

# Effectiveness of computer-assisted training for older patients with vestibular dysfunction

PhD dissertation

## Michael Smærup

Health Aarhus University 2016

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Health Aarhus University Department of Geriatrics Aarhus University Hospital

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### **Supervisors**

Else Marie Damsgaard, Professor, Lic.et Dr. Med, MD, Department of Geriatrics, Aarhus University Hospital, Denmark

Uffe Læssøe, Master of Health Science, PhD, University College North Denmark, Denmark

Erik Grönvall, MScEng, PhD, Department of Computer Science, Aarhus University, Denmark

#### Preface and acknowledgements

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### List of original publications

#### Paper I

## Computer assisted training as a complement in rehabilitation of patients with chronic vestibular dizziness – a randomized controlled trial.

Smaerup M, Laessoe U, Larsen SB, Grönvall E, Henriksen JJ, Damsgaard EM. Accepted for publication. Archives of Physical Medicine and Rehabilitation, 2015 (Appendix A)

#### Paper II

The use of computer assisted home exercises to preserve physical function after a vestibular rehabilitation programme – a randomized controlled study. Smaerup M, Laessoe U, Larsen SB, Grönvall E, Henriksen JJ, Damsgaard EM. Accepted for publication. Rehabilitation Research and Practice, 2016 (Appendix B)

#### Paper III

## Exercise gaming – a motivational approach for older adults with vestibular dysfunction.

Smaerup M, Laessoe U, Larsen SB, Grönvall E, Henriksen JJ, Damsgaard EM. Accepted for publication. Disability and Rehabilitation: Assistive Technology, 2016 (Appendix C)

## List of abbreviations

VR	Vestibular rehabilitation		
GP	General practitioner		
Mitii	Move it to improve it		
DGI	Dynamic Gait Index		
DHI	<b>Dizziness Handicap Inventory</b>		
SF-12	Short Form 12		
MST	Motion Sensitivity Test		
CST	Chair Stand Test		
VAS	Visual Analog Scale		
OLST	One Leg Stand Test		
РТ	Physiotherapist		
ANOVA	Analysis of variance		

#### Introduction

A Cochrane review from 2012 found that about 30% of people 65 years or older each year fall and that number is even higher for older people living in institutions (1). Falls are the cause of 95% of all hip fractures, resulting in prolonged hospitalization and prolonged disability (2). Half of the elderly who incur hip fracture will never be able to walk as they did before the fall, and 1 year mortality is found to be 21.2 % (3). It is estimated that the cost of fall-related accidents is greater than \$20 billion a year in healthcare costs in the United States (4). Meanwhile, the population 65 years old and older is increasing, and the National Institute of Aging notes in a 2001 report that the world's population of 65-year-olds and older is growing by 800,000 a year (5). Multifactorial fall prevention is an intensive and time-consuming intervention, which consists of either single interventions like supplemental vitamin D, drug modification, exercise therapy, or a multifactorial identification of risk factors for fall (6). Vind et al.'s study found that participation rates in studies of fall prevention are low and more knowledge of reasons for non participation of older adults is needed (7). One fall prevention intervention could be the training of older adults with a dysfunctional vestibular system called vestibular dysfunction (8).

In patients referred to the emergency room after an unexplained fall, a study of 564 patients showed that 80% of the patients had vestibular symptoms characterized by balance problems, nausea, impairment, vomiting and dizziness (8). Forty-one percent of these patients had dizziness suggesting vestibular dysfunction (8).

The following chapters will present a description of dizziness and vestibular dysfunction and the effect of vestibular rehabilitation. In addition, important aspects due to compliance will be presented: motivation, self-efficacy and acceptance of technology. Finally, the chapter presents existing technical solutions to support the patient in rehabilitation.

In appendixes D, E and F, the search terms for the literature search are presented.

#### Dizziness and vestibular dysfunction

Dizziness is a feeling often characterized by unsteadiness, disequilibrium and poor spatial orientation (9), with a reported prevalence of 27% in participants aged 79 years and younger, 38% in participants between 80 and 89 years and 54% in participants aged 90 years and older (10). Dizziness is associated with fear and increased risk of

falling (11;12). Numerous disorders can cause dizziness among older adults (13). A common cause is vestibular dysfunction. Data from the National Health and Nutrition Examination Survey Study in US adults aged 40 years and older showed a prevalence of vestibular dysfunction of 49.4%, 68.7% and 84.8% at ages 60–69, 70–79 and 80 and over, respectively (14). Vestibular dysfunction is divided into peripheral, central and mixed dysfunction. Within peripheral dysfunction, benign positional paroxysmal vertigo (BPPV) is the most common diagnose, with a lifetime prevalence of 2.4%, but in adults older than 60 years, the 1-year prevalence is approximately seven times higher than for adults 18 to 39 years old. Menière's disease accounts for 3% to 11% of diagnosed dizziness and vestibular neuritis accounts for 3% to 10% of diagnosed dizziness (13). In addition, an unknown number of vestibular symptoms can be caused by an age-related structural deterioration of the vestibular system which has been documented by measuring the vestibular-ocular-reflex (VOR) using rotational tests and/or caloric tests in adults over the age of 75 years (13). The most common central vestibular dysfunction includes brainstem strokes, head trauma, migrainerelated vestibulopathy, multiple sclerosis and cerebellar degeneration (15). The mixed vestibular dysfunction is a combination of central and peripheral dysfunction.

#### Effect of vestibular rehabilitation

There are several protocols designed to treat vestibular disorders that focus on vestibular rehabilitation (VR). In a previous systematic review of the effects of VR on adults and older people with dizziness, it was observed that the Cawthorne & Cooksey protocol was the most common therapeutic approach reported (16). VR is an exercise-based program to promote vestibular adaptation, substitution and habituation in which the term adaption involves readjusting the gain of the vestibular-ocular-reflex or vestibulospinal reflex, substitution employs alternative strategies to replace the lost vestibular function, and habitation is used to reduce position-induced dizziness through repeated exposure to noxious stimuli (17). This is called neuroplasticity, which refers to the ability of the brain and central nervous system (CNS) to adapt to environmental changes by modifying neural connectivity and function (18). Physical activity seems to be the key intervention to trigger the processes through which neurotrophins mediate energy metabolism and in turn neuroplasticity. The goals in VR are to enhance gaze stability, enhance postural stability, to reduce vertigo and to

improve activities of daily living (17). The key exercise are head-eye movement with various body postures and balance exercises (17). VR is indicated for a condition characterized by a stable vestibular deficit in which there is no progressive process, but patients with a stable central or mixed dysfunction have a more limited prognosis of rehabilitation than the average patient with a stable peripheral injury due to vestibular rehabilitation (17). Patients training VR are expected to repeatedly provoke their symptoms (17), which should induce central neurological habituation. This may lead to a higher dizziness threshold (19), but unfortunately, it can also provoke symptoms that may decrease exercise compliance.

In a Cochrane review evaluating the effect of VR to improve dizziness in patients with unilateral peripheral vestibular dysfunction, the conclusion was that there is moderate to strong evidence that VR is a safe and effective treatment (20). Table 1 shows the eight studies we found from January 2001 to December 2015 that *include elderly* in some form of vestibular rehabilitation (for search strategy see appendix D). A study by Meldrum et al. (21) regarding virtual reality in vestibular rehabilitation that did not include elderly will be discussed later. All eight studies showed an effect of VR. For example, Mantello (22) showed that geriatric patients with dizziness of vascular or metabolic origin could benefit from VR measured by the Dizziness Handicap Inventory. Bittar (23) concluded that VR was a useful tool in the management of patients with peripheral and central vestibular dysfunction measured by a questionnaire asking about routine activities like: "Can you take a bath with no difficulty." Bittar included patients from 9 to 92 years (mean=43 years) (23) but analyzed a subgroup of the 35 oldest patients.

A weakness in Bittar's study was the missing information about validation of the questionnaire used.

In Kammerlind's (24) study, 303 people 65 years or older were investigated in a Ear, Nose and Throat Department. Only elderly people with non-peripheral vertigo and/or unsteadiness were included. Exclusion reasons were, e.g., Menière's disease and peripheral vestibular loss. The patients underwent balance training twice a week for 9 weeks. Kammerlind found an effect of training measured by a visual analog score, one leg stand test and on a balance platform. Also, Hansson (25) found that balance training and VR improved the ability to stand on one leg with eyes closed in persons with dizziness, but the effect was only shown on one (one leg stand test) out of six outcome measures. In a review, Ricci et al. (16) provided evidence for the positive effects of VR in elderly and middle-aged adults with vestibular disturbances but concluded that studies evaluating the effects of VR are scarce, particularly in the middle-aged and elderly population.

Enticot et al. (26) found evidence that individualized vestibular home exercises promoted better outcomes than a placebo exercise group for patients with vestibular dysfunction, and Hall (27) showed an effect of VR as home exercises on the number of falls among elderly patients . Marioni et al. (28) compared 14 patients undergoing vestibular rehabilitation in an outpatient clinic combined with a home-based exercise program (group A) with 14 patients using only a home-based exercise program (group B). The results showed a better effect of outpatient vestibular rehabilitation when combined with home-based exercises (group A) measured by the Dizziness Handicap Inventory.

Table 1. RCT studies vestibular rehabilitation

Author	Years of publication	Sample size	Age in years	Purpose of the study
Kammerlind et al. (24)	2001	23 patients with non- peripheral vertigo and/or unsteadiness	Mean age 72	Balance training in elderly people with non peripheral vertigo and unsteadiness.
Bittar et al. (23)	2002	155 patients with vestibular dysfunction	+ 65 years	To evaluate the effect of vestibular rehabilitation
Hansson et al. (25)	2004	42 patients with dizziness of central or age related origin	Median age 77	Specific rehabilitation for patients with dizziness has any effect on clinical balance
Mantello et al. (22)	2008	40 elder citizens in 2 groups, dizziness of vascular or metabolic origin	+ 65 years	To evaluate the effect of vestibular rehabilitation in geriatric patients
Enticott et al. (26)	2008	32 patients with chronic unilateral peripheral vestibular disorder	Mean 60	To examine patient outcomes after performing a 10-week vestibular home exercise program.
Hall et al. (27)	2009	39 patients with vestibular dysfunction	Mean 74	To determine if gaze stability exercises in balance rehabilitation would lead to greater improvements in older patients
Ricci et al. (16)	2010	Review with 9 RCT studies	In 5 studies patients were + 60 years. In 4 studies + 40 years	To summarize the results of clinical trials on VR in middle- aged and elderly people with vestibular disorders
Marioni et al. (28)	2013	14 patients with central vestibular dysfunction	Mean 74	To examine the effect of posturography-assisted VR combined with a home-based exercise program

Based on the presented literature, there seems to be moderate to strong evidence that vestibular rehabilitation across age groups has an effect, but many different VR protocols and outcome measures are used, which makes it hard to draw any general conclusions about the interventions. Furthermore, the number of RCT studies evaluating VR specifically in elderly with vestibular dysfunction is small. Patients with stable central or mixed vestibular dysfunction have a more limited prognosis regarding rehabilitation than the average patient with stable peripheral dysfunction.

