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Faculteit Geneeskunde en Levenswetenschappen

master in de revalidatiewetenschappen en de kinesitherapie

Masterthesis

Software validation of a 24/7 fall risk prediction tool in community-dwelling older adults - a pilot study

Cathérine Vinken

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

PROMOTOR :
dr. Joke SPILDOOREN

COPROMOTOR :
dr. Carolien STROUWEN

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

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Research framework

This pilot study forms an important element in fall prevention in community-dwelling older adults and is therefore situated in the Geriatric Rehabilitation. Because of the high prevalence of falls in older adults, research concerning fall prevention is very important. To improve fall prevention in the community-dwelling older population, detection of increased fall risk prior to a fall is necessary.

In this comparative pilot study, the examination of a 24/7 fall risk prediction device was performed under the lead of Dr. J. Spildooren and Dr. C. Strouwen. A master student physiotherapy of the University of Hasselt collaborated with the ongoing investigation for the development of her master thesis. The recruitment of the participants was carried out by the experimental garden “Careville” after which the research design was performed by Dr. J. Spildooren and Dr. C. Strouwen who additionally performed the measurements, assisted by the master student. The data acquisition, data processing and academic writing were performed by the master student, with guidance and supervision of Dr. J. Spildooren and Dr. C. Strouwen.

Index

1 Abstract

Background: The occurrence of falls is a major problem in the community-dwelling older population because of its consequences concerning health and medical costs. This research investigates a 24/7 fall prediction device which is developed to predict an acute increase in fall risk prior to a fall in the home environment of a community-dwelling older adult (CDOA).

Objectives: This comparative pilot study aims to validate software behind this fall prediction device (i.e. the ALMA Home wearables) by comparing it to the outcomes of instrumented clinical tests (with the GAITRite electronic walkway and APDM sensors) concerning gait analysis. In addition, the comparison of the hardware of the two instrumented clinical tests (i.e. the GAITRite and the APDM sensors) was aimed.

Participants: Twenty-one community-dwelling older adults with and without a fall history participated in this study.

Measurements: A clinical test battery was performed and registered by the GAITRite electronic walkway, the APDM sensors and the ALMA Home wearables. During the test battery cadence, speed, cycle duration, mean stride length and stride length variability were measured.

Results: Software analysis proved significant differences between the APDM sensors and the ALMA Home wearables in 11 out of 25 parameters, mainly during backwards walking and concerning the measurements of stride length variability. The hardware analyses proved differences between the GAITRite and the APDM sensors concerning gait analysis in 18 out of 25 parameters, which is more compared to the software analysis. Although, the APDM sensors and the GAITRite were proven to be well correlated. The same high correlation was proved between software of the ALMA Home wearables and the APDM sensors.

Conclusion: The validity of the software behind the ALMA Home wearables for fall risk detection is proven to be good for gait analysis, except during backwards walking and the measurements of stride length variability. In addition, a good reliability of the ALMA Home wearables was proved in all parameters, except for the measurement of stride length variability. In contrary, the hardware data of the GAITRite and the APDM sensors were for the greater part not comparable because of an incongruence in registration duration of the two measuring devices. In addition, a good reliability of both the APDM sensors and the GAITRite electronic walkway was proved.

2 Introduction

Every year, 40% of the community-dwelling older adults (CDOA) above the age of 65 experience at least one fall (Rubenstein, 2006). Therefore, falls are one of the most common accidents that occur in the older population (Masud & Morris, 2001). According to the World Health Organisation (WHO), a fall is described as "an involuntary event occurring loss of balance bringing the body to the ground or other surface" (Organización Mundial de la Salud. Caídas, 2016). The occurrence of these events is in particular prevalent in the older population because of the age-related deconditioning, balance disorders and deterioration of vision, cognition and muscle strength (Chaudhry et al., 2010). In addition, it is proved that the annual occurrence of these events is higher in women above the age of 65 (40%) compared to men (28%) in the same age category, in community settings. These rates additionally increase in both groups with augmenting age (Campbell, Borrie, & Spears, 1989). Besides gender, the occurrence of falls is proven to be related to several external factors. Fifty percent of the falls in CDOA occur indoors or in the near surroundings of their house whereby women tend to fall more frequently indoors compared to men who experience more outdoor falls (e.g. in the garden) (Campbell et al., 1990; Luukinen, Koski, Hiltunen, & Kivela, 1994).

Five to ten percent of the falls experienced by this population result in serious injuries, mainly fractures or head injuries. Therefore, falls are proven to be responsible for two third of deaths in this population, caused by injuries. (Deandrea et al., 2013). Besides these consequences, falls can additionally lead to disability, impaired mobility, fear of falling and reduced quality of life (da Costa, Rutjes, Mendy, Freund-Heritage, & Vieira, 2012; Gillespie et al., 2012; Kwan et al., 2013; Leveille et al., 2009). Because of the high prevalence of falls and its consequences, the costs for the social care and health systems are high (Center for Disease Control and Prevention, 2013). For this reason and because of the ageing population, the importance of prevention of falls in older adults has increased, primarily in the aged population with an increased fall risk.

