

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 standardised 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. Intervention consisted of a diagnostic screening checklist for GPs and a guide for PTs. Implementation strategy contained specific educational trainings and a telephone helpline. Data for mixed-method process evaluation was collected via standardised questionnaires, field notes and qualitative interviews. Quantitative data were analysed using descriptive statistics, qualitative data via 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 rate GP practices: 27,8%; PT practices: 38,5%). 91% of 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). Routine in the intervention's application and positive attitudes were emphasised as facilitators for the interventions' implementation, whereas lack of time was mentioned as a barrier. Despite of difficulties in GPs' adherence to intervention protocol, GPs, PTs and patients benefited from the intervention. The patients' treatment adherence to physical therapy was good. There were minor issues in data collection, but no unintended consequences.

Conclusion

Although the process evaluation provides good support for the feasibility of study procedures, the intervention and its implementation strategy, we identified a need of improvement in recruitment, the GPs' intervention part and data collection procedures. Findings will inform the main trial to prove the interventions effectiveness in a cluster RCT.

Trial registration

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

Background

Vertigo, dizziness and balance disorders (VDB) are frequent complaints of older people [1–4] with reported prevalence of up to 50% [5–8]. VDB in older persons are distinct risk factors for falls [2] and even fear of falling may lead to activity restriction and disability [9]. Occurrence of these symptoms are common reasons for consultation in general practice, with stated consultation prevalence up to 15.5% [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 like imbalance and falls that result in limited mobility and participation restrictions [16–19]. Despite its sufficient quality of evidence, physical therapy seems not to be a standard option in 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 optimize 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 primary care setting by offering standardised 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 the 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 investigating strengths and weaknesses.

Specific objectives were to evaluate:

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

Methods

Study design

This prospective cohort feasibility study seeks to simulate the intervention arm of a future cluster RCT (cRCT). It was accompanied by a mixed-method process evaluation to allocate a detailed comprehension on how the intervention works. Since we have experienced problems with the recruitment of clusters, 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 couple consisting of a GP practice and a PT practice as a cluster, as 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 physician has professional working experience with patients with VDB and accreditation of the statutory health insurance. Initially it was considered to include only health professionals with at least three years after medical licensure, but due to organisational and availability reasons we decided to give up this limitation. GP practices were recruited in the region of Southern Bavaria, Germany and were searched via database research. Initial invitation to participate was done via telephone call followed by an electronic mail and a personal visit for further information.

Eligible patients (individuals) had to be at least 65 years old and must have consulted their GP with complaints of VDB of any etiology within the last three years. They had to have no legal guardian but appropriate verbal and cognitive command of the German language to give written informed consent, fill in questionnaires and follow verbal and written instructions. Due to the conduction of a physical performance test for outcome measurement, they had to be able to walk 10 meters (with or without walking aids). Patients were excluded from the study when in-patient hospital treatment was required. After giving informed consent, GPs were asked to identify eligible patients based on a provided list with inclusion criteria by searching their practice software using *International Statistical Classification of Diseases and Related Health Problems* codes (ICD) or free text search

(see Additional file 1 for manual for recruitment of patients) and to recruit them via sending informational documents by postal mail. With this recruitment procedure we intended to simulate a baseline assessment before randomisation for a planned future cRCT.

Local PT practices were identified by 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 of GPs applied to PTs.

The Intervention

The intervention is a CPW to improve participation and mobility in older adults with VDB in primary care setting by offering standardised 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. It was conducted by iterative involvement of health professionals, patients and experts in this field. 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 illustrating all steps of the patients' path in a structured way, that consists of two main components:

(1) A checklist for diagnostic screening for GPs, that describes evidence-based treatment and referral options and specific time lines for follow-ups. This checklist for GPs that manage patients with VDB aims to (a) exclude life-threatening conditions (b) promote reliable diagnosis and evidence-based treatment by GPs (c) ensure a rational referral regime to other health professionals.

(2) Since a referral to physical therapy is a relevant option, the CPW also comprises an evidence-based guide for clinical reasoning and treatment of VDB for PTs covering information about anamnesis, assessment, treatment options and evaluation. The PTs' intervention part additionally comprises targeted group-oriented informational and educational flyers for handing out to patients: different leaflets with home exercises (physical therapy for balance disorders, gait disorder, vertigo, instructions for the positioning manoeuvre), informational flyers (symptom control of vertigo and nausea, frequently asked questions about benign paroxysmal positional vertigo).

The checklist and the guide are not available since they are not evaluated for effectiveness and safety so far.

The relationship between the CPWs' components can be taken from Fig. 1.

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

The key components of the implementation strategy were face-to-face educational group trainings for GPs (90 minutes) and for PTs (one day) containing demonstrations of pretended skills, do-it-yourself-elements with feedback and instructions for the intended application of the corresponding CPW part each. The training for GPs was held by a neurologist, the training for PTs by a specialist PT. Both trainings included a short information about the study's background and logistics, provided by the research team. Participation in these trainings was free of charge. For participation, the health professionals received a qualification certificate. The health professionals also received supportive materials about the trainings' content, the intervention and contact details. PTs received written materials in preparation for the training and a supplementary update of a diagnostic test. GPs received written instructions about a diagnostic procedure.

Additional support was provided through mentoring. A telephone helpline for GPs was provided by an Oto-Neurologist who was also co-developer of the checklist and held the training. A telephone helpline for 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 practice as well as a case payment per treated study patient (GPs: 40 €; PTs: 20 €).

Outcomes and data collection procedures

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

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

Table 1
Overview of used outcome assessments and timeline

Outcomes	Data collection procedures/assessments	Study period				
		Enrolment	Time of data collection			Close-out
		<i>Pre T0</i>	<i>T0</i>	<i>T1</i>	<i>T2</i>	<i>Post T2</i>
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	5-level EuroQol 5-dimensions (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*	X*	X*	
- 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	Standardised questionnaire about sociodemographic data	X				
- Structural practice data of GP and PT practices	Standardised questionnaire about structural practice data based on the QCPC	X				
- Trial feasibility	Research team		X	X	X	
- Feasibility of the intervention components			X	X	X	
- Feasibility of the implementation strategy	GPs			X		
	Group interview with GPs					
	Individual interview with GPs	X				
	Standardised questionnaire about the recruitment process	X				
	Standardised evaluation forms for the educational trainings	X				
	Field notes of contact with GPs via telephone or email	X	X	X	X	X
	Field notes by GPs ²		X	X	X	

		Study period				
PTs	Individual interviews with PTs					X
	Standardised evaluation forms for the educational training	X				
	Field notes by PTs ³		X	X	X	
	Field notes of contact with PTs via telephone or email	X	X	X	X	X
Patients	Individual interviews with patients			X		X
	Patients' cancellation forms	X				
	Standardised evaluation forms after each questionnaire	X	X	X	X	
	Field notes by the patients ¹		X	X	X	
	Field notes of 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

* one week after measurement point

¹ Patients' field notes in free text option in physical activity diary

² GPs' field notes in form of filled checklist including free text option

³ PTs' field notes in form of filled guide including free text option and treatment documentation

Primary Outcome

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

Secondary Outcomes

Secondary outcomes were balance measured by the *Mini-Balance Evaluation Systems Test* (miniBEST) [29] and health-related quality of life assessed by the *5-level EuroQol 5-dimensions* (EQ-5D-5L) questionnaire [30]. The patients' physical activity was assessed by the combination of objective and subjective measurement tools: For objective assessment of physical activity profiles: patients were asked to wear the two different activity sensors: (1) the Move4 (Movisens GmbH, Germany) attached at the thigh with an adhesive tape, as well as (2) the StepWatch4 (modus health llc, USA) worn on the ankle with a strap. 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 profile. In addition, physical activity was quantitatively assessed by the International Physical Activity Questionnaire (IPAQ) [31]. Further, patients were required to keep a physical activity diary during the period of data recording to obtain qualitative information about times and types of activity, daily time spent in moving, sitting, lying and about the occurrence of VDB on the objectively recorded physical activity data.

