BMJ Open

2BALANCE: a cognitive-motor dual-task protocol for individuals with vestibular dysfunction

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To cite: Danneels M, Van Hecke R, Leyssens L, *et al*. 2BALANCE: a cognitive-motor dual-task protocol for individuals with vestibular dysfunction. *BMJ Open* 2020;**10**:e037138. doi:10.1136/bmjopen-2020-037138

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2020-037138).

Received 23 January 2020
Revised 11 May 2020
Accepted 09 June 2020

Check for updates

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ABSTRACT

Introduction Aside from primary vestibular symptoms such as vertigo and dizziness, persons with vestibular dysfunction frequently express cognitive and motor problems. These symptoms have mainly been assessed in single-task setting, which might not represent activities of daily living accurately. Therefore, a dual-task protocol, consisting of the simultaneous performance of cognitive and motor tasks, was developed. This protocol assesses cognitive and motor performance in general, as well as cognitive-motor interference in specific.

Methods and analysis The motor component of the 2BALANCE protocol consists of a static and dynamic postural task. These motor tasks are combined with different cognitive tasks assessing visuospatial cognition, processing speed, working memory and response inhibition. First, test–retest reliability will be assessed with an interval of 2 weeks in a group of young adults. Second, the 2BALANCE protocol will be validated in persons with bilateral vestibulopathy. Finally, the protocol will be implemented in persons with unilateral vestibular loss.

Discussion and conclusions The 2BALANCE project aims to elucidate the impact of vestibular dysfunction on cognitive and motor performance in dual-task setting. This protocol represents everyday situations better than single-task protocols, as dual-tasks such as reading street signs while walking are often encountered during daily activities. Ultimately, this project could enable individualised and holistic clinical care in these patients, taking into account single as well as dual-task performance.

Ethics and dissemination The current study was approved by the ethics committee of Ghent University Hospital on 5 July 2019 with registration number B670201940465. All research findings will be disseminated in peer-reviewed journals and presented at vestibular as well as multidisciplinary international conferences and meetings.

Trials registration number NCT04126798, pre-results phase.

Strengths and limitations of this study

- ► The 2BALANCE protocol comprises cognitive-motor dual tasks, which resemble daily life situations better than single-task protocols.
- ► The 2BALANCE protocol was developed based on a systematic review on the test–retest reliability and validity of dual-tasks in a variety of populations.
- ► Compared with previous studies often only comprising one dual-task, the current project assesses four general cognitive domains in combination with a static as well as dynamic motor task.
- ► The current project knows several limitations: the test–retest reliability will only be assessed in a group of healthy adults and verbal responses are required during dual-tasks to avoid adding an additional motor component such as the use of a button.

INTRODUCTION

Along with visual and proprioceptive sensory input systems, the vestibular system is essential in maintaining balance during static as well as dynamic postural tasks.[1] Consequently, persons with impaired vestibular function frequently experience postural imbalance and unsteadiness while standing upright and while walking.[2] These problems can be partially explained by impaired vestibular reflexes and are translated in aberrant spatiotemporal postural parameters.[3 4] The vestibulo-ocular reflex (VOR) enables stable vision during head movements and while walking. This reflex is optimally sensitive in the frequencies of head movements above 2 Hz, while the visual system is more precise between 0.1 Hz and 1 Hz.[5] Consequently, especially in persons with bilateral vestibulopathy (BV), this results in problems with gaze stabilisation (oscillopsia),[6] as the visual input system cannot compensate for the lack of vestibular input in the high frequencies.[7] Along with impaired vestibulospinal and vestibulocollic reflexes, this leads to an increase in postural imbalance in persons with vestibular disorders (VD). This has a significant impact during everyday activities as an increased fall risk is observed, especially on uneven surfaces and in low-light conditions.[8–10] This fall incidence is higher in persons with BV than in persons with unilateral vestibular loss (UVL).[9 11]

Likewise, impairment in the following cognitive domains has been observed in persons with VD: visuospatial cognition, attention, memory, executive function and processing speed.[12 13] The cognitive symptoms in the above domains can be attributed to a variety of higher vestibular projections throughout the cortex and subcortex, of which the vestibulohippocampal pathways play a major role in visuospatial abilities.[14–16] In persons with BV, a decrease in hippocampal volume has been observed by means of neuroimaging and has also been correlated with impaired visuospatial memory.[16 17] This decrease in hippocampal volume could not be observed in persons with UVL, which could be explained by the bilateral representation of one vestibular organ to both hippocampi. Consequently, central vestibular input might be decreased, but not absent in persons with UVL.[16] In contrast, subtle functional impairments on the virtual Morris Water Maze were detected in persons with isolated right vestibular loss, indicating visuospatial memory deficits similar to persons with BV.[18]

Although visuospatial cognition has been assessed most frequently in persons with VD, impairment in the other above-mentioned cognitive domains has also been reported.[12 13] The impact of VD on these domains appears to be more subtle and outcomes between studies are heterogeneous.[19] Once more, evidence of impaired cognitive function is most prevalent in patients with BV, but has also been observed in persons with UVL.[12 20]

All of the above cognitive deficits have been observed in single-task (ST) setting while seated, that is, without the vestibular system being challenged. However, such laboratory setting does not represent daily life situations, as performing cognitive tasks during head movements and while walking is an essential part of everyday functioning. In healthy persons, maintaining balance only requires minimal cognitive resources.[21 22] However, in persons with VD, a certain amount of cognitive capacity is required to ensure stable equilibrium and to avoid falls.[13] According to the attentional capacity theory by Kahneman (1973),[23] this indirectly results in a decrease in cognitive reserve to perform concurrent cognitive tasks, leading to increased cognitive-motor interference (CMI). Subsequently, the postural impairment in persons with VD might impose an accumulative cognitive burden, additional to the evidence indicating impaired cognitive functions in ST setting. Likewise, these cognitive impairments can pose an additional burden on their motor performance.