To assess an increased risk of falling in older adults, the Tinetti and Timed Up and Go (TUG) tests are proven to be the most useful in the screening for balance and gait disorders. The study of Borowicz, Zasadzka, Gaczkowska, Gawlowska, and Pawlaczyk (2016) proved a high correlation between the number of falls in older adults and both lower Tinetti scores and longer TUG results. Increased scores on the Timed Chair Stance test (TCST) (Delbaere et al., 2006) and the One Leg Standing test (Borowicz et al., 2016) are additional predictors for an increased risk of falling. To objectify and quantify an increased fall risk, technology is widely used. In the study of Mellone, Tacconi, and Chiari (2012), accelerometers are used to objectify the outcome of the instrumented TUG. The study of Weiss, Herman, Giladi, and Hausdorff (2014) confirmed the effectivity of body worn sensors in the assessment of an increased fall risk in patients with Parkinson's Disease (PD).

An alternative, effective device for fall risk assessment, which is frequently used in laboratory settings, is the GAITRite electronic walkway (Rantz et al., 2013). The study of Bridenbaugh and Kressig (2011) confirmed the good efficacy of the GAITRite in the detection of discrete gait disorders in the older population. Gait disorders such as an increased cycle time, stride-to-stride variability, stride time variability and swing time variability are identified as fall predictors in CDOA (Hausdorff, Edelberg, Mitchell, Goldberger, & Wei , 1997). Continuous detection of changes in these parameters prior to a fall is therefore a key element in the improvement of fall prevention in the older population.

To establish a 24/7 monitoring of fall risk in the home environment in order to predict falls in CDOA, the ALMA Home wearables are developed. This pilot study aimed to validate the software behind the ALMA Home wearables in the assessment of an increased fall risk in older adults. This leads to two research questions: (1) Is the software behind the ALMA Home wearables comparable to the software behind the APDM sensors? (2) Can the different gait analysis instruments be compared to each other (i.e. GAITRite walkway versus APDM sensors)? The hypotheses suggest a good validity and reliability of the software behind the ALMA Home wearables and comparable outcomes of both the GAITRite and the APDM sensors concerning gait analysis.

3 Methods

3.1 Recruitment of participants

Participants with and without a positive fall history were recruited from the Experimental garden “Careville” between September and November 2017. CDOA with an age above 70 years, without cognitive disorders (MMSE >24) and with the willingness to use technology were included. Participants were included as “fallers” when they experienced at least one fall in the past six months and when the cause of their increased fall risk could be attributed to at least one of the following features: orthostatic hypotension, orthostatic tachycardia, deteriorated mobility or muscle strength (TUG >20, Tinetti Test <20, TCST >14sec), syncope, diabetes mellitus with incidents of hypoglycaemia and hazardous behaviour in general and concerning intake of medication. Participants were excluded in case of the presence of degenerative disorders, inability to perform clinical tests independently and in case of revalidation of an orthopaedic or neurologic, unstable condition. The study was approved by the Ethics Committee of Jessa Ziekenhuis and the Committee of Medical Ethics UHasselt (B243201731208).

3.2 Test procedure

This comparative pilot study aimed to evaluate to which extent the ALMA Home wearables correspond to standard measuring devices (i.e. GAITRite electronic walkway and APDM sensors) concerning fall risk detection in the older, community-dwelling population. To collect comparative data for this analysis, a clinical test battery was performed in October 2017 by 21 voluntary participants in the research center REVAL of Diepenbeek. Principal researchers (dr. Joke Spildooren, dr. Carolien Strouwen) conducted the tests in the presence of a master student Physiotherapy and Rehabilitation Sciences of the University of Hasselt.

The clinical test battery consisted of the performance of a ten-meter walk test in five different conditions (walking straight, walking fast, walking with a small base of support, walking while holding a glass of water and walking backwards). Each condition was performed three times. During this clinical test battery, walking performance was registered by the GAITRite electronic walkway, the APDM sensors and the ALMA Home wearables.

Walking performance was represented by cadence, gait speed, cycle duration, stride length and stride length variability. Participants wore six APDM sensors, attached to both hands, feet, the lumbar spine and the sternum and one ALMA Home sensor, attached to their right shoe. Participants started walking two meters before the GAITRite electronic walkway of 5.80 m and ended walking two meters after the GAITRite. Because of the limited length of the GAITRite, only six meters of the ten-meter walking trial were registered by the GAITRite, whereas the APDM sensors and ALMA Home sensors registered walking parameters during the complete ten-meter walking trials. Because the ALMA Home sensor was attached to the right shoe, only the mean values of the parameters, performed by the right foot of the participants, were used for statistical analysis.

Next to the ten-meter walk trials, personal information on the participant was documented and the participants were subjected to several questionnaires (Falls Efficacy Scale, Geriatric Depression Scale, Mini Mental State Examination, registration of blood pressure and heartbeat, usage of a walking aid). For the determination of increased fall risk, the Tinetti test, Timed Chair Stance test (TCST) and an instrumented Timed Up and Go test (TUG), with and without a dual task, were performed. Cut-off scores for increased fall risk are respectively a score of <20/28 (Tinetti test), >14 seconds (TCST) and >20 seconds (TUG single task). The complete test battery took two to two and a half hours.

