Preface

We are honoured to thank our promoter Dr. J. Spildooren, for giving us the opportunity to complete a Master thesis under her supervision, especially because this was not anticipated last year. She made efforts to make sure we had a Master thesis to begin with and we could count on her years of expertise in the matter. We would like to thank her for this and for giving us her support in the process of completing the thesis. We would like to thank our co-promoters, Prof. Dr. J. Flamaing and Prof. Dr. K. Milisen, for giving us more insight into the overall workings of the project VAL-net and for the quick and efficient answering of the questions we sent regarding certain aspects of the study. We give special thanks to the coordinator of the project, Mme. E. Van Cleynenbreugel, who devoted time and effort to help the students wherever she could. She provided the students with crucial information about the study and provided them the data they needed to complete the thesis. We give final thanks to the staff working at the fall clinic at the University Hospitals Leuven. They gave us first-hand information about the workings of the fall clinic by letting us join them for a day and letting us participate in a couple of fall assessments. This gave us much information and insight in the processes a patient has to go through and this was crucial in thoroughly understanding our Master thesis.

Aarschot, The Fifth of June, 2017 A. J.

As, The Fifth of June, 2017 B. V.

Situating

Falling is a complex problem among elderly. Forty-six percent of the costs of hospital admissions in Europe are due to injuries of this age population. Injuries after a fall are the second-most expensive injuries, costing on average 2140 euros per fall (Polinder et al., 2005). In Belgium, the total cost of hip fractures due to falling is estimated at 308 million euros per year (Svedbom et al., 2013). Because of the growing incidence of the aging population, costs are likely to rise in the next years. Falling has not only an impact on society but also on the physical and emotional state of the individual. Primary and secondary prevention measures are necessary to protect the elderly in the future. However, good compliance with preventative advice against falling is needed to have significant results of these interventions. But is it possible to ameliorate the compliance with fall-prevention advice given to community-dwelling elderly? The project VAL-net investigates this question.

The project VAL-net is executed by the Flemish experimental care-platform InnovAGE, with the support of the Flemish Agency for Innovation by Science and Technology. InnovAGE uses a large set of consumers who test a product or service in health care. The platform offers support to organizations that develop projects towards complex care needs. Project VAL-net conducts research to multifactorial problems like falling among elderly and is one of the projects of InnovAGE. Project VAL-net aims for an improvement of compliance with advice to prevent falling of community-dwelling elderly with an increased fall risk through the development of a counselling network.

The Master thesis is situated within the project Val-net and focuses primarily on the compliance with physiotherapeutic advice given to the participants in the fall clinic. Because of the extent and wide time span of the project, primary outcome measurements were being executed before the students were assigned to the Master thesis subject. The students were responsible for processing the data in a database and subsequently run the statistical analyses of these data. In each stage of the Master thesis, they could count for support on their promoter Dr. J. Spildooren and two co-promoters Prof. Dr. J. Flamaing and Prof. Dr. K. Milisen. The coordinator of the project, Mme. E. Van Cleynenbreugel, helped the students if they had any questions about the project.

1 Article

1.1 Title

Advices[1] of a physical therapist about fall prevention given to community-dwelling elderly: does an individualized approach give better compliance?

1.2 Abstract

Background: Falling is a major health concern in community-dwelling elderly. Health care practitioners face the challenge of dealing with noncompliance of fall-prevention advice. Future aging of the population aggravates this problem and necessitates studies that investigate different clinical approaches to improve this compliance.

Objectives: A six-month controlled clinical trial was conducted on 104 community-dwelling elderly. A newly designed multifactorial fall intervention was compared for compliance with fall-prevention advice. The intervention group, in contrast to the control group, received prioritized advice using the Canadian Occupational Performance Measure, a fall coach and a recommendation to follow treatment with educated primary health caregivers.

Participants: The sample population consisted of 54 participants in the control group and 50 participants in the intervention group. Participants were included based on predefined inclusion criteria.

Measurements: At baseline, demographic data were collected and personal advice was composed and given to each participant. Primary outcome measures consisted of compliance, difficulty with compliance and reasons for noncompliance. Follow-up measurements were at two and six months after baseline.

Results: The results for compliance with advice showed a statistically significant difference for orthostatic hypotension advice at two months (p=0.0077) in favour of the control group. The difficulty with compliance was significantly different for physical therapy advice at two months (p=0.010) and six months (p=0.035) in favour of the intervention group and for

[1] In the English language, the word ‘advice’ has no plural. However, in our study several pieces of advice could be given for the different categories of advice. For better comprehension, the word ‘advices’ was used in this thesis for these subcategories. If the word ‘advice’ was used, it could mean a (sub)category of advice or the general term for advice. E.g. ‘physical therapeutic advice’ could mean both, where ‘physical therapeutic advices’ could only refer to the plural of a subcategory of advice.

orthostatic hypotension advice at two months (p=0.022) in favour of the control group. Most common reasons for noncompliance were cognitive-personal factors.

Conclusion: The investigated multidisciplinary approach had a positive impact on difficulty with compliance for a category of physical therapeutic advice (advice about going to a physical therapist), but not on actual compliance. Future research is recommended to study more effective combinations of multifactorial interventions.

1.3 Introduction

Falling is a multifactorial problem among elderly, needing a multifactorial approach. Hospitalized elderly between the ages of 66 and 75 have on average 2.29 first time falls in the hospital per 1000 patient days. This number nearly doubles to 4.15 per 1000 patient days between the ages of 76 and 85 and increases to 5.61 times per 1000 patient days above the age of 85 (Halfon, Eggli, Van Melle, & Vagnair, 2001). A survey in geriatric wards of 113 participating Belgian hospitals demonstrated that 95.2% of falls were registered, but only 32.8% cases enrolled in a fall-prevention program (Coussement et al., 2009). In primary care, the yearly incidence of falls in Belgium was found to be 2.5% of the older general practice population. For patients older than 65, person-based incidence was estimated around 2506 per 100 000 persons (2.5%), with a raise to 6581 per 100 000 (6.6%) for patients older than 85 years (Boffin, Moreels, Vanthomme, & Van Casteren, 2014). The mean incidence of community-dwelling elderly who fall is 34% per year. This is considerably lower than the mean incidence of falls of institutionalized elderly, which is 43% per year (Rubenstein & Josephson, 2002). However, falling of community-dwelling elderly remains a problem and therefore the primary population for our study consisted of this specific population of elderly. The greatest risk factors for falling of community-dwelling elderly that are relevant for possible physiotherapeutic advice or interventions are sedative use, disability of the lower extremities, disturbance of balance and gait and foot problems (Tinetti, Speechley, & Ginter, 1988).

