskomponenten, Prozessen und relevanten Outcomes (→ **Publikation II** [28]) hat die Doktorandin einen wesentlichen Teil der Entwicklungsphase des Versorgungspfades (Schritt 1 des *MRC Framework*) bearbeitet und seine Testung auf Machbarkeit für die folgenden Studienphase vorbereitet. Durch die standardisierte Übersetzung mit Pre-Testing zweier Instrumente zur Implementierungsforschung konnte ein hilfreicher, konstruktiver Beitrag zur Implementierungsforschung in Deutschland gemacht werden (→ s. **Anhang: Publikation III** [29]).

Methoden

Vorbereitung der Entwicklung des Versorgungspfades

Der systematische Review (→ **Publikation I** [27]) orientierte sich am *Cochrane Handbuch für systematische Übersichtsarbeiten von Interventionen 6.0* [30]. Die Suchstrategie wurde nach dem PICOS-Schema entwickelt und eine systematische Literaturrecherche über MEDLINE via PubMed, Cochrane Library CINAHL und PEDro sowie dem freien Internet und Kongressbänden der Bárány Society durchgeführt. Inkludiert wurden englisch- und deutschsprachige Studien, die zwischen 2007 und 2019 publiziert wurden und die in der Interventions- oder Kontrollgruppe Menschen ≥ 65 Jahren mit Schwindel oder Gleichgewichtsstörungen untersuchten, physiotherapeutische oder verwandte Interventionen beschrieben und im Studiendesign eine Kontrollgruppe verwendet hatten. Identifizierte systematische Übersichtsarbeiten und Metaanalysen wurden für die zusätzliche Rückverfolgung ihrer verwendeten Primärstudien verwendet. Exkludiert wurden Studien mit gesunden Menschen, unspezifischer Altersangabe, rein operativer oder medikamentöser Therapie. Das Screening von Titeln, Abstracts und Volltexten eingeschlossener Studien wurde von zwei unabhängigen Forscher*innen durchgeführt und deren Eignung für den Review bei Bedarf im Team diskutiert. Datenextraktion und Qualitätsbewertung der Studien fanden ebenso gedoppelt statt. Aufgrund der Heterogenität der gefundenen Studien hinsichtlich ihrer Interventionen und Outcomes war keine Metaanalyse möglich und eine narrative Synthese wurde vorgenommen. Die Outcomes wurden nach den Komponenten *International Classification of Functioning, Disability and Health (ICF)* [31] gegliedert dargestellt. Zudem wurden quantitativ die Mittelwerts-Differenzen berechnet und ein Vorteil/ Gleichbleiben / Nachteil der jeweiligen Intervention zur Kontrollgruppe beschrieben und mittels Harvest Plots visualisiert.

Die Mixed-Methods-Studie (→ **Publikation II** [28]) ergänzt die Vorbereitung der Entwicklungsphase um die Perspektive der Patient*innen und Anwender*innen der Primärversorgung hinsichtlich ihrer Erfahrungen, Probleme und Bedürfnisse. Dafür wurden semi-strukturierte Einzelinterviews mit Betroffenen und in die Primärversorgung involvierten Gesundheitsfachpersonen (Hausarzt*innen, Physiotherapeut*innen und ambulanten Pflegepersonen) durchgeführt. Um Erfahrungen, Probleme und Bedürfnisse hinsichtlich der multidisziplinären Zusammenarbeit der Gesundheitsberufe zu eruieren, wurden zudem semi-strukturierte Fokusgruppeninterviews durchgeführt.

Inklusionskriterien der Gesundheitsfachpersonen waren mindestens drei Jahre Berufserfahrung im jeweiligen Beruf in der Primärversorgung, ambulant arbeitende Praxen und eine selbst

eingestufte nennenswerte Erfahrung in der Versorgung älterer Menschen mit Schwindel und Gleichgewichtsstörungen. Potentielle Teilnehmende wurden über Internetrecherche und regionale Netzwerke identifiziert, telefonisch angefragt und Interessent*innen mit weiteren Information per Email oder Fax erreicht.

Die Rekrutierung von Patient*innen erfolgte über bereits angefragte Einrichtungen des Gesundheitswesens. Inklusionskriterien waren Patient*innen, die ihre*n Hausarzt*in wegen Schwindel und Gleichgewichtsstörungen konsultierten und mindestens 65 Jahre alt waren. Zusätzlich wurden Patient*innen, deren Verwandte oder Bekannte, die sich in Behandlung in einer Physiotherapiepraxis befanden durch ein Poster auf eine mögliche Teilnahme aufmerksam gemacht und Kontaktdaten bei Interesse zur Verfügung gestellt. Exklusionskriterien waren Patient*innen jünger als 65 Jahre, ernsthafte Erkrankungen, die Indikation einer Krankenhausbehandlung und Patient*innen, die nicht an der Studie teilnehmen wollten.

Nach schriftlichem Einverständnis des Teilnehmenden wurde mit einem semi-strukturierten Interviewleitfaden das Interview per Telefon durchgeführt. Der Leitfaden wurden pro teilnehmende (Berufs-) Gruppe angewandt und sollte durch vordefinierte Hauptfragen und Fragebeispiele die Reliabilität zwischen verschiedenen Interviewführenden reduzieren. Alle Interviews wurden aufgenommen und nach Kuckartz [32] transkribiert. und die Daten mittels strukturierender qualitativer Inhaltsanalyse durch zwei unabhängige Forscher*innen ausgewertet. Während der Interviews wurden zudem Notizen angefertigt und in die Analyse integriert. Die Datenanalyse zielte darauf ab, jeweilige Themen, Barrieren und Förderfaktoren aufzudecken und Erkenntnisse hinsichtlich der multidisziplinären Kommunikation zu gewinnen. Zusätzlich zum qualitativen Ansatz quantifizierten teilnehmende Patient*innen den Einfluss ihrer Beschwerden auf ihre Alltagsmobilität und soziale Partizipation anhand der deutschen Version des *Vertigo Activities and Participation Questionnaire (VAP)* [33] und durch deskriptive Statistik analysiert wurde. Die Mixed-Methods-Studie bediente sich zudem an den Ergebnissen eines zweiten systematischen Reviews hinsichtlich bekannter Barrieren und Förderfaktoren bei der Implementierung von Versorgungspfaden in der Primärversorgung [34].

Modellierung des Versorgungspfades und der Implementierungsstrategie

Die Ergebnisse der vorbereitenden Studien mündeten in einen dreitägigen, Klausur-ähnlichen Expertenworkshop, der inhaltlich vom Forschungsteam vorbereitet wurde und von einem externen Moderator während seines Ablaufs begleitet wurde. Vorab wurde der „Weg des Patienten“ durch die Versorgung anhand des *ICF Rehab Cycle* [35] analysiert, Schlüsselrollen identifiziert und dementsprechende Expert*innen rekrutiert. Diese umfassten die bereits dargestellten direkt in die Versorgung involvierten Gesundheitsberufe (Hausärzt*innen, Physiotherapeut*innen und ambulante Pflegepersonen), weitere klinische Gesundheitsfachpersonen (Neurolog*innen, Hals-Nasen-Ohren-Ärzt*innen), sowie Vertreter*innen der Krankenkassen, Vertreter*innen der Versorgungsforschung und Patientenvertreter*innen. Für die Rekrutierung nutzten wir bestehende Kontakte und Netzwerke und kontaktierten weitere lokale Praxen/Institute. Auf dem Expertenworkshop wurde ein schrittweiser Modellierungsprozess durchgeführt, in welchem zuerst eine gemeinsame Basis hinsichtlich krankheitsspezifischen Wissens und Versorgungspfaden geschaffen wurde. Die bisherigen Forschungsergebnisse aus den Vorarbeiten wurden via

Präsentationen und Factsheets vorgestellt. Um die Experten durch den Workshop zu leiten und eine konstruktive Atmosphäre zu schaffen, wurden verschiedene Kreativtechniken im Plenum, größeren und kleineren Gruppen angewendet, um zuerst mehrere Vorschläge und dann einen finalen Versorgungspfad mit seinen Interventionskomponenten zu entwickeln. Um Barrieren und Förderfaktoren systematisch zu identifizieren und evidenzbasiert in die Modellierung der Implementierungsstrategie einzuarbeiten, wurden die beiden Rahmenempfehlungen *CFIR* [24] and *ERIC* [25] genutzt. Der Expertenworkshop schloss mit der Festlegung von Meilensteinen und einem Implementierungsplan ab. Im Nachgang an den Workshop wurden die spezifischen Interventionskomponenten des Versorgungspfades (Checkliste für Hausärzt*innen, Therapieleitfaden für Physiotherapeut*innen) sowie die jeweilig dazugehörigen Schulungen in Kleingruppen via persönlichem Kontakt, Telefon- und Emailaustausch konkretisiert. Das Interventionsdesign und die Implementierungsstrategie wurden basierend auf dem *Behaviour Change Wheel (BCW)* [36] modelliert, wobei die bereits identifizierten Barrieren und Förderfaktoren nach *CFIR* [24] sowie die dazu passenden Implementierungsstrategien nach *ERIC* [25] aus dem Expertenworkshop genutzt wurden. Schließlich, um die Beziehungen zwischen den angestrebten Ergebnissen, den Wirkmechanismus und den geplanten Arbeitspaketen systematisch darzustellen, entwickelten wir ein logisches Modell basierend auf dem *Kellogg's Logic Model Development Guide* [37], welches anhand des *Context and Implementation of Complex Interventions Framework* [38] hinsichtlich seiner Vollständigkeit evaluiert wurde (→ **Publikation II** [28]).

Deutsche Versionen der beiden Instrumente zur Implementationsforschung CFIR und ERIC

Die beiden im Modellierungsprozess verwendeten Instrumente der Implementationsforschung *CFIR* [24] und *ERIC* [25] wurden in einer eigenen, noch nicht validierten, deutschen Übersetzung genutzt. Um die Instrumente einer breiteren Anwendergruppe zugänglich zu machen, folgte ein standardisierter Übersetzungsprozess, welcher sich an den Empfehlungen der *World Health Organization (WHO)* zum Vorgehen beim Übersetzungs- und Anpassungsprozess von Instrumenten orientierte [39]: (1) Beginnend mit einer Vorwärtsübersetzung, welche (2) in einer zweisprachigen Expertengruppe diskutiert wurde, dann (3) von einer Muttersprachlerin in die Originalsprache rückübersetzt und (4) mit einem Pre-Testing an potentiellen Anwendern schloss (→ s. **Anhang: Publikation III** [29]). Das Pre-Testing wurde mit deutschen Versorgungsforscher*innen geplant, welche die Übersetzung von jeweils 10 von insgesamt 112 Items in einem 20 minütigem semistrukturiertem Einzelinterview behandeln sollten und deren Kernaussage beurteilen sollten. Dadurch dass keine Pre-Testing-Strategie für ein solches Instrument vorliegt, entwickelten wir eine eigene Strategie, die einem Prozess des „Laut-Denkens“ ähnelte, in welchem die Teilnehmer*innen dazu angehalten wurden, ihre Gedanken zu verbalisieren während sie auf die Frage antworteten und ein Ampelsystem zu nutzen. Die Interviews wurden telefonisch durchgeführt, Audioaufnahmen und Notizen angefertigt. Zuletzt setzten wir die finalen Versionen in das *CFIR-ERIC-Matching Tool* ein.

Ergebnisse

Vorbereitung der Entwicklung des Versorgungspfades

Für die systematische Übersichtsarbeit (→ **Publikation I** [27]) konnten 3.299 Studien identifiziert werden, wovon 22 Studien (20 randomisiert kontrollierte Studien und 2 nicht-

randomisierte kontrollierte Studien) mit insgesamt 1.876 Patient*innen eingeschlossen wurden [39 -61]. Das Durchschnittsalter der Patient*innen lag bei 60,0 bis 85,5 Jahren. Untersucht wurden sowohl Betroffene der Leitsymptome Schwindel, Gleichgewichtsstörungen oder genereller vestibulärer Dysfunktion, aber auch Patient*innen mit spezifischen Erkrankungen wie Morbus Parkinson, benignem paroxysmalen Lagerungsschwindel, Schlaganfall, sturzbedingten Beschwerden, visuellen Einschränkungen oder zervikogenem Schwindel. Die Studien fanden in 14 Ländern zwischen 2008 und 2018 statt und wurden in Krankenhäusern, ambulanten Kliniken, ambulanten Praxen, Altenheimen oder in der Häuslichkeit der Teilnehmenden durchgeführt. Als Interventionen wurden vestibuläre Rehabilitation (VR) in ihrer klassischen Form (8 von insgesamt 22 Studien), spezielle Programme wie das *Cawthorne-Cooksey*- oder *Otago-Programm* (4 Studien), Computer-unterstützte VR (5 Studien), Tai Chi (3 Studien) und jeweils 1 Studie zu Epley-Lagerungsmanöver und manueller Therapie beschrieben. Die Studien untersuchten überwiegend Ergebnisparameter der *ICF*-Domäne der Körperfunktionen und der *ICF*-Domäne der Aktivität und Partizipation. Auffallend war dabei eine hohe Anzahl und Variabilität der gemessenen Outcomes zwischen den Studien. Es wurden Aspekte des Sturzrisikos, Lebensqualität oder verschiedene selbst berichtete Outcomes beobachtet. Primäre Outcomes wurden nur in einem Drittel aller inkludierten Studien benannt. Die methodische Qualität im Sinne der internen Validität der Studien variierte. Auffallend war insbesondere die fehlende Berichterstattung ganzer Kriterien.

Die systematische Übersichtsarbeit ergab, dass zur Förderung von Aktivität und Partizipation das Epley-Lagerungsmanöver effektiv ist und Variationen, wie das zusätzliche Tragen einer Halskrause oder eines Vibrators am Mastoid keinen zusätzlichen Nutzen für ältere Patient*innen mit Lagerungsschwindel haben ($n = 53$) [40]. Die im Review am häufigsten untersuchte Intervention VR (12 Studien; 55%; 1.284 Studienteilnehmer*innen) verzeichnete überwiegend positive Effekte zur Förderung von Aktivität und Partizipation älterer Betroffener. VR zeigte einen statistisch signifikanten Nutzen, wenn sie zusätzlich zu einem Lagerungsmanöver ($p = .05$; $n = 30$) [41] oder statt gewöhnlicher Versorgung ($p = .01$; $n = 526$) [42] angewendet wird. Einige Studien beobachteten viele Ergebnisparameter parallel und benannten kein primäres Outcome, was die Interpretation erschwerte. In diesen Studien war unklar, welche Wirktendenz VR verglichen zu gewöhnlicher [43 - 46] oder keiner Behandlung [47] hat. Weitere Studien berichteten, dass VR weder gewöhnlicher [48] noch keiner Behandlung [49] überlegen war. VR-Programme wie das *Cawthorne-Cooksey*- oder *Otago-Programm* hatten einen nachweislichen Benefit für die Aktivität und Partizipation, jedoch keinen zusätzlichen Vorteil in einer neuen Variation des bestehenden Programmes [50 - 52]. Eine computergestützte VR mit der *Wii Fit* konnte die Aktivität älterer Patient*innen fördern und war gewöhnlicher Behandlung und edukativer Sturzprävention überlegen ($p < .05$; $n = 71$) [53]. Keinen zusätzlichen Nutzen brachten virtuelle Trainingsbedingungen, wenn sie zusätzlich zu Gleichgewichtstraining durchgeführt wurden [54, 55], statt in direktem Kontakt unter Supervision zu Hause durchgeführt wurden [56] oder in einer gedruckten Version verwendet wurden [57]. Der Einsatz von Tai Chi als Form der VR verbesserte Aktivität und Partizipation im Vergleich zu keiner Intervention ($n = 40$; $p = .003$) [58]. Einfachen Atem- und Dehnungsübungen war Tai Chi aber nicht überlegen [59]. Manuelle Therapie der Halswirbelsäule konnte die Aktivität und Partizipation von älteren Patient*innen zwar fördern, jedoch nicht statistisch signifikant mehr als eine Scheinbehandlung des Nackens mittels eines

Lasers. Manuelle Therapie verursachte Nebenwirkungen, welche als leichte und vorübergehende Schmerzen der Halswirbelsäule am Tag nach der manuellen Therapie beschrieben wurden [60].

Um die Perspektive der Anwender*innen und Empfänger*innen in die Entwicklung des Versorgungspfades miteinfließen zu lassen, wurden Einzel- und Gruppeninterviews durchgeführt (→ **Publikation II** [28]).

Von 35 angefragten Hausarzt*innen konnten 9 (Antwortrate: 26%), von 14 angefragten Physiotherapeut*innen 8 (Antwortrate: 57%) und von 9 angefragten ambulanten Pflegepersonen 7 Interviewteilnehmer*innen (Antwortrate: 77%) rekrutiert werden. Jeweils 2 Vertreter*innen jeder Berufsgruppe nahmen an einer Fokusgruppe teil. Gründe für Absagen waren Urlaub, Zeit- oder Personalmangel. Nach 17 Einzelinterviews und den beiden Fokusgruppeninterviews war die Datensättigung erreicht. Die Einzelinterviews dauerten 11 bis 29 Minuten telefonisch, die Fokusgruppen je 53 Minuten. Die Interviews mit den Hausarzt*innen ergaben, dass eine Hausarzt*innen-zentrierte Versorgung als sinnvoll erachtet wird und gefördert werden soll, da viele Schwierigkeiten wie Informationsverlust an der Schnittstelle von Primär- zu Sekundärversorgung entstehen. Die Möglichkeit einer zeitnahen Diagnostik in Spezialzentrum und einem breiteren Behandlungsrepertoire mit psychosozialen Ansätzen wurde verlangt. Die Physiotherapeut*innen bemängelten eine unzureichende Therapieanweisung auf verordneten Rezepten für Patient*innen mit Schwindel und Gleichgewichtsstörungen und schlugen die forcierte Nutzung des bereits existierenden Indikationsschlüssel SO3 vor. Mangelnde Ausbildungsinhalte zur Behandlung dieser Zielgruppe erfordern spezifische Fortbildungsmöglichkeiten und das Bereitstellen von Material zur Patientenedukation. Ein Mangel an Physiotherapeut*innen, die Hausbesuche machen, beklagten die ambulanten Pflegepersonen. Die Fokusgruppeninterviews ergaben die Forderung nach einem multidisziplinären Dokumentationssystem und die Möglichkeit von Videokonferenzen zu Fallgesprächen. Eine finanzielle Honorierung der Krankenkassen von interdisziplinären Absprachen wurde gewünscht.

