UHASSELT

KNOWLEDGE IN ACTION

Faculteit Geneeskunde en Levenswetenschappen

master in de revalidatiewetenschappen en de kinesitherapie

Masterthesis

The prevalence of BPPV in a residential care centre and the effectiveness and impact of treatment

Anouk Bauduin
Enya Smeulders

Scriptie ingediend tot het behalen van de graad van master in de revalidatiewetenschappen en de kinesitherapie, afstudeerrichting revalidatiewetenschappen en kinesitherapie bij kinderen

PROMOTOR :
dr. Joke SPILDOOREN

2017
2018

UHASSELT
KNOWLEDGE IN ACTION

www.uhasselt.be
Universiteit Hasselt
Campus Hasselt:
Martelarenlaan 42 | 3500 Hasselt
Campus Diepenbeek:
Agoralaan Gebouw D | 3590 Diepenbeek

UHASSELT

KNOWLEDGE IN ACTION

Faculteit Geneeskunde en Levenswetenschappen

master in de revalidatiewetenschappen en de kinesitherapie

Masterthesis

The prevalence of BPPV in a residential care centre and the effectiveness and impact of treatment

Anouk Bauduin
Enya Smeulders

Scriptie ingediend tot het behalen van de graad van master in de revalidatiewetenschappen en de kinesitherapie, afstudeerrichting revalidatiewetenschappen en kinesitherapie bij kinderen

PROMOTOR :

dr. Joke SPILDOOREN

ACKNOWLEDGEMENT

We would like to express our special thanks of gratefulness to everyone who has contributed to and has assisted us through this master thesis.

First, we would like to thank our supervisor Dr. Spildooren Joke, for her advice, support and guidance throughout this study.

We would also like to thank the director, physical therapists and nurses of the residential care centre Sint-Elisabeth (Hasselt), for their hospitality and the use of their accommodation.

Finally, we would like to thank the residents who contributed to our study. This study could not have been possible without their participation.

Canadastraat 37 (3680 Neeroeteren),
Alsembergstraat 13 (3001 Heverlee),
05/06/2018 B. A., S. E.

RESEARCH CONTEXT

This master thesis is part of the research domain of our promoter Dr. Joke Spildooren, which is mainly focused on fall incidents and gait problems in a frail older population in residential care centres. Therefore, this study is situated within the research domain 'Geriatric Rehabilitation'.

Part one of this master thesis consisted of a literature study to evaluate the prevalence of BPPV among older adults and the influence of this condition on function, activity and participation. The conclusion of this first part was that the prevalence of BPPV was higher among older adults with dizziness than without dizziness. These people with BPPV had a higher risk of hypertension, diabetes, and osteoporosis/osteopenia. They also had an increased risk of falling, anxiety disorders, depression, fractures, a reduced quality of life and more impairments in activities of daily living. However, not all studies confirmed those findings, because older adults without BPPV can also experience these consequences due to age-related declines.

The aim of part two was to investigate the prevalence of BPPV in a residential care centre and to evaluate the effectiveness and impact of treatment. This led to our research question: "what is the prevalence of BPPV in a residential care centre and the effectiveness and impact of treatment?". Their functioning was also evaluated and their results were compared with older adults without BPPV. Of the people with this condition, a pre-test and post-test was executed and these results were compared.

This part is carried out by two students, based on an existing research protocol. The recruitment of participants, data acquisition, data processing and the academic writing process was performed by the students together, under the supervision of our promoter.

TABLE OF CONTENTS

1. ABSTRACT

Background: The prevalence and impact of BPPV in residential care centres are not investigated so far. The current prevalence of BPPV among a general population of older adults is estimated at ±10%. There could be a relationship between BPPV and a high fall incidence. An increased fall incidence is detected in residential care centres, so there could be a suspicion of an increased prevalence of BPPV in this population. Therefore, a rapid diagnosis and treatment of BPPV in this population is necessary.

Objectives: The aim of the first part of this study was to determine the prevalence of BPPV in a residential care centre and the impact on dizziness, fall risk, fear of falling, balance, depression, cognition, age and medication. The second part was developed to evaluate the effectiveness and impact of treatment.

Methods: The residents were divided into two groups: the BPPV and non-BPPV group. Their results on questionnaires and tests were compared. The participants, who were treated for BPPV, completed a pre- and post-test.

Participants: Inclusion criteria: 75 years or older, being institutionalized in a residential care centre, being able to understand simple instructions, sufficient mobility, and willing to participate. Exclusion criteria: diagnosis of a progressive neurological disorder, contraindications for the Dix-Hallpike manoeuvre, and recovering from a neurological or orthopaedic incident.

Measurements: Vestibular diagnostic tests (Dix-Hallpike manoeuvre, side-lying test, supine roll test) were performed first. The following questionnaires and balance tests were evaluated after: DHI, GDS-15, MMSE, mFES-I, 4TBS, TUG, 360° turn, sway, and 10MWT. For treatment, the Epley manoeuvre, the Barbecue roll manoeuvre or Brandt-Daroff exercises were used.

Results: Part I – a prevalence of 17% was found among older adults in a residential care centre. Statistically significant differences were found between groups for the DHI, GDS-15 and number of fall incidents. Part II – significant improvements after treatment were found in only two parameters of the sway.

Conclusion: Further research is necessary to increase the power of a study on this topic.

2. INTRODUCTION

Dizziness is a common complaint in older adults. According to Kollen, Frandin, Moller M., Olsen, and Moller C. (2012); Peluso, Quintana, and Ganança (2016); van der Zaag-Loonen, van Leeuwen, Bruintjes, and van Munster (2015), the prevalence of vertigo among this older population is respectively 23%, 61.4% and 36%.

There are several known causes for dizziness; Meniere's disease, heart diseases, infections of the inner ear and side effects from medication (Parham & Kuchel, 2016). However, the most often explanation is Benign Paroxysmal Positional Vertigo (BPPV). Among a general population older than 65 years, the prevalence of this disorder ranged between nine percent and eleven percent (Kollen et al., 2012; Oghalai, Manolidis, Barth, Stewart, & Jenkins, 2004; Yetiser & Ince, 2015; Zur, Berner, & Carmeli, 2006). In patients who have complaints of dizziness, this number is logically higher, namely 22% to 66% (Chau, Menant, Hubner, Lord, & Migliaccio, 2015; Ekvall Hansson, Mansson, & Hakansson, 2005; Gazzola, Ganança F., Aratani, Perracini, & Ganança M., 2006; Krishna T., Singh, Krishna J., Rakesh, & Sree, 2015; Lüscher, Theilgaard & Edholm, 2014; Saxena & Prabhakar, 2013; van der Zaag-Loonen et al., 2015; van Leeuwen & Bruintjes, 2014; von Brevern et al., 2007)

The vestibular system is located in the inner ear and consists of the utricle, saccule and three semicircular canals (i.e. posterior, anterior and horizontal). These canals react to rotational movements of the head. The fragments that are embedded in the utricle are called otoconia. These consist of organic components and calciumcarbonate. BPPV is an otological condition, in which these fragments of utricular otoconia are shifting into one or more semicircular canals resulting in a displacement of the cupula. The cupula is a gelatinous structure that moves as a reaction to movement of the endolymph fluid in the corresponding semicircular canal. This displacement can trigger symptoms of vertigo. There are two types: canalithiasis (i.e. where the displaced otoconia are located in one or more semicircular canals) and cupulolithiasis (i.e. the fragments adhere to the cupula).

This disorder can have several causes, for example a head trauma, medication, prolonged bedrest or it can be idiopathic (Parham & Kuchel, 2016). Unfortunately, in older adults, this feature is commonly under diagnosed or misdiagnosed by primary care clinicians and geriatricians (Tuunainen et al., 2011). A possible explanation could be that the history of BPPV is not always typical, especially in the older population. This could be due to the fact that older people make less head movements whereby less symptoms are provoked. Therefore, a correct diagnosis can be missed (Norre, 1995).

The population that does experience vertigo has more restrictions on their participation level due to this complaint (Mueller et al., 2014). In addition, their symptoms limit activities of daily living in patients older than 80 with a percentage of 50 according to Jonsson, Sixt, Landahl, and Rosenhall (2004), which is very alarming in this population. Since BPPV can have an impact on quality of life, fall incidence and therefore on fear of falling, this can result in a decrease of their mobility (Jorstad, Hauer, & Lamb, 2005). If the prevalence is known in this population, caregivers can be more aware of the possibility that a resident might have BPPV. An expeditious diagnosis is important, so a correct treatment can be performed and further consequences, like a fall, can be precluded.

The prevalence of BPPV among older people living in residential care centres is not yet investigated. In this population, there could be a higher prevalence of this condition due to the fact that the risk of BPPV increases with age (von Brevern et al., 2007), the number of medications (Parham & Kuchel, 2016) and the degree of prolonged bedrest (Cakir B., Ercan, Cakir Z., Civelek, & Turgut, 2006). Finally, people living in a residential care centre have a 50% increased fall risk in comparison to older adults living at home (Masud & Morris, 2001).

BPPV is easily treatable, with the standard treatment being a canalith repositioning manoeuvre (e.g. Epley manoeuvre or Barbecue roll manoeuvre). According to Hilton and Pinder (2014), the Epley manoeuvre is a safe and effective treatment for this condition.

This study consists of two parts. First, the prevalence of BPPV was investigated among older adults living in a residential care centre. This was examined with the Dix-Hallpike manoeuvre or the side lying test and the supine roll test. The influence of dizziness, fall risk, fear of falling, balance, depression, cognition, age and medication was examined and compared between the BPPV and non-BPPV group. Second, among the participants diagnosed with BPPV, the willingness to be treated and the effectiveness and impact of treatment was studied.

3. METHODS

3.1. Medical ethics

This study has been approved by the ethics committee of UHasselt and UZ Leuven, given in document 1 in the appendix. The participants had to sign an informed consent before they could participate in the study.

