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The validity and reliability of the Incremental Shuttle Walk Test and Six-minute Walk Test compared to an Incremental Cycle Test for people who have had a mild-to-moderate stroke☆

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Abstract

Objective To determine the construct validity and test re-test reliability of the Six-minute Walk Test (6MWT) and Incremental Shuttle Walk Test (ISWT) in the sub-acute recovery phase following mild-to-moderate severity stroke.

Participants 40 stroke patients (mean age: 68.27 years, SD: 13.48) of median National Institutes of Health Stroke Scale (NIHSS) score 1.2 (range: 0 to 8) within six months of stroke.

Method Each participant completed one Incremental Cycle Test (ICT) followed by two ISWT and two 6MWT in a randomised order. Pearson's Correlation Coefficients were used to determine the validity and Bland Altman plots were used to determine the test re-test reliability.

Results The Incremental Cycle Test (ICT) was positively correlated with the ISWT ($r = 0.59$, 95% confidence intervals 0.35 to 0.76, $P = 0.001$) and the 6MWT (0.55, 0.35 to 0.71, $P < 0.001$). The correlation of the ICT with the ISWT and 6MWT was higher for the 17 patients with no residual (ISWT: $r = 0.79$, $P < 0.001$; 6MWT: 0.826, $P < 0.001$) compared to mild-to-moderate neurological impairment (ISWT: $r = 0.45$, $P = 0.03$; 6MWT: $r = 0.38$, $P = 0.08$). Test–retest reliability for both the ISWT and the 6MWT showed that there was some variability between the first and second tests with a better performance on the second test.

Conclusion The ISWT and 6MWT have a significant, modest correlation with the ICT for stroke patients in the sub-acute recovery phase. The ISWT and 6MWT are not strongly correlated with ICT (VO_2 peak) in a stroke population that is disabled. The test–retest reliability of the ISWT and 6MWT indicated that two tests may be needed to accurately assess an individual's capabilities.

Keywords: Exercise test; Psychometrics; Rehabilitation; Stroke

Abbreviations: 6MWT, Six minute Walk Test; ISWT, Incremental Shuttle Walk Test; NIHSS, National Institute of Health Stroke Scale; VO_2 Peak, peak oxygen uptake; VO_2 Max, maximum oxygen uptake; ICT, Incremental Cycle Test; CI, confidence interval; CRf, cardiorespiratory fitness; NYHA, New York Heart Association; ACSM, American College of Sports Medicine; BMI, Body Mass Index; MHR, maximum heart rate; MBP, maximum blood pressure; Rpm, revs per minute; WRI, work rate intensity; RER, Respiratory Exchange Ratio.

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Introduction

Improved cardiorespiratory fitness can be linked to a reduction in cardiovascular risk [1] so it is essential to have a reliable and valid measure of cardiorespiratory fitness (CRf) in order to measure the effectiveness of treatments to improve CRf. Laboratory measures of CRf are the gold standard, but are expensive and not readily available for clinical practice. Therefore, field-based exercise tests offer a potential alternative, for example, the Incremental Shuttle Walk Test (ISWT) and Six-minute Walk Test (6MWT). To our knowledge, only one study [2] has compared these tests, albeit in a non-disabled chronic (>6 months) stroke population, and reported a strong correlation between the ISWT and 6MWT ($r = 0.65$, $P < 0.01$) with strong test/retest reliability (ICC = 0.961), but the authors did not compare the ISWT with an incremental exercise test reporting VO_2 peak. Performance on the 6MWT has been shown to have test-retest reliability [3] (ICC = 0.99) and validity [4] ($r = 0.64$, $P < 0.001$), when compared with the VO_2 peak in a chronic stroke population. However, Marzolini *et al.* [5] found that the 6MWT underestimated the exercise intensity in this population, when determining the target exercise training intensity. Overall, there has been limited research of these field-based assessments in the sub-acute (1 week to 6 months) [6] stroke population.

Accordingly, the aim of the present study was to compare the performance on the ISWT and 6MWT with the VO_2 peak measured using an ICT in a sub-acute, mild-to-moderate (<15 on NIHSS) [7] stroke population. The study also aimed to determine the test–retest reliability for both the ISWT and 6MWT in this population. As the level of disability post stroke is so variable, the aim was also to identify which participants could complete the tests dependent on their level of neurological impairment.

