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Validity of the activPAL3 activity monitor in people moderately affected by Multiple Sclerosis

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Title: Validation of the activPAL3 activity monitor in people moderately affected by Multiple Sclerosis

Abstract

Background: Walking is the primary form of physical activity performed by people with Multiple Sclerosis (MS), therefore it is important to ensure the validity of tools employed to measure walking activity. The aim of this study was to assess the criterion validity of the activPAL3 activity monitor during overground walking in people with MS.

Methods: Validity of the activPAL3 accelerometer was compared to video observation in 20 people moderately affected by MS. Participants walked 20-30m twice along a straight quiet corridor at a comfortable speed.

Results: Inter-rater reliability of video observations was excellent (all intraclass correlations > 0.99). The mean difference (activPAL3- mean of raters) was -4.70 ± 9.09, -4.55 s ± 10.76 and 1.11 s ± 1.11 for steps taken, walking duration and upright duration respectively. These differences represented 8.7, 10.0 and 1.8% of the mean for each measure respectively. The activPAL3 tended to underestimate steps taken and walking duration in those who walked at cadences of ≤ 38 steps/minute by 60% and 47% respectively.

Discussion: The activPAL3 is valid for measuring walking activity in people moderately affected by MS. It is accurate for upright duration regardless of cadence. In participants with slow walking cadences, outcomes of steps taken and walking duration should be interpreted with caution.

Introduction

Multiple Sclerosis (MS) is a life-long progressive condition which may affect mobility. Physical Activity (PA) can improve MS symptoms and overall physical and mental health [1]. Walking is the primary form of PA performed by people with MS. Therefore it is important to ensure measurement tools are accurate when measuring various parameters of walking activity. Physical activity can be measured using self-report questionnaires or with objective activity monitors. Subjective methods have the advantage of being inexpensive and can be used in large samples, however, self-report is often subject to overestimation and difficulties with memory recall, particularly in inactive populations [2]. Measurement devices such as pedometers and accelerometers objectively monitor PA, providing a range of outcome measures such as activity counts, energy expenditure, steps taken, time spent walking and time spent sitting/lying. The accuracy of a number of devices has been investigated previously in those with MS [3–7]. The walking speeds or cadences at which the validity was assessed has been reported for only three devices, Actigraph (Model 7164), Actigraph (GT3X+ accelerometer) and the Step Activity Monitor [5,6]. These studies included participants with Expanded Disability Status Scale (EDSS) 0 (normal neurological exam) – 6.5 (constant bilateral walking aids required to walk 20 m without resting) [8]. All three monitors were found to have low errors in step count. However, the slowest walking speeds/cadences reported, at which errors in measurement are more likely to occur, were 0.9 m/s and 0.45 m/s or 85 steps/minute [5,6]. These walking speeds/cadences may be regarded as relatively fast for some people with MS.

The activPAL3 is a second generation tri-axial accelerometer based upon the uni-axial activPAL (PAL Technologies Ltd, Glasgow, UK), providing measures such as steps taken, time spent walking, standing, upright (standing and walking) and sitting/lying and sit-to-stand transitions. The activPAL3 has a sampling frequency of 20Hz, compared to previous version's 10Hz, and has been found to be valid and reliable for healthy adults and children [9–11] with greater step detection than the original activPAL during activities of daily living [12]. The uni-axial activPAL has previously been found to have a greater than 30% error in steps taken in people with MS requiring uni-lateral or bilateral walking assistance to walk (EDSS 6.0-6.5) compared to video observation as a criterion measure [3]. However, the protocol utilised included a range of activities of daily living where incidental steps taken may not have been detected by the monitor leading to large percentage errors in step count particularly when the total number of steps is small. In addition, the discrepancies in steps taken during the individual tasks were not reported. The second generation monitor, activPAL3, which consists of a tri-axial accelerometer with a higher sampling frequency may be more accurate than the uni-axial activPAL, particularly at slow walking speeds [13].