Data collection procedures

At baseline, data collection of questionnaires (DHI, EQ-5D-5L, IPAQ) was performed together with the study assistant; at follow-up, patients were asked to complete the questionnaires by themselves but assistance was provided on request. The IPAQ had to be completed at T0 in order to assess baseline physical activity prior to wearing the activity sensors. Subsequently, the IPAQ had to be completed directly following the week of objective data recording by means of the activity sensors, i.e. one, seven and 13

weeks after baseline assessment. By this, at each measurement point physical activity performed over a period of one week was assessed by means of three different measurement tools: IPAQ, Move4 and StepWatch. This procedure was chosen to be able to compare the different measurement tools and decide on the most feasible and informative tool with regard to the prospective large-scale cRCT. The miniBEST performance test and handing-out and attachment of the actigraphy activity sensors was carried out in a personal appointment between the patient and the study assistant. Results of 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 recommended domains: recruitment of clusters and individuals, context, delivery to and response of clusters and individuals and unintended consequences. We did not consider the domain of effectiveness, because we did not aim to estimate any treatment effects in this feasibility study. We did also not consider the domain of maintenance due to the short duration of the study. However, we additionally observed the performance and feasibility of the outcome measures and data collection procedures.

For data collection, we used continuous field notes, standardised questionnaires for study participants, semi-structure individual telephone interviews with cluster members (here: GPs), patients and PTs and a face-to-face group interview with cluster members and checklist-developers. Assessment of difficulty of completing in evaluation forms for patients' questionnaires was divided into five categories (1="very simple", 2="simple", 3="difficult", 4="very difficult", 5="impossible without aid"); assessment of evaluation of educational trainings for health professionals into four categories (1="entirely true", 2="partly true", 3="rather not true", 4="completely untrue"). Interviews to gain a detailed insight into experiences were conducted by members of the research team (ES, VR); group discussion was moderated by both researchers at study centre.

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

Recruitment of health professionals was assessed before and during the intervention. Information about reasons for study participation were collected by personal interviews. We investigated the recruitment procedure and retention rate including reasons for early study termination via taking continuous field notes. The flow of recruitment and reach was documented using recruitment protocols. To evaluate their response, participants were asked about satisfaction with recruitment via personal interviews. To assess sociodemographic information and structural practice date, we used a questionnaire based on the *Questionnaire of Chronic Illness Care in Primary Care* (QCPC) [34].

Recruitment and reach of individuals

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

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

Outcome measures and data collection procedures in patients

Utilization of outcome measures and performance of data collection procedures in patients were assessed during the intervention. To evaluate the delivery, protocol deviations and missing data were documented. Response of patients regarding measurement

procedures, satisfaction with organisational aspects and effort for study participation were evaluated by analysing interviews, contact and field notes. To assess the feasibility of questionnaires, we asked patients to fill in the supplemented evaluation form about difficulties and time consumption.

Outcome measures and data collection procedures in 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 health professionals in order to evaluate their response regarding procedures, study logistics, effort and the feasibility of study participation in daily practice.

Feasibility of intervention components and implementation strategy

The evaluation of the intervention components and its implementation strategy includes assessment of context, delivery to and response of clusters, PTs, individuals and unintended consequences. Data was collected prior to, during and after the intervention to appraise changes over the time of the whole study process.

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 interventions' implementation were assessed in a group interview with GPs, in individual interviews with PTs and patients and via analysis of field notes.

Delivery to and response of clusters and PTs

Information about delivery of intervention to the health professionals was assessed during the intervention via interviews and field notes. The health professionals' response about the intervention, its integrability into daily practice including difficulties in delivery, experiences within the implementation process and adaptations were assessed during and after the intervention. To gain a deeper insight in their perception of educational trainings, we used standardised evaluation forms including aspects like content, structure and quality. Additionally, we analysed interviews, field notes and contact. Participants were asked for fidelity of helplines via interviews. The helpline was additionally analysed via field notes of contact with health professionals by the research team (e.g. content, total number, duration). The health professionals' satisfaction with the intervention, their adherence and adaptations were evaluated in interviews, analysis of contact with participants and field notes including the filled checklists/guides. Analysis of field notes was also used to evaluate deviations from implementation protocol and attendance. Attitude and behaviour changes of health professionals in daily practice and their experiences during implementation process were also assessed in interviews and in field notes. Additionally, health professionals had the possibility to take notes by free text options.

Delivery to and response of individuals

Delivery of intervention components to patients was evaluated during and after the intervention via interviews with patients and health professionals, contact and field notes including a comparison with filled checklists/guides. Predominantly, the method of telephone interviews with the target group was used to assess their experience and response of intervention including adherence and behavioural change. To consider the health professionals' perspectives we also analysed interviews with them to get a multifaceted insight.

Unintended consequences

Unintended consequences in process and outcomes of the intervention and its implementation strategy were assessed during the intervention via interviews with 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. Analysis must therefore be considered as exploratory. Based on pragmatic considerations and to obtain sufficient information about the feasibility and

acceptance of the intervention and the feasibility of study procedures, we planned to include five GP practices in the study, each with five to 10 patients.

Data analysis

For analysis of assessment instruments, standardised questionnaires and of parts of documentary data, we entered 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. Continuous data were summarised using mean, standard deviation, variance and range; discrete data via median, interquartile range and range; categorical values using absolute and/or relative frequencies. For the single items of evaluation of the educational trainings we used analysis for discrete data and for a combination of them to describe a total estimation mean of medians.

Sociodemographic data based on the QCPC was stratified on cluster level or PT practice level. In patients' data, statistical analysis was performed using R statistic software [35]. Since the focus of this study is on feasibility, we did not aim to estimate treatment effects and therefore did not calculate statistical significance, as is often erroneously done in feasibility studies [36]. The study assistant assessing and entering data was not involved in analysis.

Qualitative interviews were audio-recorded and transcribed verbatim according to the rules of Kuckartz [37] with F4 transcription software under consideration of taken field notes. Analysis was conducted using MAXQDA software [38] following content analysis according to the concept of qualitative description [39, 40] by independent researchers (ES, VR) in order to develop a shared coding through consensus. Any disagreements between coders were discussed, if required with a third researcher (MM). In terms of quality assurance, participants of group interview were offered the opportunity to verify and modify results. Analysis of the contact with study participants via the telephone helpline, hotline or email, of parts of continuous field notes and physical activity diary were also conducted qualitative.

Sensor-based activity data was evaluated in a multi-step 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 acceleration profiles were summed in bins of 1 min for the whole period of data recording. Based on that, for each time bin the following parameters were extracted: steps (Movisens and StepWatch) and activity class (sitting/lying, standing, moving, for Movisens only). All subsequent data processing was performed using Excel (Microsoft Corporation, Redmond, WA, USA). In a first step, for each patient, each measurement point and each parameter, data was pooled in 24hrs periods, i.e. days of recording. Based on that, the following parameters were calculated for each day of recording: difference in recorded steps between the two sensors, i.e. $\text{steps}_{\text{Movisens}} - \text{steps}_{\text{StepWatch}}$, the share of each activity class expressed as the percentage of the day of recording, as well as the mean duration spent consecutively in one activity class, hereafter referred to as mean bout length. Subsequently, valid days of recording were identified following the recommendations by [41–44]: for a day of recording to be counted as valid, patients had to wear the sensor for at least ten hours and walk at least 200 steps. Only patients with at least four valid days of recording were included in further analytical steps. Next, for each patient and each of the above-mentioned parameters the mean across all valid days of recording was calculated. To be able to interpret quantitative differences between activity sensors, the physical activity diary was used for qualitative assessment of 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).