3.3 Statistical analysis

The original aim of this study was to compare both the hardware and software behind the ALMA Home wearables to validated gait analysis equipment used for measuring clinical tests. During clinical testing, data registration by the ALMA Home wearables failed. Disconnection and failed data registration occurred when the distance between the ALMA Home sensor and the receiving station (i.e. smartphone) became too big for registration. For this reason, only the gait analysis software developed by ALMA Home could be compared. This software analysis compared the algorithm, developed for fall risk assessment by the ALMA Home wearables, to the software of the APDM sensors. For the hardware analysis, only the GAITRite and APDM sensors were compared. For the execution of the statistical analysis of the hardware on the one hand and the software on the other hand, the JUMP program (JMP Pro 13.2.0 SAS Institute Inc.) and SPSS (IBM SPSS Statistics 20) were used.

Dependant on the normality of the data, parametric and non-parametric tests were used for the analysis of the differences between the gait parameters. Because of the sample size of the group (n=21) and the comparison of continuous data, a parametric one sample t-test was used in case of normal divided data. When normal deviation of data was not present, a non-parametric Wilcoxon signed rank test was performed. Both tests were performed by the use of the JUMP program. In case of normal divided data, correlations between data were assessed by the Intra Class coefficient (ICC) which was computed in SPSS. The Spearman Correlation Coefficient (SCC) was estimated in case of non-normal divided data by the use of JUMP. A p-value of <0.05 was considered as statistically significant.

4 Results

4.1 Subject characteristics

After signing the informed consent, 21 CDOA with a mean age of 76 ± 4.6 years participated in the study. Based on the cut-off scores of the TCST, TUG and Tinetti test, respectively 12, two and zero participants showed an increased fall risk. Based on the presence of a positive fall history in the past six months, six participants were identified as "fallers" and therefore included as participants with an increased fall risk. Two out of the six "fallers" used more than four medicines which is in addition suggestive for an increased fall risk. The four remaining participants with poly-medication did not experience a fall in the past six months and were therefore included as participants without an increased risk of falling. The majority of the participants (85.7%) took medication with an average amount of two to three (± 2.3) medicines per person. Only one participant took sedatives and/or anti-depressant drugs. Two participants used medication for arrhythmia, four used diuretics and 11 participants used medication for hypertension. According to the FES, increased fear of falling was present in 14 participants whereas only ten participants answered Yes on the question "Do you experience fear of falling?". Table 1 presents a complete overview of the participant characteristics.

Table 1

Descriptive data participants

Parameter	**n**	**Ratio %**
Age in years [mean (SD)]	76,3 (4,6)	
Sex [M/F]	10/11	47,6/52,4
Medication [yes/no]	18/3	85,7/14,3
Amount of medication [mean (SD)]	2,9 (2,3)	
Walking aid [yes/no]	4/17	19/81
Orthostatic hypotension [yes/no]	2/19	9,5/90,5
FES total [mean (SD)]	26,1 (6,24)	
GDS total [mean (SD)]	4,0 (1,6)	
MMSE total [mean (SD)]	29 (1,4)	
TCST seconds [mean (SD)]	14 (2,8)	
Fall risk according to TCST [yes/no] *(Cut-off = >14 seconds)*	12/9	57,1/42,9

TUG ST seconds walking [mean (SD)]	11,3 (3,3)	
TUG ST right answers/sec [mean (SD)]	0,51 (0,21)	
Fall risk according to TUG [yes/no] *(Cut-off = >20 seconds)*	2/19	9,5/90,5
TUG DT seconds walking [mean (SD)]	14,1 (4,2)	
TUG DT right answers/sec [mean (SD)]	0,4 (0,19	
Tinetti balance total [mean (SD)]	14,9 (1,6)	
Tinetti gait total [mean (SD)]	11,3 (1,1)	
Tinetti total [mean (SD)]	26,2 (2,4)	
Fall risk according to Tinetti [yes/no] *(Cut-off = <20/28)*	0/21	0/100
Falls in the past 6 months [yes/no]	6/15	26,6/71,4
Number of Falls in the past 6 months [mean (SD)]	0,62 (1,2)	
Fear of falling [yes/no]	10 /11	47,6/52,4

SD = standard deviation; M = Man, F = Female; FES = Falls Efficacy Scale; GDS = Geriatric Depression Scale; MMSE = Mini Mental State Examination; TCST = Timed Chair Stand Test; TUG ST = Timed Up and Go single task; DT = Dual Task

4.2 Data analysis

Table 2 and 3 in the appendixes present an overview of the statistical analyses of respectively the hardware and software comparisons. Only eight parameters of the hardware data and five of the software data showed a good normality. In these 13 cases, a one sample t-test was carried out and the ICC was computed. The analysis of the differences of the remaining 37 parameters of the hardware and software data were carried out by the use of a non-parametric Wilcoxon signed rank test. Reliability of these non-normal divided data was assessed by the SCC.