Aim

The aim of this study was to assess the criterion validity of the activPAL3 activity monitor for measuring steps taken, walking time and upright duration during overground walking in people moderately affected by MS.

Methods

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Participants

People with MS were recruited from those already taking part in one site of the multi-centre WEBPaMS trial (ClinicalTrials.gov ref: NCT02508961). Potential participants from NHS Ayrshire and Arran were provided with information regarding the sub-study. To be included participants were required to have an EDSS of 4.0-6.5 [8]. Participants were excluded if they were unable to walk independently with or without aids. Ethical approval was obtained from the South Central-Oxford B Research Ethics Committee (Ref: 15/SC/0783) and all participants provided written informed consent.

Instrument

The activPAL3 (PAL Technologies Ltd, Glasgow, UK) is a single unit (2.4 x 4.3 x 0.5 cm^3, 10g), tri-axial accelerometer with a sampling frequency of 20Hz. The activPAL3 was positioned on the anterior mid-thigh of the participants self-reported strongest or dominant leg and for the purposes of this study it was attached using micropore tape.

Procedures

Participants began the test sitting on a chair for two minutes. The participant was instructed to stand up, walk 20 - 30 m along a straight quiet corridor at a comfortable speed. Participants then stood quietly while a chair was positioned behind them. Participants were then instructed to sit for 1 minute following which the test was repeated. A video recorder

was used to video all walking and standing activities performed by participants, with the video focused on the lower half of the body.

Three independent raters, who were experienced physiotherapists, assessed the video recordings. Raters defined a step as occuring when the foot was lifted off the ground and placed in a new position. Walking time was defined as the time between first heel strike and double support standing and the end of the 'walk'. Upright time was defined as the time between standing up from the chair with hips and knees extended until participants were again fully seated on the chair. Walking and total upright duration were measured using a stopwatch. The mean of the three raters results was used as the criterion measure.

Data analysis

Inter-rater reliability was assessed using Intraclass Correlation Coefficients (ICC) for absolute agreement. ICC values <0.4, 0.4-0.59, 0.60-0.74 and 0.75-1.00 were considered poor, fair, good and excellent respectively [14]. The activPAL3 data were downloaded using the manufacturer's software (ActivPAL Professional Software version 7.2.23). Number of steps, walking and standing duration were extracted for each walking test. Differences between the activPAL3 and direct observation was assessed by the Bland-Altman method [15,16] and paired t-tests with a two-sided level of significance of 5% using SPSS version 22 (IBM Corp, Armonk, NY, USA). Outliers were defined as data points outwith the upper and lower limits of agreement on the Bland-Altman plots. Differences in results between the activPAL3 and the mean of the three raters are calculated as 'activPAL3 – raters' throughout.

Results

Twenty participants were recruited (11 female, 9 male, mean age 53.7 ± 7.4 years). Participants had a range of EDSS levels [EDSS 4.0 (n=1), EDSS 4.5 (n=2), EDSS 5.5 (n=3), EDSS 6.0 (n=7), EDSS 6.5 (n=7)]. The majority of participants (70%) used a walking aid and overall participants walked with a mean cadence of 83.9 ± 25.1 (25.5- 123.5) steps/minute (Table 1). One participant was unable to complete both walking tests due to fatigue (Table 1). No data were lost during the study.

Table 1 Near Here

Raters

The agreement between the three independent raters was excellent for steps (ICC= 0.995, 95% CI 0.992, 0.997), walking duration (ICC= 0.999, 95% CI 0.998, 0.999) and total upright duration (ICC= 0.999, 95% CI 0.998, 0.999). For subsequent analyses, the mean values across the three raters was used for comparison with activPAL3 measures.