When interpreting the results of this trial, we took a combination of qualitative and quantitative data assessed in process evaluation into account.

Results

Trial feasibility

Recruitment of clusters

Recruitment of clusters took place between February and April 2019 and was time-consuming due to the GPs' limited reachability, issues in receiving the information via email, whereas the use of a fax was proved to be more practical. Since most GPs cancelled the initially planned collective information event for time reasons, we visited each practice for presentation of further information (mean duration: 22 minutes). GPs classified 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, nine interested GP practices were visited on site and finally five practices with a total of seven GPs agreed to take part. The mean age of GPs was 54.6 years and 14.3% of them were women (for further information see Table 2).

Table 2
Characteristics of health professionals at baseline

	GPs (n = 7)	PTs (n = 11)
Age, mean \pm SD, Var (range)	54.6 \pm 10.7, 113.6 (37.0–66.0)	41.3 \pm 13.2, 174.8 (24.0–61.0)
Sex, n female (%)	1 (14.3)	9 (81.8)
Years of professional activity, mean \pm SD, Var (range)	21.1 \pm 10.4, 107.8 (7.0–35.0)	18.3 \pm 13.1, 170.8 (1.0–40.0)
GP = general practitioner, PT = physical therapist, SD = standard deviation, Var = Variance		

Reasons for non-participation were mostly lacking time (for further information see Fig. 4), whereas for the practices cancelling by telephone no further information is available. Reasons for participation were mostly perceiving the topic as being interesting and of practical relevance, improving treatment quality through a structured approach, but also intra-professional exchange and general interest in research projects.

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

Recruitment of PTs

Telephone requests of PT practices and internal forwarding of information went without issues, but the short-term inquiry before educational training due to the delay in GPs' recruitment postponed the PTs invitation. PTs were satisfied with the recruitment approach including the structure, content and the extent of the information material.

Recruitment of PT practices took place between April and May 2019. As seven of the 15 PT practices mentioned by GPs declined to participate, we invited further 11 identified by geographical screening. Finally, 10 PT practices with 11 therapists (one practice with two PTs) agreed to participate (see Fig. 4). The PTs' mean age was 41.3 years and most of them were women (81.8%) (for further information see Table 2).

Reasons for non-participation were mostly lacking interest and time (for further information see Fig. 4), whereas reasons for participation were perceiving the topic as interesting and of practical relevance, the chance to improve quality, and 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.

All PTs completed the study.

Recruitment and reach in individuals

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

88.2% of potential eligible patients were identified via practice software as required, 5.9% were invited in direct contact in 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 to him immediately." (GP1, male, 45 years)

For this purpose, *"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 stuff, because the difficulty then was to change the daily routine and quickly convey the five or six important points of the study to him."* (GP04, male, 57 years)

An additional person was needed for 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.

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

GPs identified 68 patients (60 via practice software; 4 in direct contact, 4 missing data) between May and September 2019. A total of 46 declined participation, most of them gave no reasons for denial. A total of 23.9% sent back the cancellation form giving reasons as a poor health status or no interest (for further information see Fig. 4). A total of 22 patients (32.4%) consented to participate (range: 3–8 per practice), which undershot the planned number of 25 to 60 patients (5–10 per practice). GPs estimated the high expenditure of time and overload on study participation, concerns about devices and some patients' resignation regarding VDB for the poor willingness to participate.

"Especially with these patients, who had 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 they should possibly go to Rosenheim [...] 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." (GP3, male, 66 years)

Participants gave mostly personal suffering under VDB associated with the hope to improve the own or other affected persons' situation and general interest as reasons for participation. GPs noted that persuasion and motivation promoted the patients' participation.

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 them were women (63.6%) and four (18.2%) were rated with a level of care dependency as assessed by expert raters of the medical service of the German statutory health insurance system (0="minor", 1="considerable", 2="severe", 3="most severe"; here: degree 2: n = 3, degree 3: n = 1). Half of the patients received help from family members, friends, relatives or neighbours and one person received care by a home care nursing service within the last four months. Three patients used aids like walking sticks (n = 2) or a walker (n = 1). For further information of patients' characteristics see Table 3.

Table 3
Characteristics of patients at baseline

Cluster	C01	C02	C03	C04	C05	Total
general practitioners, <i>n</i> (%)	1 (14.3)	1 (14.3)	1 (14.3)	1 (14.3)	3 (42.8)	7 (100.0)
patients, <i>n</i> (%)	4 (18.2)	8 (36.4)	4 (18.2)	3 (13.6)	3 (13.6)	22 (100.0)
Age, mean \pm SD, Var (range)	72.5 \pm 7.5, 57.0 (65.0–79.0)	81.3 \pm 5.1, 25.6 (73.0–88.0)	78.0 \pm 2.2, 4.7 (75.0–80.0)	79.0 \pm 2.0, 4.0 (77.0–81.0)	81.0 \pm 1.7, 3.0 (80.0–83.0)	78.7 \pm 5.4, 28.7 (65.0–88.0)
Woman, <i>n</i> (%)	3 (75.0)	5 (62.5)	2 (50.0)	1 (33.3)	3 (100.0)	14 (63.6)
Current housing situation, <i>n</i> (%)						
living alone	3 (75.0)	4 (50.0)	2 (50.0)	0 (0)	2 (66.7)	11 (50.0)
living together with others	1 (25.0)	4 (50.0)	2 (50.0)	3 (100.0)	1 (33.3)	11 (50.0)
Due to the health status, assistance was received within the last 3 months, via, <i>n</i> (%)						
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, <i>n</i> (%)						
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)

Cluster	C01	C02	C03	C04	C05	Total
Degree of care, <i>n</i> (%)	1 (25.0)	1 (12.5)	2 (50.0)	0 (0)	0 (0)	4 (18.2)
degree 0	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
degree 1	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
degree 2	0 (0)	1 (12.5)	2 (50.0)	0 (0)	0 (0)	3 (13.6)
degree 3	1 (25.0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (4.5)
SD = standard deviation, Var = variance						
No missing values						

Overall, 20 patients (90.9%) completed the trial; two patients dropped out: one due a poor health status and one fell due to dizziness and was hospitalized (see Fig. 4).

Outcome measures and data collection procedures

Data collection in patients

For data collection, the majority of the participants preferred domestic setting due to mobility restrictions and their health status, only three patients opted for assessment in the study centre. Patients were satisfied with the measurement dates.

Since most patients estimated the general effort of study participating as rather low or even non-existent, the duration of measurement appointments (1:20 hours on average) was adequate for them.

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

Organisational issues did not allow to realise the intended intervals between the measurement points in all patients: Thus, the intended interval of 42 days was reached in 57.1% (range: -6 to + 10 days) between T0 and T1 and in 30% (range: -1 to + 14 days) between T1 and T2.