4.2.1 Hardware

4.2.1.1 Missing data and outliers

Despite the fact that every participant performed every walking condition three times, missing data were present. Missing APDM data were present in two clinical test batteries, performed by participant six and 12, because APDM data registration failed during all three backwards walking trials in both participants. For this reason, mean values of the backwards walking trials could not be estimated in both participants, causing complete missing APDM data of backwards walking in two clinical test batteries. In addition, missing GAITRite data were present in several walking trials in several participants. Despite these missing GAITRite

data, the estimation of a mean value of each walking condition was still possible because the GAITRite successfully registered at least one trial in every walking condition. The same finding was present in one dual task walking trial, one fast walking trial and two backwards walking trials, registered by the APDM sensors. Because every walking condition was performed three times, mean values of every condition in every participant could be calculated by the use of the successfully registered APDM data.

When normality of data of each walking condition was checked, the hardware analyses demonstrated 26 outliers. The majority of the outliers was present in the analyses of cadence (n=7), followed by cycle duration (n=6), speed (n=5), mean stride length (n=4) and stride length variability (n=4). In addition, non-normal deviation of data was present in the majority of the analyses in which outliers were present (96%), causing the performance of a non-parametric Wilcoxon signed rank test in these cases.

The analyses of the differences between data measured by the APDM sensors and by the GAITRite electronic walkway demonstrated comparable results and a good correlation in respectively seven and 24 measured parameters. An overview is presented in table 2 in the appendixes.

4.2.1.2 **Normal walking condition**

The analyses of the normal walking trials proved significant differences concerning the measurements of cadence (mean GAITRite=108.5 ± 10.73; mean APDM=107.10 ± 10.47; $p<0.0001$), cycle duration (mean GAITRite =1.11 ± 0.11; mean APDM=1.11 ± 0.12; p=0,0002), mean stride length (mean GAITRite=1.23 ± 0.18; mean APDM=1.12 ± 0.16; $p<0.0001$) and speed (mean GAITRite =1.06 ± 0.33; mean APDM=1.01 ± 0.19; p=0.005). No differences between the GAITRite and APDM data were proved concerning stride length variability during normal walking (mean GAITRite =0.04 ± 0.02; mean APDM=0.04 ± 0.02; p=0.10). In addition, a good correlation between the GAITRite and the APDM sensors was proved in all gait parameters ($r[0.83 ; 0.99]$; $p<0.05$).

4.2.1.3 Fast walking condition

The analyses of the fast walking trials proved significant differences between the GAITRite and the APDM sensors concerning the measurements of cadence (mean GAITRite= 130.10 ±

16.74; mean APDM = 128.20 ± 10.47; p<0.0001); cycle duration (mean GAITRite=0.94 ± 0.12; mean APDM=0.95 ± 0.12; p<0.0001); mean stride length (mean GAITRite=1.40 ± 0.22; mean APDM=1.28 ± 0.20; p<0.0001) and speed (mean GAITRite=1.47 ± 0.46; mean APDM=1.37 ± 0.30; p=0.0002). The analysis of the stride length variability during fast walking proved comparable results (mean GAITRite=0.04 ± 0.03; mean APDM=0.04 ± 0.02; p=0.16). According to the ICC and SCC, a good correlation between the GAITRite and the APDM sensors was found in all gait parameters (r[0.71 ; 1.00]; p<0.05).

4.2.1.4 Walking with a dual task

The analyses of the dual task walking trials proved significant differences between the two devices concerning the measurements of cadence (mean GAITRite=103.59 ± 12.60; mean APDM=102.54 ± 12.07; p=0.0006), cycle duration (mean GAITRite=1.18 ± 0.16; mean APDM=1.19 ± 0.30; p<0.0001), mean stride length (mean GAITRite=1.12 ± 0.23; mean APDM=1.01 ± 0.20; p<0.0001) and speed (mean GAITRite=0.95 ± 0.38; mean APDM=0.88 ± 0.30; p=0.0002). No significant differences were proved in the analysis of stride length variability (mean GAITRite=0.05 ± 0.03; mean APDM=0.05 ± 0.03; p=0.48). A good correlation between the GAITRite and the APDM sensors was proved in all gait parameters (r[0.70 ; 1.00]; p<0,05).

4.2.1.5 Walking with a small base of support

The analyses of the small walking trials proved no significant differences between the GAITRite and the APDM sensors concerning the measurements of cadence (mean GAITRite=89.37 ± 24.86; mean APDM=91.44 ± 19.52; p=0.9866), cycle duration (mean GAITRite=1.45 ± 0.56; mean APDM=1.38 ± 0.15; p=0.76) and stride length variability (mean GAITRite=0.12 ± 0.12; mean APDM=0.07 ± 0.03; p=0.07). Significant differences were found in the analyses of mean stride length (mean GAITRite=0.98 ± 0.31; mean APDM=0.97 ± 0.21; p=0.037) and speed (mean GAITRite=0.80 ± 0.34; mean APDM=0.76 ± 0.23; p=0.0023). All gait parameters proved a good correlation between the GAITRite and the APDM sensors (r[0.77 ; 0.98]; p<0.05), except in stride length variability (r=0.42; p=0.0586).

