Longitudinal measurement of physical activity using a novel automated system to explore early stage functional recovery after stroke

Submitted to Cardiff University in partial fulfilment of the requirements for a PhD

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DECLARATION

This work has not been submitted in substance for any other degree or award at this or any other university or place of learning, nor is being submitted concurrently in candidature for any degree or other award.

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Summary

Introduction

There is emphasis on increasing patients' **P**hysical **A**ctivity **(PA)** to reduce disability and promote independent living. Therefore a new computerised system based on real time location technology called the **R**ehabilitation **M**obility **M**easurement **S**ystem **(RMMS)** was developed to overcome limitations of the current activity monitoring methods and measure PA continuously and unobtrusively. The study objectives were to evaluate the psychometric properties of RMMS and to explore early stage functional recovery after stroke in a rehabilitation unit and at home.

Methods

Each participant wore a radio-frequency identification tag with an in-built motion sensor on their unaffected wrist. Walking-aids and transport equipment were also fitted with tags. All areas accessed by patients were fitted with infra-red room locators. The tags transmitted movement and location signals to a computer having customised software programs for data processing. Descriptive statistics and graphs were used for analysis.

Results

The RMMS was very reliable (all ICC>0.90) and demonstrated high level of agreement on validation with observational methods.

Longitudinal PA was measured successfully in the rehabilitation unit for 52 patients over 64±53 days. Outside of therapy sessions, patients spent 85% of the waking day in their own rooms undertaking limited high level activities (15%).The average mobility (walking or moving around) was 15 minutes per day only and was strongly correlated with Barthel Index and modified Rivermead Index scores on discharge (spearman's rho=.-70, p=0.00) accounting for ≥ 43% of variation in these scores.

Conclusion

RMMS was a reliable and valid tool for measuring mobility; a key factor influencing early stroke recovery. The small amount of time spent active strongly suggests that better organisation of time outside therapy sessions is warranted to maximise daily PA of in-patients. RMMS could be used for motivational feedback for patients and clinicians to ultimately enhance functional activity during rehabilitation in a stroke unit.

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Table of Contents

2. Contents

Table of Figures

List of Tables

Glossary of Abbreviations

10MWT	10 Meter Walk Test
6MWT	6 Minute Walk Test
ABLE	Accelerometry for Bilateral Lower Extremities
ADL	Activity Of Daily Living
ADM	Admission
B&A	Bland And Altman
BBS	Berg's Balance Scale
BI	Barthel Index
BM	Behaviour Mapping
BWS	Body Worn Sensor
CERISE	Collaborative Evaluation of Rehabilitation In Stroke across Europe
D/C	Discharge
DR	Day Room
EE	Energy Expenditure
FAC	Functional Ambulation Category
FMA	Fugl Meyer Assessment Scale
GCS	Glasgow Coma Scale
HADS	Hospital Anxiety And Depression Scale
HCS	Healthcare Staff
ICC	Intraclass Correlation Coefficient
ICF	International Classification Of Functioning Disability And Health
IDEEA	Intelligent Device For Energy Expenditure And Activity
IR	Infra-Red
LL	Lower Limb
LOA	Limits Of Agreement
LOS	Length Of Stay
mRMI	modified Rivermead Mobility Index
MRS	Modified Rankin's Scale
NEADL	Nottingham Extended Activities Of Daily Living
NH	Nursing Home
OBM	Observation Based Method
OM	Outcome Measure
OR	Own Room
PA	Physical Activity

PCC	Pearson's Correlation Coefficient
PhyR	Physiotherapy Room
RFID	Radio Frequency Identification
RL	Room Locator
RMA	Rivermead Motor Assessment
RMI	Rivemead Mobility Index
RMMS	Rehabilitation Mobility Measurement System
RSU	Regional Stroke Unit
RTLS	Real Time Location System
SAM	Step Activity Monitor
SEM	Standard Error Of Measurement
SSWS	Self- Selected Walking Speed
STS	Sit To Stand
SWA	SenseWear pro Armband
UL	Upper Limb
WHO	World Health Organisation

1. Introduction

Stroke is the most common reason of acquired disability in an adult population with over 50 million stroke survivors worldwide (Miller et al., 2010, Lee et al., 2011, Asplund et al., 2009, stroke-association, 2015). This is a serious cause of concern for Healthcare services and physical rehabilitation after stroke is provided to reduce disability, promote functional activities and improve quality of life (Mountain et al., 2010, Pollock et al., 2014).

A point to note is that recovery after stroke is non-linear and 'Timing' (number of days after stroke onset) is considered as an important factor. This is because best recovery is reported to occur in the early stages of rehabilitation which is within 4 weeks after stroke onset. Moreover 95% patients tend to recover within 12 weeks (Duncan et al., 1994, Jorgensen et al., 1995). After 6 months, functional recovery appears to plateau (Verheyden et al., 2008, Gresham, 1986).

However, current **P**hysical **A**ctivity (PA) levels of patients post stroke in the hospital appear to remain low across UK and Europe. Several studies report that sedentary activities such as sitting/lying make up around 50% of the patients' day (West and Bernhardt, 2012, Skarin et al., 2013, Newall et al., 1997, De Weerdt et al., 2000). As a result, measures are being taken to improve PA levels. Published guidelines recommend that in-patients should receive adequate duration and intensity of therapy (≥45 min/day, 5 days/week) (NICE, 2013, Intercollegiate-Stroke-Working-Party, 2012). Interventional strategies such as efficacy of enriched environment and early rehabilitation on PA levels are also being explored and have found to increase and facilitate PA of patients post stroke (Cickusic et al., 2011, Janssen et al., 2014b).

The above evidence suggests that it is critical to increase early stage PA to maximise functional recovery and encourage independent living. Therefore it is important to identify an effective method that can measure PA continuously and with minimal disruption of clinical routine in a rehabilitation setting.

Current PA measurement methods are mainly subjective methods such as diaries, questionnaires and surveys or objective methods such as direct observation and wearable systems (pedometers, accelerometry based system, heart rate monitors and multiple sensor systems) (Godfrey et al., 2008, Reiser and Schlenk, 2009). Recently, computer science applications are being utilised to improve efficient data recording and processing for measuring PA (Mountain et al., 2010, Patel et al., 2010, Roy et al., 2009). One such system is the Real Time Location Systems (RTLS) (Chao et al., 2007, Yao et al., 2012) and evidence suggests that this technology has the potential to be utilised for designing PA assessment tools (Barman et al., 2012). The information above has led to the following query: What would be an effective method of physical activity measurement to obtain insight into longitudinal functional recovery in the early stages post stroke?

The aim of this study therefore was to investigate functional recovery of patients after stroke by measuring their PA in the early stages of rehabilitation.

The thesis is organised as follows: Comprehensive review of the literature regarding PA methods post stroke has been presented in Chapter 2 along with the study objectives and hypotheses. The overall study design, research framework and equipment used is given in Chapter 3. The methods, results and discussion for the developmental phase is given in Chapter 4. Chapters 5 and 6 relate to the longitudinal study and the acceptability study. The final discussion is undertaken in Chapter 7 and finally the conclusions of the study are presented in Chapter 8.

2. Literature Review

To meet the aim of the present study, a comprehensive search of the literature was undertaken to review the existing evidence related to the current methods used for PA measurement after stroke. All published articles examining the psychometric properties primarily the reliability and validity of the PA measurement methods were identified and evaluated. Firstly 'Activity' in the context of rehabilitation is discussed followed by the main literature review and finally the conclusions from the findings are presented which ultimately led to the formation of the research objectives and hypotheses.

2.1 Definitions of 'Physical Activity'

There are different definitions of physical activity reported in the literature. The standard definition of 'Physical Activity' is provided by the World Health Organisation (WHO) and the ICF framework consists of clear definitions of the terms 'Activity' and 'Mobility'. Apart from these, 'Activity' has been defined or explained in other ways by authors depending on how activity has been measured. These definitions or explanations are given below.

Definition of 'Physical Activity' according to WHO

A standard definition of PA has been developed by WHO and is as follows: '*Physical activity is defined as any bodily movement produced by skeletal muscles that requires energy expenditure. **Physical** inactivity has been identified as the fourth leading risk factor for global mortality causing an estimated 3.2 million deaths globally.*' *(World-Health-Organisation, 2016)*

Definition and classification of 'Activity' and 'Mobility' according to ICF

International Classification of Functioning Disability and Health has been developed by the WHO (World-Health-Organisation, 2001) .The framework contains standardised terminologies and codes that can be applied across different countries and scientific fields related to aspects of health. Within the context of health, 'Activity' refers to the execution of a task or action and difficulties encountered by an individual in executing these tasks is termed as 'Activity Limitations'. The ICF framework can be used as a clinical tool as well as a tool for the assessment of outcome measures and rehabilitation. It describes and measures health and health related states in a population or an individual (Figure 2.1).

It consists of two parts:

1) Functioning and Disability; comprising of components 'Body Function and Structure' (BFS) as well as 'Activity' (A) and 'Participation' (P).

2) Contextual Factors; made up of Environmental factors and Personal factors. The framework explains the impact of a person's medical condition on other aspects of his/her health. It informs healthcare professionals about patients' functional limitations so that interventions can be directed to improve their abilities and thereby participation. The framework is used for functional assessment, goal setting, treatment planning and monitoring.

Figure 2. 1: ICF Framework (WHO, 2001)
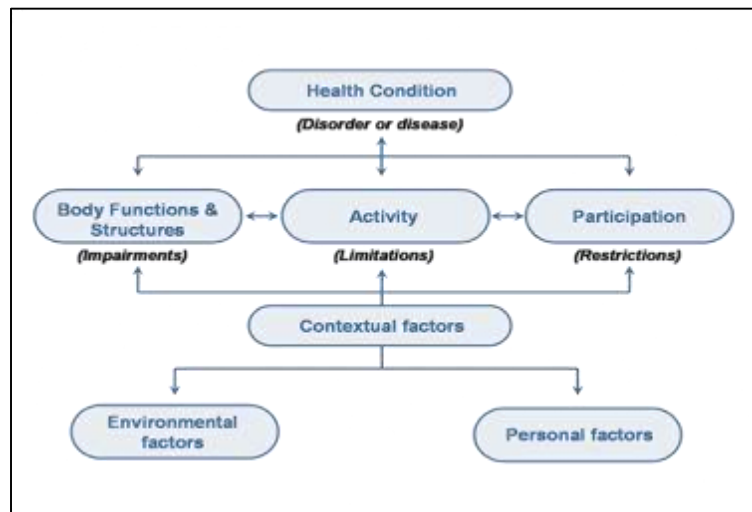
Within the context of health, 'Activity' is defined as '*the execution of a task or action by an individual*'. It deals with all aspects of daily life. Activities are considered as purposeful, integrated use of body functions and 'Activity Limitation' is the difficulty a person may have in carrying out the activities. 'Mobility' is one of the categories under the component of Activity and is defined as ' *moving by changing body position or location or by transferring from one place to another, by carrying, moving or manipulating objects, by walking, running or climbing, and by using various forms of transportation.'(*WHO, 2001*).

For patients, guidelines that have been developed also mention the importance of PA post stroke such as

"Physical activity can help your recovery and is also good for your overall health. Your rehabilitation team should encourage you to become physically active as soon as you can after your stroke. You should be assessed to see whether you are ready to start an exercise programme, and if so your physiotherapist should work with you to design a programme that helps towards meeting your rehabilitation goals.

After you have finished physiotherapy you should still be able to carry on with an exercise programme independently, and your therapist should help you to arrange this safely." (National-Institute-for-Health-and-Care-Excellence, 2013).

Other definitions of 'Activity'

The definition of 'activity' is varied in the literature depending on the measurement method used. (Kramer et al., 2013, Portney and Watkings, 2009). Bussmann et al. (2009) reviewed various subjective and objective measures applicable to the field of psychology. They defined ambulatory activity measurement as "a measurement strategy for continuous assessment of physical activity, posture and movement patterns in everyday life". In the study 'activity' comprised of movements such as walking, intensity of activity as well as postural positons such as lying and sitting. Butte et al. (2012) put forth another definition of PA by considering it as a 'construct' which can be classified qualitatively, quantitatively and contextually. Categories of sedentary behaviour, locomotion, work, exercise and leisure activities make up the items on the basis of which PA can be classified qualitatively while quantitative classification is based on the frequency of PA event occurrences, the duration in time and the intensity of PA. Contextually PA classification encompasses time, location, position or posture.

For the purpose of this study, the above definitions and descriptions have been drawn upon to be able to quantify PA as a behaviour or a construct.
For the study, PA needed to be inferred by measuring a set of interconnected variables or factors which fulfilled certain requirements (Portney and Watkings, 2009). These variables had to be meaningful in the rehabilitation context such that those patient milestones that ultimately lead to recovery could be detected. Moreover

the chosen variables needed to reflect changes in mobility because independent mobility is important for patients to live independently as discussed in the previous chapter. Moreover, under the component of 'Activity' specific items from the 'mobility' category were used to define and measure PA after stroke. These were mainly 'changing and maintaining body position' and 'walking and moving around'.

On this basis, a set of quantitative, qualitative and contextual variables that could be measured in the units of time were selected. Quantitative variables included duration of time spent walking or moving around, time spent in sitting or lying down as well as time spent in sustained activity. Qualitative variables were frequency of interaction with other people and the type of assistance required for walking. The related contextual factor was the time spent in various areas within a rehabilitation unit (Table 2.1). The exact relationship between the selected variables and the ICF framework is given below (Figure 2.2). These items were also included in the ICF core set for stroke as agreed by a formal consensus process which included experts from different backgrounds and were also most linked with other OMs used in stroke rehabilitation (Schepers et al., 2007, Geyh et al., 2004).

Table 2. 1 Selected variables to quantify physical activity

Quantitative variables	Qualitative variables	Contextual variable
Duration of time spent walking or moving around
Duration of time spent sitting or lying down
Duration of time spent in sustained activity	Frequency of interaction with other people
Type of assistance required for walking	Time spent in different areas/locations within the rehabilitation unit

Figure 2. 2 Items under the Mobility category of according to the ICF framework (WHO, 2001)
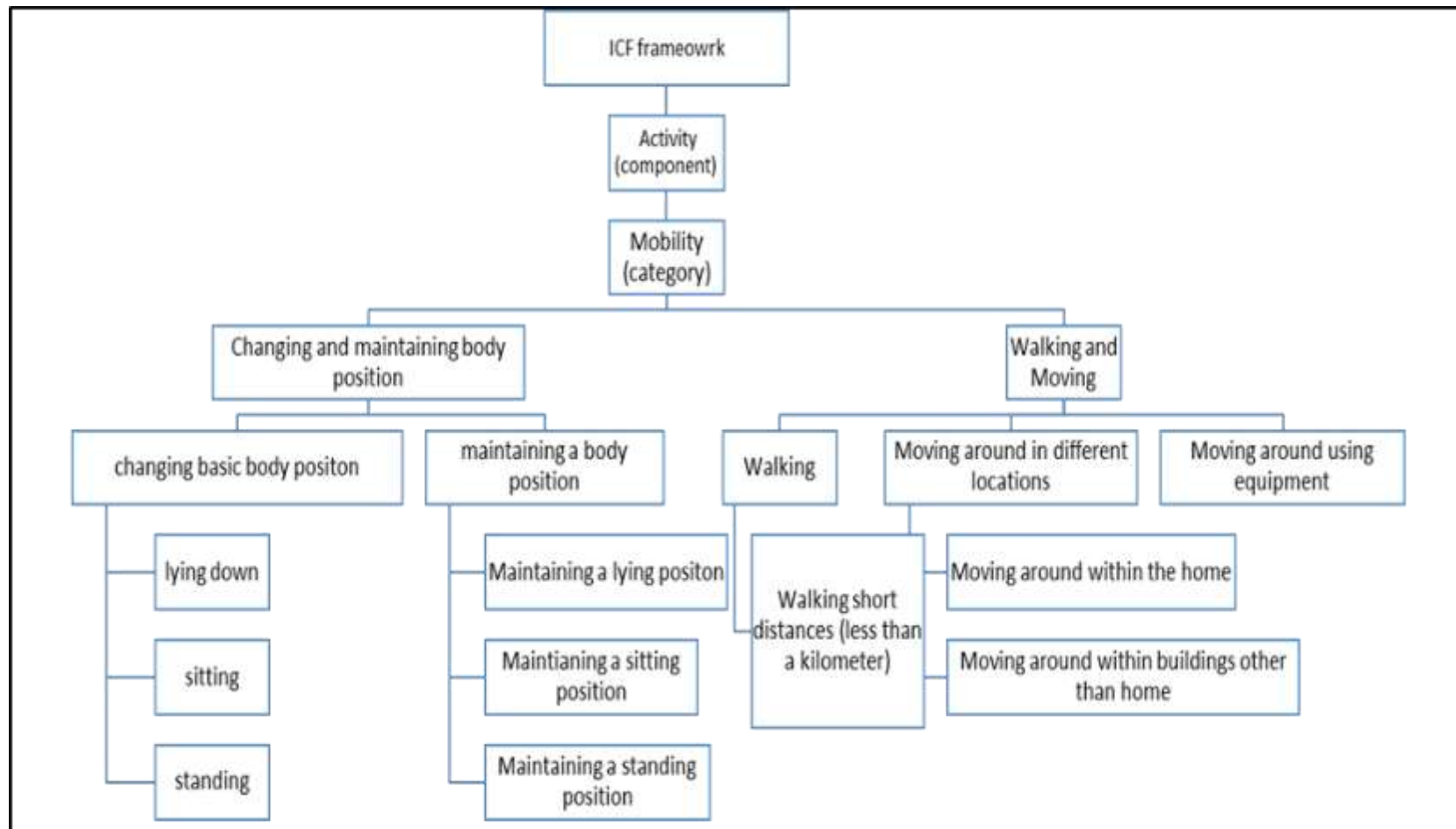
2.2 Search strategy

A search was undertaken using the following databases: Ovid MEDLINE (R) - from 1996 to December 24th 2014, Embase- from 1996 to December 3 week 24th 2014, AMED (Allied and complementary Medicine), and PsycINFO from 2002 to December week 4 2014. Deduplication was undertaken with Embase as the main database. The reference list of the selected articles was checked to find other articles that might have been missed. Apart from that, the search terms in the database '*find citing articles'* and *'find similar'* was also selected for the relevant articles. Basic search using google scholar was undertaken in case any reference was missed out.

In the first stage, search was conducted with the search terms given in Table 2.2. Additionally 2 or 3 of the search terms were combined using the term 'AND' to further narrow down the results.

Table 2. 2 Search terms for literature review and the number of articles identified

	Search Terms	Total number of articles
1	Body worn sensors	72
2	Wearable systems	92
3	Accelerometry based measures	2
4	Activity monitoring	1247
5	Physical activity monitoring	181
6	Activity measurement	1543
7	Mobility	227669
8	Stroke	457368
9	Post stroke	16265
10	Rehabilitation	334997
Combination of search terms with 'AND'		
	10,4	92
	4 ,8	48
	5,10	20
	1,10	17
	4,9	10
	2,8	2
	5,9	0

	1,4,8	0
	1,5,8	0
	1,6,10	0
	1,4,9	0
	1,7,9	0
	2,7,8	0

The above process resulted in a total of 145 articles and 10 main articles were considered most relevant (Bussmann et al., 2009, Butte et al., 2012, Reiser and Schlenk, 2009, Gebruers et al., 2010, Fini et al., 2014, Bonato, 2010, Chen and Bassett, 2005, Dobkin, 2013, Godfrey et al., 2008, LaPorte et al., 1985). From these articles the methods for PA measurement were selected for the literature review (given in Table 2.3).