Patients rated the difficulty of the questionnaires completing as simple (mean: 2.0), some patients needed support from relatives or the study assistant. Patients had the most problems with the IPAQ. Thus, they needed the most help (Post T0: 55%, T1: 46.7%, T2: 61.1%) and time (T0: 13.2, T1: 11.5, T2: 9.9 minutes) for its completion. The amount of missing values in evaluation forms (total blank questionnaires: *n* = 9, single missing item: *n* = 1) limited the interpretability, while the response rate in DHI and EQ-5D-5L was 100%. For further information about results of standardised evaluation forms see Table 4.

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

	T0 post (1 week)	T1 (6 weeks/7 weeks*)			T2 (12 weeks/13 weeks*)		
	IPAQ (n = 20)	DHI (n = 21)	EQ-5D-5L (n = 21)	IPAQ* (n = 15)	DHI (n = 20)	EQ-5D-5L (n = 20)	IPAQ* (n = 18)
Independent completion possible, <i>n (%)</i>	9 (45.0)	14 (66.7)	12 (57.1)	8 (53.3)	16 (80.0)	14 (70.0)	7 (38.9)
Dependent completion with, <i>n (%)</i>	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 completing ¹ , <i>median, IQR (range)</i>	2.0, 1.8 (1.0–5.0)	2.0, 0.5 (1.0–5.0)	2.0, 1.5 (1.0–5.0)	2.0, 1.0 (1.0 – 5.0)	2.0, 0 (1.0–5.0)	2.0, 1.8 (1.0–5.0)	2.0, 2.0 (1.0–5.0)
Time (minutes) of completion, <i>mean ± SD, Var (range)</i>	13.2 ± 14.3, 203.3 (3.0–60.0)	9.0 ± 6.8, 46.0 (3.0–30.0)	8.4 ± 4.7, 22.4 (2.0–20.0)	11.5 ± 8.0, 63.8 (1.0–30.0)	10.1 ± 6.7, 44.8 (3.0–30.0)	8.1 ± 5.4, 28.8 (2.0–22.0)	9.9 ± 9.2, 85.2 (2.0–30.0)
EQ-5D-5L=5-level EuroQol-5-dimensions, DHI=Dizziness Handicap Inventory, IPAQ=International Physical Activity Questionnaire, IQR=interquartile range, SD=Standard deviation, Var=Variance							
* IPAQ measurement times: T0 post (1 week), T1 (7 weeks), T2 (13 weeks)							
¹ 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)							

Most participants rated the miniBEST as feasible, but some felt insecure depending on the daily form or any physical handicaps. Barriers to its performance in domestic setting were narrow rooms and potential stumbling blocks, whereas the study assistants' basic qualification as a PT was an advantage in terms of safety.

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

Table 5
Results of primary and secondary outcomes during the study

	Pre T0 (n = 22)	T0: baseline* (n = 22)	T1: 6 weeks* (n = 21)	T2: 12 weeks* (n = 20)	T0 - T2	mean of the differences ± SD (95%-CI)
DHI, <i>median, IQR (range)</i>	-	38.0, 25.5 (4.0–84.0)	38.0, 38.0 (12.0–82.0)	39.0, 49.0 (6.0–80.0)	1.0	-2.9 ± 14.9 (-10.1–4.3)
EQ-5D-5L, <i>mean ± SD, Var (range)</i>						
Health state index	-	2.0 ± 0.4, 0.1 (1.6–2.5)	2.1 ± 0.4, 0.1 (1.8–2.6)	2.0 ± 0.4, 0.2 (1.5–2.5)	0	-0.03 ± 0,5 (-0.3–0.2)
VAS	-	65.9 ± 18.7, 351.5 (30.0–90.0)	67.6 ± 16.9, 286.5 (20.0–90.0)	59.9 ± 20.6, 422.6 (10.0–90.0)	-6.0	7.2 ± 14.2 (0.3–14.0)
miniBEST, <i>median, IQR (range)</i>	-	17.5, 7.0 (7.0–27.0)	20.0, 5.5 (12.0–25.0)	19.0, 7.3 (11.0–27.0)	1,5	-1,1 ± 3.8 (-2,9–0.8)
IPAQ, <i>mean ± SD, Var (range)</i>	3523.6 ± 3454.3, 1.25*10 ⁶ (66–12798)	5793.4 ± 5456.0, 3.16*10 ⁶ (198–17598)	4495.8 ± 4249.7, 1.93*10 ⁶ (146–16160)	1730.8 ± 1366.5, 2,04*10 ⁶ (198–4377)	-	-
CI = confidence interval, IQR = interquartile range, SD = standard deviation, Var = Variance						
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 = 5-level EuroQoL-5-dimensions; 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)						
* one week after measurement point (IPAQ)						

Response rate for the use of both sensors was rather high (T0: 81.8%, T1: 85.7%, T2: 80%) and patients wore the devices mostly without experiencing any restrictions in daily life, which indicates a good acceptance. While wearing the StepWatch4, patients reported sliding down, itching, skin irritations and mild oedema and skin irritation. 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 demands for this sensor might have led to a higher amount of obtained valid days of recording for the Move4 vs. the StepWatch sensor: data sets of eight (Move4) versus five (StepWatch4) patients could be analyzed across all time points. In general, both sensors revealed similar time courses of physical activity, with Move4 tending to count a higher number of steps in active phases as compared to StepWatch4. Qualitative analysis of physical activity diary entries suggest that the Move4 sensor better represent differences in physical activity levels within individuals. Thus, further outcomes will only be reported for the Move4 sensor. On average, the eight patients with valid data sets across all three time points took 6148 steps a day at T0, 5482 steps at T1 and 5306 steps at T2. This difference was statistically non-significant. Analysis of activity patterns revealed that patients spent most of their time sedentary, i.e. sitting, lying or standing. This held true for the percentage share of sedentarism as compared to activity, as well as for the bout length of sedentary phases

(see Table 6). Importantly, while total step count was within the range of that reported in other studies [45], the proportion and bout length of sedentary phases was substantially higher as compared to healthy elderly [46].

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	<i>Proportion,</i>	74%	69%	72%
	<i>mean bout length</i>	30.1 min	38.2 min	35.8 min
Standing	<i>Proportion,</i>	2%	9%	5%
	<i>mean bout length</i>	1.4 min	2.9 min	1.3 min
Moving	<i>Proportion,</i>	6%	6%	6%
	<i>mean bout length</i>	2.0 min	1.8 min	1.6 min
<i>Please note that the remaining percent of the day was classified as non-wear time</i>				

Participants evaluated the physical activity diary as understandable, but also as time consuming.

"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 what I walk or sit around at home is more or less estimated."
(P15, male, 77 years)

Response rate for fulfilment of the diary was rather high (T0: 91.0%, T1: 81.0%, T2: 90.0%), reasons for denial were overload or 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), partly (n = 4) supported by relatives in both interviews.

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

The telephone hotline was frequently used by patients and their relatives before and during enrolment in the topics of organisational aspects (e.g. study duration, scheduling postponements) and mostly about actigraphy (e.g. weight, size), indicating this approach to be feasible.

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

Data collection in clusters

All GPs submitted their completed questionnaires (QCPC, evaluation forms of training and recruitment process) and for 90.9% of patients (n = 20) the filled checklist as required.

GPs frequently used the study centres' hotline mostly with regard to the topic of recruitment, but also for the request for further recruitment documents.

There was neither a prior relationship to any of the participants nor knowledge about the interviewers in group interview. Despite the commitment of all GPs, only five of them (71.4%) attended the agreed date, so that one cluster was not represented. In the additional individual telephone interview about recruitment procedure, one GP out of each practice took part.