Hypotheses

In order to determine the validity of the ISWT and 6MWT, two null hypotheses were identified: (1) the distance measured during the ISWT shows no correlation with the VO_2 peak measured with an ICT, and (2) the distance measured during a 6MWT shows no correlation with the VO_2 peak measured with an ICT.

Methods

Participants

Participants were recruited from a large single-centre UK University teaching hospital within one week to six months (sub-acute) of mild-to-moderate stroke, defined by a National Institutes of Health Stroke Scale (NIHSS) [7] score of 0 to 15 [8]. All participants were able to walk 10 metres with or without an aid, and provided written consent. Exclusion criteria were based on cardiac contraindications and included: heart disease class III and upwards [9], Class C and D exercise risk [10], uncontrolled arrhythmias (causing symptoms), angina on exercise and uncontrolled hypertension (>180/110 mmHg at rest).

The study was approved by the National Research Ethics Service NRES Committee East Midlands – Northampton 14/EM/1067.

Procedure

All participants attended the exercise laboratory and after consenting to the study, the following information was recorded from the medical record: details about the stroke, relevant past medical history, drug history and social history. In addition, the following baseline assessments were undertaken: NIHSS, Fugl-Meyer scale [11] and lower limb strength. Height and weight (Body Mass Index (BMI)) were also recorded. Finally, routine cardiovascular parameters were measured to determine maximum heart rate (MHR) as defined by 220 minus age, and to set safety parameters for exercise, as follows: HR limit as 90% of MHR, and maximum blood pressure (MBP) of 200/110 mmHg for ischaemic and 180/100 mmHg for haemorrhagic stroke participants. HR limits were not set for those on betablockers, but BP limits were adhered to.

Each participant completed an ICT to establish VO_2 peak, with breath-by-breath analysis, followed by two ISWTs and two 6MWTs in a randomised order following standard operating procedures [12]. All tests were carried out on one day, rest times between tests varied between 30 and 40 minutes due to the availability of the testing site. Randomisation was achieved using random number tables and allocation concealment with sealed envelopes. Routine haemodynamic monitoring was undertaken throughout the exercise tests; BP was measured at two-minute intervals and continuous electrocardiogram monitoring during the ICT, and HR was recorded at minute intervals during the ISWT and 6MWT. In addition, BP and HR were recorded prior to and at the end of each test, and the Borg perceived exertion and Borg breathlessness scales were recorded.

Two ICT protocols were used to accommodate a range of participant abilities. Programme one had a two-minute warm-up at 10 W at a target cadence of 50 revs per minute (rpm), followed by a 5 W increment every minute [13]. Programme two had a two-minute warm-up at 10 W at a target cadence of 50 rpm, followed by a 10 W increment every minute, based on the pilot tests that indicated that some subjects may need a greater challenge to reach their peak VO_2. To identify which programme the patient attempted, a formula was used based on Wasserman *et al.* [14]:

$$\text{Work Rate Intensity (WRI)} = \frac{\text{Peak } VO_2 - VO_2 \text{ unloaded}}{100}$$

where: Peak VO_2 = (height − age) × 20 (males) or

Peak VO_2 = (height − age) × 14 (females) andwhere: VO_2 unloaded = 150 + (6 × weight).

If the WRI was less than seven, the participant completed the 5 W programme, if the WRI was more than seven, the participant completed the 10 W programme.

Both the ISWT and 6MWT were conducted twice as recommended by Holland *et al.* [12] to account for the learning effect, that is, participants become more familiar with the test which can improve performance so carrying out two tests reduces this error. The ISWT is an externally paced maximum exercise test using two cones, nine metres apart. The speed of walking is controlled by a pre-recorded set of bleeps and the number of laps around the cones are recorded and measured in metres. The 6MWT uses a thirty metre course marked out by two cones. The distance achieved in six minutes is recorded to the nearest metre. Standard instructions were used and the use of walking aids was consistent between the two tests as recommended by Holland *et al.* [12].