CMI can be assessed by performing dual-tasks (DTs), which consist of the simultaneous performance of two concurrent tasks that can be performed and measured separately.[24] It might be assumed that even subtle cognitive and/or motor deficits could be identified in persons with VD by employing DTs. This assumption has already been verified in persons with multiple sclerosis, where DTs were able to identify subtle deficits in the earlier stages, while STs failed to do so.[25] Similarly, DTs were able to unmask cognitive and motor impairment in athletes with a concussion, while scores on standard concussion assessment returned to normal.[26] CMI can also be observed in healthy persons, where the performance of the cognitive or motor task declines depending on the task difficulty while performing both simultaneously.[25] Because of impaired cognitive and motor performance in the VD population, increased CMI is expected. While several studies lack calculation of both the motor and cognitive task performance,[27 28] assessment of the reciprocal effect of DTs should be explored in persons with VD. The reciprocal effect takes into account the effect of an added cognitive task on motor performance, and vice versa. Additionally, as divided attention is required during dual-tasking, the brain will have to choose which task to prioritise in the absence of instructions.[29] The capacity-sharing model is based on the idea that attention will be distributed between both tasks. Different tasks can therefore compete for the same attentional resources in case of partial or complete overlap. This could lead to deterioration in one or both simultaneous tasks, depending on the allocation of capacity.[30 31] Additionally, two other theories have attempted to explain the CMI phenomenon: the bottleneck model and the cross-sharing model. The bottleneck model believes that tasks, which are processed by similar neural networks, cannot be performed in parallel, but are processed sequentially,[32] which means that processing of the second task must wait until the primary task is finished. This is reflected in the ‘stops walking while talking’ phenomenon where the motor task is temporarily paused while performing a cognitive task.[33] The cross-sharing model has been mentioned less frequently, and believes that facilitation will occur between tasks which are from a similar neural network.[34]

The use of these cognitive-motor DTs could provide information on cognitive and motor performance in the VD population, and especially the interaction between both. However, a reliable and valid protocol was lacking in these patients. A small amount of studies had implemented a DT in the vestibular population. However, the outcome to these studies was very heterogeneous. Additionally, the rationale for the chosen cognitive task was often unclear.[35] Serial subtraction tasks or naming tasks were included in most DTs.[27 28 36–38] These tasks are user friendly and have been routinely used in other populations; however, a clear rationale for their use is lacking in the vestibular population. For the motor task, static balance was assessed most frequently,[28 36 39 40] whereas, interestingly, dynamic postural DTs seemed to be most sensitive in evoking CMI in patients with VD as well as other populations.[35] However, these dynamic postural tasks were combined with easy to administer cognitive tasks such as serial subtraction and naming tasks.[27 37 38]

Because of the heterogeneity of the used test protocols and their outcomes, Danneels *et al*[35] performed a systematic review assessing test–retest reliability and validity of DT protocols in a variety of populations showing similarities with the VD population, such as Parkinson’s disease, multiple sclerosis, Alzheimer’s disease and elderly fallers and non-fallers.[35] This review article suggested combining both a static and dynamic motor task with the following cognitive domains: visuospatial abilities, memory, executive function, processing speed and attention. Based on these findings, the 2BALANCE protocol for the VD population was developed and will be presented below. This test protocol will allow insight into the reciprocal effect of cognitive and motor tasks and their prioritisation, and will additionally indicate the most sensitive tasks to identify motor and/or cognitive deficiencies in the VD population. Up until today, these deficiencies have mainly been observed in persons with BV in laboratory ST setting. We suspect that implementing a DT protocol might enable objectification of even subtle cognitive and motor problems which are experienced in everyday situations by the vestibular population, also in mild (unilateral) vestibular deficits. Eventually, this information will aid in the development of an individualised and holistic therapeutic approach for each vestibular patient, taking into account motor as well as cognitive impairments.

METHODS

Study protocol

The 2BALANCE study is a multicentre study initiated by the Ghent University (Belgium) in collaboration with the University of Antwerp (Belgium), and Maastricht University Medical Center (The Netherlands). The set-up of the project is as follows: (1) assessment of test–retest reliability in healthy adults, (2) validation of the 2BALANCE protocol in persons with BV, and (3) implementation of the 2BALANCE protocol in persons with UVL and various other peripheral VDs (figure 1). The first participant was enrolled on 12 August 2019. Taking into account delays caused by the COVID-19 pandemic, the first test phase consisting of the assessment of test–retest reliability will be finished in July of 2020. Because of these delays, normative data will not be established in a large group of healthy adults, but patients with VD will be matched according to age, gender, educational level and hearing status. Data collection in patients with BV will start in October of 2020 and is aimed to be finished in December of 2021. However, data collection will continue until December of 2022 in patients with BV as well as in patients with a unilateral vestibular dysfunction.

