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**University of Southampton**

Faculty of Environmental and Life Sciences

School of Health Sciences

**Evaluation of the validity, reliability, and feasibility of an inertial sensor system for  
trunk assessment and rehabilitation post-stroke**

by

**Norah Alhwoaimel**

Thesis for the degree of Doctor of Philosophy

[December 2020]



# University of Southampton

## Abstract

Faculty of Environmental and Life Sciences

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### **Evaluation of the validity, reliability and feasibility of an inertial sensor system for trunk assessment and rehabilitation post stroke**

by Norah Alhwoaimel

Post stroke trunk control is recognised as an important independent predictor of activities of daily living after a stroke. Clinical scales such as the Trunk Impairment Scale (TIS) are recommended to be used in clinical research to assess post stroke trunk impairment; however, they do not consider the quality of trunk movement. Assessing trunk and pelvic movement quality would inform our understanding of trunk recovery and, therefore, facilitate the development of more effective rehabilitation interventions. Three-dimensional kinematic measurement systems are used to measure trunk movement quality in research laboratories, however, these are not suitable for implementation in clinical settings due to the high cost and physical space requirements. The use of inertial sensors to measure trunk performance have the potential to overcome these limitations and, therefore, offer an alternative solution to measure trunk performance. The aim of this research is to investigate the use of the Valedo<sup>®</sup> system to assess trunk performance and, when combined with video games, as an intervention tool to deliver trunk exercises for people with chronic stroke.

In the first stage of this PhD study, a cross-sectional validity and reliability study investigated the development of an instrumented TIS (iTIS) and, subsequently, tested its validity and reliability in 20 patients with chronic stroke and 20 aged-matched healthy participants. The kinematic parameters of the trunk and the clinical TIS (cTIS) were measured simultaneously. A moderate relationship was found between the observed iTIS parameters and the clinical TIS scores, supporting the concurrent validity of the iTIS. The reliability for the dynamic subscale parameters was good to excellent (intrarater ICC = 0.60–0.95; interrater ICC = 0.59–0.93); however, reliability for the coordination parameters was poor to good (intrarater ICC = 0.05–0.72) and poor to excellent (interrater ICC = 0.04–0.78). These results demonstrate that the iTIS has important implications for objective assessments of trunk impairment in clinical practice; the iTIS can be used in conjunction with the clinical TIS to detect small changes in trunk range of movement that cannot be observed clinically.

## Abstract

In the second stage of this PhD study, a cross-sectional validity and reliability study investigated the use of Valedo<sup>®</sup> sensors to measure trunk movement during streamlined Wolf Motor Function Test (SWMFT) performance. A sample of 20 people with chronic stroke and 20 age-matched healthy participants performed the SWMFT while wearing Valedo<sup>®</sup> sensors on their trunk to capture trunk movements. The Valedo<sup>®</sup> system was able to distinguish between the stroke participants and the healthy participants; the stroke participants employed greater trunk range of movements than the healthy controls in all tasks ( $p < 0.01$ ). Furthermore, using trunk parameters recorded by the Valedo<sup>®</sup> system enabled differentiation between the affected hand and the unaffected hand of people within the stroke group. The reliability for the stroke group was good to excellent with intrarater reliability (same session; ICC = 0.70–0.95): intrarater reliability (between two days; ICC = 0.71–0.92) and interrater reliability (between two raters; ICC = 0.63–0.95). These findings indicate that the Valedo system has important potential for the objective assessment of trunk range of movement during upper limb (UL) activity in clinical practice.

In the third stage of this PhD study, a convergent parallel mixed method study investigated the feasibility of conducting a programme of 18 sessions of trunk exercises using a video game–based system (Valedo) for people with stroke. It also explored possible changes in clinical outcome measures involving trunk impairment (TIS and iTIS), trunk muscle size, balance and lower limb (Fugl-Meyer Assessment of the lower limb) and upper limb function, as well as impairment outcomes (SWMFT and Fugl-Meyer Assessment of the upper limb). Of the 10 chronic stroke survivors who participated in the intervention, 8 completed 18 sessions. Post intervention results showed adherence was excellent, no major adverse events occurred and very good-to-excellent participation (the Pittsburgh Rehabilitation Participation Scale) was achieved. The clinical outcome measures demonstrated an improvement in trunk impairment (TIS and iTIS), balance (the Berg Balance Scale) and upper limb function (SWMFT). The post intervention interview revealed a high acceptability of the intervention, associated with enjoyment and perceived physical and psychological benefits from the intervention. The use of audio-visual feedback was perceived as helpful to set a goal and motivated participants to engage in the exercises. Several points need to be considered when implementing this type of intervention in the future. For the person administering the intervention, it includes personalising the task difficulty level appropriately to avoid excessive physical and cognitive challenges and ensuring that participants understand the system-generated feedback on performance following each game. For game designers, game reward strategies need to be improved to minimise participants' frustration. In addition, using artificial intelligence in the system will help with tailoring the exercise programmes by suggesting to the therapists the most appropriate games to practise next.

The three stages of this PhD study addressed the original aim of this research and provided evidence that the Valedo® system can be used to assess trunk performance and, when combined with video games, and feasible to use as an intervention tool to deliver trunk exercises using video games for people with chronic stroke.



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# Research Thesis: Declaration of Authorship

Print name: Norah Alhwoaimel

Title of thesis: Evaluation of the validity, reliability, and feasibility of an inertial sensor system for trunk assessment and rehabilitation post-stroke

I declare that this thesis and the work presented in it are my own and has been generated by me as the result of my own original research.

I confirm that:

This work was done wholly or mainly while in candidature for a research degree at this University;  
Where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;

Where I have consulted the published work of others, this is always clearly attributed;

Where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;

I have acknowledged all main sources of help;

Where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself;

Parts of this work have been published as:

## Journal publications:

- 1- Alhwoaimel N, Turk R, Hughes AM, Ferrari F, Burridge J, Wee SK, Verheyden G, Warner M. (2020). Instrumented Trunk Impairment Scale (iTIS): A Reliable Measure of Trunk Impairment in the Stroke Population. *Topics in Stroke Rehabilitation*, 1-8. <https://www.tandfonline.com/doi/full/10.1080/10749357.2020.1834273>
- 2- Alhwoaimel, N., Warner, M., Hughes, A-M., Ferrari, F., Burridge, J., Wee, S. K., ... Turk, R. (2020). Concurrent validity of a novel wireless inertial measurement system for assessing trunk impairment in people with stroke. *Sensors*, 20(6), [1699]. <https://www.mdpi.com/1424-8220/20/6/1699>
- 3- Alhwoaimel N, Turk R, Warner M, Verheyden G, Thijs L, Wee SK, Hughes AM (2018) Do trunk exercises improve trunk and upper extremity performance, post stroke? A systematic review and meta-analysis. *NeuroRehabilitation*, 43(4), 395-412. (This publication won the Doctoral College Research Awards - School of Health Science 2020)

<https://content.iospress.com/articles/neurorehabilitation/nre182446>

Signature:

Date: 24/12/2020



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## Glossary of Abbreviations

ADL	Activities of daily living
APA	Anticipatory postural adjustment
BBS	Berg Balance Scale
EO	External oblique
FIM	Functional Independence Measure
FMA	Fugl-Meyer Assessment
ICF	International Classification of Functioning, Disability and Health
ICC	Interclass Correlation Coefficient
IMUs	Inertial measurement units
IO	Internal oblique
iTIS	Instrumented trunk impairment scale
KSA	Kingdom of Saudi Arabia
LL	Lower Limb
MCID	Minimal clinically important difference
MDC	Minimal detectable change
PASS	Postural Assessment Scale for Stroke
PIADS	Psychosocial Impact of Assistive Devices Scale
PRPS	Pittsburgh Rehabilitation Participation Scale
RCT	Randomised controlled trial
ROC	Receiver operating characteristic
ROM	Range of motion
SD	Standard deviation
SEM	Standard error of measurement
SLR	Straight leg raise
SWMFT	Streamlined Wolf Motor Function Test

SWMFT-FAS	Streamlined Wolf Motor Function Test-Functional Ability Scale
SWMFT-Time	Streamlined Wolf Motor Function Test-Time
TCT	Trunk Control Test
TIS	Trunk Impairment Scale
TrA	Transversus abdominis
UL	Upper Limb
UK	United Kingdom
WMFT	Wolf Motor Function Test

# Chapter 1 Introduction

This chapter presents the rationale for conducting this doctoral research and outlines the specific aims and objectives of each stage of this PhD study. An overview of the structure of the entire doctoral research, as well as publications and oral presentations, resulting from the study is also given.

## 1.1 Rationale for the research

### 1.1.1 Stroke and its impact

Stroke is defined as ‘rapidly developing clinical signs of focal (or global) disturbance of cerebral function, with symptoms lasting 24 hours or longer or leading to death, with no apparent cause other than of vascular origin’ (WorldHealthOrganisation, 1988). In 2016, there were approximately 13.7 million incidents of first-time stroke worldwide, making stroke the second leading cause of death (5.5 million deaths) and disability globally (Collaborators, 2019).

Approximately 1.1 million European inhabitants suffer from stroke annually, and 7% to 13% have an increased risk of recurrent stroke (Bejot et al., 2016). The European Registers of Stroke (EROS) report that in a sample of 2,033 people of all ages with first-time stroke, several people had poor outcomes – defined as 59% unable to walk, 47% unable to lift their arm and 34% being dependent (a Barthel Index (BI) score below 12 points) after stroke (Ayis et al., 2013). In addition to being difficult for the individual, this physical disability places a responsibility on carers to assist stroke patients in carrying out activities of daily living (ADL). In addition to physical disability, it also results in an economic burden on the patients and their families (Feigin et al., 2008). In 2017, the total economic cost of stroke in the 32 European countries was estimated to be €60 billion (Luengo-Fernandez et al., 2019).

### 1.1.2 Trunk control post stroke

The trunk is the central (key) point of the body; it plays a postural role in holding the body upright and performing selective trunk movements during static and dynamic postural adjustments (Davies and Klein-Vogelbach, 2012, Edwards, 1996). Trunk control has been defined as part of postural control (Gjelsvik and Syre, 2016). It involves the stabilization and selective movements of the trunk (Verheyden et al. 2007). Trunk control has been defined as part of postural control (Gjelsvik and Syre, 2016). It involves the stabilization and selective movements of the trunk (Verheyden et al. 2007). Trunk performance is an important predictor of outcomes of balance, gait and ADL after a

stroke (Franchignoni et al., 1997, Hsieh et al., 2002, Verheyden et al., 2007a). The percentage of the variance of functional recovery after a stroke has been explained by trunk control ranging from 45% to 71% (Hsieh et al., 2002, Verheyden et al., 2007a).

Trunk performance is commonly affected after stroke. People with stroke can have trunk impairments – including trunk muscle weakness, loss of selective coordinated muscle action, overactive muscles and stiffness, which can lead to insufficient trunk control (Verheyden et al., 2007b, Karthikbabu et al., 2012, Verheyden et al., 2004). This might interfere with their ability to carry out ADL (Verheyden et al., 2007a).

### **1.1.3 The gap between clinical and laboratory measures**

To ensure that any planned treatments are working or need to be adapted, therapists need accurate tools and outcome measures to assess change. To measure post stroke trunk performance and recovery, a clinical outcome measure needs to be used. However, using clinical measures alone has several limitations. Trunk control after stroke is usually measured using clinical measures such as the Trunk Impairment Scale (TIS) and the trunk control test (TCT) (Fujiwara et al., 2004, Verheyden et al., 2004, Sorrentino et al., 2018). The TCT provides relatively minimal information through measuring trunk control only in static positions, and its test–retest reliability has not been established. The TIS, however, has been shown to be a reliable measure with predictive validity, but the main limitation is that the ordinal scale nature of the TIS ignores movement quality (Verheyden et al., 2004, Verheyden et al., 2005, Verheyden et al., 2007a). Assessing the quality of trunk and pelvic movements could help with understanding the relationship between movement quality and recovery of trunk post stroke and, thereby, developing more effective rehabilitation interventions. For example, a recent cross-sectional study among 45 subacute stroke patients showed a significant relationship between trunk control (TCT) and anterior trunk movement ( $r = 0.31$ ;  $p = 0.02$ ), lateral trunk movement ( $r = 0.36$ ;  $p = 0.007$ ) and lateral pelvic movement ( $r = 0.41$ ;  $p = 0.003$ ) post stroke (Carozzo et al., 2020). However, other trunk kinematics – such as posterior trunk movement, trunk rotation, anterior and posterior pelvic movements – did not show a correlation with the TCT. In view of the findings, (Carozzo et al., 2020) concluded that trunk kinematics can be used for an integrated assessment, with lateral pelvic movement considered as the best predictor of trunk control post stroke.

After a brain insult, it has been postulated that there are two mechanisms of functional improvement, defined as recovery and compensation (Levin et al., 2009). According to clinical researchers, based on the International Classification of Functioning, Disability and Health (ICF) model, recovery and compensation may occur at three different levels, which are the neural,

performance and activity levels (Levin et al., 2009). At the neural level, recovery is characterised by activation of the brain areas surrounding the brain lesion, such as areas of diaschisis, while the compensation level is characterised by activation of alternative brain areas not normally observed in nondisabled individuals. At the performance level, recovery is distinguished by the reappearance of premorbid movement patterns during accomplishment of a task, whereas compensation is characterised by the appearance of alternative movement patterns during task achievement. At the activity level, recovery features accomplishing the task using the same joints or end effectors as before injury, while compensation at this level requires that the task is achieved using alternative end effectors or joints. Hence, recovery relates to restoration of the lost function, while compensation relates to acquiring a new function after injury to replace the lost function (Kleim, 2011).

Trunk control plays a fundamental role during seated activities, interacting with upper limb (UL) and head control by providing a stable base of support (Carr and Shepherd, 1998, Cirstea et al., 2003). Following stroke, over three quarters of patients with stroke experience UL deficits (Lawrence et al., 2001). Because of persistent UL dysfunction after stroke, people with stroke tend to recruit greater trunk movement, unlike healthy individuals, while pointing to targets or grasping objects placed within or beyond arm length (Cirstea and Levin, 2000, Levin, 1996, Roby-Brami et al., 2003). Therefore, it is crucial to identify whether any motor function improvement that occurs is due to recovery of lost motor elements rather than the use of compensatory motor patterns. The use of three-dimensional (3D) kinematic measurement systems has been suggested as able to distinguish between true recovery and compensation (Kwakkel et al., 2017, Carozzo et al., 2020); however, the challenges these pose are the high cost and large space required for installation. Inertial measurement units (IMUs) have the potential to overcome these limitations – making them more applicable to everyday clinical practice, which is why they were used in this PhD study.

#### **1.1.4 Current practice of trunk rehabilitation**

Stroke rehabilitation is a multidimensional health procedure that aims to facilitate recovery of functional activities by improving physical and psychosocial potentials, with consideration for the physiological and environmental limitations (NICE, 2013, Silva et al., 2015). A systematic review and meta-analysis of 467 randomised control trials (RCTs) by Van Peppen et al. (2004) suggested that most of the rehabilitation programmes after stroke are concerned with the effect of rehabilitation on upper limb (UL) or lower limb (LL) function. Over the last 10 years, there has been increasing research in the area of trunk rehabilitation (Alhwoaimel et al., 2018, Bank et al., 2016, Cabanas-Valdes et al., 2013, Cabrera-Martos et al., 2020, Criekeing et al., 2019, Sorinola et al., 2014, Souza et al., 2019). The findings from these systematic reviews suggest that trunk exercise, either alone

or as an additional therapy to conventional rehabilitation, can improve post stroke trunk impairment (TIS and TCT) at acute, subacute and chronic stages.

The trunk exercises described in previous studies are repetitive standard exercises without targets and feedback (i.e. standardised objective goals and ways of assessing the movements and conveying these to both the participant and the therapist). In stroke rehabilitation, repetitive exercises are required to relearn a movement and make that movement better. However, repeating the same movement numerous times without distraction is not the most interesting way to do the exercise and might make the rehabilitation boring, thereby affecting adherence. It has been reinforced through literature that intensive and repetitive practice of specific functional tasks are important for post stroke recovery (Burdea, 2003). However, the repetitive nature of exercise could decrease participant motivation, thereby affecting their adherence to the rehabilitation programme (Burdea, 2003). A systematic review of 31 qualitative studies which studied the experiences of physical rehabilitation among stroke survivors found that negative experiences (including disempowerment, boredom and frustration) were reported in all the studies (Luker et al., 2015). The participants associated practising tasks that seemed irrelevant to their recovery with boring or meaningless therapy; the participants wanted enjoyment from therapy through, for example, Wii computer games or circuit classes. Furthermore, the stroke survivors considered that recreation (the details of this recreation were not specified in the paper) was therapeutic, not only counteracting the boredom of the rehabilitation environment but also helping in stroke recovery (Luker et al., 2015). In addition, participants reported experiencing low motivation because they felt they were making slow progress. This highlights the importance of monitoring progress and recognising the link between rehabilitation and progress toward goal achievement, which was found to be motivating.

Rehabilitation motivation and exercise content and structure have been considered to be important factors that affect adherence to an outpatient rehabilitation programme (Suk and Eun, 2017, Olaleye and Suddick, 2012). Thus, patient-centred rehabilitation programmes with meaningful targets and feedback on performance within an enjoyable environment is crucial to improve stroke survivors' experience of rehabilitation. Using technology may help create this enjoyable stroke rehabilitation environment in which patients can perform motor skills, helping to keep them motivated and engaged in exercises (Lohse et al., 2014, Weiss et al., 2014).

### **1.1.5 Using technology for trunk rehabilitation**

In the past two decades, more research has been published on using technology for stroke rehabilitation. The use of video game-based rehabilitation has been described as an enjoyable form

of rehabilitation that has increased exercise engagement and facilitated adherence to post stroke interventional programmes (Lloréns et al., 2015, Proffitt and Lange, 2015). However, the majority of published papers in this research area have mainly focussed on using technology for UL, LL and balance rehabilitation (Alex et al., 2017, Henderson et al., 2007, Laver et al., 2017, Lohse et al., 2014, Swanson and Whittinghill, 2015). To the present author's knowledge, only five studies published in the literature have examined the use of technology in trunk rehabilitation (Jung et al., 2020, Kim et al., 2018, Lee and Bae, 2020, Shin, 2020, Shin and Song, 2016b). The use of video games in trunk rehabilitation has been reported to be effective in improving trunk impairment significantly ( $p < 0.05$ ) compared to conventional rehabilitation (Jung et al., 2020, Kim et al., 2018, Shin and Song, 2016b). These studies are described in detail in the literature review.

The use of technology can be applied by using a large immersive virtual reality (VR) device in a research setting or non-immersive VR commercial devices that can be used in clinical settings (Cho et al., 2012, Henderson et al., 2007). Immersive VR, such as the device used by (Jung et al., 2020) for trunk training, is not practical for implementation in clinical settings due to the large space required and high cost. Commercial VR devices (such as Nintendo Wii and Microsoft Kinect) have been suggested as alternatives for use in clinical settings (Alex et al., 2017, Anderson et al., 2015, Lange et al., 2010). However, these commercial VR devices also have limitations – including, for example, the requirement of specific UL dexterity to be able to handle a Wii controller and a high initial level of balance to be able to stand on the Wii balance board and the non-adjustability of the difficulty level of the games (Anderson et al., 2015, Chao et al., 2015, Lange et al., 2010). In addition, the Kinect sensors were unable to capture extremely small movements – which allowed 'cheating', as the participant could compensate by using excessive trunk movement which was not recorded by the system (Webster and Celik, 2014).

In clinical settings, there is a need for a commercial technology which can be tailored to different disability levels, is able to capture small compensatory movements during exercising, requires only a small installation space and is affordable. For these reasons, this doctoral study focussed on using the Valedo<sup>®</sup> system to deliver trunk exercises for chronic stroke patients. The Valedo<sup>®</sup> system is an IMU comprised of three lightweight sensors developed for low back pain treatment through VR technology, using video games to improve body awareness and stabilisation of the lower back (Bauer et al., 2015, Hugli et al., 2015). The Valedo<sup>®</sup> system includes seven components: sensors, a Bluetooth dongle, a USB stick containing software, a charging cable, a cable for firmware updates, a double-sided medical tape and a Valedo<sup>®</sup> case for transportation and storage (Figure 1-1). In addition, a computer device with at least 4 GB space is required to use the Valedo<sup>®</sup> system. The Valedo<sup>®</sup> system has been used as an assessment tool to measure trunk movement in healthy participants and showed an acceptable level of validity ( $R^2 > 0.94$ ) and reliability (3%–9% coefficient

of variation) (Bauer et al., 2015). In addition, the Valedo® can be used as an intervention tool, as the software package includes video games for trunk training. The video games can be tailored for each participant – according to their trunk range of motion (ROM), including trunk forward flexion/extension, trunk lateral flexion, trunk rotation, pelvic lateral tilt and pelvic sagittal tilt.



Figure 1-1: Overview of the Valedo® system

1. The Valedo® system case, 2. a double-sided tape, 3. a charging cable, 4. a Bluetooth dongle, 5. sensors, 6. a USB stick, and 7. a cable for firmware updates.

## 1.2 Aims, study overview and objectives

The primary aim of this PhD research is to investigate the feasibility of using a Valedo® system as an assessment and intervention tool. To achieve this, the PhD has been divided into three stages, as shown in the overview in Table 1-1. The first and second stages focus on evaluation of the Valedo® sensor system as an assessment tool for trunk impairment/control. The first stage considered the development of the iTIS and, subsequently, will test its validity and reliability among stroke and aged-matched healthy participants. The second stage will investigate the validity and reliability of the Valedo® system to measure trunk movement during performance of UL function (Streamlined Motor Function Test [SWMFT]) among stroke and aged-matched healthy participants. The third stage is proof of concept study to investigate the feasibility of using the Valedo® sensor and video game system to deliver trunk exercises for people with chronic stroke. The overview (Table 1-1) gives further details on the objectives, study design, sample size and key outcome measures used for each stage.

Table 1-1: Overview of the PhD study

	<b>Stage 1: Validity and reliability of using the Valedo® system to measure trunk control</b>	<b>Stage 2: Validity and reliability of using the Valedo® system to measure trunk ROM during upper limb functional tasks</b>	<b>Stage 3: Feasibility of using Valedo® video games to deliver trunk exercise in a chronic stroke population</b>
Objectives	<ul style="list-style-type: none"> <li>To develop an instrumented version of the Trunk Impairment Scale (iTIS) using the Valedo® system</li> <li>To assess the concurrent validity of the iTIS by using the cTIS as a gold standard</li> <li>To assess the interrater and intrarater reliability of the iTIS among both the stroke and age-matched healthy groups</li> </ul>	<ul style="list-style-type: none"> <li>To assess the validity (by means of distinguishing between healthy participants and participants with stroke) of using the Valedo® system in measuring trunk movement during performance of the SWMFT by stroke survivors and age-matched healthy participants</li> <li>To assess the interrater and intrarater reliability of the Valedo® system in measuring trunk movement during performance of the SWMFT by stroke survivors and age-matched healthy participants</li> </ul>	<p>Primary objective</p> <ul style="list-style-type: none"> <li>To investigate the feasibility (i.e. acceptability and implementation) of video game-based trunk exercises using the Valedo® system in a chronic stroke population.</li> </ul> <p>Secondary objective</p> <ul style="list-style-type: none"> <li>To explore changes in trunk impairment (TIS and iTIS), trunk muscle size, balance, and lower (FMA-LL) and upper limb function, as well as impairment outcomes (SWMFT and FMA-UL), after 18 sessions of trunk exercise using Valedo® video games</li> </ul>
Study design	Cross-sectional observational study	Cross-sectional observational study	Mixed method proof of concept feasibility study

Sample size	20 chronic stroke participants 20 age-matched healthy subjects	20 chronic stroke participants 20 age-matched healthy subjects	10 chronic stroke participants
Outcome measures	<ul style="list-style-type: none"> <li>TIS, kinematic measurement of trunk and pelvic movements during performance of TIS using the Valedo® system</li> </ul>	<ul style="list-style-type: none"> <li>SWMFT, kinematic measurement of trunk movement during performance of the SWMFT using the Valedo® system</li> </ul>	<ul style="list-style-type: none"> <li>TIS, SWMFT, FMA (UL and LL), BBS, PRPS, Safety, trunk muscle size and kinematic measurement of trunk ROM during the SWMFT using the Valedo® system</li> </ul>

TIS = Trunk Impairment Scale, iTIS = Instrumented Trunk Impairment Scale, cTIS = clinical trunk impairment scale, TCT = Trunk control test, FMA = Fugl-Meyer Assessment, BBS = Berg Balance Scale, SWMFT = Streamlined Wolf Motor Function Test, PRPS = Pittsburgh Rehabilitation Participation Scale.

### 1.3 Publications and presentations

Works from this thesis have been published or presented at scientific meetings listed below:

#### 1.3.1 Peer-reviewed journal publications

Part of the literature review (Chapter 2) published as a systematic review paper:

- 1- Alhwoaimel N, Turk R, Warner M, Verheyden G, Thijs L, Wee SK, Hughes AM. (2018). Do trunk exercises improve trunk and upper extremity performance, post stroke? A systematic review and meta-analysis. *NeuroRehabilitation*, 43(4), 395–412. (This publication won the University of Southampton School of Health Sciences, Doctoral College Research Awards – 2020.) <https://content.iospress.com/articles/neurorehabilitation/nre182446>

Study 1 (Chapter 4) published in two papers:

- 2- Alhwoaimel N, Turk R, Hughes AM, Ferrari F, Burridge J, Wee SK, Verheyden G, Warner M. (2020). Instrumented Trunk Impairment Scale (iTIS): A reliable measure of trunk impairment in the stroke population. *Topics in Stroke Rehabilitation*, 1–8. <https://www.tandfonline.com/doi/full/10.1080/10749357.2020.1834273>
- 3- Alhwoaimel N, Warner M, Hughes A-M, Ferrari F, Burridge J, Wee SK, ... Turk R. (2020). Concurrent validity of a novel wireless inertial measurement system for assessing trunk impairment in people with stroke. *Sensors*, 20(6), 1699. <https://www.mdpi.com/1424-8220/20/6/1699>

#### 1.3.2 Conference presentations (poster)

- 1- Alhwoaimel N, Hughes A-M, Warner M, Burridge J, Brown S, Verheyden G, ... Turk R. (2019). Trunk exercise programme post-stroke using a virtual reality video game-based system: A mixed methods feasibility study. Podium presentation presented at 3rd Saudi Physical Therapy Conference 2019. Riyadh, Saudi Arabia.
- 2- Busselli G, Alhwoaimel N, Warner M, Hughes A-M, Burridge J, Turk R. (2019). Intra and interrater reliability of Valedo System to measure trunk range of movement in healthy and chronic stroke participants during the streamlined Wolf Motor Function Test. Poster session presented at European Congress of Neuro Rehabilitation 2019, Budapest, Hungary.
- 3- Alhwoaimel N, Hughes A-M, Warner M, Burridge J, Brown S, Verheyden G, ... Turk R. (2019). Feasibility of delivering a trunk exercise programme post-stroke using a virtual reality video

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game-based system: A mixed methods case series. World Confederation for Physical Therapy Congress (WCPT 2019), Geneva.

- 4- Alhwoaimel N, Turk R, Warner M, Verheyden G, Thijs L, Wee SK, Hughes AM. (2018). Trunk exercise to improve trunk and upper limb performance post stroke: A systematic review and meta-analysis. Poster and platform presentation at ACPIN International Conference, Southampton, United Kingdom, 19th March 2018.
- 5- Alhwoaimel N, Ferrari F, Hughes AM, Turk R, Warner M, Wee SK, Verheyden G, Burridge J. (2017). Development and validation of a reliable instrumented version of Trunk Impairment Scale. RehabWeek 2017 Congress, London, United Kingdom, 17th July 2017.
- 6- Alhwoaimel N, Turk R, Warner M, Verheyden G, Thijs L, Wee SK, Hughes AM. (2018). Trunk exercise to improve trunk and upper limb performance post stroke: A systematic review and meta-analysis. Poster presentation at Southampton Medical and Health Research Conference, Southampton, United Kingdom, 7th June 2018.

### **1.3.3 Other oral presentation platforms**

- 1- Alhwoaimel N. (2018). Improving trunk and arm movement post stroke using video games. 3-Minute Thesis Competition, University of Southampton, United Kingdom, 27th March 2018 (first place winner in the Faculty of Health Science competition).

## **1.4 Summary of Chapter 1**

This chapter has highlighted the rationale for conducting this doctoral study and given a brief overview of the gaps in knowledge related to post stroke trunk assessment and treatment. An overview of the PhD research stages and their objectives has been outlined. Publications and oral and poster presentations produced during the study have been listed. The next chapter will explain the literature review on trunk impairment, measurement of trunk performance and trunk rehabilitation post stroke, which underpin this research.

## Chapter 2 Literature Review

This chapter details the incidence of stroke and the cost of stroke care in the UK and Saudi Arabia as part of Study 3 that was conducted in Saudi Arabia. Following is a section on the sequelae of stroke (section 2.4) and the effects on an individual based on the World Health Organization (WHO)'s International Classification of Functioning, Disability and Health (ICF) framework (section 2.5). Subsequent sections present a detailed literature review, detail the background of the research on trunk impairment post stroke and describe the correlation between trunk performance and functional outcomes. Measurement of trunk performance post stroke and trunk rehabilitation will be discussed.

### 2.1 Incidence and Cost of Stroke in the United Kingdom (UK)

First-ever stroke affected about 57,000 people in England in 2016 (PublicHealthEngland, 2018), and there are approximately 30,000 stroke-related deaths each year (Office for National Statistics, 2017). Approximately 200,000 stroke survivors required assistance, either from professional carers or from family members, to perform activities of daily living (ADL) (Saka et al., 2009). Mortality and morbidity associated with stroke leads to a considerable financial burden. A national analysis of stroke data to estimate the economic burden of stroke care in UK found that the total cost of health and social care each year was £3.60 billion in the first five years after admission (Xu et al., 2018). Recently, an epidemiological study estimated the projections of future incidence and cost of stroke in the UK per year between 2015 and 2035 (King et al., 2020). The stroke incidence in the UK was estimated to increase by 60% per year and could reach 186,900 by 2035. Moreover, the health care costs in 2035 are projected to rise by 201%.

### 2.2 Incidence and Cost of Stroke in the Kingdom of Saudi Arabia (KSA)

From the epidemiological perspective, the first reported stroke incidence rate was 29.8 per 100,000 Saudi citizens annually (al-Rajeh et al., 1998). A recent study in the Aseer region (Southwestern Saudi Arabia) reported an incidence rate of stroke by (57.64/100,000) (Alhazzani et al., 2018). A predictive model study undertaking a health-economic analysis to quantify the impact of developing stroke care in Saudi Arabia found that the estimated current stroke care programme cost is \$9,244,395,513 over 15 years (Al-Senani et al., 2019). A study by (al-Rajeh et al., 1998) was the last nationwide epidemiological study conducted in Saudi Arabia. No nationwide study has been conducted recently (Alharbi et al., 2019).

### **2.3 Stroke Sequelae**

Stroke is a global healthcare problem and has been described as a worldwide epidemic (Feigin et al., 2014). The effects of a stroke may include motor, sensory and cognitive impairment, as well as a reduced ability to perform self-care and participate in social and community activities (Sale et al., 2015). The long-term effect of stroke is determined by the site and size of the initial stroke lesion and by the extent of subsequent recovery (Seitz and Donnan, 2015). The long-term consequences of stroke can place a large burden on carers in terms of assisting stroke patients with their ADL. In addition, it also puts a huge economic burden on the patients and their families (Feigin et al., 2008).

Research on stroke rehabilitation investigates the effect of interventions on recovery in different forms of impairment and disability. Therefore, it is crucial to understand the effects of stroke on an individual in light of WHO's ICF.

### **2.4 WHO Model for Functioning and Disability: International Classification of Functioning, Disability and Health**

The ICF is a classification of health and health-related domains ((WHO), 2002). It classifies the factors that affect human function into two major parts, each of which has two components. Part 1, functioning and disability, includes body function / structures, activities and participation. Part 2, contextual factors, includes environmental factors and personal factors.

Many studies have explored the ICF framework's perspective on the stroke population (Geyh et al., 2004, Langhorne et al., 2011, Paanalahti et al., 2013). The most comprehensive review illustrating all parts of the ICF framework in stroke rehabilitation was carried out by Langhorne et al. in 2011. They developed a framework for the impact of stroke on individuals in terms of pathology (disease or diagnosis), impairment (symptoms and signs), activity limitations (disability) and participation restriction (handicap), as detailed in Figure 2-1. It details the key features of WHO's ICF framework with examples of scales used to measure those categories (Langhorne et al., 2011). This highlights the long-term effects of stroke on an individual.

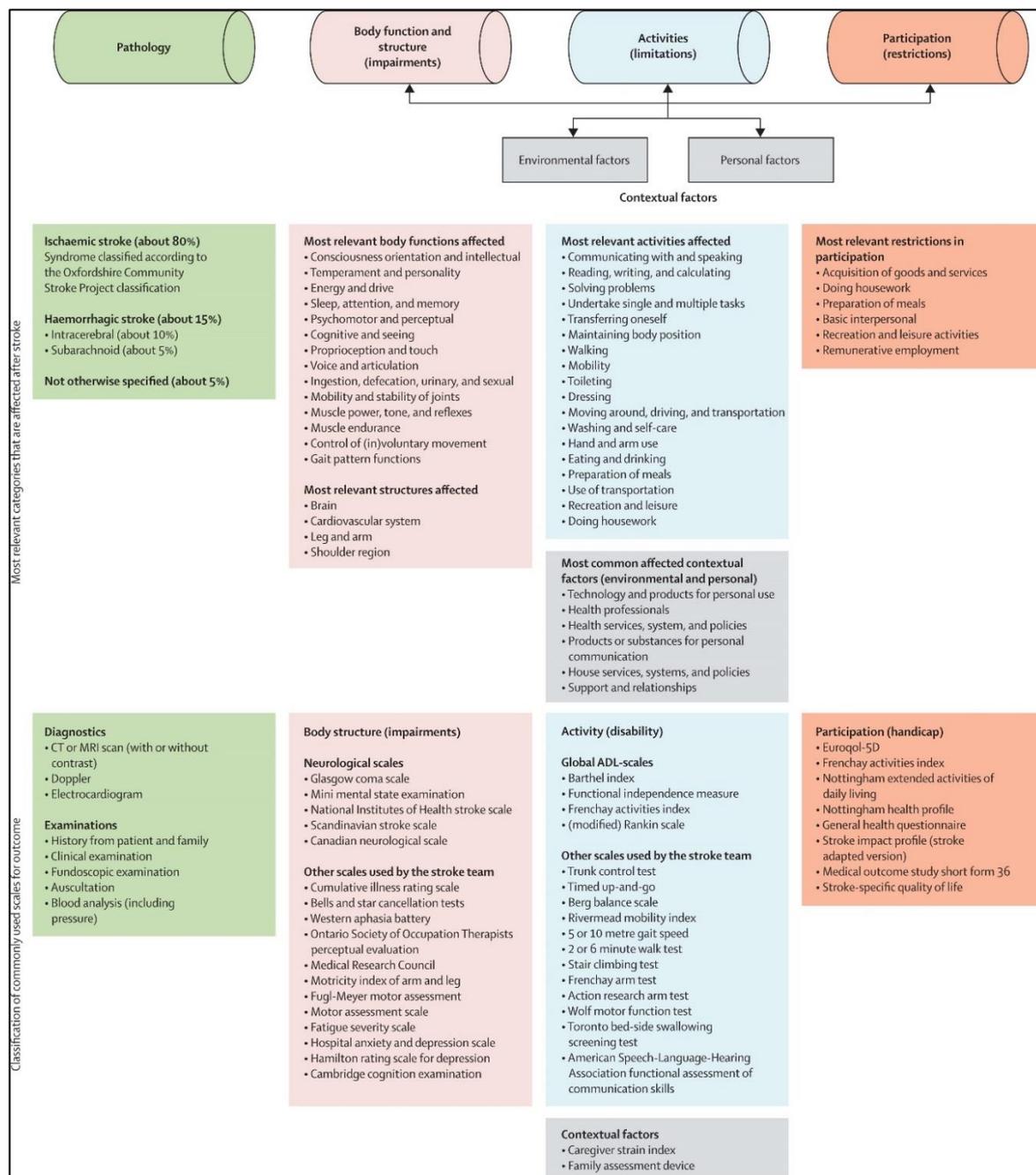


Figure 2-1: The International Classification of Functioning, Disability and Health framework for the effect of stroke on an individual.

Reprinted from Langhorne P, Bernhardt J and Kwakkel G (2011), "Stroke rehabilitation," *The Lancet*, vol. 377, pp. 1693-1702, with the permission of the publisher.

## 2.5 Trunk Impairment Post Stroke

The trunk constitutes over half of one's body mass and highly influences the dynamics of the rest of body (Winter, 2009). After stroke, patients tend to demonstrate insufficient trunk control, affecting their balance and interfering with their ability to carry out ADL, such as turning in bed, sitting, rising from a sitting position to a standing position and walking (Langhorne et al., 2009). A

recent cross-sectional study investigated sensory and motor impairment post stroke in acute, subacute and chronic stroke and found that 100% of the included stroke patients (n=50) had trunk impairment as measured by The Trunk Impairment Scale (TIS) (Savant and Telang, 2019). However, trunk impairment has received little attention compared to upper limb (UL) and lower limb (LL) disabilities (Karthikbabu et al., 2011).

The ability to evenly distribute body weight (postural symmetry) according to the task requirements is crucial to normal balance (Goldie et al., 1996, Nichols et al., 1996). However, this ability is significantly affected in individuals with stroke, as they usually demonstrate an impaired weight-shifting ability during sitting and standing, decreased dynamic stability and large trunk displacements during unsupported sitting (Tessem et al., 2007, Perlmutter et al., 2010, Tasseel-Ponche et al., 2015) . This can be due to weakness of the trunk musculature (Fujita et al., 2015), abnormal muscle tone, unilateral neglect (Taylor et al., 1994) and reduced trunk position sense (Ryerson et al., 2008). The following subsections will discuss the effect of stroke on trunk muscles and trunk position sense.

### **2.5.1 Trunk Muscle Weakness Post Stroke**

Because trunk muscles receive bilateral innervation from the motor cortex through crossed and uncrossed fibres of the anterior corticospinal tract, the pattern of impairment is different from that of the limbs (Canedo, 1997, Davidoff, 1990, Lemon, 2008). Hemiplegia affects one side of the body; however, recent literature suggests that the “healthy” side is not actually healthy, as trunk muscle function on both sides of the body can be affected (Karthikbabu et al., 2012). Studies have shown that following stroke, weakness of the trunk muscles, including the external oblique, erector spinae and paravertebral muscles, occurs in the affected and, to a lesser extent, the unaffected side of the body (Karthikbabu and Chakrapani, 2017, Tsuji et al., 2003).

Trunk muscle performance represents the overall ability of a muscle to perform work and can be characterized by peak torque (Tanaka et al., 1998). Trunk muscle strength following stroke is impaired multi-directionally. A cross-sectional study testing the muscle strength of trunk flexion-extension in hemiplegic patients and age-matched healthy control subjects reported weakness of trunk flexors and extensors in stroke patients, as the peak torque of trunk flexion and extension was significantly smaller ( $p < 0.05$ ) compared to healthy controls (Tanaka et al., 1998). More specifically, extensor muscle strength was weaker than flexor muscle strength. The trunk rotators and lateral flexors of stroke patients were also reported to be weaker than those of healthy age-matched subjects by approximately 50% (Bohannon, 1995). These findings were confirmed in a recent cross-sectional study that aimed to compare the concentric muscle performance of trunk

flexor/extensor muscles between 18 chronic stroke patients and 18 age-matched healthy subjects using the Biodex medical system (Quintino et al., 2018). The authors found that trunk muscle performance characterized by flexor/extensor peak torque was significantly lower in the stroke group than in the healthy controls ( $p \leq 0.001$ ). Moreover, the trunk extensors were shown to be more affected than the trunk flexors.

Electromyography (EMG) data collected from the rectus abdominis and erector spinae during the static phase of postural support and during limb use (i.e. reaching) in stroke patients suggested that trunk muscle weakness becomes more pronounced when the trunk muscles are required to act as pelvic stabilizers to provide support for limb action (Winzeler-Mercay and Mudie, 2002). The inability of the trunk muscles to generate the appropriate force following a stroke occurs for many reasons, such as an increase in stretch reflex excitability, a decrease in motor-unit firing rates and an increase in antagonist muscle co-activation (Gray et al., 2012).

Another potential cause of trunk muscle weakness in stroke patients is decreased muscle fibre size following the loss of mobility and the replacement of muscle fibre with fat and fibrous tissue (Gray et al., 2012). A morphological study with computed tomography (CT) scans of 83 unilateral stroke patients found that compared to muscle size on the ipsilateral side, the cross-sectional area of paravertebral muscle was significantly greater on the side contralateral to the brain lesion post stroke (Tsuji et al., 2003).

As a result, it is important to study the effect of trunk exercises on muscle size. A recent systematic review examined the effect of trunk training on muscle activity and muscle thickness in stroke survivors (Van Criekinge et al., 2019b). The results of the eight included studies revealed that trunk exercises significantly improved the muscle activity of the internal oblique abdominis and increased muscle thickness of the transversus abdominis. However, the effect of trunk exercises on the other important trunk muscles (i.e. rectus abdominis, internal and external obliques) that allow the trunk to flex, extend and rotate on both sides and the relationship to trunk impairment is still unknown.

The weakness of trunk muscles has a significant effect on sitting balance recovery post stroke. A prospective case-comparison study suggested that trunk muscle strength had a significant positive correlation with Berg Balance Scale (BBS) scores in uni-hemispheric stroke patients (Karatatou et al., 2004). In addition, the ability to balance and walk post stroke has been reported to be significantly related to the performance of trunk function as measured using the TIS (Kim et al., 2015). More recently, a systematic review of 20 cross-sectional studies investigated the correlation between trunk muscle strength and outcomes related to balance, functional performance and falls in older

adults (Granacher et al., 2013). The findings suggest there are small to medium statistically significant correlations between trunk muscle strength and balance, functional performance and falls in older adults.

Taken together, the trunk muscles are affected bilaterally post stroke. Even the mild weakness of trunk muscles can influence balance and functional ability (Karatas et al., 2004). The next section will explain how trunk position sense influences balance post stroke.

### **2.5.2 Trunk Position Sense Post Stroke**

Trunk position sense and muscle strength play a major role in trunk stability required for stable and controlled movement (Cholewicki et al., 1997, Ebenbichler et al., 2001). Trunk position sense can be measured by assessing the trunk repositioning error (TRE) (Pearcy and Hindle, 1989). TRE is the error between the target position and the reproduced position (Ryerson et al., 2008). People with stroke demonstrate an impaired trunk position sense and mislocalization of tactile stimuli applied to the trunk in the presence of spatial neglect (Rousseaux et al., 2013). To date, the first and only study measuring TRE in a stroke population was carried out by Ryerson et al. in 2008. They assessed trunk position sense and its relationship to the clinical measures of balance and extremity motor impairment post stroke. Significant differences in absolute trunk repositioning error between stroke and control groups in both the sagittal ( $p=0.0001$ ) and transverse ( $p=0.0012$ ) planes. TRE was assessed in a sample of 20 chronic stroke patients and 21 age-matched healthy individuals. The authors found significant differences in the TRE between the two groups in the frontal, sagittal and transverse planes. This suggests there was an increase in TRE in the stroke patients, as they exhibited twice the TRE in the sagittal and transverse planes compared to the controls. Moreover, TRE correlates negatively with both BBS and Postural Assessment Scale for Stroke (PASS) scores. This suggests that stroke patients who have impaired trunk position sense are more likely to have impaired balance and postural control. Therefore, trunk position sense should be considered when designing interventions to improve trunk postural control post stroke (Ryerson et al., 2008). The study results showed no relationship between trunk position sense and extremity impairment measured using the Fugl-Meyer Assessment (FMA) scale. However, the results should be interpreted with caution, as the size of the experimental group, which consisted only of chronic stroke patients, was small ( $n=20$ ). In addition, the measurement protocol in this study asked the participants to reach forward and down to the floor and then return to the initial upright sitting position with eyes closed, which requires a high level of trunk ability. As a result, the presence of trunk position sense in stroke patients with a lower level of trunk control and its impact on balance, postural control and extremity motor impairment is still unknown and requires further investigation.

In summary, trunk muscle strength and position sense are essential for trunk stability, and the impairment of trunk position sense can affect trunk control. The following section will explain the importance of trunk control in predicting functional outcomes post stroke.

## **2.6 Trunk Performance as a Predictor of Functional Outcome Post Stroke**

Trunk control has been well recognized as an important early predictor of functional recovery after stroke. It was reported that trunk control explained 45% to 71% of the variance in functional recovery post stroke (Franchignoni et al., 1997).

Although several studies have attempted to establish a correlation merely between isolated paretic components (i.e. arm, leg and trunk) of stroke individuals and functional outcome (de Niet et al., 2007, Kligyte et al., 2003, Likhi et al., 2013, Olsen, 1990, Verheyden et al., 2007a, Verheyden et al., 2008), the degree of trunk impairment is considered to be the most important predictor of post stroke outcome (Likhi et al., 2013). (Hsieh et al., 2002) conducted a prospective study of 169 stroke patients to assess the relationship between trunk control at an early stage and comprehensive ADL function in the patients at 6 months after stroke. The findings of this study provide strong evidence of the predictive value of trunk control measured using the Postural Assessment Scale for Stroke Patients (PASS-TC) on comprehensive ADL function in stroke patients measured using the Frenchay Activities Index and the Barthel Index. PASS is a 12-item performance-based-scale which was developed specifically for assessing balance in stroke patients. PASS-TC has 5 items (i.e. sitting without support, supine to affected side lateral, supine to non-affected side lateral, supine to sitting up on the edge of the table, and sitting on the edge of the table to supine) which are used to examine trunk control (Huang et al., 2016). The findings also showed that PASS-TC was able not only to predict ADL function in the early stages after stroke but also at up to 1 year after stroke (Wang et al., 2005). A multicentre cross-sectional study of 102 strokes examined the predictive validity of the TIS in predicting ADL function at 6 months post stroke (Verheyden et al., 2007a). The results of that study showed that the TIS can predict ADL ability measured using the Barthel Index ( $R^2=0.52$ ,  $p < .0001$ ); specifically, the static sitting balance subscale score was the best predictor of ADL function.

Much research on the ability of trunk control to predict walking ability post stroke has also been undertaken (Duarte et al., 2010, Huang et al., 2016, Selves et al., 2020, Smith et al., 2017, Woo, 2018). Duarte et al. (2010) conducted a prospective study of 68 stroke patients to evaluate the early predictors of ambulation in the first 6 months post stroke (Duarte et al., 2010). They found that the Trunk Control Test (TCT) can predict 61.1% of the variance in the motor Functional Independence Measure (FIM) and people with  $TCT \leq 50$  on day 14 predicts non-independent walkers (Functional

Ambulation Categories (FAC) < 4). (Huang et al., 2016) conducted a retrospective study of 341 acute stroke patients to assess the predictive validity of PASS in predicting ambulation post stroke after discharge from a rehabilitation ward. The results revealed that the PASS total score was able to predict the ability to walk by a ( $r = 0.65$ ) positive predictive value. Specifically, 12.5 points of total PASS, demonstrating the highest percentage of accurately predicted ability of independently walking at discharge. More recently, (Smith et al., 2017) conducted a study to understand the factors that affect independent walking post stroke in order to develop a predictive algorithm to predict Time to Walking Independently after Stroke (TWIST). Their prediction algorithm found that stroke patients with a TCT score >40 at 1 week walked independently within 6 weeks, while stroke patients with a TCT score <40 achieved independent walking by 12 weeks if they had hip extension strength  $\geq$  grade 3 on the Medical Research Council Scale for Muscle Strength. This algorithm accurately predicted the results of 95% of the 41 patients included in the study. These findings were confirmed in a 2020 narrative review aiming to synthesize the best available predictive factors for the recovery of walking post stroke (Selves et al., 2020). The results of that study emphasize that the best-known predictive factors for the recovery of walking post stroke are trunk control and hip extension ability.

The next section will detail the correlation between trunk control and both upper and LL function.

### **2.7 Relationship Between Trunk Performance and Limb Function Post Stroke**

Research investigating the relationship between trunk control and limb function in people with stroke has recently been undertaken. To the author's best knowledge, the first study to investigate the correlation between trunk control and both upper and LL function was conducted by (Lee et al., 2018b). The authors investigated the correlation between trunk control and both upper and LL function in 55 chronic stroke survivors. They measured trunk control using the modified TIS (mTIS) and both upper and LL function using the FMA. The results showed a high significant correlation between trunk control and both upper and LL motor function, with  $r^2 = 0.37 - 0.80$  and  $p < 0.001$ , respectively. Recently, (Kong and Ratha Krishnan, 2019) conducted a retrospective study of 577 stroke patients in Singapore admitted to Tan Tock Seng Hospital's rehabilitation centre to investigate the correlation between trunk performance (TIS) and both upper and LL function (FMA). The authors found that the admission TIS scores were positively correlated with the admission FMA scores and significantly predicted discharge FIM motor scores ( $p < 0.001$ ). Therefore, they recommended that trunk performance be evaluated for all patients with stroke at admission. (Seng Kwee et al., 2015) studied people with chronic stroke and healthy age-matched controls to investigate the relationship between trunk control and UL function and the effect of trunk support on trunk control and UL function. Their results showed a statistically significant improvement ( $p$

<.001) in trunk control (TIS) in the stroke group when trunk support was used. Moreover, a statistically significant improvement was shown in UL function in both healthy ( $p < .001$ ) and stroke ( $p < .05$ ) participants, indicated by a reduction in Streamlined Wolf Motor Function Test (SWMFT) performance time (mean difference= 0.81, stroke group) and functional ability scale scores (mean difference= 0.1, stroke group).

Santamaria et al. (2018) undertook a cross-sectional study investigating the kinematic and neuromuscular role of trunk posture and reaching control in healthy young adults. They compared the EMG data of para-spinal muscles and the kinematics of the arm and trunk when using external trunk support at different levels of the trunk (pelvic and midrib) during reaching (using the dominant hand) for an object at arm level. They collected data from 146 reach trials when the trunk support was at the pelvic level and the data from the same number of trials when the trunk support was at the mid-rib level. The results showed a significant increase in EMG activity of the ipsilateral and contralateral lumbar muscles ( $p < 0.001$ ) with the mid-rib support. In addition, the ipsilateral cervical muscle showed a borderline significant increase in the rate of anticipatory postural adjustment (APA) when the level of support was raised from the pelvic level to the mid-rib level. Interestingly, there were no changes in anteroposterior (AP) and medial-lateral (ML) trunk displacement at both support levels. This could be due to the nature of the trunk support used in the study. The support used in Santamaria's study (Figure 2-2) was rigid in nature and might have restricted trunk movement, while the trunk support used in the Wee et al. (2015) study (Figure 2-3) was a high-density foam support around the trunk that did not restrict trunk movement.

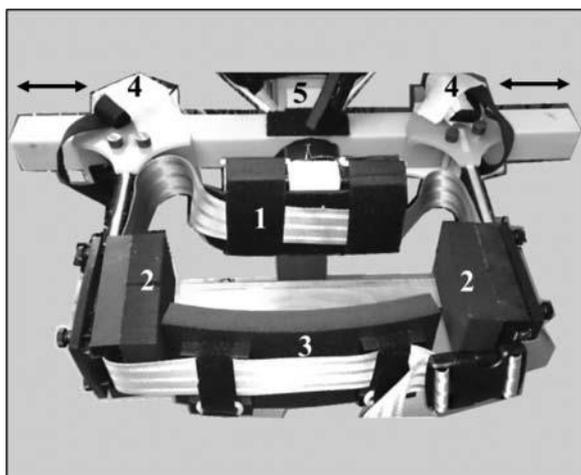


Figure 2-2: The trunk support used in Santamaria's study

Reprinted from Santamaria V, Rachwani J, Manselle W, Saavedra S, Woollacott M, "The impact of segmental trunk support on posture and reaching while sitting in healthy adults," *Journal of Motor Behavior*, vol. 50, pp. 51–64, 2018 with permission from Taylor & Francis.



Figure 2-3: The trunk support used in Wee's study.

Reprinted from Wee SK, Hughes AM, Warner M, Brown S, Cranny A, Mazomenos E, Burrige J, "Effect of trunk support on upper extremity function in people with chronic stroke and people who are healthy," *Physical Therapy*, vol. 95, pp. 1163–1171, 2015 with permission from the publisher.

Both studies (Wee & Santamaria) indicate the importance of trunk control during UL functional performance. Despite the findings, all the improvement that happened in both the Wee and Santamaria studies occurred during the use of the trunk support. However, the effect of improving trunk control via rehabilitation programs (i.e. trunk training exercises) on UL performance is still unknown. Therefore, this study aimed to investigate the changes in both UL and LL function after trunk training programme using video games in people with chronic stroke.

## 2.8 Measurement of Trunk Performance Post Stroke

Standardized clinical assessment tools are a prerequisite for scientific research and clinical practice. Trunk performance after stroke has been evaluated using various methods, such as clinical scales (Fujiwara et al., 2004, Verheyden et al., 2004), hand-held dynamometry (Bohannon et al., 1995), isokinetic dynamometry (Estrázulas et al., 2020) and movement analysis (Karthikbabu et al., 2012, Verheyden et al., 2007b, Wee, 2015). Clinical scales assessing trunk performance are commonly preferred by researchers and clinicians due to their availability and usability. The first systematic review of clinical measures to assess trunk performance was that by (Verheyden et al., 2007b). Thirty-two studies were included in the review, and the results showed that the TCT and the TIS were the standardized clinical measures available to measure trunk control.

In the last 10 years, there has been an increase in research on trunk performance measurements (Karthikbabu et al., 2012, Lee et al., 2018b, Sorrentino et al., 2018, Sullivan et al., 2013). In fact, the demonstration of sound psychometric properties in these measures is a key factor to indicate to clinicians that they can rely on such data. A 2012 review of trunk assessment tools found that the TIS is a sensitive measure to evaluate the selective movement of the upper and lower trunk (Karthikbabu et al., 2012). In addition, trunk lateral flexion movement was found to be easier than rotation of the trunk. This finding was confirmed by (Sullivan et al., 2013), who developed recommendations for outcome measures following stroke. The consensus document recommended using the TIS in all practice settings, as it has good sensitivity, specificity and reliability (ICC=0.96), whilst the TCT was not recommended due to insufficient psychometric properties. The TIS is an ordinal scale consisting of 17 items to assess trunk performance. It has three subscales to measure static sitting balance, dynamic sitting balance and coordination (Verheyden et al., 2004). A recent systematic review of 19 studies investigated the available clinical measurement tools to assess trunk performance after stroke. It found that the TIS developed by (Verheyden et al., 2004) was the most frequently used trunk impairment measure (Sorrentino et al., 2018); the scale has been translated into Norwegian, Italian and Spanish. However, it is challenging to use ordinal scales to clinically identify and evaluate specific changes related to the quality of movement. A critical question in rehabilitation intervention studies is whether improvements in motor function occur due to the recovery of lost motor elements or to the use of compensatory motor patterns. It has therefore been proposed that three-dimensional (3D) kinematic measures should be considered essential to distinguish compensation from restitution and should be developed accordingly (Kwakkel et al., 2017, Carozzo et al., 2020). In research settings, optoelectronic measurement systems (OMSs) can be used to quantify trunk movements (Cuesta-Vargas et al., 2010). However, it is difficult to use these systems in clinical settings due to their high cost and large installation space requirement. To overcome these limitations, the use of alternative, objective low-cost measuring systems, such as inertial measurement units (IMUs), may be useful. Bauer et al. (2015) examined the concurrent validity and reliability of the inertial measurement sensor system using an optoelectronic system as the gold standard for measuring trunk movement in healthy participants. The authors found that the inertial sensor system is a valid ( $r^2$  coefficients  $\geq 0.94$ ) and reliable (3%–9% coefficient of variation) measure for estimating trunk movement.

Understanding the relationship between movement quality (impairment) and performance (activity) post stroke is important for developing effective rehabilitation interventions. Therefore, this PhD study is interested in instrumenting the TIS using the clinical scale as a gold standard (Study 1). The next section will explore the trunk compensatory movement during UL tasks.

## 2.9 Compensatory trunk movements during upper limb tasks post stroke

Movement control of the upper body part is essential during performing of daily activities in a seated position. Trunk control plays a fundamental role during seated activities, as it interact with the upper limb (UL) control and head by providing a stable base support (Cirstea et al., 2003). Following stroke, over three quarters of patients with stroke experience UL deficits (Lawrence et al., 2001). Because of persistent UL dysfunction after stroke, people with stroke tend to recruit greater trunk movement, unlike healthy individuals, during pointing to targets or grasping objects placed within or beyond arm length (Cirstea and Levin, 2000, Levin, 1996, Roby-Brami et al., 2003).

Numerous kinematic analysis studies have studied the pattern of UL movement post stroke to discriminate between true motor recovery and substitutive movement patterns due to compensatory movement (Alt Murphy et al., 2011, Cirstea and Levin, 2000, Levin et al., 2002, Wade et al., 2014). In 2000, Cirstea & Levin studied the mechanism of pointing and reaching in nine right hemiplegic stroke patients and compared it to nine right handed healthy participants by measuring the kinematics of UL and trunk movements. They found that the UL movement in stroke patients is more segmented and has larger movement error. Moreover, the stroke subjects demonstrated excessive trunk movement (axial rotation and flexion) and recruited a new degree of freedom (DOFs) that was not recruited by healthy subjects. More specifically, as the degree of motor impairment increased, the tendency to recruit new DOF increased. In addition, the amount of trunk involvement (trunk forward flexion) during reaching increased as the distance of the object increased (Levin et al. 2002). A kinematic analysis study of the control mechanisms of trunk and arm in stroke and age-matched healthy subjects during reaching performance to target an object within arm length and beyond arm length distance was carried out in 2002 by Levin and his colleagues. They recorded the following kinematic data of healthy and stroke participants during reaching: trajectory curvature, trunk displacement, hand displacement, trunk velocity, hand velocity and the degree of movement in elbow extension, shoulder flexion and shoulder horizontal adduction. Their results showed that the stroke participants used more trunk displacement than healthy subject during reaching the targets within arm length and this trunk displacement increased when they reach to objects beyond arm length. Moreover, they demonstrated a sequential recruitment of the arm and trunk, and the trunk began to move with or before the hand movement and did not stop moving until the hand movement stopped. This suggested that the trunk control predicts the movement needed to accomplish the reaching task in an anticipatory way.

Data gathered from 19 participants with chronic stroke and 19 healthy controls identified the kinematic characteristics of the upper limb movement during reaching and drinking from a glass (Alt Murphy et al. 2011). During the reaching phase, the stroke participants demonstrate a significantly greater elbow extension and take longer time ( $P < 0.05$ ) to reach the glass than healthy participants. During the drinking phase, they observed a significant increase ( $P < 0.05$ ) in arm abduction among stroke participants compared to the healthy participants. Moreover, the compensatory trunk displacement in stroke participants was significantly ( $P < 0.05$ ) higher than the healthy controls. More specifically, stroke participants with moderate arm impairment (Fugl-Meyer scores of 39-57) demonstrate a significantly greater compensatory trunk displacement during reaching and take more time to do the movement ( $P < 0.05$ ) than those stroke participants with mild arm impairments (Fugl-Meyer scores of 58-64).

Persistent usage of compensatory trunk movement strategies by stroke patients to accomplish the tasks might reinforce maladaptive plasticity due to encouraging of the abnormal movement patterns which may affect motor recovery in the longer term (Jang, 2013). Maladaptive plasticity in stroke describes plastic changes that hinders the recovery of an injured function or causes the development of an unwanted symptom (Jang, 2013). Compensatory trunk movement patterns may improve performance of UL daily activities after stroke but may limit motor recovery of the normal movement pattern after stroke (Takeuchi and Izumi, 2012).

More recently, a PhD study investigated the effect of providing an external trunk support on trunk control and UL function in both stroke and age-matched healthy participants during a lift can task (Wee 2015). The kinematic analysis results found a statistically significant reduction in trunk lateral flexion in healthy participants with trunk support. Moreover, they observed a statistically significant reduction in the scapular upward rotation ( $p < 0.001$ ) for both healthy and stroke participants during task performance with trunk support. However, the motion analysis systems used in the previous studies required an expert to install, and was high cost, which make it difficult to use in clinical based settings. Therefore, the second stage of this PhD study investigating the trunk movement during the performance of UL tasks using low cost inertial sensor system (Study 2). The next section will explore the rehabilitation available for treating trunk impairment post stroke.

## **2.10 Research on Trunk Rehabilitation**

The trunk works as a unit to stabilize the body against forces generated from distal body segments and forces generated from expected or unexpected perturbations (Zazulak et al., 2007). The function of the trunk muscles is to provide sufficient spinal stability to deal with stability demands

to maintain posture and bear static and dynamic loads (Kibler et al., 2006). Trunk exercise regimens that consist of selective movements of the upper and lower parts of the trunk in the supine and/or sitting position develop the ability to control the position and motion of the trunk and to improve sitting balance post stroke (Cabanas-Valdes et al., 2013). The UK Royal College of Physicians (RCP)'s National Clinical Guidelines for Stroke has recommended that 'People with impaired sitting balance after stroke should receive trunk training exercises' (National Clinical Guideline for Stroke, 2016; p.73).

In recent years, neuro-rehabilitation researchers have become interested in exercises focused on the upper and lower parts of the trunk (Alhwoaimel et al., 2018, Bank et al., 2016, Cabanas-Valdes et al., 2013, Cabrera-Martos et al., 2020, Criekinge et al., 2019, Sorinola et al., 2014, Souza et al., 2019). The first meta-analysis, by Sorinola et al. (2014), studied the effect of trunk exercises in addition to conventional rehabilitation on post stroke recovery. The results showed a moderate non-significant effect (standardized mean difference [SMD]=0.5,  $p=0.19$ ) of the additional trunk exercise on trunk performance in acute strokes based on a meta-analysis of five randomized controlled trials (RCTs). A recent meta-analysis (Alhwoaimel et al., 2018) assessed the effect of trunk exercise on TIS scores in both acute stroke and found that trunk exercise significantly improved trunk performance, with a very large effect size (SMD=1.57 and  $p=0.0006$ ). This finding was confirmed by a meta-analysis of seven RCTs that evaluated the impact of additional trunk training on in-patient rehabilitation after recent stroke (less than 3 months) (Souza et al., 2019). The forest plot of that meta-analysis for TIS showed that additional trunk exercise significantly improved trunk impairment in a very large effect (SMD=3.3 and  $p < 0.0001$ ).

Improved trunk impairment post stroke as a result of trunk exercises has not only been reported for acute stroke. Trunk control in chronic stroke has also been reported to be improved with trunk exercises in four systematic reviews (Alhwoaimel et al., 2018, Cabanas-Valdes et al., 2013, Cabrera-Martos et al., 2020, Van Criekinge et al., 2019a). The first systematic review in this area, that by (Cabanas-Valdes et al., 2013), evaluated the effects of trunk exercise programmes on trunk impairment in stroke patients. The results showed that there is moderate evidence that trunk training exercises on stable and unstable surfaces improve dynamic sitting balance and trunk performance in both subacute and chronic stroke. However, the authors did not perform a meta-analysis to measure the degree of effectiveness of the trunk exercises on trunk performance post stroke due to the heterogeneity of the included studies. Alhwoaimel et al. (2018) conducted a meta-analysis of seven studies and 90 chronic stroke participants who received a trunk exercise rehabilitation programme compared to 87 chronic stroke participants who received conventional rehabilitation. They also assessed the effect of trunk exercise on TIS score. Their results showed a significant medium effect of trunk exercise on total TIS score (SMD=0.74,  $p < 0.00001$ ). Moreover, they also assessed the effect of trunk exercise on each TIS subscale score with a forest plot of 10

RCTs. The results of the meta-analysis showed a large significant effect of trunk exercise on improving dynamic subscale score (SMD=0.99,  $p < 0.00001$ ), while a medium effect (SMD=0.67,  $p < 0.00001$ ) and a small effect (SMD=0.45,  $p = 0.02$ ) were shown for coordination and static subscale scores, respectively. These findings were confirmed by a meta-analysis study of 22 RCTs comparing the effect of trunk training to conventional rehabilitation to improve trunk control, sitting and standing balance and mobility post stroke (Van Criekinge et al., 2019a). The forest plot of 15 studies showed that the total TIS score improved significantly post stroke with a large effect size (SMD=1.08,  $p < 0.00001$ ). More specifically, the dynamic subscale score improved with a very large effect size (SMD=1.33  $p < 0.00001$ ) and the coordination subscale score improved with a large effect size (SMD=1.08,  $p < 0.0001$ ). However, the static subscale score showed non-significant improvement with a small effect size (SMD=0.18,  $p = 0.81$ ).

Despite the benefit of trunk exercise on trunk performance following stroke, all the trunk exercises mentioned in previous studies were repetitive in nature, were performed in a non-enjoyable environment and were administered on a one-to-one basis with a healthcare specialist. Intensive and repetitive practice of specific functional tasks is important for recovery after a stroke, but the repetitive nature of exercise could make the rehabilitation session un motivating, resulting in a negative effect on adherence to the rehabilitation programme (Burdea, 2003). Therefore, the next section explores the factors that could affect adherence to such interventional rehabilitation programmes.

## **2.11 Factors Affecting Adherence to Rehabilitation Programmes**

WHO defines patient adherence as 'the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes – corresponds with agreed recommendations from a health care provider' (De Geest and Sabate, 2003). In rehabilitation, adherence is the extent to which a patient follows the prescribed components of a rehabilitation intervention (Bassett and Prapavessis, 2007). Patient adherence to prescribed rehabilitation is considered an important factor that influences the achievement of successful outcomes (Jack et al., 2010). In other words, a greater degree of adherence to post-acute stroke rehabilitation is significantly associated with better treatment outcomes of functional independence and ADL (Duncan et al., 2002). Yao et al. (2017) found adherence to rehabilitation exercises to be low in chronic stroke patients. The authors explored the longitudinal patterns of adherence to exercise in 98 hemiplegic stroke patients and followed them for 1–24 weeks post stroke. Their results showed a rapid increase in adherence 1 week post stroke, reaching its maximum level 6 weeks post stroke. After 6 weeks, adherence declined until it stabilized at 21 weeks. Between week 21 and week 24 post stroke, the functional exercise adherence rate remained within medium to low levels. The researchers argued that at the

acute stage of stroke, patients have a strong will to survive and recover and observe improvements. In the chronic stage, neurological function restoration was not as obvious. Thus, the increase in rehabilitation exercise adherence declined in later stages of stroke.

Adherence to rehabilitation can be affected by different factors, including patient-related factors and therapy-related factors (De Geest and Sabate, 2003, Khoshtakht Pishkhani et al., 2019, Olaleye and Suddick, 2012). (Ogwumike et al., 2015) conducted an observational study of 52 stroke survivors to investigate the barriers that influence out-patient physiotherapy adherence. They found that the most reported barriers were the lack of someone to accompany the stroke patient to hospital (29.3%) and financial constraints (27.6%). In addition, the rate of adherence was significantly negatively correlated with enjoying doing the exercises ( $r$  value= -0.56,  $p=0.04$ ). The more they enjoyed exercises, the more they adhered to the physiotherapy programme.

Recent mixed method study identified the influencing factors on rehabilitation adherence found that rehabilitation motivation considered as a significant predictor of rehabilitation adherence ( $r=.30$ ,  $p < .001$ ) (Suk and Eun, 2017). More recently, a qualitative study by Khoshtakht Pishkhani et al. (2019) explored in detail the factors affecting adherence to rehabilitation in stroke patients. They found that the interaction between the rehabilitation team and patients to motivate patients to perform rehabilitation exercises correctly was of great importance in enhancing recovery post stroke. Further, (Sluijs et al., 1993) found that positive feedback about patients' progress and treatment and the regular monitoring of exercise performance were found to be important factors relating to complying with exercise programmes. Further, a qualitative study exploring the factors that affect adherence to physiotherapy sessions, found that exercise content and structure were important factors (Olaleye and Suddick, 2012). Their results revealed that exercise programmes that were interesting, challenging, linked to targets and goals, monitored, reviewed and that progressed were perceived to influence the patients' participation in their exercise programme. Emphasis on the importance of the content of rehabilitation programmes was reported in a systematic review of 31 qualitative studies that explored the experiences and preferences of stroke survivors undertaking in-patient physical rehabilitation (Luker et al., 2015). The results showed that the stroke participants in seven of the included studies described the rehabilitation programme as boring or meaningless therapy. Therefore, participants wanted to enjoy therapy and wanted innovations such as computer games (Luker et al., 2015). Therefore, using technology in stroke rehabilitation to create an enjoyable environment in which to practice exercises could affect rehabilitation outcomes. The next section will discuss this idea in more detail.

## 2.12 Technology to Support Stroke Rehabilitation

In the past two decades, various technology and virtual reality (VR) game-based rehabilitation methods for stroke patients have been investigated. VR can be defined as ‘the computer-generated simulation of a 3D environment, which seems very real to the person experiencing it, using special electronic equipment’ (Linowes, 2015)p. 2).

The interaction between the individual and the physical environment is reduced after brain damage (Rose et al., 2005). Furthermore, conventional therapy that consists of a large number of repetitive movements is often perceived as tedious (Luker et al., 2015). Patients need a high motivation to stay engaged. VR is a tool that may revolutionize rehabilitation and create an enjoyable environment to keep patients motivated and engaged in rehabilitation exercise (Lohse et al., 2014, Weiss et al., 2014). VR technology in stroke rehabilitation has been considered a promising intervention that is believed to have a positive effect on participation and motivation and to improve body function and activity (Lohse et al., 2014, Swanson and Whittinghill, 2015). Implementing VR in rehabilitation can be done in two ways according to the degree of environmental immersion—immersive VR and non-immersive VR. In immersive VR, the use of a 3D environment will give the patient a strong sense of presence (Henderson et al., 2007). In non-immersive VR, the patient interacts with different visual and auditory stimuli in the environment, which are displayed on a screen, such as video games (Cho et al., 2012).

There are several advantages in using VR as an intervention tool in stroke rehabilitation. First, VR allows the patient to practice the task in a safe environment according to their specific needs, which gives the therapist control over the environment compared with real-life settings (Rizzo and Kim, 2005). For example, driving video games allow individuals with stroke to practice a virtual driving trip prior to an on-road test (Lee and Bae, 2020). Second, using video game exercises can afford a wide range of activities and different ways to practise the same movement, especially in acute and subacute rehabilitation settings (Laver et al., 2011). In the early stage of stroke, in-patient rehabilitation is often limited to practising real-world tasks due to fatigue. For instance, VR games can allow stroke patients to practise scanning for items on a supermarket shelf instead of using traditional pen and paper tasks for treating a spatial-neglect (Laver et al., 2011). Third, VR gaming systems can be used in rehabilitation to aid the individual in task learning and motor function by producing audio and visual feedback (Darekar et al., 2015). A convenient feedback type at an appropriate time and frequency is important in enhancing motor learning in stroke patients (Swanson and Whittinghill, 2015, van Vliet and Wulf, 2006).

Video games are now incorporated as stroke rehabilitation tools (Anderson et al., 2015, Bower et al., 2015, Proffitt et al., 2011). The design of video games in stroke rehabilitation is focused on several fundamental principles, such as meaningful play, valuable feedback and emphasising challenge (Mubin et al., 2020). Meaningful play comes from the relationship between the player's action and the system response. This is achieved by clear and consistent feedback from the system when a player performs some kind of action (Mubin et al., 2020). This feedback can help the individual to know the goal of the game and how to achieve it in order to make progress in the game. Feedback on performance tells individuals how well they are currently playing the game and can be delivered by audio, visual or haptic means (Burke et al., 2009). Audio feedback is any kind of sound that the player hears upon performing an action, such as cheering (Darekar et al., 2015). Visual feedback can be shown as numerical scores, rewards, etc., whereas haptic feedback consists of any kind of vibration of the controller upon an action performed by the patient (Mubin et al., 2020). Another principle of rehabilitation video games is emphasising challenge by adjusting the difficulty of the game to a prevent boredom throughout the session (Burke et al., 2009). The difficulty of the game can be increased using unpredictability in the gameplay and distractions to challenge the patient (Mubin et al., 2020). However, it is important to consider individuals' ability when increasing the level of difficulty and challenge of the game in order to maintain their engagement.

### **2.12.1 Using Technology to Deliver Trunk Exercises**

Several systematic reviews have investigated the effectiveness of game-based interventions (Alex et al., 2017, Henderson et al., 2007, Laver et al., 2017, Lohse et al., 2014, Swanson and Whittinghill, 2015). However, the majority of them focus on studying the effect of the video games on UL and LL function (Alex et al., 2017, Henderson et al., 2007), gait and balance (Laver et al., 2017, Lohse et al., 2014). The evidence of the effect of video games on trunk control post stroke is too limited at present to guide practice. Only five studies found in the literature examined the use of video games in trunk training (Jung et al., 2020, Kim et al., 2018, Lee and Bae, 2020, Shin, 2020, Shin and Song, 2016b). The first study aimed to investigate the efficacy and feasibility of smartphone game based trunk training for improving trunk performance in 24 chronic strokes carried by (Shin and Song, 2016a). The results showed that additional 20 minutes of trunk training three times a week for 4 weeks improve trunk impairment (measured by TIS) significantly compared to conventional rehabilitation ( $P < 0.05$ ). The same findings was also shown in another study that compare between two doses of additional trunk training to the conventional rehabilitation and study it's effect on trunk impairment (TIS), balance (BBS) and independency (Barthel Index) post-stroke (Kim et al., 2018). They randomly assigned 38 chronic strokes into either low dose (once daily) or high dose (twice/daily) additional trunk training using robot balance game-based intervention. Their findings

showed that both groups improved significantly ( $P < 0.05$ ) in all outcome measures including TIS. Nevertheless, the high dose group have better improvement in TIS and Barthel Index.

The video game-based trunk training wasn't only have a beneficial effect on trunk impairment and balance, trunk muscle strength was also shown to be affected positively (Jung et al., 2020). A randomized controlled trial assessed the effect of 3D active trunk training on trunk control (TIS), trunk muscle strength and balance (Brunel Balance Assessment) in 24 sub-acute strokes (Jung et al., 2020). The participants assigned into either conventional trunk exercise or 3D trunk training using balance 3D system five times a week for 3 weeks. Both improved significantly ( $P < 0.05$ ) in all outcome measures but the 3D trunk training group showed a higher improvement.

While video game-based therapies appear to hold great promise as a therapy tool in stroke rehabilitation, there are currently significant barriers to its implementation in clinical settings.

All the mentioned studies of trunk rehabilitation had limitations in applying and implementing video game-based therapies in daily clinical practice. The limitations include using large (Jung et al., 2020) and complex technology (Kim et al., 2018) that requires a large space, high healthcare costs and special expertise. Using commercial video game devices could be an alternative, as they are less expensive and easy to set up; however, they are not customizable to suit players' ability (Alex et al., 2017). Moreover, most require good balance and UL abilities to be able to sit/stand on a balance board or hold a remote controller (Alex et al., 2017). Utilizing sensor devices that do not require good balance and UL abilities to capture and track individual's movements while playing video games could address these limitations. Therefore, this PhD study aimed to investigate the feasibility of using video game-based sensor systems in delivering trunk training for chronic stroke patients. The advantages and characteristics of this system are detailed in the next chapter.

### **2.12.2 Potential Problems in using of Technology for Rehabilitation**

The large size, high costs and complexity of technology such as immersive VR systems can limit their potential use in clinical settings. Moreover, VR rehabilitation systems require computer skills and expertise to install (Burdea, 2003).

In addition, the variations in the impairment and disability levels of people with stroke could limit the use of some VR systems. For example, some stroke patients are unable to hold a remote during training using a Wii system (Tseklevs et al., 2016). Moreover, the difficulty of the tasks in most on-shelf, low-cost VR systems (e.g. Nintendo Wii, Kinect) cannot be adjusted or tailored to individual patients' abilities, which limits the rehabilitation to patients with higher levels of ability (Anderson et al., 2014).

In summary, VR gaming systems might have a positive effect on functional recovery post stroke. The requirement of a minimal level of disability and the inability to adjust the difficulty of the game to suit patient ability makes the implementation of video games for rehabilitation infeasible in daily clinical practice.

## 2.13 Summary and Research Questions

The following points summarize the research findings and gaps in the literature:

- Trunk control has been well recognized as an important early predictor of functional recovery (explaining 45%–71% of the variance in functional recovery) post stroke.
- The clinical measurement tools available to measure trunk performance are the TCT, the TIS by Fujewara (TIS-F) and the TIS by Verheyden (TIS-V). All these are observer-dependent, which might bias the results.
- Trunk exercise has been shown to positively improve trunk control post stroke. However, to the author's best knowledge, the effect of trunk exercise on UL function has not been investigated. Therefore, the third stage of this doctoral thesis will study the change in both trunk control and UL function after 18 sessions of trunk exercise delivered to a chronic strokes.
- Most of the trunk exercises used in previous clinical trials were repetitive in nature, performed in non-enjoyable environments and administered one-to-one by healthcare specialists, thus incurring comparatively high healthcare costs and being perceived as un-motivating. Technological developments might address these problems by providing interactive training environments. However, the studies investigating the use of VR games to deliver trunk exercises to stroke patients is limited. Therefore, studying the feasibility of using video game-based sensor systems to deliver trunk exercises to stroke patients is warranted.

In order to address the gaps in the literature, the following research questions will be addressed in this doctoral study:

➤ **The 1<sup>st</sup> study (validity and reliability) will address the following research questions:**

Q1: Is it possible to develop an instrumented version of the TIS (iTIS) using inertial sensor technology?

Q2: Could the iTIS be considered a valid and reliable tool for the evaluation of motor impairment of the trunk in chronic post stroke patients?

➤ **The 2<sup>nd</sup> study (validity and reliability) will address the following research questions:**

Q1: What is the interrater and intrarater reliability (both within and between sessions) of the Valedo<sup>®</sup> system to measure trunk ROM during performance of SWMFT among age-matched healthy participants?

➤ **The 3<sup>rd</sup> study (feasibility) will address the following research questions:**

Q1: Is trunk training using the Valedo<sup>®</sup> system feasible in people with chronic stroke?

Q2: Does 13.5 hours of trunk training using a video game intervention lead to changes in trunk impairment (TIS), trunk muscle size and UL function outcomes (SWMF and FMA) in people with chronic stroke?

## **2.14 Summary of Chapter 2**

This chapter presented the literature review and the research on trunk recovery post stroke. Trunk impairment post stroke as a result of muscle weakness and poor control was discussed, highlighting the effect of impaired trunk control on functional outcomes. The chapter also shed light on compensatory trunk movement in reaching tasks. The research on trunk rehabilitation and the use of technology to support trunk rehabilitation following stroke was also discussed. After that, the research findings and gaps in the knowledge were identified and summarized. Finally, the research questions of this doctoral study were listed. The next chapter will explain in detail how the research questions will be answered.

## **Chapter 3    General Methodology of Studies**

### **3.1    Introduction**

This chapter presents the philosophical approaches underpinning the research design and methods used to answer the research questions. The chapter begins with an overview of research philosophy followed by a discussion of the research methods used in each stage of this PhD. The ethical considerations considered during this PhD study are detailed in the last section.

### **3.2    Research Philosophy**

Research is conducted from various standpoints based on our understanding of what composes nature and being 'our awareness of what is real' (ontology) and how we know things 'how we can produce valid knowledge about it' (epistemology) (Creswell and Creswell, 2017). These standpoints are referred to as research paradigms that help to explain the type of research used to answer a given research question. Traditionally, research paradigms have been considered to be either positivist or constructivist (Morgan, 2007).

Quantitative purists employ quantitative methodologies (e.g. experimental, quasi-experimental and survey research methods) in data collection and analysis to answer research questions (Johnson and Onwuegbuzie, 2004). This is commonly called a positivist philosophy. Positivists believe that social science inquiry should be objective. That is, time and context free generalizations. So, the real causes of social scientific outcomes can be determined reliably and validly. However, this philosophical stance has been criticized, as it creates artificial situations, ignores the relevance of real-world situations (external validity) and does not consider how a certain phenomenon effects an individual (Johnson and Onwuegbuzie, 2004).

However, qualitative purists reject what they call positivism. Constructivists or interpretivists believe that it is impossible to fully differentiate causes and effects because subjective data collected using qualitative methodologies (e.g. interviews and focus groups) is the only source of reality (Morgan, 2007). Explanations of certain phenomena in specific patients or groups cannot be arrived at without considering the context and time. However, this philosophy lacks transferability to other situations (Morgan, 2007).

Pragmatism has been argued to reconcile the positivist and constructivist paradigms (Shaw et al., 2010). Pragmatism has been defined as a:

“... paradigm that debunks concepts such as “truth” and “reality” and focuses instead on “what works” as the truth regarding the research question under investigation. Pragmatism rejects the either/or choices associated with the paradigm wars, advocates for the use of mixed methods in research and acknowledges that the values of the researcher play a large role in the interpretation of results” (Tashakkori and Teddlie, 2010); p. 713).

Pragmatists attempt to improve communication among researchers from different paradigms by fitting the insights provided by qualitative and quantitative research into a workable solution (Johnson and Onwuegbuzie, 2004). Pragmatism supports the use of both quantitative and qualitative methodologies, which is called mixed-methods research. This allows collecting both subjective and objective data, depending on the specific research issue (Tashakkori and Teddlie, 2010).

Because this PhD study answers different research questions, every study stage had an individual method and design to suit the determined research questions. Table 3-1 summarizes the research designs and methods used at each stage of this project.

Table 3-1: Research paradigm, method and design used in each stage of the PhD

Study/Research Question	Research paradigm	Research Method	Research Design
<b>Study 1:</b> <b>Q1:</b> Is it possible to develop an iTIS using inertial sensor technology?  <b>Q2:</b> Could the iTIS be considered a valid and reliable tool to evaluate motor impairment of the trunk in chronic post stroke patients?	Positivism	Quantitative	Cross-sectional observational study
<b>Study 2:</b> <b>Q1:</b> What is the intra-rater and between-session reliability of the Valedo® system to measure trunk ROM during performance of SWMFT among age-matched healthy participants?	Positivism	Quantitative	Cross-sectional observational study
<b>Study 3:</b> <b>Q1:</b> Is trunk training using the Valedo® system feasible in people with chronic stroke?  <b>Q2:</b> Does 13.5 hours of trunk training using a video game intervention lead to changes in trunk impairment (TIS), trunk muscle size and LL and UL function outcomes (SWMF and FMA) in people with chronic stroke?	Pragmatism	Mixed method (Quantitative + Qualitative)	Convergent parallel study

### 3.3 Research Methods and Rationale for the Chosen Research Methods and Design

This section discusses the rationale for the chosen methods and designs outlined previously. The rationale behind choosing a quantitative observational design to address the research questions of Study 1 and 2 and a mixed-methods design to answer the research questions of Study 3 are discussed.

#### Study 1 and 2

A cross-sectional observational approach was used for these two studies because i) the reliability studies in this PhD do not include an intervention, and ii) the aims are to collect data about trunk and arm function by recording clinical measurements (TIS, SWMFT) at two assessment sessions from participants selected based on the inclusion and exclusion criteria set for the study.

The cross-sectional design allows the researcher to gather the data from a specific group at one point in time and to adopt an observational approach whereby the researcher does not intervene or use experimental controls (e.g. control group assignment) (Creswell and Creswell, 2017). Therefore, this is the best design fit to answer the research questions for the stage 1 and 2.

### Study 3

The term mixed methods reflects the use of both quantitative and qualitative methodological approaches within the same research study (Creswell and Clark, 2011). The reason for mixing quantitative and qualitative methods is to combine the strengths of the two methods and to compensate for their respective limitations. In addition, giving the data an expansion and depth to add more accuracy and completeness in answering the research question (Creswell and Clark, 2011, Pluye and Hong, 2014).

Several research designs have been published describing the major approaches used in mixed-method research (Creswell and Clark, 2011, Tashakkori and Teddlie, 2010). According to Creswell (2011), there are four basic approaches in mixed-method studies: convergent parallel, embedded, explanatory sequential and exploratory sequential (Creswell and Clark, 2011). The convergent parallel design is a one-phase design that involves a simultaneous concurrent collection of qualitative and quantitative data followed by combining and comparing the multiple data sources. The embedded design is a nested approach considered when one type of data (quantitative or qualitative) plays a secondary role and would not be meaningful if not embedded within the primary data set. The explanatory sequential design is a sequential approach with a two-phase design considered when the researcher is interested in explaining the quantitative data collected in the first phase using the qualitative data collected in a subsequent second phase. The exploratory sequential design focuses on developing an instrument by collecting qualitative data in the first phase to understand the phenomenon, which helps to develop the instrument, and then collecting quantitative data in the second phase to test the instrument.

The mixed-methods approach was considered for this study because this design was able to offer breadth and depth in investigating the feasibility of using video games to carry out trunk exercises in the chronic stroke population and in investigating patients' perspectives toward the use of this technology. Additionally, the author chose the convergent parallel design because it allows the research aims and questions to be addressed by concurrently collecting quantitative data (clinical outcome measures) and qualitative interview data, thereby giving multiple perspectives to understand the feasibility of implementing the video game trunk exercises in the chronic stroke

population. The author also considered the timeframe and funding available when choosing a research design. Explanatory and exploratory designs both have multiple research phases. These designs would have taken longer time and required substantially more funding. Moreover, the author planned to compare and contrast the quantitative and qualitative data and present their results together. Neither explanatory nor exploratory designs merge both quantitative and qualitative data but draw on the results of consecutive qualitative and quantitative studies.

The merging of both quantitative and qualitative data in this PhD study was applied through data integration. The purpose of data integration is to combine different data elements and various strategies for analysis of those elements (Tashakkori and Teddlie, 2010). Integration of the quantitative and qualitative data occurs during the process of interpreting the findings of the whole study using a triangulation technique. It has been argued that the triangulation of data can lead to a better understanding of complex interventions (Farmer et al., 2006). The aim of triangulation is to increase the validity of the findings by collecting different types of data relating to the same research problem (Creswell and Creswell, 2017). The effectiveness of triangulation is based on the assumption that the weakness of each single method is counteracted by the strengths of another (Jick, 1979). In this PhD study, the triangulation of quantitative and qualitative data collected in stage 3 increased the validity of the results and provided a deep understanding of using video games in trunk rehabilitation post stroke. Both quantitative (clinical outcome measures) and qualitative (interview data) data were collected at the same time and analysed independently. Both data sets were then merged and interpretation drawn from the inferences of both sets of data.

### **3.4 Ethical Consideration**

#### **3.4.1 Ethical Approval**

Ethical approval for the first study (Ethics number: 25280), second study (Ethics number: 46744) and third study (Ethics number: 30748) studies was given by the Faculty of Health Sciences Ethics Committee of the University of Southampton (Appendix 1Appendix 2Appendix 3). The recruitment and data collection of all studies commenced after ethical approval letters were issued.

#### **3.4.2 Participant Confidentiality**

All possible steps have been taken to remove any identifying characteristics from participant data. Each participant was assigned a unique ID number. The data collection forms do not include any personal information, such as name or address. The personal data is kept separately from the research documents in a locked cabinet in a secure office in the School of Health Science (Building 67). The same procedure was used for the data collected in Saudi Arabia; all personal data is stored in a locked cabinet in the researcher's office. The electronic data recorded for the purpose of the

research project will be kept on a password-protected computer using UoS computing facilities (laptop and PC). Any personal information about participants (i.e. names and addresses) will be removed from any research report forms or publications so that participants cannot be identified. All researchers involved in the processing of the data have taken appropriate measures to ensure the data is kept strictly confidential. All information collected from the participants has been protected and was not shared with any personnel not involved in the research.

### **3.4.3 Data Anonymity**

As mentioned previously, each participant was assigned a unique ID number. This number is used to identify all data for each participant. The link between a participant's information and their unique ID number is only on a single document that only the researchers have access to ensure data anonymity. All personnel involved in the processing of the data have taken appropriate measures to protect the data and treat the information as strictly confidential. In each stage of this PhD study, the invitation letter and an information package was sent to volunteers at the School of Health Science by a third party to ensure anonymity was maintained until the point of inclusion in the study.

In the case of photography, the various options on the consent form enable the participant to select the level of confidentiality they wish to impose. Photographs will not be linked to participant IDs. Photographs used for publicity may show participants' faces (subject to their consent) but will not link to any personal data.

### **3.4.4 Data Storage and Management**

The management of the research data complies with the Data Protection Act and the General Data Protection Regulation (GDPR) of May 25, 2018. The data recorded for the purpose of the research project will be kept on a password-protected computer using UoS computing facilities (laptop and pc) for at least 10 years. The paper records (e.g. consent forms) are kept in a locked filing cabinet in a secure office at the University of Southampton (building 67). For Saudi Arabian participants, the collected forms are stored in a locked cabinet in the researcher's office. Regarding use of the data by the research team, a file protection log has been created to ensure that the paper files have been returned to the locked cabinet and secured (Appendix 4).



## **Chapter 4 Study 1: Validity and Reliability of Using the Valedo® System to Measure Trunk Impairment in Chronic Stroke and Aged-matched Healthy Participants**

### **4.1 Introduction**

Trunk control is a vital part of balance and postural control; it plays an important role in holding the body upright and in performing selective trunk movements during static and dynamic postural adjustments (Davies and Klein-Vogelbach, 2012, Woo, 2018). Impairment of trunk control due to trunk muscle weakness, poor control or reduced position sense results in decreased balance and an increased risk of falls; it also interferes with the performance of daily living activities, such as turning in bed, sitting, rising from a sitting position to a standing position and walking (Langhorne et al., 2009, Ryerson et al., 2008, Sunderland et al., 1989). Moreover, stability of the upper trunk is considered to be a prerequisite of UL function and hand usage (Rosenblum and Josman, 2003).

The role of trunk ability is often overlooked as an integral part of the recovery process; trunk control has been recognized to be an important early predictor of functional recovery after stroke explaining 45%–71% of the variance in functional recovery post stroke (Franchignoni et al., 1997, Verheyden et al., 2007a). In stroke, impaired trunk control can be assessed using clinical outcome measures such as the TCT and the TIS (Collin and Wade, 1990, Verheyden et al., 2004). The TIS is recommended for use in clinical research because it has sufficient psychometric properties and has been demonstrated to have high concurrent validity ( $r=.83$ ), excellent test–retest reliability ( $ICC=0.96$ ), excellent inter-rater reliability ( $ICC=0.99$ ) and no ceiling effect (Sullivan et al., 2013, Verheyden et al., 2005, Verheyden et al., 2004). The TIS consists of three subscales that assess static sitting balance, dynamic sitting balance and trunk coordination. Following Rasch analysis, the static sitting balance subscale was eliminated, and the scale was renamed TIS Version 2.0 (TIS-V2) (Verheyden and Kersten, 2010). However, although the TIS is commonly used to evaluate trunk impairment post stroke, a limitation is that the scale uses ordinal scores to measure trunk impairment by means of the degree of task completion without considering movement quality during task performance. More detailed information on trunk movement quality can be obtained by kinematic analysis of several indices (i.e., speed, smoothness and range of motion (ROM)). Identifying these stroke-related impairment kinematic characteristics potentially offers a better understanding of the relationship between movement quality and performance during neurorehabilitation and stroke recovery.

A recent study that measured trunk movement using 3D kinematic analysis found that the lateral pelvic ROM was the best predictor ( $R^2=0.2$  and  $p < 0.006$ ) of clinical recovery measured with the TCT (Carozzo et al., 2020). It is critical to differentiate between compensatory and non-compensatory movement after neurorehabilitation, and kinematic measures may help to identify deficits even in people who have recovered well from their stroke (Karthikbabu et al., 2012). The majority of the published literature focuses on measuring trunk movement in relation to UL recovery, and there is a dearth of evidence regarding recommended kinematic parameters to use for evaluating trunk impairment (Carozzo et al., 2020, Schwarz et al., 2019). An iTIS to address this limitation is therefore warranted.

Optoelectronic measurement systems can be used to quantify trunk movements in research settings (Cuesta-Vargas et al., 2010). However, these systems are not readily clinically available because they are costly and require a large installation space. To overcome these limitations, the use of alternative, objective, low-cost measuring systems such as IMUs may be useful. The Valedo<sup>®</sup> system (Hocoma, Switzerland) is a wireless movement analysis system that comprises three lightweight sensors (IMUs) that measure trunk movement (in degrees) and the velocity of body segments with respect to magnetic fields and gravity in a non-invasive way (Bauer et al., 2015, Hugli et al., 2015). Recent research has examined the concurrent validity and reliability of the Valedo<sup>®</sup> system using an optoelectronic system as the gold standard for measuring 3D trunk movement in healthy participants. The research has found that the Valedo<sup>®</sup> system is a valid ( $r^2$  coefficients  $> 0.94$ ) and reliable (3%–9% coefficient of variation) measure for estimating trunk movement (Bauer et al., 2015). The instrumentation of the TIS could potentially provide more detailed and clinically relevant information about trunk movement and its relationship to trunk impairment for stroke participants.

To author knowledge, this is the first study that has instrumented a clinical trunk impairment scale. It was therefore the aim of this cross-sectional observational study to instrument the TIS using the Valedo<sup>®</sup> system and correlate it to the gold standard TIS (cTIS-V2) for concurrent validity testing. This will additionally establish the discriminant ability of the iTIS, as the scores of chronic stroke subjects and healthy age-matched subjects can be compared. The inter-rater and intra-rater reliability of iTIS in participants with chronic stroke and age-matched healthy subjects is also assessed.

## 4.2 Research Question(s):

Q1: Is it possible to develop an iTIS using inertial sensor technology?

Q2: Could the iTIS be considered a valid and reliable tool for the evaluation of motor impairment of the trunk in chronic post stroke patients?

Before describing the methodology of this study, indices of validity and reliability and different types of validity and reliability used in this study will be detailed.

## 4.3 Types and Measures of Validity

### 4.3.1 Types of Validity

The validity of a device or measurement scale refers to its ability to measure what it is intended to measure (Portney and Watkins, 2013). There is no clear cut point of a scale's validity. Validation of a scale can be done in different ways according to the type of validity needed. There are various types of validity, including face validity, content validity, criterion-related validity, construct validity, convergent validity and divergent validity.

#### 1. Face Validity

Face validity means that the instrument appears as though it should measure what it is supposed to measure (Portney and Watkins, 2013). It is considered as the least rigorous form of validity and for scientific purposes this form of validity never provides a sufficient basis on which to *establish an* instrument's or test's validity (Portney and Watkins, 2013). To establish face validity, a subjective process is used that includes 9–13 experts to review the instrument and its appearance (Kraska-Miller, 2013).

#### 2. Content Validity

Content validity refers to whether the components of a scale sufficiently cover all aspects of the features needed to be measured in relation to a specific domain (Bowling, 2004). This type of validity is usually used in questionnaires and inventories. There are no statistical indices to determine content validity. The determination of content validity is essentially a subjective process and should be judged by the target group being assessed (Portney and Watkins, 2013).

#### 3. Criterion-related Validity

Criterion-related validity is the ability of one test to predict results obtained for an external criterion that is known to be valid (Portney and Watkins, 2013). In other words, a measuring instrument has

## Chapter 4

criterion-related validity if its results are closely related to those given by some other, definitive instrument, the 'gold standard'. It is considered the most practical and objective approach to validity testing and can be established in two ways:

### **a. Predictive Validity**

Predictive validity refers to the ability of an instrument to predict future differences in key variables (Portney and Watkins, 2013). To establish the predictive validity of an instrument, an initial assessment using a target test is given in one session followed by a period of time after which the criterion test is obtained. The relationship between the target and criterion scores is then examined to determine if the target test score is a valid predictor of the outcome on the criterion measure (Portney and Watkins, 2013). For example, if there are theoretically sound reasons to hypothesize that people in a lower socio-economic group are more likely to report poor health status compared to people in a high socio-economic group, the health status of the two groups can be compared to check the predictive validity (Bowling, 2004).

### **b. Concurrent Validity**

Concurrent validity refers to independent corroboration that the instrument is measuring what it means to measure against a criterion measurement (e.g. corroboration of a physical functioning scale with observable function) (Bowling, 2004). It can be established by measuring a key variable with two instruments at the same time point. This type of validity is usually used to develop a new scale that is simpler, less expensive and more objective to replace an existing scale (Bowling, 2004). Criterion-related (either predictive or concurrent) validity can be calculated using correlational techniques and regression procedures (Kraska-Miller, 2013).

## **4. Construct Validity**

Construct validity is the extent to which a test measures the concept or construct that it is intended to measure (Portney and Watkins, 2013). The term 'construct' comes from the validation of scales measuring artificial constructs without any physical reality (cannot be directly observed) such as depression (Bowling, 2004). This type of validation is divided into two categories:

### **a. Convergent Validity**

Convergent validity is the extent to which two measures that intend to measure the same construct are correlated (Portney and Watkins, 2013). For example, if two measurements measuring health status are valid, they should have correlated scores.

### **b. Divergent (Discriminant) Validity**

Divergent validity is the extent to which a test measurement is unrelated to variables to which it should be unrelated if the instrument were valid (Portney and Watkins, 2013). For example, the Sickness Impact Profile (SIP) has been compared to the Carroll Rating Scale for Depression to establish its divergent validity. Divergent validity is confirmed by a lower correlation between the physical SIP scale and the Carroll Rating Scale for Depression (Portney and Watkins, 2013).

Construct (either convergent or divergent) validity can be calculated using correlational techniques between two measures (Bowling, 2004).

### **4.3.2 Measures of Validity**

#### **1. Sensitivity and Specificity**

The validity of a diagnostic test is evaluated in terms of its ability to accurately assess the presence and absence of the target condition. Sensitivity can be defined as the test's ability to obtain a positive result when the target condition is really present, or a true positive rate. Specificity is the test's ability to obtain a negative result when the condition is really absent, or a true negative rate (Portney and Watkins, 2013).

#### **2. Receiver Operating Characteristic Curves**

Although continuous scales are considered preferable for screening because they are more precise, they are often converted to a dichotomous outcome for diagnostic purposes; that is, a cut-off is established to demarcate a positive or negative result. This decision point must be based on the relative importance of sensitivity and specificity, or the cost of incorrect outcomes versus the benefits of correct outcomes (Portney and Watkins, 2013).

In this study, the iTIS was used to predict if a stroke patient had trunk impairment or not, and the patients with a low score were referred to a trunk exercise program. If the patient did not truly have trunk impairment (false positive), the outcome may be considered low cost. This is compared to the situation where an individual who is at risk is not correctly diagnosed (false negative), not referred for treatment and injures themselves in a fall.

Obviously, it is usually desirable for a screening test to be both sensitive and specific. Unfortunately, there is often a compromise between these two characteristics. One way to evaluate this decision point would be to look at several cutoff points to determine the sensitivity and specificity at each

point. We could then consider the relative trade-off to determine the most appropriate cutoff score (Portney and Watkins, 2013).

The balance between sensitivity and specificity can be examined using a graphic representation called a receiver operating characteristic (ROC) curve. This is essentially what this study is trying to do with the iTIS. It needs to detect (the presence or absence of trunk impairment—the true positive and true negative) with the least amount of interference possible (incorrect trunk impairment diagnoses—false positive and false negative). The ROC curve illustrates this relationship. It allows us to answer the question of how well a test can discriminate between the presence or absence of disease.

## **4.4 Types and Indices of Reliability**

### **4.4.1 Types of Reliability**

Reliability is defined as the extent to which a measurement scale is free of random error (McDowell, 2006). The reliability of a measurement tool can be assessed by applying it many times and comparing the results to see if they yield the same results. There are several types of reliability, including test–retest reliability, inter-rater reliability and internal consistency (Portney and Watkins, 2013).

#### **1. Test–retest Reliability**

This type of reliability is also called intra-rater reliability. It assesses the consistency of the results of repeatable measurement of the same participants (Portney and Watkins, 2013). It can be assessed by repeating the same test on the same individuals at different times. In the present study, test–retest reliability was examined in two ways. The first was by comparing the results obtained in the first session (twice) by the same rater. The second was by comparing the initial results obtained in the first session (first assessment) to the results obtained in the second session, with 7 days between the two sessions.

#### **2. Inter-rater Reliability**

This type of reliability assesses the consistency of the results obtained by different raters who collected information using the same measurement tool (Portney and Watkins, 2013). In the present study, inter-rater reliability was tested by having two raters repeat the same measurement (Norah Alhwoaimel and Federico Ferrari).

### 3. Internal Consistency

This type of reliability is concerned with the extent to which the measuring tool assesses the same characteristic, skill or quality (Portney and Watkins, 2013). It assesses the precision between different raters or different measurement tools (e.g. questionnaires, interviews).

#### 4.4.2 Indices of Reliability

Reliability can be calculated statistically using different indices, including the interclass correlation coefficient (ICC), the standard error of measurement (SEM) and Bland and Altman 95% limits of agreement (Bruton et al., 2000).

##### 1. Interclass Correlation Coefficient

The ICC is an index calculated using variance estimates obtained through the dividing of total variance into between- and within-subject variance (analysis of variance or ANOVA) (Bruton et al., 2000). The value of the ICC ranges from 0.00–1.00, with 1 considered to represent excellent reliability (Portney and Watkins, 2013). The reliability results are considered excellent when  $ICC \geq 0.75$ , good to fair when  $ICC = 0.4–0.74$  and poor when  $ICC < 0.4$  (Fleiss, 2011). In 1979, Shrout and Fleiss described the ICC as having six types based on three models and the number of measures (single or average measure) (Koo and Li, 2016). Each is appropriate for a specific situation, as described below.

##### Model 1: One-Way Random-Effects

In this model, each subject is assessed by a different set of randomly selected raters, and subjects are treated as independent variables. This model is not commonly used in clinical reliability studies. If the reliability is calculated from a single measurement,  $ICC(1,1)$  is calculated as:

$$ICC(1,1) = \frac{MSR - MSW}{MSR + (k, 1)MSW}$$

If the reliability is calculated by taking an average of the  $k$  raters' measurements,  $ICC(1,k)$  is calculated as:

$$ICC(1,k) = \frac{MSR - MSW}{MSR}$$

**Model 2: Two-Way Random Effects**

In this model, each subject is measured by each rater, and raters are considered representative of a larger population of similar raters. This model is commonly used in inter-rater reliability studies.

If the reliability calculated from a single measurement, ICC (2,1), is calculated as:

$$ICC(2,1) = \frac{MSR - MSE}{MSR + (k-1)MSE + \frac{k}{n}(MSC - MSE)}$$

If the reliability is calculated by taking an average of the k raters' measurements, ICC (2,k) is calculated as:

$$ICC(2, k) = \frac{MSR - MSE}{MSR + \frac{MSC - MSE}{n}}$$

**Model 3: Two-Way Mixed-Effects**

In this model, each subject is assessed by each rater, but the raters are the only raters of interest. This model is commonly used in test-retest reliability studies. If the reliability calculated from a single measurement, ICC (3,1) is calculated as:

$$ICC(3,1) = \frac{MSR - MSE}{MSR + (k-1)MSE}$$

If the reliability is calculated by taking an average of the k raters' measurements, ICC (3,k) is calculated as:

$$ICC(3, k) = \frac{MSR - MSE}{MSR},$$

Where MSR=mean square for rows; MSW=mean square for residual sources of variance; MSE=mean square for error; MSC=mean square for columns; n=number of subjects; and k=number of raters/measurements.

**2. Standard Error of Measurement**

When the measurement test is applied to a single subject many times, it would be expected to generate some variation from trial to trial as a result of measurement error. These results of the measurements could be plotted and their distribution would follow a normal curve, with the mean

equal to the true score and errors occurring above and below the mean. The more reliable the measurement, the less error variability would be expected around the mean. Therefore, the extent of expected error in different rating scores is known as SEM (Portney and Watkins, 2013). The SEM can be calculated by the following equation:

$$SEM = SD \sqrt{1 - ICC},$$

where SD is the standard deviation of the set of observed test scores and ICC is the reliability coefficient for those data. The SEM is expressed in the actual units of measurement, making it easy to interpret. The smaller the SEM, the greater the reliability (Bruton et al., 2000).

