

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

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Abstract

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

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

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

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

Trial Registration: The research project is registered in "Projektdatenbank Versorgungsforschung Deutschland" (Project-ID: 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) and limit the capacity to pursue daily activities and social participation. Particularly in older adults, the aetiology of VDB can be rarely attributed to distinct vestibular diseases, but more often to multifactorial deficits due to ageing, consequences of non-vestibular conditions or a combination of multiple aetiologies (2–4). VDB is a common reason for consulting a general practitioner (GP), approximately affecting every person at

least once in their lifetime (5). A recent systematic review describes a consultation prevalence of dizziness related symptoms in primary care of about 1% to 15%, benign paroxysmal positional vertigo (BPPV) being the most common specific aetiology in up to 40% (6). In contrast to medical specialists, GPs see patients from the full range of medical disciplines and need to screen every patient not to oversee serious health conditions. At the same time they treat many uncomplicated cases and have to base their clinical reasoning process on the patient's history and a few additional tests (6). VDB are known to be described unclearly, inconsistently and unreliably by patients and are, thus, difficult to standardise (7). In order to exclude life threatening health conditions GPs have to use diagnostic procedures and referrals to specialists. On the other hand, overutilization of health care resources in patients with VDB insufficiently treated in primary care has been shown (8). Most VDB cases can be improved by treatment (9), but often do not benefit from drug or surgical therapy (10). Due to the multifactorial aetiology, this might be especially true for older patients. Physical therapy is a safe and effective treatment to promote mobility and avoid imbalance and falls (11). Despite this, in the German guideline for acute VDB in primary care (12), physical therapy seems not to be a standard option, whereas a guideline for chronic VDB is lacking. Facing an aging population due to demographic changes, strategies to manage VDB safe and efficiently are essential. Therefore, management of VDB needs to be tailored for primary care with adequate referrals and treatment options (8).

A CPW is an evidence-based structured multi-disciplinary care plan comprising all relevant diagnostic and therapeutic steps in the care of patients with a specific health condition in a chronological order (13). CPWs are used to translate evidence into local practice by contemplating specific circumstances and demands; they tailor care and can reduce variations in practice to improve patient outcomes (13, 14). CPWs for VDB may standardize GPs' diagnostics, treatment options and referrals and to integrate the emphasized use of physical therapy prescriptions.

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

Methods And Results

We developed our CPW as a complex intervention according to the *UK Medical Research Council (MRC) framework* (15). This provides a methodological framework to develop, pilot test, evaluate and implement complex interventions. This paper describes the first phase of this framework, the development phase. It was carried out in a stepwise process divided into two sub-phases: First, a preparation phase that included the identification of existing evidence and of stakeholders' and consumers' demands followed

by a modelling phase, that comprised the modelling of a CPW and an implementation strategy (see Figure 1).

An overview of specific aims and methods of the development steps are shown in Figure 2.

To report development of the complex intervention we used the *Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare* (16).

Step 1: Preparation

Identifying existing evidence and theory

The first step included a synthesis of existing evidence by carrying out two systematic reviews to identify existing evidence. First, a systematic review of physical therapy interventions addressing mobility and participation in older patients with VDB was conducted. Second, barriers to and facilitators of successful implementation of multi-professional CPWs in primary care were investigated. In brief, the review of physical therapy interventions revealed that for older people, an active physical therapy using vestibular rehabilitation, regardless of any variations and also in combination with repositioning manoeuvres revealed to be most effective. The second review identified barriers to and facilitators of successful implementation of CPWs within the context, implementation and setting dimensions of *Context and Implementation of Complex Interventions (CICI) framework* dimensions (17), which need to be considered in the implementation of CPWs. Detailed results of systematic reviews are/will be published elsewhere and were used to inform a further modelling process during an expert workshop.

Exploring health care providers' and consumers' perspectives

In order to develop a tailored and successful CPW we used the co-creation approach by considering the perspectives of all involved groups, collaborating with them to allow the inclusion of their different needs and perspectives and to support development regarding designs and content (18). Health care providers were selected by identifying health professionals involved in the process of care of patients with VDB. It was assumed that GP practices were the first place to go for people aged at least 65 years with beginning problems in VDB or, in case of home care, community nursing services, who seem to act as gatekeepers for the following care process. PTs might offer interventions for patients with VDB. The target population was defined as patients older than 65 years suffering from VDB.

Individual interviews with health professionals

To explore current practice and identify needs for improvement, the ideal patient trajectory, as well as expectations, attitudes and knowledge, we carried out semi-structured individual interviews with health

professionals involved in the primary care of VDB patients: GPs, PTs and nurses working in a community setting.

Study design, recruitment, data collection, analysis

We included health professionals with at least three years of clinical experience in primary care, outpatient practices, or community/home care services. Further inclusion criteria were significant experience (determined by self-evaluation) in treatment and management of older patients experiencing VDB and written consent to participate in the study. For both individual and group interview we searched for potential health professionals via the world wide web and regional networks, used telephone requests and sent further information in case of interest as preferred via email or fax.

Participants gave their written agreement prior to the date of the interview. The interviewers had a clear structured guideline for every kind of interview and interviewee, with defined main questions and examples for requests and so tried to systematically moderate the interviews and maximize inter-interviewer reliability. All interviews were audio-recorded and field notes were taken during all interviews. Afterwards, the audio records were transcribed verbatim according to the rules of Kuckartz (19) with transcription software F4 (<https://www.audiotranskription.de/f4>). Two researchers (VR and ES) independently carried out a first draft of a coding tree using MAXQDA software (<https://www.maxqda.de/>) for every kind of interview setting and partner and then discussed differences. Subsequently, VR and ES coded the material and included field notes into analysis. Data saturation was defined as the point when no additional information was obtained.

Results

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

In total, 17 health professionals (7 GPs, 6 PTs, 5 nurses) participated in individual interviews. Most individual interviews were conducted via telephone to participants being in their institution or at home (n=16, 94%), only one PT preferred a face-to-face interview at study centre. Interviews lasted 11 to 29 minutes. Characteristics of health professionals are shown in Table 1.

Table 1 Characteristics of health professionals participating in individual interviews

	GPs (n = 7)	PTs (n = 6)	Nurses (n = 5)
Age (Mean ± SD (Range))	58.7 ± 7.87 (42 – 66)	42.0 ± 10.71 (28 – 58)	43.2 ± 11.05 (31 – 55)
Sex (female / %)	3 / 43%	5 / 71%	3 / 60%
Years of favour occupation (Mean ± SD (Range))	30.0 ± 8.04 (14 – 37) n.a.	18.3 ± 10.39 (6 - 36)	20 ± 5.87 (15 – 30)
as community nurse (Mean ± SD (Range))		n.a.	12.8 ± 10.85 (1 – 27)
Weekly hours with patients (Mean ± SD (Range))	n.a	34.8 ± 8.21 (6 – 36)	30 ± 21.11 (1 – 60)
GPs = General practitioners; n.a. = not assessed; PTs = Physical therapists; SD = Standard deviation.			