Individual device names were combined with the following search terms: 'Reliability', 'Validity', 'Test Retest', 'Accuracy', 'Reproducibility', 'Post Stroke' and 'Stroke' to assess their ability to be used as an outcome measure to measure PA post stroke in the rehabilitation unit. An example of this type of search with the device name as pedometer is given in Appendix 1. The abstract and titles of the resultant articles are checked after duplicates were removed. Subsequently several articles were not selected in this literature review. These were:

- Articles determining reliability and validity of any of the above device recruiting adult patients with neurological and/or musculoskeletal conditions other than stroke. These included conditions such as Multiple Sclerosis, Parkinson's Disease, Peripheral Neuropathy, Diabetes, Spinal cord Injury, Low Back Pain, Ankle Arthroplasty, Hip replacement, Wheelchair users, Chronic Obstructive Pulmonary Disorder, Amputation leading to use of prosthesis

- Articles evaluating devices specifically for detection of falls, balance and evaluating posture

- Observational/interventional studies with adult participants having impaired cognition or with mood disorders such as depression or anxiety

- Studies where devices were used only for gait analysis rather than PA measurement

- Articles where devices were used to measure PA with children

- Also excluded were articles in a language other than English.

Table 2.3 lists the total number of articles that reviewed to assess their feasibility for use in the current study. These are discussed in detail later on in this chapter.

Table 2. 3 Articles selected for literature review

Main Methods for PA measurement post stroke	Number of articles	Article Reference
Subjective methods	6	(Mayo et al., 2002, Hartman-Maeir et al., 2007, Patterson et al., 1993, Sirard et al., 2000, Gardiner et al., 2011, Baert et al., 2012)
Observation based methods	29	(Miller, 1973, Kennedy et al., 1988, Keith, 1980, Keith and Cowell, 1987, Lincoln et al., 1989, Newall et al., 1997, Mackey et al., 1996, Pound et al., 1999, Esmonde et al., 1997, Bear-Lehman et al., 2001, De Weerdt et al., 2000, De Wit et al., 2006, De Wit et al., 2005, Huijben-Schoenmakers et al., 2009, Bernhardt et al., 2008, Bernhardt et al., 2004, Skarin et al., 2013, King et al., 2011, Thompson, 2009, Gustafsson and McKenna, 2010, van de Port et al., 2012, Ada et al., 1999, Lang et al., 2009, van Vliet et al., 2001, Alzahrani et al., 2011, Elson, 2009, English et al., 2014, Kaur et al., 2013, Janssen et al., 2014a)
Pedometers	8	(Manns et al., 2007, Elsworth et al., 2009, Fulk et al., 2014, Vanroy et al., 2014, Carroll et al., 2012, Macko et al., 2002, Robinson et al., 2011, Sullivan et al., 2014)

SAM	16	(Macko et al., 2002, Haeuber et al., 2004, Mudge and Stott, 2008, Mudge et al., 2007, Fulk et al., 2014, Fulk et al., 2010, Mudge and Stott, 2009, Shaughnessy et al., 2005, Bowden et al., 2008, Barak et al., 2014, Manns and Baldwin, 2009, Roos et al., 2012, Bowden et al., 2013, Duncan et al., 2011, Danks et al., 2014)
Four Accelerometer system	2	(Janssen et al., 2008, Janssen et al., 2010)
Activpal	5	(Calabró et al., 2014, Taraldsen et al., 2011, Harris, 2006, Britton et al., 2008, Touillet et al., 2010)
Actical	3	(Rand et al., 2009, Hayashida et al., 2014, Rand and Eng, 2012)
Actigraph	3	(Sun, 2013, Gebruers et al., 2008, Uswatte et al., 2000)
PAL2	2	(Kramer et al., 2013, Askim et al., 2013)
Sensewear Pro Armband	3	(Manns and Haennel, 2012, Moore et al., 2010, Moore et al., 2013)
Tritrac	1	(Hale et al., 2008)
ABLE	1	(Prajapati et al., 2011)
Wireless tri-axial accelerometer system	1	(Dobkin et al., 2011)
IDEEA	2	(Zhang et al., 2008, Alzahrani et al., 2011)
Shoe based system	2	(Fulk and Sazonov, 2011, Fulk et al., 2012)
Commercial activity monitors	7	(Lee et al., 2014b, Nelson et al., 2016, Ferguson et al., 2015, Fulk et al., 2014, Gaglani et al., 2015, Evenson et al., 2015, El-Amrawy and Nounou, 2015)

Select articles were reviewed by the author to deem appropriateness of the PA measurement method for use in the current study by reviewing its psychometric properties and utility in a rehabilitation setting. **While reviewing these articles, the focus of the evaluation has been on the characteristics of the different PA measurement methods rather than the implication of results on patient**

activity. Moreover emphasis was placed more on the utility of these methods for measurement of parameters primarily linked with the quantification of PA for the current study. Evidence regarding subjective methods of PA measurement has been discussed first. Objective methods of measurement have been discussed subsequently.

2.3 Subjective methods of measurement

Subjective measures include recall diaries, questionnaires, activity logs maintained by patients and surveys. Reliability of a self-report measure has been examined with healthy subjects by Gardiner et al. (2011). The test-retest reliability one week apart for 48 healthy individuals for total self-reported sedentary time was moderate as the **I**ntraclass **C**orrelation **C**oefficients **(ICC)** was 0.52. The interpretation for the ICC value has been made according to the guidelines provided in the literature and are described in Chapter 4 section 4.2 (Walter et al., 1998, Portney and Watkings, 2009). Substantial reliability was obtained for individual activities of TV watching, computer use and reading (ICCs ≥0.74) as opposed to socialising, travelling and other activities (ICCs ≤0.52). For a method to be termed as reliable, the ICC value should be ≥0.6 (Chinn, 1991). Criterion related validity with Actigraph™ (model GT 1M, Florida USA), an objective BWS was also explored in the study. A low correlation coefficient was found between the two methods (Spearman's rho = 0.30). **B**land and **A**ltman plots **(B&A)** 95% **L**imits **O**f **A**greement **(LOA)** were wide (± 3.82 hours) and the means difference was -3.60 hours/day which means that the sedentary time recorded by Actigraph™ was at least 3 hours more than that reported by subjects themselves. Underestimation of light activities by activity recall questionnaires when validated with Actigraph™ has also been reported Sirard et al.

(2000) and by Patterson et al. (1993) in who undertook studies with healthy subjects. One possibility why under estimation of sedentary time occurs with self-reported measures is that when asked to maintain records, some participants tend to become more aware of the time spent sedentary and thereby under report the time.

In research and clinical practice specifically post stroke, subjective methods have been used to assess quality of life status and ADL in community based patients after discharge as seen below.

Mayo et al. (2002) undertook telephone interviews with 612 patients after stroke every 6 months up to two years. Along with basic and instrumental ADL monitoring, questionnaires related to quality of life were also administered. These were basic and Instrumental Activities of Daily Living questionnaire and the Health Related Quality of Life measure. While these questionnaires were deemed reliable and valid, the use of telephone interviews and the construct measured by them was not relevant for the present study.

Two studies were found where aspects of PA were measured one year after stroke using a subjective method. Participants were interviewed at home and patient outcome was evaluated using questionnaires related to activity limitation, participation restriction and dissatisfaction from life by Hartman-Maeir et al. (2007). **F**unctional **I**ndependence **M**easure **(FIM)** and the Instrumental Activities of Daily Living Questionnaire were used to assess activities such as bathing, grooming, housekeeping and laundry. Patients with receptive or global aphasia were excluded from the study. In another study a recall diary was the used by 26 patients to record their PA for 5 days (Baert et al., 2012). The aim of this study was to quantify PA one year after stroke and determine its relationship with quality of life, participation and activity limitation. As with the study by Hartman-Maeir et al. (2007), patients who

were unable to follow simple instructions were excluded from the study and objective methods such as pedometers and heart rate monitors were concurrently used with subjective measures. Apart from the fact that the studies investigated PA one year after stroke, both used subjective measures for PA measurement in conjunction with other objective methods which made the sole use of subjective methods in the early stages of recovery questionable. Moreover to gain a comprehensive understanding of milestones of recovery after stroke onset, excluding individuals with aphasia or cognitive limitations was impractical. Lord et al. (2004) designed and used a questionnaire to determine the self-reported level of community ambulation with 115 patients 4 months post stroke onset. The authors state that the new questionnaire was pilot tested beforehand with patients post stroke before using it for the study, however details have not been mentioned. Additionally **F**unctional **A**mbulation **C**ategory **(FAC)**, **R**ivermead **M**obility **I**ndex **(RMI)** and gait velocity was measured in a lab. Relatives were allowed to answer on patients' behalf which made the methodology more acceptable for the present study. However as with the studies mentioned above, the main aim of this study was to measure ambulation and the focus was purely on PA measurement in a community setting. Moreover additional clinical OMs were used to assess mobility and the content of the self-reported questionnaire itself was targeted towards ability to be mobile in the community. Similarly 87 community dwelling individuals with more than 6 months post onset were recruited for a study aimed at exploring the feasibility of using more than one method of PA measurement in the community (Resnick et al., 2008). The Yale Physical Activity Survey; an interviewer based questionnaire along with the Short Self –Efficacy for Exercise Scale were the chosen subjective methods. To determine step counts over a 48 hour period objectively, all patients wore a SAM™ (Orthocare

Innovations, Oklahoma City, Oklahoma). The results indicated wide discrepancy between the level of exercise and activity reported by the patients through questionnaires with steps measured with SAM™. The subjects reported 2 hours of exercise (moderate level of PA) and undertaking 8 hours of daily PA while the number of steps undertaken by them was an average of 4055. Moreover VO_2 peak value which was also measured indicated that the level of deconditioning exhibited by the patients meant that it was unlikely that their reported PA level was the correctly estimated and that it was perceived higher than it was. The authors rightly state that due to deconditioning, the perceived exertion reported by patients was high. However PA over estimation reported by patients for subjective methods is a limitation with their use. Besides that as seen with the other studies, exclusion of patients with aphasia limited the use of these methods for the present study.

2.4 Objective methods of measurement

Wearable systems or Body Worn Sensors (BWS) are most commonly used for PA measurement after stroke in the rehabilitation unit and in the community. The common BWS are pedometers and accelerometry based measures.

2.4.1 Step counters or pedometers

Pedometers or step counters as the name suggests quantify PA based on the number of steps taken. They are usually worn at the waist band above the hip or in some cases around the neck (Bussmann et al., 2009, Butte et al., 2012). They are reported to be most accurate when worn at the waist level aligned centrally to the dominant lower limb such that if an imaginary line was drawn from the middle of the thigh, the pedometer was placed at a point where the line intersected the torso at waist level. There are two main types of pedometers based on how they operate. The first type consists of a horizontal lever arm suspended by a spring. As the person walks and there is vertical acceleration at the hip joint, the lever arm moves up and down. This movement opens and closes an electrical circuit and that is counted as a step. In some cases, a magnet is attached to the lever end and the movement of the lever produces a magnetic field which triggers a proximity switch completing the circuit and registering a step. The second type of pedometer is based on a piezoelectric accelerometer and is able to differentiate between activities according to the intensity of acceleration. It has been utilised to calculate **E**nergy **E**xpenditure **(EE)** as well as the number of steps (Reiser and Schlenk, 2009). Pedometers have been regarded as cost effective, lightweight, simple tools for objective ambulatory monitoring for clinical use as well as for research purposes (Bussmann et al., 2009, Butte et al., 2012).

Reliability and validity of various pedometers has been evaluated in studies undertaken with healthy subjects aged between 19 and 71 years where subjects walked at different speeds on a treadmill (Melanson et al., 2004, Ryan et al., 2006, Schneider et al., 2004). Step counts obtained were compared with those counted manually for validation analysis. The main finding in all studies was that pedometer accuracy was directly proportional to speed. The percentage error or inaccuracy in step counts was as much as 40% at speeds ≤0.8 m/sec (Grant et al., 2008, Maddocks et al., 2010). Similar results were also seen for test retest reliability of both Omron and Yamax Digiwalker[TM] pedometers where at speeds ≤ 1.38m/sec, the ICC were ≤ 0.48 indicating fair reliability (Ryan et al., 2006). The reported average comfortable walking speed of 283 subjects at 20 days after stroke and 60 days after stroke is 0.18 m/s and 0.39 m/s respectively (Tilson et al., 2010). Hence the low accuracy of the pedometers at speeds of 0.44m/sec suggested that this accuracy may further decrease in patients who were in the early stage of recovery and walked slower.

The reliability and validity of Yamax Digiwalker[TM] pedometers was undertaken by a few authors recruiting healthy subjects as well as stroke survivors. Manns et al (2007) determined the accuracy of Yamax Digiwalker[TM] pedometer (New Lifestyles Canada, Deep River, Ontario) with 45 participants (mean age=53 years) having neurological disability for over one year including stroke, acquired brain injury, Parkinson's Disease, Multiple sclerosis and congenital disability. All participants wore two pedometers on the anterior waistband in the midline of the each thigh while walking indoors over 100 meters at **S**elf **S**elected **W**alking **S**peed **(SSWS)**. Pedometer estimated steps were compared to those recorded with manual observation using a hand tally counter. The average SSWS was 0.88 ± 0.34 m/s

and stroke survivors demonstrated the slowest speed (0.77 ± 0.29 m/sec). It was evident in the scatter plots that error percentage was less for speeds over 0.66 m/s. The results showed that pedometer step count underestimation was up to 76% and overestimation was 40%. The mean error was 11% ± 24% and least error (6%) was found for the 6 participant with Parkinson's disease. Although the study included a mixed neurological population, the majority were stroke patients (14/45). The study findings could be considered robust because baseline characteristics of all patients especially SSWS and age were normally distributed and the use of a hand tally counter was a reliable criterion measurement. The study again illustrated that accuracy of pedometers at slow walking speeds was questionable. Accuracy of the Yamax Digiwalker[TM] (Model SW-200, Yamax Corporation, Tokyo, Japan) in 43 patients with neurological diseases including those 6 months post stroke (n=20) was also determined in another study (Elsworth et al., 2009).   All participants wore the pedometer on the right side in midline with the thigh and were asked to walk in a rehabilitation centre for 16 meters at their normal speed for 2 minutes. Pedometer step counts were compared with those obtained via a manual step counter. The baseline BMI and OM scores (RMI and BI) were not significantly different. The reported percentage variability was 30% with the ICC value of 0.66 for the repeat error measurement (substantial reliability). When patients were grouped according to the specific neurological conditions, the underestimation of steps by the pedometer was the highest for the stroke population (31 steps) with high variability in the step count (29%) and consistent error on repeated measurements (ICC = 0.84).The average speed for all subjects and those specifically with stroke were 0.57m/s and 0.64±0.25 m/s respectively. It can be said that the statistical tests used for analysing random error cannot be justified for the kind of analysis undertaken. However on the

basis of the percentage variability and the descriptive statistics the results can be accepted. The studies by Manns et al. (2007) and Elsworth et al. (2009) further showed that in patients with stroke, the percentage error of pedometers was high. Moreover only subjects who were able to walk and were in their chronic stage of stroke were included in the study thus the use of pedometer in the first 6 months of recovery for activity monitoring appeared restricted. A two minute walk test was undertaken with 50 patients after stroke and traumatic brain injury wearing the Yamax Digiwalker^{TM} Model SW-701 pedometer (YAMAX Health & Sports Inc., San Antonio, Texas) along with SAM™™ (Orthocare Innovations, Oklahoma City, Oklahoma) and two other BWS in a recent study by Fulk et al. (2014). The criterion for validity determination was steps counted from video recording done simultaneously. Data from the 30 stroke survivors was analysed separately. The ICC between observed and pedometer steps was 0.46 (moderate reliability) with the pedometer undercounting an average of 37 steps out of average total of 195± 32 steps. On studying the B&A plots, it appeared that for 17 participants the average number of steps undercounted by the pedometer was more than 30. Additionally for some individuals the pedometer also *over counted* steps. The only other monitor with lesser accuracy than the pedometer was the Nike+ FuelBand™ (from Nike Inc., Beaverton, Oregon) (ICC = 0.19, step underestimation = 77). These results were especially relevant with respect to the current research question of identifying the most appropriate OM that can be used for early stage PA measurement after stroke. It was evident that none of the BWS had perfect agreement with video recorded steps. However large error was reported once again with pedometers. Moreover some of the other devices evaluated in the study appeared better than the pedometer. These devices have been evaluated later on in this chapter.

While all these studies included participants at least 6 months after stroke, recently one study has validated Yamax Digiwalker™ 200 with a hand held tally counter for 15 patients at least 3 months after stroke and age matched healthy subjects (Vanroy et al., 2014). The protocol was similar to the study by Elsworth et al. (2009) and participating patients were able to walk for 2 minutes with intermittent or no support from another individual or walking aid. The pedometer was worn on the non-paretic hip and on the antero-lateral side of the unaffected knee. They determined test-retest reliability for the pedometer using the following set of activities for 4 minutes each; walking at 2 different slopes on the treadmill, ascending and descending a set of stairs, cycling at 3 different rates and finally walking for 120 meters at SSWS followed by as fast as possible. Excellent (Spearman's rho = 0.90) significant correlation (p<0.05) was found between the pedometer on the hip and hand counted steps when walking on the treadmill at 0.83m/s and 5% incline. The correlation between the two methods for all other tasks was fair and non-significant (Spearman's rho < 0.46). This study was the first to assess the validity of a pedometer worn at the knee joint in addition to the hip and similar results were obtained in relation to the speed at which patients walked. Excellent significant correlations (r ≥0.95, p< 0.01) were found for the knee worn pedometer for normal and brisk 120 meter walk and good significant correlation (r= 0.69, p<0.05) with walking on the treadmill at 0.38 m/s. B&A plots were used to assess the agreement between observed counts and the knee worn pedometer and wide limits of agreement were found when patients walked at a comfortable pace with the pedometer over estimating 33 steps and under estimating 46 steps. A similar trend of wider LOA was observed for healthy subjects with comfortable walking speeds. This again suggested that the location on the body did not significantly improve the

accuracy of pedometer at slow speeds. The authors explained that most of their patients had not used a treadmill before and the gait on the treadmill could have been different to normal gait explaining some of the low correlation with observed counts. Yet high percentage error with pedometer use has been consistently reported by all articles mentioned so far and on that basis the justification given by the authors regarding the low correlation obtained in this study could not be accepted with ease. On the contrary, based on the evidence so far it can be said that the low correlation with observational step counts was not unexpected. These findings are similar to the results by Elsworth et al. (2009) and Grant et al. (2008). The results indicated that walking speed was directly proportional to pedometer accuracy. As walking speed is slow in patients after stroke and in the early stages patients may even take a few steps with an altered gait pattern, using the Yamax Digiwalker™ for the study was not appropriate. Apart from Yamax Digiwalker™, 4 other types of pedometers have been used to measure PA in patients after stroke. These are OMRON HJ-113-E™ (Omron Healthcare UK Ltd, Milton Keynes, United Kingdom), Elexis trainer model™ FM 180, 330 (International Microtech, Miami, FL) 330-Step pedometer™ (Sportline, Elmsford, NY) and a twin step pedometer™ (VKRFitness, Gilroy, California). Although the number of relevant articles where these pedometers have been used was smaller than those reported for Yamax Digiwalker™, it was important to review them to assess their feasibility for the present study.