The seriousness of falling cannot be underestimated. A study at the Department of Traumatology and Emergency Surgery in Leuven, Belgium, revealed that of the 126 multiple trauma patients of 65 years and older, 30% was caused by a simple fall at home. This makes falling, after being in a car accident, the second-most common cause of serious multiple trauma in elderly (Broos, D'Hoore, Vanderschot, Rommens, & Stappaerts, 1993). The total cost of injuries of non-fatal falls is high, counting up to 31 billion dollars in the United States in the year 2015 (Burns, Stevens, & Lee, 2016).

Multifactorial interventions for fall prevention appear to be helpful. A study (Tinetti et al., 1994) showed early on that a multifactorial approach for community-dwelling elderly resulted in a significant 12% reduction in fall incidence after a one-year follow-up in comparison with the control group. Kannus, Sievanen, Palvanen, Jarvinen, and Parkkari

(2005) stated that the multifactorial interventions that include strength and balance training are the most consistent and have the best evidence. Day et al. (2002) proved that exercise could reduce the fall risk in comparison to modifications of home hazards, which had no effect. Chang et al. (2004) concluded that multifactorial falls risk assessments in combination with an exercise program are effective in the reduction of fall risk in elderly. Arnold, Sran, and Harrison (2008) confirmed these benefits of exercise interventions alone.

However, noncompliance remains an issue. In a previous pilot-study with community-dwelling elderly, a multifactorial intervention protocol was set up, where patient-centred fall-prevention programs were given based on fall risk screening and assessment. This study showed that noncompliance with these recommendations was 58.3% (Milisen et al., 2006). Most interventions that aim to reduce fall incidence through preventative advice have low success rates because of high noncompliance with this advice (Horne, Speed, Skelton, & Todd, 2009; Yardley, Beyer, et al., 2007; Yardley, Donovan-Hall, Francis, & Todd, 2007). In the United Kingdom, Yardley et al. did research to find the most common reasons for noncompliance. One of the most common reasons appeared to be that much of this advice was regarded as unnecessary and not wanted (Yardley, Beyer, et al., 2007; Yardley, Donovan-Hall, Francis, & Todd, 2006; Yardley et al., 2008). In our study, we wanted to explore if the combination of an individualized recommendations list, the help of a fall coach and the education of primary health caregivers would result in a better compliance and less difficulty with compliance for fall-prevention advice. On top of this, this study investigated the most common reasons for noncompliance.

1.4 Method

1.4.1 Participants

Recruitment

The sample population consisted of elderly who were sent to the specialized fall clinic of the University Hospitals Leuven (UZ Leuven) because of fall issues. The participants were divided into a control and an intervention group. The allocation was in the order of sign up: the first 54 participants who met inclusion criteria were assigned to the control group, the next 50 participants were assigned to the intervention group (see flowchart).

Selection

Participants were included if they met the following five criteria: 1) experienced in the past year at least one fall incident; 2) were 65 years old or older; 3) agreed to the participation in the project VAL-net; 4) were proficient in the Dutch language; 5) had their consultation at the fall clinic for the first time.

Participants were excluded if they lived in a residential care centre, were transferred to the fall clinic during hospitalization for a fall resulting in one or more fractures (impossible to do a fall evaluation due to the functional impairments caused by the fractures), had their last fracture in the past three months prior to the sign up at the fall clinic.

1.4.2 Procedure

The study consisted of a controlled clinical trial with a control and an intervention group. Participants were included during their first visit at the fall clinic when they met the inclusion criteria mentioned above. Demographic data to compare groups at baseline were taken from all participants. Demographic continuous variables were age and scores on the Timed Up and Go Test (abbr. TUG) (Podsiadlo & Richardson, 1991), Timed Up and Go Cognitive Test (TUG-COG) (Hofheinz & Mibs, 2016), Timed Chair Stance Test (TCS) (Csuka & McCarty, 1985), Tinetti Test (Tinetti, 1986), Mini-Mental State Examination (MMSE) (Folstein, Folstein, & McHugh, 1975) and Geriatric Depression Scale (GDS) (Yesavage et al., 1982). Demographic categorical variables were gender, Four Test Balance Scale (4TBS) (Gardner, Buchner, Robertson, & Campbell, 2001; Rossiter-Fornoff, Wolf, Wolfson, & Buchner, 1995), proprioception (levels: disturbed/not disturbed), presence of F-pathology (yes/no), presence of orthostatic hypotension (yes/no), being able to get up from the ground (yes/no), use of an indoor walking aid and use of an outdoor walking aid (type of walking aid). Measurements of

the control and intervention group were in sequential order, i.e. first the measurements at baseline, the intervention and the follow-up measurements at two and six months of the control group were completed. Secondly, a three-week break was held in which the intervention phase was prepared. Thirdly, the measurements at baseline, the intervention and the follow-up measurements of the intervention group were completed.

The TUG protocol was performed as follows: the participant rises from an armchair (seat height 46 cm), walks at a safe and comfortable pace to a point three meters away, turns around this point, walks back to the chair and sits down again. The timing of the test starts when the participant rises from the chair and stops when he or she sits back down. The participant can attempt the test once before being timed. The participant is permitted to use a walking aid. A faster time to complete the test indicates better functional performance. In general, a score of 13.5 seconds or more is used as a cut-off point to identify an increased risk of falling (Barry, Galvin, Keogh, Horgan, & Fahey, 2014; Podsiadlo & Richardson, 1991). In the current study, another categorisation was made based on the time to complete the test (see infra). Only the absolute time was taken into account for statistical analysis.

The TUG-COG test was performed the same way as the TUG, with the exception that the participant has to count backward by three from a randomly selected number between 20 and 100 during the protocol. An increased risk of falling is identified if a subject performs the test in 15 seconds or more (Hofheinz & Mibs, 2016). In the current study, only absolute time was taken into account for statistical analysis.

The TCS uses a chair with no armrests. The participant, with arms crossed, has to stand up fully and sit down again and this is repeated five times. Timing starts the first time the participant stands up and stops the fifth time he or she sits back down. In general, the cut-off point is set at 14 seconds, a slower time indicating an increased risk of falling (Bohannon, Bubela, Magasi, Wang, & Gershon, 2010; Csuka & McCarty, 1985). In the current study however, only absolute time was taken into account for statistical analysis.