4.2.1.6 Backwards walking

The analyses of the backwards walking trials proved significant differences between the two devices concerning the measurements of cadence (mean GR=108.2 ± 27.37; mean APDM=111.6 ± 15.72; p=0.003), cycle duration (mean GAITRite=1.10 ± 2.26; mean APDM=

1.15 ± 0.18; p<0.0001), mean stride length (mean GAITRite=0.71 ± 0.25; mean APDM=0.62 ± 0.24; p<0.0001) and speed (mean GAITRite=0.66 ± 0.26; mean APDM=0.56 ± 0.19; p<0.0001). No differences were proved in the analysis of stride length variability (mean GAITRite=0.05 ± 0.04; mean APDM=0.06 ± 0.04; p=0.89). A good correlation between the GAITRite and the APDM sensors was proved in all gait parameters (r[0.88 ; 1.00]; p<0.05).

4.2.2 Software

4.2.2.1 Missing data and outliers

All measured software data by the ALMA Home wearables were missing, causing the comparison of the software of the APDM sensors to the algorithm of the ALMA Home wearables. Missing APDM data were the same as previously mentioned in the description of the hardware analysis.

The evaluation of normality of software data in each walking condition demonstrated 40 outliers. The majority of the outliers was present in the analysis of cycle duration (n=15), followed by cadence (n=8), mean stride length (n=7), stride length variability (n=5) and speed (n=5). In addition, a non-normal deviation of data was present in the majority of the analyses in which outliers were present (95%), causing the performance of a non-parametric Wilcoxon signed rank test.

The analyses of the differences between the APDM sensors and the algorithm of the ALMA Home wearables demonstrated comparable results and a good correlation in respectively 14 and 20 measured parameters. An overview is presented in table 3 in the appendixes.

4.2.2.2 Normal walking condition

The analyses of the normal walking trials proved comparable results between the APDM sensors and the ALMA Home wearables concerning the measurements of cadence (mean ALMA=106.96 ± 10.25; mean APDM=107.12 ± 10.47; p=0.3084), cycle duration (mean ALMA=1.13 ± 0.09; mean APDM=1.12 ± 0.12; p=0.70), mean stride length (mean ALMA=1.13 ± 0.18; mean APDM=1.12 ± 0.16; p=0.96) and speed (mean ALMA=1.00 ± 0.20; mean APDM=1.01 ± 0.19; p=0.37). Significant differences between the two devices were proved in the measurement of stride length variability (mean ALMA=0.11 ± 0.11; mean APDM=0.04 ± 0.02; p<0.0001). The software of the APDM sensors and the ALMA home wearables were

well correlated in all gait parameters (r[0.69 ; 0.99]; p<0.05), except in stride length variability (r= 0.18; p=0.43).

4.2.2.3 Fast walking condition

The analyses of the fast walking trials proved no significant differences between the two devices concerning the measurements of cycle duration (mean ALMA=0.96 ± 0.14; mean APDM=0.95 ± 0.12; p=0.23), mean stride length (mean ALMA=1.27 ± 0.28; mean APDM=1.28 ± 0.20; p=0.89) and speed (mean ALMA=1.37 ± 0.38; mean APDM=1.37 ± 0.30; p=0.89). Significant differences were proved in the measurements of cadence (mean ALMA=127.96 ± 17.03; mean APDM=128.16 ± 16.30; p=0.039) and stride length variability (mean ALMA=0.15 ± 0.09; mean APDM=0.04 ± 0.02; p<0.0001). A good correlation between the APDM sensors and the ALMA Home wearables was proved in all gait parameters (r[0.94 ; 0.99]; p<0.05), except in stride length variability (r=0.07; p=0.76).

4.2.2.4 Walking with a dual task

The analyses of the dual task walking trials proved no differences between the APDM sensors and the ALMA Home wearables concerning the measurements of cadence (mean ALMA=102.01 ± 12.40; mean APDM=102.54 ± 12.07; p=0.26), cycle duration (mean ALMA=1.21 ± 0.17; mean APDM=1.20 ± 0.15; p=0.36), mean stride length (mean ALMA = 0.97 ± 0.22; mean APDM = 1.01± 0.20; p=0.18) and speed (mean ALMA=0.83 ± 0.26; mean APDM=0.88 ± 0.23; p=0.61). The analysis of the stride length variability proved a significant difference between the results of the APDM sensors and the ALMA Home wearables (mean ALMA=0.20 ± 0.22; mean APDM=0.05 ± 0.03; p<0.0001). The correlation of the software of the two devices was high in all gait parameters (r[0.83 ; 0.99]; p<0.05), except in stride length variability (r=-0.11; p=0.65).

4.2.2.5 Walking with a small base of support

The analyses of the small walking trials proved no differences between the results of the APDM sensors and the ALMA Home wearables concerning the measurements of cadence (mean ALMA=88.50 ± 23.39; mean APDM=91.44 ± 19.52; p=0.16) and speed (mean ALMA= 0.75 ± 0.32; mean APDM=0.76 ± 0.30; p=0.61). Significant differences were found in the analyses of cycle duration (mean ALMA=1.55 ± 0.55; mean APDM=1.38 ± 0.30; p<0.0001), mean stride length (mean ALMA=1.02 ± 0.21; mean APDM=0.97 ± 0.21; p=0.006) and stride length variability (mean ALMA=0.28 ± 0.16; mean APDM=0.07 ± 0.03; p<0.0001). A good

correlation between the software of the APDM sensors and the ALMA Home wearables was proved in all gait parameters (r[0.82 ; 0.98]; p <0.05), except in stride length variability (r=0.05; p=0.379).