Additional involved resources in study participation were personnel (office staff) and time, but however, they arranged well so that study participation seems to be integrated in daily practice in an acceptable and feasible way.

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

Data collection in PTs

There were no further problems in filling and submitting the standardized questionnaires. All PTs transferred the filled guides and in 84.6% the additional treatment documentation as required.

Individual telephone interviews with PTs took place as planned.

Time expenditure and organizational efforts were limited and study participation was easy to integrate in daily practice. Study centres' hotline was mainly contacted for organisational issues (fill the prescription, study procedures, further informational and educational flyers).

Data collection (DHI and miniBEST) was reported as feasible as it was the transfer of these questionnaires via handing over 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 intervention components and implementation strategy

The Context: Characteristics GP and PT practices

GP practices treated between over 500 and 2000 patients per quarter, which were older than 60 years in 39% and had at least two chronic diseases (32.8%) (see Table 7).

Table 7
Baseline characteristics of GP practices

	C01	C02	C03	C04	C05	mean
Patients in practice per quarter						
total number, <i>predefined range</i>	> 1,000–1,500	> 500–1,000	> 500–1,000	> 1,000–1,500	> 1,500–2,000	
over 60 years old, %	40.0	33.0	30.0	57.0	35.0	39.0
with at least 2 chronic diseases, %	20.0	40.0	NA	26.0	45.0	32.8
Missing values: n = 1						

PT practices treated between less than 500 to more than 2000 patients per quarter (modus < 500 patients). Most patients (56.9%) were over 60 years old and had at least two chronic diseases (46.9%) (see Table 8).

Table 8
Baseline characteristics of PT practices

	PTP01	PTP02	PTP03	PTP04	PTP05	PTP06	PTP06	PTP08	PTP09	PTP10	mean
Patients in practice per quarter											
total number, predefined range	< 500	> 2,000	< 500	> 2,000	< 500	> 500–1,000	< 500	> 500–1,000	> 1,000–1,500	< 500	
over 60 years old, %	50.0	NA	70.0	65.0	65.0	NA	45.0	65.0	25.0	70.0	56.9
with at least 2 chronic diseases, %	20.0	NA	60.0	70.0	45.0	NA	30.0	55.0	70.0	25.0	46.9
Missing values: n = 4											

During the implementation, low treatment adherence, lacking awareness of the interventions impact and visual, writing or comprehension problems were reported as barriers for patients, whereas social support by relatives was a facilitator.

For the health professionals' motivation, positive expectations and familiarity with the intervention, and support via helplines were reported as facilitators. Lacking interdisciplinary exchange was rated as a barrier.

Organisational aspects (lacking time, short treatment units in PT practices, long waiting times for appointments with medical specialists/PTs) were rated as barriers. Intra-professional exchange was 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 learning objectives to be achieved as entirely true to partly true (total score value in mean: 1.3 ± 0.5), indicating its good acceptance. GPs especially emphasized the practical exercises, the good atmosphere and the small group size, but additionally requested the application of the checklist on a dummy patient. However, all GPs felt competent for practical application of the checklist (see evaluation domain no. 8). One GP appreciated a repetition of the educational training. Due to the scheduled time for study issues in training sessions were too short, one GP suggested to build up a separation of professional training and technical study procedure information. For further information about results of evaluation forms see Table 9.

Table 9
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, <i>median, IQR (range)</i>				
At the training I was systematically taught				
1	differentiations of the most important vertigo syndromes.	2.0, 1.5 (1.0–3.0)	1.5, n.a. (1.0–2.0)	2.0, 1.0 (1.0–3.0)
2	methods for diagnosing positional vertigo.	1.0, 0 (1.0–1.0)	1.5, n.a. (1.0–2.0)	1.0, 0 (1.0–2.0)
3	forms of therapy and their instructions for the most important vertigo syndromes.	2.0, 2.0 (1.0–4.0)	1.5, n.a. (1.0–2.0)	2.0, 1.0 (1.0–4.0)
4	how to apply the checklist in practice.	1.0, 0.5 (1.0–2.0)	1.0, n.a. (1.0–1.0)	1.0, 0 (1.0–2.0)
Gain in know-how skills, <i>median, IQR (range)</i>				
5	At the training I was systematically taught a neurological screening.	2.0, 1.0 (1.0–3.0)	1.5, n.a. (1.0–2.0)	2.0, 1.0 (1.0–3.0)
6	After the training I feel able to apply the demonstrated examination techniques.	2.0, 1.0 (1.0–2.0)	1.0, n.a. (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 (1.0–2.0)	1.0, n.a. (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 (1.0–2.0)	1.0, n.a. (1.0–1.0)	1.0, 1.0 (1.0–2.0)
Temporal organization, <i>median, IQR (range)</i>				
9	The temporal extend of the workshop was appropriate.	1.5, 1.0 (1.0–2.0)	1.0, n.a. (1.0–1.0)	1.0, 1.0 (1.0–2.0)
Total quality of educational training (No 1–9), <i>mean ± SD, Var (range)</i>		1.7 ± 0.4, 0.2 (1.0–2.0)	1.2 ± 0.3, 0.1 (1.0–1.5)	1.3 ± 0.5, 0.3 (1.0–2.0)
Other, <i>median, IQR (range)</i>				
10	In your opinion, is there a need for such training among GPs?	1.0, 0.5 (1.0–2.0)	1.0, n.a. (1.0–1.0)	1.0, 0 (1.0–2.0)
11	Do you already use the presented techniques for vertigo syndromes?	3.0, 2.0 (1.0–4.0)	2.5, n.a. (2.0–3.0)	3.0, 2.0 (1.0–4.0)
IQR = interquartile range, SD = standard deviation, Var = variance				
Coding: 1="entirely true", 2="partly true", 3="rather not true", 4="completely untrue"				
Missing values: Item 9 (n = 1)				
<i>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?</i>				

As additional materials, GPs received instructions for the positioning manoeuvres during the training sessions. Further, they asked for a brief summary of the whole examination procedure for patients with VDB in form of a written handout with pictures or a homepage with videos.

The checklist was applied to 90.9% of study participants (n = 20) at least once. The expectations of the participating GPs were not in line with the initial aim of the checklist. GPs rather expected a comprehensive guideline for anamnesis and diagnosis 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." (GP01, male, 45 years)

GPs stated, that a chronological structure with a more detailed anamnesis section, e.g. in a two-sided document to combine anamnesis, examination and consequences as referrals would be preferable. They rated the paper material in DIN A4 format as feasible, one GP stated that a digital form would be too complicated and could not be used in daily practice.

According to GPs, problems in the checklist's completion arose due to unclear instructions. Overall, GPs filled the checklist rather incomplete and made partly incomplete entries, e.g. they did not note the referral to physical therapy.

Further deviations from intervention protocol occurred in the timing of checklist application. GPs frequently combined recruitment with its first use, so that T0 could not be performed prior to the intervention as intended. According to the completed checklists, 40.9% of patients attended all GP appointments as required (initial diagnostics, follow-up after four weeks, follow-up after eight weeks/three months), 13.6% were seen by their GP twice and 36.4% only kept the initial appointment. According to the GPs, reasons for this were forgetting active re-ordering, but mostly due to the patients' poor adherence on their request to make an appointment after a certain time. Whereas patients reported lacking scheduling by the GP, as most of them proactively contacted them due to the need for a follow-up prescription to PT. In two patients (9.1%) the checklist was not used at all.