Steps taken

The mean difference in steps taken was -4.70 ± 9.09 with a maximum difference of 33 steps (Table 2). This mean difference represents an 8.7% underestimation from the activPAL3 compared to the mean number of steps observed by the raters (53.8 steps). A paired t-test suggests that the difference in steps taken between the activPAL3 and the average of the

three raters is significantly different to zero (p=0.003, 95% CI -7.65, -1.76). The Bland-Altman method demonstrated lower and upper level of agreements of -22.88 and 13.47 steps respectively (Figure 1(a)). From the Bland-Altman, five clear outliers can be identified. These large differences between raters and the activPAL3 device in terms of steps taken were found in five walking events completed by the three participants (A112, A114 and A116) with EDSS 6.5 and walking cadences of 26, 38 and 53 steps/minute respectively. When the outliers are removed, the mean difference reduces to -3.75 ± 2.59 and the lower and upper limits of agreement narrow (-8.9 and 1.4 steps respectively) (Figure 1(a)). Differences in steps taken by participants with EDSS 6.0 and below are much lower with a maximum underestimation from the activPAL3 of 9 steps (Table 2; Figure 2(a)).

Table 2 Near Here

Figure 1 Near Here

Figure 2 Near Here

Walking duration

The mean difference in walking duration was -4.55 s ± 10.76 with a maximum difference of 47.18 s (Table 2). This mean difference represents a 10.0% underestimation from the activPAL3 compared to the mean walking duration observed (45.7 s). A paired t-test suggests that the difference in walking duration between the activPAL3 and the average of

the three raters is significantly different to zero (*p*=0.012, 95% CI -8.04, -1.06). The Bland-Altman method demonstrated lower and upper level of agreements of -26.06 and 16.96 s respectively for walking duration (Figure 1(b)). Three outliers can be identified from the Bland-Altman plot. These large differences in walking duration were found in walking events completed by two participants (A112 and A114) with EDSS 6.5 and slow walking cadences (26 and 38 steps/minute). When the outliers are removed the mean difference in walking duration reduces to -1.60 s ± 2.04 and lower and upper limits of agreement narrow and become closer to zero (-5.7 and 2.5 s respectively) (Figure 1(b)). Differences in walking duration between the activPAL3 and the raters were much lower in participants with EDSS ≤ 6.0 with a maximum difference of 4 s (Table 2; Figure 2(b)).

Total upright duration

The mean difference in upright duration was 1.11 s ± 1.11 with a maximum difference of 3.84 s (Table 2). This mean difference represents a 1.8% overestimation by the activPAL3 compared to the mean total upright time observed (61.8 s). A paired t-test suggests that the difference in walking duration between the activPAL3 and the average of the three raters is significantly different to zero (*p*≤0.001, 95% CI -1.48, -0.72). The Bland-Altman method demonstrated lower and upper level of agreements of -1.12 and 3.34 s respectively for upright duration (Figure 1(c)). Two outliers (3.84 s and -2.45 s) can be identified from the Bland-Altman plot. These differences were found in events completed by two different participants (A107 and A127). Differences in upright time for the second walking tests completed by these participants were smaller with 2.17 s and 0.56 s respectively. When the

outliers are removed the limits of agreement narrow (-0.60 and 2.86). The activPAL3 was accurate for upright duration for all participants regardless of average cadence (Figure 2(c)).

Discussion

The results of this study demonstrate that the activPAL3 is valid for measuring walking activity in people moderately affected by MS (EDSS 4-6.5). Walking is the main form of PA performed by people with MS and the primary outcome of interest in many rehabilitation studies. As such, use of a valid measurement tool is of great importance.