The Tinetti Test is used to assess balance (including fall risk) and gait function in elderly. The test consists of 16 test-items, nine for balance and seven for gait. These items are scored on a three-point ordinal scale, ranging from zero to two, where two indicates independence and zero no independence. Scoring 26 or lower indicates a problem with balance and gait

function. When a subject scores 16 or less, the fall risk multiplies by five (Kopke & Meyer, 2006; Tinetti, 1986). In the current study, only absolute time was taken into account for statistical analysis.

The MMSE is a questionnaire to assess cognitive function. The test consists of 20 items. The total score varies between zero and 30 points, a higher score indicating a better cognitive function. The test is divided into seven categories: orientation in time (five points), orientation in space (five points), registration of three words (three points), concentration and counting (five points), remembering of three words (three points), language (eight points) and visual insight (one point). A score of 28 or less means a disturbed cognition (Folstein et al., 1975; Tombaugh & McIntyre, 1992). Only absolute time was taken into account for statistical analysis.

The GDS is a questionnaire to measure depression among elderly. The test consists of 15 yes-no questions. Ten questions are associated with depression if answered with 'yes'. Five questions are associated with depression if answered with 'no'. Answers associated with depression are scored with one, others with zero. A score of six or more is indicative of a depression (Yesavage et al., 1982). Only absolute time was taken into account for statistical analysis.

The 4TBS is a test to measure the amount of balance of a participant. He or she has to stand in four different positions sequentially, with a rising degree of difficulty (parallel, semi-tandem, tandem and single-leg stance) for ten seconds. The participant cannot use an assistant device and cannot wear shoes during the test. The examiner helps the participant into the right position until the test starts. Every successful position is scored with one point. If the participant cannot stand parallel for ten seconds, the score is zero. If the participant can stand parallel for 10 seconds but not in the semi-tandem position, he receives a score of one etc. (Gardner et al., 2001; Rossiter-Fornoff et al., 1995).

Control group

The intervention of the control group consisted of a standard interdisciplinary fall evaluation and advice of the fall clinic of UZ Leuven. The evaluation consisted of: the self-completion of a fall-related questionnaire at the fall clinic and separate consultations with four different health care providers: an occupational therapist, a physical therapist, a nurse and a geriatrician. Through the questionnaire, personal information (e.g. age, gender, cognition,

sight, incontinence, mood, mobility, functionality), information about current caregivers, medication use, fall-related information (e.g. fall history, fear of falling, possible risk factors) and information about their home situation was obtained. During the separate consultations, each healthcare provider measured specific demographic variables in correspondence with their area of expertise (e.g. TUG, TUG-COG, TCS, Tinetti Test, MMSE, GDS, 4TBS, proprioception, presence of F-pathology, presence of orthostatic hypotension, being able to get up from the ground, use of indoor walking aid and use of outdoor walking aid). After the evaluation, collected data were discussed in an interdisciplinary meeting with these four health care providers. Together they formulated advice to decrease the fall risk for each participant. Afterward, a debriefing was held between the geriatrician and the individual participant, notifying the participant the conclusions of the interdisciplinary meeting and the advice for maximal comprehension.

Intervention group

Before the first consultation, the intervention group received a brochure and questionnaire to fill in at home. The brochure contained general information about the functioning of the fall clinic and the fall evaluation. The questionnaire was the same as the control group. At the fall clinic, to increase efficiency, all health care providers participating in the study received an education to perform the complete assessment. This course took place during the three-week break between the control and the intervention phase of the study. The following rule was also introduced: if the TUG was less than 20 seconds, no Tinetti Test was taken. This was to shorten the fall evaluation and make it less tiresome for the participant. With the hypothesis to improve therapy compliance and decrease difficulty with compliance, the intervention group received multifactorial additions on top of the standard interdisciplinary fall evaluation of the fall clinic of UZ Leuven. These additions were: 1) patient-centred advice based on the participants' perception of importance obtained with the Canadian Occupational Performance Measure (COPM), 2) an educational course for primary health caregivers within the district of Leuven and 3) the allocation of a fall coach for every participant in the intervention group.

The COPM is a semi-structured interview combined with a Visual Analog Scale (VAS) and measures the perception of the experienced difficulties in the daily functioning by the importance the participants give to these difficulties (Law et al., 1990). With the

questionnaire, an enumeration was made of these difficulties and with the VAS score participants ordered the importance thereof. The score ranged from zero to ten (not important to most important). The five most important experienced problems were selected and scored on a VAS scale for satisfaction and performance by the participant. These results were discussed in an interdisciplinary meeting and the health care providers formulated advices based on these results. The health care providers with the involvement of each participant then sorted these in order of importance. The obtained list of advices was then discussed with the participant for maximal comprehension.

The primary health caregivers present at the educational course included: 30 physical therapists, 13 home nurses, seven occupational therapists, three general practitioners, two pharmacists and 14 others. The reason for this course was to give primary health caregivers within the district of Leuven a basic understanding of fall-related issues and to give practical instructions considering the handling of elderly with a high fall risk. The participants in the intervention group, who were advised to consult a physical therapist, were recommended to go to a physical therapist that completed the course.

The role of the fall coach consisted of obtaining a better communication between health caregivers at the fall clinic and the participants and helped them to comply with the given advices during the follow-up period. The fall coach acted as a contact person and motivator for the participants and adjusted the advices on the individual situation, as an organizer of the interdisciplinary consultation and as a communication manager with primary health caregivers.

Measurements

At the beginning of this paper, the general term for advice was ‘physical therapy advice’, because a regular physical therapist could also give them in primary care. However, these were further divided into five categories, with possible different subcategories: moving advice (MA), bending advice (BA), physical therapy advice (abbreviation PTA, representing a category within the general term ‘physical therapy advice’), walking aid advice (WAA) and orthostatic hypotension advice (OHA). MA consisted of encouraging the participant to increase daily movement to 30 minutes a day through exercise, to use a stationary bike or handbike. With a BA, the participant got the instruction to always use a fixed point to hold oneself when bending. PTA instructed the participant to go to a physical therapist for

exercise therapy or to increase the frequency of their current treatment. WAA consisted of recommendations about the use of walking aids (stick, four-wheel walking aid, three wheel walking aid, wheelchair) indoor or outdoor. OHA consisted of: transfer- and movement advice (moving the feet a while before getting up from a lying position, avoid sudden movements, sitting no longer than 30 minutes or avoid sudden bending), advice to wear support stockings or advice related to medication (cessation of certain medication that induce a low blood pressure and replacement to medication that do not have this effect).