#### VR for peripheral and central vestibular dysfunction

Patients with peripheral and central dysfunction can use both substitution and habituation exercise approaches to reduce dizziness (17;29). Although peripheral impairments may be permanent in individuals with peripheral dysfunction, they can achieve compensation faster because central vestibular function is intact (17;29). However, in individuals with central dysfunction, recovery from vestibular dysfunction is limited because pathological involvement of central vestibular structures restricts compensation (17;29). Candidates most appropriate for vestibular rehabilitation are individuals with stable peripheral dysfunction and central dysfunction presenting with reports of gaze instability, imbalance and/or dizziness. Patients with mixed central-peripheral dysfunction show a less successful rehabilitation than those with central dysfunction (17;29).

#### Long-term effect of vestibular rehabilitation

The issue concerning VR is whether improvements persist after the supervised training in the outpatient clinic. In a review that assessed the effectiveness of VR in community-dwelling adults, it was confirmed that any positive effect obtained was maintained for 3 to 12 months (20). However, the studies did not focus on patients aged 65 years or older. The review by Ricci (16) examining the effects of VR in middle-aged and elderly adults described one study with a follow-up period of 3 months in which the intervention group retained significant improvements in the one leg stand test, in comparison to a control group (25). Another study in the review

examining the effects of VR 6 months and 1 year after the intervention found that intervention and control group reached their previous functional levels and maintained the gain obtained in the training period (30). The first study included patients with central vestibular dysfunction and dizziness of age-related origin, but there may be a selection problem, since the patients were diagnosed by a general practitioner and not by a trained otoneurologist. The other study included only patients with acoustic neuroma, and the results are therefore not transferable to elderly vestibular patients with various vestibular diagnoses.

Summing up this chapter shows that:

- There is moderate to strong evidence that vestibular rehabilitation is a safe and effective treatment
- The overall effect of VR seems to be less impressive for central and the mixed central-peripheral dysfunction than for pure peripheral dysfunction.
- Studies measuring long-term effects of VR are scarce and more follow-up studies are needed.

#### Exercise compliance

The exercises in VR often provoke dizziness, which is associated with fear and increased risk of falling. The patients are expected to repeatedly provoke their symptoms when exercising since repetitions should induce central neurological habituation, which in the long run leads to reduction in dizziness symptoms (19). This presents challenges to VR compliance.

Supervised exercises in VR seem to be superior to home-based exercises and are believed to increase patient compliance (31;32). Since vestibular rehabilitation in chronic dizziness is a life-long trainable process, it seems relevant to investigate the exercise compliance with home exercises as an important part of the vestibular rehabilitation program (33).

The greatest drop in exercise compliance among the elderly occurs at the end of the training programme in an outpatient clinic, and long-term compliance to home exercises seems low (34-36). Around half dropout of a commenced exercise program within 6–12 months, and those who dropout are likely to be those most in need of regular exercise (37).

McPhates found compliance to group exercise programs for the prevention of falls to be 74%, but compliance was expected to drop over time (38).

One challenge is that compliance to center-based exercise programs is relatively easy to document, but compliance to home-based exercise relies on self-report, which may overestimate or underestimate exercise frequency and duration (36).

To understand factors important to patient compliance in VR, we did a literature search. The search included review studies regarding compliance from  $1^{st}$  January 2010 to  $31^{st}$  December 2015. Table 2 shows the nine (review) studies we refer to in this thesis (for search strategy, see appendix E).

Since the reviews only covered studies up to and including April 2012, the search strategy was repeated from 1<sup>st</sup> April 2012 to 31<sup>st</sup> December 2015, but this time with "clinical study" as a limitation. Eleven relevant clinical studies were identified. Table 3 shows the 11 studies (for search strategy, see appendix E).

*"Self-efficacy"* is the strength of one's belief in one's own ability to complete tasks and reach goals (39;40), and patients with high self-efficacy within exercise will feel the ability to be successful in exercise-related activities (41;42). This is confirmed by Motl et al. (43), who conclude that researchers should integrate strategies for promoting change in self-efficacy along with physical activity interventions to maximize motivation and improvements in disability outcomes among older adults. The reviews by Bauman and Boehm (44;45) showed that the reasons for low adherence/compliance to physical activity were age, sex, health status, self-efficacy and motivation. Simek et al. found (46) that higher levels of full adherence to home exercise programs were found in interventions delivered by a physiotherapist. Furthermore, older adults found it important that health professionals, particularly physicians, informed them of their decisions in the planning of physical activity (46). In the review by Baert et al.(47), 15 motivators and 16 barriers in relation to home exercise programs were identified. Some of the motivators were, e.g., to "stay independent" or "trust in the physical activity program".

Geraedts (48) found that 70% of the participants rated the following issues as important or very important: 1) physician's advice about exercising, 2) monitoring by a health professional, 3) an evaluation of the exercise program by a professional, and 4) the quality of the instructor. Several other factors were also found to be of high importance: 5) Easy access to exercises (close location of the exercise), 6) the type of exercise to be performed, 7) cost - program being free or providing monetary incentives from Medicare, and 8) social comfort, i.e. that the other participants are of the same age.

Self-efficacy was in the review by Baert identified as the strongest predictor of exercising (47), and self-efficacy seems to affect "*motivation*" in both positive and negative ways. The literature breaks motivation up into "controlled motivation" and "self-determination". Controlled motivation means that a patient will participate in treatment because of an external force (e.g. "the therapist is watching me"). Self-determination is defined as the internal part of motivation and is related to autonomous motivation, which again is related to clear goals of treatment (e.g. "I understand why I must do this exercise") and to feel competent regarding the outcomes of the rehabilitation process (49;50).

#### Exercise compliance in home settings

Bonnefoy (51) found that a home-based program supervised by home helpers during their normal working hours (measured by diaries) showed compliance rates of 44% among elderly people at risk for frailty or disability. In Brovold's study (52), elderly living in the community receiving home exercises showed 80% compliance, but the elderly were supervised in their homes by a physical therapist in the community 4 times during the exercise period, which lasted median 9 weeks.

In Batchelor's study (53), elderly people with stroke received an individualized home exercise program prescribed by a physiotherapist. Batchelor showed (53) that of the 64 participants, 25 % were fully adhered, 56 partially adhered and 19 % did not adhere to the exercise program. The study also showed that there was a significantly higher proportion of fallers among those who partially adhered to the exercise program.

Voglers (54) study of home-based exercise programs designed to reduce fall risk among elderly people recently discharged from hospital showed compliance rates of 62% in a group of weight-bearing functional exercises and 70% in a group of seated resistance exercises. The physical therapist visited the patients eight times in 12 weeks to individually prescribe and ensure correct performance. Participants were asked to exercise three times a week. In Deans study (55), community-dwelling people after stroke participated in exercise classes weekly for 40 weeks over a 1-year period and were given a home exercise program to be completed at least three times per week. The exercise intervention was designed to enhance mobility, prevent falls and increase physical activity. The exercise compliance was 70% at 3 months, 53% at 6 months and 37% at 12 months. To reduce fall rates in older people, Clemson (56) undertook three home-based interventions: lifestyle integrated functional exercises (balance and strength training and integrated activities into everyday routines), with a compliance rate of 47%, structured program (exercises for balance and lower limb, with a rate of 35%, and sham control programme (gentle exercises), with a rate of 47%.

In McAuley's study (57) with an evaluation of a DVD-delivered home exercise program focusing on flexibility, toning and balance on physical function in older adults three times per week, the adherence rate was 76% across the trial, indicating that participants are as likely to use a DVD activity program on a regular basis as are individuals who attend a center-based program.

Schoene et al. (58) found a high compliance level of 92% with an in-home intervention with videogame technology among older adults with increased fall risk, and Gschwind (59) found a compliance level of only 14% with an in-home intervention with Microsoft Kinect.

In van Het et al.'s study (60), participants were assigned to either the brochure group, social group or the individual group. The social and individual groups received a tablet with the ActiveLifestyle app. The app existed in two versions: an individual version containing individual motivation strategies and a social version consisting of individual and social motivation strategies. Both the social and individual group versions of the app consisted of motivation strategies, whereas social motivation strategies were added only for the social group. Participants in the brochure group did their exercises using a training plan on paper sheets. The median training adherence was 59% in the brochure group, 84% in the social group and 81% in the individual group

In the study by Sherrington (61) aiming to investigate the effects of a home-based exercise program on falls, the compliance in month 1 was 77%, in month 3 64%, in month 8 51% and in month 12 47%.

conventional or virtual reality-based vestibular rehabilitation. The virtual reality-based Meldrum randomized (21) patients with vestibular dysfunction to receive 6 weeks of group received an off-the-shelf virtual reality gaming system for home exercise and physiotherapist and a daily home exercise program. In both groups adherence was the conventional group a foam mat. The treatment comprised weekly visits to a high, 77%.

Author	Year of publication	Sample size	Age in years	Purpose of the study
Baert et al. (47)	2011	44 studies	+ 79 years	To focus on the identification of motivators and barriers for physical activity in subjects aged 80 years and over
Bauman et al. (44)	2012	32 studies	+ 18 years	To get an understanding of correlations and determinants of inactivity
Simek et al. (46)	2012	23 studies	+ 60 years	To establish the relationship between exercise program characteristics and the adherence of older adults to home exercises
Boehm et al. (45)	2013	25 studies	+ 50 years	To explore barriers and facilitators to exercise
Chase et al. (41)	2013	20 studies	+ 60 years	To conduct a review of interventions to increase physical activity among older adults
Geraedts et al. (48)	2013	32 studies	+ 65 years	To evaluate existing literature on the effectiveness of remote feedback strategies on physical activity strategies for older adults
Sun et al. (62)	2013	53 studies	+ 60 years	To establish global levels of physical activity among older people
Picorelli et al. (36)	2014	9 studies	Average age > 65 years	To review prospective studies of older people's adherence to exercise programs
French et al. (40)	2014	24 studies	+ 60 years	To identify behavior change techniques that increase self- efficacy

Table 2. Reviews, exercise compliance

Table 3. Clinical trials, exercise compliance				
Author	Years of publication	Sample size	Age in years	Purpose of the study
Sherrington et al. (61)	2014	340 older people	Mean age 81	To investigate the effects of a home- based exercise program on falls among older patients
McAuley et al. (57)	2013	307 older people	+ 65 years	Designed to test the effectiveness of a home-based DVD-delivered exercise program
Batchelor et al. (53)	2012	156 older people with stroke	Intervention: 71 years Control: 72 years (mean age)	To determine whether a falls prevention program reduces falls
Bonnefoy et al. (51)	2012	102 older people	+ 78 years	To assess whether a home-based program supervised by home helpers preserves functional level
Vogler et al. (54)	2012	180 older people	+ 65 years	To measure the extent of 12-week exercise intervention
Dean et al. (55)	2012	151 older people with stroke	Mean age 67	Investigate whether an exercise intervention can increase physical activity
Clemson et al. (56)	2012	317 older people	+70 years	To determine whether a lifestyle approach is effective in reducing rate of falls
Van Het et al. (60)	2014	44 older people	Mean age 75	To compare 3 home-based programs
Schoene et al. (58)	2013	37 older people	+65 years	To assess the feasibility and safety of unsupervised home step pad training
Gschwind et al. (59)	2015	148 older people	+ 65 years	To compare feasibility of two exergame interventions
Meldrum et al. (21)	2015	71 patients with vestibular loss	Intervention: 58 years Control: 50 years (mean age)	To compare effectiveness of virtual reality exercises to conventional balance exercises

Summing up this chapter, a great variation in compliance rates across the studies is found and the interventions differ a lot. Motivation and self-efficacy seem to be of importance to increase performance in rehabilitation. The question is if the use of rehabilitation technology or "exergames" to assist the rehabilitation will be enough to change the elderly patients' motivation or support their self-efficacy. Perry found that affecting motivation is the term "*acceptance of technology*" (63). This is linked to invasions of privacy, which in the literature are often cited as examples of technology-related obtrusiveness, and privacy concerns have been identified as a potential barrier to acceptance of assistive health technologies (64). Many topics need to be taken into account when rehabilitation is being planned by health care professionals. In vestibular rehabilitation, the following issues seem to challenge exercise compliance:

- The patient's self-efficacy, motivation and acceptance of technology seem to be important issues in planning vestibular rehabilitation programs.
- The exercises often provoke dizziness, which is associated with fear and increased risk of falling among the elderly
- The patients are expected to repeatedly provoke their symptoms when exercising

#### Older adults and exergaming

Exergames (exercise + gaming) appear promising for home training for elderly and have several advantages compared to conventional exercises. Exergaming can motivate people to exercise, and by performing dual tasks, users are able to train both cognitive and motor skills (65).

