Aus dem Institut für Medizinische Informationsverarbeitung, Biometrie und Epidemiologie (IBE)

Institut der Universität München

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Voraussetzungen für die erfolgreiche Implementierung eines Versorgungspfads für ältere Menschen mit Schwindel und Gleichgewichtsstörungen in der Primärversorgung

Dissertation

zum Erwerb des Doktorgrades der Humanbiologie

an der Medizinischen Fakultät der

Ludwig-Maximilians-Universität zu München

vorgelegt von

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aus

München

2022

Mit Genehmigung der Medizinischen Fakultät
der Universität München

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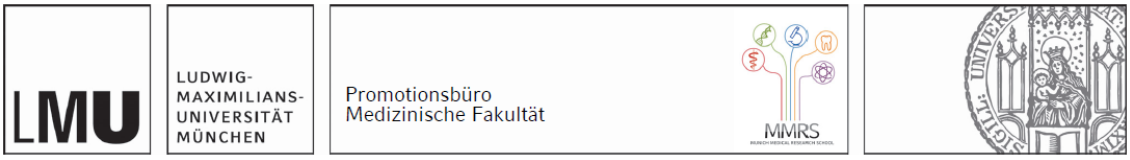

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Abkürzungsverzeichnis

BCW	Behaviour Change Wheel
CBA	Controlled Before-After study
CICI	Context and Implementation of Complex Interventions
COM-B	Capability Opportunity Motivation Behaviour
DHI	Dizziness Handicap Inventory
EQ-5D-5L	EuroQol 5-Dimension 5-Level
IPAQ	International Physical Activity Questionnaire
ITS	Interrupted Time Series
Mini-BEST	Mini-Balance Evaluation Systems Test
MobilE-Net	Münchner Netzwerk Versorgungsforschung
MobilE-PHY	Physiotherapeutische Interventionen für ältere Menschen mit Schwindel und Gleichgewichtsstörungen
MRC	Medical Research Council
NRCT	Non-Randomised Controlled Trial
RCT	Randomised Controlled Trial
UK	United Kingdom

Publikationsliste und Beiträge

Die vorliegende Dissertation umfasst zwei wissenschaftliche Fachartikel, die beide *open-access* in der internationalen *peer-reviewed* Fachzeitschrift BioMed Central Family Practice veröffentlicht wurden:

1. **Seckler E**, Regauer V, Rotter T, Bauer P, Müller M. Barriers to and facilitators of the implementation of multi-disciplinary care pathways in primary care: a systematic review. BMC Family Practice 2020; 21(113). doi:10.1186/s12875-020-01179-w [1] (siehe Anhang A)
   (im nachfolgenden Text als »Publikation Ⅰ« deklariert)

2. **Seckler E**, Regauer V, Krüger M, Gabriel A, Hermsdörfer J, Niemietz C, Bauer P, Müller M. Improving mobility and participation of older people with vertigo, dizziness and balance disorders in primary care using a care pathway: feasibility study and process evaluation. BMC Family Practice 2021; 22(62). doi:10.1186/s12875-021-01410-2 [2] (siehe Anhang B)
   (im nachfolgenden Text als »Publikation Ⅱ« deklariert)

Als Erstautorin der *Publikation Ⅰ* war die Doktorandin hauptverantwortlich für die Konzeption und Durchführung des systematischen Reviews. Dies umfasste insbesondere die Erstellung bzw. Anpassung und Anwendung der Suchstrategie, die Sichtung und Eignungsbewertung der identifizierten Literatur sowie die Extraktion, Analyse, Qualitätsbeurteilung und Synthese der inkludierten Studien. Über alle Forschungsschritte im Rahmen dieser Publikationserstellung koordinierte die Doktorandin bei Bedarf eine Abstimmung mit dem Projektteam.
Die Doktorandin verfasste das Manuskript und unternahm alle Schritte zu dessen Publikation. Auch erstellte sie das Studienprotokoll des systematischen Reviews und registrierte dieses (PROSPERO 2018 CRD42018087689).

Als Erstautorin der *Publikation Ⅱ* war die Doktorandin hauptverantwortlich für die Planung und Durchführung der Prozessevaluation sowie der Machbarkeitsstudie, was neben organisatorischen Vorbereitungen, die Rekrutierung, die Datenerhebung, deren Aufarbeitung (Transkription bei qualitativen Daten) und Analyse umfasste. Exkludiert war hierbei die Auswertung der mittels Aktivitätssensoren, Bewegungstagebuch und dem *International Physical Activity Questionnaire* (IPAQ) erhobenen Daten zur körperlichen Aktivität. Die Doktorandin stimmte die Vorgänge dieser Publikationserstellung bei Bedarf mit dem Projektteam ab.
Die Doktorandin verfasste das Manuskript und unternahm alle Schritte zu dessen Publikation. Weiter erstellte sie das Studienprotokoll der Machbarkeitsstudie und registrierte dieses (Deutsches Register Klinischer Studien: DRKS00022918) sowie das übergeordnete Gesamtprojekt (Projektdatenbank Versorgungsforschung Deutschland: VfD_MobilE-PHY_17_003910).

Im Rahmen ihrer Anstellung als wissenschaftliche Mitarbeiterin an der Technischen Hochschule Rosenheim hat die Doktorandin an allen Projektschritten sowie dementsprechend an weiteren wissenschaftlichen Publikationen als Zweitautorin mitgewirkt.

1. Einleitung

1.1 Hintergrund und Relevanz der Thematik

1.1.1 Bedeutung von Versorgungspfaden

Versorgungspfade beschreiben evidenzbasierte, strukturierte und multidisziplinäre Ablaufpläne, die alle wesentlichen Diagnose- und Behandlungsschritte in der Versorgung definierter Patient*innengruppen mit einem spezifischen gesundheitlichen Problem in zeitlicher Abfolge umfassen. Mit der Implementierung von Versorgungspfaden wird evidenzbasiertes Wissen als letzter konkreter Schritt der Translation von Evidenz in die lokale Versorgungspraxis umgesetzt, und zwar unter Einbezug regionaler Bedingungen und Anforderungen [3, 4]. Durch die Standardisierung des Vorgehens soll der Versorgungsprozess transparent definiert und strukturiert sowie dessen zeitlicher Rahmen optimiert werden. Somit können Varianzen in der Versorgung sowie Behandlungsfehler vermieden und durch einen gezielten Ressourceneinsatz potentielle Effizienzgewinne im Gesundheitssystems erreicht werden [3, 5, 6]. Da die Förderung der Versorgungsqualität und der Patient*innensicherheit als primäres Ziel der Initiativen der Qualitätsverbesserungen gelten [7], können Versorgungspfade eine bedeutsame Komponente in diesem Bestreben einnehmen.
Versorgungspfade werden bereits seit den 1980ern [6] und zunehmend weltweit eingesetzt, jedoch vornehmlich im stationären Umfeld [8]. Obwohl Hausärzt*innen selbst in deren Versorgungsbereich einen hohen Bedarf für Versorgungspfade sehen, finden diese in der Primärversorgung bisher eher selten Anwendung [9]. Auch in diesem Setting könnten Versorgungspfade dazu beitragen, unbeabsichtigte Abweichungen bei der Versorgung von spezifischen Patient*innengruppen zu vermeiden [10, 11].
Aufgrund des erheblichen Einflusses von Kontextfaktoren auf die Wirksamkeit von Versorgungspfaden, können bestehende Interventionen nicht problemlos in andere Settings oder gar in unterschiedliche Ländern übertragen werden [12]. Demzufolge ist es für eine erfolgreiche Intervention essentiell, entsprechende Bedingungen bereits vorab zu berücksichtigten. Auch muss die zugehörige Implementierungsstrategie spezifischen Gegebenheiten, Anforderungen und Kontextfaktoren Rechnung tragen [4].

1.1.2 Schwindel und Gleichgewichtsstörungen im Alter

Mit einer Prävalenz von bis zu 50% [13–16] zählen Schwindel und Gleichgewichtsstörungen zu den häufigsten Beschwerden älterer Menschen [17–20]. Da dies für Betroffene oftmals mit Einschränkungen der Mobilität und der Autonomie im Alltag [21, 22] sowie mit einem erhöhten Sturzrisiko [18] einhergeht, ist dieses Krankheitsbild besonders relevant für die Behinderungslast im Alter in Deutschland [23]. Das Auftreten genannter Symptomatik stellt einen häufigen Konsultationsgrund von Hausärzt*innen dar, wobei die Prävalenz bei bis zu 15,5% im Verhältnis zur Gesamtzahl aller Konsultationen liegt [24]. Ursächlich für Schwindel und Gleichgewichtsstörungen können vestibuläre sowie nicht-vestibuläre Erkrankungen, aber auch durch den Alterungsprozess bedingte multifaktorielle Defizite sein [16, 25–27]. Zuletzt genannte Ätiologie erschwert eine kausale Behandlung deutlich, was insbesondere Hausärzt*innen vor erhebliche Herausforderungen stellt. Resultierend daraus kommt es oftmals zu einer ungezielten und unzureichenden Behandlung Betroffener in der Primärversorgung sowie zu einer damit einhergehenden Überbeanspruchung des Gesundheitssystems [28, 29].
Es besteht eine überzeugende Evidenz für die Wirksamkeit physiotherapeutischer Maßnahmen auf die Symptomatik sowie auf die Mobilität und damit verbunden auf die soziale Teilhabe [30–33] von Menschen mit Schwindel und Gleichgewichtsstörungen. Dennoch waren bisher keine

Bestrebungen erkennbar, entsprechende Interventionen in die Primärversorgung für diese Personengruppe in Deutschland gezielt und strukturiert aufzunehmen [34]. Somit wird eine potentiell effektive Komponente zur Verbesserung der Situation Betroffener unzureichend genutzt. Ein vielversprechendes Konzept zur Integration effektiver physiotherapeutischer Maßnahmen in das genannte Setting, liegt in multidisziplinären Versorgungspfaden.

1.2 Darstellung und Begründung des Forschungsvorhabens

Aufgrund der dargelegten Relevanz der Thematik, liegt das Hauptziel des übergeordneten Forschungsprojekts *Physiotherapeutische Interventionen für ältere Menschen mit Schwindel und Gleichgewichtsstörungen* (MobilE-PHY) als Teilprojekte des *Münchner Netzwerk Versorgungsforschung* (MobilE-Net) in der Entwicklung eines evidenzbasierten multidisziplinären Versorgungspfads. Dieser verbessert die Integrierung wirksamer physiotherapeutischer Maßnahmen in die Versorgung älterer Menschen mit Schwindel und Gleichgewichtsstörungen in der Primärversorgung.
Da ein Versorgungspfad mehrere miteinander interagierende Komponenten umfasst und gleichzeitig unterschiedliche Ziele verfolgt, ist dieser als komplexe Intervention in Sinne des *UK Medical Reseach Councils* (MRC) zu bewerten [35]. Wie in der etablierten *new MRC guidance for process evaluation of complex Interventions* empfohlen, wurde der Wirksamkeitsstudie des genannten Forschungsprojekts eine Machbarkeitsstudie vorangestellt [36]. Hierfür erfolgte die Einführung des entwickelten multidisziplinären Versorgungspfads in die Versorgungspraxis sowie dessen Überprüfung auf Akzeptanz und Durchführbarkeit. Begleitet wurde diese Projektphase durch eine umfassende Prozessevaluation.

Bei einer erfolgreichen Implementierung von Versorgungspfaden handelt es sich um ein anspruchsvolles und wortwörtlich komplexes Unterfangen, das es bestmöglich vorzubereiten gilt. Diesem kommt im vorliegenden Forschungsprojekt aufgrund der innovativen eigens entwickelten Intervention, des bisherigen mangelnden Einsatzes von Versorgungspfaden im Setting der Primärversorgung und der damit einhergehenden begrenzt verfügbaren Erfahrungswerte und Erkenntnisse eine besondere Bedeutung zu. Folglich ist es ein essentieller Teil des Projektes, Bedingungen für eine gelungene Umsetzung von Versorgungspfaden zu untersuchen und zu verstehen. Die eruierten Barrieren und Förderfaktoren können so frühestmöglich berücksichtigt werden.

Das übergeordnete Ziel des Promotionsprojektes ist es, Voraussetzungen für die erfolgreiche Implementierung eines Versorgungspfads für ältere Menschen mit Schwindel und Gleichgewichtsstörungen in der Primärversorgung zu untersuchen. Dieses Forschungsvorhaben beinhaltet folgende spezifische Einzelziele, welche die beiden Veröffentlichungen als Kern der Dissertationsschrift miteinander verbinden:

1. Aufarbeitung vorhandener wissenschaftlicher Evidenz hinsichtlich Barrieren und Förderfaktoren bei der Implementierung von Versorgungspfaden in der Primärversorgung älterer Menschen. *(Publikation I)*
2. Verstehen des Implementierungsprozesses und Untersuchung von Stärken und Schwächen mittels der Bewertung der Durchführbarkeit der entwickelten Intervention, der Implementierungsstrategie und der Studienabläufe.
   Die spezifischen Ziele der Machbarkeitsstudie mit der Prozessevaluation umfassen die Untersuchung und Evaluation

a. der Durchführbarkeit der Studie hinsichtlich des vorgeschlagenen Studiendesigns, insbesondere der Rekrutierung von Hausärzt*innen (Cluster), Physiotherapeut*innen und Patient*innen sowie der Akzeptanz und Eignung der Endpunkte und der Datenerhebungsverfahren.
b. der Durchführbarkeit, Akzeptanz und Anwendbarkeit der Interventionskomponenten.
c. der Durchführbarkeit und Akzeptanz der Implementierungsstrategie durch die Identifikation von Barrieren und Förderfaktoren.
d. unbeabsichtigter Konsequenzen in Prozessen und Ergebnissen der Intervention und ihrer Implementierungsstrategie.

(Publikation II)

Somit hat die Doktorandin mit der Aufarbeitung vorhandener Evidenz mittels eines Systematischen Reviews *(Publikation I)* einen grundlegenden Teil in der Entwicklungsphase des Versorgungspfads übernommen und mit der *Publikation II* die komplette Machbarkeits-/ Pilotierungsphase abgedeckt. Diese beiden wichtigen Schritte der Identifikation verschiedener Voraussetzungen für die erfolgreiche Implementierung sind unabdingbar für die Entwicklung und Einführung eines erfolgreichen Versorgungspfad in die Praxis. Daher werden die hervorgebrachten Ergebnisse als Vorbereitung für die abschließende Studie zum Wirksamkeitsnachweis genutzt.

1.3 Vorstellung der Beiträge

1.3.1 Publikation I: Barriers to and facilitators of the implementation of multi-disciplinary care pathways in primary care: a systematic review

Die *Publikation I* [1] (siehe Anhang A) wurde im Rahmen der Entwicklungsphase erstellt und zielte darauf ab, Barrieren und Förderfaktoren bei der Implementierung von Versorgungspfaden in der Primärversorgung zu identifizieren.

1.3.1.1 Methoden

Basierend auf der Medline-Suchstrategie des Cochrane-Reviews *„Clinical pathways for primary care: effects on professional practice, patient outcomes, and costs“* [4] wurde eine systematische Literaturrecherche über CINAHL, Cochrane Library und MEDLINE über PubMed durchgeführt und um Referenzen der Sichtung grauer Literatur, Handsuche und Zitatverfolgung ergänzt.

Um als Versorgungspfad zu gelten, musste es sich bei den in den Publikationen beschriebenen Interventionen um einen strukturierten und schrittweise untergliederten multidisziplinären Ablaufplan handeln, mittels welchem Evidenz in die lokale Versorgungspraxis übersetzt wird und der auf eine Standardisierung der Versorgung einer definierten Patient*innengruppe mit einem spezifischen Gesundheitsproblem abzielt [4]. Eingeschlossen wurden englisch- und deutschsprachige Artikel, die von mindestens 65-jährigen Patient*innen in der Primärversorgung berichten und zwischen 2007 und 2019 publiziert wurden. Als weiteres Einschlusskriterium wurde das Design randomisierter kontrollierter Studien (RCT) bzw. nicht-randomisierter kontrollierter Studien (NRCT), kontrollierter Vorher-Nachher-Studien (CBA) und Studien mit unterbrochenen Zeitreihen (ITS) festgelegt. Auch wurden die dazugehörigen Prozessevaluationen berücksichtigt.

Titel, Abstracts und Volltexte der identifizierten Studien wurden von zwei Forscherinnen voneinander unabhängig gesichtet und hinsichtlich der Eignung begutachtet. Da Autor*innen die identifizierten Barrieren und Förderfaktoren teilweise nicht im Rahmen der Hauptpublikation, sondern

in einem separaten Artikel veröffentlicht haben, wurden zugehörige Publikationen der Prozessevaluation ermittelt und mit einbezogen.

Ebenso wie die Datenextraktion erfolgte auch die kritische Bewertung der Studien unabhängig von zwei Forscherinnen mittels vorab festgelegter studiendesignspezifischer Instrumente.

Die die Studienmerkmale, Interventionen und Endpunkte der eingeschlossenen Studien betreffende Heterogenität machte eine Meta-Analyse unmöglich, sodass man sich einer narrativen Synthese bediente.

1.3.1.2 Ergebnisse

Von 8.154 identifizierten Artikeln konnten insgesamt sieben Ergebnispublikationen sowie sieben Veröffentlichungen zur Prozessevaluation einbezogen werden. In allen Projekten erfolgte ein Vergleich des Versorgungspfads mit der Standardversorgung. In drei Projekten wurden Patient*innen mit spezifischen gesundheitlichen Problemen [37–39] untersucht, in den Übrigen in der Häuslichkeit lebende Menschen [40–43]. Fünf Projekte fanden in den Niederlanden [38, 39, 41–43] sowie jeweils eines in Kanada [37] und im Vereinigten Königreich [40] statt.

Ebenso wie der Aufbau und die Inhalte der Interventionen variierte auch die Qualität der Studien. Insbesondere fiel in diesem Zusammenhang die unzureichende Berichterstattung auf, wodurch einige Qualitätsaspekte nicht beurteilt werden konnten.

Die in den Projekten beschriebenen Barrieren und Förderfaktoren wurden gemäß der Domänen Kontext, Implementierung und Setting des *Context and Implementation of Complex Interventions* (CICI) *frameworks* [12] klassifiziert. Es konnten überwiegend Faktoren im Bereich der Implementierung identifiziert werden.

Bezogen auf die Domäne Kontext wurden neben fehlenden finanziellen Anreizen und Vergütungen [38, 44, 45] unbeeinflussbare patient*innenbezogene Charakteristika wie Multimorbidität [44–46], ein Alter von über 85 Jahren [44] und mentale Gesundheitsprobleme [47] als potentielle Barrieren für eine erfolgreiche Umsetzung der Intervention identifiziert. Hinzu kommen soziokulturelle Faktoren wie der kulturelle Hintergrund [44, 45], eine geringe Gesundheitskompetenz [45], das Geschlecht [44, 45] und die Anzahl an Besuchen in der Hausärzt*innenpraxis [44, 45] ebenso wie ein geringer sozioökonomischer Status [44, 45].

In der Domäne Implementierung spielen Wissen, Fähigkeiten, Einstellungen und das Verhalten eine bedeutsame Rolle für eine erfolgreiche Interventionsumsetzung. Dementsprechend wurden Fähigkeiten und Kenntnisse der involvierten Gesundheitsprofessionen [44, 45, 48] sowie insbesondere Schulungsmaßnahmen zur Anwendung der Intervention [38, 40, 44] als förderlich hervorgehoben, wobei eine Informationsüberflutung bei dieser Implementierungsstrategie restriktiv wirken kann [48]. Schriftliche Handlungsanweisungen als Anhaltspunkt im Sinne eines unterstützenden Handbuchs konnten ebenfalls als möglicher Förderfaktor beobachtet werden [45]. Mangelnde Kenntnisse in der Umsetzung der Interventionskomponenten [38, 44, 48] sowie unzureichende Erfahrungen und Kompetenzen [48] wurden im Umkehrschluss als potentielle Barrieren einer erfolgreichen Implementierung identifiziert. Hinzu kommen mangelnde Motivation [38], anfängliche Umsetzungsprobleme aufgrund nötiger Änderungen bestehender Routinen [45, 48], eine negative Einstellung gegenüber der Intervention [44] sowie die Verweigerung des Umsetzens einzelner Interventionskomponenten [38, 45]. Eine gute multidisziplinäre Kommunikation und Zusammenarbeit [44, 47, 48] ebenso wie im intraprofessionellen Team [38, 44], klar definierte Rollen und Zuständigkeiten [44, 48] und insbesondere individuell auf die Bedarfe und Wünsche

der Patient*innen zugeschnittene Interventionen [44, 49] hingegen konnten durch die Gesundheitsprofessionen als Förderfaktoren identifiziert werden. Eine mangelnde Einbindung von Gesundheitsprofessionen kann dem Interventionserfolg entgegenwirken [44], wohingegen der Einbezug von pflegenden Angehörigen positiven Einfluss nehmen kann [49]. Bedeutsam ist, dass die Intervention gut in den Arbeitsalltag der involvierten Gesundheitsprofessionen integriert werden kann [45]. Ein hoher Komplexitätsgrad [44, 48] und Zeitaufwand [44, 45, 48] bei der Interventionsanwendung sind als potentielle Barriere zu werten. Aber auch die Patient*innen können den Erfolg der Intervention beeinflussen. Gemäß der Einschätzung der Gesundheitsprofessionen spielt deren Therapietreue [44, 45, 50] eine bedeutende Rolle. Die Patient*innen selbst bewerteten beispielweise einen hohen zeitlichen [48] und bürokratischen Aufwand [40] als Barrieren. An individuelle Bedürfnisse angepasste Maßnahmen [40, 44, 49], eine gute Interaktion im Rahmen von persönlichen Treffen mit den Gesundheitsprofessionen [40, 48] und die zur Verfügungstellung schriftlicher Empfehlungen [40] haben gemäß den Patient*innen eine förderliche Wirkung.

Im der Domäne Setting wurden Mangel an zur Verfügung stehendem Personal [44, 46] bzw. an Mitarbeiter*innen mit entsprechender Qualifikation [44], Zeit [38, 44, 45, 47] oder auch Raum [45, 46] ebenso wie eine Diskontinuität behandelnder Ärzt*innen als potentielle Barrieren identifiziert. Transparente Überweisungsmöglichkeiten gelten als möglicher Förderfaktor [44].

1.3.1.3 Diskussion und Ausblick

Zusammenfassend lässt sich konstatieren, dass es bei der Implementierung von Versorgungspfaden in der Primärversorgung unterschiedliche Barrieren und Förderfaktoren zu berücksichtigen gilt, wobei einige bereits durch die Gestaltung von Interventions- und Implementierungsstrategie beeinflusst werden können.

