Efficacy of integrating vestibular rehabilitation and cognitive behaviour therapy in persons with long-term dizziness in primary care– a study protocol for a randomised controlled trial

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Study protocol

Keywords: Protocol, RCT, persistent dizziness, vestibular rehabilitation, cognitive behaviour therapy, dizziness handicap inventory, gait velocity, rehabilitation

Posted Date: June 14th, 2019

DOI: https://doi.org/10.21203/rs.2.10300/v1

Version of Record: A version of this preprint was published on October 7th, 2019. See the published version at https://doi.org/10.1186/s13063-019-3660-5.

Abstract

Background: Dizziness is a common complaint, and the symptom often persists, together with additional complaints. A treatment combining of Vestibular Rehabilitation (VR) and Cognitive Behaviour Therapy (CBT) is suggested. However, further research is necessary to evaluate the efficacy of such intervention. The objective of this paper is to present the design of a randomised controlled trial aiming at evaluating the efficacy of an integrated treatment of VR and CBT on dizziness, physical function, psychological complaints and quality of life in persons with persistent dizziness. Methods/Design: The randomised controlled trial is an assessor-blinded block randomised parallel-group design, with a 6- and 12- month follow-up. The study includes 125 participants from Bergen (Norway) and surrounding areas. Included participants present with persistent dizziness lasting at least 3 months, triggered or exacerbated by movement. All participants receive a one-session treatment (Brief Intervention) with VR before being randomised into a control-group or an intervention-group. The intervention-group will further be offered an eight-session treatment integrating VR and CBT. The primary outcomes in the study are the dizziness handicap inventory and preferred gait velocity. Discussion: Previous studies combining these treatments have been of varying methodological quality, with small samples, and long-term effects have not been maintained. In addition, only the CBT has been administered in supervised sessions, with VR offered as home-exercises. The current study focuses on the integrated treatment, sufficiently powered sample size, and a standardised treatment program evaluated by validated outcomes using a standardised assessment protocol. Trial registration: The study was registered at www.clinicaltrials.gov (NCT02655575) on January 14th 2016.

Background

Vertigo and/ or dizziness are amongst the most frequent symptoms reported in outpatient practices (1), with a lifetime prevalence reported in approximately 30% (2). Dizziness can present for a variety of reasons, many initiated through vestibular disease, however, it is not always possible to identify a specific cause or diagnosis (3).

Psychological factors, such as anxiety, seem to be closely related to prevalence of dizziness (4, 5), and it is likely that biological and psychological factors interact, maintaining the vestibular symptoms as well as anxiety (4, 6). In chronic dizziness it is common to avoid movements, activities and social settings that may provoke symptoms and discomfort (7). This fear of provoking dizziness and discomfort may also lead to an “en block” movement pattern. Some studies on persons with persistent dizziness have also reported musculoskeletal symptoms (8), like for instance postural disalignments (9) and musculoskeletal pain (10), particularly in the neck- shoulder area (10-12). Long-term consequences of such avoidance strategies may hamper compensation strategies and functional improvements, eventually leading to occupational disability (13).

Vestibular Rehabilitation (VR) is an exercise-based treatment approach for dizziness, primarily directed towards reducing vestibular symptoms (not musculoskeletal abberations), with moderate to strong

evidence of VR for conditions of unilateral vestibular hypofunction (14). A recent review has indicated that VR may also be used in other conditions, such as vestibular disorders of central origin (15). Since musculoskeletal symptoms are not specifically targeted in VR interventions, one longitudinal study (no control group) incorporated body awareness therapy (16) into VR, with positive effects on musculoskeletal aberrations, such as improved bodily flexibility and balance during ambulation, as well as improved perception of dizziness (17, 18).

As mentioned, VR treatment is developed as an exercise based treatment, however, it also contains some cognitive elements, such as graded exposure (habituation), that also facilitates cognitive restructiuring (e.g. reduce avoidance behaviour) (7, 19). A recent Randomised Controlled Trial (RCT) providing just three sessions of Cognitive Behaviour Therapy (CBT) for panic anxiety found reduced dizziness, handicap and use of safety behaviours in persons with chronic subjective dizziness (20). Furthermore, the positive changes were maintained at 6-month follow up (21), but the outcomes only focused on psychological complaints, and no objective outcomes were assessed.