The primary outcome measures were: compliance with given advices, the experienced grade of difficulty of the participant to comply with these advices (abbr. 'difficulty with compliance') and the reasons for noncompliance. Levels of compliance with advices were: yes, partial and no. Levels of difficulty with advices were: very easy, easy, hard and very hard. Answers for reasons for noncompliance were not restricted, meaning that every participant could give any reason. For statistical analysis however, these answers were later categorized by both examiners into one of ten predetermined categories: conflict with caregiver (general practitioner did not change the medication list), fear of injury, cognitive-personal factor (participant forgot the advice, believed the advice was not necessary, did not feel like following up or did not understand the reason for the advice), situational factor (difficulty with transportation, participant did not have time to execute the advice), financial factor, physical factor (pain, blood pressure fluctuations, fatigue, urinary urgency etc.), experience factor (participant did not feel comfortable while following up the advice e.g. support stockings gave too much tension), behavioural factor (participant didn't follow up because they wanted to keep doing things quickly or in an unsafe way) or no reason. Reasons for noncompliance were categorized at two and six months.

Two follow-up measurements were scheduled at two and six months after the first consultation. At two months, this consisted of a house visit, at six months of a telephone call.

1.4.3 Data-analysis

The continuous demographic variables of participants in both groups were compared using Welsh test for age, Wilcoxon rank sum test for the Timed Chair Stand test. An independent two-sample t-test was used for the Timed Up and Go test, the Timed Up and Go Cognitive, Tinetti Test, the Geriatric Depression Scale and the Mini-Mental State Examination. The

categorical demographic variables of both groups were compared using the Pearson's chi-squared test if expected cell counts were greater than five. This was the case for gender, presence of F-pathology, orthostatic hypotension and being able to get up from the ground. The Four Test Balance Scale, disturbed proprioception, indoor walking aid and outdoor walking aid were statistically analysed through the Fisher's exact test, because cell counts were less than five.

The primary outcomes 'compliance with advice' and 'difficulty with compliance' were statically analysed separately at two and six months and a difference was calculated between two and six months for both variables. This difference was calculated by first enumerating the levels of each outcome measure. For compliance with advice, the answer 'yes' was numbered two, answer 'no' was numbered zero, and the answer 'partial' was numbered one. For difficulty with compliance, the answers were numbered as follows: 'very easy' as two, 'easy' as one, 'hard' as minus one, 'very hard' as minus two. These two primary outcomes were statistically analysed with an ordinal logistic regression model for the data at two months, at six months and for the difference between six and two months. For the latter, a Bonferroni correction was used to compensate for possible statistical errors made by subtracting two groups of data. For every advice, a percentage of compliance was calculated. This by taking the amount the advice was fully complied and dividing it by the number of times the advice was given (sum of the amount of full, partial and no compliance), multiplied by 100 to obtain a percentage. Overall compliance was calculated per group by the number of times advices were fully complied, divided by the total amount of advices given, multiplied by 100 to obtain a percentage. The primary outcome 'reasons for noncompliance' was statically analysed with a Fisher's exact test. A descriptive analysis was performed to measure which reasons were the most common per category of advice. The level of significance was set at $p=0.05$. Calculations were performed using JMP Pro 12 software.

1.5 Results

The study consisted of 104 participants (i.e. 54 participants in the control group and 50 in the intervention group). Nine participants in the control group were lost to follow-up at two months and two at six months. In the intervention group, nine and five participants were lost to follow-up at two months and six months respectively. A total of 79 participants completed the study (i.e. 43 participants in the control group and 36 participants in the intervention group).

The analysis of the demographical data showed no significant difference between control and intervention group, so both groups were comparable at baseline (table 1).

The results of compliance with advice at two months only demonstrated a significant difference in compliance with orthostatic hypotension advice (p=0.0077) in favour of the control group. No significant difference was found at six months and for the difference between six and two months (table 2a, 2b, 2c). Overall compliance at two months for the intervention group was 57.1%, for the control group 60.0%. At six months, this was 57.1% for the intervention group and 64.0% for the control group.

For the outcome 'difficulty with compliance', there was a significant difference between the control and intervention group at two months for physical therapy advice (p=0.010) in favour of the intervention group, and for orthostatic hypotension advice (p=0.022) in favour of the control group. At six months there was only a significant difference for physical therapy advice (p=0.035), in favour of the intervention group. Analysis of the difference between two and six months showed no significant difference for any of the categories of advice (table 3a, 3b, 3c).

The different categories of reasons for noncompliance were statically analysed. No significant difference was found at two and six months for these reasons between the intervention and control group. Descriptively, for nearly every category of advice at two and six months, the most common reasons for noncompliance were cognitive-personal factors. Except for movement advice at six months, which had physical factors as the most common reasons (table 4).

1.6 Discussion

The aim of the study was to investigate if an individualized approach of giving fall-prevention advice to community-dwelling elderly would have a beneficial outcome regarding the compliance with this advice and the perceived difficulty with compliance. The individualized approach was: sorting the advice according to the most important problems the participant experienced in every day life, allocation of a fall coach and a recommendation (if applicable) to go to primary health caregivers that completed the educational course. Also, the study intended to offer an insight into the most common reasons for noncompliance.

In case of compliance, the study failed to find a positive influence of an individualized approach for the intervention group compared to the control group for any of the categories of advice. In contrast, it appeared that for orthostatic hypotension advice at two months follow-up, the control group showed more compliance than the intervention group. This difference was no longer present at six months follow-up. For difficulty with compliance, the study proved that the intervention group found it easier to follow up the physical therapy advice, both at two months and six months follow-up. For the orthostatic hypotension advice however, the control group found it easier to comply than the intervention group at two months follow-up. After six months, again this difference was no longer present. Numerous reasons were given to explain why the participant didn't comply. These reasons did not differ between the intervention and the control group. Most common reasons reported were for almost every advice cognitive-personal factors. This was with the exception of movement advice at six months follow-up, where physical factors were most prominent, followed by situational factors and where cognitive-personal factors were the least given reasons.