Validation of a piezoelectric pedometer (OMRON HJ-113-E™) was undertaken by comparing it with video based recorded step counts by Carroll et al. (2012). Fifty mobile patients (72 years) after stroke were recruited from a rehabilitation centre prior to discharge. Each wore 3 pedometers, one around the neck and one above

the left and right hip respectively and undertook a short walk (20 secs) and the **6-Minute Walk Test (6MWT)**. The relationship between step detection and walking speed was analysed first. On examining the plot of the percentage of steps detected by the pedometers versus walking speed it was seen that for speeds below 0.5 m/s the proportion of steps detected by all pedometers was between 20% and 60%. Moreover it was observed that for speeds below 0.40 m/s the pedometers appeared to detect only up to 20% of the steps. Secondly, B&A 95% LOA were used and showed that the LOA ranged from -9.14 to + 24 steps with the pedometers underestimating up to 24 steps when the average video recorded steps was 34. Similar results were also recorded for the 6MWT where the average video-recorded steps was a maximum of 405 steps and the B&A 95% LOA ranged from -29.4 to +94.2 steps meaning that the pedometer underestimated up to 94 steps. In this second analysis only those subjects who could walk at speeds >0.5 m/s were included. Finally feasibility of using pedometers was tested using a 5 point verbal scale. Fifty one patients were shown how to use the pedometers and then asked to wear all 3 pedometers at the respective locations. Subsequently they were asked to remove it and read the steps detected. Only 5 patients each were unable to wear the pedometer as well as read the steps on their own. All of patients could take them off and 46 patients said that pedometers were easy to use and most of them (39) would consider wearing it daily basis to monitor their PA. Although the type of pedometer used was different the results again suggested that there was a tendency of these devices to underestimate steps at speeds below 0.5m/s. Elsworth et al. (2009) in their study found no significant effect of speed on the detection of steps by a Yamax Digiwalker^{TM}; however they considered a speed of 1.3 m/s as slow. In the early stages of recovery, patients are more likely to walk at speeds below 0.5 m/s (Tilson

et al., 2010). On that basis along with the robust inclusion criteria and statistical tests the results by Carroll et al. (2012) were clinically more relevant than the former study. Also, the feasibility study results which suggested that patients found the pedometer comfortable were encouraging and authors rightly mentioned that wearing pedometer around the neck may be an easier option for some people. However it was primarily the lack of accuracy of the OMRON pedometer that restricted its use for the present study.

As with the other pedometers yet another model (Elexis trainer model FM 180™) was validated with hand held tally meter with 16 patients more than 6 months after stroke with a mean age of 67 years (Macko et al., 2002). All patients performed 2 6MWT at SSWS on separate days. They also performed the 1-minute timed walk twice on two separate days at SSWS and fast walking speeds. The average SSWS was 0.74 ± 0.29 m/s (range= 0.11 to 0.97 m/s). For all walking tasks, the pedometer accuracy was between 85% and 89% which was higher than that reported for the Yamax Digiwalker™ and the OMRON pedometer. However it has to be said that the sample size (n=16) which is smaller than the other studies and the average walking speed (0.74 m/s) which is faster than the previous studies could have led to the increased accuracy percentage. Recently, a pedometer based activity monitoring programme was undertaken with 11 participants in the community who had a stroke at least 6 months prior to involvement (Sullivan et al., 2014). Participants wore a pedometer (330 Step pedometer™, Sportline, Elmsford, NY) and PA was assessed with the 6MWT, stroke impact scale and a questionnaire. Moderate to good correlations were found between the pedometer and the three OMs ($r > 0.6$, $p< 0.05$) giving some indication of the pedometer sensitivity. However concurrent validity with visual step counts determined prior to the intervention resulted in a 'score' of 0.60. It

was difficult to comment on the agreement between the two measures used for validation due to lack of details. Also based on the evidence; a value of 0.60 indicated moderate relationship at best and it can be said that the pedometer used was not sufficiently validated. The pilot study was undertaken with 7 subjects and more information regarding the methodology was not been made available which made the results obtained somewhat questionable.

User satisfaction of pedometer use was also addressed in the same study. A pedometer satisfaction survey was completed by all participants involving 6 questions with Yes/No type responses and 1 question requiring a scaled response. Participant wore the pedometer on the non-paretic hip at the waist level consistently over 6 weeks during waking hours. Eight participants out of 10 reported that they would use a pedometer again and found it very easy or easy to use. However 3 patients said they would not use it further as the intervention had resulted in them walking faster and they did not want to count their steps. The satisfaction survey in this study as well as in the study by Carroll et al. (2012) highlighted the ease of use of pedometers. The pedometers seemed simple to take on and off and the step counts could be viewed almost immediately which meant that feedback on PA was available as and when required. These were advantages over some other more technologically advanced BWS which are discussed further on in the chapter.

The last type of pedometer reviewed was the twin step pedometer™ in a study by Robinson et al. (2011) with an aim to investigate aspects of participation in community walking in 50 chronic stroke patients (at least 6 months post stroke) with a mean age of 65 years. In the study, the relationship between subjective and objective measures was investigated. Patients wore a twin step pedometer for 7 days and noted their step counts at the end of each day. The subjective methods

used was the Mobility and Self-Care (MOSES) which is used to assess the self-perceived degree of difficulty walking with or without equipment. When the data from both methods was analysed using **P**earson **C**orrelation **C**oefficients **(PCC)** no statistically significant correlation between pedometer step counts and subjective measures was reported. The results were insufficient to indicate whether the twin-step pedometer was an appropriate and reliable measure to use for the present study. More studies with the twin step pedometer need to be undertaken with a larger sample size and a better criterion measure before its utility could be accepted for early stage PA measurement after stroke.

The results of the present review undertaken on the feasibility of pedometer in patients after stroke were similar to the findings of the systematic review undertaken by Kenyon et al. (2013). Seven studies were included in their review which validated pedometers for step counts against observation methods in children and adult populations with activity limitation. The correlation coefficients range was between 0.58 and 0.87 and the variability of step count was found to be between 0.5% and 24%. The authors also supported the findings regarding the influence of gait speed on the accuracy of pedometer.

2.4.2 Accelerometry based methods

Accelerometers measure body movements in terms of acceleration where acceleration is defined as the change in speed over time. The unit of measurement for acceleration is meter/second^2. However if the speed of an object remains constant, acceleration is measured as zero which does not mean that an object is not moving but that it is moving at a constant speed. The second way to measure acceleration directly instead of relying on speed and distance is by using Newton's second Law which is F=MA. And thus A=F/M ((Hewitt, 2002)). Therefore acceleration is directly proportional to the net force applied and inversely proportional to mass of the object. Moreover if mass is constant then acceleration and net force are equal. A sensor is considered as a device that converts a 'measureand' such as acceleration into an electric output (Olson, 2010).

Depending on the component used to gain information as a voltage signal on acceleration, accelerometers are of three main types; piezoelectric accelerometers, piezo-resistive accelerometers and differentiable capacitor accelerometers. While it is reported that piezo-resistive and the differentiable capacitor accelerometers have the capability to distinguish movement from posture, piezoelectric accelerometers are most commonly used for measuring PA (Bussmann et al., 2009).These consist of sensors with a piezoelectric element and a seismic mass. On acceleration, the seismic mass undergoes a change in shape and thus generates a force on the piezoelectric crystal. The crystal element then bends (Cantilever beam sensor) or gets compressed (Integrated Chip sensor). The crystal then generates an electric charge which is proportional to the force generated and therefore the initial acceleration produced. Although the element is the most sensitive in the direction of

bending (vertical), a voltage output can be generated in other directions as well, making the accelerometer omnidirectional (Chen and Bassett, 2005, Neuman, 2006). The accelerometer output is then processed in a number of steps to generate digital information that can be read via researchers. This information is then analysed to obtain results which are relevant for the measurement of parameters related to mobility. The processing of accelerometer output for a piezoelectric accelerometer according to Chen and Bassette (2005) is given below.

- The accelerometer output is subsequently sampled and filtered.

- The frequency of sampling is set according to the monitor computer. The sampling frequency of PA monitors that are available commercially is set between 1 HZ and 64 HZ. The PA frequencies of humans range from 8 HZ for activities such as running in the vertical direction to 25 Hz for specific movements of the arm (Winter et al., 1976). Setting the sampling frequency between 1 and 64 Hz ensures that most PA movements are detected.

- After setting the sampling frequency, a band pass filter is used to amplify the frequencies that are required and also to attenuate or reduce those frequencies which are above and below the values of the desired range (Webster, 2010). The current frequency is set between 0.25 Hz to 7 Hz. If the frequency is set very low, artefacts due to vibrations may be recorded as movement and if the frequency is not set high enough, then acceleration due to high level PA may be captured inaccurately.

- Once the output from accelerometers are sampled and passed through the band filter, raw counts are obtained. The process for this is by converting the analog voltage signals to a digital series of numbers using an Analog Digital

Converter. The digital data reaches the processor or the micro computer chips and is analysed by different methods.

- The first method is where, a digital counter is used to accumulate the number of times the digital signal crosses a set threshold. If the set value is zero this method is called the zero crossing method. It could be set to another value that is representative of human movement.

- In the second method, algorithms are used to determine the maximum value over a certain time frame. This timeframe is known as an epoch.

- The third method is where integration algorithms are used and the area under the curve is measured. In this method before using an algorithm, the negative digital numeric signals are converted into a positive number (full wave rectification) or only the positive counts are taken (half wave rectification). After which the area under the curve algorithm is applied to add up the PA counts. Usually an epoch of 1 min is used for adults.

- Choosing shorter epoch lengths can increase resolution but may be of less relevance. However if longer epochs are used in those cases where activities of different intensities are being considered, then the intensity is average. Moreover if the high intensity PA occur in short bursts over a longer epoch then the average count may not depict these high intensity PA and therefore the average intensity of the activity may be less.

Depending on the number of one directional accelerometers mounted together, accelerometers are uniaxial, biaxial and triaxial (Godfrey et al., 2008, Chen and Bassett, 2005). These refer to the number of orthogonal planes in which they are sensitive to motion. The ability to measure movement in more than a single plane make accelerometer based systems highly effective in measurement of complex

tasks and activities (Reiser and Schlenk, 2009). For PA measurement post stroke, uniaxial, biaxial as well as triaxial accelerometry based BWS have been used. Sometimes multiple accelerometers can be used in combination with each other or with other sensors to get information about PA.

Uniaxial accelerometers

In this review, 4 different types of uniaxial accelerometers were identified for PA measurement after stroke. These were ActivPAL™, Actigraph™, PAL2™ and Actical®. ActivPAL™ (PAL technologies, Glasgow, UK) is a piezoelectric accelerometer which can be worn directly on the skin of midline of the thigh between the knee and hip. It weighs 20 grams with the following dimensions 3.5x 5.3x0.7 cms. Recorded data can be transferred to the computer and is stored as Microsoft Excel files.

Actigraph™ (Florida, USA) also known as actometers consist of the sensors, a signal processing unit and the battery. The data can be transferred to a computer. It was previously also known by other names such as the Computer Science Application (CSA™) monitor (Computer Science and Applications, Inc., Shalimar, FL) or the Manufacturing Technology Inc. (MTI) monitor. It is a uniaxial piezoelectric accelerometer and can record frequency of activity and steps as well as EE. It can be worn on the waist, wrist or ankle, with dimensions of $25cm^3$ and weighs 27grams (Godfrey et al., 2008, Bussmann et al., 2009). The battery is the one that is used in a watch and can last up to 14 days.

PAL2™ (Gorman ProMed Pty. Ltd Melbourne, Australia) is another device that has been used to quantify time spent in positions such as sitting, lying and upright (standing and walking). It contains a dual axis accelerometer and 2 tilt switches one worn above and one below the knee on the lateral side and combined information

from both switches can be used to detect postures. Data can be downloaded using software.

Actical® (Bio-Lynx, Quebec, Canada) is another uniaxial accelerometer based device which has been evaluated in this literature review. It is a small (2.8x2.7x1cm3) water resistant device weighing 17 grams that can be worn around the wrist, ankle as well as at the hip. Motion can be detected in all 3 planes but is most sensitive in the vertical direction. The magnitude and duration of acceleration is proportional to the numbers recorded by the device. Intensity of activity is measured as counts every 15 seconds (epoch) where each count represents intensity and physical activity energy expenditure can be measured in kcals (Heil, 2006, Rand et al., 2009).

Out of the 4 devices, more studies evaluated ActivPAL™ as a BWS than the other methods mentioned above. All these studies have been discussed below.

ActivPAL™

Like pedometers, step counts and cadence (number of steps/ minute) can be measured but reliability and validity of the ActivPAL™ has been determined mostly with healthy subjects (Dahlgren et al., 2010, Ryan et al., 2006, Grant et al., 2008). Studies have been undertaken with adequate number of participants (n=21) and patients either walked on a treadmill at set speeds (range 0.60 to 1.84 m/sec) and/or walked over ground outside. Unlike results reported for pedometers, on validation with manual step counts, the absolute percentage error of ActivPAL™ was less than 2% with substantial test retest reliability (ICC>0.70). An advantage of ActivPAL™ over Yamax digi-walk pedometer™ and another accelerometer based BWS known

as PALite™ was that there were no false steps reported due to external vibration when participants travelled in a car wearing ActivPAL™.

Validation of ActivPAL™ for measuring lower intensity PAs along with 4 other measurement systems was undertaken based on EE which was obtained from specially created predictive algorithms (Calabró et al., 2014). The ActivPAL software can be used to allow classification of activities as sitting/lying (EE value =1.25 METs) and standing (EE value=1.4 METs). A pre-defined prediction algorithm was used was used in the study to estimate EE associated with speed. This algorithm is MET .h = (1.4 X activity duration (hours)) + (4 – 1.4) x (steps per minutes/120) x activity duration (hours)). ActivPAL™ underestimated EE by a significant 22% (p<0.001) and B&A plots also revealed that as the activity intensity increased from sedentary to light to moderate, the EE estimation error by ActivPAL™ systematically increased too. Based on the underestimated EE, the authors rightly determined that ActivPAL™ was not a sensitive BWS for the detection of lower intensity ADL.

Other parameters apart from steps that can be measured with ActivPAL™ are time spent in positions of standing and sitting/lying (Godfrey et al., 2008, Kunkel et al., 2015, Taraldsen et al., 2011). The ability to detect these positions is a useful feature for PA measurement as these postures are important milestones in post stroke recovery. Accurate recording of posture, transition and step count by ActivPAL™ was tested in a cross sectional study and concurrent validation was undertaken with video based recording (Taraldsen et al., 2011). Data from ActivPAL is collected at 10 Hz from the thigh sensor and proprietary algorithms (Intelligent Activity Classification) are used to process raw acceleration data signals. The device records the number of steps taken by the LL and the algorithm is used to double the total number of steps. The study also investigated the accuracy of step detection when

worn on affected and unaffected lower limb and if use of 2 devices (on the thigh and sternum) would aid differentiation of sitting from lying down. The study had a test group of 14 participants in the acute stroke unit, 14 participants from an in-patient geriatric ward, 8 patients 3 months post hip fracture living in the community and a reference group with 10 healthy older adults. All subjects were able to walk without walking aid or support of 1 or 2 people. Participants wore 3 sensors, one on the midline of each thigh and one at the sternum. To test the concurrent validity a standardised set of activities was devised to include all positions, transitions and walking a distance of 5 meters at slow, fast and comfortable speeds. Gait speed was calculated. A difference of only 1 second was found for detection of sedentary versus upright position for a total of 555 tasks undertaken by 34 patients excluding the healthy subjects. Transition frequency from sit to stand and sitting/lying were as accurate as with observations (total of 33 transitions).The device on the affected leg for patients post stroke and post hip fracture miscalculated more steps (95% LOA= $\pm$ 5.69 steps) than the one on the unaffected leg (95% LOA= ±4.36 steps) with the mean steps being 10.66 (±4.66). Step counts were recorded at different speeds as follows: slow walking (0.47m/s), comfortable walking (0.84m/s) and fast walking (1.26m/s). The average speed was 0.86±0.36m/s. The agreement between the 2 methods was better at speeds above 0.62 m/s (95% LOA = $\pm$ 4 steps) than at speeds below 0.43 m/s (95%LOA $\pm$ 8 steps). The absolute percentage error was 11% less at fast speed (slow speed= 40%, fast speed = 29%). Similar trends were found for the 10 healthy individuals. The results for sit to stand transitions were similar to another pilot study where the difference in the frequency between ActivPAL™ and observations was 2$\pm$5 counts out of a total of 34 (Harris, 2006).

From the above evidence it could be said that the ActivPAL™ was a reliable and valid measure for recording steps and detecting movement in healthy individuals. However based on the results by Taraldsen et al. (2011) ActivPAL™ appeared to have better reliability for identifying different postures and sit to stand transitions rather than recording step counts in patients after stroke.

None the less ActivPAL™ has been used as an OM for studies with patients in the rehabilitation unit as well as in the community setting. For a randomised controlled pilot study, the efficacy of additional sit to stand practice was investigated by comparing the frequency of sit to stand tasks for patients who received additional practice to those in the control group. All patients wore ActivPAL™ for 5 days and step counts as well as frequency of continuous PA lasting 15 minutes or more was measured (Britton et al., 2008). In a longitudinal study sedentary time was measured with 64 patients during their rehabilitation stay and discharge post home up until 3 years after stroke (Kunkel et al., 2015). At different time points, patients wore ActivPAL™ for 1 single day over 7 hours. ActivPAL™ has also been used to measure step counts in community dwelling patients after stroke to either assess their compliance with an exercise programme (Touillet et al., 2010) or to look at relationships between cardio-respiratory response via cycle ergometer and PA via ActivPAL™ (Salbach et al., 2014).

Actigraph™

Reliability and validity of Actigraph™ has been evaluated with healthy individuals for PA measurement. It has been tested for its ability to classify PA levels (sedentary to high level) for up to 20 individuals aged between 19 and 38 years (Patterson et al., 1993, Sirard et al., 2000). These studies also compared PA levels using Actigraph™ with heart rate, oxygen uptake, or with activity diaries. In both studies, fair correlation was reported on validation (PCC ≤ 0.6, p<0.05) with other measures and the percentage agreement between methods was ≤ 64%. Moreover external vibration accounted for 85% of Actigraph™ recording was reported. Test retest reliability was undertaken with only 4 subjects and PCC was used instead of ICC therefore the results appeared weak. Overall, the results from the above studies did not appear to support the use of Actigraph™ for the present study. Even with patients post stroke, Actigraph has been evaluated as a device of measuring upper limb movement disorder or arm motor impairment rather than PA. Sun (2013) determined the correlation of two variables related to Actigraph mini motion logger™ (Ambulatory Monitors Inc., Ardsley, NY) in 69 patients after acute cerebral infarct and 81 patients with Parkinson's disease. The actigraphy was calibrated at the zero cross mode with a filter range of 2-3 Hz. The sensitive threshold as set at high and the gain was set as low. The Detrended Fluctuation Analysis (DFA) and Power Law Exponent (PLE); variables that can be derived by Actigraphs are used to evaluate upper limb movement disorder severity. DFA is a type of fractal analysis which can capture the change in activity. It is not dependent on the number of activities but compares the rate of change for fluctuations corresponding to each time interval. The larger the value of DFA, the better is the ability to maintain the continuity of the action (Franca et al., 2014) All patients wore Actigraph™ on their arm (in patients with infarct the

affected arm) for 3 days or more in the hospital. For patients after stroke the correlations of **F**ugl-**M**eyer **A**ssessment as well as the upper limb part for the FIM with Actigraph scores were analysed. The Actigraph variables were significantly correlated with FMA and FIM scores, albeit moderately (PCC = 0.68 and 0.71 respectively, $p<0.05$). Similarly in another study the use of Actigraph™ to measure disuse of impaired arm in 39 patients 1 week after stroke onset was assessed (Gebruers et al., 2008). The device used has the ability to measurement movement in 3 different modes; the Zero Cross Mode (activity count is registered when the signal crosses a predefined baseline), Time Above Threshold Mode (the sensor signal remains over the pre-set threshold and the activity count increases as time increases) and the Proportional Integrating Measure (the sensor signal is integrated and the area under the rectified curve is calculated). For this device the sensitivity is set at 0.01g and the epoch length is set as 1 sec. The Proportional Integrating Measure was used to process data in this study and the raw data from the Actigraph was sent to a computer where 30 minute epoch period was used for analysis. Patients wore an Actigraph™ each on both wrists for 48 hours. Actigraph recordings of the impaired arm were correlated with National Institute of Health Stroke Scale and the FMA (arm section) using Spearman's rho. Good, significant ($p<0.001$) correlations were found between the Actigraph™ recording and National Institute of Health Stroke Scale ($r=-0.75$) as well as between Actigraph recording and FMA ($r=0.69$).