As both VR and CBT have shown positive effects on persons with dizziness, the combination of VR and CBT seems to be an appropriate treatment approach for persistent dizziness, and a few studies have investigated this combination (22-25). The effects of the combined VR and CBT treatments are reported to be reduced dizziness related handicap (23-25), improved walking (23), and reduced anxiety and depression (25). A systematic review on psychotherapy in dizziness found a small and clinically relevant effect on dizziness, but no effect on anxiety and depression (26). However, the included studies had small sample sizes (19 to 31 participants) (23-25), no random allocation (25), no standardised CBT treatment manual (25), and improvements found in the short-term were not maintained as long-term effects (22). Further as none of the combined treatments included a focus on musculoskeletal complaints, there is a need to further develop the treatment combining VR and CBT, also targeting the musculoskeletal aspects, and afterward the effects of the program must be tested in an RCT. A recent feasibility study integrating VR and CBT with an additional focus on musculoskeletal effects showed that such treatment approach was feasible and safe (Kristiansen et al, 2019- in review). Therefore, this treatment is now ready to be evaluated in an RCT.

Study objectives

The aim of the randomised controlled trial is to evaluate short- (6 months) and long-term (12 months) efficacy of an integrated treatment of VR and CBT in persons with persistent dizziness. It is hypothesised that persons receiving the additional VR-CBT program will show superior reduction in self-reported dizziness related handicap in addition to increased preferred gait velocity compared with persons receiving BI-VR alone.

Methods/design

Study design

The study is a prospective assessor-blinded block-randomised controlled trial, with a parallel group-design, with a 6- and 12-months follow-up. The protocol conforms with the recommendations from the EQUATOR network (27), using the Standard Protocol Items: Recommendations for Interventional Trails (SPIRIT) checklist and the Consolidated Standard of Reporting Trials (CONSORT) guidelines when reporting the results (28, 29). The SPIRIT checklist is available in additional file 1.

Settings and location

Participants will be recruited through general practitioners, physiotherapists, Ear-Nose and Throat specialists, and information through newspapers and the social media. Participants will be recruited from the region in and around Bergen, Norway. Blinded baseline and follow-up testing and one-session VR intervention (BI-VR) will be conducted at the Western Norway University of Applied Sciences (HVL). Group treatment (VR-CBT) will be offered at HVL, as well as at selected physiotherapy clinics in Bergen. The group treatment will be led by physiotherapists trained in the treatment protocol (please see below).

Participants

Eligible participants must meet all the following inclusion criteria: Working age (18-70 years) with acute onset of dizziness and with symptoms lasting at least 3 months, and the dizziness has to be triggered/ worsened by head movements,

Participants will be excluded if they meet one or more of the following exclusion criteria: known non-vestibular reason for dizziness, diagnosed with fluctuating vestibular diseases (e.g. Ménière's disease), scheduled for treatment of/ have had treatment for benign paroxysmal positional vertigo (BPPV) within one month, fast head movements are contraindicated (e.g. whiplash associated injuries, osteoporosis of the neck), presentation of severe/ terminal pathology (cancer, psychiatric diagnosis), participated in group-therapy for dizziness within the past year, inadequate Norwegian language proficiency (verbal and written), or unable to attend test and treatment locations.

Procedure

Eligible participants will initially be screened by a telephone interview followed by further screening at HVL. Participants fulfilling the inclusion and exclusion criteria who are willing to participate will be asked to sign an informed consent. The first meeting comprises screening and baseline testing and is scheduled to last two hours. During baseline testing the included participants will complete physical tests and questionnaires. Following baseline testing the participants attend a one-hour treatment session (BI-VR), and afterwards randomisation to either the intervention group or the control group. Follow-up testing

are scheduled 6 and 12 months after inclusion (Table. 1) comprising online or paper versions of questionnaires (completed separately from testing) and objective outcomes. Both follow-up tests are scheduled to last up to one hour.