Für die Interviews mit Betroffenen konnten von 14 angefragten Patient*innen 11 Teilnehmer*innen rekrutiert werden (Antwortrate: 79%). Gründe für Absagen waren Zeitmangel oder kein Interesse. Nach 11 Interviews war die Datensättigung erreicht. Die Einzelinterviews dauerten 13 bis 33 Minuten und fanden alle, bis auf eines im direkten Kontakt, telefonisch statt. Die Interviews mit den Patient*innen ergaben, eine Bagatellisierung von Schwindel- und Gleichgewichtsproblemen im Alter seitens der Patient*innen selbst, der Gesellschaft oder ihrer Hausarzt*innen und Interpretation als physiologische Alterungserscheinung. Wer sich bereits in physiotherapeutischer Behandlung befand kritisierte die mangelnde Kontinuität aufgrund knapper Therapieverordnungen. Gewünscht wurden mehr altersspezifische Behandlungsangebote, ein breites Spektrum von konventionell bis alternativ sowie Möglichkeiten eines Heimtrainings oder Gruppentraining.

Modellierung des Versorgungspfades mit Implementierungsstrategie

Mit den Ergebnissen aus dem systematischen Review und den Interviews wurde auf dem darauffolgenden Expertenworkshop ein Versorgungspfad mit Implementierungsstrategien modelliert (→ **Publikation II** [28]; siehe **Abbildung 1**). Am Expertenworkshop nahmen 9

klinische Expert*innen (2 Neurologen, 1 Hals-Nasen-Ohren-Arzt, 1 Hausarzt, 3 Physiotherapeut*innen, 1 Altenpflegerin, 1 Arzthelferin), 2 Vertreter*innen der Krankenkassen, 2 Vertreter*innen der Versorgungsforschung und 2 Patientenvertreter*innen teil. Besondere Probleme ergaben sich bei der Rekrutierung der Hausärzt*innen (Antwortrate: 0.1%). Eine erste Version des Versorgungspfades beinhaltete Empfehlungen der Expert*innen wie eine Info-Hotline für Betroffene, Aufklärung der Bevölkerung mit Informationen, Werkzeuge für die Gesundheitsberufe für Screening, Zuweisung, Behandlung und Evaluation von Patient*innen. Als potentielle Barrieren und Förderfaktoren, gegliedert nach dem *CFIR* [24] wurden das innere Setting (44 Punkte; 39%), Charakteristika einer Intervention (26 Punkte; 23%), Prozesse (18 Punkte; 16%), Charakteristika der Individuen (17 Punkte; 15%) und das äußere Setting (7 Punkte; 6%) priorisiert. Die identifizierten Barrieren und Förderfaktoren wurden in das *Matching Tool* eingesetzt und ergaben die passende Implementierungsstrategien nach *ERIC*, mit denen die Experten weiterhin Meilensteine und einen Implementierungsplan festlegten. Hinsichtlich der Rekrutierung potentieller Studienteilnehmer sollten die Hausärzte klare Inklusionskriterien für ihren Patientenstamm an die Hand bekommen. Für die Diagnostik in der Hausarztpraxis und Zuweisungen an andere Disziplinen sollten die Hausärzte eine Checkliste verwenden, zu welcher sie davor eine Schulung erhalten. Um die Wirksamkeit der Intervention zu evaluieren wurden keine Empfehlungen abgegeben, jedoch spezifische Follow-up Zeitpunkte definiert. Im Nachgang entwickelten wir ein logisches Modell (siehe **Abbildung 2**) und skizzierten darin die angestrebten Ziele, Wirkmechanismen und Arbeitspakete folgendermaßen: Zur Verbesserung der Mobilität und Partizipation von Schwindel und Gleichgewichtsstörungen betroffener älterer Menschen soll die Selbstwirksamkeit der involvierten Gesundheitsberufe gestärkt werden, indem sie ihr Verhalten ändern und den Versorgungspfad anwenden. Dazu gaben wir ihnen mehr Wissen an die Hand, indem wir sie schulten, wie sie Betroffene effizient diagnostizieren und behandeln können und dabei die jeweiligen Interventionskomponenten (Checkliste für Hausärzt*innen, Therapieleitfaden für Physiotherapeut*innen) nutzten. Die Checkliste für die Hausärzt*innen hat zum Ziel, lebensbedrohliche Erkrankungen auszuschließen, eine zuverlässige Diagnose und evidenzbasierte Behandlung in der Hausarztpraxis durchzuführen und zuletzt ein rationales Überweisungsregime zu Fachärzt*innen bereitzustellen. Zudem gibt sie konkrete Follow-up Zeitpunkte und Indikationsschlüssel an. Der Therapieleitfaden legt den Schwerpunkt auf Leitsymptome und gibt spezifische Assessment- und Behandlungsempfehlungen für die Physiotherapeut*innen. Beide Listen stellen einen papierbasierten Algorithmus dar. Zusammenfassend ist die Implementierungsstrategie eine Verhaltensänderung der Gesundheitsberufe, indem sie die Checkliste oder den Therapieleitfaden anwenden, wozu sie eine spezifische Schulung, Schulungsunterlagen und ein Mentoring sowie Fortbildungspunkte bekommen.

Deutsche Versionen der beiden Instrumente zur Implementierungsforschung CFIR und ERIC

Die beiden im Modellierungsprozess verwendeten Instrumente der Implementierungsforschung *CFIR* [25] und *ERIC* [26] durchliefen einen standardisierten Übersetzungs- und Validierungsprozess (→ s. **Anhang: Publikation III** [29]). Die Korrekturen der ersten Vorwärtsübersetzung durch das bilinguale Expertengremium bezogen sich überwiegend auf die Glättung des Sprachstils der Übersetzung, die Grammatik und Satzzeichen. Die Rückübersetzung resultierte teilweise in Synonymen. An den kognitiven Interviews nahmen

alle 12 angefragten Personen teil. Die Interviews dauerten zwischen 9 und 36 Minuten. In den meisten Items wurde der zentrale Fokus der Übersetzung bestätigt. Bei den *CFIR*-Items wurden insgesamt 27 Items (69 %) sofort bestätigt, Modifikationen wurden für 11 (28 %) Items vorgeschlagen und 1 Item (3%) musste überarbeitet werden (siehe **Tabelle 1**). Bei den *ERIC*-Items wurden insgesamt 2 Items in der ersten Runde abgelehnt und in der zweiten akzeptiert. Insgesamt wurden 47 Items (64 %) bestätigt, Modifikationen wurden für 26 (36%) Items vorgeschlagen und kein Item musste überarbeitet werden (siehe **Tabelle 2**). Die finalen Versionen beinhalten die neuen Überarbeitungen, zeigen aber die getestete Übersetzung in Klammern.

Diskussion

Hauptergebnisse

Die systematische Übersichtsarbeit (→ **Publikation I** [27]) zeigte die Qualität der Evidenz von Studien auf, welche physiotherapeutische Behandlungsmöglichkeiten für ältere Menschen mit Schwindel und Gleichgewichtsstörungen untersuchen. Die verwendeten Studien waren hinsichtlich ihrer internen Validität und verwendeten Messparameter heterogen. VR selbst und VR zusätzlich zu Lagerungsmanövern zeigten positive Wirkungen auf die Mobilität und Partizipation älterer Patient*innen bei moderater Qualität der Evidenz und können für die Praxis empfohlen werden.

Diese Ergebnisse konnten in der folgenden Studienphase weiter genutzt werden, in der ein Versorgungspfad im Sinne einer komplexen Intervention entwickelt wurde, mit dem Ziel, die Mobilität und Partizipation älterer Menschen mit Schwindel und Gleichgewichtsstörungen zu verbessern (→ **Publikation II** [28]). Dieser Versorgungspfad ist nun dazu bereit, auf seine Machbarkeit untersucht zu werden. Der Versorgungspfad mit seinen Implementierungsstrategien basiert auf Forschungsergebnissen von systematischen Literaturrecherchen, Einzel- und Fokusgruppeninterviews, einem Expertenworkshop und darauffolgenden spezifischen Expertenrunden. Konkrete Interventionskomponenten sind eine Checkliste für Hausärzte und ein Therapieleitfaden für Physiotherapeuten.

Bei der Entwicklung wurden die beiden Rahmenkonstrukte zur Implementierungsforschung *CFIR* und *ERIC* genutzt und dazu in deutsche Sprache übersetzt. Die deutschen Versionen von *CFIR* und *ERIC* sowie ein dazu passendes *Matchingtool* liegen vor und ein machbarer Übersetzungs- und Pre-Testing-Prozess wurden in Anlehnung an die Empfehlung der *WHO* durchgeführt (→ s. **Anhang: Publikation III** [29]).

Stärken und Schwächen

In der systematischen Übersichtsarbeit (→ **Publikation I** [27]) war die Berichterstattung durch die heterogenen Interventionen, Outcomes, Studienpopulationen und Vergleichsgruppen erschwert. Eine wünschenswerte weitere Auswertung im Sinne einer Metaanalyse war deshalb nicht möglich. Auffallend war, dass ähnliche Studien hinsichtlich dieser Parameter zwar existieren, allerdings nur für eine jüngere Studienpopulation. Mögliche Verzerrungen wurden oft nicht ausreichend in den verwendeten Studien dargestellt. Beispielsweise wurde oft die Verblindung der datenerhebenden Personen nicht beschrieben oder Drop-out Raten zwischen den Interventionsgruppen waren nicht ausgeglichen. Interventionen wurden auch kaum

detailliert als komplexe Intervention beschrieben, was einen Transfer in alltägliche physiotherapeutische Behandlungen erschwert.

Die Entwicklung (→ **Publikation II** [28]) stützte sich auf Literaturrecherche, Interviewdaten der Stakeholderperspektive, die Involvierung der Stakeholder*innen in den Modellierungsprozess und einem schließenden logischem Modell, was mit aktuellen Empfehlungen [62] einhergeht und eine klare Stärke des Entwicklungsprozesses darstellt. Die Perspektive der Hausarzt*innen mag unterrepräsentiert sein, was eine potentielle Schwäche des Versorgungspfades darstellt, da es schwierig und zeitintensiv war, Hausarzt*innen zur Teilnahme zu gewinnen.

In der ursprünglichen Vorwärtsübersetzung versuchten wir die sprachliche Struktur des englischen Original möglichst beizubehalten, was in eine deutsche Variante mit teilweise englischem Vokabular resultierte. Es konnte keine etablierte Pre-Testing Strategie genutzt werden, deshalb wurde ein eigenes Vorgehen entwickelt. Im Pre-Testing war auffallend, dass sehr wenige Items (4 von 112 Items; < 0,1%) in einem zweiten Interview überarbeitet werden mussten, was auf einen Selektionsbias bei der Auswahl der Stichprobe hindeuten könnte, welche Akademiker*innen mit Erfahrung in der Implementierungsforschung beinhaltete. Zudem war die Stichprobengröße klein gewählt und die Teststrategie so ausgelegt, dass pro Interviewteilnehmer*in bis zu 10 Items getestet wurden, sodass die Variabilität der Ergebnisse zu einer anderen Stichprobe, insbesondere Nicht-Akademiker*innen hoch sein könnte (→ s. **Anhang: Publikation III** [29]).

Schlussfolgerungen

Vestibuläre Rehabilitation in jeder Variation wird als effektivste Maßnahme empfohlen, um ältere Menschen mit Schwindel und Gleichgewichtsstörungen zu behandeln. Viele physiotherapeutische Primärstudien zielten in dieser Literaturübersicht (→ **Publikation I** [27]) mehr auf strukturelle Ergebnisparameter wie Muskelfunktion ab als auf patientenrelevante Outcomes, die Mobilität und Partizipation widerspiegeln. Um eine Variabilität an verwendeten Ergebnisparametern zu reduzieren und damit eine konkrete Datensynthese in Reviews oder Metaanalysen zu ermöglichen, sollten sich Wissenschaftler*innen bei der Studienkonzeption mehr an verfügbaren *Core Outcome Sets* orientieren [63]. Qualitativ hochwertige randomisierte Studien sollten weiter durchgeführt werden, um klinische Entscheidungen der älteren Zielgruppe fundiert treffen zu können.

Der entwickelte Versorgungspfad als komplexe Intervention, welche die Mobilität und Partizipation älterer Menschen mit Schwindel und Gleichgewichtsstörungen verbessern soll (→ **Publikation II** [28]) ist nun bereit, weiter auf seine Machbarkeit getestet zu werden. Vor seiner letztendlichen Testung auf Wirksamkeit ist dies ein wichtiger Schritt, der durch eine Prozessevaluation begleitet werden soll, um Erfahrungen, Einflussfaktoren, Barrieren und Förderfaktoren einer erfolgreichen Implementierung zu sammeln.

Die beiden übersetzten Rahmenkonstrukte *CFIR* und *ERIC* können in deutschsprachigen Ländern zur Implementierungsforschung genutzt werden (→ s. **Anhang: Publikation III** [29]). Wir würden eine leicht verständliche Patientenversion empfehlen, um Bedürfnisse Betroffener leichter in die Entwicklung komplexer Interventionen einfließen zu lassen.

Publikation I

Physical therapy interventions for older people with vertigo, dizziness and balance disorders addressing mobility and participation: a systematic review

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Eigenanteil: Nach der Antragsstellung durch den Projektleiter war die Doktorandin als Erstautorin der Publikation I hauptverantwortlich für alle wesentlichen Schritte. Diese umfassten die Konzeption und das Design des Reviews, die Registrierung beim *International Prospective Register of Systematic Reviews (PROSPERO)*, die Entwicklung, Anwendung und Anpassung der Suchstrategie, der Sichtung und Beschaffung identifizierter Literatur sowie die Extraktion, Qualitätsbewertung und Dateninterpretation der eingeschlossenen Studien. Über alle Schritte informierte die Doktorandin das Projektteam und stimmte diese bei Bedarf mit ihnen ab. Die Doktorandin verfasste das Manuskript, koordinierte das Feedback aller Autoren, Language Editors und Reviewern des Journals und erledigte alle Schritte bis zur Publikation.

RESEARCH ARTICLE

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Physical therapy interventions for older people with vertigo, dizziness and balance disorders addressing mobility and participation: a systematic review



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Abstract

Background: Vertigo, dizziness and balance disorders (VDB) are among the most relevant contributors to the burden of disability among older adults living in the community and associated with immobility, limitations of activities of daily living and decreased participation. The aim of this study was to identify the quality of evidence of physical therapy interventions that address mobility and participation in older patients with VDB and to characterize the used primary and secondary outcomes.

Methods: A systematic search via MEDLINE (PubMed), Cochrane Library, CINAHL, PEDro, forward citation tracing and hand search was conducted initially in 11/2017 and updated in 7/2019. We included individual and cluster-randomized controlled trials and trials with quasi-experimental design, published between 2007 and 2017/2019 and including individuals ≥ 65 years with VDB. Physical therapy and related interventions were reviewed with no restrictions to outcome measurement. Screening of titles, abstracts and full texts, data extraction and critical appraisal was conducted by two independent researchers. The included studies were heterogeneous in terms of interventions and outcome measures. Therefore, a narrative synthesis was conducted.

Results: A total of 20 randomized and 2 non-randomized controlled trials with 1876 patients met the inclusion criteria. The included studies were heterogeneous in terms of complexity of interventions, outcome measures and methodological quality. Vestibular rehabilitation (VR) was examined in twelve studies, computer-assisted VR (CAVR) in five, Tai Chi as VR (TCVR) in three, canal repositioning manoeuvres (CRM) in one and manual therapy (MT) in one study. Mixed effects were found regarding body structure/function and activities/participation. Quality of life and/or falls were assessed, with no differences between groups. VR is with moderate quality of evidence superior to usual care to improve balance, mobility and symptoms.

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Conclusion: To treat older individuals with VDB, VR in any variation and in addition to CRMs seems to be effective. High-quality randomized trials need to be conducted to inform clinical decision making.

Trial registration: PROSPERO 2017 CRD42017080291.

Keywords: Aged, Aged, 80 and over, Dizziness, Mobility limitation, Nervous system diseases, Physical therapy modalities, Postural balance, Social participation, Treatment outcome, Vertigo

Background

Vertigo, dizziness and balance disorders (VDB) are the most relevant factors influencing the burden of disability among older adults [1] and are associated with immobility, limitations in activities of daily living (ADL) and decreased participation [2, 3]. VDB are frequent complaints of older people [4–7] with a reported prevalence up to 50% [8, 9], and the prevalence tends to increase with age [10]. Complaints of VDB are distinct risk factors for falls [11], and even the fear of falling may lead to activity restriction and disability [12]. Especially in older individuals, a unique underlying cause of VDB is difficult to determine because of multifactorial potential underlying pathomechanisms in the vestibular, visual and proprioceptive systems [13]. With the impairment of one system, the other two have to compensate more to sustain postural control [14]. Degeneration and consecutive morphological changes in otolith organs and the vestibular epithelium can be responsible for the increasing number of older individuals suffering peripheral vestibular disorders, e.g., benign paroxysmal positional vertigo (BPPV) [15]. Postural stability is known to be decreased with visual impairment due to age-related macular degeneration [16]. Furthermore, sensorimotor deficits due to aging and a significantly increasing incidence of neurodegenerative conditions such Parkinson's disease starting at the age of >60 years lead to less proprioceptive input and neuromuscular control and therefore promote imbalance [17, 18]. The Bárány Society considered it necessary to attend to the phenomena of presbyvestibulopathy and developed diagnostic criteria for the manifestation of unsteadiness, gait disturbance, and falls [5].

Despite diagnostic advances, many cases of VDB do not benefit from a single medical or surgical therapy [19]. This might be especially true for older patients due to the multifactorial aetiology and the lack of obvious cause-specific pathology. So-called syndromes such as presbyvestibulopathy or presbystatis might pose the challenge of performing a multi-systemic efficient examination and are recommended to be treated symptomatically to achieve the fastest and most efficient therapy possible [20]. It is well established that older patients with VDB benefit from physical therapy that addresses consequences such as imbalance and falls and is

unspecific in regard to and independent of the underlying pathology [21].

Whitney et al. [22] describe key interventions of physical therapy for patients experiencing VDB. Vertigo occurring at change of position, similarly to BPPV, can be treated by canal repositioning manoeuvres (CRMs). Dizziness with head movements caused by visual blurring requires exercises for adaption of the vestibulo-ocular reflex with complex backgrounds. Despite the aetiology and especially when patients have problems with balance during standing or walking, experts recommend additional balance exercises. Patient education can be useful for phobic components of dizziness or fear of falling [22]. Especially for multifactorial VDB in older individuals, a customized and problem-oriented approach is recommended to identify key symptoms and priorities of individualized rehabilitation to promote general mobility and participation [23, 24]. Evidence-based physical therapy options have increased in recent years, whereas new interventions, e.g., virtual reality, have broadened the perspectives of physical therapists [22]. In older patients >65 years with VDB, this systematic review aims to provide an overview of the effects of physical therapy interventions, including adverse effects, that address mobility and participation in and additionally, to characterize the used primary and secondary outcomes according the International Classification of Functioning, Disability and Health (ICF).