Bei der Literaturanalyse wurde insbesondere eine erheblich mangelhafte Transparenz und umfassende Beschreibung der Komponenten der Intervention, der zugehörigen Implementierungsstrategien und Kontexte deutlich. Ursächlich für die verbesserungswürdige Berichterstattungsqualität und die Vielzahl an fehlenden Informationen –insbesondere im Sinne von Barrieren und Förderfaktoren– könnte möglicherweise sein, dass Versorgungspfade oftmals nicht als komplexe Interventionen betrachtet werden [5, 51] und diese dementsprechend nicht die spezifischen Entwicklungs- und Evaluationsschritte durchlaufen. Erschwerend hinzu kommt, dass die inkludierten Projekte lediglich in drei unterschiedlichen Regionen durchgeführt wurden, was die Übertragbarkeit der Ergebnisse auf Länder mit einem ähnlichen Gesundheitssystem beschränkt.

Demnach gilt es die Forschung im Bereich der Versorgungspfade in unterschiedlichen Kontexten voranzutreiben und die Qualität in diesem Forschungsbereich zu verbessern. Nur so können verlässliche Erkenntnisse generiert werden, auf denen weitere Projekte aufbauen können und schlussendlich in der Versorgungspraxis von erfolgreichen Interventionen profitiert werden kann.

1.3.2 Publikation Ⅱ: Improving mobility and participation of older people with vertigo, dizziness and balance disorders in primary care using a care pathway: feasibility study and process evaluation

Übergeordnetes Ziel der *Publikation Ⅱ* [2] (siehe Anhang B) war es, den Prozess der Implementierung der entwickelten komplexen Intervention zu verstehen sowie Stärken und Schwächen zu untersuchen und so die anschließende Wirksamkeitsstudie vorzubereiten.

1.3.2.1 Die entwickelte Intervention und Implementierungsstrategie

Der Entwicklungsprozess des Versorgungspfads und der Implementierungsstrategie basierte auf der *new MRC guidance for developing and evaluating complex Interventions* [35] und bediente sich eines Mixed-Method-Designs. Zunächst wurde die aktuelle Evidenzlage hinsichtlich wirksamer physiotherapeutischer Interventionen zur Förderung der Mobilität und sozialen Teilhabe älterer Menschen mit Schwindel und Gleichgewichtsstörungen [52] sowie bezüglich bekannter Barrieren und Förderfaktoren bei der Implementierung von Versorgungspfaden in der Primärversorgung [1] mittels systematischen Reviews erfasst. Anschließend erfolgte die Erhebung aktueller Anforderungen und Bedarfe der an der Primärversorgung von älteren Menschen mit Schwindel und Gleichgewichtsstörung beteiligten Gesundheitsprofessionen mittels Einzel- und Fokusgruppeninterviews. Auch fanden Befragungen Betroffener statt. Basierend auf diesen Ergebnissen wurden in der darauffolgenden Phase die Komponenten des Versorgungspfads und die spezifische Implementierungsstrategie im Rahmen einer multiprofessionellen Konsensuskonferenz sowie anschließenden kleineren Expertenworkshops modelliert [53].

Die multiperspektivisch entwickelte Intervention besteht aus zwei strukturierten Algorithmen in Papierform, genauer gesagt einer Checkliste für Hausärzt*innen, die Schritte der Diagnostik, Behandlung sowie Überweisungsoptionen (Fachärzt*innen und Physiotherapeut*innen) und Zeiträume für Nachuntersuchungen beinhaltet sowie einem evidenzbasierten Leitfaden für Physiotherapeut*innen für die klinische Argumentation und die Behandlung älterer Menschen mit Schwindel und Gleichgewichtsstörungen. Letzterer beinhaltet Informationsbroschüren und Merkblätter für Übungen in der Häuslichkeit für Betroffene.
Der Weg der Patient*innen im Versorgungspfad sowie eine Übersicht über das Zusammenspiel der beiden Komponenten kann Abbildung 1 entnommen werden.

Der zentrale Ansatz der Implementierungsstrategie umfasst spezifische Schulungen zur Interventionsanwendung inklusive der dafür benötigten Fähigkeiten und Kompetenzen für beide Gesundheitsprofessionen. Zusätzlich erhielten die Teilnehmenden unterstützende schriftliche Materialien. Für diese bestand die Möglichkeit, die Dienste einer fachlichen telefonischen Beratungsstelle in Anspruch zu nehmen.

Das dem entwickelten Versorgungspfad zugrundeliegende Wirkungsmodell, welches auf dem *Capability Opportunity Motivation-Behaviour* (COM-B) Modell als zentrales Konzept des *Behaviour Change Wheels* (BCW) [54] beruht, kann Abbildung 2 entnommen werden.

1.3.2.2 Methoden

Die Machbarkeitsstudie wurde als prospektive Kohortenstudie, die den Interventionsarm eines Cluster-RCTs simuliert, durchgeführt. Um ein tieferes Verständnis für die Funktionsweise der Intervention generieren zu können, wurde dieser Schritt durch eine Prozessevaluation begleitet. Diese bediente sich eines Mixed-Methods-Ansatzes und berücksichtigte durch die Involvierung aller relevanten Beteiligten unterschiedliche Perspektiven.

Teilnehmende waren Hausärzt*innenpraxen (Cluster) aus Südbayern. Einschlusskriterien waren deren Berufserfahrung mit Patient*innen mit Schwindel und Gleichgewichtsstörungen sowie eine Kassenzulassung. Die Hausärzt*innen wurden über eine Datenbankrecherche ausfindig gemacht, telefonisch zur Teilnahme eingeladen und in einem persönlichen Gespräch vor Ort über die Studienteilnahme informiert.
Patient*innen kamen als potentielle Teilnehmende in Frage, wenn sie mindestens 65 Jahre alt waren und bei ihrem*ihrer Hausärzt*in innerhalb der vergangenen drei Jahre mit Schwindel und Gleichgewichtsstörungen vorstellig geworden sind. Patient*innen durften keinen gesetzlichen

Vormund haben, mussten über ausreichende Deutschkenntnisse verfügen und dazu fähig sein 10 Meter weit –mit oder ohne Hilfsmittel– zu gehen. Hausärzt*innen identifizierten geeignete Patient*innen über ihre Praxissoftware und ließen ihnen die bereitgestellten Unterlagen für Teilnehmende zukommen.
Gemäß Empfehlungen der Hausärzt*innen sowie einer ergänzenden regionalen Recherche wurden nahegelegene Physiotherapiepraxen identifiziert, telefonisch zur Teilnahme eingeladen und anschließend per E-Mail näher informiert. Für diese galten dieselben Einschlusskriterien wie für die Hausärzt*innen.

Zu Studienbeginn (T0), nach sechs (T1) und 12 (T2) Wochen wurden unterschiedliche Endpunkte erhoben. Als primärer Endpunkt wurde der Einfluss von Schwindel und Gleichgewichtsstörungen auf die Aktivitäten des täglichen Lebens mittels dem *Dizziness Handicap Inventory* (DHI) erfasst [55]. Die sekundären Endpunkte wurden mittels dem *Mini-Balance Evaluation Systems Test* (mini-BEST) [56], dem *EuroQol 5-Dimension 5-Level* (EQ-5D-5L) Fragebogen [57] sowie mithilfe zwei gleichzeitig an mindestens fünf aufeinanderfolgenden Tagen zu tragenden Aktivitätssensoren (Move4, StepWatch4) erhoben. Ergänzt wurde die Erfassung der Bewegungsprofile durch ein von den Patient*innen zu führendes Tagebuch über körperliche Aktivitäten und das Auftreten von Symptomen sowie durch den IPAQ [58]. Der Fragebogen war zu vier Messzeitpunkten (vor der Baselineerhebung sowie jeweils eine Woche nach T0, T1, T2) auszufüllen.

Der Aufbau der Prozessevaluation basierte auf den Bereichen Implementierung, Wirkungsmechanismus und Kontext gemäß der *new MRC guidance for process evaluation of complex interventions* [36] sowie dem *framework for design and reporting of process evaluations* nach Grant et al. [59]. So erfolgte eine Untergliederung in die Teilbereiche der Rekrutierung, der Weitergabe an die Teilnehmenden und deren Resonanz, des Kontextes und unbeabsichtigter Konsequenzen. Die Durchführbarkeit der Endpunktmessungen sowie der Datenerhebungsverfahren wurden ergänzend aufgenommen.
Die entsprechenden Daten wurden mittels kontinuierlicher Feldnotizen, standardisierter Fragebögen, semistrukturierter telefonischer Einzelinterviews mit allen Teilnehmenden sowie eines Gruppeninterviews mit Hausärzt*innen erhoben.

Die Analyse standardisierter Daten erfolgte mithilfe deskriptiver Statistik, die der aufgezeichneten und nach Kuckartz [60] transkribierten qualitativen Interviews anhand der durch zwei Forscherinnen durchgeführten deskriptiver Inhaltsanalyse [61, 62]. Die Auswertung der Feldnotizen und des Tagebuchs wurde ebenfalls qualitativ vorgenommen. Die Analyse der Aktivitätssensoren fand in einem mehrstufigen Prozess unter Zuhilfenahme spezifischer Software statt.

Nähere Informationen zum Ablauf der Prozessevaluation in der Machbarkeitsstudie können Abbildung 3 entnommen werden.

1.3.2.3 Ergebnisse

Durchführbarkeit der Studie

Rekrutierung

Insbesondere die Rekrutierung der Hausärzt*innen erwies sich als schwierig. Daher konnten trotz einer persönlichen Projektvorstellung vor Ort insgesamt lediglich sieben Personen aus fünf Praxen für die Teilnahme gewonnen werden. Es schlossen davon jedoch alle die Studie ab. Gründe für die Nichtteilnahme wurden überwiegend nicht angegeben. Interesse an der Thematik, das Bestreben einer Verbesserung der Behandlungsqualität sowie die Möglichkeit zum intraprofessionellen Austausch hingegen motivierten zur Teilnahme.

Die Teilnahmebereitschaft der Physiotherapeut*innen lag bei 39%, sodass insgesamt 11 Therapeuten aus 10 Praxen eingeschlossen werden konnten. Zumeist sagten potentielle Teilnehmende aufgrund fehlenden Interesses und Zeitmangels ab.

Die Rekrutierung und das Erreichen der Patient*innen wiesen einige Probleme auf, insbesondere da die Hausärzt*innen deutlich verspätet mit der Identifikation potentiell geeigneter Personen begannen. 6% der Patient*innen wurden im direkten Gespräch für die Studienteilnahme gewonnen und nicht wie geplant über die Praxissoftware ausfindig gemacht. Teilweise kontaktierten Hausärzt*innen entgegen den festgelegten Einschlusskriterien auch ungeeignete Personen. Insgesamt willigten 32% der angefragte Patient*innen in die Studienteilnahme ein. Dies entspricht 22 Patient*innen (Durchschnittsalter: 78,7 Jahre; 64% Frauen), was unter der geplanten Teilnehmendenzahl von 25 bis 60 Patient*innen liegt. Als ursächlich für die geringe Motivation vermuteten die Hausärzt*innen den hohen Zeitaufwand der Studienteilnahme, eine mögliche Überforderung oder Bedenken bezüglich der Aktivitätssensoren und eine Resignation hinsichtlich vorhandener Symptome. 91% der Patient*innen schlossen die Studie ab.

Endpunktmessung und Datenerhebungsverfahren

Aufgrund von Mobilitätseinschränkungen und dem allgemeinen Gesundheitszustand entschied sich die Mehrheit der Patient*innen für eine Datenerhebung zuhause. Diese schätzten den Aufwand der Studienteilnahme als eher gering ein, ebenso wie den Schwierigkeitsgrad der Fragebögen, obwohl teilweise Unterstützung beim Ausfüllen –insbesondere beim IPAQ– benötigt wurde. Auch die Durchführung des mini-BEST bewerteten Patient*innen als machbar, jedoch waren einige Betroffene z.B. durch Tagesschwankungen verunsichert. Barrieren bei der Anwendung in der Häuslichkeit lagen in beengten Räumlichkeit und Stolperfallen. Die Grundqualifikation der Studienassistentin als Physiotherapeutin hingegen vermittelte Sicherheit.
Das Tragen beider Aktivitätssensoren war für die Patient*innen im Alltag zumeist ohne Einschränkungen möglich, wobei sich der Sensor Move4 als anwenderfreundlicher erwies und die unterschiedlichen Formen der körperlichen Aktivität besser repräsentierte.
Das Bewegungstagebuch wurde zwar als verständlich, jedoch als eher zeitaufwändig empfunden. Bedingt durch Einschränkungen des Sehens oder Schreibens, nahmen wenige Betroffene dafür Unterstützung in Anspruch.

Alle Hausärzt*innen füllten die benötigten Fragebögen aus und ließen dem Forschungsteam die bearbeitete Checkliste von 91% der Patient*innen zukommen.
Zwar berichteten die Hausärzt*innen, dass zusätzliches Büropersonal für die Identifikation potentieller Patient*innen sowie Zeit für die Studienteilnahme nötig sei, sich diese jedoch entsprechend organisiert haben und die Studienteilnahme folglich gut in den Praxisalltag integrierbar scheint.

Alle Physiotherapeut*innen füllten die erforderlichen Fragebögen aus und sendeten die Leitfäden sowie in 85% die zusätzliche Behandlungsdokumentation ein.
Physiotherapeut*innen bewerteten den organisatorischen sowie zeitlichen Aufwand der Studie als begrenzt und die Teilnahme als gut in den Praxisalltag integrierbar.

Alle Studienteilnehmenden nahmen wie geplant an den Einzel-Telefoninterviews teil und nutzen –ebenso wie Angehörige der Patient*innen– die Telefon-Hotline des Studienzentrums rege, was auf eine gute Durchführbarkeit und Akzeptanz des Ansatzes schließen lässt.

Durchführbarkeit der Intervention und der Implementierungsstrategie

Kontext

Patient*innen betonten die Unterstützung durch Angehörige als förderlich, wohingegen Einschränkungen des Sehens oder Schreibens als hinderlich bewertet wurden. Gemäß Hausärzt*innen waren eine mangelnde Therapietreue der Betroffenen und deren unzureichendes Bewusstsein über die Interventionswirkung Barrieren.

Eine positive Einstellung gegenüber der Intervention, Motivation, die Unterstützungsmöglichkeit durch die telefonische Beratungsstelle sowie insbesondere die Vertrautheit im Umgang mit der Intervention der Gesundheitsprofessionen wurden als Förderfaktoren beschrieben. Unzureichender interdisziplinärer Austausch ebenso wie organisatorische Aspekte in Sinne von Zeitmangel im Praxisalltag, langen Wartezeiten für Termine bei der Physiotherapie oder Fachärzt*innen oder kurzen physiotherapeutischen Behandlungseinheiten wurden hingegen als Barrieren eingestuft.

Weitergabe der Intervention an die Teilnehmenden und deren Resonanz

Die Hausärzt*innen waren äußerst zufrieden mit der Schulung, insbesondere mit den praktischen Übungen und der kleinen Gruppengröße. Diese fühlten sich gut auf die praktische Anwendung der Checkliste vorbereitet. Jedoch hätten teilnehmende Hausärzt*innen zusätzlich eine praktische Interventionsanwendung anhand eines Fallbeispiels sowie weitere ergänzende Materialien im Sinne einer Zusammenfassung der Untersuchungsverfahren mit bildhaften Veranschaulichungen oder im Videoformat begrüßt.

Die Hausärzt*innen brachten unterschiedliche Verbesserungsvorschläge der Checkliste an, wie detailliertere Empfehlungen und Ausfüllanweisungen sowie gegebenenfalls ein elektronisches Format.

Abweichungen vom Interventionsprotokoll entstanden durch den Zeitpunkt der Anwendung der Checkliste, da einige Hausärzt*innen diese entgegen den Vorgaben bereits vor der Baselineerhebung und überwiegend nicht zu allen drei erforderlichen Terminen einsetzten. Erschwerend kamen die teilweise differierenden Erwartungen der Hausärzt*innen an die Intervention im Vergleich zu den angestrebten Zielen der Interventionsentwickler*innen hinzu. Die Hausärzt*innen erhofften sich eine weitumfassende Abhandlungsbeschreibung mit ausführlicheren Angaben zur Anamnese und Diagnosestelle anstelle einer kurzen zeitsparenden Checkliste.

Insgesamt erhielten 64% der Patient*innen eine Überweisung zur Physiotherapie und 46% zu Fachärzt*innen. Überwiegend fand kein interdisziplinärer Austausch statt.

Aufgrund des anfänglich hohen Zeitaufwands der Checklistenanwendung fanden die Termine außerhalb der üblichen Sprechzeiten statt. Eine zunehmende Routine erwies sich als förderlich für die Durchführung im Alltag.

Trotz der geäußerten erforderlichen Anpassungen sehen die Hausärzt*innen einen Mehrwert im standardisierten Vorgehen der Intervention, da ihnen dieses Sicherheit im Handeln gibt.

Auch für die Physiotherapeut*innen war die Schulung zur vollsten Zufriedenheit. Insbesondere die zusätzlichen Informationsmaterialien erachteten diese als gewinnbringend. Jedoch hätten sie sich weitere Zusammenfassungen oder Videoanleitungen zum Behandlungsvorgehen gewünscht.

Die Physiotherapeut*innen waren mit den Inhalten und der Struktur des Leitfadens zufrieden und wendeten diesen bei allen Patient*innen, zumeist im Rahmen einer Behandlungseinheit an.

Alle Physiotherapeut*innen sahen einen Mehrwert in der Intervention, besonders durch das strukturierte Vorgehen und die damit verbundene Zeitersparnis. Der Leitfaden war für sie gut in den Alltag integrierbar, wobei praktische Übung in der Anwendung förderlich wirkte.

Obwohl beide Gesundheitsprofessionen die eingerichtete fachliche telefonische Beratungsstelle sehr begrüßten, wurde diese kaum genutzt.

Die Patient*innen waren mit der ärztlichen und physiotherapeutischen Behandlung zufrieden. Sie bewerteten das Merkblatt zu den Übungen als altersgerecht und verständlich. Die Umsetzbarkeit der Aufgaben in der eigenen Häuslichkeit beurteilten diese als gut machbar, wobei zwei Personen dabei durch Angehörige unterstützt wurden. Überwiegend führten Patient*innen die Übungen regemäßig geleitet durch die Hoffnung auf Symptomlinderung durch; wenige Betroffene hingegeben gaben an, zu wenig Zeit dafür zu haben oder die Aufgaben schlichtweg im Alltag zu vergessen.
Laut der Patient*innen selbst lagen Gründe für deren Ablehnung einer Überweisung zur Physiotherapie in mangelndem Interesse oder im aktuellen Fokus auf andere Gesundheitsprobleme. Hausärzt*innen schätzten eine geringe Motivation oder das mangelnde Bewusstsein über die Wirkung dieser Therapieform als potentielle Barrieren ein.

Unerwünschte Konsequenzen
Alle involvierten Personen erfuhren keine unerwünschten Wirkungen durch die Interventionsanwendung.

1.3.2.4 Diskussion und Ausblick

Trotz der positiven Ergebnisse zur Durchführbarkeit des entwickelten Versorgungspfads, konnten aus dieser Studie relevante Erkenntnisse zu potentiellen Erschwernissen sowie Optimierungsbedarfen der Intervention, der Implementierungsstrategie und der Studienorganisation gezogen werden. Limitierend hierbei sind mögliche Verzerrungen aufgrund der kleinen Studienpopulation zu beachten.
Gleichwohl der wie geplant umgesetzten und der durch die Gesundheitsprofessionen als positiv wahrgenommenen Weitergabe der Intervention, gab es seitens der Hausärzt*innen Schwierigkeiten bei der Einhaltung des Studien- und Interventionsprotokolls und somit bei der Umsetzung bei den Patient*innen. Zur Förderung der Umsetzung der Vorgaben könnte ein engeres Monitoring sowie ein stetiger enger Austausch zwischen den Teilnehmenden und dem Forschungsteam hilfreich sein, was auch die aufgetretenen Rekrutierungsprobleme vermeiden könnte. Ferner ist dazu eine Überarbeitung der Checkliste, die Einführung zusätzlicher unterstützender Materialien und der stärkere Einbezug praktischer Übung zur Interventionsanwendung erforderlich. Auch gilt es in der anschließenden Wirksamkeitsstudie die multidisziplinäre Kommunikation zu fördern, die trotz der anfänglichen hohe Bedeutungszumessung kaum stattfand. Selbiges gilt für den sich als positiv erwiesenen Einbezug von Angehörigen. Im Rahmen der Datenerhebung sind kleinere Anpassungen erforderlich.
Die Erkenntnisse dieser Machbarkeitsstudie ermöglichen eine Weiterentwicklung der Intervention, der Implementierungsstrategie sowie der Studienplanung. Basierend darauf kann der angepasste Versorgungspfad in einem nachfolgenden Cluster-RCT auf Wirksamkeit geprüft werden.

2. Zusammenfassung

Mit der Implementierung von Versorgungspfaden kann evidenzbasiertes Wissen unter Berücksichtigung spezifischer kontextualer Anforderungen in lokale Versorgungsstrukturen umgesetzt werden. Das übergeordnete Forschungsprojekt bedient sich diesem Ansatz, um mobilitäts- und teilhabeförderliche physiotherapeutische Interventionen für ältere Menschen mit Schwindel und Gleichgewichtsstörungen in die Primärversorgung zu integrieren. Ziel vorliegenden Promotionsprojektes ist es, die Voraussetzungen für die erfolgreiche Implementierung eines Versorgungspfads für diese Personengruppe im genannten Setting zu untersuchen.

Konform mit der *new MRC guidance for developing and evaluating complex interventions* liegt ein essentieller Schritt in der Aufarbeitung vorhandener wissenschaftlicher Evidenz. Trotz der Relevanz von Versorgungspfaden in der Primärversorgung stellt das durchgeführte systematische Review *(Publikation Ⅰ)* gemäß unserem Kenntnisstand die erste publizierte Forschungsarbeit zu dieser Thematik dar. Methodisch wurde hierfür eine Literaturrecherche über CINAHL, Cochrane Library und MEDLINE über PubMed durchgeführt; neben der Publikation der Hauptstudien (RCT, NRCT, CBA, ITS) wurden die dazugehörigen Prozessevaluationen mittels narrativer Synthese analysiert. Es konnten in allen Domänen des *CICI frameworks* beeinflussende Faktoren identifiziert werden. So sind Personal- und Zeitmangel, unzureichende Qualifikation und Motivation der Gesundheitsprofessionen, zeitintensive und komplexe Interventionskomponenten sowie fehlende finanzielle Anreize Barrieren. Schulungsmaßnahmen sowie Kenntnisse und Fähigkeiten der Interventionsanwender*innen und eine gute multidisziplinäre Kommunikation sind für eine erfolgreiche Implementierung förderlich. Die Literaturanalyse zeigte eine verbesserungswürdige Praxis der Berichterstattung, was erhebliche Wissenslücken bedingt. Die Übertragbarkeit der Ergebnisse auf Regionen mit anderen Gesundheitssystemen ist beschränkt, da die eingeschlossenen Projekte lediglich in drei unterschiedlichen Ländern durchgeführt wurden.