1.6.1 Choice of demographic data

The demographic data of choice were: age, scores on Timed Chair Stance Test, Timed Up and Go, Timed Up and Go Cognitive, Tinetti Test, Mini-Mental State Examination, Geriatric Depression Scale, 4-Test Balance Scale, gender (m/w), proprioception (disturbed/not disturbed), F-pathology (y/n), being able to get up from the ground independently (y/n), use of an indoor walking aid and use of an outdoor walking aid (y/n). The selection of tests was in consultation with the promoter Dr. J. Spildooren. These were all tests taken in the fall clinic to see if both groups were comparable at baseline. However, these tests are also

generally taken in the fall clinic from ambulatory patients, who visit the fall clinic after falling for fall preventative interventions, to predict the likelihood of future falls. A recent systematic review and meta-analysis of Lusardi et al. (2017) investigated the fall-predictability capabilities of a combination of 15 self-report measures (including GDS and MMSE) and 26 performance-based measures (including TUG). For self-report measures, GDS appeared to be the most useful, when combined with the Falls Efficacy Scale International (Tinetti, Richman, & Powell, 1990). Use of the GDS for fall assessments is confirmed in another study (Carpenter et al., 2014). As for performance-based measures, Timed Up and Go scores, in combination with the Berg Balance Scale (K. Berg, Wood-Dauphine, Williams, & Gayton, 1989; K. O. Berg, Wood-Dauphinee, Williams, & Maki, 1992), Single-limb stance (De Carli et al., 2010), Five times sit-to-stand Test (Buatois et al., 2008), and self-selected Walking speed (VanSwearingen, Paschal, Bonino, & Yang, 1996) seemed to be the best measure to predict future falls. The utility of the TUG was confirmed in another study (Singh, Pillai, Tan, Tai, & Shahar, 2015). These results are less applicable for this Master thesis, for the data were already collected when the students entered the study, but could potentially ameliorate future testing in the fall clinic at the University Hospitals Leuven to predict future falls of patients better. Also, Sjosten et al. (2007) found that good cognitive function (a score >25, measured with the MMSE) was a predictor for the attendance of educational lectures on fall prevention once a month. Although this is not the same as following up advice after six months, it gives a reason as to why the MMSE was taken from the participants in this study.

Comparison of the intervention and control group for demographic data showed no statistical difference, meaning similar demographic data at baseline. The collection of demographic data was different for both groups. In the control group, it was on paper. In the intervention group, this was on a Pyxicare application (abbr. Pyxicare app) on a Samsung Tablet (http://pyxima.net/pyxicare/platform.html). No studies with Pyxicare have yet been published. In comparing paper versus tablet-based questionnaires in the older population measuring the quality of life, Fanning and McAuley (2014) showed that tablet-based questionnaires were preferred and considered faster, although navigation could be more troublesome. Collected data were not significantly different between both methods. A Cochrane Systematic Review of Marcano Belisario et al. (2015) found no significant

difference in overall mean test scores between mobile apps on a tablet versus other methods like a laptop, paper, SMS or tablet computers (manufactured before the release of the first app-based tablet in 2007) without the use of apps. Acceptability of these apps of participants was the same as with Fanning and McAuley (2014).

To our knowledge, only one variable was negatively affected by the use of the app, namely 'the frequency of use of indoor and outdoor walking aids'. This because, where the paper version asked about the usage (y/n) of walking aids, along with the frequency of usage, the app Pyxicare didn't provide this last option. Therefore it was decided to omit this variable in the comparison of control and intervention group. It is possible that with this variable, the demographic data regarding walking aids would not have been the same at baseline. In our opinion, the use of Pyxicare provided an advantage logistically and gave a significant reduction of the data analysis time. We believe that the use of electronic files can play a role in the faster processing of data, which could decrease the total amount of time that research requires in larger institutes like hospitals and maybe even in primary care.

1.6.2 Compliance with advice and difficulty with compliance

Compliance percentages of multifactorial interventions preventing falls of the elderly have been described in previous studies (Devor, Wang, Renvall, Feigal, & Ramsdell, 1994; Nikolaus & Bach, 2003; Sjosten et al., 2007). Sjosten et al. (2007) gave a multifactorial treatment to community-dwelling elderly. They reported compliance percentages of 25% (95% Confidence Interval (CI): 0.4-49.6) for a psychosocial treatment, 58% (95% CI: 27.8-88.2) for exercise groups and 33% (95% CI: 4.8-61.2) for attendance to lectures about the risk factors of falling. For home adjustments, the percentage of compliance was 75.7% (No CI reported) (Nikolaus & Bach, 2003). Because of the broad term of a multifactorial intervention and the various forms it can have, it is difficult to compare the percentages of all these studies with the outcome compliance percentages of the current study. Studies that only gave advice as an intervention can be used for comparison. Only Devor et al. (1994) gave solely social and safety recommendations to frail elderly with a high risk of falling, and reported an overall compliance percentage of 50.2% (95% CI: 43.7-56.6). The current study had higher overall compliance percentages at two months and six months for both the intervention (57.1% at two and six months) and control group (60.0% at two months, 64.0% at six months), indicating that follow-through of advice was higher for this sample.

However, compliance between intervention and control group of the current study only seemed to differ in favour of the control group, namely for orthostatic hypotension advice at two months. In addition, the control group found this advice easier to follow up at two months. We believe this is because, although the presence of orthostatic hypotension was equal at baseline, the intervention group received much more (n=116) orthostatic hypotension advices to follow up (with 55 full compliance; 24 partial compliance; 37 no compliance) in comparison with the control group, which only received 39 advices (with 29 full compliance; 2 partial compliance; 8 no compliance). It seems logical that the higher the number of advices to follow up, the more likely the group is to miss more of them. This difference in compliance was no longer present after six months. This means that long-term deficiency of compliance between intervention and control remained absent. We did not find the reason why this advice was also perceived as less difficult at two months.

For physiotherapeutic advice, the intervention group did find it easier to follow up these advices, although this didn't lead to a better compliance than the control group. This can be explained by the help the fall coach gave in searching for a physical therapist after the visit to the fall clinic, and because of the educational course the primary health caregivers received, ameliorating their treatment and making it less difficult to comply.