The most widely used sensors in exergame input devices include accelerometers, gyroscopes, infrared (IR) and optical sensors/cameras and pressure sensors (65). Systems like Silverfit (Silverfit BV, Woerden, the Netherlands), Computer Assisted Rehabilitation Environment (CAREN, Motik Medical, Amsterdam, the Netherlands), Nintendo Wii Fit Plus (Nintendo, Kyoto, Japan), Xbox 360 Kinect (Microsoft corp., Redmond, WA) and Sony PlayStation Eyetoy (Sony, Park Ridge, New Jersey, USA) are examples of this. While Wii is a "low-budget" solution which can be bought in most toy shops, CAREN is an advanced 3D virtual reality system situated in its own

room (66). Silverfit is placed between these two products, requiring a setup of designated cameras and sensors, but can otherwise work on a standard computer system (67).

To understand which factors are important when including exergames in treatment regimens, we did a literature search. The search included review studies regarding exergames (for search strategy, see appendix F). Nine relevant reviews were identified. Table 4 shows the nine review studies (for search strategy, see appendix E). Since the reviews only covered studies up to and including July 2012, the search strategy was repeated from the 1<sup>st</sup> July, 2012 to 31<sup>st</sup> December, 2015, but this time with "clinical trial" as limitation. Five relevant clinical studies were identified. Table 5 shows the five studies (for search strategy, see appendix F).

First of all, exercise games have been used primarily in balance interventions among elderly people in clinical settings at hospitals and are not common in home settings (68).

In a review, Chao found positive effects of Wii exergames shown as improved physical function, decreased depression and increased cognition and quality of life among older adults (69), and Van Dienst et al. (65) found that of the 13 studies reviewed 10 reported improvements in at least one balance measure after an exergame intervention. The reviewed studies further showed that exergame intervention groups found the training more appealing than traditional exercises and therefore more motivating. Primack et al. (70) found that four out of five studies reported improvements in primary outcome measure after video game intervention (e.g. for rehabilitation after a stroke with Sony Eye Toy).

Goble and Molina et al. pointed out in their reviews that the most frequent limitation regarding exergames is related to the sample size, which can reduce the external validity of the studies (71;72). In addition, a limitation in the studies is the wide variability in exercise interventions regarding the dosage and duration of training. The review of McDermott et al. pointed out that it remains unclear whether exergame interventions can be used to replace staff time and whether these interventions can be effective in older adults (73). Miller found that the use of gaming systems demonstrated strong retention and adherence to training programs (74) but recommended that future studies should not only address the effectiveness of gaming

exercise programs but also the feasibility issues specific to the implementation in a home environment.

Laufer et al. concluded that Nintendo Wii-based exercise programs may serve as an *alternative* to more conventional forms of exercise aimed at improving balance control (68).

The review by Dennett et al. concluded that there was only low-quality evidence that exergames improve static balance in people with vestibular conditions compared with no therapy (75).

#### Exergames in a home setting

The study by Meldrum showed no effect of using Nintendo Wii Fit in home exercises in a vestibular rehabilitation program among patients with a mean age of 58 years (21). An explanation may be that the Nintendo Wii was used only for balance training and not for the gaze stabilization exercises in the home training program.

Wingham (76) found that Nintendo Wii was an acceptable and enjoyable tool for arm rehabilitation of stroke patients and requiring little caregiver support, and Pluchino (77) found that a Wii balance home program was as effective as Tai Chi and a standard balance exercise program performed in a clinical setting among independent seniors. Smith's (78) evaluated an open source software program, Stepmania, which requires participants to step as accurately as possible on a dancemat to the instructions on a monitor, but only two out of seven older patients found the game motivating. Kim et al. (79) evaluated the effects of an unsupervised virtual reality exercise program on hip muscle strength and balance control in older adults . When exercising in their homes, the subjects could see their own avatar on the right side of a monitor. The immersed avatar on the right side of the monitor screen could move as the subject moved and allowed the subject to consider real-time visual feedback simultaneously. The program improved hip muscle strength and dynamic balance control in older adults.

Silveira (80) evaluated the program, ActiveLifestyle, an information technology (app) for active and healthy aging aiming to motivate older people during home-based physical workouts. In the program, three levels of strength-balance training are supported, and at all levels, the balance training should be done 5 days per week at

home. The method was a pretest/posttest trial with three groups: 1) an individual group doing exercises on their own, 2) a social group using a social version of the app where it was possible to compete with other participants, and 3) a control group that followed exercises with printed instructions. The study showed 73% compliance in the social group, 68% in the individual group and 54% in the control group. This seems to be in consistency with Miller et al.'s review (74), which showed adherence/compliance rates across studies  $\geq 64$  %.

Another exergame, Move it to improve it (Mitii) has not prior to this study been evaluated in relation to vestibular rehabilitation. Mitii was developed for patients with cerebral palsy but seems to be used for other patient categories as well (81). Unlike Nintendo Wii, the Mitii training program is set up in the participants' homes using an Internet-connected computer and a web camera connected to a cloud-based interactive training system using the Adobe Flash technology. Participants log into the Mitii website and access their individualized training program. The specific content and progression of the program are based on monthly evaluations between the patient and the therapist at the hospital. The level of difficulty is easily adjusted by a therapist by increasing the task challenges like speed, number of repetitions, placing of target and pick-up area on the screen, size of objects or time to react. This can be done from the hospital, making Mitii appropriate to support home exercises both in a vestibular rehabilitation period in-hospital and after discharge to maintain functional level.

Table 4. Reviews, exergam	ing			
Author	Year of publication	Sample size	Age in years	Purpose of the study
Primack et al. (70)	2012	38 studies	20 % of studies involved patients 50- 80 years	To determine whether video games may be useful in improving health outcomes
McDermott et al. (73)	2013	11 studies	Mean age = 54 years	To investigate the effectiveness of using computers to deliver patient self-management programs to patients with chronic illness
Van Diest et al. (65)	2013	13 studies	+ 15 years	To provide an overview of the exergames that have been used for balance training balance among elderly
Goble et al. (71)	2014	19 studies	+ 18 years	Summary of Wii Fit balance research
Laufer et al. (68)	2014	8 studies	Mean aged 61-85.7 years	To systematically review RCT trials that examined the effect of Nintendo Wii on balance
Miller et al. (74)	2014	14 studies	Mean age between 47-84 years	To summarize evidence for effectiveness of VR/gaming system
Molina et al. (72)	2014	13 studies	+ 60 years	To provide the effects of exergames in improving physical functioning
Dennett et al. (75)	2015	30 studies	Age $\geq 18$ years	To determine the effectiveness of computer-based electronic devices
Chao et al. (69)	2015	22 studies	Mean aged 61.3-86 years	To summarize and synthesize the impact of using Nintendo Wii

Table 5. Clinical trials, exergaming					
Author	Years of publication	Sample size	Age in years	Purpose of the study	
Pluchino et al. (77)	2012	40 independent seniors	Mean age 73	To compare the impacts of Tai Chi and a video game balance board	
Kim et al. (79)	2013	32 older adults	Intervention: 68 years Control: 66 years (mean age)	To assess the effects of an unsupervised virtual reality program	
Silveira et al. (80)	2013	44 older adults	+ 65 years	To investigate which IT-mediated motivation strategies increase adherence	
Smith et al. (82)	2013	7 older adults	+ 65 years	To evaluate the exergame, Stepmania	
Wingham et al. (76)	2012	19 older adults	Median age: 65 years	To understand stroke survivors experience and acceptability of using Nintendo Wii Sports	

Summing up this chapter, a lot of topics need to be taken into account when exergames are included in the vestibular rehabilitation of vestibular patients:

- A generally accepted view is that exergames may improve exercise compliance and the outcome of rehabilitation, but the practicality and benefits require validation.
- More knowledge is needed about how games may be used as a motivational factor in the rehabilitation of elderly patients with vestibular dysfunction, thereby increasing their functional level.
- So far, the games have been evaluated mostly in outpatient clinic, but in the vestibular rehabilitation of elderly patients, a big part of the training should take place as home training, which can challenge exercise compliance.
- Knowledge is also needed about exergames regarding patients aged 65 and older with vestibular dysfunction and their ability to maintain the effect of VR training obtained in an outpatient clinic. We do not know whether it is possible to maintain or even improve the obtained functional level with use of a computer home exercise program compared with printed instructions handed over to the patient by a physiotherapist. We do not know whether a computer home exercise program is better to maintain or even improve the obtained functional level with use of a physiotherapist. We do not know whether a computer home exercise program is better to maintain or even improve the obtained functional level than printed instructions handed over to the patient by a physiotherapist.

#### Aim, two hypotheses and a research question

#### The overall aim of the thesis:

The overall aim of the thesis is to investigate the effect and feasibility of a computer home training program compared with conservative home training according to printed instructions as a supplement to outpatient rehabilitation in patients with vestibular dysfunction aged 65 years or older.

The following hypotheses are addressed:

Hypothesis 1 (paper 1)

Vestibular rehabilitation with assisted technology has a positive effect on functional level, balance and dizziness in everyday life compared with conservative home training according to printed instructions in the rehabilitation of patients with vestibular dysfunction aged 65 years or older.

#### Hypothesis 2 (paper 2)

Home training with assistive technology is able to maintain the effect 3 months after end of training in the outpatient clinic better than printed instructions measured on functional level, balance, quality of life and impact of dizziness on everyday life. The short follow-up period was chosen due to the patients' age and the risk of co-morbid conditions during the intervention period.

#### **Research question (paper 3)**

What are the possible reasons for the lack of motivation and the moderate level of exercise compliance during the intervention period?

The original research question was "to investigate possible reasons for effect or lack of effect of the computer program and to evaluate reasons for the level of exercise compliance during the intervention period" but due to the results of studies I and II the question was narrowed.