Measurement of functional upper limb movement was Actigraph was undertaken by Uswatte et al. (2000) with 9 patients post stroke with a mean age of 54.4 years. Eleven healthy subjects with a mean age of 21 years were also recruited alongside patients post stroke. The accelerometers used was Computer Science and

Applications, Inc. (model 7164). Accelerations are sampled at 10 Hz the user can specify the epoch. One activity count is 0.01664g for an acceleration of 2.13 g. This acceleration is parallel to the accelerometer x axis and produced by a movement with a frequency of 0.75 Hz which are recorded with a 0.1 second epoch. For the study, the raw accelerometer data was transformed using a threshold filter to determine whether transformation improved accuracy of accelerometry data. The raw accelerometer values above a low threshold were changed to a constant using the filter and therefore variation in the data was removed. Patients post stroke and healthy subjects were video recorded or observed either at home or in the rehabilitation hospital while undertaken ADLs wearing an accelerometer on each wrist. One accelerometer was placed on the non-affected leg and one was secured on the chest with a help of a belt. The activities performed at home ranged from lower limb activities such as walking to upper extremity activities such as drinking or using a TV remote. In a lab setting patients performed a set of activities such as vacuuming, eating beans with a spoon. Two observers looked at the video and coded the activities in 2 second intervals. If the raw count recorded from the accelerometers was 1 or above, the accelerometers were calibrated to record data with a 2 second epoch and the value assigned to it was 2. The duration of arm movement was reflected by the total of the activity counts that were transformed due to the threshold filter. After transforming the data, the average agreement between accelerometry data and that via observational coding was 98%. The correlation for the activities at home between the accelerometer data and via observation were ≥ 0.93.

Although the 3 studies were undertaken with patients after stroke and the findings from all 3 could be accepted, based on the variables used for analysis, it was difficult

to assess whether Actigraph would also be valid for measuring other equally important aspects of early stage PA such as sitting/lying and moving about. Several other body worn sensors were identified in the present literature search and their use for early rehabilitation activity monitoring was reviewed. Most of these devices consist of accelerometry based components.

PAL2™

Only one study was identified where reliability, validity and acceptability of PAL2™ (Gorman Promed PTY Ltd, Carnegie, Australia) was examined by Kramer and colleagues (2013). It is a dual-axis accelerometer which works in combination with tilt switches. The sampling rate is 10 Hz and for the study the default device setting for intensity and threshold were used. However these default settings have not been provided by the authors. The information from the tilt switches is used to determine the position of the wearer. The data from the device is downloaded to a computer and a raw data graph is produced in which the trace for motion and the trace for position are used in combination to provide information about activity. On the graph the trace positions (high or low) represent the position of the wearer. Twenty-one patients (median age 80) were recruited within 14 days post CVA and wore PAL2™ for 9 hours (8am to 5pm) over a single day. Validation was undertaken with OBM and a trained observer recorded pre-categorised activities in 10 minute intervals. Median percentage of time spent in lying, sitting and upright was recorded by both methods. The reliability between the two methods was ICC = 0.74 (0.46-0.89) for lying down and upright positon was 0.72 (0.43-0.88) positions and for sitting position (ICC =0.68 (0.36-0.86). The authors reported that there was proportional bias as the time spent in upright position increased, the agreement between the two systems decreased. One reason for the lower agreement between the two measured could

be due to the OBM data being recorded every 10 minutes because the time period for which upright positions were quantified could only be in multiples of 10. However if this was not the case then PA measurement with PAL2™ undertaken over many days could lead to biased data where upright position may be underestimated. Moreover the mechanism of PAL2™ to differentiate between sitting and lying positions depended on the change position of the thigh relative to the leg and this could also be a limiting factor in its use for the present study. This is because Kramer et al. (2013) reported that lying down with knees bent was detected as sitting by PAL2™ whereas sitting with legs extended was detected as lying down. In the early stages of recovery, sitting was an important milestone which needed to be measured accurately therefore using PAL2™ for the present study was ruled out. Acceptability of wearing PAL2™ was also assessed in the study with 8 participants rating their experience on a 5 point Likert scale. For the statement 'wearing the device on my leg was comfortable', 5 participants strongly agreed while 2 disagreed and 1 was undecided. However the device was found comfortable by 5 out of 8 participants whereas there were 3 comments regarding the straps being tight around the leg causing discomfort. For long term activity measurement participants' user comfort is an important factor and although there was some evidence that patients found it comfortable, lack of sensation in the leg or abnormal positioning would have limited its use for the present study

Unlike other devices such as the pedometer and the Actigraph™, PAL2™ has been used as an OM for PA measurement within 14 days of stroke onset in a rehabilitation unit. The participant wore the device for a 24 hour period at 3 different time points within 6 months (Askim et al., 2013). However it appeared that for the current study the limitations of its use outweighed the benefits.

Actical®

Validity of a modified version of Actical® (Respironics Inc., Murrysville, Pennsylvania) for measuring step counts was tested in 38 healthy participants with a mean age of 34 years with a hand tally step counter (Esliger et al., 2007). The original device was modified so that it could measure accelerometer counts and step count. PCC for slow walking at 0.83 m/sec was 0.52 and B&A plots showed that the modified Actical® undercounted up to 30 steps per minute at slow speeds making its accuracy questionable.

Another type of Actical ; Actical® (Mini-mitter Co Inc, Oregon, USA) was used for a study by Rand et al., 2009. The device has a frequency range of 0.3 Hz to 3 Hz. The sampling rate is 32 Hz and the sensitivity is between 0.05 to 2.0G forces. Data from the accelerometer is rectified and integrated before being stored as Activity counts in 15 second epochs. Intensity of activity is represented as the activity count data per epoch. Activity counts and EE were measured with the device. The algorithms used to measure EE were based on the study by Heil (2006). Reliability was determined in a study recruiting 40 community dwelling patients on an average of 2±2.4 years after stroke with a mean age of 66 years (Rand et al., 2009). Each participant wore an Actical® each over both hips with a belt around the waist for 3 days for an average of 15±1.8 hours a day. During two lab visits **6 Minute Walk Test (6MWT)** was undertaken at comfortable speeds to determine correlation between activity levels (Actical®) and walking capacity (6MWT). The average activity counts and EE values measured for the paretic hip (activity counts= 55886, EE= 163.1) and non-paretic hip (Activity count=53075, EE=155.9) were not significantly different and almost perfect between day reliability was also reported (all ICCs >0.94). The percentage of **S**tandard **E**rror of **M**easurement was 30% for activity counts and 20% for EE. The

correlation with 6MWT was excellent and significant for both devices worn on either hip (PCC ≥ 0.89, p <0.001). The study methodology was robust and appropriate analysis was undertaken. The results from the study were acceptable however SEM of 20% to 30% was considered quite large as change in PA was to be measured over weeks.

Actical® has been used for PA measurement in a study exploring functional recovery in a rehabilitation centre (Rand and Eng, 2012). Sixty-eight patients with a mean age of 76 years wore 3 Actical® devices for 3 consecutive days after admission and before discharge respectively. PA was quantified using activity counts per minute from the wrist monitors and step count per minute from the hip monitor. Change in the PA was measured from admission to discharge however measurement was done for only 6 days and this timeframe would need to be increased for gaining a better insight into recovery of function.

Actiwatch™ which is a predecessor of Actical® (Chen and Bassett, 2005) has been used to determine the correlation between night time sleep duration and effectiveness of rehabilitation through FIM discharge score (Hayashida et al., 2014). The actigraphic data were scored as asleep or awake in 30-second epochs using the analysis software provided by the company. The activity counts that are recoded by the Actiwatch are modified according to the level of activity in the surrounding ± 2 minute time frame to give a final activity count per epoch (Kushida et al., 2001). This algorithm used to derive the sum of activity counts for the 30 second epochs and the surrounding epochs (A) is given as follows:

$A = 0.04E_{-4} + 0.04E_{-3} + 0.20E_{-2} + 0.20E_{-1} + 2E + 0.20E_{+1} + 0.20E_{+2} + 0.04E_{+3} + 0.04E_{+4}$

Where E = activity counts in scored epochs and E_n is the activity counts during the previous 4 or successive 4 epochs.

If the total activity count A is above a threshold (T) then the epoch is scored as 'wake' because A>T. otherwise it is scored as 'asleep'. The high, medium and low threshold values are set at 80, 40 and 20 activity counts respectively (Kushida et al 2000).

Fifteen in-patients with hemiplegia (mean age 60 years) wore Actiwatch® on their unaffected wrist for one week on an average of 41 days after stroke. Significant (p<0.01) moderate correlation was obtained between sleep duration and FIM discharge score (r=0.69) and with FIM efficiency (r=0.70). However there are other BWS which can be used to measure additional aspects of activity including sleep time hence Actiwatch® was not considered for use for this project. Moreover the reliability of the device does not seem to have been established sufficiently.

All of the 4 uniaxial accelerometer based devices reviewed so far (ActivPAL™, Actigraph™, PAL2™ and Actical®) have been used *individually* for measuring different parameters of PA. In the next study a PA measurement method consisting of 4 uniaxial accelerometers was developed and evaluated for use.

Janssen et al. (2008) tested the validity of an accelerometry method based on 4 piezoresistive accelerometers known as the ADXL 202 accelerometers. Data from these accelerometers are sampled at 128Hz and stored on the computer. The algorithm signals are processed using specially created MatLab programs. The signals are filtered using Butterworth filter and then derivatives are calculated using specific algorithms. The visual display of how this is undertaken is explained in the study as Figure A and B in the article (Janssen et al, 2008) The aim of this study was

to validate this method with an opto-electrical device for the measurement of the time taken to complete a **S**it **T**o **S**tand transition in 6 healthy subjects (mean age 29.9 years) and 6 subjects on an average of 2.5 years after stroke (mean age 65 years). Accelerometers were attached using aluminium strips at the following points on the body: 1 at the lower part of the sternum, 1 on the left leg or the non-paretic leg and 1 each on the lateral thigh. For comparison with the opto-electrical device, 2 reflective markers were placed on the sternum and 2 on the thighs and subsequently video recording using the opto-electrical device consisting of 3 cameras was undertaken during STS movements. All subjects performed STS tasks at slow speed, comfortable speed and fast speed with exaggerated trunk flexion. The average time taken to perform the movement for all conditions was 3.36 seconds for stroke patients and 2.50 seconds for healthy subjects. The average duration of time taken for STS measured by accelerometer based method was consistently higher than that by video based analysis. The PCC values were 0.98 suggesting excellent correlation between the two methods but the SEM was 0.07 secs and 0.32 seconds for healthy subjects and patients post stroke. Also, the accelerometer system measured a significantly longer duration for STS movements than video based measurement ($p<0.00$) particularly for STS at slow speeds ($p=0.003$) and at exaggerated trunk flexion ($p<0.004$). The overestimation by the system was also reflected in the B&A plots. The study methodology was robust and validation was undertaken using appropriate statistical tests therefore the results seemed acceptable. Since then the system has been used to assess the recovery of STS task after stroke with 50 participants over 48 weeks from stroke onset (Janssen et al., 2010). However practical aspects of using this system were questionable. Requesting patients to wear devices on 4 different parts of the body and then analysing data for a single

movement could be burdensome for patients and researchers alike. Also, other uniaxial devices which can measure EE, intensity of activity and step counts seemed better options than the method proposed by Janssen et al. (2008).

Biaxial accelerometers

Biaxial accelerometers which record acceleration in two planes have been used for PA measurement in patients with Chronic Obstructive Pulmonary Disease but very rarely used post stroke (Watz et al., 2009, Gebruers et al., 2010). In the present literature search only two systems using biaxial accelerometers were identified. However as one of them known as the 'accelerometry system' was used specifically for detecting spatio-temporal gait parameters it was considered irrelevant for the present study and therefore excluded from the review (Saremi et al., 2006). The other device known as the SenseWear Pro Armband™ (from Body Media, Pittsburgh, PA, USA; software version 6.1) has been discussed below (Manns and Haennel, 2012, Moore et al., 2012)

Sense**W**ear Pro **A**rmband™ **(SWA)** consists of a bi-axial accelerometer along with 3 other sensors which are; heat flux (to detect heat dissipation from body), galvanic skin response (detect skin conductivity) and a sensor to detect skin temperature. The biaxial accelerometer is used to detect the positions of lying down and not lying down. This data about position in context with information from other sensors is used to determine EE and activities such as standing and walking (Manns and Haennel, 2012). The algorithms for estimating EE have been developed by the manufacturers and studies have been undertaken to refine these. The details regarding the algorithms have not been provided in this study and most studies only mention which version of the algorithm is used to measure EE (Andre et al., 2006).

Proprietary software are used to obtain step count data from raw accelerometer signals (Manns and Haennel, 2012).

In a study by Manns and Haennel (2012) validity of the SWA system for measuring EE and step counts was examined in 12 people at least 6 months after stroke (means age= 64.2 years). All patients wore the armband on their affected and unaffected arms. For step counts validation, SAM™ was worn on the unaffected ankle. Patients also wore a metabolic cart (Oxycon mobile metabolic cart from Viasys Healthcare Inc, Yorba Linda, CA) to measure oxygen uptake and determine EE in kcal/min. All participants completed 2 6MWTs with a 15 minute gap in between and their average walking speed was 0.60m/sec. The ICC values for EE measurement by SWA and the metabolic cart were 0.58 and 0.70 for the SWA worn on the affected and the unaffected arm. The SEMs for the device on the unaffected arm was smaller than that on the affected arm (0.48 and 0.68 respectively). This suggested good validity between the two systems for the device worn on the unaffected arm. The lower limit of agreement in the B&A plots suggested that SWA overestimated EE as compared to the metabolic cart. Fair reliability was obtained for step count measurement between SWA and SAM™™ (ICC≤ 0.35) with a measurement error of 132 steps and 151 steps for unaffected and affected arm respectively. SWA overestimated an average of 193 steps. There was also a tendency of step overestimation by SWA at gait speeds below 0.6m/s. In a study by Moore et al. (2010), patients wore SWA on the unaffected arm for 9 days and were given a set amount of doubly labelled water to drink daily. The mean age of the 9 subjects was 73 years and all were community dwellers at least 6 months post stroke. Spearman's correlation coefficients were used for analysis and good significant relationship was reported between the two measures for total EE (r= 0.85,

p=0.004). B&A plots also suggested good agreement between the two systems with a mean difference of 93 kcal/day. The results from this study can be considered as more acceptable as measurement was undertaken over more days however both studies included community dwelling patients with mild gait impairments. Similarly SWA has been used for PA measurement of 31 patients within 7 days after stroke onset but only with those subjects who exhibited mild to moderate gait deficits and were able to walk at least 10 meters independently (Moore et al., 2013). In order to measure PA in the present study, the measurement methods had to be used with all patients including those with limited mobility. Since it was seen from the evidence above that SWA has been used for only those patients who were able to walk, it was not judged sufficiently appropriate for the present study.

Triaxial accelerometers

Tri axial consist of 3 single accelerometers fixed at right angles to each other and can detect acceleration and movement in all 3 planes (Kochersberger et al., 1996). They can be used to record movement as activity counts which can also be converted into kcals. Based on the vertical and antero-posterior accelerations that occur simultaneously with step frequency movement patterns while walking can also be identified. The medio-lateral accelerations occurring with stride frequencies are also used to determine gait abnormalities (Butte et al., 2012).

'Tritrac'™ (Hemokinetics, Inc, Madison, USA) or RT3 accelerometer is a type of triaxial accelerometer that has been used for PA measurement. The current unit weighs 55 grams and can collect data for 21 days which can then be downloaded. The psychometric properties of Tritrac™ were tested at length in six studies in a research article by Kochersberger et al (1996). Reliability testing was undertaken initially using bench testing which consisted of a mechanical shaker before the

participants wore the devices and walked on a treadmill (Kochersberger et al., 1996). The sampling rate for activity was 10Hz and the data was recorded per second and then aggregated into one minute epochs of activity counts. The activity counts represented velocity over time and were calibrated as Kcal/unit of time. Validity was tested by comparing the devices to OBM recording and to an Actigraph™ .The participants were older adults (70 to 75 years) some of whom were residents of a nursing home and others were community residents The Test-retest reliability was examined when participants walked at 0.44m/s and 0.89m/s on the treadmill wearing the device over the right hip. The correlation coefficient was 0.97 but no testing of absolute reliability (B&A plots or SEM) was undertaken making the results less robust. On validation with Actigraph™ good correlation was obtained ((PCC= 0.77, p=0.001). As participants in a nursing home wearing Tritrac™ undertook ADLs staff observed and categorised activities in categories ('active', 'moderately active' and 'sedentary'). According to the results, Tritrac™ was able to significantly (p<0.00) differentiate between participants in the 3 categories based on the activity counts. It was also able to differentiate between eating, walking and treadmill stress test activities significantly (p<0.00).

Another feasibility study with TritracRT3™ (Stayhealthy Inc, 222 E Huntington Dr, Monovia, CA, USA) was undertaken in the community (Hale et al., 2008). The device measures mean acceleration (in m/sec^2) in each plane. The activity counts for each plane is calculated as the mean vector magnitude. This is expressed as (= $[x^2 + y^2 + z^2]^{0.5}$ and is also known as activity unit. Further information regarding how the acceleration data and the activity count displayed has not been given in the study due to lack of information from the manufacturers. The study included 48 patients with neurological conditions (Stroke, Parkinson's disease or Multiple sclerosis) as

well as healthy controls. All participants (mean age 63 years) wore the device on their backs at waist level with a belt for 7 days and a diary activity log was simultaneously completed. At the end of the week (Test1), participants completed the 7 day recall questionnaire and the RMI were completed. This protocol was repeated after a gap of 8 weeks for another 7 days (Test2). An additional questionnaire designed to ascertain user friendliness of wearing Tritrac™ was completed by the participants. Test-retest reliability was undertaken using all 7 days or 3 days each from both tests 1 and 2 for all participants. The overall reliability reported was almost perfect (ICCs 0.85 or 0.84) with %SEM (23% to 27%). However reliability for patients with stroke (n=20), was moderate to substantial (ICCs 0.54 to 0.68) with %SEM between 28% and 35% which can be considered as high. Exploration of the relationship between the mobility levels (RMI scores) with activity counts (Tritrac™) and with data from the 7 days recall questionnaire was undertaken. Regression analysis and ROC analyses curves were used and the results showed that data from the recall questionnaire accounted for 1% of variation in RMI and area under the curve was 0.67. In comparison, activity data from the device was accountable for 16% of variation in the RMI score however a value of 0.72 for area under the curve suggests that the device was more sensitive to differentiate between mobility levels than questionnaire data as the value is closer to 1.