Figure 1 Set-up and timeline of the 2BALANCE project: (1) assessment of test–retest reliability (TR), (2) validation in persons with bilateral vestibulopathy and (3) implementation of 2BALANCE protocol in persons with unilateral vestibular loss and various vestibular disorders. HC, healthy controls.

Inclusion and exclusion criteria and sample sizes

The group of healthy adults does not have any vestibular, neurodevelopmental, psychiatric or musculoskeletal disorders, and subjects with hearing thresholds above the age-related normative data based on the ISO7029 criteria (International Organization for Standardization, 2000) will be excluded from the healthy cohort.[41] Additionally, persons with a score lower than 26 on the Montreal cognitive assessment (MoCA) or with colour blindness will also be excluded from the healthy cohort. For the test–retest study, 20 young adults ranging between 18 and 35 years of age will be tested twice, with an interval of exactly 2 weeks.

For the validation of the 2BALANCE protocol, persons with BV will be assessed. This subgroup of vestibular patients was selected for validation as they are expected to show most aberrant cognitive and motor performance within the vestibular population compared with healthy controls (HC). These patients will be recruited at all three collaborating university hospitals. BV is characterised by oscillopsia and imbalance increasing in dark circumstances and on uneven surfaces according to the Bárány Society criteria.[42] Additionally, peripheral vestibular function will be defined by bilaterally significantly reduced or absent function of the VOR (ie, hyporeflexias and areflexias). Video head impulse testing gain values should be below 0.6, and/or the sum of the bithermal maximum peak slow phase velocity measured by caloric testing should be <6°/s on each side, and/or rotatory chair testing should show gain values smaller than 0.1 at a frequency of 0.1 Hz with a maximum velocity of 50°/s. Patients with BV with any comorbid neurodevelopmental or musculoskeletal disorders, as well as subjects with diagnosed psychiatric disorders will be excluded. Additionally, colour blindness will also be an exclusion criterion. The study of Bessot *et al*[38] was consulted to serve as input for sample size calculation. These researchers measured motor, as well as cognitive performance in ST and DT condition in the BV population, using a serial two subtraction task while walking along a 10 m walkway. Aiming for a power of 90% and an alpha value of 0.05, a sample size of 32 patients was calculated. Given the current pool of patients at all three diagnostic centres, and taking into account possible dropouts, we aim at 40 patients to be included in this study. These patients will be matched with HC based on age, gender and educational level. Because of the close anatomical proximity of the vestibular and auditory end organs, vestibular and auditory disorders co-occur. These auditory disorders have also been linked to cognitive dysfunctions. Dobbels *et al*[19] suspected that auditory disorders might mainly negatively affect immediate memory and language, while VDs might mainly affect attention performance. The patient population will ideally consist of 20 persons with and 20 persons without hearing loss, and will be used as a covariate in the statistical analyses.

For the third objective, persons with UVL will again be recruited at all three university hospitals. Given the lack of studies published on DTs in UVL resembling the

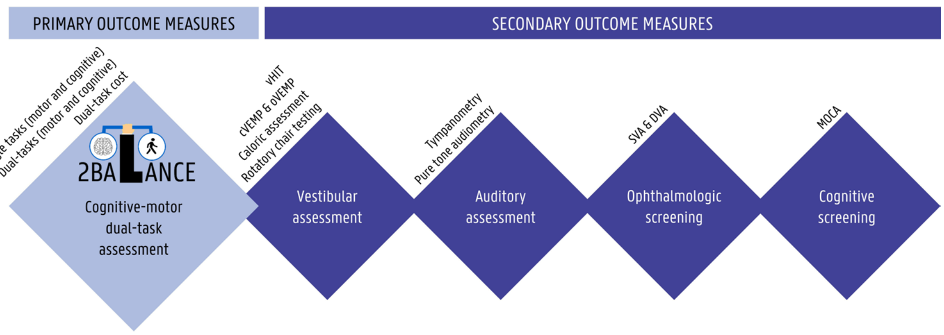

Figure 2 Primary and secondary outcome measures. cVEMP, cervical vestibular evoked myogenic potentials; DVA, dynamic visual acuity; MOCA, Montreal cognitive assessment; oVEMP, ocular vestibular evoked myogenic potentials; SVA, static visual acuity; vHIT, video head impulse test.

envisioned test design and interpretation, the sample size calculations for objective 2 were used for the unilaterally impaired population as well. As more subtle cognitive deficits are expected in this population, to reach the desired power and alpha level of, respectively, 90% and 0.05, a sample of 50 patients will be used. These participants will be matched to HC and when possible to patients with BV based on age, gender, educational level and auditory status.

Outcome measures

Primary assessment comprises cognitive and motor tests in ST as well as DT setting. To avoid fatigue, secondary assessment will take place at a different test day. This secondary assessment comprises vestibular, auditory and ophthalmological testing (figure 2). Additionally, the MoCA is also administered in all participants. Scores lower than 26 out of 30 indicate cognitive impairment and will lead to exclusion from the study. The 2BALANCE protocol is accompanied by an extensive manual to increase user friendliness. This manual contains all guidelines for instructions and scoring.