Methods

Reporting of this review was guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist [25] and the reporting guideline Synthesis Without Meta-analysis (SWiM) in systematic reviews [26]. The study protocol was registered at PROSPERO (18th of December 2017) and can be accessed at (http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017080291) with registration number PROSPERO 2017 CRD42017080291.

Identification of studies

The development of the search strategy followed the PICOS scheme and the Cochrane Handbook for Systematic Reviews of Interventions 6.0 [27]. In brief, we combined the characteristics of the target population and

variations in the spelling of “physical therapy”. For details, see Table 1. As described, literature strongly recommends to consider and treat VDB in older adults as multifactorial. Therefore, we decided to include a wide range of aetiologies and physical therapy interventions of papers into our review. We applied the following inclusion criteria:

- (1) The population: of the included studies had a mean age of ≥ 65 years in the intervention or control group or were described as a subgroup that experienced vertigo, dizziness or balance disorders.
- (2) Intervention was defined as all kinds of physical therapy and related intervention components also included as a subgroup.
- (3) All study designs with control group designs, such as individually randomized, cluster-randomized and non-randomized controlled trials were included. Systematic reviews and meta-analyses were included to be used as source for backward citation tracing.
- (4) The studies were carried out between 2007 and 2019.
- (5) Language was German or English.

We excluded studies with healthy adults, as well as with persons with no or insufficient description of age. We also excluded surgical or pharmacological interventions.

An initial systematic search of the literature was conducted in MEDLINE (via PubMed), Cochrane Library,

CINAHL and PEDro and took place on the 27th of November 2017. A search update followed on the 16th of July 2019. Additional sources were identified between November 2017 and April 2018 and between July and August 2019 by searching the World Wide Web, reference lists of included studies and the Bárány Society congress papers of 2010, 2014, 2016 and 2018. Search strategies for PubMed are shown in Table 1, strategies for all other databases are shown in Additional file 1.

Study selection

We managed records identified from database searching by Covidence software (<https://www.covidence.org/>). Additional citations from other sources were handled manually. Deduplication of database records was done with Covidence. Based on the predefined inclusion criteria, two independent authors (VR and ES) screened titles and abstracts and removed irrelevant studies. Detailed reasons for exclusion were documented.

Data extraction and critical appraisal

Two independent reviewers (VR and PB) extracted data using a template for the intervention description and assessed the methodological quality of eight (38%) studies in duplicate and 13 (62%) studies for feasibility reasons by VR following the risk-of-bias assessment of Cochrane handbook 5.1.0 [27] and using RevMan 5.3 software [28] to generate graphs. Disagreement was resolved by discussion and consensus or by consulting a third reviewer (MM), if required. The data extraction sheet is available from the authors on request.

Data synthesis

The included studies were mostly heterogeneous in terms of interventions and outcome measures. Therefore, we used inductive categories for grouping by interventions, comparisons and by outcomes. As expected, a narrative synthesis across all types of interventions was conducted respecting all outcome measures covering aspects of World Health Organization's (WHO) model of the International Classification of Functioning, Disability and Health (ICF), quality of life and general health. Mean or median differences (MD) between groups at last follow-up were used or calculated to define the change direction (advantage, no difference or unclear). A meta-analysis was not possible due to insufficiently or heterogeneous reported data [29]. Harvest plots were used for summarizing data and visualization of distinct interventions compared to no/sham intervention or to usual care. The guidelines for Grading of Recommendations Assessment, Development and Evaluation (GRADE) were used to rate certainty of findings for each outcome and were carried out in duplicate (VR and ES). We report the effects of the interventions on the

Table 1 Search strategy for MEDLINE via PubMed

No.	Search terms
1	*Labyrinth Diseases*[MeSH]
2	*Dizziness*[MeSH]
3	*Vestibule, Labyrinth*[MeSH]
4	*Vestibulocochlear Nerve Diseases*[MeSH]
5	vertig*[Title/Abstract]
6	dizz*[Title/Abstract]
7	1 OR 2 OR 3 OR 4 OR 5 OR 6
8	*Physical Therapy Modalities*[MeSH]
9	*Physical Therapists*[MeSH]
10	*Physical Therapy Specialty*[MeSH]
11	*Exercise*[MeSH]
12	physiotherap*[Title/Abstract]
13	physical therap*[Title/Abstract]
14	balanc* train*[Title/Abstract]
15	vestibul* rehabilitat*[Title/Abstract]
16	8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15
17	7 AND 16
	Publication date 2007–2017

primary outcome (if specified) and summarize the direction of the effects on secondary outcomes.

Results

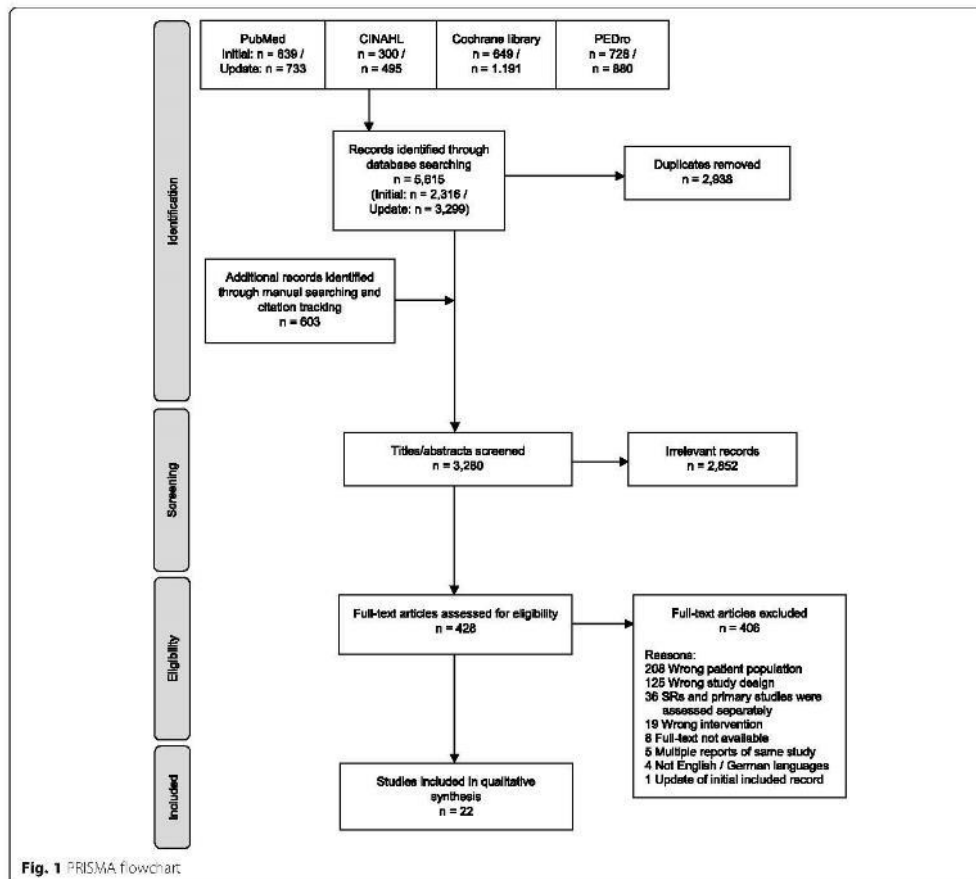
In the initial search, we identified 2316 records, and the search update revealed 3299 records through database searching. Additional 603 papers were identified through manual searching and from backwards citation tracing from identified systematic reviews. After deduplication, 3280 titles and abstracts were screened. Full texts of 428 studies were screened. The screening process is shown in Fig. 1.

The sample of the initial literature search comprised 16 studies [30–45], the search update revealed 5 additional studies [46–50], and one study that was updated due to a new follow-up publication [51]. Thus, the final

sample comprised 22 studies with 1876 participants. All studies but two were randomized controlled trials. The latter were non-randomized controlled trials [36, 50].

Setting and participant characteristics

The studies were conducted in 14 countries between 2008 and 2018 and took place in hospitals (7 studies), primary care (medical or physical therapy) practices (3 studies) or outpatient clinics (of a university) (6 studies) residential homes (1 study), at home (2 studies). The setting of three studies was not described. The mean age of the participants in the total population ranged from 60.0 to 85.5 years, since we also included studies in which either the intervention or control had a mean age of ≥ 65 years of age, and symptoms of VDB varied from cardinal symptoms of dizziness (4 studies), balance disorder (3



studies) and general vestibular dysfunction (1 study) to a specific underlying pathology such as Parkinson's disease (4 studies), benign paroxysmal positional vertigo (BPPV) (2 studies), stroke (2 studies), fall-related conditions (2 studies), visual impairment (1 study) or cervicogenic dizziness (1 study). A table listing the characteristics of subjects is shown in Additional file 2.

Interventions and comparisons

Interventions included unspecified vestibular rehabilitation (VR) (8 studies), specific programmes (e.g., Cawthorne-Cooksey or Otago) (4 studies) and other special forms of (vestibular) exercise therapy such as computer-assisted training (CAVR) (5 studies), Tai Chi (TCVR) (3 studies), canal repositioning manoeuvres (CRMs) (1 study) and manual therapy (1 study). Interventions were compared to usual care, no/sham interventions or to other interventions (e.g. variations of an established programme). A table listing the intervention and control interventions is shown in Additional file 2.

Risk of bias of included studies

The risk-of-bias assessment revealed varying methodological quality/ internal validity. Details are shown in Fig. 2. Detailed descriptions of assessment are given in supplementary data (s. Additional file 3). The risk of bias across studies is shown in Fig. 3.

Outcome measures

Reported outcome measures among the 22 included studies, varied largely. Sixteen studies investigated static or dynamic balance or postural control. Aspects of mobility, e.g., walking ability, functional mobility or activity level, were assessed in 9 studies. Dizziness symptoms, such as frequency, intensity or its impact, were addressed in 8 studies. Six studies carried out an assessment of (risk of) falls, and 5 studies addressed quality of life. Four studies reported lower extremity muscle strength, 2 analysed proprioception, and some single studies evaluated various self-perceived outcomes. Primary outcome(s) were stated in the half of all included studies (11 studies). When attributed to ICF components, 4 studies assessed body functions and structures, 5 activities and participation and 2 both components. Primary and secondary outcomes measures are shown in Additional file 4.

Effects of interventions

Summary of study results are given in Additional file 5. Additional file 6 includes harvest plots summarizing the effects of included studies. The quality of evidence and summary of findings for each outcome is shown in a detailed table in Additional file 7.

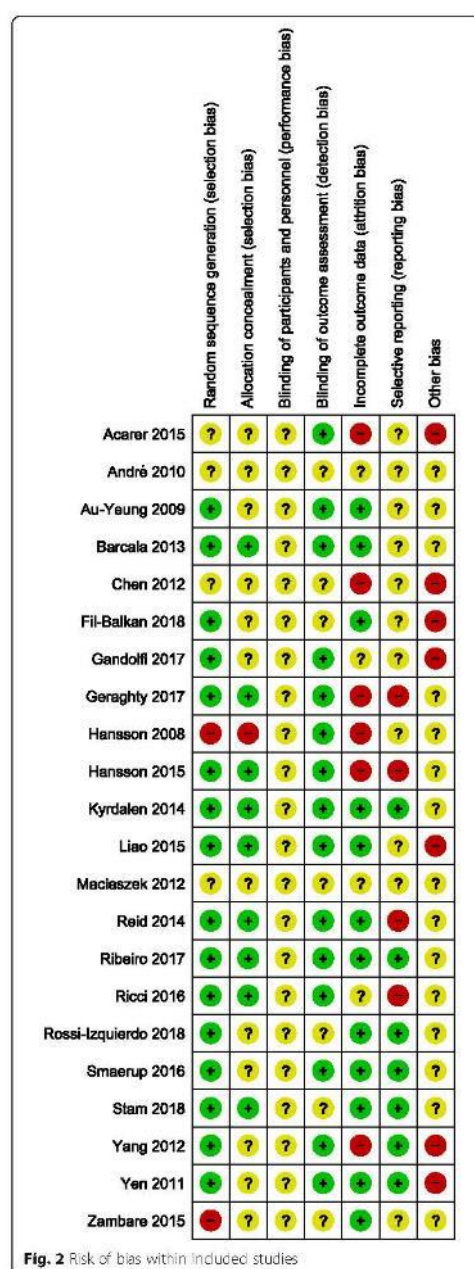


Fig. 2 Risk of bias within included studies

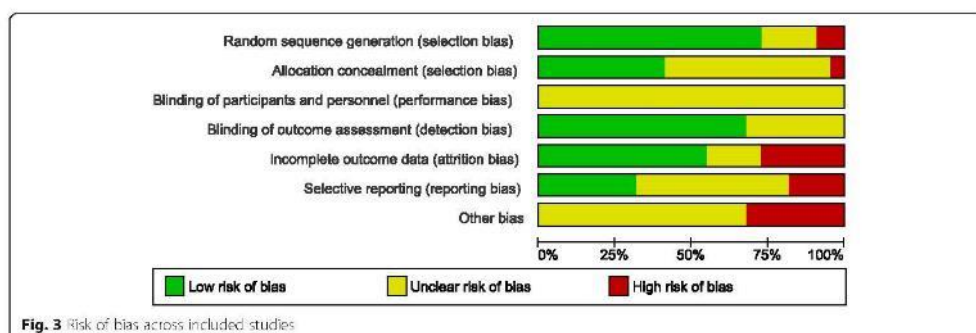


Fig. 3 Risk of bias across included studies

Canal repositioning manoeuvres

CRM versus CRM variations

Comparing CRM (Epley manoeuvre) with CRM and distinct additional instructions like wearing a neck collar for 48 h after manoeuvre or using a mini-vibrator placed on the mastoid of affected side during manoeuvre revealed no advantage for posterior canal BPPV caused by canalolithiasis as measured by the Dizziness Handicap Inventory (DHI) (no primary outcome stated, $n = 53$ participants) [31].

Vestibular rehabilitation A total of 12 studies (55%) with 1284 participants investigated vestibular rehabilitation (VR) [30, 35–37, 41, 42, 44, 47–51] which was therefore the most investigated intervention.

VR compared to usual care

The comparison of internet-based VR and usual care showed an effect on Vertigo Symptom Scale (VSS-SF) total score (primary outcome) in favour of VR ($n = 296$ participants, -2.26 points, $p = .02$) for patients with dizziness over the last 2 years and still experiencing dizziness triggered by head movements. Secondary outcomes showed mixed effects. Analysis of DHI score (-5.58 points, $p = .01$), and the patient reported improvement ($p < .001$) revealed effects in favour of VR. No significant differences were found in the Hospital Anxiety and Depression Scale (HADS) [35].

No difference in DHI (primary outcome) was reported for patients with dizziness when comparing usual care with a multicomponent program that includes the assessment of fall-risk increasing drugs (FRIDs) stepped mental health care or exercise therapy ($n = 168$ participants) in a RCT. No difference of dizziness frequency, presence of anxiety and depressive disorder, QoL and fall frequency was found [49].

A RCT with 165 participants experiencing balance disorders compared the Otago programme with receiving a

fall-prevention booklet and continuing usual activities (optimized usual care). No effect in favour of the intervention could be observed in the primary outcomes mCTSIB, Limits of Stability (LOS), Rhythmic Weight Shift (RWS). Within secondary outcomes, an effect in favour of intervention was shown in the step test (worse leg) ($+2.10$ steps/15 s, $p \leq .001$), in hip abductor muscle strength ($+ .02$ kg/kg, $p \leq .001$), in the Walk-across Test (WA) (-2.17 cm, $p \leq .001$), in the Functional Reach Test (FRT) ($+2.95$ cm, $p \leq .001$) and on the Human Activity Profile–Adjusted Activity Score (HAP-AAS) ($+4.57$ points, $p \leq .001$). No effects were reported regarding Sit to Stand Test (STS), the Five Times Sit to Stand Test (5x-STT), muscle strength of quadriceps and dorsiflexors, walking speed, the Step Quick Turn test (SQT), in quality of life as measured by Assessment of Quality of Life (AQoL) and falls measured in the Modified Falls Efficacy Scale (MFES) [44].

A non-randomized study with 60 participants experiencing balance disorders and a history of falls or having fear of falling investigated additional Cawthorne-Cooksey exercise programme versus conventional physical therapy did not specify a primary outcome. An effect in favour of the intervention (-0.77 points, $p = .030$) as measured by the Visual Analogue Scale of Fear of Falling (VAS-FOF) and in the Dynamic Gait Index (DGI) ($+1.3$ points, $p = .013$) was reported. No differences in Berg Balance Scale (BBS) and the likelihood of falls were found [50].

A RCT with 660 participants with mild to moderate Parkinson's Disease (Hoehn and Yahr stages 2–3) evaluated the effectiveness of VR versus usual care. The study did not specify a primary outcome. Mixed results were found: A significant benefit of $+9$ points ($p < .05$) on BBS, $+4$ points ($p < .05$) in DGI and $+27.5$ points for Activities-specific Balance Confidence (ABC) ($p < .05$). No significant difference was found in mCTSIB total score, Unified Parkinson's Disease Rating Scale (UPDRS), Timed-Up and Go test (TUG) and Quality of

life measured by the Parkinson's Disease Questionnaire (PDQ-39) [30].

When comparing classical physiotherapy (described as "individually tailored and including flexibility, strengthening, posture, breathing balance, walking exercises, and other functional activities") with additional sensorimotor integration training versus classical physiotherapy ($n = 30$ participants with Parkinson's Disease Hoehn and Yahr stages 2–3, no primary outcome stated), mixed results were found in a RCT. Effects in favour of intervention were found in the 5th position (+ 24.16, $p = .027$) and composite (+ 12.8, $p = .042$) of Computerized Dynamic Posturography – Sensory Organization Test (CDP-SOT) and in vestibular system score (VEST) in Computerized Dynamic Posturography – Sensory Analysis (CDP-Sensory) (+ 25.43, $p = .048$), on BBS (+ 10.34 points, $p = .037$) and in TUG (– 4.11 s, $p = .002$). No differences were reported for 6th position of CDP-SOT, somatosensory system score (SOM), visual system score (VIS) and visual preference score (PREF) in CDP-Sensory, Unified Parkinson's Disease Rating Scale (UPDRS) and the Functional Reach Test (FRT) [47].

Moderate quality of evidence exists, that VR is superior to usual care to improve VDB symptoms, balance and mobility, but not postural control, the impact of VDB on ADL and the presence of anxiety and depression, Parkinson's disease specific ADL, quality of life, frequency of falls and fear of falling.