A total of 14 patients (63.6%) were referred to physical therapy. In 78.6% GPs used an VDB specific ICD code (3 missings) and in 71.4% the VDB specific indication code (1 missing) as intended. Mostly GPs referred to physical therapy (n = 11, 78.6%; 3 missings) and in two patients (14.3%) the GP additionally prescribed classical therapeutic massage. Mostly, there was no explicit interdisciplinary exchange between GPs and PTs.

A total of 45.5% of study participants received a referral to at least one medical specialist. Apart from personal contact with medical specialists by the GPs in urgent cases, there was no differentiated exchange.

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

"If you do it 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." (GP01, male, 45 years)

Despite the required adaptations to enhance user-friendliness, GPs saw an added value due to the standardised procedure gave them security in dealing with affected persons and the exclusion of dangerous constellations gave the patients security in turn. This indicates a change of their competence and behaviour in treatment of VDB patients.

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

GPs were pleased with the qualification certificate and the certificate for study participation, which some of them hung up 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 educational training in May. All learning objectives to be achieved were rated as entirely true (total score value mean: 1.0), indicating a very good acceptance of the workshop. They especially highlighted the interplay between of theoretical and practical parts. However, all PTs felt competent for the practical application of the guide (see evaluation domain no 8). For further information about results of evaluation forms see Additional file 4.

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 filled a prescription in trained PTs. PTs evaluated its content and structure as good and the paper material in DIN A3 format as feasible and clearly arranged. Time required for its application differed between the PTs (range: 15–30 minutes) and most managed it within one treatment unit. There were no additional personal resources needed. Overall, PTs completed physical assessment section of the guide fully, but used the performed assessments rather incomplete.

All PTs stated to have profited from the guide, especially due to the structured procedure, so that patients benefit from adequate treatment and efficient clinical reasoning.

"If I save time with the diagnostic process, he 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 (PT05, female, 33 years)

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

PTs reported changes in their competence and behaviour and their self-efficacy has been strengthened by knowledge and skills.

PTs adhered well to the guide, so that all patients received VDB specific treatment and at least one target group-oriented flyer (92.3%). PTs evaluated these as targeted to patients 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." (PT10, female, 52 years)

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

Utilization of the telephone helpline was scarce (1 call, call duration < 5 minutes). Reasons were only stated by one PT (forgot 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

Nearly all patients (90.9%) received the GPs' intervention between June 2019 and January 2020 and they were mostly satisfied with their treatment. A total of 10 patients (45.5%) received a referral to at least one medical specialist (cardiologist, ophthalmologist, neurologist or ENT physician) and 63.6% (n = 14) to physical therapy. However, 13.6% (n = 3) received neither a PT prescription nor a referral to a medical specialist. Also, two patients declined a referral to PT due to lacking interest and focusing on other acute health issues. GPs reported patients' characteristics (poor motivation, lacking awareness about effects of specific therapy) as potential barriers for further referral, but also organizational issues. 92.9% patients decided to filled it in practices with specially trained PTs and reported to be satisfied with therapy. Patients rated the leaflets for home exercises as easy to understand and feasible at home, whereas two persons received help from relatives in performance. Most reported to perform exercises regularly motivated by the hope of symptom relief, but few sporadically due to lacking time, focusing 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 worse and 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." (P09, male, 67 years)

85.7% (n = 12) of patients receiving physical therapy at least felt a slight improvement of symptoms and some reported a behavioural change due to the integration of exercises in everyday life.

"I have caught myself a few times when I go into town and see cobblestones that are markers for me, I try to walk straight along them." (P12, male, 79 years)

Unintended consequences

Health professionals reported no unintended harmful consequences in application their intervention parts towards patients and themselves. 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, however also identified aspects to be optimized.

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

Recruitment of PTs was easier, although an 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 patients mostly opted for domestic setting for measurements, the need for study assistants should be calculated carefully. Engagement of relatives turned out to be a facilitator for patients' adherence and attrition. We therefore suggest a stronger involvement of them, which is consistent with previous research [50].

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

We used a combination of different implementation strategies according to 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 theoretical and practical parts [57, 59]. Since GPs mentioned lacking practical training in the checklists' use while the educational training, we plan to include its application to a dummy patient for which a longer time period of training should be set. Due to PTs were interested in information about the GPs tasks, a joint training date of both, 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 of further summaries should be taken into account, e.g. in form of a website with videos and written material.

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. Besides time issues, the main reasons for this was probably their 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 development and feasibility phase) what 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 by 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 what is a proven approach [60]. The use of the guide for PTs was implemented according as planned and turned out to be feasible. Both PTs and GPs rated the paper material as practicable, whereas some PTs would appreciate a digital form provided technical compatibility. For the main study, the option of a digital application was envisaged, but this needs to be further evaluated in view of the preferences of the participants. However, an integration of interventions into practice software could offer the possibility to promote the fitting of intervention into daily practice [58] and may additionally improve interdisciplinary exchange [61].

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

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

In contrast to results of a previous study, which identified the wish of better multi-disciplinary exchange as a key to successful treatment of VDB, our results showed a very low utilization of communication between GPs and PTs. Since a good multidisciplinary communication and cooperation was already stated as facilitator by health professionals [56, 61, 65] and patients [50], it seems to be beneficial to invest more efforts to improve this.

Overall, this study confirmed our program activities mainly to be effective for changing health professionals' behavior as hypothesized in our logic model. Despite of initial difficulties, all health professionals used the new knowledge and skills to apply their intervention part, partly with adjustments. They felt an improvement of competence and self-efficacy, which impacts the improvement of the patients 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 used mixed-method approach considering different perspectives to allocate a detailed comprehension on how the interventions works [32].

Our study has also limitations as especially problems in recruitment. Since participants were hard to include, just a small number of GPs and – as a consequence - patients could be involved what may lead to potential bias of results. It was also noticeable that mainly younger and more physical active patients were enrolled in the study, whereas the intervention was initially designed to address older patients with multimorbidity and immobility.

Conclusion

Although the study results provide good support for the feasibility of the intervention in older patients with VDB in primary care, our results revealed important insights in challenges and the need of improvement of the intervention, its implementation strategy and study procedures. Especially the recruitment of GPs and patients was challenging and needs a more detailed guidance by research team. Due to difficulties in the GPs' adherence to study and intervention protocol, intensification of regular exchange

between them and the research team is highly recommended to eliminate misunderstandings. Furthermore, a revision of 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, CFIR = Consolidated Framework for Implementation Research, CI = confidence interval, CONSORT = Consolidated Standards of Reporting Trials, CPW = Care Pathway, cRCT = cluster randomised controlled trial, CRD = Centre for Reviews and Dissemination, DHI = Dizziness Handicap Inventory, ENT = ear-nose-throat; EQ-5D-5L = 5-level EuroQol-5-dimensions, GP = general practitioner, ICD = International Statistical Classification of Diseases and Related Health Problems, IPAQ = International Physical Activity Questionnaire, IQR = interquartile range, 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; research team = research team, SD = standard deviation, STARI = Standards for Reporting Implementation Studies, STROBE = The Strengthening the Reporting of Observational Studies in Epidemiology, UK = United Kingdom, Var = variance, VDB = Vertigo, dizziness and balance disorders

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 (project number: 18-431, development phase) (project number: 19-192, feasibility study). Each participant must sign a written informed consent form prior to enrolment.

Consent for publication

All patients gave consent for the publication of anonymised data.

Availability of data and material

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

Competing interests

The authors declare that they have no competing interests.

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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. Data collection and analysis of actigraphy, IPAQ and physical activity diary was planned and conducted by AG, MK and JH. ES drafted this manuscript. MM, PB and VR critically revised the draft and all authors contributed to the final writing of the paper. MM is the principal investigators of the study and holds the senior authorship. All authors read and approved the final manuscript.