Most patients found it acceptable to wear Tritrac™ and reported that it did not interfere with their ADL and they could easily remember to wear it. Overall 89% (42/47) participants said that the device was user friendly and 55% said they would be willing to wear it again for research purposes. However some commented that the device's position on the back was uncomfortable while sitting or driving (36%) and

25% said that they feared that the accelerometer might fall off. As opposed to the study by Kochersberger et al. (1996), the sample size calculation was undertaken appropriately for this study and the methodology was well explained. In fact it can be said that the overall robustness of this study was better than many others that have been mentioned so far (Patterson et al., 1993) . The results were also acceptable and Tritrac™ appeared to be reliable. However its reliability was low for patients after stroke and it was doubtful whether patients in the early stages of recovery would be able to wear it on their backs especially when the time spent in sitting or lying down could be more that the individuals recruited in the study by Hale et al. (2008). The ROC analysis results were acceptable but for the present study it was important to use a device which could quantify activities such as sitting, lying and walking rather than a system that could only differentiate between mobility states of patients based on RMI scores. For these reasons it can be said Tritrac™ did not seem to be the most appropriate method to use for the current study.

Other than Tritrac™, two devices that previously consisted of a bi-axial or a uniaxial accelerometers now consist of a triaxial accelerometer in their latest version(M Andrés Calabró, 2014). Actigraph GT3X™ is the latest model which is based on a triaxial accelerometer instead of a uniaxial accelerometer. For counts over 1952 per minute, it estimates energy expenditure using the following equation: EE (Kcals/min = 0.00094 x vertical counts per minute + 0.1346 x body mass (kg) – 7.37418. For counts below 1952 per minute, the work-energy   theorem formula was applied. This is EE (Kcal/min = 0.0000191 x counts/minute x body mass (kg) (Calabró et al., 2014). The other device is the SenseWear Mini Armband from (BodyMedia Inc., Pittsberg, PA) (known as Mini™) which is an improved version of the SWA. Proprietary algorithm from the manufacturers (algorithm version V.2.2.3) were used

for analysis. The algorithm calculates the EE for the data every minute and then the data is classified into an activity class that best represents the data for that minute using a Naïve Bays classifier. These activity classes are mainly walking, running, rest, resistance etc. Each class of activity has a linear regression model where the sensor values and body parameters are mapped to EE (Johannsen et al., 2010). On validation with Oxycon mobile 5.0™ metabolic analyser for classification of PA into sedentary, light and moderate, ActigraphsGTX3 showed no agreement with the criterion for PA classification (Kappa value < 0.19). In comparison, better agreement was obtained for 'mini' (Kappa value >0.69) but this study was also undertaken with healthy participants. Thus the utility of the devices needs to be assessed with individuals after stroke before it can be considered for the current study.

Two wireless triaxial accelerometers were used to devise a PA measurement tool known as **A**ccelerometry for **B**ilateral **L**ower **E**xtremities **(ABLE)** system™ from Sparkfun Electronics, Colorado, USA. (Prajapati et al., 2011). It is an objective method consisting of 2 triaxial accelerometers weighing 46 grams which are 4.4x1.9x6.3cm in size. These are worn around the ankle just above the malleoli. A personal digital assistant is worn in a pouch around the waist and the signals from the accelerometers are transmitted to it via Bluetooth at a sampling rate of 50 Hz. Customised software was used to obtain data from the accelerometers. More details regarding this process has not been provided. The data can then be transferred to a computer for analysis. ABLE system™ was used to quantify walking parameters (speed, frequency and duration) as well as gait symmetry in 16 patients an average of 37 days after stroke (mean age= 59 years). To determine the accuracy of the ABLE system™ for measuring walking bouts, it was validated with a footswitch system (Prajapati et al., 2011). The temporal foot-off and foot-contact times were

calculated from the ABLE system™ and through the footswitch system with 6 healthy participants (more details not provided by authors). The difference between the two systems was 0.005 secs for a maximum of 125 steps indicating high agreement between the methods. Patients were asked to walk across the GAITRite system™ (CIR systems, New Jersey, USA) at SSWS to obtain 20 strides. The temporal gait symmetry was calculated as the ratio between the paretic swing time and the non-paretic swing time. After 1 or 2 days of assessment with GAITRite™ the patients were asked to wear the ABLE system for 8 hours over a single day and temporal symmetry from the walking bouts was calculated. A significant difference in gait symmetry was observed (p=0.006) when measured via GAITRite™ and the ABLE system™. Patients were more symmetrical in gait when measured in the clinical setting which could be due to them being more conscious about walking in a clinical setting as opposed to walking outside in a rehabilitation unit. This can be considered as a major advantage of using systems such as the ABLE system™ instead of methods like pedometers. Type and duration of lower limb activities can be more meaningful in the exploration of functional recovery instead of only step counts. Unfortunately, based on one study alone there was insufficient evidence about the ABLE system™ to consider it as an appropriate PA measurement tool at present. Similar to the ABLE system™, another wireless method using tri-axial accelerometers was reviewed for its ability to detect walking speed in 12 community dwelling patients after stroke and 6 healthy controls (Dobkin et al., 2011). These accelerometers weigh 100 grams, are 1x2x5cm in size and have a USB port to download data and charge the device. The sampling rate was 320Hz. A software system was used to process accelerometry data and classify the activity state. A vector is derived from the frequencies, amplitudes and waveforms of accelerations

and decelerations. Machine learning algorithms were used to analyse data and these algorithms identified patterns related to walking and the velocity based on the information from the sensors. The exact algorithm has not been mentioned by the authors. All participants walked over 50 feet on a flat surface at slow, casual and fast walking speeds. Subjects also walked outside over 67 feet at their usual speed. The walking duration was noted using a stopwatch. Healthy controls also followed the 50 feet walk indoors along with ascending and descending a flight of 5 stairs. For both groups; the correlation between the time measured by stopwatch and the sensor system for walking outdoors was excellent and significant (PCC=0.98, p=0.001). The test retest reliability undertaken with 9 subjects for walking outdoors thrice was also reported as 'high' however no further details were mentioned making it difficult to accept the reliability study results. Step counts obtained via manual observation were strongly correlated to step counts obtained via the system (pcc r=0.99). The use of accelerometers with USB ports is an advantage over other systems which require battery to be changed on a regular basis (ActivPAL™, Actigraph™).However the results reported need to be further clarified . Therefore the evidence from this study on its own was not sufficient to confirm that it could be utilised as a measurement tool in the current study.

2.4.3 Step Activity Monitor™

The Step Activity Monitor (SAM™) or StepWatch™ was designed in 1991 by D.G. Smith as an alternative method of measurement by counting the number of steps taken as well the measuring the intensity and duration of PA. The earlier unit weighed 65 grams and was 1.5 cms thick with a height of 6.5cms and width of 5 cms. However the one used after that weighs 38 grams and the height and thickness has been altered to 7cms and 2 cms respectively. It is designed by Modus Health llc Washington, USA, StepWatch™(2015). The battery life is 5 to 6 years. The motion sensor is a specially developed accelerometer and the sensitivity of the sensor to movement can be adjusted. The cadence and the motion (type of gait) can be chosen from a range of options to suit the wearer's gait style. Worn on the unaffected malleolus just above the ankle, the SAM™ can be calibrated and a visual cue (green light) is displayed for the first 255 steps when the person walks to check if the calibration is correct. The researchers involved with the design were working to identify what could be measured that would help in obtaining the essence of activity. They chose to measure step counts to indicate or relate to the patients activity profile. Data can be recorded for up to 14 days. Software and hardware (docking station) are used to download data from individual SAM™ (Coleman et al., 1999, Boone and Coleman, 2006).

The psychometric properties of SAM™ have been evaluated in several studies. Reliability of the SAM™ , pedometer and manually counted step counts with a hand tally counter was undertaken for 16 patients (mean age 67years) with stroke onset at least 6 months previously (Macko et al., 2002). All Patients wore SAM™ on the non-paretic leg and performed 6MWT on a flat surface at SSWS. On a separate day they also walked at a comfortable pace and fast pace for 1 minute each. All tests were

repeated twice. An average of 46±8.9 steps were recorded for the 1 minute walk tests and 245±51.8 steps for the 6MWT. The SSWS was 0.74±0.29m/s. An ICC value of 0.97 (almost perfect reliability) was obtained on repeat measurements and an accuracy of ≥ 98% was reported for the 6MWT and the 1 minute walk test at comfortable and fast pace. The study was the first of its kind to investigate the SAM™ reliability.

Subsequently PA assessment with SAM™ was undertaken with 17 individuals wearing SAM™ for 48 hours twice with a 3 week gap in-between to determine the test retest reliability (Haeuber et al., 2004). Additionally patients wore an accelerometer based device on their belt called CALTRAC™ to measure total caloric expenditure. As with the previous study, ICC for SAM™ was almost perfect (r=0.96) but that for CALTRAC™ (Muscle Dynamics California, USA) was moderate (0.44). The activity EE measured by CALTRAC™ correlated well with SAM™ stride counts (r= 0.77). Simple regression analysis was undertaken to test the validity of CALTRAC™ with SAM™ and it was found that CALTRAC™ could account for 64% of variation in ambulatory activity quantified by SAM™. The results of both the above studies were very encouraging regarding the reliability and validity of SAM™ as compared to instruments such as the pedometer and other accelerometry based methods.

Subsequently there has been evidence where reliability and validity of SAM™ has been evaluated with a larger Sample size, outside of laboratory settings with SAM™ being worn for longer time frames. Test-retest reliability was determined with 40 participants 5 years after stroke who wore the SAM™ on the unaffected leg for 3 days continuously 4 days apart (Mudge and Stott, 2008). All ICC values were above 0.83 (almost perfect reliability) and low coefficient of variation (10.7%). There was a

trend however for the variation to increase at high step rate (>60 steps/minute) with CV as 37%. As the overall reliability of the SAM™ for comfortable walking (average speed 0.67m/s) was excellent its use for measuring ambulatory activity in community living stroke survivors could be accepted with ease.

Criterion validity of SAM™ was tested against 3-dimensional gait analysis (3 DGA) in a lab setting and against foot switches worn by participants for the outside environment with 25 patients after stroke (Mudge et al., 2007). Participants wore the SAM™ around both ankles. In the lab setting participants walked over 6 meters for 6 repetitions. In the outside environment they walked over 20 meters including ascending and descending walkways and 9 stairs. In comparison to other studies sample size were calculated and appropriate statistical tests for validation were used. Good correlation was obtained between steps recorded using SAM™ and both the foot switch recording and 3DGA (r ≥ 0.95). The 95% LOA scores showed that the SAM™ undercounted 3 steps or less as compared with 3-DGA with a percentage error of below 7%. The agreement between foot switches and SAM™ was weaker with SAM™ over counting and undercounting footsteps (between 9 and 57 steps). For outdoor walking, the SAM™ around the paretic leg reported a mean error of 4.9% (±55 steps) where the step range was 58 to 902. This could be due to the mechanism of counting steps used by the accelerometer in the SAM™ and the pressure sensor in the footswitch which may count shift of pressure from one foot to another as a step.

Similar results were found in a study in which 4 different BWS were compared with video recorded steps to assess their validity in 30 patients post stroke and 20 patients post traumatic brain injury with a mean age of 53 years (Fulk et al., 2014). Other than SAM™ and the Yamax Digiwalker™ pedometer, the Fitbit Ultra™ (Fitbit

Inc, San Francisco, California) and NIKE+ FuelBand™ were worn by patients as they undertook a 2 minute walk test at SSWS (average 0.93m/s). Almost perfect level of agreement was found between SAM™ and observation (ICC > 0.92) with the former overestimating an average of 4 steps in 2 individuals out of 50 participants. As the subjects took an average of 195±32 steps for the 2 minute walk tests, an error of 4 steps by SAM™ can be considered as extremely minimal. In all studies discussed so far, the SAM™ was found to be extremely reliable and valid for step counts for patients with chronic stroke.

Studies have also determined the use of SAM™ for measuring the construct of 'ambulatory activity' with step counts as the unit of measurement. Correlation coefficients and regression analysis have been undertaken to see the relationship of SAM™ scores with routine outcome measures (RMI, FMA, Stroke Impact Scale), time and distance walk tests (6MWT, 10MWT) as well as self-related questionnaires (Fulk et al., 2010, Mudge and Stott, 2009, Shaughnessy et al., 2005). Correlation was investigated by Mudge and Stott (2009) with routine OM (6MWT, 10MWT, age, RMI, RMA). Moderate significant correlation was found with 6MWT(r=0.67) with a regression coefficient of 0.54 indicating that 6MWT could account for 54% of variation in walking performance. Similar results were reported for the correlation between SAM™ step counts and walking measured by 6MWT by Fulk et al. (2010). Community based ambulant stroke survivors wore the SAM™ for 7 days during walking hours to capture the number of steps taken. The dependent variables were their home and community walking ability (measured by SAM™) and a self-reported questionnaire. The authors determined whether specific OMs were predictors of the walking ability. The independent variables were age, SSWS with 6MWT, balance score from Bergs Balance Scale, FMA for lower extremity motor functions and the

Stroke Impact Scale. Nineteen patients with an average of 45 months post stroke were included in the study. There were good significant correlations of SAM™ scores with 6MWT (PCC = 0.68, p=0.001). On stepwise regression the 6MWT was found to be the only significant predictor of daily mean steps and could predict 46% of variation for walking ability measured using SAM™ (p=0.01). While the analysis undertaken was robust, there can be queries regarding the use of SAM™ as the best method to indicate walking ability after stroke based on just step counts. The limitations of using steps as the unit of measurement is that other aspects of recovery of walking such as amount of support required, symmetry of gait and use of wheelchairs cannot be detected (Prajapati et al., 2011).

 Shaughnessy et al. (2005) measured step counts 2 weeks after discharge and at 3 months post discharge in 19 patients using SAM™. Ambulatory activity measurement was also undertaken using an array of OMs; SSWS, FIM and the Stroke Impact Scale. There was a significant difference reported between the number of steps taken at discharge and after 3 months (p<0.001) using the paired t-test which is the apt test to use for the repeat measures design involving the same participants. Although the study stated 'strong' correlation of SAM™ with FIM mobility scores at both time points of measurement, PCC values of 0.52 and 0.62 can be considered as moderate correlations. Overall the study results could be accepted and SAM™ was found to be sensitive to change in the step counts post stroke despite the small sample size. However the results could not be generalised as the inclusion criteria were specific to those patients with mild gait deficit, and mild cognitive and communication impairments.

Bowden et al. (2008) used SAM™ to validate SSWS based classification using daily steps for 59 patients with an average of 4 years after stroke. Participants were

classified into 3 groups based on SSWS (house hold ambulators, limited community ambulators and community ambulators) and wore the SAM™ for 5 consecutive days. The average SSWS was 0.74±0.33m/s. Step counts were found associated with home based and community based walking behaviour of patients as correlation between walking speed and step counts was moderate but significant (PCC= 0.67, p< 0.001).

From the above 4 studies, it can be said the moderate correlation has been found with 6MWT only. Since the correlation with other OMs was not sufficient, its use to detect other aspects of recovery except steps was queried. However the SAM™ could be regarded as a sensitive OM.

In this review, no study investigating the user-friendliness of wearing the SAM™ in patients after stroke using questionnaires was found unlike those undertaken for Tritrac™ (Hale et al., 2008) or for PAL2™ (Kramer et al., 2013). Only 1 study investigated the adherence of wearing SAM™ by 402 community dwelling patients 2 years post stroke (Barak et al., 2014). Patients had moderate to mild gait impairments and wore the SAM™ for 2 days. Based on the duration of wearing time adherence rates were 68% and 61% for single days 1 and 2, 53% for both days and 76% for either day. Predictive factors which affect adherence were analysed using linear regression. The independent variables ranged from age, sex, balance OMs, walking endurance to 6 MWT, mini mental state and walking speed. The results showed that better balance efficacy and better walking endurance measured as >126m by 6MWT were significant predictors of adherence.

From the studies discussed so far, it has been noted that the test-retest reliability of the SAM™ with patients at least 6 months after stroke was excellent. On validation with other known methods the overall validity was high with SAM™ over/under

estimating minimal number of steps which could be acceptable for clinical or research purposes. As an objective measure of PA the strength of the SAM™ was the ability to measure 'ambulatory activity' sensitively and it was used for the same purpose in several interventional studies. Since SAM™ is a reliable, valid and sensitive method, it has been used in observational research as the main OM to detect change in activity after stroke. Manns and Baldwin (2009) and Roos et al. (2012) utilised SAM™ to measure gait related variables of stroke patients in the chronic stage to quantify walking ability such as bouts of daily walking, percentage of activity and steps per bout. SAM™ was also used as an OM which aimed to test the effectiveness of gait rehabilitation using a body weight supported treadmill (Bowden et al., 2013, Duncan et al., 2011). The potential of SAM™ for a goal-directed rehabilitation intervention has been investigated by (Danks et al., 2014) who implemented a step activity monitoring programme' where16 patients wore the SAM™ for 4 weeks . Based on the number of steps and intensity of activity per week their goal for the next week was set. A significant increase (p=0.005) in the number of steps undertaken was found at the end of the 4 week period; however the adherence and compliance of this programme in the long term needed to be investigated further.

The above evidence strongly suggested that SAM™ was an appropriate measure of PA measurement after stroke for patients who were able to walk. However with regard to the current research aim, the need was to identify a method capable of measuring PA in the early stages of recovery; therefore feasibility of SAM™ for the current study was difficult because all the patients recruited in studies so far were in the chronic stage of stroke.

2.4.4 Other body worn sensors

Besides the common methods presented so far, evidence regarding several other systems used for PA measurement was also identified in the literature.

Intelligent Device for Energy Expenditure and Activity (IDEEA™: MiniSun, Fresno, California, USA) is a system consisting of 5 sensors relatively the size of a postage stamp that are used in combination with each other and are connected to a 200 gram micro-computer worn around a belt (Zhang et al., 2008). The signals from the 5 sensors are used in different combinations to obtain body and limb motions. The motion signals are pre-processed first and further processing takes place at the microcomputer level. The exact algorithms used for correct identification of physical activity is not available in the study. The combination of signals are coded to represent the 32 different types of activities that can be monitored using this system. Seventy-six healthy subjects (mean age 36 years) wore the sensors as follows: 1 each on the anterior thigh, 1 each on the sole of the foot under the arch and 1 at the sternum. Subjects performed two different tasks one consisted of undertaking 22 postures for 10 seconds each and the second involved running and walking on a 60 meter track at SSWS and stair climbing thrice. Thirty-two types of PAs were classified based on postures, gait, and limb movements. The device could accurately detect all PAs (percentage accuracy > 96%). Based on the percentage accuracy, the system was used in a cross sectional observational study examining PA of community dwelling individuals (Alzahrani et al., 2011). Forty two participants after stroke and 21 healthy subjects wore the sensors for 2 days across 2 weeks. The authors mention that the device reliability for detecting upright positions and other body postures were substantial for patients post stroke (ICC 0.69 and 0.80 respectively). For healthy controls the ICC values were 0.68 and 0.50 respectively

(moderate reliability). However no further research using the system has been identified in this review. Moreover the system consists of 5 sensors worn on the legs and sternum along with a pouch across the waist. This may be impractical in a rehabilitation environment as patients may need help with accurate placement of all sensors and the user burden also needs to be considered. Therefore this system was considered inappropriate for the present study.