VR versus no intervention

Two studies investigated VR versus no intervention.

A RCT ($n = 85$ participants with fall-related wrist fractures) showed no differences in primary outcomes (tandem standing with eyes open and closed and walking in a modified figure of eight). In secondary outcomes, no differences were reported when measuring SOLEO, SOLEC, 5x-STs, postural sway, vibration sense, head-shake test, EQ, 5D-VAS and walking variations [37].

A non-randomized study ($n = 58$ participants with multisensory dizziness) stated no primary outcome. Mixed effects were found. An improvement in standing on one leg with eyes closed (SOLEC) (+ 1 s, $p = .038$) and in walking heel to toe (– 2 steps, $p = .044$). No difference was observed in standing on one leg with eyes open (SOLEO), tandem standing with eyes open and closed, DHI, steps outside during walking in a figure of eight and the risk of falls maintained [36].

Training computer dynamic posturography exercises compared to no intervention ($n = 139$ participants experiencing balance impairment without a vestibular disease, no primary outcome stated) revealed to no differences in SOT, LOS, DHI, TUG and FES-I in a four-arm study, for which other comparison groups are described as follows [51].

New variations versus established forms of VR

VR in addition to CRM was compared to the CRM alone ($n = 16$ participants with BPPV for at least 6 months) in a RCT. Primary outcomes showed mixed effects: A difference in Maximum Excursion (MXE) of LOS (+ 17%, $p < .05$) and DGI (+ 4 points, $p = .05$) in favour of intervention and no differences in mCTSIB and movement velocity (MVL) of LOS. Secondary outcomes also revealed mixed results: a difference in tandem end sway (1 s in the $p < .05$) favouring intervention and no difference in sway in Unilateral Stance Test (US) and VAS [41].

A RCT with 125 participants (older people referred to a Falls Outpatient Clinic) investigated the Otago exercise programme in groups compared to the Otago exercise programme at home. The primary outcome BBS showed no difference. Secondary outcomes revealed mixed effects. Significant differences in 5x-STs (+ 2.2 s, $p = .005$) and TUG (– 2.4 s, $p = .038$) were reported. No differences were shown in quality of life measuring the short-form questionnaire SF-36 and on the Fall Efficiency Scale International (FES-I) [48].

A RCT with 82 participants with dizziness resulting from a vestibular disorder assessed a multimodal version of the Cawthorne-Cooksey programme versus the conventional version and observed no difference in primary outcome DGI. Also secondary outcomes showed no difference measuring STS, Romberg, tandem stand, sensorial, unipedal and handgrip strength, TUG, multidirectional FRT and fall rate [42].

A four-arm RCT compared VR with computer dynamic posturography exercises to exposure to optokinetic stimuli and exercises at home based on the Cawthorne-Cooksey programme in patients with balance impairment without a vestibular disease. Information about changes in SOT, DHI, TUG and FES-I is missing. No primary outcome was stated [51].

Moderate quality of evidence exists, that VR in addition to CRM is superior to CRM alone to improve balance. Very low quality of evidence exists, that the Otago exercise programme in groups is superior to the Otago exercise programme at home to improve lower extremity strength and mobility.

Computer-assisted VR

Five studies investigated computer-assisted VR (CAVR) (237 participants) [34, 38, 43, 45, 46].

CAVR versus usual care

No information about the comparison between WiiFit training and traditional exercises ($n = 36$ participants with idiopathic Parkinson's Disease Hoehn and Yahr stages 2–3) is provided, but the comparison of virtual reality-based Wii Fit training with subsequent treadmill training to fall-prevention education with no structured

programme is described. This third arm of the RCT is described hereafter [38]. A RCT with 20 participants with chronic stroke-related complaints investigated additional balance training using the Wii Fit programme to conventional physical therapy in comparison to conventional physiotherapy. No primary outcome was stated. No difference was reported in balance, body symmetry, BBS, TUG and 7-level functional independence measure (FIM) [46].

CAVR versus no intervention

Neither effects in SOT nor in the Verbal Reaction Time (VRT) were found when virtual reality-augmented balance training with PT were compared with no intervention ($n = 42$ participants with Parkinson's disease Hoehn and Yahr stages 2–3). No primary outcome was stated [45].

CAVR versus other interventions

A three-arm RCT ($n = 36$ participants) explored virtual reality-based Wii Fit training with subsequent treadmill training in comparison to fall-prevention education with no structured programme for idiopathic Parkinson's Disease (Hoehn and Yahr stages 2–3). No primary outcome was stated. Mixed results were found. Advantages in gait parameters ($+12.87$ cm/s, $p < .05$) in regard to velocity, ($+15.41$ cm, $p < .05$) stride length, ($+16.5$ N, $p < .05$) hip flexors, ($+12.5$ N, $p < .05$) hip extensors, ($+14.6$ N, $p < .05$) knee flexors, ($+28.1$ N, $p < .05$) knee extensors, ($+37.5$ N, $p < .05$) ankle dorsiflexors and ($+25.5$ N, $p < .05$) ankle plantar flexors, as well as ($+20.5$, $p < .05$) in vestibular ratio of SOT. Also a significant difference ($+4.59$ points, $p < .05$) in the Functional Gait Assessment (FGA) was observed. As the third arm, when the traditional exercise group (CG) was compared with the fall-prevention education group (CoG), all parameters changed significantly in the last follow-up except for the vision component of SOT. No primary outcome was stated. Changes in general were greater when WiiFit was compared with fall-prevention education than when traditional exercises were compared with education [38].

Home exercises supported by the "Move it to improve it" (Mitii) computer programme versus a printed home programme ($n = 63$ participants with vestibular dysfunction) showed no difference in the primary outcome one-leg stand test. No difference in secondary outcomes Motion Sensitivity, VAS, Chair stand test, DHI, DGI, quality of life measured with SF-12 [43].

A RCT compared in-home virtual reality balance training (TeleWii) to in-clinic sensory integration balance training ($n = 76$ participants with Parkinson's Disease modified Hoehn and Yahr stages 2.5–3). No significant differences in the primary outcome BBS as well

as ABC, 10-MW, DGI, Quality of life measuring PDQ-39, and in falls were observed [34].

Moderate quality of evidence exists, that virtual reality-based Wii Fit training with subsequent treadmill training is superior in comparison to fall-prevention education with no structured programme to improve gait parameters, lower extremity strength, balance and to improve postural control.

Tai chi as VR Tai Chi as a form of VR was used in three studies (216 participants) [32, 33, 39].

Tai chi VR (TCVR) versus no/sham intervention

A RCT ($n = 40$ participants experiencing dizziness within the past year, no primary outcome stated) investigated TCVR compared to no intervention and reported significant differences ($+61$ cm, $p = .050$) forward, ($+1.37$ cm, $p = .024$) backward, ($+28.57$ cm², $p = .002$) in the maximal sway area of the LOS and ($-.23$ s, $p = .003$) in the 8-ft up-and-go test. No differences were found in right- and leftward of LOS [39].

TCVR was compared to music percussion as sham intervention ($n = 40$ participants with visual impairment) in a RCT where no primary outcome was stated. Mixed effects were found. Differences (-30.1% , $p = .032$) of the absolute angle error of the passive knee joint repositioning test, ($+59.7\%$, $p = .006$) in the visual ratio and ($+50.3\%$, $p = .048$) in the vestibular ratio of SOT. No difference were reported in concentric isokinetic knee extensor or flexor strength of dominant leg and in somatosensory ratio [33].

Low quality of evidence exists, that TCVR is superior to no/sham intervention to improve postural control. Very low quality of evidence exists, that TCVR is superior to no/sham intervention to improve mobility.

TCVR versus other interventions

A RCT with 136 participants with a history of stroke at least 6 months ago exploring TCVR in comparison to breathing and stretching exercises reported mixed effects in primary outcomes LOS and SOT: A difference ($p = .005$) in reaction time of non-affected side, ($p = .005$) in end-point excursion of non-affected and affected sides and ($p = .05$) backwards and forwards in LOS. No difference in all conditions of equilibrium score and sensory ratios of SOT and in reaction time of all other sides in LOS. Secondary outcome TUG showed no difference [32].

Very low quality of evidence exists, that TCVR is superior to breathing and stretching exercises.

Manual therapy Manual therapy using Sustained Natural Apophyseal Glides (SNAGs) was investigated in one RCT ($n = 86$ participants with cervicogenic dizziness),

which reported significant effects in primary outcome (-18.4 mm, $p = .01$) on visual analogue scale (VAS) dizziness intensity compared to the sham intervention. Secondary outcomes revealed mixed effects. Effects (-0.9 points, $p < .001$) in dizziness frequency, no differences in VAS pain and DHI. In the same study, using Maitland mobilizations instead of SNAGs, Maitland mobilizations did not change the primary outcome VAS dizziness intensity. Secondary outcomes showed mixed effects: Effects (-7.6 points, $p = .04$) in DHI and no effects in dizziness frequency and VAS pain [40]. Very low quality of evidence exists, that SNAGs are superior to sham intervention, but equal to Maitland mobilizations to improve dizziness intensity. Maitland mobilizations are with very low quality of evidence superior to SNAGs and sham intervention to improve the impact of VDB on ADL.

Adverse effects

Mild transient pain in the lower cervical spine or upper arm 24 h after SNAGs was reported [40]. No other adverse effects were reported.

Discussion

Main findings

This review identified the quality of evidence of studies investigating physical therapy treatment options for older people with VDB addressing mobility and participation.

Studies were heterogeneous in terms of internal validity and used outcome measures. VR, VR in addition to CRM and MT showed beneficial effects [35, 40, 41], even though the quality of evidence is rather low.

CRMs for the treatment of vertigo in adults are well researched [52] and successfully practised, but the included studies with older patients show that high-quality evidence is scarce. We identified only one study investigating Epley manoeuvre in variations for older adults [31]. Considering BPPV as the most relevant diagnosis for dizziness [53] and the increasing number of older individuals suffering BPPV across their lifespan [15], findings of this review detect a lack of evidence, if CRMs are equally effective for older individuals in particular. When VR training is applied in addition to CRM in older adults, moderate quality of evidence guides to a benefit in balance [41], which is also obviously clinically relevant [54]. Results in functional outcomes emphasize the findings of a Cochrane review [52] indicating that VR including gait and balance training is recommended regardless of aetiology and as an addition to CRM for long-term functional effects.

VR is as effective as usual care when exercise therapy has an optional character in regard to impact of dizziness on ADL [49]. Thus, our findings underline that

exercise therapy has to play a central role in treatment of VDB to support vestibular compensation [55]. VR is also as effective as no intervention in a study [37] when the investigated patients are a specific subgroup with a fall-related wrist fracture and generalisation of the results might be done with care. A further aspect relevant to clinical decisions is that more people in the VR group refrained from participation, so one might conclude that VR group training is less acceptable. Variations of established Otago-programme were not superior to the programme itself [48]. Effects pre- to post-treatment in both groups show the effectiveness of the Otago exercise programme on balance, mobility, quality of life and falls independently of whether delivered in the group session or, as usual at home. A recent systematic review including patients aged from 60 to 95 years confirms the effectiveness of the Otago exercise programme in every variation for an improvement in balance and functional ability [56].

Training with a computer might be less motivating without a personal supervision and so not superior to a leaflet with exercises. Especially for older individuals living alone in the community, a supervising PT might be a relevant social contact. Tele-rehabilitation, e.g. via skype, treating other health conditions in other countries report positive experiences from both PTs and patients [57]. Supervised training compared to unsupervised was shown to be more effective even for healthy older adults in other studies [58]. Unless social aspects, there might be an additional benefit by the enrichment of environment on visual or vestibular-ocular issues than only balance or VR training, but not on functional outcomes.

Our review showed that Tai Chi is not effective to improve postural control in older persons with VDB [32]. In contrast to that, a Cochrane review investigating fall prevention interventions underscored the potential of Tai Chi to significantly reduce risk of falling for older people living in the community [59] and also the psychosocial effects of Tai Chi on nursing home residents on quality of life, especially in mental components were shown [60]. Our study investigated patients having VDB after a stroke, the Cochrane review older adults solely with VDB. Thus, Tai Chi seems effective for VDB, but not for VDB after a stroke.

In contrast to frequent recommendations to patients with VDB, manual therapy revealed not to be effective in our target population [40]. Considering other literature and the likelihood of injuries following cervical manipulations is increased with age-related diseases like osteoporosis or long-term use of anticoagulant therapy [61] and specific red flags should be assessed before using manual interventions in elderly [62]. Considering the debatable entity of cervicogenic dizziness [63], MT cannot

be recommended for older adults. Combinations of VR with MT are already shown as synergistic in few case series with young patients [64], but further research is needed [65].

Limitations

Due to the heterogeneity of interventions, outcomes and study population, comparison of the findings was difficult. We identified many studies investigating physical therapy for VDB, but such investigations frequently had designs without control groups and were conducted in a younger population, what is especially reflected in regard to CRMs. With regard to the methodological quality of the included studies, randomization process, allocation concealment, blinding of participants and personnel were not reported sufficiently. Blinding of outcome assessors as well as drop-outs were described in several studies, but the number of withdrawals frequently was unbalanced between groups. However, we are confident, that our review added reasonable knowledge relevant to clinical decision making because its rigorous quality assessment.

Due to the restriction of the earliest publication year to 2007 and the language to English or German, some meaningful articles published before 2007 or in other languages might have been excluded. Primary outcome was clearly stated only in 7 studies [34, 35, 40, 42, 43, 48, 49]. Descriptions of more than one single primary outcome were reported in 4 studies [32, 37, 41, 44]. In regard to the GRADE approach, overall risk of bias, indirectness, inconsistency, imprecision and publication bias were assessed, whereas imprecision was ranked down for every study due to a narrative synthesis in this review.

Conclusions

Vestibular rehabilitation in any variation seems to be effective in treating older adults with VDB. The same applied to VR in addition to CRMs. Tai Chi and manual therapy did not show any additional benefit in comparison to usual care in an older population. Overall, quality of evidence is rather low, especially in regard to bias. Many physical therapy intervention studies focus on surrogate markers, such as specific postural or muscle functions than on patient relevant outcomes that reflect mobility and participation. In addition, there is a lack of transparent reporting of PT interventions as complex interventions what makes it hard to implement findings into day to day care. High-quality randomized trials need to be carried out in future to inform clinical decision making for the highly vulnerable group of older patients with VDB.

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12877-020-01899-9>.

- Additional file 1.** Search terms and records.
- Additional file 2.** Characteristics of included studies.
- Additional file 3.** Methodological quality of included studies.
- Additional file 4.** Primary and secondary outcome measures.
- Additional file 5.** Summary of study results.
- Additional file 6.** Harvest plots summarizing effects of interventions.
- Additional file 7.** Evidence tables rating quality of evidence and summary of findings.

Abbreviations

10-MW: Ten meter walking; 5x-ST5: Five times sit to stand test; ABC: Activities-specific balance confidence; ACoL: Assessment of quality of life; BBS: Berg balance scale; CAVR: Computer-assisted vestibular rehabilitation; CDP-Sensory: Computerized dynamic posturography – sensory analysis; CDP-SOT: Computerized dynamic posturography – Sensory organization test; CG: Control group; CI: Confidence interval; CoG: Comparison group; CRM: Canal repositioning manoeuvre; DGI: Dynamic gait index; DHI: Dizziness handicap inventory; EQ 5D-VAS: Visual analogue scale of five dimensions EuroQol; FES-I: 7 item falls efficacy scale international; FGA: Functional gait assessment; FM: 7-level functional independence measure; FRDs: Fall-risk-increasing drugs; FRT: Functional reach test; GAD-7: Generalised anxiety disorder assessment 7 subscale; HADS: Hospital anxiety and depression scale; HAP-AAS: Human activity profile-adjusted activity score; IG: Intervention group; LOS: Limits of stability; mCTSIB: Modified clinical test of sensory interaction on balance; MFES: Modified falls efficacy scale; MT: Manual therapy; Multidirectional FR: Multidirectional functional reach; MV: Movement velocity; MXE: Maximum excursion; PDQ-39: Parkinson's Disease Questionnaire; PHQ-9: Patient health questionnaire-9; PREF: Visual preference score; QoL: Quality of life; RWS: Rhythmic weight shift; SF-12: 12 item short form assessment of quality of life; SF-36 MH: 36 item short form assessment health-related quality of life mental health; SF-36 PH: 36 item short form assessment health-related quality of life physical health; SNAGE: Sustained natural apophyseal glides; SOLE: Standing on one leg with eyes closed; SOLEO: Standing on one leg with eyes open; SOM: Somatosensory system score; SOT: Sensory organization test; SQT: Step quick turn test; STS: Sit to stand; TCVR: Tai Chi as vestibular rehabilitation; TUG: Timed up and go test; UPDRS: Unified Parkinson's disease rating scale; US: Unilateral stance test; VAS: Visual analogue scale; VAS-FOF: Visual analogue scale for fear of fall; VEST: Vestibular system score; VIS: Visual system score; VR: Vestibular rehabilitation; VRT: verbal reaction time; vs: versus; VSS-SF: Short form of vertigo symptom scale; WA: Walk across test

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Authors' contributions

Conception and design: VK, MM, ES; screening: VK, ES; data abstraction: VK, ES, PB; data interpretation: VK, MM, ES, PB; manuscript drafting: VK, MM, PB. The authors critically reviewed the content of the report and approved its final version.

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Availability of data and materials

Data extraction sheets and further information are available from the authors by request.

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Not applicable.

Consent for publication

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Competing interests

There are no competing interests.

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Publikation II

**Development of a complex intervention to improve mobility and participation of older people with vertigo, dizziness and balance disorders in primary care:
a mixed methods study**

Regauer, Verena; Seckler, Eva; Grill, Eva; Ippisch, Richard; Jahn, Klaus; Bauer, Petra;
Müller, Martin

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Eigenanteil: Nach der Antragstellung durch den Projektleiter war die Doktorandin als Erstautorin der Publikation II hauptverantwortlich für alle wesentlichen Schritte. Die Doktorandin übernahm die Registrierung des Projekts bei der Projektdatenbank Versorgungsforschung Deutschland sowie die Formulierung und Einreichung des Ethikantrags für die Interviews bei der Ethikkommission der *Ludwig-Maximilians-Universität (LMU)* München. Sie war hauptverantwortlich für die Vorbereitung, Durchführung, Kodierung und Datenanalyse aller Einzel- und Gruppeninterviews sowie die Vorbereitung, Durchführung und Datenanalyse der Expertenkonferenz. Über alle Schritte informierte die Doktorandin das Projektteam und stimmte diese bei Bedarf mit ihnen ab oder delegierte an die Studienassistenten oder studentische Hilfskräfte. Die Doktorandin verfasste das Manuskript, koordinierte das Feedback aller Autoren, Language Editors und Reviewern des Journals und erledigte alle Schritte bis zur Publikation.