The 2BALANCE protocol assesses the different cognitive domains in which impairment in persons with VD have been identified[12 13]: visuospatial cognition, processing speed, memory, executive function and attention. Visuospatial cognition can be subdivided in three subdomains: visuospatial memory, visuospatial navigation and mental rotation. In order to avoid adding an additional motor task, the participant is asked to verbally respond for each cognitive task. However, visuospatial navigation tasks generally require manual responses using a computer mouse or button, which makes them unfit to be performed in a dynamic DT setting. Additionally, the attention cognitive domain is not assessed separately as divided attention is challenged in each DT. Therefore, a cognitive task was selected for each of the cognitive (sub) domains: (1) visuospatial memory, (2) mental rotation, (3) processing speed, (4) memory and (5) executive function. The cognitive tasks are presented visually and/or auditory on, respectively, a large projection screen (110 in diagonally) or through wireless over-ear headphones (Sony MDR-RF855RK) using a PowerPoint presentation. For all cognitive tasks, percentage of accuracy (in %) as well as response time (in seconds) is measured. The latter is quantified by recording all stimuli as well as all responses in Audacity (Audacity Team) and subsequently manually analysing the duration (in seconds) between the presentation of the stimulus and the response given by the participant. For this purpose, the visually presented stimuli are accompanied by an auditory cue which is recorded in Audacity but not heard by the participant.

In DT setting, these cognitive tasks are combined with two different motor conditions: (1) static motor performance and (2) dynamic motor performance (figure 3). The cognitive and motor tasks are performed separately (ie, ST) as well as simultaneously (ie, DT). Based on the difference between ST and DT performance, cognitive and motor DT cost (DTC) is calculated. More specifically, DTC quantifies the decrease in motor performance in DT condition, compared with ST condition and the decrease in cognitive performance in DT condition, compared with ST condition. This measure can be calculated for the motor as well as cognitive task as follows: 100 × (score in ST condition – score in DT condition)/score in ST condition. The task with the smallest deterioration (smallest DTC) is believed to be the task which is prioritised by the participant.

Motor task: static motor performance

The GymPlate (Techno concepts) force platform is used for measuring spatiotemporal parameters in static DT condition. The participant is asked to balance on a foam pad (AirEx Balance-Pad Solid) on the force platform and is instructed to stay as stable as possible, with the feet closed and the head upheld looking straight forward. The arms are held alongside the body. During the ST condition, the participant is asked to balance on the platform for 30 s. During DT condition, the participant has to balance during the entire duration of the cognitive tasks. However, to facilitate comparison with the ST condition, only the first 30 s will be recorded. The following parameters are analysed on the GymPlate: the surface (mm²) of the confidence ellipse which contains 90% of the centre of pressure (COP), the length (mm) covered by the consecutive COP positions, the average velocity of COP

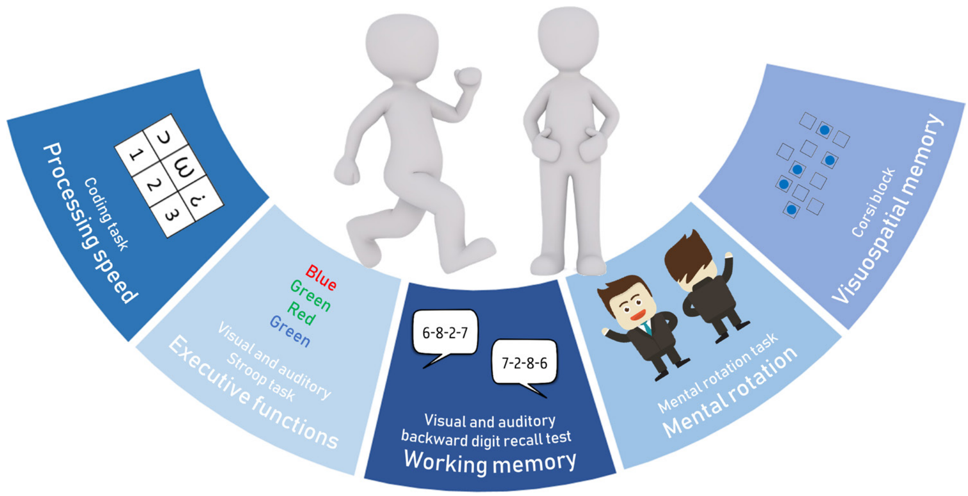

Figure 3 2BALANCE protocol consisting of five different cognitive tasks in combination with a static and dynamic postural task.

displacement (mm/s) and the variance of COP displacement velocity (mm^2/s^2) which represents the oscillatory variance of the velocity of the COP.

Motor task: dynamic motor performance

The GAITRite Walkway System is a pressure sensitive mat, containing sensors which measure various spatiotemporal parameters. The GAITRite used in 2BALANCE is 8.8 m long, with an active size of 7.93 m and contains 30 000 sensors. In order to reliably measure gait on the GAITRite Walkway System, 10–20 strides may be sufficient for measuring velocity and cadence in ST or DT walking.[43] For the ST condition, five lengths on the GAITRite Walkway are walked at a self-selected comfortable walking speed. In order to normalise the walking pattern, the participant starts walking one and a half metres before the start of the walkway and stops walking one and a half metres after the end of the walkway. These distances are marked on the floor. Subsequently, the length of each walk is 11.8 m. This is also the length during which the cognitive tasks are performed. The GAITRite Walkway provides information on a variety of spatiotemporal parameters, of which the following will be assessed: stride and step length (cm), stride and step width (cm), step and stride time (s), and ty (cm/s).