Shoe based system

A novel but intricate shoe based system was designed consisting of pressure sensors and accelerometer (Fulk and Sazonov, 2011).The system gave information about plantar pressure from force sensitive resistors under heel and 3 metatarsals as well as heel acceleration data with a 3 dimensional accelerometer in the back of the shoe. Sample frequency of the data (pressure and accelration) was 25 Hz and sent to a portable computer. Subsequently the data was further processed and a Support Vector Machine classifier was used to classify the data into 3 postures (sitting, standing or walking). In the study, the shoe based system was worn by 8 patients 3 months post stroke onset. They performed sitting and standing in different conditions such as sitting with legs crossed, sitting with reaching forward, standing and reaching towards affected/unaffected side along with walking at comfortable and fast pace on a level surface and over a GAITrite™ mat (CIR Systems, Havertown, Pennsylvania). The accuracy of the device for postures ranged from 76% to 99%. Subsequently, another study was undertaken where an improved version of the shoe based system was used to identify postures and count steps of 12 patients with an average of 65 months after stroke (Fulk et al., 2012). Patients repeated ADL in sitting and standing such as reading, computer use, folding laundry in standing 3 times and

also walked for 2 minutes at comfortable and fast pace. They were simultaneously video recorded to count the number of steps taken. As with the previous study the average accuracy of identifying postures was 97%. The B&A plot revealed a high level of agreement between video recorded and shoe based step counts; mean difference between the methods for the affect leg and unaffected leg was 0.8 and 0.04 steps each which was negligible. The 95% LOAs were also <± 4steps. The results from both these studies were very encouraging but for long term use, patients would need to be equipped with these shoes and wear only these shoes during the day. This would be impractical for PA measurement immediately after stroke in a rehabilitation setting because it is difficult to ensure that these shoes were appropriate for all patients. Based on the inclusion criteria of these two studies it was difficult to generalise the findings to patients in the acute and sub-acute stage of stroke.

Objective methods of PA measurement that have been reviewed so far consisted of many different types of accelerometers which were worn either singly or in combination with other sensors. The main unit of measurement for most of these systems was step counts (pedometer, SAM™, ActivPAL™) while some others were designed to detect body positions and intensity of activity based on EE. With respect to the lower limb, some systems detected spatio-temporal features of gait. All of the studies discussed so far *except* 5 used objective methods to measure patient PA in the chronic stage (at least 6 months after stroke). One study each for Yamax digiwalk pedometer™ (Vanroy et al., 2014) and ActivPAL™ (Kunkel et al., 2015) used the devices for PA measurement in patients who were admitted after onset of stroke. Properties of PAL2™ (Kramer et al., 2013), Actiwatch™ and ABLE system™ (Prajapati et al., 2011) were evaluated with patients who had a stroke less than 3

months before recruitment. However, these were single studies and further evidence of research with these methods for use in early stages of recovery was not identified in the literature. Besides that most of these devices were tested with patients who had the ability to walk to begin with. As defined previously measurement of 'PA' as a construct consists of more than step counts. Therefore apart from BWS, 'observation based methods' were also evaluated in this review to gauge their effectiveness of measuring activity of patients in the early stages of recovery. This method has been discussed in detail below.

2.4.5 Commercial activity monitors

Apart from the activity monitors mentioned above, commercial activity monitors were also were reviewed. These are also known as 'Consumer based activity monitors' or 'Activity Trackers'. Due to advancing technology, the cost of accelerometers has reduced and many devices have been available on the market for commercial use apart from research grade accelerometers. Moreover commercial accelerometers can provide immediate feedback using mobile or internet based applications which can be considered as an advantage. Many companies have manufactured several different versions of the same device with variable features and variable costs. Five of these are FitBit, Samsung, Jawbone, Withings and Misfit. It has reported that FitBit company (San Francisco, CA, USA) has approximately released 9 different trackers between 2008 and 2015 while Jawbone company (San Francisco, CA, USA) has made available 6 devices between 2011 and 2015 (Evenson et al., 2015). Other consumer based devices such as Nike Fuelband, Basis B1 Band (Basis Science Inc, San Francisco, USA) , BodyMedia FIT(BodyMedia Inc, Pittsburgh USA) , Garmin Vivo fit and Motorola tracker are also available for use.

The outcomes measured usually are step counts, EE (calories), stairs climbed, distance travelled, active time and sleep (Ferguson et al., 2015) . In this literature review, 4 studies were identified where the validity of 4 to 8 of these commercial devices has been tested simultaneously against the same criterion measures. These studies have been undertaken recruiting healthy participants in either a lab based setting (Nelson et al., 2016, El-Amrawy and Nounou, 2015) or in the free living environment (Ferguson 2015).

In a study by Ferguson et al. (2015) validity of 7 consumer based monitors was tested for determination of step counts, EE, duration of sleep and duration of

moderate to vigorous PA. They found that the FitBit one, FitBit zip and Withings Pulse (Withings, Issy Les Moulineaux, France) had narrow B&A 95% limits of agreement and that all devices had an ICC>0.80 for step counts when measured against the criterion Actigraph GT3X. However measurement of EE was underestimated by all devices tested and when moderate to vigorous PA duration was measured the devices tested either overestimated or underestimated the duration. This was the only study where participants wore the devices at home for a period of 24 hours rather than being tested in the laboratory and the authors state that overall FitBit one and Withings Pulse appeared to be most valid.

Healthy participants were recruited to determine the validity of commercial activity monitors to determine EE and step count in a lab based setting by Lee et al. (2014a) and Nelson et al. (2016). In both studies, healthy participants wore the devices and undertook several different activities which were later classified into categories. Lee et al. (2014a) classified these as sedentary, walking, running and moderate to vigorous activities while Nelson et al. (2016) classified activities into sedentary, household and ambulatory. Out of a total of 8 devices tested, the mean absolute percentage error for 3 devices (BodyMedia FIT, FitBit one and Fitbit Zip) was between 9%-10% for EE when compared against the EE obtained from a metabolic cart which was the criterion. The PCC was also strong with r≥0.80.

In the study by Nelson et al. (2016), when four commercial activity monitors were tested, except for Fitbit Flex, all the others (FitBit One, Fitbit Zip and Jawbone UP24 (AliphCom dba Jawbone, San Francisco)) significantly (p<0.001) underestimated EE for the household activity category which included items such as standing, dusting, sweeping, picking up items off the floor The absoluter percentage error was between 27-34%. On the other hand these devices overestimated EE by 16-40% for the

ambulatory category activities s which included items such a walking, jogging stairs.

Similarly for validation of step counts against manual observation all 4 devices significantly underestimated steps for the household category between 35% and 74% (p=0.006) and overestimated steps for the ambulatory category.

From the above, it can be said that EE measurement has been reportedly underestimated by devices in two studies (Nelson et al., 2016, Ferguson et al., 2015). Validity of the monitors for step count measurement was also variable where Ferguson et al report ICC>0.80 and valid measurement for Fitbit Flex, One and Withings Pulse while Nelson et al. (2016) that Fitbit one and flex underestimated steps for household activities and overestimated steps for the ambulatory category. The studies above have different methodologies and have been undertaken with healthy participants making it difficult to compare the findings in detail.

Apart from Fulk et al. (2014) who looked at the accuracy of FitBit ultra and Nike Fuelband for determining step counts in subjects with stroke (see section 2.4.3) only one study has been identified where four consumer based activity trackers have been compared to manual observation for step counts with participants having suspected idiopathic normal pressure hydrocephalus(Gaglani et al., 2015). In the study, FitBit-ultra appeared to be most valid (ICC=0.72, mean diff in steps=2.74) while Nike Fuelband, Omron step counter pedometer (Hj-113 Omron Corp, Kyoto, Japan) and New Lifestyles 2000 (NEW LIFESTYLES, Inc, San Francisco, USA) did not demonstrate sufficient validity (ICC≤0.19).

The evidence above seems to indicate that FitBit devices appear to be more accurate for measuring step counts than other consumer based activity monitors. In a systematic review the reliability and validity of commercial activity monitors (for measuring steps, PA, EE and sleep) were examined by Evenson et al. (2015). In

their review, studies most commonly evaluated the validity of the two devices for step counts and EE. They state that the correlation between Fitbit trackers and criterion were ≥0.80 however if the speed varied or the location changed, the devices could over/under estimate steps. Seven studies looked at the reliability of Fitbit trackers with healthy individuals and the inter-device reliability was reported to be between 0.76 and 0.90. The validity of both types of devices, Fitbit as well as Jawbone for EE was reported as less than satisfactory. No studies looked at reliability of Jawbone activity trackers.

It can therefore be said that although FitBit one and FitBit Ultra seem to demonstrate validity for measuring step counts, their validity needs to be further tested in longitudinal studies before they could be used for activity monitoring in a rehabilitation unit. Moreover accuracy for detecting other parameters such as EE, sleep detection may also need to be determine beforehand.

2.4.6 Observation based methods

OBM mainly consist of two techniques for PA measurement for patients after stroke; **B**ehaviour **M**apping (**BM)** and video based observation. In BM, a researcher walks around a stroke unit and charts patient behaviour using a pre-decided set of categories (Newall et al., 1997, De Weerdt et al., 2000, Bernhardt et al., 2004)

OBM have been used as 'gold standard' for validation of BWS by counting number of steps or recording the time spent in positions such as lying, sitting and standing (Elsworth et al., 2009, Maddocks et al., 2010, Taraldsen et al., 2011, Fulk et al., 2014, Fulk et al., 2012).

Given below is the discussion of studies that have used BM for activity measurement followed by those which have used video based observation for measuring activity in patients after stroke. The aim of all the studies mentioned was to measure patient PA in a rehabilitation setting using BM. Keeping in mind the research question for the present literature review (what is the most appropriate PAM tool to measure early stage activity after stroke), it is important to highlight that for the current review the different types of BM tools and methodology that were used in these studies were appraised rather than discussing the implications of the results.

The term behaviour mapping originated from the field of environmental psychology and is a method which investigates the effect of environment on behaviour. With respect to a rehabilitation setting, research in the early 1970's was undertaken using the participant observation method where a patient admitted in a rehabilitation hospital was the observer with only administrators being aware of the observer's role (French et al., 1972). The foundation of BM was first identifying individuals' location in a particular environment and then methodically classifying the activities these

individuals undertook into relevant categories. The main aim of BM is to objectively determine the activity undertaken by the group of interest rather than subjective assumption (Miller, 1973). For BM a map or a blue print of the unit is obtained and observations are undertaken over certain time frames and recorded in real time.

It can be said that the observational method of BM in the 1980s was undertaken using two main techniques; one developed by Miller (1973) and the other by Kennedy et al. (1988). The main category of Activity in the research by Miller and Keith (1973) was classified into three classifications; Solitary, Social or Treatment. The difference between the first two was whether the activity was undertaken with someone present or not, while the third classification involved all those activities where the patient participated in therapy sessions provided by hospitals. The Activity was graded stepwise such that first thing clarified was if the patient was in some form of treatment. If this was ruled out, then a decision was made based on whether the person was with someone (social) or alone (solitary). Location category consisted of 'dining room', 'treatment areas' (therapy areas), 'counselling areas', patient wards and interior courtyard. Hourly observations were undertaken on 1 weekday and 1 weekend and patient activity was quantified. In the study by Keith (1980), the same categories of Activity and Location were used for BM in a stroke rehabilitation unit 1 year apart. PA of 23 patients was recorded by three separate observers. In comparison to the study by Miller and Keith Miller (1973) the BM methodology was improved in this study. Firstly, 'treatment' classification of the 'Activity' category was subdivided to include repetitive exercises and the presence of other patients (group treatment). Secondly, in addition to patients, the activity of staff members was recorded to detect the interaction with patients. Thirdly observations were undertaken every 30 minutes between 8:15 and 4:15 over 5 weekdays. And

finally, inter-observer agreement was achieved beforehand between the 3 observers although the exact method of doing this was not mentioned. This method was further developed to include a separate category for 'Interaction' consisting of 16 items (Keith and Cowell, 1987). Based on pilot work by the authors, Activity category was increased to include functional tasks such as hygiene, travel, sleeping, eating to a sum total of 23 and items under the Location category were increased to 18. Moreover inter-observer agreement was formally established using Cohen's Kappa statistics and the agreement index was 96%. The aim of the study was to compare PA of patients across 3 rehabilitation units. BM was undertaken for 2 days in each hospital at 50 minute intervals and a total of 63 patients were observed. Along with methodological developments that were observed between 1973 and 1987, an increase in the total number of patients being observed was also noted. In comparison to the sample size of study by Keith (1980) (n=24) the sample size of this study was 64 patients and the authors acknowledged that it was a burden making observation for all subjects as it was physically demanding to keep track of all. Hence they chose to observe only 5 patients at any given time.

Around the same time, another study post stroke was undertaken by Lincoln et al. (1989) on a stroke rehabilitation unit for 15 in-patients. Their BM method was the one used by Kennedy et al. (1988) to observe patient activity after spinal cord injury. Patients were observed over 3 days between 8:30am and 4:30pm and 48 observations were made in total. The items under each category of Location, Activity and Interaction were pre-defined by Kennedy et al. (1988) and thus could be considered as standardised. Moreover in contrast to Keith and Cowell (1987), the more appropriate term 'therapy' was used instead of 'treatment' to label rehabilitation session with healthcare staff. While the 'Interaction' and 'Location' categories gave

relevant information, the category of 'Activity' can be considered as vague. The main categories for Activity were A) Solitary and B) Individual interaction. Solitary consisted of items such as isolated disengagement (non-specific gaze while sitting), inactive individual task, active individual tasks, independent self-maintenance and deviant behaviour. Individual interaction consisted of individual communication, group interaction task or communication and formal meetings. Rather than the focus being on the type of activity or task such as sleeping or walking, the focus was on the 'interaction' aspect to assess whether the tasks were solitary, independent or in a group. While it is understandable that BM has been derived from psychology, as an OM for PA quantification this method needed to be more robust as the main aim of the present study was to measure PA in the early stages of recovery after stroke. While the 'context' in which activity occurred was important, the focus was more on functional tasks and mobility in a rehabilitation setting. Therefore the BM method by Kennedy et al. (1988) appeared inappropriate to use for the current study.

Lincoln et al. (1996) used a similar behaviour profile chart as Kennedy et al. (1988) to compare patient PA in a stroke rehabilitation unit with individuals admitted in a general medical ward and in a ward for elderly care. Some strengths in the data collection protocol were identified. A 'blinded' assessor having no involvement with patients in the study beforehand undertook BM and this can reduce bias. The chart used for observation included patient position items under the category of Activity. The total time frame for observation was between 6:00 am and 10:00pm which was divided into three, 8 hourly shifts. The time interval between successive observations was 10 minutes. It was reported that these intervals were randomly selected and ranged between 1 minute and 19 minutes however further reasons for doing this was

not explained. This was unclear as random intervals can have an effect on the data processing when average time spent in particular activity needs to be calculated. Both methods (Miller, 1973, Kennedy et al., 1988) were utilised in further research. A BM method which was a combination of the both methods was used by Newall et al. (1997) to measure patient PA in a rehabilitation unit including those patients with Parkinson's disease and Multiple Sclerosis. The study aimed to compare patient PA levels before and after the unit was redesigned. Two observers received training before BM was undertaken and reliability was established beforehand (further details not provided). Simultaneous coding was performed by 2 observers for 514 observations from all 3 categories of Activity, Location and Interaction. There was high level of agreement reported for 500 observations (97%) overall. On the rehabilitation unit observations were first taken hourly then the interval was changed to 30 minutes to be able get better information about patient activity. Time period was also changed to start an hour earlier at 8:00am rather than 9:00am to capture activities in the morning. The BM tool was refined from another one previously designed by Tinson (1989) where only 9 activities were used (Basic care, eating, resting, social recreation, recreation, therapy, own exercise, medical attention and travelling/waiting). These activity categories appeared much more encompassing of the different kinds of activities undertaken by patients in general rather than just therapy.

Additionally, between 1996 and 1999, 2 new BM tools were designed for measuring PA levels of patients post stroke in a hospitalised settings by Mackey et al. (1996) and Pound et al. (1999). Mackey et al. (1996) observed and recorded PA of patients in a study aimed at comparing two rehabilitation units having different building layouts and routine for providing therapy. BM was undertaken on weekdays and

weekends between 7:00 am and 7:00 pm in 10 minute intervals. The motor tasks that made up Activity were sub divided mainly as 'task practice' which included general motor tasks such as standing, walking and using the affected upper limb, 'Exercises' which included exercises of upper limb and lower limb and 'unrelated tasks' consisting of those activities which were not related to the affected limbs such as talking and using the non-affected upper limb. The Location category included therapy area, dining area, living area (patient room) and transit area (corridor/bathroom). People present could be classified as therapy staff, non-therapy staff, alone and patient/visitor. 16 subjects were observed on 3-4 weekdays and a weekend by the same observer with random 10 minute breaks. While the items under the 'people present' and the Location categories were fairly simple, the same could not be said for the tasks included in the Activity category. These seemed to focus purely on therapy based tasks and did not include many functional tasks such as dressing, personal care and leisure activities which are equally important for rehabilitation. Moreover all participants in the study had hemiplegia which may have made it simpler to mark the correct item related to affected or unaffected task practice but the mapping method could not be easily used for patients with a more complex representation of stroke. If dominant hand was the unaffected upper limb, it was likely that all tasks would be undertaken using the dominant hand. These points could affect the observations.

Another BM schedule was used in an observational study to compare the care given to patients in a stroke unit, a general medicine ward and an elderly care unit (Pound et al., 1999). The process was called 'non participant observation' and the BM checklist included the patients' position (bed, chair, other) in addition to their Activity and Location. Apart from noting who the patients were interacting with, the quality of

73

Activity and Interaction was noted down in an additional category. The quality of Activity/Interaction category included items such as maintaining eye contact with patients, opportunity given to them to be independent and giving explanations. In the study the main researcher and an independent observer recorded 96 observations simultaneously using the specified format. The observers sat 3 meters away from the patients and noted their observations independently. The inter-observer reliability was undertaken using Kappa statistics. The authors report that most items on the map had the Kappa value between 0.5 and 1.00 and 12 out of 19 items had a Kappa value of > 0.75. For 2 items ('Was patient given feedback?' and 'Was the patient given a chance to be independent?') the reliability was with $K \leq 0.4$ which raised some doubts regarding the Interaction recorded using this tool. Over all the results could be accepted as a good level of agreement was obtained for most categories. On the whole, the BM schedule used to meet the objective of the project seemed appropriate however, to quantify PA, a more robust tool with more emphasis on activity categories was required.

While both studies used an observer based method for the research, the recording tool and the protocol was different for both. Mackey et al (1996), focused on the motor activities undertaken by patients as opposed to Pound et al (1999) who focused on functional activities as well. Moreover the recording of Interaction category was simpler in the first study. The study by Pound et al. (1999) was the only study identified where emphasis was given to the *quality* of Interaction and Activity. Observations were undertaken in 10 minute intervals in the former study (Mackey et al., 1996) while in the latter they were undertaken in 3 successive 5 minute intervals every hour over 8 hours.

Esmonde et al. (1997) quantified motor tasks of in-patients in a stroke rehabilitation unit outside of therapy hours based on the approach by Mackey et al (1996). Slight modification to the original recording tool was made to include the posture of the patient if found inactive. Also, an initial pilot study was undertaken to determine the inter rater agreement which was found to be high (K>0.80). Observations were undertaken every 10 minutes between 9:00am and 5:00pm. Only a single observer undertook all observations for a total of 9 weekdays. Although four random breaks were provided each day to reduce fatigue, it still appeared to be a physically demanding approach to use if undertaken continuously every day.

The number of studies undertaking PA measurement using BM was found to steadily increase from the year 2000 onwards and the methods used in these are appraised below. In an acute rehabilitation unit, activity levels of 5 patients post stroke were compared to activity of 7 patients without stroke. Observations were undertaken over 8 hours on a weekday and on a weekend day. A thirty minute time interval was used and the recording form was specifically developed by the researchers (Bear-Lehman et al., 2001) . In comparison to the studies mentioned so far the BM checklist was more comprehensive. Thirty minute time interval between observations was questionable as patients may change their activities frequently within 30 minutes; therefore observations for more days and shorter time intervals can be suggested. Further information about inter-rater agreement could have strengthened the reliability of the observation technique in-spite of the fact that the tool itself seemed well designed and easy to use.