RESEARCH ARTICLE

Open Access

Development of a complex intervention to improve mobility and participation of older people with vertigo, dizziness and balance disorders in primary care: a mixed methods study



Verena Regauer^{1,2*}, Eva Seckler^{1,2}, Eva Grill^{2,3}, Richard Ippisch⁴, Klaus Jahn^{3,5}, Petra Bauer⁶ and Martin Müller⁶

Abstract

Background: Vertigo, dizziness and balance disorders (VDB) are common in older people and cause restrictions in mobility and social participation. Due to a multifactorial aetiology, health care is often overutilised, but many patients are also treated insufficiently in primary care. The purpose of this study was to develop a care pathway as a complex intervention to improve mobility and participation in older people with VDB in primary care.

Methods: The development process followed the *UK Medical Research Council guidance* using a mixed-methods design with individual and group interviews carried out with patients, physical therapists (PTs), general practitioners (GPs), nurses working in community care and a multi-professional expert panel to create a first draft of a care pathway (CPW) and implementation strategy using the *Consolidated Framework of Implementation Research* and the *Expert recommendations for Implementing Change*. Subsequently, small expert group modelling of specific components of the CPW was carried out, with GPs, medical specialists and PTs. The *Behaviour Change Wheel* was applied to design the intervention's approach to behaviour change. To derive theoretical assumptions, we adopted *Kellogg's Logic Model* to consolidate the hypothesized chain of causes leading to patient-relevant outcomes.

Results: Individual interviews with patients showed that VDB symptoms need to be taken more seriously by GPs. Patients demanded age-specific treatment offers, group sessions or a continuous mentoring by a PT. GPs required a specific guideline for diagnostics and treatment options including psychosocial interventions. Specific assignment to and a standardized approach during physical therapy were desired by PTs. Nurses favoured a multi-professional documentation system. The structured three-day expert workshop resulted in a first draft of CPW and potential implementation strategies. Subsequent modelling resulted in a CPW with components and appropriate training materials for involved health professionals. A specific implementation strategy is now available.

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Conclusion: A mixed-methods design was suggested to be a suitable approach to develop a complex intervention and its implementation strategy. We will subsequently test the intervention for its acceptability and feasibility in a feasibility study accompanied by a comprehensive process evaluation to inform a subsequent effectiveness trial.

Trial Registration: The research project is registered in "Projektdateibank Versorgungsforschung Deutschland" (Project-ID: VID_Mobile-PHY_17_003910; date of registration: 30.11.2017).

Keywords: Critical Pathways, Implementation Science, Primary Health Care, Aged, Vertigo, Dizziness, General Practitioners, Physical Therapy Modalities

Background

Vertigo, dizziness and balance disorders (VDB) are frequent complaints of older people [1] and limit the capacity to pursue daily activities and social participation. The prevalence is reported with up to 50% in some trials [2, 3] and tends to increase with age [4]. Despite this, prevalence is difficult to describe exactly [5]. VDB represents one of the most relevant contributors to the burden of disability among older people living in the community in Germany and is associated with physical and psychological impact namely immobility, limitations in activities of daily living (ADL), decreased participation and lower psychological wellbeing [6–8]. Mobility restrictions of older people are distinct risk factors for falls [9] and even the fear of falling may lead to less activity and more disability [10]. Particularly in older people, the aetiology of VDB can rarely be attributed to distinct vestibular diseases, but more often to multifactorial deficits due to ageing, consequences of non-vestibular conditions or a combination of multiple aetiologies [3, 5, 11, 12]. VDB is a common reason for consulting a general practitioner (GP), affecting almost every person at least once in their lifetime [13]. A recent systematic review describes a prevalence of consultations for dizziness-related symptoms in primary care of approximately 1% to 15%, with benign paroxysmal positional vertigo (BPPV) being the most common specific aetiology in up to 40% [5]. In contrast to medical specialists, GPs see patients from the full range of medical disciplines and need to screen every patient to detect any serious health conditions. At the same time they treat many uncomplicated cases. Generally, GPs have to base their clinical reasoning process on the patient's history and a few additional tests [5], whereas VDB are known to be described unclearly, inconsistently and unreliably by patients and are, thus, difficult to standardise [14]. To exclude life threatening health conditions, GPs have to use diagnostic procedures and referrals to specialists. On the other hand, overutilization of health care resources in patients with VDB insufficiently treated in primary care has been shown [15]. Most VDB cases can be improved by treatment [16] but often do not benefit from drug or surgical therapy [17]. Due to the multifactorial aetiology, this might be especially true for older patients. Physical

therapy is a safe and effective treatment to promote mobility and avoid imbalance and falls [18]. Despite this, in the German guideline for acute VDB in primary care [19], physical therapy seems not to be a central treatment option, whereas a guideline for chronic VDB is lacking. Facing an ageing population due to demographic changes, strategies to manage VDB safely and efficiently are essential. Therefore, the management of VDB needs to be tailored for primary care with adequate referrals and treatment options [15].

A CPW is an evidence-based structured multidisciplinary care plan comprising all relevant diagnostic and therapeutic steps in the care of patients with a specific health condition in a chronological order [20]. CPWs are used to translate evidence into local practice by contemplating specific circumstances and demands; they tailor care and can reduce variations in practice to improve patient outcomes [20, 21]. CPWs for VDB should standardize GPs' diagnostics, treatment options and referrals, and explicitly integrate the use of physical therapy prescriptions.

The aim of this study was to develop a CPW as a complex intervention to improve the mobility and social participation of older people with VDB in primary care by integrating existing evidence and stakeholders' perspectives. Specifically, we aimed (a) to identify conditions of successful implementation by integrating the perspective of the involved health professionals regarding their expectations, attitudes, knowledge and needs, and (b) to address the issue of multi-professional communication by identification of supportive and hindering factors, and (c) to identify conditions of successful implementation by integrating the consumers' perspective regarding their experiences about accessibility and availability, expectations, motivation and beliefs.

Methods and results

We developed our CPW as a complex intervention according to the *UK Medical Research Council (MRC) framework* [22], which provides a methodological framework to develop, pilot test, evaluate and implement complex interventions. This paper describes the first phase of this framework, the development phase. It was carried

out in a stepwise process divided into two sub-phases: First, a preparation phase that included the identification of existing evidence and of stakeholders' and consumers' demands was conducted followed by a modelling phase, that comprised the modelling of a CPW and an implementation strategy. The feasibility and piloting study will be reported elsewhere. An overview of the specific aims and methods of the development steps is shown in Fig. 1.

To report the development of the complex intervention we used the *Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare* [23] (s. Additional file 1).

Step 1: Preparation

Methods step 1

Identifying existing evidence and theory

The first step included a synthesis of existing evidence by carrying out two systematic reviews to identify existing evidence. First, a systematic review to identify the quality

of evidence of physical therapy interventions addressing mobility and participation in older patients with VDB was conducted [24]. Due to the heterogeneity of the included studies, a narrative synthesis across all types of interventions was conducted concerning the outcome measures covering aspects of the *International Classification of Functioning, Disability and Health (ICF)* [25], quality of life and general health. Second, barriers to and facilitators of successful implementation of multi-professional CPWs in primary care were investigated [26]. Due to the large diversity of study characteristics, interventions and outcomes, we carried out a narrative synthesis following the *guidance for undertaking reviews in health care* from the *Centre for Reviews and Dissemination* [27].

Exploring the health care providers' perspective

To develop a tailored and successful CPW we used the co-creation approach by considering the perspectives of all involved groups, collaborating with them to allow the inclusion of their different needs and perspectives and to support development regarding designs and content [28]. Health care providers were selected by identifying health professionals involved in the process of care of patients with VDB. It was assumed that GP practices were the first place to go for people aged at least 65 years with beginning VDB problems or, in case of home care, community nursing services, who seem to act as gatekeepers for the following patient care process. PTs might offer interventions for patients with VDB. The target population was defined as patients older than 65 years suffering from VDB.

Individual interviews with health professionals

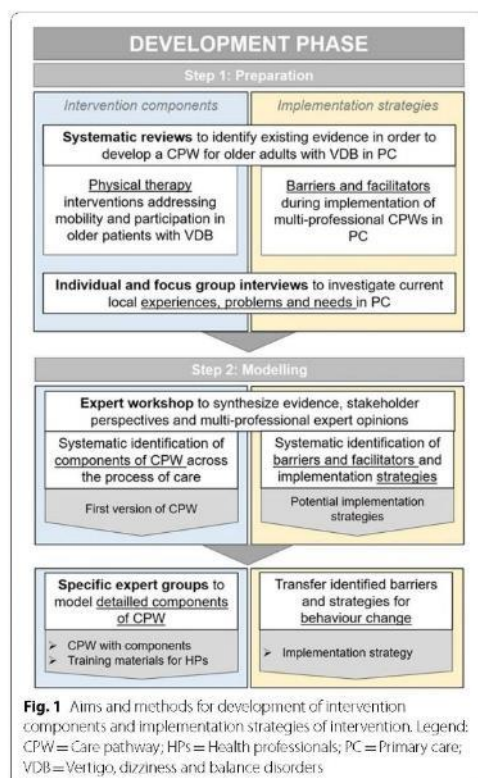
To explore current practice and identify needs for improvement, the ideal patient trajectory, expectations, attitudes and knowledge, we carried out semi-structured individual interviews with health professionals involved in the primary care of VDB patients: GPs, PTs and nurses working in a community setting.

Group interviews with health professionals

To address the issue of multi-professional communication and to identify supportive and hindering factors, we conducted interprofessional focus group interviews among health professionals involved in the primary care of VDB patients: GPs, PTs and nurses.

Study design, recruitment, data collection and analysis

We aimed to recruit approximately 10 GPs, 10 PTs and 10 nurses for the individual interviews. When data saturation from individual interviews was reached, we asked the remaining participants to participate in a focus group interview. We initially planned 2 focus groups with a



balanced number of each health care professional group: 1 GP, PT and nurse each. For both individual and focus group interviews, we included health professionals with at least three years of clinical experience in primary care, outpatient practices, or community/home care services. Further inclusion criteria were self-rated specific and extended experience in the treatment and management of older patients experiencing VDB and written consent to participate in the study. We searched for potential health professionals via the internet and regional networks, used telephone requests and, for those interested, sent further information via email or fax, as preferred.

Participants gave their written consent for participation prior to the date of the interview. The interviewers had a clear structured guideline for every kind of interview and interviewee, with defined main questions and examples for requests. The interviewers tried to systematically moderate the interviews and maximize inter-interviewer reliability. The interview guide for patients and GPs is provided as an example of the guide for health professionals (see Additional file 2). All interviews were audio-recorded, and field notes were taken during all interviews. Afterwards, the audio records were transcribed verbatim according to the rules of Kuckartz [29] with transcription software F4 (<https://www.audiotranskription.de/f4>). Data was analysed using structuring qualitative content analysis [29] to identify common themes on issues and barriers and facilitators to multi-professional communication. Two researchers (VR and ES) independently carried out a first draft of a coding tree using MAXQDA software (<https://www.maxqda.de/>) for every kind of interview setting and participant group and then discussed differences. Subsequently, VR and ES coded the material and included field notes in the analysis. Data saturation was defined as the point when no additional information was obtained.

Exploring the health care consumers' perspective

Individual interviews with patients

To identify conditions of successful CPW implementation by integrating the consumers' perspective (experiences regarding accessibility and availability, expectations, motivation and beliefs) into the development process we conducted individual interviews with affected people.

Study design, recruitment, data collection and analysis

We included patients aged at least 65 years who consulted a GP with complaints of VDB. Additionally, we recruited patients in PT practices, who are already enrolled in PT programmes. Patients were approached by putting up a poster in PT practices to recruit affected people and providing our telephone number for further

information in case of interest. Patients became aware of the opportunity to participate because of their PT or relatives/ an acquaintance. Exclusion criteria were patients aged under 65 years, patients having a serious condition/disease, patients requiring hospital treatment, and patients wishing to be excluded from the study. Additionally, we investigated the impact of VDB symptoms on the patients' activities of daily living and social participation using the German version of the vertigo activities and participation questionnaire (VAP) [30].

Participants gave their written consent for participation prior to the date of interview. The interviewers had a clearly structured guideline with defined main questions and examples for requests and, thus tried to systematically moderate the interviews and minimize inter-interviewer reliability. Interviews were audio-recorded and field notes were taken during all interviews. Afterwards, the audio records were transcribed verbatim according to the rules of Kuckartz [26] with transcription software F4 (<https://www.audiotranskription.de/f4>). Data was analysed using structuring qualitative content analysis [29] to identify common themes on issues and barriers and facilitators to multi-professional communication. Two researchers (VR, ES) independently carried out a first draft of a coding tree using MAXQDA software (<https://www.maxqda.de/>) and then discussed the differences. Subsequently, VR and ES coded the material and integrated their field notes into the analysis according to Kuckartz [29]. There, we aimed to gain knowledge about the respective issues and reported results narratively. Data saturation was defined as the point, at which no additional information was obtained. For the VAP questionnaire we calculated descriptive statistics.

Characteristics of the interviewers

The two researchers (ES and VR, both master's degree and vocational training as health professionals) conducted the interviews and the study assistant wrote the protocols. Both interviewers were trained how to develop an interview guideline and perform interviews by a separate qualitative workshop and had further experience from prior research activities. No relationships were established with participants prior to study commencement. All participants were informed about data privacy and about the intentions of doing this research prior to the interview.

Results step 1

Results of systematic reviews

The systematic review revealed that for older people, active physical therapy using vestibular rehabilitation, regardless of any variations and in combination with repositioning manoeuvres was most effective [24]. The

second review identified barriers to and facilitators of successful implementation of CPWs within the context, implementation and setting dimensions of *Context and Implementation of Complex Interventions (CICI) framework* dimensions [31], which need to be considered in the implementation of CPWs [26]. Detailed results of systematic reviews are published elsewhere [24, 26].

Results of the individual and focus group interviews with health professionals

Characteristics of the interviewees

Of the 35 invited GPs, 9 consented to participate (response rate: 26%); 7 participated in individual interviews and 2 participated in the focus group interviews. Of the 14 PTs invited, 8 consented to participate (response rate: 57%). Among those, 6 participated in individual interviews and 2 participated in focus group interviews. A total of 9 nurses were invited, and 7 participated (response rate: 77%); 5 in individual interviews and 2 in focus group interviews. Reasons for non-participation were holidays, lack of time or staff shortage.

After the analysis of a total of 17 health professionals (7 GPs, 6 PTs, 5 nurses) individual interviews, no further aspects or themes emerged and data saturation was reached. Most individual interviews were conducted via telephone to participants being in their institution or at home ($n = 16$, 94%), and only one PT preferred a face-to-face interview at the study centre. Interviews lasted 11 to 29 min. The characteristics of the health professionals are shown in Table 1.

After the analysis of the two focus group interviews with one GP, PT and nurse each no further aspects or themes emerged and data saturation was reached. Both group interviews were carried out for a duration of 53 min each. The focus group interviews were conducted face-to-face. The characteristics of the health professionals are shown in Table 2.

GP perspective

GPs see their role as gatekeepers and complain that it is difficult to act in this role after the patient has been referred to a specialist. They described an ideal patient trajectory as efficient, fast and comprising a diagnostic work up in a multidisciplinary center. Some GPs recommended, the CPW should involve a broader treatment approach including psychological coaching and social interventions, such as a pensioners' exchange or multi-purpose associations published in a GP practice.

PT perspective

From the PT perspective, the most relevant problem was that referrals from GPs are mostly without proper information on the physicians' diagnostic results. Therefore, PTs have to identify the patients' problems without this information. However, a specific German indication key (SO3—physical therapy with indication for dizziness of different origins and aetiology) was not used by the GPs.

"I think they (the GPs) are hardly informed about what they can assign to what kind of patients (...) I can remember only one patient (...) coming with this (...) indication key (...). All other (patients are assigned concerning) cervical spine." (PT, interviewee 4).

PTs reported mixed confidence in their abilities to treat VDB patients. They identified their knowledge from vocational training as less relevant and relied on skills acquired by additional trainings instead. Interdisciplinary communication, especially with GPs, was rated as insufficient and the PTs assumed that therapy reports were hardly read by GPs. A structured approach tailored to the needs of VDB patients was considered to be helpful:

"For certain things sometimes there exists very clear and beautiful guidelines, like a catalogue where you choose (...) I have a tree (...) something like a decision tree, exactly." (PT, interviewee 2)

Table 1 Characteristics of health professionals who participated in individual interviews

	GPs ($n = 7$)	PTs ($n = 6$)	Nurses ($n = 5$)
Age (Mean $\pm$ SD (Range))	58.7 $\pm$ 7.87 (42 – 66)	42.0 $\pm$ 10.71 (28 – 58)	43.2 $\pm$ 11.05 (31 – 55)
Sex (female / %)	3 / 43%	5 / 71%	3 / 60%
Years of current occupation (Mean $\pm$ SD (Range))	30.0 $\pm$ 8.04 (14 – 37)	18.3 $\pm$ 10.39 (6 – 36)	20 $\pm$ 5.87 (15 – 30)
As community nurse (Mean $\pm$ SD (Range))	n.a.	n.a.	12.8 $\pm$ 10.85 (1 – 27)
Weekly hours with patients (Mean $\pm$ SD (Range))	n.a.	34.8 $\pm$ 8.21 (6 – 36)	30 $\pm$ 21.11 (1 – 60)

GPs General practitioners, n.a. not assessed, PTs Physical therapists, SD Standard deviation

Table 2 Characteristics of the focus group interview participants

	FG 1			FG 2		
	GP (n = 1)	PT (n = 1)	Nurse (n = 1)	GP (n = 1)	PT (n = 1)	Nurse (n = 1)
Age (years)	68	50	55	66	27	31
Sex (m / f)	m	m	f	m	f	f
Years of current occupation (years)	40	25	25	41	8	7
As CN (years)	n.a	n.a	n.s.	n.a	n.a	4
Working hours per week (%)	110	100	70	130	100	100

CN Community nurse, f Female, FG Focus group, GP General practitioner, m Male, n.a. not assessed, n.s. not stated, PT Physical therapist

PTs rated more specific educational training, interdisciplinary cooperation and patient information to be beneficial.

Nurses' perspective

From the perspective of community nurses, a main problem is finding PTs that are available for home visits. It was also criticized, that interdisciplinary communication is hampered by missing reimbursement or financial incentives. The ideal would be an interdisciplinary documentation system.