GP-perspective

GP's see their role as gatekeepers and complain that it is difficult to act in this role after the patient has been referred to a specialist. An ideal patient trajectory was described to be efficient, fast and comprising a diagnostic work up in a multidisciplinary center and involving a broader treatment approach including psychological coaching and social interventions, such as pensioners' exchange or multi-purpose associations handed up in a GP-practice.

PT-perspective

From the PT perspective, the most relevant problem was that referrals from GPs are mostly without proper information of the physicians' diagnostic results and PTs have to identify patients' problems without this information. It turned out that, even though, a specific German indication key (S03 - physical therapy with indication for dizziness of different origins and aetiology) is not used by the GPs.

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

PTs reported mixed trust in their abilities to treat VDB patients, whereas they identified their knowledge from vocational training as less relevant but use skills acquired for additional trainings. Interdisciplinary communication, especially with GPs, was rated as insufficient and assumed that therapy reports were hardly read by GPs. A structured approach to and tailored for VDB patients was considered to be helpful:

“For certain things sometimes exist very clear and beautiful guidelines, like a catalog where you choose (...) I have a tree (...) something like a decision tree, exactly.” (PT, interviewee 2)

More specific educational training for PTs, interdisciplinary cooperation and patient information was rated to be beneficial.

Nurses’ perspective

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

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

In addition, specific educational training for nurses, and programs to promote a fast support of affected people was identified to be helpful.

Group interviews with health professionals

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

Study design, recruitment, data collection, analysis

Of the 35 requested GPs, 23 were interested and 9 consented to participate (GPs’ response rate: 26%); 7 in individual interviews and 2 in the focus group interviews. In PTs, 14 were requested, 14 interested and at least 8 consented to participate (PTs’ response rate: 57%); 6 in individual interviews and 2 in focus group interviews. 9 nurses were requested, 8 were interested and 7 participated (nurses’ response rate: 77%); 5 in individual interviews and 2 in focus group. Reasons for non-participation were holidays, lack of time or personnel.

Participants gave their written agreement prior to the date of interview. The interviewers had a clear structured guideline with defined main questions and examples for requests and so tried to systematically moderate the interviews. Interviews were audio-recorded and field notes were taken. Afterwards, the audio records were transcribed verbatim according to the rules of Kuckartz (19) with transcription software F4 (<https://www.audiotranskription.de/f4>). Two researchers (VR, ES)

independently carried out a first draft of a coding tree using MAXQDA software (<https://www.maxqda.de/>) and then discussed differences. Subsequently, VR and ES coded the material and included field notes into analysis. Data saturation was defined as the point, when no additional information was obtained.

Results of multidisciplinary focus group interviews with health professionals

Two focus group interviews with one GP, PT and nurse each were carried out for a duration of 53 minutes each. The focus group interviews were conducted face-to-face. Characteristics of the health professionals are shown in Table 2.

Table 2 Characteristics of participants of the focus group interviews

	FG 1			FG 2		
	GP	PT	Nurse	GP	PT	Nurse
	(n=1)	(n=1)	(n=1)	(n=1)	(n=1)	(n=1)
Age (years)	68	50	55	66	27	31
Sex (m / f)	m	m	f	m	f	f
Years of favour occupation (years)	40	25	25	41	8	7
as CN (years)	n.a.	n.a.	n.s.	n.a.	n.a.	4
Working hours per week (%)	110	100	70	130	100	100
f = Female; FG = Focus group; GP = General practitioner; m = Male; n.a. = not assessed; n.s. not stated; PT = Physical therapist.						

It was mentioned that an important barrier for good multi-professional and patient-centered communication is that there is no additional reimbursement for such activities. It was mentioned as critical that GPs do not have a central gate keeper role when the first contact point of a patient was a medical specialist. Knowing each other personally was identified as the most relevant facilitator of good cooperation, e. g. when GPs or PTs are organised in centres. Space for potential improvement is seen in the communication between GPs and PTs, especially in terms of interdisciplinary cases conferences where video conferencing and digital shared online documentation was seen as potentially helpful.

“I think the online portal is the one thing that could best be realized. (...) time is relatively tight (...) you don't have to sit down together, you can actually do it online. And then maybe just write to me. So I find that feasible now.” (Nurse, interviewee 1)

“So I think team meetings are less feasible because the different times can never be brought together (...) it is of course also unpaid time. (...) the basis could be an electronic document (...) and 80% can then be resolved (...) and the rest, you are (...) on the phone. (GP, interviewee 1)

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

Individual interviews with patients

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

Study design, recruitment, data collection, analysis

We included patients aged at least 65 years old which consulted a GP with complaints of VDB. Additionally, we recruited patients in PT practices, which are already enrolled in PT programmes. Patients were all approached, putting up a poster in PT practices to recruit affected people and providing our telephone number for further information in case of interest. Patients became aware because of their PT or relatives/acquaintance. Exclusion criteria were patients aged under 65 years or getting a serious condition/disease, requiring hospital treatment, wishing to be excluded from the study. Additionally, we investigated the impact of VDB symptoms on the patients' activities of daily living and social participation using the German version of the vertigo activities and participation questionnaire (VAP) (20).

Participants gave their written agreement prior to the date of interview. The interviewers had a clearly structured guideline with defined main questions and examples for requests and so tried to systematically moderate the interviews and minimize inter-interviewer reliability. Interviews were audio-recorded and field notes were taken during all interviews. Afterwards, the audio records were transcribed verbatim according to the rules of Kuckartz (19) with transcription software F4 (<https://www.audiotranskription.de/f4>). Two researchers (VR, ES) independently carried out a first draft of a coding tree using MAXQDA software (<https://www.maxqda.de/>) and then discussed differences. Subsequently, VR and ES coded the material and included field notes into analysis. Data saturation was defined as the point, when no additional information was obtained. For the VAP questionnaire we calculated descriptive statistics.

Results of individual interviews with patients

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

In total, 11 patients participated in individual interviews which were conducted via telephone (n=10; 91 %); only one patient preferred a face-to-face interview at the study centre. In some cases, the partner joined at the telephone interview due e.g., hearing loss. Interviews lasted 13 to 33 minutes. Characteristics of participants are shown in Table 3.

Table 3 Characteristics of patients participating in individual interviews

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

Some patients reported not to have consulted any physician because they considered symptoms as not so serious or it was due to lack of time. From the patients' perspective, optimal health care is when symptoms are taken seriously by GPs and are not only attributed to ageing, and includes continuous PT, home training, usual and alternative therapy approaches, medication, age specific offers or group sessions.