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Figures

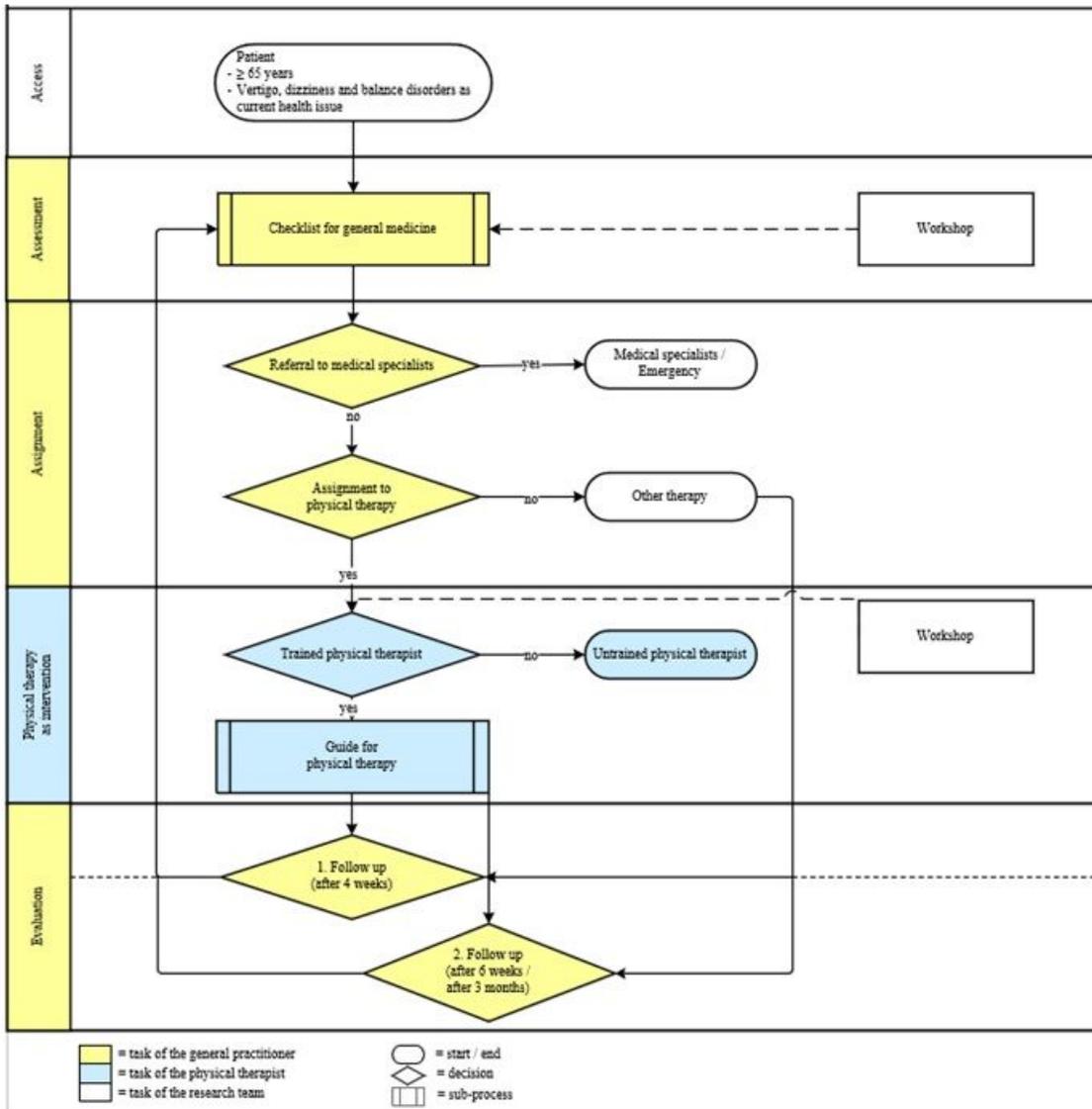
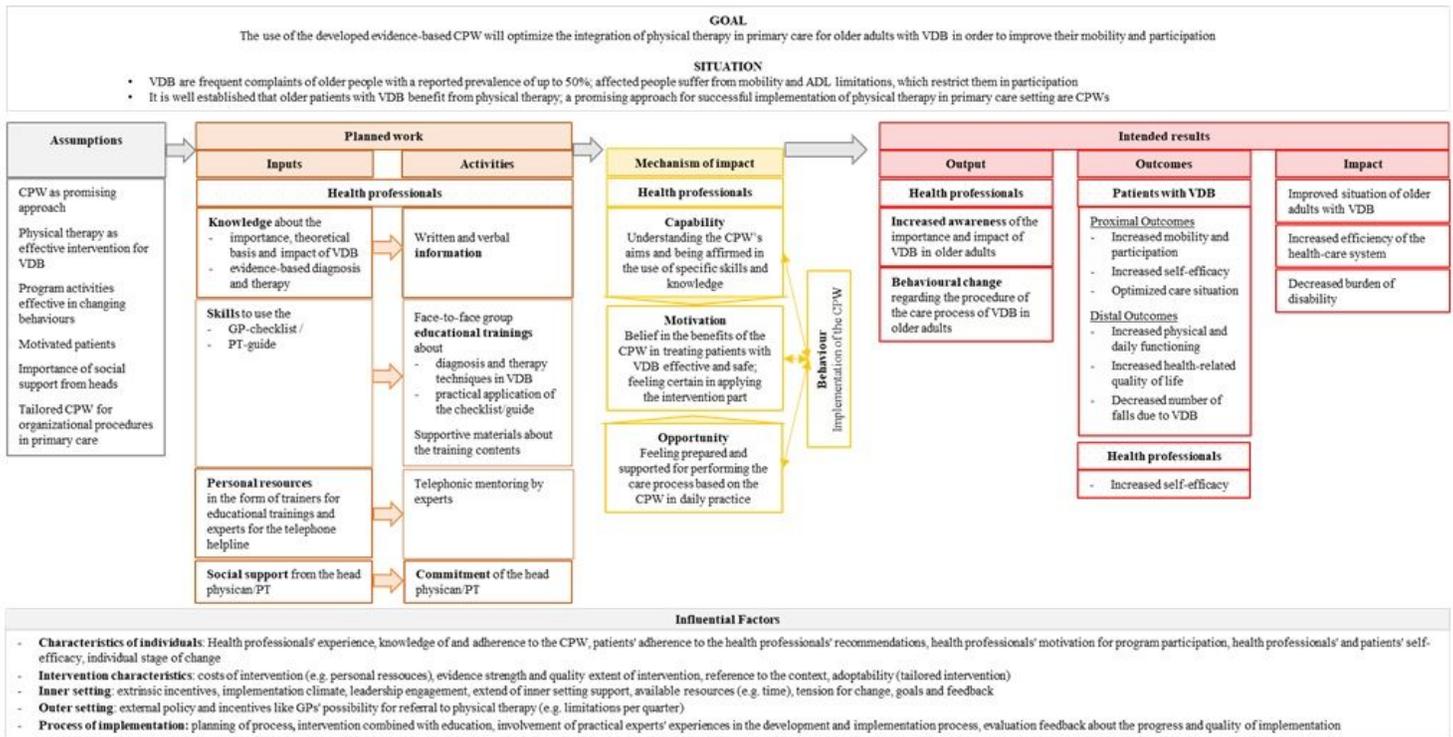