Die entwickelte Intervention und die geplanten Studienabläufe wurden in einer Machbarkeitsstudie auf Akzeptanz und Durchführbarkeit untersucht *(Publikation Ⅱ)*. Teilnehmende waren fünf Hausärzt*innenpraxen, 10 Physiotherapiepraxen und 22 Patient*innen. Als Endpunkte dieser prospektiven Kohortenstudie wurden Daten mittels Fragebögen (DHI, EQ-5D-5L, IPAQ), Performancetest (mini-BEST), Aktivitätssensoren (Move4, StepWatch4) und einem Bewegungstagebuch erhoben; für die Prozessevaluation kontinuierliche Feldnotizen, standardisierte Fragebögen und semistrukturierte Interviews. Eine positive Einstellung gegenüber der Intervention, Anwendungsroutine und die Unterstützung durch Angehörige wirkten förderlich, Zeitmangel hingegen hinderlich. Trotz der guten Bewertung der Schulungen hatten Hausärzt*innen Schwierigkeiten bei der Einhaltung des Studien- und Interventionsprotokolls. Hinsichtlich der physiotherapeutischen Maßnahmen erwies sich die Behandlungstreue der Patient*innen als gut. Trotz der sorgfältig entwickelten Intervention und Implementierungsstrategie, konnte ein Optimierungsbedarf identifiziert werden. Dennoch sahen alle Teilnehmenden einen Mehrwert in der Intervention.

Zusammenfassend lässt sich konstatieren, dass für eine erfolgreiche Implementierung von Versorgungspfaden in der Primärversorgung frühestmöglich unterschiedlichste Voraussetzungen zu berücksichtigen sind. Um von den vielversprechenden Vorteilen in der Praxis zu profitieren, ist ein sorgfältiger Interventionsaufbau und ein gezieltes Implementierungsvorgehen essentiell. Die Forschung ist in diesem Bereich weiter voranzutreiben, vorwiegend in bisher unzureichend erforschten Settings und Regionen. Zudem bedarf es einer Verbesserung der Forschungsqualität und Berichterstattung.

3. Summary

By implementing care pathways, evidence-based knowledge can be translated into local care structures, taking into account specific contextual requirements. The superordinate research project makes use of this approach to integrate physiotherapeutic interventions promoting the mobility and participation of older people with vertigo, dizziness and balance disorders in primary care. The aim of this PhD project is to investigate the conditions for the successful implementation of a care pathway for this target group in the setting mentioned.

In line with the *new MRC guidance for developing and evaluating complex interventions*, an essential step is the review of existing scientific evidence. Despite the relevance of care pathways in primary care, our systematic review *(publication Ⅰ)* is, to the best of our knowledge, the first published research on this topic mentioned. Methodologically, a literature research was conducted via CINAHL, Cochrane Library and MEDLINE via PubMed; in addition to the publication of the main project reports (RCT, NRCT, CBA, ITS), the associated process evaluations were analysed by using narrative synthesis. Influencing factors were identified in all domains of the *CICI framework*. Thus, a lack of staff and time, insufficient qualification and motivation of health professionals, time-consuming and complex intervention components and a lack of financial incentives are barriers. Training activities as well as knowledge and skills of the end-users and good multi-disciplinary communication are beneficial for a successful implementation. The literature review indicated that the reporting practice needs to be improved, which results in considerable knowledge gaps. The transferability of the results to regions with different health care systems is limited, as the projects included were only conducted in three different countries.

The developed intervention and the planned study procedures were examined for acceptability and feasibility in a feasibility study *(publication Ⅱ)*. Participants were five general practitioner practices, 10 physical therapy practices and 22 patients. The outcomes of this prospective cohort study were data collected by questionnaires (DHI, EQ-5D-5L, IPAQ), a performance test (mini-BEST), activity sensors (Move4, StepWatch4) and a physical activity diary; for process evaluation continuous field notes, standardised questionnaires and semistructured interviews. A positive attitude towards the intervention, application routine and support by the patients relatives have a beneficial effect on the success of the intervention, and lack of time has a restrictive effect. Despite the good evaluation of the trainings, general practitioners had difficulties adhering to the study and intervention protocol. The patients' adherence to physical therapy was good. Despite the carefully developed intervention and implementation strategy, a need for optimisation was identified. Nevertheless, all participants saw a benefit in the intervention.

In summary, for the successful implementation of care pathways in primary care, a variety of conditions must be taken into account as early as possible. To benefit from their promising advantages in practice, a careful intervention design and a targeted implementation procedure are essential. It is important to advance research in this area, especially in settings and regions that have not been adequately researched thus far. There is also a need to improve the quality of research and reporting.

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Abbildungen

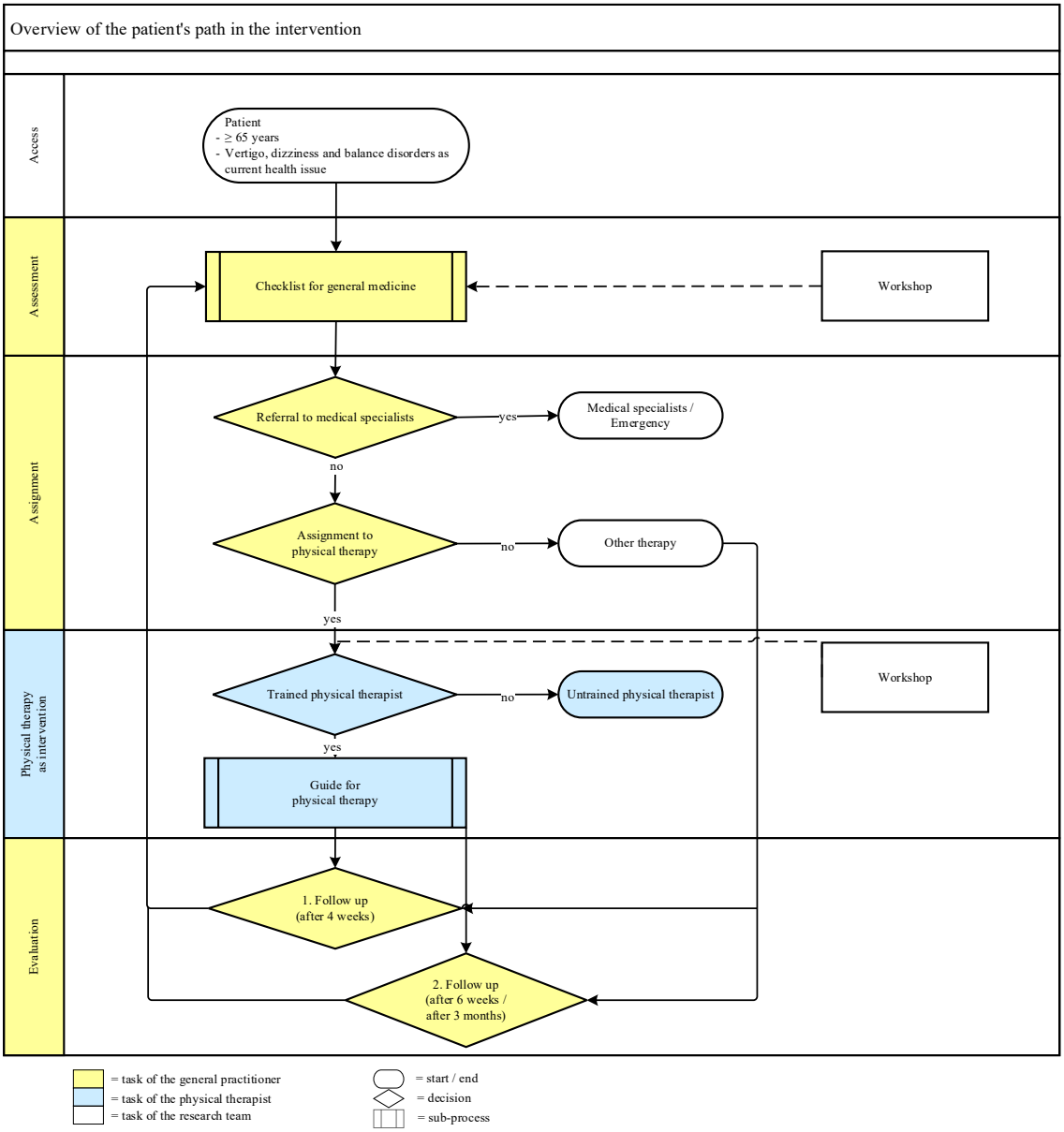

Abbildung 1 Der Weg von Patient*innen im Versorgungspfad [2]

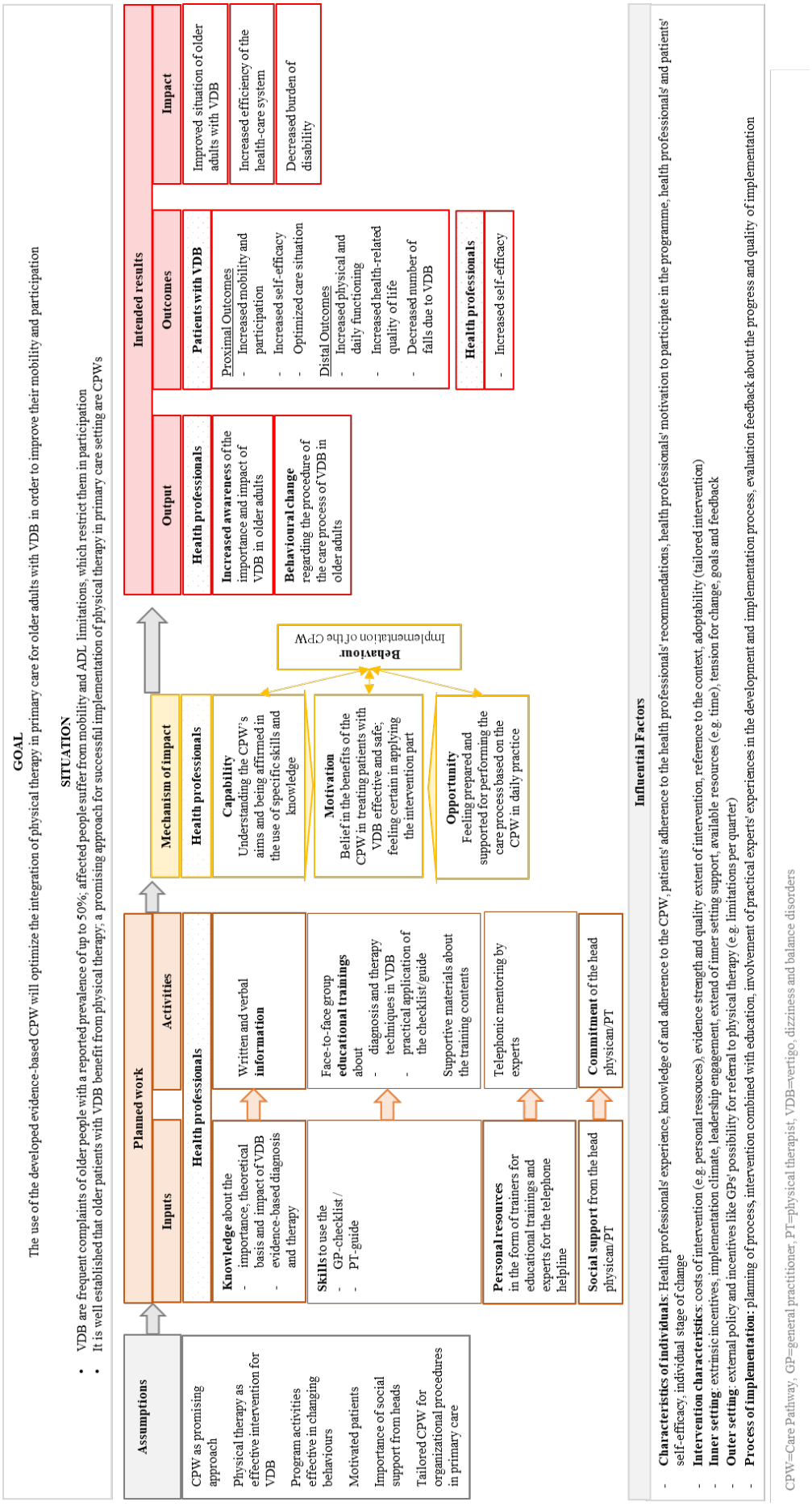

Abbildung 2 Wirkungsmodell des entwickelten Versorgungspfads [2]

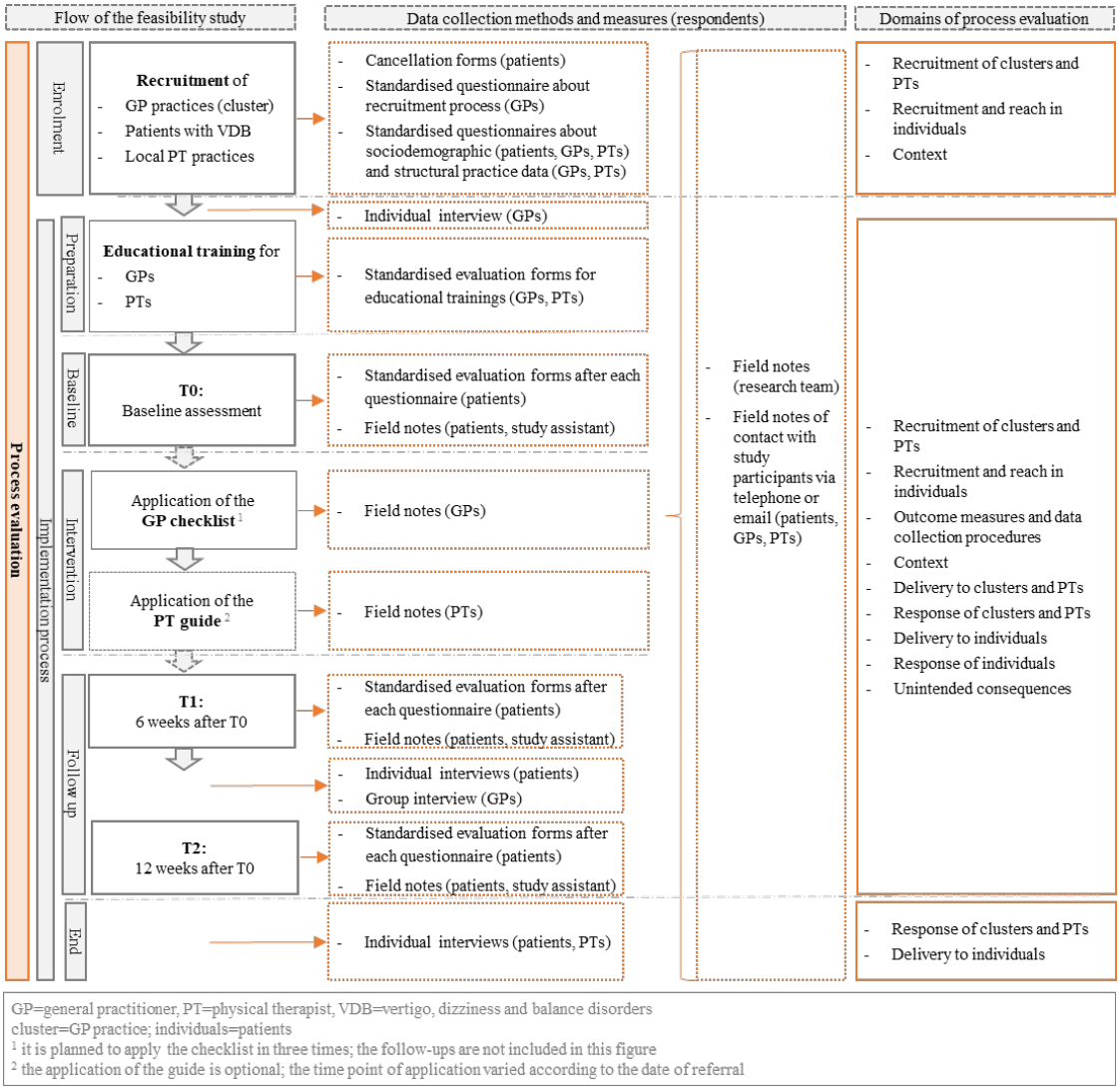

Abbildung 3 Ablauf der Prozessevaluation in der Machbarkeitsstudie [2]

Anhang A: Publikation I

Seckler E[1,2], Regauer V[1,2], Rotter T[3], Bauer P[1,4], Müller M[1,4]. Barriers to and facilitators of the implementation of multi-disciplinary care pathways in primary care: a systematic review. BMC Family Practice 2020; 21(113). doi: 10.1186/s12875-020-01179-w.

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Received: 24 January 2020; Accepted: 28 May 2020; Published online: 19 June 2020

Seckler et al. BMC Family Practice (2020) 21:113
https://doi.org/10.1186/s12875-020-01179-w

BMC Family Practice

RESEARCH ARTICLE Open Access

Barriers to and facilitators of the implementation of multi-disciplinary care pathways in primary care: a systematic review

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Abstract

Background: Care pathways (CPWs) are complex interventions that have the potential to reduce treatment errors and optimize patient outcomes by translating evidence into local practice. To design an optimal implementation strategy, potential barriers to and facilitators of implementation must be considered.
The objective of this systematic review is to identify barriers to and facilitators of the implementation of CPWs in primary care (PC).

Methods: A systematic search via Cochrane Library, CINAHL, and MEDLINE via PubMed supplemented by hand searches and citation tracing was carried out. We considered articles reporting on CPWs targeting patients at least 65 years of age in outpatient settings that were written in the English or German language and were published between 2007 and 2019. We considered (non-)randomized controlled trials, controlled before-after studies, interrupted time series studies (*main project reports*) as well as associated *process evaluation reports* of either methodology. Two independent researchers performed the study selection; the data extraction and critical appraisal were duplicated until the point of perfect agreement between the two reviewers. Due to the heterogeneity of the included studies, a narrative synthesis was performed.

Results: Fourteen studies (seven main project reports and seven process evaluation reports) of the identified 8154 records in the search update were included in the synthesis. The structure and content of the interventions as well as the quality of evidence of the studies varied.
The identified barriers and facilitators were classified using the *Context and Implementation of Complex Interventions framework*. The identified barriers were inadequate staffing, insufficient education, lack of financial compensation, low motivation and lack of time. Adequate skills and knowledge through training activities for health professionals, good multi-disciplinary communication and individual tailored interventions were identified as facilitators.

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(Continued from previous page)
Conclusions: In the implementation of CPWs in PC, a multitude of barriers and facilitators must be considered, and most of them can be modified through the careful design of intervention and implementation strategies. Furthermore, process evaluations must become a standard component of implementing CPWs to enable other projects to build upon previous experience.
Trial registration: PROSPERO 2018 CRD42018087689.

Keywords: Systematic review, Critical pathways, Primary health care, General practitioners

Background

A care pathway or clinical pathway (CPW) is an evidence-based structured multi-disciplinary care plan that describes all relevant diagnostic and therapeutic steps in the care of patients with a specific health problem in chronological order. A CPW is used to translate evidence into local practice by considering regional conditions and demands [1, 2] as the final step of implementing evidence-based knowledge into practice. Due to the standardization of care, a CPW has the potential to reduce treatment errors, impact patient outcomes and quality of care and increase the effectiveness of health care systems [1, 3]. CPWs have been implemented in international practice since the 1980s [4] and are increasingly being used worldwide, especially in inpatient care in Australia, the USA, Canada, Europe and Asia [5], for example, with the HEART Pathway [6], the Liverpool CPW for patients with cancer [7] or CPWs for total knee arthroplasty in surgery [8]. Due to the epidemiological and demographic changes in the Western world, primary health care systems must change, and it is important to align quality of care and evidence-based practice with economic aspects and patients' expectations. CPWs might be an answer to addressing unwanted variation in primary care (PC) that hampers reliable, patient-centred evidence-based care [9, 10]. However, there is still low utilization of CPWs in PC, even though general practitioners (GPs) see them as highly relevant [11]. Based on the important influence of contextual factors on the effectiveness of complex interventions [12] there is a low transferability of CPWs across different countries and settings when not understood adequately and reported in and adequate manner. The same applies to implementation strategies which have to be tailored and adapted to the different demands and contexts, e.g. of outpatient and inpatient care settings [2].

To develop successful implementation strategies for CPWs in PC, information about potential barriers and facilitators should be taken into account. Thus, our review addresses the following review question: Which barriers and facilitators to implementing multi-disciplinary CPWs for people aged ≥65 years in PC have been reported in the literature?

Since aged people often suffer from multimorbidity and therefore have special demands, we decided to focus on this particularly vulnerable group in PC. Vertigo, dizziness and balance disorders as frequent complaints of older people [13–16], for example, are a common reasons for their consultation in general practice [17]. Due to multifactorial etiology [18–21], the overutilization of health care in affected patients insufficiently treated in PC has been shown [22, 23].

Methods

Search strategy

A systematic search of literature was carried out in three electronic databases, Cochrane Library, CINAHL, and MEDLINE via PubMed. Additional sources were identified via hand searches, citation tracing and internet searches for grey literature. The initial search took place in December 19th, 2017, and a search update was conducted in July 15th, 2019. The search strategy was based on the Medline search strategy used for a Cochrane review titled *Clinical pathways for primary care: effects on professional practice, patient outcomes, and costs* [2], which is currently available as protocol.

An overview of all search strategies used, terms, filters and number of results can be accessed in Additional file 1.

The review protocol was registered at PROSPERO 2018 CRD42018087689 and is available from https://www.crd.york.ac.uk/prospero/display_record.php?%20ID=CRD42018087689.

Reporting of this systematic review followed the PRISMA checklist [24].