Interviewers' characteristics

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

Step 2: Modelling

Expert workshop

Study design and recruitment

The expert workshop was planned as a three-day event in a closed setting to create a productive and focused working space. An external moderator was introduced to the subject and process of the expert workshop. Recruitment of experts was conducted in order to cover every area of getting the affected individual in touch with during the process of care. Therefore, we brainstormed potential involved persons following the *International Classification of Functioning, Disability and Health (ICF)* rehab-cycle (21) as a basic theory of structuring the patient's rehabilitation process and characterizing steps of involved health professionals. In addition to the participants of the interviews, we identified health professionals as clinical experts, representatives of health insurances, of health care research and of affected individuals.

To recruit, collaboration partners and local practices/institutes were contacted. Recruitment of representatives of health insurances was conducted via personal contacts. We re-recruited interview partners and used member lists of the *Association of Statutory Health Insurance Physicians*. Due to loss of earning for self-employed persons by participating in our workshop, a remuneration was paid.

Methods of the workshop

At the expert workshop, a step-wise modelling process was conducted (see Figure 3). First, an update on recent disease-specific knowledge was given by a senior medical doctor and methodologic introduction in CPWs by a health care researcher. This was necessary to start with a common basic knowledge among the participating experts. Then, results of prior research were presented by the research team and accompanied by factsheets: Results of existing evidence (systematic reviews) and of health care providers' and consumers' perspective (interviews). To guide experts through different stages of the modelling process various creative techniques in plenary, alone and in small groups, were used. Good evidence exists for the *Consolidated Framework of Implementation Research (CFIR)* (22) and *Expert Recommendations for Implementing Change (ERIC)* (23) as well as a matching tool of both to systematically identify potential barriers/facilitators and select implementation strategies of interventions. The frameworks were translated into the German language and translation will be published elsewhere. In conclusion, milestones and an implementation plan were defined.

Results of the expert workshop

The expert workshop was conducted for three days in October 2018. Response rate of clinical experts, researcher and representatives of affected people and insurances were 50% to 100%. We had problems to recruit GPs (response rate: 0.1%): Recruiting regional GPs, response rate was 14% (1 participating GP out of 7 requests), but re-recruiting interview partners (9 requests) and using member lists of the *Association of Statutory Health Insurance Physicians* (124 requests) was 0%. In total, 9 clinical experts (2 neurologists, 1 ENT physician, 1 GP, 3 PTs, 1 geriatric nurse, 1 medical assistant), 2 experts in health care research, 2 health insurance representatives, 2 patient representatives participated.

First version of CPW

Experts drafted a first version of the CPW according to the steps of ICF Rehab-Cycle (21). Regarding access, a hotline for patients and population-related informing was recommended. This version included tools for health professionals in order to screen, assign, treat and evaluate VDB patients and should promote multi-disciplinary communication between all involved HPs.

Implementation strategy

Potential barriers and facilitators

Weighting potential barriers and facilitators according to CFIR (22) the most prioritized construct was the inner setting (44 points; 39%), followed by intervention characteristics (26 points; 23%), processes (18 points; 16%), characteristics of individuals (17 points; 15%) and outer setting (7 points; 6%) (see Figure 4, for detail see Table 4).

Implementation strategies

After transformation of these barriers using the matching tool software, a weighted order of matching ERIC strategies was present and the 15 most important strategies were further elaborated (see Table 4).

Table 4 Potential barriers and matched implementation strategies

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

Milestones and implementation plan

The implementation plan with milestones for the subsequent study were discussed and consented to by the experts. Regarding access, recruitment of potential study participants should be conducted by GPs using clear inclusion criteria for patients. Assessment and assignment should be conducted by the GPs

using a screening tool with accompanied and credited educational training. To evaluate the effectiveness of the (assigned) intervention, specific follow-up times are recommended. For detail see **Table 5**.

Table 5 Steps of the CPW and milestones of its implementation

Steps of the CPW	Milestones
<p>Access:</p> <ul style="list-style-type: none"> - Immediately - Direct - Involvement of relatives 	<ul style="list-style-type: none"> ® Reaching of the pre-defined number of participating GPs and patients
<p>Assessment:</p> <ul style="list-style-type: none"> - Central role of GP - Checklist - Educational training of GPs 	<ul style="list-style-type: none"> ® Development of a screening tool ® Accompanied previous educational training of GPs
<p>Assignment:</p> <ul style="list-style-type: none"> - Prompt - Physical therapy as favoured intervention - Organized in a network - Case managers 	
<p>Intervention:</p> <ul style="list-style-type: none"> - Capacity of providers - Treatment duration - Involvement of additional potential actors - Extended offer of providers (e.g., clubs, community college) 	<ul style="list-style-type: none"> ® Recruitment of collaboration partners ® Educational training of PTs
<p>Evaluation:</p> <ul style="list-style-type: none"> - Feedback to all involved actors - Follow-up appointments in checklist 	
<p>CPW = Care pathway; GPs = General practitioners; PTs = Physical therapists.</p>	

Subsequent modelling design and implementation of CPW

CPW, intervention components and educational training materials

Modelling process of design

Results of the expert workshop were collected, reviewed and analysed. According to defined milestones, a checklist for GPs and a guide for PTs with accompanied educational trainings were developed. In two expert meetings with a GP, one neurologist, one neuro-otologist and 1 ENT physician, we modelled a more detailed version of GP's part in the CPW in an iterative way. Subsequent to each of the two face-to-face meetings, feedback and further exchanges via telephone or email with the research team was done if necessary. Based on the ICF-Rehab-Cycle and its process of care as well as literature of evidence-based practice (24) the research team developed a first draft of an algorithm for the PT-guide. In telephone contacts with 3 renowned PT specialists an enhanced version was adopted.

CPW

The developed multi-disciplinary CPW is a paper-based algorithm, that illustrates all steps of the aged patients' path in a structured way (see Figure 5). Specific sub-processes of the CPW are a checklist for GPs and a guide for PTs.

GP-checklist

The screening checklist for GPs that manage patients with VDB aims (a) to exclude life-threatening conditions (b) to promote reliable diagnosis and evidence-based treatment by GPs and (c) to ensure a rational referral regime. The final checklist is a paper-based algorithm and consists of aspects of anamnesis, assessments, specific referral regimes and assignments to therapy and follow-up timelines for consultation. The checklist is not available since it is not evaluated for effectiveness and safety so far. The educational training aims to develop an in-depth understanding of the checklist and exercises.

PT-guide

An evidence-based guide for clinical reasoning and treatment for PTs focusing the leading symptom chronic dizziness and balance disorders. The guide is not available since it has not been evaluated for effectiveness and safety so far. The guide is also not available. The guide contains guidance on anamnesis, assessment, treatment and evaluation. Regarding anamnesis, background information about clinical pattern was included. The decision tree style leads to specific assessments and treatment options. Additionally, educational flyers and leaflets were included to be handed out to patients during the therapy: 4 educational leaflets about practical exercises (physical therapy for balance disorders, gait disorder, vertigo as well as instructions for the positioning manoeuvre of posterior canal benign paroxysmal positional vertigo) provided from collaborating with the *German Centre for Vertigo and Balance Disorders* and 2 informational flyers that were translated from existing literature into the German language. These include topics like symptom control of vertigo and nausea (25) and frequently asked questions about benign paroxysmal positional vertigo (26) using the American clinical practice guideline (27).