#### Materials and methods

#### Intervention

To support the rehabilitation process in the patients' home environment the computer-training program "Move it to improve it" (Mitii) was used (81;83), Mitii was installed in the participant' homes using an internet-connected computer with a web camera connected to a cloud-based specifically adapted interactive training program. A sequence of individual games was arranged for a daily exercise program of 20 to 30 minutes, with the patient in a standing position. Before each game, a short video showed the patient what to do (84). The program comprised drag-and-drop and follow-the-leader games. For drag-and-drop games, patients wore a headband with a

green marker at the front. The webcam registered the position of the marker and transferred this information to the screen cursor to be controlled by head movements. A virtual object on the screen was manipulated by grabbing and dragging it to a different location, or onto another virtual object (84). The games instigated head movements and challenged the vestibule-ocular reflex. Other games challenged the patients' postural balance. A follow-the-leader game uploaded a video sequence of the therapist's movements which the patient was expected to follow visually. These games challenged the patient's vestibule-ocular reflex. After completing each game, a "well done" appeared at the screen. No other feedback concerning the manner or quality of performance was given, but the duration was registered and displayed for the hospital project physiotherapist who contacted participants if the program was not used for 7 days (83-85).

#### Subjects

All patients (≥65 years) were presented with stable peripheral, central and/or mixed vestibular dysfunction. Some were recruited from the Fall Prevention Clinic, Geriatric Department, Aarhus University Hospital, Denmark, after referral by their GPs or from the Emergency Department at Aarhus University Hospital. Others replied to a newspaper advertisement asking for volunteers. A geriatrician evaluated the causes of the patients' fall. Those with vestibular dysfunction who agreed to participate in the project were referred to the Ear, Nose and Throat Department at Aarhus University Hospital to verify the diagnosis of vestibular dysfunction. Diagnostic tests comprised: vestibular evoked myogenic potentials; subjective visual video head impulses (vertical and horizontal); spontaneous nystagmus; the bithermal caloric vestibular-ocular reflex test (including visual suppression); an oculomotor test including saccades, smooth pursuit, and optokinetic responses; the Roll test; the Dix Hallpike, Hennebert test, gaze-induced nystagmus test; and the Romberg nystagmus test (81;83;86). Inclusion criteria were:

• Patients aged 65 years or older with stable peripheral, central and/or mixed vestibular dysfunction.

Exclusion criteria were:

- Menière's disease
- Benign Paroxysmal Positional Vertigo (BPPV)

- Acute vestibular neuronitis
- Poor vision: <u><</u>6/60
- Contra-indications to exercise therapy
- Significant cardiac problems
- Use of medicines with potential vestibular side effects (benzodiazepines and sedatives)
- Dementia measured with the Mini-Mental State Examination scores <27
- A history suggesting dementia
- Stroke in the previous 6 months
- Other cognitive dysfunctions
- Hip fracture within the last 3 months

The number of patients seen at the Fall Prevention Clinic, Aarhus University Hospital from March 2011 to December 2012 was 329. Of these, 63 met the inclusion criteria (flowchart, Figure 1). Randomization after screening and prior to baseline assessments was provided by a central computer program with permuted block-sizes and stratification according to peripheral, central or mixed vestibular dysfunction. This was done since patients with central vestibular disorders have worse outcomes of VR than patients with peripheral vestibular disorders due to a higher degree of complexity, making them harder to treat by vestibular rehabilitation (15;87). Accordingly, the computer program randomized patients to various blocks of 3, 6 or 9 patients, and assigned a total of 32 patients to the intervention group and 31 to the control group.

#### Figure 1: Flow chart



\* Diagnosed after inclusion

#### Outcome measure

Patients with vestibular dysfunction differ with respect to the onset and clinical course of their disability depending on the type and extent of the vestibular deficit. In addition, the patients have many of the same symptoms, i.e. dizziness, lightheadedness, vertigo, nystagmus, blurred vision, postural instability, fear of movement, gait disturbances and occasional falling (58;88). This makes the physical therapy assessment multifaceted, and to quantitatively establish the effects of the vestibular rehabilitation, we chose several outcome measures in this study to measure the physical functional level, the dizziness level, the subjective experience of the dizziness, the patient's quality of life and the patient's balance.

All the tests were performed by an experienced therapist, and an attempt was made to ensure that the test conditions were identical the tests performed in the same order for every patient. The order of the tests was planned in regard to the older patients' endurance and fatigue level.

Strength in the lower extremities and balance were measured by the Chair Stand Test. Static and dynamic balance by the One Leg Stand Test and Dynamic Gait Index. Quality of life was measured by Short Form 12 and dizziness by Dizziness Handicap Inventory and a Visual Analog Scale. Dizziness due to motion was measured by the Motion Sensitivity Test.

#### **Chair Stand Test**

The test was used to measure strength in the lower extremities by recording the number of times the participant managed to rise from a chair within 30 seconds with arms folded across the chest without use of armrests (89). The test provides a reasonably valid indication of lower body strength in active, community-dwelling older adults (89). We also included the Chair Stand Test since we expected the test to challenge and thereby measure the patients' balance.

The participant is encouraged to complete as many full stands as possible within 30 seconds. The participant is instructed to fully sit between each stand. While monitoring the participant's performance to ensure proper form, the tester silently counts the completion of each correct stand. The score is the total number of stands within 30 seconds (more than halfway up at the end of 30 seconds counts as a full stand).

Jones found no floor effects in the Chair Stand Test among community-dwelling elderly (89).

A possible bias seems to be that the test has not been validated in elderly patients with vestibular dysfunction nor has it been used to test balance among elderly patients.

#### One leg stand test

The one leg stand test for postural control measures the time (max 30s) taken by the patients to move their feet from the start position. Both right and left leg stands were tested, and the best leg value was used in the analysis. The test was chosen as primary outcome and was used in the power calculation of the study.

Kammerlind (90) evaluated the test in patients with vestibular dysfunction and found that the test-retest reliability (with eyes open) was ICC 0.92–0,96 and the inter-test reliability (with eyes open) was ICC 0.98–1.00.

One leg stand test was chosen as the primary outcome in our study.

#### **Dynamic Gait Index**

This test assesses dynamic postural stability as functional gait according to eight tasks with varying demands, e.g. walking at different speeds, walking with head turns, ambulation over and around obstacles, making a quick turn while walking, ascending and descending stairs. Each item is rated on a 4-level ordinal scale, and the DGI score has a range of 0 to 24, with higher scores indicating better stability Hall and Herdman found excellent concurrent validity (r=0.71) between DGI and another balance measure (Berg Balance Scale) (91). In the study, 16 patients with confirmed peripheral vestibular disorders performed two trials of each of the measures within a single physical therapy session. In order to assess test-retest reliability of the measures, intra-class correlation coefficients (ICC) were calculated. The result was that all measurement tools demonstrated excellent reliability (ICC 0.86 = 0.62-0.95). Ceiling and floor effect have not been tested in patients with vestibular dysfunction, but Pardasaney et al. found ceiling effects on DGI in community-dwelling elderly people with functional limitations (92).

#### Short Form 12

The SF-12 is preferable, compared with other longer versions of measures of quality of life, for use among the elderly, because it is short (fewer questions makes it easier

to answer) and it does not include questions about work (93). The SF-12 includes eight concepts commonly represented in health surveys: physical functioning, role functioning physical, bodily pain, general health, vitality, social functioning, role functioning emotional and mental health. Results are expressed in terms of two metascores: the Physical Component Summary (PCS) and the Mental Component Summary (MCS).

A high score in SF-12 indicates better physical function. To calculate the PCS and MCS scores, test items are scored and normalized in a complex algorithm in STATA 12.0. The PCS and MCS scores have a range of 0 to 100.

In a study including 4278 community-dwelling elderly people aged 75–105 years (93), the instrument generally showed acceptable validity and reliability. But there seems to be a limitation in the instrument's ability to measure quality of life among elderly people. The other limitation is that the instrument is not validated in elderly people with *vestibular dysfunction*.

#### **Dizziness Handicap Inventory**

The Dizziness Handicap Inventory (DHI) is used in clinical work and in research to assess the impact of dizziness on quality of life. The self-reported questionnaire was originally designed to quantify the handicapping effect of dizziness imposed by vestibular system disease, but has also been used for persons with dizziness of other origins (94). Items included in the DHI were originally derived from case stories of patients with dizziness, and the measure was further examined in several studies involving patients seen for vestibulometric testing. The DHI contains 25 items, and a total score (0–100 points) is obtained by summing ordinal scale responses, higher scores indicating more severe handicap. Validity of the DHI was indicated because higher scores were associated with higher frequency of dizziness and with greater functional impairments. Concurrent validity has been examined in several studies, presenting variable results. Satisfactory test-retest reliability has been demonstrated for the total scale as well as for the subscales, and a change in the DHI total score should decrease by at least 18 points in individual patients to be called a true change. In Tamber's study, the DHI was found to have no floor or ceiling effects in patients with "dizziness of mainly vestibular origin" (95).

#### Visual Analog Scale

Dizziness was measured using a visual analog scale (VAS). Participants rated their perceived level of dizziness. Participants were instructed to rate their dizziness severity on a scale from 0 to 100 mm: 100 indicates maximum dizziness and 0 indicates no dizziness. The participants were asked to respond to the question: "How much dizziness have you felt within the last 24 hours"? In this scale, 0 indicated no dizziness and 100 dizziness as bad as it can be. The scale has been used in several editions measuring dizziness (24;96), but in the studies the instructions to the patients were not clearly described, and it was not clear whether the VAS dizziness scale was a validated measure.

#### **Motion Sensitivity Test**

The Motion Sensitivity Test (MST) is a clinical protocol designed to measure motionprovoked dizziness during a series of 16 changes to head or body positions and a score going from 0–128, where 0 indicates no symptoms of dizziness. The MST has been used as a guide for developing an exercise program for patients with motionprovoked dizziness and as treatment outcome measure to monitor effectiveness of VR. In a study (97), 15 individuals with motion-provoked dizziness and 10 control individuals were tested during sessions occurring 90 min and/or 24 h after baseline testing. The MST was found reliable across raters and the test validity was good. The results indicated that the MST can be used reliably in clinical practice to develop exercise programs for patients with motion-provoked dizziness and to provide evidence of intervention efficacy (97).

The limitation of the study seems to be that only scores from 15 subjects with complaints of motion-provoked dizziness and 10 control subjects without complaints were tested and compared in the study. Also, the low number of subjects included in the study could make the test specificity of 80% doubtful.

Another limitation is that a possible change in the MST reflects a difference in overall motion-provoked dizziness. A change does not indicate whether the difference occurs in symptom intensity, duration or number of positions provoking dizziness (97). Akin's study (97) also showed a greater variability at higher scores (> 10), and a floor effect at lower scores (< 10) among community-dwelling individuals.

We considered including the Timed Up & Go test (98) to measure dynamic balance and the Berg Balance Scale (99) to measure static balance, but we found the tests too easy for our test persons, and for this reason, a ceiling effect would be expected. Also, the Functional Gait Assessment (FGA) (100) was considered in our test battery. FGA is an extended version of the Dynamic Gait Index. Three (vestibular) items have been added to the original DGI, including gait with narrow base of support, ambulation backwards and gait with eyes close. In the end, we decided to include DGI in the test battery since this test has been translated into Danish (101).