However, the SEM is not sufficient for clinician to distinguish between a real changes and measurement error. Therefore, minimal detectable change (MDC) and Minimal clinically important differences (MCID) can be used to enable clinicians to distinguish true performance change from meaningless fluctuations. The MDC defined as *“the amount of change that must be detected to demonstrate a true difference; the smallest amount of difference that passes the threshold of error with a 90% or 95% confidence interval”* (Avers, 2020)(p.142)

Therefore, the difference between measures should be greater than the MDC produced from the reliability data to establish a clinically meaningful difference. Minimal detectable change can be calculated using the following formula (de Vet et al., 2006):

$$MDC = 1.96 \times \sqrt{2} \times SEM$$

Another statistic that differentiate between measurement error and real clinical change is MCID which was firstly described by (Jaeschke et al., 1989). It defined as the smallest difference in a measured variable in the domain of interest, which patients mandate as beneficial rather than trivial difference in the patient’s condition, in the absence of troublesome side effects (Jaeschke et al., 1989, Avers, 2020). The MCID of an instrument can be calculated in different ways including distribution-based and anchor-based methods. 1) Distribution-based methods relied on the statistical characteristics (spread of data using standard deviation, standard error of the mean, and effect size;) of a group’s baseline patient-reported outcome measures (PROM) scores to determine—given the spread of a group’s baseline PROM scores—how much of a change may be clinically important. 2) anchor-based methods compare changes in scores with an “anchor” question (e.g. do you feel that you are improved by the treatment?) as a reference to determine if the patient is better after treatment compared with baseline according to the patient’s own experience (Sedaghat, 2019).

### **3. Bland and Altman 95% Limits of Agreement**

In 1986, Bland and Altman suggested the use of correlation coefficients to test agreement between two methods of clinical measurement could be misleading (Bland and Altman, 1986). Therefore, they suggested a graphical representation technique to assess the agreement between two measurements. They suggested using this method either for the repeated single measurement method or for method comparison studies. The advantage of this technique is that by using scatterplots, data can be visually interpreted. Thus, any outliers, bias or relationship between variance in measures and size of the mean can therefore be observed easily. This approach can be applied by calculating the mean for each measurement and using this in a series of agreement tests: plotting the difference in the two results against the mean value from the two measurements; calculating the mean and SD of the differences between the measures; and calculating the 95% limits of agreement (as the mean difference plus or minus two SDs of the differences) and the 95% confidence intervals (CIs) for these limits of agreement. The 95% limits of agreement provide a range of error that may relate to clinical acceptability, although this needs to be interpreted with reference to the range of measures in the raw data.

## **4.5 Validity and Reliability Examined in the Present Study**

The present study tested the concurrent validity of the iTIS compared to the gold stand clinical TIS (cTIS). The validity was measured using two methods, the ROC curve and the correlation between iTIS and cTIS scores.

Inter-rater reliability and intra-rater reliability were tested in the current study. The reliability was measured using two methods, including ICC. An explanation of these methods for validity and reliability will be presented in section 4.7.

## **4.6 Methods**

The next sections will describe in detail the study design, sample size, methods of recruiting participants and measurement protocol.

### **4.6.1 Study Design**

The study is a cross-sectional observational study to establish the validity and reliability of using Valedo® sensors to develop an iTIS using the cTIS as a gold stand and to test for concurrent validity, inter-rater and intra-rater reliability.

#### 4.6.2 Sample Size Calculation

The sample size was calculated based on the method described by Walter et al. (1998). The sample size 'K' was calculated based on different aspects, including the selection of the minimally acceptable level of reliability ( $p_0$ ) and the anticipated level of reliability ( $p_1$ ), the number of replicates 'n' and type 1 and type 2 errors. In the current study, the number of replicates (n) will be three to explore both inter-rater and intra-rater reliability. The value of a type I error was selected as 0.05 and the value of a type 2 error was selected as 0.20 (Walter et al., 1998). The level of reliability values ( $p_0$  and  $p_1$ ) was set based on the previous literature as 0.7–0.9 (DeVellis, 2012, Portney and Watkins, 2013). Therefore, the number of subjects required was (K=12.8), as presented in Figure 4-1. In addition, a recent reliability study that tested the reliability of IMU sensors to measure trunk movement used 20 participants to achieve a reliability level (0.95) (Bauer et al., 2015). Altogether, 20 chronic stroke patients and 20 age-matched healthy participants were recruited for this study.

$p_0$	$p_1$								
	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9
$n = 2$									
0	615.6	151.9	70.0	35.9	22.0	14.4	9.7	6.6	4.4
0.1		591.2	142.8	60.6	32.2	19.1	12.0	7.7	4.8
0.2			543.7	128.2	53.0	27.2	15.5	9.2	5.3
0.3				476.2	109.0	43.5	21.4	11.4	6.1
0.4					393.1	86.6	32.9	15.1	7.1
0.5						300.3	62.6	22.0	8.8
0.6							205.4	39.1	11.7
0.7								117.1	18.4
0.8									45.8
$n = 3$									
0	225.1	60.2	28.1	16.4	10.7	7.4	5.3	3.8	2.7
0.1		251.8	64.8	29.2	16.4	10.2	6.8	4.6	3.0
0.2			261.1	64.8	28.1	15.1	9.0	5.6	3.4
0.3				251.8	60.2	25.1	12.8	7.1	4.0
0.4					225.1	51.5	20.3	9.6	4.7
0.5						183.9	39.6	14.4	5.9
0.6							133.1	26.1	8.0
0.7								79.7	12.8
0.8									32.5

Figure 4-1: Estimates of sample size based on  $\alpha=0.05$ ,  $\beta=0.20$ .

Reprinted from Walter S.D, Eliasziw M. and Donner A., "Sample size and optimal designs for reliability studies," *Statistics in Medicine*, vol. 17, pp 101–110, with permission from the journal.

#### 4.6.3 Recruitment

A purposive sample of 20 adult chronic stroke volunteers with trunk impairment (mild to severe) and 20 aged-matched healthy participants was recruited from the School of Health Sciences' Research Participant Register, Hobbs Rehabilitation Centre and local stroke clubs. For recruiting stroke patients and healthy adults from the Faculty of Health Sciences' Research Participant Register, an information package was sent including an invitation letter (Appendix 5), participant information sheet (PIS) (Appendix 6) and reply slip with a freepost envelope (Appendix 7). The invitation letter was sent by a third party (Simon Brown) to ensure data anonymity is maintained

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until the point of inclusion in the study. If someone was interested in participating in the study, the contact details were passed to the researcher to organize the sessions. The researcher also contacted local stroke clubs in Southampton, Winchester, Romsey, Portchester and Portsmouth to give presentations about the study. If people were interested in participating in the study, they were given the same information package. In addition, an advertising poster was displayed at the University of Southampton Highfield campus in building 45 (Appendix 8 and Appendix 9). The poster contained brief information about the study with the researcher contact details. Table 4-1 and Table 4-2 show the inclusion and exclusion criteria for healthy and stroke participants.

Table 4-1: Inclusion and exclusion criteria for healthy participants

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"><li>• Age between 40 and 80</li><li>• Able to understand and follow simple instructions (assessed in telephone screening)</li></ul>	<ul style="list-style-type: none"><li>• Acute low back pain</li><li>• History of spontaneous fractures</li><li>• Uncontrolled epileptic seizures</li><li>• History of or current orthopaedic spinal pathology</li><li>• Implanted ferromagnetic materials or active devices within the body</li><li>• Skin disease or lesions in the vicinity of sensor placement</li><li>• Hip prosthesis</li></ul>

Table 4-2: Inclusion and exclusion criteria for stroke participants

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> <li>• Age between 40 and 80</li> <li>• Able to understand and follow simple instructions (assessed in telephone screening)</li> <li>• Chronic post stroke patients</li> <li>• Reduction in trunk movement</li> <li>• Able to maintain seated position</li> </ul>	<ul style="list-style-type: none"> <li>• Severe communication disorders – unable to follow simple instructions</li> <li>• Acute low back pain</li> <li>• History of spontaneous fractures</li> <li>• Uncontrolled epileptic seizures</li> <li>• History of or current orthopaedic spinal pathology</li> <li>• Implanted ferromagnetic materials or active devices within the body</li> <li>• Skin disease or lesions in the vicinity of sensor placement</li> <li>• Hip prosthesis</li> </ul>

#### 4.6.4 Procedure

On the date and time arranged, the participants were taken to the research laboratory at the Faculty of Health Sciences of the University of Southampton. The researcher ensured that the participants had read and understood the PIS and gave them an opportunity to ask any questions regarding the study. The participants then signed a consent form (CF) (Appendix 10). The researcher completed the screening form and conducted the Edinburgh Handedness Inventory (Veale, 2014) to identify the participant's dominant hand. All participants attended two baseline assessment sessions 5–7 days apart. In the first session, the measurement was recorded three times with a rest period between them. The first and third assessments were measured by a first assessor (AN) for intra-rater reliability. The second assessment was measured by a second assessor (FF) for inter-rater reliability. In the second assessment session, the measurement was recorded once by the first assessor (AN) for between-sessions reliability. Each session took less than one and a half hours.

#### 4.6.5 Measurement Protocol

While the participant was standing, three lightweight Valedo® sensors (Hocoma, Switzerland) were placed using double-sided sticky tape: sensor one on the sacral spinal level S1, sensor two on the L1 spinal level and sensor three on the sternum (Figure 4-2). To mitigate measurement error by

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ensuring the same placement of the sensors by assessors, anatomical body landmarks were used to identify the S1 and L1 levels as follows: the anterior superior iliac spine (ASIS) along the iliac crest to L4 and from there moving upward and downward to locate L1 and S. The sensors were always placed and removed by the same assessor. The Valedo<sup>®</sup> sensors contained a tri-axillar gyroscope, accelerometer and magnetometer, a wireless antenna and a signal processing unit. The specifications of the Valedo<sup>®</sup> system indicated that the measurement units were able to record  $\pm 0.1^\circ$  ROM over a range of  $360^\circ$  around all axes (Valedo<sup>®</sup> User Manual, Hocoma). The recorded data was transmitted to a laptop with a 200 Hz sampling frequency. The Valedo<sup>®</sup> system output files show the rotation of the sensors in the X, Y and Z directions in the three body planes (sagittal, frontal and transverse) over the duration of the task. Output files were exported in Excel file format.



Figure 4-2: Sensor placements

Before starting the assessment, the participants were instructed to turn off mobile phones to avoid magnetic interference with the Valedo<sup>®</sup> sensors.

To start the TIS, the participant was seated barefoot on the bed without back support with  $90^\circ$  knee and hip flexion. Participants were asked to perform dynamic and co-ordination subscale tasks (Appendix 11). Each task was demonstrated by the assessor to the participant before they performed it. Every participant was assessed using the clinical and instrumented versions of the TIS-V2 simultaneously. Each task was scored clinically 0, 1 or 2, with the total score ranging from a minimum of 0 to a maximum of 16. The estimated total time for the completion of these tests was 15–20 minutes; however, an additional 5–10 minutes were necessary for sensor placement. Participants were assessed barefoot.

Valedo<sup>®</sup> data was recorded simultaneously with observed recorded data during the performance of the cTIS-V2. Results were recorded on a relevant case record form (Appendix 12). Valedo<sup>®</sup> output

files showed the rotations of the sensors on the three body planes over the duration of the task. All output files were exported in Excel file format.

#### **4.6.6 Development of Instrumented Trunk Impairment Scale**

In previous literature, there is no consensus on the best kinematic parameters to be used for evaluating trunk movement (Carozzo et al., 2020). Therefore, the parameters of interest for each TIS task were determined based on the clinical reasoning of the team, taking into account the maximum ROM in each direction during performance of the task and direction of movement expected by the author and research team (Turk, Warner, Hughes, and Ferrari). Initially, the following parameters were exported for each dynamic task: flexion, extension and lateral flexion on both sides for the sternal, lumbar and sacral sensors. Following completion of the data collection, the data were analysed to identify the most appropriate and important kinematic parameters to be reported in each task. For the dynamic subscale parameters, the degree of ROM of lateral flexion to either the affected or unaffected side was considered. For the coordination subscale, the degree of lumbar and sternal ROM towards both sides were measured, and the symmetry of rotation movement between the affected and unaffected sides was considered. The symmetry between both sides was calculated as a percentage (%) (i.e. 100% symmetry means that the rotation ROM on both sides is equal). The parameters of interest are presented in Table 4-3. The data was exported as an Excel file for each task performed. All the recorded tasks were then processed using MATLAB (MATLAB R2016a) (The MathWorks, Inc.) to extract the parameters used for iTIS. The MATLAB algorithms were written by an experienced musculoskeletal biomechanics researcher and performed by the author (NA). The MATLAB scripts for the data processing from raw data to ROM are detailed in Appendix 13.

Table 4-3: Sensor location, plane of movement and parameters of interest for each TIS-V2 task

cTIS- V2 tasks	Sensor	Parameter of Interest	Plane of Movement
<b>Dynamic Sitting Balance Subscale</b>			
1 - Touch the bed with the hemiplegic elbow	Sternum	ROM of lateral flexion to non-dominant/affected* side (degrees)	Frontal
2 - Repeat Item 1	Sternum	ROM of lateral flexion to non-dominant/affected side (degrees)	Frontal
3 - Repeat Item 1	Sternum	ROM of lateral flexion to non-dominant/affected side (degrees)	Frontal
4 - Touch the bed with the unaffected elbow	Sternum	ROM of lateral flexion to dominant/unaffected side (degrees)	Frontal
5 - Repeat Item 4	Sternum	ROM of lateral flexion to dominant/unaffected side (degrees)	Frontal
6 - Repeat Item 4	Sternum	ROM of lateral flexion to dominant/unaffected side (degrees)	Frontal
7 - Lift pelvis from bed on the hemiplegic side	Sacrum	ROM of lateral flexion to dominant/unaffected side (degrees)	Frontal
8 - Repeat Item 7	Sacrum	ROM of lateral flexion to dominant/unaffected side (degrees)	Frontal
9 - Lift pelvis from bed on the unaffected side	Sacrum	ROM of lateral flexion to non-dominant/affected side (degrees)	Frontal
10 - Repeat Item 9	Sacrum	ROM of lateral flexion to non-dominant/affected side (degrees)	Frontal
<b>Coordination Subscale</b>			
1 - Rotate upper trunk six times	Sternum	Symmetry (%), ROM of average rotation to both sides (degrees) and total no. of rotations	Transverse
2 - Repeat Item 1 within 6 seconds	Sternum	Symmetry (%), ROM of average rotation to both side (degrees) and total no. of rotations	Transverse
3 - Rotate lower trunk six times	Lumbar	Symmetry (%), ROM of average rotation to both side (degrees) and total no. of rotations	Transverse
4 - Repeat Item 3 within 6 seconds	Lumbar	Symmetry (%), ROM of average rotation to both side (degrees) and total no. of rotations	Transverse

\*non-dominant upper limb for healthy participants; most affected upper limb for stroke participants.

## 4.7 Statistical Analysis

All the recorded data was processed using MATLAB. Data was exported into Excel files and analysed using IBM SPSS Statistics 24 (SPSS Inc., Chicago, IL, USA). Descriptive statistics were used to summarize the demographic data and the parameters of interest. The normality of the data was checked using the Shapiro–Wilks test.

### 4.7.1 Validity

The validity of any test can be measured using one of three conceptual frameworks, criterion-related validity, content validity or construct validity (Karras, 1997a, Karras, 1997b). When a gold standard is available, the criterion-related validity (i.e. concurrent validity) is used.

To evaluate the concurrent validity of the Valedo<sup>®</sup> system in measuring trunk impairment, the correlation between clinical scores (using TIS-V2) and instrumental scores (using iTIS) was examined using Spearman correlation coefficient analysis (Karras, 1997a). The correlation coefficient ranges from -1 to +1 to reflect the strength of the relationship between the variables. The positive or negative sign of the coefficient indicates positive or negative correlation (Karras, 1997b). The following correlation classification was used to interpret the correlation coefficient result: none or very low:  $\rho = 0-0.25$ ; low:  $\rho = 0.26-0.40$ ; moderate:  $\rho = 0.41-0.69$ ; high:  $\rho = 0.70-0.89$ ; and very high:  $\rho = 0.90-1.0$  (Munro, 2001).

The score difference in iTIS parameters of the stroke participants and the healthy age-matched participants were assessed using an independent samples t-test. In addition, the difference in iTIS parameters between the participants with stroke who achieved scores of one or two and those who scored zero on the cTIS-V2 tasks was calculated using an independent samples t-test and a one-way ANOVA.

In addition, ROC curve analysis and the (AUCs) were used to determine the cut-off point of the iTIS parameters for distinguishing trunk impairment (i.e. participants who scored zero, one and two on the cTIS-V2) in the stroke group (Portney and Watkins, 2013). The cut-off point was determined using the Youden index (Youden index =sensitivity value + specificity value -1) at the point where both the sensitivity and specificity values were maximized (Fluss et al., 2005). In this study, the cut-off point was the best representative point of the degree of trunk ROM recorded by the Valedo<sup>®</sup> sensors that can distinguish between stroke participants with trunk impairment (scored zero on cTIS tasks) and those without trunk impairment (scored one, or two on cTIS tasks). The AUC is a

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summary measure of the accuracy of a quantitative diagnostic test. The maximum AUC is the best cut-off score. The AUC values were interpreted according to an arbitrary guideline; one could distinguish between no ( $AUC < 0.5$ ), poor ( $0.5 \leq AUC < 0.7$ ), acceptable ( $0.7 \leq AUC < 0.8$ ), excellent ( $0.8 \leq AUC < 0.9$ ) and outstanding ( $AUC > 0.9$ ) discriminant ability.

### 4.7.2 Reliability

The normality of the data were tested using Shapiro-Wilk test. If the data was normally distributed: for test–retest and between-session reliability, measurements were tested using the [ICC 2,1] with 95% CI; for inter-rater reliability, the [ICC 2,1] with 95% CI (Bruton et al., 2000). The SEM was calculated using the following equation (Portney and Watkins, 2013):

$$SEM = SD \times (\sqrt{1 - ICC}).$$

To interpret the reliability result of the ICCs, the following scale suggested by Fleiss (2011) was used:  $ICC \geq 0.75$ , excellent reliability;  $ICC = 0.4 - 0.74$ , good to fair reliability; and  $ICC < 0.4$ , poor reliability.

If the data were not normally distributed, the Bland and Altman plots (B&A plots) was used to describe the inter-rater and inter-rater reliability (Bland and Altman, 1986). However, the B&A plots were used in this study as an additional reliability analysis to visually observe the level of reliability and to detect any outliers.

## 4.8 Results

The following sections present the participants' characteristics, concurrent validity and intra-rater and inter-rater reliability results.

### 4.8.1 Participant Characteristics

Twenty adults with chronic stroke with resulting trunk impairment (mild to severe) and 20 aged-matched healthy controls were recruited. The participants' characteristics are presented in Table 4-4.

Table 4-4: Participants' characteristics

Characteristics	Chronic stroke (n=20)	Healthy (n=20)
Age (years)	63.2±11.12 Range: 44–79	62.75±11.67 Range: 41–80
Gender		
Male	13	10
Female	7	10
Hand dominance		
Right	17	16
Left	3	4
Affected upper limb		
Right	5	N/A
Left	15	
Trunk Impairment Scale (TIS)	15.65±2.70 Range 10–23	22.8±0.62 Range: 2–23
Number of participants with TIS:		
≤10 (poor trunk control)	1	0
11–19 (fair trunk control)	18	0
≥20 (good trunk control)	1	20

#### 4.8.2 Validity

The following section summarizes the results of the concurrent validity of iTIS considering cTIS as the gold standard. The results showed the correlation between cTIS and iTIS using Spearman correlation. Then, the differences between groups, including the difference between stroke and healthy participants, and the differences between stroke patients who scored 0, 1 and 2 in cTIS-V2 are presented. In the last section, the results of ROC curve analysis to identify the cut-off score for each iTIS parameter that discriminated between stroke patients who scored 0, 1, and 2 for each task and their sensitivity and specificity are presented.

### **A. Concurrent Validity**

Significant moderate correlations (negative) were observed between the cTIS-V2 score and iTIS parameters of the dynamic subscale: lateral flexion to affected side in tasks 1 and 2 ( $r = -0.59$ ,  $p < 0.006$ ) and lateral flexion to the unaffected side in tasks 4 and 5 ( $r = -0.52$ ,  $p < 0.02$ ) (Table 4-5). Furthermore, significant moderate correlations were observed between the cTIS-V2 score and lateral flexion to the affected side in task 7 ( $r = 0.52$ ,  $p < 0.01$ ) and lateral flexion to the unaffected side in task 9 ( $r = .47$ ,  $p < 0.03$ ). The remaining parameters for tasks 3, 6, 8 and 10 in the dynamic subscale, which all assessed compensatory movement, resulted in a very low, non-significant correlation ( $r \leq 0.26$ ).

For the coordination subscale, significant high correlations were observed between the cTIS-V2 score and two variables, including symmetry in task 2 (rotate upper trunk six times within 6 second) ( $r = 0.71$ ,  $p < 0.001$ ) and the total number of rotations in task 3 (rotate lower trunk six times) ( $r = 0.73$ ,  $p < 0.001$ ) (Table 4-6). Furthermore, significant moderate correlations were shown between the cTIS-V2 scores and the following iTIS parameters: symmetry in task 1 (rotate upper trunk six times); total number of rotations in tasks 1, 2 and 3; and rotation to the affected side in task 1 ( $r \leq 0.64$ ). Following a conservative Bonferroni adjustment three associations were statistically significant at  $p \leq 0.006$ , namely symmetry in tasks 2 and 4 and the total number of rotations in task 2. The rotation to the unaffected side recorded low and very low correlations using the cTIS-V2 scores ( $r \leq 0.34$ ) in all tasks.

Table 4-5: Spearman rank correlation of iTIS data with cTIS-V2 score (dynamic subscale) in the stroke group

CTIS- V2 tasks	Parameter of interest	cTIS-V2 score=0 Mean±SD	cTIS-V2 score= 1 Mean±SD	R value	Sig.
Dynamic Sitting Balance Subscale					
1, 2 - Touch the bed with the hemiplegic elbow	ROM of lateral flexion to affected side (degrees)	29.21±5.18	21.70±7.18	-0.59**	0.006
3 - Touch the bed with the hemiplegic elbow without compensation	ROM of lateral flexion to affected side (degrees)	32.41±10.36	25.21±3.61	-0.26	0.45
4, 5 - Touch the bed with the unaffected elbow	ROM of lateral flexion to unaffected side (degrees)	35.82±4.98	29.75±5.95	-0.52*	0.02
6 - Touch the bed with the unaffected elbow without compensation	ROM of lateral flexion to unaffected side (degrees)	36.31±8.59	32.41±5.30	-0.24	0.41
7 - Lift pelvis from bed on the hemiplegic side	ROM of lateral flexion to unaffected side (degrees)	13.74±3.5	21.46±4.9	0.52*	0.01
8 - Lift pelvis from bed on the hemiplegic side without compensation	ROM of lateral flexion to affected side (degrees)	18.92±6.96	21.04±4.65	0.23	0.33
9 - Lift pelvis from bed on the unaffected side	ROM of lateral flexion to unaffected side (degrees)	15.29±2.60	18.42±3.24	0.47*	0.03
10 - Lift pelvis from bed on the unaffected side without compensation	ROM of lateral flexion to unaffected side (degrees)	17.81±2.20	17.49±4.04	-0.10	0.67

r value: correlation coefficient; Sig.: significance level

\*\*Correlation is significant at the 0.01 level , \*Correlation is significant at the 0.05 level

Table 4-6: Spearman rank correlation of iTIS data with cTIS-V2 score (coordination subscale) in stroke group

Coordination subscale						
cTIS- V2 tasks	Parameter of interest	cTIS-V2 score=0 Mean±SD	cTIS-V2 score=1 Mean±SD	cTIS-V2 score=2 Mean±SD	R value	Sig.
1-Rotate upper trunk six times	Symmetry (%)	84.86±14.40	78.46±18.9	94.51±3.61	0.54*	0.02
	ROM of average rotation to affected side (degrees)	17.76±9.00	21.45±9.43	28.01±4.21	0.57**	0.01
	ROM of average rotation to unaffected side (degrees)	26.54±19.73	15.65±7.80	25.49±4.20	0.32	0.17
	Total number of rotations	5±0	6±0	6±0	0.59**	0.007
2 - Repeat Item 1 within 6 seconds	Symmetry (%)	78.94±18.24	97.61±1.29		0.71**	0.001
	ROM of average rotation to affected side (degrees)	20.71±12.04	26.53±4.72		0.34	0.14
	ROM of average rotation to unaffected side (degrees)	18.67±11.91	26.07±3.79		0.32	0.17
	Total number of rotations	5.15±0.68	6±0		0.64**	0.002
3 -Rotate lower trunk six times	Symmetry (%)	69.42±16.52	74.36±20.57	85.89±8.80	0.28	0.24
	ROM of average rotation to affected side (degrees)	9.22±6.75	9.01±4.48	7.46±3.50	-0.03	0.87
	ROM of average rotation to unaffected side (degrees)	7.20±4.19	8.51±4.29	6.87±.45	0.02	0.92
	Total number of rotations	5.20±0.45	6±0	6±0	0.74**	0.001
4 - Repeat Item 3 within 6 seconds	Symmetry (%)	77.20±18.98	88.94±11.02		0.37	0.11
	ROM of average rotation to affected side (degrees)	9.18±4.98	8.08±4.88		-0.14	0.55
	ROM of average rotation to unaffected side (degrees)	7.39±4.48	9.21±4.66		0.20	0.39
	Total number of rotations	5.53±0.51	6±0		0.46*	0.04

r value: correlation coefficient; Sig.: significance level , \*\*Correlation is significant at the 0.01 level, \*Correlation is significant at the 0.05 level

## B. Differences Between Groups

### 1. Difference Between Stroke Participants and Healthy Age-Matched Participants

The differences in trunk lateral flexion between stroke participants and healthy participants were significantly different ( $p$  range: 0.001–0.05) in seven tasks of the dynamic subscale (tasks 1, 2, 3, 6, 8, 9 and 10) (Table 4-7). The remaining three tasks (tasks 4, 5 and 7) showed a non-significant difference between the groups ( $p > 0.05$ ). In the coordination subscale, the average rotations to both the affected and unaffected sides were significantly different between stroke and healthy participants for all tasks ( $p$  range: 0.001–0.05). However, the symmetry parameter indicated a non-significant difference between the groups for all tasks ( $p > 0.05$ ). For the last parameter, the total number of rotations, there was a significant difference between the stroke and healthy participants for only two tasks (tasks 2 and 4;  $p < 0.05$ ).

The dot plots (Figure 4-3) showed an overlap in ROM between stroke and healthy groups in all the dynamic subscale parameters. In the healthy group, the ROM for all dynamic subscale parameters was higher than in the stroke group, suggesting that the impairment being measured was different between stroke and healthy participants.

In terms of the co-ordination subscale, the dot plots (Figure 4-3, Figure 4-4 and Figure 4-5) showed an overlap in symmetry between the stroke and healthy groups for all tasks. The number of rotations for tasks 2 and 4 were clearly different between the stroke and healthy groups; the healthy participants had a higher number of rotations. For average rotation to the non-dominant/affected and dominant/unaffected side, the dot plots clearly show that the healthy participants had greater ROM when the non-dominant side moved forward first during forward and backward rotation.

Table 4-7: Differences in iTIS parameters between stroke and healthy participants

cTIS tasks	Parameter of interest	Stroke Mean±SD	Healthy Mean±SD	MD±SD	95% CI for MD	P value
<b>Dynamic Sitting Balance Subscale</b>						
Task 1	ROM of lateral flexion to non-dominant/affected side (degrees)	24.66±7.75	37.23±5.70	-12.57±7.49	-16.93 – -8.21	0.000*
Task 2	ROM of lateral flexion to non-dominant/affected side (degrees)	21.51±11.22	34±10.89	12.49±13.95	-21.21 – -3.75	0.007*
Task 3	ROM of lateral flexion to non-dominant/affected side (degrees)	28.78±7.7	35.39±8.09	6.61±10.49	-13.18 – -0.037	0.05*
Task 4	ROM of lateral flexion to dominant/unaffected side (degrees)	34.04±6.62	35.04±7.09	-1±12.8	-5.57–3.57	0.66
Task 5	ROM of lateral flexion to dominant/unaffected side (degrees)	33.21±9.55	34.37±8.26	-1.16±14.25	-7.40–5.10	0.71
Task 6	ROM of lateral flexion to dominant/unaffected side (degrees)	27.01±9.23	34.87±8.43	7.86±12.71	-14.08 – -1.63	0.01*
Task 7	ROM of lateral flexion to dominant/unaffected side (degrees)	20.11±5.54	22.44±5.2	-2.32±8.94	-5.97–1.31	0.20
Task 8	ROM of lateral flexion to dominant/unaffected side (degrees)	19.02±5.51	23.29±6.99	-4.27±9.97	-8.46 – -0.082	0.05*
Task 9	ROM of lateral flexion to non-dominant/affected side (degrees)	16.38±4.41	23.74±6.18	-7.36±7.25	-10.86 – -3.86	0.000*
Task 10	ROM of lateral flexion to non-dominant/affected side (degrees)	16.50±5.02	25.93±6.54	-9.42±8.31	-13.45 – -5.39	0.000*
<b>Coordination Subscale</b>						
Task 1	Symmetry (%)	87.58±13.15	93.75±7.92	-6.17±17.30	-14.08–1.74	0.12
	ROM of average rotation to non-dominant/affected side (degrees)	22.17±6.32	16.86±7.19	5.31±11.06	0.32–10.30	0.04*
	ROM of average rotation to dominant/unaffected side (degrees)	20.92±8.70	30.68±6.86	-9.76±10.83	-15.50 – -4.01	0.002*
	Total number of rotations	5.93±0.25	6±0.00	-0.06±0.31	-0.19–0.06	0.310

Task 2	Symmetry (%)	86.34±13.16	91.72±5.90	-5.37±13.27	-12.41–1.66	0.129
	ROM of average rotation to non-dominant/affected side (degrees)	32.59±7.18	22.70±8.69	9.88±10.74	4.15–15.62	0.001*
	ROM of average rotation to dominant/unaffected side (degrees)	21.85±8.28	29.15±7.91	-7.30±10.53	-13.06 – -1.54	0.015*
	Total number of rotations	5.60±0.73	6±0.00	-0.40±0.76	-0.75 – -0.046	0.03*
Task 3	Symmetry (%)	78.42±17.92	87.16±9.84	-8.74±25.58	-19.36–1.87	0.10
	ROM of average rotation to non-dominant/affected side (degrees)	7.43±3.83	14.95±7.52	-7.51±9.49	-12.37 – -2.64	0.004*
	ROM of average rotation to dominant/unaffected side (degrees)	7.89±2.73	13.11±5.55	-5.21±5.95	-8.79 – -1.64	0.006*
	Total number of rotations	5.83±0.38	6±0.00	-0.16±0.30	-0.35–0.02	0.08
Task 4	Symmetry (%)	80.89±18.03	87±11.34	-6.11±21.50	-16.98–4.76	0.26
	ROM of average rotation to non-dominant/affected side (degrees)	9.71±4.78	15.38±5.04	-5.67±9.51	-9.22 – -2.12	0.003*
	ROM of average rotation to dominant/unaffected side (degrees)	8.57±4.60	13.27±4.61	-4.69±7.21	-8.03 – -1.36	0.007*
	Total number of rotations	5.75±0.44	6±0.00	-0.25±0.74	-0.47 – -0.021	0.033*

\* $p \leq 0.05$

MD=mean difference

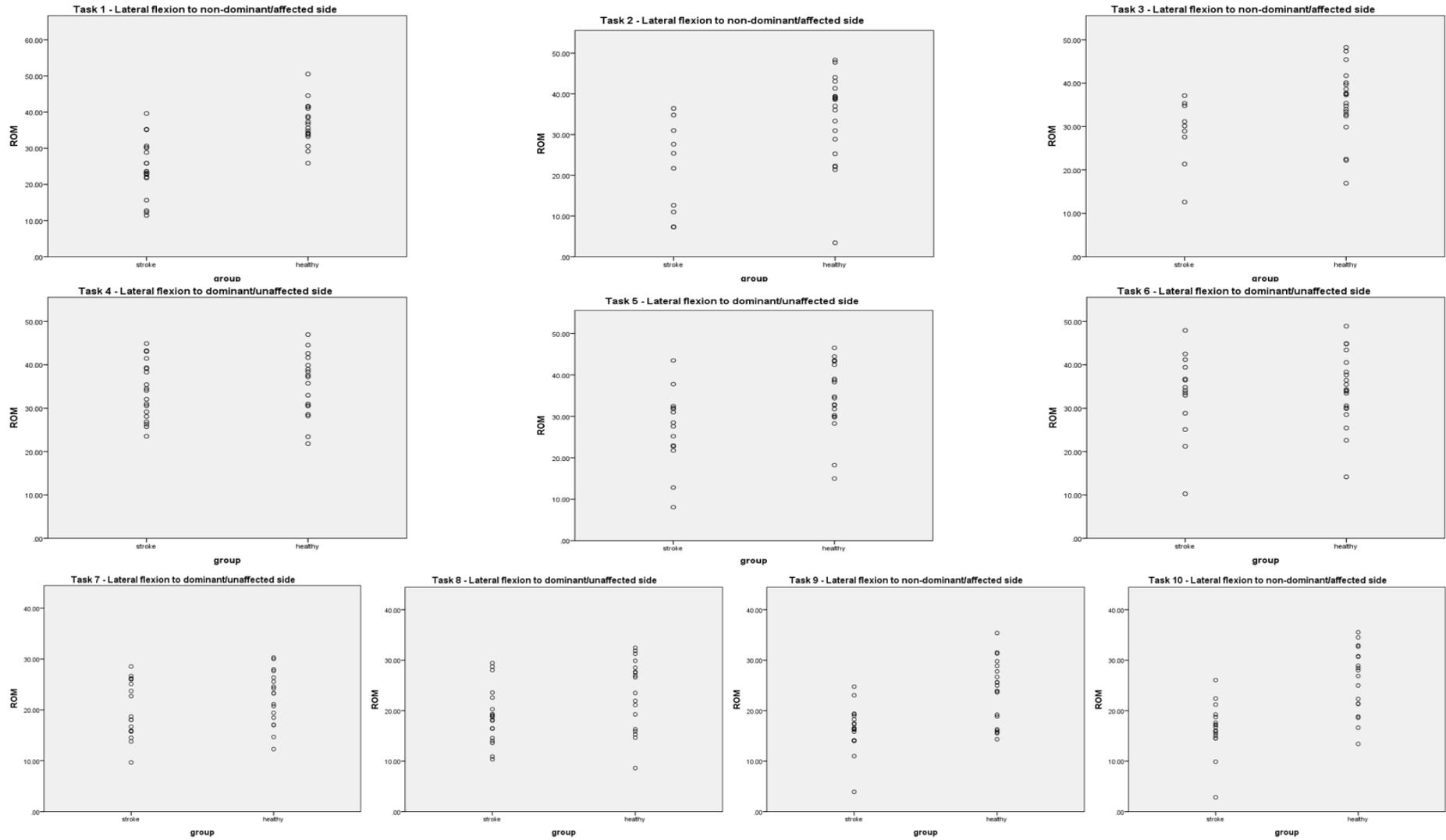


Figure 4-3: Dot plots of dynamic subscale parameters for stroke and healthy participants

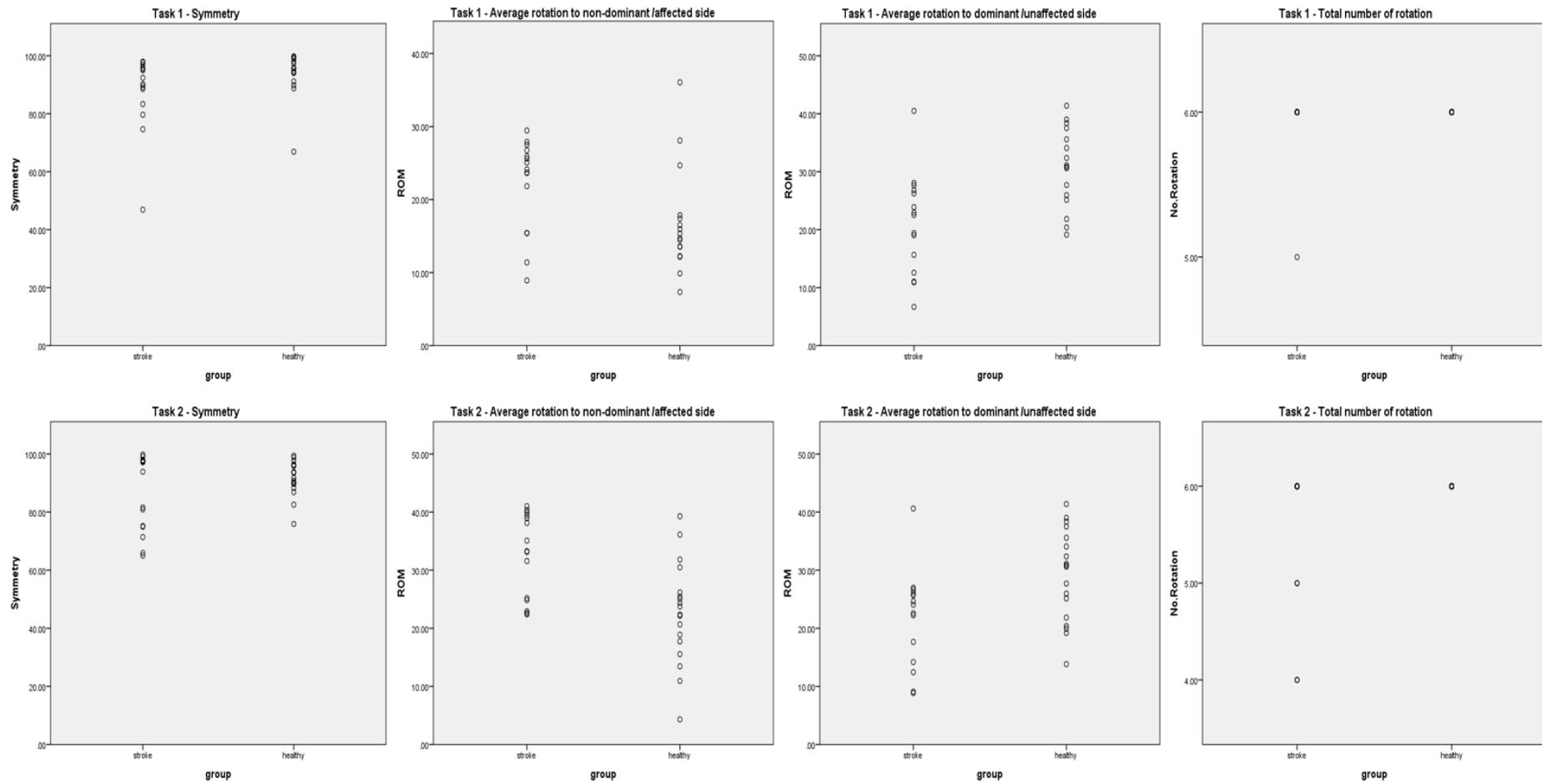


Figure 4-4: Dot plots of co-ordination subscale (tasks 1 and 2) parameters for stroke and healthy participants

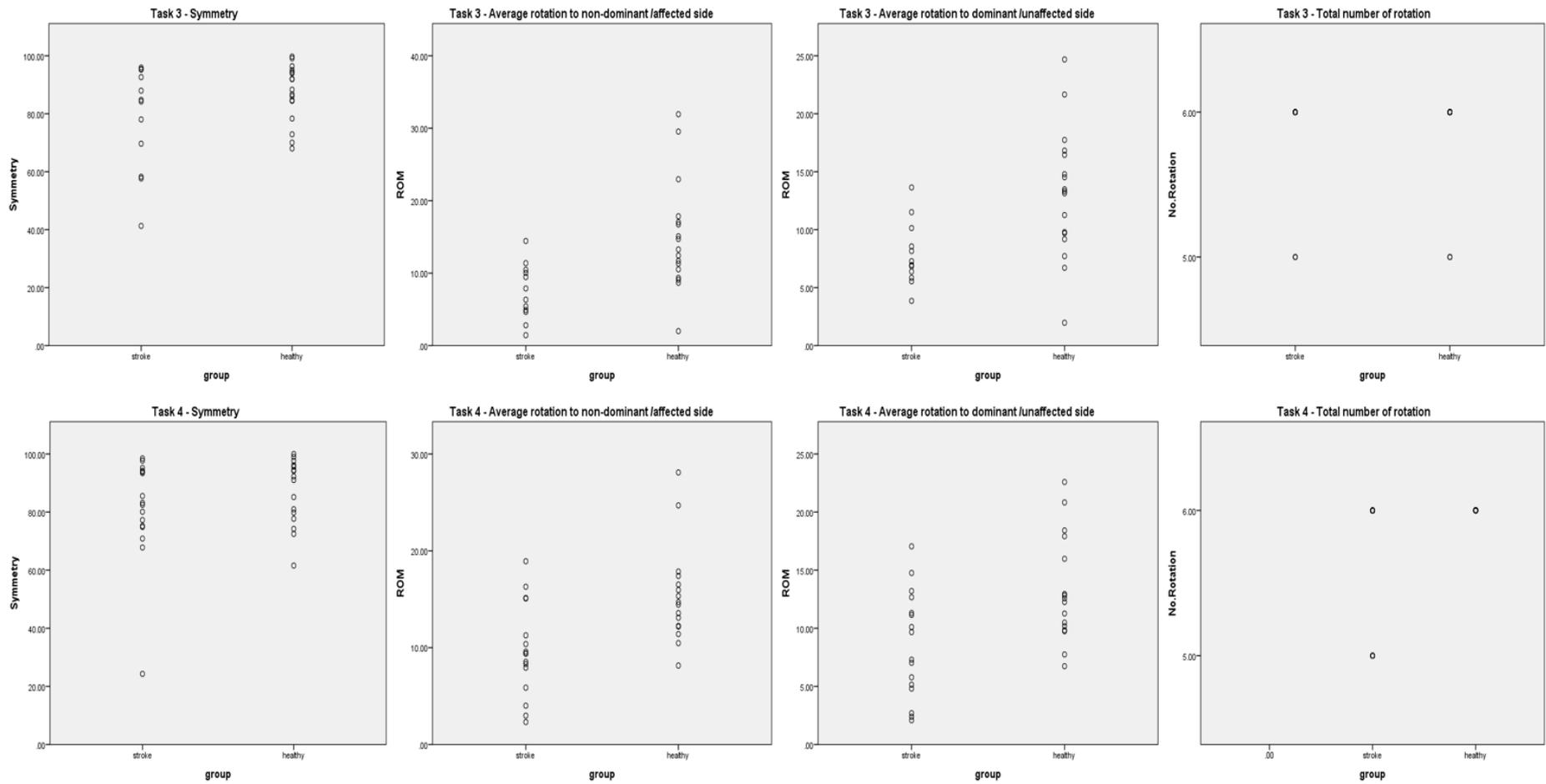


Figure 4-5: Dot plots of co-ordination subscale (tasks 3 and 4) parameters for stroke and healthy participants

## **2. Difference between Stroke Participants Who Scored Two and One on the cTIS and Stroke Participants Who Scored Zero**

In the dynamic subscale, the stroke participants who scored one showed a lower trunk ROM during tasks 1–6 and a higher trunk ROM during tasks 7–10 compared to stroke participants who scored zero, as presented in Table 4-8. The differences in trunk lateral flexion between stroke participants who scored one and those who scored zero were significantly different ( $p \leq 0.05$ ) for four tasks (tasks 1, 4, 7 and 9). The remaining tasks (tasks 3, 6, 8 and 10) showed a non-significant difference between groups ( $p > 0.05$ ). In the coordination subscale, the average rotation to both the affected and unaffected sides showed a non-significant difference between groups for all tasks ( $p > 0.05$ ) except task 1. In task 1, only the average rotation to the unaffected side was significantly different between groups ( $p=0.002$ ). In contrast, the total number of rotations parameter showed a high significant difference between the groups for all tasks ( $p$  range: 0.05–0.001). For the symmetry parameter, there was a significant difference between stroke groups for only two tasks (tasks 1 and 2;  $p < 0.05$ ).

Table 4-8: Differences in iTIS parameters between stroke participants scoring zero, one and two on the clinical TIS

TIS-V2 tasks	Parameter of interest	cTIS score=0 Mean±SD	cTIS score=1 Mean±SD	MD±SD	95% CI for MD	P value
Dynamic Sitting Balance Subscale						
1, 2 - Touch the bed or table with the hemiplegic elbow	ROM of lateral flexion to affected side (degrees)	29.21±5.18	21.70±7.18	7.51±2.80	1.62–13.39	0.01*
3 - Touch the bed or table with the hemiplegic elbow without compensation	ROM of lateral flexion to affected side (degrees)	32.41±10.36	25.21±3.61	7.19±6.31	-7.36–21.76	0.28
4, 5 - Touch the bed or table with the unaffected elbow	ROM of lateral flexion to unaffected side (degrees)	35.82±4.98	29.75±5.95	6.07±2.65	0.42–11.72	0.03*
6 - Touch the bed or table with the unaffected elbow without compensation	ROM of lateral flexion to unaffected side (degrees)	36.31±8.59	32.41±5.30	3.89±3.89	-4.67–12.46	0.33
7 - Lift pelvis from bed or table on the hemiplegic side	ROM of lateral flexion to affected side (degrees)	13.74±3.5	21.46±4.9	-7.71±3.02	-14.07 – -1.36	0.02*
8 - Lift pelvis from bed or table on the hemiplegic side without compensation	ROM of lateral flexion to affected side (degrees)	18.92±6.96	21.04±4.65	-2.12±2.59	-7.57–3.32	0.42

9 - Lift pelvis from bed or table on the unaffected side	ROM of lateral flexion to unaffected side (degrees)	15.29±2.60	18.42±3.24	-3.12 ±1.44	-6.17 – -0.07	0.04*
10 - Lift pelvis from bed or table on the unaffected side without compensation	ROM of lateral flexion to unaffected side (degrees)	17.81±2.20	17.49±4.04	0.32±1.93	-3.76–4.41	0.86
Coordination Subscale						
Tasks 2 and 4 (independent samples t-test)						
2 - Repeat Item 1 within 6 seconds	Symmetry (%)	78.94±18.24	97.61±1.29	-18.66±6.99	-33.35 – -3.97	0.01*
	ROM of average rotation to non-dominant/affected side (degrees)	20.71±12.04	26.53±4.72	-5.81±4.78	-15.86–4.23	0.24
	ROM of average rotation to dominant/unaffected side (degrees)	18.67±11.91	26.07±3.79	-7.40±4.67	-17.22–2.41	0.13
	Total number of rotations	5.15±0.68	6±0	-0.84±0.26	-1.40 – -0.29	0.001*
4 - Repeat Item 3 within 6 seconds	Symmetry (%)	77.20±18.98	88.94±11.02	-11.74±8.40	-29.47–5.99	0.18
	ROM of average rotation to non-dominant/affected side (degrees)	9.18±4.98	8.08±4.88	1.09±2.44	-4.06–6.25	0.65
	ROM of average rotation to dominant/unaffected side (degrees)	7.39±4.48	9.21±4.66	-1.82±2.23	-6.54–2.90	0.42
	Total number of rotations	5.53±0.51	6±0	-0.46±0.21	-0.91 – -0.007	0.04*
Tasks 1 and 3 (one-way ANOVA test)						
cTIS- V2 tasks	Parameter of interest	cTIS score=0 Mean±SD	cTIS score=1 Mean±SD	cTIS score=2 Mean±SD		P value

1 - Rotate upper trunk six times	Symmetry (%)	84.86±14.40	78.46±18.99	94.51±3.61	0.04*
	ROM of average rotation to non-dominant/affected side (degrees)	17.76±9.00	21.45±9.43	28.01±4.21	0.31
	ROM of average rotation to dominant/unaffected side (degrees)	26.54±19.73	15.65±7.80	25.49±4.20	0.002*
	Total number of rotations	5±0	6±0	6±0	0.001
3 - Rotate lower trunk six times	Symmetry (%)	69.42±16.52	74.36±20.57	85.89±8.80	0.48
	ROM of average rotation to non-dominant/affected side (degrees)	9.22±6.75	9.01±4.48	7.46±3.50	0.87
	ROM of average rotation to dominant/unaffected side (degrees)	7.20±4.19	8.51±4.29	6.87±.45	0.74
	Total number of rotations	5.20±0.45	6±0	6±0	0.001

\*p ≤ 0.05

\*\*p ≤ 0.01

### C. ROC Curve Analysis

Table 4-9 summarized the results of the ROC curve analysis, including the AUCs and the identified cut-off score for each iTIS parameter that discriminated between stroke participants who scored zero, one and two for each task, along with their sensitivity and specificity.

In the dynamic subscale tasks, one parameter (lateral flexion to the affected side in task 7) was considered a highly accurate test (AUC=0.92), indicating outstanding discriminant ability to distinguish between people who scored zero and people who scored one on the cTIS-V2 tasks (Figure 4-6). Three out of eight parameters (lateral flexion to affected side in task 1, lateral flexion to the unaffected side in both tasks 4 and 9) showed an AUC range of 0.78–0.84, indicating acceptable to excellent discriminant ability. The remaining four parameters were less accurate, with an AUC ranging between 0.43 and 0.67, indicating no or poor discriminant ability.

In the coordination subscale, the symmetry parameter in task 2 demonstrated an outstanding discriminant ability (AUC=0.93) and acceptable to excellent discriminative ability (AUC=0.70–0.87) in the remaining tasks (tasks 1, 3 and 4) (Figure 4-7). For the average rotation to the affected side parameter, the AUC for tasks 1 and 2 (0.85 and 0.70, respectively) indicated excellent and acceptable discriminant ability. In contrast, the average rotations to the affected side parameter in tasks 3 and 4 had no discriminant ability (AUC=0.40 and 0.41, respectively). For the average rotation to the unaffected side parameter, the AUC in tasks 1 and 2 (0.77 and 0.70, respectively) showed acceptable discriminant ability, while tasks 3 and 4 were found to have no discriminant ability. The last parameter was the total number of rotations, which was found to have poor discriminant ability in tasks 2 and 4 (AUC  $\leq$ 0.63) and acceptable to excellent discriminant ability in tasks 1 and 3 (AUC  $\geq$ 0.73).

Table 4-9: Discriminant ability of iTIS parameters in distinguishing between stroke participants with impairment (scored zero on cTIS-V2 tasks) and those without trunk impairment (scored one or two on cTIS-V2 tasks)

TIS-V2 tasks	iTIS Parameter	AUC	Std. Error	Sig.	95% CI	Cut-off point (degrees) to be scored zero in cTIS	Sensitivity	Specificity
Dynamic Sitting Balance subscale								
1, 2 - Touch the bed or table with the hemiplegic elbow	ROM of lateral flexion to affected side (degrees)	0.84	0.09	0.01	0.64–1	≥23.5	0.90	0.80
3 - Touch the bed or table with the hemiplegic elbow without compensation	ROM of lateral flexion to affected side (degrees)	0.67	0.17	0.42	0.32–1	≥26.8	0.71	0.67
4, 5 - Touch the bed or table with the unaffected elbow	ROM of lateral flexion to unaffected side (degrees)	0.80	0.12	0.03	0.57–1	≥30.7	0.88	0.75
6 - Touch the bed or table with the unaffected elbow without compensation	ROM of lateral flexion to unaffected side (degrees)	0.64	0.17	0.39	0.30–98	≥33.8	0.66	0.58
7 - Lift pelvis from bed or table on the hemiplegic side	ROM of lateral flexion to affected side (degrees)	0.92	0.06	0.02	0.79–1	≤15.8	1	0.88
8 - Lift pelvis from bed or table at the hemiplegic side without compensation	ROM of lateral flexion to affected side (degrees)	0.63	0.15	0.32	0.33–0.94	≤23.2	0.71	0.46

9 - Lift pelvis from bed or table on the unaffected side	ROM of lateral flexion to unaffected side (degrees)	0.78	0.11	0.04	0.56–1	≤16.5	0.85	0.75
10 - Lift pelvis from bed or table on the unaffected side without compensation	ROM of lateral flexion to unaffected side (degrees)	0.43	0.14	0.65	0.14–0.71	≤18.9	0.80	0.30
Coordination subscale								
1 - Rotate upper trunk six times	Symmetry (%)	0.87	0.08	0.01	0.70–1	90	0.85	0.66
	ROM of average rotation to non-dominant/affected side (degrees)	0.85	0.09	0.01	0.66–1	24.5	0.85	0.75
	ROM of average rotation to dominant/unaffected side (degrees)	0.77	0.11	0.05	0.56–0.99	23.4	0.71	0.75
	Total number of rotations	0.58	0.13	0.55	0.32–0.85	5.5	1	0.17
2 - Repeat Item 1 within 6 seconds	Symmetry (%)	0.93	0.05	0.002	0.82–1	96.7	0.85	0.84
	ROM of average rotation to non-dominant/affected side (degrees)	0.70	0.11	0.14	0.47–0.93	24.7	0.71	0.69
	ROM of average rotation to dominant/unaffected side (degrees)	0.70	0.12	0.16	0.45–0.93	23.11	0.85	0.61
	Total number of rotations	0.84	0.08	0.01	0.67–1	5.5	1	0.69

3 - Rotate lower trunk six times	Symmetry (%)	0.70	0.14	0.31	0.41–0.96	76.6	1	0.56
	ROM of average rotation to non-dominant/affected side (degrees)	0.40	0.17	0.58	0.05–0.74	5.8	0.66	0.31
	ROM of average rotation to dominant/unaffected side (degrees)	0.42	0.12	0.65	0.18–0.66	6.1	1	0.37
	Total number of rotations	0.63	0.16	0.50	0.32–0.93	5.5	1	0.25
4 - Repeat Item 3 within 6 seconds	Symmetry (%)	0.73	0.12	0.11	0.48–0.98	80.8	0.83	0.69
	ROM of average rotation to non-dominant/affected side (degrees)	0.41	0.14	0.53	0.12–0.69	6.9	0.66	0.38
	ROM of average rotation to dominant/unaffected side (degrees)	0.62	0.14	0.38	0.34–0.91	7	0.83	0.61
	Total number of rotations	0.73	0.11	0.11	0.50–0.95	5.5	1	0.46

AUC: area under curve; CI: confidence interval

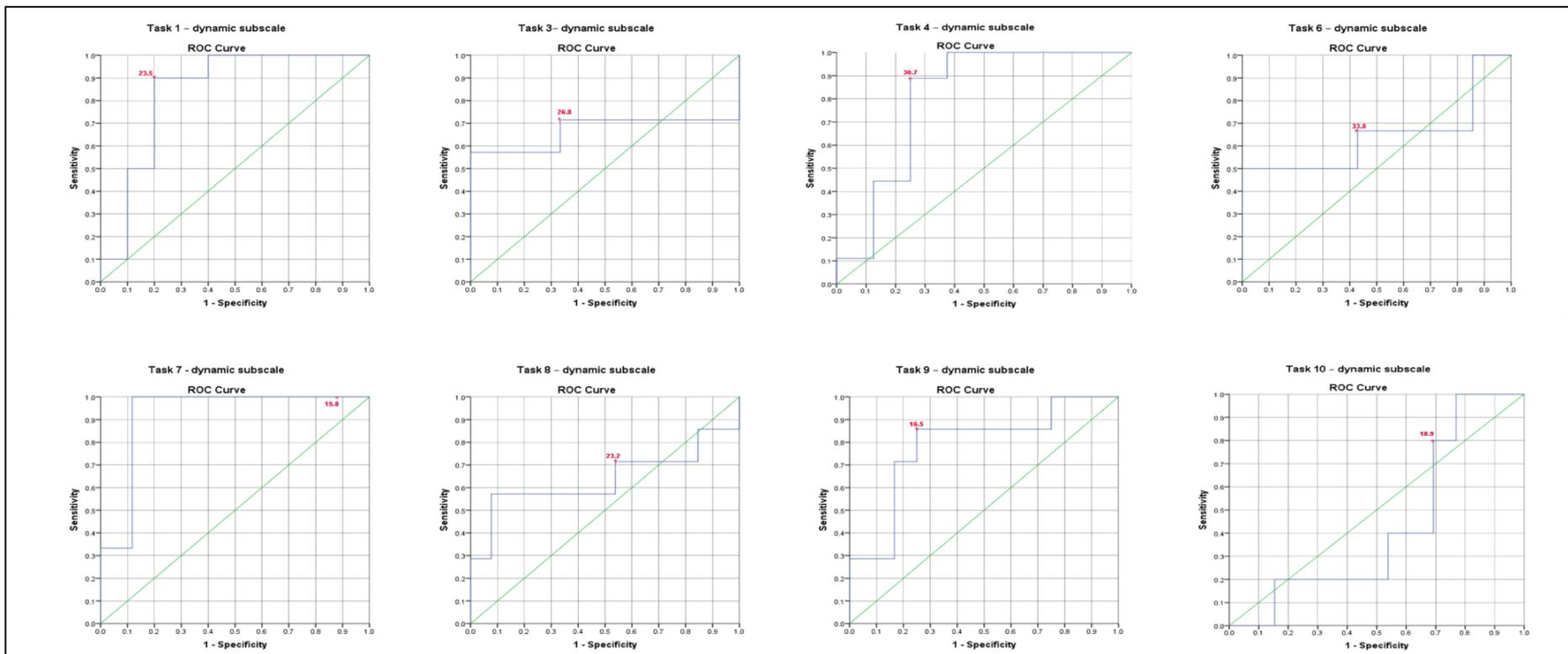


Figure 4-6: Receiver operator curves (ROC) of the iTIS dynamic subscale parameters to distinguish between stroke participants with impairment (scored zero on cTIS-V2 tasks) and those without trunk impairment (scored one, or two on cTIS-V2 tasks)

\* indicates cut-off points

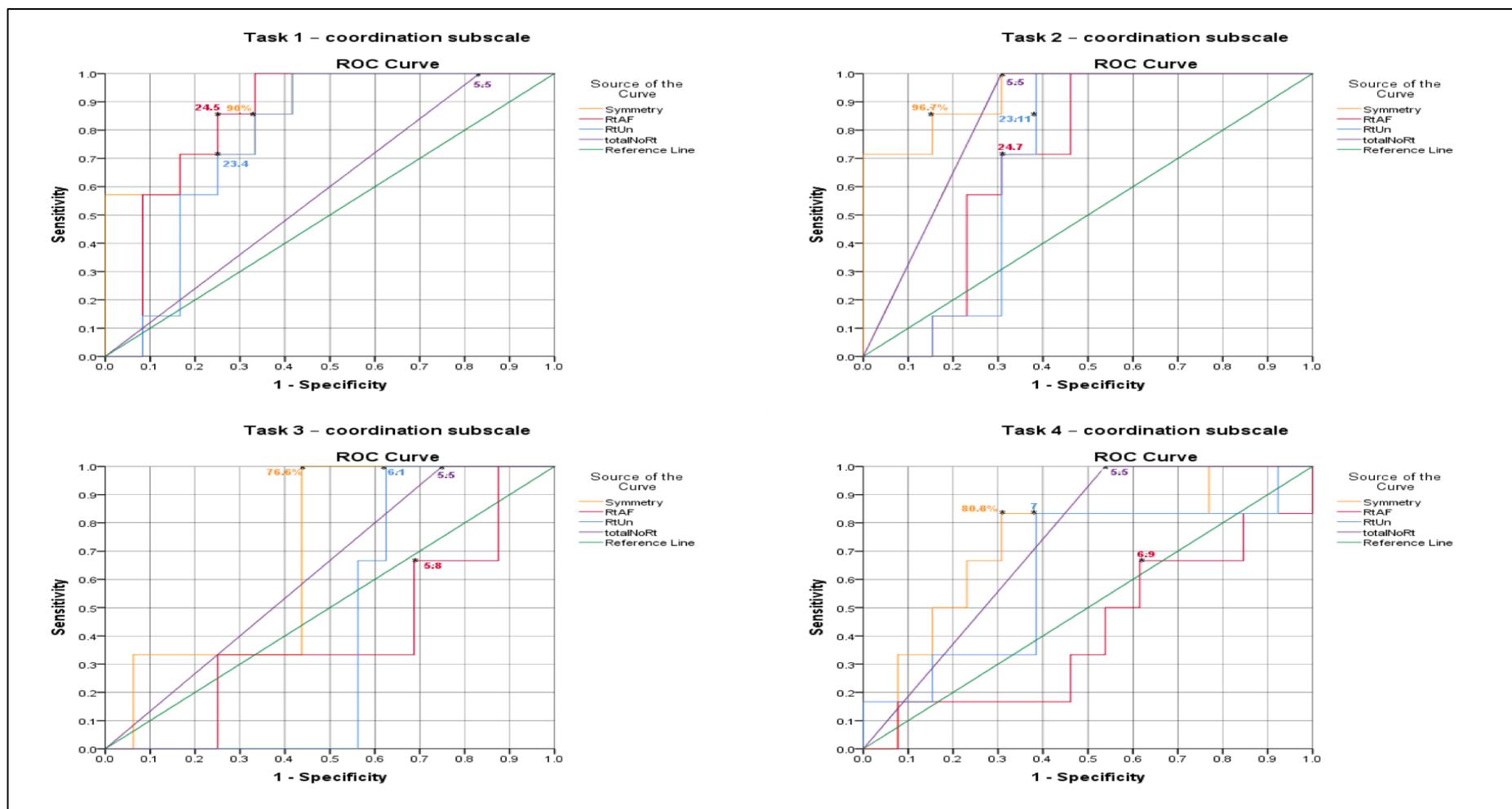


Figure 4-7: Receiver operator curves (ROC) of the iTIS coordination subscale parameters to distinguish between stroke participants with impairment (scored zero on cTIS-V2 tasks) and those without trunk impairment (scored one, or two on cTIS-V2 tasks)

\* indicates cut-off points

### 4.8.3 Reliability

The following section on reliability summarizes the results of the intra-rater reliability within and between two sessions and inter-rater reliability. The results from the dynamic subscale followed by the co-ordination subscale will be considered first for the healthy participants and then for the stroke participants.

#### A. Intra-rater (Within-session)

For the healthy participants, across the dynamic sitting balance subscale, all iTIS parameters (except tasks 7 and 9) demonstrated excellent within-session reliability with an ICC  $\geq 0.75$ . Furthermore, the SEM for those tasks was relatively low (SEM  $\leq 2.79$ ), demonstrating low variability in a test caused by measurement error. For tasks 7 and 9, the iTIS parameters showed good reliability with ICC=0.74 and SEM  $\leq 1.43$ . In addition, the CI for all dynamic subscales did not include zero value, indicating statistically significant reliability. Across the co-ordination subscale, the symmetry in task 3 showed excellent reliability with an ICC=0.78. All other iTIS parameters showed good to fair reliability with an ICC between 0.47 and 0.70 (Table 4-10).

For the stroke group, across the dynamic sitting balance subscale the same results were demonstrated (except for task 8) with an ICC  $\geq 0.75$  and SEM  $\leq 2.75$ . For task 8, the iTIS parameter showed good reliability with ICC=0.74 and SEM=2.19. In addition, all CIs for dynamic subscale tasks did not include a value of zero, indicating significant reliability. Across the co-ordination subscale, the average rotation to the affected side parameter showed excellent reliability in all tasks with an ICC  $\geq 0.78$ , while the symmetry showed good to fair reliability with an ICC of 0.40–0.60 for tasks 2, 3 and 4. The only parameter that demonstrated poor reliability was the symmetry for task 1 in the co-ordination subscale (Table 4-11).

Table 4-10: Intra-rater reliability within the same session (healthy group)

cTIS- V2 tasks	Parameter of interest	Healthy (n=20)				
		Mean diff.	SD	ICC1,1	95% CI	SEM
Dynamic Sitting Balance Subscale						
1 - Touch the bed with the non-dominant elbow	ROM of lateral flexion to non-dominant side (degrees)	0.48	2.92	0.86	0.68–0.94	1.09
2 - Repeat item 1	ROM of lateral flexion to non-dominant side (degrees)	2.71	4.21	0.76	0.37–0.91	2.06
3 - Repeat item 1	ROM of lateral flexion to non-dominant side (degrees)	0.98	3.82	0.90	0.76–0.96	1.2
4 - Touch the bed with the dominant elbow	ROM of lateral flexion to dominant side (degrees)	0.16	4.39	0.81	0.58–0.92	1.91
5 - Repeat item 4	ROM of lateral flexion to dominant side (degrees)	0.42	3.87	0.88	0.70–0.95	1.34
6 - Repeat item 4	ROM of lateral flexion to dominant side (degrees)	1.1	5.58	0.75	0.47–0.89	2.79
7- Lift pelvis from bed on the non-dominant side	ROM of lateral flexion to dominant side (degrees)	3.44	2.82	0.74	0.20–0.92	1.43
8 - Lift pelvis from bed on the non-dominant side without compensation	ROM of lateral flexion to dominant side (degrees)	2.3	3.73	0.77	0.42–0.91	1.78
9 - Lift pelvis from bed on the dominant side	ROM of lateral flexion to non-dominant side (degrees)	1.86	2.48	0.74	0.41–0.89	1.26
10 - Lift pelvis from bed on the dominant side without compensation	ROM of lateral flexion to non-dominant side (degrees)	1.13	2.62	0.92	0.79–0.97	0.74
Co-ordination Subscale						

1 - Rotate upper trunk six times	Symmetry (%)	1.49	4.72	0.47	0.02–0.76	3.43
	ROM of average rotation to non-dominant side (degrees)	1.94	7.01	0.67	0.31–0.85	4.02
	ROM of average rotation to dominant side (degrees)	2.96	7.54	0.60	0.22–0.82	4.76
2 - Repeat item 1 within 6 seconds	Symmetry (%)	0.005	5.11	0.52	0.04–0.79	3.54
	ROM of average rotation to non-dominant side (degrees)	2.54	5.71	0.70	0.39–0.87	3.12
	ROM of average rotation to dominant side (degrees)	5.26	7.56	0.60	0.21–0.82	4.78
3 - Rotate lower trunk six times	Symmetry (%)	0.87	3.38	0.78	0.43–0.92	1.58
	ROM of average rotation to non-dominant side (degrees)	1.76	3.14	0.59	0.21–0.81	2.01
	ROM of average rotation to dominant side (degrees)	1.53	3.25	0.69	0.36–0.86	1.8
4 - Repeat item 3 within 6 seconds	Symmetry (%)	4.26	7.82	0.65	0.29–0.84	4.62
	ROM of average rotation to non-dominant side (degrees)	1.99	4.07	0.67	0.33–0.85	2.33
	ROM of average rotation to dominant side (degrees)	1.63	4.7	0.60	0.20–0.81	2.97

Table 4-11: Intra-rater reliability within the same session (stroke group)

cTIS- V2 tasks	Parameter of interest	Stroke (n=20)				
		Mean diff.	SD	ICC1,1	95% CI	SEM
Dynamic Sitting Balance Subscale						
1 - Touch the bed with the hemiplegic elbow	ROM of lateral flexion to affected side (degrees)	0.6	1.68	0.93	0.83–0.97	0.44
2 - Repeat item 1	ROM of lateral flexion to affected side (degrees)	0.52	4.56	0.95	0.81–0.98	1.01
3 - Repeat item 1	ROM of lateral flexion to affected side (degrees)	1.24	0.92	0.97	0.61–0.99	0.15
4 - Touch the bed with the unaffected elbow	ROM of lateral flexion to unaffected side (degrees)	1.61	3.71	0.78	0.50–0.91	1.74
5 - Repeat item 4	ROM of lateral flexion to unaffected side (degrees)	0.65	2.56	0.96	0.84–0.98	0.51
6 - Repeat item 4	ROM of lateral flexion to unaffected side (degrees)	1.01	5.5	0.75	0.22–0.94	2.75
7 - Lift pelvis from bed on the hemiplegic side	ROM of lateral flexion to unaffected side (degrees)	3.74	4.01	0.76	0.48–0.89	1.96
8 - Lift pelvis from bed on the hemiplegic side without compensation	ROM of lateral flexion to affected side (degrees)	0.1	4.31	0.74	0.40–0.90	2.19
9 - Lift pelvis from bed on the unaffected side	ROM of lateral flexion to unaffected side (degrees)	0.21	2.19	0.88	0.72-0.95	0.75
10 - Lift pelvis from bed on the unaffected side without compensation	ROM of lateral flexion to unaffected side (degrees)	2.08	2.18	0.76	0.48–0.90	1.06
Co-ordination Subscale						

1 - Rotate upper trunk six times	Symmetry (%)	0.39	15.45	0.06	-0.50–0.55	3.43
	ROM of average rotation to affected side (degrees)	0.57	5.9	0.80	0.54–0.91	4.02
	ROM of average rotation to unaffected side (degrees)	3.88	8.12	0.39	-.01–0.69	4.76
2 - Repeat item 1 within 6 seconds	Symmetry (%)	1.15	11.69	0.40	-0.09–0.72	3.54
	ROM of average rotation to affected side (degrees)	0.95	6.1	0.80	0.55–0.91	3.12
	ROM of average rotation to unaffected side (degrees)	3.47	5.66	0.5	0.08–0.76	4.78
3 - Rotate lower trunk six times	Symmetry (%)	-1.98	20.89	0.44	-0.07–0.77	1.58
	ROM of average rotation to affected side (degrees)	0.38	3.69	0.78	0.49–0.91	2.01
	ROM of average rotation to unaffected side (degrees)	0.66	3.49	0.71	0.37–0.87	1.8
4 - Repeat item 3 within 6 seconds	Symmetry (%)	-5.58	12.3	0.60	0.17–0.83	4.62
	ROM of average rotation to affected side (degrees)	1.53	3.27	0.79	0.49–0.91	2.33
	ROM of average rotation to unaffected side (degrees)	-0.1	4.26	0.6	0.18–0.80	2.97

## **B. Intra-rater (Between Two Sessions)**

For the healthy participants across the dynamic sitting balance subscale, all iTIS parameters demonstrated excellent between-sessions reliability with an ICC >0.75. The width of the CI for those tasks was relatively narrow ( $CI \leq 0.49$ ) and did not include the value of 0, indicating statistically significant reliability. Moreover, all dynamic subscale tasks had a low SEM of  $\leq 2.21$ , indicating low measurement error. Across the co-ordination subscale, the average rotation to dominant side in task 4 showed excellent reliability with an ICC=0.76. All remaining iTIS parameters showed good to fair reliability with an ICC of 0.45–0.74 except for the symmetry parameter in task 1, which showed poor reliability with an ICC=0.20 (Table 4-12).

For the stroke participants group, the ICCs for the intra-rater reliability of the dynamic sitting balance subscale showed excellent between-sessions reliability with an ICC  $\geq 0.76$  in tasks 1, 4, 5, 6 and 10. The width of the CI for those tasks was relatively narrow ( $CI \leq 0.58$ ) and did not include the value of 0, indicating statistically significant reliability. Moreover, the SEM for the high-reliability tasks was low ( $SEM \leq 1.91$ ), indicating low variability in a test caused by measurement error. The remaining parameters in tasks 2, 3, 7, 8 and 9 showed good reliability with an ICC of 0.60–0.68 (Table 4-13).

Across the coordination subscale, the symmetry showed fair reliability in tasks 2 and 4 ( $ICC \leq 0.50$ ) and poor reliability in tasks 1 and 3 ( $ICC < 0.4$ ). The width of the CI for those tasks was relatively large ( $\geq 0.81$ ) and included 0, indicating non-significant reliability. Furthermore, the SEM of symmetry in these tasks was high and very near to the value of the SD, indicating high variability in a test caused by measurement error. All remaining coordination subscale parameters showed good to fair reliability with an ICC of 0.45–0.72. The results for the minimal detectable change (MDC) showed a relatively small MDC in all parameters except for the symmetry parameters, which revealed a very high value compared to the actual amount of movement, thereby denoting large variability, which is demonstrated by the large SD (Table 4-13).

Table 4-12: Intra-rater reliability between two sessions (healthy group)

cTIS- V2 tasks	Parameter of interest	Healthy (n=20)					
		Mean diff.	SD	ICC1,1	95% CI	SEM	MDC
<b>Dynamic Sitting Balance Subscale</b>							
1 - Touch the bed with the non-dominant elbow	ROM of lateral flexion to non-dominant side (degrees)	0.03	1.76	0.83	0.61–0.93	0.72	2
2 - Repeat item 1	ROM of lateral flexion to non-dominant side (degrees)	0.7	4.49	0.76	0.43–0.90	2.19	6.07
3 - Repeat item 1	ROM of lateral flexion to non-dominant side (degrees)	1.79	4.1	0.86	0.66–0.94	1.53	4.24
4 - Touch the bed with the dominant elbow	ROM of lateral flexion to dominant side (degrees)	0.89	4.72	0.78	0.51–0.90	2.21	6.13
5 - Repeat item 4	ROM of lateral flexion to dominant side (degrees)	0.74	4.3	0.78	0.51–0.90	2.01	5.57
6 - Repeat item 4	ROM of lateral flexion to dominant side (degrees)	0.57	4.45	0.86	0.67–0.94	1.66	4.6
7 - Lift pelvis from bed on the non-dominant side	ROM of lateral flexion to dominant side (degrees)	1.62	3.39	0.77	0.47–0.90	1.62	4.49
8 - Lift pelvis from bed on the non-dominant side without compensation	ROM of lateral flexion to dominant side (degrees)	0.57	4.19	0.77	0.42–0.91	2	5.54
9 - Lift pelvis from bed on the dominant side	ROM of lateral flexion to non-dominant side (degrees)	0.69	2.88	0.82	0.56–0.92	1.22	3.38
10 - Lift pelvis from bed on the dominant side without compensation	ROM of lateral flexion to non-dominant side (degrees)	1.03	3.66	0.84	0.60–0.94	1.46	4.05
<b>Co-ordination Subscale</b>							
1 - Rotate upper trunk six times	Symmetry (%)	3.38	6.49	0.20	-0.26–0.58	5.8	16.08
	ROM of average rotation to non-dominant side (degrees)	1.11	6.02	0.74	0.44–0.88	3.06	8.48

	ROM of average rotation to dominant side (degrees)	-1.83	3.43	0.60	0.21–0.83	2.16	5.99
2 - Repeat item 1 within 6 seconds	Symmetry (%)	-0.58	5.71	0.71	0.37–0.88	3.07	8.51
	ROM of average rotation to non-dominant side (degrees)	1.75	6.18	0.70	0.39–0.86	3.38	9.37
	ROM of average rotation to dominant side (degrees)	0.4	4.37	0.50	0.06–0.75	3.09	8.57
3 - Rotate lower trunk six times	Symmetry (%)	1.24	5.9	0.68	0.28–0.87	3.33	9.23
	ROM of average rotation to non-dominant side (degrees)	1.1	2.09	0.70	0.36–0.86	1.14	3.16
	ROM of average rotation to dominant side (degrees)	2.71	3.85	0.72	0.38–0.88	2.03	5.63
4 - Repeat item 3 within 6 seconds	Symmetry (%)	2.58	8.02	0.45	-0.04–0.76	5.94	16.46
	ROM of average rotation to non-dominant side (degrees)	1.44	3.31	0.65	0.29–0.84	1.95	5.41
	ROM of average rotation to dominant side (degrees)	0.93	3.33	0.76	0.49–0.89	1.63	4.52

Table 4-13: Intra-rater reliability between two sessions (stroke group)

cTIS- V2 tasks	Parameter of interest	Stroke (n=19)					
		Mean diff.	SD	ICC1,1	95% CI	SEM	MDC
<b>Dynamic Sitting Balance Subscale</b>							
1 - Touch the bed with the hemiplegic elbow	ROM of lateral flexion to affected side (degrees)	1.21	2.67	0.95	0.86–0.98	0.59	1.64
2 - Repeat item 1	ROM of lateral flexion to affected side (degrees)	0.98	5.05	0.58	-0.26–0.91	3.27	9.06
3 - Repeat item 1	ROM of lateral flexion to affected side (degrees)	3.95	2.75	0.68	-0.10–0.95	1.55	4.3
4 - Touch the bed with the unaffected elbow	ROM of lateral flexion to unaffected side (degrees)	0.04	2.46	0.78	0.50–0.91	1.15	3.19
5 - Repeat item 4	ROM of lateral flexion to unaffected side (degrees)	1.33	4.51	0.82	0.42–0.95	1.91	5.29
6 - Repeat item 4	ROM of lateral flexion to unaffected side (degrees)	0.42	4.33	0.84	0.38–0.96	1.73	4.8
7 - Lift pelvis from bed on the hemiplegic side	ROM of lateral flexion to unaffected side (degrees)	3.12	4.81	0.60	0.15–0.83	3.04	8.43
8 - Lift pelvis from bed on the hemiplegic side without compensation	ROM of lateral flexion to affected side (degrees)	0.41	5.19	0.66	0.27–0.86	3.02	8.37
9 - Lift pelvis from bed on the unaffected side	ROM of lateral flexion to unaffected side (degrees)	1.08	3.98	0.60	0.13–0.81	2.51	6.96

10 - Lift pelvis from bed on the unaffected side without compensation	ROM of lateral flexion to unaffected side (degrees)	-0.12	2.47	0.80	0.50–0.92	1.1	3.05
Co-ordination Subscale							
1 - Rotate upper trunk six times	Symmetry (%)	-4.61	16.75	0.30	-0.16–0.67	14.01	38.83
	ROM of average rotation to affected side (degrees)	-2.93	5.14	0.62	0.21–0.84	3.16	8.76
	ROM of average rotation to unaffected side (degrees)	2.07	4.69	0.66	0.30–0.85	2.73	7.57
2 - Repeat item 1 within 6 seconds	Symmetry (%)	2.38	10.23	0.50	-0.01–0.80	7.23	20.04
	ROM of average rotation to affected side (degrees)	-1.13	4.33	0.72	0.40–0.88	2.29	6.35
	ROM of average rotation to unaffected side (degrees)	2.5	7.19	0.52	0.09–0.78	4.98	13.8
3 - Rotate lower trunk six times	Symmetry (%)	-6.33	23.92	0.05	-0.42–0.50	23.31	64.61
	ROM of average rotation to affected side (degrees)	1.31	3.9	0.60	0.16–0.83	2.46	6.82
	ROM of average rotation to unaffected side (degrees)	0.6	3.7	0.70	0.35–0.87	2.02	5.6
4 - Repeat item 3 within 6 seconds	Symmetry (%)	-9.89	14.56	0.41	-0.11–0.76	11.18	30.99
	ROM of average rotation to affected side (degrees)	2.35	4.02	0.45	0.02–0.75	2.98	8.26
	ROM of average rotation to unaffected side (degrees)	0.72	4.43	0.65	0.25–0.86	2.62	7.26



### C. Inter-rater (Between Two Raters)

For the healthy participants, across the dynamic sitting balance subscale, most of the iTIS parameters (except tasks 2, 7 and 9) showed an excellent reliability with an ICC  $\geq 0.79$  and low SEM  $\leq 2.8$  indicating low variability resulting from measurement error. For tasks 2, 7 and 9, the iTIS parameters showed good reliability with ICC between 0.63 and 0.74. However, the CI width for the dynamic subscale tasks were relatively wide in task 7 and 8 (CI  $\geq 0.86$ ) indicating non-significant reliability. Across the co-ordination subscale, two parameters that showed an excellent reliability were symmetry in task 1 with an ICC=0.81 and average rotation to non-dominant side in task 2 with an ICC=0.76. Both tasks also demonstrate a low SEM  $\leq 3.01$  and narrow CI  $\leq 0.42$ . All remaining iTIS parameters showed a good to fair reliability with an ICC between 0.48 and 0.78 (Table 4-14).

For the stroke group, the same results were found for the inter-rater reliability of the dynamic sitting balance subscale. The ICCs showed excellent reliability between assessors, with an ICC  $\geq 0.76$  for all tasks except tasks 7, 8 and 10 (Table 4-15). For tasks 7, 8 and 10, the iTIS parameters showed good between-assessor reliability, with an ICC between 0.59 and 0.70. The CI for those tasks (tasks 7, 8 and 10) were relatively wider than the CI measured for inter-rater reliability (CI for tasks 7, 8 and 10  $\geq 0.57$ ), but did not include the value of 0, indicating statistically significant reliability. Furthermore, the SEM for these tasks was relatively high (SEM  $\geq 1.62$ ), denoting moderate variability caused by measurement error.

Across the coordination subscale, two parameters demonstrated excellent reliability: the average rotation to the unaffected side in task 1, which had an ICC=0.76, and the average rotation to the affected side in task 2, which had an ICC=0.78. All the remaining iTIS parameters showed a good to fair reliability with an ICC between 0.48 and 0.69. The CI width was high and included the value of 0 in the low-reliability parameters such as symmetry in task 3, indicating non-significant reliability, while the symmetry in task 1 showed moderate reliability (ICC=0.69), had a narrower CI (0.72) and did not include zero, indicating statistically significant reliability (Table 6-15).

Table 4-14: Inter-rater reliability (healthy group)

cTIS- V2 tasks	Parameter of interest	Healthy (n=20)				
		Mean diff.	SD	ICC1,1	95% CI	SEM
<b>Dynamic Sitting Balance Subscale</b>						
1 - Touch the bed with the non-dominant elbow	ROM of lateral flexion to non-dominant side (degrees)	0.53	3.56	0.96	0.88–0.98	0.03
2 - Repeat item 1	ROM of lateral flexion to non-dominant side (degrees)	2.09	5.2	0.71	0.38–0.88	2.8
3 - Repeat item 1	ROM of lateral flexion to non-dominant side (degrees)	0.59	4.88	0.81	0.58–0.92	2.12
4 - Touch the bed with the dominant elbow	ROM of lateral flexion to dominant side (degrees)	0.15	3.78	0.85	0.64–0.94	1.46
5 - Repeat item 4	ROM of lateral flexion to dominant side (degrees)	0.29	3.52	0.86	0.67–0.94	1.31
6 - Repeat item 4	ROM of lateral flexion to dominant side (degrees)	0.51	4.63	0.83	0.61–0.92	1.9
7 - Lift pelvis from bed on the non-dominant side	ROM of lateral flexion to dominant side (degrees)	4.31	2.23	0.63	-0.08–0.88	1.35
8 - Lift pelvis from bed on the non-dominant side without compensation	ROM of lateral flexion to dominant side (degrees)	3.74	3.44	0.74	0.06–0.92	1.75
9 - Lift pelvis from bed on the dominant side	ROM of lateral flexion to non-dominant side (degrees)	1.62	2.88	0.79	0.53–0.91	1.31
10 - Lift pelvis from bed on the dominant side without compensation	ROM of lateral flexion to non-dominant side (degrees)	0.29	3.93	0.85	0.63–0.94	1.52
<b>Co-ordination Subscale</b>						
1 - Rotate upper trunk 6 times	Symmetry (%)	0.48	4.9	0.81	0.54–0.93	2.13
	ROM of average rotation to non-dominant side (degrees)	0.24	6.81	0.74	0.43–0.89	3.47
	ROM of average rotation to dominant side (degrees)	1.19	4.74	0.67	0.31–0.86	2.72
2 - Repeat item 1 within 6 seconds	Symmetry (%)	0.71	4.57	0.63	0.22–0.84	2.77
	ROM of average rotation to non-dominant side (degrees)	0.91	6.15	0.76	0.47–0.89	3.01

	ROM of average rotation to dominant side (degrees)	2.12	5.36	0.71	0.41–0.88	2.88
3 - Rotate lower trunk six times	Symmetry (%)	2.84	6.94	0.74	0.42–0.89	3.53
	ROM of average rotation to non-dominant side (degrees)	0.4	5.57	0.60	0.22–0.81	3.52
	ROM of average rotation to dominant side (degrees)	0.78	3.16	0.66	0.31–0.85	1.84
4 - Repeat item 3 within 6 seconds	Symmetry (%)	2.05	8.35	0.48	-0.003–0.78	6.02
	ROM of average rotation to non-dominant side (degrees)	0.06	3.69	0.67	0.34–0.85	2.11
	ROM of average rotation to dominant side (degrees)	0.82	4.34	0.57	0.17–0.80	2.84

Table 4-15: Inter-rater reliability (stroke group)

cTIS- V2 tasks	Parameter of interest	Stroke (n=20)				
		Mean diff.	SD	ICC1,1	95% CI	SEM
Dynamic Subscale						
1 - Touch the bed with the hemiplegic elbow	ROM of lateral flexion to affected side (degrees)	1.59	1.72	0.93	0.78–0.97	0.45
2 - Repeat item 1	ROM of lateral flexion to affected side (degrees)	2.02	4.48	0.94	0.71–0.98	1.09
3 - Repeat item 1	ROM of lateral flexion to affected side (degrees)	0.46	1.66	0.89	0.55–0.97	0.55
4 - Touch the bed with the unaffected elbow	ROM of lateral flexion to unaffected side (degrees)	1.02	2.71	0.76	0.48–0.90	1.32
5 - Repeat item 4	ROM of lateral flexion to unaffected side (degrees)	3.03	3.36	0.86	0.33–0.96	1.25
6 - Repeat item 4	ROM of lateral flexion to unaffected side (degrees)	0.23	2.64	0.93	0.75–0.98	0.69
7- Lift pelvis from bed on the hemiplegic side	ROM of lateral flexion to unaffected side (degrees)	1.14	6.5	0.59	0.18–0.82	4.16
8- Lift pelvis from bed on the hemiplegic side without compensation	ROM of lateral flexion to affected side (degrees)	2.35	5.53	0.67	0.009–0.73	3.17
9- Lift pelvis from bed on the unaffected side	ROM of lateral flexion to unaffected side (degrees)	2.33	5.77	0.90	0.74–0.96	1.82

10- Lift pelvis from bed on the unaffected side without compensation	ROM of lateral flexion to unaffected side (degrees)	2.94	2.97	0.70	0.31–0.88	1.62
Co-ordination Subscale						
1 - Rotate upper trunk six times	Symmetry (%)	-7.33	9.74	0.67	0.16–0.88	5.59
	ROM of average rotation to affected side (degrees)	0.16	8.37	0.58	0.18–0.81	5.42
	ROM of average rotation to unaffected side (degrees)	2.12	7.07	0.76	0.48–0.89	3.46
2 - Repeat item 1 within 6 seconds	Symmetry (%)	2.7	14.81	0.04	-0.55–0.47	14.51
	ROM of average rotation to affected side (degrees)	0.87	6.69	0.78	0.53–0.90	3.13
	ROM of average rotation to unaffected side (degrees)	2.17	6.25	0.67	0.34–0.85	3.59
3 - Rotate lower trunk six times	Symmetry (%)	6.9	21.07	0.48	-0.04–0.80	15.19
	ROM of average rotation to affected side (degrees)	-0.08	3.89	0.65	0.28–0.84	2.3
	ROM of average rotation to unaffected side (degrees)	0.92	3.7	0.65	0.29–0.84	2.18
4 - Repeat item 3 within 6 seconds	Symmetry (%)	-3.3	14.99	0.52	0.05–0.80	10.38
	ROM of average rotation to affected side (degrees)	2.21	3.73	0.69	0.30–0.87	2.07
	ROM of average rotation to unaffected side (degrees)	0.79	3.86	0.60	0.21–0.82	2.44

## 4.9 Discussion

The present study demonstrated a moderate relationship between the observed iTIS parameters and the clinical score of TIS, supporting the concurrent validity of the iTIS using the Valedo® system. In addition, good to excellent intra-rater and inter-rater reliability of the iTIS was demonstrated in both the stroke and healthy groups.

### 4.9.1 Validity

The validity of the iTIS was demonstrated by correlating the iTIS parameters to the clinical scores of the cTIS-V2 using Spearman rank correlation. The results indicated a moderate negative correlation in the dynamic subscale parameters for tasks 1, 2, 4 and 5 (touching the bed with the affected elbow and the unaffected elbow). The negative correlation arose because of the higher lateral flexion ROM towards the affected and unaffected sides recorded by stroke participants who scored zero compared to those who scored one on the clinical TIS. This was because most of the participants ( $n=2/20$ ) lost their sitting balance and fell to their side. This is in line with the findings of (Jijimol et al., 2013), who found a significant high correlation ( $r=0.91, p < 0.01$ ) between balance and TIS. Only one participant who scored zero did not lose her balance; she had a low ROM because she was not able to touch the bed with her elbow due to a lack of ROM and stopped moving during her performance of tasks 4 and 5.

The correlation in tasks 7 and 9 (lift pelvis from bed on the affected side and the unaffected side) of the dynamic subscale had moderate positive correlations. The results could be explained by the higher lateral flexion ROM values reported in people who scored one compared to those who scored zero on the clinical TIS. Moreover, for the clinical TIS in task 7, only two stroke participants scored zero, while 18 participants scored one. In tasks 3, 6 and 8 in the dynamic subscale, poor correlation values between the clinical TIS and iTIS can be explained by the presence of compensatory movements (e.g. the use of the UL, contralateral hip abduction, hip flexion, knee flexion, sliding of the feet and the loss of contact between the heel and the floor), which if observed by the assessor in the clinical TIS (dynamic subscale) is given a score of zero. However, these could not be measured by the setup of the Valedo® sensors, as the sensors were only attached to the trunk. This compensatory movement can be measured with an alternative method of applying the sensors (i.e. fixing one of the sensors on the LL) to be able to record the movement. The compensatory movements observed were likely due to impaired postural control and weight-shifting ability during the performance of these tasks. The findings of this study are consistent with the findings of the cross-sectional study by (Messier et al., 2004), who reported a significantly lower

weight-bearing ability in chronic stroke participants for both paretic and non-paretic feet when comparing a weight-bearing value on both the dominant and non-dominant feet in healthy age-matched participants ( $p=0.05$ ) during the performance of trunk lateral flexion (45 degrees) from a sitting position. Furthermore, LL sensory deficits may have affected the trunk movements; it has been suggested that somatosensory information from the feet determines how people with stroke adjust themselves on a support surface (Gillen, 2015). Another possible cause of the reduction in ROM for those who scored zero in the pelvis-lifting tasks may be the reduction in the activity of the rectus abdominis and latissimus dorsi muscles on the affected side of the body compared to the unaffected side.

For the coordination subscale, the symmetry showed a moderate to high correlation of iTIS to cTIS for tasks 1 and 2 (rotate upper trunk six times), while for tasks 3 and 4 (rotate lower trunk six times), the correlation was low. The result could be explained by the low values of lower trunk rotation ROM detected by the sacral sensor in tasks 3 and 4, whereas in the clinical scale rotation of the lower trunk is easily observable through forward and backward movements of the knees. As a result of the low ROM values, a small change in rotation leads to asymmetry. In addition, a combination of factors, such as spasticity in the lower extremities, weakness of the trunk and proximal lower extremity muscles, can contribute to the difficulty of performing rotation of the pelvis (Davies and Klein-Vogelbach, 2012, Messier et al., 2004). This explanation is supported by (Verheyden et al., 2005), suggesting that identifying this movement in stroke participants is more difficult. Furthermore, the total number of rotations demonstrates a moderate to high correlation, as stroke participants with a moderately impaired trunk were unable to complete six rotation movements within 6 seconds. Rotation ROM towards the affected and unaffected sides in general showed a low correlation with the cTIS. This parameter is not measured in the cTIS (whereas symmetry and total number of rotations are), so whilst it may provide additional information about the quality of movement, the results suggest this parameter should be excluded from the iTIS because it does not contribute to the validity. Therefore, the important parameters to be considered in the coordination subscale of iTIS should be symmetry and total number of rotations. This is supported by the results of the Bonferroni adjustment, which showed significant correlation ( $p \leq 0.006$ ) noted between cTIS score and both symmetry (tasks 2 and 3) and total number of rotations (task 2) parameters.

#### **4.9.2 Differences Between Groups**

The results of the *t*-test and the ROC curve analysis indicated the ability of the iTIS dynamic subscale parameters to distinguish both between participants with and without stroke and those stroke participants with and without trunk impairment. As expected, the performance of the stroke

participants was lower than that of the healthy controls in most of the dynamic subscale tasks. This may be explained by the difficulties stroke participants face in fine-tuning the length of the lateral trunk muscles according to the task requirement compared to the healthy controls (Dickstein et al., 2004b). The non-significant difference in some of the dynamic subscale tasks (tasks 3, 6, 8 and 10) between stroke participants who scored zero and those who scored one on the clinical TIS-V2 was likely due to the unmeasured compensatory movements mentioned previously. The participants who scored one on the cTIS-V2 recorded a high trunk lateral flexion ROM in the dynamic subscale tasks, while those who scored zero reached a high ROM by compensating (using the UL or LL), which explains the non-significant difference in some of the dynamic subscale tasks.

In the coordination subscale, the differences between the stroke participants and the healthy group were significantly different in terms of the amount of axial rotation ROM in the direction of both the affected and unaffected sides, suggesting a decrease in trunk rotational ability in the stroke group. This finding is supported by (Tanaka et al., 1997), who found a significant reduction in trunk rotatory muscle performance in stroke participants compared to healthy age-matched participants during trunk rotation at angular velocities of 60°, 120° and 150° per second ( $p < 0.05$ ). However, the symmetry parameters were not significantly different between the groups, which could be because of the compensatory strategy used by stroke participants to perform coordination subscale tasks. Some of the stroke participants completed the tasks with compensation, resulting in a symmetrical movement during the performance of the coordination tasks (e.g. the participants leaned to both sides instead of rotating the lower trunk in tasks 3 and 4 or carried the affected arm with the other hand to assist the movement of the upper trunk rotation in tasks 1 and 2). In contrast, the number of rotations showed a significant difference between healthy and stroke participants in tasks 2 and 4, when the task was required to be completed within 6 seconds. This could be explained by a reduction in the participants' ability to initiate the trunk movement in the stroke group; onset latencies of trunk muscles (lumbar erector spinae) have been shown to be delayed in stroke participants when compared with healthy age-matched controls ( $p < 0.04$ ) (Dickstein et al., 2004b).

#### **4.9.3 Reliability**

In the current study, the within-session measurement of dynamic subscale parameters (except tasks 7,8 and 9) using the Valedo® system proved to be excellent in both stroke and healthy groups according to criteria for ICC levels by (Fleiss, 2011). In tasks 7, 8 and 9, the reliability was good (ICC=0.74). This could be due to the variability in performing this task, as analysis of the videotape showed that some participants did tasks 7–9 using compensatory movement of the LL (pushing off with the ipsilateral foot). The coordination subscale parameters showed fair to good within-session intra-rater reliability in the healthy group and poor to fair reliability in the stroke group due to the

instructions given to the participants to perform the task. The instructions given before the coordination task did not encourage the participants to do the task symmetrically (i.e. the instructions were: Could you please move your shoulder/knee forward and backward until you complete six times (three times for each shoulder/knee) Starting from (Rt/Lt) side ). As a result, participants did not try to do the rotation symmetrically, which may have reduced the reliability level for symmetry parameters in the coordination subscale. The Valedo® system picked up the number of rotations correctly for all coordination subscale tasks, but the ICC was not calculated because the ICC calculation is dependent on the variability of the test score, and it was not varied across participants and trials.

In terms of between-session intra-rater reliability, the healthy group showed excellent reliability for all dynamic subscale parameters, while the stroke group showed good reliability for tasks 2, 3, 7, 8 and 9. A possible explanation for the reduced reliability in tasks 2 and 3 was the compensatory movements (e.g. using the UL to touch the bed, which led to an increase in the trunk lateral flexion ROM compared to performing the same task without using the UL) by participants during the performance of these tasks. This compensation was observed by the assessor but could not be measured by the setup of the Valedo® sensors, as the sensors were only attached to the trunk. Furthermore, the stroke participants used these compensatory movements variably in the first and second assessments (i.e. used in the first assessment but not used in the repeated assessment or used much more in the first assessment compared to the repeated assessment), which could affect reliability. Another possible factor that might have affected the reliability level is that a few stroke participants ( $n \leq 12$ ) were recorded using the Valedo® system during the performance of tasks 3 and 8 because they had scored 0 on the clinical TIS-V2 in previous tasks, and so they automatically scored 0 without performing the tasks (tasks 3 and 8). As these results were included in the analysis of this task, the reliability (ICC level) decreased (Bujang, 2017).

A possible reason for the reliability levels in tasks 7, 8 and 9 being affected could be less variability in the performance of these tasks; most of the stroke group ( $n=14/20$ ) scored 1 on this task, indicating that these tasks challenged participants' balance less than the previous tasks (tasks 1–6), which could have resulted in the reduced use of compensatory movements. This explanation is supported by Portney and Watkins (2013, p. 607): 'The variability among subjects' scores must be large to demonstrate reliability. A lack of variability can occur when samples are homogeneous, when raters are all very lenient or strict in their scoring, or when the rating system falls within a restricted range'.

For the coordination subscale, intra-rater reliability was poor to fair for all parameters in the stroke group. This could have been due to a lack of detail within the TIS instructions, namely the lack of an explicit request for the participants to perform the task symmetrically (Russek, 2004, Lee et al., 2003). The assessors gave these instructions: 'Could you please move your shoulder/knee forwards and backwards until you complete the movement six times (three times for each shoulder/knee), starting from the (right/left) side'. Furthermore, for the symmetry parameter, we measured the extent to which the rotation (degree of ROM) on both sides was identical (%); therefore, the reliability of the symmetry parameter only reached the maximum if both sides were rotated equally. Additionally, the rotation in the lower trunk recorded from participants was limited (ROM < 10°), and any error might therefore be magnified and could affect the reliability (Russek, 2004). The Valedo® system correctly identified the number of rotations for all the coordination subscale tasks, but the ICC was not calculated (as the calculation is dependent on the variability of the test score, which was low across participants and trials in this study).

For inter-rater reliability, the healthy group demonstrated excellent reliability in most dynamic subscale parameters except for tasks 2, 7 and 8, which showed good reliability. The variability in performing task 2 could justify this result, as the analysis of the videotape of the performance showed that some participants did touch the bed with their elbows by moving too far compared to the previous trial; this led to an increase in lateral flexion ROM and variance in the results. The stroke group demonstrated excellent reliability in most dynamic subscale parameters, except for in tasks 7, 8 and 10, which revealed moderate reliability. The explanation for good reliability in tasks 7, 8 and 10 was provided in the previous section. Possible reasons for the reduced inter-rater reliability in certain tasks could be human error from palpation during the reapplication of the sensors between repeated sessions. Variability in sensor placement was found to affect inter-rater reliability in a study assessing the reliability of inertial measurement systems when measuring seated spinal postures (Schless et al. 2015) . However, this contrasts with the results of a previous study that assessed the reliability of the Valedo® system in measuring trunk ROM in healthy participants in a standing position. That study tested the system against a gold standard optoelectronic system and found that the Valedo® system showed excellent reliability in measuring trunk flexion and lateral flexion to both sides (Bauer et al. 2015). The repeated measures in the Bauer et al. study were sometimes taken by the same rater and at other times by a different rater. Surprisingly, the reliability results of the symmetry parameter in the coordination subscale demonstrated good to excellent reliability in the healthy group and good inter-rater reliability in the stroke group, even with standardized instructions given for each trial. This result gives an indication of the ability of the Valedo® system to reliably measure the symmetry when the task is performed correctly and symmetrically by participants.

## **4.10 Limitations of the Study**

A limitation of the methodology that may affect the reliability and validity results is that the three sensors used in this study were placed on the trunk, which meant that the Valedo® system was unable to detect any compensation exerted by the upper or lower limbs during task performance. As a result, reliability and validity might have been affected.

In addition, the instruction given to the participants did not encourage them to rotate the trunk symmetrically, which could have resulted in the lower reliability results in the coordination subscale parameters. Moreover, in the dynamic subscale, tasks 1–6 (touch bed with elbow) there was no specific point for the elbow to touch, which may have contributed to a variation in performance between trials.

Another potential factor that could have affected the reliability was human error in palpation when replacing the sensors on the trunk. The sensors might not have been placed back in the exact starting position, even though the same rater repositioned them. System errors may also have affected both validity and reliability (Stenlund et al., 2014). The Valedo® system crashed during the completion of tasks in some sessions. Although the data was deleted, the task re-performed and the next data recording checked, potential errors in the system's recording before the crash could affect the recording.

The number of participants was sufficient to examine reliability (n=20 stroke patients) but too small to allow definitive conclusions to be drawn about differences in parameters between stroke groups (stroke patients who scored 0 and 1 in clinical TIS) and establish cut-off points for each parameter. In addition, due to the nature of clinical TIS scoring, which assumes people who score 0 in tasks 1 and 2 will automatically be scored 0 in task 3, fewer than 20 participants performed task 3. The findings indicate that a higher number of stroke participants is warranted to robustly investigate the validity and reliability of iTIS.

## **4.11 Potential Clinical Implications and Future Research**

Clinicians commonly use clinical tests such as the TIS to assess trunk impairment and to monitor changes in impairment after intervention. This study presents the iTIS as an objective tool to enable clinicians to assess and monitor trunk impairment considering the quality of the trunk movement. iTIS had the ability to detect the small changes in trunk ROM that may not have been detected by sight in the cTIS-V2. It will give clinicians detailed information about trunk movement by quantifying the trunk ROM in each task. This feature could be used effectively in clinical practice and research

with stroke participants to reduce compensation in trunk movement. However, the iTIS exhibits a limitation in detecting the compensatory movement exerted by the LL, which is commonly observed clinically. To overcome this limitation, a further research study to investigate the ability of the Valedo® system to detect compensatory movements during performance of the iTIS by moving one of the trunk sensors to the LL is warranted.

#### **4.12 Conclusion**

This study is the first to demonstrate the feasibility of an iTIS. Moderate validity has been shown, and different methods of application of the iTIS could be used where the validity was low. In addition, good to excellent test–retest reliability was found for most of the iTIS parameters measured. Unlike the cTIS-V2, the iTIS provides much more information about the quality of trunk movements by detecting small changes in trunk ROM that may not be observed clinically and that may be important in justifying treatment approaches. These findings indicate that the use of iTIS measures in combination with the cTIS-V2 has important potential for improving understanding of trunk impairment and compensatory trunk movements post stroke. Further studies should employ larger sample sizes and seek to improve the iTIS methodology by using additional sensors on the upper and/or LLs to detect compensatory movements.



# **Chapter 5 Study 2: Intra-rater and Inter-rater Reliability of Valedo<sup>®</sup> System to Measure Trunk Range of Motion During Streamlined Wolf Motor Function Test in Chronic Stroke and Aged-matched Healthy Participants**

## **5.1 Introduction**

Persistent UL impairment is highly prevalent after stroke, and impairments of the arm and hand are the major contributors to daily activity limitations (Bae et al., 2015). UL impairments after stroke include paresis, impaired control of voluntary movement, abnormal muscle tone and/or changes in somatosensation resulting in slow, inaccurate and uncoordinated task-related movement (Alt Murphy and Häger, 2015). Compensatory movement patterns are adopted by stroke survivors during UL task accomplishment to compensate for UL motor deficits, thereby hindering the potential for motor recovery after stroke (Levin et al., 2016). Trunk compensatory movement during reaching tasks has been well recognized as a critical factor in studies of UL performance after stroke (Cirstea and Levin, 2000).

Clinical function tests (e.g. *FMA* for upper limb (FMA-UL) and Wolf Motor Function Test (WMFT) are frequently used to assess UL function after stroke (Wolf et al., 2001, Duncan et al., 1983). However, most UL function tests mainly quantify function using ordinal scales to measure the degree of task completion or the time taken to complete the task without considering movement quality (Demers and Levin, 2017). In rehabilitation intervention studies, it is critical to know the effect of the intervention on motor function and whether improvements in function occur due to recovery of the lost motor function or to the use of compensatory movement patterns.

It is challenging to use observational clinical function tests to distinguish between true motor recovery and the use of alternative (compensatory) movement patterns during task performance (Alt Murphy et al., 2015). Therefore, it has been suggested that 3D kinematic measures should be considered to distinguish between compensation and true motor recovery (Kwakkel et al., 2017). However, motion analysis systems require a large installation space, are costly and are not readily clinically available. An alternative objective and reliable measurement system is needed to allow clinicians to assess and monitor movement dysfunction changes after stroke. Wearable sensors, such as IMUs that are easily portable, low in cost and easy to set up, might help to overcome these

limitations. The Valedo® system is an IMU comprised of three lightweight sensors that measure the angular tilt and velocity of body segments with respect to magnetic fields and gravity (Bauer et al., 2015). The validity and reliability of the Valedo® system in measuring trunk movement among healthy adults (age range: 27–52) have been established by Bauer et al. (2015). The system showed sufficient psychometric properties with high validity ( $r^2$  coefficients  $\geq 0.94$ ) and test inter-rater reliability (3%–9% coefficient of variation). However, the validity and reliability of the Valedo® system for the stroke population during the performance of UL activities have still not been established. The aim of this study is to investigate the validity and inter-rater and intra-rater reliability of the Valedo® system in measuring trunk movement during performance of the SWMFT by stroke survivors and age-matched healthy participants.