To ensure correct and confident application of the guide including assessments and interventions, educational training was performed. Prior to the training, informational material, in order to prepare the participants and ensure a common base of knowledge, was provided.

Implementation strategy of the CPW

Modelling behaviour change

We conducted a step-wise approach to intervention design and implementation strategy using the guide to approach the *Behaviour Change Wheel (BCW)* (28). We also took identified barriers and facilitators according to CFIR (22) and matched implementation strategies according to ERIC (23) from our expert panel in consideration. In an iterative way, we moved between the BCW and CFIR/ERIC. These frameworks helped to organize and develop specific behaviour change techniques and implementation strategies. To design behaviour change, we conducted the 7 steps of the guide using the provided worksheets (see Additional file 1). We applied the *Capability-Opportunity-Motivation-Behaviour (COM-B)* model and *Theoretical Domains Framework* and used potential barriers according to CFIR and ERIC strategies from our expert workshop.

Implementation strategy

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

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

Development of a Logic Model

To systematically present the relationships between the intended results, the underlying mechanism of change and the planned work, we developed a logic model according to *Kellogg's Logic Model Development Guide* (29). We finally checked the model for its completeness regarding context, implementation and setting with the *Context and Implementation of Complex Interventions framework* (17).

Logic Model

We developed a logic model using Kellogg's Logic Model (see Figure 6) combining the findings of prior results regarding assumptions and influential factors. Since the key to practice development is behaviour change among health professionals, to define planned work, mechanism of impact (using the COM-B model, the inner layer of BCW (28)) and intended results. To improve VDB patients' situation regarding mobility and participation, we aim to promote self-efficiency of health professionals by supporting them in behaviour change. Therefore, we plan to give them more in-depth knowledge and skills via written

information and face-to-face educational trainings in how to diagnose and treat VDB patients efficiently using distinct parts of the CPW (GP-checklist and PT-guide).

Discussion

Main findings

We developed a theoretically based and practically informed CPW as a complex intervention in order to improve the mobility and social participation of older individuals with VDB in primary care, that now can be tested for its feasibility. This intervention is based on findings from literature, the perspective of older individuals with VDB and experiences of health professionals working in primary care with those patients. In an expert workshop and subsequent small expert workshops, a CPW and its components were modelled, and specific implementation strategies were defined: A checklist for GPs and a guide for PTs working in primary care with accompanied educational trainings to support the use of an evidence-based standardized approach to VDB patients in daily practice.

The optimized integration of physical therapy in primary care of VDB patients and a consecutive, targeted promotion of physical activity of affected people is a central aspect of our intervention. Findings from literature show promising effects of complex interventions in supporting older people to live independently in the community, reduce nursing-home and hospital admissions as well as the occurrence of falls, increase physical function and health-related quality of life, especially, because they can be tailored to meet individuals' needs (30, 31).

By collecting data using mixed-methods design, we were able to identify not only complementary evidence, but also were able to include different perspectives of all stakeholders. Rousseau et al. (32) highlighted the importance of paying attention to study design when developing a complex intervention and to capture different types of knowledge during design progress to maximise creativity. We also confirm the mixed-methods design as a feasible development design to gather insights and understanding (33).

For development of CPW components we used the co-creation approach, which is known to have high potential for societal impact via community-academic partnerships (34). As we found in a recent published guidance for the development of complex interventions (35), involving stakeholders and undertaking primary data collection is crucial to create an acceptable and real-world intervention.

The complex intervention was developed according to the *UK MRC framework* (15) that not only explicitly gives reason about what and how the intervention should be implemented, but Kellogg's logic model (29) helped us to understand how the intervention might work and what activities are needed.

Strength And Limitations

A clear strength of our study is that we conducted development based on a broad range of sources: The review of published research evidence, primary data collection with different stakeholders to explore their needs and understand context and involving stakeholders in the iterative modelling process resulting in a logic model. These activities are in line with a recent published development guidance (35).

Participation of GPs in expert workshop was hard to realize. Extensive and time-consuming recruitment revealed in only one participating GP. As we used the co-creation approach, the opinion of GPs who afterwards apply the CPW, might be biased and misinterpreted by participation of too few GPs in our development process.

Conclusion

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

Abbreviations

BCW = Behaviour change wheel

CFIR = Consolidated framework for implementation research

COM-B = Capability-Opportunity-Motivation-Behaviour

CPW = Care pathway

ENT = Ear-nose-throat

ERIC = Expert recommendation for implementing change

GP = General practitioner

ICF = International classification of functioning, disability and health

P = Patient

PT = Physical therapist

VDB = Vertigo, dizziness and balance disorders

Declarations

Ethics approval and consent to participate

The Ethical Committee of the Ludwig Maximilian University of Munich has approved the study protocol under the number 18-431.

Consent for publication

All participants gave consent for the publication of anonymised data.

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.

Competing interests

The authors declare that they have no competing interests.

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Author's contributions

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

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References

1. Lin HW, Bhattacharyya N. Balance disorders in the elderly: epidemiology and functional impact. *Laryngoscope* 2012; 122(8):1858–61.
2. Gomez F, Curcio CL, Duque G. Dizziness as a geriatric condition among rural community-dwelling older adults. *J Nutr Health Aging* 2011; 15(6):490–7.
3. Jahn K, Kressig RW, Bridenbaugh SA, Brandt T, Schniepp R. Dizziness and Unstable Gait in Old Age: Etiology, Diagnosis and Treatment. *Dtsch Arztebl Int* 2015; 112(23):387–93.
4. Radtke A, Lempert T, Brevern M von, Feldmann M, Lezius F, Neuhauser H. Prevalence and complications of orthostatic dizziness in the general population. *Clin Auton Res* 2011; 21(3):161–8.
5. Laux G, Rosemann T, Körner T, Heiderhoff M, Schneider A, Kühlein T et al. Detaillierte Erfassung von Inanspruchnahme, Morbidität, Erkrankungsverläufen und Ergebnissen durch episodenzugewandene Dokumentation in der Hausarztpraxis innerhalb des Projekts CONTENT. *Gesundheitswesen* 2007; 69(5):284–91.
6. Bösner S, Schwarm S, Grevenrath P, Schmidt L, Hörner K, Beidatsch D et al. Prevalence, aetiologies and prognosis of the symptom dizziness in primary care - a systematic review. *BMC Fam Pract* 2018; 19(1):33.
7. Newman-Toker DE, Cannon LM, Stofferahn ME, Rothman RE, Hsieh Y-H, Zee DS. Imprecision in patient reports of dizziness symptom quality: a cross-sectional study conducted in an acute care setting. *Mayo Clin Proc* 2007; 82(11):1329–40.
8. Grill E, Penger M, Kentala E. Health care utilization, prognosis and outcomes of vestibular disease in primary care settings: systematic review. *J Neurol* 2016; 263:36–44.
9. Mendel B, Bergenius J, Langius-Eklöf A. Dizziness: A common, troublesome symptom but often treatable. *J Vestib Res* 2010; 20(5):391–8.
10. Spiegel R, Rust H, Baumann T, Friedrich H, Sutter R, Göddlin M et al. Treatment of dizziness: an interdisciplinary update. *Swiss Med Wkly* 2017; 147:w14566.
11. McDonnell MN, Hillier SL. Vestibular rehabilitation for unilateral peripheral vestibular dysfunction. *Cochrane Database Syst Rev* 2015; 1:CD005397.
12. Jendyk R, Abholz H-H. Akuter Schwindel in der Hausarztpraxis: S3-Leitlinie.
13. Lawal AK, Rotter T, Kinsman L, Machotta A, Ronellenfitch U, Scott SD et al. What is a clinical pathway? Refinement of an operational definition to identify clinical pathway studies for a Cochrane systematic review. *BMC Med* 2016; 14:35.