#### Ethics

The patients in this PhD thesis were all enrolled in the study approved by the Danish Data Protection Agency on the 24<sup>th</sup> of September 2009 (ref:1-16-02-84-09) and approved by The Central Denmark Region Committees on Health Research Ethics on the 20<sup>th</sup> of November 2009 (ref: 1-10-72-62-13) and registered at ClinicalTrials.gov (ref: m-20090189).

When the outcome tests were done, especially the Motion Sensitivity Test, an increase in the patients' dizziness could be seen for a short time (minutes). The tester therefore was aware of balance problems and fall risk shortly after the testing. VR is designed to retrain the brain to recognize and process signals from the vestibular system and coordinate them with information from vision and proprioception. This often involves desensitizing the balance system to movements that provoke dizziness symptoms. Therefore exercising at home could potentially result in fall. Patients were recommended to place a chair in front of them during exercise sessions at home.

Telephone numbers to the persons in charge could be found in the written information, and patients were able to contact health professionals if they experienced adverse effects.
# Summary of methods used in the studies

# Study I

Study I (83) compared a computer-assisted home exercise program with conservative home-training following printed instructions in the rehabilitation of elderly patients with vestibular dysfunction (83) (Appendix D).

# Participants

The study population included 63 patients ( $\geq$ 65 years) with stable peripheral, central and/or mixed vestibular dysfunction. Some were recruited from the Fall Clinic, Geriatric Department, Aarhus University Hospital, Denmark, after referral by their GPs or from the Emergency Department at Aarhus University Hospital. Others replied to a newspaper advertisement asking for volunteers.

# Sample size

Findings of a previous rehabilitation exercise trial in patients with dizziness showed a mean improvement of 6.6 seconds (SD 8.4) on the one leg stand test in the intervention group compared to 0.4 seconds (SD 6.9) in the control group (24). Based on these figures, we expected a mean improvement in the present study of 6 seconds (approx.) for the intervention group, compared to the control group. With a two-tailed significance of 80% power and an expectation of 15% dropouts, the sample size was estimated to be 29 patients in each rehabilitation group.

# Design

A randomized controlled trial comparing outpatient vestibular rehabilitation supported by Mitii for home training with a control group supported by printed instructions at home.

# Statistical analyses

Repeated measurement ANOVA (102) was used analyzing the three examinations at baseline, 8 and 16 weeks. Secondarily, the groups were compared with a 2-sample independent t-test with respect to the change from baseline to 16 weeks (within group test).

# Study II

Study II (85) was a 3-month follow-up of study I and examined whether the effect of vestibular rehabilitation was maintained 3 months after the patients had stopped the outpatient clinic vestibular rehabilitation. A second objective was to investigate whether computer assisted home training was able to maintain the obtained functional level better than printed instructions (85) (Appendix E).

# Participants

The study population included patients who completed study I and had stopped outpatient vestibular rehabilitation. They were all told to continue with home exercises as before after dropping out of the outpatient clinic training.

# Sample size

The sample in study I was followed up in this study excluding dropouts, which led to 30 patients in the intervention and in the control group.

### Design

A single-blinded randomized, controlled design with an intervention consisting of home exercises supported by a computer program compared to a control group who had printed instructions of home exercises handed out on a sheet of paper.

# Statistical analyses

We compared the difference in outcome measures in the groups from end of training in the outpatient clinic to the follow-up at 12 weeks by using t-tests and Wilcoxon signed-rank when data was not normally distributed.

The data were analyzed on an intention-to-treat and per-protocol basis, using STATA statistical software, version 12. The groups were compared at discharge from hospital using an independent t-test. The within-group changes n outcome measures between baseline and 12 weeks were compared by paired and independent t-test (with 95% CIs) to evaluate the effect of home exercises in the two groups.

# Study III

Study III (84) should find explanations for the moderate exercise compliance and elusive clinical effect of an earlier randomized study (84) (Study III: Appendix F).

# Participants

The first seven participants randomized to the intervention group of the RCT were included.

# Design

Qualitative longitudinal design in which seven semi-structured interviews were conducted at the time when the participants were included in study I and seven interviews when the same participants ended the rehabilitation period at the outpatient clinic. In both interviews with the same seven patients, the interviews evolved around themes such as the elderly participants' self-efficacy, motivation and acceptance of the technology (Box 1). The themes were chosen on the basis of the scientific literature, where the concept of 'self-efficacy' is consistently identified as an important determinant of exercise behavior among various populations and in many types of behavioral learning (39;103;104). "Motivation" as such has numerous definitions. In this paper, we focus on 'controlled motivation,' which means that a patient will participate in treatment because of an external force (e.g. "the therapist is watching me"). "Self-determination" is the internal part of motivation and is related to autonomous motivation, which again is related to the identification of the goals of treatment (e.g. "I understand why I must do this exercise") and to feel competent regarding the outcomes of the rehabilitation process (49;50). Also, affecting motivation is the term "acceptance of technology". Invasions of privacy are often in the literature cited as examples of technology-related obtrusiveness, and privacy concerns have been identified as a potential barrier to acceptance of assistive health technologies (64).

#### **Box 1: Guiding interview questions**

#### Patient background and dizziness:

How does dizziness affect your daily life? Can you illustrate this with an example? How long have you experienced dizziness? When did you first experience dizziness? And under which circumstances?

Self-efficacy:

What is your general experience of rehabilitation?
What do you think about rehabilitation in your own home?
How is the rehabilitation being described?
What is your family's reaction?
Motivation:
Which treatments have you been offered?
What would you like to do when your dizziness limits your activities?
What are your expectations of using the Mitii system for rehabilitation?
What motivates you to use the system?
Technology experience at home:
What do you think about using a computer?
Do you own a computer? What do you use it for?
Do you own other digital devices (television, videocamera, radio)?
What do you think about using a computer for rehabilitation?

The post interview when the participants ended the rehabilitation period at the hospital was constructed with the same three focuses but with different interview questions (Box 2)

# Box 2: Interview questions serving as guidance through data collection after intervention with Mitii

#### Self-efficacy:

Which exercises affected your dizziness the most? And why? Which exercises did you like the most? And why? Did you feel safe exercising in your own home?

#### Motivation:

What is your experience of using a computer system for home exercise? How did you experience the rehabilitation period with Mitii? How were the exercises, compared to the exercises at the hospital? When during the day did you do your home exercises? And why? How do you compare using a computer for rehabilitation with rehabilitation facilitated by a therapist?

#### Technology experience at home:

What kind of problems with the computer did you experience during the

rehabilitation period? Do you have any suggestions for improving Mitii?

All 14 interviews lasted between 30 and 45 minutes and took place in the participants' homes. All interviews were digitally-recorded and transcribed verbatim. The transcribed interviews can be required by contacting the author of this thesis.

# Data analysis

The gathered data was analyzed by using Kvale & Brinkmann's hermeneutic meaning interpretation (105). The data undergo the processes self-understanding, critical common sense and a theoretical understanding (105). The interpreter goes beyond what is directly stated in the interviews to identify structures and relations of meanings not immediately apparent in the text (105). Earlier research literature on older adults, exercise and compliance constituted the theoretical framework of the analysis (see chapter: Exercise compliance).

# Results

A total of 63 patients with vestibular dysfunction were enrolled as patient population for the studies comprising the thesis (flowchart, Figure 1). All patients completed a baseline test battery as described in the method section and seen in the Table 6. A total of 60 patients participated in study II. A 7-month follow-up was possible in 57 patients (end of study II) (flowchart, Figure 1).

The main findings from the three studies conducted for this thesis are listed below. Additional information about the studies can be found in appendices D-F (83;84;85). Characteristics of the 63 patients are presented in Table 6.

Table 6	. Participant	characteristics*
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	Mitii group (n=32)	Control group (n=31)
Women, <i>n</i> (%)	18 (58)	20 (65)
Age	$76.65 \pm 7.56$	$78.68 \pm 6.56$
Duration of dizziness, months	$58.03 \pm 51.31$	$71.35 \pm 51.08$
Rehab sessions at the hospital	$23.45 \pm 8.73$	$24.23 \pm 8.09$
Types of vestibular dysfunction, $n(\%)$		
Peripheral	2 (6)	2 (6)
Mixed	4 (13)	6 (20)
Central	25 (81)	23 (74)
Baseline score for outcome measures		
Dynamic Gait Index (points)	$16.35 \pm 4.02$	$14.87 \pm 3.65$
Dizziness Handicap Inventory (points)	$41.61 \pm 17.96$	$42.26 \pm 18.81$
Motion Sensitivity Test (points)	$25.48 \pm 17.42$	$25.74 \pm 23.14$
Visual Analog Scale (mm)	$37.81 \pm 22.15$	$36.65 \pm 22.20$
Chair Stand Test (repetitions)	$11.74 \pm 2.98$	$10.71 \pm 2.82$
One Leg Stand Test (seconds)	$10.06 \pm 10.06$	$8.27 \pm 8.97$
SF-12. Physical Composite Score (points)	$38.86 \pm 12.63$	$35.13 \pm 11.65$
SF-12. Mental Composite Score (points)	$51.66 \pm 9.27$	52.25 ± 12.76

\* Values with a plus/minus sign are means (± SD). Wilcoxon, Student t-test and chi-2 were used.

The intervention and control groups did not differ significantly (>0.05) on any variable at baseline. The mean duration of dizziness was >6 years. Central vestibular dysfunction was the most common diagnosis. The mean number of hospital sessions was 23 for the Mitii group and 24 for the control group, *contra* 32 sessions recommended for both groups.

#### **Results - Study I**

Both groups improved significantly during 16 weeks of rehabilitation with respect to the Dynamic Gait Index and Chair Stand Test. The intervention group also improved significantly in the Dizziness Handicap Inventory and Motion Sensitivity Tests, but not significantly more than the control group (table 7) (83).

Measure <sup>b</sup>	Mitii group	Control group			Difference between groups	
		p- value		p- value		p- value
One leg stand test (seconds)	2.09 (-0.15 to 4.32)	0.066	2.63 (-0.17 to 5.44)	0.065	-0.55 (-4.06 to 2.96)	0.755
Dynamic Gait Index (points)	1.37 (0.18 to 2.55)	0.025	1.53 (0.44 to 2.63)	0.007	-0.17 (-1.74 to 1.41)	0.833
Dizziness Handicap Inventory (points)	-9.93 (-15.27 to -4.60)	<0.001	-5.20 (-10.70 to 0.30)	0.063	-4.73 (-12.23 to 2.77)	0.212
Motion Sensitivity Test (points)	-10.50 (-16.70 to -4.30)	0.002	-7.17 (-15.76 to 1.43)	0.099	-3.33 (-13.71 to 7.04)	0.523
Visual Analog Scale (mm)	-5.93 (-14.55 to 2.69)	0.170	-6.30 (-14.21 to 1.61)	0.114	0.37 (-11.08 to 11.82)	0.949
Chair Stand Test (repetitions)	1.33 (0.31 to 2.36)	0.013	1.33 (0.48 to 2.19)	0.004	0.00 (-1.31 to 1.31)	1.000
Short Form-12 Physical Functioning	2.70 (-0.88 to 6.28)	0.134	3.18 (-0.63 to 7.00)	0.098	-0.48(-5.60 to 4.64)	0.851
(points) Short Form-12 Mental Functioning (points)	3.33 (-0.72 to 7.38)	0.103	1.09 (-2.66 to 4.84)	0.557	2.24 (-3.16 to 7.64)	0.410

Table 7. Mean (SD) changes in outcome measures between baseline and at 16-week follow-up<sup>a</sup>

We used repeated measures ANOVA to analyze differences in outcome measures between baseline, 8 and 16 weeks after baseline. The ANOVA did not show significant differences between the two groups. Neither did the analysis per-protocol show any significant difference between the intervention and control groups. During 112 possible days of home training, patients in the intervention group used the Mitii system once daily on 57% of the days (median=51 sessions; 25th percentile=19 sessions; 75th percentile=65 sessions). The total duration of training sessions was not associated with outcome when tested by Spearman's rank correlation test (Figure 2).