Cognitive task: Corsi block

The Corsi block test[44,45] assesses the visuospatial subdomain *visuospatial memory*. Additionally, working memory is also challenged in this task. The participant has to remember the position of 5 geometric figures (circles) sequentially appearing in a raster of 12 squares. Each circle is visible for 0.8 s, with a variable interstimulus interval ranging between 0.3 s and 0.6 s, resulting in a total stimulus duration of 5.5 s. Afterwards, the raster is presented again and this time accompanied by 12 numbers. The participant now has to indicate the exact position of the geometric figures, in the correct order, by orally giving their respective numbers (figure 4). These numbers are

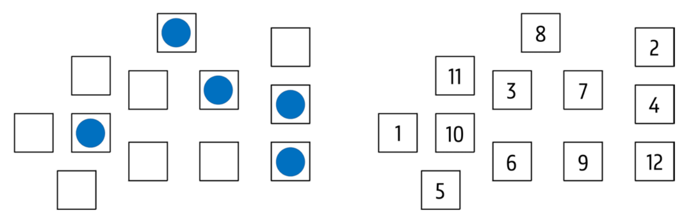

Figure 4 Example of Corsi block stimuli[44] and raster for indicating responses.

randomised each sequence so that the participant is not able to memorise their position. For each condition, 10 items are presented. A manual response by use of a button or computer mouse was avoided in order not to add an additional manual motor task. This would also not have been feasible during the dynamic motor condition. During the dynamic DT, one sequence is presented during each length walked. During the ST and the static DT, all items are presented sequentially without a break. The raster with numbers remains on the screen until a response is given. A score of 1 is appointed for each correctly identified geometric figure, leading to a score ranging from 0 to 50. The percentage of accuracy (in %), the mean response time (in s) and the mean reaction time (in s) are calculated. Reaction times represent the duration from the end of the final stimulus until the start of the participant's response. Response times represent the duration from the end of the final stimulus until the end of the final response. The latter will only be calculated in case of the correct repetition of the whole sequence.

Cognitive task: mental rotation

The mental rotation task assesses the visuospatial subdomain *mental rotation*. Additionally, processing speed is also challenged. Two human figures are presented to the participants until a response is given (figure 5). Either the front or the back of these figures is displayed, and both figures are rotated with respect to each other (0°, 60°, 120° or 180°). These human figures are presented with outstretched arms or bent arms. When outstretched,

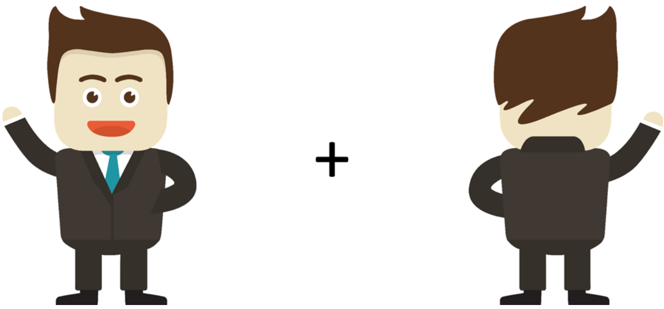

Figure 5 Example of the mental rotation task.

these arms can be held downwards or upwards. Regardless of their rotation, these images are the same figure or each other's mirror image. The participant has to indicate whether these images are the same ('yes') or mirrored ('no'). The stimuli are balanced for the following items: identical/mirrored, back/back—front/front—back/front—front/back, arm outstretched/bent, arm up/down when outstretched, and angle of rotation (0°/60°/120°/180°). For example, each participant will be shown the same images comprising nine identical and nine mirrored images. Before each item, a fixation cross appears for 1 s in the middle of the screen. To enable comparison between all conditions, 18 test items are performed in each condition. Approximately, three items are presented for each length walked, resulting in six lengths walked on the pressure sensitive walking mat during the dynamic DT condition. For the ST and static DT, all stimuli are presented sequentially. The stimuli remain on the screen until a response is given, after which the examiner moves on to the next item. The percentage of accuracy (in %) and the mean reaction time (in s) are again calculated.

Cognitive task: coding task

The coding task mainly assesses *processing speed*.[46] However, attention, oculomotor scanning and working memory are also important in performing this task.[47] This task is based on the symbol digits modalities test[48] and consists of a sequence of geometric figures which can all be matched with a different numerical digit. Figure 6 provides each geometric figure and its respective number, accompanied by nine practice items which include all nine different geometric figures. The participant is also presented with a second table where all numerical digits are missing and is then asked to verbally substitute each geometric figure

⊢	⅃	C	+	Λ	/	Ↄ	=	>
1	2	3	4	5	6	7	8	9

>	=	C	Ↄ	⊢	Λ	+	⅃	/

Figure 6 Symbols and their respective numerical digit for the coding task; coding set 1.

with its respective numerical digit. In order to prevent a learning and memorisation effect, a different coding system is presented for each condition. For the dynamic DT, one table of nine items is presented during one length on the walkway, with a total of eight tables. For the ST and static DT, the participant is asked to complete as many items for 1 min. The tables are sequentially presented by the examiner. Each correctly substituted geometric figure will lead to a score of 1, resulting in the amount of responses given per minute.