Interventions

Brief Intervention Vestibular Rehabilitation (BI-VR)

All the participants receive Brief Intervention Vestibular Rehabilitation (BI-VR), a single-session treatment based on elements from traditional VR (30, 31), but adapted to a single session in line with a brief intervention model developed for patients with low back pain (32). The purpose of the treatment is to give the participant the understanding that movement is the key factor in improving symptoms and that dizziness rarely is related to serious illness. BI-VR comprises examination, information regarding the vestibular system, what causes dizziness, advice related to specific findings, and supervision in selected standardised VR exercises. All participants are encouraged to stay active, and provoke dizziness in line with established recommendations (14, 33).

Control group

Participants allocated to BI-VR only, will be encouraged to do the prescribed exercises on their own. The BI-VR physiotherapist will call twice during a four-month period, to encourage compliance with the home-exercises and answer questions that may arise.

Intervention group

Vestibular Rehabilitation and Cognitive Behavioural Therapy (VR-CBT).

Participants in the intervention group will be invited to attend an additional structured group-treatment program integrating vestibular rehabilitation and cognitive behaviour therapy (VR-CBT). The VR-CBT manual was developed through collaboration between researchers, physiotherapists and clinical psychologists. The treatment offers eight weekly two-hour sessions with five to eight participants in each group, with the aim of addressing both the physical and psychological challenges of persistent dizziness. The CBT approach is based on previous findings indicating that treatment for panic disorders can also be efficacious for persons with chronic dizziness (20). CBT focuses on the vicious cycle between somatic anxiety symptoms elicited by the “fight or flight” response, the catastrophic misinterpretations of these and other bodily symptoms, and the resulting safety- and avoidance behaviour (34). The VR comprises habituation, gaze stability and balance exercises, with body awareness promoted throughout, in addition

to guided relaxation (33, 35). The exercises may be individually adapted, by for instance adjustments in base of support, speed of movement, and environmental conditions. All sessions will have elements of both VR and CBT, however, the first three sessions mostly emphasise CBT, while the subsequent five sessions mostly emphasise VR. This set up allows the participants to practice exercises in a safe environment, and provides opportunities to reflect on dizziness, safety and avoidance behaviours that may occur. Participants are further asked to carry out and register home exercises following the treatment sessions, and daily VR exercises are introduced from session three onwards. A brief description of the VR-CBT manual is presented in Table 2.

(TABLE 2 INSERTED APPROXIMATELY HERE)

Physiotherapists

One physiotherapist experienced in VR, and trained in the BI-VR protocol, will run all BI-VR sessions. Six physiotherapists delivering the VR-CBT treatment will attend a competency course to before leading the treatment. The competency course contains the principles of VR-CBT, the elements of the treatment manual, and training of practical skills related to the manual, as described in the feasibility study (Kristiansen et al, 2019- in review). After each of the first two treatment sessions a clinical psychologist and the principal investigator will be available for support and guidance, without unblinding participant allocation.

Data collection and follow up

Three assessors (principal investigator, project lead, and one research assistant) are involved in the blinded data collection at baseline and follow up adhering to the standardised test protocol. In addition, the assessors will practise together before and during data collection, in order to unify performance and interpretation of the outcome measures. The principal investigator will perform the majority of the data collection.

Outcome measures

Table 3 describes the outcomes that will be collected at the various stages in the study.

Primary outcome measures

The primary outcome measures are the Dizziness Handicap Inventory (DHI) and preferred gait velocity. The DHI is a questionnaire developed in order to assess the impact of dizziness on quality of life (36). It is translated into Norwegian and has shown satisfactory test-retest reliability (37). Preferred gait velocity is assessed using 6-meter timed gait test, with one additional meter at each end allowing acceleration

and deceleration (38). The test has been found reliable in healthy adults (39), as well as in persons with vestibular disorders (38).

Secondary outcome measures

The secondary outcomes include dizziness severity, psychological complaints, fatigue, subjective health complaints, standing balance, walking, strength, flexibility, and general quality of life.