14. Rotter T, Kinsman L, Machotta A, Zhao F-L, van der Weijden T, Ronellenfitsch U et al. Clinical pathways for primary care: effects on professional practice, patient outcomes, and costs. *Cochrane Database of Systematic Reviews* 2013.
15. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008; 337:a1655.
16. Möhler R, Köpke S, Meyer G. Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare: revised guideline (CReDECI 2). *Trials* 2015; 16:204.
17. Pfadenhauer LM, Gerhardus A, Mozygemba K, Lysdahl KB, Booth A, Hofmann B et al. Making sense of complexity in context and implementation: the Context and Implementation of Complex Interventions (CICI) framework. *Implementation Sci* 2017; 12(1):1–17. Available from: URL: <https://implementationscience.biomedcentral.com/track/pdf/10.1186/s13012-017-0552-5>.
18. OHern MS, Rindfleisch A. Customer Co-Creation. In: Malhotra NK, editor. *Review of marketing research: Volume 6*. Armonk, N.Y: M.E. Sharpe; 2010. p. 84–106 (Review of Marketing Research).
19. Kuckartz U. *Qualitative Inhaltsanalyse: Methoden, Praxis, Computerunterstützung*. 2., durchgesehene Auflage. Weinheim, Basel: Beltz Juventa; 2014. (Grundlagentexte Methoden).
20. Mueller M, Whitney SL, Alghwiri A, Alshebber K, Strobl R, Alghadir A et al. Subscales of the vestibular activities and participation questionnaire could be applied across cultures. *J Clin Epidemiol* 2015; 68(2):211–9.
21. Kirschneck M, Rauch A, Stucki G, Cieza A. Rehabilitationsmanagement in der Praxis unter Anwendung der Internationalen Klassifikation der Funktionsfähigkeit, Behinderung und Gesundheit (ICF). *Phys Rehab Kur Med* 2011; 21(01):11–21.
22. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci* 2009; 4:50.
23. Powell BJ, Waltz TJ, Chinman MJ, Damschroder LJ, Smith JL, Matthieu MM et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. *Implement Sci* 2015; 10:21.
24. Schädler S. *Gleichgewicht und Schwindel: Grundlagen Untersuchung Therapie*. München: Urban et Fischer in Elsevier; 2016. Available from: URL: <http://www.sciencedirect.com/science/book/9783437451478>.
25. Yardley L. *Controlling Your Symptoms: How to reduce dizziness and nausea* [cited 2020 May 8]. Available from: URL: <https://www.menieres.org.uk/files/pdfs/controlling-your-symptoms.pdf>.
26. *Frequently Asked Questions: Benign Paroxysmal Positional Vertigo (BPPV): Patient information* [cited 2020 May 8]. Available from: URL: https://www.entnet.org/sites/default/files/uploads/PracticeManagement/Resources/_files/eng-bppv_faq.pdf.
27. Bhattacharyya N, Gubbels SP, Schwartz SR, Edlow JA, El-Kashlan H, Fife T et al. *Clinical Practice Guideline: Benign Paroxysmal Positional Vertigo (Update)*. *Otolaryngol Head Neck Surg* 2017;

156(3_suppl):S1-S47.

28. Michie S, Atkins L, West R. The behaviour change wheel: A guide to designing interventions. First edition. London: Silverback Publishing; 2014.
29. W.K. Kellogg Foundation. Logic Model Development Guide: Using Logic Models to Bring Together Planning, Evaluation, and Action. Available from: URL: Retrieved from <https://www.wkkf.org/resource-directory/resource/2006/02/wk-kellogg-foundation-logic-model-development-guide>.
30. Beswick AD, Rees K, Dieppe P, Ayis S, Gooberman-Hill R, Horwood J et al. Complex interventions to improve physical function and maintain independent living in elderly people: a systematic review and meta-analysis. *The Lancet* 2008; 371(9614):725–35.
31. Wong KC, Wong FKY, Yeung WF, Chang K. The effect of complex interventions on supporting self-care among community-dwelling older adults: a systematic review and meta-analysis. *Age Ageing* 2018; 47(2):185–93.
32. Rousseau N, Turner KM, Duncan E, O'Cathain A, Croot L, Yardley L et al. Attending to design when developing complex health interventions: A qualitative interview study with intervention developers and associated stakeholders. *PLoS One* 2019; 14(10):e0223615.
33. Brady MC, Stott DJ, Norrie J, Chalmers C, St George B, Sweeney PM et al. Developing and evaluating the implementation of a complex intervention: using mixed methods to inform the design of a randomised controlled trial of an oral healthcare intervention after stroke. *Trials* 2011; 12(1):168.
34. Greenhalgh T, Jackson C, Shaw S, Janamian T. Achieving Research Impact Through Co-creation in Community-Based Health Services: Literature Review and Case Study. *Milbank Q* 2016; 94(2):392–429.
35. O'Cathain A, Croot L, Duncan E, Rousseau N, Sworn K, Turner KM et al. Guidance on how to develop complex interventions to improve health and healthcare. *BMJ Open* 2019; 9(8):e029954.