Later, De Weerdt and colleagues (2000) built on the BM checklist designed by Miller (1973) and used the refined version to compare use of time by patients post stroke in two rehabilitation units, one in Belgium and the other in Switzerland. Prior to the

actual research, the data collection protocol was standardised between the researchers for the two stroke unit. Inter-observer agreement was determined for observational data collected over 8 hours in 10 minute intervals and Cohen's Kappa was used for analysis. The agreement for all 3 categories of Activity, Location and Interaction was reported as K ≥ 0.95; which in comparison to other studies has been the highest level of agreement obtained (Pound et al., 1999, Esmonde et al., 1997). This could also be due to the systematic layout of the BM tool that was used in the research. The category of Activity consisted of 16 items and was sub divided into only 2 sub categories; therapeutic and non-therapeutic activities. The Location category and the Interaction category included 8 and 6 items respectively. This was the first study where medical care and nursing care were included as items in the therapeutic activity sub category. Another important point to note is the same BM tool was used for data collection across stroke units in two different countries highlighting the generalisability of the tool. This is an important psychometric property for effective use of any outcome measure. The tool designed by De Weerdt et al. (2000) was used for research purposes by a network known as **CERISE** (**C**ollaborative **E**valuation of **R**ehabilitation **I**n **S**troke across **E**urope) (De Wit et al., 2006). Comparison of the use of time by patients in stroke units situated in 4 European countries was determined by De Wit et al. (2005) and BM was undertaken over 5 random weekdays. Three five hour sessions were used to observe patient activity between 7:00am and 10:00pm. In addition to training the observers/researchers in the use of the BM tool, a manual was provided to all researchers in the 4 centres to ensure standardisation. The lead researcher made 4 visits to each centre to further ensure that the recording criteria were the same across all centres. Overall it can be said that the BM tool and the methodology

undertaken in this study was the most appropriate OBM so far. This method was used by Huijben-Schoenmakers et al. (2009) in their study measuring PA of stroke patients in a nursing home rehabilitation unit for 17 days in an 8 hour period.

A robust BM approach was also adopted by (Bernhardt et al., 2004) when exploring PA of patients in 5 stroke units across Melbourne. Observations were conducted on 1 day over 8 hours every 10 minutes. The Location and Interaction categories consisted of 5 and 11 items respectively and were similar to those included in the checklist devised by Bear-Lehman et al. (2001). The 11 items under the Activity category were classified into 5 categories depending on the extent of physical work required where the score of 1 represented no activity, 2 represented non therapeutic activity, 3 and 4 were mild and moderate therapeutic activities each and 5 was high therapeutic activity. The study was the first of its kind to categorise patient activity based on the amount to physical work required however ADL such as dressing and hygiene were not included in the Activity category. Along with weighted Kappa statistical testing to ascertain intra-observer reliability, a modified McNemar's test was also undertaken to test for systematic bias between the two observers. The weighted Kappa values for all categories were > 0.67 and no systematic bias was detected (p=>0.50). The extent of agreement was less than that reported by De Wit et al. (2005); however, a weighted Kappa test has not been used in their study and the BM tool used was also different to the one by Bernhardt et al. (2004) therefore direct comparison between the two studies was appropriate. In 2008, the BM technique was used to compare stroke patients' activities in a unit in Australia with one in Norway (Bernhardt et al., 2008) .

Several recent studies were found during the present literature search where BM was undertaken based mostly on methods used by Bernhardt et al. (2004) and De

Weerdt et al. (2000). In Sweden, an OBM was undertaken to establish the current

PA levels in 4 stroke rehabilitation units on a single weekday (Skarin et al., 2013). As

more evidence has been found regarding the issue of low activity of patients in

rehabilitation stay, BM has been undertaken more and more. In some cases, more

categories apart from Activity, Location and Interaction have been added while in

other cases the researchers have modified the pre-existing categories. Two

additional categories of Position (sitting, lying, roll over) and of Arm use (affected,

unaffected, none) were added to quantify PA of 11 patients in a stroke unit (King et

al., 2011). The items under the Activity category additionally included tasks such as

'dysarthria training'. While the BM tool is quite comprehensive as opposed to others,

during the process of data analysis, the individual items were grouped together. As

collating of items was also observed in the results presented by previous studies, it

appeared as though addition of more items was not beneficial. It can also lead to

more confusion during observation. Thirteen observers who were recruited for the

study undertook a one hour training session. For BM, the lead author and an

observer recorded the observations. The inter-observer agreement was analysed

using Kappa statistics and for 41 out of the 42 categories the Kappa values ranged

from K= 0.6 to 1(p=0.01). For the category of 'expressive communication' the

agreement was low (K= 0.40). An additional category of posture was included in the

behaviour map (Gustafsson and McKenna, 2010) and data was analysed separately

for each item. However it was unclear why positions such as sitting, standing and

lying down could not be included under the Activity category as seen in previous

studies.

Conversely, a good example of the BM tool modification was observed where the

Activity category was sub classified into physical, cognitive and social activities

respectively (Janssen et al., 2014a). These sub classifications were very relevant for answering the research questions posed by the authors and the definition of each of them was clarified to ensure standardisation. For the current study, the Activity classification was considered appropriate however accurate identification of cognitive activities (puzzles, reading) based on subjective observations may need to be assessed for reliability before use. Although there was no reference manual, the methods section of the article was found to be clear and concise making it easily repeatable in the future.

Behaviour mapping in interventional studies

BM has been utilised as an OM in interventional studies aimed at improving patient PA post stroke. Several studies evaluated the effectiveness of additional group therapy where the time period between the pre intervention and post intervention BM ranged from 6 months to 2 years (Thompson, 2009, Gustafsson and McKenna, 2010, van de Port et al., 2012). A non- randomised control study investigated the effect of environmental enrichment on patients' social, cognitive and PA where a modified BM tool was used for activity monitoring of 14 control and 15 experimental subjects after stroke. As with the other recent studies, the recording charts used were either the one designed by Bernhardt et al. (2004) or by De Weerdt et al. (2000).

Observational recording during therapy sessions

Evidence regarding use of observational methods to specifically determine the content of Physiotherapy and Occupational therapy sessions ; in-patient as well as out-patient settings was also noted in the literature search (Ada et al., 1999, Lang et al., 2007, Lang et al., 2009). These studies aimed to explore the quantity and quality of activities that patients performed during therapy sessions. Additionally

effectiveness of two different approaches for Physiotherapy rehabilitation (Bobath and Movement science based methods) was investigated by direct observation of therapy sessions where PA, conversation and behaviour were recorded in 12 sessions and analysed (van Vliet et al., 2001). All 4 studies used direct non participatory observation methods which can be considered as an extension of the BM approach used for observing patient behaviour over days .However for the present study PA measurement needed to be undertaken over the entire day instead of only therapy sessions, therefore these methods were not reviewed further.

Behaviour mapping in the home setting

Only one study measured PA using observational methods in a community setting (Alzahrani et al., 2011). Termed as 'behaviour streaming, observations were undertaken in 16 patients' own homes either in the morning or afternoon for 5 or 6 hours on a single weekday. The aim was to investigate the relationship between the amount of walking and community based activities undertaken by patients post stroke. The subjects were in their chronic stage of stroke (1- 5 years post stroke). As opposed to recording activities every 10 minutes, change in activity was recorded along with the time. The CERISE framework was followed although the components under the 'Activity' categories were modified to suit the community setting such as including the category of domestic extrinsic activities (food preparation, gardening) and the category of leisure activities involving other people (shopping, bowling). Methodologically, the study was considered sound with however its feasibility as a BM method in the home environment could be questioned. While ethical approval and consent was obtained for the mentioned study, this approach was deemed as intrusive as it would mean observing patients in their homes on multiple occasions.

Video based observations

Limited evidence of indirect observation and quantification of PA post stroke was found in the literature. The method of video recording patient activity and then scoring the Activity via observing the video clip was used only during Physiotherapy and Occupational therapy sessions. The aims of these studies ranged from comparison of Occupational therapy and Physiotherapy sessions across different European centres (De Wit et al., 2006) to observing the intensity and duration of standing and walking activities during these sessions (Kuys et al., 2006). As many as 79 video recording of individual and circuit training sessions were retrospectively observed to compare the PA levels of patients (Elson, 2009, English et al., 2014, Kaur et al., 2013). Although was provided to observers and high inter-rater reliability ICC values> 0.90 was reported by most studies, this method could not be extended to cover the entire working day due to issues such as patient privacy and resources that would be required to first video record patients over 8 hours and then analyse the activity types from the video clips.

2.5 Summary of literature review

The main objective of this review was to identify the appropriate methods to measure patient PA in the early stages of recovery after stroke primarily in a rehabilitation setting. After a comprehensive review of over 10 relevant subjective and objective systems, there was no single method identified that could meet all the requirements for PA for the present study. The reasons for this were insufficient evidence (limited number of published or robust studies), practical issues (placement on body, dimension, and battery) or lack of generalisability of evidence for patients in a rehabilitation unit. Apart from these, use of different units of measurements (step counts, activity counts, intensity of activity, and detection of posture) and different algorithms used for data analysis from accelerometer outputs were reasons that appeared to support the finding above. The brief characteristics of PA methods are given in Table 2.4. The brief summary of results from the main studies reviewed in this chapter are given in Table 2.5

Table 2. 4 Summary of the characteristics of the main methods of PA measurement evaluated in the literature review

Subjective methods	Pedometers	ActivPAL™	Actigraph™	Actical®	Biaxial or Triaxial systems	SAM™	OBM
-Limited evidence for reliability. -Patients with speech and language impairments excluded from studies. -Patients may underestimate self-reported sedentary behaviour.	-Step counts can be read in real time. -Easy / no calibration required. -Used mostly in community setting. -Consistently underestimated steps at low speed.	-Smaller and lighter than SAM™ and no docking station required. -Apart from step count, posture detected. -Direct contact with skin may not be feasible. -More accurate for step detection but did show a tendency to underestimate step counts at low speeds. -Inpatient PA measurement undertaken but for less than 24 hours at a time	-Can be worn on wrist, hip, back. -Able to detect sleep time. -EE estimation is possible. -Most studies undertaken with young healthy participants. -Classification of postures possible. -Activity count was the unit of measurement	-EE can be estimated. Same constraint as pedometer and Actigraph™ which was reduced accuracy at low speeds.	-Several systems used with limited number of studies assessing reliability and validity of each device.	-Evidence of use in patients after stroke was large and robust compared to other devices. -Worn on the ankle rather than other body areas. -Reliable at low speeds. -Easy to calibrate. Standardisation of step counts was possible. -Used for PA measurement with patients in the chronic stage of recovery who resided in the community -Some inaccuracy	-Most used in rehabilitation units. -No need for calibration. -Can be modified for use in different settings. -Contextual information regarding Location and other people possible. -Observation may lead to performance bias. -Different methods and tools made standardisation difficult. -Inclusion criteria was broad as opposed to body worn sensors which required patients to be able to walk.

						reported when gait was affected.	-Extensively used as validation criteria for wearable systems

To begin with, subjective measurement systems were relatively inexpensive and practical to use however the main drawbacks for their use after stroke were the reliance on the person's memory and compliance. Poor memory and other cognitive impairments after stroke which could lead to missing or unreliable data prohibited their use for measuring PA especially in the early stages of recovery after stroke onset (Tatemichi et al., 1994, Reiser and Schlenk, 2009). Apart from that, measuring PA longitudinally over months either in a hospital or at home could have an adverse effect on patients' compliance with maintaining a diary (Stone et al., 2003). Although they can be used in the later stages of recovery discrepancy between self-reported PA and that measured via objective methods was known to occur because of over estimation or increased perceived PA exertion by patients (Patterson et al., 1993, Sirard et al., 2000). This could further reduce the reliability of the present study's findings (Resnick et al., 2008). It was also observed that when activity recall diaries or questionnaires were used for PA studies, patients with aphasia were excluded (Hartman-Maeir et al., 2007, Baert et al., 2012). And finally it was observed that subjective measures were utilised in combination with other objective methods of PA measurement such as OMs and Actigraphs™. From the above it can be said that subjective methods would be far from appropriate to utilise for PA measurement in the early stages of recovery after stroke in the current study. In comparison to diaries and questionnaires, objective methods were used more regularly and more reliably to quantify PA post stroke at different stages of recovery (acute stage, rehabilitation stage and post discharge) as well as in both settings (hospital and community). This was mainly because issues such as poor recall or cognitive limitations were ruled out.

Objective PA measurement systems can be broadly divided into body worn sensors and observation based methods (Reiser and Schlenk, 2009, Fini et al., 2014). 'Body Worn Sensors' are also known as 'Wearable systems' or 'Wearable monitors' (Bonato, 2010). In the field of stroke rehabilitation, pedometers, ActivPAL™ and Step Activity Monitor™ were most commonly used. The simplest and the earliest form of a BWS is a step counter or a pedometer. Containing a simple motion sensor, pedometers can be worn around the ankle or at hip level with a belt and were used to count the number of steps taken by a person thereby quantifying PA (Bussmann et al., 2009, Butte et al., 2012). One major drawback reported with pedometers was the poor validity due to under estimation of steps at slow speeds (Manns et al., 2007, Vanroy et al., 2014). Several studies reported that at speeds below 0.60 m/s the percentage of error in step counting by pedometers was as high as 40% (Melanson et al., 2004) (Schneider et al., 2004, Bravata et al., 2007). In comparison to a pedometer ActivPAL™, an accelerometer based BWS was used to measure the number of steps as well as the amount of time spent in positions of sitting/lying, standing and walking (Godfrey et al., 2007, Kunkel et al., 2015). Studies that assessed its feasibility reported minimal inaccuracy with step counts at slow speeds (Ryan et al., 2006, Grant et al., 2008). It was also able to accurately detect body positions (Taraldsen et al., 2011). However more evidence was needed for its use with patients for long term monitoring and since it needs to be worn around the thigh its feasibility for use in a rehabilitation setting was further limited.

The use of the SAM™ was an important development in the ability to quantify PA after stroke. Along with obtaining the step count, PA levels could be classified as low, moderate or high depending on the number of steps taken per minute (Coleman et al., 1999, Boone and Coleman, 2006) . As opposed to pedometers and

ActivPAL™, SAM™ could be considered as highly reliable and valid PA measurement system for individuals post stroke as well as other neurological populations (Mudge and Stott, 2008, Mudge and Stott, 2009, Fulk et al., 2014, Busse et al., 2009). While both pedometers and SAM™ were more feasible than subjective methods, certain common features of both instruments restricted their utility for quantifying Activity in the early stages after stroke onset. Firstly, they were not sensitive in measuring the early stages of gait recovery when the swing phase of the gait cycle is not easily distinguishable. This in turn could lead to underestimation of step counts. Secondly other aspects of 'mobility' such as transport using wheelchairs or mobility equipment which are also important indicators of recovery in the early stages could not be directly detected with pedometers or SAM™. Thirdly most studies that evaluated their psychometric properties or used them as OMs did so with participants who were able to walk at the time of recruitment and had a stroke at least 6 months before participation in the study. All these factors made their use for the purpose of early stage PA assessment as questionable. Several other accelerometry based systems were also reviewed for this study. Though some of them such as the ABLE system™ (Prajapati et al., 2011) or the shoe based system (Fulk and Sazonov, 2011) appeared as promising, better more robust studies investigating their feasibility in patients who were in the early stages of recovery were warranted before these methods could be considered for the current project. A point to note is that with most BWS methods, quantification of PA was been undertaken on the basis of number of steps, detection of postures and energy expenditure. Detection of postures appeared to be a better method for PA detection in the early stages of recovery after stroke because increased time spent sitting and upright are important indicators or milestones for functional recovery after stroke.

Commercial activity monitors were also reviewed for the present study alongside research based activity monitors mentioned above. These devices are easier to use however as with other BWS, on undertaking a literature search, limited number of studies were found evaluating the psychometric properties of these devices. Moreover only one study was identified where the validity of one such activity monitor was determined with patients after stroke (Fulk et al., 2014).

In comparison, PA quantification using OBM seemed much more appropriate for use in the early stages of recovery after stroke (Newall et al., 1997, De Weerdt et al., 2000, Bernhardt et al., 2004). The categories included for observing the type of activity patient is engaged in, the patients' location and their interaction with other people. Observations were recorded at certain intervals throughout the day and the intervals range from 1 observation every 30 minutes to 1 observation every 10 minutes (Keith and Cowell, 1987, De Wit et al., 2005). The percentage of time spent in each activity was then recorded. This method was extensively made use of for PA measurement of patients in stroke units; which are considered as specialist in-patient units where patients after stroke should receive their rehabilitation. As recommended in the guidelines for rehabilitation post stroke specialist professionals involved in the multidisciplinary team assess and treat patients for variety of impairments and disabilities (NICE-clinical-guideline, 2013a, NICE-clinical-guideline, 2013b)). With OBM, it is also possible to obtain quantifiable information about the duration and frequency of interaction between in-patients and members of the multi-disciplinary team which could lead to the desired, efficient patient centred, planning and implementation of rehabilitation therapy. Moreover studies indicate that patients undertake more walking and standing in the presence of staff and appear to engage in very little self-directed activity outside of therapy time (Skarin et al., 2013,

Bernhardt et al., 2004).Thus ability to record Location and Interaction could be considered as important advantages for the current study.

Other advantages also made it preferable to use over BWS for activity measurement. Long term monitoring using BWS could be restricted due to the battery life of devices, calibration before use and the number of days over which data would be recorded. Besides that some of the devices may be bulky or heavy to wear over long periods of time and these issues did not limit the use of behaviour mapping.

However a number of observers would be needed to undertake BM if data over many days was required as data collection could be very demanding if undertaken by 1 person alone. Moreover this method could be considered as obtrusive as the data collector would need to be present throughout. Therefore OBM was difficult to use for continuous activity monitoring without some obstruction to the day to day running of the rehabilitation unit. Table 2.3 summarises all this information in brief.