Figure 2. The association between exercise time and outcome in the intervention group

Compliance with training peaked between 1 and 2 months after start of training. Thereafter, compliance decreased and flattened for the rest of the study period. Testing with Wilcoxon signed rank test showed no significant difference in compliance from month 1 to month 4.

### Results - Study II

Both groups had maintained their high functional levels 3 month after finishing the outpatient rehabilitation. No decrease in functional level, quality of life or increase in dizziness was observed in the two groups. At the between-group change, no difference was observed in the selected outcome measures (Table 8) (85). Analysis per-protocol did not show any difference between Mitii and Control groups.

-		0	•	•	
Mitii group		Control group		Difference between gr	oups
Mean change	P-	Mean change	P-	Group change	P-
during intervention	value	during intervention	value	difference	value
period (95% CI)		period (95% CI)		intervention period	
				(95% CI)	
	~ ~ .				
0.41 (-1.34 to 2.15)*	0.54	1.66 (-0.61to 3.93)*	0.18	-1.04 (-2.45 to 0.36)*	0.26
$0.07(0.70 \pm 0.02)$	0.86	$0.29(1.06 \pm 0.51)$	0.49	$0.25(1.49 \pm 0.79)$	0.54
0.07 (-0.79 10 0.93)	0.80	-0.28 (-1.00 10 0.51)	0.40	-0.35 (-1.48 10 0.78)	0.54
1.64 (-1.76 to 5.05)	0.33	0.97 (-3.78 to 5.71)	0.68	-0.67 (-6.43 to 5.07)	0.81
$2.11(1.70 \pm 6.00)$	0.15*	152(950 to 547)	0.41*	$0.26(4.20 \pm 2.68)$	0.12*
2.11 (-1.79 to 6.00)	0.15*	-1.52 (-8.50 to 5.47)	0.41*	-0.20 (-4.20 to 5.08)	0.12*
3.20(.0.10  to  2.53)	0 35*	2.76 (11.18 to 5.66)	0 /8*	0.53 ( 9.51 to 10.56)	0.92
-5.29 (-9.10 to 2.55)	0.55* -2.70 (-11.18 to 5.	-2.70 (-11.10 to 5.00)	) 0.46	0.55 (-9.51 to 10.50)	0.92
$0.54(1.28 \pm 0.21)$	0.17	0.03 (1.02  to  0.05)	0.86	0.50(0.71  to  1.72)	0.41
-0.34 (-1.28 to 0.21)	0.17	-0.03 (-1.02 to 0.93)	0.80	0.30 (-0.71 to 1.72)	0.41
$1.11(2.69 \pm 0.01)$	0.05*	$1.70(2.04 \pm 5.61)$	0.27*	$1.46(4.07 \pm 1.16)$	0.58
1.11 (-2.08 to 4.91)	0.93*	1.79 (-2.04 to 3.01)	0.27*	-1.40 (-4.07 to 1.10	0.38
2 10 ( 4 54 ( 0 10)	0.00*		0 1 4 4		0.00*
-2.19 (-4.54 to 0.16)	0.08*	-0./4 (-4./3 to 3.26)	0.14*	1.45 (-3.10 to 6.01)	0.99*
	during intervention period (95% CI) 0.41 (-1.34 to 2.15)* 0.07 ( -0.79 to 0.93)	Mean change       P-         during intervention       value         period (95% CI)       0.54         0.41 (-1.34 to 2.15)*       0.54         0.07 (-0.79 to 0.93)       0.86         1.64 (-1.76 to 5.05)       0.33         2.11 (-1.79 to 6.00)       0.15*         -3.29 (-9.10 to 2.53)       0.35*         -0.54 (-1.28 to 0.21)       0.17         1.11 (-2.68 to 4.91)       0.95*	Mean change       P-       Mean change         during intervention       value       during intervention         period (95% CI)       0.54       1.66 (-0.61 to 3.93)*         0.41 (-1.34 to 2.15)*       0.54       1.66 (-0.61 to 3.93)*         0.07 (-0.79 to 0.93)       0.86       -0.28 (-1.06 to 0.51)         1.64 (-1.76 to 5.05)       0.33       0.97 (-3.78 to 5.71)         2.11 (-1.79 to 6.00)       0.15*       -1.52 (-8.50 to 5.47)         -3.29 (-9.10 to 2.53)       0.35*       -2.76 (-11.18 to 5.66)         -0.54 (-1.28 to 0.21)       0.17       -0.03 (-1.02 to 0.95)         1.11 (-2.68 to 4.91)       0.95*       1.79 (-2.04 to 5.61)	Mean change during intervention period (95% CI)P- value during intervention period (95% CI)Mean change during intervention period (95% CI)P- value value period (95% CI)P- value value 	Mean change during intervention period (95% CI)       P- value       Group change difference intervention (95% CI)         0.41 (-1.34 to 2.15)*       0.54       1.66 (-0.61 to 3.93)*       0.18       -1.04 (-2.45 to 0.36)*         0.07 (-0.79 to 0.93)       0.86       -0.28 (-1.06 to 0.51)       0.48       -0.35 (-1.48 to 0.78)         1.64 (-1.76 to 5.05)       0.33       0.97 (-3.78 to 5.71)       0.68       -0.67 (-6.43 to 5.07)         2.11 (-1.79 to 6.00)       0.15*       -1.52 (-8.50 to 5.47)       0.41*       -0.26 (-4.20 to 3.68)         -3.29 (-9.10 to 2.53)       0.35*       -2.76 (-11.18 to 5.66)       0.48*       0.53 (-9.51 to 10.56)         -0.54 (-1.28 to 0.21)       0.17       -0.03 (-1.02 to 0.95)       0.86       0.50 (-0.71 to 1.72)         1.11 (-2.68 to 4.91)       0.95*       1.79 (-2.04 to 5.61)       0.27*       -1.46 (-4.07 to 1.16

Table 8. Mean changes in outcome measure between discharge from hospital and 12-week follow-up<sup>a</sup>

a: For all measures except Motion Sensitivity Test, Dizziness Handicap Inventory and Visual Analog Scale, higher values indicate better functioning.

\*: Wilcoxon rank sum test

The patients in the intervention group used the Mitii system once a day 41% of the 84 possible days in the home training period (median: 30 sessions, 25th percentile = 0 sessions, 75th percentile = 49 sessions). The summarized time of the training sessions at home was not associated with outcome when tested by Spearman's rank correlation.

A reduction in training compliance was seen in the period from the first month to the third month of training (Figure 3). When testing with Wilcoxon signed rank test, a significant decrease in compliance was observed from month 2 to month 3 (P<0.001).



Figure 3. Compliance to Mitii home-exercise-program

When study II started, we saw the compliance rate going from a compliance rate of 43% in month 4 to 47% in month 5 when the patients stopped VR in the outpatient clinic (Figure 4).

Figure 4. Compliance in the whole study period



# Results - Study III

The first seven participants randomized to the intervention group participated in the study (Flowchart, Figure 1). The participants represented a wide range of educational levels and former occupations (Table 9) and the age varied from 67 to 86 years (mean  $76 \pm 7.14$ ) (84).

Informant No.	Sex	Age	Education
Participant 1	Female	70 years	Clerk
Participant 2	Female	74 years	Unemployed
Participant 3	Female	70 years	Biologist
Participant 4	Male	86 years	Journalist
Participant 5	Female	81 years	Nurse
Participant 6	Male	67 years	Pianist
Participant 7	Male	81 years	Unemployed

The participants were active persons and spent much time with their families and friends and participated in other social activities. Three of the participants lived with a spouse or partner, and two moved from a house to a flat during the study period. During the interviews, we observed that the participants owned a number of home technologies like computers and mobile phones. The participants were given a 5-page manual presenting the exercises and a frequently asked questions section (84).

#### **Self-efficacy**

The participants in our study showed various indications of high self-efficacy. For example, they contacted us on their own initiative in response to a recruitment ad in a local newspaper. Furthermore, one participant had earlier taken the initiative by being enrolled in a yoga class and another participant had a disappointing meeting with a physiotherapist and took matters into his/her own hands. The participants had a high belief in their ability to complete tasks and/or reach goals (84).

#### **Controlled motivation**

Our preconception before the study was that Mitii would motivate the participants to exercise and thereby increase exercise compliance because the physiotherapists could observe the patients' exercise times and goals within Mitii should motivate them. The study showed that most of the participants felt comfort with being monitored. Although initially motivated and adequately supported by the monitoring, the interviews also revealed that the exercise group wished for social support because four of seven participants missed the contact with the physiotherapists, hence missing opportunities for feedback, when exercising at home (84).

One patient found that the hospital training was not intense enough and thought that she might do better at home with Mitii. On the other hand, five of the seven participants found the exercises with Mitii monotonous and demotivating and asked for greater variety when exercising at home.

The post-interviews showed that only three participants out of seven felt that Mitii met their expectations. Thus, although initial motivation was strong, the intervention should have offered more support from physiotherapists and fellow patients to sustain motivation and thereby increase compliance (84).

#### **Self-determination**

The findings in the post-interviews in particular showed indications that the selfdetermination could have been better before and during the intervention; however, one participant experienced better comprehensibility of the disease after the rehabilitation period (84).

In an introductory video played prior to each exercise, a physiotherapist demonstrated how the exercise was carried out, but one patient felt that these introductions should be more detailed. The participants complained that they received only a "well done" after every exercise, but needed more elaborate feedback about the quality of their performance.

#### Acceptance of the technology

The participants were no strangers to technology and owned a number of home technologies (84). One participant used his computer for his writing, whereas others used the computer for email and browsing the Internet. During the study, the complete study intervention group (n=32) made use of telephone support on only five occasions, and the most common problems were because of Adobe Flash Player updates, unstable internet connections and flat mouse batteries.

However, it turned out that four of the seven could have used more guidance and training in basic IT, but despite this, the participants were generally capable of using the technology, and age-related computer illiteracy did not seem to be a determining factor (84).

More critically, some functional issues were found in the use of the Mitii system. First of all the system did not support the full range of VR training. During the first weeks of the intervention, the system could not display the graphical screen interface in full-screen mode, and the Mitii system exercises were displayed on a smaller, 15-inch area of the computer screen. The limited active screen size especially affected exercises with side-to-side head movements, where the participants made movements of approximately only 20 to 25° when using Mitii (rather than the intended 45°) (106). Secondly the functional issue was that dynamic exercises, e.g. walking while rotating the head, were not possible with Mitii.