Figures

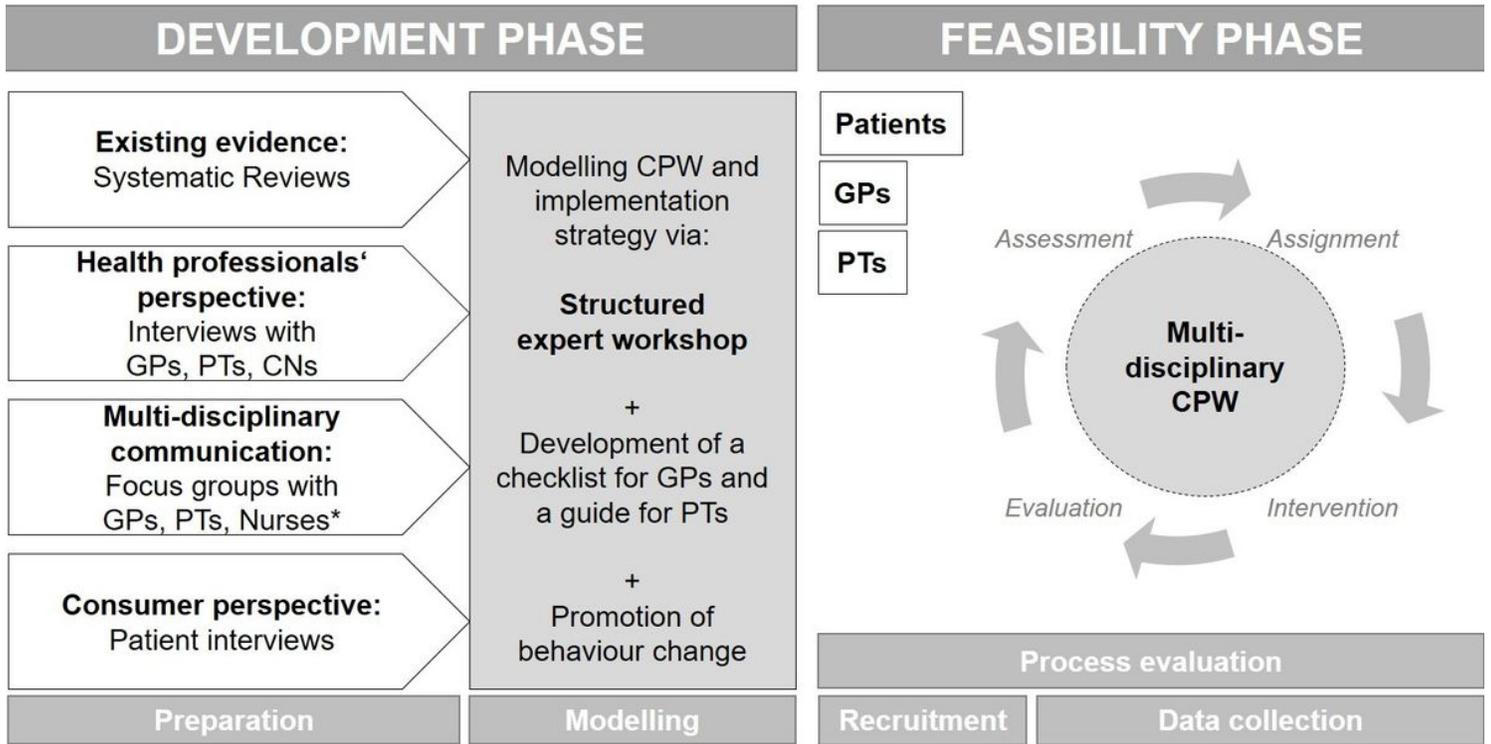


Figure 1

Overall development phase of research project and planned subsequent feasibility phase Legend:

*Nurses working in community / home care services; CPW = Care pathway; GPs = General practitioners; PTs = Physical therapists

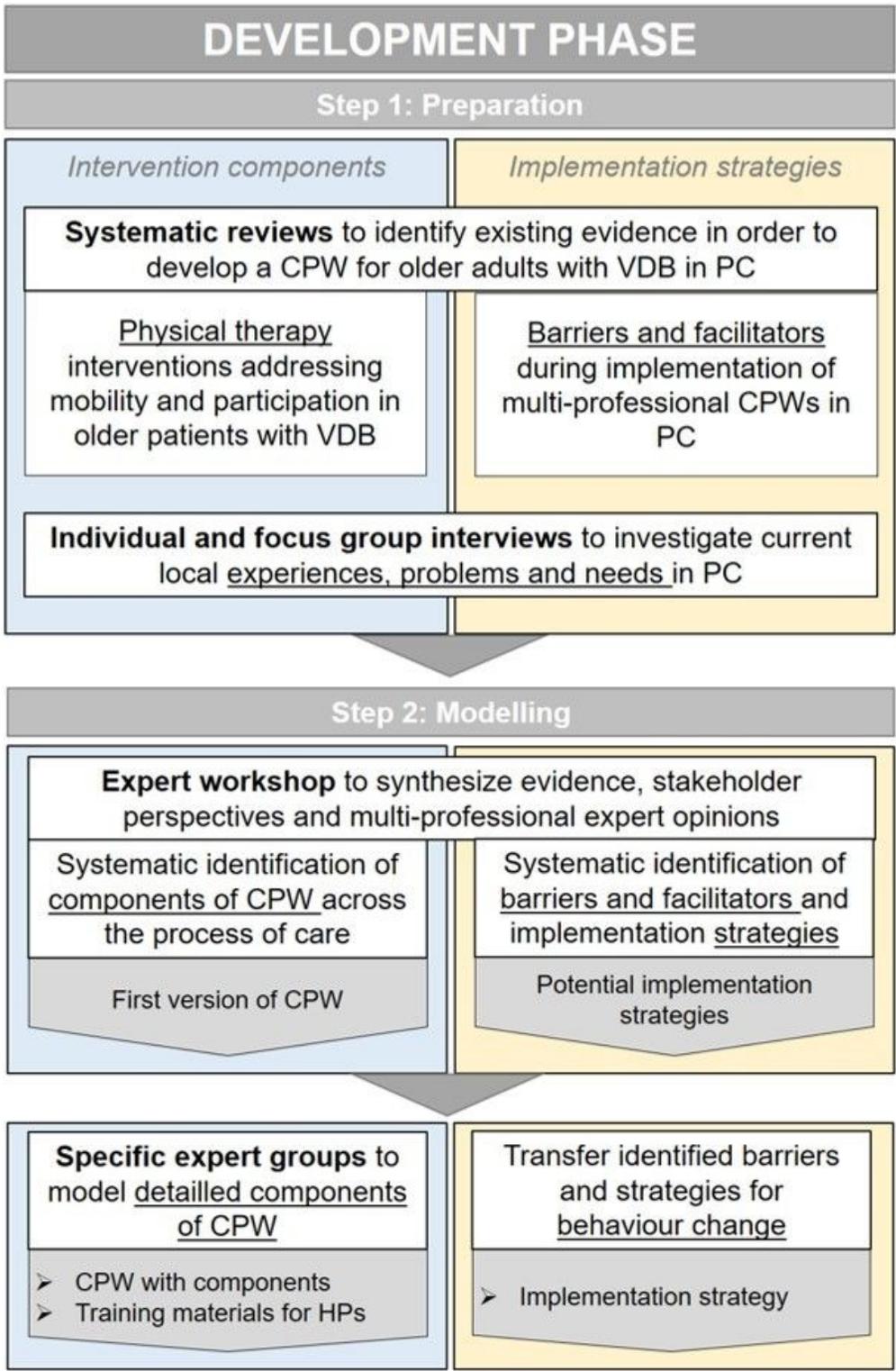


Figure 2

Aims and methods for development of intervention components and implementation strategies of intervention Legend: CPW = Care pathway; HPs = Health professionals; PC = Primary care; VDB = Vertigo, dizziness and balance disorders