## **5.2 Research Question(s):**

Q1: What is the validity (i.e. ability to distinguish healthy participants from stroke participants) of the Valedo® system in measuring trunk ROM during performance of SWMFT in stroke and age-matched healthy participants?

Q2: What is the inter-rater and intra-rater reliability of the Valedo® system in measuring trunk ROM during performance of SWMFT by stroke and age-matched healthy participants?

## **5.3 Methods**

The following sections describe the study design, sample size, methods of recruiting participants and measurement protocol.

### **5.3.1 Study Design**

This is an observational cross-sectional study to establish the reliability of the Valedo® system to measure the trunk ROM in stroke and age-matched healthy participants during the performance of eight SWMFT tasks.

### **5.3.2 Sample Size Calculation**

The sample size for this study is the same as in Study 1 that was described in section 4.6.2.

### 5.3.3 Recruitment

A purposive sample of 20 adult chronic stroke patients with UL impairment and 20 age-matched healthy participants was recruited. The School of Health Sciences' Research Participant Register was used to recruit both healthy and stroke participants. As recruitment from the database was insufficient, the researcher visited the local stroke clubs to recruit additional stroke participants (Portsmouth, Romsey and Worthing stroke clubs) by giving a presentations about the study and distributing an information package to the club members. The information package included an invitation letter (Appendix 14), PIS (Appendix 15) and reply slip with pre-paid envelope. Healthy participants were recruited after stroke participants to be able to match the age of the stroke participants. The recruitment from Health Sciences' database was insufficient to obtain enough age-matched healthy participants; therefore, the School of Psychology's Research Participant Register was used to recruit some of the healthy participants. In addition, an advertising poster was displayed at the University of Southampton Highfield campus in building 67 (Appendix 16 and Appendix 17). Table 5-1 shows the inclusion and exclusion criteria for healthy and stroke participants.

Table 5-1: Inclusion and exclusion criteria for healthy and stroke participants

Inclusion criteria for healthy	Inclusion criteria for stroke	Exclusion criteria for both groups
<ul style="list-style-type: none"> <li>• Aged 18 years or over</li> <li>• Able to understand the purpose of the study and follow simple instructions (e.g. put hand on table and fold towel)</li> </ul>	<ul style="list-style-type: none"> <li>• Aged 18 years or over</li> <li>• Able to understand the purpose of the study and follow simple instructions (assessed by telephone screening)</li> <li>• More than 6 months from stroke.</li> <li>• Able to maintain seated position</li> <li>• Able to lift the hand from lap to a table in front or able to move the arm sideways across a table</li> </ul>	<ul style="list-style-type: none"> <li>• History of spontaneous fractures.</li> <li>• Uncontrolled epileptic seizures (less of consciousness or uncontrolled rapid movements).</li> <li>• Acute shoulder, elbow or hand pain or problems that affect the movement of the arm.</li> <li>• Implanted ferromagnetic materials or active devices within the body (i.e. pacemaker, acoustic devices).</li> <li>• Skin disease or lesions in correspondence of: sternum, L1, S1 (i.e. Psoriasis or eczema).</li> <li>• Severe communication disorders - unable to follow simple instructions (i.e. to cross one leg, to clap hands, or unable to ask a simple question if needed).</li> <li>• Pregnancy</li> <li>• Complete arm paralysis</li> </ul>

### 5.3.4 Measurement Protocol

#### A. Upper Limb Functional Activity: Streamlined Wolf Motor Function Test

The WMFT has been recommended for assessing upper extremity function in research and clinical practice (Alt Murphy et al., 2015). This test can differentiate between patients who are considered higher or lower functioning among mild to moderate stroke patients (Winstein et al., 2003). Moreover, the test is unaffected by whether the more affected limb is dominant or not (Bogard et al., 2009). The shortened version, known as SWMFT and recommended for chronic stroke patients, is used in this study (Appendix 18) because the administration time of the full version might cause fatigue for stroke patients with low levels of exercise tolerance. SWMFT has sufficient psychometric properties and a high sensitivity to change on the part of persons over time, based on a Rasch analysis study (Chen et al., 2012). Two versions of SWMFT are recommended based on Rasch analysis (Chen et al., 2012, Bogard et al., 2009). One version of SWMFT is appropriate for subacute stroke patients and the other is appropriate for chronic stroke patients. For both versions, there are four common tasks—hand to box (Front), lift can, lift pencil and fold towel. In addition, the subacute version of SWMFT (SWMFT-S) includes hand to table (Front) and reach and retrieve tasks, while the chronic version of SWMFT (SWMFT-C) includes extend elbow (1 lb weight) and turnkey in lock (Bogard et al. 2009) tasks. All eight tasks were used in this study (Figure 5-1) to provide data that could be used for a comparison with subacute stroke patients in the future.



Figure 5-1: Stroke participant performing the eight tasks of SWMFT.

A: hand to table; B: hand to box; C: lift can; D: lift pencil; E: turn key in lock; F: folding towel; G: reach and retrieve; H: extend elbow (1lb weight).

## **B. Trunk Range of Motion: Kinematic Analysis**

The kinematic analysis of the trunk ROM during the performance of SWMFT tasks was conducted using the Valedo® system. The Valedo® system has been validated to measure the trunk ROM compared to an optoelectronic system ( $r^2$  coefficients  $\geq 0.94$ ) (Bauer et al., 2015). The Valedo® sensors contained a tri-axillar gyroscope, accelerometer and magnetometer, wireless antenna and signal processing unit. The specifications of the Valedo® system indicated that the measurement units were able to record  $\pm 0.1^\circ$  ROM over a range of  $360^\circ$  around all axes (Valedo® User Manual, Hocoma). The recorded data was transmitted to a laptop with a 200 Hz sampling frequency. The Valedo® system output files show the rotation of the sensors in the X, Y and Z directions on the three body planes (sagittal, frontal and transverse) over the duration of the task. Output files were exported in Excel file format. The parameter of interest for each SWMFT task was determined according to clinical reasoning and discussion with the team. Table 5-2 shows the parameter of interest for each task with clinical reasoning.

Table 5-2: The parameters of interest for each SWMFT task (when the affected hand tested)

SWMFT tasks - Parameter of interest	Clinical observation	Supporting literature
<p>1. Hand to table and 2. Hand to box</p> <p>Trunk flexion</p> <p>Trunk lateral flexion toward unaffected/dominant side</p> <p>Trunk axial rotation toward affected/non-dominant side</p>	<p>1 - The direction of the movement is forward.</p> <p>2 - From video observation: lateral flexion movement toward unaffected side in combination with axial rotation of the affected side observed during reaching to the table and to the top of the table/box.</p>	<p>Significant trunk forward flexion and axial rotation shown during reaching forward while more trunk lateral flexion exerted during forward reaching in stroke subjects compared to healthy subjects from the sitting position (Messier et al., 2006).</p>
<p>3. Lift can and 4. Lift pencil</p> <p>Trunk flexion</p> <p>Trunk lateral flexion toward unaffected/dominant side</p> <p>Trunk axial rotation toward affected/non-dominant side</p>	<p>1 - The direction of the movement is forward. So, participants move forward in order to reach the can/pencil.</p> <p>2 - From video observation: stroke patients will need to do contralateral trunk flexion to be able to move their hand from their lap to reach the can/pencil in the middle of the table</p> <p>3 - From video observation: trunk rotated toward affected side in order to take the can from table to mouth or to lift the pencil</p>	<p>“Stroke patients used considerably larger forward trunk displacements compared with controls” during reaching and drinking from a glass (Alt Murphy et al., 2011).</p>

<p>5. Fold towel</p> <p>Trunk flexion</p> <p>Trunk lateral flexion toward unaffected/dominant side</p> <p>Trunk lateral flexion toward affected/non-dominant side</p>	<p>1 - The direction of the movement starts with forward flexion and the movement required to move laterally to both sides</p> <p>2 - The task started with bilateral movement of the arms (to fold the towel lengthwise), followed by unilateral movement of tested arm (to fold the towel to the side).</p>	<p>Trunk muscle strength impaired bilaterally for both trunk flexors and extensors after stroke (Tanaka et al., 1998).</p> <p>During bilateral movement a greater trunk flexion used to do the task, while more trunk lateral flexion exerted during unilateral movement (Messier et al., 2006).</p>
<p>6. Turnkey in lock</p> <p>Trunk flexion</p>	<p>1 - From video observation: the key is in the middle of the table and very near to the participant (at the 8 cm. line). So, the stroke participants move forward to as much control as possible of the key. In addition, initial analysis of the data showed very small ROM for lateral flexion and axial rotation movements.</p>	
<p>7. Reach and retrieve</p> <p>Trunk extension</p>	<p>1 - The starting position of the task is shoulder flexion with arm extended on the table (hand at the 40 cm line). From video observation: no visible lateral flexion or trunk rotation happens during task performance, visible trunk</p>	

	<p>extension exerted to pull the weight until the thumb crosses the 8 cm line. In addition, initial analysis of the data showed very small ROM for trunk lateral flexion and axial rotation.</p>	
<p>8. Extend elbow (1 lb weight)</p> <p>Trunk flexion</p> <p>Trunk lateral flexion toward affected/non-dominant side</p>	<p>1 - The movement required is to push the weight away from the body using the affected side from a side sitting position. So, the direction of movement is laterally toward the side being tested.</p> <p>2 - From video observation: some participants did the task with major trunk lateral flexion toward affected side.</p>	<p>Stroke survivors demonstrate significant trunk flexion during reaching to 45 degrees on both paretic and non-paretic sides compared to age-matched healthy controls (Messier et al., 2006).</p>

### C. Procedure

Each participant attended two assessment sessions 7–10 days apart. In the first session, the SWMFT was recorded three times (the first and third assessment by assessor 1, the second assessment by assessor 2) with a rest period between them for inter-rater reliability and intra-rater reliability purposes. In the second assessment session, the SWMFT data was recorded once by assessor 1 for the purpose of between-sessions reliability.

Before starting the assessment, the participant was instructed to turn off their mobile phone to avoid interference with the Valedo® sensors. The three Valedo® sensors were placed on the participant's trunk while standing using double-sided sticky tape. The sensors were placed as follows: sensor one on the sacral spinal level S1, sensor two on the L1 spinal level and sensor three on the sternum. The following anatomical body landmarks were used to identify the S1 and L1 levels: the anterior superior iliac spine (ASIS) along the iliac crest to L4 and from there moving upward and downward to locate L1 and S1 (Figure 5-2).



Figure 5-2: Sensor placements

To start the SWMFT, the participant had to be seated on a chair with back support, with 90° knee and hip flexion, behind a height-adjustable table. Then, the participant was verbally instructed to perform the following eight tasks: hand to box, hand to table, lift can, lift pencil, fold towel, turnkey in lock, reach and retrieve and extend elbow (with 1 lb weight). During SWMFT performance, the Valedo® sensors recorded the trunk ROM for each task onto a laptop via Bluetooth. The recorded ROM data was exported as Excel sheets and processed using the MATLAB program (MATLAB R2019a). At the same time, the time for performing each task and FAS scores were given for SWMFT. FAS scores ranged between a minimum 0 (participant did not attempt to move) to a maximum score of 5 (normal arm movement). The performance of the tasks was also filmed for later review (according to participant consent).

## 5.4 Statistical Analysis

All the recorded data was processed using (MATLAB R2019a). The MATLAB scripts for the data processing from raw data to ROM are detailed in (Appendix 18). Data was exported into Excel files and analysed using IBM SPSS 24 (SPSS Inc, Chicago, IL). Descriptive statistics were used to describe the mean and SD of the data. The normality of the data and the reliability were tested using the same statistical analysis plan used in Study 1 (chapter 4). In this study, validity was defined as the ability to distinguish between unimpaired (healthy) and impaired (stroke) groups, determined using two independent samples T-tests, and the ability to distinguish between the affected hand and the unaffected hand in the stroke group using a paired sample T-test.

## 5.5 Results

The next sub-sections describe the participants' characteristics, the validity and the intra-rater and inter-rater reliability results.

### 5.5.1 Participant Characteristics

Twenty adults with chronic stroke with resulting UL impairment (mild to severe) and 20 age-matched healthy controls were recruited. The participants' characteristics are presented in Table 5-3.

Table 5-3: Participant characteristics

Characteristics	Healthy (n=20)	Chronic stroke (n=20)
Age range (years) Mean±SD	(43-86) 66.9±11.1	(48-82) 63.14±9.7
Gender		
Male	10	13
Female	10	7
Hand dominance (before stroke)		
Right	19	19
Left	1	1
Affected upper limb		
Right		11
Left		9
Streamlined Wolf motor function test (SWMFT)		
FAS (Mean±SD)	5±0	3.1±0.33
Time (Mean±SD)	3.4±1.04	6.2±2.20

FAS: functional ability scale; SD: standard deviation

## 5.5.2 Validity

The validity (here defined as the ability to distinguish between impaired and unimpaired groups) was tested using two independent sample T-tests comparing the non-dominant hand in healthy participants to the affected hand in stroke participants. In addition, the ability to distinguish between the affected hand and the unaffected hand in the stroke group was determined using a paired sample t-test.

### A. Ability to Distinguish Between Impaired (Stroke) and Unimpaired (Healthy) Group

All the parameters of interest were able to statistically significantly distinguish between impaired and unimpaired participants at a p level of <0.01 or less except four parameters (trunk axial rotation ( $p=0.6$ ) in task 2: hand to box; trunk flexion ( $p=0.83$ ) and lumber lateral flexion toward non-dominant/affected side ( $p=0.35$ ) in task 5: fold towel; and trunk flexion ( $p=0.18$ ) in task 8: extend elbow) (Table 5-4)

### B. Ability to Distinguish Between Affected and unaffected Hand Within Stroke Group

Most of the parameters of interest showed a statistically significant difference between the affected hand and the unaffected hand in stroke participants at a p level of <0.05 or less, indicating that the Valedo® system is valid to measure trunk ROM parameters during SWMFT performance (Table 5-5). Only five parameters showed a statistically non-significant difference between the affected hand and the unaffected hand (trunk axial rotation ( $p=0.56$ ) in task 2: hand to box; trunk axial rotation ( $p=0.18$ ) in task 3: lift can; trunk flexion ( $p=0.8$ ) and lumber lateral flexion toward affected/unaffected side ( $p=0.17$ ) in task 5: fold towel; and trunk flexion ( $p=0.06$ ) in task 8: extend elbow), indicating the inability of those parameters to distinguish between the affected hand and the unaffected hand.

Table 5-4: Differences between healthy (non-dominant hand) and stroke (affected hand) groups

SWMFT task	Parameter of interest	Healthy Mean ± SD	Stroke Mean ± SD	Mean Diff ± SD	95% CI for Mean Diff. (lower-upper)	P value
Hand to table (Front)	Trunk flexion	1.38± 0.78	5.20±5.59	3.81±1.26	1.26–6.38	0.004*
	Trunk lateral flexion toward dominant/unaffected side	3.20± 1.36	8.96±6.43	5.76±1.45	2.82–8.69	0.0003*
	Trunk axial rotation toward non-dominant/affected side	4.08± 2.12	8.60±4.51	4.52±1.12	2.26–6.77	0.0002*
Hand to box (Front)	Trunk flexion	4.85± 2.86	9.41±5.53	4.56±1.39	1.74–7.38	0.002*
	Trunk lateral flexion toward dominant/unaffected side	5.08± 2.60	9.31±6.75	4.22±1.62	0.94–7.5	0.01*
	Trunk axial rotation toward non-dominant/affected side	9.9± 4.07	9.16±4.63	0.73±1.37	-3.5–2.05	0.6
Lift can	Trunk flexion	4.49± 2.56	12.61±6.72	8.12±1.61	4.79–11.43	0.00001*
	Trunk lateral flexion toward dominant/unaffected side	3.19± 2.43	7.97±5.09	4.78±1.26	2.19–7.36	0.001*
	Trunk axial rotation toward non-dominant/affected side	7.19± 3.11	10.13±5.65	2.93±1.44	-0.02–5.88	0.003*
Lift pencil	Trunk flexion	3.64± 2.47	10.72±7.22	7.08±1.71	3.63–10.54	0.0001*
	Trunk lateral flexion toward dominant/unaffected side	3.90± 1.91	8.96±6.10	5.06±1.43	2.16–7.95	0.001*

	Trunk axial rotation toward non-dominant/affected side	5.77± 2.83	11±4.55	5.23±1.2	2.8–7.65	0.0001*
Fold towel	Trunk flexion	32.88± 6.65	33.39±8.39	0.51±2.39	-4.34–5.35	0.83
	Lumber lateral flexion toward non-dominant/affected side	2.21±1.97	9.29±10.25	7.07±3.16	2.34–11.79	0.004*
	Lumber lateral flexion toward dominant/unaffected side	15.54±10.6	12.54±9.37	3±3.16	-9.41–3.39	0.35
Turn key in a lock	Trunk flexion	1.47± 0.94	5.97±5.94	4.50±1.34	1.78–7.22	0.002*
Reach and retrieve	Trunk extension	6.06± 4.06	10.49±6.83	-4.429±1.78	-8.03 – -0.83	0.01*
Extend elbow (side)	Trunk flexion	2.72± 4.24	4.99±6.08	2.27±1.66	-1.09–5.62	0.18
	Trunk lateral flexion	0.69± 0.91	5.19±5.65	4.5±1.28	1.91–7.09	0.001*

\*p ≤0.05

Table 5-5: Differences between the affected hand and the unaffected hand in the stroke group (paired t-test)

SWMFT task	Parameter of interest	AF hand Mean ± SD	Un-AF hand Mean ± SD	Mean Diff ± SD	95% CI for Mean Diff. (lower-upper)	P value
Hand to table (Front)	Trunk flexion	5.20±5.59	1.02±1.88	4.18±1.27	1.50–6.85	0.004*
	Trunk lateral flexion toward affected/unaffected side	8.96±6.43	3.58±2.04	5.38±1.34	2.57–8.19	0.001*
	Trunk axial rotation toward affected/unaffected side	8.60±4.51	4.34±2.43	4.27±1.01	2.16–6.38	0.0004*
Hand to box (Front)	Trunk flexion	9.41±5.53	5.15±3.68	4.27±1.48	1.61–6.92	0.003*
	Trunk lateral flexion toward affected/unaffected side	9.31±6.75	5.99±2.79	3.32±1.56	0.05–6.59	0.04*
	Trunk axial rotation toward affected/unaffected side	9.16±4.63	8.69±3.62	0.48±0.82	-1.24–2.20	0.56
Lift can	Trunk flexion	12.61±6.72	5.32±2.88	7.29±1.64	3.65–10.93	0.0004*
	Trunk lateral flexion toward affected/unaffected side	7.97±5.09	3.74±1.66	4.23±1.28	1.54–6.91	0.004*
	Trunk axial rotation toward affected/unaffected side	10.13±5.65	8.31±3.17	1.81±1.30	-0.92–4.54	0.18
Lift pencil	Trunk flexion	10.72±7.22	4.17±2.79	6.55±1.73	2.48±10.64	0.003*
	Trunk lateral flexion toward affected/unaffected side	8.96±6.10	4.03±1.71	4.93±1.45	1.90–7.96	0.003*
	Trunk axial rotation toward affected/unaffected side	11±4.55	6.75±2.62	4.25±1.02	2.11–6.39	0.001*
Fold towel	Trunk flexion	33.39±8.39	33.59±9.28	-0.20±2.80	-1.87–1.47	0.80
	Lumber lateral flexion toward affected/unaffected side	9.29±10.25	10.44±9.39	-1.16±0.82	-2.88–0.57	0.17

	Lumber lateral flexion toward affected/unaffected side	12.54±9.37	7.19±7.35	5.35±2.08	1–9.70	0.01*
Turn key in a lock	Trunk flexion	5.97±5.94	2.06±1.23	3.91±1.36	1.36–6.45	0.005*
Reach and retrieve	Trunk extension	10.49±6.83	-6.35±3.51	-4.14±1.72	-7.26 – -1.02	0.01*
Extend elbow (side)	Trunk flexion	4.99±6.08	2.16±2.68	2.83±1.49	-0.14–5.80	0.06
	Trunk lateral flexion	5.19±5.65	1.61±2.80	3.58±1.22	1.02– .15	0.009*

\*p ≤0.05

### 5.5.3 Reliability

The reliability of the Valedo® system in measuring trunk ROM during SWMFT performance was determined using the ICC. Reliability was excellent when  $ICC > 0.75$ , good to fair when  $ICC = 0.4 - 0.74$  and poor when  $ICC < 0.4$  (Fleiss, 2011). The ICC (2,1) model was used and 95% CIs were calculated for all ICC values. In addition, B&A plots were used to demonstrate the level of agreement and spread of data.

#### A. Intra-rater (Within-session)

Generally, most of the trunk ROM parameters demonstrated good to excellent reliability in both healthy and stroke groups, as shown in Table 5-6. A total of 19 trunk ROM parameters were tested in both healthy and chronic stroke participants in the present study, and seven (37%) of these (trunk flexion in tasks 6 and 8, trunk lateral flexion toward dominant side in tasks 2 and 5, trunk lateral flexion toward non-dominant side in task 5 and trunk axial rotation toward non-dominant side in tasks 1 and 2) in healthy participants and 15 (79%) (trunk flexion in tasks 1, 2, 3, 4 and 5, trunk lateral flexion toward unaffected side in tasks 1, 2, 3, 4 and 5, trunk lateral flexion toward affected side in task 5 and trunk axial rotation toward affected side in tasks 1, 2 and 3) in stroke participants demonstrated excellent reliability ( $ICC \geq 0.75$ ) according to Fleiss (2011). The remaining parameters for both groups showed good reliability with an  $ICC \geq 0.66$  (Fleiss, 2011). The potential differences in reliability between the healthy and stroke groups indicated by the limits of the B&A range between groups were greater in the stroke group than in the healthy group, demonstrated in the B&A plots (Appendix 20). In addition, the CI for all tasks was relatively narrow and does not include the value of zero, indicating statistically significant reliability. Moreover, the SEM for the high reliability tasks in both groups was low ( $SEM \leq 3.06$ ), indicating low variability in a test caused by measurement error.

#### B. Intra-rater (Between Two Days Sessions)

Intra-rater reliability between days for measuring trunk ROM was very high in both the healthy and stroke groups, and seven parameters (37%) (trunk flexion in tasks 3, 4 and 6, trunk lateral flexion toward dominant side in task 1, trunk lateral flexion toward non-dominant side in task 5 and trunk axial rotation toward non-dominant side in tasks 3 and 4) in healthy and 14 parameters (74%) (trunk flexion in all tasks, trunk lateral flexion toward unaffected side in tasks 1, 2, 3, 4 and 8, trunk lateral flexion toward affected side in task 5 and trunk axial rotation toward affected/non-dominant side in task 2) in the stroke group reached a level of excellent reliability with an  $ICC \geq 0.75$ . The remaining parameters for both groups showed good reliability with an  $ICC \geq 0.64$  (Fleiss, 2011). Similarly, the reliability coefficient in the stroke group was greater across parameters compared to the healthy

group (Table 5-7). This could be due to a wider limit of agreement resulting from high variation in task performance between participants in the stroke group, as demonstrated in the B&A plot (Appendix 21). The MDC was relatively small in all parameters, except for the trunk flexion parameter in task 5 (fold towel) (MDC in the healthy group=10.17, MDC in the stroke group=13.3) due to large trunk ROM exerted in this task compared to the remaining seven tasks.

### C. Inter-rater (Between Two Raters)

The same results were demonstrated for the inter-rater reliability for trunk ROM parameters. The ICCs showed excellent reliability between assessors, with an ICC  $\geq 0.75$  for six parameters (32%) (trunk flexion in tasks 2 and 6, trunk lateral flexion toward dominant side in tasks 1 and 2, trunk lateral flexion toward non-dominant side in task 5 and trunk axial rotation toward non-dominant side in tasks 2 and 3) in the healthy group and 14 parameters (74%) (trunk flexion in tasks 1, 2, 3, 4 and 8, trunk lateral flexion toward unaffected side in tasks 1, 2, 3, 4 and 5, and trunk axial rotation toward affected/non-dominant side in tasks 1, 2, 3 and 4) in the stroke group (Table 5-8). The remaining parameters for both groups showed good reliability with an ICC  $\geq 0.63$  (Fleiss 2011). The greater variability in trunk ROM between group subjects demonstrated greater reliability (Appendix 22). The reliability in the stroke group was greater for the same reason mentioned previously. The SD difference between the two assessor measurements was high because the amount of ROM (degrees) exerted in each task was relatively low, and for some tasks (such as hand to table and hand to box) participants did the task with 0 value (degree) trunk flexion, resulting in a higher SD. None of the CIs of any task included the value of zero, indicating statistically significant reliability.

Table 5-6: Intra-rater reliability for measuring trunk ROM during SWMFT performance (within same day)

SWMFT	Healthy (n=20)					Stroke (n=20)				
	Mean± SD	Mean diff. ± SD	ICC <sub>2,1</sub>	95% CI	SEM	Mean± SD	Mean diff. ± SD	ICC <sub>2,1</sub>	95% CI	SEM
1. Hand to table										
Trunk flexion										
T1	1.2±0.8	0.3±0.6	0.66	0.31–0.85	0.4	4.8±6.1	0.4±3.1	0.86	0.69–0.94	1.15
T2	1.5±0.9					5.2±5.5				
Trunk lateral flexion toward unaffected/dominant side										
T1	3.1±1.3	0.03±1.1	0.72	0.41–0.88	0.58	8.1±6.6	1.5±3.3	0.79	0.55–0.91	1.51
T2	3.2±1.5					9.6±6.5				
Trunk axial rotation toward affected/non-dominant side		0.04±1.2								
T1	4±2.2		0.87	0.70–0.94	0.42	9±4.5	0.5±3.3	0.76	0.49–0.90	1.61
T2	4±2.3					8.5±4.9				
2. Hand to box										
Trunk flexion										
T1	4.8±3.1	0.8±3.1	0.71	0.42–0.88	1.66	9.8±5.6	0.7±1.5	0.95	0.87–0.98	0.33
T2	5.7±4.2					9±5.2				
Trunk lateral flexion toward unaffected/dominant side										

T1	4.6±2.9	0.4±2.3	0.84	0.64–0.93	0.92	9.4±8	0.6±4.8	0.8	0.54–0.91	2.14
T2	5.2±3					8.8±6.				
Trunk axial rotation toward affected/non-dominant side										
T1	9.5±4.8	0.4±2.9	0.80	0.56–0.91	1.29	9.4±4.9	0.1±2.5	0.88	0.72–0.95	0.86
T2	9±4.2					9.3±5.3				
3. Lift can										
Trunk flexion										
T1	4.5±2.7	0.4±2.3	0.71	0.40–0.87	1.23	13.2±6.3	0.5±3.2	0.9	0.75–0.96	1.01
T2	5±3.4					12.6±7.5				
Trunk lateral flexion toward unaffected/dominant side										
T1	2.8±2.5	0.1±2.1	0.7	0.37–0.87	1.15	8.2±5.7	0.3±3.1	0.86	0.67–0.94	1.15
T2	3±2.3					8.5±5.5				
Trunk axial rotation toward affected/non-dominant side										
T1	7.4±3.1	0.3±2.4	0.71	0.41–0.87	1.29	11±6.8	1.6±3.9	0.8	0.56–0.92	1.74
T2	7± 3.3					9.4±6.1				

4. Lift pencil										
Trunk flexion										
T1	3.8±2.4	0±2.2	0.72	0.42–0.88	1.16	10.7±6.9	0.2±2.6	0.94	0.85–0.97	0.63
T2	3.8±3.4					10.5±7.4				
Trunk lateral flexion toward unaffected/dominant side										
T1	3.7±1.8	0.4±1.4	0.71	0.41–0.87	0.75	8.9±6.1	0.6±3.9	0.83	0.63–0.93	1.6
T2	3.5±1.9					9.6±7.2				
Trunk axial rotation toward affected/non-dominant side										
T1	6±3.1	0.6±2.3	0.7	0.39–0.87	1.25	11.7±5.3	0.5±4	0.7	0.37–0.87	2.2
T2	5.3±2.7					11.2±4.7				
5. Fold towel										
Trunk flexion										
T1	32.6±7.7	1±5.8	0.72	0.42–0.88	3.06	33.5±8.8	1.1±6.4	0.78	0.53–0.91	3
T2	33.6±7.5					32.4±10.4				
Trunk lateral flexion toward unaffected/dominant side										
T1	9.4±11.6	1.6±7	0.79	0.54–0.91	3.2	9.3±11.5	0.1±4.4	0.93	0.82–0.97	1.16
T2	11.2±10.9					9.1±10.9				
Trunk lateral flexion toward affected/non-dominant side										
		1.7±7.6	0.77	0.51–0.90	3.64	14.4±11.3	2.1±5.6	0.85	0.66–0.94	2.16

T1	8.3±12.2					12.3±10				
T2	6.7±9.1									
6. Turn key in lock										
Trunk flexion										
T1	1.5±1.1	0.1±2.7	0.84	0.63–0.93	1.08	5.3±4.8	0.1±3.4	0.73	0.44–0.88	1.76
T2	1.4±1.1					6±6.6				
7. Reach and retrieve										
Trunk extension										
T1	6.8±5.1	0±0.8	0.73	0.43–0.88	0.41	11.1±8.2	0.9±3.7	0.88	0.73–0.95	1.28
T2	5.6±4.6					10.2±7				
8. Extend elbow (1 lb weight)										
Trunk flexion										
T1	2.5±4.6	1.2±3.2	0.77	0.50–0.90	1.53	5.6±7	0.8±4	0.71	0.41–0.87	2.15
T2	2.7±4.6					4.2±5.1				
Trunk lateral flexion toward unaffected/dominant side										
T1	0.7±1.1	0.2±0.9	0.68	0.36–0.86	0.5	4.9±5.5	0.1±4.5	0.72	0.42–0.88	2.38
T2	0.6±0.8					5±6.5				

SD: standard deviation; SEM: standard error of measurement; T1: first test by assessor 1; T2: re-test by assessor 1; CI: confidence interval

Table 5-7: Intra-rater reliability for measuring trunk ROM during SWMFT performance (between two days)

SWMFT	Healthy (n=20)						Stroke (n=20)					
	Mean± SD	Mean diff. ±SD	ICC <sub>2,1</sub>	95% CI	SEM	MDC	Mean± SD	Mean diff. ± SD	ICC <sub>2,1</sub>	95% CI	SEM	MDC
1. Hand to table												
Trunk flexion												
T1	1.2±0.8	0.2±0.6	0.7	0.37–0.86	0.32	0.88	4.8±6.1	0.2±4.2	0.8	0.55–0.91	1.87	5.18
T2	1.4±0.8						5.3±5.8					
Trunk lateral flexion toward unaffected/dominant side												
T1	3.1±1.3	0.1±0.9	0.82	0.61–0.92	0.38	1.05	8.1±6.6	0.3±4.2	0.86	0.66–0.94	1.57	4.35
T2	3.2±1.7						8.2±7.4					
Trunk axial rotation toward affected/non-dominant side												
T1	4±2.2	0.06±1.6	0.71	0.40–0.87	0.86	2.38	9±4.5	1±3.6	0.71	0.39–0.87	1.93	5.34
T2	4.1±2.1						9±6					
2. Hand to box												

Trunk flexion												
T1	4.8±3.1	0.6±2.9	0.7	0.37–0.86	1.58	4.37	9.8±5.6	1±4.2	0.77	0.49–0.90	2.01	5.57
T2	4.7±3.4						9.2±5.7					
Trunk lateral flexion toward unaffected/dominant side												
T1	4.6±2.9	0.3±3.2	0.73	0.42–0.88	1.66	4.6	9.4±8	0.4±5.4	0.77	0.50–0.91	2.58	7.15
T2	5.5±4.4						9.5±6.1					
Trunk axial rotation toward affected/non-dominant side												
T1	9.7±4.8	0.4±3.4	0.66	0.31–0.85	1.98	5.48	9.4±4.9	1.3±3.3	0.84	0.64–0.94	1.32	3.65
T2	9.3±4.3						8.6±5.1					
3. Lift can												
Trunk flexion												
T1	4.5±2.7	0.1±1.6	0.8	0.54–0.91	0.71	1.96	13.2±6.3	1.7±5.7	0.92	0.82–0.97	1.61	4.46
T2	4.6±2.1						12±7.3					
Trunk lateral flexion toward unaffected/dominant side												
T1	3.2±2.8	0±2.1	0.71	0.40–0.88	1.13	3.13	8.2±5.7	0.1±4.7	0.85	0.66–0.94	1.82	5.04
T2	3.2±2.7						8.6±5.8					

Trunk axial rotation toward affected/non-dominant side												
T1	7.4±3.1	0.7±2.03	0.75	0.48–0.9	1.01	2.79	11±6.8	0.7±4.3	0.72	0.40–0.88	2.27	6.29
T2	6.7±2.6						10.8±4.9					
4. Lift pencil												
Trunk flexion												
T1	3.8±2.4	0.1±1.7	0.76	0.49–0.90	0.83	2.3	10.7±6.9	1.1±5.6	0.87	0.69–0.95	2.01	5.57
T2	3.9±2.6						10.1±6.7					
Trunk lateral flexion toward unaffected/dominant side												
T1	3.9±1.9	0.2±1.7	0.64	0.27–0.83	1.02	2.82	8.9±6.1	0.6±4.5	0.91	0.78–0.96	1.35	3.74
T2	4.1±2.1						8.8±5.40					
Trunk axial rotation toward affected/non-dominant side												
T1	6±3.1	0.4±1.7	0.83	0.62–0.93	0.7	1.94	11.7±5.3	1.6±3.4	0.73	0.42–0.89	1.76	4.87
T2	5.6±2.6						10.6±4.2					

5. Fold towel												
Trunk flexion												
T1	32.6±7.7	0.1±6.4	0.67	0.32–0.86	3.67	10.17	33.5±8.8	2.9±9.6	0.75	0.46–0.90	4.8	13.3
T2	32.7±7.7						32.2±9.3					
Trunk lateral flexion toward unaffected/dominant side												
T1	9.4±11.6	2.7±5.9	0.67	0.35–0.86	3.38	9.36	9.3±11.5	2±7.7	0.72	0.42–0.88	4.07	11.28
T2	12.1±11						10±11.4					
Trunk lateral flexion toward affected/non-dominant side												
T1	8.3±12.2	1.3±10	0.75	0.47–0.9	5	13.85	14.4±11.3	1±7.3	0.78	0.52–0.91	3.42	9.47
T2	9.6±12.2						15.5±10.3					
6. Turn key in lock												
Trunk flexion												
T1	1.5±1.1	0.2±0.9	0.87	0.71–0.95	0.32	0.88	5.3±4.8	0.6±3.5	0.8	0.56–0.92	1.56	4.32
T2	1.6±1.2						6.6±6.6					
7. Reach and retrieve												
Trunk extension												
T1	6.8±5.1	0.3±3.6	0.68	0.35–0.86	2.03	5.62	11.1±8.2	1.1±5.5	0.71	0.38–0.88	2.96	8.2

T2	6.5±4.5						1.30±2					
8. Extend elbow (1 lb weight)												
Trunk flexion												
T1	2.5±4.6	0.6±2.2	0.73	0.43–0.88	1.14	3.15	5.6±7	1.9±4.2	0.77	0.49–0.90	2.01	5.57
T2	1.9±4.2						3.90±5.6					
Trunk lateral flexion toward unaffected/dominant side												
T1	0.7±1.1	0.2±1.3	0.68	0.36–0.86	0.73	2.02	4.9±5.5	2±3.5	0.8	0.52–0.92	1.56	4.32
T2	1.1±2						3.1±5.7					

Table 5-8: Inter-rater reliability for measuring trunk ROM during SWMFT performance

SWMFT	Healthy (n=20)					Stroke (n=20)				
	Mean± SD	Mean diff. ± SD	ICC 2,1	95% CI	SEM	Mean± SD	Mean diff.± SD	ICC 2,1	95% CI	SEM
1. Hand to table										
Trunk flexion										
T1	1.2±0.8	0.2±0.6	0.67	0.34–0.85	0.34	4.8±6.1	0.6±2.8	0.9	0.75–0.95	0.88
T2	1.3±0.7					5.5±5.7				
Trunk lateral flexion toward unaffected/dominant side										
T1	3.1±1.3	0.02±0.9	0.8	0.56–0.91	0.4	8.1±6.6	0.9±4.4	0.83	0.62–0.93	1.81
T2	3.2±1.5					9±6.9				
Trunk axial rotation toward affected/non-dominant side										
T1	4±2.2	0.06±1.7	0.74	0.46–0.89	0.86	9±4.5	0.6±2.3	0.86	0.67–0.94	0.86
T2	4±2.1					8.1±4.9				
2. Hand to box										
Trunk flexion										
T1	4.8±3.1	0.9±2.5	0.77	0.51–0.90	1.19	9.8±5.6	0.4±2	0.94	0.86–0.98	0.48
T2	3.9±2.7					9.3±6				

Trunk lateral flexion toward unaffected/dominant side										
T1	4.6±2.9	0.4±2.6	0.81	0.59–0.92	1.13	9.4±8	0.2±5.4	0.77	0.47–0.90	2.58
T2	5.2±3.1					9.6±7.3				
Trunk axial rotation toward affected/non-dominant side										
T1	9.7±4.8	1.6±2.6	0.79	0.47–0.91	1.19	9.4±4.9	0.7±3.3	0.75	0.48–0.89	1.65
T2	11.1±4.2					8.7±4.4				
3. Lift can										
Trunk flexion										
T1	4.5±2.7	0.7±2.1	0.73	0.43–0.88	1.09	13.2±6.3	1.3±2.7	0.9	0.75–0.96	0.85
T2	3.8±2.5					11.9±6.8				
Trunk lateral flexion toward unaffected/dominant side										
T1	2.8±2.5	0.1±2.1	0.7	0.37–0.86	1.15	8.2±5.7	1.1±2.8	0.84	0.64–0.94	1.12
T2	3.3±2.8					7.1±4.9				
Trunk axial rotation toward affected/non-dominant side										
T1	7.4±3.1	0.4±2.3	0.77	0.51–0.90	1.11	11±6.8	1.1±3.9	0.8	0.56–0.91	1.74
T2	7±3.7					9.9±5.4				
4. Lift pencil										
Trunk flexion										
T1	3.8±2.4	0.6±1.7	0.72	0.43–0.88	0.89	10.7±6.9	0.05±2.4	0.95	0.87–0.98	0.53

T2	3.2±2.3					10.8±7.6				
Trunk lateral flexion toward unaffected/dominant side										
T1	3.7±1.8	0.2±1.7	0.71	0.40–0.87	0.91	8.9±6.1	0.7±4.2	0.78	0.52–0.90	1.96
T2	4.1±2.4					8.2±6.3				
Trunk axial rotation toward affected/non-dominant side										
T1	6±3.1	0.2±2.6	0.69	0.73–0.95	1.44	11.7±5.3	1.8±2.5	0.83	0.46–0.94	1.03
T2	5.8±3.3					9.9±4.7				
5. Fold towel										
Trunk flexion										
T1	32.6±7.7	0.4±6.1	0.71	0.40–0.88	3.28	33.5±8.8	0.6±7.2	0.68	0.34–0.86	4.07
T2	32.2±8.1					34.1±8.9				
Trunk lateral flexion toward unaffected/dominant side										
T1	9.40±11.6	1.4±8.4	0.74	0.45–0.9	4.28	9.3±11.5	0.05±5.6	0.86	0.68–0.94	2.09
T2	10.8±11.2					9.3±9.4				
Trunk lateral flexion toward affected/non-dominant side										
T1	8.3±12.2	1.5±5.9	0.75	0.47–0.89	2.95	14.4±11.3	3.8±6.7	0.74	0.41–0.90	3.41
T2	6.8±9.3					10.7±8.8				
6. Turn key in lock										
Trunk flexion										

T1	1.5±1.1	0.2±0.7	0.8	0.56–0.92	0.31	5.3±4.8	0.4±2.9	0.63	0.28–0.84	1.76
T2	1.3±0.8					6.4±7.6				
7. Reach and retrieve										
Trunk extension										
T1	6.8±5.1	1.1±3.4	0.73	0.45–0.88	1.76	11.1±8.2	1.2±5.4	0.73	0.45–0.88	2.8
T2	5.7±3.9					10±6.5				
8. Extend elbow (1 lb weight)										
Trunk flexion										
T1	2.5±4.6	0.3±2.9	0.71	0.41–0.87	1.56	5.6±7	0.5±4.1	0.84	0.63–0.93	1.64
T2	2.8±4.1					5±7				
Trunk lateral flexion toward unaffected/dominant side										
T1	0.7±1.1	0.3±0.8	0.64	0.28–0.84	0.48	4.9±5.5	0.5±4.6	0.73	0.43–0.88	2.39
T2	0.4±0.7					5.5±6.9				

SD: standard deviation; SEM: standard error of measurement; MDC: minimum detectable change; T1: first test by assessor 1; T2: re-test by assessor 2; CI: confidence interval

## **5.6 Discussion**

The present study demonstrated a high ability of trunk ROM parameters during SWMFT performance to distinguish between impaired (stroke) and age-matched unimpaired (healthy) groups and between the affected hand and the unaffected hand within the stroke group, thus supporting the validity of trunk ROM parameters using the Valedo<sup>®</sup> system. In addition, good to excellent intra-rater and inter-rater reliability of trunk ROM parameters using the Valedo<sup>®</sup> system were demonstrated in both the healthy and stroke groups.

### **5.6.1 Validity**

The validity of the Valedo<sup>®</sup> system in measuring trunk ROM during SWMFT was measured by its ability to distinguish between impaired (stroke) and unimpaired (healthy) groups and between the affected hand and the unaffected hand within the stroke group.

As expected, the stroke participants employed more trunk movements than the healthy controls in all tasks. This may be explained by the UL deficit (i.e. greater UL severity, more trunk compensatory movement used (Levin et al., 2016)). In terms of between-group differences, the results showed a high ability ( $p < 0.01$  or less) of the Valedo<sup>®</sup> system to distinguish between healthy and stroke participants for all parameters except four (trunk axial rotation in task 2: hand to box; trunk flexion and lumbar lateral flexion toward non-dominant/affected side in task 5: fold towel; and trunk flexion in task 8: extend elbow).

In terms of differences between the affected hand and the unaffected hand within the stroke group, the same findings were revealed—the high ability ( $p < 0.01$  or less) of the Valedo<sup>®</sup> system to distinguish between the affected hand and the unaffected hand for all parameters except the same four mentioned previously.

For task 2 (hand to box), the results of this study contradicted those of a previous study (Massie et al., 2012) that examined the contribution of trunk movement during reach between two targets 35 cm apart in a parasagittal plane at a height of 71 cm. That study found a significant difference ( $p < 0.05$ ) in trunk axial rotation between reaching with the affected side compared to reaching with the unaffected side. The disagreement between results could be due to the difference in the distance and the height of reaching. In this study, the box height was 11 cm and the box was located

at the 20 cm line, which was lower and nearer to the participants, thus requiring less ROM to accomplish the task (Ma et al., 2017).

For task 5 (fold towel), the non-significant difference shown in both comparisons between groups in the trunk flexion and lumbar lateral flexion toward non-dominant/affected side parameters could be explained by different factors, as follows: 1) the diameter of the towel (H50 x W65 cm) which makes the edge of the towel placed on table at 50 cm (beyond arm length), requiring forward high trunk flexion and lateral flexion movements for both groups to reach it; and 2) the functional level of the UL in the stroke group was low (FAS  $\leq 2$ ), and 35% (n=7) of the stroke participants used both hands (affected and unaffected) to accomplish the task, which could lead to an increase in the trunk ROM during task performance; these bilateral movement might affect the overall results. This explanation was confirmed by a previous study that measured the amount of trunk flexion and lateral flexion during unilateral and bilateral reaching tasks in chronic stroke patients (Messier et al. 2006). The results of that study showed greater trunk flexion and trunk lateral flexion exerted during bilateral involvement of the UL compared to unilateral movement in the stroke group.

For task 8, the non-significant difference in trunk flexion, either when comparing healthy participants to stroke participants or affected hands to unaffected hands, might be due to the nature and direction of the task. In this task, the participants sit at the side of a table (side of chair attached to the side of table) with the arm resting on the table (parallel to front edge of table with elbow at the 14 cm line) and are asked to extend the elbow until the thumb crosses the 40 cm line. Thus, the direction of the movement is toward the side being tested, and the weight needs to be pushed toward the lateral/backward direction while the trunk is supported by the back of the chair. As a result, it is unexpected to perform forward trunk flexion to accomplish task 8.

In addition to the previous three tasks discussed, the trunk flexion in task 3 (lift can: participant required to move the tested hand from the lap and grasp the can placed just beyond the 20 cm line and then move it toward the mouth) showed a non-significant ( $p=0.8$ ) difference between the affected hand compared to the unaffected hand within the stroke group. This finding is expected in the stroke group, as it has been reported in previous literature that trunk muscle strength is impaired bilaterally for both trunk flexors and extensors, which might affect the performance of participants in this task (Jung et al., 2020, Tanaka et al., 1998). Furthermore, 45% (n=9) of the stroke participants used both hands to accomplish that task due to their low functional level of the UL (FAS  $\leq 2$ ), which could affect the overall results for that task. This explanation is supported by Alt Murphy (2011), who found that stroke patients with a moderately affected arm used considerably larger

forward trunk displacements ( $p < 0.05$ ) during the reaching and drinking task performed from the sitting position compared with stroke patients who had a mildly affected arm.

### **5.6.2 Reliability**

In the current study, the inter-rater and intra-rater reliability showed good to excellent reliability in both groups, as follows: intra-rater reliability (within day 1) in healthy participants (ICC=0.66-0.87) and stroke participants (ICC=0.70-0.95); intra-rater reliability (between 2 days) in healthy participants (0.64-0.87) and stroke participants (0.71-0.92); and inter-rater reliability (between two raters) in healthy participants (0.64-0.81) and stroke participants (0.63-0.95). All types of reliability were better for the stroke group than for the healthy group. The possible explanation for this finding is that the variation in trunk ROM between subjects was limited in the healthy group compared to the stroke group, which led to a restricted spread of scores. Moreover, the participants in the healthy group had the highest FAS score (FAS average=5) for the UL, while the participants in the stroke group varied in their UL ability (average FAS=3.1, and the FAS in each task varied from 0-5), which makes the stroke group non-homogenous and leads to an increase in the reliability level. This explanation has been confirmed by Portney and Watkins, who state 'the variability among subjects' scores must be large to demonstrate reliability. A lack of variability can occur when samples are homogeneous, when raters are all very lenient or strict in their scoring, or when the rating system falls within a restricted range' (2013; p. 607).

The other possible explanation for the higher reliability in the stroke group is the instructions used in this study to perform the required tasks. SWMFT instructions were used, which focus on doing each task as quickly as possible without encouraging non-use of the trunk, because we wanted to explore how healthy and stroke participants move their trunk during UL activities. However, some ( $n=2-5$ ) of the healthy participants moved their trunk too far compared to other healthy participants in trunk flexion in tasks 5 and 8, which could affect the reliability level. Another possible reason for the good reliability in task 7 in both groups is that the standardisation of the starting position in that task is quite challenging because the starting position required the tested arm to be extended and the palm of the hand to be in contact with the weight (placed beyond the 40 cm line); sometimes, it is not possible to fully extend the arm for stroke participants who have spasticity. In addition, the healthy participants who have short arm length are in full contact with the table, which could affect their performance.

The last factor that could affect the reliability is the variability in sensor placement between each assessment and between the two raters, as it has been found to be a factor that affected inter-rater

reliability in a study assessing the reliability of inertial measurement systems when measuring seated spinal postures (Schless et al. 2015).

## **5.7 Limitations of the Study**

This study has several limitations. The inclusion criteria for the UL ability of stroke participants was included a wide variation of UL (FAS 0-5), which could affect the generalizability of the results. The human error in palpation when replacing the sensors on the trunk might have affected the reliability in both groups.

The sample size was enough to examine reliability (n=20 stroke) but too small to allow definitive conclusions to be drawn about differences in parameters between stroke participants (stroke participants who scored 0, 1, 2, 3, 4 and 5 in the clinical SWMFT) and to do subgroup analysis for each FAS.

## **5.8 Conclusion and Clinical Implications**

Good to excellent inter-rater and intra-rater reliability was found for the trunk ROM parameter measured during SWMFT, suggesting an acceptable level of reliability for the Valedo<sup>®</sup> system to be used to measure trunk ROM in healthy and stroke participants. The Valedo<sup>®</sup> system gives more information about trunk performance during SWMFT, with the ability to detect small changes in trunk ROM that may not be observed clinically. These findings indicate that the Valedo<sup>®</sup> system has important potential for the objective assessment of trunk ROM during UL activity in clinical practice to address trunk control issues. Another potential use of the Valedo<sup>®</sup> system is in future research to better understand compensatory trunk movements during UL activities. The potential research and clinical applications of the Valedo<sup>®</sup> system include the wider neurological community. Further studies with larger sample sizes are warranted to establish reference data for trunk ROM parameters using a different FAS in the stroke population.

# **Chapter 6 Study 3: Feasibility of using Valedo system to deliver trunk exercise through video games in chronic stroke population**

## **6.1 Introduction**

Trunk performance is an important predictor for outcomes of balance, gait and activity of daily living (ADL), after a stroke (Franchignoni et al., 1997, Hsieh et al., 2002, Verheyden et al., 2007a). Several studies have demonstrated that trunk performance is impaired post-stroke (Bohannon et al., 1995, Carozzo et al., 2020, Chen et al., 2015, Davies and Klein-Vogelbach, 2012, De Baets et al., 2016, Dickstein et al., 2000, Dickstein et al., 2004a, Gera et al., 2016). Impairments in trunk are characterized by trunk muscle weakness, reduced trunk position sense and impaired inter-segmental coordination (Langhorne et al., 2009, Ryerson et al., 2008, Sunderland et al., 1989).

Several clinical trials and systematic reviews have emphasized the effectiveness of trunk exercise on trunk performance in stroke patients (Alhwoaimel et al., 2018, Bae et al., 2013, Cabanas-Valdes et al., 2013, de Sèze et al., 2001, Sorinola et al., 2014, Verheyden et al., 2009). Effective post-stroke interventions are characterised by high intensity training and repetitive practice of a task-oriented movement (Langhorne et al., 2009). In keeping with this, The UK Royal College of Physicians' (RCP) National Clinical Guidelines for Stroke recommend 'at least 45 minutes of each appropriate therapy every day, at a frequency that enables them to meet their rehabilitation goals' (National Clinical Guidelines for Stroke, 2016, p.25). Moreover, these guidelines emphasise the importance of including trunk exercises for those with impaired balance: 'People with impaired sitting balance after stroke should receive trunk training exercises' (National Clinical Guidelines for Stroke, 2016, p.73). Intensive exercise is important to enhance the therapeutic effect but most of the conventional exercises were repetitive in nature without targets and feedback, therefore perceived by patient as boring and meaningless (Luker et al., 2015). Patients tend to lose interest which lead to reducing adherence and treatment effectiveness (Burdea, 2003, Kwakkel et al., 2006). Patient motivation and exercise content and structure were considered as an important factors to improve adherence to an outpatient rehabilitation programme (Suk and Eun, 2017, Olaleye and Suddick, 2012). Technological developments might address these issues by providing interactive training environments.

In the previous two decades, various studies have been undertaken on rehabilitation technologies including virtual reality (VR) game-based methods for stroke patients. VR technology is considered a promising intervention in stroke rehabilitation in that it is believed to positively affect participation and improve body function and activity (Lohse et al., 2014).

The positive effect of such rehabilitation on trunk performance was reported in recent literature (Lee and Bae, 2020, Kim et al., 2018, Alhwoaimel et al., 2018, Bank et al., 2016, Cabanas-Valdes et al., 2013, Cabrera-Martos et al., 2020, Sorinola et al., 2014, Souza et al., 2019, Van Criekeing et al., 2019a). Video games are considered as a non-immersive VR, as the patient interacts with different visual and auditory stimuli in the environment via a screen (Cho et al., 2012). A Recent randomised controlled trial (RCT) in chronic stroke patients with poor sitting balance investigated the effect of an intensive trunk control training program (10 sessions per week for 4 weeks) using video games on trunk control. Post training results indicated an improvement in the Trunk Impairment Scale (TIS) and its subscales, with a significant difference between pre- and post-training ( $p < 0.05$ ) (Kim et al., 2018). Another study showed an agreement with this study when comparing the effect of conventional exercise with driving-based interactive video games (DBIVG) on trunk control in people with chronic stroke (Lee and Bae, 2020). Their results also demonstrate a significant improvement in the TIS and coordination subscale when comparing between groups ( $p < 0.05$ ). However, the limitations with the suggested interventions were that they used an expensive device that requires a large space for installation (Kim et al., 2018), thereby incurring high health care cost and making it difficult to be applied in clinical settings. In addition, the video games used in previous studies (Lee and Bae, 2020, Jung et al., 2020) required a high level of UL motor function to be able to handle the device.

Therefore, this doctoral study aims to address these limitations by investigating the feasibility of video game-based trunk exercises using Valedo inertial sensors in chronic stroke populations. Valedo sensor system was originally developed to be an assessment tool to measure trunk movements in healthy adults and intervention tool to treat low back pain by video games exercise (Bauer et al., 2015, Hugli et al., 2015). This technology has the potential to be used as tool for performing trunk exercises but requires an evaluation of its feasibility for people with chronic stroke.

## **6.2 Research question(s)**

Q1: Is the use of the Valedo system for trunk training feasible in people with chronic stroke?

Q2: Does 13.5 hours of trunk training using a video game intervention lead to changes in the trunk impairment scale (TIS), trunk muscle size, balance, and lower and upper limb function and impairment outcomes (SWMF and FMA) in people who suffer from chronic stroke?

### **6.3 Operationalisation of feasibility within the Thesis:**

The term feasibility is used in the literature to encompass any type of study that can produce a set of findings to help the investigators to determine whether an intervention should be recommended for a large scale efficacy testing (Bowen et al., 2009). According to the NIHR, a feasibility study focuses on conducting research to examine whether the study can be done (NIHR, 2012). The findings of a feasibility study not only enable researchers to identify the aspects that needed to be modified or changed in the research methods or protocols but also how changes might occur (Bowen et al., 2009). Feasibility studies can address eight different focus areas including acceptability, demand, implementation, practicality, adaptation, integration, expansion and limited-efficacy testing (Bowen et al., 2009). For the purpose of this study, the acceptability and implementation of delivering trunk exercise using video games in people with chronic stroke were tested, with a focus on how acceptable the stroke participants found the intervention (Bowen et al., 2009). Details of how these focus areas were operationalised within the thesis and definition of each construct (El-Kotob and Giangregorio, 2018, Sekhon et al., 2017) are presented in Table 6-1.

Acceptability can be defined as “A multi-faceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention” (Sekhon et al. 2017, p4). Acceptability of interventions is important to measure as it has been reported that if the recipients of an intervention deem it to be acceptable, they are more likely to adhere and benefit from improved clinical outcomes (Fisher et al., 2006). According to the theoretical framework of acceptability, the acceptability of an intervention is determined by seven factors including; 1) Ethicality, 2) Affective Attitude, 3) Burden, 4) Opportunity Costs, 5) Perceived effectiveness, 6) Self-efficacy and 7) Intervention Coherence (Sekhon et al., 2017). This PhD study address four of these components (i.e. affective attitude, perceived effectiveness, burden, and Intervention Coherence). Acceptability can be measured either quantitatively (i.e. using a satisfaction scale) or qualitatively by interviewing the participants (Sekhon et al. 2017).

The other area of feasibility tested in this study, implementation, focuses on the extent and manner with which an intervention can be implemented as planned and proposed in an uncontrolled study design (Bowen et al., 2009). Feasibility outcomes could include recruitment and retention rate,

adherence to the intervention and adverse events (El-Kotob and Giangregorio, 2018). There are four reasons to conduct feasibility studies including; 1) to inform process (e.g., feasibility of recruitment, retention, intervention adherence), 2) to estimate resource requirements (e.g., time and funding issues), 3) to inform management (e.g., personnel challenges, data collection or organization), and 4) to understand scientific inquiry (e.g., safety, intervention dose, potential treatment effect)(El-Kotob and Giangregorio, 2018). The need to perform the current study is indicated because there are only five studies published in the literature that study the delivery of trunk exercise using video games (Jung et al., 2020, Kim et al., 2018, Lee and Bae, 2020, Shin, 2020, Shin and Song, 2016b) and neither evaluated the acceptability (participant’s feedback toward the intervention) or implementation of this type of intervention.

Table 6-1: The operationalisation of feasibility within thesis

<b>Focus area</b>	<b>How operationalised within thesis</b>
<b>Acceptability</b>	Affective Attitude: How an individual feels about the intervention, after taking part in trunk training program using video games
	Experienced effectiveness: the extent to which the trunk exercise programme is perceived to have achieved its intended purpose (Sekhon et al.2017).
	Burden: the amount of effort that was required to participate in the intervention (Sekhon et al.2017).
	Intervention Coherence: The extent to which the participant understands the intervention and how it works (Sekhon et al.2017).
<b>Implementation</b>	Efficiency, or quality of implementation by looking to the practicability of the gameplay
	Safety: reporting any adverse event during the study
	Recruitment: the ratio of invited people who agreed to participate in the study to those who did not.
	Retention: the proportion of participants who completed the study
	Inclusion and exclusion rates: how inclusion and exclusion criteria affecting the recruitment rate
	Adherence to the intervention

## **6.4 Methods**

### **6.4.1 Study design**

In order to answer the research questions, a mixed-method convergent parallel design combining quantitative data with qualitative data 'QUAN+ QUAL' was used concurrently (Robson, 2002, Tashakkori and Teddlie, 2010). The quantitative phase (single group pre-post-test design) was followed by qualitative data collection using semi-structured interviews. Each phase was analysed independently and then integrated in the results and discussion sections.

### **6.4.2 Sample size**

Feasibility studies are not expected to have the large sample sizes that are needed to adequately power statistical null hypothesis testing (Tickle-Degnen, 2013). Therefore, it was not necessary to do a formal sample size calculation for statistical comparison of outcomes between pre-post intervention. It was a convenience sample based on previous research and the scope of the PhD . Previous feasibility studies of stroke rehabilitation using video games recruited between 10 and 14 participants for their intervention group (Aramaki et al., 2019, Hung et al., 2016a, Warland et al., 2019). A sample size of between 12 (Julious, 2005) and 50 participants (Sim and Lewis, 2012) has been recommended for feasibility studies. However, because the study was required to be completed within three years of the PhD programme and on account of limited resources, 10–14 participants were considered realistic for this feasibility study.

### **6.4.3 Recruitment procedure**

Chronic stroke patients with trunk impairment (mild to severe), who were not currently receiving any form of therapy, were recruited from the Faculty of Health Sciences' Research Participant Register and local stroke clubs. For recruiting stroke patients, the same procedure of recruitment used in the previous studies (study 1 & study 2 of this PhD) was followed. The invitation letter (Appendix 23), a reply slip, a freepost envelope (Appendix 24), and a participant information sheet (PIS) (Appendix 25) were sent via a third party. In addition, the researcher contacted Stroke Association and volunteers from local stroke clubs to give presentations regarding the study. If people were interested in participating in the study, they were given the information pack. In addition, an advertising poster was displayed at the University of Southampton Highfield campus in building 45 (Appendix 26). Table 6-2 presents the inclusion and exclusion criteria for stroke participants.

Due to the limited number of participants recruited in Southampton, plans were then made to conduct the study in Riyadh, Saudi Arabia (plan initiated from December 2018 onward). The researcher presented the study to two private centres (Alfaran centre, Mayo clinic) to host the study (January 2019) and both agreed to give the researcher a clinic in their centres and invite the possible patients in their database to participate in the study. Further, the researcher presented the study to the head of stroke rehabilitation department in Prince Sultan Humanity City and obtained an agreement to promote the study among the possible participants in their database. Following ethics approval (Appendix 27). A recruitment package including Arabic version PIS (Appendix 28) and advertising poster (Appendix 29) were distributed to the stroke survivors by each centre. Interested participants who received the package were instructed to contact the researcher either by mail (pre-paid envelope), email, or telephone. Thereafter, potential participants were screened for eligibility and invited to attend a scheduled baseline assessment session.

Table 6-2: Inclusion and exclusion criteria for stroke participants

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> <li>• Age &gt; 18 years</li> <li>• Over 6 months from last stroke</li> <li>• Able to understand and follow simple instructions (confirmed through asking participants to perform three tasks: cross one leg, clap hands, blow).</li> <li>• Able to sit unsupported for 10 seconds</li> <li>• Presence of trunk balance disturbance (TIS dynamic subscale 8/10 or less)</li> </ul>	<ul style="list-style-type: none"> <li>• Orthopaedic spine pathology or acute lower back pain</li> <li>• History of spontaneous fractures</li> <li>• Uncontrolled epileptic seizures (loss of consciousness or rapid uncontrolled movements). This is necessary because the Valedo sensor is highly sensitive to movement and consequently, rapid movement may affect the readings captured by Valedo.</li> <li>• Existence of implanted ferromagnetic materials or active devices within the body (e.g. pacemaker, acoustic device). This is because the magnetic field might affect such devices.</li> <li>• Skin disease or lesions in correspondence to the sternum, L1, and S1 (e.g. psoriasis or eczema).</li> <li>• Hip surgical replacement on the unaffected side. This is because the TIS will require a movement involving crossing the legs. This is contraindicated for hip replacement.</li> <li>• Severe communication disorders: unable to follow simple instructions (i.e. to cross one leg over the other, clap hands, or being unable to ask a simple question, if necessary).</li> <li>• Severe neglect deficits.</li> </ul>

In order to ensure inclusion and exclusion criteria were met, a telephone call screening was made, and participants were provided an opportunity to ask any questions regarding the study. In the first appointment, the researcher ensured that all participants read the PIS and understood the

procedure of the study and possible risks before signing the written informed consent (Appendix 30).

#### 6.4.4 Study Setting and Procedure

For UK participants, all appointments were conducted in the research laboratory of the University of Southampton (Building 67, School of Health Sciences). For Saudi Arabia participants, the appointments conducted in either Alfaran or Mayo centres according to the participant preferences. The study procedure is outlined in Figure 6-1.

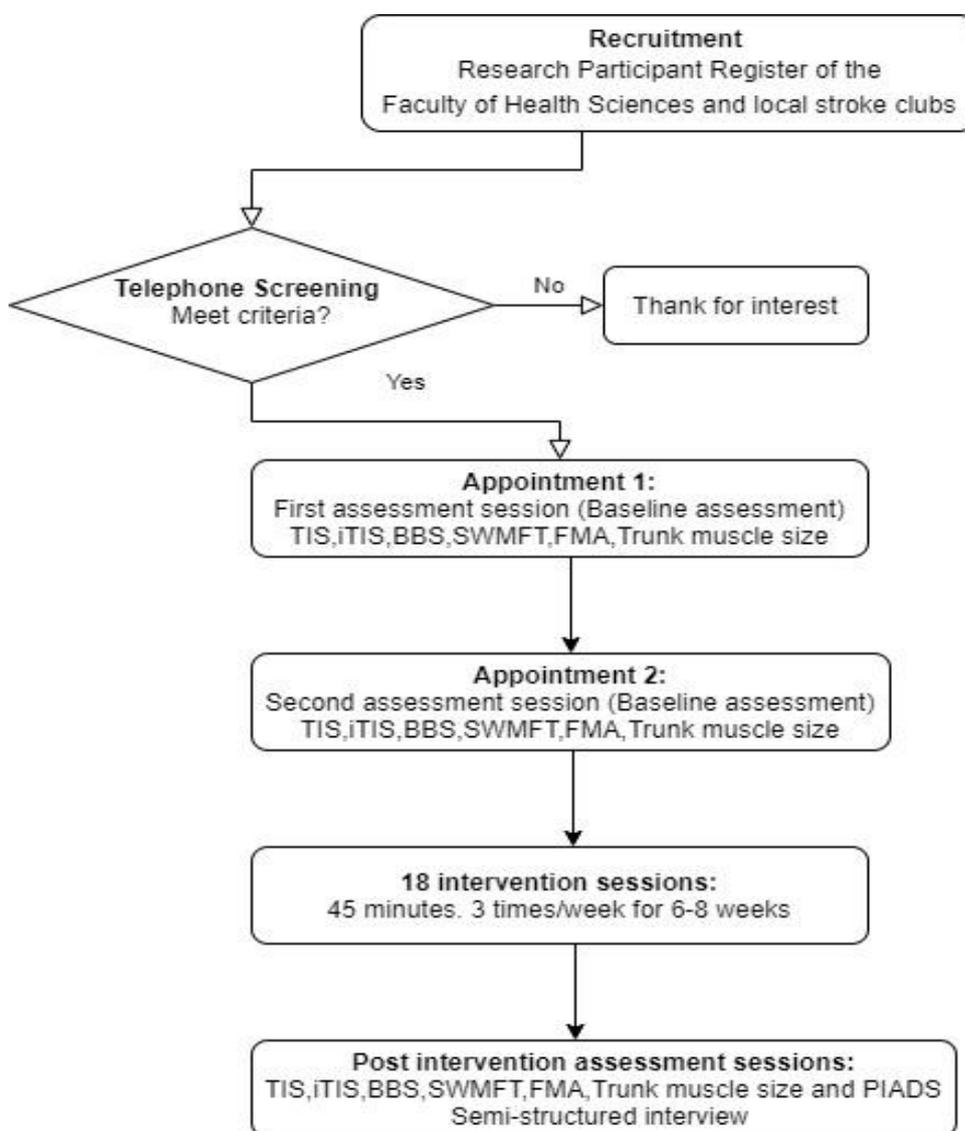


Figure 6-1: Study procedure flowchart

In order to ensure standardisation, the equipment used for the intervention included the Valedo system, a laptop computer loaded with the Valedo software, an adjustable plinth, and a standard 46" television screen for visualisation of the activities (Figure 6-2).

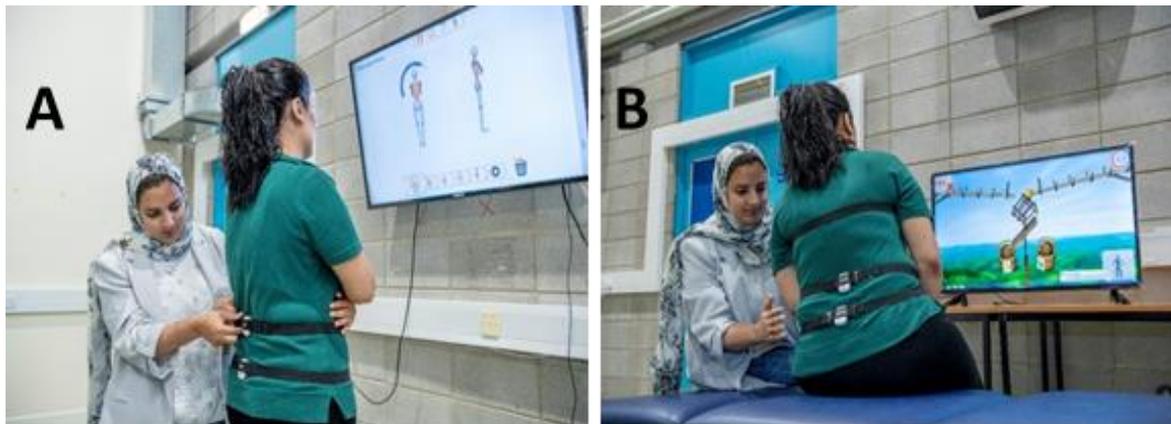


Figure 6-2: Study set-up

- A) researcher placing Valedo sensors on participant's trunk;
- B) participant sitting on the bed and playing Valedo games

Participants were asked to attend two assessment sessions followed by participation in the trunk training program using the Valedo system. Each participant received a total of 18 sessions, divided into three sessions per week (45 min/session) within a period of 8–10 weeks. If participants were feeling unwell or were unable to attend the session for any reason, they were offered an alternative date that week or the following week. Sufficient flexibility was built into the programme to allow for this. In the training session, participants wore the three sensors on belts over clothing (the first one at the sternal level and the second and third sensors on L1 and S1) and played five individually prescribed video games incorporating trunk movements such as bending to one side, rotating trunk, and pelvic tilting. The participant was given the opportunity to rest between games and as needed. In order to ensure safety, the researcher stood beside the participant during the exercise. The Valedo video games required performance of either one or two trunk movements to play the game (e.g. lateral trunk flexion or a combination of lateral trunk flexion and forward flexion). A description of each of the games and their required movements is presented in Table 6-3.

#### 6.4.5 Individualised video game programme and progression

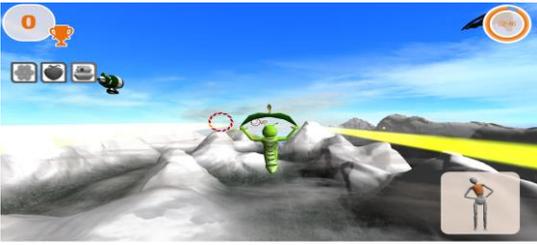
The video game program was personalized for each participant according to their ability (see Table 6-4) based on their TIS and BBS results. The initial position of training was determined according to the Berg Balance Scale (BBS) score. A score of 45 points in BBS was considered as a cut-off score, indicating greater balance ability and functional independence. Participants with  $BBS \geq 45$  practiced trunk exercise from standing position, while those with lower BBS did the exercise from sitting. In addition, TIS used to determine the content of the trunk exercise programme. For example, participants able to stand-alone safely ( $BBS \geq 45$ ) and having a full static sitting subscale but their

dynamic balance was decreased due to limited pelvic shortening/ lengthening ability practised the exercise from both sitting and standing. The goal of sitting exercise is to improve dynamic subscale by practicing pelvic tilting exercise when playing golf and glider games Table 6-3. The detailed description of the games prescribed for each level of ability is presented in Appendix 31.

Progression of the exercise entailed changing the position of the training and increasing game difficulties according to the score gained by the end of the game and changes in the BBS score. Each Valedo game has three levels of difficulty (easy, medium, and hard). Every participant begins at the easy level and progress to the next level of difficulty when he/she achieves the maximum score for that level. In addition, the participants' balance was re-assessed using the BBS at the mid-training period (in the ninth session). Exercise progression from sitting practice to a standing position is applied according to two criteria:

1. Participants gaining a high balance score in the re-assessment of BBS (>45 points) at the mid-treatment period (in the ninth session).
2. When participants achieve a full score in three games (one game targeting the static sitting balance subscale, one game targeting the dynamic sitting balance subscale, and one game targeting the co-ordination subscale) (even prior to the mid-treatment period).

Table 6-3: Description of Valedo video games

Game	Description	Goal of training
<p><b>Diver</b></p> 	<p>Patients must execute fine, controlled trunk or pelvic movements in a sagittal plane to ensure that the caterpillar collects the pearls and avoid the obstacles.</p>	<p>Trunk mobilization (pelvic anteversion/retroversion will make the caterpillar swim up or down)</p>
<p><b>Glider</b></p> 	<p>Patients must execute fine, controlled trunk or pelvic movements to fly up and down in order to ensure that the caterpillar flies through the hoops.</p>	<p>Trunk mobilization (trunk flexion/ extension or pelvic anteversion/retroversion will make the caterpillar fly up or down, trunk lateral flexion left/right or pelvic tilt left/right will make the caterpillar fly left and right)</p>
<p><b>Clock</b></p> 	<p>Patients must execute fine trunk or pelvic movement and return to the neutral position with full and limited visual feedback.</p>	<p>Movement awareness (trunk flexion/ extension or pelvic anteversion/retroversion will cause the platform to swing forward and backward, trunk lateral flexion left/right or pelvic tilt left/right will cause the platform to swing left and right)</p>

<p><b>Colours</b></p> 	<p>Patients must execute fine, combined trunk or pelvic movements to roll the ball to the corresponding colour (e.g. green ball to green colour)</p>	<p>Mobilization (trunk flexion/ extension or pelvic anteversion/retroversion will cause the platform to swing forward and backward, trunk lateral flexion left/right or pelvic tilt left/right will cause the platform to swing left and right)</p>
<p><b>Treasure island</b></p> 	<p>Patients must execute fine, combined trunk or pelvic movements to take the key successfully to the treasure chest.</p>	<p>Mobilization (trunk flexion/ extension or pelvic anteversion/retroversion will move the rolling avatar up and down; trunk lateral flexion left/right or pelvic tilt left/right will move the rolling avatar left and right)</p>
<p><b>Brick-breaker</b></p> 	<p>Patients must rotate trunk left and right in a controlled manner to avoid losing the ball.</p>	<p>Mobilization (trunk rotation to the left and right)</p>
<p><b>Fruits</b></p> 	<p>Patients must make controlled lateral pelvic tilt movements while keeping the trunk still to put every piece of fruit in a corrected respective basket (e.g. watermelon into the watermelon basket)</p>	<p>Movement isolation</p>

Table 6-4: Identifying the level of a participant’s ability by researcher based on TIS and BBS results

Level	Description	TIS and BBS scores
Level 1	<ul style="list-style-type: none"> <li>• Able to sit independently for over 10 seconds.</li> <li>• Able to passively put and hold the non-paretic leg on the paretic leg.</li> <li>• Able to actively place and hold the paretic leg on the non-paretic leg; backward displacement of the trunk over 10 cm is allowed.</li> </ul>	<ul style="list-style-type: none"> <li>• TIS ≤ 6</li> <li>• BBS &lt; 45</li> </ul>
Level 2	<ul style="list-style-type: none"> <li>• Able to sit independently for over 10 seconds.</li> <li>• Able to passively place and hold the non-paretic leg on the paretic leg.</li> <li>• Able to actively place and hold the paretic leg on the non-paretic leg; no backward displacement of the trunk for over 10 cm.</li> <li>• Touch bed/ table with hemiplegic and non-hemiplegic elbow and return. Patients moves actively with or without compensations. However, the appropriate shortening or lengthening is not necessary.</li> </ul>	<ul style="list-style-type: none"> <li>• TIS static =7</li> <li>• TIS dynamic (1-7) ≤ 6</li> <li>• BBS &lt; 45</li> </ul>
Level 3	<ul style="list-style-type: none"> <li>• Able to sit independently and with appropriate shortening/ lengthening touch bed/ table with hemiplegic and non-hemiplegic elbow.</li> <li>• Shortening/ lengthening when lifting the pelvic must not be correct.</li> <li>• Asymmetrical rotation of the upper portion of the trunk.</li> <li>• Static standing is safe.</li> </ul>	<ul style="list-style-type: none"> <li>• TIS static =7</li> <li>• TIS dynamic (1-7) ≤ 6</li> <li>• BBS ≥ 45 (stand-alone safely)</li> </ul>
Level 4	<ul style="list-style-type: none"> <li>• Able to lift the pelvis from bed/table without compensation.</li> <li>• Rotation of the lower portion of the trunk is possible with or without compensation.</li> <li>• Dynamic standing is safe.</li> </ul>	<ul style="list-style-type: none"> <li>• TIS static =7</li> <li>• TIS dynamic (1-10) =10</li> <li>• TIS coordination (1-2= 4, 3-4 &lt;3)</li> <li>• BBS ≥ 45 (stand-alone safely)</li> </ul>

#### 6.4.6 Outcome assessments (Quantitative Phase)

##### A. Primary outcomes (Assessment of feasibility)

##### 1) Acceptability (psychological impact)

The concept of acceptability focuses on how the study participants react to the intervention; it includes satisfaction, perceived appropriateness, and intent to continue use (Bowen et al., 2009).

Thus, this concept concentrates on the assessment of the psychosocial impact of using the assistive technology (Valedo video games). A systematic search looking for appropriate psychosocial impact assessment scales was conducted (Appendix 32). Measures were mostly limited by a lack of establishment of psychometric properties among stroke patients, they tended to assess only cognitive and confidence aspects and omit numerous other factors related to the assistive device, such as safety and practicality. However, the Psychosocial Impact of Assistive Devices Scale (PIADS), a self-rating questionnaire comprising 26 items was found to measure the psychological impact by addressing the following three indicators: competence, adaptability, and self-esteem (Day et al., 2002). Scores can range from -3 (maximum negative impact) through zero (no perceived impact) to +3 (maximum positive impact). It has well-established psychometric properties (Jutai and Day, 2002) and clinical utility (MacPhee et al., 2004), and has been shown to be a sensitive and responsive measurement tool in terms of the impact of several assistive devices across various disability populations (Devitt et al., 2004, Yachnin et al., 2017). The PIADS was therefore chosen for this study; the questionnaire form and manual are attached in Appendix 33.

## **2) Recruitment and retention**

Recruitment was defined as the ratio of invited people with strokes who agreed to participate in the study to those who did not. Retention was determined by the proportion of patients who completed the trunk rehabilitation programme (Bower et al., 2014).

## **3) Adherence**

In this study, adherence was considered as the compliance of the participants with regard to attending sessions, regardless of their behaviour during intervention sessions. It was determined by using an adherence index involving dividing the number of sessions attended by the number of planned sessions (Brewer et al., 2000).

## **4) Participation**

Patient participation was measured using the Pittsburgh Rehabilitation Participation Scale (PRPS) (Skidmore et al., 2010), a clinician-rated measure that quantified the participants' participation in a prescribed rehabilitation session. The PRPS score ranges from 1 (patient refused the session) to 6 (patient completed all the exercises). The psychometric properties of PRPS are validated for different conditions, including stroke (Lenze et al., 2004), and it has been used to assess the participation of stroke participants using technology (Im et al., 2015). It demonstrates a good level of construct validity, with an excellent correlation between PRPS and the Functional Independence Measures (FIM) ( $r = 0.51$ ) and a high inter-rater reliability (ICC = 0.96).

## **5) Safety**

Safety was recorded in every session by monitoring any events that occur during sessions and by asking the participants at the beginning of each session if they fell or experienced any pain or other symptoms after the last exercise session (Appendix 34).

### **B. Secondary outcomes (Clinical outcome measures)**

#### **1) Trunk impairment - trunk impairment scale**

An extensive literature search was performed to identify articles reporting a clinical measure of trunk performance in stroke participants—three trunk control measurement scales were found and are summarized in Appendix 35. Trunk impairment was assessed using the 17 tasks that are part of the TIS developed by (Verheyden et al., 2004) because it has no ceiling effect (Verheyden et al., 2005). In addition, the TIS has a sufficient psychometric property with high concurrent validity ( $r = 0.83$ ) and excellent test-retest (ICC = 0.96) and interrater reliability (ICC = 0.99) (Verheyden et al., 2005, Verheyden et al., 2004).

#### **2) Trunk impairment - Instrumented trunk impairment scale**

In addition to the TIS, additional information regarding trunk performance (e.g. ROM of trunk lateral flexion when performing dynamic subscale tasks) can be found from the instrumented TIS (iTIS) developed in Study 1 of this doctoral study (see Chapter 3). The iTIS has a sufficient psychometric property, with good to excellent properties in dynamic (intarater ICC = 0.60–0.95; interrater ICC = 0.59–0.93) and coordination subscales (intrarater ICC = 0.05–0.72; inter-rater ICC = 0.04–0.78). Moreover, the construct validity of iTIS indicated a moderate correlation with clinical trunk impairment scale (cTIS) ( $r = 0.52–0.73$ ) (Alhwoaimel et al., 2020).

#### **3) Kinematics of trunk movement during arm function**

The data from trunk kinematics informs understanding of the effect of the intervention, enabling differentiation between actual and substitutional improvement of upper limb performance. Trunk kinematics during the SWMFT task performance were captured using Valedo system as described in Chapter 5.

#### **4) Abdominal muscle size**

Trunk muscle strength has been reported to be statistically significantly correlated to balance, functional performance, and falls (Granacher et al., 2013). Furthermore, transverse abdominis muscle thickness has been reported to be positively correlated with total TIS ( $r = 0.389$ ,  $P < 0.05$ ) in people with chronic stroke (Lee et al., 2018a). A recent RCT studies the effect of trunk stabilization exercise (20 min. X 3times/week for 6 weeks) on abdominal muscle thickness in people with chronic

stroke and found that the transverse abdominis (TrA) and external oblique (EO) muscle thickness on hemiplegic side increased significantly ( $p < 0.05$ ) post intervention (Lee et al., 2020). Further, their balance (BBS) and gait (10 MWT) ability were improved significantly ( $p < 0.01$ ). Thus, muscle thickness of bilateral trunk muscles was imaged by an expert assessor (Simon Brown) who is qualified and experienced in rehabilitative ultrasound for the following muscles: rectus abdominis (RA), transverse abdominis (TrA), internal and external oblique (EO & EO).

A real-time portable ultrasound scanner was used for this purpose (Imagic Agile, Pie Data, Ltd) at 5-6.6 MHz with a linear transducer (Teyhen et al., 2012). The use of sonographic measurement to measure trunk muscle thickness in people with stroke showed to be reliable (ICC = 0.95–0.98) (Seo et al., 2013). The scanning measurements taken while participant lies in a supine position, with a pillow under their knees. As the trunk muscles have the potential to be affected bilaterally post-stroke, the measurements taken from both side of trunk (Karthikbabu et al., 2012). Water-based ultrasound gel was used between the head of the transducer and the participant's skin. For the external and internal obliques and the transverse abdominis muscles, the location of the transducer was immediately below the ribcage in direct vertical alignment with the anterior superior iliac spine (ASIS). For the rectus abdominis, the location of the transducer was immediately above the umbilicus and then moved laterally from the midline until the muscle cross-section was centred on the image (Rankin et al., 2006). Images were taken at rest and during an active straight leg raise (ASLR) on both sides in order to assess change in muscle thickness of the lateral muscles (not RA) (a total of 12 scans) (Teyhen et al., 2012). If participants were unable to perform an ASLR on the hemiplegic side, these scans were not taken. The test procedure took less than half an hour. The images taken were saved onto a disc for analysed offline using MATLAB program (MATLAB R2019a). Muscle thickness was measured as the distance between the superior and inferior border of each muscle (Teyhen et al., 2012). The MATLAB algorithm was written by an expert (Martin Warner) to measure the thickness of each muscle in cm, as depicted in Figure 6-3. The reliability for using this algorithm to measure muscle thickness was tested by author (NA) and the experienced and reliable rater (Simon Brown) (Appendix 36). The thickness of the trunk muscles was only measured for the UK participants due to the availability of the ultrasound muscle measuring device at the University of Southampton but not at KSA.

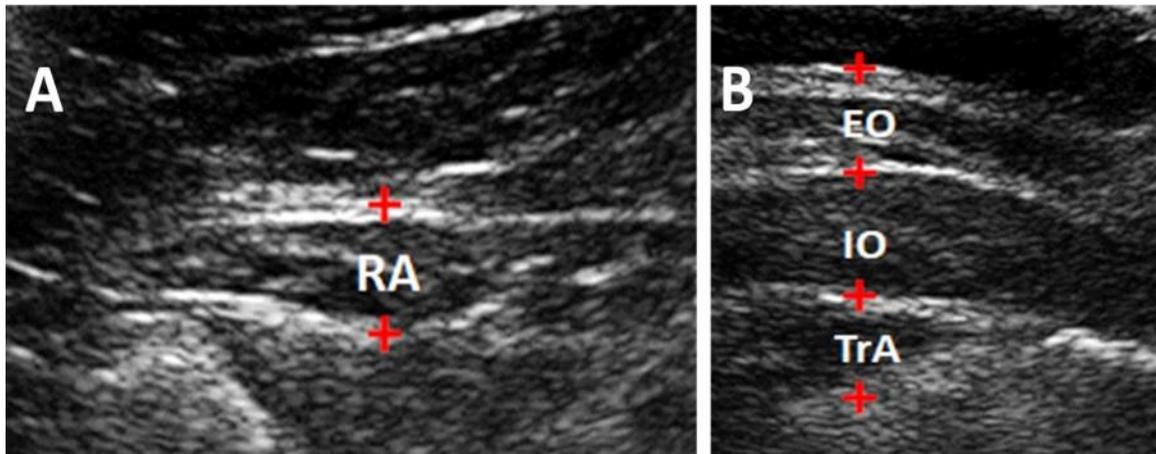


Figure 6-3: Ultrasound images of the abdominal muscles of Participant 1—affected side

A) A cross-sectional scan of rectus abdominis (RA)

B) Ultrasound scans of the external oblique (EO), internal oblique (IO), and transversus abdominis (TrA)

### 5) Balance assessment: Berg Balance Scale

The Berg Balance Scale (BBS), which was developed to measure balance in the elderly, was used to measure static and dynamic balance (Berg et al., 1995). It comprises 14 items rated from 0 (indicating lowest level of function) to 4 (indicating highest level of function), and the total score is calculated over a range of 0–56. Scoring was done according to the participant’s ability to perform the task independently and/or against time. The BBS has sufficient psychometric properties for the stroke population: excellent test-retest reliability (ICC = 0.98) (Liston and Brouwer, 1996), excellent interrater and intrarater reliability (ICC = 0.98; ICC = 0.97) (Berg et al., 1995), and excellent construct validity ( $r = 0.91$ ) (Mao et al., 2002). The cut-off score for the BBS is 45 points; participants with less than 45 points indicate that these individuals may be at a greater risk of falling (Dogan et al., 2011). As a result, this cut-off point used to determine the position of exercise (sitting or standing) later in the intervention section.

### 6) Upper and lower limb impairment: Fugl-Meyer Assessment (FMA)

This is a multi-item Likert-type scale that measures motor impairment following a stroke (Fugl-Meyer et al., 1975). The UE subsection of FMA contains 33 items, while the LE subsection contains 17 items. All UL and LL items are designed to measure the movement, coordination, and reflex action of the shoulder, elbow, wrist, hand, hip, knee, and ankle. Each item of the FMA is scored on a three-point ordinal scale (0 = cannot perform, 1 = performs partially, 2 = performs fully). The total score of the FMA can range from a minimum of 0 to a maximum of 100 points.

It has been reported that FMA has sufficient psychometric properties for research and in clinical practice, including excellent test-retest reliability (ICC = 0.97 for the UL subsection; ICC = 0.86 for the LL subsection) (Kim et al., 2012, Platz et al., 2005) and interrater reliability ( $r = 0.995$  for the UL

subsection;  $r = 0.96$  for the LL subsection) (Duncan et al., 1983, Kim et al., 2012) among chronic stroke patients. In addition, FMA demonstrates a high level of construct validity (excellent correlation between FMA and Functional Independence Measures (FIM),  $r = 0.63$ ) (Shelton et al., 2001) and predictive validity (excellent correlation between FMA and the Barthel Index at discharge,  $r = 0.66$ ) (Hsueh et al., 2008). Further, a recent overview of systematic reviews evaluating the clinical utility of upper extremity outcome measures for use in stroke revealed that the Fugl-Meyer Assessment (FMA, motor part) demonstrated the strongest level of psychometrics and clinical utility' (Alt Murphy et al., 2015)(p.4).

### **7) Upper limb functional activity: Streamlined Wolf Motor Function Test (SWMFT)**

The Wolf Motor Function Test (WMFT) has been recommended for assessment of the UE function at activity level in research and clinical practice (Alt Murphy et al., 2015). This test can differentiate between patients who are considered higher or lower functioning among mild-to-moderate stroke patients (Bogard et al., 2009). Moreover, the test is unaffected by whether or not the affected limb is dominant (Bogard et al., 2009). The shortened version, known as the Streamlined Wolf Motor Function Test (SWMFT), as recommended for chronic stroke patients, is used in this study (Appendix 37) because the administration time of the full version could cause fatigue for stroke patients with low levels of exercise tolerance (Bogard et al., 2009, Chen et al., 2012). The SWMFT has sufficient psychometric properties and a high sensitivity to change on the part of individuals over time, based on a Rasch analysis study (Chen et al., 2012, Wu et al., 2011). It comprises the following six tasks: hand to table (front), hand to box (front), reach and retrieve, lift can, lift pencil, fold towel, turn key in lock, and extend elbow (with 1-lb weight). The rates of the SWMFT-FAS range from 0 (no attempt made to use the more affected upper extremity) to 5 (movement appears to be normal) (Chen et al., 2012). The mean performance time of the tasks has been calculated for each participant (SWMFT-Time) and compared with the normative data for WMFT (Wolf et al., 2006).

#### **6.4.7 Qualitative Phase**

To inform the acceptability and feasibility of using the Valedo system to deliver trunk exercise, qualitative data was collected. The semi-structured interview was chosen because it is suitable for people's perceptions and opinions by focusing on the issues that were related to the research questions (Kallio et al., 2016). In addition, the semi-structured interview allowed the interviewee to expand their answers and views in more details when using a prompting questions.

In the current study, the main focus was the acceptability of this type of intervention among people with chronic stroke. Therefore, semi-structured interview topic guide (Appendix 38) comprises

eight categories of questions including; attractiveness and enjoyment of the programme, impact of intervention, motivation to exercise, influence of audio-visual feedback, safety, commitment to the programme, usability of the system and general questions for improving the study. the questions were designed as open questions with prompting questions. Further, Likert questions were used to answer the questions related to the difficulty of each game played. The topic guide was developed using Psychosocial Impact of Assistive Devices Scale (PIADS) and according to the previous studies using technologies (e.g. Wii Sports and Microsoft Kinect Sensor) in stroke rehabilitation which investigated the participant's perspective towards using these technologies (Celinder and Peoples, 2012; Proffitt and Lange, 2015).

Each participant was interviewed by the researcher after completion of the intervention. Each interview lasted 20–30 minutes and was audio recorded; subsequently, each interview was transcribed verbatim and saved as a Word document.

#### **6.4.8 Data analysis**

##### Quantitative data analysis

Descriptive analysis was used to summarize the participants' baseline demographic data (age, gender, time since last stroke, type of stroke, affected side, etc.) and clinical data (total TIS, TIS subscales, FMA, SWMFT-FAS, SWMFT-time, Berg Balance Scale).

For acceptability and feasibility outcome measures, the PPRS data was presented as the mean of the participation for each participant. For PIADS scoring and clinical outcomes, non-parametric tests were used due to concerns regarding the small sample size and normal distribution.

In order to evaluate whether there was any change in the clinical outcome measurements after completion of the intervention programme, the change in scores between pre- and post-intervention, with percentage of change, were presented.

##### Qualitative data analysis

Interviews were transcribed verbatim by the lead researcher. For the semi-structured questions, the qualitative data were analysed using the framework approach (Gale et al., 2013). The framework method was developed by the qualitative researchers Jane Ritchie and Liz Spencer in the late 1980s (Ritchie et al., 2013). This method belongs to a broad family of analysis methods often collectively termed thematic analysis (Gale et al., 2013). The rationale for using the framework approach is that it is easy to follow by novice researchers with clear instructions on how to move from data management to developing the analysis and producing highly structured

summarized data. The interconnected stages within the framework approach explicitly describe the processes that guide the systematic analysis of data from the development of descriptive to explanatory accounts. Thus, the researchers' interpretations of participants' experiences are transparent (Ritchie and Lewis 2003). Although the framework approach is similar to the thematic analysis in the initial stages, including transcription, familiarisation with the interviews, coding and developing the themes (Gale et al., 2013), traditional thematic analysis has been criticised for being subjective and lacking transparency in relation to the development of themes (Attride-Stirling, 2001). The clarity of developing themes in the framework approach by developing a framework matrix helps to reduce the burden of dealing with a large data set at the interpretation stage. Further, a researcher who works on data analysis can understand how the codes are developed and categorised under each theme (Gale et al., 2013).

Table 6-5 details the stages of the framework approach and how the researcher applied it. The resultant analysis produces a thematic framework comprising the main themes and subthemes. Data analysis is not purely inductive or deductive due to the nature of the research questions. A question such as 'Is trunk training using the Valedo® system feasible in people with chronic stroke?' requires a deductive approach to both data collection and analysis (e.g., semi-structured interviews with topic guide that can explore specific aspects in feasibility) to understand the experiences of participants with regards to the acceptability of the intervention and its implementation. As a result, the framework analysis is informed by some expectations of what the data will show. However, there was space to discover other unexpected aspects of the participants' experience in practicing trunk exercise using video games. In summary, the framework approach used for analysing the qualitative data in this study was adapted for use in combined types (inductive and deductive) of qualitative analysis.

The qualitative data collected from participants in Saudi Arabia were translated from Arabic into English before performing any form of qualitative analysis. To ensure that credibility is maintained and not affected by the translation, a meaning-based approach was used to translate the transcripts (Al-Amer et al., 2015). Furthermore, the same certified translator who has a BSc degree in English translation did the whole translation of the five transcripts. Subsequently, a group of three physiotherapists with bilingual (Arabic-English) skills checked the translation validity by using a backward translation technique for the translated transcripts (Al-Amer et al., 2015). A good similarity was found in the meaning compared with the original transcripts, and a good compatibility was observed between the three translators.

The NVivo12 qualitative data software package (QSR International Pty Ltd. Version 12) was used to manage the qualitative data and identify the initial themes (Appendix 39). Each overarching sub-theme was then displayed in a matrix table, allocating rows to each participant and columns to each code (Appendix 412). This matrix enables researchers to clearly see the data of all participants included in the analysis and facilitates easily moving forwards and backwards between the original data and emerging interpretations. This aids the comparisons among cases (e.g., between severely disabled and mildly disabled participants) (Spencer et al., 2014).

In recognition of the influence of the researcher on qualitative data, different techniques and measures were considered to improve the trustworthiness of the data. Trustworthiness refers to the degree of confidence that qualitative researchers have in their data and can be assessed using five criteria: credibility, transferability, dependability, confirmability and reflexivity (Korstjens and Moser, 2018, Polit and Beck, 2012, Shenton, 2004). The credibility of the data implies the congruence of the findings with reality (Shenton, 2004). To ensure credibility of the data, data triangulation was applied using different methods of data collection (quantitative and qualitative), different types of participants (independent, mildly disabled, and severely disabled), and different sites of data collection (UK and KSA) (Shenton 2004). To ensure the transferability of this study—‘the extent to which the findings of one study can be applied to other situations’, detailed description was provided for the contextual information (participant demographic data and disability level) to enable readers to have an appropriate understanding of participants’ views (Shenton, 2004. p69). The criterion of dependability is linked to the issue of reliability—the extent to which the study could be repeated by other researchers and that the findings would be consistent (Shenton, 2004). This criterion is difficult to achieve in qualitative research, as it may require the use of ‘overlapping methods’, such as the focus group and individual interviews, and this was not applicable to this study (Shenton 2004). However, in-depth methodological descriptions—including the recruitment process, intervention, and data analysis—were provided to enable the study to be repeated. The fourth criterion of trustworthiness of the data is confirmability. This criterion is concerned with objectivity in science and shows that the findings of the research study are clearly derived from the data gathered from participants and not figments by the researchers’ (Polit and Beck, 2012; Shenton, 2004). To aid the confirmability of this study, an audit trail technique was used to detail the process of data collection, data analysis, and interpretation of the data. An explanation of how the codes merged under each theme was provided in the qualitative analysis (Appendix 41) and results sections. Lastly, regular meetings were conducted with the supervisory team at all stages of analysis to improve the trustworthiness of the findings. In the meeting, the lead researcher and both supervisors conducted a small part of

the analysis to ensure consensus on the initial codes. Additionally, supervisors regularly checked the analysis output by feedback on the framework matrix. However, despite the steps and measures that were undertaken to increase research rigour, it is acknowledged that personal and professional experiences, gender, culture, and roles as a physiotherapist and researcher might have influenced the development of study design, data collection, analysis, and interpretation of study findings. As a result, reflexivity was considered in all stages of this research to ensure the transparency and quality of the qualitative research. Reflexivity is an attribute of being self-aware of oneself as researcher (own biases, preferences, preconceptions), and the research relationship (relationship to the respondent, and how the relationship affects participant's answers to questions) (Korstjens and Moser, 2018). Reflexive notes of an interview described the setting noted during the interview itself and while transcribing the audio tape and analysing the transcript.

Table 6-5: Stages of the framework approach

Stage	Description
1. Transcription	Verbatim (word-for-word) transcription of the interviews done by researcher
2. Familiarisation with the interviews	Using the audio recording and transcript and/or any reflective notes that were recorded by the interviewer. Reading and re-reading the data, noting down initial ideas.
3. Coding	Reading the transcript line by line, applying a paraphrase or label (a 'code') that described whether what had been interpreted in the passage was important. The coding was conducted by the researcher in three cycles. The first two cycles were conducted manually using printed interviews (Appendix 40). The final coding cycle was conducted using NVivo software (version 12) to facilitate the process of coding transcripts and for data management (Appendix 39).
4. Developing a working analytical framework	After coding the first few transcripts, all those involved in the research (PhD researcher (NA) and her supervisors (AMH and RT)) met to compare the labels that have been applied and agree on a set of codes to apply to all subsequent transcripts. Codes were grouped together into categories, which are then clearly defined (Appendix 41). This formed the working analytical framework.
5. Applying the analytical framework	The researcher applied the working analytical framework to all transcripts using the existing categories and codes. Each code was typically assigned a number or abbreviation for easy identification (therefore, the full names of the codes did not have to be written out each time) and were written directly onto the transcripts.
6. Charting data into the framework matrix	A spreadsheet was used to generate a matrix, and the data were 'charted' into the matrix. Charting involved summarizing the data by category from each transcript. The charting tables are presented in (Appendix 412). Each participant was represented by a row, and each code was represented by a column with the represented data from each transcript.

7. Interpreting the data	Characteristics of and differences between the data were identified, perhaps generating typologies, interrogating theoretical concepts (either prior concepts or ones emerging from the data), or mapping connections between categories to explore relationships and/or causality. Interpretation of the data applied in both results and discussion sections to fulfil the aim of the study.
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## 6.5 Integration of Quantitative and Qualitative Findings

How qualitative and quantitative data fit together is a critical concept in developing a mixed methods study (Fetters et al., 2013). In the current study, the quantitative and qualitative data were integrated at the interpretation level and displayed side by side through side by side joint display, as recommended by Creswell and Clark (2011). Initial integration was undertaken by the researcher (NA), with validation of findings through discussion and review of themes with the research supervisors (AM and RT).

## 6.6 Quantitative Results

This study was conducted from April 2018 to September 2019, and ten chronic stroke survivors completed the intervention. Two participants withdrew from the study after the initial assessment session—one had thought that the exercise involved lower limb training and the other wanted to travel to another city to try traditional medicine. The enrolled participants included 8 males and 2 females, with a mean age of  $63 \pm 15$  years. Five participants were recruited from Southampton, United Kingdom, and five participants were recruited from Riyadh, Saudi Arabia. The two initial baseline assessments were compared using a T-test and showed a stable measurement with no significant change found; therefore, the second baseline assessment was considered and used. The baseline clinical outcome measures are presented in Table 6-6.

Table 6-6: Characteristics of the Participants

Data collection site	ID	Age (years)	Gender	Time since stroke (months)	Side of weakness	FMA-LL		FMA-UL		SWMFT-FAS	SWMFT-time	TIS		BBS	Assistive device
						Score	Mobility function level	Score	Impairment level			Score	Trunk control level		
UK	P1	49	Male	155	Left	32	High	57	Mild	4.00	6.61	14	Fair	52	None
	P2	54	Female	75	Right	19	Low	20	Severe	1.63	5.49	11	Fair	44	None
	P3	62	Male	40	Left	7	Low	4	Severe	NT	NT	12	Fair	24	W/C
	P4	69	Male	169	Left	12	Low	4	Severe	1.75	10.50	9	Poor	27	Cane
	P5	59	Male	104	Left	20	Low	28	Moderate	2.25	12.36	16	Fair	46	None
KSA	P6	92	Male	20	Right	18	Low	51	Mild	4.00	12.68	11	Fair	25	Cane
	P7	75	Male	21	Left	25	High	56	Mild	4.50	10.06	13	Fair	40	Cane
	P8	40	Male	127	Left	19	Low	15	Severe	2.13	8.69	11	Fair	45	None
	P9	75	Male	53	Right	17	Low	11	Severe	1.38	15.93	15	Fair	26	Cane
	P10	54	Female	44	Right	9	Low	0	Severe	0.13	13.16	12	Fair	11	W/C

FMA-LL = Fugl-Meyer Assessment Lower Extremity, FMA-UL = Fugl-Meyer Assessment Upper Extremity, SWMFT-FAS = Streamlined wolf motor function test—Functional Ability Scale, TIS = Trunk Impairment Scale, BBS = Berg Balance Scale; W/C = Wheelchair, UK = United Kingdom, KSA = Kingdom of Saudi Arabia, NT = not tested

## 6.6.1 Primary outcomes (Assessment of feasibility)

### 1- Acceptability (psychological impact)

The Psychosocial Impact of Assistive Devices Scales (PIADS) was measured for each participant at the end of the intervention programme and is illustrated in Figure 6-4. The rating shows the three subscales of the PIADS scale, including competence, adaptability, and self-esteem. The median score of PIADS questionnaire subsections—competence (median = 1.7), adaptability (median = 1.6), and self-esteem (median = 1.8)—indicated that the participants experienced mostly positive psychosocial experiences (maximum positive impact = 3) as a result of using video games to deliver trunk exercise. Furthermore, participant 3 demonstrated the lowest total score (total PIADS = 7), as most of his answers were zero (no perceived impact). The only item that was reported as negative (maximum negative impact = -3) by three participants (P1, P4, and P8) was ‘frustration’, as presented in Table 6-7. The scores of -2 and -3 in frustration meant that the participant was upset about the lack of progress in achieving his/her desires or feeling disappointed.

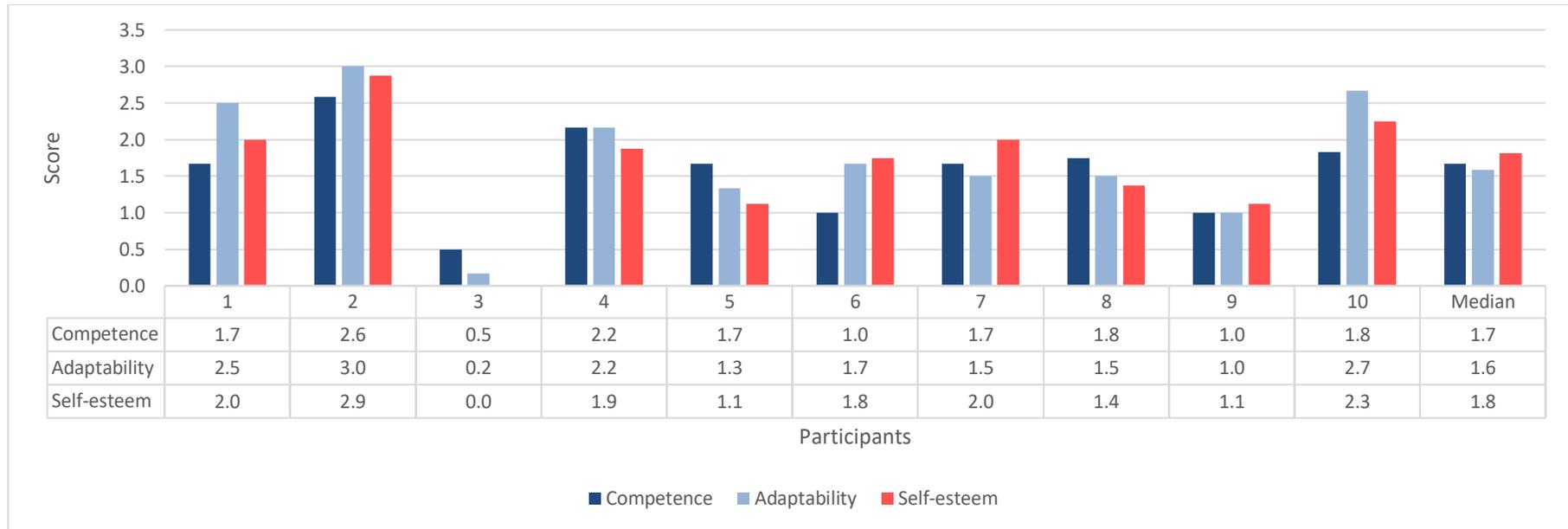


Figure 6-4: Bar chart of PIADS ratings from participants for the use of Valedo video games to deliver trunk exercise

Table 6-7: Psychosocial impact of PIADS scoring for each participant

ID	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10
ITEM	Score	Score	Score	Score	Score	Score	Score	Score	Score	Score
Competence	2	3	2	2	2	1	2	2	2	2
Happiness	3	3	0	3	2	3	3	3	2	3
Independence	2	3	0	3	2	1	1	2	0	3
Adequacy	1	3	0	2	2	1	3	0	2	3
Confusion	0	3	0	1	0	1	1	3	3	3
Efficiency	1	3	0	2	2	1	2	2	0	3
Self-esteem	2	3	0	1	2	3	3	3	0	3
Productivity	3	3	0	3	2	2	2	2	0	3
Security	2	3	0	3	0	2	2	2	2	3
Frustration	1	-3	0	2	0	0	-2	2	-2	0
Usefulness	1	2	1	2	2	0	1	2	0	0
Self-confidence	3	2	0	2	2	1	2	2	0	3
Expertise	2	2	1	2	2	0	2	0	0	0
Skilfulness	2	2	1	2	2	0	1	3	3	1
Well-being	3	3	0	2	2	3	3	3	0	3
Capability	1	2	1	2	2	1	2	3	0	0
Quality of life	2	3	0	2	1	2	1	0	0	2
Performance	3	2	0	3	1	2	2	2	2	2
Sense of power	3	3	0	3	2	2	2	3	1	3
Sense of control	3	3	0	3	1	0	2	0	2	3
Embarrassment	1	3	0	2	0	3	0	0	0	0
Willingness to take chances	1	3	0	1	2	2	2	3	2	3
Ability to participate	2	3	0	1	1	0	1	0	0	3
Eagerness to try new things	3	3	1	3	1	1	0	0	2	3
Ability to adapt to the activities of daily living	3	3	0	3	1	2	1	0	0	2
Ability to take advantage of opportunities	3	3	0	3	1	2	2	3	2	2
<b>Total</b>	<b>51</b>	<b>54</b>	<b>7</b>	<b>52</b>	<b>37</b>	<b>28</b>	<b>39</b>	<b>39</b>	<b>17</b>	<b>50</b>

## **2- Recruitment and retention**

The recruitment process took place between April 2018 and April 2019 in Southampton (United Kingdom) and between January and May 2019 in Riyadh (Saudi Arabia). In the UK, six chronic stroke participants enrolled in the study (five recruited from the Health Sciences School registry and one recruited from a stroke club in Southampton). In Saudi, six chronic stroke patients enrolled in the study (three recruited from Alfaran Medical Centre and three recruited from Prince Sultan Humanity City).