Although Mitii did support the correct performance of the majority of the VR exercises, the above-mentioned issues may have contributed to the modest compliance level (84).

### Discussion

#### Functional level after completion of 4 months of outpatient training

Both the intervention and control group showed significant improvements after 16 weeks of rehabilitation in an outpatient clinic. Thus, our results confirm the conclusions of other studies, that VR has an effect on patients with vestibular dysfunction (20). The study showed that computer-assisted training and printed instructions were equally effective, and it seems that home exercises are challenging to optimize.

In no previous studies has a comparison been made between printed and computerassisted home training programs among elderly vestibular patients. The closest approximation is the study by Pavlou (107) comparing a vestibular exercise program (both clinic training and printed instructions at home) with a simulator-based regime (therapeutic stimulation at the clinic and video stimulation at home). Pavlou found that exercises both with and without simulator-based exposure improve subjective symptoms, postural stability and emotional status in chronic vestibular patients (108). The simplest explanation for the missing effect is that printed instructions are as effective as an exercise program with Mitii. Another explanation could be the frequency of patient contacts and program adjustments in the rehabilitation period. We contacted patients only once a month, confronted them with data generated by the Mitii system to show their number of training sessions and total exercise times, and adjusted the program to the patient's present functional level. This was done to challenge and motivate the patients.

In another study by Hansson (25)including vestibular patients with a median age of 77 years, a statistically significant difference between a sham group and an intervention group receiving group sessions in a physiotherapy center for 6 weeks was found. Statistically significant differences were found between the two groups, comparing the results at baseline and after 6 weeks on the One Leg Stand Test with eyes closed. After 3 months, the difference between the groups was statistically significant, with an improvement in the intervention group and deterioration in the control group.

Maybe Hansson results could tell us something about the importance of outpatient training since both intervention *and* control groups showed an improvement after 4 months of clinic training.

#### Functional level 3 months after completion of outpatient training

We did not find any significant difference in functional levels 3 months after end of hospital training between patients instructed in a printed home training program and those taking part in a computer-assisted training program. It seems as if elderly patients trained in an outpatient clinic for vestibular dysfunction are able to maintain functional level for up to 3 months. These results confirm Yardley (32), who included patients older than 60 years with vestibular dysfunction. At the 6-month follow-up, Yardley found that improvement obtained during a 3-month home exercise program delivered by nurses was maintained in the intervention group. Unfortunately, measurement of the outcome measures in the control group receiving usual medical care was not presented, perhaps because the design was a crossover (the controls were instructed in home exercises after 3 months). Perhaps our study did not show any effect because the follow-up period (after end of training in outpatient clinic) was not long enough to show the effect of computer-assisted exercising on functional level. Maybe a follow-up time of 1 year could identify whether Mitii could increase compliance in the long term. This would be relevant with regard to the elderly vestibular patients who may need lifelong training (33).

#### Compliance

The compliance peaked between 1 and 2 months of training and decreased in the rest of the rehabilitation period, including the 3 months of follow-up, with a small peak in month 5. This is supported by prior studies that found that compliance was highest at the beginning of a period of training and decreased over time (36;108).

In one of the few VR studies measuring compliance, Yardley (109) compared two intervention groups with a waiting list control group. The study showed that reported compliance levels were low and strongly related to outcome, and that further research is needed to determine whether therapist support in VR interventions might result in better compliance and larger treatment effects.

The simplest explanation for the small peak in month 5 could be random variation or it could be the finishing of the patients hospital training, which meant that patients

had more time and energy to exercise with Mitii. Unfortunately, the compliance decreased the following months, indicating that Mitii could not motivate in the long run.

As mentioned before, we observed a significant improvement in both groups in spite of the moderate overall compliance rate of 49% (4 months of outpatient training + 3 months' follow-up). Maybe the observed improvement combined with the moderate level of compliance reflects the normal history of disease in this type of patients – that the time period itself had improved the patient's functional level. On the other hand, we found a great variation in compliance rates in computer-based intervention studies focusing on the elderly. Gschwind et al. (59) found a low compliance level (14%) with an in-home intervention with Microsoft Kinect, and Schoene et al. (58) found a high compliance level of 92% with another in-home intervention with videogame technology.

#### Self-efficacy

Overall, the participants had a high belief in their ability to complete tasks and/or reach goals. Four of the seven participants, for example, contacted us on their own initiative in response to a recruitment ad in a local newspaper, indicating high self-efficacy. Among the elderly, self-efficacy predicts exercise compliance, and the elderly exhibit less exercise self-efficacy than other age groups (103;110). The participants in the present study had high self-efficacy, and therefore, lack of coaching may not be the reason for their modest exercise compliance.

#### The outpatient training is considered necessary

Most of the participants found that they missed social interaction with other patients when using Mitii. This is a finding similar to the one of Gajadhar et al.(111), who have studied older adults' experiences with different forms of co-play and confirmed the importance of social interaction and cooperative play in digital gaming in increasing enjoyment. A study by Aarhus et al. (112) concluded that in game-based exercising in groups in a setup in which each patient plays the game at the same time, the setup should allow the group to watch the active gamer as an audience. Perhaps computer-assisted training could be provided with a kind of split screen, so several of the elderly participants could exercise simultaneously, or they could be divided into competitive teams in which each participant collects points for the team in order to provide common social responsibility when exercising. Such social game elements may also increase motivation.

Most informants asked for closer contact with the physiotherapist and expressed a need for feedback. The study by Baert et al. showed that the influence of professional advice is important, in terms of compliance, especially when a health care provider is advised to engage in the patients' exercise with support (47). Monthly adjustments to the programme did not seem to keep up with the participants' expectations of the exercises. Most participants expressed comfort with being monitored and felt that registering their exercise times and exercise duration created security in their daily lives. It is possible to cheat the Mitii system, because we had no quality evaluation of the exercises done within the system. Even though VR programs may be performed at home, it is still necessary to allocate specialist/physiotherapist time to the intervention to assure that the patients execute the exercises correctly.

#### The computer training program

This study has shown that the system used for vestibular rehabilitation, Mitii, has some limitations, which may affect exercise compliance. Systems like Nintendo Wii, Xbox Kinect and Mitii are dependent on participants standing in front of a webcam or sensor, which limits the option of dynamic exercises. Another limitation is the small screen size, as some of the head movement exercises need up to a 120-inch screen (given a specific distance between trainee and screen), although a projector may be used with these consoles. Compared with training games for the Nintendo Wii, Mitii has the advantage that the program may be adjusted from the hospital, and that Mitii data (exercise times and exercise duration) are stored and may be visualized on a chart by health care professionals. In addition, it is possible to change the variety of exercises with regard to speed and duration.

We continue to believe that assisted technology consists of some elements that support participants' vestibular rehabilitation process, but the system should address the challenge that only a part of the rehabilitation programme available at the clinic is transferable, for example, clinical activities such as walking on boards are hard to incorporate. In addition, it is challenging to incorporate dynamic exercises, which is important since it is the highest progression of vestibular-ocular-reflex training. Technology in rehabilitation should in the future include more patient information and education about vestibular dysfunction and more often follow-up contact by health

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staff. In addition, the technology should include the possibility to do group exercising, perhaps together with a therapist.

#### The vestibular dysfunction patients

In this study, we had to examine 329 patients with dizziness to find 63 patients with vestibular dysfunction. It does not seem to harmonize with the literature, which has shown a prevalence of vestibular dysfunction of 49.4%, 68.7% and 84.8% at ages 60–69, 70–79 and 80 and over, respectively, among American citizens aged 40 years or older with balance problems (14). However, Agrawal (14) diagnosed the patients with vestibular dysfunction by only one test, the modified Romberg test condition four, in which the participants stand unassisted on a foam padded surface with eyes closed, making the diagnostic procedure biased.

Another explanation for the few vestibular patients could be that the patients do not take their disease seriously and therefore have not contacted their general practitioner with their symptoms. Another explanation could be that general practitioners in general are not aware of the vestibular dysfunction diagnosis and/or the existing treatment, e.g., vestibular rehabilitation.

#### Outcome

The outcome measures chosen to assess the efficacy of vestibular rehabilitation were selected from similar studies (25;32;113;114). The big challenge when studying this group of patients is the heterogeneity of the condition, with varied symptoms and clinical signs (e.g. abnormal vestibular-ocular-reflex, abnormal gaze-induced nystagmus test and/or positive vestibular evoked myogenic potentials test). Therefore, it is essential to use several outcome measures to encompass the complexity of vestibular dysfunction.

### Strengths and limitations

#### Strengths

The study has several strengths. First, we mixed qualitative and quantitative methods that have the potential to ensure good scientific practice by enhancing the validity of methods and research findings (115). Mixed method studies can be used to gain a more complete picture and a deeper understanding of the investigated phenomenon by

relating complementary findings to each other which result from the use of methods from the different methodological traditions of qualitative and quantitative research. Randomization allocation was adequately concealed, and participants were comparable at baseline, thus randomization appeared to be successful. Data on outcome were recorded prospectively and collected by blinded research assistants unaware of allocation status.

#### Limitations

Areas of weakness in the study are the relative small study sample and therefore the risk of type II errors. If we, for example, calculated power (116) on the basis of the mean changes from baseline to 4 months of vestibular rehabilitation on the DHI scale, the SD for the mean change and the sample size, we only get a power of 24 %. This indicates that there is a 76% risk of a type II error – the probability of accepting no difference between the two groups although a difference is the true state. This risk could be reduced including more patients – on the other hand, it is probably not clinically relevant if the difference cannot be shown with 30 patients in each group. Jacobson et al. (94) concluded that the Minimal Relevant Difference (MIREDIF) would have to be at least 18 point on the DHI scale. In our study we found that the intervention group in study I only improved 9.93 on the DHI scale.

High mean scores were found in the groups at baseline on the Dynamic Gait Index ( $\approx$  16 out of a possible max score on 24), on the Motion Sensitivity Test ( $\approx$  26 out of a possible max score on 128) and on the One Leg Stand Test ( $\approx$  9 s out of 30). Maybe the long clinical investigation of the patients and the natural disease history of the patients reduced their dizziness before the patients started the rehabilitation period in this project. A better (psychological) outcome measure could therefore be the Falls Efficacy Scale (117) to measure the fear of falling among the patients, which would be expected to be reduced over a longer time period. A possible bias is that the Visual Analog Scale was not validated in patients with vestibular dysfunction and with regard to the question "How much dizziness have you felt within the last 24 hours." We do not know about the test-retest reliability of the scale either. In addition, several of our outcome measures were not validated in vestibular dysfunction patients

In our qualitative part of the study, there is a possible risk of bias since the research question was changed in the middle of the study because it appeared that the first part of the question: "To investigate possible reasons for effect or lack of effect of the computer program" was not possible to answer on the basis of the collected data material.