The patient reported outcomes is used to evaluate dizziness severity using the Norwegian version (40) of the Vertigo Symptom Scale short form (VSS) (41). In addition, the Hospital Anxiety and Depression Questionnaire (HADS) (42), the Body Sensations Questionnaire (BSQ) (43), the Agoraphobic Cognition Questionnaire (ACQ) (43), the Mobility Inventory of Agoraphobia- Alone (MIA) (44), and an adapted version of the Panic Attack Scale (PAS) (45) describes levels of anxiety, depression, panic-related symptoms, and avoidance behaviour. Further, fatigue is assessed using the Chalder's Fatigue questionnaire (CFQ) (46), while the subjective health complaint inventory (SHC) reports incidents and extent of subjective somatic and psychological complaints (47). Patient Specific Functional Scale (PSFS) assesses perceived functional change (48), while information regarding quality of life is gathered using the EQ5D-5L (49).

Secondary objective measures include standing balance (sway measured during the four conditions in the modified clinical test for sensory interaction and balance (mCTSIB)) (50) using balance trainer BTG4 (HUR health, Norway), walking (fast velocity and with dual task (51)), visual acuity (clinical dynamic visual acuity test (CDVA) (52)), and grip strength (53). Musculoskeletal aberrations is registered using four elements from the Global Physiotherapy Examination (GPE) (17) and Head movement induced dizziness (38) measured using the numeric rating scale (HmDizz). The Patient Global Impression of Change questionnaire (PGIC) (54) is used to evaluate perceived improvement at follow-up testing at 6 and 12 months

(TABLE 3 INSERTED APPROXIMATELY HERE)

Demographic data and other measurements

In addition to the outcomes, information regarding gender, age, work status, medication, and activity level will be gathered. The VR-CBT physiotherapists will register attendance to sessions and reasons for absence and collect the home-exercise registrations.

Satisfactory compliance to VR-CBT will be defined as minimum 75% attendance to VR-CBT sessions (6/8 sessions), and minimum 80% completion of the exercise diary for home-exercises, where 100% completion is defined by reporting exercises and following a walking program five times per week. Satisfactory compliance in the control-group will be defined as completion of at least one telephone call with the BI-VR physiotherapist.

Sample size and power considerations

The study is designed as a randomised controlled trial comparing two groups (BI-VR, and BI-VR with VR-CBT). To obtain a clinical important group difference in DHI of 11 points (37) with a significance level of 0.05 and a power of 80%, 47 participants will be required per group. To obtain a clinical important change in preferred gait velocity of 0.1 m/s (55) with a significance level of 0.05 and a power of 80%, 36 participants will be required in each group. In order to ensure power of both primary outcomes at least 47 participants are selected as basis for the sample size needed in the study. The final sample size is set at 125 participants, allowing for approximately 35% drop-out, based on drop-outs in the feasibility study (Kristiansen, 2019 -in review), and in previous studies (18, 20, 56, 57).

Randomization and concealment of allocation

The participants are block-randomised in groups of 16, and randomly assigned to BI-VR followed by VR-CBT (intervention group) or BI-VR alone (control group). Group allocation is performed using a random number generator and is presented on a folded paper, in a concealed envelope. The principle investigator is blinded from group allocations. The envelopes are stored in a locked cupboard only accessible to the BI-VR physiotherapist handing out the allocation envelopes. After group allocation the VR-CBT participants will be contacted by the project lead regarding the first VR-CBT appointment.

Blinding

The principal investigator and assessors are blinded from group allocation and not involved in the treatment of the participants. Blinding of group allocation for VR-CBT physiotherapists and participants are not possible. However, both groups are informed that the optimal treatment is not known, and the study hypothesis is not presented. In order to ensure blinding of assessors the participants are encouraged not to reveal their allocation during testing.

Statistical analysis plan

The efficacy analysis is assessment of the between-group differences in changes in DHI score and preferred gait velocity at 6 and 12 months follow up. The analysis will use the intention to treat (ITT) principle, analysing all randomised participants independent of compliance and withdrawals. In the event of missing data two methods will be used. For missing single questions, the mean baseline value for the respected group will be assigned. If complete questionnaires or objective measures are missing a non-responder imputation will be used, including baseline data carried forward. Sensitivity analyses will be performed to study whether those who drop out differ from those who complete the required program.