A total of 27 patients expressed interest in participating in the study, but only 12 of them (44.44% of the interested participants) were eligible to participate in the study as presented in the recruitment flowchart (Figure 6-5). The reasons for exclusion included the inability to adhere to the programme due to logistical reasons (i.e., transportation, distance, and frequent travel), regular neuro-physio treatment, hip replacement, acute stroke, severe hearing deficit, cognitive impairment, severe tremors and balancing problems, implemented device (defibrillator), and inability to attend the whole programme due to busyness of caregiver during working hours. Two participants (17% of the enrolled participants) dropped out after the initial assessment (1 in Southampton and 1 in Riyadh), while 10 participants (83% of the enrolled participants) completed the study. The reasons for dropout were the content of the intervention programme (participant thought that the programme included LL exercise) and a sudden need to travel.

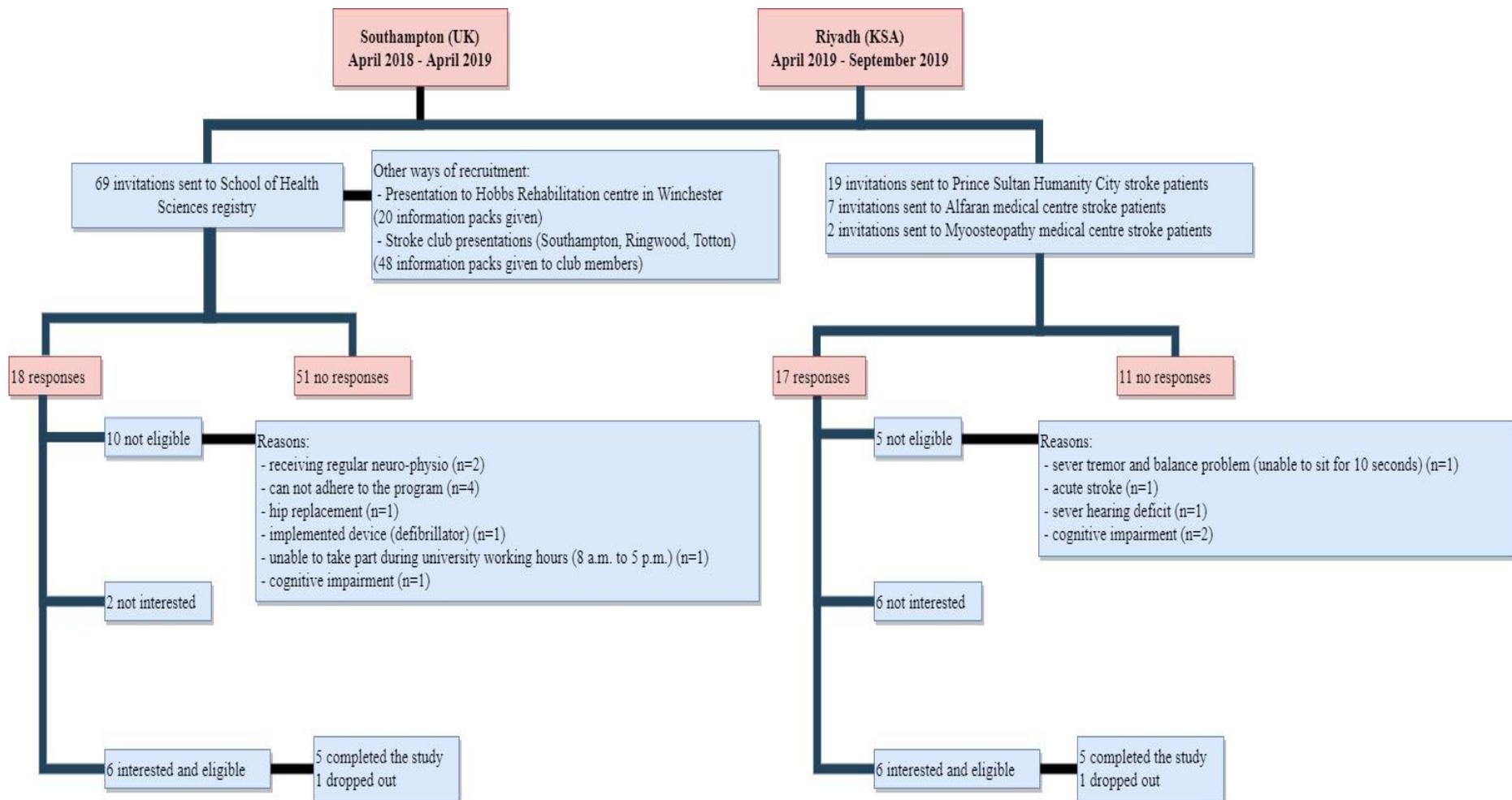


Figure 6-5: Recruitment process diagram

### 3- Adherence

The number of sessions attended by each participant was recorded in an attendance sheet (Appendix 44). Each participant received a table for all scheduled appointments in the first session and an amendment on the date and time applied according to the participant's convenience. All participants completed the pre- and post-assessments, but only eight out of ten participants attended all planned sessions within six to eight weeks. The remaining two participants (P3 and P9) were each only able to complete 17/18 and 12/18 sessions due to sickness (P3) and busy caretaker (P9). In general, the percentage of attendance was 96.11%, as presented in Table 6-8. All participants completed the planned time for each exercise session (45 minutes of actual training).

Table 6-8: Participant adherence

Location	ID	Planned sessions	Attended sessions	Completion time	Percentage %
Southampton (UK)	P1	18	18	6 weeks	100
	P2	18	18	6 weeks	100
	P3	18	17	8 weeks	94.44
	P4	18	18	6 weeks	100
	P5	18	18	6 weeks	100
Riyadh (KSA)	P6	18	18	6 weeks	100
	P7	18	18	8 weeks	100
	P8	18	18	8 weeks	100
	P9	18	12	8 weeks	66.67
	P10	18	18	6 weeks	100
<b>Mean</b>				6.8 weeks	96.11%

### 4- Participation

The average level of active participation measured using the Pittsburgh Rehabilitation Participation Scale (PRPS) varied between good (4.9) and very good (5.8). The PRPS scores increased in the third and tenth training sessions and reached the lowest score in the last training session, as depicted in Figure 6-6. The lowest participation was reported for those participants who did not attend all sessions (P3 and P9), as presented in Table 6-9. In addition, the lowest participation was recorded in session 13 and the last session.

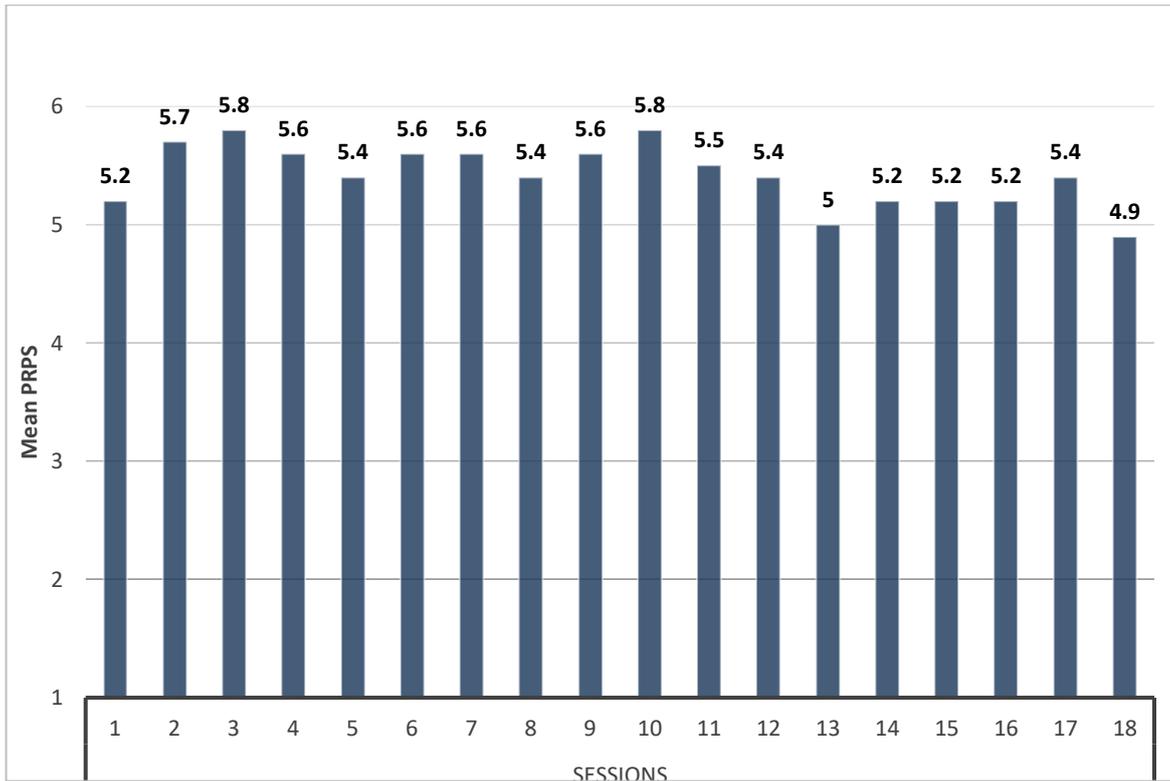


Figure 6-6: Pittsburgh Rehabilitation Participation Scale (PRPS) scores measured at each session

Table 6-9: Pittsburgh Rehabilitation Participation Scale (PRPS) scores for each participant

Country	United Kingdom (UK)					Kingdom of Saudi Arabia (KSA)				
ID	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10
Mean PRPS	5.7	5.8	4.4	5.7	5.8	5.8	5.7	5.7	3.7	5.8

### 5- Safety

No major adverse events were reported. Two participants (P3 and P10) reported fatigue at the end of the day after the trunk exercise. Participant 3 mentioned that he experienced mental fatigue more than physical fatigue. Three participants (P4, P8, and P10) reported that they felt tightness in the lateral trunk muscle of the affected side at the end of the day when playing the Clock game (the game required lateral trunk flexion on both sides) in the initial few sessions. The tightness disappeared in the last two weeks of intervention and did not affect their sleep or daily activities. During the exercise session, one participant (P9) asked for two or three pause intervals within nine minutes of the Brick Breaker game exercise practice because he felt dizzy as a result of the high concentration required to follow the ball. The Brick Breaker game was replaced by another game for participant 9 because he could not play the Break Breaker game due to its high cognitive effort demands.

## 6.6.2 Secondary outcomes (Clinical outcome measures)

The changes in the clinical outcome measured between pre- and post-trainings are presented in Tables 7.5–7.10. The changes in score were compared with the minimal detectable changes (MDCs) to ascertain whether the change is by chance or reflects the true effect of an intervention (Haley and Fragala-Pinkham, 2006). Further, where the minimal clinically important difference (MCID) has been established for the clinical outcome measure, a comparison of the change with MCID was also reported (Haley and Fragala-Pinkham, 2006).

### 1- Trunk impairment scale (TIS)

The TIS improved post-trunk training in all participants, as presented in Table 6-10. The highest improvement was a seven-point difference in the total TIS score post-training among the people who had fair pre-training trunk control (a total TIS score ranging from 11 to 19). However, one participant (P9) with fair trunk control showed the lowest improvement compared to the other participants with only a three-point increase in total TIS post-training. For Participant 4, who had a poor trunk control (total TIS score  $\leq 10$ ) a five-point improvement in total TIS was gained post-training. The gains for all participants were greater than the minimal detectable change (0.67) (Monticone et al., 2017).

Table 6-10: Median (IQR) change in the Trunk Impairment Scale (TIS)

ID	Pre	Post	Difference (post-pre)	Change % (post-pre)*100/23 (Max TIS score)
P1	14	21	7*	30.43
P2	11	16	5*	21.74
P3	12	17	5*	21.74
P4	9	14	5*	21.74
P5	16	19	3*	13.04
P6	11	18	7*	30.43
P7	13	20	7*	30.43
P8	11	18	7*	30.43
P9	15	18	3*	13.04
P10	12	19	7*	30.43
<b>Median (IQR)</b>	12(3.5)	18(2.5)	7(3)	30.43(13.04)

\* The change  $\geq$  minimum detectable change (MDC = 0.67)

## **2- The instrumented trunk impairment scale (iTIS)**

In the dynamic subscale, for Tasks 1–3 (touching bed with hemiplegic elbow), five participants (P5, P6, P7, P8, and P10) scored the highest change in trunk lateral flexion for the first three tasks as they were able to touch the bed with their affected elbow post intervention, which was not possible pre-intervention (they had stopped moving towards the hemiplegic side to avoid losing balance (Table 6-11). However, Participants 2, 3, and 4 could not touch the bed with the affected elbow in both baseline and post intervention assessment sessions, thereby resulting in a negative change in trunk lateral flexion towards the affected side for Task 1 (P2 and P4) and no change in Task 2 and Task 3 (P2, P3, and P4). For Tasks 4–6 (touching the bed with the unaffected elbow), all participants, except Participant 1, demonstrated a change in trunk lateral flexion towards the unaffected side  $\geq$  MDC. The MDCs for each task were calculated in Chapter 4. Particularly, Participant 2 showed a negative change in Task 4, while Participant 7 showed a negative change in Tasks 4–6. The negative change here implies that the trunk ROM decreased because the participants were able to control their trunk and did not lose their balance and fall when performing post-intervention TIS, thereby decreasing the ROM of lateral flexion. Moreover, pelvic movement was improved dramatically for Participants 1, 3, 4, 6, 8, and 10, as shown in the last four tasks of the dynamic subscale.

For the co-ordination subscale, the symmetry parameter indicated a major difference ( $\geq$  MDC) between pre- and post-intervention measurements for Participant 7 in Tasks 1 and 2, for Participant 8 in Task 3, and for Participant 10 in Task 4 (Table 6-11). These changes agreed with the improvement in the score of clinical TIS for the same tasks. However, the score of Participant 5—who showed an improvement in symmetry for Task 4—did not improve in the cTIS.

## **3- Trunk range of motion (ROM) during the streamlined wolf motor function test (SWMFT)**

Participant 4, who had severe UL impairment and poor trunk control, showed the best improvement in the reduction of trunk ROM during the performance of SWMFT compared to the other participants (Table 6-12). He recorded an improvement in all the parameters for Task 1 (hand to table), Task 4 (lift pencil), and Task 7 (reach and retrieve). None of the participants recorded a meaningful ( $\geq$  minimum detectable change (MDC) reduction in trunk ROM for Task 6 (turn key in a lock). The MDCs for each task were calculated in Chapter 5. The MDC value means that the change falls outside the measurement error. Further, Participants 5, 8, and 10 showed a rather high meaningful ( $\geq$  MDC) reduction in both trunk flexion and lateral flexion towards the unaffected side for the last task (extend elbow–side). The detailed data for each participant’s performance during each task are presented in Appendix 43.

Table 6-11: Median (IQR) change in the instrumented Trunk Impairment Scale (iTIS)

Task	Task description	Parameter of interest	Difference (post-pre)										Median (IQR)
			P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
<b>Dynamic Sitting Balance Subscale</b>													
1	Touch the bed with the hemiplegic elbow	Lateral flexion to affected side	-2.3*	-2.8*	3.6	-6.8*	25.5*	-0.4	18.7*	-0.4	0.4	6.3*	0 (22.35)
2		Lateral flexion to affected side	-6.6	0	0	0	25.2*	51.7*	51.2*	41.2*	3.5	38.4*	14.35 (43.70)
3		Lateral flexion to affected side	-3.4	0	0	0	32.8*	45.4*	47.6*	45*	0.4	38.1*	16.60 (45.10)
4	Touch the bed with the unaffected elbow	Lateral flexion to unaffected side	1.4	-21.3*	13.6*	-3	32.1*	8.5*	-32*	2.1	-7.6*	15.6*	5.30 (23.85)
5		Lateral flexion to unaffected side	-4.6	9*	22.2*	17.6*	28.5*	35.9*	-16.1*	51.5*	-8.2*	46.3*	19.90 (44)
6		Lateral flexion to unaffected side	-1.1	10.8*	40.1*	10.3*	29.2*	37.1*	-21.4*	51*	-12.2*	43.1*	20 (44.73)
7	Lift pelvis from bed on the hemiplegic side	Lateral flexion to unaffected side	-0.5	-10.8*	18.1*	-22.3*	-3.3	16.6*	-2.6	-4.8	-1.5	24.7*	-2.05 (23.28)
8		Lateral flexion to unaffected side	1.8	3.7	8.6*	3.7	-6	20.9*	-4.5	16.8*	-2.6	13.6*	3.7 (17.48)
9	Lift pelvis from bed on the unaffected side	Lateral flexion to affected side	-13.3*	0.1	9.6*	-8.4*	0.8	-5.1	-3.3	7.9*	-1.6	6.2	-0.75 (12.55)
10		Lateral flexion to affected side	-10.9*	0	5.1*	3.3*	4.6*	3.7*	-6.6*	-5.4*	-5.6*	7.8*	1.65 (10.58)
<b>Coordination subscale</b>													
1	Rotate upper trunk six times	Symmetry	-1	1.7	1.6	13.2	7.2	0.9	57.1*	-3.9	9.5	17.7	4.45 (13.90)
		total number of rotations	0	0	0	0	0	0	2	0	0	0	2.05 (7.35)
2	Repeat item 1 within 6 seconds	Symmetry	1.6	4.9	14.1	4	1.8	18.1	25.1*	1.9	7.6	-0.3	4.45 (13.35)

		total number of rotations	0	0	0	3	0	0	2	1	0	0	2.3 (20.83)
<b>3</b>	Rotate lower trunk six times	Symmetry	33.2	20.8	-3.3	6.2	34.1	28	-20.1	68.3*	1.1	-12.6	13.5 (39.05)
		total number of rotations	0	1	0	1	0	2	0	0	0	1	3.8 (8.25)
<b>4</b>	Repeat item 3 within 6 seconds	Symmetry	0.4	15.1	-4.6	18.6	71.3*	3.1	3	13.4	-1.9	35*	8.25 (22.88)
		total number of rotations	0	1	0	2	0	2	-1	1	-1	-1	3.45 (6.23)

\* The change  $\geq$  minimum detectable change (MDC)

Table 6-12: Median (IQR) change in trunk ROM during SWMFT performance

Task	Parameter of interest	Difference (post-pre)									
		P1	P2	P4	P5	P6	P7	P8	P9	P10	Median (IQR)
<b>1. Hand to table (front)</b>	Trunk flexion	0.54	3.20	-15.03*	0.45	-2.08	0.97	-9.58*	-9.35*	-2.57	-2.08(10.22)
	Trunk lateral flexion toward unaffected side	-5.96*	-15.83*	11.28*	7.13*	-11.46*	-3.16	-1.48	-8.89*	-16.91*	-5.96(19.20)
	Trunk axial rotation toward affected side	-0.70	2.81	-8.38*	4.84	-2.56	-1.27	-6.34*	-3.13	1.12	-1.27(6.70)
<b>2. Hand to box (front)</b>	Trunk flexion	-0.83	-2.75	-4.71	-4.18	-0.09	-4.49	-3.78	0.47	-2.20	-2.75(3.88)
	Trunk lateral flexion toward unaffected side	-0.03	-6.26	-14.86	-9.84	2.16	1.08	-7.49	-1.49	-3.40	-3.4(9.19)
	Trunk axial rotation toward affected side	-3.65*	-2.29	-5.86*	-1.29	0.36	2.89	-7.62*	-3.52	-6.63*	-3.52(5.78)
<b>3. Lift can</b>	Trunk flexion	-8.11*	-1.04	-3.85	-11.22*	-1.42	-14.37*	-2.23	0.86	-7.97*	-3.85(8.44)
	Trunk lateral flexion towards unaffected side	-7.35*	3.58	0.24	-5.08*	-0.86	-5.52*	-1.03	-3.72	-1.90	-1.9(4.99)
	Trunk axial rotation toward affected side	-4.43	1.99	4.56	1.16	-7.15*	3.20	-2.34	-1.25	0.86	0.86(5.98)
<b>4. Lift pencil</b>	Trunk flexion	-0.15	-1.47	-7.74*	0.49	-26.10*	-27.72*	2.02	-1.18	-4.19	-1.47(17.09)
	Trunk lateral flexion toward unaffected side	-1.86	-3.37	-6.12*	0.83	-4.20*	-1.39	-3.54	-0.48	1.79	-1.86(4.05)
	Trunk axial rotation toward affected side	-3.68	-12.18*	-9.40*	0.61	-3.32	-3.86	1.97	-2.15	-4.33	-3.68(6.10)
	Trunk flexion	-0.93	-0.49	-4.20	-5.02	-1.80	0.23	-14.55*	-1.16	-0.93	-1.16(3.90)

<b>5. Fold towel</b>	Lumber lateral flexion toward affected side	-0.05	0.02	-7.61	0.28	-2.63	-0.01	0.42	-0.78	-1.75	-0.05(2.34)
	Lumber lateral flexion toward unaffected side	-1.35	-1.40	-9.70*	-7.55	-3.36	-2.07	-8.20	-2.57	-1.49	-2.57(6.43)
<b>6. Turn key in a lock</b>	Trunk flexion	-0.93	-3.45	-3.85	0.21	-1.95	-1.13	0.21	-0.38	-0.18	-0.93(2.72)
<b>7. Reach and retrieve</b>	Trunk extension	-7.83	0.29	-9.73*	-3.66	-6.31	-16.03*	-2.34	-0.71	-1.27	-3.66(7.79)
<b>8. Extend elbow (side)</b>	Trunk flexion	-1.95	-0.31	2.52	-33.68*	-1.28	-2.67	-10.13*	-0.31	-8.31*	-1.95(8.91)
	Trunk lateral flexion towards unaffected side	-3.93	5.93*	-12.29*	-20.83*	-3.22	-1.27	-6.71*	5.93*	-12.82*	-3.93(14.89)

\* The change  $\geq$  minimum detectable change (MDC) based on Study 2

#### **4- Trunk muscle thickness**

The thickness of the external oblique (EO), internal oblique (IO), transversus abdominis (TrA), and rectus abdominis (RA) was measured at rest and during a straight leg raise (SLR) on both the affected and unaffected sides.

On the affected side in the resting position, the highest increase in muscle thickness after the intervention was recorded in the TrA muscle, with a median change of 16% (Table 6-13). In the SLR position, however, the EO muscle exhibited the highest increase in muscle thickness, with a median change of 33.33%. In the resting position, the EO muscle thickness changed slightly, by 3.7%, post intervention. The increase in the trunk muscle thickness on the affected side was the greatest in participants with a less impaired trunk (e.g., P1) compared to others.

On the unaffected side, the IO muscle showed the most improved muscle thickness after intervention in the resting position, with a median change of 29.63% (Table 6-14). By contrast, the TrA muscle thickness in the resting position did not change after intervention. However, the increase in the TrA muscle thickness was recorded as the greatest in the SLR position post intervention, with a median change of 23.07% in thickness.

The change in RA muscle post intervention reported a high increase in thickness for the unaffected side (median = 15.15%) compared to the affected side (median = 9.68%) (Table 6-15). In general, a participant with a more impaired trunk showed a greater increase in the % muscle thickness in the unaffected side compared to those with less impaired trunks.

Table 6-13: Median (IQR) change in transverse abdominus muscle size—affected side

Resting muscle thickness (cm)												
ID	EO				IO				TrA			
	Pre	Post	Difference	Change %	Pre	Post	Difference	Change %	Pre	Post	Difference	Change %
P1	0.14	0.14	0.01	3.70	0.24	0.26	0.03	10.64	0.13	0.18	0.05	38.46
P2	0.17	0.20	0.03	18.18	0.15	0.15	0.00	0.00	0.14	0.16	0.02	14.29
P3	0.17	0.18	0.01	6.06	0.15	0.15	0.00	0.00	0.14	0.14	0.00	0.00
P4	0.13	0.13	0	0	0.11	0.15	0.04	36.36	0.13	0.15	0.02	16.00
P5	0.17	0.18	0.01	2.94	0.16	0.17	0.01	6.25	0.12	0.14	0.02	16.67
<b>Median (IQR)</b>	0.17 (0.04)	0.18 (0.06)	0.01 (0.02)	3.7 (10.65)	0.15 (0.07)	0.15 (0.07)	0.01 (0.04)	6.25 (23.50)	0.13 (0.02)	0.15 (0.03)	0.02 (0.03)	16 (20.42)
SLR muscle thickness (cm)												
ID	EO				IO				TrA			
	Pre	Post	Difference	Change %	Pre	Post	Difference	Change %	Pre	Post	Difference	Change %
P1	0.13	0.17	0.05	36.00	0.17	0.19	0.02	10	0.11	0.16	0.05	47.62
P2	0.12	0.18	0.07	56.52	0.10	0.18	0.09	89.47	0.10	0.12	0.03	26.32
P3	0.15	0.18	0.03	20.00	0.18	0.20	0.02	11.11	0.12	0.16	0.05	39.13
P4	0.12	0.16	0.04	33.33	0.13	0.14	0.01	7.7	0.13	0.13	0.00	0.00
P5	0.14	0.16	0.02	14.29	0.11	0.13	0.02	18.18	0.12	0.15	0.03	20.83
<b>Median (IQR)</b>	0.13 (0.03)	0.17 (0.02)	0.04 (0.04)	33.33 (29.12)	0.13 (0.07)	0.18 (0.06)	0.02 (0.04)	11.11 (44.98)	0.12 (0.02)	0.15 (0.04)	0.03 (0.04)	26.32 (32.96)

EO = External oblique; IO = Internal oblique; TrA = Transversus abdominis; SLR = Straight leg raising

Table 6-14: Median (IQR) change in transverse abdominus muscle size—unaffected side

Resting muscle thickness (cm)												
ID	EO				IO				TrA			
	Pre	Post	Difference	Change %	Pre	Post	Difference	Change %	Pre	Post	Difference	Change %
P1	0.18	0.175	-0.01	-2.78	0.26	0.26	0	0	0.22	0.21	-0.01	-4.65
P2	0.185	0.23	0.05	24.32	0.14	0.18	0.04	29.63	0.18	0.18	0	0
P3	0.15	0.21	0.07	44.83	0.12	0.21	0.09	75.00	0.14	0.15	0.01	7.14
P4	0.22	0.23	0.01	4.65	0.10	0.14	0.04	42.11	0.14	0.14	0	0
P5	0.23	0.28	0.05	22.22	0.24	0.23	-0.01	-2.13	0.15	0.16	0.01	6.67
<b>Median (IQR)</b>	0.18 (0.06)	0.23 (0.06)	0.05 (0.06)	22.22 (33.64)	0.14 (0.14)	0.21 (0.09)	0.04 (0.07)	29.63 (59.62)	0.15 (0.06)	0.16 (0.05)	0.01 (0.02)	0 (9.23)
SLR muscle thickness (cm)												
ID	EO				IO				TrA			
	Pre	Post	Difference	Change %	Pre	Post	Difference	Change %	Pre	Post	Difference	Change %
P1	0.16	0.17	0.02	9.68	0.21	0.20	-0.01	-4.88	0.12	0.18	0.06	50.00
P2	0.17	0.24	0.07	42.42	0.11	0.15	0.04	31.82	0.15	0.14	-0.01	-6.90
P3	0.21	0.20	-0.01	-4.76	0.16	0.24	0.08	46.88	0.22	0.22	0	0
P4	0.15	0.16	0.01	6.6	0.12	0.13	0.01	8.33	0.13	0.16	0.03	23.07
P5	0.18	0.23	0.06	31.43	0.19	0.18	-0.01	-5.41	0.14	0.18	0.04	28.57
<b>Median (IQR)</b>	0.17 (0.04)	0.20 (0.07)	0.02 (0.07)	9.68 (36.01)	0.16 (0.09)	0.18 (0.08)	0.01 (0.07)	8.33 (44.5)	0.14 (0.06)	0.18 (0.05)	0.03 (0.06)	23.07 (42.74)

EO = External oblique; IO = Internal oblique; TrA = Transversus abdominis; SLR = Straight leg raising

Table 6-15: Median (IQR) change in rectus abdominus muscle size

ID	RA—unaffected side				RA—affected side			
	Pre	Post	Difference	Change %	Pre	Post	Difference	Change %
P1	1.22	1.40	0.18	15.15	0.16	0.17	0.02	9.68
P2	1.01	1.12	0.11	10.63	0.17	0.24	0.07	42.42
P3	1.12	1.12	0.00	0	0.20	0.20	0	0
P4	1.01	1.20	0.19	18.32	0.15	0.15	0	0
P5	1.02	1.50	0.47	46.38	0.18	0.23	0.06	31.43
<b>Median (IQR)</b>	1.02 (0.16)	1.2 (0.33)	0.18 (0.28)	15.15 (27.04)	0.17 (0.04)	0.20 (0.08)	0.02 (0.07)	9.68 (36.93)

RA = Rectus abdominis

### 5- The Berg Balance Scale (BBS)

Balance was found to improve post intervention for all participants (Table 6-16). The change was greater than the level of MDC = 4.66 (Hiengkaew et al., 2012), except for Participant 1 (change = 4), who had the highest baseline score (BBS = 52), near normal. A BBS score less than 45 was reported to be a cut-off point for detecting the high risk of falling (Dogan et al., 2011). Participants with low balance ability at baseline seemed to improve the most, with three participants (P4, P6, and P10) improving by  $\geq 12$  points and two participants improving by 6 (P3) and 9 (P9) points post intervention.

Table 6-16: Median (IQR) Change in Berg Balance Scale (BBS)

ID	Pre	Post	Difference (post-pre)	Change % (post-pre)*100/total BBS (56)
P1	52	56	4	7.14
P2	44	53	9*	16.07
P3	24	30	6*	10.71
P4	27	39	12*	21.43
P5	46	54	8*	14.29
P6	25	37	12*	21.43
P7	40	47	7*	12.50
P8	45	50	5*	8.93
P9	26	35	9*	16.07
P10	11	28	17*	30.36
<b>Median (IQR)</b>	40 (20)	47 (17.5)	9 (6)	16.07 (10.72)

\* The change  $\geq$  minimum detectable change (MDC = 4.66) (Hiengkaew et al., 2012)

## **6- Upper limb impairment (FMA-UL)**

The commonly used FMA-UE cut-off scores categorize upper-limb motor impairment into three levels: severe (FMA-UL = 0 to 20), moderate (FMA-UL = 21 to 50), and mild (FMA-UL = 51 to 66) (Veloza and Woodbury, 2011). Changes were seen only in four participants (P1, P4, P6 and P7) by a 2- to 3-point increase in FMA-UL, as shown in Table 6-17. Three of them had a mild severity of UL impairment (P1, P6, and P7) at baseline. The highest change in score was recorded for P7 by an increase of 3 points in FMA-UL. This increase mainly came from the biceps and triceps reflexes, elicited only post intervention. Change in FMA-UL did not reach the level of either MDC (5.2) or MCID (4.25 to 7.25) (Page et al., 2012, Wagner et al., 2008).

## **7- Upper limb function (SWMFT-FAS, and SWMFT-time)**

The upper limb functional score was found to increase in six participants for the SWMFT-FAS and for the SWMFT-time in all participants, as presented in Table 6-17. Although the participants could do the task quicker because of the learning effect, the change in SWMFT reached the MDC levels for both FAS (MDC = 0.1) and time (MDC = 0.7) (Lin et al., 2009). SWMFT-FAS reached the MDC (0.1) level for all improved participants, whereas four participants (P1, P2, P4, and P7) demonstrated a clinically important improvement (MCID = 0.2 to 0.4) (Lin et al., 2009). Maximal improvement in both SWFT-FAS and time was found in participants with a higher UL function pre-training compared to other participants, such as P1, P5, and P7. Only one participant (P6) with high functional ability (SWMFT-FAS = 4) showed minor improvement in SWMFT time (-13.68% reduced time) after training. The SWMFT was not tested for one participant (P3) because he was not comfortable doing SWMFT with his paralysed limb.

Table 6-17: Median (IQR) change in upper limb function and impairment

ID	Pre-training			Post-training			Difference (post-pre)			Change %		
	SWMFT-FAS	SWMFT-time	FMA	SWMFT-FAS	SWMFT-time	FMA	SWMFT-FAS	SWMFT-time	FMA	SWMFT-FAS	SWMFT-time	FMA
P1	4.00	6.61	57	4.38	4.45	59	0.49* <sub>+</sub>	-2.16** <sub>++</sub>	2	9.8	-48.60	3.03
P2	1.63	5.49	20	1.75	4.88	20	0.5* <sub>+</sub>	-0.61	0	10	-12.42	0
P3	NT	NT	4	NT	NT	4	NT	NT	0	NT	NT	0
P4	1.75	10.50	4	1.88	8.13	6	0.38* <sub>+</sub>	-2.38** <sub>++</sub>	2	7.6	-29.23	3.33
P5	2.25	12.36	28	2.50	7.31	28	0	-5.05** <sub>++</sub>	0	0	-69.17	0
P6	4.00	12.68	51	4.13	11.15	53	0.13 <sub>+</sub>	-1.53** <sub>++</sub>	2	2.6	-13.68	3.33
P7	4.50	10.06	56	4.75	4.90	59	0.25* <sub>+</sub>	-5.16** <sub>++</sub>	3	5	-105.30	5
P8	2.13	8.69	15	2.25	7.84	15	0.12 <sub>+</sub>	-0.85 <sub>++</sub>	0	2.4	-10.85	0
P9	1.38	15.93	11	1.38	13.17	11	0	-2.76** <sub>++</sub>	0	0	-20.93	0
P10	0.13	13.16	0	0.13	11.66	0	0	-1.50** <sub>++</sub>	0	0	-12.89	0
<b>Median (IQR)</b>	2.13(2.5)	10.5(5.27)	20(46)	2.25(2.69)	7.84(6.52)	20(47.5)	0.12(0.19)	-2.16(2.73)	0(2)	2.6(8.70)	0(20.93(46.23))	0(3.33)

SWMFT-FAS = streamlined wolf motor function test-functional ability scale, SWMFT-time = streamlined wolf motor function test-time, FMA-UL = Fugl-Mayer assessment-upper limb; NT = not tested

\* SWMFT-FAS: Clinically important change based on MCID of 0.2 to 0.4 points; <sub>+</sub>The change ≥ minimum detectable change for SWMFT-FAS (MDC = 0.1)

\*\*SWMFT-Time: Clinically important change based on MCID of 1.5 to 2 seconds; <sub>++</sub>The change ≥ minimum detectable change for SWMFT-Time (MDC = 0.7)

\*\*\*FMA: Clinically important change based on MCID range from 4.25 to 7.25; <sub>+++</sub>The change ≥ minimum detectable change for FMA (MDC = 5.2)

### 8- Lower limb impairment: Fugl-Mayer assessment (FMA)

Lower limb impairment was not changed for half of the participants post intervention (Table 6-18). FMA-LE score of 21 of 34 was reported as the best cut-off score (sensitivity: 0.87; specificity: 0.81) to represent the mobility function in chronic stroke survivors (Kwong and Ng, 2019). A FMA-LE score of 21 or higher indicates a high level of mobility function. One participant (P1) had a high mobility function at baseline (FMA-LL = 32), while the remaining participants showed low mobility function levels. The highest increase in FMA-LL score was observed in two participants (P2 and P8) with a low mobility level (FMA-LL = 19) at baseline. Only one of them (P2) demonstrated a change beyond the MDC (3.57) (Hiengkaew et al., 2012) and none of them reached the MCID (6) (Pandian et al., 2016).

Table 6-18: Median (IQR) change in Fugl-Mayer assessment—lower limb (FMA-LL)

ID	Pre	Post	Difference (post-pre)	Change % (post-pre)*100/ total FMA-LL (32)
P1	32	32	0	0
P2	19	23	4+	11.76
P3	7	7	0	0
P4	12	12	0	0
P5	20	21	1	2.94
P6	18	20	2	5.88
P7	25	26	1	2.94
P8	19	22	3	8.82
P9	17	17	0	0
P10	9	9	0	0
<b>Median IQR)</b>	19(8)	21(10)	1(2.5)	2.94(7.35)

\*FMA-LL Clinically important change based on MCID of 6

+The change  $\geq$  minimum detectable change (MDC = 3.57)

#### 6.6.3 Summary of quantitative results

In summary, the results from the quantitative phase of this study demonstrated high levels of acceptability as determined by PIADS and participation level. Based on PIADS, three participants were frustrated, indicating disappointment due to lack of progress in achieving their desires. A high level of feasibility was demonstrated by study retention, safety, and adherence to the intervention.

No major adverse event was reported; however, fatigue and lateral trunk tightness at the end of the day was reported by four participants in a few sessions.

Secondary clinical outcome measurements suggested that 18 sessions of trunk exercises using Valedo video games had a positive change in trunk impairment (TIS, iTIS), trunk muscle thickness, balance (BBS), and UL function (SWMFT). People with fair trunk control and low balance ability (BBS  $\leq$  27) had a higher opportunity to improve compared to those with high trunk control and balance ability (BBS  $\geq$  45). Further, the TrA muscle on the hemiplegic side showed the highest increase in muscle thickness compared to the IO and EO post intervention. The results of both UL and LL impairment measured by FMA showed no substantial change in the impairment level post intervention.

## **6.7 Qualitative Results**

The aim of the qualitative phase of this study was to explore the feasibility of using Valedo video games for trunk rehabilitation from stroke participants' perspective. The feedback from participants supported the quantitative findings by explaining in depth the factors affecting the acceptability and implementation of the study protocol and intervention. The following section presents the qualitative findings from the data analysis of interviews with 10 stroke survivors. Participants are identified by (participant ID, age), as provided in Section 6.6 (Table 6-6).

### **6.7.1 Study recruitment and participant details**

Details of participant characteristics are provided in Section 6.6 (Table 6-6).

### **6.7.2 Findings from the framework analysis**

Following the framework analysis approach, all raw data were indexed to the appropriate theme and sub-theme derived during the analysis and charted in a matrix formatted chart, which is presented in Appendix 7.19. A chart was created for each theme. As this study aimed to explore feasibility through two main areas of acceptability and implementation, the themes were divided into two thematic maps (Figure 6-7 and Figure 6-8) to answer the research question. To enhance the clarity of reporting, each concept is discussed independently in light of its thematic map.

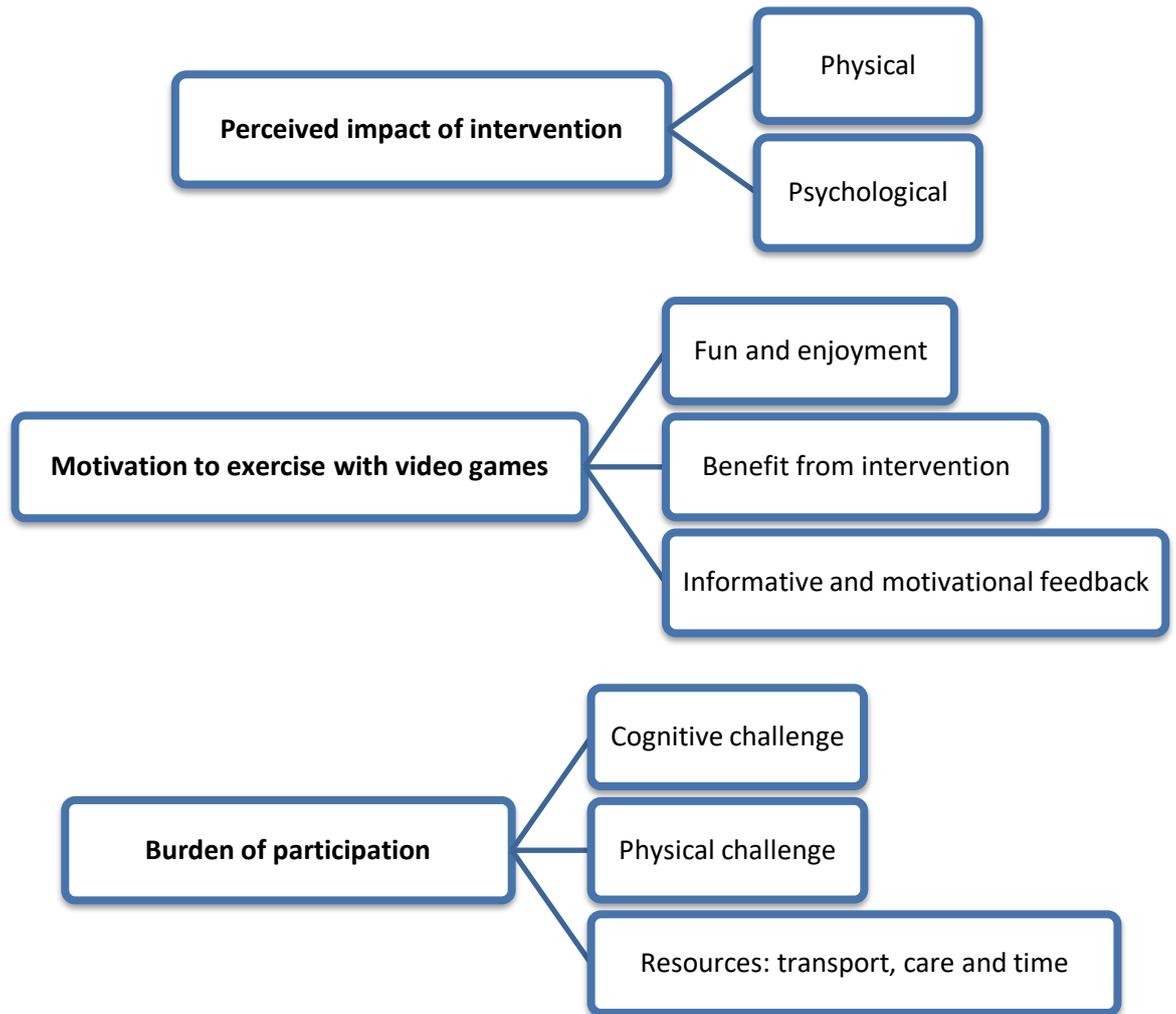


Figure 6-7: Thematic map of the acceptability of delivering trunk exercises using the Valedo video game system

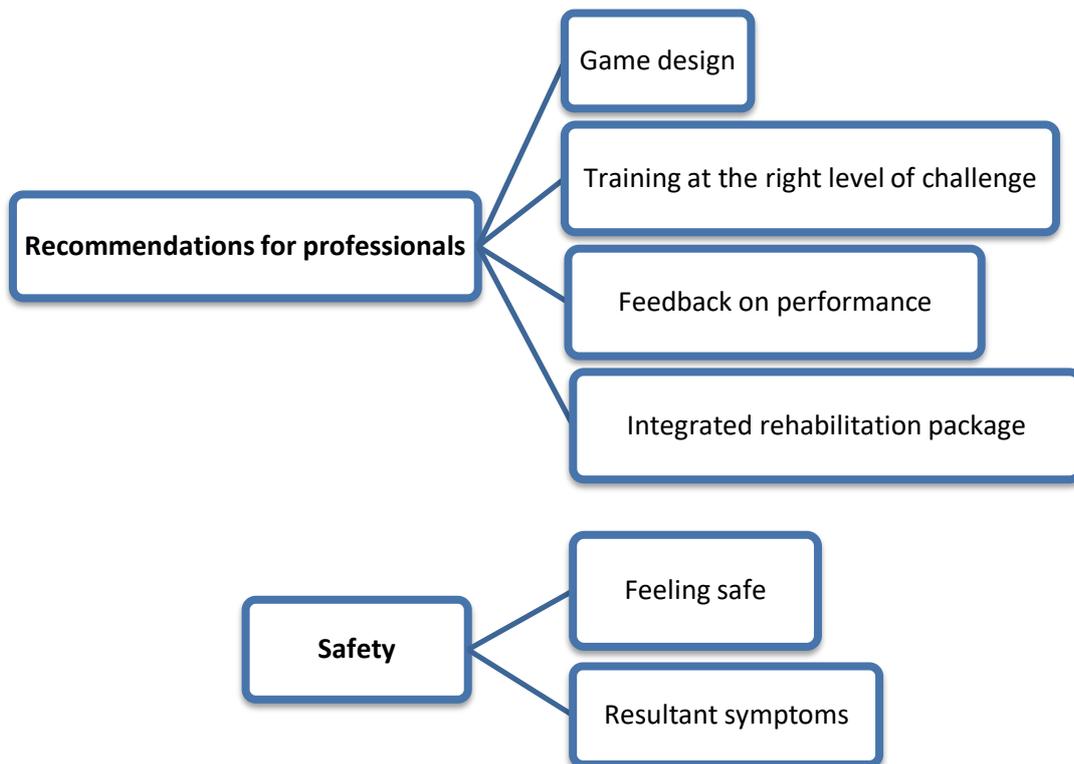


Figure 6-8: Thematic map of implementation of trunk exercises using the Valedo video game system.

### 6.7.3 Acceptability of trunk exercises using the Valedo video game system

Over the course of the interviews, participants shared their experiences of using the video games to engage in trunk exercises and also commented on the acceptability of this technique. Three key themes that emerged from interviews were related to the experience and acceptability of using Valedo video games as a rehabilitation tool to deliver trunk exercises (Figure 6-7). The three main themes were 1) perceived impact, 2) motivation to exercise with video games, and 3) burden of participation. These themes are discussed below, with supporting participant quotes.

#### 1- Perceived impact

A strong theme of the perceived impact of Valedo video games was underpinned by two subthemes: 'physical impact', which was as a result of doing trunk exercises using the system, and 'psychological impact' experienced while playing the games.

#### Physical impact

The majority of participants perceived that by the end of the intervention programme, their daily activities improved and became much easier.

*'I found that when I was doing those trunk exercises, when I was kind of walking out of here, I found then that my leg was quite light, and in fact I'd say that I was walking a little bit better. And I walked round to the car... My leg felt lighter when I walked' (P2, 54)*

An improvement in daily activities was perceived even by those with high mobility function.

*'Thank God, my daily activities have changed 70% for the better. I used to have difficulty when sitting on the toilet seat and needed my sons' help. Now, I can do that by myself. Also, with walking, I used to move my whole body as one piece when I turned. Now, I can turn better like this (Participant acts out the movement of turning right and left)'. (P7, 75)*

Trunk training with Valedo video games was felt to also help improve the ability to balance when performing recreational activities that required balance, such as sailing. One participant who used to sail frequently found that his ability to shift his weight from side to side during sailing activities was improved.

*'I've been able to move around in my boats a little bit easier now to the left and right*

*Interviewer: So, it's mainly weight shifting?... Participant: Yes'. (P1, 49)*

Interestingly, one participant found that his ability to correct posture and body balance during walking was improved as he was able to walk on uneven surfaces post intervention.

*'Before the programme, I used to walk hunchbacked, but now I walk with a straight back and with my shoulders up. Walking has also become better as I have noticed that I have become more confident and better balanced when I walk on the grass'. (P8, 40)*

While playing the games, a few participants used to move quickly, attempting to do the exercise and win the games at early sessions. These fast movements appeared to be movements that the participant had little control over. However, by the end of the programme, the movement of the trunk was more controlled, as reported by participant 2:

*'When I was first doing it, I was moving too fast. And that's why I think I was trying to get moving too fast. That's why the pictures got me. But at the end, like I say, obviously I found that was more controlled'. (P2, 54)*

Moreover, the feeling of movement control was perceived to be improved during daily activities, such as walking and turning, as reported by the participants with poor trunk control.

*'Turning round. It's less mechanical now'. (P4, 69)*

Three participants noticed a remarkable improvement in the overall fitness level, as they felt much fitter when performing their usual daily activities post-treatment.

*'I have become fitter at home... I can go to the toilet and the kitchen and walk around easily. Before taking the programme, I used to get tired once I had gone to the toilet'. (P9, 75)*

*'I have become fitter... My activity has changed. Now I can leave home and come back feeling better compared with before engaging the programme'. (P10, 54)*

In early sessions, a few participants felt tightness in their trunk, particularly in their lower back and sides. This tightness was reported when playing games that required stretching of their muscles in those areas. However, a perceived reduction in the tightness of trunk muscles was reported by the participants at the end of the interventional programme.

*'My movement has improved, and the tightness has decreased in this area', pointing to his lower back and thigh. (P8, 40)*

*'The muscle tightness on my sides became less'. (P10, 54)*

#### Psychological impact

Psychological impact resulting from using Valedo video games emerged as a sub-theme when participants spoke about their experience, particularly when they were asked about whether they would continue to exercise with video games. The novelty factor of using the video games to deliver trunk exercise influenced the appeal and acceptability of this form of exercise. The psychological impact perceived by participants in several forms, including reduced fear of falling, increased balance confidence, positive feeling of hope, increased participant engagement, and improved cognitive function such as concentration and multi-tasking ability.

One participant expressed fear of falling in early sessions, especially when she played the games that required leaning on the hemiplegic side. By completion of the programme, the fear of falling had significantly reduced.

*'At first, I felt scared of falling down, but over time the feeling went away... The Clock Game made my movement easier, and I overcame my fear after using it'. (P10, 54)*

The resultant improvement of balance ability had positively impacted on the participants as they felt more competent and confident during the performance of daily movements and usual activities, such as walking.

*'I think I'm more confident in my movements. I do feel a little bit stronger and a little bit more capable'. (P5, 59)*

*'I have become more confident and better balanced when I walk on the grass'. (P8, 40)*

Another factor that appeared to positively influence the psychological aspect of participants was the feeling of hope associated with the unexpected improvement in function that participants experienced after completing their programme.

*'It's just opened my eyes to more possibilities of my improvements that I can make'. (P1, 49)*

The majority of participants reported that video game activities elicited a sense of excitement, which made them heavily engaged in the exercise.

*'It gave me a sense of excitement to do more and more exercises... I wished that I could play the games longer'. (P8, 40)*

*'Doing exercises by playing video games was a great experience because it made me excited to do the exercises'. (P6, 92)*

Moreover, the game's characteristics, such as multi-tasking and seeing the real-time movement on the screen, were perceived to help cognitive performance by increasing concentration during the exercise and improving multi-tasking ability. The perceived improvement in cognitive function particularly emerged when participants were asked whether they would recommend this type of exercise to other stroke survivors.

*'I loved the idea of exercising through playing and watching the movement on the screen. It increases my focus on the exercises'. (P6, 92)*

*'It helped me mentally in terms of focus'. (P7, 75)*

*Researcher: Would you recommend this type of exercise using video games to patients who have had a stroke?*

*Participant: 'Yes, it improves the concentration ability'. (P10, 54)*

*'You're doing multitasking, in a way. So, you're concentrating on moving, and also concentrating on scoring and on the game itself. And that's why I think it's brilliant'. (P5, 59)*

## **2- Motivation to exercise with video games**

Another theme that emerged through the analysis was focused on participants' motivation to exercise with video games. This theme strongly emerged when the participants spoke about the reasons that could influence their preference for trunk exercises using Valedo video games and their personal recommendation for this type of intervention to other stroke survivors. The "fun and enjoyment" when using the Valedo video game system and the resultant "benefit from

intervention” were identified as subthemes that affected the motivation to exercise with video games.

### Fun and enjoyment

Most participants enjoyed performing the trunk training exercises using Valedo video games. The sense of enjoyment and fun provided by playing the video games appeared to be a motivator to exercise with video games, as reported by six participants. Interestingly, some participants said that without video games, they would not exercise at all.

All participants revealed that they enjoyed the trunk exercises using video games and that feeling of fun encouraged them to do the exercises.

*‘I enjoyed it immensely. I enjoyed it a lot’. (P4, 69)*

*‘They made me feel like I was entertaining myself and exercising the hemiplegic body parts at the same time’. (P10, 54)*

*‘Because it's fun, and obviously, I would do it’. (P2, 54)*

Another aspect of making the exercise interesting and motivating them to continue to exercise during the training period is that time seemed to fly when playing these games and they did not even realise that they were actually exercising.

*‘Because it's fun, and the time goes fast. So, therefore, you don't realise that you're doing exercises’. (P2, 54)*

As a result of enjoyment in playing the games, they were able to keep going and repeated numerous exercises without realizing it.

*‘It is an excellent way of getting a lot of work done without realizing it... When you told me how many repetitions I'd done, it was amazing’. (P4, 69)*

There was a universal agreement among participants that they would not do the exercise if it merely involved repetitive movement without video games, because traditional exercise was perceived as boring.

*‘Well, you just wouldn't do those exercises without it. Because it would just be repetitive boringness. I knew I just wouldn't do’. (P3, 62)*

*Researcher: What is the difference between using video games to help you practice trunk exercise to the other trunk exercise without video games?*

*Participant: Boring [laughter]. Quite boring. And obviously, when you do games, at least you got to keep going. Because if I were at home doing it, I would probably do it for a little while, and then I'd probably give up and stop’. (P2, 54)*

The distraction from merely thinking about repeating the exercise and instead actually playing the game makes the exercise interesting.

*'Well, might give you something to concentrate on rather than thinking about the exercise you're doing. So, it's sort of a distraction, what the little avatar or whatever move he's doing is more interesting than what you're doing'. (P3, 62)*

The sense of competition perceived by participants when they knew about their performance during playing and by the end of the game merged as a score (out of five stars) motivated them to exercise with video games.

*'I think for me as well, more motivating because it could be quite boring just doing same exercise. Just do it. Just do it. But if you're playing games, you are in it with your head rather than just doing bland sort of repetitive exercises.*

*Interviewer: Why is it motivating?*

*Participant: Because you're competing with yourself'. (P5, 59)*

Benefit from intervention

The potential physical and psychological improvements resulting from participating in the interventional programme were associated with motivating the participants to do the exercise with video games using the Valedo system. They perceived that video games can aid their rehabilitation through improving trunk control and balance.

*Researcher: If you have the Valedo system available for use at home, would you use it?*

*Participant: Yes. Because it's an aid to my rehabilitation... It makes my trunk and my core stronger and makes my movements more confident'. (P5, 59)*

*'Because from experience, I know it is doing my upper trunk some good'. (P4, 69)*

*'Because I noticed an improvement in my balance'. (P8, 40)*

One participant linked the improvement with doing the exercise.

*'What are the things that make you want to use it? Motivate me to make more about improvements.*

*Because if you need-- if you want to make improvements, you have to do exercises'. (P1, 49)*

Furthermore, potential psychological benefits were identified in exercising by playing a multitasking game. It was perceived to be helpful in improving cognitive abilities by teaching the participants how to move and concentrate on the other things at the same time.

*'I would say that it will encourage you to move affected areas of your body, and it can be good for your cognition... I think it's brilliant for teaching you—you are doing multitasking, in a way. So, you're concentrating on moving, and also concentrating on score and on the game itself. And that's why I think it's brilliant'. (P5, 59)*

Interestingly, one participant said that he would use the Valedo system because he perceived it to be useful to improve his memory.

*Interviewer: Why would you use it?*

*Participant: To improve my memory. (P7, 75)*

Among perceived improvements in cognition abilities, participants feel that an increase in the concentration on the exercise performance resulting from using Valedo video games motivated them to exercise with Valedo video games.

*'It helps me to focus and I become engrossed in the exercise'. (P6, 92)*

*'It improves the concentration ability and it is good for the body movement as well'. (P10, 54)*

Informative and motivational feedback

The Valedo system provided a different form of visual and auditory feedback while playing the trunk exercise games. The feedback varied from audio-visual feedback such as (+10) shown in the fruit game when the correct fruit entered the basket, indicating that the knowledge of good performance to the knowledge of results at the end of each game was shown as a rating (out of five stars). Thus, the feedback from the Valedo system played a significant role as a facilitator to encourage participants to do the trunk using video games.

About half of participants found that the audio-visual feedback given during and after playing each game encouraged them to keep going and do more exercise repetitions to get more points.

*'They encourage me to get more points every time and assure me that I am doing the exercises correctly' (P6, 92).*

Interestingly, a sense of success was perceived from audio-visual feedback and encouraged participants to perform the exercise to increase their sense of success.

*'The sounds and pictures gave me a sense of success and motivated me to perform the exercise until I won'. (P8, 40)*

The instant real-time visual feedback shown by the movement of the avatar in some games, such as the glider game, assured the participants that they could move their trunk.

*'I could see my movements on the screen, and I loved that. It assured me that my body was moving. This feeling was perfect and motivated me'. (P7, 75)*

In fact, the instant feedback in scores received assisted the participants in gauging their improvement and helping in setting a goal at every session.

*'It helps set a goal... Motivated me more to be where I had to be'. (P1, 49)*

*'I felt happy when I achieved the goals, and the sounds motivated me to do more'. (P10, 54)*

In addition, the provided encouragement feedback made the exercise more fun and motivated participants to keep going.

*'I think it gives you more incentive to carry on. And obviously when I do, obviously, get the fruit or whatever, it goes, "Woohoo," that's nice. That's a bit of a tease, I think'. (P2, 54)*

### **3- Burden of participation**

The potential amount of effort required to participate in the trunk exercise was recognised as a prominent theme when the participants were asked about the difficulty level of exercises and how hard it was to commit to the planned sessions. The 'cognitive challenge', 'physical challenge' and 'Resources: transport, time and care' were identified as substantial contributors to the burden of participation.

#### **Cognitive challenge**

A subtheme of 'cognitive challenge' was identified and associated with mental challenges required during the performance of video game-based trunk exercises. The multi-tasking games (e.g., Brick Breaker, High-flyer, Golf) required a relatively prolonged period of concentration on different tasks simultaneously, which may have been too demanding for some participants.

*'That was a lot of problem-solving and predicting where the ball is going to be and the obstacles you have to get around'. (P1, 49)*

*'You've really got to concentrate [laughter]. You've really got to do about three things at once like find out where the ball's got to go, and obviously, do the obstacles'. (P2, 54)*

The high concentration was associated with the fast reaction time required to play some games like Brick Breaker and Glider, which made them difficult and cognitively demanding for some participants.

*'It was hard at the beginning because I couldn't follow the ball... It was too fast, so I had to concentrate on where the ball was going to move'. (P8, 40)*

However, one participant found that the cognitively demanding games like Brick Breaker were more interesting, and he classified it as his favourite game.

*Researcher: What is your favourite game to play?*

*'Probably the Break Breaker one because it was more to do. It was more interesting... there was a lot more involved with it. You had to sort of watch targets'. (P3, 62)*

The unpredictability characteristic of some games (e.g., Fruits game) also made the game cognitively challenging, as some participants felt that a combination of high concentration and fast reaction time were required to play the game. This could be an indication of the intensity of practice.

*'Because it needs a great deal of mental effort. I couldn't anticipate which fruit would come, whether orange or watermelon. So, I had to focus in order to be able to move quickly towards the goal. Otherwise, I would lose it'. (P9, 75)*

#### Physical challenge

As this study included participants with different disability levels post-stroke, several reported that some games were physically challenging for them. There were many aspects that made the trunk exercise using video games physically challenging, including the physical position of exercise (i.e., sitting or standing), prolonged hold of a specific position, practising of unusual movement (i.e., pelvic tilting), and the high range of movement required to play some games.

The standing position with the arms on the sides was felt to be physically challenging for participants with complete arm paralysis, especially when practicing trunk rotation exercise.

*'I found that quite hard at first because I had my hands down by my side, which I thought my right arm was getting in the way. So, when I started doing it with my arms across my chest, I found it much easier'. (P2, 54)*

Further, leaning towards a hemiplegic side was reported to be challenging for some participants and became harder when they were required to hold that position for a long time.

*'At first, it was difficult. Then it became easy when I kept playing it. I think it was easier if I leaned on the left side, but when I leaned on the right side, it was difficult'. (P10, 54)*

*'That was the worst. Trying to hold it one way or the other. It's just trying to keep your butt cheek up one side or the other when they kept on sticking the same fruits down all the time'. (P3, 62)*

Lower trunk exercises such as pelvic tilting were perceived to be difficult and unusual movements to practice from a sitting position, as they did not usually do this movement before participating in the intervention programme.

*'It is hard to move my pelvis backwards and forwards. Before playing the game, I didn't normally practice this pelvic movement in my daily life'. (P8, 40)*

*'It requires more effort on the hemiplegic side. I have to load all my body weight onto it... This game was difficult for me'. (P8, 40)*

Interestingly, one participant explained this physical challenge by the feeling of heaviness, while another participant explained it by the loss of sensation.

*'The pelvic movement was difficult... Because if we look at the human body, the pelvis is in the lower body. The upper body parts are heavy, whereas the lower body parts are light, which makes it difficult for me to move my pelvis. I think the movement would be easier if the exercise required me to move the upper body parts only'. (P7, 75)*

*'It drives you crazy... It is not easy for me, yeah. Because I don't have sensation, I don't have to move like that. Or I do now. And I'm only just, since playing the game, is the first time I've started to move like that. So, it's very difficult, that game'. (P5, 59)*

Although the range of movement was tailored to each participant's ability, the trunk movements (flexion, rotation, lateral flexion) were felt to be difficult by some participants.

*'I found it quite difficult sometimes because I couldn't seem to twist far enough. Or if I could, I couldn't hold it there when I needed to hit the ball. It was- so in that respect it was actually quite tricky'. (P3, 62)*

Resources: transport, care, and time

When participants were asked about the acceptability of the study's commitment requirements (45 minutes per session, three times a week for six weeks), a prevalent theme of 'resources: transport, care and time' was identified. Although most participants reported that the commitment to the whole sessions was easy, it was nevertheless associated with a high degree of effort related to the transportation, business of the caregiver (the person who responsible for bringing the participant to the study location), and time convenience.

Before taking part in the study, one participant felt he might be unable to commit to the 18 sessions of the interventional programme. However, after completion of the study, he found it acceptable.

*'I know that when you came to the stroke club, my immediate response was, "Gosh, I'm not going to the university 18 times"... I don't have a problem with this at all'. (P4, 69)*

Participants who drove their cars independently found adherence to the sessions quite easy.

*'You know I drive my car. So, I could come to the sessions by myself'. (P8, 40)*

Carers were identified as facilitators for committing to the interventional programme.

*'It was easy for me to commit to the sessions... thank God for having great sons, because if one couldn't drive me to the clinic, the other would do instead'. (P7, 75)*

However, one participant could not commit to the programme due to the travel burden and business of the caregiver.

*'My sons drove me to the clinic. However, sometimes they were busy so I couldn't commit to all the sessions'. (P9, 75)*

The other effort made for committing to the interventional programme was time management. Managing the time between the sessions and other daily activities contributed to the study's commitment.

*'It was easy to commit to the sessions because having them after the noon prayer was suitable for me'. (P6, 92)*

One of the participants who used to join a sailing class found it easy to commit to the programme because the time of the sessions was organised to fit with his schedule and did not conflict with his classes.

*Researcher: Was it difficult for you to commit to these intervention programmes?*

*Participant: No... because I knew I could jump over in my sailing'. (P1, 49)*

#### **6.7.4 Implementation of trunk exercise using Valedo video game system**

While implementation was one of the main areas for discussion, participants were asked about the factors that might help or hinder the practicing of trunk exercise, including the difficulty of the games, whether they felt safe while practicing trunk exercises, and their suggestions to enhance the implementation. Thus, two main themes generated from the data analysis that represented implementation were: 1) recommendation for professionals; and 2) safety (Figure 6-8).

##### **1- Recommendations for professionals**

The feedback from participants suggested different points that need to be considered by professionals, including physiotherapists and games developers, when implementing these kind of video game-based trunk exercises. These points were supported by subthemes of game design,

training at the right level of challenge, feedback on performance, and integrated rehabilitation package, which are discussed below.

### Game design

This theme was particularly strong when participants discussed the Fruit game. The movement required in the fruit game was pelvic tilting towards the right and left sides while keeping the upper trunk upright. Four participants found this game difficult to practise for different reasons related to the game design.

The lack of clarity of the movement required by the upper and lower trunk, even with the physiotherapist instructions (lift up the pelvic while keeping the upper trunk still), made this game difficult for three participants. Also, the avatar in the corner who was responsible for showing the movement required was slow, which led to confusion about which side of the pelvis needed to be lifted.

*'Well, it's as soon as I made the distinction that the top part was my trunk... I got my head around that, then I could suddenly decide which way to go and how far to lean'. (P1, 49)*

Moreover, the randomness of the fruits was not enough, which led to repetitive movements in one side of the pelvis, and some participants suggested introducing more randomness in the fruits.

*'I would introduce more randomness in the Fruit game'. (P4, 69)*

*'In the fruit game, I wish that the fruits would come down in order, like 10 oranges then 10 watermelons'. (P8, 40)*

The Colour game was found to be difficult for all participants who played it. The design of the game required a highly controlled trunk movement to be able to practice it successfully.

*'How sensitive it can be at times... you think the ball is not going to go out, but it goes out for some unknown reason'. (P1, 49)*

*'It drives you crazy... Because it's so twitchy. It's so unforgiving. If you overextend or if you move too quickly, it's really difficult to control'. (P5, 59)*

Adding video games to the repetitive exercise was not enough to make it interesting. Three participants described the Clock game as 'boring' because of the repetitive nature of this game.

*'It was only sort going backwards and forwards. So, it I was boring because of that'. (P3, 62)*

*'What is my least favourite game? The Clock game, because the movement was monotonous and repetitive'. (P6, 92)*

The scoring strategy of the Diver game made one participant upset because he lost many points for a small mistake, which made this game his least favoured one.

*'If I made a small mistake, I lost everything I had earned. This was upsetting'. (P8, 40)*

#### Training at the right level of challenge

Although the level of challenge and position of exercise were determined based on the participant's balance, other aspects need to be considered by clinicians, such as muscle flexibility and attention ability. Two participants reported the Clock game as difficult because of the tightness they felt in lateral trunk muscles when doing the exercise.

*'It was difficult because I felt tightness in my muscles when I was playing'. (P10, 54)*

The Break Breaker game was stopped and changed for two participants because they could not speedily react to the change in movement direction and always lose the game.

*'Following the ball movement was exhausting and it required a very fast movement' (P9, 75)*

#### Feedback on performance

Feedback on performance was shown as a score for each game and was perceived by participants as a useful way to set a goal, as mentioned previously. However, the feedback was not understood by all participants.

One participant disagreed with the Likert questionnaire item when he asked about whether he understood the score given at each game.

*Likert scale question: I did understand the score showing my performance at each game  
Participant: No, I disagree... I didn't necessarily understand where the scores came from'  
(P3, 62)*

Another three participants mentioned that they understood the score for each game after the physiotherapist's explanation.

*Likert scale question: I understood the score that showed my performance in every game.  
Participant: Agree. I understood it at the end and after the physiotherapist had explained it to me'. (P7, 75)*

Thus, it is important for clinicians who want to implement this type of video game exercise to explain the score given by the end of the session for patients.

Integrated rehabilitation package

Two participants wished that the rehabilitation programme was longer than 18 sessions.

*'I wished the sessions were longer because I loved them'. (P10, 54)*

Moreover, two participants suggested an inclusive interventional programme that included an exercise for UL and LL in addition to the trunk exercise.

*'I would like to have a programme that combines video games for the torso with exercises designed for increasing fitness, such as walking on a treadmill. Also include movements for a hemiplegic hand and leg'. (P8, 40)*

## 2- Safety

A further theme that affected the implementation of trunk exercise using video games was the safety of the exercises. This was a particular issue for those with moderate and severe stroke and highlighted the factors that contributed to 'feeling safe' and the possible 'resultant symptoms'.

### Feeling safe

When asked directly about the feeling of safety during practicing trunk exercise through video games, most participants indicated it was safe to do the exercise and that feeling arose from two main reasons. The first reason was that they exercised in a safe environment from a safe exercise position.

*'I feel perfectly safe while playing the video games. I know that there is nowhere to fall'. (P4, 69)*

*'I felt safe mostly on the standing up ones. I didn't feel as though I was going to go over or whatever. But when I sat down in doing it, on some of the games, my feet started moving a little bit. So, therefore, I prefer to do them standing up than I would sitting down, especially the Break Breaker one because obviously when I was sitting down, and obviously I reckon my arm was getting in the way, so I felt easier to do it standing up'. (P2, 54)*

The second reason was they knew that the physiotherapist was around them if things went wrong.

*'Initially, I felt that I would fall, but I knew that the physiotherapist was there. As the sessions progressed, I felt much safer'. (P8, 40)*

*'I'm on the bed, and my physiotherapist was close by in order to make sure that I didn't go anywhere untoward'. (P4, 69)*

Resultant symptoms

Two participants mentioned some symptoms resulting from practising specific games. Participant (8) reported a feeling of muscle tightness during practising the trunk lateral flexion exercise when playing the Clock game.

*'The tightness that I felt on the sides of the trunk when I performed this exercise made this game difficult for me' (P8, 40)*

Another participant revealed a feeling of dizziness resulting from concentration in following the ball movement in the Break Breaker game.

*'Follow the ball movement was exhausting and it required a very fast movement. It made me feel dizzy. Therefore, I needed to pause for a few minutes and have a rest'. (P9, 75)*

The same participant also reported fatigue when playing games that concentrated on pelvic movements, such as the Fruit game.

*'The pelvic movement was very difficult and made me feel a bit fatigued sometimes'. (P9, 75).*

#### **6.7.5 Summary of qualitative results**

Thematic analysis of interview transcripts from 10 participants resulted in the identification of five key themes related to both acceptability and implementation of the video game-based trunk exercise Figure 6-7 and Figure 6-8. The three themes related to acceptability were the perceived impact of the intervention, motivation to exercise with video games, and burden of participation. Participants showed acceptability of the intervention by their perceived positive physical and psychological improvements post intervention. These perceived impacts include improvement in ADL, balance, and cognitive function, such as concentration and multi-tasking skills. Participants felt these improvements motivated them to exercise with video games. Furthermore, the fun and enjoyment when playing Valedo video games contributed to motivating participants to exercise with the video games. The audio-visual feedback played an important role in the participant's motivation to exercise, but participants felt that the therapist needed to explain the feedback given by the system to the participant.

A burden of participation associated with adherence to the study sessions, such as the availability or busyness of the carer, affected the ability to attend the planned session. Further, physical and psychological challenges experienced when practising exercise within some games (such as Break

Breaker and Fruit games) made the exercise physically and cognitively challenging for some participants.

The remaining two themes were related to the implementation of this type of intervention and were recommendations for professionals and safety of intervention. Participants expressed some physical and cognitive challenges when they played Valedo video games. Thus, clinicians need to consider the physical and cognitive abilities of participants before implementing video game-based interventions. Further, participants felt that an integrated rehabilitation programme including UL and LL exercise in addition to the trunk training would be better. Additionally, the game design could affect the participant's experience by making the game either boring or frustrating due to the monotonous and scoring strategy of the games, respectively. Lastly, the implementation of trunk exercises using video games was felt to be safe by the participants as they exercised in a safe exercise position and environment. Only minimal resultant symptoms, including fatigue and lateral trunk muscle tightness, were reported.

To obtain a more comprehensive and robust understanding of the study findings, integrated findings from quantitative and qualitative datasets will be presented in the next section.

## **6.8 Integration of quantitative and qualitative results**

Key findings from the integration of the quantitative and qualitative data sets are presented in this section using joint displays. Joint displays are a visual and tabular presentation of qualitative and quantitative data to illustrate integration and mixed methods conclusions drawn based on the integration. Ascertaining to what extent (if any) quantitative results confirm interview findings enables a more complete answering of the research questions of the third phase of this PhD study mentioned in Section 2.13.

Integrated findings regarding feasibility, including acceptability, and implementation of trunk training exercise using a video game-based system are presented in Table 6-19 and Table 6-20, respectively.

### **6.8.1 Integrated findings of acceptability**

Integrated findings related to the acceptability of the intervention are presented in Table 6-19 and summarised below.

## 1- Experienced improvement post intervention

The perceived physical and psychological benefits expressed in the interviews after completion of the programme were confirmed by the quantitative findings.

The quantitative data supported the qualitative data in physical improvement related to trunk impairment and balance. The qualitative data reported under a physical impact subtheme about balance improvement were supported by an improvement in TIS and BBS in quantitative clinical measures (Table 6-19). The improvement in TIS applied to all participants, including the one who attended only 12 sessions (P9). The balance clinical measurement also supported the perceived physical improvement mentioned in the qualitative data by a marked increase in total BBS for nine participants ( $\geq$  MDC = 4.66). These findings suggest that the dosage of therapy may be sufficient to produce a positive change in trunk impairment and balance ability in patients with chronic strokes.

However, the quantitative data did not support the qualitative data in terms of UL impairment. Although the qualitative data indicated that participants perceived an improvement in their ability to reach for objects (beyond UL length), this was not substantiated by improvements in UL impairment observed in quantitative data measured by FMA. Even P10, who reported that she could reach things better beyond her usual reach, did not show any improvement in FMA or SWMFT-FAS. However, there was an improvement in UL function in terms of reduction in the time taken to perform UL tasks of SWMFT, and this change was clinically important for seven participants, including P10. Further, another quantitative data that could support this qualitative finding of UL improvement were compensatory trunk flexion, trunk lateral flexion, and axial rotation movements, kinematic measures that were substantially reduced during performance of UL tasks that required forward and side reach (Task 1 to Task 4 and task 8 in SWMFT).

Another disagreement was shown with the quantitative data of LL impairment that did not support the qualitative data in the perceived physical improvement of walking, as there were no indications of improvement in FMA-LL. Moreover, there was no measurement taken for testing walking ability in this study. The perceived physical improvement reported previously could potentially promote a psychological improvement, thereby enhancing the positive attitude towards the intervention. The quantitative data of PIADS related to independence, capability, self-confidence, and productivity supported the qualitative data sets related to the psychological impact of intervention. There was qualitative evidence of the psychological impact of intervention expressed by participants as they felt more capable, independent in some ADL, confident in their ability to balance, and more productive in managing their daily tasks. These findings were also reflected in the quantitative data,

as the majority of participants (80%) positively scored the PIADS items related to these aspects, as presented in (Table 6-19).

## **2- Positive attitudes**

Overall, both quantitative and qualitative data showed a positive attitude towards the trunk exercise interventional programme using Valedo video games. Participants who expressed their positive feelings in qualitative findings by feeling happy, excited to do the exercise and enjoying the programme also recorded a high level of participation measured each session by PRPS. Further, 90% of participants (9/10) were pleased with the programme as they rated the happiness items in PIADS positively.

The audio-visual feedback given during playing each game was recognised as being critical for both participant motivation and helping participants to know whether they did the exercises in the correct way. The qualitative data reflected the importance of visual and auditory feedback through a subtheme of informative and motivational feedback. There was no quantitative evidence for motivation level, as it was not measured quantitatively.

## **3- Effort and challenges in participation**

The quantitative data supported the qualitative data in factors related to the effort required to take part in this study and the challenges faced by participants when practicing the exercise. The burden of participation in qualitative findings was linked with the adherence level (ability to commit to the 18 planned sessions) in quantitative findings. Only one participant (P9) who attended 12 sessions expressed difficulty committing to the programme during the interviews, as he reported that this was because of his reliance on carers who were too busy.

Moreover, the physical and psychological challenges relevant to the games made the exercise challenging for some participants. The quantitative data of balance supported the qualitative data in terms of physical challenges experienced when the exercise required a weight shifting towards the hemiplegic side. Seven participants with a lower balance (BBS  $\leq$ 45) assessed at baseline expressed difficulty in the games that required high weight shifting towards the hemiplegic side, such as the Clock game. Further, concentrating on different aspects at the same time when playing some games made the exercise cognitively challenging. For example, tracing the ball movement, doing trunk rotation exercises according to the direction of the ball, and making sure that you respond quickly to the change in the direction of the ball by doing a fast trunk rotation movement in the Break Breaker game made it cognitively challenging. One participant (P9) could not continue

to practise the trunk exercise using the Break Breaker game because it was too challenging for him, which led to changing the game. Nonetheless, there was no quantitative data to support these qualitative findings, as cognitive ability was not measured at baseline.

Table 6-19: Integrated Acceptability Findings

Construct	Quantitative Findings	Qualitative Findings	Level of agreement
<p>Experienced improvement:</p> <p>Physical impact</p>	<p>Group changes in cTIS, iTIS, BBS, trunk kinematic measures, SWMFT, FMA-UL, and FMA-LL</p> <ol style="list-style-type: none"> <li>1. High improvement in trunk impairment measured by TIS (<math>\geq</math> MDC = 0.67) with at least +3 points increasing in TIS post intervention (median: 7, IQR: 3)</li> <li>2. Five participants or more had improvements (<math>\geq</math> MDC) in each dynamic subscale task, as presented in Table 6-11.</li> <li>3. Marked improvement in balance measured by the BBS (<math>\geq</math> MDC = 4.66) with at least +4 points increasing in total BBS score post intervention (median 16.07, IQR 10.72)</li> </ol>	<p>A theme of perceived impact of intervention was supported by subthemes of physical and psychological:</p> <ol style="list-style-type: none"> <li>1. 'It makes my torso and my trunk and my core stronger and makes my movements more confident' (P5, 59)</li> <li>2. 'Interviewer: Can you give me an example of the movement that you are able to do better or confidently than you could before? Participant: 'The lateral movements. To the left and to the right' (P5, 59)</li> <li>3. 'It has improved my balance' (P3, 62)</li> </ol>	<p>Agreement</p> <p>Agreement</p> <p>Agreement</p> <p>Partial agreement</p>

<p>Psychological impact</p>	<p>4. The changes in trunk kinematics during UL task performance (including reaching) varied between participants, as presented in Table 6-12. None of the participants improved in all tasks. However, clinically meaningful improvements (<math>\geq</math> MCID of 1.5 to 2 seconds) in time taken to do the UL tasks (SWMFT-time) were noted in seven participants. None of the participants scored any meaningful improvement in UL impairment measured by FMA-UL (median: 0, IQR: 2).</p> <p>5. None of the participants scored any meaningful improvement (all participants scored <math>&lt;</math> MDC and MCID) in LL impairment measured by FMA-LL (median 2.94, IQR 7.35)</p> <p>The post-intervention PIADS scores (pre-interview) present aspects of the psychological impact of using the Valedo system to deliver video game-based trunk exercises as follows:</p>	<p>4. 'The ability to reach the things with my hands that were beyond my reach has become easier' (P10, 54)</p> <p>5. 'In fact, I'd say that I was walking a little bit better... My leg felt lighter when I walked' (P2, 54)</p> <p>The psychological perceived impacts of intervention were shown as a feeling of capability, independency, self-confidence, being more</p>	<p>Disagreement</p>
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	6. Eight participants positively scored the independence item in PIADS by a score of 1-3/3.	productive, and improvement in cognitive performance	Agreement
		6. 'I used to have difficulty when sitting on the toilet seat and needed my sons' help. But now, I can do that by myself' (P7, 75)	Agreement
	7. Eight participants positively scored the capability item in PIADS by a score of 1-3/3.	7. 'I do feel a little bit stronger and a little bit more capable' (P5, 59)	Agreement
	8. Eight participants positively scored the self-confidence item in PIADS by a score of 1-3/3.	8. 'I have noticed that I have become more confident and better balanced when I walk on the grass' (P8, 40)	Agreement
	9. Eight participants positively scored the Productivity item in PIADS by a score of 2-3/3.	9. 'My activity has changed. Now I can leave home and come back feeling better compared with before going on the programme' (P10, 54)	Silence in quantitative data
	10. No data	10. 'I think it's brilliant for teaching you—you are doing multitasking, in a way' (P5, 59)	

<p>Affective attitude:</p> <p>Exercise engagement</p> <p>Feeling happy</p> <p>Enjoyment</p>	<ol style="list-style-type: none"> <li>1. Eight participants showed a high level of participation, with a very good (<math>\geq 5.7/6</math>) score in participation, as measured by PRPS.</li> <li>2. Nine participants highly scored the happiness item in PIADS scale by a score of ( score: 2-3/3 point) positively</li> <li>3. No data</li> </ol>	<p>The positive attitude towards intervention was expressed in different ways:</p> <ol style="list-style-type: none"> <li>1. 'It gave me a sense of excitement to do more and more exercises' (P8, 40)</li> <li>2. 'Doing the exercises made me happy' (P7, 75)</li> <li>3. 'It made me feel like I was entertaining myself and exercising the hemiplegic body parts at the same time' (P10, 54)</li> </ol>	<p>Agreement</p> <p>Agreement</p> <p>Silence in quantitative data</p>
<p>Importance of feedback</p> <p>Assists in doing the exercise correctly</p>	<p>No data</p>	<p>A subtheme of <b>informative and motivational feedback</b> reflected the importance of feedback in the rehabilitation process.</p> <p>'The sounds are not annoying. Rather, they are good like the bell sound (ding) when I do something correctly' (P10, 54)</p>	<p>Silence in quantitative data</p>

Motivation		‘The sounds and pictures gave me a sense of success and motivated me to perform the exercise until I won... I wanted more of these motivational sounds and pictures’ (P8, 40)	
Effort and challenges in participation	<ol style="list-style-type: none"> <li>1. No data</li>   <li>2. Seven participants scored low in BBS in the initial assessment of BBS <math>\leq</math> 45.</li> </ol>	<p>A theme of burden of participation was supported by subthemes of cognitive challenge, physical challenge and resources: transport, care and time:</p> <ol style="list-style-type: none"> <li>1. ‘Because that was a lot of problem-solving and predicting where the ball is going to be—and the obstacles you have to get around’ (P1, 49)</li>   <li>2. ‘Moving towards the right and left sides was exhausting, especially when I leaned on the hemiplegic side... I was afraid of losing my balance and falling’ (P6, 92)</li> </ol>	<p>Silence in quantitative data</p> <p>Agreement</p>

	<p>3. Adherence level: Eight participants completed the entire planned intervention sessions (18 sessions), one completed 12 sessions, and one completed 17 sessions.</p>	<p>3. 'Was it difficult for you to commit to the intervention programme? No... You know I drive my car. So, I could come to the sessions by myself' (P5, 59)</p> <p>'My sons were driving me to the clinic. However, sometimes they were busy so I couldn't commit to all the sessions' (P9, 75)</p>	<p>Agreement</p>
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## **6.8.2 Integrated findings on implementation**

The integration of quantitative and qualitative findings related to the implementation are presented in Table 6-20 and summarised below.

### **1- Study attrition**

The quantitative data supported the qualitative data in study attrition. Low attrition levels were recorded quantitatively: two participants withdrew after assessment sessions. The rehabilitation programme content was cited as one of the reasons to withdraw from the study, as it did not include any LL exercise. Interestingly, the qualitative findings showed that two participants suggested that an integrated rehabilitation programme that included UL, LL, and trunk exercise would be better.

### **2- Safety**

The quantitative data supported the qualitative data in terms of the safety of using Valedo video games to deliver trunk exercise (Table 6-20). The adverse event form used in each session did not record any major adverse events, and the qualitative data revealed minimal infrequent resultant symptoms. Although trunk muscle tightness was experienced by three participants (adverse event form) after a couple of early intervention sessions, it was thought to be mainly associated with unaccustomed muscular activity, as participants in the interviews reported that it disappeared as sessions progressed. Also, the fatigue reported by participants was mainly mental fatigue resulting from the effort required as well as exercise intensity.

### **3- Considerations for clinical implementation**

Despite the good records for study attrition and safety, some considerations need to be taken into account for a clinical implementation of this type of video game intervention for patients with stroke. Both the game design and the level of effort introduced by each game were challenging for the implementation of this intervention. Confusion and frustration related to some games (especially the Fruit and High Flyer games) were reported by three participants in the qualitative interview data. The quantitative data supported the qualitative data as the “frustration” item in the questionnaire (PIADS) rated negatively. However, the quantitative data did not support the qualitative data for “confusion”.

Another aspect to consider in clinical implementation was the difficulty level in terms of physical and cognitive abilities needed to play the game. Tailoring the programme by balance ability (using the BBS at baseline) seemed to be insufficient for personalising the programme to individual needs. Other aspects reported in the qualitative findings, such as cognitive ability and trunk muscle flexibility, should be critically considered when personalising a more tailored programme in future studies.

### **6.8.3 Summary of integrated results**

In summary, results from this mixed-methods study found high levels of acceptability of using Valedo video games in delivering trunk exercise. The acceptability resulting from positive attitudes towards intervention and the perceived physical and psychological impacts of the intervention reported in the interviews were reflected in the quantitative clinical outcomes. Further, the feedback given by video games motivated participants to do the exercise and informed them whether they did it correctly. Quantitative data showed a high adherence level to this intervention; however, the availability of supportive carer was reported in the interviews as an important factor in adherence.

Implementing this type of intervention in patients with chronic stroke is safe, as quantitative data supported qualitative data in reporting no major adverse event and only minimal infrequent symptoms (e.g., fatigue) resulting from the intervention. The design of some games reported in the interviews made participants frustrated because in some games, such as the High Flyer game, for unknown reasons, participants could not hit the goal, and the quantitative data supported this finding by reporting frustration in the PIADS questionnaire. Lastly, the balance ability measured quantitatively was used to progress the difficulty of exercise; however, participants found some games physically and cognitively challenging for them, suggesting that both physical and cognitive abilities need to be considered when implementing this type of intervention. Thus, therapists need to determine the level of challenge (cognitively and physically) and how to progress the patient to the next level.

A discussion of key findings, study limitations, and clinical implications are presented in the next sections.

Table 6-20: Integrated Implementation Findings

Construct	Quantitative Findings	Qualitative Findings	Level of agreement
Study attrition	<p>12 participants completed the first session of baseline assessment, and two withdrew after the first assessment session. One reason for withdrawal was participant realisation that the intervention programme did not include LL exercise.</p> <p>Ten participants completed the study assessments (baseline and post intervention), and only eight completed the planned 18 intervention sessions</p>	<p>Two participants who completed the study suggested inclusion of an <b>integrated rehabilitation programme</b>.</p> <p>‘I would like to have a programme that combines video games for the torso with exercises designed for increasing fitness, such as walking on a treadmill. Also include movements for a hemiplegic hand and leg’. (P8, 40)</p> <p>The same two participants wished the rehabilitation programme had lasted for more than 18 sessions.</p> <p>‘The programme is great. I wish it had been longer with 35 sessions rather than only 18 sessions’ (P8, 40)</p>	<p>Agreement</p> <p>Agreement</p>
Safety	<p>No major adverse events were reported.</p> <p>The Adverse Event form completed each session showed that minor symptoms were experienced by the end of sessions consisting of fatigue (2 participants) and trunk tightness (3 participants)</p>	<p>A theme of <b>safety</b> of the Valedo system was supported by subthemes of <b>feeling safe</b> and <b>resultant symptoms</b>.</p> <p>‘I know I was in a safe environment doing it’. (P1, 49)</p> <p>As discussed in the qualitative results section, fatigue has been mentioned as a factor that contributed to safety:</p> <p>‘The pelvic movement was very difficult and made me feel a bit fatigued sometimes’. (P9, 75)</p>	<p>Agreement</p>

Considerations for clinical implementation:	There is a conflict in the quantitative results of PIADS as:	A subtheme of <b>game design</b> highlighted aspects that need to be considered when implementing this type of intervention in the stroke population.	Disagreement
Game design	<ol style="list-style-type: none"> <li>1. None of the participants rated the confusion item negatively in PIADS.</li> <li>2. Three participants negatively rated (1-2/3) the frustration item in PIADS.</li> </ol>	<ol style="list-style-type: none"> <li>1. 'My mind got confused too many times about which side of my buttock to lift'. (P4, 69)</li> <li>2. 'I found that very frustrating in that I thought I had got the aim to do that, but I haven't'. (P4, 69)</li> </ol>	Agreement
Patient-tailored rehabilitation programme	Seven participants started the programme by doing the exercises in sitting (stratified by their BBS), and two of them progressed to doing the exercises while standing in the middle of the programme (if BBS ≥ 45)	<p>Cognitive ability and trunk muscle flexibility should be considered when tailoring the exercise programme for every patient.</p> <p>'I had to move my entire body to follow the ball and, in the end, I was not able to hit the goal correctly'. (P7, 75)</p>	Partial agreement

## **6.9 Discussion**

The primary objective of this study was to explore the feasibility of using the Valedo video game-based system to deliver trunk exercises for people with chronic stroke. Another objective was to monitor changes in the clinical outcome measures related to trunk impairment, balance, and upper limb and lower limb impairment. The findings of this study showed that the use of the Valedo system was acceptable to people with chronic stroke for delivering trunk exercises and could be implemented in clinical settings. Furthermore, the post-intervention clinical outcomes showed an improvement in trunk impairment, balance, and partial positive change in upper limb function. The next sections will explicitly discuss the study findings.

### **6.9.1 The Valedo system was acceptable in delivering trunk exercise**

Findings from this study confirmed that study participants considered the Valedo video games an acceptable method for delivering trunk exercise to people with chronic stroke (Section 6.8.1). Acceptability was linked to the enjoyment experienced while exercising with the Valedo system and the ability to address issues of boredom experienced with traditional exercises. The boredom of doing conventional repetitive trunk exercises was widely reported by participants in the interviews. There was a consensus among participants that they would not do the trunk exercise without video games because they find the repetitive movements boring. The use of video games could limit the feeling of boredom resulting from conventional rehabilitation, and this was clearly observed in some participants who engaged with the exercise and even lost track of time. These are some prerequisites for the feeling of 'flow', which focuses on the enjoyment and immersion experienced by a person during a given activity, in a state of intense focus in which he or she loses track of time (Swanson and Whittinghill, 2015). This is in agreement with recent published literature that used sensor-related video games (Microsoft Kinect) for balance rehabilitation post stroke (Lloréns et al., 2015, Proffitt and Lange, 2015). The acceptability in these studies was measured either quantitatively using Intrinsic Motivation Inventory (IMI) or qualitatively through interviewing participants, and both studies revealed that participants with stroke found video games-based rehabilitation enjoyable.

Perceived benefits from the intervention were also considered an important factor in the study participants' contribution to the acceptability of this study. Participants reported that the physical and psychological improvement they noted after the intervention motivated them to do the exercise using the Valedo video games. These findings could be interpreted in light of self-

determination theory (SDT) (Ryan et al., 2008). According to SDT, the adoption and maintenance of a behaviour is influenced by valuing or enjoying the behaviour (Ryan et al., 2008). Thus, the enjoyment reported while exercising using the Valedo system and the perceived physical and psychological impact indicate the possibility of video game-based trunk rehabilitation in improving exercise adherence. However, this conclusion should be viewed with caution because it is not possible to determine whether the enjoyment and perceived impact would last as the participants became more familiar with the games over a longer period.

Adherence to therapeutic interventions was identified to be linked with acceptability, as recipients are more likely to adhere to the intervention if they accept it (Fisher et al., 2006). In the current study, adherence to the planned sessions was high, as 80% of the enrolled participants completed the programme. The health status (i.e., feeling unwell) was one of the reasons for the lack of completion of the last session by P3. Previous literature reported that the largest barrier to adherence to an exercise programme was change in health status (Forkan et al., 2006, Tiedemann et al., 2012). The availability or busyness of the carer was the other reason for reducing adherence in the current study. Further, people who completed the intervention programme in this PhD study indicated that having a supportive carer and convenient timing of the sessions were the main factors that facilitated adherence. This is in keeping with findings by Proffitt and Lange (2013) and (Jack et al., 2010) who identified that insufficient time and family support can be a barrier to adhering to a physical therapy programme. Consequently, tailoring the time of the sessions and available family support appeared to facilitate adherence to the interventional programme in this study.

However, despite the enjoyment and adherence to the interventional programme that indicate acceptability in this study, the cognitive challenge faced when playing some video games (such as Break Breaker and High Flyer games) influenced acceptability in different manners. Even in the absence of cognitive deficits among study participants, the games themselves were perceived as difficult to practise due to the high cognitive multi-tasking ability required. The participants reported the games requiring a high cognitive multi-tasking ability as their least preferred games to play. The inability to master the required components of exercise could decrease exercise participation (Simpson et al., 2011). This suggests the necessity of considering the required level of cognitive ability when designing video games intervention programmes for stroke survivors. This is in keeping with findings by Proffitt and Lange (2015) who identified that poor cognitive ability impeded exercise engagement and was considered a barrier to using a game-based rehabilitation system in balance training post stroke. In future studies, it may be helpful to measure cognitive

ability using a clinical scale such as the Mini Mental State Examination to determine the minimum cut-off scores required to practise this type of intervention.

### **6.9.2 Valedo video game-based trunk exercise is feasible for clinical implementation**

The findings of this study showed that there were no major adverse events reported when performing Valedo video game-based trunk exercises; however, a minority of participants ( $n = 3$ ) experienced fatigue and lateral trunk muscle tightness by the end of the session, which were alleviated over time. The incidence of fatigue has been reported in other research studies using video games as forms of rehabilitation (Celinder and Peoples, 2012, Stockley et al., 2017, Tornbom and Danielsson, 2018). The authors reported the incidence of fatigue either by using field notes during sessions or in the interviews post intervention. Furthermore, Stockley et al. (2017) measured the fatigue using the Fatigue Severity Score (FFS) and found that fatigue significantly increased in the video games rehabilitation group compared to the conventional stroke rehabilitation group. The experienced fatigue could be due to physical impairments related to selective motor control and balance as well as cognitive impairments related to concentration or mental fatigue (Celinder and Peoples, 2012). The experience of trunk muscle tightness alleviated over time could be due to a reduction in lateral and lower trunk muscle flexibility. This is in line with a recent RCT that suggested that core stability training, including pelvic control exercises, enhanced the flexibility of the lower trunk measured by pelvic tilt active range of motion (pelvic AROM) (Haruyama et al., 2017). Neither fatigue nor muscle flexibility were measured quantitatively in this current study; thus, the clinical significance of fatigue and muscle tightness are an important area for future research.

While the recruitment procedure was somewhat slow (only 18 responses within one year in the UK), the recruitment rate was high (44.44% of the interested participants were eligible) compared to other studies that have investigated the use of similar forms of intervention in stroke rehabilitation (26% of the target population screened were recruited) (Laver et al., 2015). Further, a study of 114 trials in the UK indicated that only 31% met enrolment goals (Bower et al., 2009). The high eligibility rate in the current study could be due to the suitability of the Valedo system to different levels of disability, as it did not require a specific UL ability to hold controllers like Wii games or to be at a high level of dynamic balance to practise the virtual reality (VR) exercises. However, the main reasons for the lack of eligibility in the current study were the inability to attend 18 sessions or the receipt of another form of neuro-rehabilitation (Section 6.6.1). This finding is in line with those of Attwood et al. (2016) and Rogers et al. (2014) (Attwood et al., 2016, Rogers et al.,



reinforce the findings of previous research that identified the need for tailoring the level of challenge to match stroke participants' ability, as they noted that participants' disappointment and frustration were closely connected to the challenges experienced (i.e., speed of reaction) during the playing of Wii video games (Celinder and Peoples, 2012). For successful rehabilitation, personalising an optimal task difficulty level according to individuals' capacities has been suggested to ensure exercise engagement and thereby improve adherence (Finley and Combs, 2013, Proffitt and Lange, 2015). However, the current study was unable to personalise each game for the participants because some factors, such as the speed of ball and randomness of fruits, could not be adjusted.

### **6.9.3 Audio-Visual Feedback Is Motivational and Informative**

Existing literature suggests that extrinsic feedback (either audio, visual, or tactile feedback) in the form of knowledge of results and knowledge of performance may be key components in encouraging motivation (Alankus et al., 2011, Burke et al., 2009). The off-shelf commercial video game systems, such as Nintendo Wii used in studies using video games for stroke rehabilitation, cited the advantages of being less expensive than robotic or immersive video games systems, easy to set up, and giving feedback on performance (Alex et al., 2017). However, a majority of studies that used video game-based rehabilitation reported several limitations in the feedback given, including insufficient, inaccurate, and disappointing feedback (Alex et al., 2017, Deutsch et al., 2011, Parker et al., 2014).

The results of this study indicate that multimodal feedback (audio feedback such as cheering and visual feedback such as number of repetitions or scores) given by the Valedo system during exercising played a major role in participants' motivation (Section 6.7). The audio-visual feedback given while playing was perceived as informative and useful to provide confirmation of performance. The score and star reward given by the end of each game gave the participant the drive to win a game and inherent motivation to participate in the activity to get better results each time. These findings agree with previous studies that highlighted the importance of feedback given by video games systems in encouraging participants' motivation and exercise engagement (Alankus et al., 2011, Alex et al., 2017, Burke et al., 2009, Deutsch et al., 2011, Parker et al., 2014). However, the participants raised some limitations of the feedback during the interviews. First, the rewarding strategy used in the Diver game was found to be upsetting by one participant because he could lose lots of points collected in this game. Participants would need a fast pelvic tilting to overcome a big fish, but if the pelvic tilting is insufficient or very slow, it could lead to the big fish stealing a lot of collected points during the game. Another raised limitation (n=1) was that the feedback given at

the end of each game was not always understandable and highlighted the importance of having someone explain the score given at the end of each game. A published guideline concerning feedback given in VR training recommends providing timely feedback on successful or erroneous actions in a simple and salient manner, and the need for simple instructions for participants on recovering or solving an error, or about inhibiting specific behaviours in a salient and concise manner, especially for the elderly (Moran et al., 2015). In summary, providing clear, simple informative feedback with information on how to improve performance and avoiding discouraging reward strategies might help in encouraging participant motivation.

#### **6.9.4 Perceived impact of intervention and change in clinical outcomes**

Physical and psychological benefits, including improvement in balance, reaching, managing ADL, multi-tasking ability, and self-confidence, were reported in the post- intervention interviews (section 6.7). Although the current study was not designed as an efficacy study, quantitative results of clinical outcomes showed positive changes in trunk impairment, balance, and UL function post intervention, suggesting possible improvement resulting from using Valedo video game trunk exercise for participants with various levels of disability ( Table6.6). However, changes in UL and LL impairment did not reach MDC or MCID.

Trunk impairment, as measured by the TIS, showed an increase by 3 to 7 ( $\geq$  MDC) points in the overall TIS total score (23) for all participants post intervention. The least improved participant was the participant who did not attend all the sessions (P9); his TIS score increased by only 3 points. This finding is in agreement with results from recent RCTs that used video games trunk training for people with chronic stroke (Kim et al., 2018, Lee and Bae, 2020). In 2018, Kim and colleagues compared the effect of a high dose training (HDT) (40 sessions) to a low dose training (LDT) (20 sessions) video game-based trunk exercise programme on trunk impairment. They found that both groups who attended 30 minutes of trunk training improved significantly ( $p \leq 0.001$ ). However, the HDT group improved ( $p= 0.000$ ) better than the LDT group. More recently, a randomised control trial showed that 30 minutes of additional driving-based interactive video games practised for three times/week for four weeks can produce a significant improvement in TIS ( $p \leq 0.001$ ) (Lee and Bae, 2020). However, neither study explored the participant's experience towards this type of intervention. Improvement of the TIS seen in the current study is not surprising given the results of previous systematic reviews and meta-analysis that showed that trunk exercises significantly improve TIS total score in acute, subacute, and chronic strokes (Alhwoaimel et al., 2018, Bank et

al., 2016, Cabanas-Valdes et al., 2013, Cabrera-Martos et al., 2020, Crieckinge et al., 2019, Sorinola et al., 2014, Souza et al., 2019).

The instrumented version of the TIS also revealed a positive change in trunk impairment. The trunk lateral flexion range of movement towards the hemiplegic side increased ( $\geq$  MDC) for five participants post intervention. This change implied an improvement in the dynamic trunk subscale, as participants were able to touch the bed with the elbow at hemiplegic side. Furthermore, the symmetry between the affected and less affected side was increased for three participants, indicating an improvement in the co-ordination subscale. The same participants reported an improvement in clinical TIS tasks. The existing literature on measuring trunk and pelvic kinematics from a sitting position post intervention is limited to a single study that measured both trunk control and trunk kinematics post conventional neurorehabilitation (Carozzo et al., 2020). Their results demonstrated a significant relationship between trunk control (TCT) and lateral trunk movement ( $r = 0.36$ ;  $p$ -level= 0.007) and lateral pelvic movement ( $r = 0.41$ ;  $p$ -level= 0.003). In addition, the lateral pelvic movement was found to be the best predictor ( $R^2 = 0.2$ ;  $p$ -level < 0.006) of clinical recovery of trunk as measured by TCT.

A possible mechanism behind a change in trunk impairment could be increasing abdominal muscle thickness. The total TIS score has been reported to be positively correlated with TrA muscle ( $r = 0.389$ ,  $P < 0.05$ ) in people with chronic stroke (Lee et al., 2018a). However, this possible justification needs to be viewed with caution, given that trunk muscle thickness was only measured in the UK participants due to limited resources. The 18 sessions of trunk exercises were associated with an increase in trunk muscle thickness of TrA only in the hemiplegic side, but minimal increases were found in EO, IO, and RA in the hemiplegic side. The increase in TrA thickness was the greatest on the hemiplegic side compared to the less affected side. These findings support those within a recent systematic review and meta-analysis that investigated the effect of trunk exercise on trunk muscle thickness and activity in people with stroke (Crieckinge et al., 2019). The findings showed large significant effect sizes in TrA muscle thickness (effect size = 2.22) favouring the trunk exercise, while the IO and EO were not significant. However, only two studies were included in this meta-analysis, which limits the generalizability of the results (Lee et al., 2020, Seo et al., 2012, Yoo et al., 2014). To the author's knowledge, these three studies were the only studies in the literature that measured trunk muscle thickness post trunk exercise programme, and none established a MCID. Furthermore, the author tried to compare the results of the current study to the MDC values by contacting the authors of a reliability study measuring the TrA, EO, and IO in a stroke population, but did not receive a response (Seo et al., 2013).

The qualitative data revealed a perceived improvement in walking ability among the majority of participants—participants reported feeling more balanced during walking. Although walking ability was not measured quantitatively in clinical outcomes, the perceived improvement in walking ability could be associated with the improvement in TIS and BBS shown post intervention. The BBS results showed an increase in the total BBS ( $\geq$  MDC) for nine participants. This finding supports those of a cross-sectional study (Kim et al., 2015) that suggested that the TIS score was significantly correlated with the BBS and 10MWT ( $r^2=0.52$ ,  $p<0.05$ ) measured in people with chronic stroke. Furthermore, two recent systematic reviews that investigated the effect of core exercise on BBS and a meta-analysis showed that trunk exercise can significantly improve the BBS in subacute and chronic stroke patients with a large effect size (effect size= 3.7,  $p = 0.0002$ ) (effect size= 5.3,  $p < 0.0001$ ) (Cabrera-Martos et al., 2020, Criekinge et al., 2019).