Aim and result	Topic	Material	Method
Input Common basic knowledge	<ul style="list-style-type: none"> Disease-specific (VDB) Methodologic (CPW) Research results (existing evidence, health care providers' and consumers' perspective) 	Accompanied fact sheets	 Presentation (plenum)
Brainstorming Definition of extremes	<ul style="list-style-type: none"> Optimal case of health care Worst case of health care 		 Mind map, Reversal method (plenum)
Modelling Draft of first version of CPW	<ul style="list-style-type: none"> Transfer in steps of health care process to model concrete ideal processes Model an practicable process 	ICF-Rehab-Cycle	 Discussion (mixed small groups, plenum)
Contextualization Potential barriers / facilitators and implementation strategies	<ul style="list-style-type: none"> Weighting potential barriers / facilitators Using software Creating implementation strategies in context 	CFIR Definitions Matching tool ERIC Definitions	 Points and Pinboards (alone), 6-3-5 Method (specific small groups)
Concretization Milestones / implementation plan	<ul style="list-style-type: none"> Defining milestones and implementation plan 		 Discussion (plenum)

Figure 3

Process of the expert workshop Legend: CFIR = Consolidated framework of implementation research; CPW = Care pathway; ERIC = Expert recommendations for implementing change; ICF = International classification of functioning, disability and health; VDB = Vertigo, dizziness and balance disorders. "Specific groups" means 1 kind of experts in 1 group; "Mixed groups" means every kind of experts in 1 group.