3.2. Selection and description of participants

The recruitment of participants took place at the residential care centre, St. Elisabeth in Hasselt, Belgium. Inclusion criteria were: (1) 75 years or older; (2) being institutionalized in a residential care centre for at least three months; (3) being able to understand and follow simple instructions, (4) sufficient mobility to perform the diagnostic tests with the support of maximum three persons; (5) willing to participate in the research. Exclusion criteria for this study were the following: (1) a diagnosis of a progressive neurological disorder (such as amyotrophic lateral sclerosis) that results in a rapid decline within three months; (2) contraindications for the implementation of the Dix-Hallpike manoeuvre (e.g. a high level of anxiety, extensive cervical arthrosis or insufficient cervical mobility); (3) older adults that are recovering from a neurological or orthopaedic incident (such as a stroke or a hip- or knee replacement). The main characteristics and the results of the participants are given in supplementary table 1 in the appendix.

3.3. Procedure

In the first part of the study, the vestibular diagnostic tests were performed in the morning: the Dix-Hallpike manoeuvre (i.e. posterior and anterior canal - Dix & Hallpike, 1952) and the supine roll test (i.e. horizontal canal - McClure, 1985). In case of extensive thoracal kyphosis, the side lying test (Cohen, 2004) was performed instead of the Dix-Hallpike manoevre. To avoid visual fixation, Frenzel glasses were used during these tests. Both sides were evaluated. A positive diagnosis was noted if the patient showed a nystagmus, whether or not accompanied by dizziness. The

participants who were tested the same day had a visit in their room for an interview in the afternoon on the following questionnaires: Mini Mental State Questionnaire (MMSE - Folstein M., Folstein S., & McHugh, 1975), Geriatric Depression Scale 15 (GDS-15 - Yesavage et al., 1982), Dizziness Handicap Inventory (DHI - Jacobson & Newman, 1990), and the Fall Efficacy Scale International (FES-I - Yardley et al., 2005). Their age, gender, medication (dietary supplements and vitamins excluded, supplementary table 2), number of falls in the past year and their functional ambulation category (FAC - Holden, Gill, Magliozzi, Nathan, & Piehl-Baker, 1984) were noted as well.

The influence of medication on the vestibular system, fall risk, depression and cognition was also investigated. The following scores were given for the frequency of the previously given side effects: very rare (1), rare (2), sometimes/possible (3), often (4), very often (5). The sum of the scores for each side effect are given in supplementary table 3 in the appendix.

- **Mini Mental State Examination:** a questionnaire for screening cognitive impairments in older adults. This questionnaire consists of 11 questions with a total score of 30. A low score on the MMSE corresponds with a low cognitive level.

- **Geriatric Depression Scale-15:** this questionnaire screens for depression and has been specifically developed for the older adults. The questions of the GDS are part of a nominal scale (yes/no), with a maximum score of 15. The GDS-15 can be interpreted as follows: not depressed (score 0-4), mild depressed (score 5-10), certainly depressed (score 11+).

- **Dizziness Handicap Inventory:** the purpose of the DHI is to identify difficulties that a person may be experiencing due to their dizziness. It consists of three subscales (functional, emotional, physical) and is defined by an ordinal scale (always/sometimes/no). These 25 questions can be scored with the following numbers; 0 (no), 2 (sometimes) or 4 (always). The total score can range between

0 and 100. Interpretation: mild handicap (score 16-34), moderate handicap (score 36-52), severe handicap (score 54+).

- **Fall Efficacy Scale International:** the FES-I measures fear of falling during activities of daily life and social activities. It consists of 16 items, with a score from 1 to 4 per item (1 = not concerned, 2 = a little concerned, 3 = fairly concerned, 4 = very concerned). The questions of the FES-I are ordinal. The total score is calculated by summing the scores on the 16 questions; the minimum sum score is 16, the maximum sum score is 64. The higher the score, the greater the fear of falling. The FES-I was modified since a number of questions were not applicable in this population (e.g. activities such as cooking and cleaning). This modified version with the excluded questions is given in figure 3 in the appendix.
- **Functional Ambulation Categories:** the FAC is used to describe the degree of independent walking. The score ranges from 0 to 5 (0 = no or non-functional ambulation, 1 = dependent level II, 2 = dependent level III, 3 = supervision, 4 = independently limited, 5 = independently unlimited).

The primary outcome measures of this part consist of the result on the vestibular diagnostic tests, the scores on the questionnaires, gender and age. The secondary outcome measures were fall incidence in the past year and the number of medications.

In the second part of the study, persons with BPPV and willing to be treated, performed additional balance tests before and after treatment, namely: Four Test Balance Scale (4TBS - Rossiter-Fornoff, Wolf, Wolfson, & Buchner, 1995), Timed Up and Go test (TUG - Podsiadlo & Richardson, 1991), 360 degree Turn (Snijders, Haaxma, Hagen, Munneke, & Bloem, 2012), Sway (Feet Together, Eyes Closed, Firm Surface) and the ten meter walking test (10MWT - Collen, Wade, & Bradshaw, 1990). These tests were performed two or three times, and the mean of the scores were used in the results.

These tests were all performed with inertial measurement units (Opal™, APDM's Mobility Lab™, APDM Inc, http://apdm.com) to assess their balance and to objectify these findings. The patients wore sensors on the feet, wrists, sternum and vertebra L5.

- **Four Test Balance Scale:** the participant was asked to maintain four positions in a specific order (parallel position, semi-tandem position, tandem position, unipodal stance on the leg of preference), each for ten seconds. It was allowed to take the position with assistance, however, the test itself was performed independently. The test ended when the participant was unable to maintain a position for ten seconds. The end score was the summation of all achieved seconds (e.g. parallel position for 10 seconds, semi-tandem position for 10 seconds and tandem position for four seconds gives an end score of 24 seconds).

- **Timed Up and Go test:** the participant was instructed to stand up from a chair with a back- and armrest, walk three meters forward, make a 180° turn, walk back three meters and sit down on the chair. A walking aid was allowed to complete the test. The TUG was performed three times. The duration of the entire test and the duration and velocity of the turn were extracted.

- **360-degree turn:** the participant had to perform a 360° turn from standstill. This was executed two times. The of the duration and velocity were noted.

- **Sway:** this test was performed with both feet together, eyes closed and on a firm surface. The participant had to try to maintain this position for 30 seconds. This test was also performed twice. The duration, sway area, velocity and path length were registered.

- **10 Meter Walk Test:** the participant was asked to walk five meters forward, make a 180° turn and to walk back five meters. The time stopped when the participant crossed the indication line. Walking aids were allowed to complete the test. This test was only performed once. The following parameters were extracted: duration, cadence, gait speed, turn duration, turn velocity, number of steps in the turn, stride length and the variability of the stride length.

The primary outcome measures of part two were the following: (1) the willingness to be treated; (2) the effectiveness of the treatment. The secondary outcome measures were the impact on the additional balance tests.

If the resident wanted to be treated in case of a positive result on the diagnostic test, the number of treatments necessary were registered. The treatment consisted of the Epley manoeuvre (i.e. posterior and anterior canal), or the Barbecue Roll manoeuvre (i.e. horizontal canal). These manoeuvres were executed once, or twice if necessary. At least three days were left between two treatments. On the day of treatment, the patients were advised to rest and to make as less head movements as possible. Patients with persistent complaints after two treatments were given Brandt-Daroff exercises. After at least two days after the last treatment, the additional balance tests and questionnaires were evaluated for the second time to see if improvements occurred.

3.4. Statistics

Our data was analysed by JMP Pro 13.2.0. For both parts, the model assumptions (normality, homoscedasticity, independence) were checked first. For assessing normal distribution, the Shapiro-Wilk test was used. Homoscedasticity was evaluated with the Brown-Forsythe test. Finally, for checking the independency, we looked at our design. The statistical significance was set at $P < 0.05$. The one-sided p-values are used for all parameters, except for gender, age and the side effects of medication.

For these statistical tests, we based ourselves on the decision tree (figure 2 in appendix) and on the theory of 2nd bachelor.

Part I

For the first part, two independent groups (BPPV group and non-BPPV group) were studied. In one of both groups there were less than 30 participants (n = 8).

The results of the mFES-I, GDS-15, MMSE, medication and fall incidents were normally distributed for at least one group and had equal variances whereby the non-parametric Wilcoxon rank-sum test was used. For the FAC, both groups were not normally distributed but had equal variances, so the Wilcoxon rank-sum test was also used in this case. This test was also applied for age, because both groups were normally distributed and showed equal variances. For the DHI, both normality and homoscedasticity were not met. In this case, a decision was made with our supervisor to also use the Wilcoxon rank-sum test. All these outcome measurements provided a continuous score. For one outcome measure (e.g. gender), a contingency table was used, due to two categorical variables, and the Fisher's exact test because the expected cell numbers were less than five.

Part II

Part two concerns a one group pre-test, post-test design. Because of this design and the very small sample size (n = 5), the Wilcoxon signed rank test was used for both the outcome parameters that were normally distributed and those that were not normally distributed.

4. RESULTS

The results are given in table 1 and 2 in the appendix.

Part I

Participants

Fifty residents of the residential care centre Sint-Elisabeth participated in our study. Three older adults were excluded due to insufficient cervical mobility (n = 2) and fear of the testing manoeuvres (n = 1). Of the 47 included participants, a diagnosis of BPPV was made in eight participants. A BPPV group (n = 8) and a non-BPPV group (n = 39) was created. A flowchart of the participants is given in figure 1 in the appendix.

Prevalence

Eight out of 47 showed a positive result on the vestibular diagnostic tests. This corresponds to a prevalence of 17%. The most affected canal was the right posterior canal (n = 6), followed by the left posterior canal (n = 1) and right horizontal canal (n = 1). Seven out of eight patients had a positive diagnosis on the right side.

Questionnaires

The BPPV group showed a statistical significant higher score than the non-BPPV group for the DHI (mean 16.5 ± 18.91 vs. mean 1.13 ± 3.46; $P < 0.001$) and the GDS-15 (mean 3.63 ± 2.13 vs. mean 2.49 ± 2.58; $P = 0.0491$).