Participants was also mentioned that they felt reaching for objects became easier and they could do it without losing balance. Notably, UL impairment as measured by FMA did not change, while UL function as measured by the SWMFT-time improved beyond the MCID (1.5 to 2 seconds) post intervention. A possible explanation for the improvement in UL function could be related to the improvement in trunk control mentioned previously, as it has been reported that core stabilization exercises enhance trunk stabilization to improve upper extremity function (Miyake et al., 2013). The results are in line with a previous research finding that concluded that supporting the trunk can improve trunk control (TIS) and have a statistically significant effect on UL function (SWMFT) in people with chronic stroke, with a performance time reduction of 2 seconds for the SWMFT (Wee et al., 2015).

The improved UL function in the current study contradicts the findings of (El-Nashar et al., 2019) who reported no differences in UL function as measured by WMFT (both time and FAS) between conventional and core stabilization exercises groups after completion of 18 sessions within six weeks. However, the statistical analysis in this study only reported the (pre-post) difference between the two groups, while (pre-post) within-group differences were not reported.

The unchanged UL impairment could be due to the nature of the programme, as the intervention was purely trunk exercise without any involvement of UL training. Furthermore, the included participants were patients with chronic stroke, and it is well documented that the time post stroke is a primary factor that affects neural plasticity and motor recovery (Kang et al., 2000). Video games that involve the usage of the UL to perform a balance exercise, such as the Canoe game-based virtual reality used in Wii sports, have been shown to improve both TIS and UL impairment (FMA) significantly ( $p \leq 0.05$ ) as reported in RCT among subacute stroke patients (Lee et al., 2016).

However, their results must be interpreted with caution due to the small sample size (only five participants in the experimental group).

The trunk kinematics during the UL task performance (SWMFT) showed positive changes post intervention in terms of a reduction in trunk ROM (flexion, lateral flexion, and axial rotation). These changes varied between participants; none improved in all tasks. Furthermore, the tasks that required forward reaching from a resting position to a specific target located in the front of the participant (such as Task 1: hand to table, Task 2: hand to box, Task 3: lift can, Task 4: lift pencil) recorded the most changes in reducing trunk ROM exerted during the task performance. However, to the author's knowledge, this is the first study that considered measuring trunk kinematics during UL task performance after a trunk training programme. The author postulates that the reduction in trunk movements could be due to the improvement in trunk control that leads to an improvement in anticipatory postural adjustment (APA). APA occurs prior to voluntary movements (e.g., reaching) to minimize the perturbation associated with the movement by activating the upper limb and trunk muscles (Bonney et al., 2009, Slijper et al.). However, people with stroke demonstrate a delay of APA in the lower trapezius and latissimus dorsi muscles on both sides of the body (Pereira et al., 2014). This is in line with the findings of (Park and Song, 2017) who found a statistically significant improvement ( $p < 0.05$ ) in onset of contraction in trunk muscles (rectus abdominis, external oblique, internal oblique, and erector spinae) after 8 weeks (3 times/week and 30 min/session) of trunk stabilization exercise in the elderly. To the author's knowledge, the current study is the first to investigate the changes in trunk kinematics during UL performance after trunk exercise intervention in people with chronic stroke.

## **6.10 Limitations of the study**

Regardless of the study findings, limitations were apparent and findings must therefore be interpreted within this context.

The author (NA) undertook all interviews because use of an interviewer unknown to the participants was not possible due to limited time and funding. Thus, participants may respond more positively as they were aware of the study purpose and role of the researcher. However, before conducting interview, every participant was reminded that their responses either positive or negative will not affect the researcher and must truly reflected their experiences. Further, the researcher (NA) coded the data and developing the themes which also considered as a methodological limitation and to avoid the possible biases, a regular supervisory meeting were held

to review the coding and developing the themes. Furthermore, each supervisor did code one interview independently and compare it with the lead researcher coding.

In addition, given the low-cost nature of the device there are a number of limitations inherent in using the Valedo video games as an intervention tool for trunk rehabilitation among people with chronic stroke. Although the games were played by participant with mild and moderate disability, the games cannot be personalised according to the participant's physical and cognitive ability. For example, the speed of Break Breaker ball and randomness of Fruit cannot be adjusted which made those games physically and cognitively challenging. Furthermore, the feedback given by the end of any game needs to be explained to the participants to understand it and it did not guide the participants on how to improve in future sessions.

As the primary objective of this study was to explore the factors that could affect the feasibility of using this type of intervention, not efficacy, the study was not powered and did not compare the intervention to a control group of conventional rehabilitation. Therefore, it is not possible to assert that the changes in clinical outcome measures were due to the intervention or other factors such as familiarity with the tests.

## **6.11 Conclusion and clinical implications**

In summary, findings from this feasibility study demonstrated that it is feasible and acceptable to use Valedo video games to deliver trunk exercise in people with chronic stroke. However, several considerations including physical and cognitive abilities needs to be taken to avoid inappropriate task difficulty and frustration. Only minimal resultant symptoms reported throughout the intervention and this includes fatigue, temporary dizziness and lateral trunk muscle tightness. Therefore, it is useful to assess cognitive ability and muscle flexibility in the future studies.

Clinicians might consider using this type of intervention to limit the boredom from conventional repetitive exercise. Furthermore, 18 sessions of video games trunk exercise using Valedo system might be beneficial in improving trunk impairment, balance and upper limb function. Further studies with larger sample sizes and using control groups to compare the effects of Video games based trunk exercises to conventional trunk exercises are warranted.

## Chapter 7    General discussion

This PhD study comprised three stages (Table 1-1). The first two stages were validity and reliability studies using the Valedo® system. The first stage investigated an instrumented version of the TIS, while the second investigated trunk movement measurement during performance of the SWMFT. The third stage assessed the feasibility of using Valedo® video games to deliver trunk exercises to people with chronic stroke. This chapter includes an overall discussion of the key findings of using the Valedo® system as a trunk assessment tool and using Valedo® video games as an intervention tool for delivering trunk exercise to people with chronic stroke. The strengths and limitations of the overall study are then considered, followed by an assessment of the novel contributions, recommendations and a conclusion.

### 7.1    Using the Valedo® as a trunk assessment tool

The assessment of post stroke trunk impairment is critical, as trunk control has been reported to be correlated with balance, gait, functional ability and UL function post stroke (Verheyden et al., 2006, Wee et al., 2015, Wiskerke et al., 2021). However, the available clinical outcome measures used to assess trunk impairment use ordinal scales to measure the degree of task completion without considering the quality of movement (Sorrentino et al., 2018). A recent study showed the importance of trunk kinematic parameters in predicting post stroke trunk recovery (Carozzo et al., 2020). The results suggest that lateral pelvic ROM ( $R^2 = 0.2$ ;  $p < 0.006$ ; beta = 0.41) is the best predictor of trunk control recovery after intensive conventional neurorehabilitation treatment. Hence, clinical outcome measures, combined with trunk kinematics, can inform assessments and the understanding of trunk recovery.

Furthermore, to ensure appropriate intervention strategies, clinicians must be able to detect compensatory mechanisms. Trunk kinematics have been reported to be important in distinguishing between the use of compensatory movement patterns and true motor recovery during UL task performance (Alt Murphy et al., 2015, Demers and Levin, 2017, Kwakkel et al., 2017). A cross-sectional study showed that trunk displacement was strongly correlated ( $r_s = -0.64$ ;  $p = 0.44$ ), with the total FMA-UL motor score when assessing reaching kinematics in stroke survivors and healthy adults during reach to a target at 90% of the arm length (Valdés et al., 2017). However, most of the studies used expensive and space-consuming optoelectronic measurement systems to measure the trunk kinematics, and as mentioned before, this means they are difficult to use in clinical settings (Cuesta-Vargas et al., 2010).

The first stage of the present thesis investigated an instrumented version of the clinical TIS (Chapter 4). The results demonstrate moderate validity and good-to-excellent test–retest reliability for most of the iTIS parameters measured. Additionally, the use of the iTIS gave more informative data about trunk impairment (such as the percentage of symmetry between both sides during trunk rotation) compared with the use of the cTIS alone. However, the iTIS was unable to detect compensatory movements by the ULs and LLs during task performance, suggesting the need to use additional sensors in future studies on the ULs and/or LLs.

The second stage investigated trunk movement during performance of the SWMFT. It assessed the validity, interrater and intrarater reliability of the Valedo<sup>®</sup> system in measuring trunk movement during performance of the SWMFT among chronic stroke survivors and age-matched healthy participants (Chapter 5). The results demonstrate that the trunk ROM parameters, measured by the Valedo<sup>®</sup> sensors during the SWMFT performance, were able to distinguish between the impaired (stroke) and unimpaired (healthy) groups and between the affected and unaffected ULs within the stroke group, suggesting the Valedo<sup>®</sup> sensors could be a valid measure of trunk ROM. Additionally, the results show an acceptable level of reliability for the Valedo<sup>®</sup> system to be used to measure trunk ROM in the stroke and healthy groups, with good-to-excellent interrater and intrarater reliability for the majority of the parameters. These findings support (Wu et al., 2014) view that using the Valedo<sup>®</sup> system to measure trunk kinematics during UL task performance may be a more useful method to measure trunk compensation in clinical settings in terms of cost and practicality compared to other systems such as Vicon.

This PhD study represents the first step in developing an integrated outcome measure which combines a standardised validated clinical measure with a quantitative movement analysis that is capable of assessing the trunk post stroke. Clinicians may benefit from using the Valedo<sup>®</sup> system to bridge the gap between laboratory-based quantitative objective measures of trunk movement and the standardised, but more, subjective rating measures of trunk impairment and UL function. Using the Valedo<sup>®</sup> system to measure trunk kinematics in clinical settings could be helpful for therapists to monitor the small changes in movement, detecting compensatory trunk movement during UL tasks and, thereby, helping to amend the treatment plan for better outcomes. Measuring pelvic and trunk ROM could help therapists to amend intervention plans and focus on specific trunk exercises required to improve trunk control. In addition, detecting compensatory movements when doing UL tasks could be beneficial for distinguishing between true recovery of UL function and compensation.

However, several points need to be considered before recommending the use of the Valedo® system in clinical settings. The iTIS cannot replace the gold standard TIS because the current sensor placement along the trunk cannot identify the compensatory movements exerted by the ULs and/or LLs during the performance of TIS tasks (Section 4.10). Additionally, the current process of using the Valedo® system to measure trunk kinematics is not ready for clinical setting implementation. To use the data exported from the Valedo® system, the data need to be processed by MATLAB for exporting the required parameters (e.g. maximum trunk lateral flexion movement). Therefore, a specific programmed software must be designed for clinical settings to enable direct extraction of the parameters without the need for MATLAB data processing.

Additionally, future studies could face some challenges when using the Valedo® system. A possible source of error in rater reliability may include differences in identifying bony landmarks during sensor placement (Schless et al., 2015). Therefore, standardisation and training should be considered to ensure the reliability when different raters perform the measurement.

The Valedo® system has previously been shown to be valid and reliable in measuring trunk ROM in healthy adults when compared to a gold standard Vicon (Bauer et al., 2015). However, the current study did not measure the validity of using the Valedo® system in measuring trunk ROM in a stroke population against a gold-standard optoelectronic system such as Vicon because of the resource limitations of this PhD study.

In addition, the responsiveness of the iTIS developed in the first stage and trunk ROM parameters during SWMFT developed in the second stage was not measured. Responsiveness means the ability of an instrument to detect a meaningful or clinically important change (Portney and Watkins, 2013). Responsiveness was planned to be evaluated in the third stage as the iTIS and trunk ROM parameters during SWMFT were used as outcome measures to detect changes due to the trunk exercise intervention. This is was not possible, however, because the results from inferential statistics that are used as indicators of responsiveness (e.g. paired t-test and ANOVA statistical methods) would have been adversely affected by the small sample size (Portney and Watkins, 2013).

The Valedo® system is simpler in terms of data output and more affordable than other sensor systems previously reported in the literature to measure trunk movement (Bourke et al., 2008, Plamondon et al., 2007, Wong and Wong, 2008, Brice et al., 2018, Dahl et al., 2020). All the previous

sensors are body-worn IMU systems developed specifically to measure trunk movement. The common disadvantage of those sensor systems is that data from these devices were exported as signals which required an expert to read and signal processing to be able to interpret the data. Although the Valedo® sensors require an expert in MATLAB to extract the parameters, the data transmitted from the sensors to the computer via Bluetooth as Excel sheets include trunk movement in all three planes (sagittal, frontal, and transverse), which were easy to read. Additionally, the sensor used in (Wong and Wong, 2008) study cannot be implemented in most clinical settings, as it requires a 3D motion system with six cameras to be able to detect the 3D coordinates of the reflective markers. Further, the system used in Brice et al.'s (2018) and Dahl et al.'s (2020) studies require infrared cameras (17 cameras used in Dahl et al.'s (2020) study, while Brice et al. (2018) did not mention the number of cameras) and retroreflective markers positioned over anatomical landmarks to be able to capture movement. The use of infrared cameras requires a large installation space, which makes this technology infeasible for clinical setting usage. In addition, the sensor used in the same study had uni-axial gyroscopes, while the Valedo® system contains tri-axillar gyroscopes, which can measure rotation around three axes: x, y, and z (Wong and Wong, 2008). A further limitation of the aforementioned research is that only one sensor was used at the cervical level, which would have limited the measurement of movement from the lower trunk (pelvic) (Bourke et al., 2008). In terms of affordability, the Valedo® system comprises three sensors and includes two custom software (one for trunk ROM measurement and the other for trunk training). Valedo video games system (including both assessment and intervention software's) could cost around \$5,000 or less (still not available commercially), while other sensors cost \$1,500 per sensor (without software) (Plamondon et al., 2007). The needs of software development in (Plamondon et al., 2007) study made this technology difficult to transfer to clinical settings.

In summary, the Valedo® system is an affordable tool demonstrating moderate validity and good-to-excellent test-retest reliability for measuring trunk movement post stroke. The Valedo® has the potential to be used as a trunk assessment tool in research labs or clinical settings, providing additional data which can be used to inform treatment decisions and monitor patients' progress and outcomes. There are limitations to using the Valedo® system in both research and clinical settings, such as inability of the iTIS to detect UL/LL compensatory movements; however, it also has benefits over previous systems.

## 7.2 Using Valedo® video games as an intervention tool

The third stage of this PhD study was a feasibility study to answer the following question: Is the use of the Valedo® system for trunk training feasible in people with chronic stroke? This stage investigated the acceptability and implementation of Valedo® video games to deliver post stroke trunk exercise (Chapter 6). In addition, trunk impairment, trunk muscle thickness, balance, UL function, and UL and LL impairment were measured to observe any post intervention changes. The results show that there was a high degree of acceptability of the Valedo® video games for delivering trunk exercises; the participants enjoyed practising trunk exercises using video games and reported both physical and psychological improvement post intervention. The quantitative results also demonstrate that 18 sessions of trunk exercise using Valedo® video games has the potential to improve post stroke trunk impairment, balance and UL function; however, the study was not powered to detect this. Some measures showed more positive change than others, such as the TIS, which showed an improvement in total score more than MDC (0.67) for all participants. The Berg Balance Scale (BBS) and SWMFT demonstrated more positive change than MDC in nine and seven participants, respectively. With MCID established only for the SWMFT (MCID for FAS = 0.2 to 0.4 points, time = 1.5 to 2 seconds), four participants showed improvement beyond MCID in SWMFT-FAS, while seven participants showed improvement in SWMFT-time beyond MCID (Lin et al., 2009).

The implementation of this type of intervention was found to be safe, with no major adverse events reported; however, some aspects related to game design and the difficulty level of the task need to be considered for clinical use to avoid frustration. Three participants (P1, P4, and P8) rated the frustration item in PIADS negatively, as they felt frustrated due to inability to achieve the goals in some games as a result of either game design or task difficulty. There are several other issues which need to be considered for future research and clinical implementation, including the recruitment process, sample size calculation for future RCT, inclusion criteria, selection of outcome measures, intervention content and duration, and Valedo® system features.

### 1. Recruitment process

One of the major challenges of this study was the recruitment process of people with chronic stroke. It took about nine months to recruit six participants from Southampton, UK (using the Health Science school database and recruiting through community stroke clubs), with an additional three months to recruit six further participants in Riyadh, Saudi Arabia. The differences in recruitment duration may have been influenced by population levels at the recruitment locations. Recent figures report the Southampton population as 259,833, while 5,236,901 people live in

Riyadh. This could account for differences in the prevalence of stroke and, therefore, the number of people eligible to participate in the study (Stats, 2015, Council, 2019). Furthermore, the recruitment in Riyadh took place in three clinical sites, using their database to identify interested participants. One of those sites was Prince Sultan Bin Abdulaziz Humanitarian City, which is one of the largest rehabilitation centres in the Middle East. This is in line with the (Bower et al., 2009) narrative literature review, which outlined three core areas of improving recruitment and retention: infrastructure (e.g. networks and resources), professional and public engagement with research and methodological innovation (the development of an evidence base around effective methods of recruitment). Using the networks to market research participation to possible participants could facilitate recruitment (Bower et al., 2009).

Another factor which might have contributed to the slow rate of recruitment in Southampton was that many people on the database and local stroke clubs have already participated in rehabilitation research in the University of Southampton, which could have led them to be less motivated to take part in rehab. In contrast, clinical stroke rehabilitation research in Riyadh is rare (the author was the first academic who undertook clinically based research on stroke subjects at her workplace). Further, recruiting participants from private clinics is more likely to result in finding people who have a shorter post-stroke time and are still interested in rehabilitation compared to those who are many years post-stroke and have been involved in an exhaustive list of rehabilitation.

## 2. Sample size calculation for a future RCT

One of the objectives of feasibility studies is to estimate the sample size for a future large scale RCT based on one of the potential primary outcome measures. The trunk impairment scale (TIS) was selected as a primary outcome measure for measuring trunk impairment in a future RCT because the TIS is a reliable clinical measure to measure trunk impairment and the data collected in this study showed the highest positive change compared to other clinical outcomes used in this study. To the author's knowledge, the minimal clinical important difference (MCID) for the TIS has not been previously published. Therefore, *Cohen's d* effect size was used to calculate the number needed to treat when a minimum of 10% change was chosen as a clinically significant change (Machin et al., 2008). Using the pre and post measurements of this feasibility study, the standardised effect size estimated is  $d = 0.74$ . Therefore, to calculate a sample size required to detect a 10% increase in TIS (post- intervention compared to pre-intervention) with 90% power and significance level of  $p = .05$ , the effect size of 0.74 will be used. The sample calculation using G\*power (Appendix 45) showed that in order to find significant differences between groups, 40 participants are required in each group with a total sample size of 80 participants.

There was 17% drop out of the enrolled participants on this study. Therefore, it is suggested that an additional 14 participants (7 in each group) should be considered in a future RCT to allow for possible dropouts. Thus, a total of 94 participants, with 47 in each group should be considered.

### **3. Inclusion criteria**

The inclusion criteria for this study were amended according to recommendations by examiners in the Confirmation Viva (June 2018). Initially, the inclusion criteria included a specific UL ability (mild-to-moderate impaired arm function) to be able to gather sufficient data when measuring trunk kinematics during performance of the SWMFT. This criterion led to the exclusion of some interested participants. The author decided to amend the ethics – removing this criterion, as it did not affect the study's main aim of testing the feasibility of doing trunk exercise using video games. This led to an additional three participants taking part in the study.

In addition, key inclusion criteria were that the participant could not undertake any form of rehabilitation during the study period and that they had to be able to complete the 18 interventions and 2 assessment sessions. This criterion substantially affected the eligibility rate in the UK (Figure 6-5). About 30% of potential participants in Southampton did not join the study, as they were excluded after telephone screening due to currently receiving neurorehabilitation or due to inability to complete all the sessions. These criteria did not affect the eligibility rate in Riyadh – which could be due to the scarcity of rehabilitation research, as mentioned previously. The criterion of completion of all planned sessions was chosen due to limited financial resources (used to help in transportation reimbursement) and time to do this PhD study, as incomplete post intervention assessments could lead to insufficient data to answer the main research question of this study.

### **4. Selection of outcome measures**

The main outcome measure used to investigate the psychological impact of using this type of intervention was PIADS. The results of this study showed positive psychosocial experiences in most participants post intervention. However, aspects related to enjoyment and motivation were not included in PIADS. Quantitatively assessing enjoyment and motivation and how it is correlated to intervention effectiveness has been recommended by a recent scoping review (Rohrbach et al., 2019).

In clinical outcome measures, LL and UL impairment measured by FMA did not show any potential post intervention improvement. These findings might have occurred because the selected outcome measure did not reflect the effect of the intervention. In addition, most of the participants enrolled in the study had low mobility function levels in LLs (80%) and severely impaired ULs (60%) (Table 6-6). Therefore, different measures for UL and LL impairment might be considered for severely impaired ULs and LLs.

## 5. Intervention content and duration

The Valedo® video games were designed to be played by people with low back pain; therefore, several points need to be considered when using these games for stroke rehabilitation. The main issue raised in the qualitative data set was the level of challenge, either physical or psychological, in the Brick Breaker, Fruit, Colours and Clock games. Each game will be discussed separately based on the participants' feedback and task requirements.

### Brick Breaker game

This game requires trunk rotation and a fast reaction time to be able to visually follow the ball moving on the screen and avoid losing it. The ball movement is fast and multidirectional (right, left, up and down), which requires a high level of concentration and fast reaction times to follow it. Some of the participants found it difficult to follow the ball and became frustrated when they kept losing it. In addition, people with complete arm paralysis found it difficult physically because they had to support their paralysed arm and, at the same time, rotate their trunk quickly according to the ball direction. The heaviness of the paralysed limb made it more difficult to play, especially while standing.

### Fruit game

This game requires a lateral pelvic tilt movement while keeping the upper trunk still to put the fruit in its respective basket. The upper trunk is represented by a cage, while a slide represents the pelvis. The participants needed to coordinate the movement between the upper trunk and the pelvis to be able to put the fruit in the basket but reported the movement of the cage and slide as quite confusing. Inability to coordinate this movement led to losing the fruit and, therefore, points. Furthermore, as the fruits appeared randomly from the right and the left, the participants were confused as to which side of the pelvis they needed to tilt.

### Colours game

This game requires a combined trunk and pelvic movements to roll a ball to a circle of the same colour (e.g. orange ball to orange circle) and avoid losing the ball. The colours of the ball changed randomly when the movement to the circle had been completed, and the participants were required to do the movement in the direction of the colour until the ball touched the corresponding circle. Sometimes, the participants moved too fast, which led to them losing the ball. Further, people with low dynamic TIS found it difficult to quickly react and do the exercise in the other direction when the colour changed.

#### Clock game

This game requires using lateral trunk flexion to hit a light on the right and left sides of a clock. The participants reported this game as boring; the only change when increasing the level of challenge was the ROM (the participants were required to move in a more lateral trunk flexion ROM). The light shone on the right and left sides alternatively, so participants reported it as predictable and monotonous. This finding suggests that adding video games to exercise is not sufficient to overcome the boring sense when doing exercise, but it needs to engage participants by giving a variety of appropriate challenges. This is supported by a previous study which studied the opinions and expectations of stroke patients toward using video games in rehabilitation (Hung et al., 2016b). More than half of the 17 participants (n = 9) reported that they found it 'easy to get bored' when answering a survey after video game rehabilitation experiences. The boredom resulted from a limited diversity of games.

Therefore, Valedo's game developers need to consider designing games with more adjustable features that allow adjusting the speed of the required movement, the randomness of fruits and the predictability of the games. Adjusting the speed and the game's predictability might enhance participation and engagement with the exercise.

Interestingly, some participants reported lateral muscle tightness in early sessions after playing this game (Section 6.7.4). This suggests that the developed flow chart for game choice and plan according to the TIS (Appendix 31) is not sufficient and that further aspects, such as muscle flexibility, need to be considered.

#### 6. Valedo® system features

The Valedo® video game system has several features that make it more feasible for implementation in clinical setting compared to other video game systems (such as Nintendo Wii and Microsoft Kinect). These features include no large space required for installation, suitability for different levels

of disability, the provision of different levels of difficulty for each game and a meaningful play experience by giving a valuable feedback. Each feature is discussed below and compared to those of other systems mentioned in the literature.

Unlike other systems used in the literature to deliver trunk exercise to people with stroke, the Valedo<sup>®</sup> system does not require a large installation space (Kim et al., 2018, Jung et al., 2020). The system used in recent studies to deliver post stroke trunk exercise are the Space Balance 3D system and the Trunk Stability Rehabilitation Robot Balance Trainer – which require a large installation space, making them difficult for clinical implementation. However, only a small space that fits laptops and TV screens, as shown in Figure 6-2, was used to set up the Valedo<sup>®</sup> system.

In addition, the use of the Valedo<sup>®</sup> system to deliver trunk exercise in people with chronic stroke did not require a specific skill or high balance ability. This is clearly shown in the included participants' characteristics (Table 6-6) that demonstrate different levels of disability, including people with severe UL and LL impairment who are in wheelchairs, as well as those who have mild UL and LL impairment and walk independently. The three straps worn around the trunk to hold the Valedo<sup>®</sup> sensors (Figure 6-2) made it easy for people with severe UL impairment to be involved in the study, as Valedo<sup>®</sup> does not require a specific UL ability to handle a controller such as the Wii system (Anderson et al., 2015, Chao et al., 2015, Lange et al., 2010). Further, recent RCTs that have studied the effect of driving-based interactive video games on post stroke trunk control excluded those who could not grasp a handle (Lee et al., 2018b). Moreover, unlike the Wii balance board that requires a high initial level of balance to be able to stand on the board, the Valedo<sup>®</sup> system allows doing exercise either while sitting or while standing, according to the participant's ability (Anderson et al., 2015, Chao et al., 2015, Lange et al., 2010). Recent RCTs that have investigated the effect of 3D video game trunk training exercise on trunk control and balance ability in subacute stroke have required the ability to stand for more than 30 min with a walking aid to be able to participate in the study and practice the exercises, as reported in (Jung et al., 2020). In addition, the smartphone-based visual feedback trunk control training (SPVFTCT) system used in (Shin, 2020) study requires stroke participants to have a high balance ability that allows them to sit and balance on a balance board.

Challenge and meaningful play are two principles of game design identified to be particularly relevant to rehabilitation (Burke et al., 2009, Shapi'i et al., 2015). Valedo<sup>®</sup> video games have three different levels of difficulty for each game: easy, medium and hard levels. The difficulty level changes in different ways, including reducing visual cues; making the task more cognitively

demanding, thereby requiring problem solving; and increasing trunk ROM required to achieve the task. This feature could help in exercise engagement and boredom avoidance throughout a session (Burke et al., 2009, Shapi'i et al., 2015). The diversity in game challenge was seen as an important factor for maintaining the 'flow' of a therapy session (Borghese et al., 2013, Swanson and Whittinghill, 2015). However, the selection of the level of challenge for each game was complicated by the need for clinical judgement with respect to its utility for the participants. Compared to other studies, only one study that used video games for post stroke trunk rehabilitation described how to progress through the difficulty level of each game (Jung et al., 2020). The difficulty level of each exercise programme in (Jung et al., 2020) study comprised 1–10 steps and progressed from one step to another when the exercise score exceeded 75%. However, there was no detailed description on how to reach the 75% exercise score. Therefore, recommendations for game design and selection of the level of challenge and how the patient can progress to the next challenge level are reported in Section 7.5.

In addition, it has been suggested that the goal of a successful game design is the creation of meaningful play (Burke et al., 2009). Meaningful play emerges from interactions between a player's actions and the system's outcome, and this can be achieved through feedback (Shapi'i et al., 2015). The feedback is given by the Valedo® system either during play to show how the game responds to the participant's action or by the end of the game to inform the participants about their overall performance (out of five stars). The feedback is given in different forms, including audiovisual feedback given during the game to inform the participant that they did well and collect/lose points according to their performance. By the end of each game, the participant is informed about overall performance by a numerical score of the total points collected for each game. This feedback might increase the participant's motivation and enjoyment and generate a desire to complete particular tasks to attain a certain goal (Shapi'i et al., 2015). As discussed in 6.9.3, participants in the current PhD study perceived this feedback to be informative and motivated. None of the five studies that used video games for post stroke trunk rehabilitation investigated the influence of feedback on the participant's performance (Jung et al., 2020, Kim et al., 2018, Lee and Bae, 2020, Shin, 2020, Shin and Song, 2016b).

## **7.3 Strengths and limitations**

### **1- Study strengths**

- The stage 1 and 2 studies represent a first step in demonstrating that the Valedo® system is a portable, cost-effective kinematic assessment tool (Stages 1 and 2, Chapter 4 and Chapter

5) and has the potential to bridge objective lab measurements and clinical measures. This would give clinicians more objective data on which to base their clinical choices of treatments.

- The comparison between stroke and aged-matched healthy adults in the first and second stages of this PhD study have given insight into the differences in trunk function between people with stroke and those who are healthy.
- The feasibility study (Chapter 6) performed in two countries (Riyadh, KSA, and Southampton, UK) will inform future studies on the practicality of doing this type of intervention in those countries in terms of the ethics application and recruitment process and rate.
- Unlike other types of VR systems mentioned in the literature which require high UL or balance abilities, the use of Valedo<sup>®</sup> video games as an intervention tool in this study included people with mild-to-moderate disabilities (even wheel chair users participated in the feasibility study).
- The use of a mixed methods study design in the third stage provides a greater insight than the use of a single method. The mixed methods design gave a deeper understanding of the feasibility of using the video game–based intervention in terms of explaining the factors that could affect acceptability and implementation (e.g. the qualitative data set explained the factors that could affect the level of adherence). The design also increased the credibility of the findings when the quantitative and qualitative data sets agreed on the same findings (e.g. agreement between quantitative and qualitative data on balance improvement).

## **2- Study limitations**

- Recruiting chronic stroke participants with low TIS scores in the first stage of this PhD study was challenging (only one participant with poor trunk control was recruited). This affected the validity of the iTIS in distinguishing between the stroke participants who scored 0 and those who scored 1 in the dynamic subscale tasks (Chapter 4) and limits the ability to draw general conclusions from the findings.
- There was a lack of kinematic data from the ULs and LLs due to the sensor placement used in the first stage – which meant that it was not possible to use the iTIS to replace the clinical TIS, affecting both the validity and reliability of this study.
- The trunk movements measured in the first and second stages of this PhD study were not compared against a gold standard motion system such as Vicon due to the limited time resources available for this PhD study.
- The interviews in the third study were not conducted by an independent interviewer but by the lead researcher (NA) due to limited project financial resources. This may lead to

response bias by influencing the responses of participants (e.g. participants might respond positively to avoid upsetting researcher); however, the researcher did advise participants to express their true feelings and reiterated that negative responses would not affect the researcher or results of this study.

- The translation of Arabic interviews to English might have affected the trustworthiness of the data. However, accredited translators were used to translate the interviews by meaning. Additionally, a group of four bilingual (Arabic-English) speakers validated the translated transcripts to ensure that the translation transcripts reflected the actual data.
- The low sample size of 10 participants and the absence of a control group in the third stage feasibility study limited the ability to assess the effectiveness of the Valedo® video games or conduct any other correlational analysis (i.e. correlation between UL function and trunk impairment post intervention).
- The Hawthorne effect might confound the observed improvements in the clinical outcome measures in the third stage, and it has been suggested in the literature to use a control group to minimise it (McCarney et al., 2007). However, the option of having a control arm of this study was not possible due to the limited resources (time and finance) for this study.
- The lead researcher (NA) conducted all measurements in this PhD study (due to limited study resources), which may have resulted in an observer bias. However, a standardisation in the administration of assessments were taken into consideration throughout all stages.

## **7.4 Novel contributions**

This body of work contains several novel contributions. To the author's knowledge, the systematic review and meta-analysis conducted in the development of this PhD study is the first to investigate the effect of trunk exercise on both trunk impairment and UL function. The review found no study investigating the effect of trunk exercise on the ULs, but a meta-analysis was conducted to study the effect of trunk exercise on trunk impairment. In addition, the use of the Valedo® sensors as an assessment and intervention tool for assessing and treating trunk impairment in people with chronic stroke in the three stages of this PhD study added to the body of knowledge in several areas. The following findings are the key original contributions of this PhD study:

1. According to a meta-analysis of 17 RCTs, trunk exercises have a large, statistically significant effect on trunk performance, as measured by the TIS in people with stroke. More specifically, the meta-analysis of the TIS dynamic and coordination subscales showed a statistically significant large effect size, indicating high

improvement, while static subscale showed a medium nonstatistically significant improvement.

2. Trunk exercise is more effective in the acute stroke stage; the meta-analysis showed a very large statistically significant effect, while a medium statistically significant effect was found in the subacute and chronic stroke stages. Improvement in the TIS was also shown in the third stage of this PhD study (feasibility study) after 18 sessions of video game trunk exercises in people with chronic stroke.
3. The iTIS showed an acceptable level of validity and reliability. The use of the iTIS, combined with the clinical TIS, can give more information about the quality of trunk movement than can be observed by sight, such as the percentage of symmetry in pelvic rotation during performance of the coordination subscale.
4. The use of the Valedo<sup>®</sup> system to measure trunk movement during SWMFT demonstrated a high level of validity (distinguishing between stroke and healthy participants and between affected and less-affected ULs in the stroke group) and reliability. The stroke survivors used a higher trunk ROM in all planes of movement during performance of the SWMFT compared to age-matched healthy adults.
5. The feasibility study is one of the first studies that informs the literature gap concerning using video games to deliver trunk exercises for people with chronic stroke. Using this type of intervention is acceptable by people with chronic stroke with mild-to-moderate disabilities. The acceptability was associated with enjoyment, perceived physical and psychological improvement and the novelty of this device in giving motivational and informative feedback.
6. Implementation of this type of intervention is feasible; however, special consideration should be given regarding the physical and cognitive abilities of people with chronic stroke. Further, the use of Valedo<sup>®</sup> as an intervention tool to deliver trunk exercise is safe; no major adverse events were reported.
7. The third study also provided proof of concept to the literature regarding possible improvements in trunk impairment, balance and UL function after 18 sessions of trunk exercise using video games.

## 7.5 Recommendations

The limitations reported impact on the level of recommendations that can be made. Implications and recommendations from this study for future research and clinical practice are presented as

follows:

### **7.5.1 Implications and recommendations for future studies**

- A study to further establish the validity of the iTIS (in terms of distinguishing between people who scored 0 and 1 on the dynamic subscale) is required. This will mean recruiting people with stroke with different levels of trunk control (poor, fair and good). In addition, the Valedo® system requires further development to allow placing two sensors on the ULs and LLs to detect compensatory movements, thereby improving the validity of the iTIS.
- The Valedo® system has already been compared with gold standard optoelectronic measurement systems (Vicon) in healthy adults; however, as stroke survivors move differently, a comparison using a stroke population is warranted to ensure the validity of Valedo® in measuring trunk ROM.
- To increase the generalisability of the results, a feasibility study using a blinded assessor and an external interviewer is required to assess the feasibility of using Valedo® video games to deliver trunk exercises to people at different stages of stroke, including acute, subacute and chronic stroke.
- To conduct a similar study in the UK in the future, recruitment through the NHS (for acute/subacute) and other physiotherapy clinics might need to be considered to increase the recruitment rate. A mobile trial (national & multicentre) including different cities would also be recommended to obtain a larger sample; however, this option requires a larger budget.
- A longer-term feasibility study that comprises more than 18 sessions and explores using video games to deliver a trunk exercise intervention is required to ascertain if stroke survivors will continue to find the games enjoyable and be motivated over a longer time period.
- In the future, a nested pilot study within a larger-scale study with more flexible criteria would inform recruitment rates and adherence levels. Giving participants the flexibility to attend the number of sessions they prefer to attend could be beneficial for increasing recruitment rates and informing the number of sessions that stroke survivors could adhere to.
- A nested pilot RCT with large sample size is needed to assess the effectiveness of using video game-based trunk exercise on balance, trunk impairment, trunk muscle thickness and UL function. Using interventional analysis to study any correlation between trunk impairment,

trunk kinematics and UL function would inform the relationship between the trunk and UL function and provide data for responsiveness of the iTIS.

- Investigating the changes in ADL and functional independency using clinical measures could be useful in future studies to inform clinical practice.
- Future studies that plan to use the same type of intervention (the Valedo® software) in stroke rehabilitation need to consider testing participants' cognitive abilities and trunk muscle flexibility to efficiently design the intervention programme according to individual needs and abilities. This is important to avoid participant frustration.
- Designing games with more adjustable characteristics (e.g. changing the speed of movement required, the number of cognitive distractions and the ROM required to do the tasks) is recommended for more tailored intervention programmes using video game-based interventions.
- Developing a table that can map the challenge of the game against participants' physical and cognitive abilities to have a planned progression would be useful for therapists to plan interventions that meet patient needs. This can be done in two ways: either by writing an algorithm with specific clinical criteria to give the therapist suggestions for suitable games or by creating a database by the system developers to collect information from clinicians about the clinical measures (physical and cognitive) for their patients and the games that suit them. Then data mining and artificial intelligence should be used to develop recommendations for the therapist.

### **7.5.2 Implications and recommendations for clinical practice**

- The validity and reliability study of the iTIS has demonstrated that the Valedo® system is an affordable assessment tool demonstrating moderate validity and good-to-excellent test-retest reliability. As the validity of the iTIS is still lacking due to the inability to detect compensatory UL and LL movements, therapists should consider the using the iTIS as an adjunct to the clinical TIS and as a means of gathering more information about trunk movement quality when assessing trunk impairment. This additional information may allow changes to be seen earlier, validating the use of a particular treatment option.
- The results from the second stage suggest that therapists could consider using the Valedo® system as a valid and reliable tool to detect trunk compensatory movements during UL tasks, which could be useful when designing rehabilitation for people with chronic stroke.
- Physiotherapists should consider treatment options such as using video games when designing a trunk rehabilitation (this is more common for the ULs and LLs but rarely in the

trunk) plan for people with chronic stroke. In this study, video game–based trunk exercises were shown to be acceptable for people with stroke.

- Different points need to be considered before implementing video game–based interventions for people with chronic stroke. Assessing cognitive and physical abilities and appropriately tailoring the exercise difficulty is important to ensure proper implementation of this type of intervention.

## Chapter 8 Final Conclusions

This chapter presents the conclusion for each stage of this PhD study, highlighting the original contributions to the body of knowledge in post stroke trunk assessment and rehabilitation.

### 8.1 Study 1: Validity and reliability of using the Valedo® system to measure trunk control

- 1) A moderate relationship was observed between the iTIS parameters and the clinical scores of TIS, indicating moderate concurrent validity of the iTIS using the Valedo® system.
- 2) The iTIS dynamic subscale parameters are able to distinguish between both participants with and without stroke and those stroke participants with and without trunk impairment.
- 3) The iTIS parameters demonstrated good-to-excellent intrarater and interrater reliability in both people with chronic stroke and aged-matched healthy groups.
- 4) Using the iTIS provides additional information about the quality of trunk movement that may not be observed clinically; however, it cannot replace the clinical TIS because the current setting of sensor placements is unable to detect the compensatory movements exerted by ULs and LLs during TIS performance. Further studies with powered sample sizes, different trunk control levels and improved iTIS methodology by using additional sensors on the ULs and LLs to detect compensatory movements are required.

### 8.2 Study 2: Validity and reliability of using the Valedo® system to measure trunk ROM during upper limb functional tasks

- 1) The validity of the Valedo® system in measuring trunk ROM during UL task performance is supported by its ability to distinguish between people with chronic stroke and healthy participants through measuring trunk kinematics (trunk flexion, trunk lateral flexion and trunk axial rotation) during performance of SWMFT tasks.
- 2) The Valedo® system is also valid in distinguishing between the affected UL and the less-affected UL within the stroke group.
- 3) People with chronic stroke employed more trunk movements (trunk flexion, trunk lateral flexion and trunk axial rotation) than aged-matched healthy controls during performance of eight SWMFT tasks.

- 4) Trunk ROM parameters measured during the SWMFT demonstrated good-to-excellent interrater and intrarater reliability, indicating an acceptable level of reliability for the Valedo® system to be used to measure trunk ROM in people with chronic stroke and healthy adults.
- 5) The use of the Valedo® system to measure trunk movement during SWMFT performance provides additional information by measuring small changes in trunk ROM that may not be observed clinically. In addition, using the Valedo® as an assessment tool in future studies to detect post stroke trunk compensatory movements might be helpful in designing rehabilitation plans.

### **8.3 Study 3: Feasibility of using Valedo® video games to deliver trunk exercise in a chronic stroke population**

1. The use of Valedo® video games to deliver 18 sessions (45 minutes/session) of trunk exercise to people with chronic stroke is highly acceptable, as determined by positive PIADS scoring, a high participation level and a high adherence rate.
2. The participants' interviews demonstrate that the acceptability of Valedo® video game trunk exercises was linked with the enjoyment when exercising and perceived physical and psychological positive impact resulted from the intervention.
3. Implementation of Valedo® video game trunk exercises was safe, as no major adverse events were reported. Minimal resultant symptoms (including fatigue, lateral trunk muscle tightness and slight dizziness) could arise during or after a session.
4. The audio-visual feedback given during and after each session played an important role in informs participants about their performance and motivated them to exercise.
5. Valedo® video games could produce a sort of cognitive and physical challenge for some chronic stroke survivors, suggesting a consideration for cognitive and physical abilities of patients when implementing this type of intervention.
6. Adherence to the 18 sessions of intervention was feasible but was affected by several factors, including independency in driving, a convenient time when planning the sessions and availability of a supportive carer.
7. Eighteen sessions of trunk exercise using Valedo® video games had the potential to improve trunk impairment, balance and UL function in people with chronic stroke. In contrast, the intervention effected no major change in UL and LL impairment.
8. There was a reduction seen in trunk movements (including trunk flexion, lateral flexion and axial rotation) during performance of the SWMFT after 18 sessions of trunk

exercise using Valedo® video games, but there was a great variation overall, as there was no common pattern shown by all participants.

9. People with chronic stroke who have fair trunk control (total TIS between 11 to 19) and a low balance ability (BBS  $\leq$  27) improved better compared to those with high trunk control and balance ability (BBS  $\geq$  45).
10. Limited data showed that trunk muscle thickness of the hemiplegic side (including TrA and EO muscles) might increase after 18 sessions of trunk exercise using Valedo® video games.
11. The sample required for an RCT with 90% power to identify the true effect (10% change) of Valedo® video game trunk exercise on trunk performance measured by the TIS is at least 80 participants with 40 participants in each group. To allow for a similar level of drop out (17%), a total of 94 participants, with 47 in each group should be considered.

**END OF THESIS**

# Appendix 1 Ethics approval letter from Ethics and Research Governance Online system (ERGO), University of Southampton (Study 1) - (Ethics number 24605)

**From:** [ERGO](#)  
**To:** [Alhwoaimel.N.](#)  
**Subject:** Research Governance Feedback on your Ethics Submission (Ethics ID:24605)  
**Date:** 31 January 2017 15:14:27

---

Submission Number 24605:  
Submission Title Development and validation of a reliable instrumented version of Trunk Impairment Scale:  
The Research Governance Office has reviewed and approved your submission

You can begin your research unless you are still awaiting specific Health and Safety approval (e.g. for a Genetic or Biological Materials Risk Assessment) or external ethics review (e.g. NRES). The following comments have been made:

"

**Dear Norah, please ensure all your study documents including protocol, info sheets, consent forms and posters should contain a version number and date before using them.**

This is to confirm that the work detailed in your protocol and Ethics Application will be covered by the University of Southampton insurance programme. As Chief or Principal Investigator, you are responsible for the conduct of the study and you are expected to:

1. Ensure the study is conducted as described in the protocol/study outline approved by this office
2. Advise this office of any amendment/change to the protocol, methodology, study documents, research team, participant numbers or start/end date of the study
3. Report to this office as soon as possible any concern, complaint or adverse event arising from the study

Failure to do any of the above may invalidate your ethics approval and therefore the insurance agreement, affect funding and/or sponsorship of your study; your study may need to be suspended and disciplinary proceedings may ensue.

On receipt of this letter you may commence your research but please be aware other approvals may be required by the host organisation if your research takes place outside the University. It is your responsibility to check with the host organisation and obtain the appropriate approvals before recruitment is underway in that location.

May I take this opportunity to wish you every success for your research

Submission ID : 24605  
Submission Name: Development and validation of a reliable instrumented version of Trunk Impairment Scale  
Date : 31 Jan 2017  
Created by : Norah Alhwoaimel

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## Appendix 2 Ethics approval letter from Ethics and Research Governance Online system (ERGO), University of Southampton (Study 2) - (Ethics number 46744)

**From:** [ERGOTI](#)  
**To:** [Alhwoaimel N.](#)  
**Subject:** Approved by Faculty Ethics Committee - ERGO II 46744  
**Date:** 07 January 2019 14:22:16

Approved by Faculty Ethics Committee - ERGO II 46744



ERGO II – Ethics and Research Governance Online <https://www.ergo2.soton.ac.uk>

Submission ID: 46744  
Submission Title: Reliability of Valedo sensors to measure trunk range of movement, in healthy and chronic stroke individuals, during the SWMFT  
Submitter Name: Norah Alhwoaimel

Your submission has now been approved by the Faculty Ethics Committee. You can begin your research unless you are still awaiting any other reviews or conditions of your approval.

Comments:

- 

[Click here to view the submission](#)

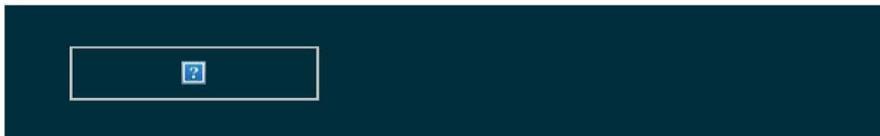
Tid: 23011\_Email\_to\_submitter\_\_\_Approval\_from\_Faculty\_Ethics\_committee\_\_cat\_B\_\_C\_\_Id: 103138  
N.Alhwoaimel@southampton.ac.uk coordinator

**Please do not reply to this message as it has been automatically generated by the system. This email address is not monitored.**

# Appendix 3 Ethics approval letter from Ethics and Research Governance Online system (ERGO), University of Southampton (Study 3) - (Ethics number 30748)

**From:** [ERGOII](#)  
**To:** [Alhwoaimel N.](#)  
**Subject:** Approved by Faculty Ethics Committee - ERGO II 30748.A3  
**Date:** 21 December 2018 10:48:39

Approved by Faculty Ethics Committee - ERGO II 30748.A3



ERGO II – Ethics and Research Governance Online <https://www.ergo2.soton.ac.uk>

Submission ID: 30748.A3  
Submission Title: Feasibility of Trunk Exercise Using Video Games in People with Stroke (Amendment 3)  
Submitter Name: Norah Alhwoaimel

Your submission has now been approved by the Faculty Ethics Committee. You can begin your research unless you are still awaiting any other reviews or conditions of your approval.

Comments:

- 

[Click here to view the submission](#)

Tid: 23011\_Email\_to\_submitter\_\_Approval\_from\_Faculty\_Ethics\_committee\_cat\_B\_\_C\_Id: 100838  
N.Alhwoaimel@southampton.ac.uk coordinator

Please do not reply to this message as it has been automatically generated by the system. This email address is not monitored.

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## Appendix 4 File Protection Log

Document	Date Taken For Use	Name, Signature	Date Returned	Name, Signature

## Appendix 5 Invitation letter for participant (Study 1)

Ethics Number: ~~FoHS~~-ETHICS: 24605

UNIVERSITY OF  
**Southampton**

Dear Sir / Madam

We would like to invite you to take part in a research study based at the University of Southampton. This study aims to develop a new test which can be used to help test sitting balance in people with stroke.

To do this we need the help of both people who have had a stroke and healthy people. Please note that this research is not testing a rehabilitation intervention but is helping to develop a test.

We have also sent an information sheet that explains in more detail what the study involves. Please take time to read the information sheet carefully. We are happy to answer any questions if anything you read is not clear or if you would like more information. Please find the contact details of the researchers at the end of this letter.

If you are interested in taking part in this study, please complete and return the reply slip, email or call us. We will ask you a few questions about your health to check if this project is suitable for you. Then, we will make an appointment at a convenient time and day for you to come in to the Faculty of Health Sciences, University of Southampton (Building 45)

Thank you for your consideration.

Yours faithfully,

**Dr Federico Ferrari**

Email : F.Ferrari@soton.ac.uk

**Norah Alhwoaimel**

Telephone : 02380595000 , Email : n.alhwoaimel@soton.ac.uk

**The address for both is:**

Faculty of Health Sciences (Building 45),

University of Southampton, Southampton SO17 1BJ

# Appendix 6 Participant Information Sheet (Study 1)

**Ethics number:** 24605  
Appendix B



## Participant Information Sheet

**Study Title:** Development and validation of a reliable instrumented version of the Trunk Impairment Scale

**Researchers:** We are a team of Physiotherapists, Movement Scientists, and Doctors who have a specialist interest in stroke rehabilitation. Our names are Dr Federico Ferrari, Norah Alhwoaimel, Dr Martin Warner, Dr Ruth Turk, Professor Jane Burridge, Professor Geert Verheyden and Dr Seng Kwee Wee. Federico is a Medical Doctor with four years' experience in neurological rehabilitation. Norah, Ruth, Jane, Geert and Seng Kwee are physical therapists and Martin is a movement scientist. Norah is studying for her PhD at the Faculty of Health Sciences.

**Please read this information carefully before deciding to take part in this research. If you are happy to participate you will be asked to sign a consent form.**

It is important for you to understand why the research is being carried out and what it will involve before you decide. Please take time to read the following information carefully and discuss it with friends, relatives, and your GP if you wish. If something is not clear, or you would like further information, please do not hesitate to contact me at the address below or by telephone using the number given at the end of this information sheet. Thank you for reading this.

[31/01/2017] [Version 2.0]

### **What is the research about?**

Many people have problems controlling their body after a stroke, particularly their trunk and arms, which can affect their ability to perform activities such as sitting upright, being able to balance, and using their arms. To help improve rehabilitation we need to use good tests to be able to measure improvements in people's movement.

To help us in testing people's trunk movement we can use a scale called the Trunk Impairment Scale (TIS). However, there are some problems with this scale. It takes time to complete the scale and the documentation, and different testers may score the same person differently. Our team is developing a solution to this.

The purpose of this study is to develop an instrumented TIS version (iTIS) using wearable sensors. The results of this study will make it easier and faster for therapists to test trunk movement in a clinical setting. As part of this we want to use sensors, but we have to check that they provide the right information, and that this information is the same between different sessions and different assessors.

We need both people who have had a stroke and healthy people to help us do this.

### **Why have I been chosen?**

We are looking for volunteers to take part in our study who have an interest in improving trunk movement for people who have had a stroke. You have been contacted to take part as you are either a volunteer on the user databases in the Faculty of Health Sciences, University of Southampton, or you have shown

interest in our research study. You may have had a stroke, or be healthy.

**Inclusion/Exclusion Criteria**

- You have been chosen to take part in this study as you are aged between 40 and 80 years, are able to understand what this research project involves, are able to give informed consent and are able to commit to attending two sessions within five days.
  
- You are able to understand and follow simple instructions (to cross one leg, to clap hands, to blow)
  
- You do not present any of the following conditions:
  - 1) Orthopaedic spine pathology or acute low back pain
  - 2) History of spontaneous fractures
  - 3) Uncontrolled epileptic seizures (loss of consciousness or uncontrolled rapid movements)
  - 4) Implanted ferromagnetic materials or active devices within the body (e.g. Pace Maker, acoustic devices)
  - 5) Skin disease or lesions in correspondence of: sternum, L1, S1 (e.g. psoriasis or eczema)
  - 6) Hip surgical replacement
  
- You are healthy, without any relevant health problems interfering with daily activities

OR

You have had a stroke more than six months ago which has left you with some problems with your trunk balance, and you are able to sit unsupported for 10 seconds even if you

suffer from trunk balance disturbance (excessive trunk movements during reaching tasks)

**Do I have to take part?**

No, you decide whether or not to take part. If you do decide to take part, you will be given this information sheet and will be asked to sign a consent form. If you decide not to take part or you decide later to withdraw, you do not have to give a reason. This will not affect your current or future health care.

**What will happen to me if I take part?**

If you return the form saying you are interested in taking part, you will be contacted by the researchers by telephone or by email. They will answer any questions you might have and will ask you some general questions about yourself. These questions will inform the researchers as to whether or not the research study is suitable for you. They will then make two appointments for you to come in to the Faculty of Health Sciences, University of Southampton (Building 45) at a convenient day and time for you.

You will be required to make two visits to the laboratory, each of which should take no longer than one and a half hours. We would like you to wear a vest top and comfortable trousers, and be prepared to take off your shoes and socks.

In the research laboratory, you will undergo a series of assessments which will be performed by the researcher to look at your ability to control your trunk in a seated position using the TIS. This will consist of three main parts including static sitting (e.g. at a rest position), dynamic sitting (e.g. sitting whilst using your arms) and trunk coordination (e.g. sitting whilst turning).

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These assessments will be performed three times at the first session while only once at the second session, wearing 3 sensors each time. Two different assessors will be taking the measurements.



**Figure 1: Valedo sensors**

During the assessments, we will collect both clinical and sensor data. A video recording will be made throughout the assessment sessions. This will aid our understanding of how you perform trunk movements. The sensors will be taped to your sternum and low back using hypoallergenic double sided sticky tape. See Figure 2.



**Figure 2: Sensors placement**

You will need to come back for a second session two to five days later to repeat the process outlined above.

[31/01/2017] [Version 2.0]

**Are there any benefits in my taking part?**

We will reimburse travel expenses or arrange for taxis to bring you to and from each meeting up to a maximum of £20. There will be no direct benefit to you from taking part in the study. However, the data collected will be useful for healthcare professionals to gain a better understanding of trunk balance after a stroke. It is hoped that this will lead to better rehabilitation programmes for stroke patients in the future.

**Are there any risks involved?**

There are unlikely to be any side effects or risks from the assessment session. You may feel slightly tired during, at the end of, or after the sessions. During the sessions you may rest at any time. If you feel unable to continue, you may withdraw. Throughout the session, the researchers will ensure that you are comfortable. Skin irritation from the double sided tape used to stick on the sensors is unlikely. However, to reduce this risk, we make sure that you wear the sensors for as short a time as possible.

**Will my participation be confidential?**

All the information collected about you during the course of this research will be kept strictly confidential. Any information about you on research report forms or publications will have your name and address removed so that you cannot be identified from it. You will be assigned a unique number that connects your data to you. Your personal details will be kept separately from the research records. The data recorded, for the purpose of the research study, will be held on a password-protected computer or as paper records kept in a locked filing cabinet.

**What happens if I change my mind?**

You decide if you want to take part or not. If you decide to take part, you are still free to withdraw at any time without giving a reason. A decision to withdraw or to not take part in the study will not affect your future or be held against you in any way. Please note that if you withdraw, data will be retained up to the point that you withdraw.

**What happens if something goes wrong?**

If you become uncomfortable or distressed during the session, you will be offered assistance there and then by the researcher. If you have a concern or a complaint about this study you should contact Isla Morris at the Research Governance Office (Address: University of Southampton, Building 37, Highfield, Southampton, SO17 1BJ; Tel: +44 (0)23 8059 5058; Email: rgoinfo@soton.ac.uk. If you remain unhappy and wish to complain formally, the Research Governance Office can provide you with details of the University of Southampton Complaints Procedure.

**What will happen to the results of the research study?**

We will use the data to inform research with regard to people who have had a stroke. These results will be presented at scientific conferences and may be published in scientific journals. Please let us know if you would like a copy of the published results at the end of the study. On completion of the research study, the data collected will be securely stored at the University of Southampton for 10 years according to University policy.

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**Who is organising the research study?**

The research is organized through the University of Southampton.

**Who has reviewed the study?**

The Ethics Committee in the Research Governance Office of the University of Southampton has reviewed the research proposal and granted approval before commencement of this study.

**Contact for further information**

If you would like any further information, please contact:

1) Dr Federico Ferrari  
Visitor Student  
Rehabilitation & Health Technologies Research Group  
Faculty of Health Sciences (Building 45)  
University of Southampton  
Southampton SO17 1BJ  
United Kingdom

Email: F.Ferari@soton.ac.uk

2) Norah Alhwoaimel  
PhD Student  
Rehabilitation & Health Technologies Research Group  
Faculty of Health Sciences (Building 45)  
University of Southampton  
Southampton SO17 1BJ  
United Kingdom

Telephone: +44(0)2380595000

Email: N.Alhwoaimel@soton.ac.uk

3) Professor Jane Burridge  
Professor of Restorative Neuroscience  
Faculty of Health Sciences (Building 45)  
University of Southampton  
Southampton SO17 1BJ  
United Kingdom

Telephone: +44(0)2380598885  
Email: J.H.Burridge@soton.ac.uk

4) Dr Ann-Marie Hughes  
Associate Professor  
Faculty of Health Sciences (Building 45)  
University of Southampton  
Southampton SO17 1BJ  
United Kingdom

Telephone: +44(0)2380595191  
Email: A.Hughes@soton.ac.uk

5) Dr Ruth Turk  
Lecturer / Clinical Academic Lecturer Intern  
Faculty of Health Sciences (Building 45)  
University of Southampton  
Southampton SO17 1BJ  
United Kingdom  
Telephone : +44(0)2380598928  
Email: R.Turk@soton.ac.uk

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6) Dr Martin Warner  
Senior Research Fellow (Musculoskeletal Biomechanics)  
Arthritis Research UK Centre for Sport, Exercise and  
Osteoarthritis  
Faculty of Health Sciences (Building 45)  
University of Southampton  
Southampton SO17 1BJ  
United Kingdom

Telephone: +44(0)2380598990  
Email: m.warner@soton.ac.uk

Thank you for your consideration with regard to taking part in this study. You will be given a copy of the information sheet and a signed consent form to keep.

[31/01/2017] [Version 2.0]

## Appendix 7      Reply slip (Study 1)

Ethics Number: ~~EoHS~~-ETHICS: 24605



**Yes I am interested in taking part in the study: iTIS: development of a sitting balance test**

**Please contact me with further details.**

<b>NAME</b>	
<b>Age</b>	
<b>Date of stroke</b>	
<b>Which side is most affected</b>	
<b>TELEPHONE/ EMAIL</b>	
<b>BEST TIME TO CONTACT</b>	

**Please return the reply slip in the pre-paid envelope.**

**Thank you for your participation in the research.**

## Appendix 8 Advertisement for recruitment of stroke participants (Study 1)

Health Sciences  
Ethics number: 24605

UNIVERSITY OF  
Southampton

# How is your balance?

Have you had a stroke?  
Are you between 40 and 80 years old?



Would you like to participate in research?

We are looking for men and women who have had a stroke to develop a new instrumental balance test.

This project will require TWO separate visits to the motion analysis laboratory in the University of Southampton, Faculty of Health Sciences (Building 45).

We will assess and record your trunk balance using three sensors while you are sitting and performing balance tasks like leaning to one side.

Your participation would be greatly appreciated. If you are interested, please contact Dr Federico Ferrari or Norah Alhwoaimel:

Trunk Research Federico or Norah <a href="mailto:F.Ferrari@soton.ac.uk">F.Ferrari@soton.ac.uk</a> Tel: 02380595000								
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# Appendix 9 Advertisement for recruitment of healthy participants (Study 1)

Health Sciences  
Ethics number: 24605

UNIVERSITY OF Southampton

## How is your balance?

Are you between 40 and 80 years old?



Would you like to participate in research?

We are looking for healthy men and women to develop a new instrumental balance test.

This project will require TWO separate visits to the motion analysis laboratory in the University of Southampton, Faculty of Health Sciences (Building 45).

We will assess and record your trunk balance using three sensors while you are sitting and performing balance tasks like leaning to one side.

Your participation would be greatly appreciated. If you are interested, please contact Dr Federico Ferrari or Norah Alhwoaimel:

Trunk Research Federico or Norah F.Ferrari@soton.ac.uk Tel: 02380595000									
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## Appendix 10 Consent form (Study 1)

Ethics Number: FoHS-ETHICS: 24605

UNIVERSITY OF  
**Southampton**

### CONSENT FORM 1

**Study title:** Creation and validation of a reliable instrumented version of Trunk Impairment Scale

**Researchers:** Federico Ferrari, Norah Alhwoaimel, Ann-Marie Hughes, Ruth Turk, Martin Warner, Seng Kwee Wee, Geert Verheyden, Jane Burridge.

Please **initial the box(es)** if you agree with the statement(s):

I have read and understood the information sheet (31/01/2017 /version no 2.0) and have had the opportunity to ask questions about the study.

**Initial**

I agree to take part in the research project and agree for my data to be used for the purpose of this study.

I understand that my participation is voluntary and I may withdraw at any time without my legal rights being affected.

I consent to video tapes being made of the sessions to aid the research

**Data Protection:** I understand that information collected about me during my participation in this study will be stored on a password protected computer and that this information will only be used for the purpose of this study. All files containing any personal data will be anonymised.

[23/01/2017] [Version Number 2.0]

I am happy to be contacted regarding other unspecified research projects. I therefore consent to the University retaining my personal details on a database, kept separately from the research data detailed above. The 'validity' of my consent is conditional upon the University complying with the Data Protection Act and I understand that I can request my details be removed from this database at any time.



Name of participant (print name).....

Signature of participant.....

Date.....

Name of Researcher:

Signature of Researcher.....

Date:.....

## Appendix 11 Trunk Impairment Scale (TIS)

The starting position for each item is the same. The patient is sitting on the edge of a bed or treatment table without back and arm support. The thighs make full contact with the bed or table, the feet are hip width apart and placed flat on the floor. The knee angle is 90°. The arms rest on the legs. If hypertonia is present the position of the hemiplegic arm is taken as the starting position. The head and trunk are in a midline position. If the patient scores 0 on the first item, the total score for the TIS is 0.

Each item of the test can be performed three times. The highest score counts. No practice session is allowed. The patient can be corrected between the attempts. The tests are verbally explained to the patient and can be demonstrated if needed.

Item

1	<b>Static sitting balance</b> Starting position	Patient falls or cannot maintain starting position for 10 seconds without arm support	0
		Patient can maintain starting position for 10 seconds If score=0, then TIS total score=0	2
2	Starting position Therapist crosses the unaffected leg over the hemiplegic leg	Patient falls or cannot maintain sitting position for 10 seconds without arm support	0
		Patient can maintain sitting position for 10 seconds	2
3	Starting position Patient crosses the unaffected leg over the hemiplegic leg	Patient falls	0
		Patient cannot cross the legs without arm support on bed or table	1
		Patient crosses the legs but displaces the trunk more than 10 cm backwards or assists crossing with the hand	2

		Patient crosses the legs without trunk displacement or assistance	3
Total static sitting balance			/7
1	<p><b>Dynamic sitting balance</b></p> <p>Starting position</p> <p>Patient is instructed to touch the bed or table with the hemiplegic elbow (by shortening the hemiplegic side and lengthening the unaffected side) and return to the starting position</p>	<p>Patient falls, needs support from an upper extremity or the elbow does not touch the bed or table</p> <p>Patient moves actively without help, elbow touches bed or table</p> <p>If score=/0, then items 2 and 3 score 0</p>	<p>0</p> <p>1</p>
2	Repeat item 1	<p>Patient demonstrates no or opposite shortening/lengthening</p> <p>Patient demonstrates appropriate shortening/lengthening</p> <p>If score=/0, then item 3 scores 0</p>	<p>0</p> <p>1</p>
3	Repeat item 1	<p>Patient compensates. Possible compensations are: (1) use of upper extremity, (2) contralateral hip abduction, (3) hip flexion (if elbow touches bed or table further than proximal half of femur), (4) knee flexion, (5) sliding of the feet</p> <p>Patient moves without compensation</p>	<p>0</p> <p>1</p>
4	<p>Starting position</p> <p>Patient is instructed to touch the bed or table with the unaffected elbow (by shortening the unaffected side and lengthening the hemiplegic side) and return to the starting position</p>	<p>Patient falls, needs support from an upper extremity or the elbow does not touch the bed or table</p> <p>Patient moves actively without help, elbow touches bed or table</p>	<p>0</p> <p>1</p>

		If score=/0, then items 5 and 6 score 0	
5	Repeat item 4	<p>Patient demonstrates no or opposite shortening/lengthening</p> <p>Patient demonstrates appropriate shortening/lengthening</p> <p>If score=/0, then item 6 scores 0</p>	<p>0</p> <p>1</p>
6	Repeat item 4	<p>Patient compensates. Possible compensations are: (1) use of upper extremity, (2) contralateral hip abduction, (3) hip flexion (if elbow touches bed or table further than proximal half of femur), (4) knee flexion, (5) sliding of the feet</p> <p>Patient moves without compensation</p>	<p>0</p> <p>1</p>
7	<p>Starting position</p> <p>Patient is instructed to lift pelvis from bed or table at the hemiplegic side (by shortening the hemiplegic side and lengthening the unaffected side) and return to the starting position</p>	<p>Patient demonstrates no or opposite shortening/lengthening</p> <p>Patient demonstrates appropriate shortening/lengthening</p> <p>If score=/0, then item 8 scores 0</p>	<p>0</p> <p>1</p>
8	Repeat item 7	<p>Patient compensates. Possible compensations are: (1) use of upper extremity, (2) pushing off with the ipsilateral foot (heel loses contact with the floor)</p> <p>Patient moves without compensation</p>	<p>0</p> <p>1</p>

9	<p>Starting position</p> <p>Patient is instructed to lift pelvis from bed or table at the unaffected side (by shortening the unaffected side and lengthening the hemiplegic side) and return to the starting position</p>	<p>Patient demonstrates no or opposite shortening/lengthening</p> <p>Patient demonstrates appropriate shortening/lengthening</p> <p>If score=0, then item 10 scores 0</p>	<p>0</p> <p>1</p>
10	Repeat item 9	<p>Patient compensates. Possible compensations are: (1) use of upper extremity, (2) pushing off with the ipsilateral foot (heel loses contact with the floor)</p> <p>Patient moves without compensation</p>	<p>0</p> <p>1</p>
Total dynamic sitting balance			/10
1	<p><b>Co-ordination</b></p> <p>Starting position</p> <p>Patient is instructed to rotate upper trunk 6 times (every shoulder should be moved forward 3 times), first side that moves must be hemiplegic side, head should be fixated in starting position</p>	<p>Hemiplegic side is not moved three times</p> <p>Rotation is asymmetrical</p> <p>Rotation is symmetrical</p> <p>If score=0, then item 2 scores 0</p>	<p>0</p> <p>1</p> <p>2</p>
2	Repeat item 1 within 6 seconds	<p>Rotation is asymmetrical</p> <p>Rotation is symmetrical</p>	<p>0</p> <p>1</p>
3	<p>Starting position</p> <p>Patient is instructed to rotate lower trunk 6 times (every knee should be moved forward 3 times), first side that moves must be hemiplegic side, upper trunk should be fixated in starting position</p>	<p>Hemiplegic side is not moved three times</p> <p>Rotation is asymmetrical</p> <p>Rotation is symmetrical</p> <p>If score=0, then item 2 scores 0</p>	<p>0</p> <p>1</p> <p>2</p>

4	Repeat item 3 within 6 seconds	Rotation is asymmetrical	0
		Rotation is symmetrical	1
Total co-ordination			/6
Total Trunk Impairment Scale			/23

**Reference: Verheyden G, Nieuwboer A, Mertin J, Preger R, Kiekens C and De Weerd W (2004) The Trunk Impairment Scale: a new tool to measure motor impairment of the trunk after stroke. Clinical Rehabilitation 18(3): 326- 334**

**\*This outcome measure is freely available for use and reproduction**

## Appendix 12 Case record form

Creation and validation of a reliable instrumented version of Trunk Impairment Scale

Session:		Date:	
Assessor:		Assessment number:	

### Dynamic Sitting Balance

TASKS	SCORE Rep 1	SCORE Rep 2	SCORE Rep 3	Time	COMMENTS
To touch the with the hemiplegic elbow					
Repeat					
Repeat					
To touch the bed with the unaffected elbow					
Repeat					
Repeat					
To lift pelvis from bed at the hemiplegic side					
Repeat					
To lift pelvis from bed at the unaffected side					
Repeat					

Coordination

TASKS	SCORE Rep 1	SCORE Rep 2	SCORE Rep 3	Time	COMMENTS
To rotate upper trunk 6 times					
Repeat item within 6 seconds					
To rotate lower trunk 6 times					
Repeat item within 6 seconds					

# Appendix 13 MATLAB scripts for data processing - 1<sup>st</sup> study

## 2- MATLAB coding for data analysis

```
close all
clear all

eFname = '';

fid = uipickfiles('FilterSpec','');

e = actxserver('Excel.Application');
e.Visible = 0;
e.DisplayAlerts = 0;

eWorkbook = e.Workbooks.Open(eFname);

%     tokens = regexp(fid{1}, '(\d+)\.(\d+)', 'tokens', 'once');

prompt = {'Participant ID:', 'Observation:'};
dlg_title = 'Input';
num_lines = 1;
%     defaultans = {tokens{1}, '0'};
defaultans = {'0', '0'};
answer = inputdlg(prompt, dlg_title, num_lines, defaultans);

ID = str2double(answer{1});
Observation = str2double(answer{2});

h = waitbar(0, 'Please wait...');

row = num2str(ID + 4);
rowD = ID + 4;

eSheet = eWorkbook.Sheets.get('Item', 1);
eSheet.Activate

eActivesheetRange = get(eSheet, 'Range', ['D' num2str(row)]);
Affected = eActivesheetRange.Value;

if isnan(Affected)
    eActivesheetRange = get(eSheet, 'Range', ['F' num2str(row)]);
    Affected = eActivesheetRange.Value;
end

for j = 1 : size(fid, 2)

    [num, txt, raw] = xlsread(fid{j});

    OpenBracket = strfind(fid{j}, '(');
    ClosedBracket = strfind(fid{j}, ')');
    Task = str2double(fid{j}(OpenBracket+1:ClosedBracket-1));
```

```

d = str2double(raw);

SensorOne = d(3:size(d,1),1:4);
SensorOne(:,5) = d(3:size(d,1),9);
SensorTwo = d(3:size(d,1),10:13);
SensorTwo(:,5) = d(3:size(d,1),18);
SensorThree = d(3:size(d,1),19:22);
SensorThree(:,5) = d(3:size(d,1),27);

SensorOneE = zeros(size(SensorOne,1),5);
SensorTwoE = zeros(size(SensorTwo,1),5);
SensorThreeE = zeros(size(SensorThree,1),5);

for i = 1 : size(SensorOne,1) %Calculate Excursion. Sort Time variable

    SensorOneE(i,:) = SensorOne(i,:) - SensorOne(1,:);
    SensorTwoE(i,:) = SensorTwo(i,:) - SensorTwo(1,:);
    SensorThreeE(i,:) = SensorThree(i,:) - SensorThree(1,:);

end

if Task == 1 || Task == 2;
    Task_1_2(SensorThreeE,row,Affected,Observation,Task,eWorkbook)
end

if Task == 3;
Task_3(SensorTwoE,SensorThreeE,row,Affected,Observation,Task,eWorkbook)
end

if Task >= 4 && Task <=9;
    Task_4_9(SensorThreeE,row,Affected,Observation,Task,eWorkbook)
end

if Task >= 10 && Task <= 13;
Task_10_13(SensorOneE,SensorThreeE,row,Affected,Observation,Task,eWorkboo
k)
end

if Task == 14 || Task == 15
Task_14_17(SensorThreeE,rowD,Affected,Observation,Task,eWorkbook)
end

if Task == 16 || Task == 17
    Task_14_17(SensorOneE,rowD,Affected,Observation,Task,eWorkbook)
end

clearvars -except j h fid ID Observation e eWorkbook eFname row
Affected rowD

waitbar(j/size(fid,2),h);

end

close(h)

invoke(eWorkbook, 'SaveAs', eFname);

```

```

invoke(e, 'Quit');
delete(e);
clear all

```

### 3- MATLAB coding for static subscale

```

function Task_1_2(SensorThreeE,row,Affected,Observation,Task,eWorkbook)

```

```

    if Affected == 3
        FrtAff = max(SensorThreeE(:,3));
        FrtNon = min(SensorThreeE(:,3));
    else
        FrtAff = min(SensorThreeE(:,3));
        FrtNon = max(SensorThreeE(:,3));
    end

    Results(:,1) = abs(FrtAff);
    Results(:,2) = abs(FrtNon);
    Results(:,3) = abs(FrtAff - FrtNon);
    Results(:,4) = std(SensorThreeE(:,3),1,'omitnan');

```

```

Results(:,5)= max(SensorThreeE(:,2));
Results(:,6) = min(SensorThreeE(:,2));

```

```

Results(:,7) = abs(Results(:,5) - Results(:,6));
Results(:,8) = std(SensorThreeE(:,2),1,'omitnan');

```

```

    if Observation == 1
        CellRange = ['G' row ':N' row];
    end

```

```

    if Observation == 2
        CellRange = ['O' row ':V' row];
    end

```

```

    if Observation == 3
        CellRange = ['W' row ':AD' row];
    end

```

```

    if Observation == 4
        CellRange = ['AE' row ':AL' row];
    end

```

```

eSheet = eWorkbook.Sheets.get('Item',Task);
eSheet.Activate

```

```

eActivesheetRange = get(eSheet,'Range',CellRange);
eActivesheetRange.Value = Results;

```

```

function

```

```

Task_3(SensorTwoE,SensorThreeE,row,Affected,Observation,Task,eWorkbook)

```

```

    if Affected == 3
        FrtAff = max(SensorThreeE(:,3));

```

```

    FrtNon = min(SensorThreeE(:,3));
else
    FrtAff = min(SensorThreeE(:,3));
    FrtNon = max(SensorThreeE(:,3));
end

Results(:,1) = abs(FrtAff);
Results(:,2) = abs(FrtNon);
Results(:,3) = abs(FrtAff - FrtNon);
Results(:,4) = std(SensorThreeE(:,3),1,'omitnan');

Results(:,5) = max(SensorThreeE(:,2));
Results(:,6) = min(SensorThreeE(:,2));

Results(:,7) = abs(Results(:,5) - Results(:,6));
Results(:,8) = std(SensorThreeE(:,2),1,'omitnan');

Results(:,9) = max(SensorTwoE(:,2));
Results(:,10) = min(SensorTwoE(:,2));

Results(:,11) = abs(Results(:,10) - Results(:,9));
Results(:,12) = std(SensorTwoE(:,2),1,'omitnan');

if Observation == 1
    CellRange = ['G' row ':R' row];
end

if Observation == 2
    CellRange = ['S' row ':AD' row];
end

if Observation == 3
    CellRange = ['AE' row ':AP' row];
end

if Observation == 4
    CellRange = ['Aq' row ':BB' row];
end

eSheet = eWorkbook.Sheets.get('Item',Task);
eSheet.Activate

eActivesheetRange = get(eSheet,'Range',CellRange);
eActivesheetRange.Value = Results;

```

#### 4- MATLAB coding for dynamic subscale

```
function Task_4_9(SensorThreeE,row,Affected,Observation,Task,eWorkbook)
```

```

if Affected == 3
    Results(:,1) = max(SensorThreeE(:,3));
    Results(:,2) = abs(min(SensorThreeE(:,3)));
else
    Results(:,1) = abs(min(SensorThreeE(:,3)));
    Results(:,2) = max(SensorThreeE(:,3));
end

Results(:,3) = max(SensorThreeE(:,2));
Results(:,4) = min(SensorThreeE(:,2));

```

```

if Observation == 1
    CellRange = ['G' row ':J' row];
end

if Observation == 2
    CellRange = ['K' row ':N' row];
end

if Observation == 3
    CellRange = ['O' row ':R' row];
end

if Observation == 4
    CellRange = ['S' row ':V' row];
end

eSheet = eWorkbook.Sheets.get('Item',Task);
eSheet.Activate

eActivesheetRange = get(eSheet, 'Range', CellRange);
eActivesheetRange.Value = Results;
function
Task_10_13(SensorOneE, SensorThreeE, row, Affected, Observation, Task, eWorkboo
k)

if Affected == 3
    Results(:,1) = max(SensorThreeE(:,3));
    Results(:,2) = abs(min(SensorThreeE(:,3)));
else
    Results(:,1) = abs(min(SensorThreeE(:,3)));
    Results(:,2) = max(SensorThreeE(:,3));
end

Results(:,3) = max(SensorThreeE(:,2));
Results(:,4) = min(SensorThreeE(:,2));

if Affected == 4
    Results(:,5) = max(SensorOneE(:,3));
    Results(:,6) = abs(min(SensorOneE(:,3)));
else
    Results(:,5) = abs(min(SensorOneE(:,3)));
    Results(:,6) = max(SensorOneE(:,3));
end

Results(:,7) = max(SensorOneE(:,2));
Results(:,8) = min(SensorOneE(:,2));

if Observation == 1
    CellRange = ['G' row ':N' row];
end

if Observation == 2
    CellRange = ['O' row ':V' row];
end

if Observation == 3

```

```

    CellRange = ['W' row ':AD' row];
end

if Observation == 4
    CellRange = ['AE' row ':AL' row];
end

eSheet = eWorkbook.Sheets.get('Item',Task);
eSheet.Activate

eActivesheetRange = get(eSheet,'Range',CellRange);
eActivesheetRange.Value = Results;

```

## 5- MATLAB coding for co-ordination subscale

function

Task\_14\_17(SensorThreeE,rowD,Affected,Observation,Task,eWorkbook)

```

    SubjectRow = num2str(rowD + 1);

    x = SensorThreeE(:,4);
    x = x(~isnan(x));

%     [~,maxI] = max(x);
%     [~,minI] = min(x);
m = mean(x);
%     th = find(abs(x)>1,1,'first');
zerIdx = crossing(x,[],m);
%     zerIdx(1) = th;
%     zerIdx = zerIdxT + th;
%

if size(zerIdx,2) > 7
    zerIdx = zerIdx(1:7);
end

h = figure('units','normalized','outerposition',[0 0 1 1]); hold on
plot(x)
if Affected == 3
    text(zerIdx(1),max(x)+0.5,'Affected / nondominant side = RIGHT.
First movement should be POSITIVE','fontsize',14);
end

if affected == 4
    text(zerIdx(1),max(x)+0.5,'Affected / nondominant side = LEFT.
First movement should be NEGATIVE','fontsize',14);
end

for i = 1 : size(zerIdx,2)
    line([zerIdx(i)                                zerIdx(i)], [min(x)
max(x)], 'color','r', 'linestyle','--');
end

cycles = questdlg('Are the cycles correctly identified?', ...
                  'Cycles', ...
                  'Yes', 'No', 'Yes');

if strcmp(cycles,'Yes')
    close(h)
else

```

```

cla
plot(x)
line([1 size(x,1)], [m m], 'color', 'k', 'linestyle', '--');
[zerIdxTemp,~] = getpts;
zerIdx = round(zerIdxTemp)';

for i = 1 : size(zerIdx,2)
    line([zerIdx(i) zerIdx(i+1)], [min(x)
max(x)], 'color', 'r', 'linestyle', '--');
end

pause(1)
close(h)
end

if Affected == 3
    for i = 1 : size(zerIdx,2) -1
        if mod(i,2)
            Rotvals(i) = max(x(zerIdx(i) : zerIdx(i+1)));
        else
            Rotvals(i) = min(x(zerIdx(i) : zerIdx(i+1)));
        end
    end
else
    for i = 1 : size(zerIdx,2) -1
        if mod(i,2)
            Rotvals(i) = min(x(zerIdx(i) : zerIdx(i+1)));
        else
            Rotvals(i) = max(x(zerIdx(i) : zerIdx(i+1)));
        end
    end
end

AffectedRotT = Rotvals(1:2:end);
NonAffectedRotT = Rotvals(2:2:end);

if Affected == 3
    AffectedRot = AffectedRotT(AffectedRotT>=0);
    NonAffectedRot = NonAffectedRotT(NonAffectedRotT<0);
else
    AffectedRot = AffectedRotT(AffectedRotT<0);
    NonAffectedRot = NonAffectedRotT(NonAffectedRotT>=0);
end

NumAffectedRot = size(AffectedRot,2);
NumNonAffectedRot = size(NonAffectedRot,2);

AverageAffected = abs(mean(AffectedRot));
AverageNonAffected = abs(mean(NonAffectedRot));

SymmetryIndex = 100 - abs((AverageAffected - AverageNonAffected) /
(AverageAffected + AverageNonAffected) * 100); % See http://biomch-1.isbweb.org/threads/8897-Symmetry-index-summary-of-replies
%%% to see where this has come from.
% Dingwell, J.B., Davis, B.L., and Frazier, D.M., (1996) "Use Of An
% Instrumented Treadmill For Real-Time Gait Symmetry Evaluation And
Feedback
% In Normal And Below-Knee Amputee Subjects," Prosthetics And Orthotics
% International, 20:

```

```

% 101-110.
% Herzog, W., Nigg, B.M., Read, L.J., and Olsson, E. (1989).
Asymmetries in
% Ground Reaction Force Patterns in Normal Human Gait. Medicine and
Science
% in Sports and Exercise, 21 (1): 110 - 114.

Results = [NumAffectedRot, NumNonAffectedRot, AverageAffected,
AverageNonAffected, SymmetryIndex];

if Observation == 1
    CellRange = ['G' SubjectRow ':K' SubjectRow];
end

if Observation == 2
    CellRange = ['L' SubjectRow ':P' SubjectRow];
end

if Observation == 3
    CellRange = ['Q' SubjectRow ':U' SubjectRow];
end

if Observation == 4
    CellRange = ['V' SubjectRow ':Z' SubjectRow];
end

eSheet = eWorkbook.Sheets.get('Item',Task);
eSheet.Activate

eActivesheetRange = get(eSheet,'Range',CellRange);
eActivesheetRange.Value = Results;

```

## Appendix 14 Invitation letter for participant (Study 2)



Dear Sir / Madam

We would like to invite you to take part in a research study based at the University of Southampton. This study aims to develop a new intervention to train trunk movement in people with stroke.

To do this we need the help of people who had a stroke more than 6 months ago.

We have also sent an information sheet that explains in more detail what the study involves. Please take time to read the information sheet carefully. We are happy to answer any questions if anything you read is not clear or if you would like more information. Please find the contact details of the researchers at the end of this letter.

If you are interested in taking part in this study, please complete and return the reply slip, email or call us. We will ask you a few questions about your health to check if this project is suitable for you. Then, we will make an appointment at a convenient time and day for you to come in to the Faculty of Health Sciences, University of Southampton (Building 45)

Thank you for your consideration.

Yours faithfully,  
Simon Brown

**Address:**

Faculty of Health Sciences (Building 45),  
University of Southampton, Southampton SO17 1BJ

For more information: you can contact the researcher:

**Norah Alhwoaimel**

Telephone: 02380592021 , Email: [n.alhwoaimel@soton.ac.uk](mailto:n.alhwoaimel@soton.ac.uk)

## Appendix 15 Participant Information Sheet (Study 2)



### Participant Information Sheet

#### **Study Title: Reliability of Valedo Sensors to Measure Trunk Range of Movement, In Healthy and Chronic Stroke Individuals, During SWMFT**

**Researcher:** Norah Alhwoaimel, Giulia Busselli, Dr Ann-Marie Hughes, Dr Ruth Turk, Dr Martin Warner

**ERGO number:** 46744

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

#### **What is the research about?**

Many people have problems controlling their body after a stroke, particularly their trunk and arms, which can affect their ability to perform activities such as sitting upright, being able to balance, and using their arms.

After stroke, people used to show an excessive trunk movement during reaching tasks. To help improve rehabilitation we need to use good tests to measure the trunk movement during arm function. The available technology to measure trunk movement had problems such as high cost and complicated process of installation.

The purpose of this study is to develop an objective trunk movement measurement using a low cost wearable sensor. The results of this study will make it easier and faster for therapists to test trunk movement in a clinical setting.

#### **Why have I been asked to participate?**

You have been chosen to take part in this study as we are looking for volunteers who have an interest in help improving trunk control for people who have had a stroke. You have been contacted to take part as you are either a volunteer on the

[21-11-2018] [Version 1]

[Ethics number 46744]

user databases in the School of Health Sciences, University of Southampton, or you have shown interest in our research study.

You have been chosen to take part in this study as you:

- are an adult healthy, able to understand what this research project involves, follow simple instructions (e.g. folding towel, put hand on table) and can commit to attending 2 assessment sessions with 7-10 days apart.

**OR**

- had a stroke more than six months ago
- are able to sit unsupported
- are able to understand what this research project involves
- are able to understand and follow simple instructions (e.g. folding towel, put hand on table)
- can commit to attending 2 assessment sessions with 7-10 days apart.

In addition you do not have any of the following conditions:

- acute low back or shoulder pain
- history of or current problems with your spine
- history of bones breaking for no apparent reason
- uncontrolled epilepsy
- an artificial hip
- Implanted materials or devices within the body (e.g. pace maker, hearing device)
- pregnancy
- Skin disease or lesions in your back (i.e. Psoriasis or eczema).
- Complete arm paralysis

**What will happen to me if I take part?**

If you return the form saying you are interested in taking part, you will be contacted

by the researcher by telephone or by email. She will answer any questions you might have and will ask you some general questions. These questions will inform the researcher as to whether or not the research study is suitable for you. She will then make an appointment for you to come in to the Faculty of Health Sciences, University of Southampton (Building 67) at a convenient day and time for you.

You will need to make two visits with 7-10 days apart to the laboratory, each of which should take no longer than one hour.

**Are there any benefits in my taking part?**

We will reimburse travel expenses or arrange for taxis to bring you to and from each meeting up to a maximum of £20. There will be no direct benefit to you from taking part in the study. However, the data collected will be useful for healthcare professionals to gain a better understanding of trunk movement after a stroke. It is hoped that this will lead to better rehabilitation programmes for stroke patients in the future.

**Are there any risks involved?**

There are unlikely to be any side effects or risks from the assessment session. You may feel slightly tired during, at the end of, or after the sessions. During the sessions you may rest at any time. If you feel unable to continue, you may withdraw. Throughout the session, the researcher will ensure that you are comfortable.

**What data will be collected?**

You will be asked to come to the laboratory wearing a vest top and comfortable trousers, and be prepared to remove your shoes and socks.

In the research lab, you will be asked to fill out a questionnaire to assess hand dominance as well as to provide participation details such as age and date of stroke.

Session 1: Three Valedo sensors (Figure 1) will be taped onto your trunk by researcher (one on the upper chest and two on the lower back (Figure 2). You will then perform the Streamline Wolf Motor Function Test with your both hands. The test will consist of eight simple tasks, which includes lifting hand onto the table, lifting hand onto a box, picking up a pen, picking up a can, turning key in a lock, pulling a weight (1lb), folding a towel and pushing a weight across the table as quick as possible.

The test will be recorded 3 times (the first and third time by assessor 1 (NA), the second by assessor 2 (GB)). The reason for the repetition is to assess the level of agreement between measurements by different assessors at different times.

You will be given a 10-15 minutes break before being re-assessed again.

Session 2: You will then need to come back for a second session 7-10 days later. You will be reassessed by same researcher and asking to do the same eight tasks.

The performance of the tasks will also be filmed (unless you choose to opt out of this) so that we can check the movements later.



**Figure 1: Valedo Sensors**



**Figure 2: Sensor placement**

**Will my participation be confidential?**

Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

Only members of the research team and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

Any information about you on research report forms or publications will have your name and address removed so that you cannot be identified from it. A unique number will connect your data to your personal details. Your personal details will be kept separately from the research records. The data recorded, for the purpose of the research study, will be held on a password-protected computer or as paper records kept in a locked filing cabinet.

**Do I have to take part?**

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to

take part. If you decide to take part, you are still free to withdraw at any time without giving a reason.

**What happens if I change my mind?**

You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights being affected.

If you withdraw from the study, we will keep the information about you that we have already obtained for the purposes of achieving the objectives of the study only.

**What will happen to the results of the research?**

Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent. The results of the research will be used to publish a research paper and share it with the participants upon publication.

**Where can I get more information?**

If you would like any further information, please contact:

1) Norah Alhwoaimel

PhD Student

Rehabilitation & Health Technologies Research Group

Faculty of Health Sciences (Building 45)

University of Southampton

Southampton SO17 1BJ

United Kingdom

Telephone: +44(0)2380592021

Email: N.Alhwoaimel@soton.ac.uk

2) Dr Ann-Marie Hughes

Associate Professor  
Faculty of Health Sciences (Building 45)  
University of Southampton  
Southampton SO17 1BJ  
United Kingdom

Telephone: +44(0)2380595191

Email: [A.Hughes@soton.ac.uk](mailto:A.Hughes@soton.ac.uk)

3) Dr Ruth Turk

Lecturer / Clinical Academic Lecturer Intern  
Faculty of Health Sciences (Building 45)  
University of Southampton  
Southampton SO17 1BJ  
United Kingdom  
Telephone : +44(0)2380598928

Email: [R.Turk@soton.ac.uk](mailto:R.Turk@soton.ac.uk)

**What happens if there is a problem?**

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions.

If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, [rqoinfo@soton.ac.uk](mailto:rqoinfo@soton.ac.uk)).

**Data Protection Privacy Notice**

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you

agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (<https://www.southampton.ac.uk/legal/services/what-we-do/data-protection-and-foi.page>).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at

<http://www.southampton.ac.uk/assets/sharepoint/intranet/Is/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf>

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information – may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer ([data.protection@soton.ac.uk](mailto:data.protection@soton.ac.uk)).

**Thank you for your consideration with regard to taking part in this study.**

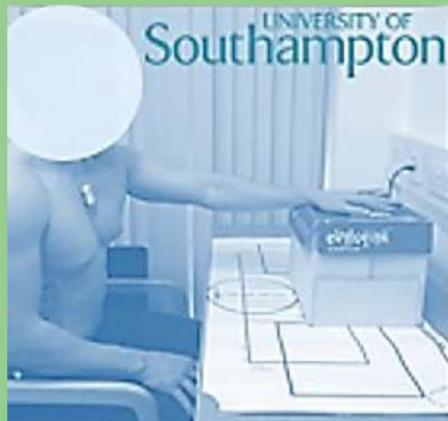
## Appendix 16 Advertisement for recruitment of stroke participants (Study 2)

Health  
Sciences

Ethics number: 46744

UNIVERSITY OF  
**Southampton**

### How does your trunk movement relate to ARM function?



- ✓ Have you had a stroke more than six months ago?
- ✓ Do you have arm problems?
- ✓ Are you over 18 years old?
- ✓ Are you interested in taking part in research?

We will capture your trunk movement using three sensors while you perform 8 simple arm tasks in a seated position.

This project will require 2 visits to the laboratory in the University of Southampton, Faculty Health Sciences (Building 67).

Your participation would be greatly appreciated. If you are interested, please contact Norah Alhwoaimel:

Trunk Research Norah na1n15@soton.ac.uk Tel: (0)23 80592021						
--	--	--	--	--	--	--

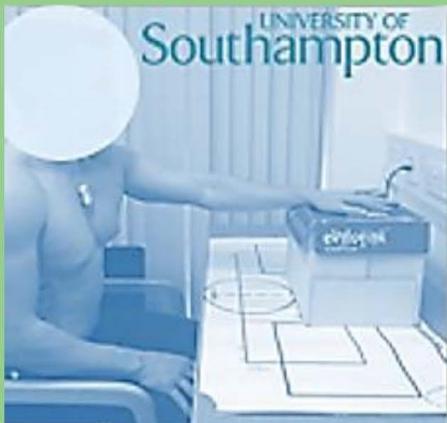
# Appendix 17 Advertisement for recruitment of healthy participants (Study 2)

Health  
Sciences

Ethics number: 46744

UNIVERSITY OF  
**Southampton**

## How does your trunk movement relate to ARM function?



- ✓ Have you had a stroke more than six months ago?
- ✓ Do you have arm problems?
- ✓ Are you over 18 years old?
- ✓ Are you interested in taking part in research?

We will capture your trunk movement using three sensors while you perform 8 simple arm tasks in a seated position.

This project will require 2 visits to the laboratory in the University of Southampton, Faculty Health Sciences (Building 67).