4.2.2.6 Backwards walking

The analyses of the backwards walking trials proved significant differences between the two devices concerning the measurements of cadence (mean ALMA=94.29 ± 32.97; mean APDM=108.17 ± 15.72; p=0.0005), cycle duration (mean ALMA=1.59 ± 1.37; mean APDM=1.15 ± 0.18; p<0.0001), stride length variability (mean ALMA=0.35 ± 0.23; mean APDM=0.06 ± 0.04; p<0.0001) and speed (mean ALMA=0.51 ± 0.21; mean APDM=0.56 ± 0.19; p=0.001). No significant differences were proved concerning the measurement of mean stride length (mean ALMA=0.77 ± 0.34; mean APDM=0.63 ± 0.24; p= 0.62). The APDM sensors and ALMA home wearables were well correlated in all gait parameters (r[0.50 ; 0.97]; p<0.05), except in stride length variability (r=0.44; p=0.65).

5 Discussion

This pilot study aimed to validate the ALMA Home wearables as a part of the development of 24/7 fall risk detection in the community-dwelling older population. To establish this validation, a clinical test battery was performed by CDOA with and without an increased risk of falling. Despite the proved effectivity of the TUG, Tinetti and TCST in assessing fall risk (Borowicz et al., 2016; Delbaere et al., 2006), fall risk determination was established based on the presence of a fall in the past six months because of concurrent results of the clinical tests. According to the TCST, an increased fall risk was present in 12 participants. These results did not correspond to the results of the TUG and Tinetti test which found an increased fall risk in only two participants. These latest two tests examine primarily gait and balance whereas the TCST examines the muscle strength of the lower legs. For this reason, the most plausible cause of the detected increased fall risk in six participants is a deterioration of muscle strength. This corresponds to the study of Tirrell et al. (2015) who proved the muscle strength to be one of the most frequently researched risk factors in the examination of older adults with a positive fall history, because of its importance in causing falls.

The performance on the clinical test battery was registered by the GAITRite, APDM sensors and the ALMA Home wearables. The study originally aimed to perform two main comparisons to investigate the quality of the development of the software and hardware of the ALMA Home wearables. During clinical testing, data registration by the ALMA Home wearables failed in case of disconnection between the ALMA Home sensor and the smartphone. Disconnection occurred when the distance between the sensor and the smartphone became too big, causing failed registration and missing hardware and software data of the ALMA Home sensors. Because hardware analysis of the ALMA Home wearables was impossible due to missing data, a hardware analysis was established by the comparison of the GAITRite electronic walkway and the APDM sensors. Registered data were well correlated, but differences were found in the majority of the parameters (72%), except in stride length variability. These findings do not correspond to the hypotheses which suggested comparable outcomes of both the GAITRite and APDM sensors concerning gait analysis. The large amount of differences between GAITRite data and APDM data can be

caused by the fact that the GAITRite registered only six meters of the ten-meter walking trials whereas the APDM sensors registered during the entire walking trials. Participants were therefore already walking before GAITRite registration started, whereas APDM registration started when participants took their first steps. For this reason, participants walked with a higher cadence, speed and mean stride length when they stepped on the GAITRite. This probably explains the large number of measured differences and the larger value of most GAITRite data in comparison to APDM data. The lower values measured by the GAITRite for cycle duration in comparison to APDM data can also be due to the incongruence in the registration duration between the two measuring devices (i.e. ten meter vs six meter). Irrespective of walking on or off the electronic walkway, stride length variability did not change which explains the absence of measured differences in stride length variability. In addition, the hardware analyses demonstrated more significant differences (n=18) compared to the software analyses (n=11), which can also be due to the incongruence in the registration onset of the devices. There was no difference in onset of registration by the APDM sensors and ALMA Home wearables whereas an incongruence was present in the registration onset of the APDM sensors and the GAITRite.

To establish software comparison, the developers released the algorithm which was specifically developed for fall risk assessment by the ALMA Home wearables. The results of the software analyses correspond for the greater part to the hypotheses which suggested a good validity and reliability of the software of the ALMA Home wearables concerning gait analysis. Software comparison proved a good quality and validity of the developed algorithm behind the ALMA Home wearables concerning gait analysis, except during the more challenging backwards walking trials and concerning the measurements of stride length variability. A possible explanation for this finding are missing APDM data in backwards walking trials in three participants (i.e. missing data of two trials in participant 12 and missing data of all three trials in participant six and 12). The measured differences in stride length variability can possibly be attributed to the incongruence in the number of sensors attached to the body: six APDM sensors versus one ALMA Home wearable. This can be taken into account in future research.