Selection criteria

To identify publications with relevant interventions, we used criteria as the intervention must be a structured and stepwise detailed multi-disciplinary plan that must be applied to translate evidence into practice in the local context and aims the standardization of care for a specific health problem in a specific group of patients [2]. We did not include screening, detection, risk prediction or primary preventive CPWs or pharmacological guidelines. This also refers to CPWs that deal exclusively with diagnostics and are not an intervention according to our underlying definition [2]. The target population was

people aged ≥65 years in PC setting, which was defined as "[...] products or services designed to address acute and episodic health conditions and to manage chronic health conditions. It is also [...] where patients receive first contact care and where those in need of more specialized services are connected with other parts of the healthcare system." [25]. Thus, we considered providers as all health professionals (HPs), including doctors as GPs and medical specialists, nurses, physical therapists, pharmacists, occupational therapists, social workers, dietitians, psychologists, and dentists involved in CPW utilization in PC setting. As patients sometimes inappropriate tend to go to the emergency rather than to their GP for reasons as intricate appointment systems and appointment availability in general practice [26], hospital stays less than 24 h were also included.

For more detail of selection criteria based on PICO construct, see Table 1.

Study designs considered for inclusion

We included randomized controlled trials (RCTs), non-randomized controlled trials (NRCTs), controlled before-after studies (CBAs) and interrupted time series (ITS) studies, according to the Effective Practice and Organisation of Care (EPOC) study design criteria [27], written in German or English language and published from 2007 to 2019, whereby preliminary results or pilot/feasibility studies were excluded. For further detail, see Table 1.

In general, we did not exclude studies with a high risk of bias (RoB), indicating lower quality, but we did consider the RoB in the rating.

The titles, abstracts and subsequent full texts of the identified studies were screened and assessed for eligibility independently by two researchers (ES, VR). Disagreement between them was resolved through discussion, and a third reviewer (MM) was consulted if necessary. The study selection process, including deduplication, was documented, made consistent between the researchers and managed by using the Cochrane technology platform Covidence.

Since we assumed that it is possible, that barriers to and facilitators of implementation are not reported within the main publication of the respective project (*main project report*) but in independent publications, we carried out citation tracing of eligible articles to identify and include associated *process evaluation reports*.

Data extraction and analysis

After the exclusion of non-eligible articles through the removal of obviously irrelevant reports based on the title and abstract screening and through the examination of the retrieved full texts of the potentially relevant reports, the remaining studies were extracted by using a previously piloted template based on the *EPOC good practice*

Table 1 Selection criteria

Domain	Selection criteria	
Participants	People aged ≥65 years *(Operationalization according to the reported mean age of the study population of at least 60.0 years or 80% of the population aged over 60 years)*	
Setting	Primary care setting - outpatient hospital care - hospital stays < 24 h - transition from primary care to other settings Providers all health professionals including doctors as general practitioners and medical specialists, nurses, physical therapists, pharmacists, occupational therapists, social workers, dietitians, psychologists, and dentists involved in CPW utilization in PC setting	
Intervention	Criteria for considering an intervention as care pathway - (1) the intervention must be a structured, multi-disciplinary care plan that - (2) details the steps in the course of a treatment in the plan, algorithm, pathway, guide or the like and - (3) must be applied to translate evidence into practice in the local context - Aim: standardization of care for a specific health problem in a specific group of patients	
Comparator(s)	No restrictions	
Study designs	*Main project reports* - randomized controlled trials - non-randomized controlled trials - controlled before-after studies - interrupted time series	*Additional process evaluation reports* No restrictions
Outcome	No restrictions	
Publication period	2007 to 2019	
Language	- German - English	

data extraction form [28] supplemented by items from the *data extraction tool of the Context and Implementation of Complex Interventions (CICI) framework* [12]. If there were more relevant articles published for one original project, the various related records were extracted in one form. Data extraction forms are available from the authors on request.

The data collection process was performed by two independent researchers: ES extracted the data from all studies, and this process was duplicated by VR until the point of perfect agreement between the two reviewers. Discrepancies in the comparison of the forms were resolved by discussion and consensus.

Due to the large diversity of study characteristics and heterogeneous interventions and outcomes, a meta-analysis was not possible. Thus, a narrative synthesis following the *guidance for undertaking reviews in health care from the Centre for Reviews and Dissemination (CRD)* [29], as well as a synthesis in tabular form (see Tables 2 and 3) was undertaken.

Critical appraisal

The critical appraisal was carried out by two independent researchers (the critical appraisal was conducted in its entirety by ES and then duplicated by VR until the point of perfect agreement between the two reviewers), and a third reviewer (MM) was involved if necessary.

We used the *Cochrane Collaboration's tool for assessing RoB* for (N)RCTs and CBAs by completing the RoB table via Review Manager (RevMan) 5.3 software [44]; in cluster randomized trials, we also considered the risk of particular bias as recommended by the *Cochrane Handbook for Systematic Reviews of Interventions* [45]; in ITS we used the seven standard criteria [46]. We judged each domain as being at *low*, *high*, or *unclear risk* (Additional file 2) and created a RoB summary figure (see Additional file 3) and a graph to illustrate the proportion of studies with each of the judgements (see Fig. 2).

For the process evaluation reports, we used the *Critical Appraisal Skills Programme* (CASP) *Checklist* for qualitative research [47] and the *Mixed Methods Appraisal Tool* (MMAT) [48]. An overview of critical appraisal tools used for the included study designs is given in Additional file 4.

Results

Study selection

The search generated 8154 hits. After removing duplicates and irrelevant publications based on the title and abstract screening, we assessed 367 full-text articles for eligibility, six of which originated from the additional hand and citation searching. After the exclusion of 353 articles (see Fig. 1 for the PRISMA flow chart), a total of 14 studies (seven main project reports and seven process evaluation reports) were included in the synthesis.

The presentation of the results is based on the different included CPWs of the seven main project reports.

Characteristics of included studies

One main project report was a RCT [30] and six were cluster RCTs (cRCTs) [32, 36, 37, 39, 41, 42]. Two included nested process evaluation components in the main report [36, 41] and for five additional process evaluation reports were published separately. Details on the characteristics and results of the included studies can be found in Table 2.

The studies were published between 2008 and 2017 and took place in PC settings in three different countries: five in the Netherlands [32, 37, 39, 41, 42], one in the UK [36] and one in Canada [30].

The included projects comprised 5822 participants (3634 patients in intervention groups; 2188 patients in control groups).

The mean ages in the intervention groups ranged from 67.1 to 81.7 years and from 66.0 to 82.8 years in the control groups. One study only reported overall age range and did not report mean age [36].

All projects compared CPWs with usual care to assess their effectiveness. Three projects tested a CPW for persons with specific health conditions, which were type 2 diabetes [41], chronic obstructive pulmonary disease (COPD) [42], and heart failure [30]. The other projects targeted on community-dwelling people [32, 36, 37, 39]. More detailed information about the study characteristics and the results of single studies can be found in Table 2.

Despite the general diversity of the seven CPWs, there were commonalities with regard to the development and structure of the interventions. Thus, e.g. the development of all interventions was evidence-based, and four studies reported the involvement of clinicians. A total of six CPWs provided an individually tailored treatment. Education and training for health care providers was included in six CPWs. More detailed information about the structure of the interventions is displayed in Additional file 5. No project provided a clear and comprehensive distinction between intervention components and used implementation strategy. For details of the components of the seven CPWs, see Table 2.

Detailed information about characteristics of excluded studies and reasons for exclusion are available from the authors upon reasonable request.

Outcome measures

Five projects used patient-relevant primary outcomes, such as disability [39], daily functioning [32], functional performance in activities of daily living and mental well-being [37], quality of life and functional capacity for

Table 2 Summary of the characteristics and results of the included studies

Source, year	Design/method of data collection	Primary aim	Setting, country	Included participants: n (intervention group (IG)/ control group (CG))	Age in years: mean (range)	Groups in the intervention, provider	Results of the main project reports	Source of the barrier and facilitator data extraction
Azad et al., 2008 [30]	RCT	Effectiveness of the intervention	Primary care, Canada	Female patients with heart failure and their family caregivers 91 (45/46)	**IG:** 74.2 **CG:** 75.7 Caregivers: n.a.	**IG:** multi-disciplinary care pathway for heart failure - 12 visits - assessment and evidence-based treatment by various disciplines - group sessions/ workshops: heart failure management and education **CG:** usual care **Provider:** medicine, pharmacy, nursing, occupational therapy, physical therapy, social work	No significant difference in primary outcome	
Byszewski et al., 2010 [31]	with an additional publication focusing the intervention arm	Variance, adherence		All patients from the IG ($n = 45$)	**IG:** 74.2			Barrier and facilitator typology derived from data
Bleijenberg et al., 2016a [32]	cRCT	Effectiveness of the intervention	Primary care, Netherlands	Community-dwelling elderly people 3092 (790_{IGa}/ 1446_{IGb}/ 856_{CG})	**IGa:** 73.5 **IGb:** 74.0 **CG:** 74.6	**IGa:** frailty screening followed by routine care from a general practitioner **IGb:** Proactive Primary Care Program on Preserving Daily Functioning of Older People: frailty assessment followed by personalized nurse-led care - geriatric assessment - tailored care planning - care coordination - follow-up - educational training for	Significant differences in primary outcome in both IGs	

Table 2 Summary of the characteristics and results of the included studies *(Continued)*

Source, year	Design/method of data collection	Primary aim	Setting, country	Included participants: n (intervention group (IG)/ control group (CG))	Age in years: mean (range)	Groups in the intervention, provider	Results of the main project reports	Source of the barrier and facilitator data extraction
						providers **CG:** usual care **Provider:** practice nurses, general practitioners		
Bleijenberg et al., 2013b [33]	with a nested mixed-methods study: - quantitative: pre-and post-questionnaires - qualitative: focus groups with health professionals	Barriers, needs, expectations		32 general practitioners 21 practice nurses	General practitioners: 55.0 Practice nurses: 46.5			Barrier and facilitator themes Respondents' agreement with pre-defined barrier statements
Bleijenberg et al., 2015 [34]	with a nested qualitative study: interviews with patients	Perceptions, experiences		11 patients from IG_b (subsample)	79			Barrier and facilitator themes
Bleijenberg et al., 2016b [35]	with a nested mixed-methods study: - quantitative: descriptive data - qualitative: focus group with nurses	Intervention delivery		835 patients (identified as frail) from IG_b Subsample of practice nurses from IG_b (n = n.a.)	Patients: 75.4 Practice nurses: n.a.			Barrier and facilitator themes
Harris et al., 2015 [36]	cRCT	Effectiveness of the intervention	Primary care, UK	Community-dwelling aged people 298 (150/148)	(60–75)	**IG:** Pedometer accelerometer consultation evaluation (PACE)-Lift intervention - individually tailored consultations - patient handbook - individual physical walking/activity plan - physical activity diary - pedometer, accelerometer - educational training for providers **CG:** usual care **Provider:** practice nurse	Positive effect on primary outcome *(significant differences at 3 months but not at 12 months)*, with no effect on adverse events	

Table 2 Summary of the characteristics and results of the included studies *(Continued)*

Source, year	Design/method of data collection	Primary aim	Setting, country	Included participants: n (intervention group (IG)/ control group (CG))	Age in years: mean (range)	Groups in the intervention, provider	Results of the main project reports	Source of the barrier and facilitator data extraction
	with nested qualitative studies: interviews with patients, group interview with health professionals	Acceptability, Barriers, facilitators		30 patients 4 practice nurses				Barrier and facilitator themes
Melis et al., 2008 [37]	cRCT	Effectiveness of the intervention	Primary care, Netherlands	Community-dwelling independently living elderly people and their family caregivers 151 (85/66)	**IG:** 81.7 **CG:** 82.8 Caregivers: n.a.	**IG:** Dutch Geriatric Intervention Program (DGIP) - multi-professional assessment - individualized, integrated treatment plan - regular evaluation and follow-up visits **CG:** regular medical care **Provider:** primary care physician, geriatric specialist nurse (and geriatricians)	The intervention had a positive effect on primary outcomes *(significant differences at 3 months but not at 6 months)*	
Melis et al., 2010 [38]	with a nested process evaluation	Content, adherence		All patients from the IG ($n = 85$)	81.7			Barrier and facilitator typology derived from data
Metzelthin et al., 2013b [39]	cRCT	Effectiveness of the intervention	Primary care, Netherlands	Community-dwelling frail elderly people 346 (193/153)	**IG:** 77.5 **CG:** 76.8	**IG:** Prevention of Care (PoC) approach- multi-dimensional assessment - interdisciplinary care - tailored treatment plan - evaluation and follow-up - educational training for providers **CG:** usual care **Provider:** practice nurses, general practitioners, occupational therapists, physical therapists	No significant differences in primary outcomes	

Table 2 Summary of the characteristics and results of the included studies *(Continued)*

Source, year	Design/method of data collection	Primary aim	Setting, country	Included participants: n (intervention group (IG)/ control group (CG))	Age in years: mean (range)	Groups in the intervention, provider	Results of the main project reports	Source of the barrier and facilitator data extraction
Metzelthin et al., 2013a [40]	with additional mixed-method components: - quantitative: logbooks, evaluation forms - qualitative: interviews with patients and health professionals, focus groups with health professionals	Extent to which the implementation occurred as planned, experiences regarding benefits, burden, barriers and facilitators		7 practice nurses 12 general practitioners 6 occupational therapists 20 physical therapists 194 patients	Patients: 77.7 Health professionals: n.a.			Barrier and facilitator themes
van Bruggen et al., 2008 [41]	cRCT	Effectiveness of the intervention	Primary care, Netherlands	People with type 2 diabetes 1640 (822/818)	**IG:** 67.1 **CG:** 67.2	**IG:** - locally adapted shared care guidelines - educational training for providers **CG:** usual care (national guidelines) **Provider:** general practitioners, nurses, practice assistance	No significant differences in outcomes, but improvement in the process of diabetes care	
	with nested qualitative studies: interviews with health professionals	Barriers, facilitators						Barrier and facilitator themes
Weldam et al., 2017a [42]	cRCT	Effectiveness of the intervention	Primary care, Netherlands	People with mild to severe COPD 204 (103/101)	**IG:** 68.0 **CG:** 66.0	**IG:** nurse-led Chronic Obstructive Pulmonary Disease – Guidance, Research on Illness Perception (COPD-GRIP) intervention - three extra face-to-face consultations with individualized content, based on the patient's responses and the needs - assessment - individualized care plan - evaluation - educational	No significant difference in outcomes	

Table 2 Summary of the characteristics and results of the included studies *(Continued)*

Source, year	Design/method of data collection	Primary aim	Setting, country	Included participants: n (intervention group (IG)/ control group (CG))	Age in years: mean (range)	Groups in the intervention, provider	Results of the main project reports	Source of the barrier and facilitator data extraction
						training for providers **CG:** usual care **Provider:** practice/ respiratory nurse		
Weldam et al., 2017b [43]	with nested mixed-method components: - quantitative: pre- and post-questionnaires - qualitative: focus groups with health professionals	Facilitators, barriers, expectations		24 nurses	Questionnaires: 45.5 Focus group: 47.4			Barrier and facilitator themes Respondents' agreement with pre-defined barrier statements

IG intervention group; *CG* control group; *COPD-GRIP* Chronic Obstructive Pulmonary Disease – Guidance, Research on Illness Perception; *DGIP* Dutch Geriatric Intervention Program; *PACE* Pedometer accelerometer consultationevaluation; *PoC* Prevention of Care

Table 3 Overview of the reported barriers and facilitators

Domain*	Barriers	Facilitators
CONTEXT		
Geographical context	–	–
Epidemiological context	Multi-morbidity [31, 33, 43] People aged ≥85 years [33] Mental health problems [35]	–
Socio-cultural context	Cultural background [33, 43] Low health literacy [43] Gender [33, 43] Frequency of general practice visits [33, 43]	–
Socio-economic context	Low socio-economic status [33, 43]	–
Ethical context	–	–
Legal context	–	–
Political context	Lack of financial incentives/compensation [33, 41, 43]	–
IMPLEMENTATION		
Implementation theory	–	–
Implementation process	–	–
Implementation strategies	Overload of information in training activities for health professionals [40]	Training and educational activities for health professionals [33, 36, 41] Handbook as a clear guideline for health professionals [43]
Implementation agents		
Health professionals		
Knowledge and skills	Insufficient knowledge [33, 40, 41] Lack of competence [40] Lack of experience [40]	Professional skills [33, 40, 43] Organizational skills [40] Communication skills [40] Empathic capacity [40]
Behaviour-related factors	Lack of motivation [41] Initial difficulties in implementation due to changes in routines [40, 43] Negative attitudes towards intervention [33] Reluctance regarding an intervention component [41, 43]	Positive expectations regarding intervention [33, 43] Type of recommendation [38]
Interaction-related factors	Communication and collaboration issues [33] Difficulties in organizing team meetings [40] Insufficient involvement of professionals [33]	Interdisciplinary communication and cooperation [33, 35, 40] Intradisciplinary communication and cooperation [33, 41] Sufficient involvement of family caregivers [34] Clear responsibilities [33, 40]
Application of the intervention	Time expenditure [33, 40, 43] Complexity of intervention [33, 40]	Individual, flexible, tailored intervention [33, 43] Practicable layout [43] Good fit of the intervention to daily practice [43]
Patients		
External assessment		
Behaviour-related factors	Low treatment adherence [33, 38, 43]	–
External factors influencing adherence	Transportation issues [31] Scheduling problems [31]	–
Self-assessment		
Behaviour-related factors	–	Positive expectations regarding intervention [33, 40]
Components of intervention	High temporal expenditure effort [40] High bureaucratic effort [36] Difficulties in distinguishing the involved disciplines [40]	Interventions tailored to individual needs [33, 34, 36] Possibility for adaptation [40] Close monitoring of changing situations [34] Provision of written advice [36] Use of technical devices for outcome measurement [36]
Interaction with health professionals	–	Personal meetings with health professionals [36, 40] Good professional-patient relationship [33, 34, 40] Good internal exchange between HPs [34]

Table 3 Overview of the reported barriers and facilitators *(Continued)*

Domain*	Barriers	Facilitators
Implementation outcomes	Difficulties in identifying the appropriate target group [33, 40]	–
SETTING		
Work environment	Lack of available staff [31, 33] Lack of sufficiently educated staff [33] Lack of time [33, 35, 41, 43] Lack of space [31, 43] Discontinuity [34]	Transparency about referral possibilities [33]

*CICI framework domains are **bolded**, additional categories are in *italics*

older females living with heart failure [30] and health status of COPD patients [42]. Two studies investigated surrogate endpoints, such as changes in average daily step count [36] and the percentage of people with poor glycaemic control [41].

Quality of evidence

Details of the judgements about each RoB item in the included (cluster-)randomized controlled studies and across these trials are shown in Additional file 2, Additional file 3 and Fig. 2.

Due to a lack of information in almost all studies, the authors judged a total of 43,6% ($n = 24/55$) of RoB domains as being *unclear* (38,2% as *low risk*: $n = 21/55$; 18, 2% as *high risk*: $n = 10/55$). For a detailed information on RoB assessment see Fig. 2 and Additional file 3.

The problem of poor reporting was also relevant in the quality assessment of the process evaluation reports (see Additional file 6 for CASP and Additional file 7 for MMAT). None of the studies that use qualitative methods adequately described the relationship and interaction between the participants and the researcher. This also applies to qualitative parts of

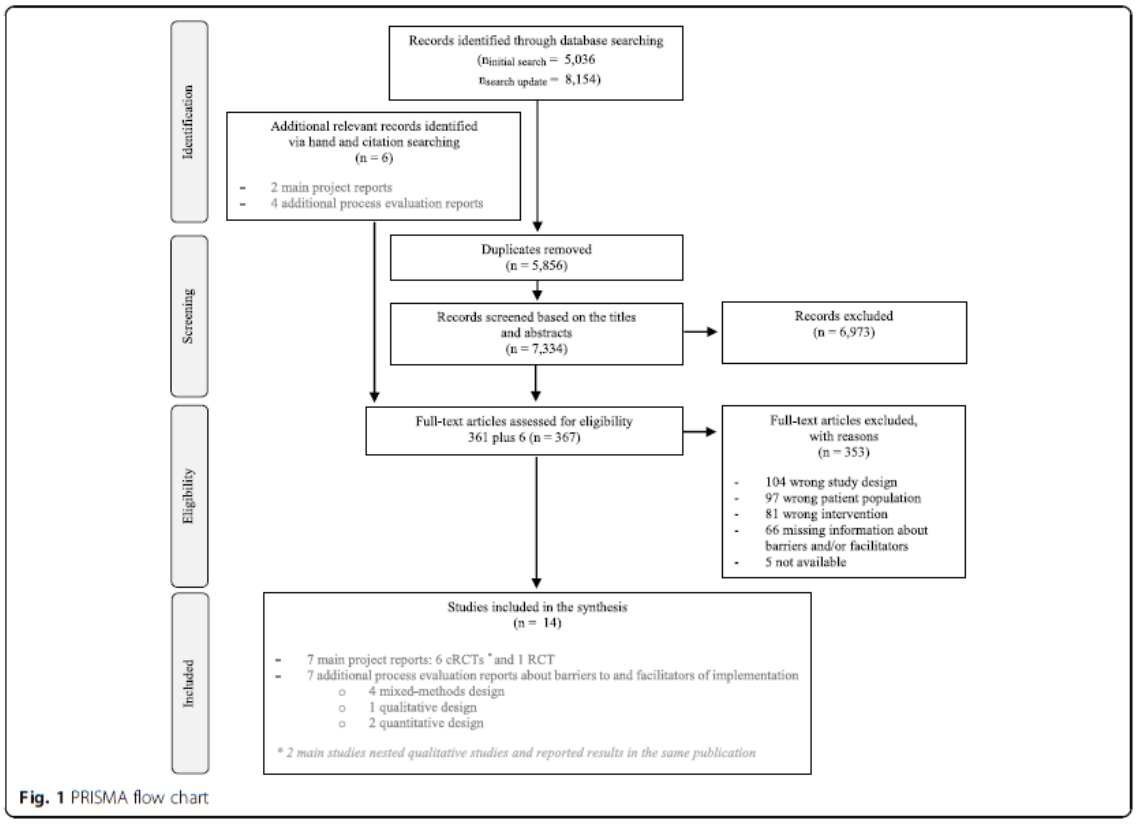

Fig. 1 PRISMA flow chart

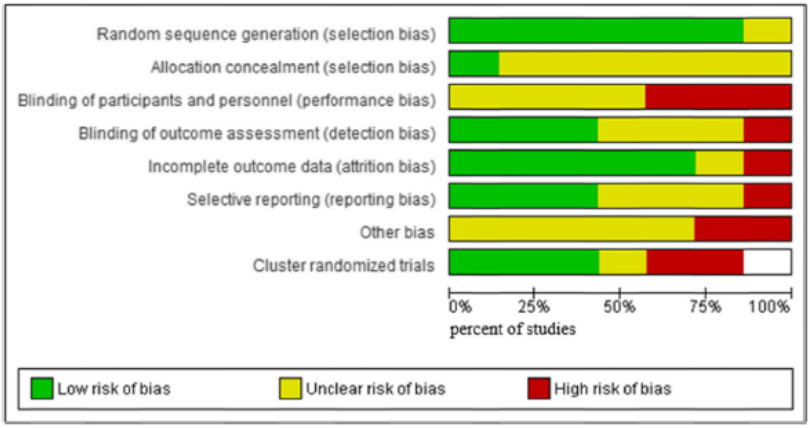

Fig. 2 Risk of bias graph of RCTs and cRCTs (designed by using RevMan [44])

mixed-methods studies. One qualitative study did not report approval of an ethics committee or institutional review board.