Your participation would be greatly appreciated. If you are interested, please contact Norah Alhwoaimel:

Trunk Research Norah na1n15@soton.ac.uk Tel: (0)23 80592021						
--	--	--	--	--	--	--

## Appendix 18 Streamlined Wolf Motor Function Test

Participant ID : \_\_\_\_\_

Assessment session: 1 / 2

Date of assessment : \_\_\_\_\_

Assessor : \_\_\_\_\_ Signature : \_\_\_\_\_

Arm tested :  More affected  Less affected

Task	Time (seconds)	Functional Ability scale						Remarks
		0	1	2	3	4	5	
Hand to box (front)		0	1	2	3	4	5	
Hand to table (front)		0	1	2	3	4	5	
Lift can		0	1	2	3	4	5	
Lift pencil		0	1	2	3	4	5	
Fold towel		0	1	2	3	4	5	
Turn key in lock		0	1	2	3	4	5	
Extend elbow (1 lb weight)		0	1	2	3	4	5	
Reach and retrieve		0	1	2	3	4	5	

Mean Time	Mean FAS

Score	Functional Ability Scale (FAS)
0	Does not attempt
1	Does not participate functionally – attempt to make use of upper extremity (UE)
2	Does, but requires assistance of the UE not being tested for minor readjustments or change of position; or require more than 2 attempts to complete; or accomplishes very slowly
3	Does, but movement is influenced to some degree by synergy or is performed slowly or with effort
4	Does; movement close to normal but slightly slower; may lack precision, fine coordination or fluidity
5	Movement appears normal

### Reference:

Bogard K, Wolf S, Zhang Q, Thompson P, Morris D and Nichols-Larsen D (2009) Can the Wolf Motor Function Test be streamlined? *Neurorehabilitation and Neural Repair* 23(5): 422- 428

**\*This outcome measure is freely available for use and reproduction**

## Appendix 19 MATLAB scripts for data processing – 2<sup>nd</sup> study

```
close all
clear all

eFname = '\\filestore.soton.ac.uk\users\naln15\mydocuments\4th year
documents\matlab SWMFT\SWMFT_undergrad_results.xlsx';

prompt = {'Dominant Session 1A','Non-Dominant Session 1A','Dominant
Session 1B','Non-Dominant Session 1B','Dominant Session 2A','Non-Dominant
Session 2A','Dominant Session 2B','Non-Dominant Session 2B'};

for i = 1 : 8
    f(i).fid =
uipickfiles('FilterSpec','\\filestore.soton.ac.uk\users\naln15\mydocument
s\4th year documents\matlab SWMFT\UG 2019-2020\OneDrive_2019-12-02\Team
Trunk','Prompt',prompt{i});
end

sideQ = questdlg('Which was their dominant
side?','Side','Right','Left','Right');

e = actxserver('Excel.Application');
e.Visible = 1;
e.DisplayAlerts = 0;

eWorkbook = e.Workbooks.Open(eFname);

prompt = {'Participant ID:'};
dlg_title = 'ID';
num_lines = 1;
defaultans = {'0'};
answer = inputdlg(prompt,dlg_title,num_lines,defaultans);

ID = str2double(answer{1});

h = waitbar(0,'Please wait...');

row = num2str(ID + 4);
rowD = ID + 4;

for k = 1 : 8

    clear Results results results_temp num SensorOne SensorTwo SensorThree
SensorOneE SensorTwoE SensorThreeE d raw

    results_temp = [];

    if k == 1 || k == 2
        s = 1;
    end

    if k == 3 || k == 4
        s = 2;
```

```

end

if k == 5 || k == 6
    s = 3;
end

if k == 7 || k == 8
    s = 4;
end

eSheet = eWorkbook.Sheets.get('Item',s);
eSheet.Activate

    oddeve = mod(k,2);

    if oddeve == 1
        eActivesheetRange = get(eSheet,'Range',['C' num2str(row) ':BF'
num2str(row)]);
    else
        eActivesheetRange = get(eSheet,'Range',['BG' num2str(row) ':DI'
num2str(row)]);
    end

    if strcmp(sideQ,'Right') && oddeve == 1
        side = 1;
    end

    if strcmp(sideQ,'Right') && oddeve == 0
        side = 0;
    end

    if strcmp(sideQ,'Left') && oddeve == 1
        side = 0;
    end

    if strcmp(sideQ,'Left') && oddeve == 0
        side = 1;
    end

for j = 1 : 8

    [num,txt,row] = xlsread(f(k).fid{j});

    d = str2double(row);

    SensorOne = d(3:size(d,1),1:4);
    SensorOne(:,5) = d(3:size(d,1),9);
    SensorTwo = d(3:size(d,1),10:13);
    SensorTwo(:,5) = d(3:size(d,1),18);
    SensorThree = d(3:size(d,1),19:22);
    SensorThree(:,5) = d(3:size(d,1),27);

    SensorOneE = zeros(size(SensorOne,1),5);
    SensorTwoE = zeros(size(SensorTwo,1),5);
    SensorThreeE = zeros(size(SensorThree,1),5);

```

```

for i = 1 : size(SensorOne,1) %Calculate Excursion.

    SensorOneE(i,:) = SensorOne(i,:) - SensorOne(1,:);
    SensorTwoE(i,:) = SensorTwo(i,:) - SensorTwo(1,:);
    SensorThreeE(i,:) = SensorThree(i,:) - SensorThree(1,:);

end

if j <= 4

    results(j).task(:,1) = max(SensorThreeE(:,2));

    results(j).task(:,2) = min(SensorThreeE(:,3));
    results(j).task(:,3) = max(SensorThreeE(:,3));
    results(j).task(:,4) = min(SensorThreeE(:,4));
    results(j).task(:,5) = max(SensorThreeE(:,4));

    results(j).task(:,6) = min(SensorTwoE(:,3));
    results(j).task(:,7) = max(SensorTwoE(:,3));
    results(j).task(:,8) = min(SensorTwoE(:,4));
    results(j).task(:,9) = max(SensorTwoE(:,4));

    end

if j == 5

    results(j).task(:,1) = max(SensorThreeE(:,2));

    if side == 1
        results(j).task(:,2) = min(SensorThreeE(:,3)); % Check
frontal plane of trunk sensor was needed.
    else
        results(j).task(:,2) = max(SensorThreeE(:,3)); % Check
frontal plane of trunk sensor was needed.
    end

    results(j).task(:,3) = min(SensorTwoE(:,3));
    results(j).task(:,4) = max(SensorTwoE(:,3));
    results(j).task(:,5) = min(SensorTwoE(:,4));
    results(j).task(:,6) = max(SensorTwoE(:,4));

end

if j == 6

    results(j).task(:,1) = max(SensorThreeE(:,2));

    results(j).task(:,2) = min(SensorTwoE(:,3));
    results(j).task(:,3) = max(SensorTwoE(:,3));
    results(j).task(:,4) = min(SensorTwoE(:,4));
    results(j).task(:,5) = max(SensorTwoE(:,4));

end

if j == 7

    results(j).task(:,1) = max(SensorThreeE(:,2));
    results(j).task(:,2) = min(SensorThreeE(:,2));

```

```

end

if j == 8

    results(j).task(:,1) = max(SensorThreeE(:,2));
    results(j).task(:,2) = max(SensorTwoE(:,2));

    if side == 1

        results(j).task(:,3) = min(SensorThreeE(:,3));
        results(j).task(:,4) = max(SensorThreeE(:,4)); % Check
that rotation to non-dominant side is what is needed

        results(j).task(:,5) = min(SensorTwoE(:,3));
        results(j).task(:,6) = max(SensorTwoE(:,4)); % Check that
rotation to non-dominant side is what is needed

    else

        results(j).task(:,3) = max(SensorThreeE(:,3));
        results(j).task(:,4) = min(SensorThreeE(:,4)); % Check
that rotation to non-dominant side is what is needed

        results(j).task(:,5) = max(SensorTwoE(:,3));
        results(j).task(:,6) = min(SensorTwoE(:,4)); % Check that
rotation to non-dominant side is what is needed

    end

for i = 1 : 8
    results_temp = [results_temp results(i).task];
end

if oddeve == 1
    Results = [ID results_temp];
else
    Results = [results_temp];
end

eActivsheetRange.Value = Results;

waitbar(k/8,h);

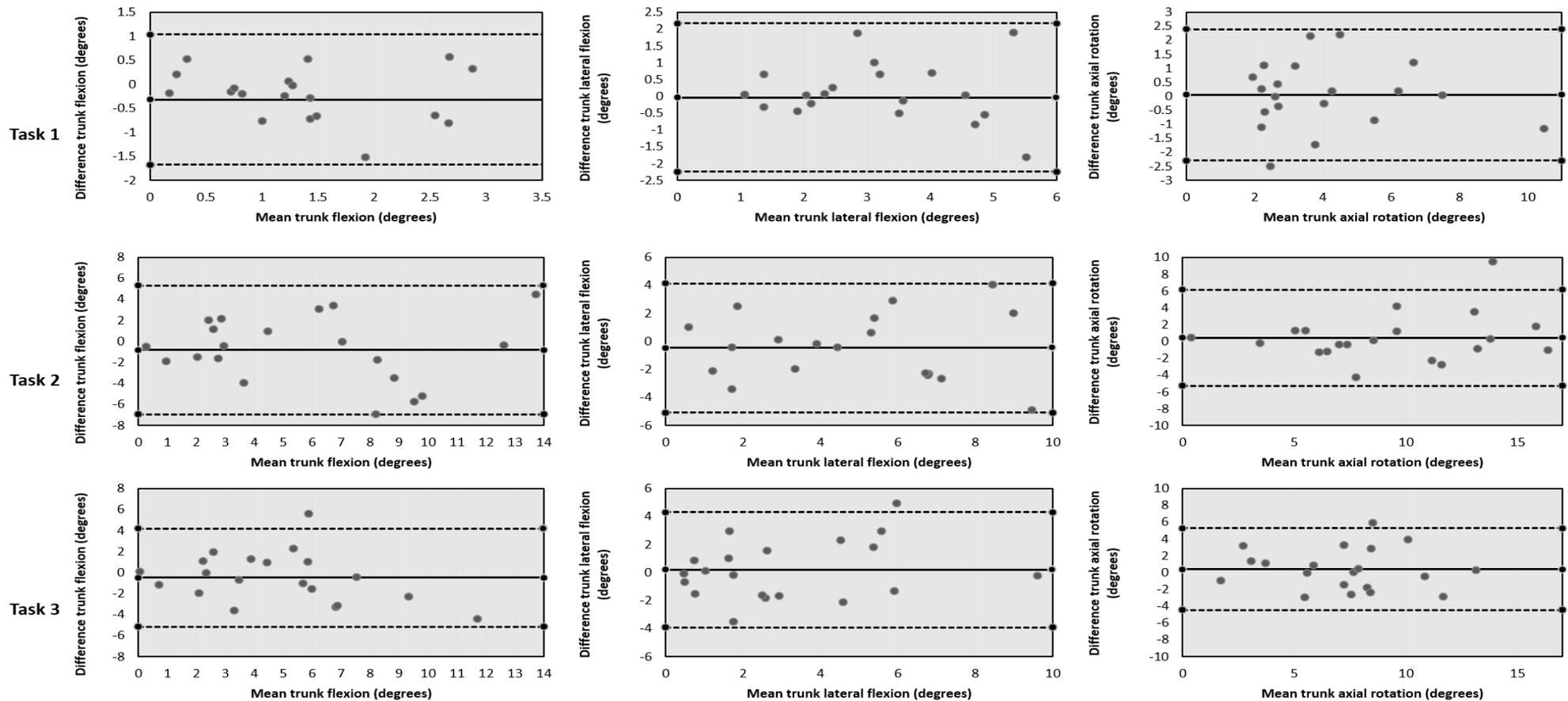
end

close(h)
invoke(eWorkbook, 'SaveAs', eFname);
invoke(e, 'Quit');
delete(e);

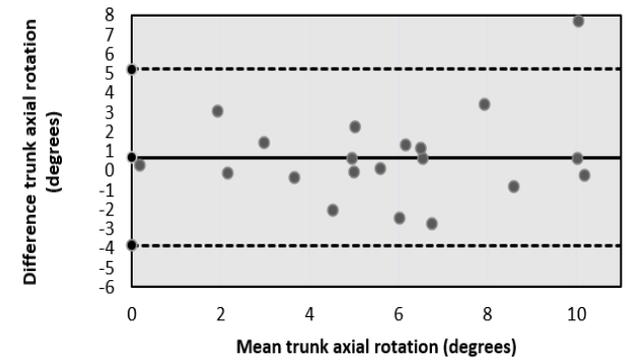
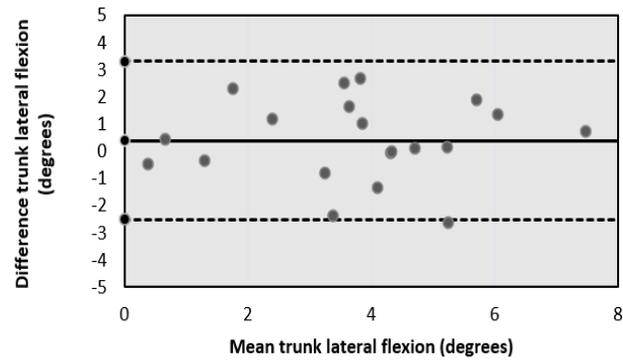
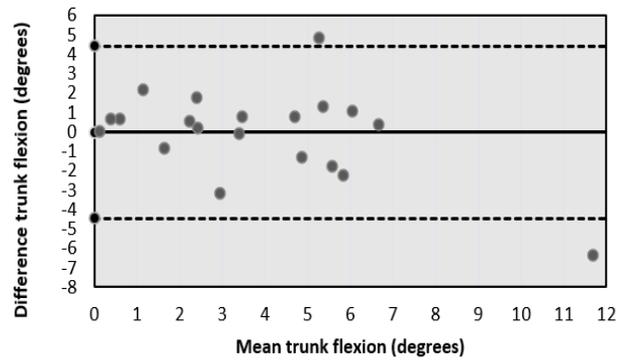
```

## Appendix 20 Bland and Altman plots for Intra-rater reliability (within same session)

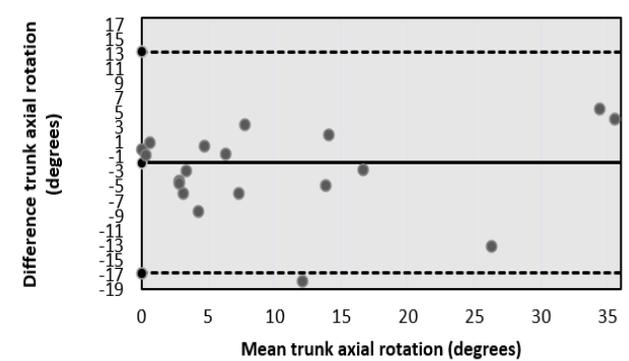
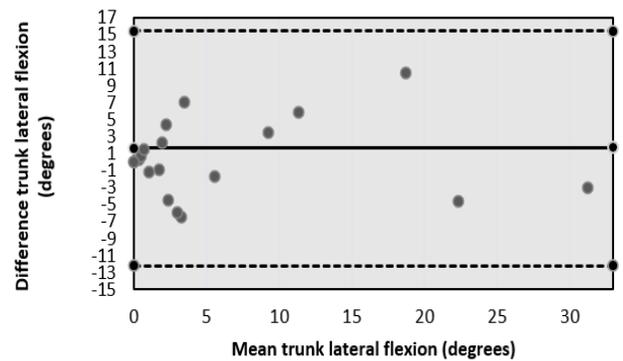
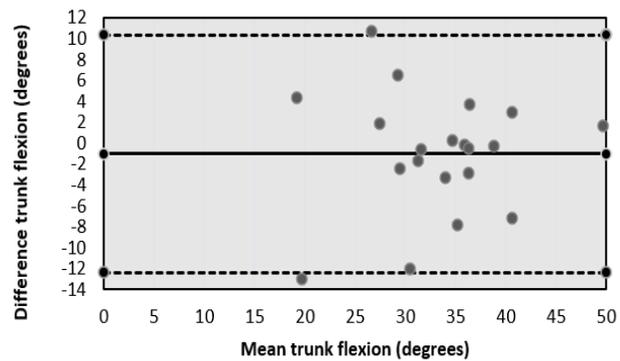
### 1- Healthy



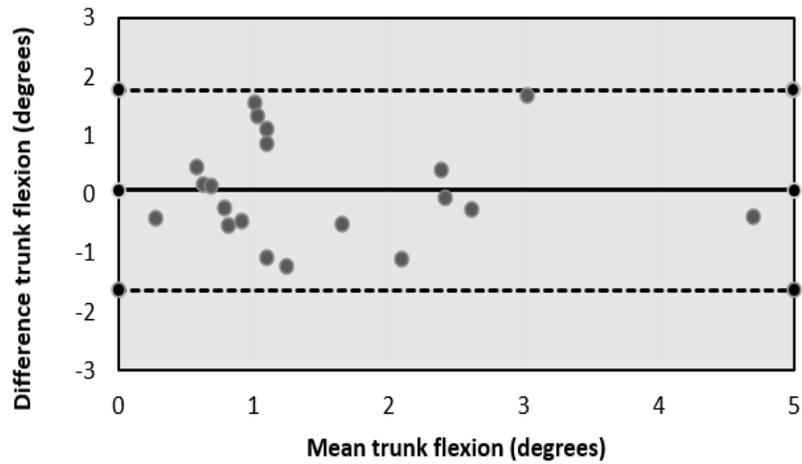
Task 4



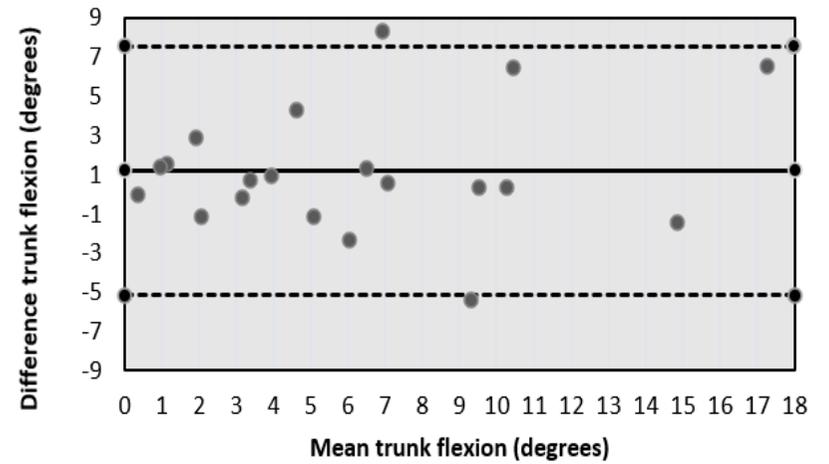
Task 5



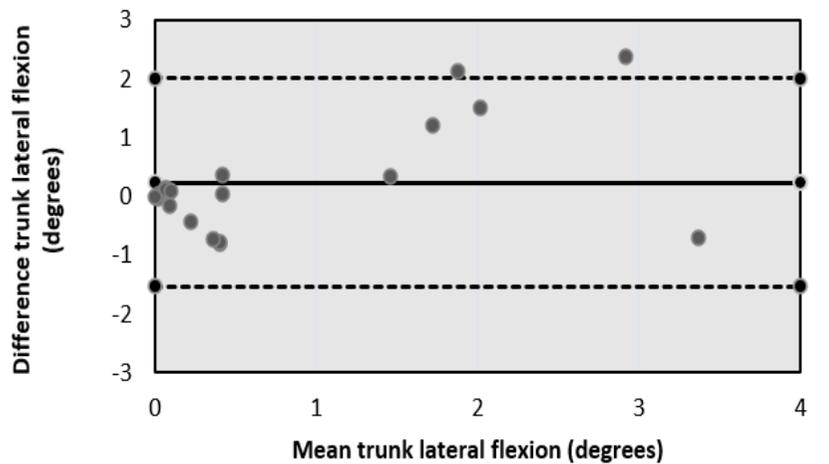
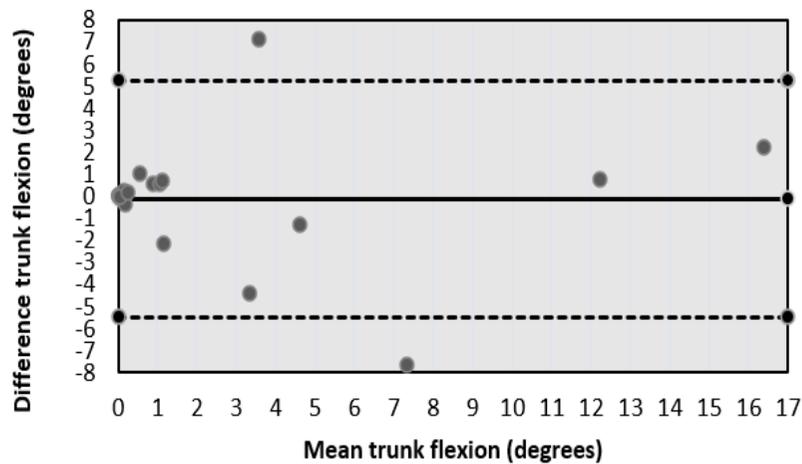
Task 6



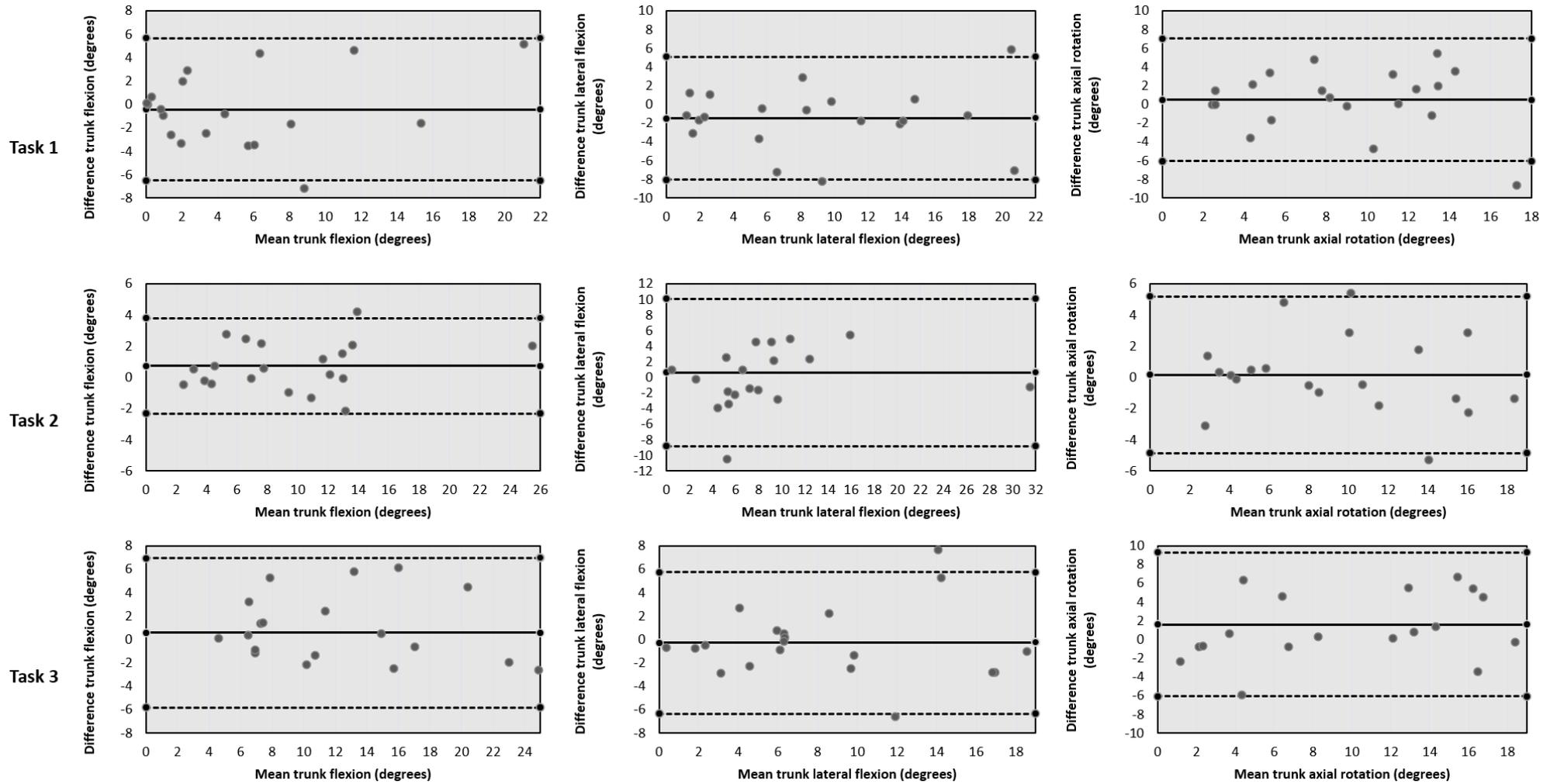
Task 7



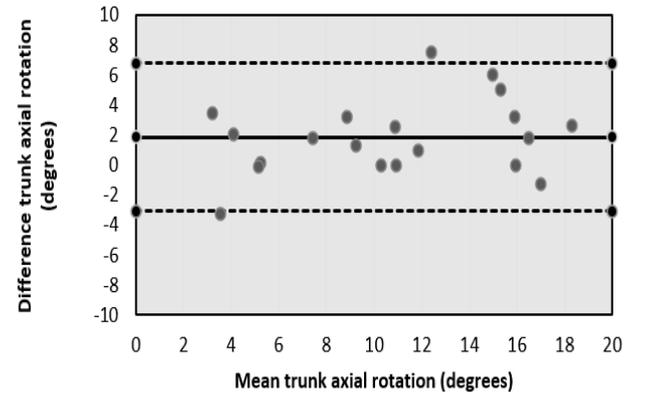
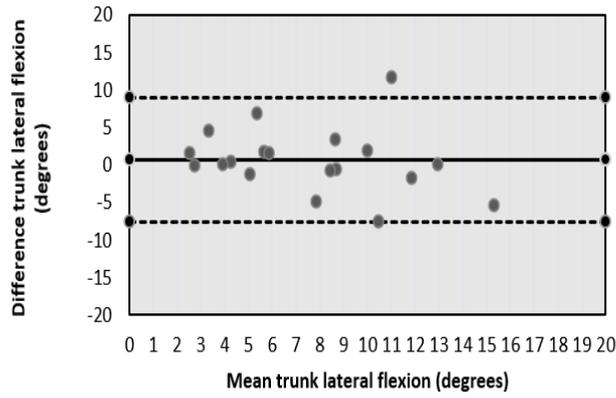
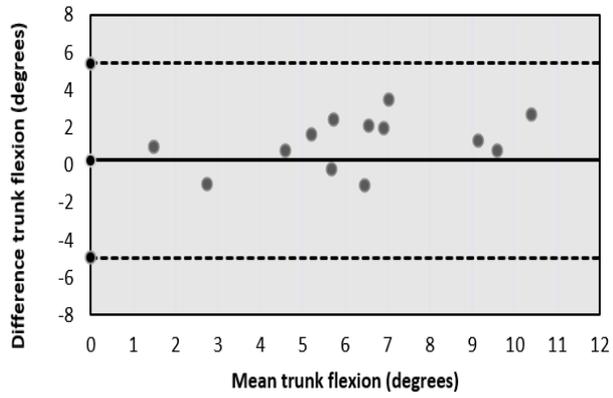
Task 8



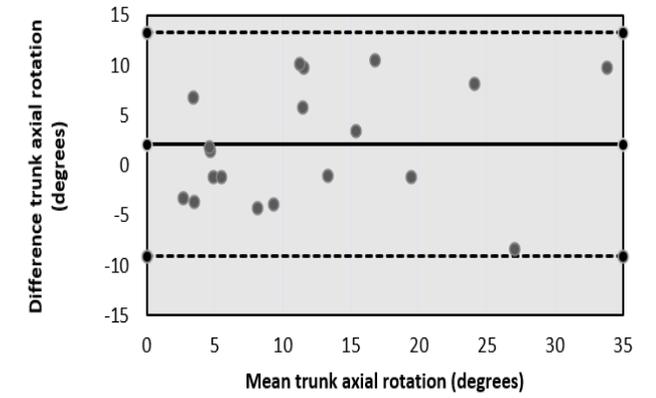
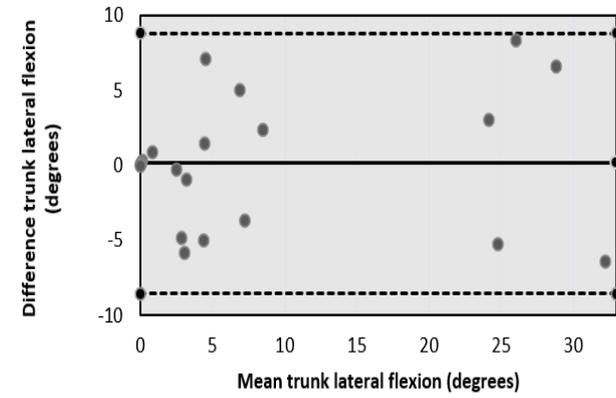
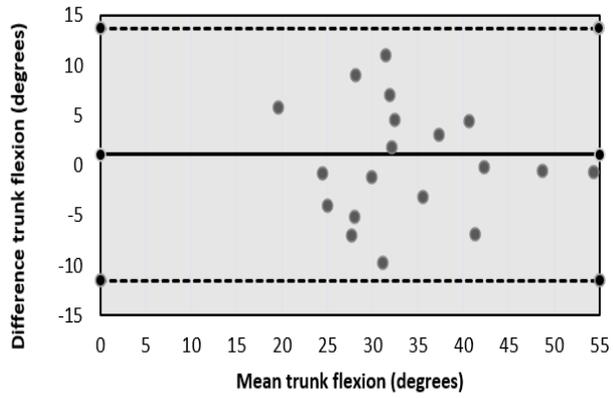
## 2- Stroke



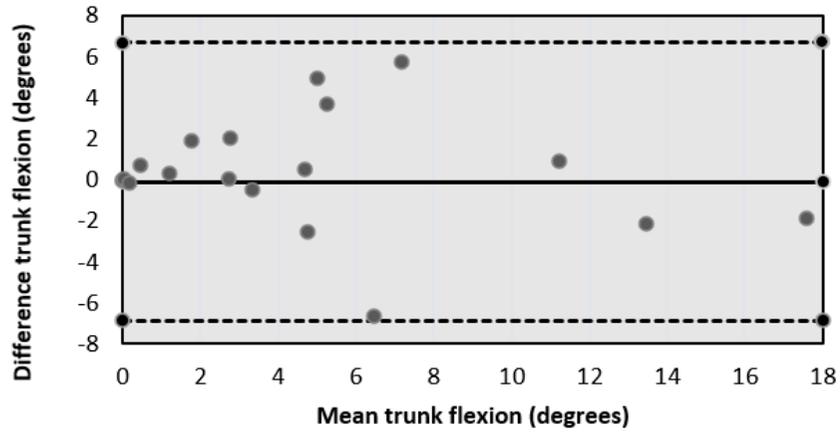
Task 4



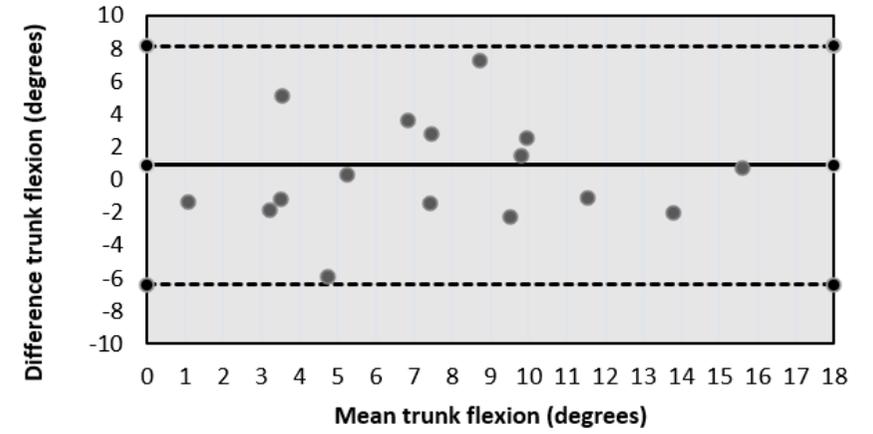
Task 5



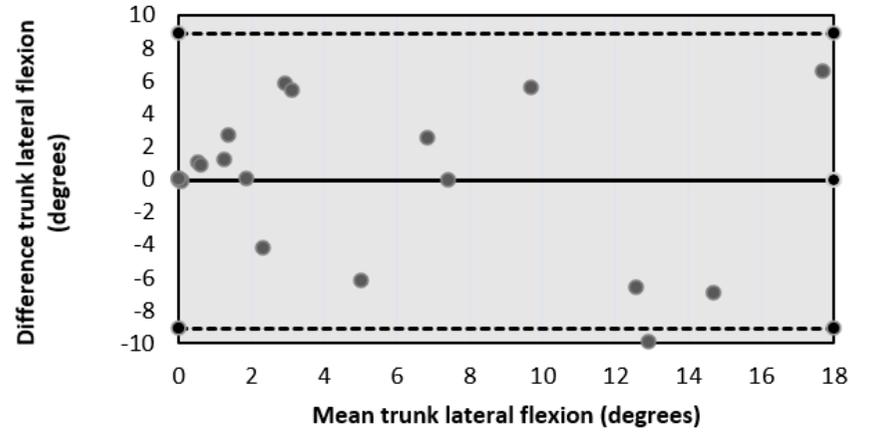
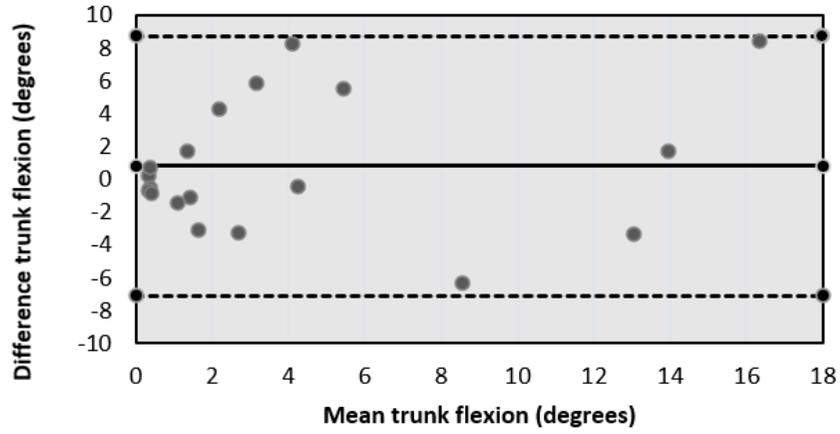
Task 6



Task 7

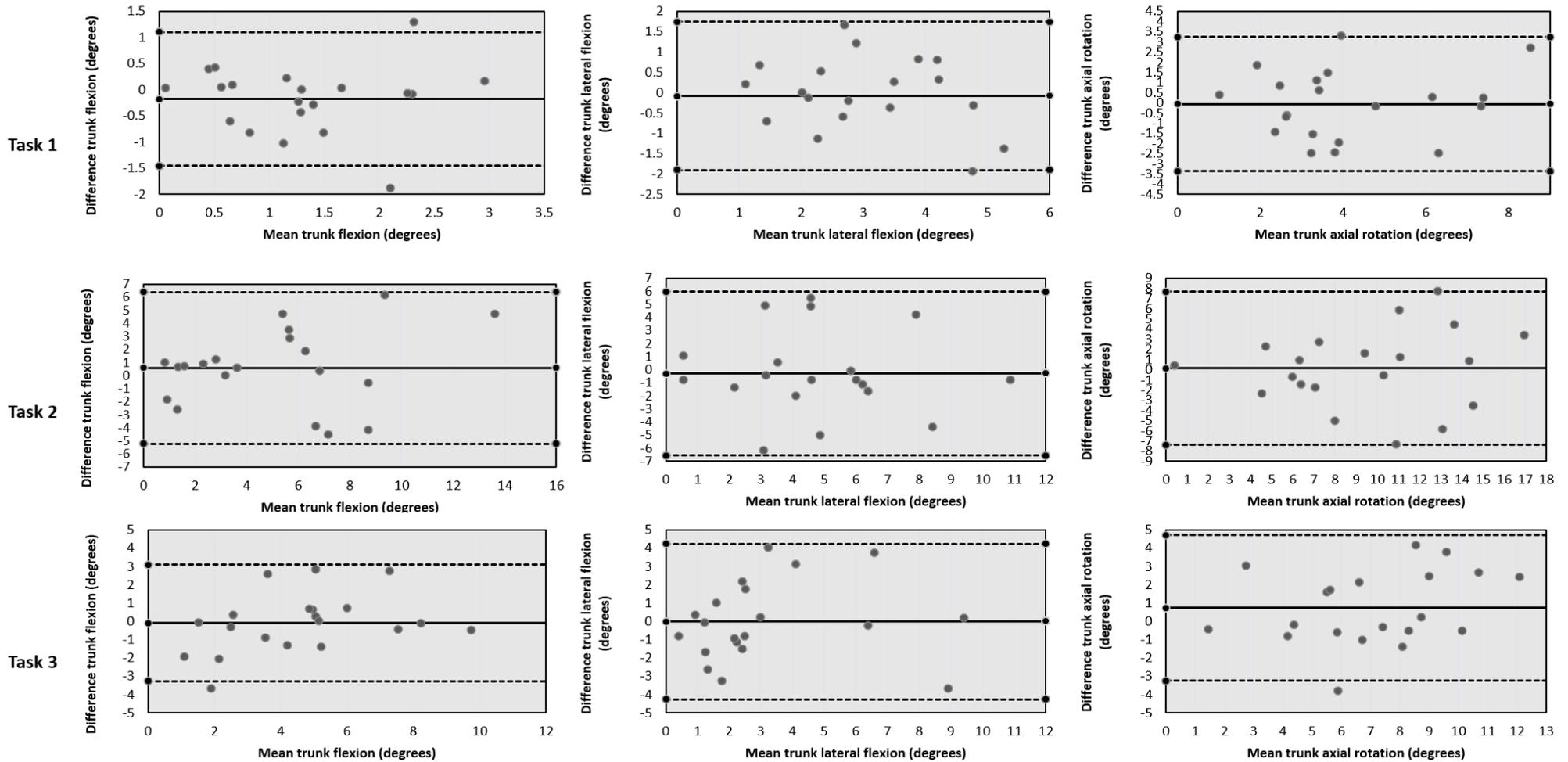


Task 8

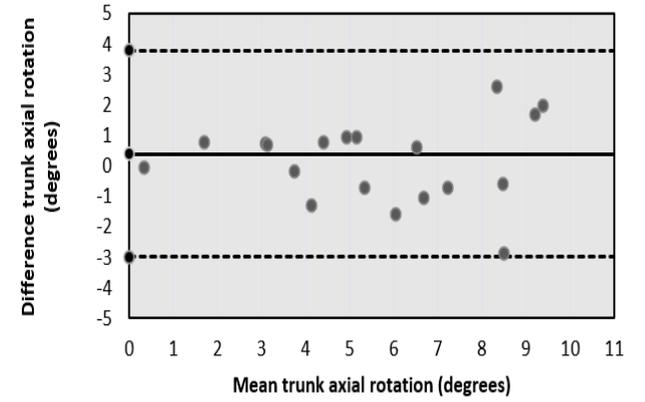
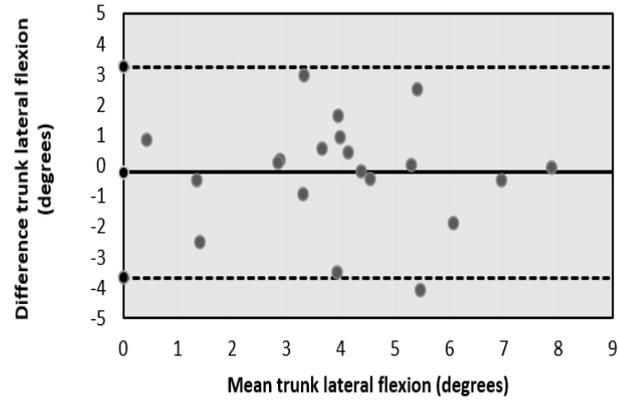
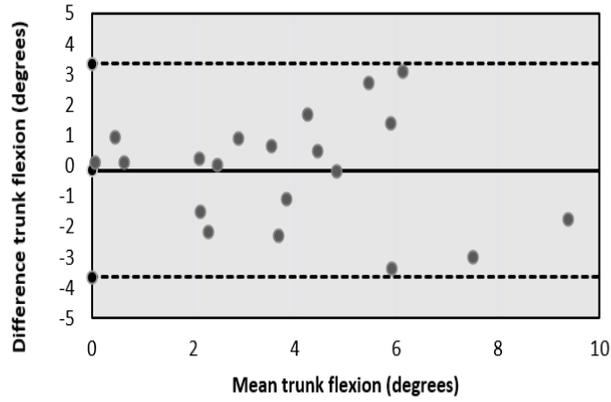


# Appendix 21 Bland and Altman plots for Intra-rater reliability (between two days sessions)

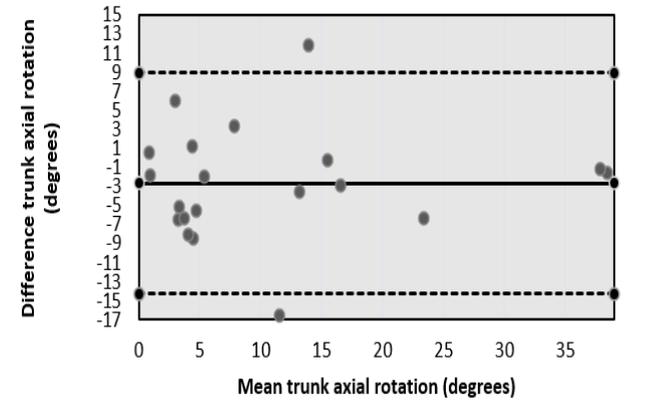
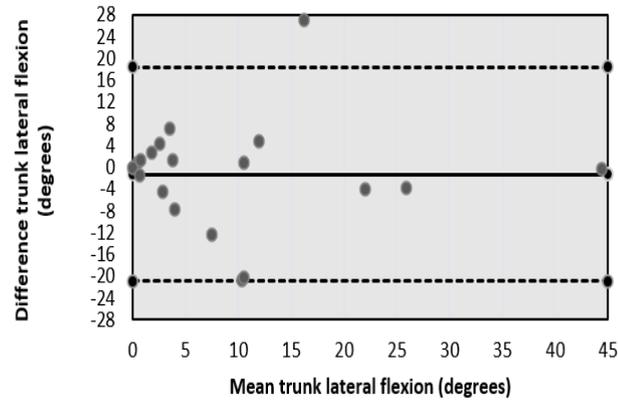
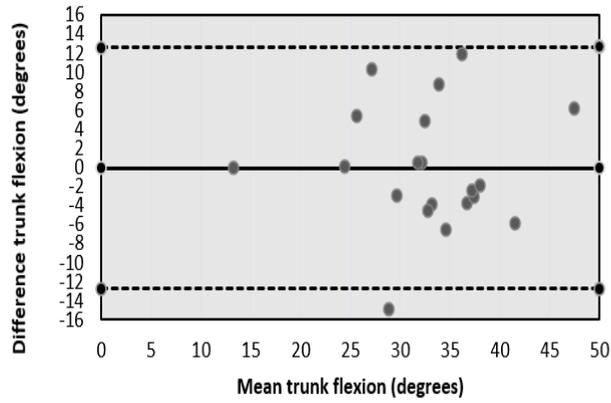
## 1- Healthy



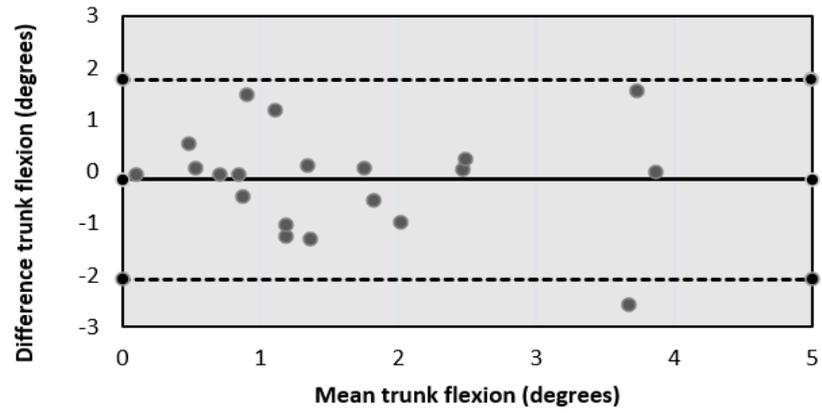
Task 4



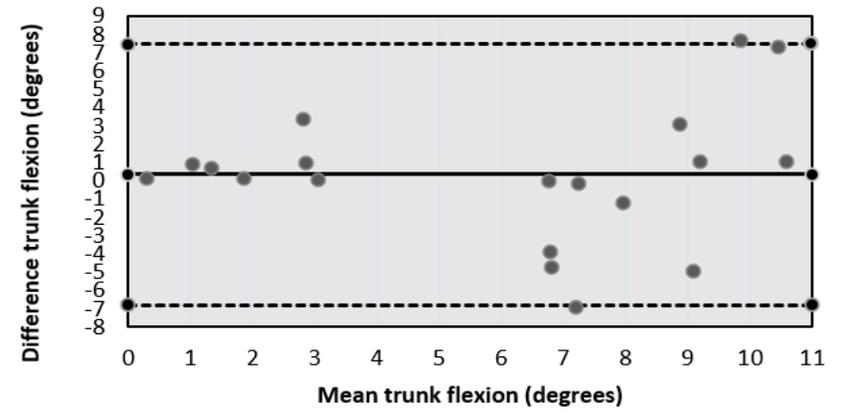
Task 5



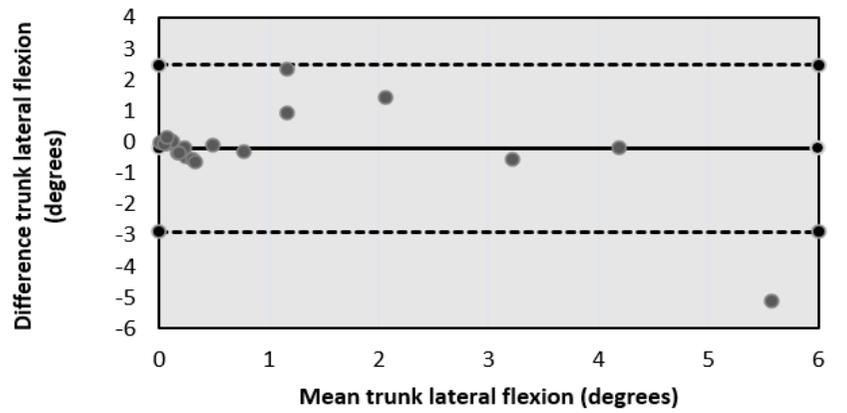
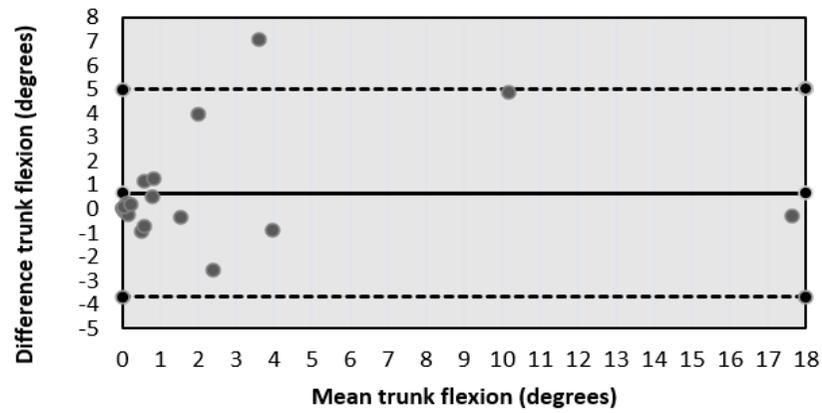
Task 6



Task 7

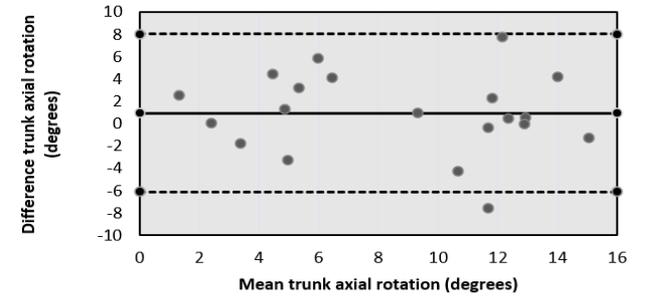
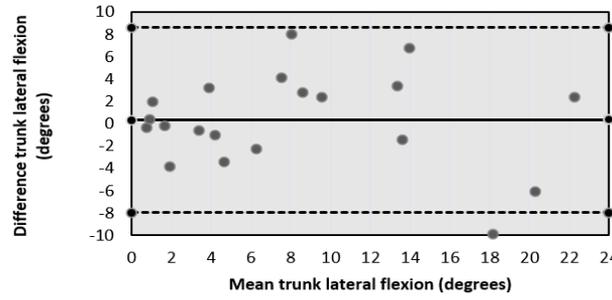
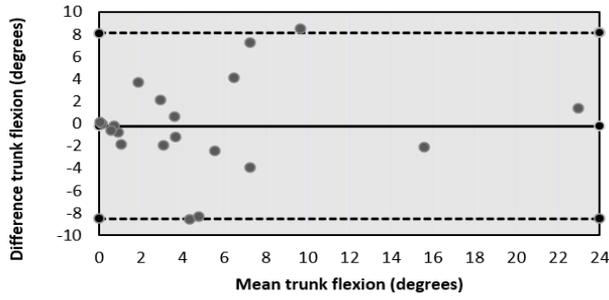


Task 8

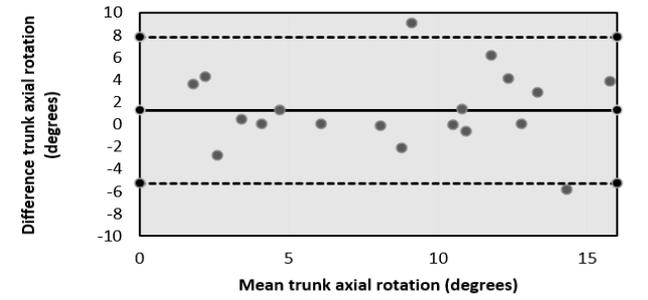
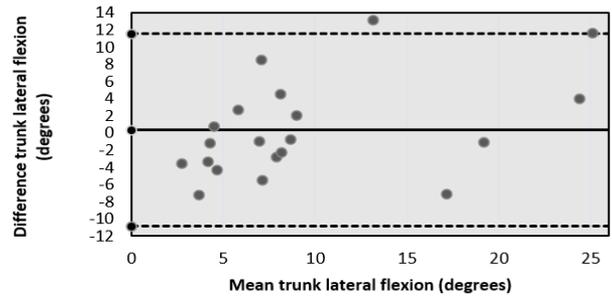
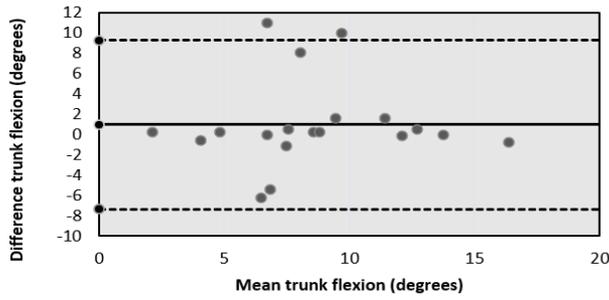


## 2-Stroke

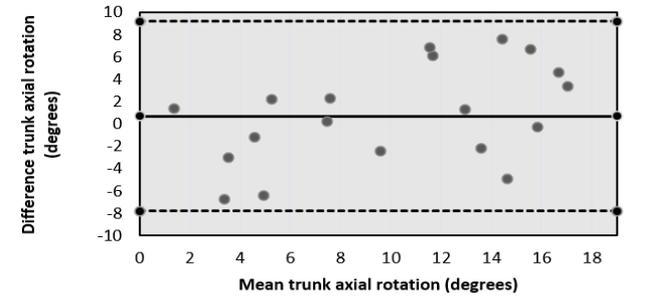
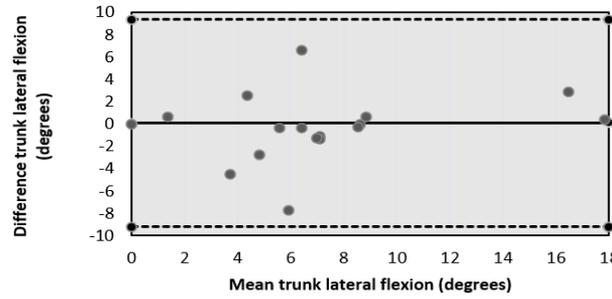
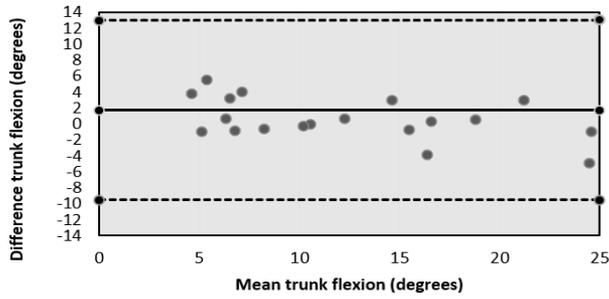
Task 1



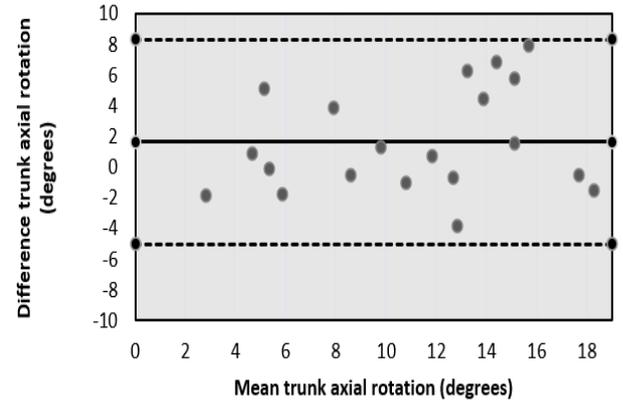
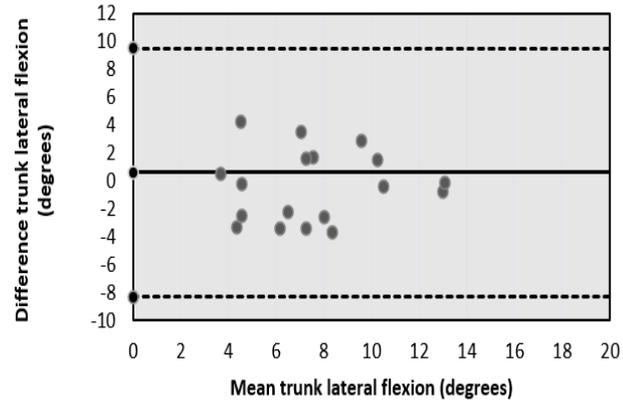
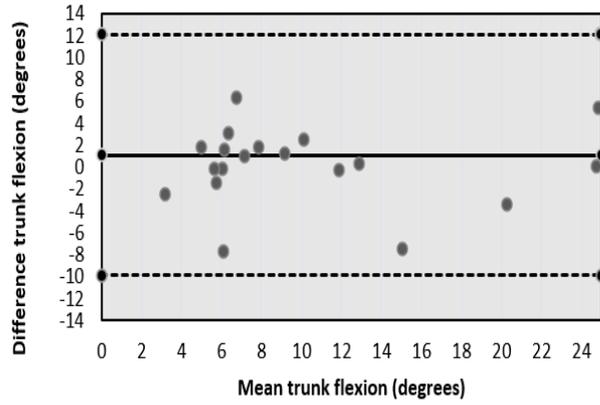
Task 2



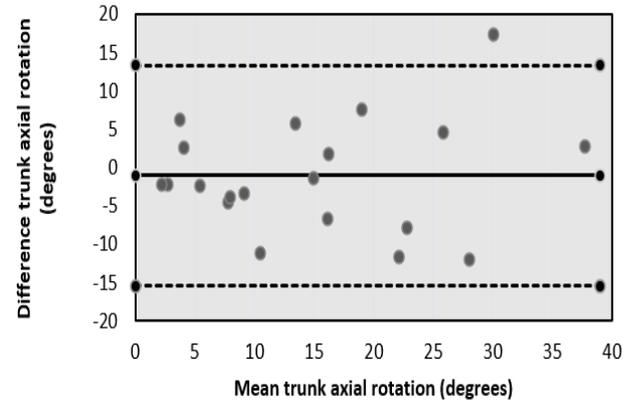
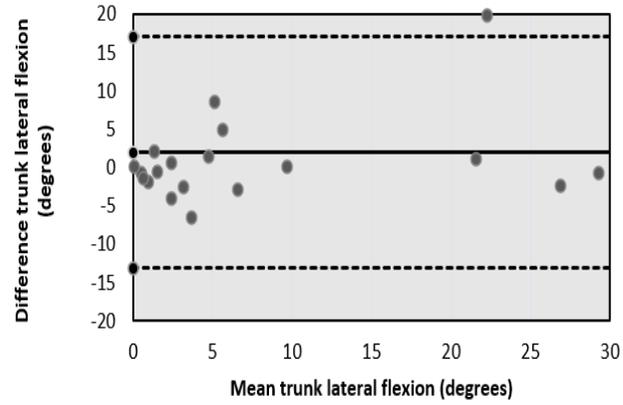
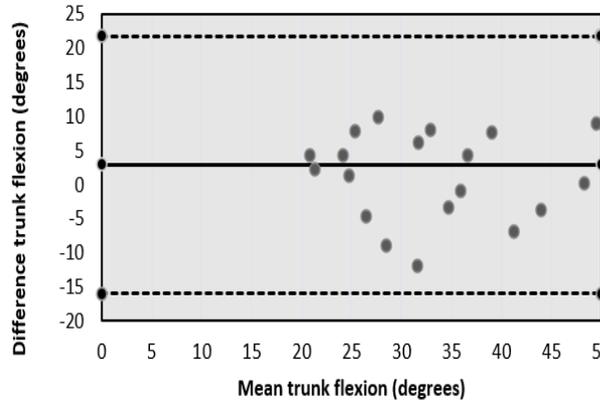
Task 3



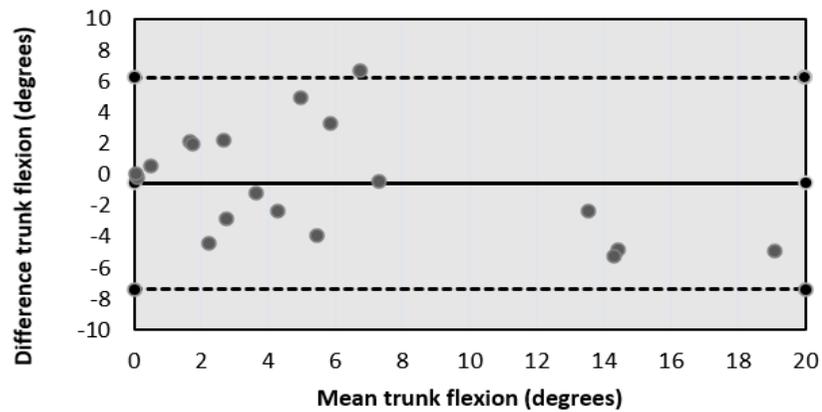
Task 4



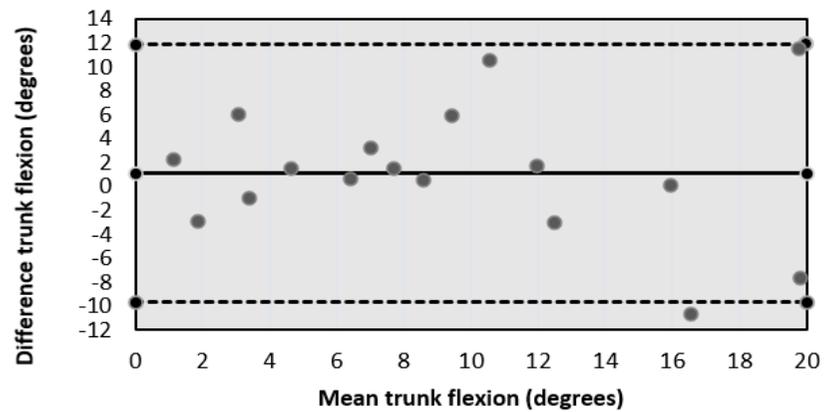
Task 5



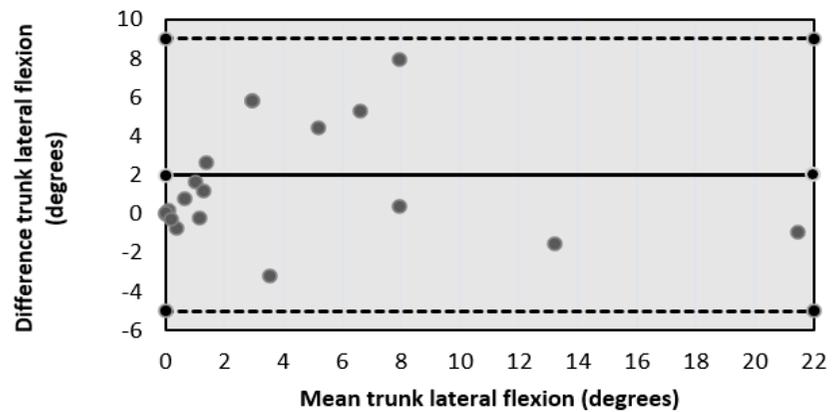
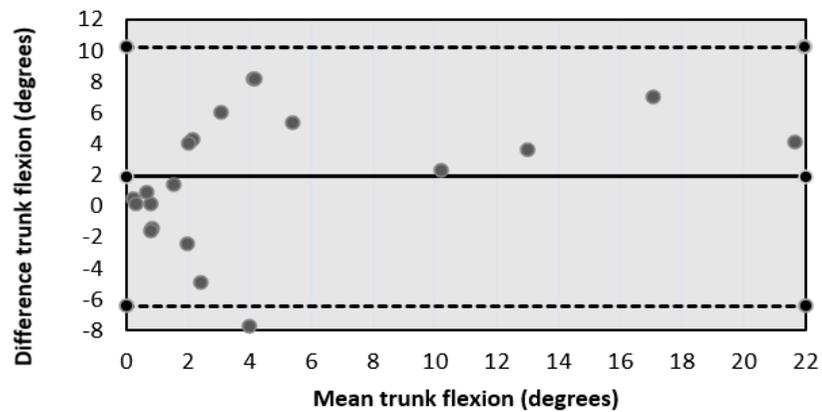
Task 6



Task 7

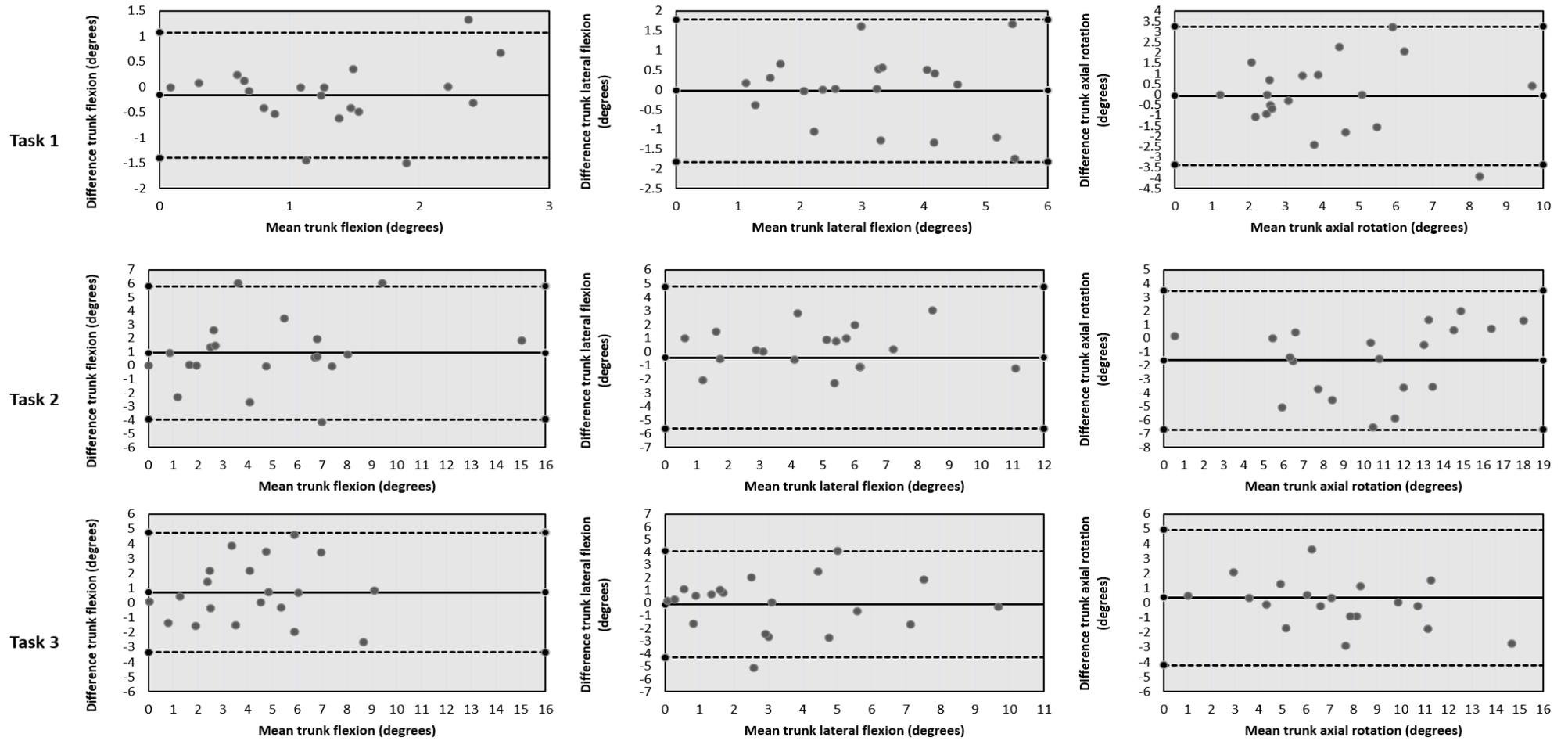


Task 8

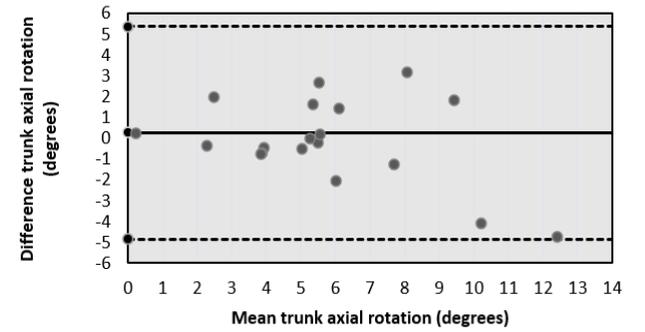
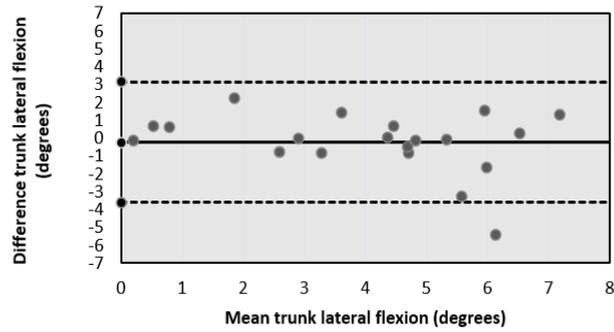
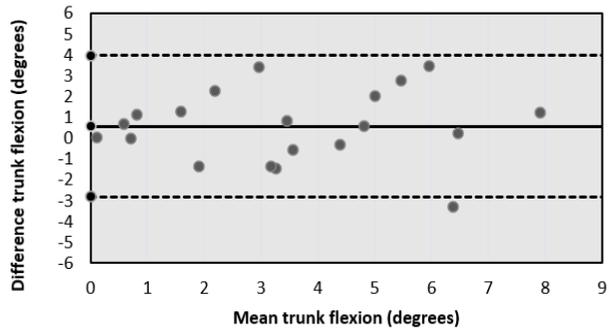


## Appendix 22 Bland and Altman plots for Inter-rater reliability

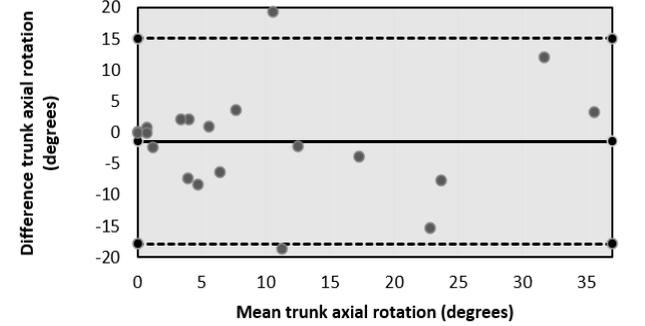
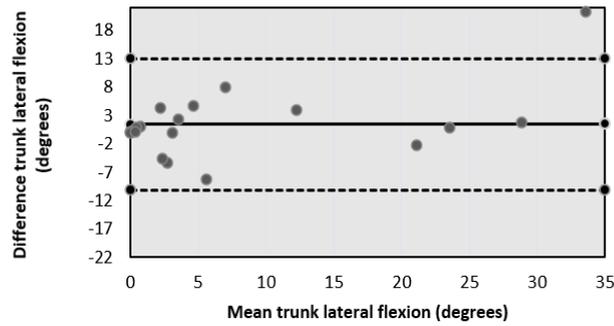
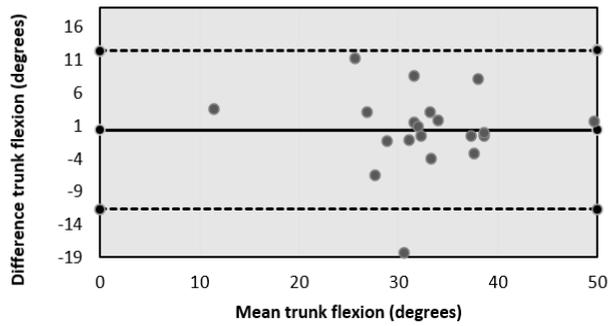
### 1- Healthy



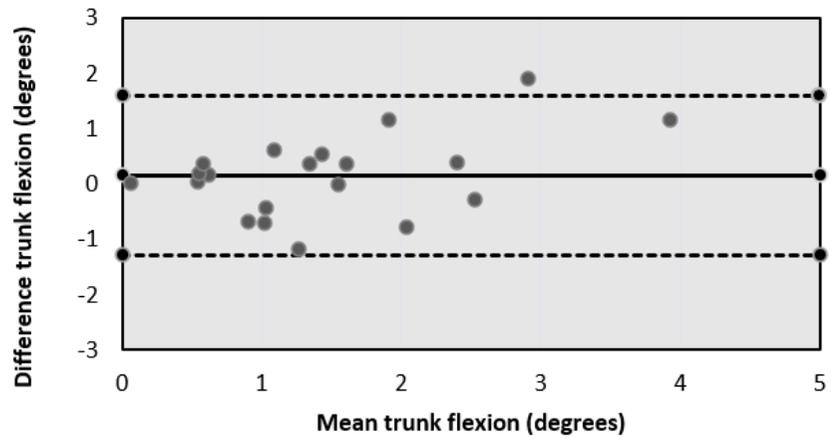
Task 4



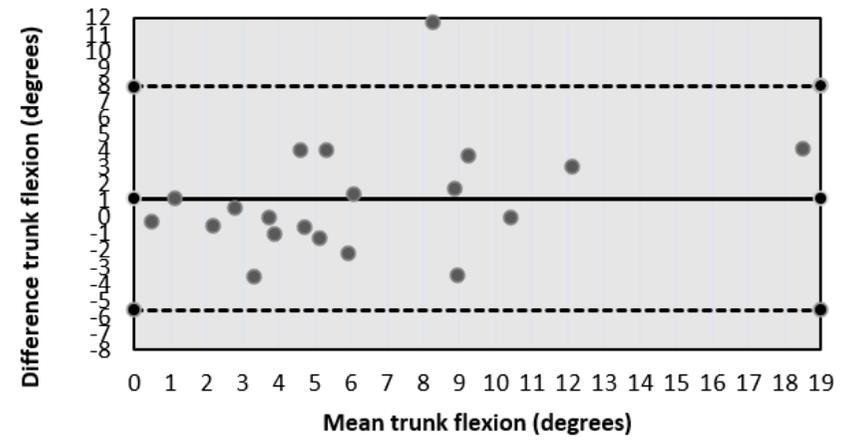
Task 5



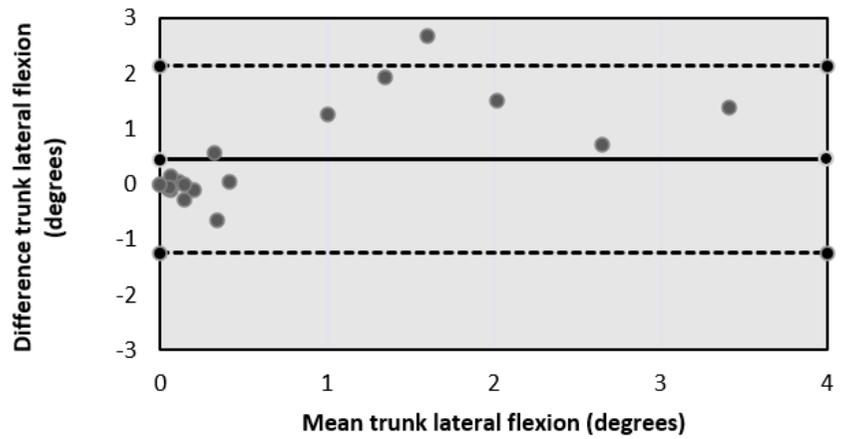
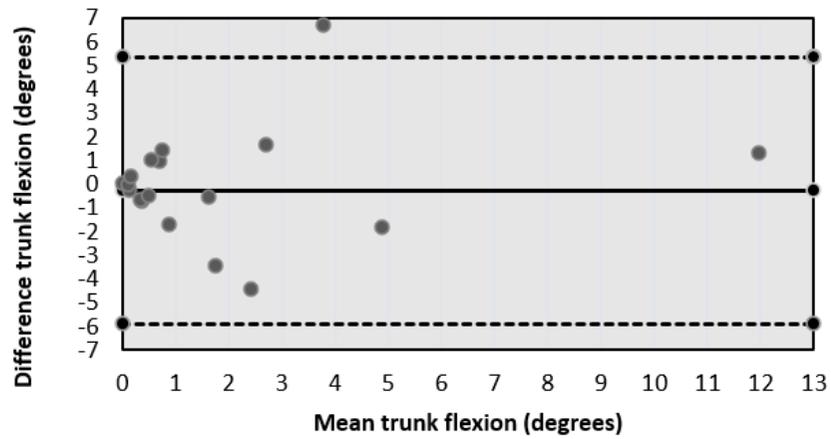
Task 6



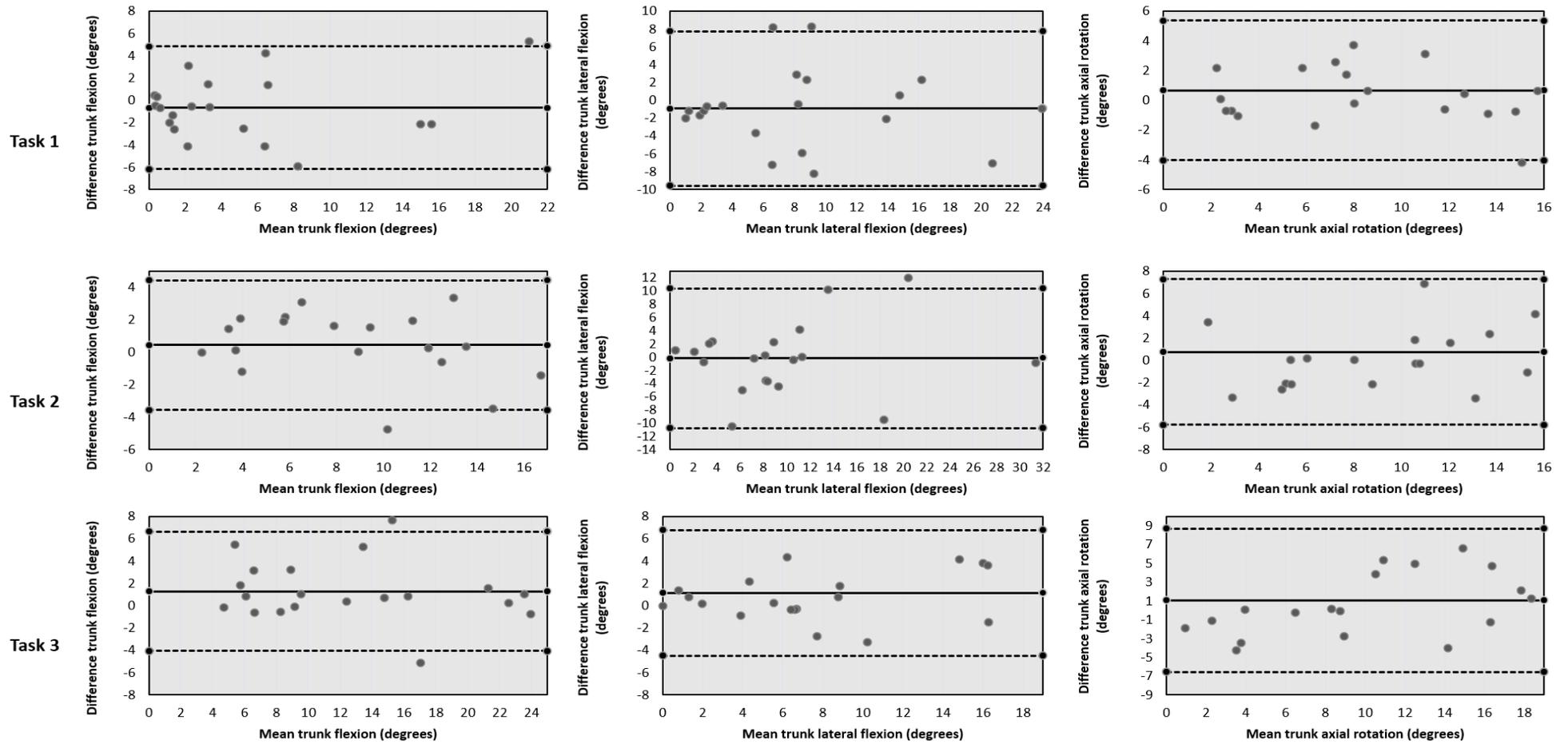
Task 7



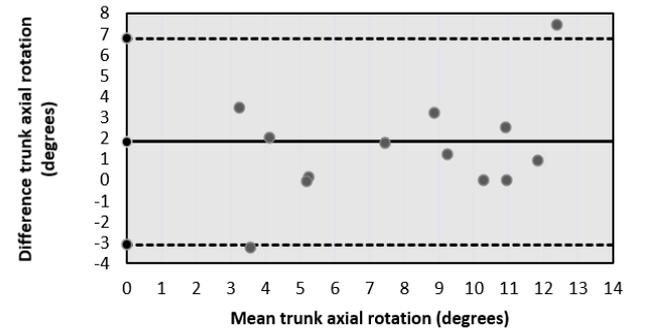
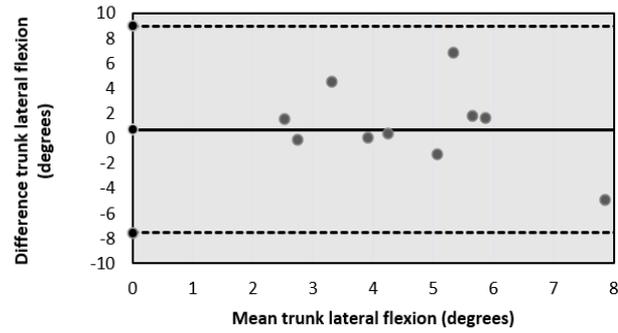
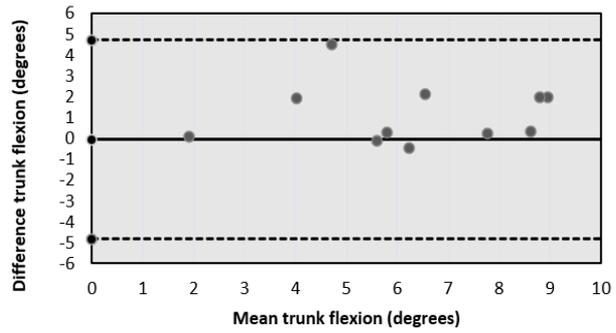
Task 8



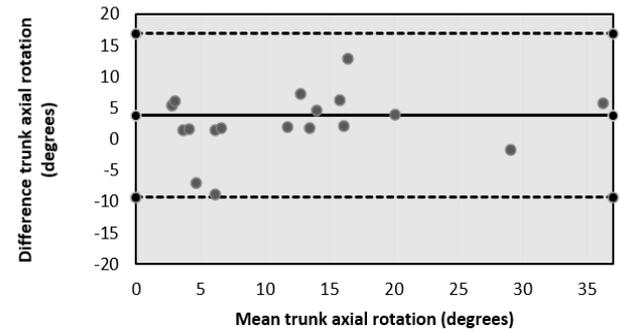
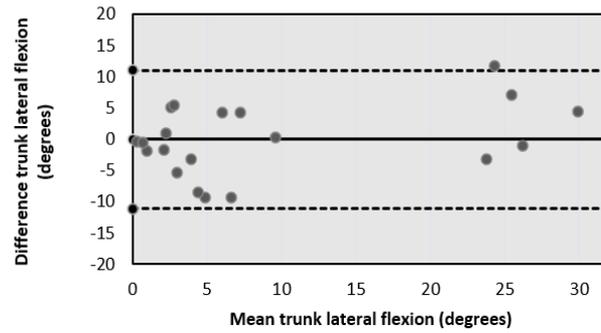
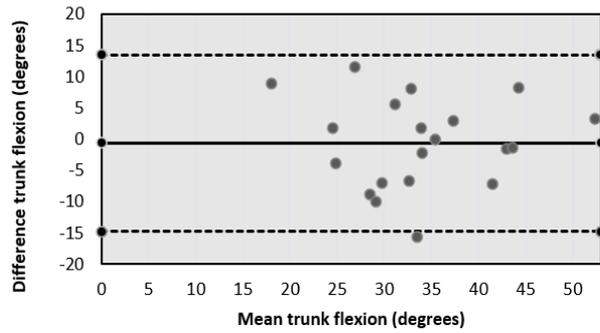
## 2- Stroke



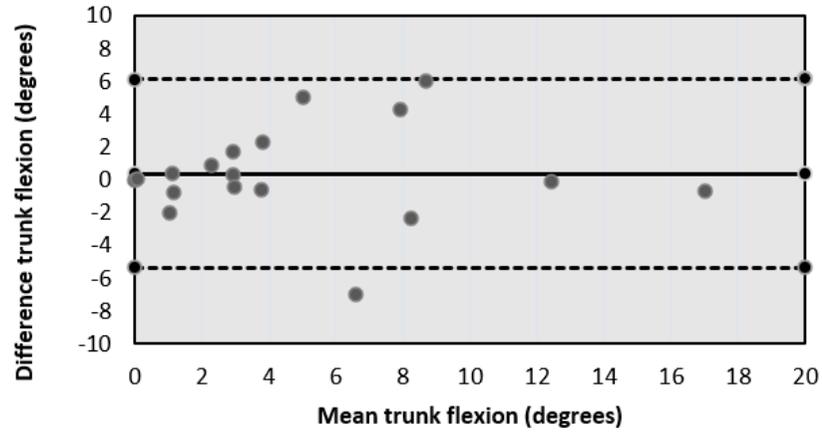
Task 4



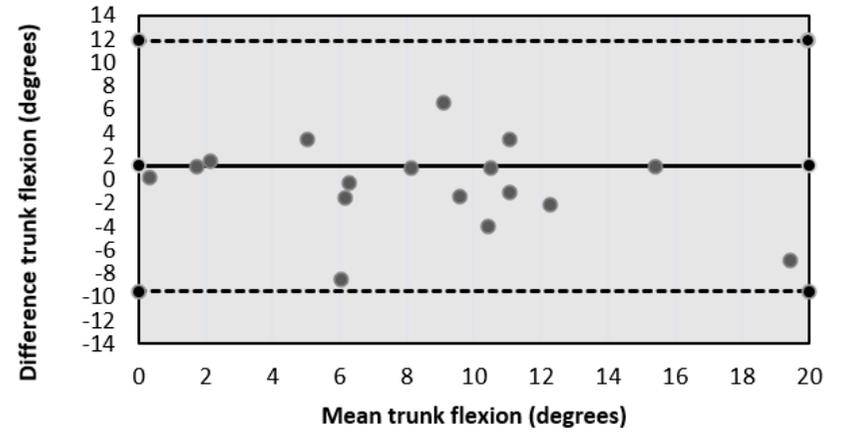
Task 5



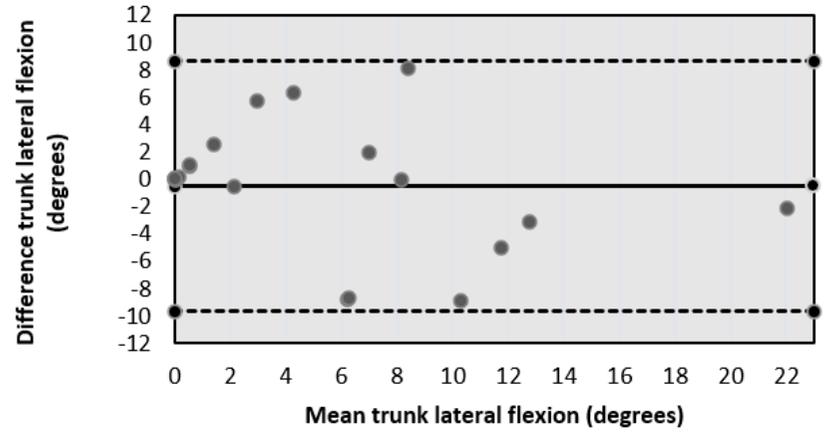
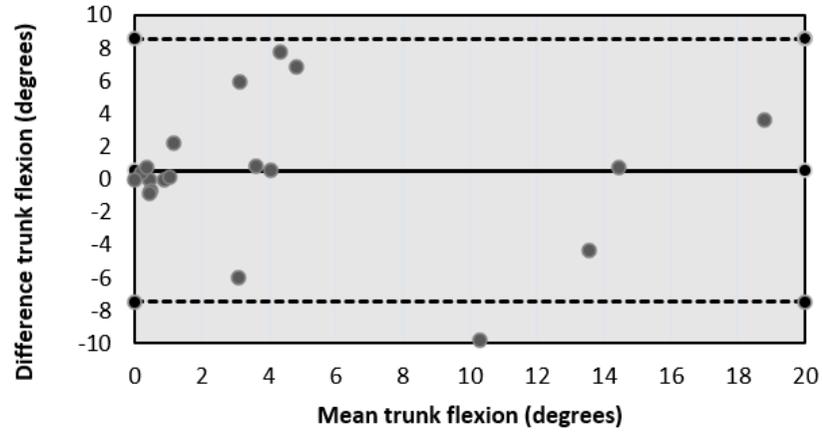
Task 6



Task 7



Task 8



## Appendix 23 Invitation letter – feasibility study



Dear Sir / Madam

We would like to invite you to take part in a research study based at the University of Southampton. This study aims to develop a new intervention to train trunk movement in people with stroke.

To do this we need the help of people who had a stroke more than 6 months ago.

We have also sent an information sheet that explains in more detail what the study involves. Please take time to read the information sheet carefully. We are happy to answer any questions if anything you read is not clear or if you would like more information. Please find the contact details of the researchers at the end of this letter.

If you are interested in taking part in this study, please complete and return the reply slip, email or call us. We will ask you a few questions about your health to check if this project is suitable for you. Then, we will make an appointment at a convenient time and day for you to come in to the Faculty of Health Sciences, University of Southampton (Building 67)

Thank you for your consideration.

Yours faithfully,  
**Norah Alhwoaimel**

For more information: you can contact the researcher:

**Norah Alhwoaimel**  
Telephone : 02380592021 , Email: n.alhwoaimel@soton.ac.uk

## Appendix 24 Reply slip – feasibility study



### Reply slip:

**Yes I am interested in taking part in the study:** Trunk exercises using Valedo sensors and video games for people with chronic stroke

**Please contact me with further details.**

<b>NAME</b>	
<b>Age</b>	
<b>Date of stroke</b>	
<b>Which side is most affected</b>	
<b>TELEPHONE/ EMAIL</b>	
<b>BEST TIME TO CONTACT ME</b>	

**Please return this reply slip in the pre-paid envelope.**

**Thank you for your participation in the research.**

# Appendix 25 Participant information sheet (PIS) – feasibility study



## Participant Information Sheet

**Study Title: Trunk exercises using Valedo sensors and video games for people with chronic stroke**

**Researcher:** We are a team of Physiotherapists, Movement Scientists, and Doctors who have a specialist interest in stroke rehabilitation. Our names are Norah Alhwoaimel, Dr Ann-Marie Hughes, Dr Ruth Turk, Dr Federico Ferrari, Liselot Thijs, Dr Martin Warner, Professor Jane Burridge, Professor Geert Verheyden and Dr Seng Kwee Wee.

Federico is a Medical Doctor with four years' experience in neurological rehabilitation. Norah, Ann-Marie, Ruth, Jane, Geert, Liselot and Seng Kwee are physical therapists and Martin is a movement scientist. Norah is studying for her PhD at the Faculty of Health Sciences.

**ERGO number:** 30748

***Please read this information carefully before deciding to take part in this research. It is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.***

### **What is the research about?**

People with stroke tend to have problems controlling their body, particularly their trunk and arm, affecting their balance and interfering with their ability to carry out activity of daily living (ADL), such as turning in bed, sitting, rising from sitting to standing and walking. Stroke rehabilitation, often through exercises, aims to restore movement to as near normal as possible.

We want to see if practising trunk exercises using Valedo sensors and video games can change your ability to control your trunk.

### **Why have I been asked to participate?**

You have been chosen to take part in this study as we are looking for volunteers who have an interest in improving trunk control for people who have had a stroke. You have been contacted to take part as you are either a volunteer on the user databases in the Faculty of Health Sciences, University of Southampton, or you have shown interest in our research study.

[08/12/2017] [Version 1]

[Ethics number: 30748]

You have been chosen to take part in this study as you:

- had a stroke more than six months ago which has left you with some problems with your trunk balance.
- are not currently receiving any form of therapy
- are able to sit unsupported for 10 seconds
- are able to understand what this research project involves
- are able to understand and follow simple instructions (e.g. bending sideways, twisting your body to the right and left side)
- can commit to attending 18 sessions within 6-8 weeks.

In addition you do not have any of the following conditions:

- acute low back pain
- history of or current problems with your spine
- history of bones breaking for no apparent reason
- uncontrolled epilepsy
- an artificial hip
- Implanted materials or devices within the body (e.g. pace maker, hearing device).

**What will happen to me if I take part?**

If you return the form saying you are interested in taking part, you will be contacted by the researcher by telephone or by email. She will answer any questions you might have and will ask you some general questions. These questions will inform the researcher as to whether or not the research study is suitable for you. She will then make an appointment for you to come in to the Faculty of Health Sciences, University of Southampton (Building 45) at a convenient day and time for you.

You will need to make 20 visits (2 initial assessment visits and 18 sessions for trunk training program) over 6 – 8 weeks to the laboratory, each of which should take no longer than one and a half hours. A final assessment and interview will be combined

with either the last training session or if the participant prefers, within one week of the last training session.

**Are there any benefits in my taking part?**

We will reimburse a total travel expenses to a maximum 70£. You will be enrolled in a balance training programme devised for you by a qualified physiotherapist. In addition, the data collected may be useful for healthcare professionals to develop better rehabilitation programs for people with stroke in the future.

**Are there any risks involved?**

There are unlikely to be any side effects or risks from the intervention sessions. You may feel slightly tired during, at the end of, or after the sessions. During the sessions you may rest at any time. If you feel unable to continue, you may withdraw. Throughout the session, the researchers will ensure that you are comfortable.

**Will my participation be confidential?**

All the information collected about you during the course of this research will be kept strictly confidential. Any information about you on research report forms or publications will have your name and address removed so that you cannot be identified from it. A unique number will connect your data to your personal details. Your personal details will be kept separately from the research records. The data recorded, for the purpose of the research study, will be held on a password-protected computer or as paper records kept in a locked filing cabinet.

**What should I do if I want to take part?**

You will need to attend 21 sessions (3 sessions for assessment and 18 sessions for the training program) over 6 – 8 weeks. This will take place in the laboratory. Each session should take no longer than one and a half hours

In the laboratory, we will ask you to sit down and then will assess your ability to balance, your ability to control your trunk and your arm and leg impairment.

During balance assessment, the researcher will ask you to do 14 simple tasks from sitting and standing such as: stand without using your hands to support, turn to look behind and stand with one foot in front.

During your trunk assessment, the researcher will use three sensors (figure 1) and tape them on your skin using double sided medical tape (figure 2). She will ask you to sit down and do a series of 17 simple movements (such as cross your legs and bending sideways) to look at your ability to control your trunk. These movements will include static sitting (at a rest position), dynamic sitting (sitting whilst using your arms) and trunk coordination (sitting whilst turning).



**Figure 1: Valedo sensors**



**Figure 2: Sensors placement**

In your arm and legs assessments, the researcher will ask you to perform 50 simple and quick tasks (e.g. holding a tennis ball, bending your elbow, and bending your knee) to measure your movement and coordination of your shoulder, elbow, wrist, hand, hip, knee and ankle.

In the last assessment, you will be asked to sit on a wooden stool in front of a height-adjustable table. You will be asked to perform 8 simple tasks (e.g. hand to table (front), lift can, fold towel) to measure the amount of trunk movement during performance of those 8 tasks. During the performance of the tasks, we will capture the degree of trunk movement by using the Valedo sensors (figure 2). This assessment will be done twice in the 1<sup>st</sup> visit but once in the 2<sup>nd</sup> assessment visit. After 7 days, you will be asked to come to the laboratory for a second assessment session. The same measurements will be taken.

After the two initial assessment sessions, you will be asked to take part in a trunk training programme using Valedo video games for 18 sessions over 6-8 weeks. In each session, you will be trained from sitting or standing (based on your balance ability). The training session will last for 45 minutes with a rest period whenever needed. In the training sessions, you will wear 3 belts over your clothing (1 on your upper chest and two on your lower back) (Figure 3) to hold the sensors on. You will then play five video games by doing simple movements such as bending to each side, twisting and pelvic tilting. Rest period will be given to you during training session whenever you want.



**Figure 3: Person playing games from a sitting position**

[08/12/2017] [Version 1]

[Ethics number: 30748]

After completing the programme, test the same movements as were performed in the initial assessments. In addition we will invite you to take part in an interview (maximum 30 minutes) to tell us what you think about the rehabilitation programme.

**What happens if I change my mind?**

You decide if you want to take part or not. If you decide to take part, you are still free to withdraw at any time without giving a reason. A decision to withdraw or to not take part in the study will not affect your future or be held against you in any way. Please note that if you withdraw, data will be retained up to the point that you withdraw.

**What will happen to the results of the research?**

We will use the data to inform research with regard to people who have had a stroke. These results will be presented at scientific conferences and may be published in scientific journals. Please let us know if you would like a copy of the published results at the end of the study. On completion of the research study, the data collected will be securely stored at the University of Southampton for at least 10 years according to University procedures.

**Where can I get more information?**

If you would like any further information, please contact:

- 1) Norah Alhwoaimel  
PhD Student  
Rehabilitation & Health Technologies Research Group  
Faculty of Health Sciences (Building 45)  
University of Southampton  
Southampton SO17 1BJ  
United Kingdom

Telephone: +44(0)2380592021

Email: [N.Alhwoaimel@soton.ac.uk](mailto:N.Alhwoaimel@soton.ac.uk)

2) Dr Ann-Marie Hughes

Associate Professor

Faculty of Health Sciences (Building 45)

University of Southampton

Southampton SO17 1BJ

United Kingdom

Telephone: +44(0)2380595191

Email: [A.Hughes@soton.ac.uk](mailto:A.Hughes@soton.ac.uk)

3) Dr Ruth Turk

Lecturer / Clinical Academic Lecturer Intern

Faculty of Health Sciences (Building 45)

University of Southampton

Southampton SO17 1BJ

United Kingdom

Telephone : +44(0)2380598928

Email: [R.Turk@soton.ac.uk](mailto:R.Turk@soton.ac.uk)

**What happens if something goes wrong?**

If you become uncomfortable or distressed during the session, you will be offered assistance there and then by the researcher. If you have a concern or a complaint about this study you should contact Professor Mark Spearing at the Research Governance Office (Address: University of Southampton, Building 37, Highfield, Southampton, SO17 1BJ; Tel: +44 (0)23 8059 5058; Email: [rgoinfo@soton.ac.uk](mailto:rgoinfo@soton.ac.uk)). If you remain unhappy and wish to complain formally, the Research Governance Office can provide you with details of the University of Southampton Complaints Procedure.

Thank you for your consideration with regard to taking part in this study. You will be given a copy of the information sheet and a signed consent form to keep.

[08/12/2017] [Version 1]

[Ethics number: 30748]

## Appendix 26 Advertising poster – feasibility study (study 3)

Health  
Sciences  
Ethics number: 30748



### Trunk exercises using sensors and video games for people with chronic stroke



- ✓ Have you had a stroke more than six months ago?
- ✓ Do you have balance problems?
- ✓ Are you over 18 years old?
- ✓ Are you interested in taking part in research?

We will test if using a trunk exercise programme with video games will improve your sitting balance.

This project will require 20 visits to the human performance laboratory in the University of Southampton, Faculty of Health Sciences (Building 45).

**Your participation would be greatly appreciated. If you are interested, please contact Norah Alhwoaimel:**

Trunk Research Norah na1n15@soton.ac.uk Tel: (0)23 80592021						
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## Appendix 27 Ethical approval – Saudi Arabia

Kingdom of Saudi Arabia  
Ministry of Health  
King Fahad Medical City  
(162)



المملكة العربية السعودية  
وزارة الصحة  
مدينة الملك فهد الطبية  
(١٦٢)

IRB Registration Number with KACST, KSA: H-01-R-012  
IRB Registration Number with OHRP/NIH, USA: IRB00010471  
Approval Number Federal Wide Assurance NIH, USA: FWA00018774

March 28, 2019  
**IRB Log Number: 19-190E**  
Department: External - University of Southampton  
Category of Approval: EXPEDITED

Dear Norah Alhwoaimel and Dr. Ann-Marie Hughes,

I am pleased to inform you that submission dated March 26, 2019 for the study titled '**Feasibility of Trunk Exercise Using Video Games in People with Stroke - A Feasibility Study**' was reviewed and was approved according to Good Clinical Practice guidelines.

Please be informed that in conducting this study, you as the Principal Investigator are required to abide by the rules and regulations of the Government of Saudi Arabia, the KFMC/IRB policies and procedures, and the ICH Good Clinical Practice guidelines. Further, you are required to submit a Progress report every 6 months starting from the date of approval. Approvals are for 1 year and are renewable on submission of satisfactory 6-monthly reports. The approval of this proposal will automatically be **suspended on March 28, 2020** pending the acceptance of the end-of-year Progress Report. You also need to notify the IRB as soon as possible in the case of:

1. Any amendments to the project;
2. Termination of the study;
3. Any serious unexpected adverse events (within two working days);
4. Any event or new information that may affect the benefit/risk ratio of the proposal.

Please observe the following:

1. Personal identifying data should only be collected when necessary for research;
2. The data collected should only be used for this proposal;
3. Data should be stored securely so that a few authorized users are permitted access to the database;
4. Secondary disclosure of personal identifiable data is not allowed;
5. Copy of the Consent Form should be kept in the Research Subject's Medical Record and the consent process should be documented in the medical record;
6. Copy of the pharmacy clearance (IDS) must be in the medical record.

Please be advised that regulations require that you submit a progress report on your research every 6 months. You are also required to submit any manuscript resulting from this research for approval by IRB before submission to journals for publication.

Kingdom of Saudi Arabia  
Ministry of Health  
King Fahad Medical City  
(162)



المملكة العربية السعودية  
وزارة الصحة  
مدينة الملك فهد الطبية  
(١٦٢)

As a researcher you are required to have current and valid certification on protection human research subjects that can be obtained by taking a short online course at the US NIH site or the Saudi NCBE site followed by a multiple choice test. Please submit your current and valid certificate for our records. Failure to submit this certificate shall a reason for suspension of your research project.

We wish you every success in your research endeavor.

If you have any further questions feel free to contact me.

Sincerely yours,

*Omar Kasule*

**Prof. Omar H. Kasule**  
Chairman, Institutional Review Board (IRB)  
King Fahad Medical City, Riyadh, KSA  
Tel: + 966 1 288 9999 Ext. 26913  
E-mail: okasule@kfmc.med.sa



وزارة الصحة  
مدينة الملك فهد الطبية  
King Fahad Medical City

# Appendix 28 Participant information sheet – Arabic

## Version

UNIVERSITY OF  
Southampton

### صحيفة المعلومات

عنوان الدراسة: تقييم أداء الجذع والأطراف العلوية عند مرضى السكتة الدماغية المزمنة بعد التدريب باستخدام ألعاب الفيديو - دراسة جدوى

يرجى قراءة هذه المعلومات بحناية قبل اتخاذ القرار بالمشاركة في هذا البحث. الأمر متروك لك لتقرر ما إذا كنت ستشارك أم لا. إذا كنت راضياً عن المشاركة ، س يُطلب منك التوقيع على نموذج موافقة.

ما هو أساس البحث؟

يميل الأشخاص الذين يعانون من السكتات الدماغية إلى مشاكل في التحكم في أجسامهم ، وخاصة الأطراف العلوية والسفلية مما يؤثر على توازنهم ويتداخل مع قدرتهم على القيام بأنشطة الحياة اليومية ، مثل التخطي في الفراش ، الجلوس ، التنقل من وضع الجلوس إلى الوقوف ، والمشي. يُهدف إعادته تأهيل مرضى السكتة الدماغية إلى إعادته الحركة إلى أقرب ما يمكن من الطبيعي ويكون ذلك غالباً من خلال التمارين الرياضية.

نريد أن نرى ما إذا كانت تمارين الجذع باستخدام أجهزة استشعار فاليدو وألعاب الفيديو يمكن أن تغير قدرتك على التحكم في الجذع.

لماذا نطلب مني المشاركة؟

لقد تم اختيارك للمشاركة في هذه الدراسة لأننا نبحث عن متطوعين لديهم اهتمام بتحسين السيطرة على الجسم للأشخاص الذين أصيبوا بسكتة دماغية.

نقد تم اختيارك للمشاركة في هذه الدراسة لآتك :

- تعرضت لسكتة دماغية منذ أكثر من سنة أشهر ، مما جعلك تواجه بعض المشاكل في توازن جسمك.
- لا تتلقى حالياً أي شكل من أشكال العلاج الطبيعي الفعال.
- قادراً على الجلوس دون دعم لمدة ١٠ نواب.
- قادراً على فهم ما ينطوي عليه هذا المشروع البحثي.
- قادراً على فهم ومناقشة التعليمات البسيطة (مثل الانحناء على الجنب ، تحريك جسمك إلى اليمين واليسار).
- يمكن أن تلتزم بحضور ١٨ جلسة للبرنامج التدريبي على مدى ٦-٨ أسابيع.

بالإضافة إلى ذلك ، ليس لديك أي من المشكلات التالية:

- آلام شديده أسفل الظهر
- مشاكل حالية مع عضلات الفخري
- تاريخ مرضي لكسر في العظام دون سبب واضح
- صرع
- مفصل الفخذ الصناعي
- المواد أو الأجهزة المزروعة داخل الجسم (مثل منظم ضربات القلب ، جهاز السمع).

### ماذا سيحدث لي إذا قمت بالمشاركة؟

إذا قمت بإعادة النموذج فإثلاً أنك مهتم بالمشاركة ، فسوف يتم الاتصال بك من قبل الباحث عبر الهاتف أو البريد الإلكتروني. سوف نجيب على أي أسئلة قد تكون لديكم وسنطرح عليك بعض الأسئلة العامة. سيطلع الباحث من خلال هذه الأسئلة ما إذا كانت الدراسة البحثية مناسبة لك أم لا. سنقوم بعد ذلك بتحديد موعد لك للظهور الى مركز الفاران الطبي في اليوم والوقت المناسب لك.

سنحتاج إلى حضور ٢١ جلسة (٣ جلسات للتقييم و ١٨ جلسة للتدريب) على مدى ٦-٨ أسابيع ، كل منها يجب أن لا يستغرق أكثر من ساعة ونصف. سيتم الجمع بين التقييم النهائي والمقابلة مع آخر جلسة تدريبية.

### هل هناك أي مخاطر تتطوي على ذلك؟

من غير المحتمل أن يكون هناك أي آثار جانبية أو مخاطر من جلسات التدخل. قد تشعر بالانحب قليلاً أثناء ، أو في نهاية الجلسة ، بمكانك الراحة في أي وقت. إذا كنت تشعر بعدم القدرة على الاستمرار ، فيمكنك الانسحاب. سوف يضمن الباحثون لك أن تكون مرتاح طوال الوقت.

### هل ستكون مشاركتي سرية؟

سيتم الاحتفاظ بالسرية التامة لجميع المعلومات التي يتم جمعها عنك خلال هذا البحث. سيتم إزالة اسمك وعنوانك من أية معلومات عنك في النماذج أو التقارير البحثية بحيث لا يمكن التعرف عليك من خلالها. سيؤدي الرقم الفريد إلى ربط بياناتك بملفاتك الشخصية. سيتم الاحتفاظ ببياناتك الشخصية بشكل منفصل عن سجلات الأبحاث. ستحفظ البيانات المسجلة ، لعرض الدراسة البحثية ، على جهاز كمبيوتر محمي بكلمة مرور أو كسجلات ورقية محفوظة في خزانة محكمة الإغلاق لحفظ الملفات.

### ماذا أفعل إذا كنت أرغب في المشاركة؟

سنحتاج إلى حضور ٢١ جلسة (٣ جلسات للتقييم و ١٨ جلسة للتدريب) على مدى ٦-٨ أسابيع وسنتم تلك الجلسات في عيادة العلاج الطبيعي. يجب أن تستغرق كل جلسة مدة لا تزيد عن ساعة ونصف.

ستطلب منك الجلوس ثم تقييم قدرتك على التوازن ، وقدرتك على التحكم في الجذع والاطراف العلوية والسفلية.

أثناء تقييم التوازن ، سيطلب منك الباحث القيام بـ ١٤ مهمة بسيطة من وضعية الجلوس والوقوف مثل: الوقوف دون استخدام يديك لدعم نفسك ، النظر خلفك ، والوقوف بقدم واحدة أمام الأخرى.

أثناء تقييم الجذع ، سيستخدم الباحث ثلاثة أجهزة استشعار (الشكل ١) ويضعها على جلدك باستخدام شريط طبي مزدوج (الشكل ٢). سوف نطلب منك الجلوس والقيام بـ ١٧ حركة بسيطة (مثل انحناء سفليك والانحناء الجانبي) للتحرف على مدى قدرتك في التحكم في الساق الخالص بك. تتضمن هذه الحركات الجلوس الثابت (في وضعية الراحة) ، الجلوس الديناميكي (الجلوس أثناء استخدام ذراعيتك) التناهي الحركي للجذع (الانحناء أثناء الجلوس).



الشكل ١: أجهزة استشعار فاليديو



الشكل ٢: مواضع أجهزة الاستشعار

"سنطلب منك ارتداء ملابس تمكثنا من وضع أجهزة الاستشعار دون الحاجة لازالة الملابس حفاظا على خصوصيتك"

في تقييم الاطراف الطوية والسفلية ، سيطلب منك الباحث إجراء عدة مهام بسيطة وسريعة (على سبيل المثال ، الامساك كرة tennis ، نبي المرفق ، نبي ركبتيك) لقياس حركة وتنسيق الكتف ، الكوع ، اليد ، الورك والركبة والكلحل .

في التقييم الأخير ، سيطلب منك الجلوس على كرسي أمام طاولة . وسيطلب منك تنفيذ ٨ مهام بسيطة (على سبيل المثال ، وضع يدك على الطاولة ، الامساك بعلبة مشروب ، طوي منشقة) لقياس كمية حركة الجذع أثناء أداء هذه المهام الثمانية . أثناء أداء المهام ، سنقيس درجة حركة الجذع باستخدام أجهزة استشعار فاليديو (الشكل ٢) .

بعد أسبوع من أول تقييم ، سيطلب منك الحضور إلى المختبر لحضور جلسة تقييم ثانية . سيتم القيام بنفس الاجراءات .

بعد دورتي التقييم المبدئية ، سيطلب منك المشاركة في برنامج التدريب باستخدام ألعاب فيديو فاليديو . ويكون ذلك البرنامج لمدة ١٨ جلسة تمتد من ٦ إلى ٨ أسابيع . في كل جلسة ، سوف يتم تدريبك أثناء الجلوس أو الوقوف (بناءً على قدرتك على التوازن) . تستمر الجلسة التدريبية لمدة ٤٥ دقيقة مع فترة راحة كلما احتجت إليها . في جلسات التدريب ، سنقوم بإهداء ٣ أحزمة فوق ملابسك (واحد على صدرك الطوي واثنتان في أسفل ظهرك) (كما في الشكل ٣) . سنقوم بعد ذلك بتشغيل خمسة ألعاب فيديو تتضمن حركات بسيطة مثل الانحناء لكل جانب ، الالتفاف أثناء الجلوس . سيتم إعطاء فترات الراحة لك خلال الجلسة التدريبية وفما نساء .



الشكل ٣: شخص يلعب ألعاب فيديو أثناء وضع الجلوس

بعد الانتهاء من البرنامج ، سنختبر نفس الحركات التي تم إجراؤها في التقييمات الأولية . بالإضافة إلى ذلك ، سوف ندعوك للمشاركة في مقابلة (٢٠ دقيقة كحد أقصى) لإخبارنا عن رأيك في برنامج إعادة التأهيل .

#### ماذا يحدث إذا غيرت رأيي؟

عليك أن تقرر ما إذا كنت ترغب في المشاركة أم لا . إذا قررت المشاركة ، فلا يزال لديك الحرية في الانسحاب في أي وقت دون إبداء سبب . إن قررت الانسحاب أو عدم المشاركة في الدراسة لن يؤثر عليك بأي شكل من الأشكال . يرجى ملاحظة أنه في حالة الانسحاب ، سيتم الاحتفاظ بالبيانات التي تم جمعها .

#### ماذا سيحدث لنتائج البحث؟

سوف استخدم البيانات التي تم جمعها لانتماء رسالة الدكتوراه . كما سافرح بنشر نتائج البحث في المؤتمرات العلمية ومجلات النشر العلمية العالمية . يرجى إعلامنا إذا كنت ترغب في الحصول على نسخة من النتائج المنشورة في نهاية الدراسة . عند الانتهاء من الدراسة البحثية ، سيتم تخزين البيانات التي تم جمعها بشكل آمن في جامعة ساوثهامبتون لمدة ١٠ سنوات على الأقل وفقاً لإجراءات الجامعة .

أين يمكنني الحصول على مزيد من المعلومات؟

يمكنك الحصول على المزيد من المعلومات عبر الاتصال بالباحثه نوره الهويل

بريد الكتروني:

N.Alhw oaimel@southampton.ac.uk

هاتف: ٠٥٠٦٢٢٦٨٦٣

ماذا لو حدث خطأ ما؟

إذا شعرت بعدم الارتياح أو الإزعاج خلال الجلسة ، فسوف يتم تقديم المساعدة لك من خلال الباحث. إذا كان لديك اهتمام أو شكوى حول هذه الدراسة ، فيجب عليك الاتصال بالسيد مارك سيرنج في مكتب إدارة البحوث .

العنوان: University of Southampton, Building 37, Highfield, Southampton, SO17 1BJ

هاتف: +٤٤(٠)٣٢٩٥٠٨٨٥٠٥

البريد الإلكتروني: [rgoinfo@soton.ac.uk](mailto:rgoinfo@soton.ac.uk)

إذا كنت غير سعيد وترغب في تقديم شكوى رسمية ، يمكن لمكتب إدارة البحوث أن يزودك بتفاصيل حول إجراءات شكوى جامعة ساوثهامبتون.

أشكركم على اهتمامكم بالمشاركة في هذه الدراسة.

## Appendix 29 Advertising poster – Arabic Version

Health  
Sciences

UNIVERSITY OF  
Southampton

### تمارين الجذع باستخدام ألعاب الفيديو للأشخاص الذين يعانون من السكتة الدماغية المزمنة



- ✓ هل أصبت بسكتة دماغية منذ أكثر من ستة أشهر؟
- ✓ هل لديك مشاكل في التوازن؟
- ✓ هل عمرك أكثر من 18 عامًا؟
- ✓ هل أنت مهتم بالمشاركة في هذه الدراسة البحثية؟

- هذه الدراسة هدفها اختبار ما إذا كان برنامج تمارين الجذع باستخدام ألعاب الفيديو سيحسن التوازن الحركي لدى مرضى السكتة الدماغية في المملكة العربية السعودية وبريطانيا.
- سيتطلب هذا البحث ٢١ زيارة إلى عيادة العلاج الطبيعي في مركز مايوأوستيوباثي الطبي
- سنقوم بترتيب المواصلات لك من منزلك الى المركز خلال مدة البرنامج أو تعويضك ماديا عنها

\* هذه الدراسة مرخصة من جامعة ساوثامبتون - بريطانيا (رقم الموافقة الأخلاقية: ٣٠٧٤٨) وموافق عليها من وزارة الصحة السعودية (رقم الموافقة الأخلاقية: ١٩٠-١٩٠)

مشاركتك ستكون موضع تقديرنا الكبير

إذا كنت مهتمًا أو لديك أي استفسار عن الدراسة ، فيرجى الاتصال بالباحثه نوره الهويل:



٠٥٠٦٢٢٦٨٦٣



n.alhwoaimel@soton.ac.uk

## Appendix 30 Consent form – feasibility study



### CONSENT FORM

**Study title: Trunk exercises using Valedo sensors and video games for people with chronic stroke**

**Researcher name:** We are a team of Physiotherapists, Movement Scientists, and Doctors who have a specialist interest in stroke rehabilitation. Our names are Norah Alhwoaimel, Dr Ann-Marie Hughes Dr Ruth Turk, Dr Federico Ferrari, Liselot Thijs, Dr Martin Warner, Professor Jane Burridge, Professor Geert Verheyden and Dr Seng Kwee Wee. Federico is a Medical Doctor with four years' experience in neurological rehabilitation. Norah, Ann-Marie, Ruth, Jane, Geert, Liselot and Seng Kwee are physical therapists and Martin is a movement scientist. Norah is studying for her PhD at the Faculty of Health Sciences.

**ERGO number:** 30748

**Please initial the box(es) if you agree with the statement(s):**

I have read and understood the information sheet (08/12/2017 /version no 1.0 of <i>participant information sheet</i> ) and have had the opportunity to ask questions about the study.	
I agree to take part in this research project and agree for my data to be used for the purpose of this study.	
I understand my participation is voluntary and I may withdraw at any time for any reason without my rights being affected.	
I consent to video tapes being made of the sessions to aid the research (use for analysis of TIS,SWMFT)	
<b>Data Protection:</b> I understand that information collected about me during my participation in this study will be stored on a password protected computer and that this information will only be used for the purpose of this study. All files containing any personal data will be anonymised.	
I am happy to be contacted regarding other unspecified research projects. I therefore consent to the University retaining my personal details on a database, kept separately from the research data detailed above. The 'validity' of my consent is conditional upon the University complying with the Data Protection Act and I understand that I can request my details be removed from this database at any time.	

[08-12-2017] [Version 1]

[Ethics number: 30748]

Name of participant (print name).....

Signature of participant.....

Date.....

Name of researcher (print name).....