"They should document or record everything. Either that or have a kind of online portal; that would of course be the easiest. That means, where you can exchange information about the patient and (...) where everyone can write something there or in the documentation folders on site. In the end, it takes just a minute that you write in there." (Nurse, interviewee 14).

In addition, specific educational training for nurses, and programmes to promote faster support for affected people was identified to be helpful.

Multidisciplinary perspective

It was mentioned in both focus groups that an important barrier for good multiprofessional and patient-centred communication is that there is no additional reimbursement for such activities. It was mentioned as critical that GPs do not have a central gatekeeper role when the first contact point of a patient was a medical specialist. Knowing each other personally was identified as the most relevant facilitator of good cooperation, e. g. when GPs or PTs are organised in centres. Space for potential improvement is seen in the communication between GPs and PTs, in particular, interdisciplinary case conferences with video conferencing and digital shared online documentation were seen as potentially helpful.

"I think the online portal is the one thing that could best be realized. (...) time is relatively tight (...) and you do not have to sit down together, you can actually do it online. In addition, maybe just write to me. So I find that feasible now." (Nurse, interviewee 1)
"So, I think team meetings are less feasible because the different times can never be brought together (...) it is of course also unpaid time. (...) the basis could be an electronic document (...) and 80% can then be resolved (...) and the rest, you are (...) on the phone. (GP, interviewee 1)

In summary, the optimal health care strategy for older VDB patients was described as long-term, continuous and target-group-specific.

Results of the individual interviews with patients

Characteristics of the interviewees

A total of 14 patients contacted the study centre because of interest and 11 consented to participate (patients' response rate: 79%). Reasons for non-participation were lack of interest or time.

At the point of data saturation, a total of 11 patients participated in individual interviews, which were conducted via telephone (n=10; 91%); only one patient preferred a face-to-face interview at the study centre. In some cases, the patients' partners joined the telephone interview if the interviewee had impaired hearing abilities. The interviews lasted 13 to 33 min. Characteristics of participants are shown in Table 3.

Patient perspective

Some patients reported not having consulted any physician because they considered their symptoms as not very serious or lacked time for a visit. From the patients' perspective, optimal health care was described by all interviewed patients when symptoms are taken seriously by GPs and are not only attributed to ageing. Therapy should include continuous PT, home training, conventional and alternative therapy approaches, medication, age specific offers or group sessions.

Step 2: Modelling

Methods step 2

Modelling the first version of the CPW and implementation strategies

Expert workshop The expert workshop was planned as a three-day event in a closed setting to create a productive and focused working space. An external moderator was introduced to the subject and process of the expert workshop.

Table 3 Characteristics of patients participating in individual interviews

	Patients (n = 11)
Age (Mean ± SD (Range))	75.5 ± 6.9 (65 – 89)
Sex (female / %)	7 / 64%
Symptoms (n / %):	
Dizziness	9 / 82%
Balance disorder	4 / 36%
Gait instability	10 / 91%
Fall history	8 / 73%
Other additional symptoms	6 / 55%

SD Standard deviation

Study design, recruitment, data collection and analysis We aimed to recruit all experts and at least one of them who are involved in the process of care of our target group. Therefore, we identified potentially involved persons following the *International Classification of Functioning, Disability and Health (ICF)* rehab-cycle [32] as a basic theory of structuring the patient's rehabilitation process and characterizing the steps of involved health professionals. In addition to the participants in the interviews, we identified health professionals such as clinical experts, representatives of health insurances, of health care researchers and of affected individuals.

To recruit participants, collaboration partners and local practices/institutes were contacted. Recruitment of health insurance representatives was conducted via personal contacts. We re-recruited interview partners and used member lists of the *Association of Statutory Health Insurance Physicians*. Self-employed persons received remuneration for the time spent participating in the workshop.

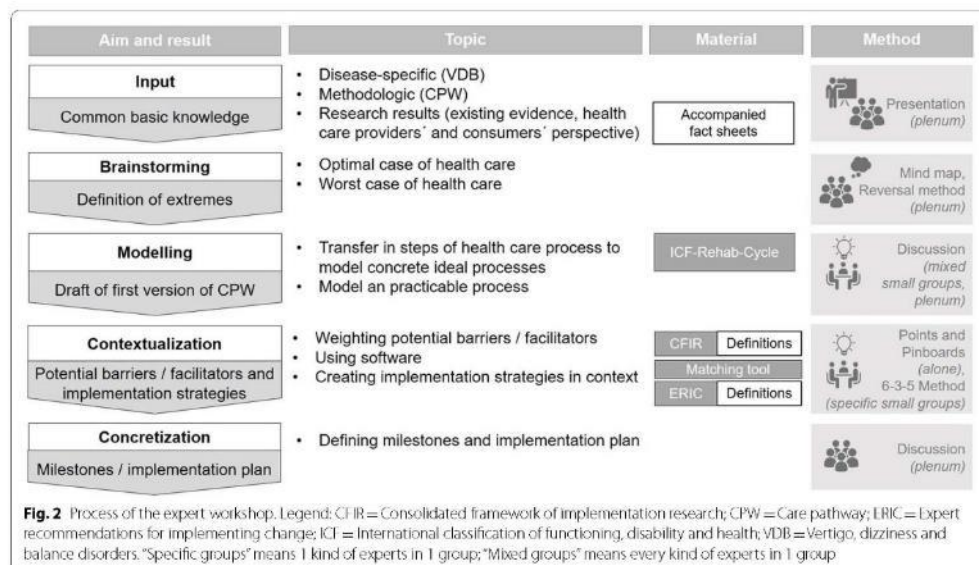
Methods of the workshop At the expert workshop, a step-wise modelling process was conducted (see Fig. 2). First, an update on recent disease-specific knowledge was given by a senior medical doctor and methodologic introduction to CPWs was given by a health care researcher. This was necessary to start with a common basic knowledge base among the participating experts. Then, the results

of prior research were presented by the research team and accompanied by factsheets. The results of existing evidence (systematic reviews) and of health care providers' and consumers' perspectives (interviews). To guide experts through different stages of the modelling process various creative techniques in the plenary session, individually and in small groups, were used. Good evidence exists for the *Consolidated Framework of Implementation Research (CFIR)* [33] and *Expert Recommendations for Implementing Change (ERIC)* [34] as well as for a matching tool to both systematically identify potential barriers/facilitators and select implementation strategies for interventions. To identify potential barriers of and facilitators to by implementing a CPW in a real-world setting, CFIR barriers were used and prioritized by the experts. These barriers were transformed by the CFIR/ERIC matching tool into a weighted order of matching ERIC strategies. The frameworks were translated into the German language and the translation will be published elsewhere. In conclusion, milestones and an implementation plan were defined.

Subsequent modelling of the CPW, intervention components and educational training materials

Modelling process of CPW design in a specific expert group

The results of the expert workshop were collected, reviewed and analysed. According to defined milestones, a checklist for GPs and a guide for PTs with accompanied



educational trainings were developed. In two expert meetings, we modelled a more detailed version of the GP's role in the CPW in an iterative way. Subsequent to each of the two face-to-face meetings, feedback and further exchanges via telephone or email with the research team was done if necessary. Based on the ICF-Rehab cycle and its process of care as well as the literature regarding evidence-based practice [35], the research team developed a first draft of an algorithm for the PT-guide. In telephone contacts with renowned PT specialists an enhanced version was adopted.

Modelling behaviour change

We conducted a stepwise approach to intervention design and implementation strategy using the *Behaviour Change Wheel (BCW)* [36] to guide the approach. We also took barriers and facilitators identified according to CFIR [33] and matched implementation strategies according to ERIC [34] from our expert panel into consideration. In an iterative way, we moved between the BCW and CFIR/ERIC. These frameworks helped to organize and develop specific behaviour change techniques and implementation strategies. To design behaviour change, we conducted the 7 steps of the guide using the provided worksheets (see Additional file 3). We applied the *Capability-Opportunity-Motivation-Behaviour (COM-B)* model and *Theoretical Domains Framework* and used potential barriers according to the CFIR and ERIC strategies from our expert workshop.

Developing a Logic Model

To systematically present the relationships between the intended results, the underlying mechanism of change and the planned work, we developed a logic model according to *Kellogg's Logic Model Development Guide* [37]. Finally, we checked the model for its completeness regarding context, implementation and setting with the *Context and Implementation of Complex Interventions Framework* [31].

Results Step 2

Results of the expert workshop

Characteristics of the experts

The expert workshop was conducted for three days in October 2018. The response rates of clinical experts, researchers and representatives of affected people and insurances were 50% to 100%. We had problems recruiting GPs (response rate: 0.1%): When recruiting regional GPs, the response rate was 14% (1 participating GP out of 7 requests), but the response when re-recruiting interview partners (9 requests) and using member lists of the *Association of Statutory Health Insurance Physicians* (124 requests) was 0%. In total, 9 clinical experts

(2 neurologists, 1 ENT physician, 1 GP, 3 PTs, 1 geriatric nurse, 1 medical assistant), 2 experts in health care research, 2 health insurance representatives, and 2 patient representatives participated.

First version of the CPW

Experts drafted a first version of the CPW according to the steps of the ICF Rehab cycle [32]. Regarding access, a hotline for patients and population-related information was recommended. This version included tools for health professionals to screen, assign, treat and evaluate VDB patients and was intended to promote multi-disciplinary communication between all involved HPs.

Implementation strategy

Potential barriers and facilitators

Weighting potential barriers and facilitators according to the CFIR [33] the most prioritized construct was the inner setting (44 points; 39%), followed by intervention characteristics (26 points; 23%), processes (18 points; 16%), characteristics of individuals (17 points; 15%) and outer setting (7 points; 6%) (see Fig. 3, details see Table 4).

Implementation strategies

After transformation of these barriers using the matching tool software, a weighted order of matching ERIC strategies was presented and the 15 most important strategies were further elaborated (see Table 4). From them, the experts could choose, specify and discuss which implementation strategy would be appropriate to implement the CPW. It was also possible to deselect a strategy if the strategy did not match the implementation context.

Milestones and implementation plan

The implementation plan with milestones for the subsequent study was discussed and approved by the experts.

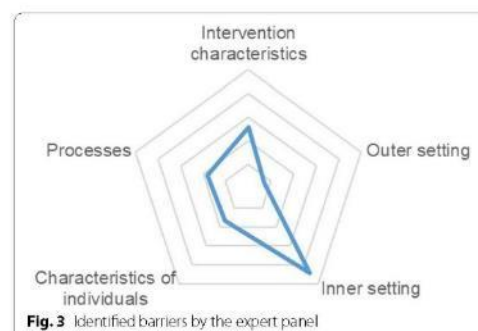


Fig. 3 Identified barriers by the expert panel

Table 4 Potential barriers and matched implementation strategies

CFIR			ERIC	
Priority	Construct	Barrier	Priority	Strategy
1	Intervention characteristics	Cost	1	Identify and prepare champions
2	Inner setting	Organizational Incentives & Rewards	2	Alter incentive/allowance structures
3	Characteristics of individuals	Knowledge & Beliefs about the Intervention	3	Assess for readiness and identify barriers and facilitators
4	Processes	Reflecting and evaluating	4	Conduct local consensus discussions
5	Inner setting	Implementation climate	5	Inform local opinion leaders
6	Inner setting	Available resources	6	Conduct educational meetings
7	Processes	Planning	7	Access new funding
8	Intervention characteristics	Evidence strength & quality	8	Capture and share local knowledge
9	Outer setting	External policy & incentives	9	Conduct local needs assessment
10	Characteristics of individuals	Individual stage of change	10	Develop a formal implementation blueprint
11	Intervention characteristics	Relative advantage	11	Audit and provide feedback
12	Inner setting	Tension for Change	12	Build a coalition
13	Inner setting	Goals and Feedback	13	Develop and implement tools for quality monitoring
14	Inner setting	Leadership Engagement	14	Identify early adopters
			15	Involve executive boards

CFIR Consolidated framework for implementation research, ERIC Expert recommendation for implementing change

Regarding access, recruitment of potential study participants should be conducted by GPs using clear inclusion criteria for patients. Assessment and assignment should be conducted by GPs using a screening tool with accompanied and credited educational training. Regarding assignment and evaluation, no milestones were defined. To evaluate the effectiveness of the (assigned) intervention, specific follow-up times were recommended. For detail see Table 5.

Results of subsequent modelling design and Implementation of the CPW

Logic Model of the CPW's intervention components and implementation strategies

We developed a logic model by using Kellogg's Logic Model (see Fig. 4) and combining the findings of prior results regarding assumptions and influential factors. Since the key to practice development is behaviour change among health professionals, we defined the planned work, mechanism of impact (using the COM-B model, the inner layer of the BCW [28]) and intended results. To improve VDB patients' mobility and participation, we aim to promote the self-efficacy of health professionals by supporting them in behaviour change to use the CPW. Therefore, we plan to give them more in-depth knowledge and skills via written information and face-to-face educational trainings in how to diagnose and treat VDB patients efficiently using distinct parts of the CPW (GP-checklist and PT-guide). The mechanisms of impact can be explicated as follows: When the health professionals understand the aims of the CPW and are affirmed

in the use of specific skills and knowledge (capability), if they feel prepared and supported for performing the care process based on the CPW in daily practice (opportunity), they can believe in the benefits of the CPW in treating patients with VDB effectively and safely and can feel certain in applying the intervention part (motivation) and then will implement the CPW.

Characteristics of the small expert group

The small expert group consisted of the participants of the expert workshop: 1 GP, 1 neurologist, 1 neuro-otologist and 1 ENT physician and the research team. For the telephone contacts, 1 PT from the expert workshop and 2 additional renowned PT specialists from collaborating partners participated.

CPW

The developed multi-disciplinary CPW is a paper-based algorithm, that illustrates all steps of the aged patients' care path in a structured way (see Fig. 5). The specific subprocesses of the CPW are a checklist for GPs and a guide for PTs which are described in detail in the following section:

Intervention components and educational training materials

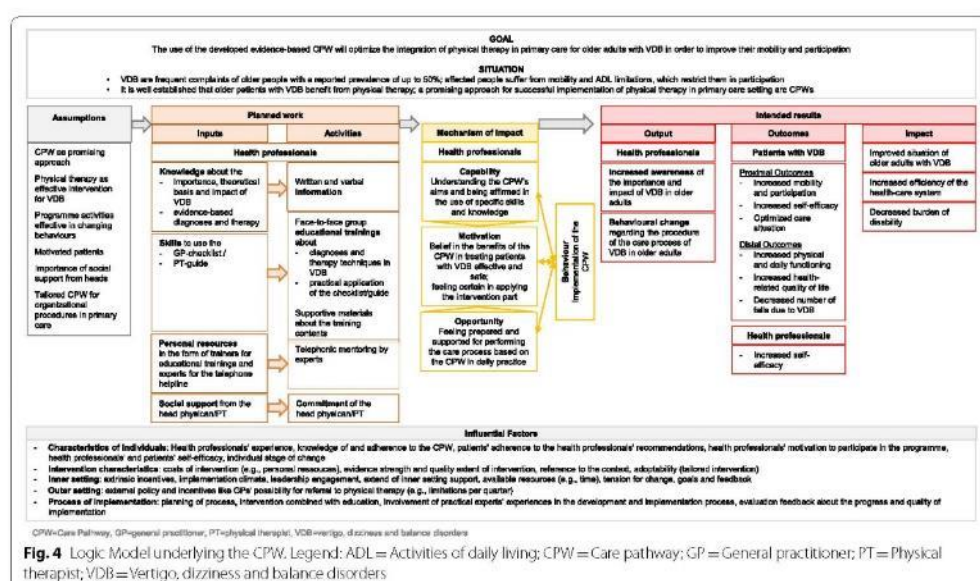
GP checklist

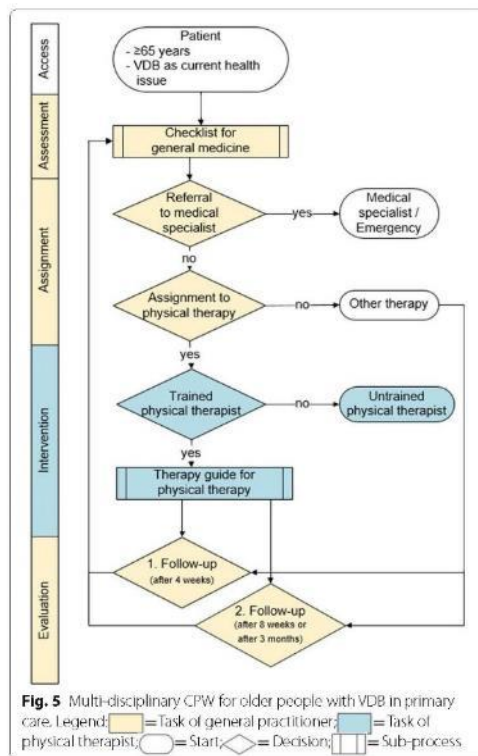
The screening checklist for GPs that manage patients with VDB aims (a) to exclude life-threatening conditions (b) to promote reliable diagnosis and evidence-based treatment by GPs and (c) to ensure a rational referral

Table 5 Steps of the CPW and milestones of its implementation

Steps of the CPW	Milestones
Access:	
- Immediately	→ Reaching of the pre-defined number of participating GPs and patients
- Direct	
- Involvement of relatives	
Assessment:	
- Central role of GP	→ Development of a screening tool
- Checklist	→ Accompanied previous educational training of GPs
- Educational training of GPs	
Assignment:	
- Prompt	
- Physical therapy as favoured intervention	
- Organized in a network	
- Case managers	
Intervention:	
- Capacity of providers	→ Recruitment of collaboration partners
- Treatment duration	
- Involvement of additional potential actors	→ Educational training of PTs
- Extended offer of providers (e.g., clubs, community college)	
Evaluation:	
- Feedback to all involved actors	
- Follow-up appointments in checklist	

CPW Care pathway, GPs General practitioners, PTs Physical therapists





regime. The final checklist is a paper-based algorithm and consists of aspects of anamnesis, assessments, specific referral regimes (e.g. prescription guide for physical therapy) and assignments to therapy and follow-up timelines for consultation. The checklist is not available since it has not yet been evaluated for effectiveness and safety. Linking to our Logic Model, we use the checklist as an input on GPs' knowledge and skills to change their behavior in respect to having an increased awareness of the importance of VDB in older people and their procedure of care (output). As an activity to reach this behavior change, we provide an educational training for GPs. This training aims to develop an in-depth understanding of the checklist and exercises.