The activPAL3 tended to underestimate steps taken and walking duration in participants with relatively slow cadences. These differences are due to the activPAL3 misclassifying walking periods as standing events. For instance, it registered between two and four separate standing events lasting between 6.9 s and 12.8 s each while these participants were walking. This is likely to be attributed to the lower acceleration of the thigh during the swing phase of gait that does not exceed the threshold required by the activPAL3 to register a step had taken place. At these slow cadences the activPAL3 underestimated steps and walking duration by as much as 60% and 47% respectively. Therefore, walking measured using the activPAL3 in people with slow cadences should be interpreted with caution. Other devices have also experienced errors in steps taken at slow cadences. For instance, the Actigraph (Model 7164) was found to have a 4 ± 9% error in steps taken at 0.9 m/s and the Actigraph (GT3X+ accelerometer) was found to have a 12.7% error at average walking speeds of 0.45 ± 0.18 m/s or 85 steps/minute [5,6]. Recently, the accuracy of the activPAL3

was assessed in healthy adults walking slowly on a treadmill [10]. At a cadence of 69 steps/minute 90% of steps were detected, while at 0.1 m/s or below 24 steps/minute zero steps were detected [10]. The cadences in some participants with EDSS 6.5 within the present study were particularly slow (38 and 26 steps/minute) and therefore inaccuracies are to be expected. The validity of walking duration has not been assessed in other devices in people with MS. As such comparisons between devices cannot be made for this outcome.

The activPAL3 was accurate for upright duration for all participants with an average difference of 1.11 ± 1.11 s (1.8% error). Although two outliers were identified these were found in two different participants (EDSS levels 5.5 and 6.5) and these errors did not appear to be due to slow cadence or disability level. When these outliers were removed the changes to the mean, standard deviation and limits of agreement were minimal. Due to the activPAL3's unique position on the thigh it is also capable of accurately classifying posture and sedentary time and providing measures of sit-to-stand transitions [17,18]. It is possible that for people with very slow cadences, outcomes of upright duration, sit-to-stand transitions and sedentary time may be valid since these outcomes have been found to be accurate regardless of walking speed in older people with impaired function [19]. In contrast, the Actigraph monitors cannot accurately measure posture classification [20]. Therefore, these additional outcomes generated from the activPAL3 may be of particular use for those with slow walking cadences.

Limitations

The study has a number of limitations. The study involved a small sample of 20 participants who only completed two short linear walks. In addition, one participant was only able to complete one walk due to fatigue. When the sample is considered by EDSS the numbers in each group are small. While it was possible to accurately estimate the mean bias for the majority of participants, our sample was not sufficient to determine the lower cut-off for walking cadence. Future studies could use an adaptive design to recruit participants until a sufficiently precise description of the EDSS and cadence bias association can be established. Validity was assessed during a controlled testing protocol in which participants walked in a straight line indoors. It is possible that greater errors would have been present if walking had been assessed in the free-living environment. However, walking events within this protocol were short and therefore it is possible that relatively smaller errors over longer walking events may be found.

The activPAL3 is valid for measuring walking activity in people moderately affected by MS. It is accurate for upright duration regardless of cadence. In participants with slow walking cadences, outcomes of steps taken and walking duration should be interpreted with caution.

Conclusion

The activPAL3 is valid for measuring walking activity in people moderately affected by MS. Small but statistically significant differences were demonstrated for measuring steps taken, walking and upright duration. The activPAL3 underestimated steps and walking duration in

those with slow cadences of less than 38 steps/minute while upright duration was accurate for all participants regardless of walking cadence.

Completing interests: None declared.

Ethical approval: Ethical approval was obtained from the South Central-Oxford B Research Ethics Committee (Ref: 15/SC/0783).

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Legends to Tables and Figures

Table 1. Characteristics of participants and maximum step difference between activPAL3 and the average of three independent raters.

Table 2. Summarised results, in relation to level of disability for differences in steps taken, walking and upright duration.

Figure 1. Bland-Altman plots for (a) number of steps taken; (b) walking duration; (s) upright duration; vs differences between activPAL3 and the raters (activPAL3- raters).
Solid lines indicate mean, upper and lower limits of agreement. Dotted lines indicate mean, upper and lower limits of agreement with outliers removed.