1.6.3 Reasons for noncompliance

The most common reason for noncompliance was cognitive-personal oriented, with the exception of a physical factor for movement advice at six months. For movement advice, it seems logical that for advice that encourages movement of the body, physical constraints as reasons for noncompliance would be prominent. Given the current sample of elderly, it was not unexpected that cognitive-personal factors would be the most prominent reason. People of older age commonly have more cognitive difficulties, like remembering of advice. Due to their older age they also tend to have a rigid personality, that doesn't allow them to change habits easily. Bunn, Dickinson, Barnett-Page, McInnes, and Horton (2008) confirmed that both under-estimation of the risk of falling and denial (corresponding partially with cognitive-personal factors in the current study) play a significant role as barriers towards treatments in fall clinics. Also poor functional ability and health play a role (corresponding with physical factors). Child et al. (2012) confirmed most of these factors. However, in this

last study practical considerations like financial barriers seemed to be of much greater importance than in the current study.

An interesting reason given by participants was a conflict with a caregiver. This was the case when advice at the fall clinic was given to stop medication but the general practitioner told them not to. Maybe in the future a better communication between the fall clinic and primary health caregivers could prevent this problem. Fear of injury was also given as a reason. However, this was only experienced during the use of a four-wheel walking aid.

1.6.4 Possible measurement and statistical errors

Because of the chosen study design (first doing the control treatment, then a three-week preparation and lastly the intervention treatment), the caregiver examiners could not be blinded. During the three-week break after completing the phase of the control group, an educational program was held for all caregivers of the fall clinic, so that one caregiver could complete the entire assessment of the demographic data. Because of this, the assessment of the intervention group was not done the same way. This could have had an effect on the obtained results, with higher inter-rater variability for the control group (see infra).

Logistically, it wasn't possible for the students to use the best statistical model for the statistical analysis of the primary outcome variables compliance and difficulty with compliance. With repeated measures, it was most optimal to use a mixed model analysis. However, this was not achievable with the statistical software (JMP Pro 12) we had available. An alternative approach was chosen, in which we analysed the data for every follow-up time separately (at two months and six months) and subsequently ran an analysis of the difference of both values (six months minus two months) for compliance and difficulty with compliance. Although we believe this was the best alternative for a mixed model design, it remains the second best choice. In statistics the more calculations are made with given data, the more statistical errors are likely to be made. With this analysis, we may have made more errors than with a mixed models design. Data from the difference between six months and two months were compared for statistical significance using a Bonferroni correction: the new significance level was set on 0.025 (0.05/2) because of comparison of two groups: one group at two months and one group at six months.

1.6.5 Limitations of the study and possible improvements for future studies

One limitation of the study is that participants in the intervention group did not receive the same method of measurements of the demographical data. Exact differences are explained above. This poses a measurement bias on the demographical data. If only one variable of this measurement was different, this could have been part of the intervention protocol. This was not the case. Another limitation consisted in the fact that participants who received physical therapy advice (PTA) could not be forced to go to a physical therapist that completed the educational course. In the initial design of the study, this was never the plan. Now it is unclear if the educational course of primary health caregivers could be effective in ameliorating compliance of patients. Better control of this variable in the future by for example arranging physical therapy sessions in the fall clinic could be useful in the future studies.

We cannot say with certainty why compliance and difficulty with compliance were not as high as expected. A hypothesis is that a two-time follow-up (at two and six months) is not enough to make sure patients remember and carry out their advice. However, van Haastregt et al. (2000) showed no effect of five follow-up measurements during one year on falls. Also, we believe that more involvement of spouse and family members in the advice given by the fall clinic could have a positive impact. Cognitive-personal factors remained the main issue, and support of family can be a facilitator for these factors (Bunn et al., 2008).

1.7 Conclusion

We can conclude that the proposed multifactorial approach did not have a positive influence on compliance with fall-prevention advice. Only a category of advice (about going to a physical therapist) seemed less difficult for the participant, but the intervention had no effect on the compliance itself. Future research is recommended to study better and more effective combinations of multifactorial treatments in the battle against noncompliance of advice.

Flowchart:

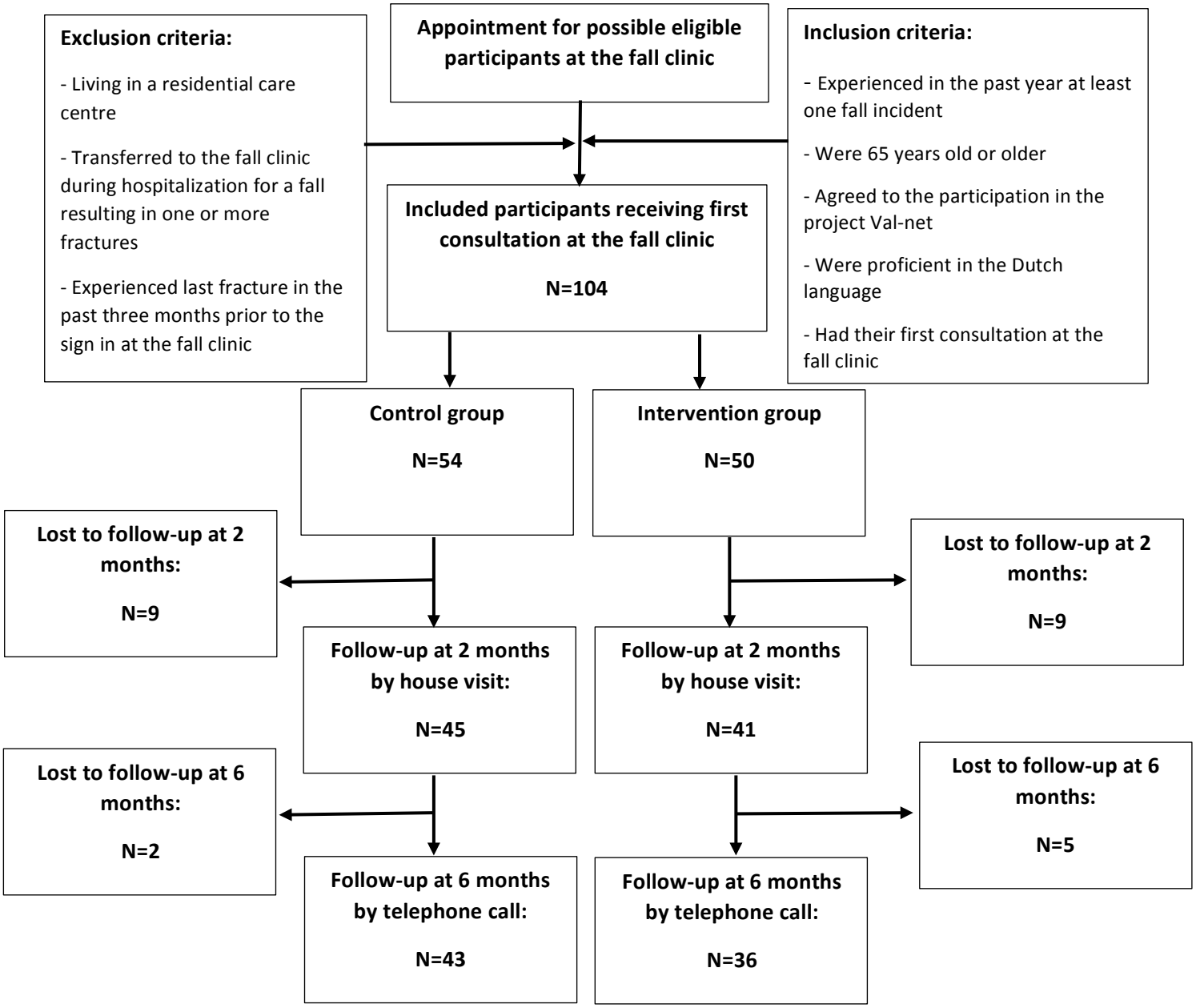
Exclusion criteria:
- Living in a residential care centre
- Transferred to the fall clinic during hospitalization for a fall resulting in one or more fractures
- Experienced last fracture in the past three months prior to the sign in at the fall clinic
Appointment for possible eligible participants at the fall clinic
Inclusion criteria:
- Experienced in the past year at least one fall incident
- Were 65 years old or older
- Agreed to the participation in the project Val-net
- Were proficient in the Dutch language
- Had their first consultation at the fall clinic
Included participants receiving first consultation at the fall clinic
N=104
Control group
N=54
Intervention group
N=50
Lost to follow-up at 2 months:
N=9
Lost to follow-up at 2 months:
N=9
Follow-up at 2 months by house visit:
N=45
Follow-up at 2 months by house visit:
N=41
Lost to follow-up at 6 months:
N=2
Lost to follow-up at 6 months:
N=5
Follow-up at 6 months by telephone call:
N=43
Follow-up at 6 months by telephone call:
N=36