Cognitive task: backward digit recall test

The backward digit recall test assesses *working memory*. The auditory as well as visual variant is administered. For this task, a sequence of digits (ranging from three until eight items) is presented auditory through headphones or visually on the projection screen. The participant is asked to repeat this sequence in reverse order. For example: when presented with '7-1-9', the participant has to respond with '9-1-7'. The sequence length is fixed for each participant over all test conditions. This fixed sequence length is based on baseline calculations where at least three out of five sequences have to be repeated correctly in reverse order. For each DT and ST condition, 10 items are presented with a fixed minimum of 2 digits and a maximum of 8 digits per item. Each digit is presented for 0.8 s, and immediately followed by the next digit. For the auditory variant, all digits were recorded in Dutch (Flemish accent) by a speech therapist. The sequences complied to several prerequisites such as: the digits are not repeated more than once in the same sequence, no double jumps are presented (eg, 2-4-6), no immediate ascending or descending numbers are presented and no consecutive sequences begin or end with the same digit. Each correctly repeated digit will lead to a score of 1. Subsequently, participants being presented with a fixed sequence length of, for example, 5 will be able to score from 0 to 50. To enable comparison between sequence lengths, percentage of accuracy (in %), mean reaction time (in s) and mean response time (in s) are calculated.

Cognitive task: Stroop task

Stroop tasks mainly assess *response inhibition*, which is part of the cognitive domain executive function.[49 50] The auditory as well as the visual variant is administered. These tasks are based on a mismatch principle.

For the visual Stroop task, the words of four colours are given (red, yellow, green or blue). These words are all presented in a different colour ink. Compatible (same colour and word written) and incompatible (word and colour in which the word is written are different) stimuli are presented. The participant is asked to indicate the colour in which the word is written, without reading the word. After completion of each word, the examiner goes to the next item. Compatible and incompatible items are presented with a 1:1 ratio, and each written word and colour in which the words are written are balanced. To enable comparison between all conditions, 32 items are performed in each condition. Prior to the visual Stroop task, the participant is asked to name the colour of four different squares (red, yellow, green and blue) to ensure correct interpretation of all colours. Percentage of accuracy (in %) as well as mean reaction times (in s) are calculated for the compatible and incompatible items separately as well as the combined scores.

For the auditory Stroop task, the words 'high' and 'low' are presented in a high or low pitch. These words were recorded in Dutch by a speech therapist. Compatible (high in high pitch and low in low pitch) and incompatible (high in low pitch and low in high pitch) items are presented with a 1:1 ratio, and each word and pitch in which the word is spoken are balanced. The participant is asked to identify the pitch in which the word in presented, without repeating the spoken word. After each response, the examiner presents the next stimulus. Again, 32 test items are presented in each condition. Prior to the auditory Stroop task, several sequences of two pure tones are presented. The participant is asked to indicate whether high or low tones are heard, to ensure correct interpretation of high and low. Again, percentage of accuracy (in %) as well as mean reaction times (in s) are calculated for the compatible and incompatible items separately as well as the combined scores.

Clinical variant of the laboratory 2BALANCE protocol

This research ultimately aims to develop a clinically feasible variant with a shorter test duration than the above-described laboratory 2BALANCE protocol. For the static motor aspect, the laboratory instrument (GymPlate) will eventually be replaced by the Wii Balance Board, which is a valid and reliable tool for the measurement of spatiotemporal parameters during static postural balance.[51] For the dynamic motor component, the laboratory instrument (GAITRite) will be replaced by a Smartphone App. At present, accelerometry (MOX, Maastricht Instruments) is included in the 2BALANCE protocol to enable comparison to the GAITRite Walkway. This Physical Activity Monitoring Sensor comprises a 3D-accelerometer sensor. The accelerometer data are sampled at a 100 Hz frequency by a 12-bit analogue-to-digital converter. These data are stored in a raw, non-filtered format in the gravity units (G's), and can be analysed in the MOX software. This accelerometer is attached to the sacrum of the participant. The use of a single accelerometer is chosen to enable translation to a Smartphone App in a later stage. During the course of this project, the MOX data will be compared with the GAITRite data. This will indicate whether all temporal and spatial parameters acquired by the accelerometer show similar results to the GAITRite Walkway, which is considered a golden standard for gait analysis. Only these parameters will be used in a later stage. This innovative clinical test protocol will be easily included in the vestibular test battery, as there is only need for a smartphone (motor task) and a computer with projection screen (cognitive task). It will also be low cost and easy to administer as it will be accompanied by a comprehensive manual.

Practical considerations and influencing factors

When performing the 2BALANCE protocol, several influencing factors and effects should be taken into account: more specifically, fatigue, age and gender effects, learning effects, floor and ceiling effects, comorbid visual and auditory impairment, strenuousness and prioritisation, which were all accounted for in the development of the test protocol.

To prevent *fatigue*, the protocol is performed in the morning and breaks are included in between testing conditions. To account for *age, gender and educational* effects, patients will be matched with healthy adults based on these factors. A *learning effect* can be identified by an improvement in task performance in the later presented items compared with the first presented items. This learning effect will be minimised by performing practice items and by randomising all test items. Before each cognitive task, practice items (trials) are performed prior to the test items to get the participant acquainted with each task. The following items are presented in a randomised order: (1) ST or DT, (2) cognitive or motor task, (3) type of cognitive task, (4) type of motor task and (5) visually or auditory presentation of the cognitive tasks. Schaefer *et al*[52] suggest individually adjusting the difficulty level for the DTs in order to avoid a potential floor or ceiling effect.[52] Therefore, the sequence length for the backward digit recall test is based on the participant's performance in baseline condition, which is performed while seated. Additionally, *floor and ceiling effects* are also avoided by measuring the continuous variable reaction time for each cognitive task instead of only the percentage of accuracy. *Language effects* are prevented by limiting language tasks and instead including stimuli such as numerical digits and symbols. Additionally, only native Dutch speakers are included. To avoid adding a third (fine) motor task to the 2BALANCE protocol, verbal responses are given instead of using a computer mouse or manual responses.