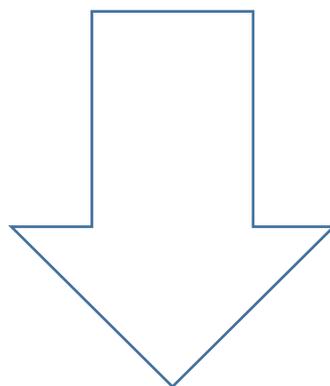
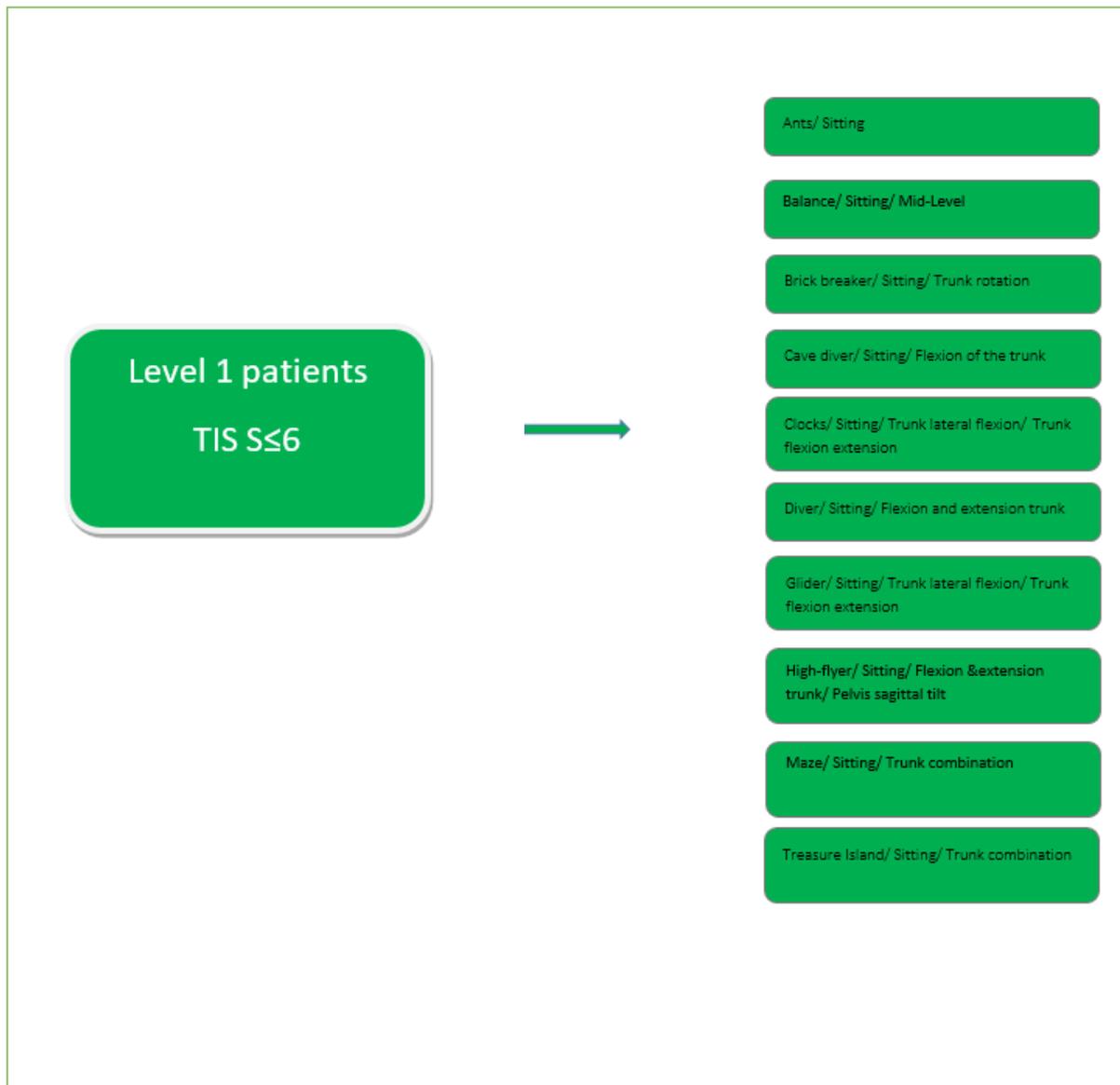
Signature of researcher .....

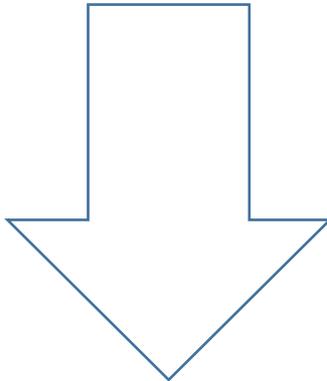
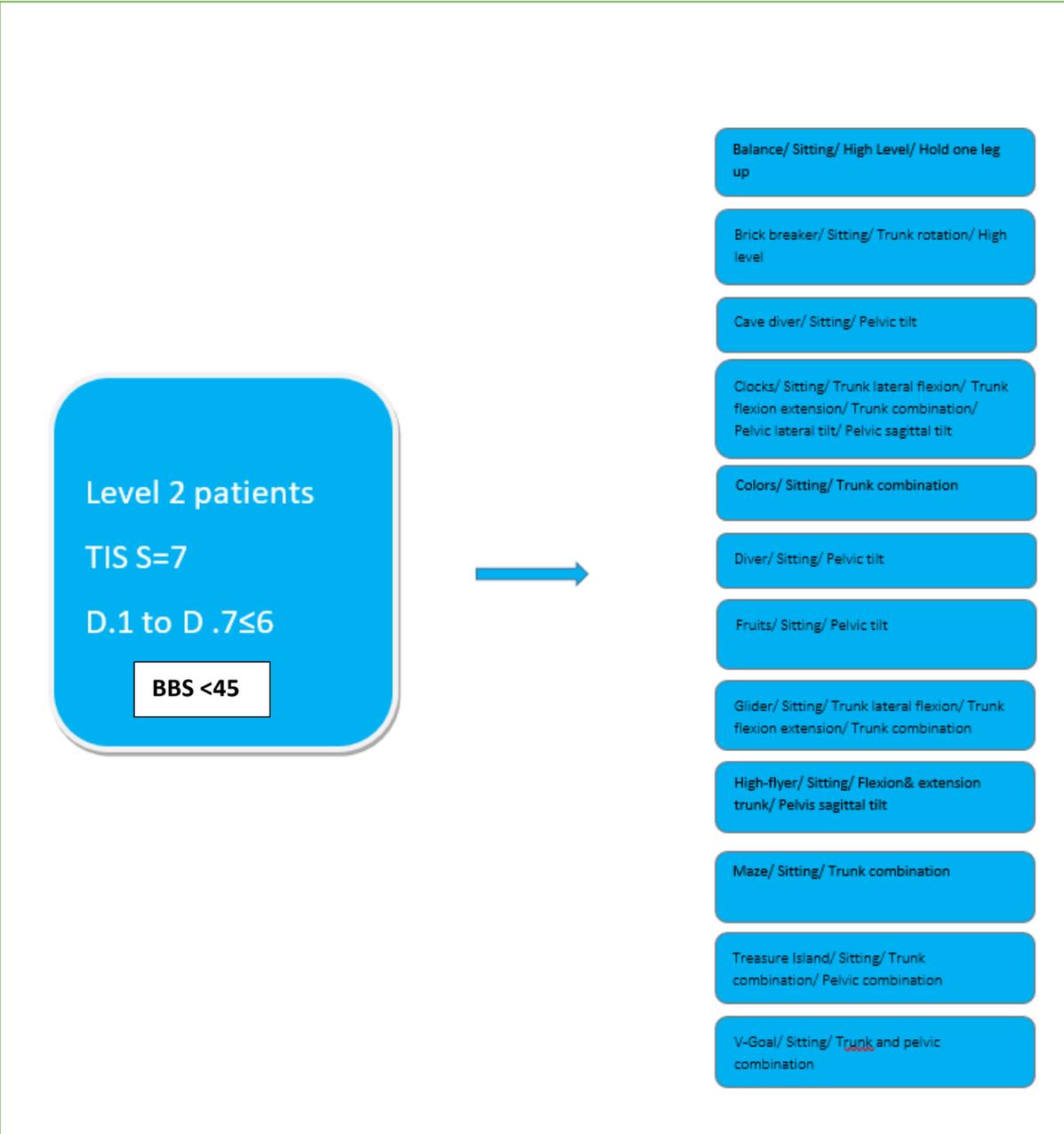
Date.....

***Optional - please only initial the box(es) you wish to agree to:***

Photographs of me can be used in printed material such as academic papers, reports, or book chapters	
Photographs or videos of me may be used in academic and non-academic presentations	
Photographs or videos of me can be used on the university website or websites associated with the project.	
Photographs or videos of me can be used in publicity such as newspaper or TV	
Photographs or videos of me must attempt to disguise my identity by blurring the face	

## Appendix 31 Flow chart for prescribing Valedo exercises based on patient ability







**Level 4 patients**  
TIS S=7  
D.1 to D .10=10  
C.1-C.2= 4  
C.3-C.4<3  
**Stand-alone safely**  
**BBS ≥ 45**



- Brick breaker/ Sitting & standing/ Trunk rotation/ Higher level
- Cave diver/ Standing/ Pelvic tilt
- Clocks/ Sitting/ Pelvic combination  
Clocks/ Standing/ Trunk lateral flexion/  
Trunk flexion extension/ Pelvic rotation/  
Pelvic sagittal tilt
- Colors/ Standing/ Trunk combination/  
Pelvic combination
- Glider/ Standing/ Trunk lateral flexion/  
Trunk flexion extension/ Trunk  
combination/ Pelvic sagittal tilt/ Pelvic  
combination
- Golf/ Standing/ Pelvic combination
- High flyer/ Standing/ Pelvic sagittal tilt
- Maze/ Standing/ Pelvic combination
- Treasure Island/ Standing/ Pelvic  
combination
- V-Goal/ Standing
- V-Goal Isolation

### Level 1

- Able to sit independently for more than 10 seconds.
- Able or not to passively put and hold the non-paretic leg on the paretic leg.
- Able or not to actively put and hold the paretic leg on the non-paretic leg, backward displacement of the trunk more than 10 cm is allowed.

### Level 2

- Able to sit independently for more than 10 seconds.
- Able to passively put and hold the non-paretic leg on the paretic leg.
- Able to actively put and hold the paretic leg on the non-paretic leg, no backward displacement of the trunk for more than 10 cm.
- Touch bed/ table with hemiplegic and non-hemiplegic elbow and return. Patients moves actively with or without compensations. However, the appropriate shortening or lengthening is not necessary.

### Level 3

- Able to sit independently and with appropriate shorting/ lengthening touch bed/ table with hemiplegic and non-hemiplegic elbow.
- Shortening/ lengthening when lifting the pelvic must not be correct.
- Rotation of upper part of the trunk is asymmetrical.
- Static standing is safe.

### Level 4

- Patient is able to lift the pelvis from bed/table without compensation.
- Rotation of the lower part of the trunk is possible with or without compensation.
- Dynamic standing is safe.



## Appendix 32 Search strategy and founded scales for psychosocial impact assessment scales

- 1- ('assistive technolog\*' or 'assistive device\*' or 'assistive product\*' or 'technical aid\*' or 'electronic aid\*' or 'electronic assistive technology').tw.  
 2- (participat\* or ' user satisfaction' or ' quality of life' or safety or 'self efficacy' or acceptability or usability or 'psychosocial impact').tw.  
 3- (stroke or poststroke or post-stroke or "cerebrovascular accident" or cva)  
 4- (hemipleg\* or hemipar\* or (paresis or paretic))  
 5- 3 or 4  
 6- 1 AND 2 AND 5

Test	QUEST	PIADS	PETS	Stroke self-efficacy questionnaire	MOCA
Measurement aim	Used to assess satisfaction with a specific assistive device in the following domains; size, weight, adjustments, safety, durability, simplicity of use, comfort and effectiveness	Self-report questionnaire used to assess the effects of an assistive device on functional independence, well-being and quality of life.	Used to reflect the most commonly reported reasons for discontinuing therapy given to the patients as self-managed home-based rehabilitation	Used to assess the confidence of stroke patients in doing some tasks that may have been difficult for them since stroke	Used to assess different cognitive domains including; attention and concentration, executive functions, memory, language, visuoconstructional skills, conceptual thinking, calculations, and orientation.
Number of Items	12	26	12	13	11

Score of each item	5 point Likert Scale ranging from "not satisfied" at all to "very satisfied"	7 point Likert Scale ranging from -3 (Maximum Negative Impact) to +3 (Maximum Positive Impact)	5 point Likert Scale ranging from 1 (disagree strongly) to 5 (agree strongly)	10 point Likert Scale ranging from 0 = not at all confident and 10 = very confident	Each item had different scoring criteria to earn the points.
Appropriateness for 3 <sup>rd</sup> study	No	Yes	No	No	No

QUEST= Quebec User Evaluation of Satisfaction with Assistive Technology, PIADS= Psychosocial Impact of Assistive Devices Scale, PETS= The Problematic Experiences of Therapy Scale, MOCA= Montreal Cognitive Assessment Scale

# Appendix 33 Psychosocial Impact of Assistive Devices Scale (PIADS) and manual

Table 3: PIADS Questionnaire Version 3.0

Psychosocial Impact of Assistive Devices Scale (PIADS) Today's Date: \_\_\_\_\_  
month/day/year

Client Name: \_\_\_\_\_  male  female  
(last name, then first name)

Diagnosis: \_\_\_\_\_ Date of Birth: \_\_\_\_\_  
month/day/year

The form is being filled out at (choose one) 1.  home 2.  a clinic 3.  other (describe): \_\_\_\_\_  
The form is being filled out by (choose one) 1.  the client, without any help 2.  the client, with help from the caregiver (e.g., client showed or told caregiver what answers to give) 3.  the caregiver on behalf of the client, without any direction from the client 4.  other (describe): \_\_\_\_\_

Each word or phrase below describes how using an assistive device may affect a user. Some might seem unusual but it is important that you answer every one of the 26 items. So, for each word or phrase, put an "X" in the appropriate box to show how you are affected by using the \_\_\_\_\_ (device name).

	Decreases	-3	-2	-1	0	1	2	3	Increases
1) competence	<input type="checkbox"/>								
2) happiness	<input type="checkbox"/>								
3) independence	<input type="checkbox"/>								
4) adequacy	<input type="checkbox"/>								
5) confusion	<input type="checkbox"/>								
6) efficiency	<input type="checkbox"/>								
7) self-esteem	<input type="checkbox"/>								
8) productivity	<input type="checkbox"/>								
9) security	<input type="checkbox"/>								
10) frustration	<input type="checkbox"/>								
11) usefulness	<input type="checkbox"/>								
12) self-confidence	<input type="checkbox"/>								
13) expertise	<input type="checkbox"/>								
14) skillfulness	<input type="checkbox"/>								
15) well-being	<input type="checkbox"/>								
16) capability	<input type="checkbox"/>								
17) quality of life	<input type="checkbox"/>								
18) performance	<input type="checkbox"/>								
19) sense of power	<input type="checkbox"/>								
20) sense of control	<input type="checkbox"/>								
21) embarrassment	<input type="checkbox"/>								
22) willingness to take chances	<input type="checkbox"/>								
23) ability to participate	<input type="checkbox"/>								
24) eagerness to try new things	<input type="checkbox"/>								
25) ability to adapt to the activities of daily living	<input type="checkbox"/>								
26) ability to take advantage of opportunities	<input type="checkbox"/>								

---

*Glossary of PIADS Items*

---

**Ability to Adapt to the Activities of Daily Living** (item 25) Ability to cope with change; ability to make basic tasks more manageable

**Ability to Participate** (item 23) Ability to join in activities with other people

**Ability to take advantage of opportunities** (item 26) Ability to act quickly and confidently when there is a chance to improve something in your life

**Adequacy** (item 4) Capable of handling life situations, and handling little crises

**Capability** (item 16) Feeling more capable; able to cope

**Competence** (item 1) Ability to do well the important things you need to do in life

**Confusion** (item 5) Unable to think clearly, act decisively

**Eagerness to Try New Things** (item 24) Feeling adventuresome and open to new experiences

**Efficiency** (item 6) Effective management of day to day tasks

**Embarrassment** (item 21) Feeling awkward or ashamed

**Expertise** (item 13) Knowledge in a particular area or occupation

**Frustration** (item 10) Being upset about lack of progress in achieving your desires; feeling disappointed

**Happiness** (item 2) Gladness, pleasure; satisfaction with life

**Independence** (item 3) Not dependent on, or not always needing help from, someone or something

**Performance** (item 18) Able to demonstrate your skills

**Productivity** (item 8) Able to get more things done in a day

**Quality of Life** (item 17) How good your life is

**Security** (item 9) Feeling safe rather than feeling vulnerable or insecure

**Self-Confidence** (item 12) Self-reliance; trust in yourself and your abilities

**Self-Esteem** (item 7) How you feel about yourself, and like yourself as a person

**Sense of Control** (item 20) Sense of being able to do what you want in your environment

**Sense of Power** (item 19) Sense of inner strength; feeling that you have significant influence over your life

**Skillfulness** (item 14) Able to show your expertise; perform tasks well

**Usefulness** (item 11) Helpful to yourself and others; can get things done

**Well-being** (item 15) Feeling well; optimistic about your life and future

**Willingness to Take Chances** (item 22) Willing to take some risks; willing to take on new challenges

## Appendix 34 Adverse event form

### Adverse Event Form

**Participant ID:** ..... **Date:**..... **Time:**.....

#### Subjective evaluation:

How are you feeling today?

.....

Have you had any general health problems (common cold, back-pains, etc.) since last meeting? If yes – what kind, when, and are you recovered?

.....

Have you had any falls in the last week?

.....

Have you had any change in medication?

.....

Are you happy with your participation in this study?

.....

Is there anything else you would like to talk about?

.....

#### Adverse event report:

Description of the event

.....

.....

.....

Location of the event .....

Start of the event

**Date:**..... **Time:**.....

Measure taken to manage the adverse event

.....

.....

**Responsible contact person (patient relative/friend)**

Name: .....

Address: .....

Telephone: .....

Email: .....

**Person who report the adverse event**

Name:.....

Signature:.....

## Appendix 35 Instrument review of trunk assessment scales

Outcome measure Criteria	TCT (Collin & wade 1990)	TIS-F (Fujiwara et al.; 2004)	TIS (Verheyden et al.; 2004)
<b>Number of Items</b>	4	7	17
<b>Items description</b>	<ol style="list-style-type: none"> <li>1. rolling to weak side,</li> <li>2. rolling to strong side,</li> <li>3. balance in sitting position,</li> <li>4. sit up from lying down</li> </ol>	<ol style="list-style-type: none"> <li>1. perception of trunk verticality</li> <li>2. trunk rotation muscle strength on the affected side</li> <li>3. trunk rotation muscle strength on the unaffected side</li> <li>4. righting reflex on the affected side</li> <li>5. righting reflex on the unaffected side</li> <li>6. stroke impairment assessment set verticality</li> <li>7. stroke impairment assessment set abdominal muscle strength</li> </ol>	Three subscales: <ol style="list-style-type: none"> <li>1. static sitting balance (3 items)</li> <li>2. dynamic sitting balance (10 items)</li> <li>3. coordination (4 items)</li> </ol>
<b>Score of each item</b>	0, 12 or 25	0-3	0-3, 0-1or 0-2
<b>Total score range</b>	0-100	0-21	0-23
<b>Equipment Required</b>	Bed or plinth	Bed or plinth Goniometer	Bed or plinth Stop watch
<b>ICF Domain</b>	Body Function and Structure (impairment) Activity (limitation)	Body Function and Structure (impairment) Activity (limitation)	Body Function and Structure (impairment) Activity (limitation)

<b>Populations Tested</b>	Stroke Elderly	Stroke	Stroke Cerebral Palsy Multiple Sclerosis Parkinson's Disease Traumatic Brain Injury
<b>Test-retest Reliability</b>	Not Established	Not Established	Sub-Acute Stroke: Excellent reliability (ICC =0.93) (Verheyden & Nieuwboer, 2004)  Sub-acute to chronic Stroke: Excellent reliability (ICC = 0.96) (Verheyden et al, 2004)
<b>Interrater Reliability</b>	Excellent interrater reliability (r = 0.76, p<0.001) (Collin and Wade, 1990)	weighted kappas for each of the seven items were 0.89 (Fujiwara et al.; 2004)	Sub-Acute Stroke: excellent reliability (ICC = 0.97) (Verheyden et al, 2005)  Sub-acute to chronic Stroke: Excellent reliability (ICC = 0.99) (Verheyden et al, 2004)
<b>internal Consistency</b>	Cronbach's index at admission and at discharge were alpha=0.86 and alpha=0.83, respectively  (Franchignoni et al,1997)	Rash analysis- The mean square (MNSQ) fit statistic was within 1.3 except for item1, item2 and item7  (Fujiwara et al.; 2004)	Excellent for the total TIS (Cronbah's alpha 0.89)  (Verheyden et al, 2004)
<b>Predictive Validity</b>	Excellent inverse correlation between TCT and length of stay (r=-0.722).  Excellent correlation between admission TCT scores and FIM at discharge (r = 0.738)  (Duarte et al, 2002)	Adding the TIS scores to age, time from onset, and motor part of FIM scale at admission to predict discharge FIM motor scores increased the adjusted R <sup>2</sup> up to 0.75 (P < 0.0001).  (Fujiwara et al.; 2004)	Acute Stroke: Excellent validity between TIS at admission and Barthel Index score at 6 months after stroke (R <sup>2</sup> = 0.52, p < 0.0001) (Verheyden et al, 2007)

			Excellent validity between TIS at admission and FIM scores at discharge ( $R^2 = 0.695$ , $P < 0.001$ ) (Di Monaco et al, 2010)
<b>Construct Validity</b>	Excellent construct validity between the TCT and the gross motor function subscale of the Rivermead Motor Assessment at 6, 12 and 18 weeks post stroke. ( $r = 0.70$ to $0.79$ )  (Collin and Wade, 1990)	Not Established	Acute to Sub-acute Stroke:  Construct validity of dynamic sitting balance and coordination subscale confirmed using Rasch analysis. (chi-square = 42.65; p-value = 0.0052 for dynamic sitting balance, chi-square = 7.87, p-value = 0.446 for coordination subscale)  Sub-acute to chronic stroke: Excellent spearman rank correlation between the TIS and the Barthel Index ( $\rho = 0.86$ )  (Verheyden et al, 2004)
<b>Discriminant ability</b>	Not Established	Not Established	Significant differences between stroke patients and healthy individuals ( $P < 0.0001$ ) (Verheyden et al 2005)

<b>Concurrent Validity</b>	Not Established	Not Established	Excellent correlation between the TIS and TCT ( $r = 0.83$ ) in patients with acute to sub-acute stroke (Verheyden et al, 2004)
<b>Responsiveness</b>	TCT test showed a good sensitivity to change as 72% of stroke patients changed the overall TCT score at discharge  (Franchignoni et al, 1997)	Not Established	Not Established
<b>Minimal Detectable Change (MDC)</b>	Not Established	Not Established	Not Established
<b>Minimally Clinically Important Difference (MCID)</b>	Not Established	Not Established	Not Established
<b>Cut-Off Scores</b>	Stroke: scores of 50 or more were associated with recovery of walking Patients score under 40 were non-ambulatory  (Collin and Wade, 1990)	Not Established	Not Established
<b>Floor/Ceiling Effects</b>	Large Ceiling Effect  (Verheyden et al, 2006)	Not Established	No Ceiling Effects  (Verheyden et al, 2006)



## Appendix 36 Intra-rater (between session) and inter-rater reliability:

	Area	ICC (value (UL, LL 95% confidence levels))
intra-rater (between session)	non cont.	0.989 (0.972, 0.996)
	muscle	0.960 (0.900, 0.984)
inter-rater (NA - SB)	non cont.	0.989 (0.971, 0.995)
	muscle	0.973 (0.931, 0.989)

non cont.= non contractile tissue

UL = Upper Limit

LL = Lower Limit

# Appendix 37 Streamlined Wolf Motor Function Test

Participant ID : \_\_\_\_\_

Assessment : 1 (baseline) / 2 (end of study)

Date of assessment : \_\_\_\_\_

Assessor : \_\_\_\_\_ Signature : \_\_\_\_\_

Arm tested :  More affected  Less affected

Task	Time (seconds)	Functional Ability scale						Remarks
		0	1	2	3	4	5	
Hand to box (front)		0	1	2	3	4	5	
Hand to table (front)		0	1	2	3	4	5	
Lift can		0	1	2	3	4	5	
Lift pencil		0	1	2	3	4	5	
Fold towel		0	1	2	3	4	5	
Turn key in lock		0	1	2	3	4	5	
Extend elbow (1 lb weight)		0	1	2	3	4	5	
Reach and retrieve		0	1	2	3	4	5	

Mean Time	Mean FAS

Score	Functional Ability Scale (FAS)
0	Does not attempt
1	Does not participate functionally – attempt to make use of upper extremity (UE)
2	Does, but requires assistance of the UE not being tested for minor readjustments or change of position; or require more than 2 attempts to complete; or accomplishes very slowly
3	Does, but movement is influenced to some degree by synergy or is performed slowly or with effort
4	Does; movement close to normal but slightly slower; may lack precision, fine coordination or fluidity
5	Movement appears normal

**Reference:**

Bogard K, Wolf S, Zhang Q, Thompson P, Morris D and Nichols-Larsen D (2009) Can the Wolf Motor Function Test be streamlined? *Neurorehabilitation and Neural Repair* 23(5): 422- 428

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## Appendix 38 Semi-structured interview topic guide

Category/Statement/Question	Question Style	Likert Responses/ Probing questions						
<b>A. The attractiveness and enjoyment of the trunk exercise using Valedo video games</b>								
1. Tell me about your experience with practicing trunk exercise by playing video games?	Open							
2. Did you enjoy practicing trunk exercise?	Open	Yes/No. Please tell us what parts of exercise did you enjoy? Why?						
<b>B. Effect of the intervention program</b>								
3. Have you noticed any changes in your movement or strength as a result of the Valedo training programme?	Open	Yes/No; if yes; please give an example about the things that you able to do it better than you could before?						
4. Have you noticed any changes in your daily activity after completion of training program	Open	Yes/No; what activities you are now able to do that you could not do before?						
The difficulties and challenges of each game (I will show you a couple of cards about the games that you've played during the intervention programme and ask you some questions about them)								
On a scale of 1 – 5; with 5 being the most difficult in terms of balance challenges, how would you rate the following games?	Likert	Likert Responses					Probing question:	
		Very easy 1	Easy 2	Neither easy nor difficult 3	Difficult 4	Very difficult 5	What aspect(s) made it easy/difficult	
		5. Game1	Likert					
		6. Game 2	Likert					
		7. Game 3	Likert					
		8. Game 4	Likert					
9. Game 5	Likert							
11. Which was your favourite game to play?	Open	Game: ..... Please tell us why you favour to play this game?						
12. Which was your least favourite game to play?	Open	Game: ..... Please tell us why you less likely to play this game?						

<b>C. Motivation</b>					
13. What is it you find motivating about doing trunk exercise using video games?	Open				
14. What is the difference between using video games to help you practice trunk exercise to do trunk exercise without video games?	Open	What characteristics of the video game helped or hindered you to practice trunk exercise?			
<b>D. The influence of the auditory and visual feedback on their performance</b>					
15. What do think about the sounds and figures/avatars that were produced by the Valedo video games?	Open	How did they make you feel?			
<b>E. The safety during performance of exercise</b>					
16. Did you feel safe while playing the Valedo video games?	Open	Yes/No. Please tell us what makes you feel safe/unsafe?			
<b>F. intervention program time and commitment</b>					
17. Was it difficult for you to commit to this intervention program?	Open	Yes/No; why it is difficult or not difficult?			
<b>G. Usability of the Valedo video game system</b>					
18. To which extent do you agree or disagree with the following statements	Likert	Likert response			
		Strongly agree	Agree	Undecided	Disagree
19. It was clear what I need to do in each game	Likert				
20. The straps around trunk for holding sensors was comfortable	Likert				
21. I did understand the score showing my performance at each game	Likert				
22. I think I will be able to play the Valedo video games independently without therapist guidance	Likert				
<b>H. General Questions</b>					
23. If the Valedo video game system was available for use at home; would you use it?	Open	Yes/No; why you will use it or not use it?			

24. If you had an opportunity to change anything in the games, what would you change? Why?	Open	
25. Would you recommend this type of video games to other stroke participants? Why?	Open	Yes/No; why you will recommend it or not recommend it?

## Appendix 39 Screen Shots of Themes and Nodes Generated in NVIVO

Acceptability			
Name	Files	References	
Benefits from intervention		0	0
Balance improvement		2	2
Concentration improvement		2	3
Memory improvement		1	1
Movement improvement		3	4
Trunk control improvement		2	2
Cognitive challenge		0	0
High concentration		5	7
Multitasking		4	6
Problem-solving		2	3
Fun and enjoyment		0	0
Boring repetitive conventional exercise		7	7
Enjoyable way of exercising		2	3
Sense of accomplishment		2	3
Sense of competition		2	2
Sort of distraction		1	1
Informative and motivational feedback		0	0
Carry on		2	2
Collect more points		3	3
Exercice correctly		4	5
Happy feeling		4	4
Help to set a goal		2	3
Sense of success		2	2
Physical challenge		0	0
arm out by side		2	3
difficult pelvic movement		3	4
exhausting multi-movement		3	3
extreme movement		3	3
fast movement required		3	4

## Acceptability

Name	Files	References	
Physical impact		0	0
Balance ability		4	5
Become fitter at home		3	4
Improvement in weight shifting ability		3	3
Independent in ADL		3	3
More controlled movement		2	2
Reaching away		2	2
Standing and sitting ability Improvement		4	5
Walking improvement		3	6
Psychological impact		0	0
Cognitive ability improvement		2	4
Confident & capable		2	2
Excited to exercise		2	4
Eye opening to the recovery possibilities		2	2
Feeling happy		1	1
Frustration		1	1
Fun and enjoyment		5	5
Highlighting the possible exercise can do		1	1
Lots of work and repetitions without realizing it		1	2
Upsetting		1	1
Resources		0	0
Busy carers		1	1
Convenience		2	2
Independent driving		1	1
Supportive carer		2	2

## Implementation

Name	Files	References
Training at the right level of challenge		3
Exhausting Break Breaker game		4
Easy clock game		4
Difficult clock game		4
Resultant symptoms		0
Physical symptoms		3
Integrated rehabilitation programme		0
UL and LL training		1
Longer sessions		2
Game design		10
Sensitive colour game		3
Lost everything		1
Confused fruit game		3
Boring clock game		3
Feeling safe		0
Safe exercise position		3
Patient exercising in a safe environment		3
Close physiotherapist		4
Feedback on performance		4
Unclear feedback		1
Clear feedback		3

# Appendix 40 Photograph Of Initial Thematic Analysis

## Using Printed Interview

S1= researcher, S2= participant, S3= [REDACTED]

Coding labels	Transcription (003):	Notes and ideas
	S1 00:00 Okay. So first of all, tell me about your experience with practicing trunk exercise by playing video games.	
good - repetitive Ex's - don't normally do	S2 00:11 I think it's a good idea because it means you do a lot of repetitive exercise that you wouldn't do normally. It's only because you're playing the game and you're involved with the game that it makes you do the movements is not something you would normally do. So in that respect, it's got a useful thing.	- good idea because it allow him to do a lot of Ex. repetitive - unusual Movement
	S1 00:38 Did you enjoy practicing trunk exercise?	
	S2 00:50 Oh, I enjoyed playing the games.	
	S1 00:59 Tell us what part of the playing or exercising did you enjoy, specifically, and why?	
Balance improvement	S2 01:09 So it was just a usual way of doing the exercises. And it has improved my balance.	
	S3 01:24 [REDACTED]	
	S1 01:28 And have you noticed any changes in your movement or strength as a result of the Valedo training program?	
	S2 01:37 Yes. I think so.	
	S3 01:40 [REDACTED]	
	S1 01:42 Can you give me an example of the things that you are able to do better than you could before?	
	S3 01:48 Your balance in general.	
	S2 01:53 Yeah.	- carers feels that he is flexible in transfer
Flexible steady transfers	S3 01:54 [REDACTED]	
	S2 02:02 Yeah. From sit to stand.	- sit to stand improves the most
	S3 02:04 [REDACTED]	
	S1 02:11 And in your daily activities are there anything changes after completing for any program, for example, is there any activity you are now able to do it without help than before?	
	S2 02:25 No.	

## Appendix 41 Developing a working analytical framework

1- Acceptability			
Codes	Initial categories	Subthemes	Theme
1. Standing and sitting ability Improvement 2. Walking improvement 3. Independent in ADL 4. Become fitter at home	1. Daily activities	Physical	Perceived impact
5. More controlled movement	2. Movement control/quality		
6. Balance ability improvement 7. Improvement in weight shifting ability 8. Reaching away	3. Balance		
9. Eye opening to the recovery possibilities	4. Source of hope	Psychological	
10. Confident & capable	5. Self-efficacy		
11. Cognitive ability improvement	6. Mental capacity		
12. Feeling happy 13. Fun and enjoyment	7. Positive feeling		
14. Frustration 15. Upsetting	8. Negative feeling		
16. Lots of work and repetitions without realizing it 17. Excited to exercise	9. Exercise engagement		
18. Boring repetitive conventional exercise 19. Sort of distraction 20. Enjoyable way of exercising	10. Exercise characteristics		
21. Sense of competition 22. Sense of accomplishment	11. Positive sense		
23. Trunk control improvement 24. Movement improvement 25. Balance improvement	12. Physical Improvement	Benefits from intervention	
26. Memory improvement 27. Concentration improvement	13. Psychological improvement		
28. Collect more points 29. Carry on	14. Motivation through feedback		

30. Sense of success 31. Happy feeling		Informative and motivational feedback	Burden of participation
32. Help to set a goal 33. Exercise correctly	15. Information through feedback		
34. Fast movement required 35. Weight bearing on hemiplegic side 36. Extreme movement	16. Balance challenge	Physical challenge	
37. Arm out by side 38. Remain steady	17. Challenging exercise position		
39. Difficult pelvic movement 40. Exhausting multi-movement	18. Complex movement		
41. High concentration 42. Multitasking 43. Problem-solving	19. Mental effort	Cognitive challenge	
44. Supportive carer 45. Independent driving 46. Convenience 47. Busy carers	20. facilitators and barriers to commit to the intervention	Resources: transportation, care, and time	

<b>2- Implementation</b>			
<b>Codes</b>	<b>Initial categories</b>	<b>Subthemes</b>	<b>Theme</b>
48. Confused fruit game 49. Sensitive colour game 50. Boring clock game	21. Game features	Game design	Recommendations for professionals
51. Lost everything	22. Scoring strategy		
52. Difficult clock game 53. Easy clock game 54. Exhausting Break Breaker game	23. Task difficulty level	Training at the right level of challenge	
55. Clear feedback 56. Unclear feedback	24. Clarity of feedback	Feedback on performance	

57. Longer sessions 58. UL and LL trining	Participant's suggestions	Integrated rehabilitation package	
59. Patient exercising in a safe environment 60. Close physiotherapist	1. Safe environment	Feeling safe	Safety
61. Safe exercise position	2. Safe exercise position		
62. Feeling dizzy 63. muscle tightness 64. Fatigue	3. Physical symptoms	Resultant symptoms	

## Appendix 42 Charting Data into The Framework Matrix

Theme: Perceived impact of intervention

Subtheme: Physical

Category: Daily activities

Code Case	Standing and sitting ability Improvement	Walking improvement	Independent in ADL	Become fitter at home
P2		I found that when I was doing those trunk exercises, when I was kind of walking out of here, I found then that my leg was quite light, and in fact I'd say that I was walking a little bit better. And I walked round to the car.  My leg felt lighter when I walked.		
P3	seem more flexible in transfers and more steady. P3: Yeah. From sit to stand.			
P4			I now quite normally get up without holding the seat at home. So make the movements straight away.	
P6	I have noticed that his sitting down then standing up, and going upstairs have improved at least 30-40%.		Climbing the stairs became easier. Before the program, he used to have two people to help him go upstairs and downstairs. After the program, he requires only one person to help him	

			and he is using both sides (the hemiplegic and healthy sides) in climbing up and down the stairs instead of relying on the healthy side only.	
P7	It also helped me to stand up and sit down.	Also, with walking, I used to move my whole body as one piece when I turned. Now, I can turn better like this (Patient acts out the movement of turning right and left).	Thank God, my daily activities have changed 70% for the better. I used to have difficulty when sitting on the toilet seat and needed my sons' help. But now, I can do that by myself.	
P8		Walking is now better. Before the program, I used to walk hunchbacked, but now I walk with a straight back and with my shoulders up		I feel that my fitness is much better.
P9	My body movement have not changed that much, but perhaps the standing up and sitting down have become slightly easier.  Before the program, I used to be able to stand up after several attempts, and sometimes my son had to help me to stand up. Now I can stand up by myself.			I have become fitter at home.  I can go to the toilet and the kitchen and walk around easily. Before taking the program, I used to get tired once I had gone to the toilet.

P10			Caregiver: At the beginning of the program and in the first few days, when we had to move my mother from the wheelchair into the car to go for physical therapy, we had to put a high effort to transfer her. Now, in the last few sessions, we put the chair near to the car and she moves on her own without any help.	Interviewer: Do you mean physical fitness? P10: Yes, I have become fitter. Yes, my activity has changed. Now I can leave home and come back feeling better compared with before going on the program.
-----	--	--	--	---

Category: Movement control/quality	
Code	More controlled movement
Case	
P2	When I was first doing it, I was moving too fast. And that's why I think trying to get moving too fast. That's why the pictures got me. But at the end, like I say, obviously I found that was more controlled. When I first started it, I found it quite difficult. But obviously, then I got used to having think through something I need to do, like the movements much slower, more controlled. So at first, I found it quite difficult, but then obviously, as time went by, it got easier. I tend to control my movement.
P4	Interviewer: More flexible in which activities? P4: Turning round. It's less mechanical now.

Category: Balance				
Code	Balance improvement	ability	Improvement in weight shifting ability	Reaching away
Case				
P1			I've been able to move around in my boats a little bit easier now to the left and right Interviewer: So it's mainly weight shifting? .. Participant: Yes	
P3	it has improved my balance.			
P5	all of the studies that I have taken part in and all of the physio that I've ever had involved lower limb or upper limb. This is first-time		Can you give me an example of the movement that you are able to do it better than you could before or confident?	

	<p>trunk has been focused on, and it's made me feel balanced and more controlled in my movement</p> <p>I have noticed a difference in my strength-- an increase in my strength and balance. Which strength do you mean? Or which activity you feel most strength?</p> <p>In my general moving around, I feel more confident and stronger. When I get knocked off balanced, I'm able to correct it quicker and not fall. It makes my torso and my trunk and my core stronger and makes my movements more confident.</p>	<p>The lateral movements. To the left and to the right.</p>	
P7		<p>Now, I can turn right and left more quickly.</p>	
P8			<p>Before the program, it was very difficult for me to collect anything from the ground by myself. Now I can pick up the box of tissue from the floor by myself while standing.</p>
P10			<p>the ability to reach the things with my hands that were beyond my reach has become easier. Thank God, I can now stretch out to pick up things better than before.</p>

**Theme: Perceived impact of intervention**

**Subtheme: Psychological**

<b>Category: Source of hope</b>	
<b>Code</b>	<b>Eye opening to the recovery possibilities</b>
<b>Case</b>	
P1	it's just opened my eyes to more possibilities of my improvements that I can make
P9	When I practiced pelvic movement in the Clock Game and found myself able to move my pelvis.

<b>Category: Self-efficacy</b>	
<b>Code</b>	<b>More capable &amp; confident</b>
<b>Case</b>	
P5	I do feel a little bit stronger and a little bit more capable.  I think I'm more confident in my movements.
P8	I have noticed that I have become more confident and better balanced when I walk on the grass.

<b>Category: Mental capacity</b>	
<b>Code</b>	<b>Cognitive ability improvement</b>
<b>Case</b>	
P5	I think it's brilliant for teaching you-- you're doing multitasking, in a way. So you're concentrating on moving, and also concentrating on score and on the game itself. And that's why I think it's brilliant.  it can be good for your cognition. Because whenever I move, when I walk, to make sure that I don't fall over, I have to concentrate. I mean, normally, when you walk, or when you walk, you don't even think about it. You just do it. But for me, I have to think about where I'm placing my feet and what I'm-- is it safe? Am I planting my foot properly? What obstacles are coming? People going to walk in front of me? Etc. Etc. So all the time I've been like this, I've had to concentrate on the areas that don't move naturally.  I've developed the ability to switch between concentrating on movement and then not having to-- so I can drive, because the areas that I drive just with one hand, and I don't have to change gear, so I can focus 100% on driving. But if I had to start thinking about putting down the clutch with my left foot and then using this hand to change gear, then that would be a different thing entirely.
P6	I loved the idea of exercising through playing and watching the movement on the screen. It increases my focus on the exercises.

<b>Category: Positive feeling</b>		
<b>Code</b>	<b>Feeling happy</b>	<b>Fun and enjoyment</b>
<b>Case</b>		
P2		Really enjoyed it. It was good fun.
P4		I enjoyed it immensely. I enjoyed it a lot.
P6		I somewhat enjoyed them

P7	Doing the exercises made me happy	
P9		I have enjoyed it a lot.
P10		It made me feel like I was entertaining myself and exercising the hemiplegic body parts at the same time.

<b>Category: Negative feeling</b>		
<b>Code</b>	<b>Frustration</b>	<b>Upsetting</b>
<b>Case</b>		
P4	I found that very frustrating in that I thought I had got the aim to that but I haven't.	
P8		What is your least favourite game? The Diver game. Why? Because if I made a small mistake, I lost everything I had earned. This was upsetting.

<b>Category: Exercise engagement</b>		
<b>Code</b>	<b>Lots of work and repetitions without realizing it</b>	<b>Excited to exercise</b>
<b>Case</b>		
P4	It is an excellent way of getting a lot of work done without realizing it.  When you told me how many repetitions I'd done, it was amazing.	
P6		I think that doing exercises by playing video games was a great experience because it made me excited to do the exercises.
P8		The exercises were very enjoyable and they offered excellent rehabilitation. It gave me a sense of excitement to do more and more exercises.  Video games give me more energy and are more exciting. Nothing has hindered me and I wished that I could play the games longer.  Because doing the exercise using video games is exciting. For example, when I get points when playing a game, I become more excited, and want to get more points.

**Theme: Motivation to exercise with video games**

**Subtheme: Fun and enjoyment**

<b>Category: Exercise characteristics</b>			
<b>Code</b>	<b>Boring repetitive conventional exercise</b>	<b>Sort of distraction</b>	<b>Enjoyable way of exercising</b>
<b>Case</b>			
P1	Well, that's not very interesting. I would like that to just doing an exercise on a static bicycle just peddling around, and around, and around all the time. You're not going anywhere. Even though you know it's good for you. You need to-- rather than concentrating on just peddling around, and around, and around on a bike, you need to do other things as well at the same time.		
P2	Boring [laughter]. Quite boring. And obviously, when you do games, at least you got to keep going. Because if I was at home doing it, I would probably do it for a little while, and then I'd probably give up and stop.		Because I find it if you're doing it with a game, it's fun  Because it's fun, and the time goes fast. So, therefore, you don't realize that you're doing exercises.
P3	Well, you just wouldn't do those exercises without because it just be just repetitive boringness. I knew it just wouldn't do.	Well, might give you something to concentrate on rather than thinking about the exercise you're doing. So it's sort of a distraction, more interesting what the little avatar or whatever move he's doing rather than what you're doing.	Because it's an enjoyable way of doing exercise, and keep things together.
P4	Trunk exercise without video games, like a lot of physiotherapy, is a bit boring. This manages to accomplish the task and also		

	to enjoy what you're doing at the same time.		
P5	I think for me as well, more motivating because it could be quite boring just doing same exercise. Just do it. Just do it. But if you're playing games, you are in it with your head rather than just doing bland sort of repetitive exercises		
P6	Video games make me more excited to exercise. If I did the same exercises without the games, I think I would get bored from repeating the same exercise.		
P10	Without playing video games, I will get bored doing the same exercise over time.		

<b>Category: Positive sense</b>		
<b>Code</b>	<b>Sense of competition</b>	<b>Sense of accomplishment</b>
<b>Case</b>		
P5	I think it's good. It's a good way to rehabilitate. I've done all my rehabilitation at Southampton playing, nearly all of it, computer games, so.	
P9		The scores I got gave me a sense of accomplishment, and I knew that I did the exercise very well.  every time I played it, I wanted to collect more coins than the previous session, and this gave me a sense of accomplishment
P10	And why it is motivating do you think? Because you're competing with yourself.	I felt happy when I achieved the goals,

**Theme: Motivation to exercise with video games**

**Subtheme: benefits from intervention**

<b>Category: Physical Improvement</b>			
<b>Code</b>	<b>Trunk control improvement</b>	<b>Movement improvement</b>	<b>Balance improvement</b>
<b>Case</b>			
P1		It's just to improve my movement.  Because if you need-- if you want to make improvements, you have to do exercises.	
P4	Because from experience, I know it is doing my upper trunk some good.		
P5	It makes my torso and my trunk and my core stronger and makes my movements more confident.		
P6		Because I consider it as a rehabilitation program. It might be beneficial and improve my body health despite using video games.	
P8			because I noticed an improvement in my balance.
P9			Because I think that the program might be useful for improving their balance and enjoyable at the same time.
P10		it improves the concentration ability and it is good for the body movement as well	

<b>Category: Psychological improvement</b>		
<b>Code</b>	<b>Memory improvement</b>	<b>Concentration improvement</b>
<b>Case</b>		
P6		Because it helps me to focus and I become engrossed in the exercise.
P7	To improve my memory	
P10		playing games helps me to focus on exercising and winning  it improves the concentration ability and it is good for the body movement as well

**Theme: Motivation to exercise with video games**  
**Subtheme: Informative and motivational feedback**

<b>Category: Motivation through feedback</b>				
<b>Code</b>	<b>Collect more points</b>	<b>Carry on</b>	<b>Sense of success</b>	<b>Happy feeling</b>
<b>Case</b>				
P2		I think it gives you more incentive to carry on. And obviously, when I do, obviously, get the fruit or whatever, it goes, "Woohoo," that's nice. That's a bit of a tease, I think		how did they make you feel? Pleased what I've done. Maybe smile [laughter]
P4				I loved the sounds on what I call the pinball game. And how these sounds and these avatars or figures make you feel? They give me a happy feeling.
P6	They encourage me to get more points every time			
P7				It made me feel happy
P8		motivated me to perform the exercise until I won	The sounds and pictures gave me a sense of success ..	

P9	The sounds when performing the exercises are good. The continuous sounds that appear when I collected a lot of coins in High Flyer made me excited about doing the exercise, and collecting more coins		It makes me feel like I am a real success	
P10	It made me excited to get more			I felt happy when I achieved the goals and the sounds motivated me to do more.

<b>Category: Information through feedback</b>		
<b>Code</b>	<b>Help to set a goal</b>	<b>Exercise correctly</b>
<b>Case</b>		
P1	Well, it helps set a goal.  Motivated me more to be where you had to be.	
P5	it made me feel like they're an asset to help me improve in my rehabilitation.	
P6		assure me that I am doing the exercises correctly
P7		it proved that I am excellent and that I had done the exercise very well.
P10	I felt happy when I achieved the goals	It also told me if had done it right or wrong.  The sounds are not annoying. Rather, they are good like the bell sound (ding) when I do something correctly.

**Theme: Burden of participation**

**Subtheme: physical challenge**

**Category: Balance challenge**

Code Case	Fast movement required	Weight bearing on hemiplegic side	Extreme movement
P3		<p>That was the worst. Trying to hold it one way or the other.</p> <p>It's just trying to keep your butt cheek up one side or the other when they kept on sticking the same fruits down all the time</p>	<p>I found it quite difficult in some times because I couldn't seem to twist far enough. Or if I could I couldn't hold it there when I needed to hit the ball. it was- so in that respect it was actually quite tricky</p>
P5	<p>your reaction times are what's important. You can see. So you're right down here on the screen with the avatar, and you can see the next target coming. It's here and it's coming fast. So you have to move from there up to there fast and be able to not overcook it, but get it just right or else you will miss.</p> <p>Yeah, making those extreme movements quickly. So the ball's coming down the table and it suddenly changes at the last minute, so you're sort of lining it up and suddenly it just veers off. And so I'm all over this way, and I've suddenly got to switch quickly. And that is not easy.</p>		<p>it's difficult because you change the range of movement scale and so I had to move even more extreme to be able to hit the targets.</p>

P6		<p>Why was it difficult? Because it was tiring. Moving toward right and left side was exhausting, especially when I leaned on the hemiplegic side</p> <p>I was afraid of losing my balance and falling when I leaned on my hemiplegic side.</p>	
P7			From the second session, it got difficult. If we divide the sessions into two parts, the first part was easy and the second part was difficult. Besides, when I upgraded my level in the game, it became difficult as the movements increase.
P8		Because it requires more effort on the hemiplegic side. I have to load all my body weight onto it. Also, the tightness that I felt on the sides of the trunk when I performed this exercise made this game difficult for me.	
P9	Because following the ball movement was exhausting and it required a very fast movement.		
P10	It required me to move very fast and I can't do that. Also, in terms of difficulty, the bombs made me feel that it was hard for me to collect the coins and avoid them at the same time.	<p>Why was it difficult? At first, it was difficult. Then it became easy when I kept playing it. S1 I think it was easier if I leaned on the left side, but when I leaned on the right side (the hemiplegic side), it was difficult.</p>	

<b>Category: Challenging exercise position</b>		
<b>Code</b>	<b>Arm out by side</b>	<b>Remain steady</b>
<b>Case</b>		
P2	<p>I found that quite hard at first because I had my hands down by my side, which I thought my right arm was getting in the way. So when I started doing it with my arms across my chest, I found it much easier</p> <p>When I had my arms across my chest, I found it easier. But when I had done it before, it felt as if my hand was getting in the way.</p>	
P3		It wasn't very challenging apart from trying to get your pelvic in one position for a very lengthened time
P5	More difficult with arm out---by the side	
P9		It also requires me to remain steady in a certain position and control my movement until I could enter through the ring or collect the beehives.

<b>Category: Complex movement</b>		
<b>Code</b>	<b>Difficult pelvic movement</b>	<b>Exhausting multi-movement</b>
<b>Case</b>		
P5	<p>it drives you crazy.</p> <p>It is not easy for me, yeah. Because I don't have sensation, I don't have to move like that. Or I do now. And I'm only just, since playing the game, is the first time I've started to move like that. So it's very difficult, that game.</p>	
P6		<p>Why was it difficult?</p> <p>It was exhausting. I had to perform more than one movement at the same time to win the ring. The more I moved forward, the more difficult it was to collect the beehives and strawberries.</p> <p>Do you mean exhausting physically or mentally? Physically.</p>

P7	The pelvic movement was difficult. S1 Why? S2 Because if we look at the human body, the pelvis is in the lower body. The upper body parts are heavy whereas the lower body parts are light, so that makes it difficult for me to move my pelvis. I think the movement would be easier if the exercise required me to move the upper body parts only.	It also requires more than one movement at the same time (forward and backward, right and left).
P8	Why do you think it was difficult? Because it is hard to move my pelvis backwards and forwards. Before playing the game, I didn't normally practice this pelvic movement in my daily life. That was not easy for me. Do you find moving the pelvis backward and forward is more difficult than moving it right or left? Yes.	
P9		Because I had to make more than one move at the same time and this was difficult for me.

**Theme: Burden of participation**

**Subtheme: Cognitive challenge**

<b>Category: Mental effort</b>			
<b>Code</b>	<b>High concentration</b>	<b>Multitasking</b>	<b>Problem-solving</b>
<b>Case</b>			
P1			Because that was a lot of problem-solving and predicting where the ball is going to be--and the obstacles you have to get around.
P2	<p>Because you've got to concentrate more. You've got, obviously, you have movement, and obviously, think where the ball is and where the hole is for the ball to go in to.</p> <p>The Easy level was really easy. But obviously, with the harder level because there's more obstacles and it's faster.</p>	<p>you've really got to concentrate [laughter]. You've really got to do about three things at once like find out where the ball's got to go, and obviously, do the obstacles.</p>	
P4	<p>What make it difficult? There is quite a lot to concentrate on.</p>		
P7	<p>I need to be accurate, like in basketball. If I don't hit the goal, I'll lose. I have to be very accurate to get the ball in the basket.</p>		
P8	<p>It was hard at the beginning because I couldn't follow the ball .. it was too fast, So, I had to concentrate on where the ball was going to move. But it became easier over time.</p> <p>It required more effort and strong concentration.</p>	<p>In what way did it require effort? It consisted of various movements. It required me to perform two movements at the same time. I also had to be highly focused on my body movements until I could move through the ring.</p> <p>Why do you think it is very difficult?</p>	

		Because I have to perform more than one movement and, at the same time, I have to focus more on the colors when they change.	
P9			Because it needs a great deal of mental effort. I couldn't anticipate which fruit would come, whether orange or watermelon. So, I had to focus in order to be able to move quickly towards the goal.
P10		It required me to move very fast and I can't do that. Also, in terms of difficulty, the bombs made me feel that it was hard for me to collect the coins and avoid them at the same time.	

**Theme: Burden of participation**

**Subtheme: Resources: transportation, care and time**

<b>Category: facilitators and barriers to commit to the intervention</b>				
<b>Code</b>	<b>Supportive carer</b>	<b>Independent driving</b>	<b>Time convenience</b>	<b>Busy carers</b>
<b>Case</b>				
P1			because I knew I could jump over in my sailing.	
P3	was it difficult for you to commit to the intervention program? No, I don't think so. Carer: you had a willing taxi driver. P3: Well, yes, fortunately, yes [laughter]			
P5			What make it easy? You know I drive my car. So, I can come to the sessions by myself.	
P7	It was easy for me to commit to the sessions because I could see they were beneficial. I also thank God for having great sons, because if one couldn't drive me to the clinic, the other would do instead.			
P8		What make it easy? Because I can come anytime by myself using my car		
P9				my sons were driving me to the clinic. However, sometimes they were busy so I couldn't commit to all the sessions.

**Theme: Recommendations for professionals**

**Subtheme: Game design**

<b>Category: Game features</b>			
<b>Code Case</b>	<b>Confused fruit game</b>	<b>Sensitive colour game</b>	<b>Boring clock game</b>
P1	Once I realized that the crate at the top was my trunk and the bottom one was my pelvis well, it-it's as soon as I made the distinction that the top part was my trunk-- I got my head around that, then I could suddenly decide which way to go and how far to lean	It's very hard to put my finger on the exact reason why I found it difficult. is it the movements required very difficult, or is it because the ball is very fast? quite a combination of-it's how sensitive it can be at times	
P2	The only thing that I had problems with is trying to do the hip. I can't get my head around that, but everything else seemed okay. Because once you move to the movement to get the fruit in the basket, you stay put. And of course, then you're going to realize that you've stayed put and you've got to move a little bit to actually get it into the basket. So I kind of got my head around that.	Because you've got to concentrate more. You've got, obviously, you have movement, and obviously, think where the ball is and where the hole is for the ball to go in to. I was thinking at first, I was doing it too sharpish, too fast. And then afterwards, obviously, you've got to control it, haven't you? So that's why. You know, control it.	
P3			That was boring. it was only sort going backwards and forwards. So, it I was boring because of that.
P4	My mind got confused too many times with which side of my buttock to lift		
P5		it's so twitchy. It's so unforgiving. If you overextend or if you move too quickly, it's really difficult to control.	Clock is boring
P6			What is your least favourite game? The Clock Game, because the movement was monotonous and repetitive

Category: Scoring strategy	
Code	Lost everything
Case	
P8	What is your least favorite game? The Diver game. Why? Because if I made a small mistake, I lost everything I had earned. This was upsetting

**Theme: Recommendations for professionals**

**Subtheme: Training at the right level of challenge**

Category: Task difficulty level			
Code	Easy clock game	Difficult clock game	Exhausting Break Breaker game
Case			
P4	That was very easy. There is only one thing to concentrate on which is hitting the blue dot		
P5		it's difficult because you change the range of movement scale and so I had to move even more extreme to be able to hit the targets.	And what about break breaker game? Drive you crazy, really unpredictable ball changing direction at the last second.
P6		The game was difficult. I will give it four. Why was it difficult? Because it was tiring. Moving toward right and left side was exhausting, especially when I leaned on the hemiplegic side.	
P7	It required one movement so it was easy for me.		Because I had to move my entire body to follow the ball and, in the end, I wasn't able to hit the goal correctly. "You never know what you can do until you try." (laughter)
P8		it requires more effort on the hemiplegic side. I have to load all my body weight onto it. Also, the tightness that I felt on the sides of the trunk when I performed this exercise made this game difficult for me.	I couldn't follow the ball .. it was too fast, So, I had to concentrate on where the ball was going to move.

P9	it was easy because it doesn't need so much focus. The ball here moves only when I move and I don't lose it.		Because following the ball movement was exhausting and it required a very fast movement.
P10		At first, it was difficult because I felt tightness in my muscles when I was playing.	

**Theme: Recommendations for professionals**

**Subtheme: Feedback on performance**

<b>Category: Clarity of feedback</b>		
<b>Code</b>	<b>Clear feedback</b>	<b>Unclear feedback</b>
<b>Case</b>		
P3	"I did understand the score showing my performance at each game." No, I didn't necessarily understand where the scores came from.	
P4		Very good, and when do you see your scores, what did you understand from the scores showing in each game? That I had done well or not so well
P7		I understood it after the physiotherapist had explained it.
P8		I understood it at the end and after the physiotherapist had explained it to me

**Theme: Recommendations for professionals**

**Subtheme: Integrated rehabilitation package**

<b>Category: Participant's suggestions</b>		
<b>Code</b>	<b>65. Longer sessions</b>	<b>UL and LL training</b>
<b>Case</b>		
P8	I wish it had been longer with 35 sessions rather than only 18 sessions	Nothing needs to be changed, but I would prefer to increase the time of the program and to include games for moving a hemiplegic hand.  I would like to have a program that combines video games for the torso with exercises designed for increasing fitness, such as walking on a treadmill. They should also include movements for a hemiplegic hand and leg.
P10	Wished the sessions were longer because I loved them.	

**Theme: Safety**

**Subtheme: Feeling safe**

<b>Category: Safe environment</b>		
<b>Code</b>	<b>Patient exercising in a safe environment</b>	<b>Close physiotherapist</b>
<b>Case</b>		
P1	I know I was in a safe environment doing it, you know.	
P4	I feel perfectly safe while playing the video games. I know that there is nowhere to fall.	I'm on the bed, and my physiotherapist was close by in order to make sure that I didn't go anywhere untoward.
P6		Sometimes I was afraid of falling because my balance was weak, but having the physiotherapist next to me made it less scary.
P8		Initially, I felt that I would fall, but I knew that the physiotherapist was there. As the sessions progressed, I felt much safer.
P9		I felt safe because while I was doing the exercises, the physiotherapist and my son were standing near me

<b>Category: Safe exercise position</b>	
<b>Code</b>	<b>Safe exercise position</b>
<b>Case</b>	
P2	I felt safe mostly on the standing up ones. I didn't feel as though I was going to go over or whatever. But when I sat down in doing it, on some of the games, my feet started moving a little bit. So, therefore, I prefer to do them standing up than I would sitting down, especially the Break Breaker one because obviously when I was sitting down, and obviously I reckon my arm was getting in the way, so I felt easier to do it standing up.
P6	I was doing the exercise in a sitting-down position, so it didn't require much effort compared to the standing clock game

**Theme: Safety**

**Subtheme: Resultant symptoms**

<b>Category: Physical symptoms</b>			
<b>Code</b>	<b>Feeling dizzy</b>	<b>Muscle tightness</b>	<b>Fatigue</b>
<b>Case</b>			
P8		the tightness that I felt on the sides of the trunk when I performed this exercise made this game difficult for me.	
P9	following the ball movement was exhausting and it required a very fast movement. It made me feel dizzy. Therefore, I needed to pause for a few minutes and have a rest.		The pelvic movement was very difficult and made me feel a bit fatigued sometimes
P10		it was difficult because I felt tightness in my muscles when I was playing.	

## Appendix 43 Trunk ROM during SWMFT performance in each task

### Task 1

Parameters of interest	ID	Pre	Post	Change %	Difference (post-pre)
Trunk flexion	1	3.21	3.75	16.89	0.54
	2	7.42	10.62	43.11	3.20
	4	16.02	0.99	-93.83	-15.03
	5	17.90	18.35	2.55	0.46
	6	2.29	0.21	-91.01	-2.08
	7	4.80	5.77	20.25	0.97
	8	9.68	0.10	-98.97	-9.58
	9	11.64	2.29	-80.35	-9.35
	10	4.67	2.10	-55.12	-2.58
	Trunk lateral flexion toward unaffected side	1	8.16	2.20	-72.97
2		8.60	-7.23	-184.10	-15.83
4		12.94	24.22	87.22	11.28
5		17.16	24.29	41.51	7.12
6		7.34	-4.12	-156.11	-11.46
7		4.33	1.17	-73.04	-3.17
8		18.06	16.58	-8.19	-1.48
9		31.55	-7.34	-123.27	-38.89
10		12.36	-4.55	-136.8	-16.92
Trunk axial rotation toward affected side		1	5.53	4.83	-12.6432
	2	13.63	16.44	20.64336	2.81
	4	22.57	14.19	-37.1096	-8.37
	5	12.33	17.17	39.24388	4.84
	6	3.13	0.57	-81.8532	-2.56
	7	2.83	1.56	-44.8844	-1.27
	8	16.10	9.76	-39.3795	-6.34
	9	6.26	3.13	-49.9912	-3.13
	10	9.86	10.98	11.41259	1.13

Task 2

Parameters of interest	ID	Pre	Post	Change %	Difference (post-pre)
Trunk flexion	1	12.39	11.56	-6.70	-0.83
	2	2.78	0.03	-98.78	-2.75
	4	6.49	1.78	-264.85	-4.71
	5	7.44	3.26	-56.09	-4.17
	6	7.67	7.58	-1.16	-0.09
	7	11.28	6.79	-39.78	-4.49
	8	5.83	2.05	-64.91	-3.79
	9	7.58	8.05	6.13	0.46
	10	3.87	1.67	-56.94	-2.20
	Trunk lateral flexion toward unaffected side	1	0.22	0.19	-12.34
2		15.73	9.47	-39.80	-6.26
4		28.81	13.95	-51.57	-14.86
5		23.09	13.25	-42.61	-9.84
6		6.48	8.64	33.39	2.16
7		3.43	4.51	31.61	1.08
8		13.23	5.74	-56.66	-7.50
9		27.13	8.64	-68.16	-18.49
10		8.03	4.63	-42.32	-3.40
Trunk axial rotation toward affected side		1	5.61	1.96	-64.95
	2	3.53	1.24	-64.90	-2.29
	4	33.89	28.03	-17.29	-5.86
	5	4.56	3.27	-28.31	-1.29
	6	1.65	2.01	21.25	0.35
	7	2.49	5.38	115.98	2.89
	8	14.48	6.86	-52.62	-7.62
	9	11.17	1.65	-85.19	-9.52
	10	10.40	3.77	-63.74	-6.63

**Task 3**

<b>Parameters of interest</b>	<b>ID</b>	<b>Pre</b>	<b>Post</b>	<b>Change %</b>	<b>Difference (post-pre)</b>
<b>Trunk flexion</b>	1	18.31	10.20	-44.30	-8.11
	2	13.22	12.18	-7.86	-1.04
	4	16.44	12.59	-23.42	-3.85
	5	24.27	13.05	-46.21	-11.21
	6	3.95	2.53	-35.91	-1.42
	7	18.32	3.95	-78.45	-14.37
	8	10.22	17.99	75.93	7.76
	9	4.23	5.09	20.19	0.85
	10	18.64	10.67	-74.73	-7.97
	<b>Trunk lateral flexion toward unaffected side</b>	1	9.67	2.32	-75.97
2		16.14	19.72	22.18	3.58
4		17.67	17.91	1.36	0.24
5		12.09	7.01	-42.02	-5.08
6		9.02	8.16	-9.50	-0.86
7		7.01	1.49	-78.75	-5.52
8		16.52	15.49	-6.23	-1.03
9		22.74	9.02	-60.33	-13.72
10		16.44	14.54	-11.60	-1.91
<b>Trunk axial rotation toward affected side</b>		1	10.56	6.13	-42.00
	2	12.49	14.48	15.96	1.99
	4	14.18	18.74	32.14	4.56
	5	14.78	15.94	7.86	1.16
	6	11.04	3.89	-64.78	-7.15
	7	5.66	8.86	56.63	3.20
	8	14.21	11.87	-16.41	-2.33
	9	12.29	11.04	-10.13	-1.24
	10	11.75	12.61	7.31	0.86

**Task 4**

Parameters of interest	ID	Pre	Post	Change %	Difference (post-pre)
<b>Trunk flexion</b>	1	6.68	6.53	-2.21	-0.15
	2	19.42	17.95	-7.55	-1.47
	4	26.29	18.55	-29.44	-7.74
	5	25.21	25.70	1.93	0.49
	6	32.08	5.98	-81.35	-26.10
	7	39.22	11.50	-70.68	-27.72
	8	33.96	35.98	5.97	2.03
	9	31.24	20.06	-35.80	-11.18
	10	14.82	10.63	-28.30	-4.19
	<b>Trunk lateral flexion toward unaffected side</b>	1	7.01	5.15	-36.04
2		27.13	23.76	-14.17	-3.37
4		22.86	16.74	-36.56	-6.12
5		7.14	7.97	10.41	0.83
6		12.35	8.15	-51.48	-4.20
7		2.02	0.63	-222.09	-1.39
8		16.56	13.02	-27.26	-3.55
9		10.13	9.65	-4.98	-0.48
10		6.20	7.99	22.42	1.79
<b>Trunk axial rotation toward affected side</b>		1	7.95	4.27	-86.23
	2	25.97	13.79	-88.24	-12.17
	4	27.24	17.84	-52.68	-9.40
	5	4.51	5.12	11.91	0.61
	6	9.52	6.20	-53.54	-3.32
	7	8.92	5.06	-76.38	-3.86
	8	14.28	16.25	12.13	1.97
	9	12.09	9.94	-21.65	-2.15
	10	9.55	5.22	-82.89	-4.33

Task 5

Parameters of interest	ID	Pre	Post	Change %	Difference (post-pre)
Trunk flexion	1	6.68	5.75	-13.94	-0.93
	2	17.95	17.46	-2.77	-0.50
	4	26.29	22.09	-15.98	-4.20
	5	25.21	20.19	-19.91	-5.02
	6	32.08	30.28	-5.61	-1.80
	7	39.22	39.45	0.58	0.23
	8	35.98	21.43	-40.45	-14.55
	9	31.24	30.08	-3.71	-1.16
	10	14.82	13.89	-6.28	-0.93
	Trunk lateral flexion toward affected side	1	0.15	0.10	-36.89
2		0.45	0.47	3.93	0.02
4		22.86	15.25	-33.29	-7.61
5		7.14	7.42	4.02	0.29
6		8.35	5.72	-31.55	-2.64
7		1.02	1.01	-0.80	-0.01
8		7.56	7.98	5.46	0.41
9		7.13	6.35	-10.91	-0.78
10		11.20	9.45	-15.66	-1.75
Trunk lateral flexion toward unaffected side		1	8.69	7.34	-15.45
	2	13.79	12.39	-10.19	-1.41
	4	27.24	17.54	-35.61	-9.70
	5	36.51	28.96	-20.67	-7.54
	6	9.52	6.16	-35.30	-3.36
	7	8.92	6.85	-23.18	-2.07
	8	14.28	6.08	-57.45	-8.20
	9	12.09	9.52	-21.23	-2.57
	10	9.55	8.06	-15.55	-1.48

**Task 6**

Parameters of interest	ID	Pre	Post	Change %	Difference (post-pre)
Trunk flexion	1	5.44	4.51	-17.03	-0.93
	2	18.84	15.39	-18.34	-3.46
	4	15.64	11.79	-24.58	-3.84
	5	2.69	2.90	7.79	0.21
	6	12.91	10.96	-15.11	-1.95
	7	5.16	4.03	-21.86	-1.13
	8	1.89	2.10	11.01	0.21
	9	6.84	6.46	-5.62	-0.38
	10	5.03	4.85	-3.66	-0.18

**Task 7**

Parameters of interest	ID	Pre	Post	Change %	Difference (post-pre)
Trunk Extension	1	28.48	20.65	-27.51	-7.83
	2	26.23	26.52	1.12	0.29
	4	19.09	9.36	-50.99	-9.74
	5	13.92	10.26	-26.25	-3.65
	6	13.01	6.70	-48.51	-6.31
	7	27.25	11.22	-58.82	-16.03
	8	30.16	27.82	-7.75	-2.34
	9	26.23	25.52	-2.69	-0.71
	10	19.22	17.95	-6.61	-1.27

**Task 8**

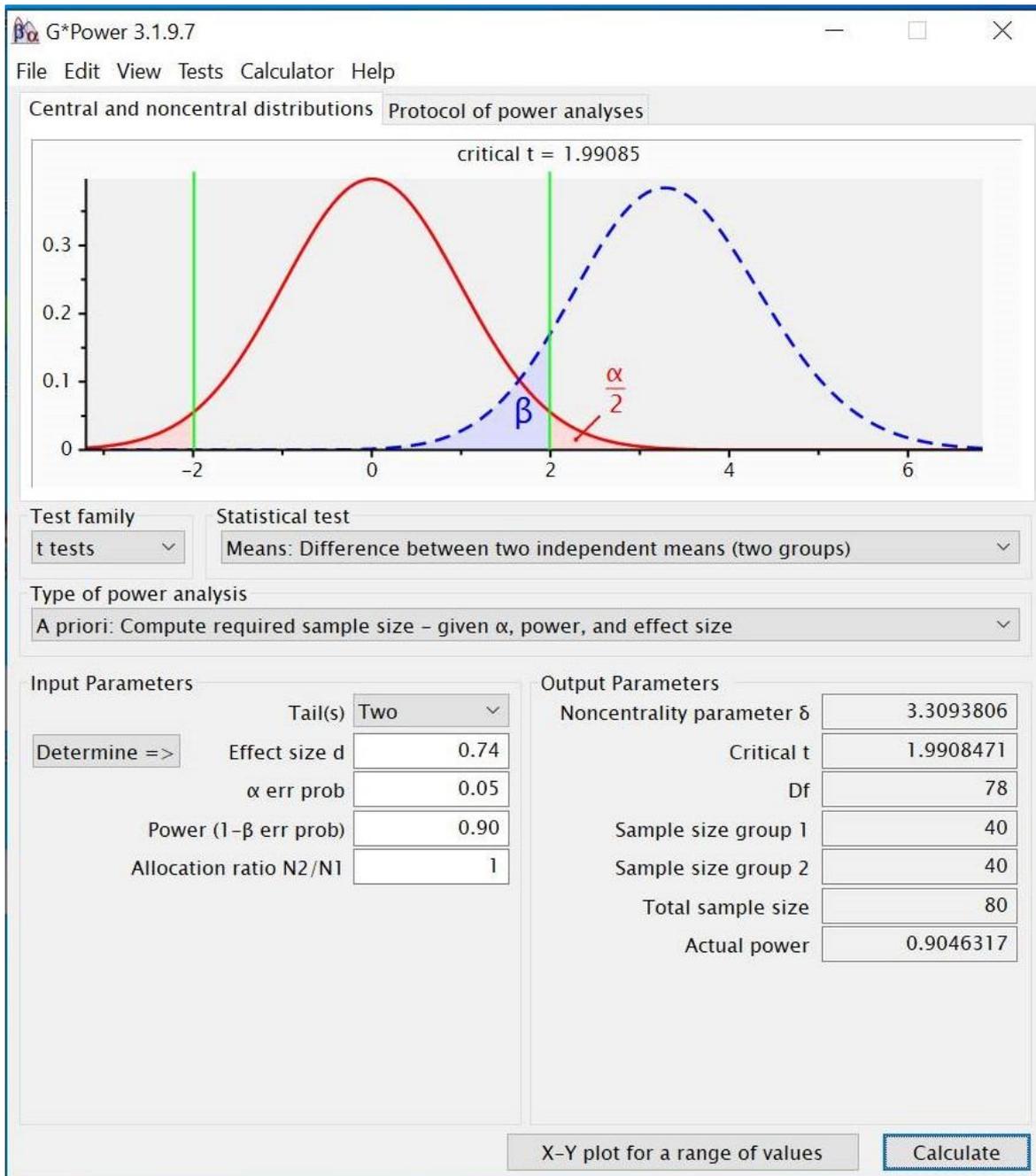
Parameters of interest	ID	Pre	Post	Change %	Difference (post-pre)
Trunk flexion	1	4.37	2.42	-44.69	-1.95
	2	7.62	7.31	-4.03	-0.31
	4	3.94	6.46	63.83	2.52
	5	42.13	8.45	-79.94	-33.68
	6	3.34	2.06	-38.32	-1.28
	7	3.78	16.44	335.54	12.67
	8	18.82	8.69	-53.81	-10.13
	9	7.62	7.31	-4.03	-0.31
	10	16.44	8.14	-50.51	-8.31
	Trunk axial rotation toward affected side	1	4.36	0.43	-90.10
2		9.75	15.68	60.83	5.93
4		26.53	14.24	-46.34	-12.29
5		34.95	14.12	-59.60	-20.83
6		9.38	6.16	-34.31	-3.22
7		13.44	21.17	57.54	7.73
8		11.92	5.21	-56.31	-6.71
9		9.75	15.68	60.83	5.93
10		21.17	8.34	-60.58	-12.82

## Appendix 44 Participants' attendance sheet

ID:

Sessions	Date	Time
First assessment session		
Second assessment session		
Intervention session 1		
Intervention session 2		
Intervention session 3		
Intervention session 4		
Intervention session 5		
Intervention session 6		
Intervention session 7		
Intervention session 8		
Intervention session 9		
Intervention session 10		
Intervention session 11		
Intervention session 12		
Intervention session 13		
Intervention session 14		
Intervention session 15		
Intervention session 16		
Intervention session 17		
Intervention session 18		
Post intervention - assessment session		

## Appendix 45 Using G\*power to calculate sample size



### Review Article

# Do trunk exercises improve trunk and upper extremity performance, post stroke? A systematic review and meta-analysis

Norah Alhwoaimel<sup>a,b,\*</sup>, Ruth Turk<sup>a</sup>, Martin Warner<sup>a</sup>, Geert Verheyden<sup>c</sup>, Liselot Thijs<sup>c</sup>,  
Seng Kwee Wee<sup>d,e</sup> and Ann-Marie Hughes<sup>a</sup>

<sup>a</sup>University of Southampton, Southampton, UK

<sup>b</sup>Prince Sattam University, Al-Kharj, Kingdom of Saudi Arabia

<sup>c</sup>KU Leuven – University of Leuven, Department of Rehabilitation Sciences, Leuven, Belgium

<sup>d</sup>Tan Tock Seng Hospital, Singapore

<sup>e</sup>Singapore Institute of Technology, Singapore

#### Abstract.

**BACKGROUND:** Post-stroke trunk control is reported to be associated with trunk performance and recovery of the upper limb, but the evidence for the influence of trunk exercise on both of these is unclear.

**OBJECTIVE:** To evaluate the effect of trunk exercises on trunk performance post-stroke, and to determine if these exercises result in improved upper limb function.

**METHODS:** A comprehensive search of the literature published between January 1990 and February 2017 was conducted using the following electronic databases; AMED, CINAHL, Cochrane Library, EMBASE, MEDLINE, PsychInfo and SPORT-Discus. Only randomized, controlled trials, published in English, evaluating the effect of trunk exercises on trunk performance and/or upper limb function post-stroke, were included.

**RESULTS:** A total of 17 studies involving 599 participants were analysed. Meta-analysis showed that trunk exercises had a large significant effect on trunk performance post-stroke. This effect varied from very large for acute stroke to medium for subacute and chronic stroke. None of the included studies had measured the effect of trunk exercise on upper limb impairment or functional activity.

**CONCLUSIONS:** Trunk exercises improve trunk performance for people with acute, subacute and chronic strokes. As yet there is no evidence to support the effect of trunk exercise on upper limb function.

Keywords: Meta-analysis, systematic review, stroke, trunk exercise, trunk, upper limb

#### 1. Introduction

The trunk is the central, key point of the body; it plays a postural role in holding the body upright and in performing selective trunk movements, during static and dynamic postural adjustments (Davies and

Klein-Vogelbach 2012; Edwards 1996). Trunk performance is an important predictor for outcomes of balance, gait and activity of daily living (ADL), after a stroke (Franchignoni et al. 1997; Hsieh et al. 2002; Verheyden et al. 2007). The percentage of the variance of functional recovery after a stroke is explained by trunk control ranges from 45% to 71% (Hsieh et al. 2002; Verheyden et al. 2007). One study has shown an overall functional independency evaluated in the

\*Address for correspondence: Norah Alhwoaimel, University of Southampton, Highfield Campus, Southampton SO17 1BJ, UK. E-mail: N.alhwoaimel@soton.ac.uk.

early acute phase, post-stroke; it has been shown to be highly correlated to levels of trunk impairment, followed by upper extremity impairments but not lower extremity impairments (Likhi et al. 2013).

Studies measuring trunk performance after a stroke have used various clinical tools, including the Trunk Control Test (TCT), the Trunk Impairment Scale by Fujiwara (TIS-F) and the Trunk Impairment Scale by Verheyden (TIS-V) (Collin et al. 1990; Verheyden et al. 2004; Fujiwara et al. 2004). These three tools exhibit good psychometric properties and are suitable for use within the clinical setting; they do not require specialised equipment. The TCT measures trunk control in static positions, giving relatively minimal information. The TIS-V measures during selective movements of the trunk, in both static and dynamic positions, including flexion, extension, lateral flexion and rotation (Verheyden et al. 2004). The TIS-F has only been used in two studies to assess the impairment of the trunk in people with a stroke, neither of which applied trunk exercises (Likhi et al. 2013; Fujiwara et al. 2004). The trunk impairment scale (TIS) that will be referred to throughout the rest of this paper is the TIS-V. Rasch analysis of the TIS led to the elimination of the static sitting balance subscale (Verheyden & Kersten, 2010).

People with strokes can have trunk impairments (weakness, loss of selective coordinated muscle action, overactive muscles and stiffness) that lead to insufficient trunk control. This might interfere with their ability to carry out ADL (Verheyden et al. 2007). The Barthel Index measures the degree of independence in performing ADL, such as feeding, transfer, toilet use, bathing, walking, climbing stairs, dressing, bowel and bladder control (Verheyden et al. 2007). It has been reported that the static sitting balance subscale of TIS predicted 50% of the variance in the Barthel Index score, six months after a stroke (Verheyden et al. 2007). Moreover, a recent cross-sectional study has reported that there is a relationship between trunk control, as measured by the TIS, and the ability to use the upper extremities in functional activities amongst people with chronic strokes (Wee et al. 2015).

Trunk control is considered to be a vital component in many facets of stroke recovery, such as balance, gait and functional ability (Verheyden et al. 2004). Several studies emphasize the importance of including trunk training exercises to improve trunk performance and functional recovery after a stroke (Langhorne et al. 2009). The UK Royal College of

Physicians (RCP) National Clinical Guidelines for Stroke recommends, "People with impaired sitting balance after stroke should receive trunk training exercises" (National clinical guideline for stroke 2016; p.73). A systematic review conducted in 2013 explored the effects of focused trunk exercise programmes on trunk impairment (Cabanas-Valdes et al. 2013). Efficacy results from a total of 11 RCTs, included in the systematic review, demonstrated that there was moderate evidence for using trunk training exercises, on stable and unstable surfaces, as a method of improving dynamic sitting, balance and trunk performance in both sub-acute and chronic strokes. However, the intensity of trunk exercise and the best trunk training strategies are still unclear. Although a recent study reported that trunk control has an association with the recovery of the upper extremities, the influence of trunk exercise on both trunk impairment and upper extremity function is still unclear (Wee et al. 2015). Therefore, the aim of this systematic review is to evaluate the effects of trunk training or sitting balance exercises on trunk control and upper extremity function, following strokes.

## 2. Methodology

This systematic review was conducted in accordance with the Cochrane Handbook for Systematic Reviews and Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Higgins & Green 2011, Moher et al. 2009).

### 2.1. Literature search procedure

A comprehensive search of the literature published between January 1990 and February 2017 was conducted, using the following electronic databases; AMED, CINAHL, Cochrane Library, EMBASE, MEDLINE, Physiotherapy Evidence Database (PEDro), PsychInfo and Sport Discus. The following keywords were used; stroke, cerebrovascular accident, paresis, trunk, balance, equilibrium, physical therapy, exercise, motion therapy, rehabilitation, upper limb, upper extremity, reach, reach-to-grasp, grasp. Truncations were used where deemed appropriate. A secondary search of hand-searching of reference lists was also performed to identify additional relevant studies. An example search strategy for MEDLINE is found in Appendix 1.

The title and abstract of the retrieved search results were examined to identify potential eligible publications. If the title and abstract fitted the inclusion criteria, the full text articles were retrieved. The inclusion criteria were the following:

1. Randomised controlled trials (RCT) published in the English language.
2. Involving adults with strokes (age 18 years or older).
3. Intervention involved any form of balance exercise, trunk strength training and/or any form of trunk exercise with or without conventional physiotherapy (CPT). Trunk exercises (TE) were defined as any form of exercises regimens consist of selective movements of the upper and lower part of the trunk with or without raising the upper extremities in supine and/or sitting position (Cabanas-Valdes et al. 2013).
4. Interventions not performed with robotics or functional electrical stimulation alone
5. The studies include a minimum of one of the following primary outcomes:
  - a. Trunk performance as measured by Trunk Control Test (TCT) or the Trunk Impairment Scale (TIS).
  - b. Upper extremity function as measured by valid and reliable upper extremity outcome measures.

The following data were extracted from included studies: author, year, participant's age, sample size, stroke stage, outcome measures, treatment characteristics and main findings (Tables 1 and 2). The main author (AN) assessed the methodological quality of all the included studies using the Cochrane risk of bias tool and the PEDro scale (Table 3), which uses a cut-off score of six points to distinguish high from low quality studies (Higgins & Green 2011). The papers were split between two other reviewers (AMH, RT) to independently assess the methodological quality using the same tools. The authors discussed any inconsistencies related to the quality criteria until a consensus was reached.

## 2.2. Data synthesis

A meta-analysis was conducted where suitable data were available, to examine the effect of trunk exercise on trunk performance and upper extremity function. For the outcome measure of trunk performance, the numbers of each group, means and standard deviations were extracted from the correspond-

ing measures. The overall effect size was calculated by using standardised mean differences (SMD) with 95% Confidence Intervals (CI) using Review Manager Software 5.1 (<http://ims.cochrane.org/revman/download>). The SMD was chosen because of the different measurement tools used to measure the same outcome (trunk performance) (Higgins & Green 2011). The effect size was categorized as; 0.2, 0.5, 0.8, and 1.3, considered as small, medium, large and very large, respectively (Turner et al. 2013).

Further subgroup analysis explored the effect of trunk exercise on trunk performance, relative to the stroke stage (time from stroke), and duration of the intervention ( $\geq 16$  hours, or  $< 16$  hours). The stroke stage was divided, according to the subject inclusion criteria of the studies included, into three stages; the acute stage for subjects who were less than one month post-stroke duration; the sub-acute stage for subjects who were more than one month and less than six months since the onset, and the chronic stage for subjects who were at more than six months' post-stroke duration (Bae et al. 2013, Buyukavci et al. 2016, Cabanas-Valdes et al. 2016, Chan et al. 2015, de Sèze et al. 2001, Fujino et al. 2016, Haruyama et al. 2017, Jung et al. 2014, 2016, Karthikbabu et al. 2011, Kilinc et al. 2016, Kumar et al. 2011, Lee et al. 2012, Saeys et al. 2012, Shine et al. 2016, Verheyden et al. 2009, Yoo et al. 2010). The choice of a 16 hours cut-off duration for the exercise time was based upon the last systematic review, which reported that a study which used 16 hours of specific trunk exercise resulted in the highest improvement in trunk performance (Cabanas-Valdes et al. 2013). When the data were not suitable to be included in the pooled analysis, a descriptive analysis was performed. The heterogeneity was measured using the  $I^2$  statistic; when the heterogeneity was  $\leq 50\%$ , the fixed-effect model was used, otherwise the random-effect model was used for the meta-analysis (Higgins & Green 2011).

## 3. Results

The search procedure is presented in the PRISMA flowchart in Fig. 1. A total of 224 studies were retrieved (after the removal of duplicates). Of these, 87 studies were excluded, after screening the titles and abstracts, because they did not meet the inclusion criteria. Full-text copies were obtained for the remaining 22 studies and reviewed independently by the author (NA). Five articles were excluded because they did not meet the inclusion criteria (Appendix 2).

Table 1  
Included studies characteristics

Author, year	N	Age (yr) Mean (SD)	Stroke stage
Bae et al. 2013	16	E1 : 53.4 (5.8) E2 : 52.4 (7.6)	Chronic
Buyukavci et al. 2016	65	E : 62.6 (10.5) C : 63.6 (10.4)	Acute
Cabanas-Valdés et al. 2016	80	E: 74.92 (10.70) C: 75.69 (9.40)	Sub-acute
Chan et al. 2015	37	E1 : 58.2 (10.7) E2 : 56.3 (7.4) C: 59.3 (10.4)	Chronic
de Sèze et al. 2001	20	E:63.5 (17) C: 67.7 (15)	Sub-acute
Fujino et al. 2016	43	E: 67.9 (7.8) C: 64.4 (7.5)	Acute
Haryama et al. 2017	32	E: 67.56 (10.11) C: 65.63 (11.97)	Sub-acute
Jung et al. 2014	18	E: 51.9 (10.3) C: 57.9 (8.5)	Chronic
Jung et al. 2016	24	E: 58.9 (11) C: 60.7 (7.8)	Chronic
Karthikbabu et al. 2011	30	E: 59.8 (10.5) C: 55 (6.5)	Acute
Kilinc et al. 2016	22	E: 55.91 (7.92) C: 54 (13.64)	Chronic
Kumar et al. 2011	20	E: 59.5 (12.09) C: 57.8 (13.49)	Acute
Lee et al., 2012	28	E: 59 (11) C: 62.3 (4.2)	Chronic
Saeyns et al. 2012	33	E: 61.04 (13.83) C: 61.07 (9.01)	Sub-acute
Shin et al. 2016	30	EG: 60 (8.4) CG: 57.4 (10.3)	Chronic
Verheyden et al. 2009	33	E: 55 (11) C: 62 (14)	Sub-acute
Yoo et al. 2010	59	E:59.61(18.16) C:61.77(12.58)	Sub-acute

E=experimental group, C=control group, Acute=less than one month since onset, Subacute = more than 1 month and less than 6 months since onset, Chronic = more than 6 months since onset.

Finally, 17 full-text articles met the inclusion criteria and were included in this study (Bae et al. 2013, Buyukavci et al. 2016, Cabanas-Valdes et al. 2016, Chan et al. 2015, de Sèze et al. 2001, Fujino et al. 2016, Haryama et al. 2017, Jung et al. 2014, 2016, Karthikbabu et al. 2011, Kilinc et al. 2016, Kumar et al. 2011, Lee et al. 2012, Saeyns et al. 2012, Shine et al. 2016, Verheyden et al. 2009, Yoo et al. 2010).

The sample size of the studies included ranged from 16 to 80 participants, totalling 590 stroke patients, with a mean age range from 51.9 to 75.69 years. The stroke patients were also at different stages, from acute through to chronic phases, post-stroke.

Trunk performance was assessed using the Trunk Impairment Scale (TIS) in 15 studies and in three studies using the Trunk Control Test (TCT). The outcome measures and key findings of the studies are summarized in Table 2.

The total intervention time of the exercise regime ranged from a minimum of 1.5 hours to a maximum of 36 hours, and the duration ranged from 1 to 12 weeks. The dose of the intervention ranged from 15 minutes per day, five days a week, to 120 minutes per day, five days a week. The type of exercise ranged from exercises related to the trunk impairment scale tasks, use of technology (e.g. Functional Electrical Stimulation (FES), Smartphone-Based Visual Feedback Trunk Training), to those using training on a stable or unstable surface (Table 2).

### 3.1. Risk of bias assessment

The assessment of methodological quality and risk of bias are presented in Fig. 2 and Table 3.

### 3.2. Meta-analysis

A meta-analysis of the 17 clinical trials, using the TIS and TCT as a common outcome measure, was undertaken. The meta-analysis was made between the trunk exercise group and the conventional therapy group.

The meta-analysis of the TCT and total TIS score, pooled the data from 17 studies with a total of 320 participants in the trunk exercise group and 317 in the control group. The results demonstrated that trunk exercises had a large, significant effect on improving trunk performance, as measured by TCT and/or TIS, in favour of the experimental group (SMD=0.85; 95% CI=0.58 to 1.12;  $P<0.00001$ ;  $I^2=59%$ , random effect model; Fig. 3).

The meta-analysis of the TCT score only pooled data from three studies with a total of 53 participants in a trunk exercise group and 56 in the control group. The results showed that trunk exercise had a small, non-significant effect on improving trunk performance as measured by TCT, in favour of the experimental group (SMD=0.34; 95% CI=-0.04 to 0.72;  $P=0.08$ ;  $I^2=0%$ , fixed effect model; Fig. 4).

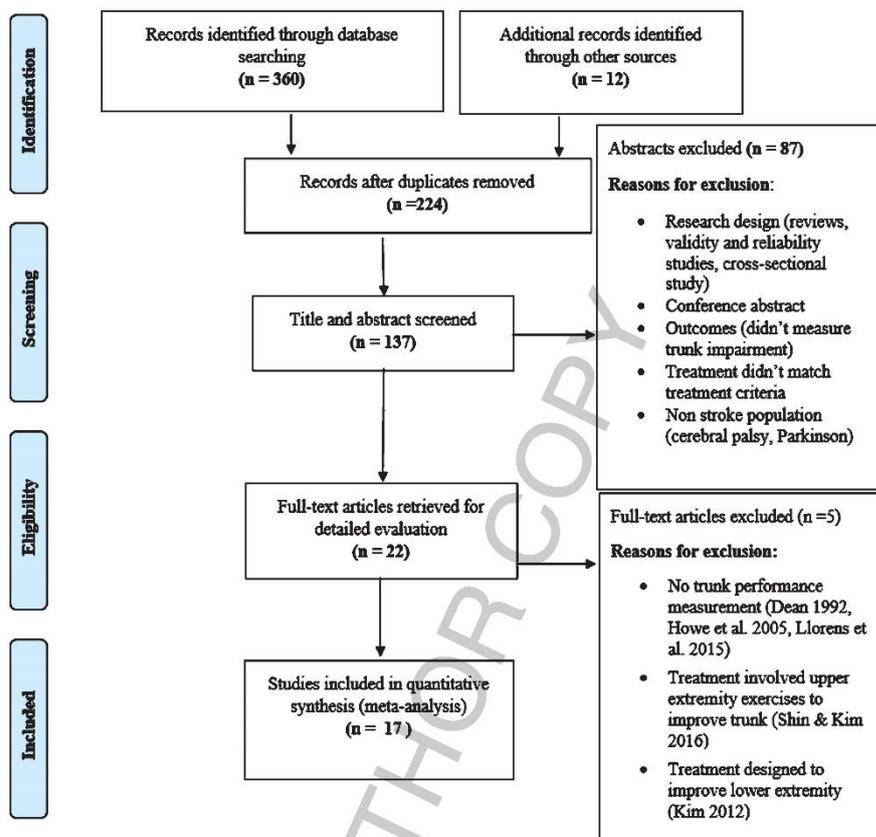


Fig.1. Prisma Flow chart.

The meta-analysis of the total TIS score only pooled data from 14 studies with a total of 227 participants in the trunk exercise group and 222 in the control group. The results showed that trunk exercise had a large, significant effect upon improving trunk performance as measured by TIS, in favour of the experimental group (SMD = 0.98; 95% CI = 0.65 to 1.32;  $P < 0.001$ ;  $I^2 = 61\%$ , random effect model; Fig. 5).

The subgroup analysis of trunk impairment subscales revealed a medium, non-significant effect size in the pooled data of the static subscale (SMD = 0.45; 95% CI = -0.06 to 0.95;  $P = 0.08$ ;  $I^2 = 64\%$ , random effect model; Fig. 6), a large, significant effect in pooled data of the dynamic subscale (SMD = 0.99; 95% CI = 0.76 to 1.21;

$P < 0.001$ ;  $I^2 = 45\%$ , fixed effect model; Fig. 6) and a large, significant effect in pooled data of the coordination subscale (SMD = 0.76; 95% CI = 0.41 to 1.12;  $P < 0.001$ ;  $I^2 = 58\%$ , random effect model; Fig. 6).

The subgroup analysis of the TCT and total TIS pooled data at different stroke stages demonstrated a very large, significant effect on improving trunk performance in favour of the experimental group at the acute stroke stage (SMD = 1.57; 95% CI = 0.76 to 2.47;  $P = 0.0006$ ;  $I^2 = 79\%$ , random effect model; Fig. 7). In the sub-acute stage, trunk exercise had a medium, significant effect on improving trunk performance in favour of the experimental group (SMD = 0.67; 95% CI = 0.44 to 0.90;  $P < 0.00001$ ;  $I^2 = 42\%$ , fixed effect model; Fig. 7). In the chronic

Table 2  
Treatment characteristics of the included studies

Author, year	Experimental group intervention	Control group intervention	Follow-up	Outcome measures	Results
Bae et al. 2013	E1: Trunk stabilization exercises on a stable support surface - 12 wk (30 min./d,5X/wk) E2: Trunk stabilization exercises on an un-stable support surface - 12 wk (30 min./d,5X/wk)	—	NO	TIS	** Total TIS E1 ** Total TIS E2
Buyukavci et al. 2016	Conventional rehabilitation for 2-3 hours+additional trunk balance exercise - 3 wk (120 min./d,5X/wk)	Conventional rehabilitation includes group-neurodevelopmental facilitation techniques and OT - 3 wk (120 min./d,5X/wk)	NO	TIS	-Total TIS,static sitting, dynamic, coordination subscales
Cabanas-Valdés et al. 2016	1 hour of patient specific conventional physiotherapy+Additional core strengthening exercise - 5 wk (15 min./d,5X/wk)	1 hour of patient specific conventional physiotherapy - 5 wk (15 min./d,5X/wk)	No	TIS	** Total TIS, dynamic, coordination subscales
Chan et al. 2015	E1: transcutaneous electrical nerve stimulation (TENS)+task-related trunk training (TRTT) - 6 wk (60 min./d,5X/wk) E2: placebo-TENS+(TRTT) - 6 wk (60 min./d,5X/wk)	Placebo-TENS - 6 wk (60 min./d,5X/wk)	Yes	TIS	* TIS dynamic subscale in all groups * TIS coordination subscale in E1 group -Total TIS,static sitting subscale in all groups
de Sèze et al. 2001	Phase1 : 1 hour conventional rehabilitation+1 hour on Saint Come Device - 4 wk (60 min./d,5X/wk) Phase 2: conventional rehabilitation	Phase1: 2 hours of conventional rehabilitation - 4 wk(120 min./d,5X/wk) Phase 2:conventional rehabilitation	NO	TCT	*
Fujino et al. 2016	1 hour of conventional rehabilitation+lateral sitting exercise on plinth tilted 10 degree in the paretic side - 1 wk (15 min./d,6X/wk) Conventional PT includes 20 min. of core stabilization exercises - 4 wk (60 min./d,5X/wk)	1 hour of conventional rehabilitation+lateral sitting exercise on flat plinth - 1 wk (15 min./d,6X/wk) Conventional PT: 4 wk (60 min./d,5X/wk)	NO	TCT	**
Hanyama et al. 2017	Weight-shift training on an unstable surface - 4 wk (30 min./d,5X/wk)	patient-specific and consisted physiotherapy including stretching, strengthening, and stationary bicycle - 4 wk (30 min./d,5X/wk)	NO	TIS	** Total TIS * TIS dynamic subscale -TIS static sitting, coordination subscales
Jung et al. 2014	Weight-shift training on an unstable surface - 4 wk (30 min./d,5X/wk)	patient-specific and consisted physiotherapy including stretching, strengthening, and stationary bicycle - 4 wk (30 min./d,5X/wk)	NO	TIS	** Total TIS * TIS dynamic subscale -TIS static sitting, coordination subscales

(Continued)

Table 2  
(Continued)

Author, year	Experimental group intervention	Control group intervention	Follow-up	Outcome measures	Results
Jung et al. 2016	Trunk exercise include weight shifting and arm flexion from sitting position on unstable surface - 4 wk (30 min./d,5X/wk)	Trunk exercise include weight shifting and arm flexion from sitting position on stable surface - 4 wk (30 min./d,5X/wk)	NO	TIS	* Total TIS, dynamic, coordination subscales -TIS static sitting subscale
Karthikbabu et al. 2011	task specific trunk exercises on an unstable surface from supine and sitting - 3 wk (60 min./d,4X/wk)	task specific trunk exercises on an stable surface from supine and sitting - 3 wk (60 min./d,4X/wk)	NO	TIS	** TIS total scale, dynamic, coordination subscales -TIS static sitting subscale
Kilinc et al. 2016	Trunk exercises according to the Bobath concept - 12 wk (60 min./d,3X/wk)	Functional activities, strengthening, stretching and ROM exercises - 12 wk (60 min./d,3X/wk)	NO	TIS	-Total TIS, static sitting, dynamic, coordination subscales
Kumar et al. 2011	Conventional rehabilitation+additional exercise consisted of selective movements of the upper and lower part of the trunk in supine and sitting - 3 wk (45 min./d,6X/wk)	Conventional patient-specific rehabilitation - 3 wk (45 min./d,6X/wk)	NO	TIS	** Total TIS, dynamic, coordination subscales -TIS static sitting subscale
Lee et al. 2012	1 hour of conventional exercise+dual motor training in the sitting position - 6 wk (30 min./d,3X/wk)	1 hour of conventional exercise - 6 wk (4X/wk)	NO	TIS	* Total TIS
Saeyes et al. 2012	Trunk muscle strength, coordination, and selective trunk movement exercise - 8 wk (30 min./d,4X/wk)	passive mobilization of the upper extremity and TENS for hemiplegic shoulder - 8 wk (30 min./d,4X/wk)	NO	TIS	** Total TIS, dynamic, coordination subscales -TIS static sitting subscale
Shin et al. 2016	Conventional rehabilitation+Smartphone-Based Visual Feedback Trunk Control Training (SPVFCT) System - 4 wk (20 min./d,3X/wk)	Conventional rehabilitation consisted of PT, OT and ES - 4 wk (20 min./d,3X/wk)	NO	TIS	** Total TIS
Verheyden et al. 2009	Conventional rehabilitation+additional trunk exercise from supine and sitting - 5 wk (30 min./d,4X/wk)	Patient-specific Conventional treatment (PT, OT and nursing care) - 5 wk (30 min./d,4X/wk)	NO	TIS	** TIS dynamic subscale -TIS total scale, static sitting, coordination subscales
Yoo et al. 2010	Control treatment+additional core strengthening - 4 wk (30 min./d,3X/wk)	Neuro-developmental technique, walking, and OT - 4 wk (30 min./d,3X/wk)	NO	TIS TCT	** Total TIS -TCT

\*Statistically significant difference between groups at  $p \leq 0.05$  from pre-post; \*\*Statistically significant difference between groups at  $p \leq 0.01$  from pre-post; -No significant difference at  $p > 0.05$  between groups.

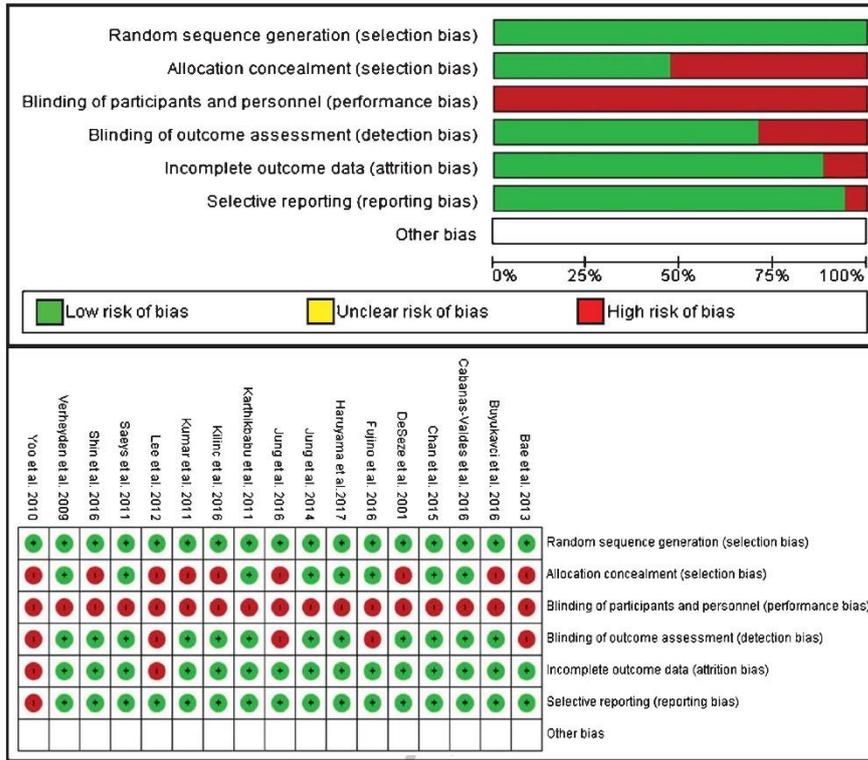


Fig. 2. Cochrane risk of bias summary.

stage, trunk exercise had a medium, significant effect on improving trunk performance in favour of the experimental group (SMD=0.74; 95% CI=0.42 to 1.05;  $P < 0.00001$ ;  $I^2 = 37%$ , fixed effect model; Fig. 7).

The subgroup analysis based upon the treatment duration demonstrated that the trunk exercise had a large, significant effect on improving trunk performance in the studies that applied  $\geq 16$  hours of trunk exercise in favour of the experimental group (SMD=0.77; 95% CI=0.32 to 1.22;  $P = 0.0007$ ;  $I^2 = 56%$ , random effect model; Fig. 8). Likewise, the pooled data from the studies that applied  $< 16$  hours of trunk exercise also showed a large, significant effect on trunk performance in favour of the experimental group (SMD=0.90; 95% CI=0.55 to 1.26;  $P < 0.00001$ ;  $I^2 = 64%$ , random effect model; Fig. 8).

#### 4. Discussion

The aim of this review was to evaluate the effects of trunk exercises on trunk performance following a stroke, as well as other secondary outcomes, such as upper extremity function after a stroke. In this review, we included 17 trials with a total of 599 people with strokes and found strong evidence that the inclusion of trunk training in rehabilitation sessions may improve trunk performance after a stroke. None of the included and excluded studies assessed upper extremity impairment or function, though there were studies which considered trunk exercise in relation to a lateral reach test, reach distance (both measures of dynamic sitting balance or stability) and reaching time.

The results from 17 RCTs suggest a large, significant effect from trunk exercises on trunk performance, as measured by TCT and TIS. However,

Table 3  
PEDro score for included studies

Authors, year	Bae 2013	Buyukavci 2016	Cabans Valdes 2016	Chan 2015	deSeze 2001	Fujino 2016	Haru-yama 2017	Jung 2014	Jung 2016	Karthik-babu 2011	Kiline 2016	Kumar 2011	Lee 2012	Saeys 2011	Shin 2016	Verheyden 2009	Yoo 210
Random allocation	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Concealed allocation	NO	NO	YES	YES	NO	YES	YES	YES	NO	YES	NO	NO	NO	YES	NO	NO	NO
Groups similar at baseline	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Participants blinding	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
Therapists blinding	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO
Outcome assessor blinding	NO	YES	YES	YES	YES	YES	YES	YES	NO	YES	YES	YES	NO	YES	YES	YES	NO
Less than 15% dropouts	YES	YES	YES	YES	YES	NO	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Intention-to-treat analysis	NO	NO	NO	YES	NO	NO	YES	YES	NO	YES	NO	NO	NO	NO	YES	YES	NO
Between groups statistical comparison	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Point measures and variability data	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Total PEDro score	5	6	7	8	6	6	8	8	5	8	6	6	5	7	7	7	5

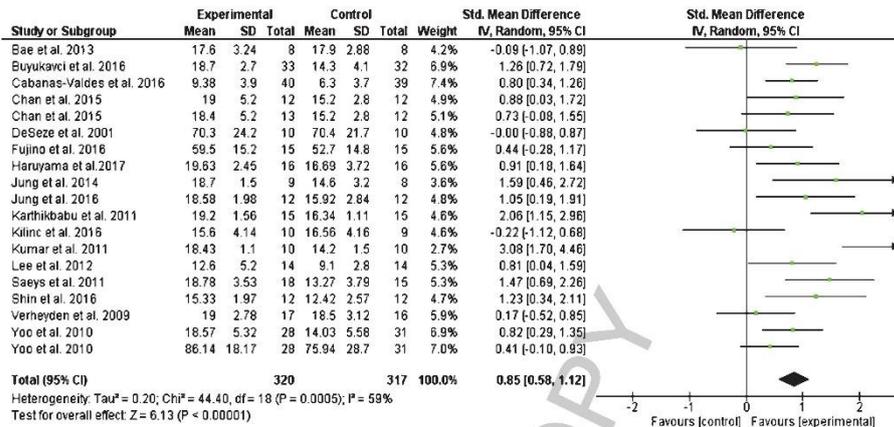


Fig. 3. Forest plot for the effect of trunk exercise on trunk performance (TCT and TIS scales).