An analysis of covariates (ANCOVA) will be used to analyse mean changes in continuous variables, and logistic regression for categorical variables. The model will include the respective dependent variable, in addition to fixed effects of group allocation, baseline value, age, gender and height.

The results will be expressed as a difference between the group means and 95% confidence intervals with associated p-values. All data analysis will be performed according to a pre-established statistical analysis plan and interpreted according to a consensus document signed by all authors. All analyses will be performed using Statistical Package for Social Sciences (SPSS) (version 25, IBM, New York, USA).

Interim analyses

Drop-out rates will be assessed in interim analyses to determine potential need for adjustment in sample-size in line with the power calculations.

Ethical considerations

Although participants may experience increased symptoms in the short-term, it is not anticipated that participation will cause any serious adverse events or harms. A recent feasibility study (Kristiansen et al, 2019- in review) has confirmed that the intervention BI-VR and VR-CBT is feasible and safe for persons with persistent dizziness. The study will follow the criteria and principles of the Declaration of Helsinki. It has been approved by the Regional Committee for Medical and Health Research Ethics (2014-00921) and is registered at www.clinicaltrials.gov (NCT02655575)

Discussion

In recent years there has been more focus on including cognitive approaches into treatment of persistent dizziness (20, 58). However, as previously mentioned there are only a few studies conducted on the effect of combining VR and CBT in persons with persistent dizziness (23-25). All of the studies have scientific limitations as mentioned, categorizing them as moderate quality. The promising result of the recent studies, and the lack of high-quality studies have shown the need for further studies on the efficacy of combining CBT and VR for participants with persistent dizziness.

The novelty of the current study is the integration of VR and CBT, with an additional focus on musculoskeletal complaints, as treatment for persons with persistent dizziness. The previous studies conducted CBT as supervised sessions (individually (25) or in small groups (23, 24)) while VR exercises where administered as home exercises (24, 25). The integration of the supervised VR-CBT sessions in the current RCT allows the participants to practice excises in a safe environment supervised by physiotherapists, and the exercises may be adapted to meet the level of complaints and capacity in each participant.

One possible limitation in the study, as with all exercise trials, is the inability to blind physiotherapists and participants to treatment allocation. Thus, only the testers can be blinded to group-allocation. Another possible limitations may include the specification of compliance criteria, which to our knowledge has not been done in this research area before, and there is no consensus for how much is sufficient. Also, a block-randomisation of 16 may be seen as a limitation as it may take time before group number is reached. In addition, confounding factors like for instance age, gender, duration of complaints and psychological factor may have an impact on primary and secondary outcomes. However, the randomised design is expected to distribute these variables equally between the allocation-groups.

The strength of the current study is the inclusion of relevant reliable main outcomes with a sufficiently powered sample size. In addition, the study utilizes standardised testing procedures, evaluating both short- and long-term efficacy. Another strength is the initial feasibility study conducted, showing that test procedures and interventions were feasible and sage for the present population (Kristiansen et al, 2019- in review). To our knowledge, the current RCT study is the largest study to date, combining VR and CBT to treat persons with persistent dizziness.

The aim of the current study is to evaluate the efficacy of BI-VR followed by VR-CBT, compared with BI-VR alone. If the treatment group improves more than the control group, the description of a standardised program may help practitioners to treat persons with persistent dizziness. If there is no difference between the groups, it may indicate that persons with persistent dizziness may manage their complaints with minimal support from physiotherapists.

Trial status and publication plan

Recruitment of participants to the main study, applying version 2 (dated 30.01.16) of the study protocol, started February 1st 2016 and is expected to end by May 1st 2019. At the time of submission of this protocol (April 2019) the trial is ongoing and still recruiting. Currently, 106 participants have been included. When recruitment is finished the data will be analysed, interpreted and published regardless of positive, negative or inconclusive results.