In order to enable comparison of objective and subjective measures, a Visual Analogue Scale (VAS) asking about the subjective *strenuousness* is presented after every cognitive task (figure 7). This 10-point VAS ranges from 1 (extremely easy) to 10 (extremely difficult).

All visual cognitive tasks are presented on a projection screen. As this should be visible for all participants, dual-tasking is preceded by visual screening. Six nonsense words complying to the Dutch spelling and pronunciation (Klepel, Van den Bos et al., 1999, Pearson) are projected at the smallest font size presented during the

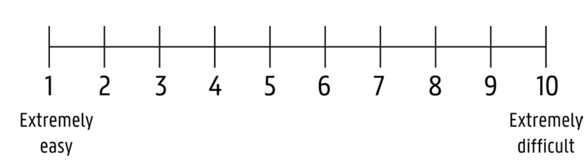

Figure 7 Visual Analogue Scale for strenuousness.

2BALANCE protocol (UGent Panno Text, 60, capital letters) to ensure that each participant can optimally perceive all stimuli. The distance between the projection screen and the patient is fixed at 5 m for the ST and static postural DT condition. For the dynamic DT, the distance from the projection screen decreases from 11.8 to 1.5 m as the participant is asked to walk towards the screen. The visual screening test is therefore performed at 11.8 m distance. An anamnestic questionnaire additionally queries visual performance (eg, glasses/contact lenses and colour blindness). Persons with colour blindness will be excluded from the study as accurate colour perception is necessary in the visual Stroop colour and word test. Additionally, static visual acuity is performed using a Snellen chart. Fifty to seventy per cent of persons with BV have problem of oscillopsia.[6] This blurred vision during walking will hinder patients from clearly perceiving visual stimuli during dynamic postural tasks. Therefore, visual as well as auditory cognitive tasks were developed when possible. More specifically, the backward digit span test and the Stroop task are presented in an auditory and visual manner. However, auditory presentation is not feasible for the symbol digits modalities test, the mental rotation task and the Corsi block, so they are only presented in a visual manner. Before conducting the 2BALANCE protocol, oscillopsia is quantified by assessing dynamic visual acuity.

Persons with VDs may suffer from comorbid hearing disorders because of the anatomical proximity between the auditory and vestibular organ, which might hinder them from clearly perceiving auditory stimuli. Therefore, all cognitive tests are presented in a visual manner. The auditory tests are presented at the most comfortable level (MCL) for each participant. The speech samples used in the Backward Digit Recall test are used for determination of the MCL. Each participant is asked to adjust the volume of the computer to a level which is perceived to be most comfortable. Before starting the cognitive tasks, test instructions are given verbally as well as visually on the projection screen.

The participants are asked to perform both tasks to the best of their abilities. No prioritisation is asked as the natural distribution of cognitive resources during static and dynamic postural tasks will be observed. Prioritisation is calculated based on the analysis of the motor and cognitive DTC.

Questionnaires

To account for a multitude of influencing factors, several questionnaires are administered: an anamnestic questionnaire, the Dizziness Handicap Inventory,[53] the Tinnitus Handicap Inventory,[54] the Hospital Anxiety and Depression Scale,[55] the Headache Impact Test 6,[56 57] Activities-Specific Balance Confidence Scale,[58] Falls Efficacy Scale I,[59 60] standard assessment of negative affectivity, social inhibition, and Type D personality (DS14),[61] and the '*Algemene toestandslijst*'.[62] These questionnaires specifically query the subjective vestibular problems, as well as possible confounding factors for cognitive and/or motor performance such as anxiety and depression, stress, headache, hearing loss, tinnitus, fall frequency, and so on. The anamnestic questionnaire is subdivided into the following categories: general information, general medical history, hearing, balance, vision and motor performance. In order to minimise test duration and fatigue, these questionnaires are presented electronically on the Research Electronic Data Capture system (REDCap) platform, and participants are asked to fill these out within 1 week after assessment.

Statistical analyses

All data will be analysed using SPSS software (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, V.26.0. Armonk, New York). The level of significance will be set at p=0.05. For the test–retest reliability study, values such as intraclass correlation coefficients (ICC), SE of measurement, CIs and minimal detectable difference will be measured. ICC values will be measured using the two-way random effects model with absolute agreement. For the validation study, descriptive statistics will be used to summarise the mean ST and DT performance as well as DTC for each group. The normality of the data will first be assessed using the Kolmogorov-Smirnov test, QQ plots and histograms. DT performance will be assessed for the motor as well as cognitive component using analysis of variance with repeated measures for two groups for the validation study (BV and HC) and three groups when including UVL (BV, UVL, and HC) and three task conditions (ST, static DT, and dynamic DT). The Tukey's Honest Significant Difference test will be used for post hoc analyses.

Limitations

The 2BALANCE protocol knows several methodological limitations. First, the test–retest reliability will be assessed in a group of healthy young adults and not in patients with BV. As the 2BALANCE protocol is newly developed, the mere test–retest reliability of the protocol should first be assessed without being subject to confounding factors possibly caused by the patient population. Second, verbal responses are asked instead of manual responses to limit the influence of an added motor task on postural sway. However, verbal responses are also known to possibly affect postural sway to a small extent.[63] This is both true for the healthy as well as patient population. Therefore, we believe that differences between both will not be due to this effect.