There was no statistical significant lower score in the BPPV group compared with the non-BPPV group on the MMSE (mean 25.25 ± 3.41 vs. mean 23.56 ± 5.67; $P = 0.3453$) and the FAC (mean 4.13 ± 1.46 vs. mean 4.23 ± 0.93; $P = 0.3788$).

The mFES-I shows a p-value close to the significance level 0.05, but is still not statistically significant (mean 19.13 ± 8.37 vs. mean 14.46 ± 6.16; $P = 0.0619$).

Gender and age

No statistically significant differences were found for age (mean 87.63 ± 4.47 vs. mean 87.72 ± 5.24; P = 0.4943) and gender (100% female vs. 74.36% female; P = 0.1736).

Medication and fall incidents

A statistical significant increase was found in the BPPV group on the number of fall incidents during the past year (mean 1.25 ± 1.04 vs. mean 0.38 ± 0.54; P = 0.0054), but not on the number of medications (mean 5.88 ± 4.29 vs. mean 6.33 ± 3.54; P = 0.3137), compared with the non-BPPV group.

In terms of the side effects of medication, statistical analysis showed no significant differences between groups in influence on the vestibular system (mean 21.15 ± 12.55 vs. mean 18.88 ± 12.92; P = 0.7126), on fall risk (mean 4.77 ± 4.85 vs. mean 4.88 ± 3.14; P = 0.6451), on depression (mean 6.64 ± 4.14 vs. mean 5.63 ± 3.34; P = 0.5875) and on cognition (mean 4.51 ± 4.10 vs. mean 3.38 ± 2.83; P = 0.5679).

Part II

Willingness to be treated

Of these eight people with BPPV, five wanted to be treated. The other three dropped out because they experienced no complaints of this condition and therefore did not see the added value of a treatment. The following results are therefore only related to the five patients who were treated.

Effectiveness of treatment

Four out of five participants showed a negative result on the diagnostic vestibular test after their treatment. Three of these were treated once, and two participants were treated twice. Only one person still showed a positive result after two treatment moments. In this case, the Brandt-Daroff exercises were offered. After a period of two months, BPPV was still present in this person. A conclusion can be

made that a treatment for this condition was effective in 80% in our study, although it is difficult to make an appropriate conclusion based on only five patients.

Impact of treatment

- Questionnaires: no statistical significant decrease was found for the GDS-15 (mean difference -1.2; P = 0.1563) after treatment. The p-values of the DHI (mean difference -10.8), mFES-I (mean difference -1.4) and MMSE (mean difference +1.6) showed a certain trend toward significance (P = 0.0625).

- Four Test Balance Scale: there was no significant increase found between the pre- and post-test for the 4TBS (mean difference +3.8; P = 0.3125).

- Timed Up and Go test: no statistical significant lower score was found for the duration of the TUG (mean difference +0.89; P = 0.6875) and the duration of the turn (mean difference +1.19; P = 0.5938). There was even a very slight increase in the number of seconds, but this was not significant. Also no statistical significant increase in the velocity of the turn (mean difference -4.63; P = 0.6875), but even a decrease in the velocity.

- 360° Turn: there was no significant decrease found for the duration (mean difference -0.51; P = 0.2188) and no significant increase for the turn velocity (mean difference -1.01; P = 0.5000) of the 360° turn. Regarding the turn velocity, there even is a slight decrease in the post-test, but this was not significant.

- Sway (feet closed, eyes open, firm surface): for the sway, statistical significant decreases were found for the ellipse sway area (mean difference -0.43; P = 0.0313) and the path length (mean difference -11.23; P = 0.0313), indicating a smaller sway after treatment. No statistical significant increase of the duration (mean difference +2.15; P = 0.5000) or decrease of the velocity (mean difference -0.07; P = 0.0625).

- 10 meter walking test: no statistical significant decreases were found for the following parameters of the 10MWT; duration (mean difference -0.22; P = 0.5000), cadence (mean difference +3.74; P = 0.8438), turn duration (mean

difference +0.32; P = 0.6875), turn velocity (mean difference +0.38; P = 0.5000), steps in turn (mean difference +1.2; P = 0.8750), stride length (mean difference -0.04; P = 0.9063), and variability of stride length (mean difference +0.02; P = 0.2500). No statistical significant increase was found for the gait speed (mean difference -0.004; P = 0.6875).

5. DISCUSSION

The participants in this residential care centre are older adults who have never been tested for BPPV before. According to this study, 17% of these participants suffer from BPPV. This is a higher number than the prevalence among a general population, with a range between nine and eleven percent (Kollen et al., 2012; Oghalai et al., 2004; Yetiser & Ince, 2015; Zur et al., 2006). Because of this high prevalence, it is important that caregivers are aware of this condition, to prevent any possible consequences.

The residents with BPPV had a significant higher score on the DHI, as could be expected since dizziness is often the main complaint of BPPV (von Brevern et al., 2007). Nevertheless, five out of eight participants suffering from this condition, had a score lower than the cut-off value of a mild handicap (Jacobson & Newman, 1990). Three participants even had a score of zero on this questionnaire, which means they experienced no dizziness at all (Jacobson & Newman). This could be due to the fact that older people are more sedentary, and therefore perform less head movements and thus less displacement of the otoconia are provoked, resulting in less vertigo. Another possible explanation could be that they may have limited insight in their body awareness and therefore may not be aware of these sensations of dizziness. A logical consequence of this increased dizziness is a higher fall risk. This was confirmed by our findings with significant more fall incidents in the BPPV group and by the studies of Gazolla et al., (2006), Krishna et al. (2015), and Oghalai et al. (2004).

A significant higher prevalence of depression occurred in the BPPV group. A possible explanation could be that these dizzy patients can be more socially isolated because of their complaints. This way of reasoning could also possibly occur the other way around. People who are depressed can be more sedentary and isolated, and therefore might develop BPPV due to the prolonged bedrest (Cakir et al., 2006).

The group with BPPV had also a higher score on the mFES-I, which corresponds with more fear of falling. However, this difference was not statistical significant. This could be due to the fact that older people in general are more afraid of falling, which is confirmed by our findings of the non BPPV group, who also showed a high score on this questionnaire.

Other studies found that BPPV is more common in females. The female dominance ranged between 60.5% and 87.9% (De Stefano et al., 2014; Kasse et al., 2012; Kollen et al., 2012; Saxena & Prabhakar, 2013; van der Zaag-Loonen et al., 2015; Yetiser & Ince, 2015). However, our study did not find a significant gender difference. This could be explained by our included population that consisted of 80% women.

The posterior semicircular canal was found the most involved canal by Batuecas-Caletrio et al. (2013); Kasse et al. (2012); Kollen et al. (2012), with a range between 64% and 82.5%. This is confirmed by our study with a prevalence of 87.5%. The most affected side in our study was the right side (87.5%). Other studies also showed a dominance of this side (Batuecas-Caletrio et al.; Kasse et al.; Kollen et al.; Vibert, Kompis & Hausler, 2013).

After treatment, successful results were obtained in 80% of the patients. Due to the small sample size, a careful conclusion has to be made. Although the study from Monobe, Sugasawa, and Murofushi (2001) showed the same results, they found a successful outcome in 82.2% of the included participants after the first treatment. A success rate of 90.3% was obtained after they were treated twice. A possible explanation for the lack of success in the remaining patients could be that a part of the otoconia did not transfer into the utricle, that the patients did not rest after treatment or that they did still make excessive head movements. According to this study, treatment of idiopathic BPPV showed a higher success rate than secondary BPPV. They state that patients with this type of BPPV may have quantitatively or qualitatively different lesions than patients with idiopathic BPPV. This statement can be confirmed by our study, because the person who was not cured after two treatments and the Brandt-Daroff exercises, suffered from secondary BPPV. However, this was only one person, thus a careful interpretation is needed.

There were no significant improvements in dizziness, fear of falling, depression and cognition after treatment. In terms of balance, significant improvements were only determined in the ellipse sway area and the path length of the sway. The other parameters did not show any significant improvements. A possible explanation for these limited improvements could be that these parameters have multifactorial causes because older people often suffer from multiple comorbidities and take a lot of medication, which can cause many side effects (e.g. a higher fall risk or dizziness). Therefore, resolving BPPV, does not guarantee improvements on other parameters. Another important reason can be that our sample size was very small, making it difficult to find statistical significances.

For some of the parameters, there was an opposite effect after treatment than expected (e.g. there was an increase in the duration of the TUG, while we would expect a decrease after treatment). Because the testings were just on one specific moment in time, the results can vary from day to day. Future studies should therefore include repeated testings to control for the day-to-day variability in older adults. Another explanation could be that in some cases the post-test was assessed a few weeks later. Due to the fact that an older and frail population was studied, their functional ability could be decreased after these weeks (Oghalai et al., 2004).

Limitations of this study were: (1) there could be an expectancy bias since the diagnostic tests were performed before the questionnaires and additional balance tests. Therefore, there is a possibility that there was a prejudice towards the further examination. However, this is limited due to the use of objective measurements; (2) many questionnaires that were used were not fully applicable on an older geriatric population. Thus, there were questions that could not be answered.

This study had also a few strengths. First, many parameters were examined to get an extended picture of the possible causes and consequences of BPPV. Second, study material was used to objectify our findings, namely the APDM sensors and Frenzel glasses.

Recommendations for further research are to use adjusted questionnaires for an older geriatric population or other instruments to assess these parameters. A longer examination period and a larger sample size could increase the power of a study about this topic.

6. CONCLUSION

Almost one out of five older adults living in a residential care centre has BPPV. They experience significant more complaints of dizziness, depression and fall incidents than residents without BPPV. In this small study, treatment for this condition was effective in 80% of the participants. However, after the treatment for BPPV, there were only improvements in the sway, but not in all the other parameters that were studied.

More research on this topic is necessary to assess the prevalence and balance parameters among a larger population of older adults for prevention of the consequences of BPPV.