Abbreviations

ACQ: Agoraphobic Cognitions Questionnaire

ANCOVA: Analysis of Covariance

BI-VR: Brief Intervention Vestibular Rehabilitation

BPPV: Benign Paroxysmal Positional Vertigo

BSQ: Body Sensation Questionnaire

CBT: Cognitive Behaviour Therapy

CDVA: Clinical Dynamic Visual Acuity

CFQ: Chalders Fatigue Questionnaire

DHI: Dizziness Handicap Inventory

DTW: Dual task walking

GP: General practitioner

GPE: Global Physiotherapy Examination

HADS: Hospital Anxiety and Depression Scale

mCTSIB: Modified test for sensory interaction and balance

MIA: Mobility Index- Alone

PAS: Panic Attack Scale

QOL: Quality of Life

SHC: Subjective Health Complaints

VR: Vestibular Rehabilitation

VR-CBT: Vestibular Rehabilitation and Cognitive Behaviour Therapy

VSS: Vertigo Symptom Scale short form

Declarations

Ethics and consent to participate: Ethical approval was gained by the Regional Committee for Medical and Health Research Ethics (2014-00921) prior to recruitment of participants. All participants signed an informed consent prior to study participation.

Consent for publication: Not applicable.

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

Funding: This study is supported by The Norwegian Fund for Postgraduate training in Physiotherapy. The funding body had no active part in planning and conducting the study.

Availability of data and materials: Not applicable

Author contributions: The primary investigator in the study is LK. She developed the study in collaboration with KTW, LM, SM, SHGN, BJK and RC. The VR-CBT treatment manual was developed in collaboration between AH, LK, LM, KTW, SW in addition to one physiotherapist and a clinical psychologist. LK is responsible for the screening and testing of participants and collaborating with the BI-VR therapist, while LM is responsible for the randomisation procedure and organising the VR-CBT sessions. LK drafted the manuscript, with contributions from all authors with critical revision. All authors have read and approved the manuscript.

Acknowledgments: Not applicable

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Tables

Table 1. Spirit figure of study protocol

	STUDY PERIOD				
	Enrolment			Post allocation	
Timepoint		Month 0-2	Month 1-6	6 months	12 months
ENROLMENT					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTIONS					
BI-VR		X			
VR-CBT			X		
ASSESSMENTS					
Dizziness Handicap Inventory	X			X	X
Preferred gait velocity	X			X	X
Vertigo Symptom scale- Short form	X			X	X
Body Sensation Questionnaire	X			X	X
Adapted Panic attack Scale	X			X	X
Mobility Index, Alone	X			X	X
Panic attack scale	X			X	X
Patient Specific function questionnaire	X			X	X
Subjective Health complaints	X			X	X
Patient global impression of change				X	X
Chalders fatigue questionnaire	X			X	X
EQ5D-5L	X			X	X
Body sway in standing	X			X	X
Head movement induced dizziness	X			X	X
Fast gait velocity	X			X	X

Clinical dynamic visual acuity	X	X	X
Elements from GPE	X	X	X
Dual task walking	X	X	X
Grip strength	X	X	x

Table 2. Brief description of the Vestibular Rehabilitation – Cognitive behaviour therapy (VR-CBT) group treatment protocol

Session nr	Focus	Example of tasks/ exercises
1	Dizziness and additional/ secondary complaints	Discussion on dizziness and additional complaints. Introducing the vicious circle that can arise between somatic symptoms and the catastrophic misinterpretation of these. Exercises: Body awareness in sitting and standing. Habituation (nodding and head turns)
2	The “vicious circle”	How somatic symptoms related to both dizziness and anxiety can be appraised appropriately, by mapping the relevant symptoms, thoughts, and potential avoidance behaviour for each participant. Introducing the “fight or flight” response, and how this may be relevant for chronic dizziness. Exercises: Body awareness in standing and walking, habituation through games with planned and unplanned head turns. Relaxation.
3	The “fight or flight-response”	Discussion regarding experiences related to symptoms similar to the fight or flight response. How can these symptoms be appraised in relation to persistent dizziness. Exercises: Habituation and body awareness (standing balance, walking with directional changes). Reflection during and after exercises. What happened? What was your response? (every session from now) Relaxation.
4	The fight or flight response and management.	Discussion: How did you respond to the fight or flight response in every-day life following the last session? Individual goal setting. Exercises: Habituation, visual acuity, walking and ball games with change of place, turning and rotation. Relaxation
5	Relaxation	Discussion/ reflection: Exercises, dosage and “relaxation”. It is normal to be dizzy and tired after exercises Exercises: Progression of visual acuity, habituation and balance using ball during exercise. Working alone and in pairs. Relaxation
6	Movement induced dizziness	Any changes in relation to the dizziness circle described in first session? Group and individual reflection. Exercises: Habituation games: in larger groups and pairs. Walking with head rotations, velocity changes, and externally induced stop/start. Relaxation
7	What next? Preparation for the future	Discussion before, reflection during and group reflection after exercises: “How do I cope/ deal/ manage the dizziness. What thoughts are formed when I get dizzy?”