Ethics and dissemination

The current study was approved by the ethics committee of Ghent University Hospital on 5 July 2019 (registration number B670201940465). All participants are asked to give written informed consent in accordance with the Declaration of Helsinki. A register for the processing activities of the study is kept by the investigators. Personal information is pseudonymised and only the principal investigator knows the coding system. Questionnaires are administered using the European Union General Data Protection Regulation proof REDCap system. All research findings will be disseminated in peer-reviewed journals and presented at vestibular as well as multidisciplinary international conferences and meetings.

Patient and public involvement

The research question was developed based on problems expressed by patients. They were not involved in the outcome measures, the design or implementation of the study. All patients will receive an individual report on the results of their vestibular and auditory assessment. The results of the overall project will be sent to the communication department of Ghent University, University of Antwerp and Maastricht University for a press release of the research highlights to the general public. Additionally, because of the multidisciplinary nature of the current research, the results of the study will not only be published in specialised journals, but also in more general journals and physiotherapy journals to reach a broader audience.

DISCUSSION

The 2BALANCE project aims to elucidate the impact of a vestibular dysfunction on motor and cognitive performance in ST setting as well as in a more everyday resembling situation (DT). Patients with VD experience an accumulative cognitive burden in DT condition, which has been overlooked in the previously performed ST studies. This might result in an underestimation of cognitive as well as motor problems in this population compared with the reported problems on a daily basis. To be able to identify these problems and to ultimately develop specialised vestibular, motor and cognitive training programmes, the 2BALANCE protocol was developed. We believe that this test protocol might be sensitive to subtle cognitive impairments, which might be missed in ST setting.

DTs have already been sporadically performed in persons with VD. However, several concerns relating to the test protocol and sample selection should be expressed. First, several authors solely used a static postural task.[28 36 39 40] Consequently, the complexity level of this motor task might not be sufficient to evoke CMI. Second, to assess the reciprocal effect of the DTs, measurement of the cognitive as well as motor task is necessary. However, two studies did not calculate the cognitive component.[27 28] Third, several studies did not select a clean cohort. More specifically, several VDs such as Menière's disease and benign paroxysmal positional vertigo were combined in studies by Andersson *et al*[36] and Yardley *et al.*[39] Another study combined central and peripheral VDs.[39]

This methodological heterogeneity resulted in heterogeneous outcomes as well. Three studies did not measure any difference on cognitive and motor performance between HC and patients in DT setting.[28 36 39] These studies all used a static postural task. Redfern *et al*[40] and Nascimbeni *et al,*[37] who, respectively, used a moving platform and a dynamic postural task only observed a decline in cognitive DT performance compared with the HC, but could not observe any decline in motor DT performance. Finally, two studies only measured a difference in motor DT performance in persons with VD compared with the HC.[27 38] The motor task consisted of a dynamic postural task in both studies. The cognitive task in the study by Bessot *et al*[38] was of a low complexity level (counting backwards by two), while the cognitive task by Roberts *et al*[27] was not measured. In summary, dynamic postural tasks appear to be more sensitive in evoking CMI in persons with VD. Similarly, a higher sensitivity using dynamic motor tasks compared with static motor tasks in DT setting has also been observed in various other populations presenting with cognitive and motor deficiencies.[35] These studies highlight the lack of a standardised DT protocol in persons with VD.

The first step into filling this gap has been taken by realising a systematic review.[35] Based on this literature overview, the 2BALANCE protocol was developed. Before being able to implement this protocol in persons with VD, the reliability of the test protocol should be ensured in a group of healthy adults. This will be assessed in 20 young healthy adults ranging from 18 until 35 years of age. This will also provide knowledge on ST and DT performance and DTC in the healthy population. To the best of our knowledge, this thorough preparatory work has never been performed in the vestibular population before. Only then, the 2BALANCE protocol can be reliably implemented in persons with VD. Validation will be performed in persons with BV as this population is expected to show most aberrant performance on the cognitive as well as motor tasks.

Current vestibular rehabilitation often lacks a multidisciplinary approach and mainly focuses on the peripheral vestibular organ. The 2BALANCE protocol could guide us to a specialised and holistic therapeutic plan taking into account a broader spectrum of symptoms.

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Acknowledgements The authors would like to express their appreciation to speech-language pathologist Julie Daelman from the Ghent University department of Rehabilitation Sciences for the speech samples of the auditory backward digit span test and the auditory Stroop task. Additionally, they would like to thank Tanneke Palmans from the Ghent University Department of Rehabilitation Sciences and Alice Nieuwboer, Pieter Ginis and Carolien Strouwen from the KULeuven Department of Rehabilitation Sciences for their input concerning the practical set-up of the test protocol.

Collaborators N/A.

Contributors All authors substantially contributed to the article. Their role can be summarised as follows: MD: development of the test protocol, drafting of the

initial article and improving revised versions. LM: supervision, refinement of the test protocol, critically reviewing and revising the article. RVH, LL, SD, DC, RvdB and WVR: critically reviewing, and revising test protocol and the article. All authors approved the final article as submitted and are accountable for all aspects of the study.

Funding This work was supported by Ghent University and Fonds voor Wetenschappelijk Onderzoek (FWO) with grant number 3F020219.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not required.

Ethics approval The current study was approved by the ethics committee of Ghent University Hospital on 5 July 2019 (registration number B670201940465).

Provenance and peer review Not commissioned; externally peer reviewed.

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