Factors influencing the success of implementation

The classification of barriers to and facilitators of successful implementation of CPWs in PC was based on the context, implementation and setting dimensions of the *CICI framework* [12].

An overview of barriers and facilitators in the individual studies is shown Table 3. Barriers were most frequently identified within the dimensions of implementation agents ($n = 7$) and setting ($n = 4$). Facilitators were most frequently determined within the implementation agents ($n = 6$) and implementation strategies ($n = 4$) (see Table 4).

Context

Three CPWs considered aspects of the *epidemiological context* such as multi-morbid [31, 33, 43] patients aged at least 85 years [33] with mental health problems [35] as barriers to applying an intervention.

Two of the CPWs reported the cultural background [33, 43], a low health literacy [43] and gender [33, 43] as potential barriers that could be attributed to the domain of *socio-cultural context*. Such patient-related characteristics can lead to a time lag in the application of an intervention. Additionally, the frequency of general practice visits [33, 43] have been reported to have a negative impact by two CPWs and could therefore be seen as barrier according to two CPWs.

Additionally, two CPWs considered a low socioeconomic status [33, 43] within the domain of *socio-economic context* as barriers to applying an intervention.

Furthermore, aspects related to the *political context*, such as a lack of an incentive systems [41] or adequate reimbursement models [43] or absent monetary compensations [33], were reported in three CPWs as potential barriers for the effective implementation of an intervention.

No barriers or facilitators within the domains *geographical, ethical* and *legal context* could be identified. None of the CPWs described facilitators in any of the dimensions of the domain context.

Implementation

Within the domain of *implementation strategies* the involved HPs of three CPWs emphasized the importance of training activities and reported appropriate training and education in applying an intervention [33, 36, 41] as facilitator. One CPW considered an overload of information during training activities as potential barrier [40]. According to the results of one CPW, a handbook as facilitator can serve as a clear guideline for HPs to promote a structured application of intervention [43].

The domain of *implementation agents* can be divided into the two areas of HPs and patients.

On the one hand, HPs' insufficient or even lack of knowledge about how to perform intervention components such as assessments or tests [33, 40, 41], their lack of competence in general [40] and their insufficient experience and job training [40] were considered barriers regarding knowledge and skills in three CPWs. On the other hand, three CPWs identified knowledge and skills such as professional [33, 40, 43], organizational [33] and communication skills [33] and empathic capacity [33] as serving as facilitators to the implementation of the approach. The behaviour-related factors of attitude and awareness, such as a lack of motivation of end-users [41] ($n = 1$) and initial difficulties in implementation due to changes in routines [40, 43] ($n = 2$) were reported as barrieres, which can reduce the success of intervention. Further barriers were negative attitude towards the intervention, such as doubts about the expected results

Table 4 Distribution of barriers and facilitators

Source of main project report, year	Barriers													Setting
	Context							Implementation						
	Geographical context	Epidemiological context	Socio-cultural context	Socio-economic context	Ethical context	Legal context	Political context	Implementation theory	Implementation process	Implementation strategies	Implementation agents	Implementation outcomes		
Azad et al., 2008 [30]		X									X			X
Bleijenberg et al., 2016a [32]		X	X	X			X				X	X		X
Harris et al., 2015 [36]											X			
Melis et al., 2008 [37]											X			
Metzelthin et al., 2013b [39]										X	X	X		
van Bruggen et al. 2008 [41]							X				X			X
Weldam et al., 2017a [42]		X	X	X			X				X			X

Table 4 Distribution of barriers and facilitators (*Continued*)

Source of main project report, year	Facilitators													Setting
	Context								Implementation					
	Geographical context	Epidemiological context	Socio-cultural context	Socio-economic context	Ethical context	Legal context	Political context	Implementation theory	Implementation process	Implementation strategies	Implementation agents	Implementation outcomes		
2008 [30]														
Bleijenberg et al., 2016a [32]										X	X		X	
Harris et al., 2015 [36]										X	X			
Melis et al., 2008 [37]											X			
Metzelthin et al., 2013b [39]											X			
van Bruggen et al. 2008 [41]										X	X			
Weldam et al., 2017a [42]										X	X			

[33] in one CPWs, and reluctance regarding an intervention component due to a lack of agreement [41, 43] in two included CPWs, e.g., the prescription of multiple drug regimes [41]. In contrast, a positive attitude towards the effectiveness of the intervention [33, 43] is reported to be a facilitator according to two CPWs. One CPW stated that interventions that provide recommendations to both patients and GPs increased adherence among HPs and affected patients and are therefore facilitators [38].

Interaction-related factors were identified in five CPWs as influencing aspects. In this regard, HPs named communication and collaboration issues [33] and difficulties in organizing team meetings [40] as barriers. HPs considered good interdisciplinary communication and cooperation [33, 35, 40] in two included CPWs as well as clear roles and task definition [33, 40] in two CPWs as facilitators. In addition to the consideration of the multi-disciplinary team, the positive impact of intradisciplinary communication and cooperation was identified in two included CPWs as a facilitator [33, 41], e.g., by making comparisons with peers [41]. The integration of family caregivers into the intervention, if possible, was identified as facilitator in one CPW [34], whereas insufficient involvement of single professions was mentioned as barrier in one CPW [33]. According to three CPWs, further barriers in application of the CPW arise due to the extent of intervention, such as time-consuming parts [33, 40, 43] and overly complex intervention components [33, 40]. Two CPWs reported an individual, flexible, tailored intervention customized to patients' needs, wishes and preferences providing the HPs as major facilitator in application [33, 43]. Another facilitator in implementation is a good fit of the intervention to the day-to-day work of the delivery agents [43]. A practicable layout of the intervention can ease adoption in daily practice [43] as facilitator sccording to one included CPW.

In addition to HPs, patients as consumers of the intervention, were also considered to affect implementation success. Aspects in this domain were partly identified by the patients themselves (self-assessments) and partly by HPs based on their experiences with affected patients (external assessments): regarding behaviour-related factors, HPs in three CPWs assumed patients' motivational issues to be a reason for their low treatment adherence and therefore as barrier [33, 38, 43]. Furthermore, external factors such as transportation issues, sometimes due to adverse weather conditions or scheduling conflicts with other appointments, affected the adherence of intervention recipients and serve as barriers [31]. Similar to HPs, patients in two studies also indicated that positive expectations regarding interventions [33, 40] were a facilitator. The delivery was also affected by the structure of the intervention components. Participants of one CPW perceived high temporal expenditure due to time-consuming participation to be a barrier [40]. Recipients of each one CPW classified high bureaucratic effort [36] and difficulties in distinguishing the involved disciplines [40] as barriers. On the other hand, two CPWs reported tailored interventions meeting patients' current needs [33, 34, 36]; one CPW the possibility for adaptations to avoid excessively restricting their own decision making, e.g., through self-management approaches [40]; and one CPW close monitoring of changing situations, which transmits a sense of security [34], as facilitators. Furthermore, in one CPW the provision of written advice such as a handbook [36] and the use of technical devices for outcome measurement [36] were seen as facilitators by consumers. In addition, patients considered interactions with HPs through personal meetings [36, 40] in two CPWs, good professional-patient relationships [33, 34, 40] in two CPWs and good internal exchange between HPs [34] in one CPW to be facilitators.

Within the domain of *implementation outcomes* two CPWs reported a barrier in problems occurred during the identification of the appropriate target group as the first step of the intervention [33, 40], e.g., due to dysfunctional screening methods [40].

No barriers or facilitators within the domains *implementation theory* and *implementation process* were reported. In addition, no facilitators within the domain of *implementation outcomes* were mentioned by included CPWs.

Setting

Barriers reported in four CPWs within the *work environment* in the dimension of setting are inadequate staffing due to the general lack of available staff [31, 33], e.g., due to illness or part-time employment [31] and lack of sufficiently educated staff [33]. Structural conditions lead to time pressure [33, 35, 41, 43], e.g., due to excessive workload in daily practice [35, 43], which negatively affects the situational performance of intervention components. Additionally, two CPWs mentioned a lack of space as barrier [31, 43]. Also, one CPW cited discontinuity problems in GPs as a barrier [34]. Transparency about referral possibilities promoting the familiarity of HPs with these options was identified as a facilitator [33].

Discussion

This study analysed barriers to and facilitators of the implementation of CPWs in PC to gain a better understanding of the factors needed for their successful implementation.

We found that the implementation of interventions into practice requires changes and adaptations in the

knowledge, attitudes and behaviour of HPs to achieve a positive impact on outcomes. The finding on the negative influence of personal factors of HPs, such as their lack of knowledge and their attitudes, is in line with findings from a review about barriers and strategies in guideline implementation [49] and a review of staff-reported barriers and facilitators to implementation of hospital-based, patient-focused interventions [50]. Our results show that appropriate training activities for HPs are particularly relevant, as confirmed by a larger feasibility study evaluating a local coronary heart disease treatment pathway in PC [51]. Two systematic reviews focusing on in-hospital settings showed similar results [49, 50]. We found that HPs considered the use of a structured, step-by-step explanatory handbook as a facilitator [43]. This finding is in line with the results of a feasibility study in PC [37]. Findings from another feasibility study suggested that additional material such as small portable cards with inclusion criteria, telephone numbers and listed referral options are helpful [52]. A meta-analysis of the effectiveness of implementation strategies for non-communicable disease guidelines in primary health care concluded that the simple provision of educational materials without training is ineffective [53]. In line with our findings, a review on secondary care found that providing information about successful examples can lower implementation barriers and enhance adherence [50]. Regarding the results showing that HPs have difficulties accepting interventions due to negative attitudes or reluctance regarding intervention components, similar studies also stated that it seems to be advisable to integrate local end-users into the development and implementation process [49, 51], which is in line with the *UK Medical Research Council* (MRC) *guidance* that recommends involving local end-users to promote successful long-term establishment of effective intervention in practice [54].

Our results show that intervention success also depends on patients' acceptance and adherence, e.g., due to the risk of a lack of understanding of recommendations. The identified facilitators such as precise and thoroughly explained recommendations [38] as well as the provision of written advice for patients [36] seem to be easy to use in practice. Reasons for negative attitudes towards interventions must be analysed individually to find solutions to promote acceptance and adherence. We also found that the application of an intervention can be made more difficult and time consuming due to several unavoidable patient-related factors, such as age [33], multi-morbidity [31, 33, 43] and cultural background [33, 43]. To counteract this difficulty, CPWs should be designed to be truly contextualised to the local settings, as well as taking into consideration common issues faced by the elderly age group.

We identified a good fit of the intervention with the day-to-day work of the delivery agents as a facilitator [43]. To promote a good fit, other studies suggested the integration of interventions into practice software in PC [51] or the use of tablets or smartphones in in-hospital settings [49]. Metzelthin et al. [40], in relation to a process evaluation of the implementation of a nurse-led care approach for community-dwelling frail older people, observed that digitalization of forms may additionally favour interdisciplinary exchange of data. Our results showed that clearly defined responsibilities with regard to tasks and roles are the basic prerequisite for multi-disciplinary communication and cooperation to promote efficient healthcare delivery [33, 40], which is in line with findings for in-hospital settings [49]. These findings underline the importance of the careful CPWs design in order to build upon current practice and take into account day-to-day practice to ensure the uptake by HPs. Since we identified a lack of time [33, 35, 41, 43] as well as overly time-consuming [33, 40, 43] and complex [33, 40] intervention components as barriers, the CPW application should not be associated with too much effort, especially since HPs are already under time pressure. Recommendations and tools have to be plausible, clear and transparent and be presented in a user-friendly, simplified and short form, consistent with findings for in-hospital settings [49, 50]. Furthermore, they must be evidence-based, which is in line with findings in PC [51] as well as with secondary care setting [49]. Thus, Kramer et al. [51] stated that recommendations must conform to the advice of guidelines or other (inter)-national guidance to avoid contradictory or overlapping recommendations, whereas an integration into a larger geographic context may facilitate implementation.

A lack of financial incentives and compensation [33, 41, 43] were reported to be important barriers. To overcome this issue, projects should plan to use case payments, and new reimbursement options should be considered to facilitate long-term implementation.

Notably, the retrieved studies originated from a few different studies, and most of them were conducted in the Netherlands [32, 37, 39, 41, 42].

Limitations

This systematic review has some limitations. An important issue is the evaluation of the main inclusion criterion. The terms *care pathways* and *critical pathways* were not consistently used in the literature. We tried to overcome this issue by applying a broad definition of CPWs [2] to allow for consistency among the compared studies. Eventhough both the European Pathway Association (E-P-A) in 2007 [55] and a Cochrane review from 2010 [3] indicated that CPWs have to be considered as a complex intervention, it seems not to be common sense

[54] that therefore, CPWs have to be developed and evaluated in a specific manner. This might explain the lack of systematic and rigorous investigation of the context, in terms of barriers and facilitators that would allow thorough evaluation of the external validity of the implemented CPWs.

Transferability of review results

Despite the general interest of GPs in CPWs, there is a low utilization of CPWs in PC [11]. Therefore, the included studies in this systematic review were conducted in the UK, Canada, and the Netherlands. This limits the transferability of our findings to similar healthcare contexts. It is obvious that the transferability of our findings might be limited to similar healthcare contexts with a strong gate-keeper role of the GP in PC, and the publicly funded healthcare systems in the UK and Canada [56]. The Dutch healthcare system is based on a different funding model, but with the same gatekeeper role of GPs to refer patients to specialists which are based at hospitals.

The varying funding mechanisms in the different countries were the primary studies were conducted may represent another limitation. The publicly funded (tax-based) healthcare systems in the UK and Canada differ significantly from the Dutch system. The Dutch system is funded by a dual system that came into effect in January 2006 [56]. It consists of a publicly funded component, and via a basic healthcare insurance package which is mandatory. Every Dutch resident has to choose their basic insurance package in order to define the scope of the healthcare services provided [56]. This means that the transferability of our systematic review findings are limited to countries with a similar healthcare system. Moreover, the financial incentives offered in the Dutch healthcare system could be confounding mechanisms or facilitators of successful implementation itself, and not the CPW as a causal factor [56].

In addition, the poor quality of reporting in terms of missing information for many core items made a straightforward assessment of internal validity difficult and might have led to inappropriate downgrading. We are, however, confident that our rigorously applied approach and reporting of all steps makes the conclusions transparent.

Conclusions

In the implementation of CPWs in PC practice, a multitude of barriers and facilitators must be considered, and most of them can be modified through careful design of intervention and implementation strategies. We observed a lack of transparent and comprehensive reporting of the intervention components, their implementation strategies and contexts. There is an urgent need to improve the quality of research on CPWs and to follow the established guidelines in conducting and reporting research involving comprehensive process evaluations to produce reliable and transferable evidence to make this promising technology available for practice.

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10.1186/s12875-020-01179-w .

Additional file 1. Overview of literature database search strategies, used search terms, filters and number of results.

Additional file 2. Methodological quality of included main project reports.

Additional file 3. Risk of bias summary of RCTs and cRCTs (designed by using RevMan [44]).

Additional file 4. Overview of critical appraisal tools used for different study designs.

Additional file 5. Main components of the interventions reported in the included main project reports.

Additional file 6. Quality assessment results of aspects of the qualitative studies (CASP Checklist).

Additional file 7. Quality assessment results of aspects of the mixed-method studies (MMAT).

Abbreviations

CASP: Critical Appraisal Skills Programme; CBA: Controlled before-after study; CG: Control group; CICI: Context and Implementation of Complex Interventions; COPD: Chronic obstructive pulmonary disease; CPW: Care pathway; cRCT: Cluster randomized controlled trial; CRD: Centre for Reviews and Dissemination; E-P-A: European Pathway Association; EPOC: Effective Practice and Organisation of Care; GP: General practitioner; HP: Health professional; IG: Intervention group; ITS: Interrupted time series; MMAT: Mixed Methods Appraisal Tool; MRC: Medical Research Council; NRCT: Non-randomized controlled trial; PC: Primary care; PICO: Population, Intervention, Comparison(s) and Outcome; RCT: Randomized controlled trial; RoB: Risk of bias

Acknowledgements

We have to thank Adegboyega K. Lawal for the help in designing and adapting the search strategy.

Authors' contributions

ES and MM wrote the study protocol and registered the review with PROSPERO. ES, VR, PB, MM and TR conceived the structure of the systematic review. ES, VR, TR and MM designed the search strategy. ES and VR independently screened the titles and abstracts and assessed the eligibility for inclusion of all identified publications. ES extracted the data and performed a quality assessment of all included studies, and this process was partly duplicated by VR. MM was consulted in case of conflicts. ES corresponded with all other study authors and wrote the drafts of the review. All authors revised the manuscript critically for important intellectual content and read and approved the final version.

Funding

This systematic review is part of the "MobilE-PHY" multicentre study, which aims to develop and feasibility test a CPW as a tailored complex intervention to improve mobility and participation among older individuals with vertigo, dizziness and balance disorders in PC.
This study is part of the project "Munich Network Health Care Research - MobilE-NET" and was funded by the German Federal Ministry of Education and Research (grant number 01GY1603C).
This work was also supported by the Bavarian Academic Forum (BayWISS) – Doctoral Consortium "Health Research" and was funded by the Bavarian State Ministry of Science and the Arts.

Availability of data and materials
Data extraction forms are available from the authors on request.

Ethics approval and consent to participate
Not applicable.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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Received: 24 January 2020 Accepted: 28 May 2020
Published online: 19 June 2020

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Publisher's Note

Anhang B: Publikation Ⅱ

Seckler E[1,2], Regauer V[1,2], Krüger M[3], Gabriel A[4], Hermsdörfer J[4], Niemietz C[1], Bauer P[5], Müller M[5]. Improving mobility and participation of older people with vertigo, dizziness and balance disorders in primary care using a care pathway: feasibility study and process evaluation. BMC Family Practice 2021; 22(62). doi: 10.1186/s12875-021-01410-2.

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Received: 6 September 2020; Accepted: 10 March 2021; Published online: 02 April 2021

Seckler et al. BMC Fam Pract (2021) 22:62
https://doi.org/10.1186/s12875-021-01410-2

BMC Family Practice

RESEARCH ARTICLE Open Access

Improving mobility and participation of older people with vertigo, dizziness and balance disorders in primary care using a care pathway: feasibility study and process evaluation

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Abstract

Background: Community-dwelling older people are frequently affected by vertigo, dizziness and balance disorders (VDB). We previously developed a care pathway (CPW) to improve their mobility and participation by offering standardized approaches for general practitioners (GPs) and physical therapists (PTs). We aimed to assess the feasibility of the intervention, its implementation strategy and the study procedures in preparation for the subsequent main trial.

Methods: This 12-week prospective cohort feasibility study was accompanied by a process evaluation designed according to the *UK Medical Research Council's Guidance for developing and evaluating complex interventions*. Patients with VDB (≥65 years), GPs and PTs in primary care were included. The intervention consisted of a diagnostic screening checklist for GPs and a guide for PTs. The implementation strategy included specific educational trainings and a telephone helpline. Data for mixed-method process evaluation were collected via standardized questionnaires, field notes and qualitative interviews. Quantitative data were analysed using descriptive statistics, qualitative data using content analysis.

Results: A total of five GP practices (seven single GPs), 10 PT practices and 22 patients were included in the study. The recruitment of GPs and patients was challenging (response rates: GP practices: 28%, PT practices: 39%). Ninety-one percent of the patients and all health professionals completed the study. The health professionals responded well to the educational trainings; the utilization of the telephone helpline was low (one call each from GPs and PTs). Familiarisation with the routine of application of the intervention and positive attitudes were emphasized as facilitators of the implementation of the intervention, whereas a lack of time was mentioned as a barrier. Despite difficulties in the GPs' adherence to the intervention protocol, the GPs, PTs and patients saw benefit in the intervention. The patients' treatment adherence to physical therapy was good. There were minor issues in data collection, but no unintended consequences.

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Conclusion: Although the process evaluation provided good support for the feasibility of study procedures, the intervention and its implementation strategy, we identified a need for improvement in recruitment of participants, the GP intervention part and the data collection procedures. The findings will inform the main trial to test the interventions effectiveness in a cluster RCT.

Trial registration: Projektdatenbank Versorgungsforschung Deutschland (German registry Health Services Research) VfD_MobilE-PHY_17_003910, date of registration: 30.11.2017; Deutsches Register Klinischer Studien (German Clinical Trials Register) DRKS00022918, date of registration: 03.09.2020 (retrospectively registered).

Keywords: Critical pathways, Primary health care, General practitioners, Aged, Vertigo, Dizziness, Physical therapy modalities, Implementation science, Feasibility studies

Background

Vertigo, dizziness and balance disorders (VDB) are frequent complaints of older people [1–4], with a reported prevalence of up to 50% [5–8]. VDB in older persons are a distinct risk factor for falls [2] and even fear of falling may lead to activity restriction and disability [9]. The occurrence of these symptoms is a common reason for consultation in general practice, with a reported consultation prevalence of up to 16% [10]. Due to multifactorial aetiology [8, 11–13], the overutilization of health care in affected patients insufficiently treated in primary care has been shown [14, 15]. Physical therapy is likely to be a valuable component in the management of patients with VDB regarding consequences such as imbalance and falls that result in limited mobility and participation restrictions [16–19]. Despite the sufficient quality of evidence indicating the value of physical therapy for managing VDB, physical therapy seems not to be a standard option in the primary care of patients with chronic VDB in Germany [20].

A care pathway (CPW) is an evidence-based, structured, multi-disciplinary care plan that describes all relevant diagnostic and therapeutic steps in the care of patients with a specific health problem in chronological order; it is used to translate scientific evidence into local practice by considering regional conditions and demands [21, 22]. CPWs might be a promising approach to optimizing the care of older patients with VDB by integrating specific physical therapy interventions and referral guidelines into primary care. We previously developed a multi-disciplinary CPW that aims to improve participation and mobility in older adults with VDB in the primary care setting by offering standardized approaches for general medicine and physical therapy. Since the implementation of complex interventions is a challenging task, the *UK Medical Research Council (MRC) Guidance for the systematic development and evaluation of complex interventions* [23] recommends a feasibility/piloting phase prior to a future definitive trial. Consequently, we aimed to assess our developed intervention in a feasibility study. To understand the process, we conducted a comprehensive process evaluation to investigate its strengths and weaknesses.