Data and statistical analysis

VO_2 peak was determined when either: Respiratory Exchange Ratio (RER) was greater than 1.0 [13] or the participant had reached 90% of their maximum age-predicted MHR. Pearson's correlation coefficients were used to determine the correlation of the ISWT and 6MWT compared to the ICT, with a value of 0.20 to 0.39 indicating a weak correlation, 0.4 to 0.69 indicating a modest correlation, 0.70 to 0.90 indicating a strong correlation and 0.90 to 1.00 indicating a very strong correlation [15]. Bland Altman plots were used to determine the test re-test reliability of the ISWT and 6MWT. Pearson's correlations between the different measures, were also calculated for those with no neurological impairment (NIHSS = 0) or mild-to-moderate (NIHSS < 15) neurological impairment. Statistical significance was taken at $P < 0.05$. A power calculation determined that 30 subjects were needed to test the validity of each measure if r = 0.8, with 80% power at the 5% significance level [16].

Results

Forty participants (27 male) of mean age 68.3 (SD: 13.48) years were recruited a mean of 84 days (SD: 41.1) following stroke onset. Median NIHSS was 1.2 (range 0 to 8), and other baseline demographic data are shown in Table 1.

Table 1
Participant demographics.

Age (years)	
Mean (SD)	68.28 (13.48)
Gender (male) *n* (%)	27 (68)
Ethnicity *n* (%)	Caucasian: 36 (90)
	Asian: 3 (8)
	Afro-Caribbean: 1 (2)
Ischaemic stroke *n* (%)	38 (95)
Side of body affected (left) *n* (%)	19 (48)
Length of time post stroke (days)	
Mean (SD)	84.7 (41.19)
NIHSS[a] – median (range)	1.0 (0 to 8)
NIHSS – score of 0 – *n* (%)	17 (43)
NIHSS – score > 0 – *n* (%)	23 (57)
Fugl-Meyer	
Mean (SD)	113.6 (16.5)
Current smokers *n* (%)	4 (10)
Diabetes mellitus *n* (%)	11 (28)
Hypertension *n* (%)	17 (43)
Atrial fibrillation *n* (%)	3 (8)
Ischaemic heart disease *n* (%)	6 (15)
No. of co-morbidities	
Mean (SD)	2.25 (1.41)
No. with pain *n* (%)	20 (50)
Body Mass Index	
Mean (SD)	28.63 (4.63)
No. on betablockers *n* (%)	10 (25)

Data are presented as mean (SD) or *n* (%), unless stated. NIHSS: National Institute of Health Stroke Scale.

[a] Median (range) NIHSS scores presented; score of 1 to 5 classified as mild, 6 to 15 classified as moderate [8]. For this study, the population was divided into those that had no disability post stroke (NIHSS = 0) and those that had disability post stroke (NIHSS > 0).

Construct validity between VO_2 Peak, ISWT and 6MWT

All 40 participants completed the incremental cycle protocol; 13 completed the 10 W and 27 the 5 W increment programme. Of these participants, 31 achieved an RER > 1.0, indicating that they were nearing exhaustion. Of the nine participants who did not achieve an RER > 1.0, three stopped the test due to fatigue, and six were stopped by the therapist due to reaching MHR (1), reaching MBP (4) or not keeping up the required speed (1). In total, 19 of the incremental tests were stopped by the therapist and 19 by the participant, with two participants completing the assigned programme.

Mean values for ICT (VO_2 peak), and the best performance (m) of each of the two ISWTs and two 6MWTs were significantly reduced compared to normative values for an age-matched healthy cohort (Table 2). ICT (VO_2 peak) had a modest correlation with both the ISWT (Fig. 1; r = 0.59, 95% confidence intervals (CI) 0.34 to 0.76, $P = 0.001$) and 6MWT distance (Fig. 2; r = 0.55, 95% CI 0.35 to 0.71, $P < 0.001$). It is acknowledged that the CIs are relatively large for both tests making it difficult to conclude the magnitude of both relationships. In addition, a very strong correlation was observed between the ISWT and 6MWT distance (r = 0.93, 95% CI 0.89 to 0.97, $P < 0.001$).

When participants were grouped by NIHSS scores into those with no neurological impairment (NIHSS = 0) and those with mild-to-moderate neurological impairment (NIHSS < 15) and the relationship between ISWT and 6MWT with ICT was explored, differences in the strength of agreement were noted. In 17 participants with no neurological impairment, a significant strong correlation between the ISWT (r = 0.80, $P < 0.001$) and 6MWT (r = 0.83, $P < 0.0001$) with ICT (VO_2 peak) was observed. However, only a modest correlation was reported in those with residual mild-to-

Table 2
Results of the Incremental Cycle Test, Incremental Shuttle and 6-minute Walk Tests.