Another possible risk of bias was that the project physiotherapist (first author) held all the interviews, and afterward coded all the transcribed interviews. The participants may have been reticent about expressing any other than positive comments, for fear of upsetting the researcher, causing offence or reprisal. To reduce the risk of confirmation bias, we could have used an independent interviewer and could have employed independent coders of the material to insure high reliability of the interpretations. On the other hand it could be a strength that the interviewer was well informed about the study and was able to ask probing questions according to the aim of the study. In addition, answers from the participants not only confirmed the aim, e.g., they expressed closer contact and greater variation in the exercises. The sample mostly consisted of highly active and involved people, and a different participant selection process might have been beneficial to avoid possible selection bias. We sampled the first seven participants included in the project, but we could have selected a greater variety of participants, for example, with regard to age, extent of comorbidity, or mental health. On the other hand, we minimized selection bias by continuously recruiting the first seven participants in the intervention groups The study design could have been supplemented with observations of older adults to increase the validity of the study since there exists a recognized source of bias in interviews, referred to as a 'social desirability set,' which means that in many spheres of social life there are socially desirable ways of behaving and, consciously or unconsciously, individuals will tend to respond in that way, although in real life they

As mentioned before in the thesis, another limitation is the fact that the participants were a very inhomogeneous group of vestibular patients since they had a lot of vestibular limitations, e.g., abnormal vestibular-ocular-reflex, abnormal gaze-induced nystagmus test and/or positive vestibular evoked myogenic potentials test. We tried to meet this challenge by block-randomizing the patients according to type of vestibular

might behave differently.

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damage to make the two groups comparable, but still a majority of patients had central vestibular dysfunction, making them challenging to rehabilitate.

# Conclusion

The conclusions of this thesis are that:

- A computer-assisted program to support home training for elderly patients with vestibular dysfunction did not improve the vestibular rehabilitation more than printed instructions.
- Both groups maintained the obtained functional level, level of dizziness and quality of life 3 months after discharge from the outpatient clinic, but no further effect was found for computer-assisted training in a home setting compared with printed instructions

Based on the analyses of the interviews, we argue that the explanation for the modest level of compliance observed in this study is that patients

May not be due to resistance to technology or low self-efficacy. It seems that
the patients were insufficiently motivated by the technology and requested for
a greater variety of exercise speed and duration, or new exercises in Mitii.
The participants' desire for a deeper understanding of the purpose of each
element of the training program calls for supplying information (in Mitii) on
the parts of the vestibular system addressed by the training. In addition,, the
participants asked for more interaction with the physiotherapist regarding
their performance, and they missed the social contact with other patients

The overall conclusion of the present study is that assistive technology does not improve the results of vestibular rehabilitation in the described settings. However it may motivate patients to a higher compliance rate when accompanied by a closer contact to a professional physiotherapist and maybe other patients.

# Perspectives

Although sufficient evidence to determine the benefits of the use of assisted technology in vestibular rehabilitation was not obtained, we still think that computer technology may have a place in future rehabilitation of patients with vestibular damage. Based on the results of this thesis, focus on the following issues may be recommended in the future:

- To make real-time training with a physiotherapist since the Mitii itself could not motivate the patients to rehabilitation in the long run. Virtual rehabilitation based on Microsoft Kinnect for Windows that works with Skype has already been developed and may be integrated in Mitii. The physiotherapist has then the opportunity to guide the patients through the rehabilitation exercises and correct movements in real time, making it possible for the therapist to see whether patients have completed their rehabilitation. Also the fact that the patient has an appointment with the therapist online could motivate the patient and increase compliance
- The patients with vestibular dysfunction are a very inhomogeneous group since they may have a lot of vestibular limitations, e.g., nystagmus and reduced vestibular-ocular-reflex, subjective visual vertical and/or smooth pursuit eye movements. In future studies, the patients should perhaps be categorized into subgroups to be trained more individually, making it possible to target the assisted technology
- Several of the outcome measures in this study showed possible ceiling and/or floor effect. Future studies should evaluate possible floor and ceiling effects internal consistency reliability with Bland-Altman plots according to outcome measures and vestibular dysfunction patients. Studies should focus on developing existing or new outcome measures that are sensitive enough to measure changes in data among vestibular patients
- RCT studies involving assisted technology in home exercises should comprise a control group without active training to determine whether the observed effect in the groups comprises the natural history of disease among the included patients. Unfortunately, the use of non-active group will raise ethical

issues because to these patients are often at high risk of falling. The studies should also include a longer follow-up period since the effect of computerassisted training may be seen later in the period after end of rehabilitation due to a decrease in motivational level among the patients. The studies should measure exercise compliance in both the computer-assisted group and the group with printed exercise instructions to clarify any difference

• Future qualitative studies aiming to investigate participant experience of assistive technology interventions should include other methods like observations to validate the participant statements from the interviews and/or include semistructured interviews of the participants' relatives. These studies could focus more on investigation of "motivation" in rehabilitation when constructing the interview guide to gain more knowledge about this term in relation to vestibular rehabilitation

# **English summary**

Vestibular dysfunction is a common cause of dizziness and leads to an increased incidence of fall among older adults. There is statistically significant evidence to support the use of vestibular rehabilitation (VR) for people with vestibular dysfunction in order to reduce dizziness and improve balance and mobility. Nevertheless, when implementing the rehabilitation schemes in daily practice and outside a supervised, clinical context such as in private homes, VR initiatives face a unique set of challenges aggravated by a number of issues. These are 1) VR in itself may demotivate physical activity since the patient is encouraged to move into positions that provoke symptoms (e.g. dizziness, impaired equilibrium) and 2) the major part of VR schemes is performed in the older adult's home without motivation and feedback from a physiotherapist. Computer-supported rehabilitation may help to maintain a high level of motivation to the hard work of rehabilitation and thereby increase the effect of *home training*, but no controlled trials in older patients with vestibular dysfunction have been published to examine this question.

The overall purpose of this thesis is to evaluate the effect of a computer program to support exercises in vestibular rehabilitation at home. The thesis consists of three papers with the following aims: Study I is a randomized controlled trail in 63 patients aged + 65 years recruited from the Fall Clinic, Geriatric Department, Aarhus University Hospital. All patients ( $\geq$ 65 years) are diagnosed with stable peripheral, central and/or mixed vestibular dysfunction. Two different supporting home training programs were compared (computer-assisted training versus printed instructions) as a supplement to VR in an outpatient clinic. In study II we examined if the obtained functional level was better preserved after the end of the outpatient course of VR by continuing the computer-assisted training than by the printed instructions alone. The aim of study III was to elucidate reasons for non-compliance to the computer training program. This was done by seven interviews of patients from the intervention group at the beginning and at the end of the rehabilitation period.

In the thesis, the following conclusions were reached:

Study I: Both intervention and control group showed significant improvements at the end of the outpatient rehabilitation period. A computer-assisted program to support home training for elderly patients with vestibular dysfunction did not improve the vestibular rehabilitation more than printed instructions.

Study II: Elderly patients with vestibular dysfunction who had been trained by specialized physiotherapists in an outpatient clinic seem to maintain their functional level 3 months later. No further effect was found of a computer-assisted training program compared with printed instructions alone.

Study III: The explanation for the absence of the effects observed in study I and study II may not be due to resistance to technology or low self-efficacy. On the contrary, it appears that the patients have been insufficiently motivated by the computer program. The participants requested a greater variety of exercises in the computer program with regard to speed and duration, or new exercises. The participants' desire for a deeper understanding of the purpose of each element of the training program calls for information on the part of the vestibular system addressed by the training. In addition, the participants asked for more personal feedback from the physiotherapist regarding their performance. They also missed the social contact with other patients. The overall conclusion of the present study is that assistive technology does not improve the results of vestibular rehabilitation in the described settings. However it may motivate patients to a higher compliance rate when accompanied by a closer contact to a professional physiotherapist and maybe other patients.

# Dansk resumé

Vestibulær dysfunktion er en hyppigt forekommende årsag til svimmelhed, der fører til øget forekomst af fald blandt ældre. Der er evidens for at anvende vestibulær rehabilitering (VR) til patienter med vestibulær dysfunktion for at reducere svimmelhed og forbedre balance og mobilitet. Alligevel er der en række udfordringer når VR skal implementeres i daglige praksis og i private hjem udenfor en superviseret klinisk kontekst. Disse udfordringer er at 1) VR i sig selv kan demotivere patienten, da patienten i VR opfordres til at træne i positioner, der fremprovokerer symptomer (f.eks. svimmelhed, nedsat balance) og 2) en stor del at træningen foregår i patientens hjem uden en fysioterapeut til at motivere og hjælpe med korrigering af øvelserne. Computer-støttet rehabilitering kan måske hjælpe til at opretholde en høj grad af motivation i rehabiliteringen og derigennem øge effekten af træningen, men endnu har ingen resultater fra klinisk kontrollerede forsøg dog vist, at dette gælder for ældre patienter med vestibulær dysfunction.

Det overordnede formål med denne afhandling er at evaluere effekten af computerstøttet hjemmetræning i VR.

Afhandlingen består af tre studier som har følgende formål: Studie I er et klinisk randomiseret kontrolleret forsøg med 63 patienter +65 år rekrutteret fra Fald Klinikken, Geriatrisk afdeling, Aarhus Universitets Hospital. Alle patienterne (≥65 år) blev diagnosticeret med stabil perifer, central og/eller blandet vestibulær dysfunktion. To forskellige hjemmetrænings programmer blev sammenlignet (computerstøttet versus printede instruktioner på papir) som et supplement til VR i klinikken. I studie II undersøgte vi, om det opnåede funktionsniveau efter afslutning på genoptræningen i klinikken bedst kunne opretholdes ved at fortsætte med det computer støttede program eller med de printede instruktioner. Formålet med studie III var at afdække årsager til non-compliance i forhold til det computerstøttende program. Dette blev undersøgt via syv interviews med patienter fra interventionsgruppen i starten og i slutningen af genoptræningsperioden.

I afhandlingen kom vi frem til følgende konklusioner:

Studie I: Både interventions- og kontrolgruppen forbedrede sig signifikant gennem rehabiliteringsperioden. Computer programmet til støtte af hjemmetræning forbedrede dog ikke den vestibulære rehabilitering mere end de printede instruktioner. Studie II: Ældre patienter med vestibulær dysfunktion som er blevet trænet af specialiserede fysioterapeuter i klinikken kan bibeholde deres funktionsniveau tre måneder efter afslutning på vestibulær rehabilitering på sygehuset. Der ses dog ikke bedre effekt af computerprogrammet til støtte af hjemmetræningen sammenlignet med printede instruktioner.

Studie III: Forklaringen på den manglende effekt af computerprogrammet i studie I og studie II var ikke på grund af modstand mod teknologi eller lav self-efficacy. Det så ikke ud til at patienter blev motiverede af computerprogrammet. Deltagerne gav udtryk for et behov for et bredere udvalg af øvelser i computerprogrammet herunder oftere justeringer af øvelser med hensyn til hastighed og varighed eller helt nye øvelser. Derudover udtrykte deltagerne ønske om at opnå en dybere forståelse af formålet med hver enkelt øvelse samt information om hvilken del af det vestibulære system der blev trænet. Udover dette ønskede deltagerne mere personligt feedback fra fysioterapeuterne vedrørende kvaliteten af deres udførelse af øvelserne samt udtrykte et behov for social kontakt med andre patienter.

Den overordnede konklusion af det præsenterede studie er at computerstøttende teknologi ikke forbedrer vestibulær rehabilitering under de beskrevne omstændigheder. Dog kunne computerprogrammet måske motivere patienterne til en øget compliance med en samtidig tættere kontakt til fysioterapeuter eller andre patienter.

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