Specific objectives were to evaluate:

1. The trial feasibility of the proposed study design (1.1) to explore the recruitment of clusters (general practitioners (GPs)), physical therapists (PTs), and individuals and (1.2) to test the acceptability and eligibility of the outcome measures and data collection procedures;
2. The feasibility, acceptability and usability of the intervention components;
3. The feasibility and acceptability of the implementation strategy by identifying facilitators and barriers in the domains of context and delivery to and response of clusters, PTs, and individuals;
4. The unintended consequences of the processes and outcomes of the intervention and its implementation strategy.

Methods

Study design

This prospective cohort feasibility study aimed to simulate the intervention arm of a future cluster RCT (cRCT). It was accompanied by a mixed-method process evaluation to obtain a detailed comprehension of how the intervention works. Since we experienced problems with the recruitment of clusters in the study, we decided to focus on the experimental intervention rather than a control intervention.

Reporting of this study followed the *Consolidated Standards of Reporting Trials* (CONSORT) *statement* extension for pilot and feasibility trials [24] and the *Template for Intervention Description and Replication* (TIDieR) [25].

Participants and setting

Participants were patients (individuals), GP practices (clusters) and PT practices. We decided not to define a dyad consisting of a GP practice and a PT practice

as a cluster, as the patients were free to choose all PTs trained within the study context and therefore did not necessarily opt for the nearest PT practice.

GP practices (clusters) were eligible when the physicians had professional working experience with patients with VDB and statutory health insurance accreditation, which means that a GPs is authorized to treat patients who are compulsorily insured by statutory health insurance, which covers almost 90% of the population. Initially, we considered including only health professionals with at least 3 years of working experience after medical licensure, but due to organizational and availability reasons, we decided not to employ this limitation. GP practices were recruited in the region of southern Bavaria, Germany, and were identified via a database search. The initial invitation to participate was made via telephone call followed by an email and a personal visit for further information.

Eligible patients (individuals) had to be at least 65 years old and had to have consulted with their GP regarding complaints of VDB of any aetiology within the last 3 years. They had to have no legal guardian and appropriate verbal and cognitive command of the German language to give written informed consent, complete the questionnaires and follow verbal and written instructions. Due to the administration of a physical performance test for outcome measurement, the patients also had to be able to walk 10 m (with or without walking aids). Patients were excluded from the study if in-patient hospital treatment was required. After giving informed consent, the recruited GPs were asked to identify eligible patients based on a provided list of inclusion criteria by searching their practice software using *International Statistical Classification of Diseases and Related Health Problems* (ICD) codes or free text searches (see Additional file 1 for manual for the recruitment of patients) and to recruit them by sending informational documents by postal mail. With this recruitment procedure we intended to simulate a baseline assessment before randomization for a planned future cRCT.

Local PT practices were identified based on the GPs' recommendations and additional geographic screening. PTs were invited to take part in the study via telephone call followed by an email with further information. The same inclusion criteria for GPs applied for PTs.

The intervention

The intervention is a CPW to improve participation and mobility in older adults with VDB in the primary care setting by offering standardized approaches for general medicine and physical therapy.

Development

The development of the CPW and its implementation strategy systematically combined existing evidence from previous research with a co-creation approach considering different perspectives. Health professionals, patients and experts in the field were systematically involved. Further information about the intervention, its development and the modelling process of intervention strategies will be published elsewhere in detail.

Content and implementation strategy

The developed multi-disciplinary CPW is a paper-based algorithm providing a structured illustration of all steps of the patient's path; it consists of two main components:

(1) A checklist for diagnostic screening for GPs that describes evidence-based diagnostics, treatment and referral options and specific time lines for follow-ups.
(2) An evidence-based guide for clinical reasoning and treatment of VDB for PTs that includes evidence-based patient information (leaflets with home exercises) and informational flyers (on symptom control and frequently asked questions about specific conditions), as a referral to physical therapy is a relevant option for patients with VDB.

The checklist and the guide are not available since they have not yet been evaluated for effectiveness and safety.

The relationship between the CPW components is illustrated in Fig. 1.

We developed a logic model (see Fig. 2) describing a mechanism of change using the central model of the *Behaviour Change Wheel* (BCW), the *Capability-Opportunity-Motivation-Behaviour* (COM-B) model [26]. In addition, we considered potential influencing factors classified according to the five main elements of the *Consolidated Framework of Implementation Research* [27].

The key components of the implementation strategy were face-to-face educational group trainings for the GPs (90 min) and for the PTs (one day) containing demonstrations of required skills, do-it-yourself-elements with feedback and instructions for the intended application each part of the corresponding CPW. The participants received additional written information. The training for the GPs was held by a neurologist, and the training for the PTs was held by a specialist PT. Both trainings included a brief information about the study background and logistics provided by the research team. Participation in these training sessions was free of charge and included a qualification certificate. A telephone mentoring helpline for the GPs was provided by an oto-neurologist who was also the co-developer of the checklist and administered

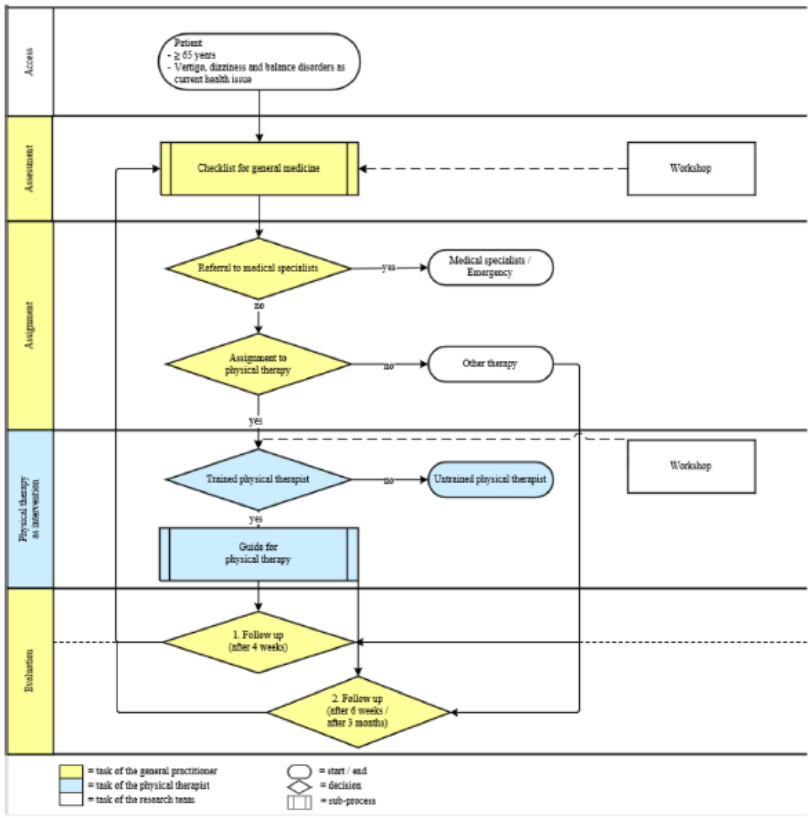


Fig. 1 Overview of the patient's path in the intervention

the training. A telephone mentoring helpline for the PTs was provided by a member of the research team, who is an experienced PT.

The health professionals obtained a certificate for study participation to display in their practice as well as a payment per treated study patient (GPs: 40€; PTs: 20€).

Outcomes and data collection procedures

We collected patient data for the primary and secondary outcomes at three measurement points: at baseline (T0), after 6 weeks (T1) and after 12 weeks (T2). The patients could opt to participate in the data collection in their homes or at a study centre visit. Prior to conducting this trial, we pre-tested all documents on two volunteers.

An overview of used outcome assessments and timeline is shown in Table 1.

Primary outcome

The impact of VDB on the Activities of Daily Living, as the primary outcome, was assessed by the *Dizziness Handicap Inventory* (DHI) [28].

Secondary outcomes

The secondary outcomes were balance, measured by the *Mini-Balance Evaluation Systems Test* (miniBEST) [29], and health-related quality of life assessed by the *EuroQol 5-dimension 5-level* (EQ-5D-5L) questionnaire [30]. Table 1 displays all secondary outcomes (patient-reported outcomes and performance tests). For the objective assessment of physical activity profiles, the patients were asked to wear two different activity sensors: (1) Move4 (Movisens GmbH, Germany), attached at the thigh with adhesive tape, and (2) StepWatch4 (modus health llc, USA), worn on the ankle with a strap. The patients were asked to wear both sensors simultaneously for five consecutive days within the week following T0, T1 and T2 to collect information about their daily life physical activity. In addition, physical activity was quantitatively assessed by the *International Physical Activity Questionnaire* (IPAQ) [31]. Furthermore, the patients were required to maintain a combined physical activity/dizziness-diary while wearing the sensor.

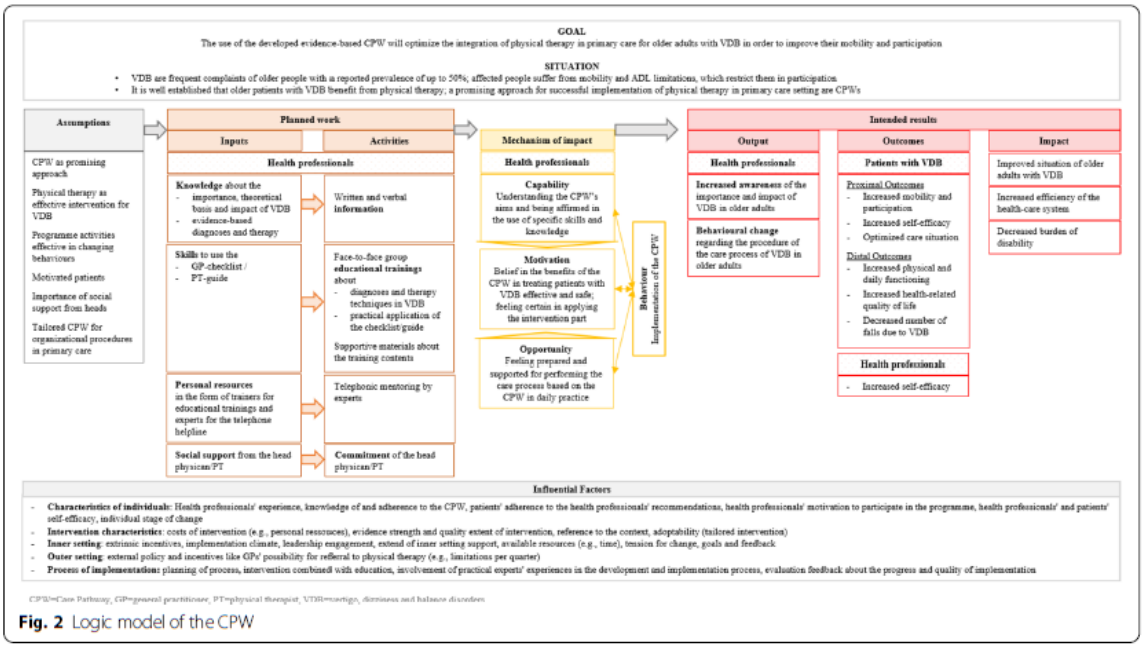


Fig. 2 Logic model of the CPW

Data collection procedures

At baseline, the patients completed the patient-reported outcome questionnaires together with a study assistant; at follow-up, the patients were asked to complete the questionnaires by themselves, but assistance was provided on request. The completition of the miniBEST performance test and the distribution and attachment of the sensors were done in a personal appointment with the patient and the study assistant. The results of the miniBEST and DHI were shared with the treating PTs to inform further therapy planning.

Process evaluation

The process evaluation followed the respective *UK MRC Guidance for process evaluation of complex interventions* covering the domains of implementation, mechanism of impact and context [32] along with the *Framework for design and reporting of process evaluation* by Grant et al. [33]. The process evaluation was structured according to the following domains: recruitment of clusters and individuals, context, delivery to and response of clusters and individuals and unintended consequences. We did not consider effectiveness domain, because we did not aim to estimate any treatment effects. Due to the short duration of the study, we also did not consider the maintenance domain. We additionally observed the performance and feasibility of the outcome measures and data collection procedures.

For data collection, we used continuous field notes; standardized questionnaires for the study participants; semi-structured individual telephone interviews with the GPs, patients and PTs; and a face-to-face group interview with the GPs and checklist developers. The interviews were conducted by members of the research team (ES, VR), and group discussion was moderated by both researchers.

For an overview of the procedure of the process evaluation alongside the feasibility study see Fig. 3.

Detailed information about data collection methods in the different domains and time points can be taken from Additional file 2.

Trial feasibility

Recruitment of clusters and PTs The recruitment of health professionals was assessed before and during the intervention. Reasons for study participation were documented by personal interviews. The recruitment procedure and retention rate including reasons for early study termination were investigated via continuous field notes. The flow of recruitment and the reach of the intervention were documented using protocols. The participants were asked about their satisfaction with the recruitment via personal interviews. To

Table 1 Overview of used outcome assessments and timeline

Outcomes	Data collection procedures/assessments		Study period				
			Enrolment	Time of data collection			Close-out
			Pre T0	*T0*	*T1*	*T2*	*Post T2*
Primary outcome							
- Impact of dizziness on activities of daily living	Dizziness Handicap Inventory (DHI)			X	X	X	
Secondary outcomes							
- Static and dynamic balance	Mini-Balance Evaluation Systems Test (miniBEST)			X	X	X	
- Health-related quality of life	EuroQol 5-dimension 5-level (EQ-5D-5L)			X	X	X	
- Daily-life physical activity profile	Actigraphy (StepWatch4, Move4)			X	X	X	
- Types of physical activity in daily life	International Physical Activity Questionnaire (IPAQ)		X	X[a]	X[a]	X[a]	
- Time and types of physical activity; daily time spent moving, sitting, lying; and occurrence of VDB	Physical activity diary			X	X	X	
Process evaluation							
- Characteristics of participants	Standardized questionnaire on sociodemographic data		X				
- Structural practice data of GP and PT practices	Standardized questionnaire on structural practice data based on the QCPC		X				
- Trial feasibility - Feasibility of the intervention components - Feasibility of the implementation strategy	Research team	Field notes by the research team		X	X	X	
		Field notes by the study assistant after each measurement appointment		X	X	X	
	GPs	Group interview with GPs			X		
		Individual interview with GPs	X				
		Standardized questionnaire on the recruitment process	X				
		Standardized evaluation forms for the educational trainings	X				
		Field notes on contact with GPs via telephone or email	X	X	X	X	X
		Field notes by GPs[c]		X	X	X	

Table 1 (continued)

Outcomes	Data collection procedures/assessments		Study period				
			Enrolment	Time of data collection			Close-out
			Pre T0	*T0*	*T1*	*T2*	*Post T2*
	PTs	Individual interviews with PTs					X
		Standardized evaluation forms for the educational training	X				
		Field notes by PTs[d]		X	X	X	
		Field notes on contact with PTs via telephone or email	X	X	X	X	X
	Patients	Individual interviews with patients			X		X
		Patients' cancellation forms	X				
		Standardized evaluation forms after each questionnaire	X	X	X	X	
		Field notes by the patients[b]		X	X	X	
		Field notes on contact with patients via telephone or email	X	X	X	X	X

GP general practitioner, *PT* physical therapist, *QCPC* Questionnaire of Chronic Illness Care in Primary Care, *VDB* vertigo, dizziness and balance disorders

[a] one week after measurement point

[b] Patients' field notes in free text option in physical activity diary

[c] GPs' field notes in form of a completed checklist including a free text option

[d] PTs' field notes in form of a completed guide including a free text option and treatment documentation

assess sociodemographic information and structural practice data, we used a questionnaire based on the *Questionnaire of Chronic Illness Care in Primary Care* (QCPC) [34].

Recruitment and reach of individuals The recruitment of individuals and intervention reach among patients were assessed before and during the intervention. To investigate the recruitment procedure, we performed personal or telephone interviews with the patients and GPs, used a standardized questionnaire on the recruitment procedure used by the GPs and analysed field notes. To evaluate the patients' motivation, we collected information about their reasons for participation in interviews and for their non-participation using a short questionnaire. The flow of recruitment of individuals and intervention reach among patients was documented using recruitment protocols. To evaluate the responses, we asked about the patients' satisfaction with recruitment in the interviews. Sociodemographic information was collected at baseline via a standardized questionnaire.

The retention rate including reasons for early study termination in all participants was documented.

Outcome measures and data collection procedures in the patients The utilization of the outcome measures and the performance of data collection procedures in the patients were assessed during the intervention. To evaluate delivery, protocol deviations and missing data were documented. The patients' responses regarding measurement procedures, satisfaction with organizational aspects and effort required for study participation were evaluated by analysing the interviews and the contact and field notes. To assess the feasibility of the

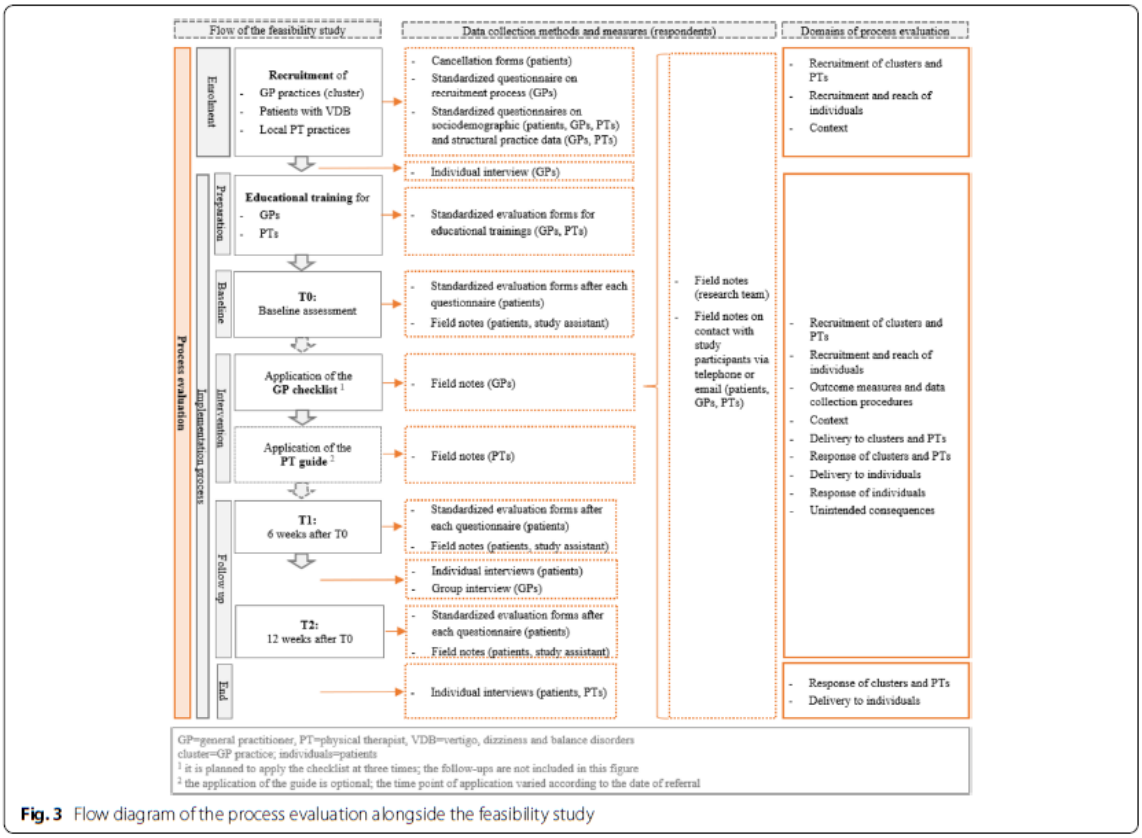


Fig. 3 Flow diagram of the process evaluation alongside the feasibility study

questionnaires, we asked patients to complete a supplemental evaluation form about difficulties and time consumption.

Outcome measures and data collection procedures in the clusters and PTs The acceptability and eligibility of the selected outcome measures and data collection procedures were determined during the intervention via field notes, interviews and contact with the health professionals to evaluate their responses regarding the procedures, study logistics, effort and feasibility of study participation in daily practice.

Feasibility of the intervention components and implementation strategy The evaluation of the intervention components and its implementation strategy included the assessment of context; delivery to and response of the clusters, PTs, and individuals; and unintended consequences. The data were collected prior to, during and after the intervention to appraise changes over time.

Context Information about the GP and PT practices was collected by a questionnaire based on the QCPC [34] immediately after study enrolment. Contextual factors in terms of barriers and facilitators in the implementation of the interventions were assessed through a group interview with the GPs, individual interviews with the PTs and patients and the analysis of field notes.

Delivery to and response of clusters and PTs The delivery of the intervention to health professionals was assessed during the intervention via interviews and field notes. The health professionals' responses about the intervention and its integrability into daily practice, including difficulties in delivery, experiences within the implementation process and adaptations were assessed during and after the intervention. Standardized evaluation forms were used to evaluate educational trainings. Additionally, we analysed the interviews, field notes and contact notes. The support offered by the helplines (e.g., satisfaction and use) was assessed via interviews and the analysis of the contact field notes. The health

professionals' satisfaction with the intervention, their adherence to it and any adjustments they made were evaluated in interviews and via the analysis of notes from contact with the participants and field notes, including the completed checklists/guides. Analysis of field notes was also used to evaluate deviations from the implementation protocol and attendance. Attitude and behaviour changes of the health professionals in daily practice and their experiences during the implementation process were assessed through interviews and field notes.

Delivery to and response of individuals The delivery of the intervention components to the patients was evaluated during and after the intervention through interviews with the patients and health professionals and contact and field notes, including a comparison with the completed checklists/guides. Telephone interviews with the target group were used to assess the patients' experience of and response to the intervention, including their adherence and behavioural change.

Unintended consequences Unintended consequences of the process and outcomes of the intervention and its implementation strategy were assessed during the intervention through interviews with the participants and field notes by the research team.

Sample size

A sample size calculation was not performed since we did not aim to estimate any treatment effects. The analysis must therefore be considered exploratory. Based on pragmatic considerations and to obtain sufficient information about the feasibility and acceptance of the intervention and the feasibility of the study procedures, we planned to include five GP practices, each with five to 10 patients, in the study.

Data analysis

For the analysis of the assessment instruments, standardized questionnaires and some of the documentary data, we entered the data in a secure, web-based software platform designed to support data capture for research studies named Research Electronic Data Capture (REDCap) and used descriptive statistics.