7. REFERENCE LIST

Batuecas-Caletrio, A., Trinidad-Ruiz, G., Zschaeck, C., de Dios, J. C. D., Gil, L. D., Martin-Sanchez, V., & Martin-Sanz, E. (2013). Benign Paroxysmal Positional Vertigo in the Elderly. Gerontology, 59(5), 408-412. doi:10.1159/000351204

Cakir, B. O., Ercan, I., Cakir, Z. A., Civelek, S., & Turgut, S. (2006). Relationship between the affected ear in benign paroxysmal positional vertigo and habitual head-lying side during bedrest. J Laryngol Otol, 120(7), 534-536. doi:10.1017/s002221510600082x

Chau, A. T., Menant, J. C., Hubner, P. P., Lord, S. R., & Migliaccio, A. A. (2015). Prevalence of Vestibular Disorder in Older People Who Experience Dizziness. Front Neurol, 6, 268. doi:10.3389/fneur.2015.00268

Cohen, H. S. (2004). Side-lying as an alternative to the Dix-Hallpike test of the posterior canal. Otol Neurotol, 25(2), 130-134.

Collen, F. M., Wade, D. T., & Bradshaw, C. M. (1990). Mobility after stroke: reliability of measures of impairment and disability. Int Disabil Stud, 12(1), 6-9.

De Stefano, A., Dispenza, F., Suarez, H., Perez-Fernandez, N., Manrique-Huarte, R., Ban, J. H., . . . Croce, A. (2014). A multicenter observational study on the role of comorbidities in the recurrent episodes of benign paroxysmal positional vertigo. Auris Nasus Larynx, 41(1), 31-36. doi:10.1016/j.anl.2013.07.007

Dix, M. R., & Hallpike, C. S. (1952). The Pathology, Symptomatology and Diagnosis of Certain Common Disorders of the Vestibular System. Proceedings of the Royal Society of Medicine, 45(6), 341–354.

Ekvall Hansson, E., Mansson, N. O., & Hakansson, A. (2005). Benign paroxysmal positional vertigo among elderly patients in primary health care. Gerontology, 51(6), 386-389. doi:10.1159/000088702

Folstein, M. F., Folstein, S. E., & McHugh, P. R. (1975). "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. J Psychiatr Res, 12(3), 189-198.

Gazzola, J. M., Gananca, F. F., Aratani, M. C., Perracini, M. R., & Gananca, M. M. (2006). Circumstances and consequences of falls in elderly people with vestibular disorder. Braz J Otorhinolaryngol, 72(3), 388-392.

Hilton, M. P., & Pinder, D. K. (2014). The Epley (canalith repositioning) manoeuvre for benign paroxysmal positional vertigo. Cochrane Database Syst Rev(12), Cd003162. doi:10.1002/14651858.CD003162.pub3

Holden, M. K., Gill, K. M., Magliozzi, M. R., Nathan, J., & Piehl-Baker, L. (1984). Clinical gait assessment in the neurologically impaired. Reliability and meaningfulness. Phys Ther, 64(1), 35-40.

Jacobson, G. P., & Newman, C. W. (1990). The development of the Dizziness Handicap Inventory. Arch Otolaryngol Head Neck Surg, 116(4), 424-427.

Jonsson, R., Sixt, E., Landahl, S., & Rosenhall, U. (2004). Prevalence of dizziness and vertigo in an urban elderly population. Journal of Vestibular Research-Equilibrium & Orientation, 14(1), 47-52.

Jorstad, E. C., Hauer, K., Becker, C., & Lamb, S. E. (2005). Measuring the psychological outcomes of falling: a systematic review. J Am Geriatr Soc, 53(3), 501-510. doi:10.1111/j.1532-5415.2005.53172.x

Kasse, C. A., Santana, G. G., Branco-Barreiro, F. C., Scharlach, R. C., Gazzola, J. M., Gananca, F. F., & Dona, F. (2012). Postural control in older patients with benign paroxysmal positional vertigo. Otolaryngol Head Neck Surg, 146(5), 809-815. doi:10.1177/0194599811434388

Kollen, L., Frandin, K., Moller, M., Fagevik Olsen, M., & Moller, C. (2012). Benign paroxysmal positional vertigo is a common cause of dizziness and unsteadiness in a large population of 75-year-olds. Aging Clin Exp Res, 24(4), 317-323

Krishna, T. B. R., Singh, T. D., Krishna, J. R., Rakesh, G., & Sree, U. (2015). HOW BENIGN IS BPPV IN THE ELDERLY? Journal of Evolution of Medical and Dental Sciences-Jemds, 4(3), 375-379

Luscher, M., Theilgaard, S., & Edholm, B. (2014). Prevalence and characteristics of diagnostic groups amongst 1034 patients seen in ENT practices for dizziness. J Laryngol Otol, 128(2), 128-133. doi:10.1017/s0022215114000188

Masud, T., & Morris, R. O. (2001). Epidemiology of falls. Age Ageing, 30 Suppl 4, 3-7

McClure, J. A. (1985). Horizontal canal BPV. J Otolaryngol, 14(1), 30-35.

Monobe, H., Sugasawa, K., & Murofushi, T. (2001). The outcome of the canalith repositioning procedure for benign paroxysmal positional vertigo: are there any characteristic features of treatment failure cases? Acta Otolaryngol Suppl, 545, 38-40.

Mueller, M., Strobl, R., Jahn, K., Linkohr, B., Ladwig, K. H., Mielck, A., & Grill, E. (2014). Impact of vertigo and dizziness on self-perceived participation and autonomy in older adults: results from the KORA-Age study. Qual Life Res, 23(8), 2301-2308. doi:10.1007/s11136-014-0684-x

Norre, M. E. (1995). Reliability of examination data in the diagnosis of benign paroxysmal positional vertigo. Am J Otol, 16(6), 806-810

Oghalai, J. S., Manolidis, S., Barth, J. L., Stewart, M. G., & Jenkins, M. A. (2000). Unrecognized benign paroxysmal positional vertigo in elderly patients. Otolaryngology-Head and Neck Surgery, 122(5), 630-634. doi:10.1016/s0194-5998(00)70187-2

Parham, K., & Kuchel, G. A. (2016). A Geriatric Perspective on Benign Paroxysmal Positional Vertigo. J Am Geriatr Soc, 64(2), 378-385. doi:10.1111/jgs.13926

Peluso, E. T., Quintana, M. I., & Gananca, F. F. (2016). Anxiety and depressive disorders in elderly with chronic dizziness of vestibular origin. Braz J Otorhinolaryngol, 82(2), 209-214. doi:10.1016/j.bjorl.2015.04.015

Podsiadlo, D., & Richardson, S. (1991). The timed "Up & Go": a test of basic functional mobility for frail elderly persons. J Am Geriatr Soc, 39(2), 142-148.

Rossiter-Fornoff, J. E., Wolf, S. L., Wolfson, L. I., & Buchner, D. M. (1995). A cross-sectional validation study of the FICSIT common data base static balance measures. Frailty

and Injuries: Cooperative Studies of Intervention Techniques. J Gerontol A Biol Sci Med Sci, 50(6), M291-297.

Saxena, A., & Prabhakar, M. C. (2013). Performance of DHI Score as a Predictor of Benign Paroxysmal Positional Vertigo in Geriatric Patients with Dizziness/Vertigo: A Cross-Sectional Study. PLoS One, 8(3). doi:10.1371/journal.pone.0058106

Snijders, A. H., Haaxma, C. A., Hagen, Y. J., Munneke, M., & Bloem, B. R. (2012). Freezer or non-freezer: clinical assessment of freezing of gait. Parkinsonism Relat Disord, 18(2), 149-154. doi:10.1016/j.parkreldis.2011.09.006

Tuunainen, E., Poe, D., Jantti, P., Varpa, K., Rasku, J., Toppila, E., & Pyykko, I. (2011). Presbyequilibrium in the oldest old, a combination of vestibular, oculomotor and postural deficits. Aging Clin Exp Res, 23(5-6), 364-371. doi:10.3275/7623

van der Zaag-Loonen, H. J., van Leeuwen, R. B., Bruintjes, T. D., & van Munster, B. C. (2015). Prevalence of unrecognized benign paroxysmal positional vertigo in older patients. Eur Arch Otorhinolaryngol, 272(6), 1521-1524. doi:10.1007/s00405-014-3409-4

van Leeuwen, R. B., & Bruintjes, T. D. (2014). Dizziness in the elderly: Diagnosing its causes in a multidisciplinary dizziness unit. Ent-Ear Nose & Throat Journal, 93(4-5), 162

Vibert, D., Kompis, M., & Hausler, R. (2003). Benign paroxysmal positional vertigo in older women may be related to osteoporosis and osteopenia. Ann Otol Rhinol Laryngol, 112(10), 885-889. doi:10.1177/000348940311201010

von Brevern, M., Radtke, A., Lezius, F., Feldmann, M., Ziese, T., Lempert, T., & Neuhauser, H. (2007). Epidemiology of benign paroxysmal positional vertigo: a population based study. J Neurol Neurosurg Psychiatry, 78(7), 710-715. doi:10.1136/jnnp.2006.100420

Yardley, L., Beyer, N., Hauer, K., Kempen, G., Piot-Ziegler, C., & Todd, C. (2005). Development and initial validation of the Falls Efficacy Scale-International (FES-I). Age Ageing, 34(6), 614-619. doi:10.1093/ageing/afi196

Yesavage, J. A., Brink, T. L., Rose, T. L., Lum, O., Huang, V., Adey, M., & Leirer, V. O. (1982). Development and validation of a geriatric depression screening scale: a preliminary report. J Psychiatr Res, 17(1), 37-49.