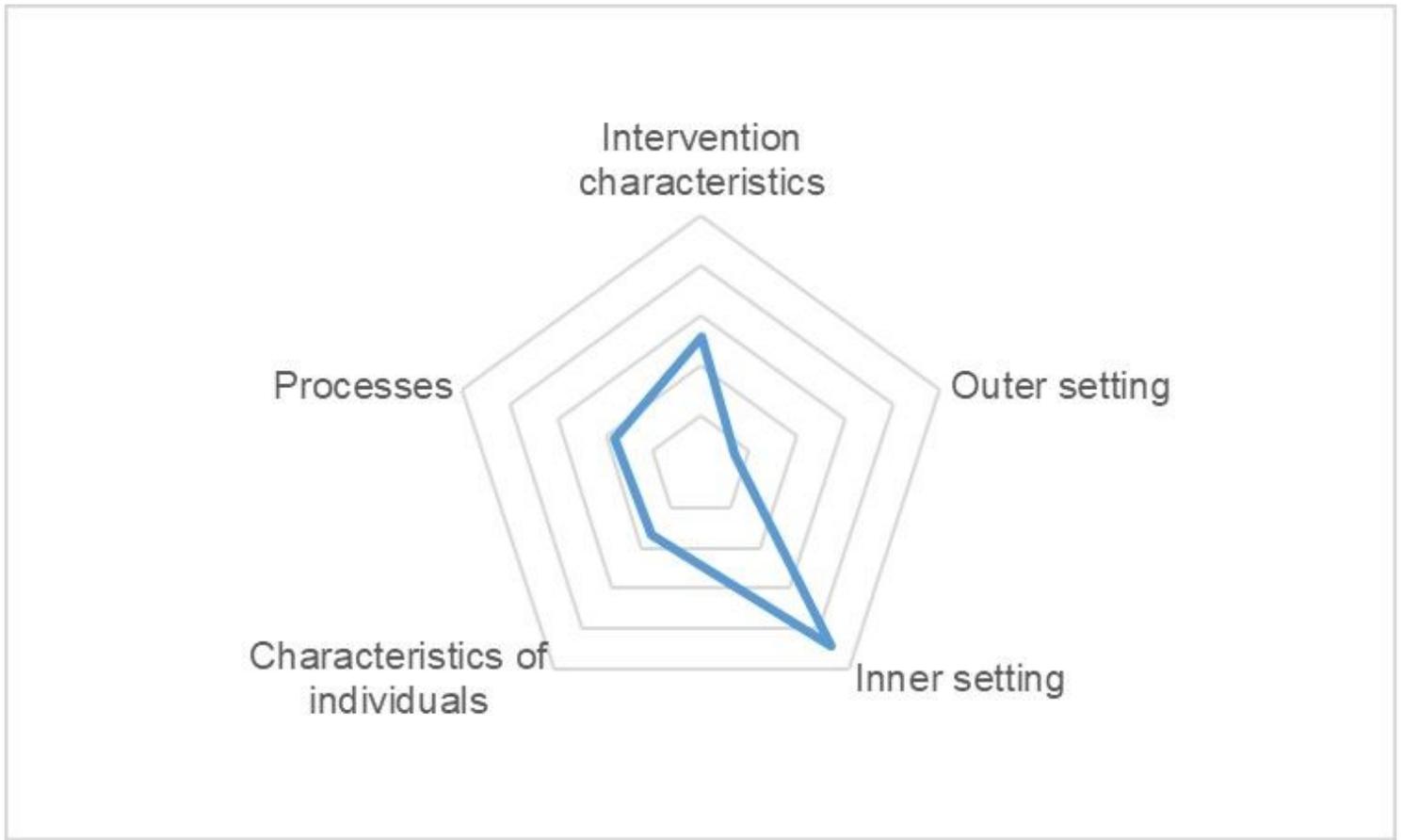


Figure 4

Identified barriers by the expert panel

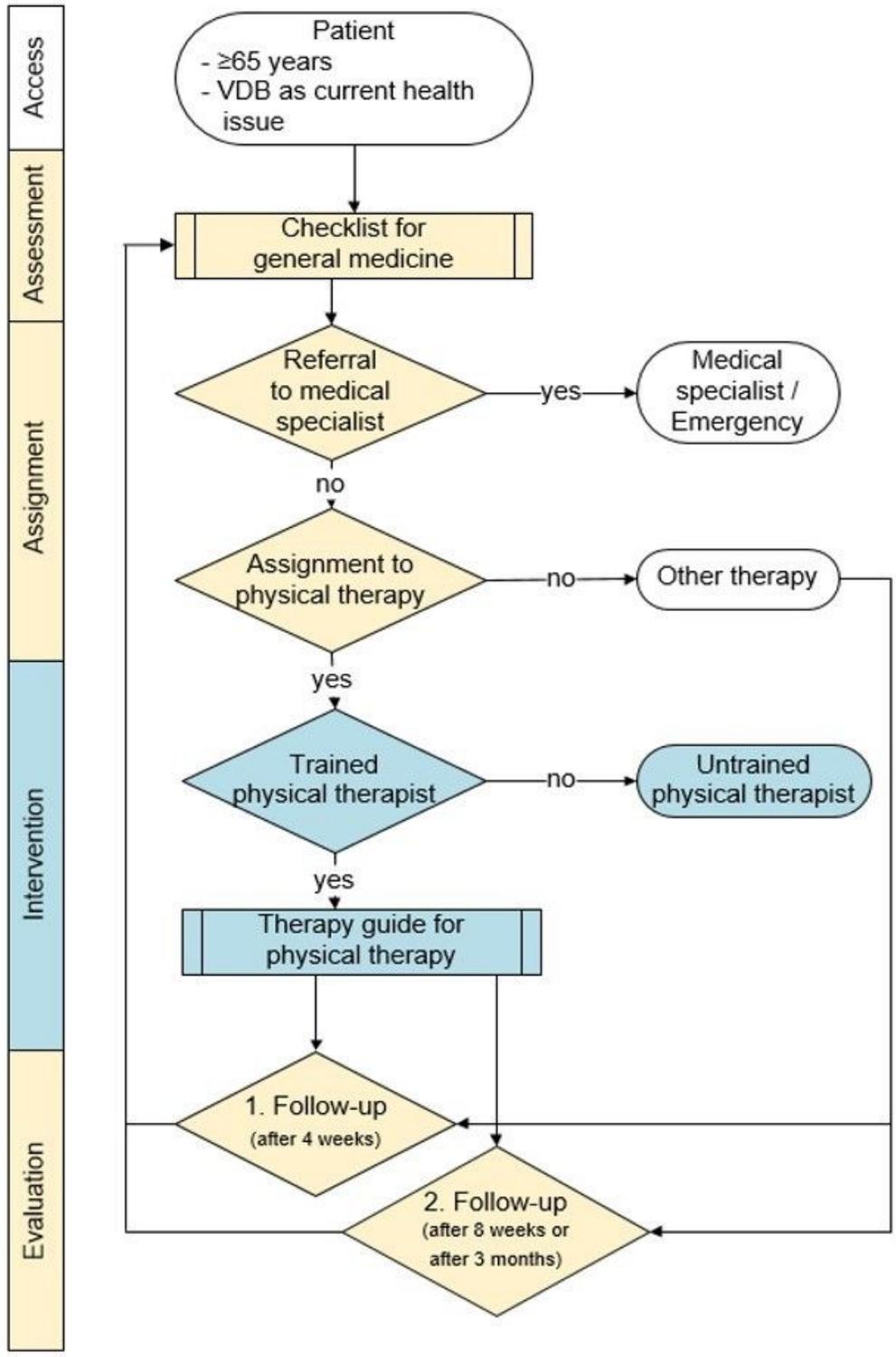


Figure 5

Multi-disciplinary CPW for older adults with VDB in primary care

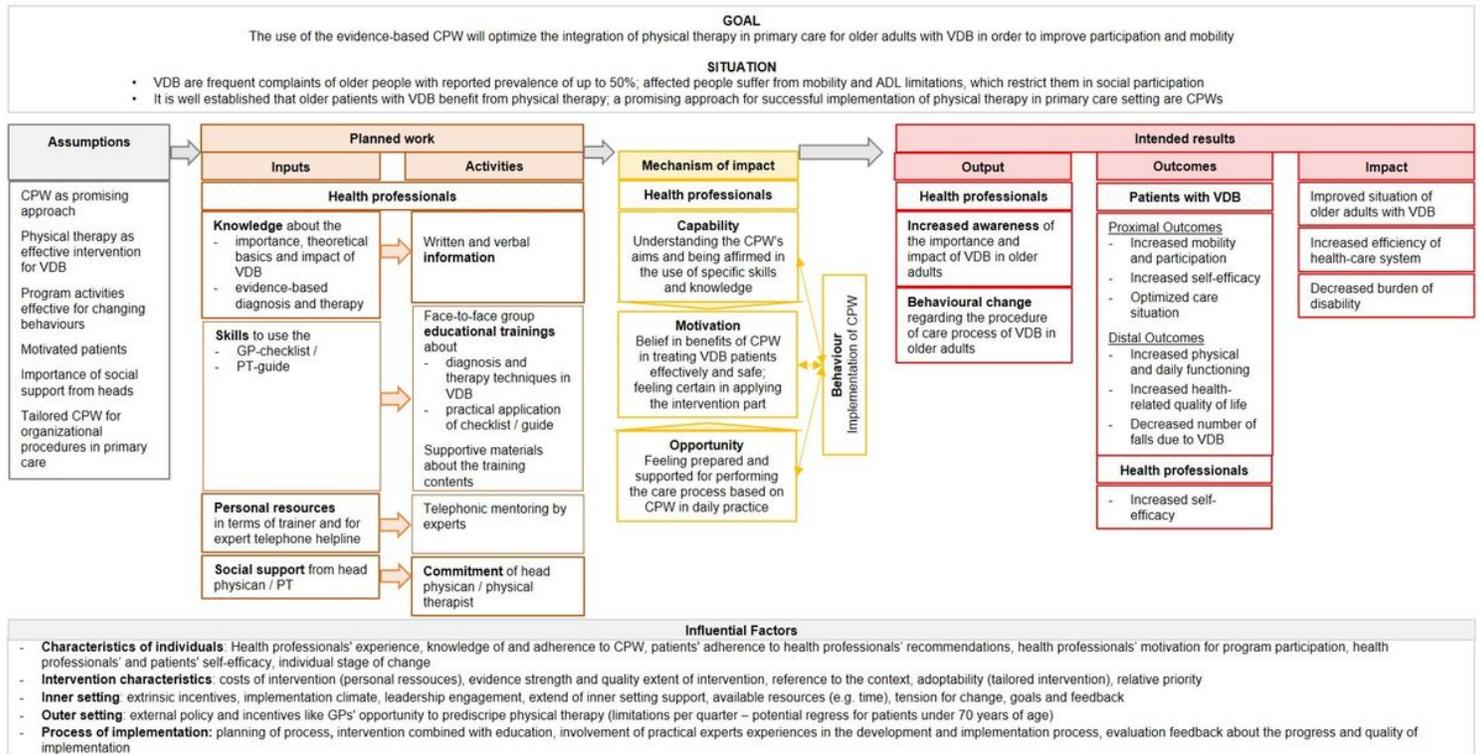


Figure 6

Logic Model underlying the CPW Legend: ADL = Activities of daily living; CPW = Care pathway; GP = General practitioner; PT = Physical therapist; VDB = Vertigo, dizziness and balance disorders

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