	ICT	ISWT	6MWT
Mean (SD)			
All	12.1 (3.1) ml/minute/kg	261 (177) m	365 (143) m
Male	13.2 (3.1) ml/minute/kg	301 (180.1) m	397 (138.7) m
Female	9.9 (1.7) ml/minute/kg	179 (144.8) m	298 (130.9) m
Normative aged matched data*			
Male	26 to 32 ml/minute/kg	478 m	572 m
Female	20 to 24 ml/minute/kg	441 m	538 m
Mean Peak HR (SD) bpm	112 (20)	98 (20)	94 (18)

ICT: Incremental Cycle Test; ISWT: Incremental Shuttle Walk Test; 6MWT: 6-minute Walk Test; SD: standard deviation; bpm: beats per minute. Normative data from Machars.net [17] and Rehabilitation Measures Database [18].

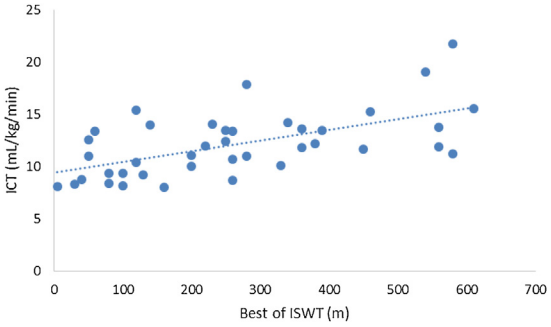

Fig. 1. Scatter plot demonstrating the correlation between Incremental Cycle Test and Incremental Shuttle Walk Test.

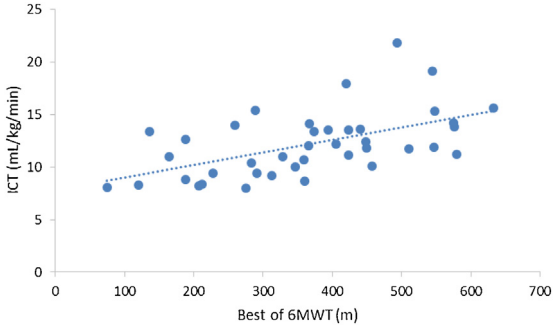

Fig. 2. Scatter plot demonstrating the correlation between the Incremental Cycle Test and 6-minute Walk Test.

moderate neurological impairment (ISWT: r = 0.45, $P = 0.03$, 6MWT: r = 0.38, $P = 0.08$).

The Pearson correlation coefficients between the maximum HRs for each test was ICT (VO_2 peak) and ISWT (r = 0.60, $P = 0.001$, 95% CI 0.34 to 0.86), ICT (VO_2 peak) and 6MWT (r = 0.67, $P = 0.001$, 95% CI 0.43 to 0.91), and ISWT and 6MWT (r = 0.76, $P = 0.001$, 95% CI 0.55 to 0.97).

Test re-test reliability of 6MWT and ISWT

Results of the first and repeat ISWT and 6MWTs are shown in Table 3. Increased distances were covered in both repeat tests and may indicate a learning effect (Table 3). There was no order effect, that is, the mean difference between tests did not change irrespective of whether the ISWT or 6MWT was undertaken first (data not shown). Bland Altman plots for the ISWT and 6MWT are shown Figs. 3 and 4, respectively. Given the limits of agreement, and the fact that both plots show a fairly even scatter of data points across all values of test results, repeatability is not influenced by whether the test results are at the lower or higher range of the population values. For the ISWT where patient values ranged between 5 and 600 m, on 95% of occasions a patient would score between 40 m lower and 70 m higher on the second occasion than they did on the first. For the 6MWT where patient values ranged between 50 and 580 m, on 95% of occasions a patient would score between 80 m lower and 100 m higher on the second occasion than they did on the first.

Adverse events

No adverse events were recorded, however, two participants were excluded just prior to testing due: identification of a 2 cm aneurysm on MRI scan, and left ventricular abnormality on ECG.

Participant comments

Six participants complained of pain during the ICT: hip pain (1), knee (1), ‘leg pain’ (2), and pain from the seat (2). When asked which test was preferred, 23 (60%) indicated the ICT due to: ‘easier to push yourself’, ‘walking was limited by speed’, ‘leg fatigue with walking’, ‘dizziness with walking tests’, ‘gets the knee bending’, ‘walking tests limited by moving legs quickly enough’ and ‘leg stiffened with walking tests’.