Further research is necessary to investigate the quality of the software behind the ALMA Home wearables in combination with the developed ALMA Home hardware (i.e. sensors) in gait analysis and fall risk detection. Previous research already validated instrumented shoe insoles concerning gait analysis and proved a high correlation with the GAITRite electronic walkway (Jagos et al., 2017). The participants in this study wore two insoles in both the right and left shoe. For this reason, future research concerning the ALMA Home wearables should consider the use of two ALMA Home sensors, attached to both feet, instead of one sensor. It is in addition recommended for future research to recruit more participants because this current study is limited by its small power (n=21). To avoid the incongruence in registration onset between the measuring devices, future research can replace the GAITRite by other gait analysis equipment to compare the ALMA Home wearables to. Previous research in children with cerebral palsy proved a good accuracy and precision of foot-worn inertial sensors concerning spatio-temporal gait analysis in comparison to an optical motion capture system (i.e. Vicon, UK) (Bregou Bourgeois, Mariani, Aminian, Zambelli, & Newman, 2014). This optical motion capture system can be used in future research to validate the ALMA Home wearables hardware concerning gait analysis and fall risk detection. Before future research concerning software and hardware of the ALMA Home wearables can be conducted, registration problems in case of disconnection between the sensor and the smartphone should be resolved. It is in addition more relevant for fall risk detection in CDOA if registration by the wearables remains possible when being in another room than the smartphone. At this point of development, registration will occur when participants hold their smartphone and fails when a certain distance between the sensor and the smartphone is reached.

In addition to the limitations of this study, several strengths should be reported. Despite the presence of the large number of outliers (n=66) in the analyses, the performance of non-parametric Wilcoxon signed rank tests compensated for this bias. In addition, each walking condition was performed three times to limit the presence of missing data and measuring errors. This resulted in complete missing APDM data of all three trials in the backwards walking condition in only two participants (i.e. missing backwards walking data of participant six and 12), causing a limited influence on the estimation of the mean values of the walking conditions.

In conclusion, many differences were found in the hardware analysis of the APDM sensors and the GAITRite electronic walkway concerning gait analysis because of an incongruence in registration onset and duration. Despite this finding, the hardware of the APDM sensors and the GAITRite were well correlated to each other causing a good reliability of both devices. The software analyses proved a good validity and reliability of the software behind the ALMA Home wearables concerning gait analysis. Future research should focus on the examination of the validity of the hardware of the ALMA Home wearables in combination with the developed software behind the ALMA Home sensors concerning fall risk detection, in comparison to instrumented clinical tests.

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7 Appendixes

Table 2

Statistical analysis - Hardware

Parameter	Normality	Mean GAITRite	Std Dev GAITRite	Mean APDM	Std Dev APDM	P-value differences	Correlation-coëfficiënt	P-value correlation
Cadence (steps/min) Normal	Normal	108,50	10,73	107,10	10,47	< 0,0001*	0,99	0,000*
Cadence (steps/min) Fast	Normal	130,10	16,74	128,20	16,30	< 0,0001*	0,99	0,000*
Cadence (steps/min) DT	Not normal	103,59	12,60	102,54	12,07	0,0006*	1,00	<0,0001*
Cadence (steps/min) Small	Not normal	89,37	24,86	91,44	19,52	0,9866	0,97	<0,0001*
Cadence (steps/min) Back	Normal	108,20	27,37	111,60	15,72	0,0003*	0,98	0,000*
Cycle duration (s) Normal	Not normal	1,11	0,11	1,11	0,12	0,0002*	0,83	<0,0001*
Cycle duration (s) Fast	Normal	0,94	0,12	0,95	0,12	< 0,0001*	0,99	0,000*
Cycle duration (s) DT	Not normal	1,18	0,16	1,19	0,30	< 0,0001*	1,00	<0,0001*
Cycle duration (s) Small	Not normal	1,45	0,56	1,38	0,15	0,76	0,93	<0,0001*
Cycle duration (s) Back	Not normal	1,10	2,26	1,15	0,18	< 0,0001*	1,00	<0,0001*
Stride length (m) mean Normal	Normal	1,23	0,18	1,12	0,16	< 0,0001*	0,90	0,000*
Stride length (m) mean Fast	Normal	1,40	0,22	1,28	0,20	< 0,0001*	0,92	0,000*
Stride length (m) mean DT	Normal	1,12	0,23	1,01	0,20	< 0,0001*	0,93	0,000*
Stride length (m) mean Small	Not normal	0,98	0,31	0,97	0,21	0,037*	0,77	<0,0001*
Stride length (m) mean Back	Not normal	0,71	0,25	0,62	0,24	< 0,0001*	0,99	<0,0001*
Stride length (m) SD Normal	Not normal	0,04	0,02	0,04	0,02	0,10	0,67	0,0009*