Figure 2. Differences in (a) steps taken, (b) walking duration, and (c) upright duration by walking cadence.

Table 1. Characteristics of participants and maximum step difference between activPAL3 and the average of three independent raters.

Participant	Gender	Age	EDSS	Walking aid	Average cadence (steps/min)	Maximum difference in steps
A117	M	51	4.0	None	83.7	3
A121	F	52	4.5	None	113.2	4
A128	F	51	4.5	None	109.2	2
A118	F	48	5.5	None	121.1	3
A124	F	47	5.5	None	111.6	4
A127	F	59	5.5	None	82.1	7
A123	M	44	6	1 stick	107.2	8
A126	M	62	6	1 stick	106.7	4
A119	M	63	6	1 stick	94.6	3
A108	M	60	6	1 stick	94.2	8
A129	M	42	6	1 stick	84.5	7
A106	M	64	6	1 stick	84.4	2
A113	F	48	6	1 stick	79.7	9
A107	M	64	6.5	4 wheeled walker	86.3	4
A103	M	63	6.5	3 wheeled walker	68.0	5
A122	F	46	6.5	4 wheeled walker	59.1	3
A116	F	46	6.5	4 wheeled walker	53.2	19
A101	F	54	6.5	2 sticks	47.3	8
A112	F	59	6.5	4 wheeled walker	37.6	33
A114	F	49	6.5	2 crutches	25.5*	28

*Only completed one walk due to fatigue.

Table 2. Summarised results, in relation to level of disability for differences in steps taken, walking and upright duration.

| Total number of events (n=39)	Average cadence (steps/min)	Difference in steps taken	Difference in walking duration (s)	Difference in upright duration (s)
EDSS 4.0 (n=2)	83.7 ± 2.3 (82.0, 85.3)	-0.50 ± 3.53 (-3.00, 2.00)	0.89 ± 4.67 (2.41, 4.19)	1.57 ± 0.03 (1.55, 1.59)
EDSS 4.5 (n=4)	111.2 ± 2.5 (108.2, 113.8)	-2.83±1.60 (-4.33, -1.00)	-0.61 ± 2.92 (-3.03, 3.32)	0.31 ± 0.52 (-0.46, 0.67)
EDSS 5.0 (n=0)	-	-	-	-
EDSS 5.5 (n=6)	104.9 ± 18.3 (81.4, 123.5)	-3.50 ± 1.87 (-7.00, -2.00)	-1.41 ± 0.50 (-1.95, -0.81)	0.62 ± 1.81 (-2.45, 2.69)
EDSS 6.0 (n=14)	93.1 ± 10.7 (79.0, 109.2)	-4.31 ± 3.02 (-9.00, 0.33)	-1.92 ± 1.37 (-4.05, 1.29)	0.88 ± 0.54 (0.20, 2.27)
EDSS 6.5 (n=13)	56.0 ± 18.1 (25.5, 86.9)	-6.90 ± 15.44 (-33.33, 19.00)	-10.88 ± 17.14 (-47.18, 4.21)	1.77 ± 1.13 (0.04, 3.84)
Total	83.9 ± 25.1 (25.5- 123.5)	-4.70± 9.09 (-33.33, 19.00)	-4.55 ± 10.76 (-47.18, 4.21)	1.11 ± 1.11 (-2.45, 3.84)