Table 3
Test retest results for the Incremental Shuttle and 6-minute Walk Tests.

	First test	Second test	Mean difference (limits of agreement)
ISWT (m)	243.3 (174.0)	263.0 (171.1)	19.7 (−37.2 to 76.7)
6MWT (m)	356.9 (134.1)	373.2 (145.5)	16.2 (−67.9 to 100.4)

Data are shown as mean (SD). ISWT: Incremental Shuttle Walk Test; 6MWT: 6-minute Walk Test.

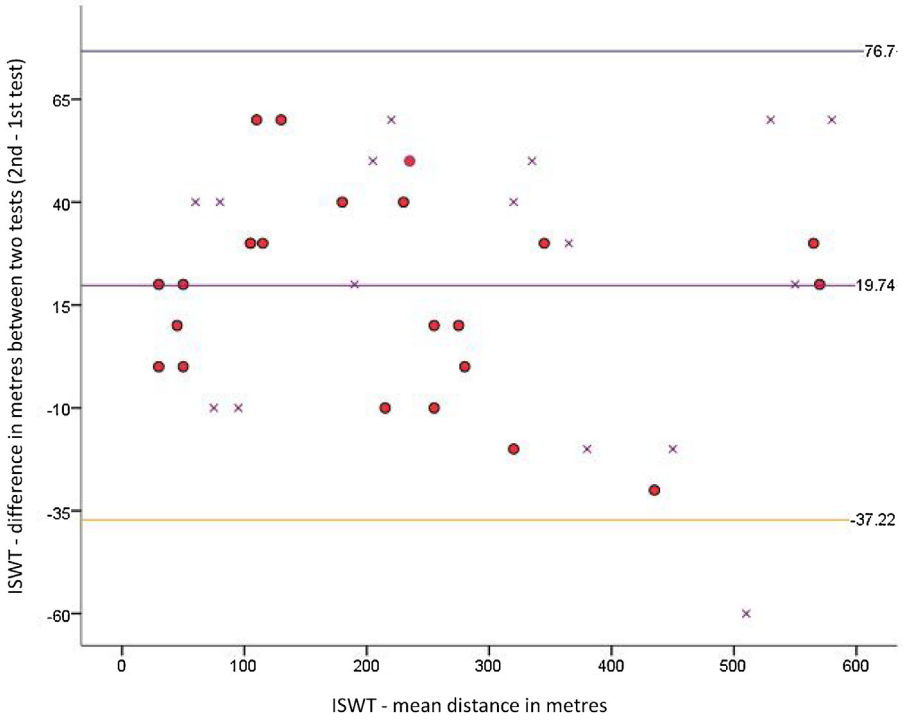

Fig. 3. Bland Altman plot demonstrating the relationship between the first and second Incremental Shuttle Walk Test. Purple line – mean difference line, blue line – upper confidence limit, orange line – lower confidence limit, red dots – participants with NIHSS > 0, purple cross – participants with NIHSS = 0.

Discussion

With increasing importance being given to secondary prevention and healthy lifestyle in this population, it is important to have a reliable and valid measure of CRf in order to measure the effectiveness of treatments to improve CRf. Laboratory tests can be expensive and time consuming and therefore cheap alternatives have been validated in many disease groups [16,19–22]. This study aimed to determine the construct validity of the ISWT and 6MWT compared to the gold standard measure of cardiorespiratory fitness in a post stroke population of mild-to-moderate stroke severity in the subacute recovery period. We found that both the ISWT and 6MWTs demonstrated a modest correlation with the VO_2 peak measured with the ICT. The study also aimed to determine the test–retest reliability for the ISWT and the 6MWT, and found that there was some variability between the first and second tests. This was different to previous studies for the ISWT that found the test to be reliable with respiratory [19], cardiac [20] and chronic stroke patients [2], and previous results for the 6MWT with cardiac [21], respiratory [22] and chronic stroke patients [3]. As with previous studies, it was found that there was a learning effect with both tests, and therefore the recommendation would be that two ISWTs and two 6MWTs are completed, with the results of the second test used.