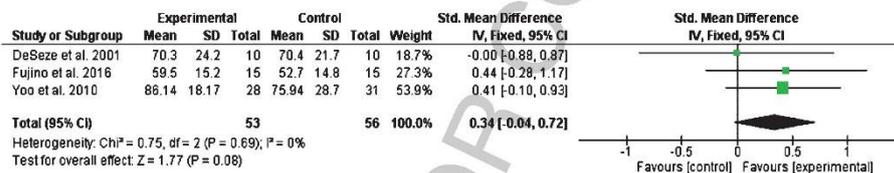


Fig. 4. Forest plot for the effect of trunk exercise on TCT.

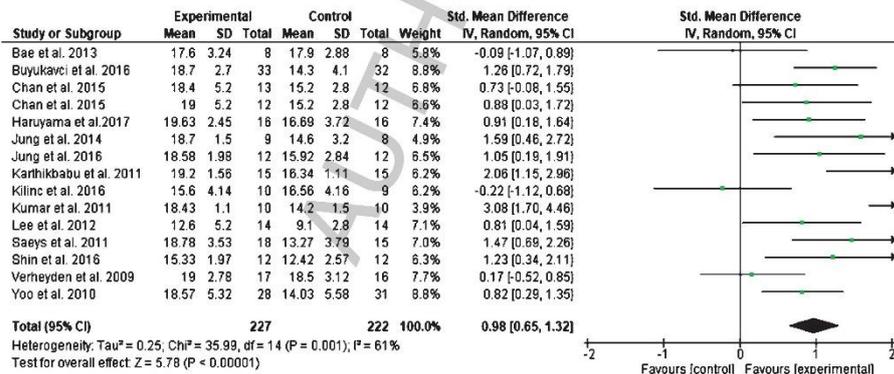


Fig. 5. Forest plot for the effect of trunk exercise on trunk performance measured by total TIS.

the sub-group analysis of each outcome measure demonstrated that the TIS was more sensitive and showed a large, significant effect of trunk exercise, favouring the experimental group compared to only a small (SMD=0.34), non-significant effect on TCT sub-group analysis. This finding was in

line with that of one of the studies included (Yoo et al., 2010) which used both the TIS and TCT. Yoo et al. (2010) identified a statistically significant change between groups ( $P < 0.01$ ) as measured by the TIS, whilst the TCT failed to show any difference ( $p > 0.05$ ) between groups. This finding has also been

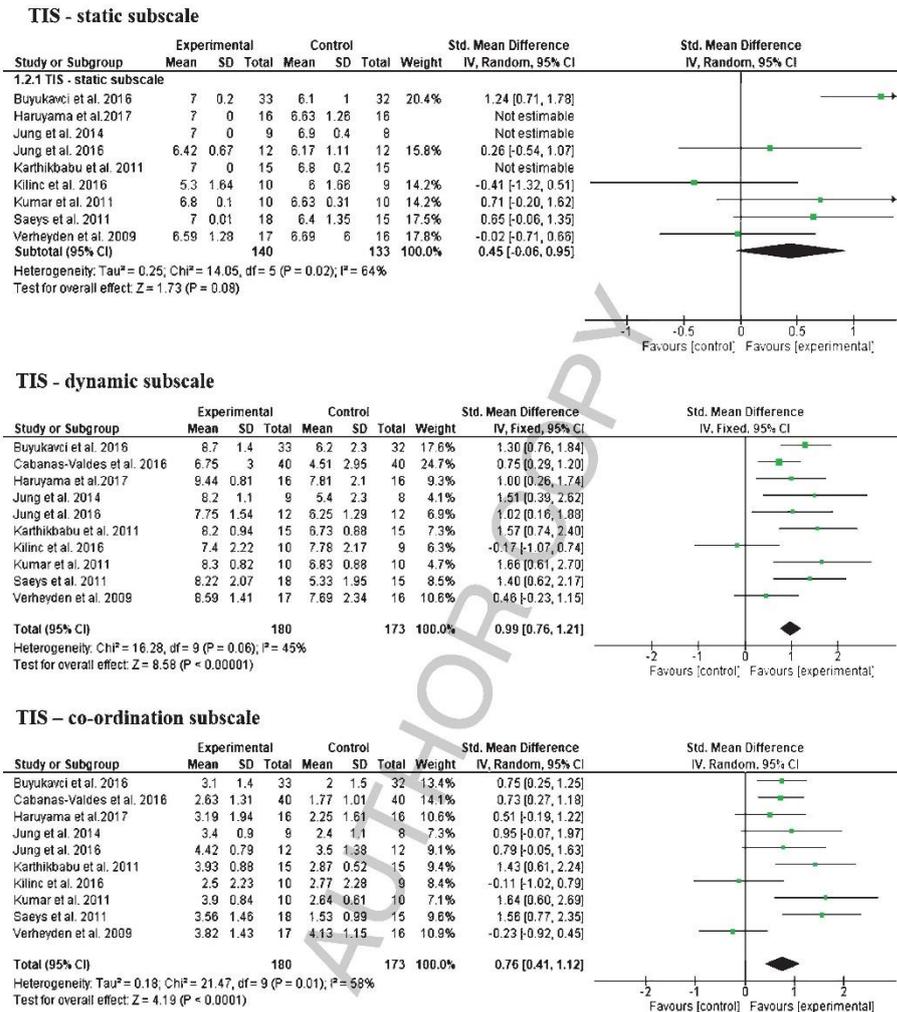


Fig. 6. Forest plot for the effect of trunk exercise on trunk performance measured by TIS - Subscales.

validated in a report (Sullivan et al., 2013) to develop recommendations for outcome measures following strokes. The consensus document recommended using the TIS in all practice settings as it had good sensitivity, specificity and reliability (ICC=0.96), whilst the TCT was not recommended (Sullivan et al., 2013, Verheyden et al. 2008, Verheyden et al. 2004, Bohannon et al. 1995).

The sub-group analysis of TIS revealed that trunk exercise had a large effect (SMD=0.98) on

improving trunk performance for the experimental group, as measured by the TIS. More specifically, the TIS dynamic sub-scales significantly improved ( $p < 0.05$  and/or  $p < 0.01$ ) in nine out of 15 studies (Buyukavci et al. 2016, Cabanas-Valdes et al. 2016, Haruyama et al. 2017, Jung et al. 2014, 2016, Karthikbabu et al. 2011, Kilinc et al. 2016, Kumar et al. 2011, Saeyns et al. 2012, Verheyden et al. 2009). However, the results of the TIS static subscale were negative in ten out of 14 studies (Buyukavci et al.

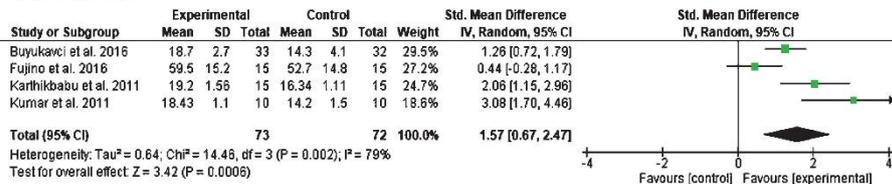
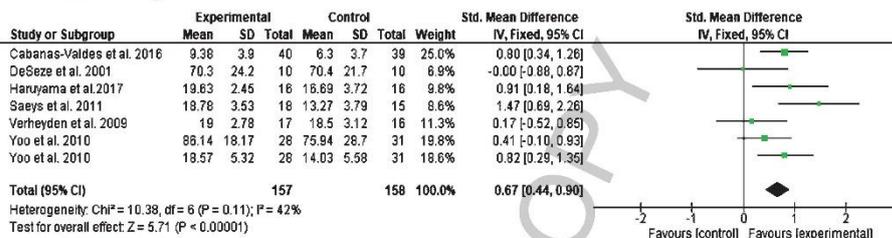
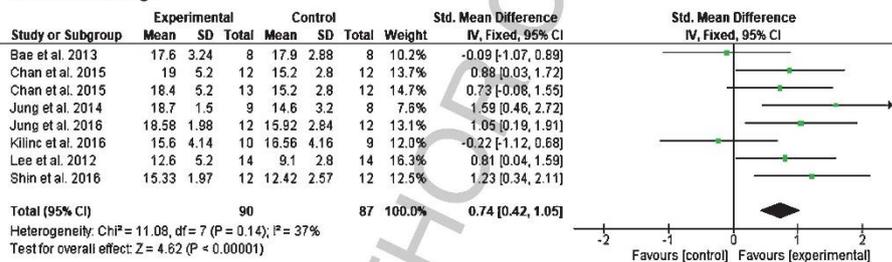
**Acute stroke stage****Sub-acute stroke stage****Chronic stroke stage**

Fig. 7. Forest plot for the effect of trunk exercise on trunk performance at different stroke stages.

2016, Haruyama et al. 2017, Jung et al. 2014, 2016, Karthikbabu et al. 2011, Kilinc et al. 2016, Kumar et al. 2011, Saeyns et al. 2012, Verheyden et al. 2009). A likely explanation for the latter point may relate to the inclusion criteria for the study participants; only one study (Cabanas-Valdes et al., 2016) recruited participants who couldn't tolerate a sitting position, whilst the remaining studies recruited participants who were able to sit unsupported for at least ten seconds (Buyukavci et al. 2016, Haruyama et al. 2017, Jung et al. 2014, 2016, Karthikbabu et al. 2011, Kilinc et al. 2016, Kumar et al. 2011, Saeyns et al. 2012, Verheyden et al. 2009). Consistent with our findings, Cabanas-Valdes et al. (2013), in their systematic review of 11 studies with 317 participants, reported a significant improvement in trunk performance, especially in terms of the dynamic subscale ( $P < 0.01$ )

with no effect on the static sitting subscale after a trunk exercise rehabilitation programme.

For people post-stroke, trunk exercise programmes result in a very large, (SMD = 1.57) statistically significant improvement ( $P < 0.0001$ ) in trunk performance in the acute stage, whilst only having a medium effect in the sub-acute and chronic stages (SMD = 0.67 and 0.74, respectively). These findings are not surprising; the recovery pattern of the trunk was explored at different time points following stroke, by Verheyden et al. in 2008. They reported that trunk recovery followed an exponential pattern, with the most pronounced recovery (21.74%) occurring in the first month post-stroke and these changes in TIS (2.17%) subsequently, gradually, levelled off, between 3 to 6 months. Trunk exercise seems to lead to positively improved trunk performance at all

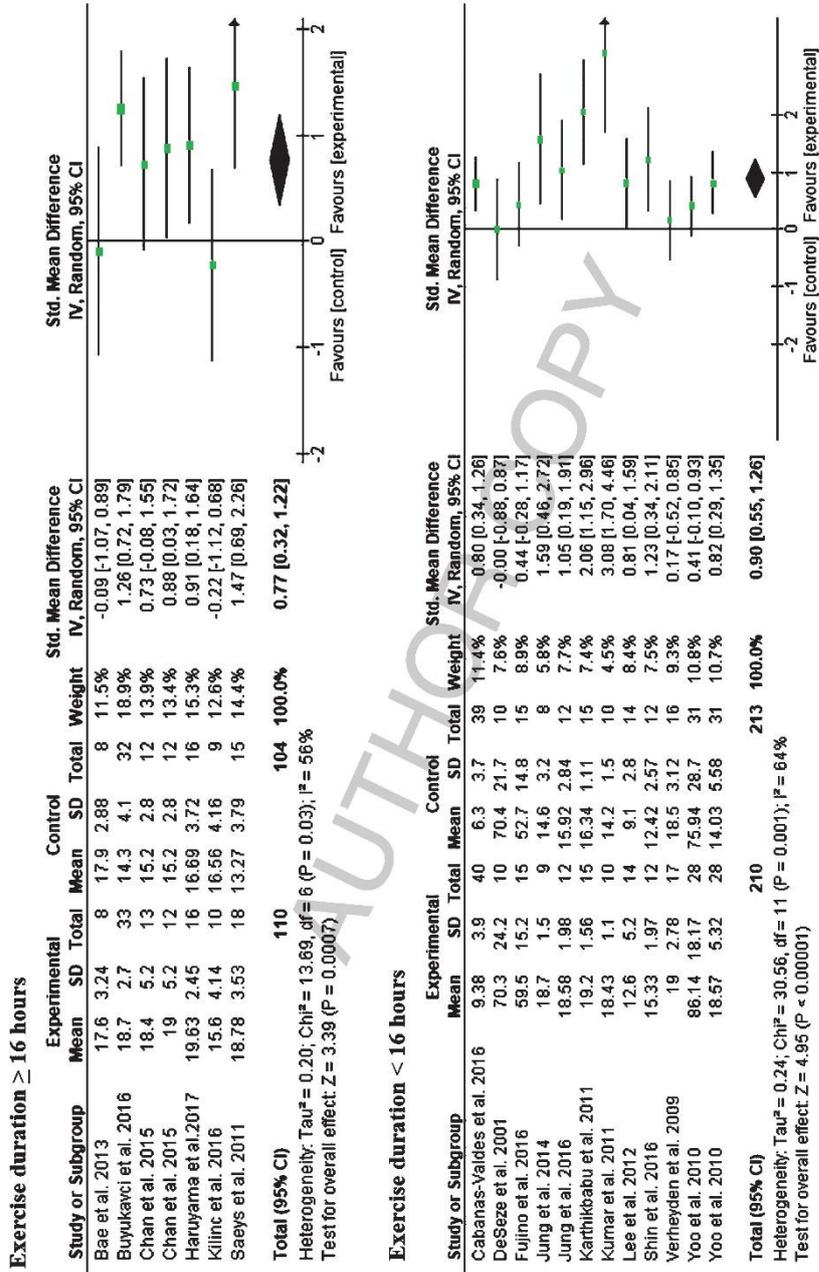


Fig. 8. Forest plot for the effect of duration of trunk exercises on trunk performance.

stroke-stages. This is probably due to a reduction of trunk control after a stroke, as a result of the loss of trunk muscle strength in acute as well as chronic stroke (Bohamon et al. 1995, Fujiwara et al. 2001). More specifically, a hand-held dynamometer measurement showed that strength in the lateral trunk flexors was reduced in people post-stroke to approximately 50% of age-matched healthy people (Fujiwara et al. 2001). Trunk exercises aimed at improving trunk performance are likely to change the strength of the trunk musculature. This may occur due to an increase in cross-sectional area of the muscles; one study included in this review measured the cross-sectional areas of trunk muscles (i.e., multifidus and paravertebral muscles) and found a statistical improvement ( $P < 0.05$ ) after 12 weeks of trunk stabilization exercises (Bae et al. 2013).

The analysis from the studies included in this review did not provide details of the optimal intensity of trunk exercise intervention needed to improve trunk performance. Although the concept of a greater intensity of practice is widely accepted in stroke rehabilitation, the study that applied the greatest amount of exercise (36 hours) reported no significant difference ( $p > 0.05$ ) in TIS between the groups at the end of the study (European Stroke Organisation Executive 2008, Kilinc et al. 2016). The results of our meta-analysis differ from those of the previous systematic review (11 RCTs) by Cabanas-Valdes et al. (2013), who identified that the best results in trunk performance were observed in a study that used 16 hours of trunk exercise over eight weeks on eighty subacute patients. The most noticeable improvement in trunk performance (SMD = 3.08) in our review was reported by Kumar et al. (2011), in which 13.5 hours of trunk exercise was provided over three weeks in twenty acute stroke patients. However, these findings should be interpreted with caution, due to the small sample size in the trunk exercise group and control group ( $n = 10$  per group).

Although the sub-group analysis of the studies based on the time of intervention showed a large, significant effect on trunk performance across all the sub-groups, the studies that applied less than 16 hours of trunk exercise had a larger significant effect, compared to the studies that applied trunk exercise for 16 hours or more (Fig. 8).

However, these findings should be interpreted with caution, due to the variation in the number of participants in each subgroup analysis. There were 214 participants in the subgroup analysis of the studies

that applied < 16 hours of trunk exercise, as compared to 423 participants in the studies that applied > 16 hours of trunk exercise. As a result, the studies that applied > 16 hours of trunk exercise constitute 63.4% of the average weight of the meta-analysis of the trunk performance outcomes. Furthermore, five studies included in sub-group analysis (less than 16 hours of exercise) did not use a control for therapy time, giving the experimental group additional time for trunk exercises, which might account for the improvement in trunk performance (Cabanas-Valdes et al. 2016, Shin et al. 2016, Kumar et al. 2011, Yoo et al. 2010, Verheyden et al. 2009).

The studies included in this review varied, in terms of both the duration of the exercise sessions and the amount of repetition. The duration of trunk exercises ranged from 15 to 120 minutes. In terms of repetition, seven studies reported five sessions per week (Bae et al. 2013, Buyukavci et al. 2016, Cabanas-Valdes et al. 2016, Chan et al. 2015, Haruyama et al. 2017, Jung et al. 2014, 2016) with only one study reporting six sessions per week (Kumar et al. 2011). The meta-analysis to calculate comparisons in terms of treatment repetition and duration was not possible, due to heterogeneity in the intervention characteristics of the studies included. This finding is consistent with that reported in the systematic review by Cabanas-Valdes et al. (2013), which stated that the optimal frequency and duration of trunk exercises remains unclear.

#### 4.1. Limitations of this review

There are several limitations to this review which will affect the generalizability of the results. The first is that the comprehensive search strategy considered only relevant publications in the English language. The small sample size of participants in the included studies ( $n = 16-80$ ) may have affected the validity of the results in meta-analysis, as it has been shown that the inclusion of small studies might lead to Type-I error (Turner et al. 2013). Furthermore, the fact that four of the included studies were of poor methodological quality (PEDro score  $\leq 5$  points) is a significant limitation of this review (Bae et al. 2013, Jung et al. 2016, Lee et al. 2012, Yoo et al. 2010). Finally, the heterogeneity in the treatment characteristics and the lack of longer-term follow-up in the studies included may have affected the interpretation of the results.

Trunk exercises improve trunk performance as measured by the TIS for people with acute, subacute and chronic strokes. This is especially true for

the dynamic sitting sub-scale of the TIS. The optimal intensity and duration of trunk exercises remains unknown, due to the heterogeneity of the included studies. There is currently no evidence for the effect of trunk exercise on upper extremity function in people with strokes.

#### 4.2. Future research

Our understanding of the effects of trunk exercise following stroke will be enhanced if future studies with a large sample size at different levels of severity evaluate the long-term effects of trunk exercise on trunk performance at different stroke stages. Furthermore, it is recommended that an appropriate selection of standardised valid and reliable outcomes to measure trunk performance is used to facilitate data pooling in future meta-analyses. Nevertheless, a previous study found that trunk control has an association with the recovery of the upper extremities (Wee et al. 2015). Therefore, it is important that future studies should assess the upper extremity function, in addition to trunk performance. Understanding the underlying mechanisms of how trunk exercise is associated with upper extremity function may provide insights into a new therapeutic approach for the management of trunk control and upper extremity function following stroke.

#### 5. Conclusion

Trunk exercises improve trunk performance as measured by the TIS for people with acute, subacute and chronic strokes. This is especially true for the dynamic sitting sub-scale of the TIS. The optimal intensity and duration of trunk exercises remains unknown, due to the heterogeneity of the included studies. There is currently no evidence for the effect of trunk exercise on upper extremity function in people with strokes.

#### Conflict of interest

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Appendix 1:  
Search Strategy for MEDLINE

- 
1. exp. stroke/or poststroke/or post-stroke/ or "cerebrovascular accident"
  2. (hemipleg\$ or hemipar\$).tw.
  3. (paresis or paretic).tw.
  4. 1 or 2 or 3
  5. trunk.tw
  6. exp. exercise
  7. exp. physical therapy
  8. motion therapy
  9. rehabilitat\*
  10. 6 or 7 or 8 or 9
  11. 5 AND 10
  12. "upper limb" /or "upper extremity"
  13. (arm or shoulder or elbow or forearm or hand or wrist or finger or fingers).tw.
  14. reach\* /or grasp\*/or " reach to grasp
  15. 12 or 13 or 14
  16. 4 AND 11 AND 15
- 

Appendix 2:  
Excluded Studies

Study	Reason for Exclusion
Dean 1992	There is no trunk performance measurement
Howe et al. 2005	There is no trunk performance measurement
Llorens et al. 2015	There is no trunk performance measurement
Shin & Kim 2016	The treatment program involved upper extremity exercises to improve trunk
Kim et al. 2012	The treatment program designed to improve lower extremity (walking-related tasks)

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Article

# Concurrent Validity of a Novel Wireless Inertial Measurement System for Assessing Trunk Impairment in People with Stroke

Norah Alhwoaimel <sup>1,2,\*</sup>, Martin Warner <sup>1</sup>, Ann-Marie Hughes <sup>1</sup> , Federico Ferrari <sup>3,4</sup>, Jane Burridge <sup>1</sup>, Seng Kwee Wee <sup>5,6</sup> , Geert Verheyden <sup>7</sup>  and Ruth Turk <sup>1</sup>

<sup>1</sup> School of Health Sciences, University of Southampton, Southampton SO17 1BJ, UK; m.warner@soton.ac.uk (M.W.); A.Hughes@soton.ac.uk (A.-M.H.); J.H.Burridge@soton.ac.uk (J.B.); R.Turk@soton.ac.uk (R.T.)

<sup>2</sup> Department of Physical Therapy and Rehabilitation, Prince Sattam Bin Abdulaziz University, Alkharj 11942, Saudi Arabia

<sup>3</sup> Department of Neurosciences, Biomedicine and Movement Sciences, University of Verona, 37134 Verona, Italy; federico.ferrari\_01@studenti.univr.it

<sup>4</sup> Department of Rehabilitation, Sacro Cuore Don Calabria Hospital, 37024 Negrar, Italy

<sup>5</sup> Centre for Advanced Rehabilitation Therapeutics (CART), Tan Tock Seng Hospital, Singapore 308433, Singapore; SengKwee.We@Singaporetech.edu.sg

<sup>6</sup> Health and Social Sciences Cluster, Singapore Institute of Technology, Singapore 138683, Singapore

<sup>7</sup> Department of Rehabilitation Sciences, KU Leuven—University of Leuven, 3001 Leuven, Belgium; geert.verheyden@kuleuven.be

\* Correspondence: n.alhwoaimel@soton.ac.uk

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**Abstract:** *Background:* The Trunk Impairment Scale (TIS) is recommended for clinical research use to assess trunk impairment post-stroke. However, it is observer-dependent and neglects the quality of trunk movements. This study proposes an instrumented TIS (iTIS) using the Valedo system, comprising portable inertial sensors, as an objective measure of trunk impairment post-stroke. *Objective:* This study investigates the concurrent and discriminant ability of the iTIS in chronic stroke participants. *Methods:* Forty participants (20 with chronic stroke, 20 healthy, age-matched) were assessed using the TIS and iTIS simultaneously. A Spearman rank correlation coefficient was used to examine concurrent validity. A ROC curve was used to determine whether the iTIS could distinguish between stroke participants with and without trunk impairment. *Results:* A moderate relationship was found between the observed iTIS parameters and the clinical scores, supporting the concurrent validity of the iTIS. The small sample size meant definitive conclusions could not be drawn about the parameter differences between stroke groups (participants scoring zero and one on the clinical TIS) and the parameter cut-off points. *Conclusions:* The iTIS can detect small changes in trunk ROM that cannot be observed clinically. The iTIS has important implications for objective assessments of trunk impairment in clinical practice.

**Keywords:** objective assessment; inertial sensor; trunk impairment scale; instrumented trunk impairment scale; stroke; validity

## 1. Introduction

Trunk control is a vital part of balance and postural control; it plays an important role in holding the body upright and in performing selective trunk movements during static and dynamic postural adjustments [1,2]. Impairment of trunk control due to trunk muscle weakness, poor control or reduced

position sense results in decreased balance and an increased risk of falls; it also interferes with the performance of daily living activities, such as turning in bed, sitting, rising from sitting to standing and walking [3–5]. Moreover, stability of the upper trunk is considered to be a prerequisite of upper limb function and hand usage [6]. The role of trunk ability is often overlooked as an integral part of the recovery process; trunk control has been recognized to be an important early predictor of functional recovery after stroke explaining 45% to 71% of the variance of functional recovery post-stroke [7,8].

In stroke, impaired trunk control can be assessed using clinical outcome measures such as the Trunk Control Test (TCT) and the Trunk Impairment Scale (TIS) [9,10]. The TIS is recommended for use in clinical research because it has sufficient psychometric properties demonstrated in a high concurrent validity ( $r = 0.83$ ), excellent test–retest reliability ( $ICC = 0.96$ ), excellent inter-rater reliability ( $ICC = 0.99$ ) and has no ceiling effect [10–12]. The TIS consists of three sub-sections which assess static sitting balance, dynamic sitting balance and trunk coordination. Following Rasch analysis the static sitting balance subscale was eliminated, and the scale was renamed TIS Version 2.0 (TIS-V2) [13]. However, although the TIS is commonly used to evaluate trunk impairment post-stroke, a limitation is that the scale uses ordinal scores to measure trunk impairment by means of the degree of task completion without considering movement quality during task performance. More detailed information on trunk movement quality can be obtained by kinematic analysis of several indices (i.e., speed, smoothness and range of movement). Identifying these stroke-related impairment kinematic characteristics potentially offers a better understanding of the relationship between movement quality and performance during neurorehabilitation and stroke recovery. A recent study which measured trunk movement using 3D kinematic analysis found that the lateral pelvic ROM was the best predictor ( $R^2 = 0.2$  and  $p < 0.006$ ) of clinical recovery measured with the TCT [14]. It is critical to differentiate between compensatory and non-compensatory movement after neurorehabilitation and kinematic measures may help to identify deficits even in people who have recovered well from their stroke [15]. The majority of published literature focuses on measuring trunk movement in relation to upper limb recovery, and there is a dearth of evidence regarding recommended kinematic parameters to use for evaluating trunk impairment [14,16]. An instrumented version of TIS (iTIS) to address this limitation is therefore warranted.

Optoelectronic measurement systems can be used to quantify trunk movements in research settings [17]. However, these systems are not readily clinically available because they entail a high cost and require a large installation space. To overcome these limitations, the use of alternative, objective low-cost measuring systems such as inertial measurement units (IMUs) may be useful. The Valedo system (Hocoma, Switzerland) is a wireless movement analysis system that comprises three lightweight sensors (IMUs) that measure trunk movement (in degrees) and the velocity of body segments with respect to magnetic fields and gravity in a non-invasive way [18,19]. Recent research has examined the concurrent validity and reliability of the Valedo system using an optoelectronic system as the gold standard for measuring 3D trunk movement in healthy participants and found that the Valedo system is a valid ( $r^2$  coefficients  $> 0.94$ ) and reliable (3%–9% coefficient of variation) measure for estimating trunk movement [18]. The instrumentation of the TIS could potentially provide more detailed and clinically relevant information about trunk movement and its relation to trunk impairment for stroke participants. To our knowledge, this is the first study that has instrumented a clinical trunk impairment scale. It was therefore the aim of this cross-sectional observational study to instrument the TIS using the Valedo system (iTIS) and correlate it to the gold-standard TIS (cTIS-V2) for concurrent validity testing. This will additionally establish the discriminant ability of the iTIS, as the scores of chronic stroke subjects and healthy, age-matched subjects can be compared. We hypothesize that the iTIS is a valid tool for the evaluation of trunk impairment in chronic strokes and is able to discriminate between people who do, and those who do not have trunk impairment using the cTIS-V2 as a gold standard.

## 2. Materials and Methods

### (1) Participants

Forty participants (20 with chronic stroke and 20 healthy, age-matched) were recruited from the University of Southampton (School of Health Sciences' Research Participant Register), the Hobbs Rehabilitation Centre and local stroke clubs (Hampshire, UK). The inclusion criteria for healthy participants were that the individuals were between 40 and 80 years old and able to understand and follow simple instructions. In addition, the stroke participants needed to have trunk impairment resulting from the stroke ( $cTIS \leq 20$ ) and the ability to maintain a seated position for 10 s. The exclusion criteria for both groups were acute low back pain, a history of spontaneous fractures, a hip prosthesis, uncontrolled epileptic seizures, implanted ferromagnetic materials or active devices within the body, and skin diseases or lesions near the sensor placement. After potential participants demonstrated an interest in taking part in the study, a screening telephone call was made by the researcher to ensure that the participant matched the inclusion and exclusion criteria. All participants were encouraged to wear vest tops and comfortable trousers to enable the researchers to attach the sensors to the participants' skin easily. The Ethics Committee of University of Southampton approved this study (ethical approval code: 25280) and all participants signed informed consent.

### (2) Measurement Protocol

While the participant was standing, three lightweight Valedo sensors (Hocoma, Switzerland) were placed using double-sided sticky tape: sensor one on the sacral spinal level S1, sensor two on the L1 spinal level and sensor three on the sternum (Figure 1). To mitigate measurement error by ensuring the same placement of the sensors was made by assessors, the following anatomical body landmarks were used to identify the S1 and L1 levels: the anterior superior iliac spine (ASIS) along the iliac crest to L4 and then palpation upward and downward to locate L1 and S1 respective, whilst the third sensor was placed 2.5 cm below the sternal notch. Training on how to place the sensors was provided and standardized by the assessors (and could potentially be given to anyone). The sensors were placed and removed by the same assessor. The Valedo sensors can record a  $\pm 0.1^\circ$  range of motion over a range of  $360^\circ$  around all axes (Valedo User Manual, Hocoma). The recorded data output, formatted as an Excel file, indicates the rotation of each sensor at X, Y and Z direction on the three body planes (sagittal, frontal and transverse) over the duration of the task.



Figure 1. Sensor placements.

The participant was then seated on a plinth without any back support, their hip and knees were flexed at  $90^\circ$ , and they were barefoot with their feet resting on the floor. The participants were asked to perform the 14 cTIS-V2 tasks. Each task was demonstrated by the assessor to the participant before they performed it. Every participant was assessed using the clinical and instrumented versions of the TIS-V2 simultaneously.

### (3) Development of the instrumented Trunk Impairment Scale (iTIS)

In previous literature, no consensus exists on the best kinematic parameters to be used for in the evaluation of trunk movement [14]. Therefore, the parameters of interest for each TIS task were determined based on the clinical reasoning of the team, taking into account the maximum range of movement in each direction expected from performance of the task and direction of movement by the author and research team (Turk, Warner, Hughes, and Ferrari). Initially the following parameters were exported for each dynamic task: flexion, extension and lateral flexion on both sides for the sternal and sacral sensors. Following completion of the data collection, the data were analyzed to identify the most appropriate and important kinematic parameters to be reported in each task. For the dynamic subscale parameters, the degree of range of motion (ROM) of lateral flexion to either the affected or unaffected side was considered. For the coordination subscale, the degree of lumbar and sternal ROM towards both sides were measured, and the symmetry of rotation movement between the affected and unaffected sides was considered. The symmetry between both sides was calculated as a percentage (%) (i.e., 100% symmetry means that the rotation ROM on both sides is equal). The parameters of interest are presented in Table 1. The data exported as an excel file for each task performed. Then, all of the recorded tasks processed by MATLAB (MATLAB R2016a) (The MathWorks, Inc.) to extract the parameters used for iTIS. The MATLAB script The MATLAB algorithms were written by an experienced musculoskeletal biomechanics researcher and performed by the author N.A. The MATLAB scripts for the data processing from raw data to ROM is documented in Supplementary Materials.

### (4) Statistical Analysis

The data were imported into Excel and analyzed using IBM SPSS Statistics 24 (SPSS Inc., Chicago, IL, USA). Descriptive statistics were used to summarize the demographic data and the parameters of interest. The normality of the data was checked using the Shapiro–Wilks test.

To evaluate the concurrent validity of the Valedo system in measuring trunk impairment, the correlation between clinical scores (using TIS-V2) and instrumental scores (using iTIS) was examined using a Spearman correlation coefficient analysis [20]. The correlation coefficient ranges from  $-1$  to  $+1$  to reflect the strength of the relationship between the variables. The positive or negative sign of the coefficient indicates positive or negative correlation [20]. The following correlation classification was used to interpret the correlation coefficient result: none or very low:  $\rho = 0-0.25$ ; low:  $\rho = 0.26-0.40$ ; moderate:  $\rho = 0.41-0.69$ ; high:  $\rho = 0.70-0.89$ ; very high:  $\rho = 0.90-1.0$  [21]. Following this, for the coordination subscale a conservative adjustment to compensate for the number of similar tasks (task 1 and 2, task 3 and 4) with four parameters of interest for each task was applied to achieve a family wise significance Bonferroni level of 5% (test-wise significant levels 0.6%).

The score differences of the stroke participants and the healthy, age-matched participants were assessed using an independent samples *t*-test. In addition, the difference between the participants with stroke who achieved scores of one or two and those who scored zero on the cTIS-V2 tasks was calculated using an independent samples *t*-test and a one-way ANOVA.

A receiver operating characteristic (ROC) curve analysis and the area under curves (AUCs) were used to determine the cut-off point of the iTIS parameters for distinguishing trunk impairment (i.e., participants who scored zero, one and two on the cTIS-V2) in the stroke group [22]. The cut-off point was determined using the Youden index (Youden index = sensitive value + specificity value  $- 1$ ) at the point where both the sensitivity and specificity values were maximized [23]. In this study, the cut-off point will be the best representative point of the degree of trunk ROM recorded by the Valedo sensors that can distinguish between stroke participants with trunk impairment (scored zero on cTIS tasks) and those without trunk impairment (scored one, or two on cTIS tasks). The area under curve (AUC) is a summary measure of the accuracy of a quantitative diagnostic test. The maximum AUC is the best cut-off score. The AUC values were interpreted according to an arbitrary guideline; one could distinguish between no ( $AUC < 0.5$ ), poor ( $0.5 \leq AUC < 0.7$ ), acceptable ( $0.7 \leq AUC < 0.8$ ), excellent ( $0.8 \leq AUC < 0.9$ ) and outstanding ( $AUC > 0.9$ ) discriminant ability.

**Table 1.** Sensor location, plane of movement and parameters of interest for each TIS-V2 task.

cTIS-V2 Tasks	Sensor	Parameter of Interest	Plane of Movement
<b>Dynamic Sitting Balance Subscale</b>			
1—Touch the bed with the hemiplegic elbow	Sternum	ROM of lateral flexion to non-dominant/affected * side (degrees)	Frontal
2—Repeat Item 1	Sternum	ROM of lateral flexion to non-dominant/affected side (degrees)	Frontal
3—Repeat Item 1	Sternum	ROM of lateral flexion to non-dominant/affected side (degrees)	Frontal
4—Touch the bed with the unaffected elbow	Sternum	ROM of lateral flexion to dominant/unaffected side (degrees)	Frontal
5—Repeat Item 4	Sternum	ROM of lateral flexion to dominant/unaffected side (degrees)	Frontal
6—Repeat Item 4	Sternum	ROM of lateral flexion to dominant/unaffected side (degrees)	Frontal
7—Lift pelvis from bed at the hemiplegic side	Sacrum	ROM of lateral flexion to dominant/unaffected side (degrees) **	Frontal
8—Repeat Item 7	Sacrum	ROM of lateral flexion to dominant/unaffected side (degrees) **	Frontal
9—Lift pelvis from bed at the unaffected side	Sacrum	ROM of lateral flexion to non-dominant/affected side (degrees) **	Frontal
10—Repeat Item 9	Sacrum	ROM of lateral flexion to non-dominant/affected side (degrees) **	Frontal
<b>Coordination Subscale</b>			
1—Rotate upper trunk 6 times	Sternum	Symmetry (%), ROM of average rotation to both side (degrees) and total no. of rotations	Transverse
2—Repeat Item 1 within 6 s	Sternum	Symmetry (%), ROM of average rotation to both side (degrees) and total no. of rotations	Transverse
3—Rotate lower trunk 6 times	Lumbar	Symmetry (%), ROM of average rotation to both side (degrees) and total no. of rotations	Transverse
4—Repeat Item 3 within 6 s	Lumbar	Symmetry (%), ROM of average rotation to both side (degrees) and total no. of rotations	Transverse

\* Non-dominant upper limb for healthy participants; affected upper limb for stroke participants. \*\* In task 7 and 8: The unaffected side is not tested. The stroke participants used lateral flexion towards the unaffected side to be able to lift-up the pelvis on the affected side. As a result, we chose the lateral flexion toward the unaffected (untested) side to be the most important parameter to measure in these tasks. In task 9 and 10: The unaffected side is tested. The stroke participants used lateral flexion towards the affected (untested) side to be able to lift-up the pelvis on the unaffected side. As a result, we chose the lateral flexion toward the affected (untested) side to be the most important parameter to measure in these tasks.

### 3. Results

#### 3.1. Participant Characteristics

Twenty adults with chronic stroke and resulting trunk impairment (mild to severe) and 20 healthy, aged-matched controls were recruited. The participants' characteristics are presented in Table 2.

#### 3.2. Concurrent Validity

Significant moderate correlations (negative) were observed between the cTIS-V2 score and iTIS parameters of the dynamic subscale: lateral flexion to affected side in Tasks 1 and 2 ( $r = -0.59, p < 0.006$ ) and lateral flexion to the unaffected side in Tasks 4 and 5 ( $r = -0.52, p < 0.02$ ) (Table 3). Furthermore, significant moderate correlations were observed between the cTIS-V2 score and lateral flexion to the affected side in Task 7 ( $r = 0.52, p < 0.01$ ) and lateral flexion to the unaffected side in Task 9 ( $r = 0.47, p < 0.03$ ). The remaining parameters for Tasks 3, 6, 8 and 10 in the dynamic subscale, which all assessed compensatory movement, resulted in a very low, non-significant correlation ( $r \leq 0.26$ ).

Table 2. Participant Characteristics.

Characteristics	Chronic Stroke (N = 20)	Healthy (N = 20)
Age (years)	63.2 ± 11.12 Range: 44–79	62.75 ± 11.67 Range: 41–80
Gender		
Male	13	10
Female	7	10
Hand dominance		
Right	17	16
Left	3	4
Affected upper limb		
Right	5	N/A
Left	15	
Trunk Impairment Scale (TIS)	15.66 ± 2.70 Range: 10–23	22.8 ± 0.62 Range: 2–23
Number of participants with TIS:		
≤10 (poor trunk control)	1	0
11–19 (fair trunk control)	18	0
≥20 (good trunk control)	1	20

Table 3. Spearman rank correlation of iTIS data with cTIS-V2 score (dynamic subscale) in the stroke group.

cTIS-V2 Tasks	Parameter of Interest	cTIS-V2 Score = 0 Mean ± SD	cTIS-V2 Score = 1 Mean ± SD	r-Value	Sig.
<b>Dynamic Sitting Balance Subscale</b>					
1, 2—Touch the bed with the hemiplegic elbow	ROM of lateral flexion to affected side (degrees)	29.21 ± 5.18	21.70 ± 7.18	−0.59 **	0.006
3—Touch the bed with the hemiplegic elbow without compensation	ROM of lateral flexion to affected side (degrees)	32.41 ± 10.36	25.21 ± 3.61	−0.26	0.45
4, 5—Touch the bed with the unaffected elbow	ROM of lateral flexion to unaffected side (degrees)	35.82 ± 4.98	29.75 ± 5.95	−0.52 *	0.02
6—Touch the bed with the unaffected elbow without compensation	ROM of lateral flexion to unaffected side (degrees)	36.31 ± 8.59	32.41 ± 5.30	−0.24	0.41
7—Lift pelvis from bed at the hemiplegic side	ROM of lateral flexion to unaffected side (degrees)	13.74 ± 3.5	21.46 ± 4.9	0.52 *	0.01
8—Lift pelvis from bed at the hemiplegic side without compensation	ROM of lateral flexion to affected side (degrees)	18.92 ± 6.96	21.04 ± 4.65	0.23	0.33
9—Lift pelvis from bed at the unaffected side	ROM of lateral flexion to unaffected side (degrees)	15.29 ± 2.60	18.42 ± 3.24	0.47 *	0.03
10—Lift pelvis from bed at the unaffected side without compensation	ROM of lateral flexion to unaffected side (degrees)	17.81 ± 2.20	17.49 ± 4.04	−0.10	0.67

r value = correlation coefficient; Sig. = significance level. \*\* Correlation is significant at ≤0.01. \* Correlation is significant at ≤0.05.

For the coordination subscale, significant high correlations were observed between the cTIS-V2 score and two variables, including symmetry in Task 2 (rotate upper trunk 6 times within 6 s) ( $r = 0.71$ ,  $p < 0.001$ ) and the total number of rotations in Task 3 (rotate lower trunk 6 times) ( $r = 0.73$ ,  $p < 0.001$ ) (Table 4). Furthermore, significant moderate correlations were shown between the cTIS-V2 scores and the following iTIS parameters: symmetry in Task 1 (rotate upper trunk 6 times); total number of rotations in Tasks 1, 2 and 3; and rotation to the affected side in Task 1 ( $r \leq 0.64$ ). Following a

conservative Bonferroni adjustment three associations were statistically significant at  $p \leq 0.006$ , namely symmetry in Tasks 2 and 4, and the total number of rotations in Task 2. The rotation to the unaffected side recorded low and very low correlations using the cTIS-V2 scores ( $r \leq 0.34$ ) in all tasks.

**Table 4.** Spearman rank correlation of iTIS data with cTIS-V2 score (coordination subscale) in stroke group.

cTIS-V2 Tasks	Parameter of Interest	cTIS-V2 Score = 0 Mean $\pm$ SD	cTIS-V2 Score = 1 Mean $\pm$ SD	cTIS-V2 Score = 2 Mean $\pm$ SD	r-Value	Sig.
<b>Coordination Subscale</b>						
1—Rotate upper trunk 6 times	Symmetry (%)	84.86 $\pm$ 14.40	78.46 $\pm$ 18.9	94.51 $\pm$ 3.61	0.54 *	0.02
	ROM of average rotation to affected side (degrees)	17.76 $\pm$ 9.00	21.45 $\pm$ 9.43	28.01 $\pm$ 4.21	0.57 **	0.01
	ROM of average rotation to unaffected side (degrees)	26.54 $\pm$ 19.73	15.65 $\pm$ 7.80	25.49 $\pm$ 4.20	0.32	0.17
	Total number of rotations	5 $\pm$ 0	6 $\pm$ 0	6 $\pm$ 0	0.59 **	0.007
2—Repeat Item 1 within 6 s	Symmetry (%)	78.94 $\pm$ 18.24	97.61 $\pm$ 1.29		0.71 **†	0.001
	ROM of average rotation to affected side (degrees)	20.71 $\pm$ 12.04	26.53 $\pm$ 4.72		0.34	0.14
	ROM of average rotation to unaffected side (degrees)	18.67 $\pm$ 11.91	26.07 $\pm$ 3.79		0.32	0.17
	Total number of rotations	5.15 $\pm$ 0.68	6 $\pm$ 0		0.64 **†	0.002
3—Rotate lower trunk 6 times	Symmetry (%)	69.42 $\pm$ 16.52	74.36 $\pm$ 20.57	85.89 $\pm$ 8.80	0.28	0.24
	ROM of average rotation to affected side (degrees)	9.22 $\pm$ 6.75	9.01 $\pm$ 4.48	7.46 $\pm$ 3.50	−0.03	0.87
	ROM of average rotation to unaffected side (degrees)	7.20 $\pm$ 4.19	8.51 $\pm$ 4.29	6.87 $\pm$ 0.45	0.02	0.92
	Total number of rotations	6 $\pm$ 0	6 $\pm$ 0	5.20 $\pm$ 0.45	0.74 **†	0.001
4—Repeat Item 3 within 6 s	Symmetry (%)	77.20 $\pm$ 18.98	88.94 $\pm$ 11.02		0.37	0.11
	ROM of average rotation to affected side (degrees)	9.18 $\pm$ 4.98	8.08 $\pm$ 4.88		−0.14	0.55
	ROM of average rotation to unaffected side (degrees)	7.39 $\pm$ 4.48	9.21 $\pm$ 4.66		0.20	0.39
	Total number of rotations	5.53 $\pm$ 0.51	6 $\pm$ 0		0.46 *	0.04

r value= correlation coefficient; Sig. = significance level. \*\* Correlation is significant at  $\leq 0.01$ . \* Correlation is significant at  $\leq 0.05$ . † Correlation is significant at  $\leq 0.006$ .

### 3.3. Differences between Groups

Difference between stroke participants and healthy, age-matched participants: the differences in trunk lateral flexion between stroke participants and healthy participants were significantly different ( $p$ -value range: 0.001 to 0.05) in seven tasks of the dynamic subscale (Tasks 1, 2, 3, 6, 8, 9 and 10) (Table 5). The remaining three tasks (Tasks 4, 5 and 7) showed a non-significant difference between the groups ( $p > 0.05$ ). In the coordination subscale, the average rotations to both the affected and unaffected sides were significantly different between stroke and healthy participants for all tasks ( $p$ -value range: 0.001 to 0.05). However, the symmetry parameter indicated a non-significant difference between the groups for all tasks ( $p > 0.05$ ). For the last parameter, the total number of rotations, there was a significant difference between the stroke and healthy participants for only two tasks (Tasks 2 and 4;  $p$ -value  $< 0.05$ ).

Table 5. Differences in iTIS parameters between stroke and healthy participants.

cTIS-V2 Tasks	Parameter of Interest	Stroke Mean $\pm$ SD	Healthy Mean $\pm$ SD	Mean Diff $\pm$ SD	95% CI for Mean Diff	p-Value
<b>Dynamic Sitting Balance Subscale</b>						
Task 1	ROM of lateral flexion to non-dominant/affected side (degrees)	24.66 $\pm$ 7.75	37.23 $\pm$ 5.70	-12.57 $\pm$ 7.49	-16.93 to -8.21	0.000 *
Task 2	ROM of lateral flexion to non-dominant/affected side (degrees)	21.51 $\pm$ 11.22	34 $\pm$ 10.89	12.49 $\pm$ 13.95	-21.21 to -3.75	0.007 *
Task 3	ROM of lateral flexion to non-dominant/affected side (degrees)	28.78 $\pm$ 7.7	35.39 $\pm$ 8.09	6.61 $\pm$ 10.49	-13.18 to -0.037	0.05 *
Task 4	ROM of lateral flexion to dominant/unaffected side (degrees)	34.04 $\pm$ 6.62	35.04 $\pm$ 7.09	-1 $\pm$ 12.8	-5.57 to 3.57	0.66
Task 5	ROM of lateral flexion to dominant/unaffected side (degrees)	33.21 $\pm$ 9.55	34.37 $\pm$ 8.26	-1.16 $\pm$ 14.25	-7.40 to 5.10	0.71
Task 6	ROM of lateral flexion to dominant/unaffected side (degrees)	27.01 $\pm$ 9.23	34.87 $\pm$ 8.43	7.86 $\pm$ 12.71	-14.08 to -1.63	0.01 *
Task 7	ROM of lateral flexion to dominant/unaffected side (degrees)	20.11 $\pm$ 5.54	22.44 $\pm$ 5.2	-2.32 $\pm$ 8.94	-5.97 to 1.31	0.20
Task 8	ROM of lateral flexion to dominant/unaffected side (degrees)	19.02 $\pm$ 5.51	23.29 $\pm$ 6.99	-4.27 $\pm$ 9.97	-8.46 to -0.082	0.05 *
Task 9	ROM of lateral flexion to non-dominant/affected side (degrees)	16.38 $\pm$ 4.41	23.74 $\pm$ 6.18	-7.36 $\pm$ 7.25	-10.86 to -3.86	0.000 *
Task 10	ROM of lateral flexion to non-dominant/affected side (degrees)	16.50 $\pm$ 5.02	25.93 $\pm$ 6.54	-9.42 $\pm$ 8.31	-13.43 to -5.39	0.000 *

Table 5. Cont.

cTIS-V2 Tasks	Parameter of Interest	Stroke Mean $\pm$ SD	Healthy Mean $\pm$ SD	Mean Diff $\pm$ SD	95% CI for Mean Diff	p-Value
<b>Coordination Subscale</b>						
Task 1	Symmetry (%)	87.58 $\pm$ 13.15	93.75 $\pm$ 7.92	-6.17 $\pm$ 17.30	-14.08 to 1.74	0.12
	ROM of average rotation to non-dominant/affected side (degrees)	22.17 $\pm$ 6.32	16.86 $\pm$ 7.19	5.31 $\pm$ 11.06	0.32 to 10.30	0.04 *
	ROM of average rotation to dominant/unaffected side (degrees)	20.92 $\pm$ 8.70	30.68 $\pm$ 6.86	-9.76 $\pm$ 10.83	-15.50 to -4.01	0.002 *
	Total number of rotations	5.93 $\pm$ 0.25	6 $\pm$ 0.00	-0.06 $\pm$ 0.31	-0.19 to 0.06	0.310
Task 2	Symmetry (%)	86.34 $\pm$ 13.16	91.72 $\pm$ 5.90	-5.37 $\pm$ 13.27	-12.41 to 1.66	0.129
	ROM of average rotation to non-dominant/affected side (degrees)	32.59 $\pm$ 7.18	22.70 $\pm$ 8.69	9.88 $\pm$ 10.74	4.15 to 15.62	0.001 *
	ROM of average rotation to dominant/unaffected side (degrees)	21.85 $\pm$ 8.28	29.15 $\pm$ 7.91	-7.30 $\pm$ 10.53	-13.06 to -1.54	0.015 *
	Total number of rotations	5.60 $\pm$ 0.73	6 $\pm$ 0.00	-0.40 $\pm$ 0.76	-0.75 to -0.046	0.03 *
Task 3	Symmetry (%)	78.42 $\pm$ 17.92	87.16 $\pm$ 9.84	-8.74 $\pm$ 25.58	-19.36 to 1.87	0.10
	ROM of average rotation to non-dominant/affected side (degrees)	7.43 $\pm$ 3.83	14.95 $\pm$ 7.52	-7.51 $\pm$ 9.49	-12.37 to -2.64	0.004 *
	ROM of average rotation to dominant/unaffected side (degrees)	7.89 $\pm$ 2.73	13.11 $\pm$ 5.35	-5.21 $\pm$ 5.95	-8.79 to -1.64	0.006 *
	Total number of rotations	5.83 $\pm$ 0.38	6 $\pm$ 0.00	-0.16 $\pm$ 0.30	-0.35 to 0.02	0.08
Task 4	Symmetry (%)	80.89 $\pm$ 18.03	87 $\pm$ 11.34	-6.11 $\pm$ 21.50	-16.98 to 4.76	0.26
	ROM of average rotation to non-dominant/affected side (degrees)	9.71 $\pm$ 4.78	15.38 $\pm$ 5.04	-5.67 $\pm$ 9.51	-9.22 to -2.12	0.003 *
	ROM of average rotation to dominant/unaffected side (degrees)	8.57 $\pm$ 4.60	13.27 $\pm$ 4.61	-4.69 $\pm$ 7.21	-8.03 to -1.36	0.007 *
	Total number of rotations	5.75 $\pm$ 0.44	6 $\pm$ 0.00	-0.25 $\pm$ 0.74	-0.47 to -0.021	0.033 *

\*  $p \leq 0.05$ .

(1) Difference between stroke participants who scored two and one on the cTIS and stroke participants who scored zero

In the dynamic subscale, the stroke participants who scored one showed a lower trunk ROM during Tasks 1–6 and a higher trunk ROM during Tasks 7–10 compared to stroke participants who scored zero, as presented in Table 6. The differences in trunk lateral flexion between stroke participants who scored one and those scoring zero were significantly different ( $p \leq 0.05$ ) for four tasks (Tasks 1, 4, 7 and 9). The remaining tasks (Tasks 3, 6, 8 and 10) showed a non-significant difference between groups ( $p > 0.05$ ). In the coordination subscale, the average rotation to both the affected and unaffected sides showed a non-significant difference between groups for all tasks ( $p > 0.05$ ) except for Task 1. In Task 1, only the average rotation to the unaffected side was significantly different between groups ( $p = 0.002$ ). In contrast, the total number of rotations parameter showed a high significant difference between the groups for all tasks ( $p$ -value range: 0.05 to 0.001). For the symmetry parameter, there was a significant difference between stroke groups for only two tasks (Tasks 1 and 2;  $p$ -value  $< 0.05$ ).

**Table 6.** Differences in iTIS parameters between stroke participants scoring zero, one and two on the clinical TIS.

TIS-V2 Tasks	Parameter of Interest	cTIS Score = 0 Mean $\pm$ SD	cTIS Score = 1 Mean $\pm$ SD	Mean Diff $\pm$ SD	95% CI for Mean Diff	$p$ -Value
<b>Dynamic Sitting Balance Subscale</b>						
1, 2—Touch the bed or table with the hemiplegic elbow	ROM of lateral flexion to affected side (degrees)	29.21 $\pm$ 5.18	21.70 $\pm$ 7.18	7.51 $\pm$ 2.80	1.62 to 13.39	0.01 *
3—Touch the bed or table with the hemiplegic elbow without compensation	ROM of lateral flexion to affected side (degrees)	32.41 $\pm$ 10.36	25.21 $\pm$ 3.61	7.19 $\pm$ 6.31	−7.36 to 21.76	0.28
4, 5—Touch the bed or table with the unaffected elbow	ROM of lateral flexion to unaffected side (degrees)	35.82 $\pm$ 4.98	29.75 $\pm$ 5.95	6.07 $\pm$ 2.65	0.42 to 11.72	0.03 *
6—Touch the bed or table with the unaffected elbow without compensation	ROM of lateral flexion to unaffected side (degrees)	36.31 $\pm$ 8.59	32.41 $\pm$ 5.30	3.89 $\pm$ 3.89	−4.67 to 12.46	0.33
7—Lift pelvis from bed or table at the hemiplegic side	ROM of lateral flexion to affected side (degrees)	13.74 $\pm$ 3.5	21.46 $\pm$ 4.9	−7.71 $\pm$ 3.02	−14.07 to −1.36	0.02 *
8—Lift pelvis from bed or table at the hemiplegic side without compensation	ROM of lateral flexion to affected side (degrees)	18.92 $\pm$ 6.96	21.04 $\pm$ 4.65	−2.12 $\pm$ 2.59	−7.57 to 3.32	0.42
9—Lift pelvis from bed or table at the unaffected side	ROM of lateral flexion to unaffected side (degrees)	15.29 $\pm$ 2.60	18.42 $\pm$ 3.24	−3.12 $\pm$ 1.44	−6.17 to −0.07	0.04 *
10—Lift pelvis from bed or table at the unaffected side without compensation	ROM of lateral flexion to unaffected side (degrees)	17.81 $\pm$ 2.20	17.49 $\pm$ 4.04	0.32 $\pm$ 1.93	−3.76 to 4.41	0.86

Table 6. Cont.

TIS-V2 Tasks	Parameter of Interest	cTIS Score = 0 Mean ± SD	cTIS Score = 1 Mean ± SD	Mean Diff ± SD	95% CI for Mean Diff	p-Value
Coordination Subscale						
Task 2 & 4 (Independent Samples <i>t</i> -Test)						
2—Repeat Item 1 within 6 s	Symmetry (%)	78.94 ± 18.24	97.61 ± 1.29	−18.66 ± 6.99	−33.35 to −3.97	0.01 *
	ROM of average rotation to non-dominant/affected side (degrees)	20.71 ± 12.04	26.53 ± 4.72	−5.81 ± 4.78	−15.86 to 4.23	0.24
	ROM of average rotation to dominant/unaffected side (degrees)	18.67 ± 11.91	26.07 ± 3.79	−7.40 ± 4.67	−17.22 to 2.41	0.13
	Total number of rotations	5.15 ± 0.68	6 ± 0	−0.84 ± 0.26	−1.40 to −0.29	0.001 *
4—Repeat Item 3 within 6 s	Symmetry (%)	77.20 ± 18.98	88.94 ± 11.02	−11.74 ± 8.40	−29.47 to 5.99	0.18
	ROM of average rotation to non-dominant/affected side (degrees)	9.18 ± 4.98	8.08 ± 4.88	1.09 ± 2.44	−4.06 to 6.25	0.65
	ROM of average rotation to dominant/unaffected side (degrees)	7.39 ± 4.48	9.21 ± 4.66	−1.82 ± 2.23	−6.54 to 2.90	0.42
	Total number of rotations	5.53 ± 0.51	6 ± 0	−0.46 ± 0.21	−0.91 to −0.007	0.04 *
Task 1 & 3 (One-Way ANOVA Test)						
cTIS-V2 Tasks	Parameter of Interest	cTIS Score = 0 Mean ± SD	cTIS Score = 1 Mean ± SD	cTIS Score = 2 Mean ± SD		p-Value
1—Rotate upper trunk 6 times	Symmetry (%)	84.86 ± 14.40	78.46 ± 18.99	94.51 ± 3.61		0.04 *
	ROM of average rotation to non-dominant/affected side (degrees)	17.76 ± 9.00	21.45 ± 9.43	28.01 ± 4.21		0.31
	ROM of average rotation to dominant/unaffected side (degrees)	26.54 ± 19.73	15.65 ± 7.80	25.49 ± 4.20		0.002 *
	Total number of rotations	5 ± 0	6 ± 0	6 ± 0		0.001
3—Rotate lower trunk 6 times	Symmetry (%)	69.42 ± 16.52	74.36 ± 20.57	85.89 ± 8.80		0.48
	ROM of average rotation to non-dominant/affected side (degrees)	9.22 ± 6.75	9.01 ± 4.48	7.46 ± 3.50		0.87
	ROM of average rotation to dominant/unaffected side (degrees)	7.20 ± 4.19	8.51 ± 4.29	6.87 ± 0.45		0.74
	Total number of rotations	5.20 ± 0.45	6 ± 0	6 ± 0		0.001

\*  $p \leq 0.05$ . \*\*  $p \leq 0.01$ .

### 3.4. ROC Curve Analysis

Table 7 summarizes the results of the ROC curve analysis, including the AUCs and the identified cut-off score for each iTIS parameter that discriminated between stroke participants who scored zero, one and two for each task, along with their sensitivity and specificity.

**Table 7.** Discriminant ability of iTIS parameters in distinguishing between stroke participants with impairment (scored zero on cTIS-V2 tasks) and those without trunk impairment (scored one, or two on cTIS-V2 tasks).

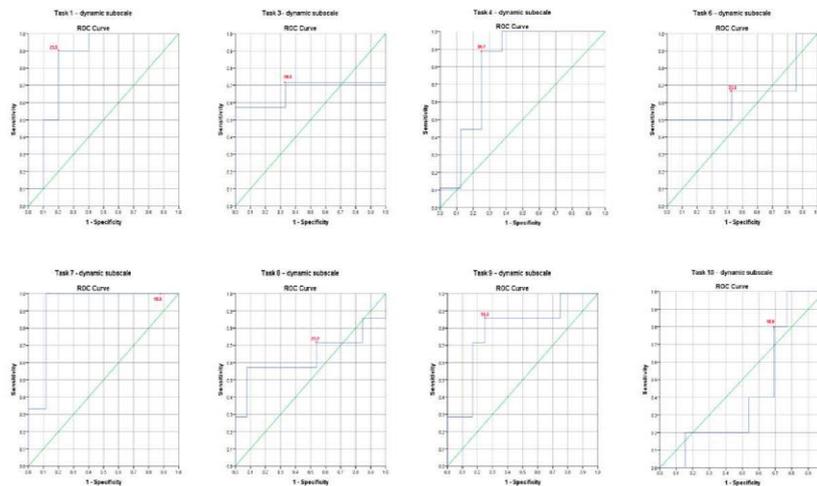
TIS-V2 Tasks	iTIS Parameter	AUC	Std. Error	Sig.	95% CI	Cut-Off Point (Degrees) to Be Scored Zero in cTIS	Sensitivity	Specificity
<b>Dynamic Sitting Balance Subscale</b>								
1, 2—Touch the bed or table with the hemiplegic elbow	ROM of lateral flexion to affected side (degrees)	0.84	0.09	0.01	0.64–1	≥23.5	0.90	0.80
3—Touch the bed or table with the hemiplegic elbow without compensation	ROM of lateral flexion to affected side (degrees)	0.67	0.17	0.42	0.32–1	≥26.8	0.71	0.67
4, 5—Touch the bed or table with the unaffected elbow	ROM of lateral flexion to unaffected side (degrees)	0.80	0.12	0.03	0.57–1	≥30.7	0.88	0.75
6—Touch the bed or table with the unaffected elbow without compensation	ROM of lateral flexion to unaffected side (degrees)	0.64	0.17	0.39	0.30–0.98	≥33.8	0.66	0.58
7—Lift pelvis from bed or table at the hemiplegic side	ROM of lateral flexion to affected side (degrees)	0.92	0.06	0.02	0.79–1	≤15.8	1	0.88
8—Lift pelvis from bed or table at the hemiplegic side without compensation	ROM of lateral flexion to affected side (degrees)	0.63	0.15	0.32	0.33–0.94	≤23.2	0.71	0.46
9—Lift pelvis from bed or table at the unaffected side	ROM of lateral flexion to unaffected side (degrees)	0.78	0.11	0.04	0.56–1	≤16.5	0.85	0.75
10—Lift pelvis from bed or table at the unaffected side without compensation	ROM of lateral flexion to unaffected side (degrees)	0.43	0.14	0.65	0.14–0.71	≤18.9	0.80	0.30

**Table 7. Cont.**

TIS-V2 Tasks	iTIS Parameter	AUC	Std. Error	Sig.	95% CI	Cut-Off Point (Degrees) to Be Scored Zero in cTIS	Sensitivity	Specificity
<b>Coordination Subscale</b>								
1—Rotate upper trunk 6 times	Symmetry (%)	0.87	0.08	0.01	0.70–1	90	0.83	0.66
	ROM of average rotation to non-dominant/affected side (degrees)	0.83	0.09	0.01	0.66–1	24.5	0.83	0.75
	ROM of average rotation to dominant/unaffected side (degrees)	0.77	0.11	0.05	0.56–0.99	23.4	0.71	0.75
	Total number of rotations	0.58	0.13	0.55	0.32–0.85	3.3	1	0.17
2—Repeat Item 1 within 6 s	Symmetry (%)	0.93	0.05	0.002	0.82–1	96.7	0.83	0.84
	ROM of average rotation to non-dominant/affected side (degrees)	0.70	0.11	0.14	0.47–0.93	24.7	0.71	0.69
	ROM of average rotation to dominant/unaffected side (degrees)	0.70	0.12	0.16	0.43–0.93	23.11	0.83	0.61
	Total number of rotations	0.84	0.08	0.01	0.67–1	3.3	1	0.69
3—Rotate lower trunk 6 times	Symmetry (%)	0.70	0.14	0.31	0.41–0.96	76.6	1	0.56
	ROM of average rotation to non-dominant/affected side (degrees)	0.40	0.17	0.58	0.03–0.74	3.8	0.66	0.31
	ROM of average rotation to dominant/unaffected side (degrees)	0.42	0.12	0.63	0.18–0.66	6.1	1	0.37
	Total number of rotations	0.63	0.16	0.50	0.32–0.93	3.3	1	0.25
4—Repeat Item 3 within 6 s	Symmetry (%)	0.73	0.12	0.11	0.48–0.98	80.8	0.83	0.69
	ROM of average rotation to non-dominant/affected side (degrees)	0.41	0.14	0.53	0.12–0.69	6.9	0.66	0.38
	ROM of average rotation to dominant/unaffected side (degrees)	0.62	0.14	0.38	0.34–0.91	7	0.83	0.61
	Total number of rotations	0.73	0.11	0.11	0.50–0.95	3.3	1	0.46

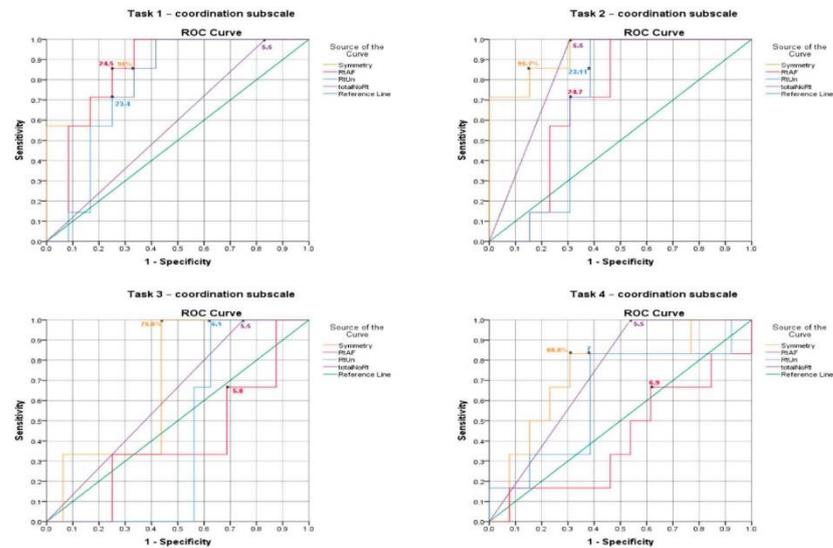
AUC = area under curve; CI = confidence interval.

In the dynamic subscale tasks, one parameter (lateral flexion to the affected side in Task 7) was considered a highly accurate test ( $AUC = 0.92$ ), indicating outstanding discriminant ability to distinguish between people who scored zero and who scored one on the cTIS-V2 tasks (Figure 2). Three out of eight parameters (lateral flexion to affected side in Task 1, lateral flexion to the unaffected side in both Tasks 4 and 9) showed an AUC range of 0.78–0.84, indicating acceptable to excellent discriminant ability. The remaining four parameters were less accurate, with an AUC range between 0.43 to 0.67, indicating no or poor discriminant ability.



**Figure 2.** Receiver operator curves (ROC) of the iTIS dynamic subscale parameters to distinguish between stroke participants with impairment (scored zero on cTIS-V2 tasks) and those without trunk impairment (scored one, or two on cTIS-V2 tasks). \* indicates cut-off points.

In the coordination subscale, the symmetry parameter in Task 2 demonstrated an outstanding discriminant ability ( $AUC = 0.93$ ), and acceptable to excellent discriminative ability ( $AUC = 0.70$ – $0.87$ ) in the remaining tasks (Tasks 1, 3 and 4) (Figure 3). For the average rotation to the affected side parameter, the AUC for Tasks 1 and 2 (0.85 and 0.70, respectively) indicated excellent and acceptable discriminative ability. In contrast, the average rotations to the affected side parameter in Tasks 3 and 4 had no discriminative ability ( $AUC = 0.40$  and  $0.41$ , respectively). For the average rotation to the unaffected side parameter, the AUC in Tasks 1 and 2 (0.77 and 0.70, respectively) showed acceptable discriminative ability, while Tasks 3 and 4 were found to have no discriminative ability. The last parameter was the total number of rotations, which was found to have poor discriminative ability in Tasks 2 and 4 ( $AUC \leq 0.63$ ) and acceptable to excellent discriminative ability in Tasks 1 and 3 ( $AUC \geq 0.73$ ).



**Figure 3.** Receiver operator curves (ROC) of the iTIS coordination subscale parameters to distinguish between stroke participants with impairment (scored zero on cTIS-V2 tasks) and those without trunk impairment (scored one, or two on cTIS-V2 tasks). \* indicates cut-off points.

#### 4. Discussion

The present study demonstrated a moderate relationship between most of the observed iTIS parameters and the clinical score of the cTIS-V2, supporting the concurrent validity of the instrumented TIS using the Valedo system. A few parameters demonstrated a weak relationship between the iTIS and the clinical score of the cTIS-V2, including trunk lateral flexion in Task 3, 6, 8 and 10 in the dynamic subscale and rotation towards the unaffected side in all tasks of the coordination subscale.

##### 4.1. Validity

The validity of the iTIS was demonstrated by correlating the iTIS parameters to the clinical scores of the cTIS-V2 using a Spearman rank correlation. The results indicated a moderate negative correlation in the dynamic subscale parameters for Tasks 1, 2, 4 and 5 (touching the bed with the affected and unaffected elbow). The negative correlation arose because of the higher lateral flexion ROM towards the affected and unaffected sides recorded by stroke participants who scored zero compared to those who scored one on the clinical TIS. This was because most of the participants ( $n = 12/20$ ) lost their sitting balance and fell to their side. This is in line with the findings of Jijimol et al. (2013), who found a significant high correlation ( $r = 0.91, p < 0.01$ ) between balance and TIS [24]. Only one participant who scored zero did not lose her balance; she had a low ROM because she was not able to touch the bed with her elbow due to lacking in ROM and stopped moving during her performance of Tasks 4 and 5.

The correlation in Tasks 7 and 9 (lift pelvis from bed on the affected and unaffected side) of the dynamic subscale had moderate positive correlations. The results could be explained by the higher lateral flexion ROM values reported in people who scored one compared to those who scored zero on the clinical TIS. Moreover, for the clinical TIS in Task 7, only two stroke participants scored zero, while 18 participants scored one. In Tasks 3, 6 and 8 in the dynamic subscale, poor correlation values between the clinical and instrumented TIS can be explained by the presence of compensatory movements (e.g., the use of the upper limb, the contralateral hip abduction, the hip flexion, the knee flexion, sliding of

the feet and the loss of contact between the heel and the floor), which if observed by the assessor, in the clinical TIS (dynamic subscale), a score of zero is given. However these could not be measured by the setup of the Valedo sensors, as the sensors were only attached to the trunk. This compensatory movement can be measured with an alternative method of application of the sensors (i.e., fixing one of the sensors on the lower limb) to be able to record the movement. The compensation movements observed are likely to be due to impaired postural control and weight-shifting ability during the performance of these tasks. The findings from this study are consistent with those of Messier et al. (2004), who reported a significantly lower weight-bearing ability in chronic stroke participants for both paretic and non-paretic feet when comparing a weight-bearing value on both the dominant and non-dominant feet in healthy, age-matched participants ( $p = 0.05$ ) during the performance of trunk lateral flexion (45 degrees) from a sitting position [25]. Furthermore, lower limb sensory deficits may have affected the trunk movements; it has been suggested that somatosensory information from the feet determines how people with stroke adjust themselves on a support surface [26]. Another possible cause of the reduction in ROM for those who scored zero in the pelvis-lifting tasks may result from the reduction in the activity of the rectus abdominis and latissimus dorsi muscles on the affected side of the body in comparison to the unaffected side.

For the coordination subscale, the symmetry showed a moderate to high correlation of iTIS to cTIS for Tasks 1 and 2 (rotate upper trunk 6 times), while for Tasks 3 and 4 (rotate lower trunk 6 times), the correlation was low. The result could be explained by the low values of lower trunk rotation ROM detected by the sacral sensor in Tasks 3 and 4, whereas in the clinical scale rotation of the lower trunk is easily observable through forward and backward movements of the knees. As a result of the low ROM values, a small change in rotation leads to asymmetry. In addition, a combination of factors such as spasticity in the lower extremities, weakness of the trunk and proximal lower extremity muscles can contribute to the difficulty performing rotation of the pelvis [2,25]. This explanation is supported by Verheyden et al. (2005), suggesting that identifying this movement in stroke participants is more difficult [12]. Furthermore, the total number of rotations demonstrates a moderate to high correlation, as stroke participants with a moderately impaired trunk were unable to complete six rotation movements within six seconds. Rotation ROM towards the affected and unaffected side in general showed a low correlation with the cTIS. This parameter is not measured in the cTIS (whereas symmetry and total number of rotations are), so whilst it may provide additional information about the quality of movement, the results suggest this parameter should be excluded from the iTIS because it does not contribute to the validity. Therefore the important parameters to be considered in the co-ordination subscale of iTIS should be symmetry and total number of rotations. This is supported by the results of the Bonferroni adjustment which showed significant correlation at  $p \leq 0.006$  was noted in symmetry (Tasks 2 and 3) and total number of rotations (Task 2) parameters.

#### 4.2. Differences between Groups

The results of the *t*-test and the ROC curve analysis indicated the ability of the iTIS dynamic subscale parameters to distinguish both between participants with and without stroke as well as those stroke participants with and without trunk impairment. As expected, the performance of the stroke participants was lower than that of the healthy controls in most of the dynamic subscale tasks. This may be explained by the difficulties stroke participants face in fine-tuning the length of the lateral trunk muscles according to the task requirement compared to the healthy controls [27]. The non-significant difference in some of the dynamic subscale tasks (Tasks 3, 6, 8 and 10) between stroke participants who scored zero and those who scored one on the clinical TIS-V2 is likely to be due to the unmeasured compensatory movements mentioned previously. The participants who scored one on the cTIS-V2 recorded a high trunk lateral flexion ROM in the dynamic subscale tasks, while those who scored zero reached a high ROM by compensating (using the upper or lower limb), which explains the non-significant difference in some of the dynamic subscale tasks.

In the coordination subscale, the differences between the stroke participants and the healthy group were significantly different in their amount of axial rotation ROM in the direction of both the affected and unaffected sides, suggesting a decrease in trunk rotational ability in the stroke group. This finding is supported by (Tanaka et al. 1997), who found a significant reduction in trunk rotatory muscle performance in stroke participants compared to healthy, age-matched participants during trunk rotation at angular velocities of 60, 120, and 150 degrees per second ( $p < 0.05$ ) [28]. However, the symmetry parameters were not significantly different between the groups, and this could be because of the compensatory strategy used by stroke participants to perform coordination subscale tasks. Some of the stroke participants completed the tasks with compensation, resulting in a symmetrical movement during the performance of the coordination tasks (e.g., the participants leaned to both sides instead of rotating the lower trunk in Tasks 3 and 4 or carried the affected arm with the other hand to assist the movement of the upper trunk rotation in Tasks 1 and 2). In contrast, the number of rotations shows a significant difference between healthy and stroke participants in Tasks 2 and 4, when the task was required to be completed within six seconds. This could be explained by a reduction in the participants' ability to initiate the trunk movement in the stroke group; onset latencies of trunk muscles (lumbar erector spinae) have been shown to be delayed in stroke participants when compared with healthy, age-matched controls ( $p < 0.04$ ) [27].

#### 4.3. Limitations

This study had several limitations. The methodology limitation which affected the validity results was that the three sensors used in this study were placed solely on the trunk, so were unable to detect any compensation by the upper or lower limbs during the task performance.

System errors may also have affected both the validity and reliability [29]. The Valedo system crashed during the completion of the tasks during some sessions. Although the data were deleted, the task was performed again and the next data recording was checked, it is possible that potential errors in the system's records from before the crash could have affected the recording. The system crashes during the test performance may have been due to using the Valedo system for more than 6 h continuously recording data leading to a slower laptop performance. When we removed the recorded data to another hard drive, the problem was solved.

The sample size was too small to allow definitive conclusions to be drawn about the differences in parameters between stroke groups (stroke participants who scored zero and one on the clinical TIS) or to establish cut-off points for each parameter. All stroke data were used to perform the cut-off point analysis. This might have led to the performance of the proposed approach being overestimated, especially because of the small number of participants. In addition, due to the nature of clinical TIS scoring, which assumes that people who score zero on Tasks 1 and 2 will automatically score zero in Task 3, fewer than 20 participants performed Task 3. The findings indicate that a higher number of stroke participants are needed to robustly investigate the validity and reliability of the iTIS.

#### 5. Clinical Implications and Recommendations

Clinicians commonly use clinical tests such as the TIS to assess trunk impairment and to monitor changes in impairment after intervention. This paper presents the iTIS as an objective tool to enable the clinician to assess and monitor the trunk impairment considering the quality of the trunk movement. It will give them detailed information about trunk movement by quantifying the trunk ROM in each task. However, the iTIS exhibits a limitation in detecting the compensatory movement exerted by lower limb which is commonly observed clinically. To overcome this limitation, a further research study to investigate the ability of Valedo system to detect compensatory movements during performance of the iTIS by moving one of the trunk sensors to the lower limb is warranted.

## 6. Conclusions

This study is the first to demonstrate the feasibility of an iTIS. Moderate validity has been shown, and different methods of application of the iTIS could be used where the validity was low. Future studies with larger sample sizes and a robust standardized application of iTIS using additional sensors on the upper and/or lower limbs to detect compensation are warranted to establish reference data for iTIS parameters.

The iTIS provides more information about trunk performance than the cTIS-V2, as it has the ability to detect small changes in trunk ROM that may not be observed clinically. These findings indicate that the inertial sensor-based iTIS measures have important implications for the objective assessment of trunk impairment in clinical practice. The data-rich set could be useful in the customization of physiotherapy to address individuals' trunk control issues. Another potential use of the iTIS is to advance research into understanding the mechanisms of trunk control and compensatory trunk movements throughout recovery from a stroke.

**Supplementary Materials:** The following are available online at <http://www.mdpi.com/1424-8220/20/6/1699/s1>.

**Author Contributions:** Conceptualization, F.F., N.A., A.-M.H., R.T., S.K.W. and G.V.; methodology, F.F., N.A., J.B., M.W., A.-M.H., R.T., S.K.W. and G.V.; software, M.W.; validation, N.A., A.-M.H. and R.T.; formal analysis, N.A.; investigation, F.F., N.A.; data curation, F.F., N.A.; writing—original draft preparation, N.A.; writing—review and editing, N.A., M.W., A.-M.H., F.F., J.B., S.K.W., G.V. and R.T.; supervision, A.-M.H. and R.T.; project administration, A.-M.H. and R.T.; funding acquisition, N.A. All authors have read and agreed to the published version of the manuscript.

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## Instrumented trunk impairment scale (iTIS): A reliable measure of trunk impairment in the stroke population

Norah Alhwoaimel<sup>a,b</sup>, Ruth Turk<sup>a</sup>, Ann-Marie Hughes<sup>a</sup>, Federico Ferrari<sup>c,d</sup>, Jane Burridge<sup>a</sup>, Seng Kwee Wee<sup>e,f</sup>, Geert Verheyden<sup>g</sup>, and Martin Warner<sup>a</sup>

<sup>a</sup>School of Health Sciences, University of Southampton, Southampton, UK; <sup>b</sup>Department of Physical Therapy and Rehabilitation, Prince Sattam Bin Abdulaziz University, Alkharj, Saudi Arabia; <sup>c</sup>Department of Neurosciences, Biomedicine and Movement Sciences, University of Verona, Verona, Italy; <sup>d</sup>Department of Rehabilitation, Sacro Cuore Don Calabria Hospital, Negrar, Italy; <sup>e</sup>Centre for Advanced Rehabilitation Therapeutics (CART), Tan Tock Seng Hospital, Singapore, Singapore; <sup>f</sup>Health and Social Sciences Cluster, Singapore Institute of Technology, Singapore, Singapore; <sup>g</sup>Department of Rehabilitation Sciences, KU Leuven—University of Leuven, Leuven, Belgium

### ABSTRACT

**Background:** The Trunk Impairment Scale (TIS) is recommended for use in clinical research to assess trunk impairment post-stroke. However, it is observer dependent and does not consider the quality of trunk movement. To address these challenges, this study proposes an instrumented TIS (iTIS).

**Objective:** This study aims to investigate the intra-rater and inter-rater reliability of the iTIS in chronic stroke patients.

**Method:** Trunk impairment was assessed in 20 patients with stroke using the iTIS Valedo system; three sensors were fixed to the skin on the sternum, L1 and S1 levels. Interclass correlation coefficients were used to assess the inter-rater and intra-rater reliability (between days) with 95% CI.

**Results:** Reliability for the dynamic subscale parameters was good to excellent (intra-rater ICC = 0.60–0.95; inter-rater ICC = 0.59–0.93); however, reliability for the coordination parameters was poor to good (intra-rater ICC = 0.05–0.72) and poor to excellent (inter-rater ICC = 0.04–0.78).

**Conclusion:** The iTIS demonstrates an acceptable level of reliability for dynamic subscale measurement in research and clinical practice. Further studies could use larger sample sizes and improve the iTIS methodology by employing additional sensors on the limbs to detect compensatory movements.

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impairment scale; stroke;  
validity

### Introduction

Trunk control has been recognized as an important early predictor of functional recovery after stroke, explaining 45% to 71% of the variance in functional recovery post-stroke [1, 2]. Systematic reviews and meta-analyses emphasize the importance of including trunk exercises to improve trunk performance and functional recovery after a stroke.<sup>3–6</sup>

To ensure that any planned treatment is effective, therapists need accurate tools and outcome measures to assess change. Trunk control after a stroke can be measured using clinical tools, such as the Trunk Control Test (TCT) and the Trunk Impairment Scale (TIS).<sup>7–10</sup> The TCT and the TIS differ in how they measure trunk control in relation to movements involving the head and extremities. The TCT measures the ability to control the trunk during two movements involving the head and

extremities, one when moving from a supine to a side-lying position and the other from a supine to a sitting position. In contrast, the TIS, developed by<sup>9</sup>, assesses trunk impairment post-stroke by measuring the ability to control the trunk in a sitting position in both static and dynamic postures without additional movements of the head or extremities. It consists of three sub-sections that assess static sitting balance, dynamic sitting balance and trunk coordination. Following Rasch analysis, the static sitting balance subscale was eliminated, and the scale was renamed TIS Version 2.0 (TIS-V2).<sup>10</sup> Additionally, there is a reported difference in the ability of these tools to differentiate between subjects with stroke: the TCT has been shown to lack discriminative ability,<sup>11</sup> whereas the TIS has been reported to have discriminant validity.<sup>12</sup> For this reason, the TIS-V2 was investigated in this study.

The TIS-V2 has no ceiling effect and has sufficient psychometric properties along with high concurrent validity ( $r = 0.83$ ), excellent test-retest reliability ( $ICC = 0.96$ ) and excellent inter-rater reliability ( $ICC = 0.99$ ).<sup>9,12</sup> The limitations of both versions of the TIS include that the quality of movement is not measured by means of trunk range of motion (ROM) during task performance and that the scales are observer dependent, requiring rater training to increase competence and preclude biasing results. Therefore, an instrumented version of TIS (iTIS) that will address these limitations is warranted.

Trunk movement can be quantified using an optoelectronic measurement system that uses a radiographic approach.<sup>13</sup> However, this method has disadvantages, including high cost and the required expert installation of the equipment in an appropriate research environment, which make the method difficult to use in clinical settings. To overcome these limitations, the use of low-cost measuring systems such as inertial measurement units (IMUs) may be useful. The Valedo system (Hocoma, Switzerland) is a wireless movement analysis system that comprises three lightweight sensors (IMUs) worn on the sternal, lumbar and sacral spinal levels to measure trunk movement.<sup>13,14</sup> The present study is a cross-sectional, repeated measures observational study designed to investigate the inter-rater and intra-rater reliability of iTIS in participants with chronic stroke.

## Methods

### Participants

Stroke participants were recruited from the University of Southampton, the School of Health Sciences' Research Participant Register, the Hobbs Rehabilitation Center and local stroke clubs (Hampshire, UK). The inclusion criteria were that individuals had chronic stroke (more than 6 months), were between 40 to 80 years old, had trunk impairment resulting from the stroke and were able to maintain a seated position for 10 seconds. The exclusion criteria were acute low back pain, history of spontaneous fractures, hip prosthesis, uncontrolled epileptic seizures, implanted

ferromagnetic materials or active devices within the body, and skin disease or lesions near the sensor placement. The Ethics Committee of University of Southampton approved this study (ethical approval code: 25280) and all participants signed informed consent.

### Apparatus and measurement protocol

The Valedo sensors (Hocoma, Switzerland) contain a tri-axial gyroscope, an accelerometer and magnetometer, a wireless antenna and a signal processing unit. The specifications of the Valedo system indicate that the measurement units are able to record a  $\pm 0.1^\circ$  range of motion (ROM) over a range of  $360^\circ$  around all axes (Valedo User Manual, Hocoma). The recorded data are transmitted to a laptop with a 200-Hz sampling frequency. The Valedo system output files show the rotation of the sensors at X, Y and Z directions on the three body planes (sagittal, frontal and transverse) over the duration of the task. The output files were exported to an Excel file.

Three lightweight Valedo sensors were placed using double-sided tape: sensor one on sacral spinal level S1, sensor two on spinal level L1 and sensor three on the sternum (Figure 1). The sensors were placed and removed by the same assessor. The participant was seated on a plinth without any back support, with a hip and knee flexion of 90 degrees, and barefoot with feet resting on the floor. Participants were then asked to perform the 14 TIS Version 2 (cTIS-V2) tasks.

All participants attended two baseline assessment sessions 7 to 10 days apart. In the first session,



Figure 1. Sensor placements.

the TIS was recorded two times with a rest period between them. The first assessments were measured by the first assessor (NA), and the second assessments were measured by the second assessor (FF) to determine inter-rater reliability. In the second assessment session, the TIS data were recorded once by the assessor (NA) for the purpose of intra-rater reliability. The performance of the tasks was also filmed for checking later.

#### **Development of the instrumented trunk impairment scale (iTIS)**

The parameters of interest for each TIS task were determined by the author and research team (Martin Warner, Ann-Marie Hughes, Ruth Turk and Federico Ferrari) based on the most important movement required for each task and the sensor which captured the most movement. For the dynamic subscale parameters, the degree of range of motion (ROM) of lateral flexion to either the affected or unaffected side was considered. For the coordination subscale, the degree of lumbar and sternal ROM toward both sides was measured, and the symmetry of rotation movement between the affected and unaffected sides was considered. The symmetry between both sides was calculated as a percentage (%) (100% symmetry means that the rotation ROM on both sides is equal). The parameters of interest are presented in Table 1. All parameters were extracted from the exported Excel files mentioned previously using MATLAB (MATLAB R2016a) (MathWorks). The MATLAB algorithms were written by an experienced musculoskeletal biomechanics researcher.

#### **Statistical analysis**

The data were imported into Excel and analyzed using IBM SPSS Statistics 24 (SPSS Inc, Chicago, IL). Descriptive statistics were used to summarize the demographic data and the parameters of interest. The normality of data was checked using a Shapiro-Wilks test.

**Table 1.** Sensor location, plane of movement and parameters of interest for each TIS-V2 task.

cTIS-V2 tasks	Sensor	Parameter of interest	Plane of movement
<b>Dynamic Sitting Balance Subscale</b>			
1 – Touch the bed with the hemiplegic elbow	Sternum	ROM of lateral flexion to affected side (degrees)	Frontal
2 – Repeat item 1	Sternum	ROM of lateral flexion to affected side (degrees)	Frontal
3 – Repeat item 1	Sternum	ROM of lateral flexion to affected side (degrees)	Frontal
4 – Touch the bed with the unaffected elbow	Sternum	ROM of lateral flexion to unaffected side (degrees)	Frontal
5 – Repeat item 4	Sternum	ROM of lateral flexion to unaffected side (degrees)	Frontal
6 – Repeat item 4	Sternum	ROM of lateral flexion to unaffected side (degrees)	Frontal
7 – Lift pelvis from bed at the hemiplegic side	Sacrum	ROM of lateral flexion to unaffected side (degrees)	Frontal
8 – Repeat item 7	Sacrum	ROM of lateral flexion to unaffected side (degrees)	Frontal
9 – Lift pelvis from bed at the unaffected side	Sacrum	ROM of lateral flexion to affected side (degrees)	Frontal
10 – Repeat item 9	Sacrum	ROM of lateral flexion to affected side (degrees)	Frontal
<b>Coordination Subscale</b>			
1 – Rotate upper trunk 6 times	Sternum	Symmetry (%), ROM of average rotation to both side (degrees) and total no. of rotations	Transverse
2 – Repeat Item 1 within 6 seconds	Sternum	Symmetry (%), ROM of average rotation to both side (degrees) and total no. of rotations	Transverse
3 – Rotate lower trunk 6 times	Lumbar	Symmetry (%), ROM of average rotation to both side (degrees) and total no. of rotations	Transverse
4 – Repeat Item 3 within 6 seconds	Lumbar	Symmetry (%), ROM of average rotation to both side (degrees) and total no. of rotations	Transverse

Using the interclass correlation coefficient (ICC),<sup>15</sup> the reliability of the iTIS for the stroke group was determined to be excellent when  $ICC \geq 0.75$ , good to fair when  $ICC = 0.4-0.74$  and poor when  $ICC < 0.4$ .<sup>16</sup> The intra-rater reliability and inter-rater reliability were assessed using the ICC (2,1) model, and 95% confidence intervals (CI) were calculated for all ICC values. The precision of the measurements was assessed using the standard error of measurement (SEM), which provides values in meaningful units for measuring ROM in degrees and was used to calculate the minimum detectable change (MDC), which is the minimal

Table 2. Participants' characteristics.

Characteristics	Chronic stroke (N = 20)
Age (years) (Mean±SD)	63.2 ± 11.12 Range: 44–79
Gender	13
Male	7
Female	
Hand dominance	17
Right	3
Left	
Affected upper limb	5
Right	15
Left	
Trunk Impairment Scale (TIS) (Mean±SD)	15.65 ± 2.70
Participants' scores on the TIS:	range 10–23
≤10 (poor trunk control)	1
11–19 (fair trunk control)	18
≥20 (good trunk control)	1

change that falls outside the measurement error. The SEM and MDC were calculated from the ICC as follows: SEM = SD ( $\sqrt{1 - \text{ICC}}$ ); MDC =  $1.96 \times \sqrt{2} \times \text{SEM}$ .

## Results

### Participants' characteristics

Twenty adults with chronic stroke and resulting trunk impairment (mild to severe) were recruited. The participants' characteristics are presented in Table 2.

## Reliability

### Intra-rater reliability

The ICCs for the intra-rater reliability of the dynamic sitting balance subscale showed excellent between-sessions reliability with an ICC  $\geq 0.76$  in Tasks 1, 4, 5, 6 and 10. The width of the CI for those tasks was relatively narrow ( $\leq 0.58$ ) and did not include the value of 0, indicating statistically significant reliability. Moreover, the SEM for the high-reliability tasks was low (SEM  $\leq 1.91$ ), indicating low variability in a test caused by measurement error. The remaining parameters in Tasks 2, 3, 7, 8 and 9 showed good reliability with an ICC between 0.60 and 0.68 (Table 3). Across the coordination subscale, the symmetry showed fair reliability in Tasks 2 and 4 (ICC  $\leq 0.50$ ) and poor reliability in Tasks 1 and 3 (ICC  $< 0.4$ ). The width of the CI for those tasks was relatively large ( $\geq 0.81$ ) and included 0, indicating non-significant reliability. Furthermore, the SEM of symmetry in these tasks was high and very near to the value of SD, indicating high variability in a test caused by measurement error. All remaining coordination subscale parameters showed good to fair reliability with an ICC between 0.45 and 0.72. The results for the MDC showed a relatively small MDC in all

Table 3. Intra-rater reliability between two-day sessions for each task.

cTIS-V2 tasks	Parameter of interest	Mean (average)	Mean diff.	SD	ICC2,1	95% CI	SEM	MDC
Dynamic Sitting Balance Subscale								
Task 1	ROM of lateral flexion to affected side (degrees)	25.93	1.21	2.67	0.95	0.86–0.98	0.59	1.64
Task 2	ROM of lateral flexion to affected side (degrees)	27.21	0.98	5.05	0.58	–0.26–0.91	3.27	9.06
Task 3	ROM of lateral flexion to affected side (degrees)	26.40	3.95	2.75	0.68	–0.10–0.95	1.55	4.3
Task 4	ROM of lateral flexion to unaffected side (degrees)	34.9	0.04	2.46	0.78	0.50–0.91	1.15	3.19
Task 5	ROM of lateral flexion to unaffected side (degrees)	30.56	1.33	4.51	0.82	0.42–0.95	1.91	5.29
Task 6	ROM of lateral flexion to unaffected side (degrees)	33.72	0.42	4.33	0.84	0.38–0.96	1.73	4.8
Task 7	ROM of lateral flexion to unaffected side (degrees)	19.98	3.12	4.81	0.60	0.15–0.83	3.04	8.43
Task 8	ROM of lateral flexion to unaffected side (degrees)	20.29	0.41	5.19	0.66	0.27–0.86	3.02	8.37
Task 9	ROM of lateral flexion to affected side (degrees)	18.61	1.08	3.98	0.60	0.13–0.81	2.51	6.96
Task 10	ROM of lateral flexion to affected side (degrees)	17.89	–0.12	2.47	0.80	0.50–0.92	1.1	3.05
Coordination Subscale								
Task 1	Symmetry (%)	79.82	–4.61	16.75	0.30	–0.16–0.67	14.01	38.83
	ROM of average rotation to affected side (degrees)	22.1	–2.93	5.14	0.62	0.21–0.84	3.16	8.76
	ROM of average rotation to unaffected side (degrees)	20.32	2.07	4.69	0.66	0.30–0.85	2.73	7.57
Task 2	Symmetry (%)	84.3	2.38	10.23	0.50	–0.01–0.80	7.23	20.04
	ROM of average rotation to affected side (degrees)	23.3	–1.13	4.33	0.72	0.40–0.88	2.29	6.35
	ROM of average rotation to unaffected side (degrees)	20.19	2.5	7.19	0.52	0.09–0.78	4.98	13.8
Task 3	Symmetry (%)	77.61	–6.33	23.92	0.05	–0.42–0.50	23.31	64.61
	ROM of average rotation to affected side (degrees)	8.89	1.31	3.9	0.60	0.16–0.83	2.46	6.82
	ROM of average rotation to unaffected side (degrees)	8.54	0.6	3.7	0.70	0.35–0.87	2.02	5.6
Task 4	Symmetry (%)	79.25	–9.89	14.56	0.41	–0.11–0.76	11.18	30.99
	ROM of average rotation to affected side (degrees)	9.74	2.35	4.02	0.45	0.02–0.75	2.98	8.26
	ROM of average rotation to unaffected side (degrees)	8.41	0.72	4.43	0.65	0.25–0.86	2.62	7.26

Mean diff. = mean difference; SD = standard deviation; ICC = interclass correlation coefficient; SEM = standard error of measurement; MDC = minimal detectable change

parameters except for the symmetry parameters, which revealed a very high value compared to the actual amount of movement, thereby denoting large variability, which is demonstrated by the large SD.

#### *Inter-rater reliability*

The same results were found for the inter-rater reliability of the dynamic sitting balance subscale. The ICCs showed excellent reliability between assessors, with an ICC  $\geq 0.76$  for all tasks except Tasks 7, 8 and 10 (Table 4). For Tasks 7, 8 and 10, the iTIS parameters showed good between-assessor reliability, with an ICC between 0.59 and 0.70. The CI for those tasks (Tasks 7, 8 and 10) were relatively wider than the CI measured for intra-rater reliability (CI for Tasks 7, 8 and 10  $\geq 0.57$ ), but did not include the value of 0, indicating statistically significant reliability. Furthermore, the SEM for these tasks was relatively high (SEM  $\geq 1.62$ ), denoting moderate variability caused by measurement error. Across the coordination subscale, two parameters demonstrated excellent reliability: the average rotation to the unaffected side in Task 1, which had an ICC = 0.76, and the average rotation to the affected side in Task 2, which had an ICC = 0.78. All the remaining iTIS parameters showed a good to fair reliability with an ICC between 0.48 and 0.69. The CI width was high and included the value of 0 in the low-reliability parameters such as symmetry in Task 3, indicating non-significant reliability, while the symmetry in Task 1 showed moderate reliability (ICC = 0.69), had a narrower CI (0.72) and did not include zero, indicating statistically significant reliability.

#### **Discussion**

The present study demonstrated good to excellent intra-rater and inter-rater reliability of the iTIS in the stroke group.

In the current study, the intra-rater reliability showed good reliability for all dynamic subscale parameters for the stroke group for Tasks 2, 3, 7, 8 and 9. A possible explanation for reduction of the reliability in Tasks 2 and 3 was the compensatory movements (e.g. using the UL to touch the bed, which led to an increase in the trunk lateral flexion

ROM compared to performing the same task without using the UL) by participants during the performance of these tasks. This compensation was observed by the assessor but could not be measured by the setup of the Valedo sensors, as the sensors were only attached to the trunk. Furthermore, the stroke participants used these compensatory movements variably in the first and second assessments (i.e. used in the first assessment but not used in the repeated assessment or used much more in the first assessment compared to the repeated assessment) which could affect reliability.

Another possible factor that might have affected the reliability level is that a few stroke participants ( $n \leq 12$ ) were recorded using the Valedo system during the performance of Tasks 3 and 8 because they had scored 0 on the clinical TIS-V2 in previous tasks, and so they automatically scored 0 without performing the tasks (Tasks 3 and 8). As these results were included in the analysis of this task, the reliability (ICC level) decreased.<sup>17</sup>

A possible reason for the reliability levels in Tasks 7, 8 and 9 being affected could be due to less variability in the performance of these tasks; most of the stroke group ( $n = 14/20$ ) scored 1 on this task, indicating that these tasks challenged participants' balance less than the previous tasks (Tasks 1 to 6), which could have resulted in a reduced use of compensatory movements. This explanation is supported by Portney and Watkins [18 p. 607]: 'The variability among subjects' scores must be large to demonstrate reliability. A lack of variability can occur when samples are homogeneous, when raters are all very lenient or strict in their scoring, or when the rating system falls within a restricted range'.

For the coordination subscale, intra-rater reliability was poor to fair for all parameters in the stroke group. This could have been due to a lack of detail within the TIS instructions, namely the lack of an explicit request for the participants to perform the task symmetrically.<sup>19,20</sup> The assessors gave this instruction: 'Could you please move your shoulder/knee forwards and backwards until you complete the movement 6 times (3 times for each shoulder/knee), starting from the (right/left) side'. Furthermore, for the symmetry parameter, we measured the extent to which the rotation (degree of ROM) on both sides was

Table 4. Inter-rater reliability for each task.

cTIS-V2 tasks	Parameter of interest	Mean (average)	Mean diff.	SD	ICC <sub>2,1</sub>	95% CI	SEM
Dynamic Sitting Balance Subscale							
Task 1	ROM of lateral flexion to affected side (degrees)	25.18	1.59	1.72	0.93	0.78–0.97	0.45
Task 2	ROM of lateral flexion to affected side (degrees)	23.65	2.02	4.48	0.94	0.71–0.98	1.09
Task 3	ROM of lateral flexion to affected side (degrees)	26.66	0.46	1.66	0.89	0.55–0.97	0.55
Task 4	ROM of lateral flexion to unaffected side (degrees)	34.04	1.02	2.71	0.76	0.48–0.90	1.32
Task 5	ROM of lateral flexion to unaffected side (degrees)	29.28	3.03	3.36	0.86	0.33–0.96	1.25
Task 6	ROM of lateral flexion to unaffected side (degrees)	34.24	0.23	2.64	0.93	0.75–0.98	0.69
Task 7	ROM of lateral flexion to unaffected side (degrees)	20.84	1.14	6.5	0.59	0.18–0.82	4.16
Task 8	ROM of lateral flexion to unaffected side (degrees)	19.82	2.35	5.53	0.67	0.01–0.73	3.17
Task 9	ROM of lateral flexion to affected side (degrees)	18.43	2.33	5.77	0.90	0.74–0.96	1.82
Task 10	ROM of lateral flexion to affected side (degrees)	17.4	2.94	2.97	0.70	0.31–0.88	1.62
Coordination Subscale							
Task 1	Symmetry (%)	80.53	–7.33	9.74	0.67	0.16–0.88	5.59
	ROM of average rotation to affected side (degrees)	22.26	0.16	8.37	0.58	0.18–0.81	5.42
	ROM of average rotation to unaffected side (degrees)	20.95	2.12	7.07	0.76	0.48–0.89	3.46
Task 2	Symmetry (%)	86.06	2.7	14.81	0.04	–0.55–0.47	14.51
	ROM of average rotation to affected side (degrees)	24.02	0.87	6.69	0.78	0.53–0.90	3.13
	ROM of average rotation to unaffected side (degrees)	21.63	2.17	6.25	0.67	0.34–0.85	3.59
Task 3	Symmetry (%)	75.39	6.9	21.07	0.48	–0.04–0.80	15.19
	ROM of average rotation to affected side (degrees)	9.25	–0.08	3.89	0.65	0.28–0.84	2.3
	ROM of average rotation to unaffected side (degrees)	8.44	0.92	3.7	0.65	0.29–0.84	2.18
Task 4	Symmetry (%)	78.07	–3.3	14.99	0.52	0.05–0.80	10.38
	ROM of average rotation to affected side (degrees)	9.94	2.21	3.73	0.69	0.30–0.87	2.07
	ROM of average rotation to unaffected side (degrees)	8.35	0.79	3.86	0.60	0.21–0.82	2.44

Mean diff. = mean difference; SD = standard deviation; ICC = interclass correlation coefficient; SEM = standard error of measurement

identical (%); hence, the reliability of the symmetry parameter only reached the maximum if both sides were rotated equally. Additionally, the rotation in the lower trunk recorded from participants is limited (ROM < 10 degrees), and any error might therefore be magnified and could affect the reliability.<sup>20</sup> The Valedo system correctly identified the number of rotations for all the coordination subscale tasks, but the ICC was not calculated (as the calculation is dependent on the variability of the test score, which was low across participants and trials in this study).

As for inter-rater reliability, the stroke group demonstrated excellent reliability in most dynamic subscale parameters, except for in Tasks 7, 8 and 10, which revealed moderate reliability. The explanation for good reliability in Tasks 7, 8 and 10 was provided in the previous section. Possible reasons for reduction in the level of inter-rater reliability in certain tasks could be due to human error from palpation during the reapplication of the sensors between repeated sessions. Variability in sensor placement was found to affect inter-rater reliability in a study assessing the reliability of inertial measurement systems when measuring seated spinal postures.<sup>21</sup> However, this contrasts with the results of a previous study which assessed the reliability of

the Valedo system in measuring trunk ROM in healthy participants in a standing position. That study tested the system against a gold-standard optoelectronic system and found that the Valedo system showed excellent reliability in measuring trunk flexion and lateral flexion to both sides.<sup>13</sup>

#### Study limitations

Limitations of this study include that the three sensors used were placed on the trunk, so no compensatory movement by the upper or lower limbs was measured during the task performance, which could affect both intra-rater and inter-rater reliability. In addition, system technical errors may also have affected the reliability results<sup>22</sup> as the system crashed during the completion of tasks during certain sessions. Furthermore, any measurement device designed to quantify spinal movements with sensors attached to the skin could be subject to error due to relative movements between the soft tissues and the vertebrae<sup>19</sup>.

The iTIS would benefit from more explicit instructions and details to improve the reliability of its results. For example, the participant instructions in the cTIS-V2 for the coordination subscale (Tasks 2 and 4) did not encourage participants to

rotate their trunk symmetrically, which may have affected the symmetry parameter in those tasks. Another potential factor that could have affected reliability was human error due to palpation while replacing the sensors on the trunk.

### Conclusion and clinical implications

Good to excellent test-retest reliability was found for most of the iTIS parameters measured. Unlike the cTIS-V2, the iTIS provides much greater information about the quality of trunk movements by detecting small changes in trunk ROM that may not be observed clinically and which may be important in justifying treatment approaches. These findings indicate that the use of iTIS measures in combination with the cTIS-V2 has important potential for enhancing the understanding of trunk impairment and compensatory trunk movements post-stroke. Further studies should explore larger sample sizes and seek to improve the iTIS methodology by using additional sensors on the upper and/or lower limbs to detect compensatory movements.

### Author contributions

Conceptualization, F.F., N.A., A.-M.H., R.T., S.K.W. and G.V.; methodology, F.F., N.A., J.B., M.W., A.-M.H., R.T., S.K.W. and G.V.; software, M.W.; validation, N.A., A.-M.H. and R.T.; formal analysis, N.A.; investigation, F.F., N.A.; data curation, F.F., N.A.; writing—original draft preparation, N.A.; writing—review and editing, N.A., M.W., A.-M.H., F.F., J.B., S.K.W., G.V. and R.T.; supervision, A.-M.H. and R.T.; project administration, A.-M.H. and R.T.; funding acquisition, N.A.

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### ORCID

Norah Alhwoaimel  <http://orcid.org/0000-0001-9448-4365>

Seng Kwee Wee  <http://orcid.org/0000-0002-5206-6269>

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