Table 1: Demographic data (effect mean ± SD/amount, percentage/P-value)

Variable	**Control**	**Intervention**	**P-value**
Age	80.09 ± 1.64	78.56 ± 1.70	0.20
TCS	25.49 ± 4.43	25.41 ± 5.82	0.85
TUG	20.78 ± 3.39	20.98 ± 3.53	0.94
TUG-COG	27.52 ± 7.83	30.95 ± 6.95	0.52
Tinetti Test	20.13 ± 1.33	19.44 ± 1.71	0.52
MMSE	25.82 ± 1.02	25.37 ± 1.03	0.53
GDS	8.70 ± 1.71	7.05 ± 1.18	0.12
Gender			
Men/women	18 (33.33%)/ 36 (66.67%)	18 (36.00%)/ 32 (64.00%)	0.78
4TBS			
0	2 (4.26%)	2 (5.71%)	0.57
1	7 (14.89%)	5 (14.29%)	-
2	27 (57.45%)	21 (60.00%)	-
3	9 (19.15%)	3 (8.57%)	-
4	2 (4.26%)	4 (11.43%)	-
Total	47	35	-
Proprioception			
Disturbed/ not disturbed	7 (14.00%)/ 43 (86.00%)	3 (8.57%)/ 32 (91.43%)	0.51
Total	50	35	-
F-pathology			
Yes/no	23 (42.59%)/ 31 (57.41%)	24 (51.06%)/ 23 (48,94%)	0.40
Orthostatic hypotension			
Yes/no	15 (28.30%)/ 38 (71.70%)	18 (43.90%)/ 23 (56.10%)	0.12
Being able to get up			

from the ground			
Yes/no	23 (44.23%)/ 29 (55.77%)	23 (47.92%)/ 25 (52.08%)	0.71
Indoor walking aid			
Two-wheel walking aid	1 (1.85%)	0 (0.00%)	0.75
Four-wheel walking aid	11 (20.37%)	6 (13.04%)	-
Walking rack	1 (1.85%)	2 (4.35%)	-
Stick	16 (29.63%)	14 (30.43%)	-
None	25 (46.30%)	24 (52.17%)	-
Total	54 (54.00%)	46 (46.00%)	-
Outdoor walking aid			
Three-wheel walking aid	1 (1.85%)	0 (0.00%)	0.052
Four-wheel walking aid	19 (35.19%)	8 (19.05)	-
Arm of partner	1 (1.85%)	0 (0.00%)	-
Wheelchair	1 (1.85%)	0 (0.00%)	-
Stick	17 (31.48%)	11 (26.19%)	-
None	15 (27.78%)	23 (54.76%)	-
Total	54 (56.25%)	42 (43.75%)	-

Categorical variables are presented with associated levels.

Continuous data are presented with effect mean and standard deviation of 95 percent, categorical data with amounts and percentages relative to the total amount per group.

Table 2a: Compliance with advice at 2 months, 6 months and difference between times (p-value)

	2M	**6M**	**6M - 2M***
MA	0.34	0.45	0.86
BA	0.70	0.43	0.094
PTA	0.18	0.78	0.23
WAA	0.43	0.42	0.41
OHA	**0.0077**	0.12	0.51

*Corrected with Bonferroni correction to a significance level of 0.025.

Abbr.: MA: moving advice; BA: bending advice; PTA: physical therapy advice; WAA: walking aid advice; OHA: orthostatic hypotension advice

Significant p-values of every advice are highlighted in bold.

Table 2b: Compliance with advice at 2 months (amount, percentage, p-value)

	Group	**Complete compliance**	**Partial compliance**	**No compliance**	**Compliance percentage**	**P-value**
MA	I	14 (50.00%)	3 (10.71%)	11 (39.29%)	50.00%	0.34
	C	6 (66.67%)	1 (11.11%)	2 (22.22%)	66.67%	-
BA	I	9 (64.29%)	1 (7.14%)	4 (28.57%)	64.29%	0.70
	C	11 (68.75%)	2 (12.50%)	3 (18.75%)	68.75%	-
PTA	I	22 (73.33%)	4 (13.33%)	4 (13.33%)	**73.33%**	0.18
	C	19 (61.29%)	1 (3.23%)	11 (35.48%)	61.29%	-
WAA	I	3 (37.50%)	1 (12.50%)	4 (50.00%)	37.50%	0.43
	C	8 (47.06%)	4 (23.53%)	5 (29.41%)	47.06%	-
OHA	I	55 (47.41%)	24 (20.69%)	37 (31.90%)	47.41%	**0.0077**
	C	29 (74.36%)	2 (5.13%)	8 (20.51%)	**74.36%**	-

Highest compliance percentages per group and significant p-values of every advice are highlighted in bold.