Mean ± standard deviation (range)
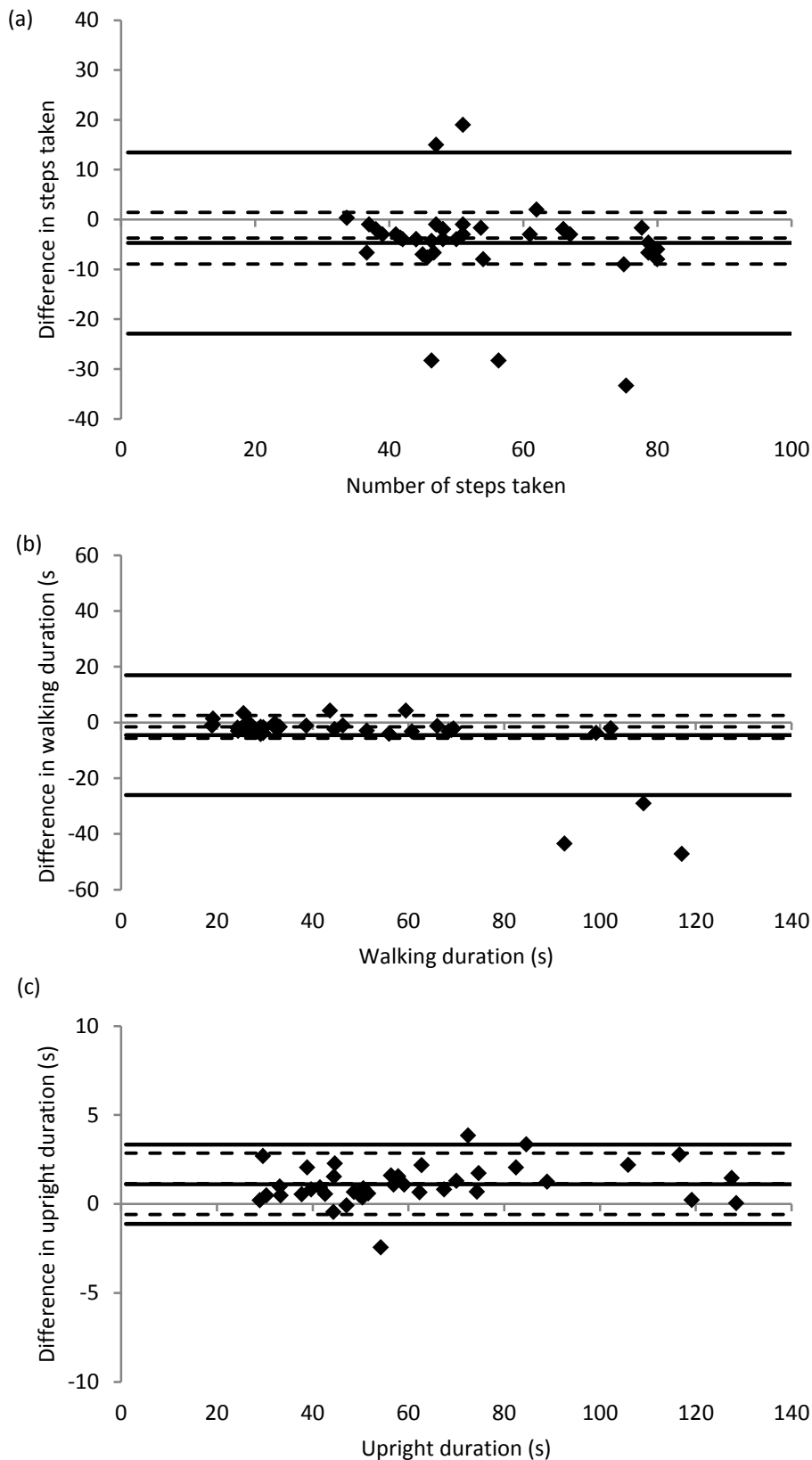
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Solid lines indicate mean, upper and lower limits of agreement. Dotted lines indicate mean, upper and lower limits of agreement with outliers removed.
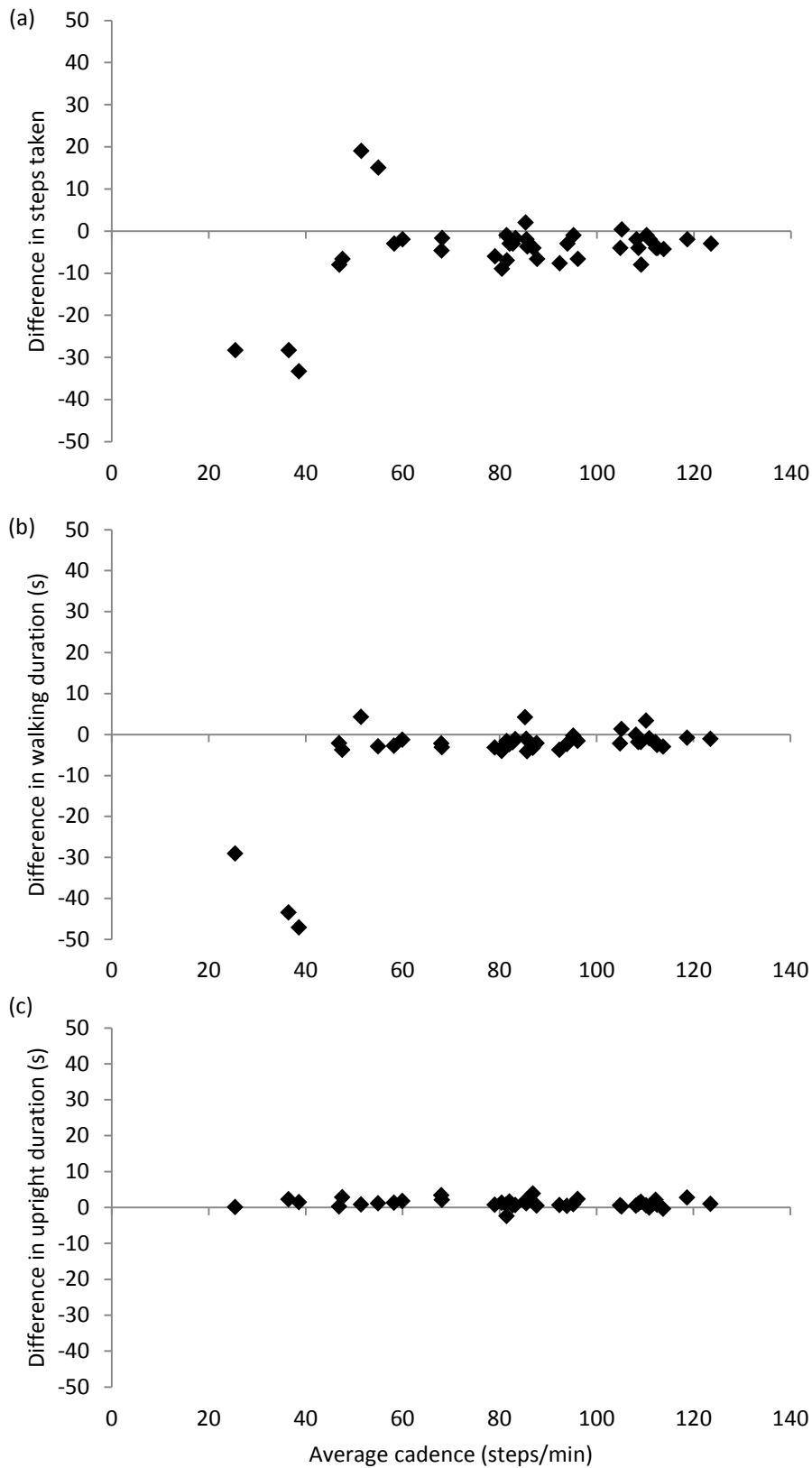
Figure 2. Differences in (a) steps taken, (b) walking duration, and (c) upright duration by walking cadence.

Highlights

- The criterion validity of the activPAL3 accelerometer in comparison to video observation was assessed in people with Multiple Sclerosis.
- The activPAL3 underestimated steps and walking duration in those with slow cadences of less than 38 steps/minute
- The activPAL3 was accurate for measuring upright duration regardless of walking cadence