Yetiser, S., & Ince, D. (2015). Demographic analysis of benign paroxysmal positional vertigo as a common public health problem. Annals of Medical and Health Sciences Research, 5(1), 50-53. doi:10.4103/2141-9248.149788

Zur, O., Berner, Y. N., & Carmeli, E. (2006). Correlation between vestibular function and hip fracture following falls in the elderly: a case-controlled study. Physiotherapy, 92(4), 208-213. doi:10.1016/j.physio.2006.02.010

8. APPENDIX

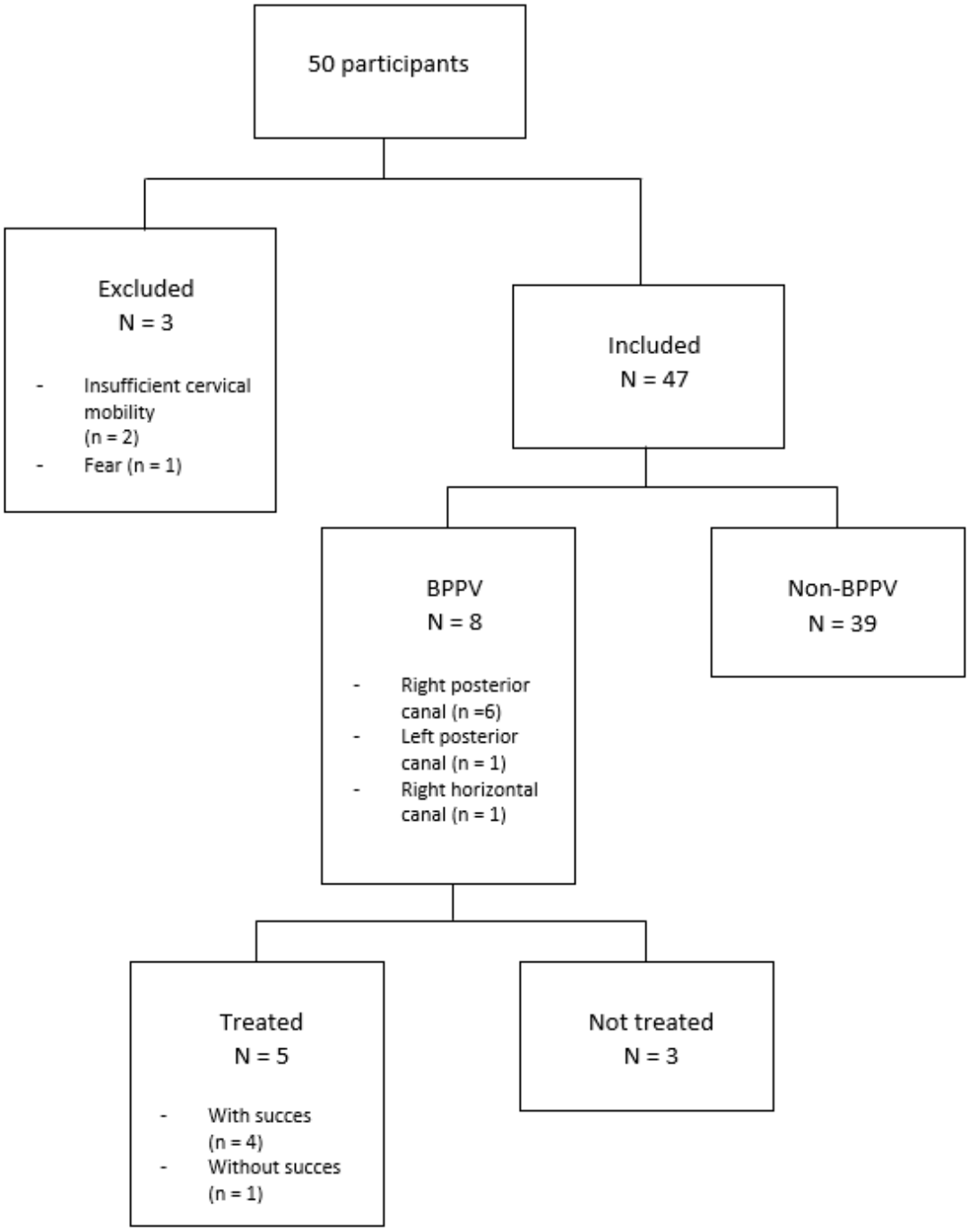

Figure 1: Flowchart

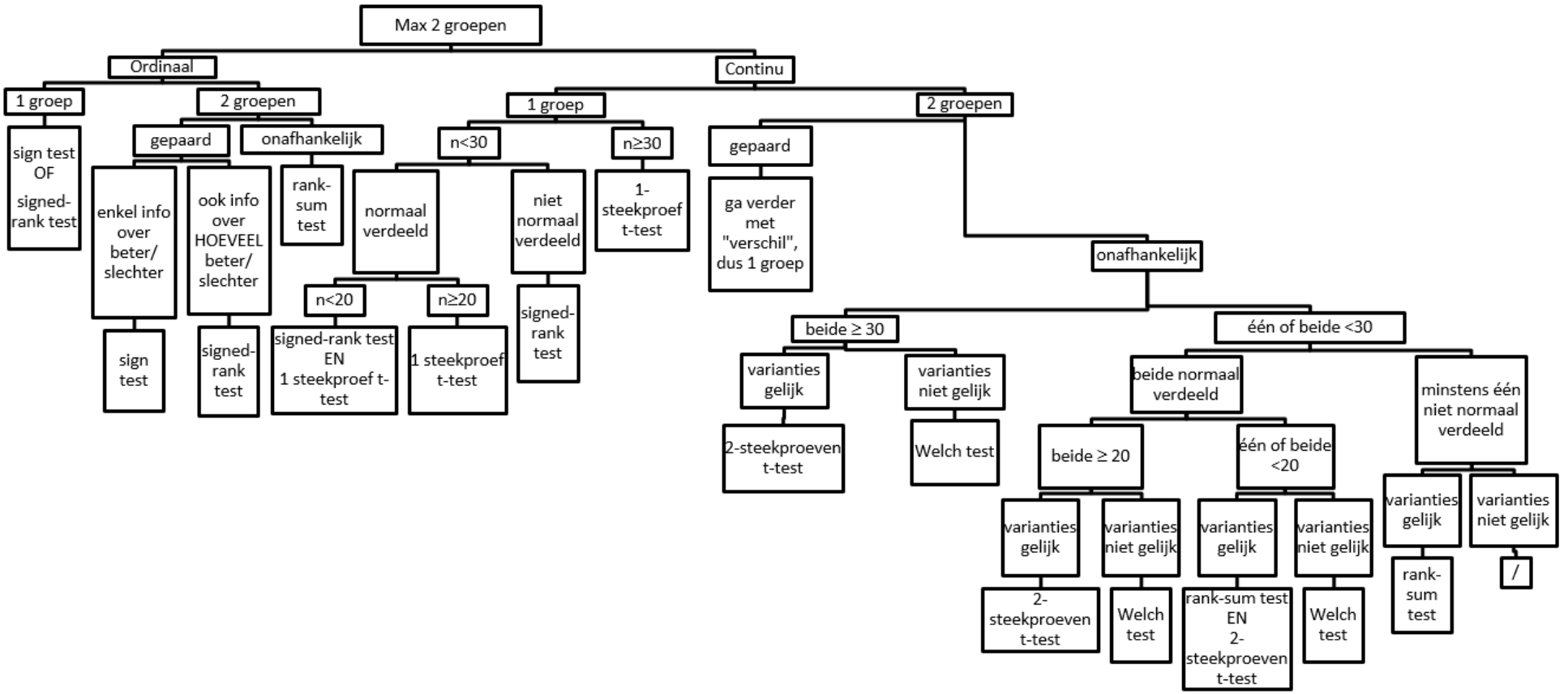

Figure 2: Decision tree

De Nederlandstalige Falls Efficacy Scale International (FES-I)

(Yardley et al., 2005; Kempen et al., in druk)

Instructies:

we willen u graag enkele vragen stellen over hoe bezorgd u bent dat u zou kunnen vallen bij het uitvoeren van een bepaalde activiteit
het gaat er hierbij om hoe u **gewoonlijk** deze activiteit uitvoert
als u tegenwoordig deze activiteit **niet doet** willen we u vragen of dit zo is uit *bezorgdheid om (opnieuw) te vallen* of om een *andere reden*

Hoe bezorgd bent u dat u zou kunnen vallen bij…	Helemaal niet bezorgd	Een beetje bezorgd	Tamelijk bezorgd	Erg bezorgd	(*) Deze activiteit wordt niet uitgevoerd uit bezorgdheid om te vallen
1. Het schoonmaken in huis (zoals vegen, stofzuigen of afstoffen)	1☐	2☐	3☐	4☐	- ja ☐ neen ☐ - andere reden:
2. Het aan- of uitkleden	1☐	2☐	3☐	4☐	- ja ☐ neen ☐ - andere reden:
3. Het klaarmaken van eenvoudige maaltijden	1☐	2☐	3☐	4☐	- ja ☐ neen ☐ - andere reden:
4. Het nemen van een bad of douche	1☐	2☐	3☐	4☐	- ja ☐ neen ☐ - andere reden:
5. Het doen van boodschappen	1☐	2☐	3☐	4☐	- ja ☐ neen ☐ - andere reden:
6. Het in of uit een stoel komen	1☐	2☐	3☐	4☐	- ja ☐ neen ☐ - andere reden:
7. Het op- of aflopen van een trap	1☐	2☐	3☐	4☐	- ja ☐ neen ☐ - andere reden:
8. Het maken van een wandeling in de buurt	1☐	2☐	3☐	4☐	- ja ☐ neen ☐ - andere reden:
9. Het reiken naar iets boven uw hoofd of naar iets op de grond	1☐	2☐	3☐	4☐	- ja ☐ neen ☐ - andere reden:
10. Het beantwoorden van de telefoon voordat deze ophoudt met overgaan	1☐	2☐	3☐	4☐	- ja ☐ neen ☐ - andere reden:
11. Het lopen op een gladde ondergrond (bijvoorbeeld nat of bevroren)	1☐	2☐	3☐	4☐	- ja ☐ neen ☐ - andere reden:
12. Het bezoeken van een vriend(in), kennis of familielid	1☐	2☐	3☐	4☐	- ja ☐ neen ☐ - andere reden:
13. Het lopen op een plek waar veel mensen zijn	1☐	2☐	3☐	4☐	- ja ☐ neen ☐ - andere reden:
14. Het lopen op oneffen ondergrond (zoals kinderkopjes of slecht onderhouden trottoir)	1☐	2☐	3☐	4☐	- ja ☐ neen ☐ - andere reden:
15. Het op- of aflopen van een helling	1☐	2☐	3☐	4☐	- ja ☐ neen ☐ - andere reden:
16. Het bezoeken van een sociale gelegenheid (zoals kerkdienst, familiebijeenkomst of verenigingsactiviteit)	1☐	2☐	3☐	4☐	- ja ☐ neen ☐ - andere reden:

(*) Redenen voor restrictie activiteit toegevoegd door de wetenschappelijke werkgroep "Uniforme Aanpak Valpreventie Vlaanderen"

Figure 3: Modified FES-I

Table 1: Overview of the means, standard deviations and p-values of the results of part I

Parameter	BPPV group		Non-BPPV group		P-value Significant *
	Mean	Standard deviation	Mean	Standard deviation	
DHI	16.5	18.91	1.13	3.46	< 0.001*
GDS-15	3.63	2.13	2.49	2.58	0.0491*
MMSE	25.25	3.41	23.56	5.67	0.3453
FAC	4.13	1.46	4.23	0.93	0.3788
mFES-I	19.13	8.37	14.46	6.16	0.0619
AGE	87.63	4.47	87.72	5.24	0.4943
FALLS	1.25	1.04	0.38	0.54	0.0054*
MEDICATION	5.88	4.29	6.33	3.54	0.3137
SIDE EFFECTS MEDICATION					
- Vestibular system	21.15	12.55	18.88	12.92	0.7126
- Fall risk	4.77	4.85	4.88	3.14	0.6451
- Depression	6.64	4.14	5.63	3.34	0.5875
- Cognition	4.51	4.10	3.38	2.83	0.5679

Table 2: Overview of the means, standard deviations and p-values of the results of part II

Parameter	Pre-test (mean)	Post-test (mean)	Mean difference	P-value Significant *
DHI	27.2	16.4	-10.8	0.0625
GDS-15	4.4	3.2	-1.2	0.1563
MMSE	26	27.6	+1.6	0.0625
mFES-I	23.6	22.2	-1.4	0.0625
4TBS	25	28.8	+3.8	0.3125
TUG				
- Duration (s)	21.51	22.4	+0.89	0.6875
- Duration turn (s)	2.3	4.17	+1.87	0.5938
- Velocity turn (degrees/s)	122.14	117.78	-4.36	0.6875
SWAY				
- Duration (s)	26.68	28.83	+2.15	0.5000
- Sway area (m^2/s^4)	0.81	0.37	-0.43	0.0313*
- Velocity (s)				
- Path length (m/s^2)	0.35	0.29	-0.07	0.0625
	33.18	21.95	-11.23	0.0313*
360° TURN				
- Duration (s)	8.55	8.04	-0.51	0.2188
- Velocity turn (degrees/s)	89.95	88.99	-0.96	0.5000
10MWT				
- Duration (s)	26.21	25.99	-0.22	0.5000
- Cadence (steps/min)	91.86	95.6	+3.74	0.8438
- Gait speed (m/s)	0.67	0.66	-0.01	0.6875
- Duration turn (s)	2.77	3.09	+0.32	0.6875
- Velocity turn (degrees/s)	114.84	115.22	+0.38	0.5000
- Steps in turn (#)	4.4	5.6	+1.2	0.8750
- Stride length (m)	0.84	0.8	-0.04	0.9063
- Stride length variability (std)	0.048	0.064	+0.016	0.2500

Document 1: Approval of Medical ethics committee.

UZ LEUVEN

Leuven, 31 augustus 2016

Commissie Medische Ethiek
UZ KU Leuven / Onderzoek
U.Z. Gasthuisberg
Herestraat 49
B 3000 Leuven (Belgium)

dr. Joke Spildooren

Ons kenmerk:	EudraCT-nr:	Belg. Regnr:
S59389		B322201629379

Inactiviteit, evenwichtsstoornissen en valrisico bij fragiele ouderen in woonzorgcentra: Wat is de impact van Benigne Paroxysmale Positie Vertigo en hoe doeltreffend is een behandeling?

DEFINITIEF GUNSTIG ADVIES

Geachte Collega,

De Commissie Medische Ethiek van UZ KU Leuven / Onderzoek heeft vermeld protocol onderzocht en besproken op haar vergadering van 8 juli 2016.

Na inzage van de bijkomende informatie en/of aangepaste documenten met betrekking tot dit dossier is de Commissie van oordeel dat de voorgestelde studie, zoals beschreven in het protocol, wetenschappelijk relevant en ethisch verantwoord is. Na raadpleging van de ethische commissie van de andere deelnemende centra verleent ze dan ook een gunstig advies over deze studie.

Bij het beoordelen van dit dossier werd rekening gehouden met de documenten en informatie gerelateerd aan deze studie, ingediend op 23 juni 2016, 28 juni 2016, 23 augustus 2016 en 29 augustus 2016.

Dit gunstig advies betreft:

Protocol:
Versie 3 dd 29/08/2016
Informatie en toestemmingsformulier:
ICF Versie 3 dd 29/8/2016 NI
Bewijs van "no-fault" verzekering:
Opgemaakt 23 juni 2016

De Commissie bevestigt dat ze werkt in overeenstemming met de ICH-GCP principes (International Conference on Harmonization Guidelines on Good Clinical Practice), met de meest recente versie van de Verklaring van Helsinki en met de van toepassing

Tel +32 16 34 86 00
Fax +32 16 34 86 01

website: www.uzleuven.be/ec/
e-mail : ec@uzleuven.be

zijnde wetten en regelgeving.

De Commissie bevestigt dat in geval van belangenconflict, de betrokken leden niet deelnemen aan de besluitvorming omtrent de studie.

Een ledenlijst wordt bijgevoegd.

Aandachtspunten: (indien van toepassing)

De opdrachtgever is verantwoordelijk voor de conformiteit van de anderstalige documenten met de Nederlandstalige documenten.

*Indien er een **Clinical Trial Agreement** is, kan de studie in ons centrum pas aangevat worden wanneer dit Clinical Trial Agreement goedgekeurd en ondertekend is door de gedelegeerde bestuurder van UZ Leuven (en/of desgevallend door bevoegde vertegenwoordiger(s) van KU Leuven R&D).*

Studies met geneesmiddelen en sommige studies met "medische hulpmiddelen" dienen door de opdrachtgever aangemeld te worden bij het FAGG.
Studies met geneesmiddelen mogen slechts aanvangen op voorwaarde dat de minister (FAGG) geen bezwaren heeft kenbaar gemaakt binnen de wettelijke termijnen zoals beschreven in art.13 van de Belgische wet van 7/5/2004 inzake experimenten op de menselijke persoon.
Voor bepaalde studies met medische hulpmiddelen gelden eveneens wettelijke termijnen (zie KB van 17/3/2009). Voor meer informatie hieromtrent verwijzen we naar de website van het FAGG www.fagg-afmps.be.

Onderzoek op embryo's in vitro valt onder de wet van 11 mei 2003. Voor dergelijk onderzoek is er naast een positief advies van het Ethisch Comité ook een goedkeuring van de Federale Commissie voor medisch en wetenschappelijk onderzoek op embryo's in vitro noodzakelijk vooraleer dit onderzoeksproject kan doorgaan.

Gelieve ook rekening te houden met de regelgeving van het ziekenhuis betreffende weefselbeheer en met de beschikkingen van de wet van 19 december 2008.

Dit gunstig advies van de Commissie houdt niet in dat zij de verantwoordelijkheid voor de geplande studie op zich neemt. U blijft hiervoor dus zelf verantwoordelijk. Bovendien dient U erover te waken dat uw mening als betrokken onderzoeker wordt weergegeven in publicaties, rapporten voor de overheid enz., die het resultaat zijn van dit onderzoek.
U dient ongewenste voorvallen en ernstige bijwerkingen te rapporteren zoals aangegeven door de Belgische Wet aangaande Experimenten op de menselijke persoon van 7 mei 2004 (Art 27 en 28) en de omzendbrief 586 van het FAGG.

Gelieve ons mee te delen indien een studie niet wordt aangevat of wanneer ze wordt afgesloten of vroegtijdig onderbroken (met opgave van reden).

*Indien de studie niet binnen het jaar beëindigd is, vereist de ICH-GCP dat een **jaarlijks vorderingsrapport** aan de commissie wordt bezorgd.*

*Gelieve tenslotte het (vroegtijdige of geplande) stopzetten van een studie binnen de door de wet vastgestelde termijnen mee te delen en een **Clinical Study Report** aan de*

Tel +32 16 34 86 00
Fax +32 16 34 86 01

website: www.uzleuven.be/ec/
e-mail : ec@uzleuven.be

Commissie te bezorgen.

Met vriendelijke groet,

Prof. Dr. Minne Casteels
Voorzitter
Commissie Medische Ethiek UZ KU Leuven / Onderzoek

Cc:
FAGG (Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten)

CTC (Clinical Trial Center UZ Leuven)

Externe Commissie(s) :

1- De Commissie heeft rekening gehouden met het advies van de volgende lokale commissie(s). De Commissie gaat er dan ook van uit dat deze centra de studie aanvaarden, tenzij tegenbericht:

Lokale Commissie	*Onderzoeker*
Universiteit Hasselt	dr. Joke Spildooren

2- De volgende commissie(s) heeft (hebben) een negatief advies uitgebracht:

Lokale Commissie	*Onderzoeker*

3- Van onderstaande commissie(s) ontvingen wij geen advies. Bijgevolg kunnen deze centra niet deelnemen aan deze studie (cfr. Wet van 7 mei 2004 inzake experimenten op de menselijke persoon). Deze centra kunnen enkel via amendement aan de studie worden toegevoegd.