Statistical analysis of the patient data was performed using R statistical software [35]. Since the focus of this study was on feasibility, we did not calculate statistical significance, as is often erroneously done in feasibility studies [36]. The study assistant who assessed and entered the data was not involved in the analysis.

The qualitative interviews were audio-recorded and transcribed verbatim according to the rules proposed by Kuckartz [37] with F4 transcription software, and the field notes were used to provide context in this process. Analysis was conducted by two researchers (ES, VR) independently using MAXQDA software [38] following the process of content analysis according to the concept of qualitative description [39, 40]. If necessary, any disagreements between the coders were discussed with a third researcher (MM). In terms of quality assurance, the group interview participants were offered the opportunity to verify and modify the results. Analysis of the notes from contact with study participants via the telephone helpline, the hotline or email and analysis of parts of the continuous field notes and physical activity diaries were also conducted qualitatively.

Sensor-based activity data were evaluated in a multistep process. The pre-processing of sensor-based activity data was performed using the software provided by the manufacturers, i.e., SensorManager (Movisens) and StepWatch 4 RE (StepWatch). For both sensors, recorded accelerometer data were aggregated into 1 min-epochs for the whole period of data recording. Based on this approach, for each time epoch, the following parameters were extracted: steps (Movisens and StepWatch) and activity class (sitting/lying, standing, and moving, for Movisens only). All subsequent data processing was performed using Excel (Microsoft Corporation, Redmond, WA, USA). In the first step, for each patient, each measurement point and each parameter, the data were pooled in 24-h periods, i.e., recording days. Based on this approach, the following parameters were calculated for each recording day: difference in the number of recorded steps between the two sensors, i.e., $steps_{Movisens}$ - $steps_{StepWatch}$; the share of each activity class, expressed as the percentage of the recording day; and the mean duration spent consecutively in one activity class, hereafter referred to as the mean bout length. Subsequently, valid recording days were identified by the following factors [41–44]: the patients had to wear the sensor for at least 10 hours and walk at least 200 steps. Only patients with at least four valid recording days were included in further analytical steps. Next, for each patient and each of the above-mentioned parameters, the mean across all valid recording days was calculated. To interpret quantitative differences between activity sensors, the physical activity diaries were used for qualitative assessment of the patients' physical activity. In addition, the main outcome measure of the IPAQ, i.e., metabolic equivalent task minutes per week (METmin/week), was included in the analysis. Statistical analysis was performed using SPSS Statistics 23 (IBM Corp., Armonk, NY, United States).

Results

Trial feasibility

Recruitment of clusters

The recruitment of clusters took place between February and April 2019 and was time consuming due to the GPs' limited availability, and issues in receiving the information via email; the use of fax was found to be more practical. Since most GPs cancelled the initially planned information event for time reasons, we visited each practice to provide further information (mean duration: 22 min). The GPs characterized the information documents as complete and sufficient.

For further information and an overview of barriers and facilitators subdivided in all domains see Additional file 3.

A total of 18 GP practices were approached via telephone calls, and nine GP practices of interest were visited on site; five practices with a total of seven GPs agreed to take part. See Table 2 for further details.

In most cases, reasons for non-participation were not given (for further information see Fig. 4). Reasons for participation mostly included a perception of the topic as interesting and of practical relevance, the desire to improve treatment quality through a structured approach, and the desire for intra-professional exchange and a general interest in research projects.

All clusters completed the study. For flow of participants through this study see Fig. 4.

Recruitment of PTs

The telephone requests to PT practices and internal forwarding of information proceeded without issues. The PTs were satisfied with the recruitment approach including the structure, content and the extent of the information material.

The recruitment of PT practices took place between April and May 2019. A total of 10 PT practices out of the 26 approached agreed to participate and completed the study (see Fig. 4). The PTs' mean age was 41.3 years, and most of them were women (82%) (for further information see Table 2).

Reasons for non-participation were a lack of interest and time (for further information see Fig. 4), whereas reasons for participation were a perception of the topic as interesting and of practical relevance, the chance to improve quality, and an interest in educational trainings and in research projects in general.

For further information and an overview of barriers and facilitators subdivided in all domains see Additional file 3.

Recruitment and reach of individuals

Several problems in the implementation of the intended recruitment approach for patients occurred since there was a considerable delay in the GPs' initiation of recruitment in spite of repeated reminders. It was difficult for the GPs to apply the inclusion criteria and some invited younger patients ($n=2$) and those with cognitive impairment ($n=1$). Hence, the initial planned recruitment period was extended by 3 months. It was noted that the timing was unfavourable, e.g., due to holiday season.

Table 2 Characteristics of the health professionals at baseline

	GPs ($n=7$)	PTs ($n=11$)
Age, *mean (range)*	54.6 (37.0–66.0)	41.3 (24.0–61.0)
Sex, *n female (%)*	1 (14.3)	9 (81.8)
Years of professional activity, *mean (range)*	21.1 (7.0–35.0)	18.3 (1.0–40.0)

GP general practitioner, *PT* physical therapist

Eighty-eight percent of the potential eligible patients were identified via practice software (as planned), and 6% were invited by direct contact in a GP practice.

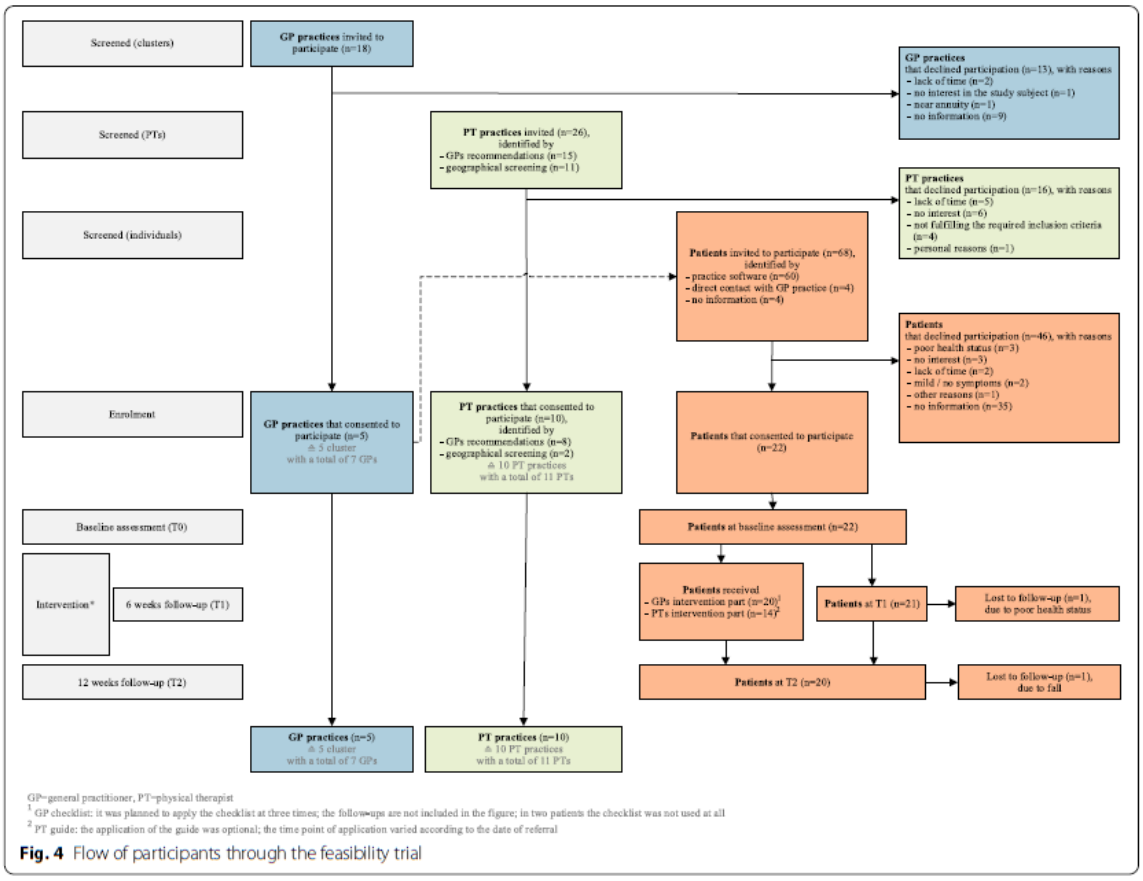
> *"I think that is always much more convincing for the patient than if he somehow gets a letter. [...] That is why it would have been the natural course of action for me to give it [the study information] to him immediately." (GP, 45 years)*

> *"A kind of one-pager I have at my desk [...] where I quickly have the essential points ready to tell the patient what to expect. So, in the next step, if he shows interest, I can simply give him the whole thing, because the difficulty then was to change the daily routine and quickly convey the five or six important points of the study to him." (GP, 57 years)*

An additional person was needed to help with the time-consuming search via practice software. One GP assigned an office assistant to inform the potential participants about the study by telephone before sending the documents.

The patients were satisfied with information documents regarding their comprehensibility, content and extent, but problems in readability occurred due to visual impairment. During the group discussion with the GPs, it was suggested that patients should receive an additional sheet summarizing the most important information.

The GPs identified 68 patients (60 via practice software, 4 through direct contact, and 4 missing data) between May and September 2019. A total of 46 declined participation, and only 24% sent back the cancellation form giving reasons such as a poor health status or no interest (for further information see Fig. 4). A total of 22 patients (32%) consented to participate



GP=general practitioner, PT=physical therapist

[1] GP checklist: it was planned to apply the checklist at three times; the follow-ups are not included in the figure; in two patients the checklist was not used at all

[2] PT guide: the application of the guide was optional; the time point of application varied according to the date of referral

Fig. 4 Flow of participants through the feasibility trial

(range: 3–8 per practice), which was below the planned number of 25 to 60 patients. The GPs suggested the reasons for the poor willingness to participate were the high expenditure of time and work overload involved in study participation, concerns about devices and some patients' acceptance of their VDB symptoms as given and unchangeable .

> *"Especially with these patients, who have been complaining about dizziness for a long time, the willingness to take part and to take on [...] a longer examination, then also the announcement that someone is coming to them or that they should possibly go to Rosenheim [...] [the participation] is suddenly low. I think that if I had said, 'Look, I have a pill here, take it and then we will see how it gets better' - then I would have had no problems." (GP, 66 years)*

The reasons given by the participants for participation were predominantly personal psychological strain due to VDB symptoms, the hope of improving their own situations or those of others, and general interest.

For further information and an overview of barriers and facilitators subdivided in all domains see Additional file 3.

The patients' mean age was 78.7 years; most of the patients were women (64%), and four had been rated as having a level of care dependency by expert raters of the medical service of the German statutory health insurance system (0 = "minor", 1 = "considerable", 2 = "severe", 3 = "most severe"; level 2: $n = 3$, level 3: $n = 1$). Half of the patients had received help from family members, friends, relatives or neighbours, and one person had received care from a home care nursing service within the last 4 months. For further information of the patient characteristics see Table 3.

Overall, 20 patients completed the trial. Two patients dropped out, one due a poor health status and one due to dizziness and subsequent hospitalization (see Fig. 4).

Table 3 Characteristics of the patients at baseline

Cluster	C01	C02	C03	C04	C05	Total
General practitioners, *n (%)*	1 (14.3)	1 (14.3)	1 (14.3)	1 (14.3)	3 (42.8)	7 (100.0)
Patients, *n (%)*	4 (18.2)	8 (36.4)	4 (18.2)	3 (13.6)	3 (13.6)	22 (100.0)
Age, *mean (range)*	72.5 (65.0–79.0)	81.3 (73.0–88.0)	78.0 (75.0–80.0)	79.0 (77.0–81.0)	81.0 (80.0–83.0)	78.7 (65.0–88.0)
Woman, *n (%)*	3 (75.0)	5 (62.5)	2 (50.0)	1 (33.3)	3 (100.0)	14 (63.6)
Due to the health status, assistance was received within the last 3 months, via, *n (%)*						
Care by a home care nursing service	0 (0)	0 (0)	0 (0)	0 (0)	1 (33.3)	1 (4.5)
Paid domestic help	0 (0)	1 (12.5)	2 (50.0)	0 (0)	1 (33.3)	4 (18.2)
Help from family members, friends, relatives or neighbours	2 (50.0)	4 (50.0)	2 (50.0)	1 (33.3)	2 (66.7)	11 (50.0)
Areas where assistance from other people is usually needed, *n (%)*						
Dressing and undressing	1 (25.0)	2 (25.0)	1 (25.0)	0 (0)	0 (0)	4 (18.2)
Body care	1 (25.0)	1 (12.5)	1 (25.0)	0 (0)	1 (33.3)	4 (18.2)
Get up	1 (25.0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (4.5)
Food and drink	0 (0)	1 (12.5)	2 (50.0)	0 (0)	0 (0)	3 (13.6)
Walking	1 (25.0)	3 (37.5)	1 (25.0)	0 (0)	0 (0)	5 (22.7)
Domestic help	2 (50.0)	4 (50.0)	3 (75.0)	0 (0)	2 (66.7)	11 (50.0)
Shopping	2 (50.0)	5 (62.5)	2 (50.0)	0 (0)	1 (33.3)	10 (45.5)
Takeover of driving services	1 (25.0)	6 (75.0)	3 (75.0)	1 (33.3)	1 (33.3)	12 (54.5)
Drug intake	0 (0)	5 (62.5)	3 (75.0)	0 (0)	2 (66.7)	10 (45.5)
Other	1 (25.0)	1 (12.5)	0 (0)	1 (33.3)	0 (0)	3 (13.6)
Level of care, *n (%)*	1 (25.0)	1 (12.5)	2 (50.0)	0 (0)	0 (0)	4 (18.2)
Level 0	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Level 1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Level 2	0 (0)	1 (12.5)	2 (50.0)	0 (0)	0 (0)	3 (13.6)
Level 3	1 (25.0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (4.5)

No missing values

Outcome measures and data collection procedures

Data collection in the patients The majority of the participants preferred data collection to take place in their homes due to their mobility restrictions and health status, and only three patients opted for assessment in the study centre.

Since most patients estimated the general effort of study participation to be rather low or even non-existent, the duration of the measurement appointments was satisfactory for them.

In some patients (T0: $n=8$; T1: $n=6$; T2: $n=2$) a relative was present during the measurement.

The patients rated the difficulty of the questionnaires as simple (mean: 2.0; coding: 1="very simple", 2="simple", 3="difficult", 4="very difficult", 5="impossible without aid"), but some patients needed support from relatives or the study assistant. The patients had the most problems with the IPAQ. The number of missing values in evaluation forms (total blank questionnaires: $n=9$; questionnaires with a single missing item: $n=1$) limited the interpretability, while the response rates for the DHI and EQ-5D-5L were 100%. For further information about the results of the standardized evaluation forms see Table 4.

Most participants rated the miniBEST as feasible, but some felt insecure depending on their condition on a particular day or any physical handicaps. Barriers to the performance of the miniBEST in the patients' homes were narrow rooms and potential stumbling blocks, but the study assistants' basic qualifications as PTs were an advantage in terms of safety.

The results of the DHI, EQ-5D-5L, IPAQ and miniBEST during the study process of intervention implementation are presented in Table 5. Due to the high number of missing values, no detailed analysis of IPAQ is given in Table 5.

The rate for the use of both sensors was rather high (T0: 82%, T1: 86%, T2: 80%), and the patients mostly wore the devices without experiencing any restrictions in daily

Table 4 Results of the standardized evaluation forms for the patients' questionnaires (DHI, EQ-5D-5L, IPAQ)

	T0 post (1 week)	T1 (6 weeks/7 weeks[a])			T2 (12 weeks/13 weeks[a])		
	IPAQ ($n=20$)	DHI ($n=21$)	EQ-5D-5L ($n=21$)	IPAQ[a] ($n=15$)	DHI ($n=20$)	EQ-5D-5L ($n=20$)	IPAQ[a] ($n=18$)
Independent completion possible, *n (%)*	9 (45.0)	14 (66.7)	12 (57.1)	8 (53.3)	16 (80.0)	14 (70.0)	7 (38.9)
Dependent completion with, *n (%)*	11 (55.0)	7 (33.3)	9 (42.9)	7 (46.7)	4 (20.0)	6 (30.0)	11 (61.1)
Relative	5 (25.0)	3 (14.3)	4 (19.0)	1 (6.7)	2 (10.0)	3 (15.0)	3 (16.7)
Acquaintance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Study assistant	6 (30.0)	4 (19.0)	5 (23.8)	6 (40.0)	1 (5.0)	3 (15.0)	7 (38.9)
Difficulty of completition[b], *median (range)*	2.0 (1.0–5.0)	2.0 (1.0–5.0)	2.0 (1.0–5.0)	2.0 (1.0–5.0)	2.0 (1.0–5.0)	2.0 (1.0–5.0)	2.0 (1.0–5.0)
Time (minutes) of completion, *mean (range)*	13.2 (3.0–60.0)	9.0 (3.0–30.0)	8.4 (2.0–20.0)	11.5 (1.0–30.0)	10.1 (3.0–30.0)	8.1 (2.0–22.0)	9.9 (2.0–30.0)

EQ-5D-5L EuroQol 5-dimension 5-level, *DHI* Dizziness Handicap Inventory, *IPAQ* International Physical Activity Questionnaire

[a]IPAQ measurement times: T0 post (1 week), T1 (7 weeks), T2 (13 weeks)

[b]Coding: 1 = "very simple", 2 = "simple", 3 = "difficult", 4 = "very difficult", 5 = "impossible without aid"

Missing values: IPAQ: total blank questionnaires T0 ($n=1$), T1 ($n=6$), T2 ($n=2$); single missing item T0 ($n=1$)

life, indicating good acceptance. While wearing the StepWatch4, the patients reported the device sliding down, itching, skin irritations and mild oedema and skin irritation. The Move4 required less patient compliance, as this sensor did not need to be removed and replaced by the patients (e.g., before and after taking a shower) during the week of data recording, and allowed better data handling and processing. The lower demand of this sensor might have led to a higher number of obtained valid recording days for the Move4 vs. the StepWatch sensor. Qualitative analysis of the physical activity diary entries suggests that the Move4 sensor better represented differences in physical activity levels within the patients. Thus, further outcomes will be reported only for the Move4 sensor. On average, the eight patients with valid data sets across all three time points took 6148 steps per day at T0, 5482 steps per day at T1 and 5306 steps per day at T2. Analysis of the patients' activity patterns revealed that the patients spent most of their time sedentary, i.e., sitting, lying or standing. This observation held true for the percentage share of sedentarism compared to that of activity, as well as for the bout length of sedentary phases (see Table 6). Importantly, while the total step count was within the range of that reported in other studies [45], the proportion and bout length of sedentary phases were substantially higher than those of healthy persons of the same age [46].

The participants evaluated the physical activity diary as understandable but also as time consuming.

Table 5 Results for the primary and secondary outcomes during the study

	Pre T0 ($n=22$)	T0: baseline[a] ($n=22$)	T1: 6 weeks[a] ($n=21$)	T2: 12 weeks[a] ($n=20$)
DHI, *median, (range)*	–	38.0 (4.0–84.0)	38.0 (12.0–82.0)	39.0 (6.0–80.0)
EQ-5D-5L, *mean (range)*				
Health state index	–	2.0 (1.6–2.5)	2.1 (1.8–2.6)	2.0 (1.5–2.5)
VAS	–	65.9 (30.0–90.0)	67.6 (20.0–90.0)	59.9 (10.0–90.0)
miniBEST, *median (range)*	–	17.5 (7.0–27.0)	20.0 (12.0–25.0)	19.0 (11.0–27.0)
IPAQ, *mean (range)*	3523.6 (66–12,798)	5793.4 (198–17,598)	4495.8 (146–16,160)	1730.8 (198–4377)

DHI Dizziness Handicap Inventory; coding: 0 = "no", 2 = "sometimes", 4 = "yes"; missing values: T0 ($n=1$, item = 1), T1 ($n=1$, item = 5), T2 ($n=1$, item = 4)

EQ-5D-5L EuroQol 5-dimension 5-level; coding health state index (see distinct item descriptions): 1 = "no problem", 2 = "slight problem", 3 = "moderate problem", 4 = "severe problem", 5 = "extreme problem"; no missing values

miniBEST Mini Balance Evaluation Systems Test; coding (see distinct item descriptions): 0 = "not possible", 1 = "medium", 2 = "normal"; no missing values

IPAQ International Physical Activity Questionnaire; coding: metabolic equivalent task minutes per week (METmin/week), missing values: preT0 ($n=1$), T0 ($n=5$), T1 ($n=5$), T2 ($n=8$)

VAS visual analogue scale

[a]one week after measurement point (IPAQ)

Table 6 Activity pattern in percent of time of the day spent in each class and mean bout length

Activity class		T0	T1	T2
Sitting/lying	*Proportion,*	74%	69%	72%
	mean bout length	30.1 min	38.2 min	35.8 min
Standing	*Proportion,*	2%	9%	5%
	mean bout length	1.4 min	2.9 min	1.3 min
Moving	*Proportion,*	6%	6%	6%
	mean bout length	2.0 min	1.8 min	1.6 min

Please note that the remaining percent of the day was classified as non-wear time

> *"I have entered this once every hour. I do not do that anymore. If I am completely honest, I calculate that as an average. When I am on the road or out for a walk, I can of course record it exactly. But how much I walk or sit around at home is more or less estimated." (Patient, 77 years).*

The rate of completition the diary was rather high (T0: 91%, T1: 81%, T2: 90%), and reasons for refusal were overload or an inability to complete it without assistance, e.g., due to visual impairment or writing problems. Despite the different levels of accuracy of the described activities, the diary was a helpful and necessary aid for the interpretation of the sensor data.

All participants took part in the telephone interviews (each one after T1 and T2); 4 persons were supported by relatives in both interviews.

There were no further problems in scheduling personal or telephone appointments or in the transfer of study documents and actigraphy to the study centre by the patients.

The telephone hotline was frequently used by the patients and their relatives before and during enrolment regarding organizational aspects (e.g., study duration and scheduling postponements) and mostly actigraphy (e.g., weight and size), indicating that this approach was feasible.

For further information and an overview of barriers and facilitators subdivided in all domains see Additional file 3.

Data collection in the clusters All GPs submitted their completed questionnaires (the QCPC and evaluation forms for the training and the recruitment process), and for 91% of the patients ($n = 20$) the completed checklist as required.

The GPs frequently used the study centre hotline, mostly regarding recruitment but also to request additional recruitment documents.

Despite the commitment of all GPs, only five GPs attended on the agreed date, so one cluster was not represented. In the additional individual telephone interview about the recruitment procedure, one GP out of each practice took part.

Additional resources involved in the GPs' study participation included personnel (office staff) and time; nevertheless, the GPs were well organized, so their study participation seemed to be integrated into their daily practice in an acceptable and practicable way.