Figure 1

Overview of the patients' path in the intervention



CPW=Care Pathway, GP=general practitioner, PT=physical therapist, VDB=vertigo, dizziness and balance disorders

Figure 2

Logic model of the CPW

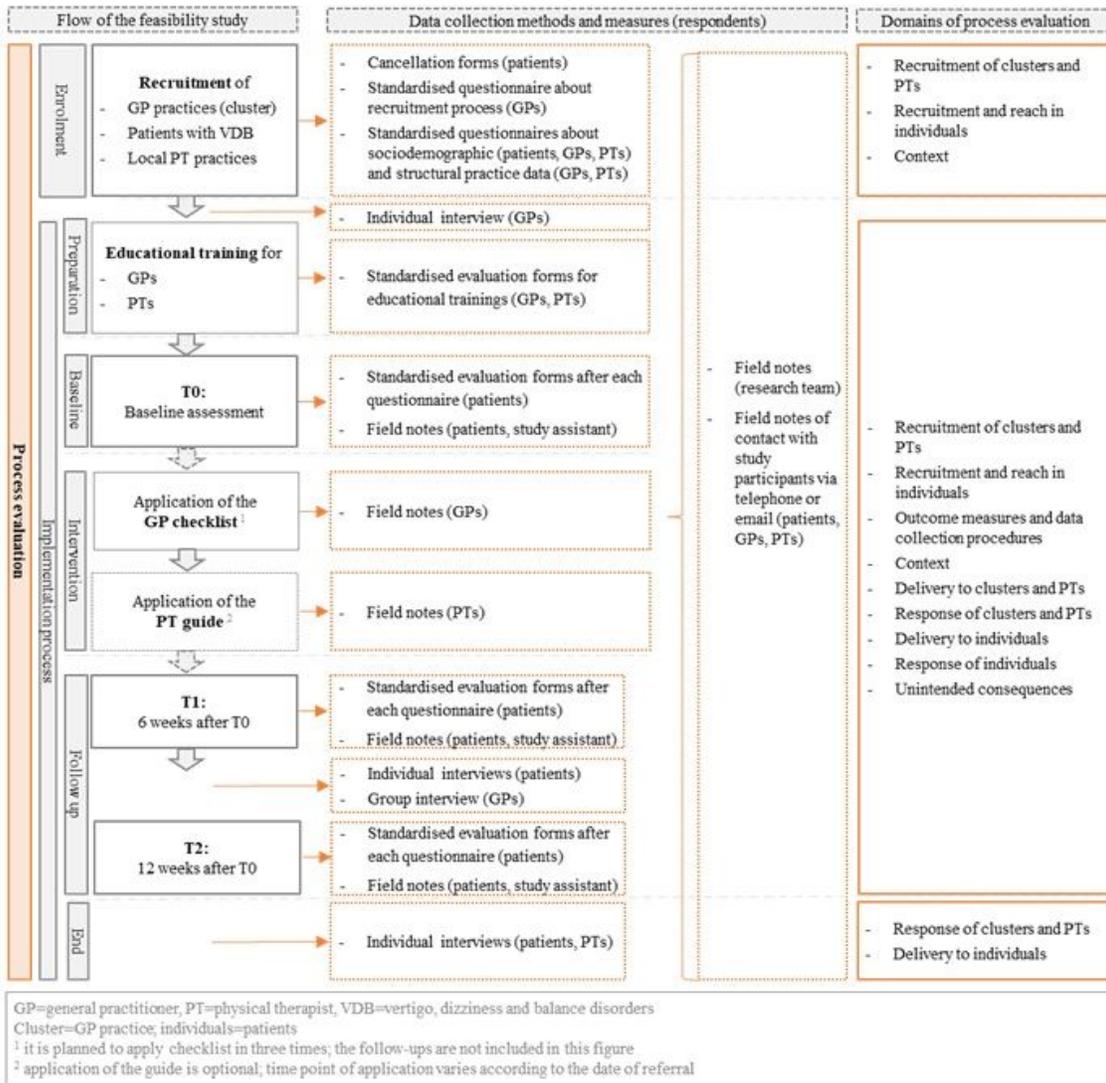
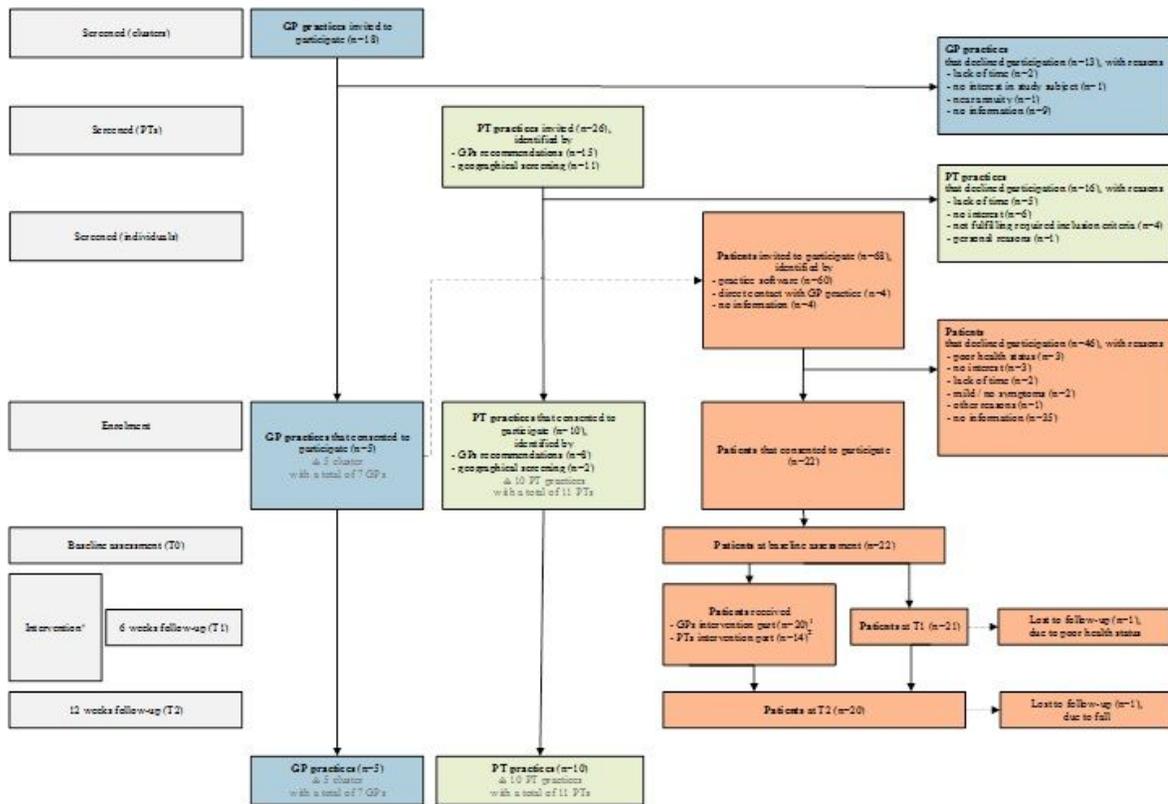


Figure 3

Flow diagram of the process evaluation alongside the feasibility study



GP=general practitioner, PT=physical therapist

¹ GP checklist: it was planned to apply the checklist 3 times, the follow-ups are not included in the figure; in 3 practices the checklist was not used at all

² PT guide: application of the guide was optional, time points of application varied according to the date of referral

Figure 4

Flow of participants through the feasibility trial

Supplementary Files

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