		Exercises: Combination of balance and habituation – Activities and games in groups and in pairs. (e.g. obstacle course, standing back to back, passing ball at different heights.) Relaxation
8	Reflection and conclusion	Discussion: “What have I learnt? What will I take with me? What do I do when/if dizziness returns?” Exercises: Balance and body awareness in standing and walking, changing directions, different velocities, stop/start. Ball activities alone, in pairs and in larger group Relaxation

Table 3. Description and test metrics of outcome measures

Name	Scoring/ description	Test metrics
Primary outcome measures		
Dizziness Handicap inventory (DHI)	25 items, each item has three alternative scores 0 (no), 2 (sometimes), and 4 (yes) giving a score-range of 0-100 DHI points (36). Higher scores indicate greater perceived disability; 0-30; mild, 31-60; moderate, 61-100; severe (59).	Cut-off 29 points, MIC 11 DHI points, ICC 1,1 0.90 (37).
Preferred gait velocity (m/sec)	Participants walked at normal pace, down an 8m pathway, timed in the middle 6m. It was timed using a stopwatch from when the first foot passed the start point to when the last foot passed the stop point. Mean velocity over two trials were calculated.	Substantial meaningful change 0.1 m/s (60), ICC (3.1): 0.88 (CI 0.81-0.98) (38)
Secondary outcomes /Patient reported outcomes		
The shortened version of the Vertigo Symptom Scale (VSS)	15 items, each scoring from 0 (never) to 4 (very often) giving a score range of 0-60. Higher scores indicate higher symptom severity (41). Severe dizziness: ≥ 12 (41).	Norwegian version cut-off 6.5 points (40). Clinical significant change in original version ≥ 3 points (61). ICC Norwegian version: 0.89 (40).
Agoraphobic Cognitions Questionnaire (ACQ)	14 items, each rated on a scale ranging from 1 (thought never occurs when I am nervous) to 5 (thought always occurs when I am nervous) (43). Measures fear of fear. Mean score is reported, and higher scores imply greater levels of fear.	Chronbach's alpha for outpatients with agoraphobia: 0.80 (43)
Body Sensation Questionnaire (BSC)	18 items, each with a score range from 1 (not at all frightened by the sensations) to 5 (extremely frightened by this sensation). The mean score reported, and higher scores implies greater fear of somatic sensations (43).	Chronbach's alpha for outpatients with agoraphobia 0.87 (43).
Mobility Inventory of	27 items, each rated from 1 (never avoids) to 5 (always avoids). Mean score is reported and, and higher scores indicated greater avoidance behaviour.	Chronbach's alpha in