Table 2c: Compliance with advice at 6 months (amount, percentage, p-value)

	Group	Complete compliance	Partial compliance	No compliance	Compliance percentage	P-value
MA	I	10 (41.67%)	6 (25.00%)	8 (33.33%)	41.67%	0.45
	C	5 (55.56%)	2 (22.22%)	2 (22.22%)	55.56%	-
BA	I	10 (71.43%)	2 (14.29%)	2 (14.29%)	**71.43%**	0.43
	C	9 (56.25%)	4 (25.00%)	3 (18.75%)	56.25%	-
PTA	I	17 (60.71%)	2 (7.14%)	9 (32.14%)	60.71%	0.78
	C	19 (65.52%)	1 (3.45%)	9 (31.03%)	65.52%	-
WAA	I	3 (42.86%)	1 (14.29%)	3 (42.86%)	42.86%	0.42
	C	8 (53.33%)	4 (26.67%)	3 (20.00%)	53.33%	-
OHA	I	56 (58.95%)	9 (9.47%)	30 (31.58%)	58.95%	0.12
	C	28 (73.68%)	2 (5.26%)	8 (21.05%)	**73.68%**	-

Highest compliance percentages per group and significant p-values of every advice are highlighted in bold.

Table 3a: Difficulty with compliance at 2 months, 6 months and difference between times (p-value)

	2M	**6M**	**6M-2M***
MA	0.58	0.25	0.47
BA	0.56	0.54	0.32
PTA	**0.010**	**0.035**	0.73
WAA	0.44	0.79	0.49
OHA	**0.022**	0.16	0.73

*Corrected with Bonferroni correction to a significance level of 0.025

Significant p-values of every advice are highlighted in bold.

Table 3b: Difficulty with compliance at 2 months (amount, percentage, p-value)

	Group	**Very hard**	**Hard**	**Easy**	**Very easy**	**P-value**
MA	I	1 (3.57%)	14 (50.00%)	13 (46.43%)	0 (0.00%)	0.58
	C	0 (0.00%)	4 (44,44%)	5 (55.56%)	0 (0.00%)	-
BA	I	0 (0.00%)	1 (7.69%)	11 (84.62%)	1 (7.69%)	0.56
	C	0 (0.00%)	3 (18.75%)	12 (75.00%)	1 (6.25%)	-
PTA	I	0 (0.00%)	5 (17.24%)	17 (58.62%)	7 (24.14%)	**0.010**
	C	3 (9.68%)	8 (25.81%)	19 (61.29%)	1 (3.23%)	-
WAA	I	0 (0.00%)	2 (25.00%)	5 (62.50%)	1 (12.50%)	0.44
	C	2 (11.76%)	4 (23.53%)	10 (58.82%)	1 (5.88%)	-
OHA	I	5 (4.35%)	30 (26.09%)	74 (64.35%)	6 (5.22%)	**0.022**
	C	0 (0.00%)	4 (10.26%)	33 (84.62%)	2 (5.13%)	-

Significant p-values of every advice are highlighted in bold.

Table 3c: Difficulty with compliance at 6 months (amount, percentage, p-value)

	Group	Very hard	Hard	Easy	Very easy	P-value
MA	I	3 (12.50%)	12 (50.00%)	9 (37.50%)	0 (0.00%)	0.25
	C	0 (0.00%)	4 (44.44%)	5 (55.56%)	0 (0.00%)	-
BA	I	0 (0.00%)	1 (7.14%)	12 (85.71%)	1 (7.14%)	0.54
	C	0 (0.00%)	4 (25.00%)	12 (75.00%)	0 (0.00%)	-
PTA	I	0 (0.00%)	5 (17.86%)	22 (78.57%)	1 (3.57%)	**0.035**
	C	0 (0.00%)	12 (41.38%)	17 (58.62%)	0 (0.00%)	-
WAA	I	0 (0.00%)	3 (42.86%)	3 (42.86%)	1 (14.29%)	0.79
	C	0 (0.00%)	4 (26.67%)	11 (73.33%)	0 (0.00%)	-
OHA	I	8 (8.42%)	23 (24.21%)	61 (64.21%)	3 (3.16%)	0.16
	C	0 (0.00%)	7 (18.92%)	30 (81.08%)	0 (0.00%)	-

The significant p-values of every advice are highlighted in bold.

Table 4: Reasons for noncompliance (amount, P-value)

	Factors	Intervention	Control	Total	P-value
MA 2M	**Cognitive-personal**	7	1	8	0.49
	Physical	5	1	6	-
	Situational	1	1	2	-
MA 6M	**Physical**	7	1	8	0.24
	Situational	4	1	5	-
	Cognitive-personal	1	2	3	-
BA 2M	**Cognitive-personal**	4	4	8	1.00
	Situational	1	0	1	-
BA 6M	**Cognitive-personal**	1	4	5	1.00
	Situational	0	2	2	-
PTA 2M	**Cognitive-personal**	3	5	8	0.50
	Situational	2	3	5	-
	Conflict caregiver	0	3	3	-
	Financial	0	1	1	-
	Physical	1	0	1	-
PTA 6M	**Cognitive-personal**	6	4	10	0.16
	Situational	1	4	5	-
	Conflict caregiver	2	0	2	-
	Physical	1	0	1	-
WAA 2M	**Cognitive-personal**	3	5	8	0.52
	Situational	1	3	4	-
	Fear of injury	1	0	1	-
WAA 6M	**Cognitive-personal**	2	4	6	0.82
	Situational	1	2	3	-
	Fear of injury	1	0	1	-
	Behavioural	0	1	1	-
OHA 2M	**Cognitive-personal**	35	6	41	0.86
	Experience factor	8	2	10	-
	Physical	6	1	7	-
	Behavioural	7	0	7	-
	Conflict	2	0	2	-

	caregiver				
	Situational	1	0	1	-
OHA 6M	**Cognitive-personal**	21	5	26	0.29
	Experience factor	4	3	7	-
	Physical	6	0	6	-
	Conflict caregiver	3	0	3	-
	Behavioural	2	0	2	-
	Situational	1	1	2	-

The reasons that have the highest number of participants per category of advice at two and six months are highlighted in bold.

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