In relation to the validity of the tests, one of the reasons why there was only a modest correlation between the tests appears to be due to the range of residual neurological impairment studied from none, 0 on the NIHSS scale, to moderate, 8 on the NIHSS scale. A strong correlation was seen between the ICT and both clinical tests in participants with no residual neurological impairment (NIHSS = 0). Therefore, the ISWT or 6MWT could be used to measure CRf or cardiovascular capacity in such patients. In those with residual neurological impairment there was only a modest correlation. However, it needs to be acknowledged that the study was not powered for these sub-group analyses. In addition, this may in part be because some participants found it difficult to complete the walking-based tests compared to the cycle test. The

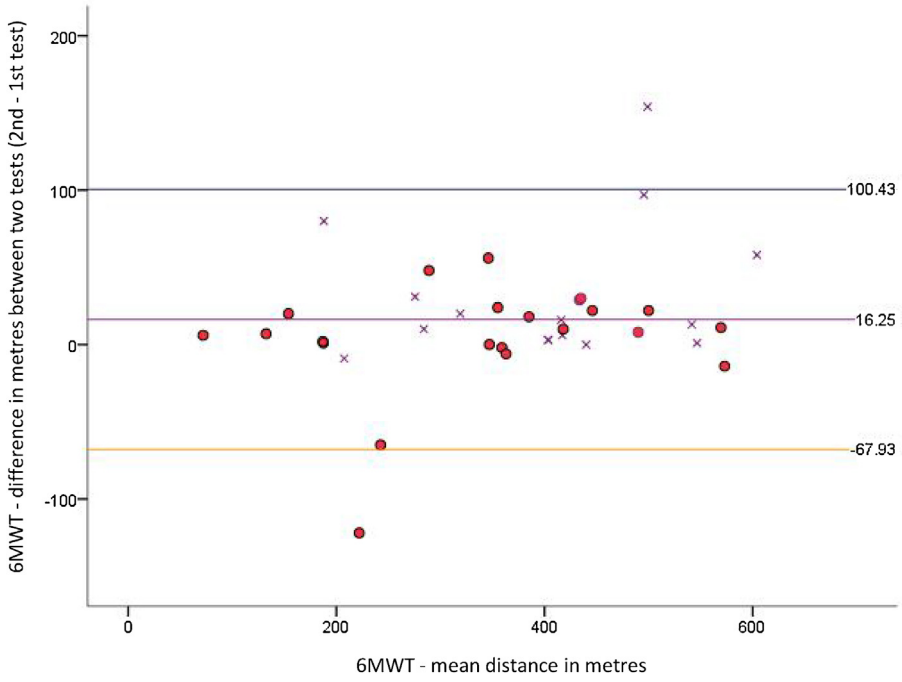

Fig. 4. Bland Altman plot demonstrating the relationship between the first and second 6-minute Walk Test. Blue line – upper confidence limit, purple line – mean difference, orange line – lower confidence limit, red dot – participants with NIHSS > 0, purple cross – NIHSS = 0.

majority of subjects completed the ICT without assistance; only two participants needing their affected foot strapped to the pedal and support with their arm, and one participant help to initiate pedaling. Furthermore, the majority of participants preferred the cycle-based test (60%). This indicates that further research is needed to explore the most valid measure of CRf in people with residual neurological impairment post stroke in order to inform guidelines [23,24].

However, additional questions need to be addressed in respect of the use of a cycle-based test. First, whether a conventional or recumbent cycle should be used. Tang *et al.* [13] used a semi-recumbent position for testing, but found that this 'may not help to address the potential problems arising from local limb fatigue related to motor dyscontrol or asymmetry' [13,p. 1104]. Although six of the participants in the present study complained of pain with the cycle test, only two were related to the seat of the cycle and the rest were due to leg pain that occurred with all of the tests. Secondly, it is still important that stroke participants can achieve VO_2 peak even if it is as a cycle-based test. Cycle-based VO_2 testing measures 10% to 15% lower than treadmill-based tests in healthy adults [23] but Tang *et al.* [13] highlighted the importance of measuring VO_2 peak as accurately as possible to ensure that the exercise prescription is appropriate. Therefore, *clinical* cycle-based tests need to be devised to measure the CRf of people who have had a stroke in the sub-acute phase of recovery.