Stride length (m) SD Fast	Normal	0,04	0,03	0,04	0,02	0,16	0,71	0,003*
Stride length (m) SD DT	Not normal	0,05	0,03	0,05	0,03	0,48	0,70	0,0004*
Stride length (m) SD Small	Not normal	0,12	0,12	0,07	0,03	0,07	0,42	0,0586
Stride length (m) SD Back	Not normal	0,05	0,04	0,06	0,04	0,89	0,88	<0,0001*
Speed (m/s) Normal	Not normal	1,06	0,33	1,01	0,19	0,005*	0,96	<0,0001*
Speed (m/s) Fast	Not normal	1,47	0,46	1,37	0,30	0,0002*	1,00	<0,0001*
Speed (m/s) DT	Not normal	0,95	0,38	0,88	0,30	0,0002*	0,99	<0,0001*
Speed (m/s) Small	Not normal	0,80	0,34	0,76	0,23	0,0023*	0,98	<0,0001*
Speed (m/s) Back	Normal	0,66	0,26	0,56	0,19	<0,0001*	0,93	0,000*

DT = Dual Task; GR = GAITRite

Table 3

Statistical analysis – Software

Parameter	Normality	Mean Algorithm	Std Dev Algorithm	Mean APDM	Std Dev APDM	P-value differences	Correlation-coëfficiënt	P-value correlation
Cadence (steps/min) Normal	Not normal	106,96	10,25	107,12	10,47	0,3084	0,99	<0,0001*
Cadence (steps/min) Fast	Not normal	127,96	17,03	128,16	16,30	0,039*	0,99	<0,0001*
Cadence (steps/min) DT	Not normal	102,01	12,40	102,54	12,07	0,26	0,99	<0,0001*
Cadence (steps/min) Small	Not normal	88,50	23,39	91,44	19,52	0,16	0,98	<0,0001*
Cadence (steps/min) Back	Not normal	94,29	32,97	108,17	15,72	0,0005*	0,53	0,0201*
Cycle duration (s) Normal	Not normal	1,13	0,09	1,12	0,12	0,70	0,69	0,0006*
Cycle duration (s) Fast	Not normal	0,96	0,14	0,95	0,12	0,23	0,95	<0,0001*
Cycle duration (s) DT	Not normal	1,21	0,17	1,20	0,15	0,36	0,95	<0,0001*
Cycle duration (s) Small	Not normal	1,55	0,55	1,38	0,30	<0,0001*	0,98	<0,0001*
Cycle duration (s) Back	Not normal	1,59	1,37	1,15	0,18	<0,0001*	0,50	0,0303*
Stride length (m) mean Normal	Not normal	1,13	0,18	1,12	0,16	0,96	0,91	<0,0001*
Stride length (m) mean Fast	Normal	1,27	0,28	1,28	0,20	0,89	0,94	0,000*
Stride length (m) mean DT	Not normal	0,97	0,22	1,01	0,20	0,18	0,83	<0,0001*
Stride length (m) mean Small	Not normal	1,02	0,21	0,97	0,21	0,006*	0,82	<0,0001*
Stride length (m) mean Back	Not normal	0,77	0,34	0,63	0,24	0,62	0,63	0,004*
Stride length (m) SD Normal	Not normal	0,11	0,11	0,04	0,02	<0,0001*	0,18	0,43

Stride length (m) SD Fast	Not normal	0,15	0,09	0,04	0,02	<0,0001*	0,07	0,76
Stride length (m) SD DT	Not normal	0,20	0,22	0,05	0,03	<0,0001*	-0,11	0,65
Stride length (m) SD Small	Normal	0,28	0,16	0,07	0,03	<0,0001*	0,05	0,379
Stride length (m) SD Back	Not normal	0,35	0,23	0,06	0,04	<0,0001*	0,44	0,06
Speed (m/s) Normal	Normal	1,00	0,20	1,01	0,19	0,37	0,99	0,000*
Speed (m/s) Fast	Normal	1,37	0,38	1,37	0,30	0,89	0,96	0,000*
Speed (m/s) DT	Not normal	0,83	0,26	0,88	0,23	0,099	0,93	<0,0001*
Speed (m/s) Small	Not normal	0,75	0,32	0,76	0,30	0,61	0,96	<0,0001*
Speed (m/s) Back	Normal	0,51	0,21	0,56	0,19	0,001*	0,97	0,000*

DT = Dual Task; GR = GAITRite

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

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VOORTGANGSFORMULIER WETENSCHAPPELIJKE STAGE DEEL 2

DATUM	INHOUD OVERLEG	HANDTEKENINGEN
oktober 2017	metingen in REVAL met deelnemers	Promotor: Copromotor: Student(e): Student(e):
22/12/2017	opstart + uitleg uitwerking data extractie + uitschrijven introductie en methode	Promotor: Copromotor: Student(e): Student(e):
14/2/2018	Feedback data extractie en aanpassingen onderzoeksdelen (verdelingen nagaan)	Promotor: Copromotor: Student(e): Student(e):
15/3/2018	Uitleg statistische analyse + feedback geschreven tekst	Promotor: Copromotor: Student(e): Student(e):
maart-april-mei 2018	Feedback geschreven tekst via mail.	Promotor: Copromotor: Student(e): Student(e):
		Promotor: Copromotor: Student(e): Student(e):
		Promotor: Copromotor: Student(e): Student(e):
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Richting: **master in de revalidatiewetenschappen en de kinesitherapie-revalidatiewetenschappen en kinesitherapie bij musculoskeletale aandoeningen**
Jaar: **2018**

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