Agoraphobia, Alone (MIA)		agoraphobia: 0.96 (44)
Adapted Panic Attack Scale		
· Attack frequency	Measures frequency of distress related to sudden onsets of episodes with four or more strong sensations of dizziness and dizziness related symptoms on a five point scale ranging from 0 (no attacks) to 4 (one or more attacks per day). Adapted from the Panic Attack Scale (45)	
· Attack severity	Severity rating of the degree of distress related to the episodes described above. Numeric rating scale with a score range 0-8. Higher score indicates increased symptom related distress/ disability. Adapted from the Panic Attack Scale (45)	
Hospital Anxiety and Depression Scale (HADS)	14 items, each rated from 0 (not present) to 3 (considerable), giving a score range of 0-42 points (42). Higher score indicates greater psychological distress.	Cut-off 12 points, Chronbach's alpha: 0.88. (62).
EQ5D-5L	Generic instrument describing and valuing health (63).	
· EQ5D-5L	Five dimensions, each rated from 1 to 5. Higher scores indicate increased problems health (64).	
· EQ5D-5L Vas	Score range 0-100 %. Higher scores indicate better perceived health related quality of life.	MCID in stroke: 8.61-10.82 (65) .
Subjective Health Complaints (SHC)	29 items, each item is scored from 0 (no complaints) to 3 (serious complaints). Higher scores indicate higher severity of complaint. Split into 5 subcategories: Musculoskeletal 8 items (score 0-24), Pseudoneurology 7 items (score 0-21), Gastrointestinal 7 items (score 0-21), Flu 2 items (score 0-6), and Allergy 5 items (score 0-15) (66).	Chronbach's alpha musculoskeletal pain: 0.74, Pseudoneurology: 0.73, Gastrointenstinal: 0.62, Allergy: 0.58, and Flu: 0.67 (66).
Chalder's Fatigue Questionnaire (CFQ)	13 items. The first 11 items are scored from 0 (better than usual) to 3 (much worse than usual), giving a score range of 0-33. The last two items rates duration and constancy of fatigue (46). Higher scores indicating more fatigued.	Chronbach's alpha in Norwegian population: 0.86 (67).
Patient Specific Functional Scale (PSFS)	Registers up to 3 activities participants find difficult. In addition the level of difficulty is rated on an 11 point scale (48), where 0 maximum difficulty and 10 is no difficulty.	Reliability established in various musculoskeletal

		problems (ICC: 0.76- 0.97) (68) MCID in various musculoskeletal problems: 0.99-2.5 (68)
Patient Global Impression of Change (PCIG)	1Item, rated from 1 (very much improved) to 7 (very much worse), with a score of 4 indicating no change (54).	
Secondary outcomes/ Physical tests		
Dual-Task walking	Similar walking protocol as for preferred gait velocity, with an added task of counting backwards by three out loud, while walking. Each trial was timed and the numbers of miscounts were documented. Mean velocity, and mistakes over two trials calculated.	
Fast gait velocity (m/s)	Similar protocol to preferred gait velocity, however, participants were asked to walk as fast as possible.	
Clinical dynamic visual acuity (CDVA)	Evaluates gaze stability by assessing visual acuity using examiner mediated head oscillations at 2Hz relative to head stationary.	Cut-off ≥ 3 lines indicates potential vestibular hypofunction (52). Reliability in bilateral peripheral hypofunction ICC(2.2): 0.94 (69).
Head movement induced dizziness	Perceived dizziness reported using the Numeric Rating Scale (NRS) on two conditions. One while sitting stationary, and one after 1 minute of active head oscillations at 1 Hz (following a metronome). Score range 0 (no dizziness) to 10 (as bad as it can be), with higher scores indicating higher perceived intensity of head movement-induced dizziness. Difference between the two conditions will also be calculated.	VAS Head movement induced dizziness (Hall 2006): Reliability 0.48 for all subject Reliability of male subjects 0.82
Grip strength	Maximal grip strength in both hands assessed using hand-held dynamometer. Measured in kg. Averaged between two trials calculated for each hand	Genuine change in healthy adults; 6kg (70).
Body sway in standing	Assessed using the Modified test for interaction and balance (mCTSIB) with arms crossed over the chest, using the HURlabs Balance trainer BTG4. Four conditions tested, standing with eyes open and closed, on a firm surface or on a foam cushion. Each trial is timed for 30 seconds.	ICC in healthy subjects: 0.91-0.97 (71).
Elements	Four elements from the main domain Movement of the GPE	ICC 2.1 Lumbro-

from Global Physiotherapy Examination (GPE)	examination were selected (17, 35). The items include lumbo-sacral flexion, head-nod flexion, shoulder retraction and elbow drop. Score range -2.3 to 2.3, scored in relation to a predefined standard (0) (35).	sacral flexion: 0.82, ICC 2.1 Head nod-flexion: 0.84, ICC2.1 Shoulder retraction: 0.75, ICC 2.1 Elbow drop: 0.89 (Personal communication: A. Kvåle).

Supplementary Files

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