Lokale Commissie	*Onderzoeker*

Tel +32 16 34 86 00
Fax +32 16 34 86 01

website: www.uzleuven.be/ec/
e-mail : ec@uzleuven.be

Ledenlijst/Samenstelling van de Commissie op 8 juli 2016 (datum van de laatste bespreking van het dossier):

Voorzitter	prof. dr. em. Ivo De Wever	Surgical Oncology
Vice-voorzitter	prof. dr. em. Guido Verhoeven	Experimental Medicine
Secretaris	dr. Sabine Graux	Physician
Secretaris	dr. Sonja Haesendonck	Physician
	Mevr. Christine Mathieu	Medical Legislation
	Mevr. Els Raets	Nurse
	Mevr. Godelieve Goossens	Nurse
	Mevr. Hélène De Somer	Nurse
	dr. José Thomas	Medical Oncology
	dr. Lut De Groote	General Practitioner
	prof. Ben Van Calster	Statistics
	prof. J.R. Thomas	Clinical Pharmacology
	prof. dr. Dominique Bullens	Paediatrics
	prof. dr. Gregor Verhoef	Haematology
	prof. dr. Jan Van Hemelrijck	Anesthesiology
	prof. dr. Jan de Hoon	Clinical Pharmacology
	prof. dr. Xavier Bossuyt	Immunology
	prof. dr. em. Raymond Verhaeghe	Cardiology
	prof. dr. em. Willem Daenen	Cardiac Surgery

Tel +32 16 34 86 00
Fax +32 16 34 86 01

website: www.uzleuven.be/ec/
e-mail : ec@uzleuven.be

Document 2: Progress form.

www.uhasselt.be
Campus Hasselt | Martelarenlaan 42 | BE-3500 Hasselt
Campus Diepenbeek | Agoralaan gebouw D | BE-3590 Diepenbeek
T + 32(0)11 26 81 11 | E-mail: info@uhasselt.be

UHASSELT
KNOWLEDGE IN ACTION

VOORTGANGSFORMULIER WETENSCHAPPELIJKE STAGE DEEL 2

DATUM	INHOUD OVERLEG	HANDTEKENINGEN
25/08/2017	Eerste afspraak promotor: instellen APDM sensoren + uitleg metingen	Promotor: Spiild Copromotor: Student(e): Student(e):
26/08/2017	Eerste meting met promotor	Promotor: Spiild Copromotor: Student(e): Student(e):
2017	Data: 5/10, 6/10, 11/10, 20/10, 24/10, 28/11, 29/11, 30/11, 1/12, 4/12, 6/12, 11/12, 21/12 → Inhoud: metingen met promotor	Promotor: Spiild Copromotor: Student(e): Student(e):
2018	Data: 2/2, 5/2, 6/2, 7/2, 14/2. → Inhoud: metingen	Promotor: Spiild Copromotor: Student(e): Student(e):
2/2/2018	Afspraak promotor: feedback inhoud en methode	Promotor: Spiild Copromotor: Student(e): Student(e):
6/2/2018	Communicatie via mail over inclusie artikel	Promotor: Spiild Copromotor: Student(e): Student(e):
14/2/2018	Afspraak promotor: bespreking statistiek	Promotor: Spiild Copromotor: Student(e): Student(e):
27/4/2018	Afspraak promotor: bespreking statistiek	Promotor: Spiild Copromotor: Student(e): Student(e):
25/4/2018	Communicatie via mail: over inclusie artikel.	Promotor: Spiild Copromotor: Student(e): Student(e):
20/4/2018	Communicatie via mail: verbetering masterproef	Promotor: Spiild Copromotor: Student(e): Student(e):

Supplementary table 1: Overview of the results and characteristics of the participants.

PARTICIPANT	*FAC*	*# MEDICATION*	*# FALLS*	*DHI*	*mFES-I*	*GDS*	*MMSE*	*AGE*	*GENDER*
1	EXCLUDED								
2	3	13	0	0	13	3	15	80	M
3	3	5	1	0	11	1	9	89	M
4	3	15	1	0	24	2	16	87	F
*5**	5	6	2	6	17	5	28	84	F
6	5	8	0	0	13	0	28	89	M
*7**	3	11	1	30	27	5	26	93	F
8	4	5	0	0	19	5	28	89	F
9	3	4	0	0	11	2	21	94	F
10	3	15	0	8	24	1	26	86	F
11	5	9	0	0	10	0	17	87	F
12	3	10	1	18	18	3	24	99	F
13	5	7	1	0	10	0	19	86	F
14	5	9	1	0	15	3	18	91	F
15	4	4	1	0	29	3	26	82	M
*16**	1	13	1	0	10	1	24	91	F
17	5	4	0	0	13	4	28	90	M
*18**	5	7	2	12	23	4	20	83	F
19	1	11	1	0	21	1	22	86	F
20	4	4	0	0	10	0	13	84	F
21	4	9	1	0	13	2	30	96	F
22	4	3	0	0	10	9	14	96	F
23	5	4	0	0	10	3	21	92	F
24	5	2	0	0	10	0	24	87	F
25	5	6	0	2	10	1	30	77	F
26	4	7	0	0	11	2	27	93	M
27	5	4	0	2	12	3	30	86	F
28	5	4	0	0	18	4	30	88	M
29	3	9	0	2	14	2	26	82	F
30	4	5	1	0	16	2	24	80	M
31	4	7	1	0	10	1	23	98	M
*32**	4	3	1	0	10	4	21	93	F
33	4	9	0	0	13	3	25	81	F
34	4	5	1	0	10	2	22	83	F
35	5	10	0	0	10	0	29	87	F
36	4	3	0	0	12	0	27	93	F
37	4	5	0	0	37	13	27	90	F
38	5	1	1	0	15	2	17	84	F
39	5	4	0	10	10	2	28	87	M
*40**	5	2	3	48	34	7	26	86	F
41	5	6	0	0	10	2	29	83	F
42	5	2	0	0	10	0	28	83	F
*43**	5	4	0	36	17	1	30	82	F
44	5	4	1	0	19	2	30	91	F
45	5	4	0	0	10	3	30	84	F
*46**	5	1	0	0	15	2	27	89	F
47	5	10	2	2	23	7	22	86	F
48	5	1	0	0	10	4	16	95	F
49	EXCLUDED								
50	EXCLUDED								

* Participants diagnosed with BPPV

Supplementary table 2: Overview of the side effects of medication

MEDICATION	*SORT*	*INFLUENCE ON VESTIBULAR SYSTEM*			*INFLUENCE ON FALLING*	*INFLUENCE ON DEPRESSION*	*INFLUENCE ON COGNITION*
		DIZZINESS	*VERTIGO*	*BALANCE DISORDER*			
ACETYLCYSTEINE	Mucolytica	Very rare					
ADENURIC	Xanthine oxidase inhibitor	Sometimes			Sometimes		
ALDACTAZINE	Diuretica	Often					Often
ALDACTONE	Diuretica	Rare			Rare		Rare
ALLOPURINOL	Xanthine oxidase inhibitor	Very rare			Very rare		Very rare
ALPRAZ	Benzodiazepine	Very often			Very often		Often
ALPRAZOLAM	Benzodiazepine	Often		Often	Very often	Often	Often
AMLODIPINE	Blood pressure reducer (Calciumantagonist)	Often			Often	Sometimes	Rare
AMLOR	Blood pressure reducer (Calciumantagonist)	Often			Often	Sometimes	Rare
AMOXICLAV	Penicillines (antibiotics)	Sometimes					
ANAFRANIL	Antidepressants	Very often			Very often	Often	Often
ANORO	Bronchodilator						
APROVEL	Blood pressure reducer (Angiotensine-II-receptorantagonist)	Often					
ASAFLOW	Antithrombotica	Sometimes			Sometimes		
ATORSTATINE	Statins	Sometimes					
ATORVASTATINE	Statins	Sometimes					
ATROVENT	Bronchodilator	Often					
AZITHROMYCINE	Macrolids (antibiotics)	Sometimes			Sometimes		
BETAHISTINE	Anti-vertigo medication						
BETMIGA	Bèta-3-adrenoreceptor-agonist (bladder muscle relaxer	Often					
BISOPROLOL	Blood pressure reducer (Bètablocker)	Often				Sometimes	
BURINEX	Diuretics	Often			Often		

CARDIOASPIRINE	Heart medication?					
CEDOCARD	Heart medication? (Angina pectoris)	Often		Often		
CELEBREX	NSAID	Often		Sometimes	Sometimes	Rare
CELESTONE	Corticosteroids	Possible			Possible	
CETISANDOZ	Anti-allergic medication	Often		Often	Rare	Rare
CHOLEMED	Statins	Rare			Sometimes	Sometimes
CHOLESFYTOL	Cholesterol medication					
CITALOPRAM	Antidepressant	Very often		Very often		Often
CLOPIDOGREL	Platelet aggregation inhibitors	Sometimes				Very rare
CO AMILORIDE TEVOX	Diuretica	Possible	Possible	Possible	Possible	Possible
CO DIAVAN	Blood pressure reducer	Often	Sometimes		Rare	Very rare
CO LISINOPRIL	Blood pressure reducer	Often	Sometimes		Possible	Rare
COMBIVENT	Bronchodilator	Sometimes				
CONTRAMAL	Painkiller	Very often				Rare
CORUNO	Vasodilator		Possible			
COVERAM	Blood pressure reducer	Often	Often	Sometimes	Sometimes	
COZAAR	Angiotensine II-receptorantagonist + diuretic	Often			Sometimes	Sometimes
CRESTOR	Statins	Often				Possible
CUTIVATE	Corticosteroids					
DAFALGAN	Painkiller + antipyretics					
DAFLON	Flebotroop medium	Rare				
DEANXIT	Antidepressant	Often				
DECA DURABOLIN	Anabolic steroids					
DICLOFENAC	Anti-inflammatory drugs	Often				Rare
DOMPERIDON MYLAN	For nausea					
DONEPEZIL	Acetylcholinesterase inhibitors	Often				
DUPHALAC	Laxative					
ELIQUIS	Anticoagulantics				Sometimes	
EMCONCOR	Betablocker	Often				
ESCITALOPRAM	Antidepressant	Often				