The exclusion criteria and termination of testing procedures were based on ACSM guidelines [10] and are all based on cardiac contraindications. These enabled a safe and acceptable level of testing for the stroke population studied. It is recommended that BP limits for people who had an ischaemic stroke are set at 200/110 mmHg and for people who had a haemorrhagic stroke, set at 180/100 mmHg, as although ten tests were stopped by the therapist due to hypertension, six of those participants achieved an RER over one. Indeed, compared to previous studies with subacute stroke participants, where only 44% of participants achieved RER [13], a high percentage of participants in the present study (78%) achieved RER. It is also recommended that the MHR is set at 90% of the age-predicted MHR, as only five participants were stopped due to maximum HR limits and three of those achieved an RER over one. However, it may be necessary to add more stroke-specific exclusion criteria for testing based on issues identified in the present study. One participant had a 2 cm brain aneurysm, and another potential participant had greater than 50% bilateral carotid stenosis; both of these participants were excluded by their treating stroke consultant. It is therefore, recommended that cerebral aneurysms and >50% carotid stenosis should be added to the list of exclusion criteria for future studies investigating VO_2 peak with stroke participants. Further investigation of stroke specific contraindications should be considered, such as post stroke epilepsy and tonal issues.

As has been seen in other studies [13,24], VO_2 peak values were significantly lower than age-related data, that is, in the sub-acute phase of stroke recovery the mean values found in this study, 12.1 ml/kg/minute, were lower than the 15 ml/kg/minute required for independent living [25]. This further supports the need for cardiovascular training for people with mild-to-moderate stroke in the sub-acute phase, as recommended by the NICE guidelines [26].

Study limitations

The preferred duration of an incremental exercise test is between eight and nine minutes [13], however, the mean length of time for the test in the present study was 10.2 minutes. This was because four participants managed to reach the end of the testing (16 minutes). In future studies it might be necessary to set three test protocols to accommodate participants at the higher end of the physical ability scale.

Though it would have been interesting to measure oxygen consumption during the walking tests in the present study, in order to make a true comparison of the level of oxygen consumed in each walking test compared to the ICT, it was anticipated that using the portable equipment required would be too cumbersome for the stroke participants. However, it is acknowledged that the ISWT and 6MWT are submaximal clinical tests of CRf and so true VO_2 peak may not have been reached. In order to determine VO_2 peak during ISWT and 6MWT testing, future studies need to attempt to use portable oxygen consumption devices, perhaps with a small pilot study to determine if people post stroke can use these devices.

Future studies also need to identify a cycle-based, *clinical* test that would adequately measure CRf in this sub-acute, mild-to-moderate stroke population and need to test this measure against the VO_2 peak measured with an ICT.

Conclusion

The ISWT and 6MWT have a significant, modest correlation with the ICT for stroke patients in the sub-acute recovery phase. The ISWT and 6MWT are not strongly correlated with ICT (VO_2 peak) in a stroke population that is disabled and the best way to determine cardiovascular fitness may be with a cycle-based test with this population. BP and HR limits have been identified for people who have had haemorrhagic and ischaemic strokes, and additional contraindications to testing have also been established. The test–retest reliability of the ISWT and 6MWT indicated a difference between the first and second tests with a better performance on the second test indicating that two tests may be needed to accurately assess an individual's capabilities.

Key messages

1. The ISWT and the 6MWT are both valid clinical measures to measure cardiorespiratory fitness in people with *no neurological impairment* post stroke, however, people *with neurological impairment* post stroke may need alternative measures, such as a cycle-based test, to determine their cardiorespiratory fitness.
2. The ISWT and 6MWT both had differences in their first and second tests.
3. This adds to the limited knowledge on the validity and reliability of the 6MWT and ISWT with a stroke population in the *sub-acute* as opposed to the chronic stage of recovery.

New knowledge

The ISWT has not been tested against the ICT and 6MWT in people with stroke in the sub-acute phase of stroke recovery. The ISWT is important as it is an incremental test that has the potential to challenge the cardiorespiratory system more than the 6MWT. The study identifies that routine field-based tests of CRf such as the ISWT and 6MWT both have limitations for measuring CRf in a stroke population.

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Ethics approval and consent to participate: Ethical approval was approved by the NRES Committee East Midlands – Northampton. REC reference — 14/EM/1067 . Written consent to participate was obtained from all participants.

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Conflict of interest: TR is an NIHR Senior Investigator.

Consent for publication: Written consent for publication was

obtained from all participants.

Availability of data and material: The datasets used and analysed during the current study are available from the corresponding author on reasonable request.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.physio.2018.12.005.

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