PT guide

An evidence-based guide for clinical reasoning and treatment for PTs focusing on the leading symptoms of chronic dizziness and balance disorders. The guide is not available since it has not yet been evaluated for

effectiveness and safety. The guide contains guidance on the prescription header (specific code and assignment of the GP), anamnesis, assessment, treatment and evaluation. Regarding anamnesis, background information about clinical patterns was included. The decision tree style leads to specific assessments and treatment options. Additionally, educational flyers and leaflets were included to be handed out to patients during the therapy: 4 educational leaflets about practical exercises (physical therapy for balance disorders, gait disorder and vertigo as well as instructions for the positioning manoeuvre of posterior canal benign paroxysmal positional vertigo) provided through collaboration with the *German Centre for Vertigo and Balance Disorders* and 2 informational flyers that were translated from existing literature into the German language. These flyers include topics such as symptom control of vertigo and nausea [38] and frequently asked questions about benign paroxysmal positional vertigo [39] using the American clinical practice guideline [40].

As was done for the GP checklist, we used the PT guide as an input on PTs' knowledge and skills to change their behavior. PTs should be aware of the importance of VDB in older people and their approach to physical therapy (output). To ensure correct and confident application of the guide including assessments and interventions, educational training was performed as an activity. Prior to the training, informational material, was provided to prepare the participants and ensure a common base of knowledge.

Implementation strategy of the CPW

As a result, behaviour change of health professionals is needed to apply evidence-based checklists or guides. The implementation strategy comprises an face-to-face educational training in groups, accompanying information or instruction manuals and social support by mentoring during the first phase of application and by providing a phone helpline at an individual-level. A material incentive such as accreditation points for educational training or case payments seemed to be useful for participation.

Discussion

Main findings

We developed a theoretically-based and practically-informed CPW as a complex intervention to improve the mobility and social participation of older people with VDB in primary care, which can now be tested for its feasibility. This intervention is based on findings from the literature, the perspective of older people with VDB and the experiences of health professionals working in primary care with these patients. In an expert workshop and subsequent small expert workshops, a CPW and its components were modelled, and specific implementation

strategies were defined: A checklist for GPs and a guide for PTs working in primary care with accompanied educational trainings to support the use of an evidence-based standardized approach to VDB patients in daily practice.

The optimized integration of physical therapy in the primary care of VDB patients and a subsequent, targeted promotion of physical activity of affected people is a central aspect of our intervention. Findings from the literature show promising effects of complex interventions in supporting older people to live independently in the community, reducing nursing-home and hospital admissions and the occurrence of falls, increasing physical function and health-related quality of life, especially, because these interventions can be tailored to meet individuals' needs [41, 42].

By collecting data using a mixed-methods design, we were able to identify not only complementary evidence, but also to integrate different perspectives of all stakeholders. Rousseau et al. [43] highlighted the importance of paying attention to study design when developing a complex intervention and capturing different types of knowledge during the design progress to maximise creativity. We also confirm the mixed-methods design as a feasible developmental design to gather insights and understanding [44].

For the development of the CPW components, we used an approach, where we involved stakeholders, which is known to have high potential for societal impact via community-academic partnerships [45]. Involving stakeholders and undertaking primary data collection is also crucial in creating an acceptable and real-world intervention. We involved both those who are targeted by the intervention (patients) and those who are involved in its delivery (health professionals), which is a clear strength of this study.

The complex intervention was developed according to the *UK MRC Framework* [22], which explicitly gives reason about what and how the intervention should be implemented, additionally, Kellogg's logic model [37] helped us to understand how the intervention might work and what activities are needed.

Strengths and limitations

A clear strength of our study is that we conducted development based on a broad range of sources: The review of published research evidence, primary data collection with different stakeholders to explore their needs and understand context, and involvement of stakeholders in the iterative modelling process resulting in a logic model. These activities are in line with a recently published development guidance [46].

The participation of GPs in the expert workshop was hard to realize. Extensive and time-consuming

recruitment resulted in only one participating GP. As we used the co-creation approach, the opinion of GPs who subsequently apply the CPW might be biased and misinterpreted due to the participation of too few GPs in our development process. To evaluate the GPs' contribution to the developed intervention and its implementation strategy we firmly plan to include the participating GPs of the feasibility study into the process evaluation in a combined qualitative group interview together with the developers and to further incorporate their feedback.

Conclusion

The complex intervention to improve mobility and participation of older people with vertigo, dizziness and balance disorders in primary care is now ready for feasibility testing. This step should be used prior to the main trial for assessment of its effectiveness and accompanied by a comprehensive process evaluation to identify experiences, relevant influences and explore barriers to and facilitators of successful implementation.

Abbreviations

BCW: Behaviour change wheel; CFR: Consolidated framework for implementation research; COM-B: Capability-Opportunity-Motivation-Behaviour; CPW: Care pathway; ENT: Ear-nose-throat; ERC: Expert recommendation for implementing change; GP: General practitioner; ICF: International classification of functioning, disability and health; P: Patient; PT: Physical therapist; VDB: Vertigo, dizziness and balance disorders

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12875-021-01441-9>.

Additional file 1
Additional file 2
Additional file 3

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Authors' contributions

MM, EG and PB contributed to the conception of the study, applied for funding and conceived the study design. VR and ES coordinated all study processes and conducted interviews. ES and VR conducted data analysis. All of the authors contributed to the interpretation of data. EG, PB and KJ were involved in modelling process during expert workshop and PB and KJ figured prominently into development of the GP checklist. VR drafted this manuscript. All authors critically revised the draft and contributed to the final writing of the paper. MM is the principal investigator and holds the senior authorship. All authors read and approved the manuscript.

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Availability of data and materials

All data generated or analysed and the measurements used during this study, not included in this report, are available from the authors on request.

Declarations

Ethics approval and consent to participate

The Ethical Committee of the Ludwig Maximilian University of Munich has approved the study protocol under the number 18–431. All participants of the individual and focus group interviews gave their written consent to participation.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Abbildungen

Abbildung 1 Logisches Modell des Versorgungspfades

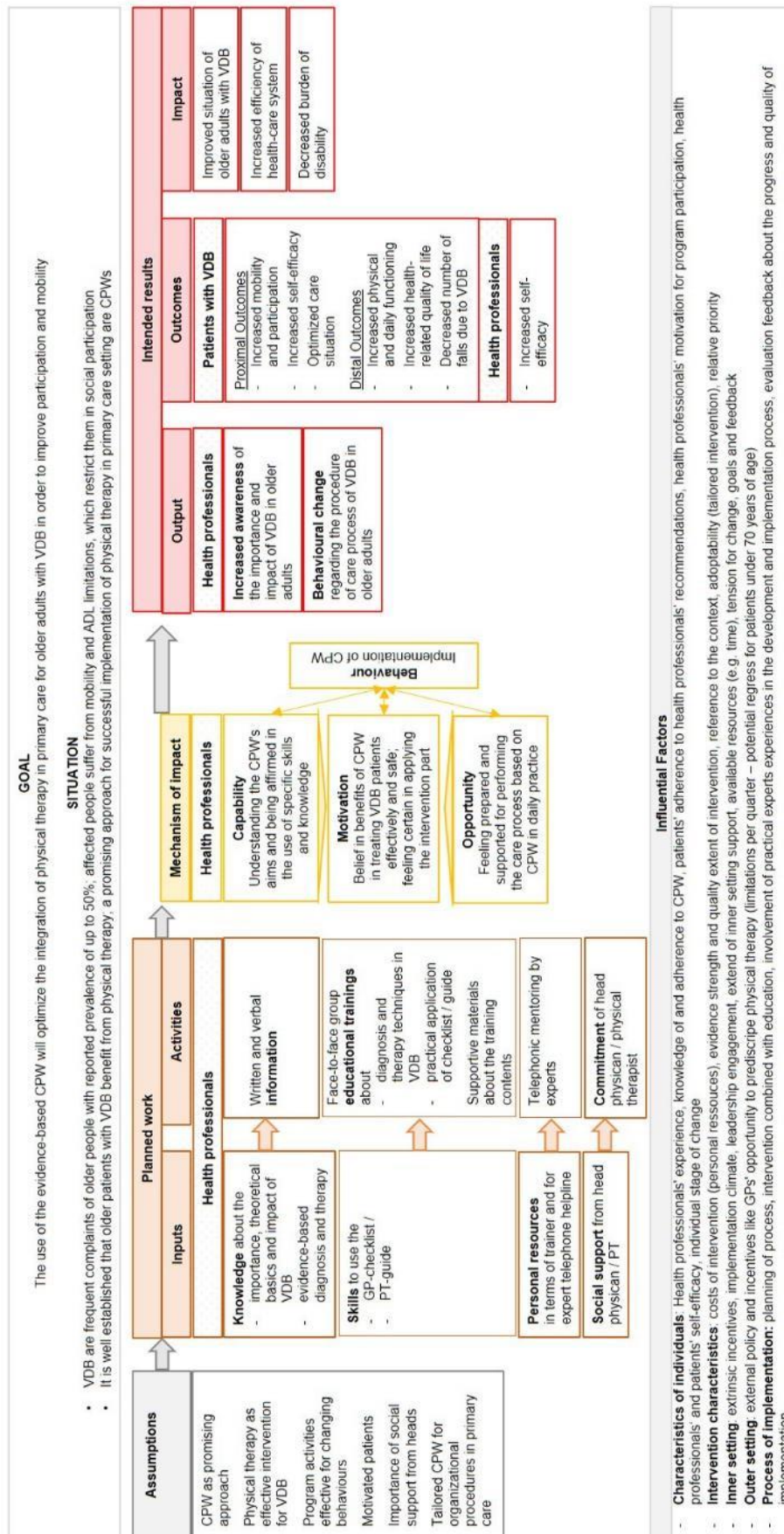
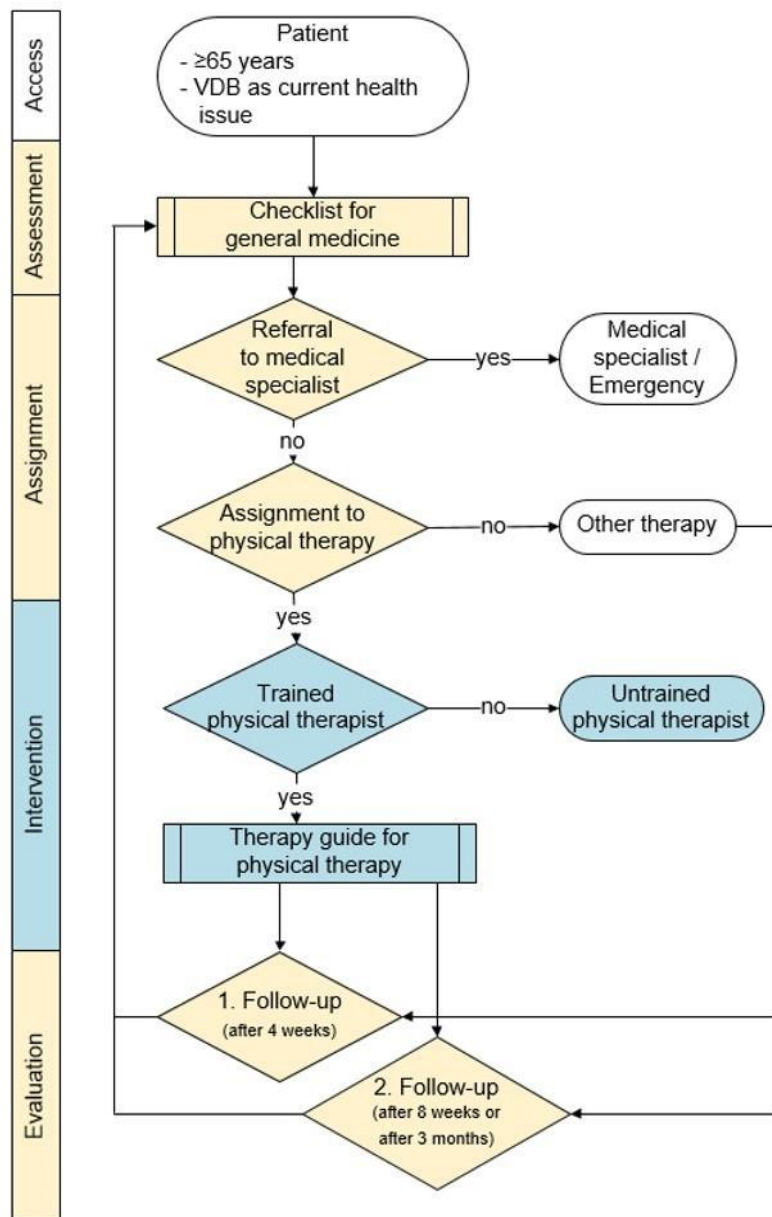


Abbildung 2 Multidisziplinärer Versorgungspfad für ältere Menschen mit Schwindel und Gleichgewichtsstörungen in der Primärversorgung



Tabellen

Tabelle 1 Ergebnisse des Pre-Testings von *CFIR*

Items	approved (n / %)	partially approved	rejected
1. Round: Randomised items (n = 39)			
37381115513239264	5 / 50%	4 / 40%	1 / 10%
143418241213121108	9 / 90%	0 / 0%	1 / 10%
7393328161922253235	9 / 90%	1 / 10%	0 / 0%
292317273662030-	4 / 44%	5 / 56%	0 / 0%
Sub-total 1:	27 / 69%	10 / 26%	2 / 5%
2. Round: Added items (n = 2)			
1037	0 / 0%	1 / 50%	1 / 50%
Sub-total 2:	0 / 0%	1 / 50%	1 / 50%
Final (n = 39)	Total:	27 / 69%	11 / 28%1 / 3%

Tabelle 2 Ergebnisse des Pre-Testings von *ERIC*

Items										approved (n / %)	partially approved	rejected	
1. Round: Randomised items (n = 73)													
44	61	77	107	62	63	51	68	101	60	7 / 70%	3 / 30%	0 / 0%	
58	108	42	100	80	76	97	95	45	103	6 / 60%	4 / 40%	0 / 0%	
84	93	91	90	46	105	89	54	87	72	7 / 70%	2 / 20%	1 / 10%	
83	57	98	109	81	71	111	79	96	41	5 / 50%	5 / 50%	0 / 0%	
74	88	53	106	70	67	40	59	82	48	6 / 60%	4 / 40%	0 / 0%	
104	52	78	92	43	75	64	86	102	55	6 / 60%	4 / 40%	0 / 0%	
49	66	69	94	73	85	110	99	56	65	6 / 60%	3 / 30%	1 / 10%	
47	50	112	-	-	-	-	-	-	-	2 / 62%	1 / 33%	0 / 0%	
Sub-total 1:										45 / 62%	26 / 36%	2 / 3%	
2. Round: Added items (n = 2)													
72	69										2 / 100%	0 / 0%	0 / 0%
Sub-total 2:										2 / 100%	0 / 0%	0 / 0%	
Final (n = 73)										Total:	47 / 64%	26 / 36%	0 / 0%

Anhang: Publikation III

German translation and pre-testing of Consolidated Framework for Implementation Research (CFIR) and Expert Recommendations for Implementing Change (ERIC)

Regauer, Verena; Seckler, Eva; Campbell, Craig; Phillips, Amanda; Rotter, Thomas; Bauer, Petra; Müller, Martin

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Eigenanteil: Die Doktorandin war als Erstautorin der Publikation III hauptverantwortlich bei allen Forschungsschritten von der Konzeption, der Übersetzung ins Deutsche, dem Koordinieren und Diskutieren zwischen dem bilingualen Expertenpanel und der Projektgruppe sowie zwischen der Rückübersetzerin und der Projektgruppe. Die Formulierung und Einreichung des Ethikantrags für die Interviews bei der Ethikkommission der *Ludwig-Maximilians-Universität (LMU)* München wurde von der Doktorandin erledigt. Sie war hauptverantwortlich für die Vorbereitung, Durchführung, Kodierung und Datenanalyse aller Interviews. Die Doktorandin verfasste das Manuskript, koordinierte das Feedback aller Autoren, Language Editors und Reviewern des Journals und erledigte alle Schritte bis zur Publikation.

RESEARCH

Open Access

German translation and pre-testing of Consolidated Framework for Implementation Research (CFIR) and Expert Recommendations for Implementing Change (ERIC)



Verena Regauer^{1,2*} , Eva Seckler^{1,2}, Craig Campbell³, Amanda Phillips², Thomas Rotter⁴, Petra Bauer⁵ and Martin Müller⁵

Abstract

Background: Implementation frameworks may support local implementation strategies with a sound theoretical foundation. The *Consolidated Framework for Implementation Research (CFIR)* facilitates identification of contextual barriers and facilitators, and the *Expert Recommendations for Implementing Change (ERIC)* allows identifying adequate implementation strategies. Both instruments are already used in German-speaking countries; however, no standardised and validated translation is available thus far. The aim of this study was to translate the CFIR and ERIC framework into German, in order to increase the use of these frameworks and the adherence to evidence-based implementation efforts in German-speaking countries.

Methods: The translation of the original versions of the CFIR and ERIC framework was guided by the World Health Organisation's recommendations for the process of translating and adapting both conceptual frameworks. Accordingly, a four-step process was employed: first, forward translation from English into German was conducted by a research team of German native speakers with fluent knowledge of the English language. Second, a bilingual expert panel comprising one researcher with German as his mother tongue and expert command of the English language and one English language expert and university teacher reviewed the translation and discussed inconsistencies with the initial translators. Third, back-translation into English was conducted by an English native speaking researcher. The final version was pre-tested with 12 German researchers and clinicians who were involved in implementation projects using cognitive interviews.

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Results: The translation and review process revealed some inconsistencies between the original version and the German translations. All issues could be solved by discussion. Central aspects of the items were confirmed in 60 to 70% of the items, and modifications were proposed in 30% of the items. Finally, we revised one CFIR-item heading after pre-testing. The final version was given consent by all involved parties.

Conclusions: Now, two validated and tested implementation frameworks to guide implementation efforts are available in the German language and can be used to increase the application of agreed-on implementation strategies into practice.

Keywords: Implementation science, Implementation strategies, Knowledge translation strategies, Consolidated Framework for Implementation Research, Expert Recommendations for Implementing Change.

Contributions to the literature

- To increase the application of CFIR and ERIC implementation frameworks in German-speaking countries, these concepts are now available in German
- The conceptual frameworks can be used by clinicians, researchers, managers and organisations to increase adherence to evidence-based implementation activities, and to improve the transferability of this experience into local practice
- The frameworks were translated into German using a standardised WHO approach, including pre-testing with German health care professionals, researchers, and clinicians.

Background

Many interventions in health care are considered to be effective, but efficacy in terms of achieving desired changes in patient-relevant health outcomes is critically dependent on successful implementation [1, 2]. Lack of information about a study's local context and poor reporting of implementation strategies employed may be accountable for the critical gap between implementation research and clinical practice [2, 3]. The use of implementation frameworks may help to increase adherence to evidence-based implementation strategies and to establish a consensus terminology for German-speaking implementation experts [4].