For further information and an overview of barriers and facilitators subdivided in all domains see Additional file 3.

Data collection in the PTs There were no problems with the PTs completing and submitting the standardized questionnaires. All PTs submitted the completed guides, and 85% the additional treatment documentation as required.

Individual telephone interviews with the PTs took place as planned.

Time expenditure and organizational efforts were limited, and study participation was reported to be easy to integrate into daily practice. The study centre hotline was mainly contacted regarding organizational issues (prescription filling, study procedures, and requests for informational and educational flyers).

Data collection (the DHI and miniBEST) was reported as feasible, as it was the delivery of these questionnaires by the patients and additional emails from the research team.

For further information and an overview of barriers and facilitators subdivided in all domains see Additional file 3.

Feasibility of the intervention components and implementation strategy

The context: characteristics of the GP and PT practices

The GP practices treated over 500 to 2000 patients per quarter with 39% (mean) of patients being older than 60 years and an average of 33% (mean) of the patients having at least two chronic diseases.

The PT practices treated between fewer than 500 patients and more than 2000 patients per quarter (mode < 500 patients). On average, 57% of the patients were over 60 years old, and 47% had at least two chronic diseases.

During the intervention implementation, the following were reported as barriers for patients: low

treatment adherence; a lack of awareness of the intervention impact; and visual, writing or comprehension problems. Social support by relatives was reported as a facilitator.

Regarding the health professionals' motivation, positive expectations and familiarity with the intervention and support via the helpline were reported as facilitators. A lack of interdisciplinary exchange was rated as a barrier.

Organizational aspects (lack of time, short treatment units in the PT practices, and long waiting times for appointments with medical specialists/PTs) were rated as barriers. Intra-professional exchange was reported as a facilitator.

For further information and an overview of barriers and facilitators subdivided in all domains see Additional file 3.

Delivery to and response of clusters

All GPs took part in one of the offered training sessions in May/June and rated all statements regarding the achievement of the learning objectives as entirely true to partly true, indicating the good acceptance of the training. The GPs especially emphasized their satisfaction with the practical exercises, the good atmosphere and the small group size but requested the additional application of the checklist in a case study. All GPs believed that they had the competence to apply the checklist in practice. For further information about the results of the evaluation forms see Table 7.

Furthermore, the GPs asked for a brief summary of the whole examination procedure for patients with VDB in the form of a written handout with pictures or a homepage with videos.

The checklist was applied to 91% of the study participants ($n=20$) at least once. The expectations of the participating GPs were not in line with the initial aim of the checklist. The GPs expected a more comprehensive guideline to patient history and diagnoses rather than a short checklist.

> *"If the patient goes and says 'He asked me three questions and then sent me to an otolaryngologist', then he feels as usual that someone has not really taken him seriously and has not even examined him in a structured way." (GP, 45 years).*

The GPs stated that a chronological structure with a more detailed patient history section would be preferable, e.g., a two-sided document to combine the patient history; examination; and outcomes, such as referrals. They rated the paper format of the checklist (210 mm × 297 mm, ISO DIN A4) as feasible, and one GP stated that a digital form would be too complicated and could not be used in daily practice.

According to the GPs, problems completing the checklist arose due to unclear instructions. Overall, the GPs completed the checklist rather incompletely and made partly incomplete entries; e.g., they did not note referral to physical therapy.

Further deviations from the intervention protocol occurred in the timing of checklist application. The GPs frequently first completed the checklist during recruitment, which results in the baseline assessment not being able to be performed prior to the intervention as intended. A total of 41% of the patients attended all GP appointments as required (initial diagnostics, and follow-up after 4 weeks, follow-up after 8 weeks/3 months), 14% were seen by their GP twice and 36% kept only the initial appointment. According to the GPs, the reasons for the patients not attending all appointments were the GPs forgetting to actively schedule patients for their next appointment at the practice, but mostly the patients' poor adherence to the prescribed treatment schedule. The patients reported lack of scheduling by the GP, as most of them proactively contacted their GP due to the need for a follow-up referral to a PT. In two patients (9%) the checklist was not used at all.

A total of 14 patients (64%) were referred to physical therapy. For 79% of the patients, the GPs used a VDB-specific ICD code (3 missing) and for 71% the VDB-specific indication code (1 missing) was used as intended. Most GPs referred patients to physical therapy ($n=11$, 79%; 3 missing), and for two patients (14%), the GP additionally prescribed classical therapeutic massage. Mostly, there was no interdisciplinary exchange between the GPs and PTs.

A total of 46% of the study participants received a referral to at least one medical specialist.

All GPs stated that the high time expenditure required to apply the checklist (range: 20–30 min) made an appointment outside office hours necessary. Routine was mentioned to be beneficial for the application of the checklist in daily practice.

> *"If you do it [the checklist] more often, you can easily get it done in 15 to 20 minutes. [...] And these are worthwhile 20 minutes [...]. So, you save a lot of time afterwards." (GP, 45 years).*

Despite the required adaptations to the procedure to enhance its user-friendliness, the GPs saw added value because the standardized procedure gave them security in dealing with affected persons, and the exclusion of patients with alarm symptoms. This finding indicates a change in the GPs competence and behaviour in the treatment of patients with VDB.

Although all GPs appreciated the offered telephone helpline, only one GP used it for a question in completing the checklist (call duration < 5 min).

Table 7 Evaluation of educational training of GPs

No.	Evaluation area and domain	1st educational training date (*n* = 5)	2nd educational training date (*n* = 2)	Total (*n* = 7)
Dissemination of knowledge, *median (range)*				
	At the training, I was systematically taught			
1	The differences between the most important vertigo syndromes.	2.0 (1.0–3.0)	1.5 (1.0–2.0)	2.0 (1.0–3.0)
2	Methods for diagnosing positional vertigo.	1.0 (1.0–1.0)	1.5. (1.0–2.0)	1.0 (1.0–2.0)
3	Forms of therapy and their instructions for the most important vertigo syndromes.	2.0 (1.0–4.0)	1.5. (1.0–2.0)	2.0 (1.0–4.0)
4	How to apply the checklist in practice.	1.0 (1.0–2.0)	1.0 (1.0–1.0)	1.0 (1.0–2.0)
Gain in know-how skills, *median (range)*				
5	At the training, I was systematically taught a neurological screening.	2.0 (1.0–3.0)	1.5 (1.0–2.0)	2.0 (1.0–3.0)
6	After the training, I feel able to apply the demonstrated examination techniques.	2.0 (1.0–2.0)	1.0 (1.0–1.0)	1.0 (1.0–2.0)
7	The contents of the training were adequate for the independent practical application of the checklist.	2.0 (1.0–2.0)	1.0 (1.0–1.0)	1.0 (1.0–2.0)
8	The workshop was well-structured and organized for practical application of the checklist.	2.0 (1.0–2,0)	1.0 (1.0–1.0)	1.0 (1.0–2.0)
Temporal organization, *median (range)*				
9	The duration of the workshop was appropriate.	1.5 (1.0–2.0)	1.0 (1.0–1.0)	1.0 (1.0–2.0)
Total quality of educational training (No 1–9), *mean (range)*		1.7 (1.0–2.0)	1.2 (1.0–1.5)	1.3 (1.0–2.0)
Other, *median (range)*				
10	In your opinion, is there a need for such training among GPs?	1.0 (1.0–2.0)	1.0 (1.0–1.0)	1.0 (1.0–2.0)
11	Do you already use the presented techniques for vertigo syndromes?	3.0 (1.0–4.0)	2.5 (2.0–3.0)	3.0 (1.0–4.0)

Coding: 1 = "entirely true", 2 = "partly true", 3 = "rather not true", 4 = "completely untrue"

Missing values: Item 9 (*n* = 1)

Note: Besides these 11 domains, the following 3 questions could be answered in free text form (qualitative analysis): What did you particularly like about the training? What did you not like about the training? What else would you have liked?

The GPs were pleased with the qualification certificate and the certificate for study participation, which some of them displayed in their practice.

For further information and an overview of barriers and facilitators subdivided in all domains see Additional file 3.

Delivery to and response of PTs

All PTs attended the educational training at the beginning of the study directly after recruitment of all participating PTs in May. All statements regarding the achievement of learning objectives were rated as entirely true, indicating a very good acceptance of the workshop. They especially highlighted the interplay between the theoretical and practical parts, and all PTs believed they had the competence to apply the guide in practice. For further information about the results of the evaluation forms see Additional file 4.

The PTs rated the supportive materials as helpful for understanding the content, whereas they requested further summaries of treatment techniques in written form or video tutorials.

The guide was applied to all study participants who were referred to trained PTs. The PTs evaluated the content and structure of the guide as good and rated the paper format (297 mm × 420 mm, ISO DIN A3) as feasible and clearly arranged. The time required for the application of the guide differed between the PTs (range: 15–30 min), and most managed to complete it within one treatment unit. There were no additional personal resources needed. Overall, the PTs completed the physical assessment section of the guide fully but used the performed assessments rather incompletely.

All PTs stated to have profited from the use of the guide, especially due to the structured procedure, which allowed the patients to benefit from adequate treatment and efficient clinical reasoning.

> *"If I save time with the diagnostic process, he [the patient] has more time for therapy at the 1st appointment. [...] If I know in a more focused way where exactly the problem is, I can help even better, offer support. [...] So, I think he simply benefits from the fact that you know much more focused (PT, 33 years)*

Overall, the PTs rated the intervention as acceptable and feasible in daily practice, with practical exercise through repeated application of the guide leading to safety in use and thus to time savings.

The PTs reported changes in their competence and behaviour and indicated that their self-efficacy was strengthened by the knowledge and skills they acquired during the training.

The PTs adhered to the guide well so that all patients received VDB-specific treatment and at least one target group-oriented flyer (92%). The PTs evaluated the treatment as targeted to patient needs and age.

> *"I always put a cross on the exercises that we have discussed or that they can or should do at home. And that simply makes it easier. There is the picture and the text, well explained. I find it very helpful." (PT, 52 years)*

Most PTs reported that interdisciplinary interaction with the GPs was scarce, whereas intra-professional exchange in practice teams and with colleagues outside increased.

The utilization of the telephone helpline was scarce (1 call, call duration < 5 min). A reason for a lack of use of the helpline was stated only by one PT (forgot about the option).

For further information and an overview of barriers and facilitators subdivided in all domains see Additional file 3.

Delivery to and response of individuals

Almost all patients (91%) received the GP intervention between June 2019 and January 2020, and they were mostly satisfied with their treatment. A total of 10 patients (46%) received a referral to at least one medical specialist (cardiologist, ophthalmologist, neurologist or ENT physician) and 64% ($n=14$) received a referral to physical therapy. However, 14% ($n=3$) received neither a referral to PT nor a referral to a medical specialist. Additionally, two patients declined a referral to a PT due to lack of interest and focus on other acute health issues. The GPs reported patients' characteristics (poor motivation and lack of awareness about the effects of specific therapy) as potential barriers for further referral, as well as organizational issues. 93% of the patients with referrals to a PT decided to go to practices with specially trained PTs and reported being satisfied with therapy. The patients rated the leaflets for home exercises as easy to understand and the exercises to be feasible to complete at home, whereas two persons received help from relatives in performing the exercises. Most reported that they performed the exercises regularly, motivated by the hope of symptom relief, but a few reported that they only sporadically performed exercises due to lack of time, a focus on other health issues or forgetting.

> *"I just realized it is getting better. [...] Vertigo seems to be a vicious circle. That means when I have vertigo, I do less activity. Less activity means, especially in older people, that the muscles weaken and the problem becomes increasingly worse. [...] So if I now try to at least do exercises and train these areas a little bit [...] I hope that the strength, i.e., the intensity of the vertigo, is no longer the same as before." (Patient, 67 years)*

Unintended consequences

Health professionals reported no unintended harmful consequences for patients or themselves of the application their parts of the intervention. No patients suffered harm, e.g., due to a fall event directly related to the intervention, which indicates its safety.

Discussion

This study mainly confirmed the feasibility of the proposed intervention and study design but also identified aspects to be optimized.

We made use of reported promising recruitment strategies, such as personal contact [47, 48]; aimed to minimize the time demand for participants [47]; and provided payment [49]. Nevertheless, the recruitment of GPs was difficult, as reported in other studies [47, 49]. However, in contrast to these findings, we did not experience any dropouts during the study. In line with previous recommendations [48], we planned to involve practice staff in informing patients about the study. However, we observed that brief training and written guidelines would have been useful. In addition, we found that close contact between the research team and the GPs to identify problems early and misunderstandings might have led to the more efficient recruitment of patients. Additionally, even though the reported prevalence of VDB has been reported to be up to 50% in patients over 65 years [5–8], the identification of appropriate patients is difficult and cannot be explained by the characteristics of GP practices alone. We hypothesize that the frequently reported problem of diagnosing VBD, which favours extensive health care utilization [14, 15] might have led to that issue.

The recruitment of PTs was easier, but early contact seems to be advisable. In addition, more than a single PT per practice should be trained to both avoid long waiting times and optimize the reach of the intervention.

As the patients mostly opted for measurements in their homes, the need for study assistants should be calculated

carefully. The engagement of relatives was found to facilitate patient adherence and attrition. We therefore suggest a stronger involvement of relatives, which is consistent with previous research [50].

Completing the IPAQ, which was developed to be used in a younger population [31], was challenging and resulted in many missing values, so its use in a larger trial is not recommended. The response rate and acceptance for both physical activity sensor models were high, but one (Move4) model provided better data; therefore, we recommend its use with an adapted version of the physical activity diary including standardized, quantitative dizziness assessment (e.g., DHI) for the evaluation of physical activity in future trials. For adequate interpretation of objective activity measures, patients should be classified according to their gait mobility (e.g. use of a walking aid) [51, 52]. In addition, we recommend a standardized gait test (100 m or 20 m) [51, 52] at the beginning of each measurement period for the evaluation of relevant gait parameters.

We used a combination of different implementation strategies according to the Expert Recommendations for Implementing Change [53]. In line with previous trials [54–58], all health professionals emphasized the training to be essential and appreciated the interlocking of the theoretical and practical parts [57, 59]. Since GPs mentioned that they were not sufficiently trained in the practical application of the checklist during the educational training, we plan to include the application of the checklist in a case study, for which a longer time period of training should be set. Since the PTs were interested in information about the GP tasks, joint training of both GPs and PTs, including an overlapping introduction, may be reasonable and might additionally have a positive impact on interdisciplinary communication. The use of supportive resources is well established as part of effective interventions [57] and the materials were positively received and used. For the main trial, the request for further summaries, e.g., in the form of a website with videos and written material, should be taken into account.

Although the intervention was delivered to health professionals as intended, it was not sufficiently delivered to the patients by the GPs, especially due to adherence issues in application of the checklist. In addition to time issues, the main reason for the lack of adherence in the application of the checklist was probably the GPs' different expectations of the intervention compared to the initial aim of the developers. This deviation could be due to the small number of participants (at the development and feasibility phase), which may have led to distorted and non-generalizable opinions from overly motivated participants. We are confident that the GPs' adherence to the intervention protocol could be improved through a combined application of a revised version of the checklist; more pronounced practical exercises; and improved supportive material related to diagnostic and therapeutic techniques, such as positioning manoeuvres. The compliance of GPs with planned timelines could be improved by using telephone reminders, which is a well-established approach [60]. The use of the PT guide was implemented as planned and was found to be feasible. Both the PTs and GPs rated the paper material as practicable, while some PTs reported that they would appreciate a digital form, provided that the form would be technically compatible with existing systems. For the main study, the option of a digital application was envisaged, but this option needs to be further evaluated in view of the preferences of the participants. However, the integration of interventions into practice software could offer the possibility to promote the fitting of interventions into daily practice [58] and may additionally improve interdisciplinary exchange [61].

Despite the health professionals' enthusiasm for the telephone helpline, its utilization was low, and contact on a regular basis might be beneficial [62].

Our results show that the success of intervention also depends on patient adherence, which was mostly good in this study, e.g., in the regular performance of home exercises. Only a few patients showed a lack of adherence, which is a well-known problem in implementation of interventions [56, 63, 64]. Reasons for the well-known problem of lack of adherence [56, 63, 64] must be analysed individually to find solutions to promote acceptance and intervention implementation. Since we found that individual characteristics impacted the success of the intervention application, patients' abilities and behaviour must be taken into account.

In contrast to the findings of the previous part of this study (development phase), which identified the wish for better multi-disciplinary exchange as a key to successful treatment of VDB, our results showed very low communication between the GPs and PTs. Since good multi-disciplinary communication and cooperation have been stated as facilitators by health professionals [56, 61, 65] and patients [50], it seems to be beneficial to invest more efforts to improve this communication.

Overall, this study confirmed that our programme activities were mainly effective in changing health professionals' behaviour, as hypothesized in our logic model. Despite the initial difficulties, all health professionals used the new knowledge and skills to apply their part of the intervention, with some adjustments. They perceived an improvement in competence and self-efficacy,

which contributed to the improvement in the patient's situation.

There were no harmful unintended consequences of the intervention.

Strengths and limitations

A strength of the study is the rigorous and comprehensive process evaluation in the feasibility stage, which is highly recommended for newly developed interventions [32], and the mixed-method approach considering different perspectives to achieve a detailed comprehension of how the intervention works [32].

Our study also has limitations, especially regarding problems in recruitment. Since the participants were difficult to recruit, only a small number of GPs and – consequently – patients were included, leading to a potential bias in the results. Notably, mainly younger and more physically active patients were enrolled in the study, whereas the intervention was initially targeted at older patients with multi-morbidity and immobility.

Conclusion

Although the study results provide good support for the feasibility of the intervention in older patients with VDB in primary care, they reveal important insights into challenges and the need for improvement of the intervention, its implementation strategy and study procedures. In particular, the recruitment of GPs and patients is challenging, and more detailed guidance from the research team for GPs is required. Due to difficulties with GPs' adherence to the study and intervention protocol, the intensification of regular exchange between the GPs and the research team is highly recommended to eliminate misunderstandings. Furthermore, a revision of the checklist is necessary. In a next step, the further developed and optimized intervention might be investigated for its effectiveness in a large cRCT.

Abbreviations

BCW: Behaviour Change Wheel; CONSORT: Consolidated Standards of Reporting Trials; COM-B: Capability-Opportunity-Motivation-Behaviour (model); CPW: Care pathway; cRCT: Cluster randomized controlled trial; CRD: Centre for Reviews and Dissemination; DHI: Dizziness Handicap Inventory; ENT: Ear-nose-throat; EQ-5D-5 L: EuroQol5-dimension 5-level; GP: General practitioner; ICD: International Statistical Classification of Diseases and Related Health Problems; IPAQ: International Physical Activity Questionnaire; MET-min/week: Metabolic equivalent task minutes per week; miniBEST: Mini-Balance Evaluation Systems Test; MRC: Medical Research Council; PT: Physical therapist; QCPC: Questionnaire of Chronic Illness Care in Primary Care; REDCap: Research Electronic Data Capture; TIDieR: Template for Intervention Description and Replication; UK: United Kingdom; VAS: Visual analog scale; VDB: Vertigo, dizziness and balance disorders.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12875-021-01410-2.

Additional file 1. Manual for the recruitment of patients

Additional file 2. Overview of components and methods of the process evaluation alongside the feasibility study (based on Logic model, study process and domains by Grant et al. [33])

Additional file 3. Barriers and facilitators alongside the feasibility study

Additional file 4. Evaluation of educational training of PTs

Acknowledgements

We would like to thank all participating GPs, PTs and patients. Furthermore, we would like to thank Caren Horstmannshoff and Martin Elgeti for their support in analysing the quantitative data of our study.

Authors' contributions

MM and PB contributed to the conception of the study, applied for funding and conceived the study design. ES and VR developed the concept for process evaluation. ES, VR and CN coordinated all study processes and conducted qualitative group and individual interviews. CN contributed to the acquisition of the data of questionnaires, performance tests and actigraphy devices and was responsible for data management. ES and VR conducted data analysis except for actigraphy, IPAQ and physical activity diary. The data collection and analysis of actigraphy, IPAQ and physical activity diary was planned and conducted by AG, MK and JH. ES drafted the manuscript. MM, PB and VR critically revised the draft, and all authors contributed to the final writing of the paper. MM is the principal investigator of the study and holds senior authorship. All authors read and approved the final manuscript.

Funding

Open Access funding enabled and organized by Projekt DEAL. This study is part of the project "Munich Network Health Care Research - MobilE-NET" and was funded by the German Federal Ministry of Education and Research (grant number 01GY1603C).
This work was also supported by the Bavarian Academic Forum (BayWISS) – Doctoral Consortium "Health Research" and was funded by the Bavarian State Ministry of Science and the Arts.
The funding body had no influence on the design of the study; the collection, analysis, or interpretation of the data; or the writing of the manuscript.

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

All relevant study-related documents were submitted to the Ethics Committee of the Medical Faculty of the Ludwig-Maximilians-Universität München prior to the start of the study (project number: 18–431, development phase) (project number: 19–192, feasibility study). Each participant had to sign a written informed consent form prior to enrolment.

Consent for publication

All patients gave consent for the publication of anonymised data.

Competing interests

The authors declare that they have no competing interests.

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Received: 6 September 2020 Accepted: 10 March 2021
Published online: 02 April 2021

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Publisher's Note

Danksagung

An dieser Stelle möchte ich allen beteiligten Personen, die mich bei der Anfertigung meiner Dissertation unterstützt haben, meinen großen Dank aussprechen.

Besonders danken möchte ich Herrn Prof. Dr. Martin Müller für das Überlassen des spannenden und vielseitigen Promotionsthemas und das mir damit entgegengebrachte Vertrauen, ebenso wie für seine stetige Bereitschaft zum fachlichen Austausch, die wertvollen Anregungen sowie für die kompetente wissenschaftliche Betreuung und die Unterstützung bei der Umsetzung der gesamten Arbeit.

Außerdem möchte ich mich bei Frau Prof. Dr. Eva Grill für deren Bereitschaft der Übernahme meiner Betreuung seitens der Ludwig-Maximilians-Universität München und demnach für die Ermöglichung einer kooperativen Promotion bedanken.

Den Co-Autoren gilt mein Dank für die gute und konstruktive Zusammenarbeit.

Für die finanzielle Unterstützung danke ich dem BayWISS-Verbundkolleg.

Mein größter Dank gilt meinen Eltern, die immer an mich glauben, mich bei allen meinen Vorhaben in jeglicher Hinsicht unterstützen, mich motivieren und ermutigen. Ein besonderer Dank gilt meinem Partner für seinen Zuspruch, seine Aufmunterung und die Ablenkung. Danke, dass ich immer auf euch zählen kann.