ESCIDIVULE	Antidepressant	Often				
FLECAINIDE RETARD	Antiarrhythmics	Very often	Rare		Rare	Rare
FORLAX	Laxative					
FRAXIPARINE	Blood thinner (anticoagulant)					
FURADANTINE	For infections urinary tract	Possible				
FUROSEMIDE	Lisdiuretics	Possible				
GAMBARAN	Anti-inflammatory drugs	Sometimes			Sometimes	
GLICLAZIDE	Sulfonylureumderivatives (diabetes)	Rare				
HUMULINE	Medicine for diabetes					
HYGROTON	Thiazidediuretics	Often				
HYLO-COMOD	Eye drops					
IBANDRONINEZUUR	Biphosphonates	Sometimes				
IMODIUM	Medicine for diarrhea	Often				
INUVAIR	Corticosteroids + bronchodilator	Possible			Possible	
LAXOBERON	Laxative					
LEDERTREXATE	Antineoplastic agent	Possible				
LENDORMIN	Tranquilizer	Sometimes				Rare
LERCANIDIPINE	Calciumantagonist (blood pressure reducer)	Sometimes				
LETROZOL	Aromatase inhibitors (breast cancer)	Often			Often	Sometimes
LEVOCETIRIZINE	Anti-allergic	Often			Rare	
LEXOTAN	Benzodiazepine	Possible		Possible		
LIPITOR	Statins	Sometimes			Possible	
LISINOPRIL	ACE inhibitor (blood pressure reducer)	Often			Possible	
LOPERAMIDE	Loperamidehydrochlorid (intestines)	Often				
LORMETAZEPAM	Benzodiazepine	Often			Possible	Often
LOSARTAN	Angiotensine II-receptor antagonists (blood pressure reducer)	Often			Possible	

LODIXAL	Blood pressure reducer	Possible		Often			
L-THYROXINE	Medicine for thyroid						
LYRICA	Medicine for epilepsy, neuropathic pain, GAD	Very often	Often	Often	Often	Sometimes	Often
LYSANXIA	Benzodiazepinederivatives (fear)	Often	Often			Very rare	Rare
LYSOX	Mucolytica						
MARCOUMAR	Anti-coagulants						
MEDROL	Anti-inflammatory drugs (corticoids)	Possible				Possible	Possible
METFORMINE	Medicine for diabetes						
MICTONORM	Treatment overactive bladder	Sometimes					
MINIPRESS	Blood pressure reducer	Possible				Possible	
MIRTAZAPINE	Antidepressant	Often					
MONOPROST	Prostaglandins	Possible					
MONTELUKAST	Leukotriene receptor antagonist (bronchodilator?)	Sometimes				Sometimes	
MONURIL	Antibiotics (infection urinary tract)	Often					
MOVICOL	Laxative						
MOVOLAX	Laxative						
NEBIVOLOL	Bètablokker (blood pressure reducer)	Very often					
NESTROLAN	Antidepressant	Possible					Possible
OLANZAPINE	Antipsychotics	Often					Sometimes
OLMETEC	Angiotensine II-receptor antagonists (blood pressure reducer)	Often	Sometimes				
OMEPRAZOL	Reducing production stomach acid (selective proton pump inhibitor)	Sometimes	Sometimes			Rare	
OXYBUTYNINE	Spasmolytic	Very often	Often			Possible	
PANTOMED	Reducing production stomach acid (selective proton pump inhibitor)	Sometimes					

PANTOPRAZOLE	Reducing production stomach acid (selective proton pump inhibitor)	Sometimes					
PARACETAMOL	Painkiller	Rare					
PENTASA	Anti-inflammatory drug for intestines	Rare					
PRAREDUCT	Statins	Sometimes				Possible	Sometimes
PROGOR	Antihypertensiva (calciumantagonist)		Often			Possible	
PROTHIADEN	Antidepressant	Possible					
QUETIAPINE	Antipsychotics	Very often			Possible	Often	
QUINAPRIL	ACE inhibitor (blood pressure reducer)	Often	Sometimes	Rare		Sometimes	
RAMIPRIL	ACE inhibitor (blood pressure reducer)	Often	Sometimes	Sometimes		Sometimes	
RANITIDINE	Histamine H2-receptorantagonists	Sometimes				Very rare	
REDOMEX	Antidepressant	Very often					
RELVAR ELLIPTA	Corticosteroid + bronchodilator						
RISEDRONAAT	Biphosphonate						
RIVASTIGMINE	Cholinesterase inhibitor				Rare		
RIVOTRIL	Benzodiazepine	Often				Possible	Possible
RYTMONORM	Heart medication (irregular rithm)	Very often	Sometimes				
SELECTOL	Betablocker	Often				Often	
SERENASE	Benzodiazepine	Often				Sometimes	Rare
SERETIDE	Bronchodilator					Possible	
SERTRALINE	Antidepressant	Very often				Often	
SIMVASTATINE	Statins	Rare				Possible	Rare
SIPRALEXA	Antidepressant	Often					
SPIRIVA	Bronchodilator	Sometimes					
SPIRONOLACTONE	Diuretic	Possible					
TAMSULOSINE	α1A-adrenoreceptorblocker	Often					

TOTALIP	Statins	Sometimes				Possible	Sometimes
TOVIAZ	Antimuscarinic treament (reducing overactive bladder)	Often	Sometimes		Sometimes		
TRADONAL	Painkiller	Very often			Often		
TRAMADOL RETARD	Painkiller (opiates)	Very often					
TRANDATE	Bètablokker (blood pressure reducer)	Often				Sometimes	
TRANXENE	Benzodiazepine	Possible			Possible	Possible	Possible
TRAZODONE MYLAN	Antidepressant	Possible	Possible		Possible	Possible	Possible
TRAZOLAN	Antidepressant	Possible	Possible		Possible	Possible	Possible
VASEXTEN	Calciumantagonist (blood pressure reducer)	Often					
VEINOFYTOL	Medicine for chronic venous insufficiency	Possible					
XANAX	Benzodiazepinederivatives	Very often		Often	very often	Very often	Very often
XARELTO	Anticoagulant (blood thinner)	Often					
ZALDIAR	Painkiller	Very often			Very often		Sometimes
ZANIDIP	Calciumantagonist (blood pressure reducer)	Sometimes			Rare		
ZOLPIDEM SANDOZ	Benzodiazepine	Often	Often	Often	Often		Often
ZYLORIC	Medicine for gout		Rare		Rare	Rare	

Supplementary table 3: Overview of the sum scores of the side effects of medication

Subjects	*Influence on vestibular system*	*Influence on falling*	*Influence on depression*	*Influence on cognition*
2	54	12	14	17
3	16	3	3	0
4	38	6	6	0
*5**	21	6	8	8
6	24	3	9	6
*7**	37	8	6	7
8	9	0	3	2
9	12	3	0	0
10	31	11	9	9
11	30	15	13	8
12	30	7	12	2
13	23	8	9	9
14	29	12	12	10
15	11	1	2	4
*16**	30	10	9	3
17	11	0	6	4
*18**	32	3	0	0
19	49	8	14	4
20	19	6	7	3
21	31	14	6	3
22	12	3	6	3
23	13	2	3	5
24	3	0	0	0
25	17	0	5	6
26	30	7	13	2
27	12	2	5	3
28	17	0	9	4
29	36	14	13	12
30	21	6	9	14
31	28	11	3	8
*32**	12	3	7	1
33	33	3	9	2
34	29	0	10	6
35	35	10	7	5
36	8	0	0	4
37	21	0	9	6
38	4	0	3	0
39	14	10	4	0
*40**	5	5	4	4
41	16	0	9	6
42	8	0	3	0
*43**	10	0	9	2

44	15	3	3	7
45	4	0	6	0
*46**	4	4	2	2
47	32	6	5	2
48	0	0	0	0

* Participants diagnosed with BPPV

Very rare = 1
Rare = 2
Sometimes/possible = 3
Often = 4
Very often = 5

Auteursrechtelijke overeenkomst

Ik/wij verlenen het wereldwijde auteursrecht voor de ingediende eindverhandeling:
The prevalence of BPPV in a residential care centre and the effectiveness and impact of treatment

Richting: **master in de revalidatiewetenschappen en de kinesitherapie-revalidatiewetenschappen en kinesitherapie bij kinderen**
Jaar: **2018**

in alle mogelijke mediaformaten, - bestaande en in de toekomst te ontwikkelen - , aan de Universiteit Hasselt.

Niet tegenstaand deze toekenning van het auteursrecht aan de Universiteit Hasselt behoud ik als auteur het recht om de eindverhandeling, - in zijn geheel of gedeeltelijk -, vrij te reproduceren, (her)publiceren of distribueren zonder de toelating te moeten verkrijgen van de Universiteit Hasselt.

Ik bevestig dat de eindverhandeling mijn origineel werk is, en dat ik het recht heb om de rechten te verlenen die in deze overeenkomst worden beschreven. Ik verklaar tevens dat de eindverhandeling, naar mijn weten, het auteursrecht van anderen niet overtreedt.

Ik verklaar tevens dat ik voor het materiaal in de eindverhandeling dat beschermd wordt door het auteursrecht, de nodige toelatingen heb verkregen zodat ik deze ook aan de Universiteit Hasselt kan overdragen en dat dit duidelijk in de tekst en inhoud van de eindverhandeling werd genotificeerd.

Universiteit Hasselt zal mij als auteur(s) van de eindverhandeling identificeren en zal geen wijzigingen aanbrengen aan de eindverhandeling, uitgezonderd deze toegelaten door deze overeenkomst.

Voor akkoord,

Bauduin, Anouk **Smeulders, Enya**

Datum: **4/06/2018**