The *Consolidated Framework for Implementation Research (CFIR)* [1] provides a tool box of different constructs arranged across five domains that should be used in a range of settings. It can help to identify potential barriers and help facilitators to change, and can be used as theory-based constructs for developing effective implementation strategies [1]. The *Expert Recommendations for Implementing Change (ERIC)* systematically catalogued implementation strategies via input from a wide range of stakeholders and structured them into different categories and definitions [5, 6].

Identifying barriers and facilitators at different dimensions and tailoring interventions appear crucial to

successful implementation of interventions into practice. Moreover, a Cochrane review [7] concluded that tailored interventions addressing implementation barriers are more likely to improve professional practice than untailored interventions, e.g., clinical practice guidelines alone, while more research is needed on the causal mechanisms for successful implementation and how to address these determinants. As a first step for implementation researchers, the CFIR provides a systematic framework to categorise potential barriers and facilitators. As a second step and to tailor the implementation, ERIC catalogues potential implementation strategies. To connect those, a tool was built that linked the context assessment using CFIR and implementation strategies to be considered using ERIC, the *CFIR-ERIC-matching tool* (available under www.cfirguide.org) [8].

Both taxonomies are already used in various studies with a wide range of objectives, methods, and settings [9] including German-speaking countries [10]. However, no standardised and validated translation into German was available thus far.

The aim of this study was to develop a German translation of both CFIR and ERIC in order to increase adherence to evidence-based implementation activities in German-speaking countries.

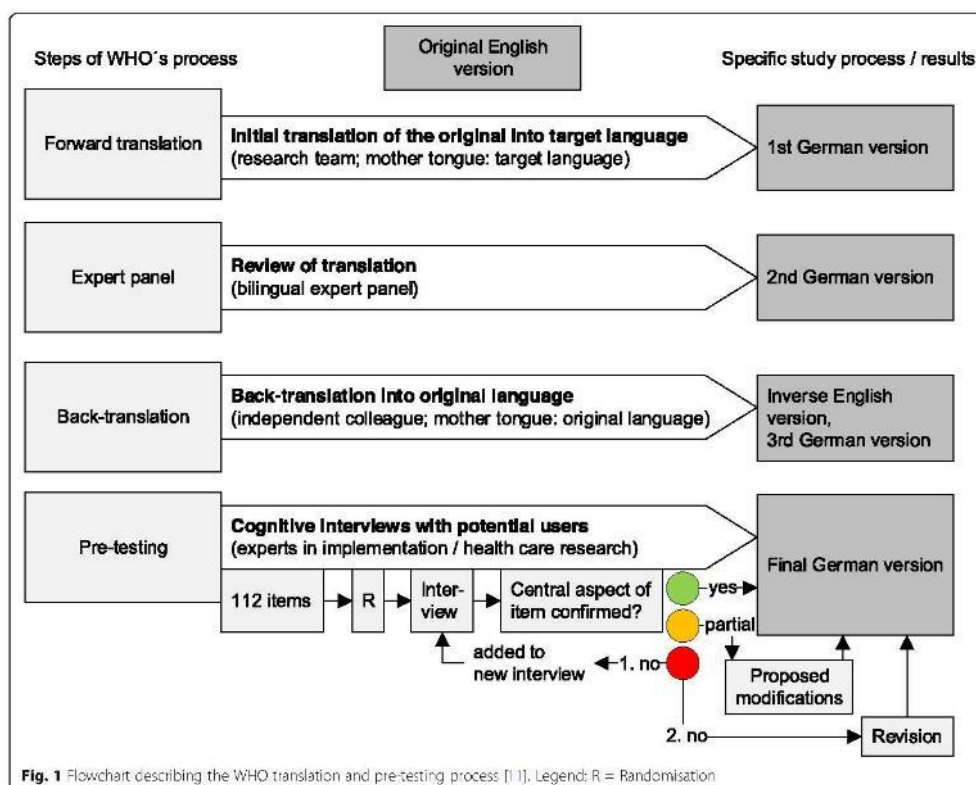
Methods

Study design

We followed the translation process suggested by the *World Health Organisation (WHO)* [11] that comprises forward translation, expert panel discussion, back-translation, and pre-testing (see Fig. 1).

Forward translation

The research team, all familiar with the content of CFIR and ERIC and German native speakers with fluent knowledge of the English language, translated the original English version of CFIR [1] and ERIC [6] into German. The aim was to find conceptually equivalent wordings and phrases.



Expert panel and back-translation

First, a small (unilingual) expert panel with a German-speaking researcher, who already had translated and used a German version of CFIR, and members of the research team was established. Differences between the result of the forward translation of CFIR and the older version were discussed and led to the revision of some items.

Second, a bilingual expert panel discussed both the translation of CFIR and ERIC. The expert panel, which consisted of a collaborating Canadian researcher (TR) with German as his mother tongue and expert command of the English language and one English language expert and university teacher (CC), revised the German translation. They recommended changes of distinct phrases. Inconsistencies were discussed among the research team and the bilingual experts.

The work of the expert panels led to a first German version of CFIR and ERIC.

Back-translation

Back-translation of the instruments into English was conducted by an independent English native-speaking researcher (AP) living and working in Germany for several years. As recommended by the WHO method, the back-translator had no specific knowledge of the instruments. Inconsistencies between the back-translation and the original versions were discussed among the research team using dictionaries and several online translators. This resulted in the second version of the German translation that went into pre-testing with potential users of the tools.

Pre-testing

Research team

VR and ES conducted the individual, semi-structured interviews with experts working in implementation and/or health care research and who could potentially use the translated instruments. The interviewers knew some of

the participants personally. No bias or assumptions are to be reported from the interviewers.

Recruitment and design

We conducted individual semi-structured interviews. Potential participants, in particular health care researchers were recruited from universities and research institutes in German-speaking countries and were approached via e-mail. To limit the burden for the participants, we decided to present only a subset of the items to each participant. Considering a total number of 112 items and an estimated interview time of about 2 min for each item, we predefined a sample size of 12 participants to discuss 10 items per 20-min interview. Items of each instrument were randomised to the number of participants using a computer-generated sequence number (Random Sequence Generator, available at <https://www.random.org/sequences/>). All participants gave written informed consent and filled in a short sociodemographic questionnaire prior to the interview.

Data collection and analysis

Since there was no established strategy for pre-testing or validating of these instruments, we had to develop our own strategy. This contains cognitive interviews that involve a “think-aloud-probing” procedure, in which interviewers instruct participants to verbalise thoughts while answering the posed questions [12]. In parts, we relied on the key stages of cognitive interviewing according to Willis et al. [13]. This full strategy comprised five steps.

Step 1: To warm up with the item during the interview, the interviewees were asked to describe the given definition in their own words.

Step 2: Interviewees were asked to formulate a heading that describes the content best after reading the detailed definitions. The aim of this step was to generate information about the perceived central focus of those items.

Step 3: Then, the translated heading in German was compared with the interviewee-suggested heading and discussed afterwards.

Step 4: To rate this comparison, a traffic light system was used to rate whether our translated heading was perceived as appropriate. In this rating system, “green” means “approved”, “yellow” “partially approved”, and “red” “rejected”. Additionally, text notes were made about why the participants rate “yellow” or “red”.

Step 5: Items rated “green” were immediately considered to be accepted. In the case of “yellow”, the proposed modifications were recorded and discussed within the research team and adapted if the considered modifications were rated to be meaningful. In the case of “red”, the item was re-tested in a second interview.

When the item was then rated as “green”, it was considered approved. In any other case, we revised the item as recommended by the two interviews and amended the heading with our initial translation in brackets.

Interviews were conducted by phone. Researchers had a short interview guide, and questions were allocated by the randomised items per interviewee. The interview guide was pilot tested with two persons and adapted prior to the interviews. Our initial pilot-tests revealed that rating CFIR barriers together with ERIC strategies was too complex and confusing due to the different foci. Thus, we decided to present items of only one respective framework per interview. In our interviews, we provided the example of implementing an electronic assessment system in a general practice or physiotherapy practice to support participants contextualising implementation items.

No repeated interviews were carried out. All interviews were guided and audio-recorded by one of the two experienced research associate (VR or ES). Field notes were made during the interviews. Audio-records were neither transcribed nor coded. Interviews were recorded to be available as backup for the field notes. Field notes were used to categorise items, and percentages of ratings per interview were calculated. Total percentages were calculated using mean values of percentages for each tool.

CFIR-ERIC-Matching Tool

We translated the short instructions of the tool into German and contacted the authors. We inserted the final versions of CFIR and ERIC into the matching tool and checked its function.

Results

Process

Our initial forward translation of each instrument (see Additional file 1) was revised by the expert panel. Recommendations for changes and our decisions for or against changes are described in Additional file 2. The recommendations included correctness and style like using linguistic synonyms, keeping the ideas of “and/or”, using correct grammar and punctuation marks. For example: CFIR; Item no. 2.3: *Peer pressure*. Initial translation: *Druck durch Kollegen*. Recommendation by the expert panel: *Change “Druck durch Kollegen” into “Gruppendruck” because this word is more usual*. All issues could be solved by discussion. Then, these first versions were translated back into the original language (see Additional file 3). Then we compared the original English version to the back-translated version, and synonyms were identified. For example: CFIR; Item no. 1.5: *Trialability*. Backtranslation into original language: *Testability*. ERIC; Item no. 61. Original: *Stage implementation*

scale up; Backtranslation into original language: Proceed step by step with the implementation.

Cognitive interviews

Characteristics of participants

We contacted 12 individuals, all of whom agreed to participate. Mean age of the participants was 36 years, and most of the participants were female ($n = 10$; 83%). All participants had at least a master's degree, and most were working as research associates ($n = 10$; 83%) and had experience in implementation of health care interventions (see Table 1). The interviews lasted between 9 and 36 min.

Findings

In brief, the similar central focus of our German translations of CFIR and ERIC compared to the English original was confirmed in most items.

Among the CFIR items (see Table 2), two items (5%) were rejected in the first round and presented in a second interview. Of these, one item was again rejected, and one was partially approved. In total, 27 items (69%) were approved in the first round. Modifications were proposed for 11 (28%) items. Only one item (3%) had to be revised after pre-testing. Recommendations for modifications can be seen in Additional file 4.

Among the ERIC items (see Table 3), two items were rejected in the first round and accepted in the second round. In summary, 47 items (64%) were approved. No item had to be revised. Modifications were proposed for 26 items (36%). Recommendations for modifications can be seen in Additional file 4.

Final version

After pre-testing, we revised the rejected item, but kept our pre-tested translation in brackets (see Additional file 5). The final versions were agreed upon by all parties involved in the translation process. A German version of CFIR-ERIC-Matching tool is available upon request.

Discussion

Main findings

A German version of two conceptual frameworks for shaping implementation activities in health care, CFIR and ERIC, as well as the corresponding matching tool, are now available.

A rigorous translation and pre-testing process guided us through the WHO translation process to a final version of each framework. The pre-testing process proved to be feasible.

In our initial forward translation, we aimed to keep the original linguistic structure as far as possible. In the expert panel, we discussed alternative translations to items which appeared to be in "Denglish" jargon (a

Table 1 Characteristics of interview participants

	n = 12
Age (years), mean $\pm$ SD	36.3 $\pm$ 7.5
Sex, female/%	10/83
Educational level, n/%	
Master's degree	7/58
Doctoral degree	5/42
Professional position, n/%	
Research associate	10/83
Other, namely:	
Substitute professorship	1/8
Head of nursing development	1/8
Years of experience in implementation research, n/%	
< 2 years	4/33
$\geq$ 2–4 years	3/25
$\geq$ 5–9 years	3/25
$\geq$ 10 years	2/17
Research experience regarding MRC-framework phase (multiple answers possible), n/%	
Development	9/75
Feasibility/piloting	8/67
Evaluation	7/58
Implementation	3/25
None of them	1/8
Number of published papers in implementation research, n / %	
< 2 papers	8/67
> 2–4 papers	3/25
> 5–9 papers	1/8
> 10 papers	0/0
Working experience using implementation research literature in (multiple answers possible), n/%	
Research	10/83
Teaching	6/50
Other, namely:	
Development of care practice	1/8
Not at all	1/8

Legend: SD standard deviation

variety of German containing a high proportion of English words), but accepted English words which are common in German (e.g., CFIR, headings 2 and 3, "Äußeres/Inneres Setting"; ERIC, item 35, "Champions identifizieren und vorbereiten"). Beside this, we also tried to keep a coherent structure of the Original and our German translation as possible. Since we referred to Powell et al. [6] in carrying out our forward translation of ERIC, we did not additionally translate the nine categories outlined in Waltz et al. [5]. When using the CFIR-ERIC-matching tool, the categories above the implementation

Table 2 Results of pre-testing CFIR

Items	approved (n / %)	partially approved	rejected	
1. Round: Randomised items (n = 39)				
37 38 11 15 5 13 23 9 26 4	5 / 50%	4 / 40%	1 / 10%	
14 34 18 24 12 1 31 21 10 8	9 / 90%	0 / 0%	1 / 10%	
7 39 33 28 16 19 22 25 32 35	9 / 90%	1 / 10%	0 / 0%	
29 2 3 17 27 36 6 20 30 -	4 / 44%	5 / 56%	0 / 0%	
Sub-total 1:	27 / 69%	10 / 26%	2 / 5%	
2. Round: Added items (n = 2)				
10 37	0 / 0%	1 / 50%	1 / 50%	
Sub-total 2:	0 / 0%	1 / 50%	1 / 50%	
Final (n = 39)	Total:	27 / 69%	11 / 28%	1 / 3%

Legend: Green = approved, Yellow = partially approved, Red = rejected

strategies appear not crucial to know, but we would recommend its translation when using ERIC itself in a conceptual context.

Faced with the high number of items, the bilingual expert panels were quite time-consuming. Both ERIC and CFIR documents were very detailed, including health care-specific vocabulary, and nuances that required careful translation, all of which led to taking a lot of time. We recommended a considerable number of changes to the early translation.

Regarding back-translation of the instruments, we predominantly found synonyms to the English original.

Close attention was given to the health care-specific vocabulary. This remained a difficult task for the back-translator:

We were not able to identify and use an established strategy for pre-testing or validating these frameworks. A developed checklist in form of a traffic light system to test the usefulness of the translated heading was successful.

The translation and pre-testing process also revealed that even headings in the original version did not comprise the whole content of the detailed definition. For example, CFIR 4.1; Original heading: *Knowledge and*

Table 3 Results of pre-testing ERIC

Items	approved (n / %)	partially approved	rejected										
1. Round: Randomised Items (n = 73)													
44	61	77	107	62	63	51	68	101	60	7 / 70%	3 / 30%	0 / 0%	
58	108	42	100	80	76	97	95	45	103	6 / 60%	4 / 40%	0 / 0%	
84	93	91	90	46	105	89	54	87	72	7 / 70%	2 / 20%	1 / 10%	
83	57	98	109	81	71	111	79	96	41	5 / 50%	5 / 50%	0 / 0%	
74	88	53	106	70	67	40	59	82	48	6 / 60%	4 / 40%	0 / 0%	
104	52	78	92	43	75	64	86	102	55	6 / 60%	4 / 40%	0 / 0%	
49	66	89	94	73	85	110	99	56	65	6 / 60%	3 / 30%	1 / 10%	
47	50	112	-	-	-	-	-	-	-	2 / 62%	1 / 33%	0 / 0%	
Sub-total 1:										45 / 62%	26 / 36%	2 / 3%	
2. Round: Added items (n = 2)													
72	69									2 / 100%	0 / 0%	0 / 0%	
Sub-total 2:										2 / 100%	0 / 0%	0 / 0%	
Final (n = 73)										Total:	47 / 64%	26 / 36%	0 / 0%

Legend: Green colour = approved, Yellow = partially approved; Red = rejected

Beliefs about the Intervention; Original description: *Stakeholders have negative attitudes toward the innovation, they place low value on implementing the innovation, and/or they are not familiar with facts, truths, and principles about the innovation.* Pre-tested description: *Beteiligte haben negative Einstellungen gegenüber der Innovation, sie schreiben ihr geringen Wert zu und/oder sind mit den Fakten, Wahrheiten und Prinzipien der Innovation nicht vertraut*; Pre-tested heading: *Wissen und Überzeugungen über die Innovation*; Selected heading by the interviewee: *Ablehnung der Innovation*; Recommendation of the interviewee: *The negative perception is missing in the original heading.*

Limitations

During the translation, expert panel and back-translation process, several issues were discussed and kept in the original English language to provide a clear and correct message.

In total, 4 of 112 items were discussed in a second interview. This might indicate selection bias in terms of our interview participants (e.g., allocating an item to “yellow” (partly approved) rather than to “red” (rejected) because participants wanted to be perceived as nice). Since we predominantly tested one item per interviewee, a different sample of participants might have rejected more items. Our sample comprised different researchers and academics experienced in specific terms like “evidence” or “validity”. A pre-test with a different sample of non-academic individuals might have led to different results.

Transferring theoretical frameworks from one language to another is challenging beyond the linguistic perspective but also from the perspective of validity since the contained constructs and relationships between them largely depend on context, such as different health care systems. However, since both frameworks are already being used in German health care, we believe that a standardised and agreed on translated version may increase understanding, uptake, transparency, and reproducibility of implementation research in German speaking countries. Moreover, the standard of English may differ widely between healthcare professionals in Germany.

Future applications of the translated German version of CFIR and ERIC should monitor and report problems and limitations and may lead to further revisions.

Conclusions

Both translated frameworks can now be used within implementation research in German-speaking countries. This might improve adherence to evidence-based implementation into practice in German-speaking countries. We recommend a patient version of the translated

implementation frameworks, which use a lay language (not exceeding German 6th class middle school writing).

Abbreviations

CFIR: Consolidated Framework for Implementation Research; ERIC: Expert Recommendations for Implementation Change; WHO: World Health Organisation

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s43058-021-00222-w>.

Additional file 1. Initial forward version
Additional file 2. Summary of recommendations by the expert panel
Additional file 3. Back translation
Additional file 4. Summary of problems found during the pre-testing of the instrument and the modifications proposed
Additional file 5. Final version

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Declarations

Ethics approval and consent to participate

Ethics approval and consent: both implementation frameworks (CFIR and ERIC) have been published in the literature, and are publicly available. The Ethical Committee of the Ludwig Maximilian University of Munich has approved the study protocol under the number 20-601. Moreover, all interviewed participants are close collaborators of the senior author and gave their written informed consent to participate in the interviews.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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