Table 2. 5 summary of articles reviewed for the study

Article	Worn where	Participants	Study Design and methods	Results
Manns et al. (2007) **Yamax Digiwalker**	2 pedometers; anterior waistband in the midline of each thigh	N= 45 (Stroke n=14) + acquired brain injury, PD,MS, congenital disability) one year post condition	Pedometer accuracy and reliability of left and right pedometers Walking indoors at ssws for 100 meters Criterion: hand held tally counter	Reliability of error scores between both pedometers =0.87. Pedometer underestimated the number of steps by an average of 11% Gait speed accounted for 41% of variance in error score and step length variability accounted for 8% variance. Step length variability and gait speed were significant predictors of pedometer error scores
Elsworth et al. (2009) Yamax DigiwalkerTM model SW-200	Right side midway between iliac crest and umbilicus, in midline with the thigh	N=43 (6 months post stroke n=20) + Multiple Sclerosis ,muscular dystrophy, spinal cord injury ,traumatic brain injury	To determine the accuracy of pedometer at ssws and for healthy individuals at slow speed. Walk indoors for 16 meters at ssws for 2 minutes. Criterion: hand held tally counter.	Significant difference between pedometer and manual step count p=0.003 and especially for stroke p=0.02. ICC= 0.58 for stroke and overall ICC= 0.66. percentage variability for group was 30% and for stroke was 29% Pedometer significantly undercounted steps
Vanroy et al. (2014) DigiwalkerTM 200	1 on non-paretic hip and 1 on the antero-lateral side of unaffected knee	N=30 (at least 3 months post stroke n=15) and matched controls	To determine the reliability and validity of pedometer. test-retest reliability with 2 repeat measurements Criterion: hand held tally counter	Stroke group: Knee pedometer correlation with criterion: for treadmill walking at 0.41m/sec r=0.69,walking on flat surface at ssws and brisk speed r>0.95 Hip pedometer correlation with criterion: treadmill walking at 0.83m/sec r=0.90, for all other activities r≤ 0.46. For slow walking the pedometer OVER estimated steps

				For brisk walking the pedometer UNDER estimated steps. Test retest reliability for all treadmill walking ICC≥0.88 for hip and knee
Carroll et al. (2012) OMRON HJ-113-E™)	1 around neck, 1 above left and right hip respectively	N= 50 from rehab centre prior to discharge	To determine the feasibility of wearing the pedometer and the level of agreement between pedometer and video recorded step count. Relationship between walking speed and step counts was analysed Short walk for 20 secs at ssws and one 6 minute walk test as fast as they can.	For the short walk at speeds > 0.50m/s, the average steps recorded via video=31.The 95% LOA from B& A plots (video minus pedometer) = -9.14 to +24. For the 6MWT at speeds > 0.50m/s, the average steps via video=398. The 95% LOA =-29.4 to +94.2.pedometer generally undercounted steps. For walking speed ≤0.50m/s, the difference between pedometer and video recording steps count was more than that for speed > 0.50m/s. For speed< 0.50 m/s the pedometers did not detect any steps 92% said pedometers were easy or very easy to apply.
Macko et al. (2002) Elexis trainer model FM 180 and SAM	Pedometer-Non paretic hip via belt at midline of the thigh SAM-non paretic ankle above malleolus	N=16 Average 68 months after stroke	To determine the accuracy and reliability Pedometer and SAM Two 6-min walk test on separate days at ssws and 2 sets of 1-minute walk test at ssws and fast speed on separate days. Criterion: hand held tally counter	Pedometer accuracy ≥ 85% for all tests and at both speeds Pedometer test-retest reliability ICC= 0.64. SAM accuracy ≥ 97% for all tests and at both speeds SAM test-retest reliability ICC= 0.97.
Sullivan et al. (2014) 330 step pedometer	Non paretic hip with a belt or waist band.	N= 11 at least 6 months after stroke	Single group pre-test-post-test design with a 3 month follow-up. To assess PA with pedometer	Correlation (r) between increase in steps and: SIS= 0.82; BAC= 0.60; Prior to study, concurrent validity with visual step count resulted in score of 0.60 and test retest reliability was 0.99 with n=7.

			Correlation with 6MinWT,10MWT, activity specific balance confidence scale and SIS A user satisfaction survey to judge satisfaction with pedometer use Participants wore pedometers during waking hours for 6 weeks.	8 out 10 subjects said they would use the pedometer again and that it was easy/very easy to use.
Robinson et al. (2011) twin step pedometer	On waist band or on top of sock	N= 50 at least 6 months after stroke	To determine relationship between step count and subjective measures (Activity LOG, Mobility scale) and with objective measures (average steps per day ,total number of walking related activity) Wear pedometer for 7 days and note down daily step count.	No statistically significant association between pedometer data and subjective measures.
Taraldsen et al. (2011) ActivPAL Professional single-axis accelerometer	1 each on right and left mid-thigh and 1 on chest at mid sternum	N=46 (acute stroke n=14) + 3 months post hip fracture at home=8, older inpatients=14, healthy= 10	Cross sectional study To evaluate the ability of ActivPAL to recognise posture (sitting, standing, walking, lying down), step counting, and transitions (sit to stand), also evaluate if step counts were dependent on gait speed. Participants performed test protocol of 23 tasks and 5 meter walking tests at slow, preferred and fast speeds.	100% accuracy of ActivPAL for classifying sedentary and standing position and detecting transitions. Walking at speeds <0.47 m/s absolute percentage error= 40.31% and for fast speed, the absolute percentage error= 19.32%. Sensor underestimated step counts at slow speeds.

			Criterion: video observation and manual step count	
Harris (2006) ActivPAL Professional single-axis accelerometer	Thigh	N= 6 stroke inpatients	sit to stand performed by patients in training sessions Criterion= observation count of sit to stand	mean difference between active pal and observation = 2.3 counts(SD=5.1) CI=-7.7 to +12.2
Sun 2013 Actigraph Mini-Motion logger	Affected arm	N= 81PD and N= 61 hospitalised patients with Anterior Cerebral Infarction having upper limb motor function disorder	To evaluate if a specific objective analytical scale based on PA of patients can represent disease severity .Correlation with FIM and FMA was undertaken.	There was linear correlation between improvement rates from FIM and FMA with DFA values (r=0.689 and 0.716) respectively. the DFA value may be an objective analysis in assessing upper limb motor dysfunction
Gebruers et al. (2008) Actigraph/activity count	1 on each wrist	N=43 Less than 7 days after Ischaemic stroke with UL involvement	To investigate the validity of actigraphy to objectively measure motor deficits in acute stroke. Also to investigate the sensitivity, specificity and diagnostic accuracy to score motor activity. Worn for 48 hours.	The spearman's correlation of arm activity ratio to NIHSS r=-0.59 and between impaired arm activity was=-0.75 (p<0.001). With FMA the arm activity ratio r=0.54 and impaired arm activity was=0. 69 p<0.001. For the ratio variable, the negative predictive value=100% and positive predictive value= 91%
Uswatte et al. (2000) Actigraph CSA model (7164)/activity counts	1 on each wrist, 1 on non-affected or right ankle, 1 across chest	N= 21 (3.7 yrs post stroke n=9) and 12 healthy subjects	To determine the accuracy of transformed accelerometry recording for measuring upper limb and walking activity Criterion: Two observers coded the activities from video recordings	Correlation between observation coded activities for duration of arm, torso and ambulatory movements were 093,0.90 and 0.99 respectively
Kramer et al. (2013) PAL2	Lateral side of unaffected leg attached with 2 straps above and below the knee.	N= 21 ≤14 days post CVA	To determine agreement between behaviour mapping and time spent lying, sitting and upright. To	Comparison PAL2 and OBM: For sitting ICC=0.68 (0.36-0.86), lying ICC=0.74(0.46-0.89) and upright ICC =0.72 (0.43-0.88). 8 subjects rated their experience of wearing PAL 2 and 5 strongly agreed that it was

	And two tilt switches, one on upper leg and one on lower leg		determine acceptability of PAL2 Criterion: OBM every 10 minutes	comfortable. 3 said that the straps were tight and uncomfortable. The authors state there was proportional bias as time spent upright increased the difference between the two methods increased.
Rand et al. (2009) Actical (Mini-Mitter Co activity counts (which represents intensity of activity) and Energy Expenditure)	1 each over the anterior superior iliac spine with a belt	N= 40 average 2.9 years post stroke	To determine reliability of accelerometers, determine reliability between devices worn on each hip, determine relationship of activity recorded during 6 min walk test with activity in community. 3 days of activity recorded. Subjects did the 6 minute walk test as fast as they could.	All ICCs for activity counts and EE (Paretic and non-paretic hip) ≥ 0.94. SEMs for activity counts = 32% and for EE = 19%. ICCs for reliability between devices on paretic and non-paretic hip ≥ 0.96 with SEM = 17% Spearman's correlation coefficient between distance walked for 6MWT and activity counts for paretic hip, r=0.89 (p<0.001) and non-paretic hip r=0.98 (p<0.001. Spearman's correlation coefficient for distance walked and activity counts at home- paretic hip r=0.67(p<0.001) non paretic hip r=0.73, (p<0.001.
Janssen et al. (2008) 4 uniaxial accelerometers used in combination (ADXL 202)	2 attached to the sternum; upper and lower part. 1 on lateral side of each thigh halfway between the greater trochanter and lateral knee joint. For the opto-electronic device, reflective markers on the proximal and distal part of an aluminium strap over sternum and 2 reflective markers on proximal and distal of	N=12; average 2 years 9 months after stroke n= 6 healthy = 6	To determine validity of device to count sit to stand (STS) movements at comfortable, slow and fast speed and at exaggerated trunk flexion. Criterion: opto electronic device	Overall co-relation between the two methods was r=0.98. In patients with stroke, there was significant difference between methods STS at slow speed (p=0.003) and with exaggerated flexion (p=0.004). Accelerometry system showed fixed bias of 0.07sec in healthy subjects and 0.32 sec in stroke subjects

	an aluminium strip on the lateral leg.			
Manns and Haennel (2012) SenseWEAR Pro ArmBand (SWA). Step counts and EE.	1 worn posteriorly on each arm over triceps. SAM on lateral malleolus of non-paretic leg. Facemask for the metabolic cart.	N= 12; average 6 years after stroke	To determine validity of SWA for EE and steps during walking Validity Criterion: Oxycon Mobile metebolic cart and SAM Participants undertook a 90 minute lab session and two 6- min walk test.	For EE, ICC (Hemiplegic arm) =0.58; SEM= 0.68. ICC (non-hemi arm) =0.70, SEM=0.48 where average EE from metabolic cart = 4.4 kcal/min. For step counts, ICC (hemiplegic arm) =0.22;SEM=151.5 and ICC (non-hemi arm) ICC=0.35, SEM=132.34 where average SAM counted steps=510.5.SWA consistently underestimated steps
Moore et al. (2012) Bi axial accelerometer Senewear Pro3 Bodymedia Inc. EE	On the back of the non-affected UL, mid-way between the shoulder and elbow	N=9; >6 months after stroke	To determine validity of device for EE Participants wore SWA for 10 days. Validity Criterion: Doubly labelled water (DLW)	Spearman's Correlation between SWA and DLW r= 0.85 and the mean diff between two methods= 94kcal/day
Hale et al. (2008) Tri axial accelerometer Tritrac. Mean vector magnitude was converted to activity counts	On the back at the waist level with a belt	N= 47. (At least 6 months post stroke n=20) PD=7, MS=11 Healthy but sedentary controls=9.	Repeated measures design to determine the reliability, validity and utility of device to measure PA. A utility questionnaire for user feedback. Participants wore the device for 7 days RMI at the end. Repeat protocol after 8 weeks. Validity criterion 7 day-recall questionnaire and activity diary	For test retest reliability (all subjects) ICC=0.85 (CI 0.74-0.91); SEM%= 23%. For stroke only ICC=0.68(0.36-0.86); SEM%=28%. Activity data from device accounted for 16% variation in RMI score. 85% subjects said that device was user friendly and 55% said they would wear it again for research.
Prajapati et al. (2011) ABLE	both ankles proximal to the lateral malleoli and a PDA in a	N=16 inpatients with mean 37 days after stroke	To compare gait symmetry using GAITrite in Lab with gait symmetry captured with device during the day. To	Significant difference in gait symmetry (p=0.006) when measured in lab using Gaitrite and when measured routinely in the stroke unit using device

	pouch around the waist		quantify total walking and duration of individual bouts of walking. Patients wore the device for one day.	
Dobkin et al. (2011) Triaxial accelerometer based system walking speed and step count	On ankle over the bony tibia	N=18 (Average 27 months post stroke =12) and 6 healthy controls.	To determine the reliability of device and validity of machine learning algorithms used for analysing sensor data. /walking indoors for 50feet walking out of clinic for about 300ft at SSWS and timed 67 feet walk test outside, wearing the monitor at home for 24 hours Validity criterion: stopwatch and manual step counts.	Pearson's correlation coefficient between stopwatch measured speed and via algorithms for walking outside r= 0.98; p=0.001. Pearson's correlation coefficient between manual step count and algorithm derived step counts r= 0.99
Alzahrani et al. (2011) IDEEA time spent on feet and activity counts	5 sets of sensors attached to front of chest, front of each thigh, underneath each foot	N=53 (average 2.8 yrs since stroke n=42) healthy elderly controls n=21	To determine between day reliability device worn for one day and then another day a week later	For patients post stroke: time on feet ICC= 0.69 and activity count ICC=0.80. For healthy controls: time on feet ICC= 0.68 and activity counts ICC =0.50.
Fulk and Sazonov (2011) Shoe based system/pressure and acceleration data	1 tri-axial accelerometer at the back of shoe and sensors in the foot and heel area of shoe	N=8;average 51 months post stroke	To determine accuracy of system to identify sitting, standing and walking posture. Subjects wore the shoes and undertook 4 positions each in sitting and standing. Walking at ssws and fastest safe pace on gaitrite mat.	99.91% to 100% accuracy for identifying correctly sitting, standing and walking postures using individual models. The accuracy ranged from 76% to 100% for group model developed from data belonging to all subjects.
Fulk et al. (2012) Shoe based system/pressure	1 tri-axial accelerometer at the back of shoe and sensors in the foot	N=12; average 65 months post stroke	To determine accuracy of the improved version of system to identify sitting, standing and walking	The accuracy for identifying postures for individuals ranged from 93.1% to 99.99%. The accuracy for all participants was average of 97.2%.

and acceleration data	and heel area of shoe		posture as subjects undertook common ADLs. Walking was videotaped to measure step counts	Mean diff (observed – system) for step count at SSWS unaffected leg = 0.80 steps, affected leg 0.04 steps. Mean diff (observed – system) for step count at fast speed unaffected leg = 0.55 steps, affected leg 0.14 steps.
Haeuber et al. (2004) stride counts from SAM and daily caloric expenditure of PA from Caltrac	SAM on paretic ankle above malleolus, Caltrac on non-paretic hip at waist level along mid-axillary line	N=17;average 41 months post stroke	Cross sectional study with repeated measures. To determine feasibility and reliability of SAM and reliability of CALTRAC and the correlation between SAM and Caltrac. 48 hours monitoring at home that was repeated within 3 weeks	SAM test retest reliability ICC=0.96, p<0.001) and Caltrac test retest reliability ICC= 0.44, p>0.05). PCC between SAM and Caltrac r= 0.82,P<0.001).Caltrac accounted for 64% of ambulatory activity quantified by SAM
Mudge and Stott (2008) 2008 SAM/	Ankle	N=40;average 5 years post stroke	Test-retest reliability with variables for SAM. Test-retest reliability undertaken one week apart. Each session was for 3 days. Variables for SAM were total step count, peak activity index, sustained activity indices of 1,5,20,30,60 minutes, steps at high, medium and low stepping rates	Test retest reliability for total step counts when all 3 days were used ICC=0.98 CV=10.7%. For all variables the ICCs were >0.90. Bland and Altman 95% LOA were <40% for 4 variables; step count, highest step rate in one minute, highest step rate in 5 minutes and peak activity index Seven other variables had 95% LOAs >40%
Mudge et al. (2007) SAM/total step count	On both ankle malleoli. Retro-reflective markers were placed for 3DGA and foot	N=25; at least 6 months post stroke	To determine the validity of SAM. Participants walked at SSWS for 6 trials wearing SAM and analysis with 3DGA. Walking at ssws and fast pace for 8 meters each.	Pearson's Correlation Coefficient between SAM and 3DGA for total steps: paretic leg r=0.89 with 95%LOA= ±10steps and non-paretic leg r=0.95, 95%LOA=±7. Pearson's Correlation Coefficient between SAM and foot switch: paretic leg r=0.96

	switches for walking outdoors		Validity Criterion: 3DGA and foot switch	95%LOA=±57 steps. For non-paretic leg, r=0.99, 95%LOA=±9 steps. validity when worn on paretic leg was low
Mudge and Stott (2009) SAM/Step watch outputs: daily step count and stepping rates (total 7	On lateral side of non-paretic ankle	N=50;average 66 months after stroke	Correlational Study Participants wore SAM for 3 days at home during waking hours	Between SAM outputs and RMA spearman's r=0.36 to 0.48,p=<0.05) Between SAM outputs and RMI spearman's r=0.31 to 0.52 P<0.05). 6minWT was a significant predictor for SAM outputs accounting for between 38% and 54% of variance.
Fulk et al. (2010) SAM	On non-paretic ankle	N= 32 (chronic stroke average 42 months post stroke n =19) and 13 age matched controls	Cross sectional study. To determine the ability of variables to predict walking in community. Independent variables=FMA, Bergs balance scale, 6minWT with SSWS, SIS, walking ability questionnaire. participants wore SAM for one week at home	6MinWT was significant predictor of community and home based activity p=0.001 and r^2=0.46. PCC between SAM and 6MWT= 0.68 and between SAM and SSWS=0.65. Other correlations <0.54 and not significant.
Shaughnessy et al. (2005) SAM daily step counts	---	N=19 post stroke	To assess if outcomes (FIM-mobility, SIS, SSWS) detect change in ambulatory activity over time (sensitivity) outcome measures were used 2 weeks post discharge and then repeated 3 months later.	Significant change in step counts over a three month period; an average of 80% increase p=0.001. The other OM did not show change significantly. SAM is a sensitive indicator of ambulatory recovery
Bowden et al. (2008) SAM/average steps per day	On non-paretic ankle	N=59;average 4 years post stroke	To validate the established speed based classification of post stroke function by measuring amount of	Pearson's correlation coefficient between SSWS and step counts r= 0.68 p<0.001; and between SSWS and pre-paretic leg swing r= -0.67 p<0.001). Steps per day was significantly

			walking in home and community	different between three groups classified based on SSWS p<0.001
			SSWS was measured and subjects were classified based on the speed. Patients wore SAM for 5 days at home .FMA- lower extremity was used, along with biomechanical indicators. Validity criterion: GAITRite mat	
Barak et al. (2014) SAM	On non-paretic ankle	N=408; community dwelling adults 2 months post stroke	Cross sectional design. To determine the rate and predictors for inferred adherence of SAM use. SAM worn for 5 days, data was used from 2 days.	52% adhered to wearing SAM on both days and 76% adhered to wearing it on day. There was significant difference between adherers and non-adherers for FMA scores, balance and endurance (p<0.0036). Significant predictors of adherence were balance r^2=0.52, walking endurance r^2=0.62 and age r^2= -0.71 (for age group 18-64 years)
Fulk et al. (2014) Fitbit Ultra and Nike+ Fuelband and SAM,YAMAX Digi-Walker SW-701 Pedometer used for comparison/steps	FitBit Ultra and pedometer worn on the side on the less involved lower limb on the belt or waist between anterior superior iliac spine and the umbilicus. Nike+ Fuelband was worn on the less involved wrist and SAM on lateral malleolus on the less involved ankle	N=50 (average 56 months post stroke n=30) and average 81 months post traumatic brain injury n=20	Cross sectional design. To determine the accuracy of FitBit Ultra and Nike+ Fuelband. Also compare accuracy with SAM and a pedometer. Validity Criterion: Manual step counts from video recording. Participants wore the activity monitors and performed the two minute walk test at SSWS	Average number of steps via observation= 195.4. On comparison with the manually counted number of steps: SAM ICC=0.97(0.92 to0.99) and the mean difference (observed-SAM) steps=4.7 steps. FitBit Ultra ICC=0.73 (0.56 to 0.83) mean diff=-9.7, Pedometer ICC=0.42(0.14 to 0.63)mean diff = -28.8, Nike+ Fuelband ICC=0.20 (-0.76 to0.46) mean diff =-66.2. SAM overestimated steps taken as observed in B&A plots. FitBit was more accurate when people took more steps. Pedometer and Nike+ Fuelband systematically underestimated steps.

From the above discussion it was concluded that no system, subjective or objective could be used effectively for continuous long term PA measurement with patients in a stroke rehabilitation setting especially in the early stages of recovery when patients were not walking. Moreover no measurement method appeared comprehensive enough to measure multiple variables related to PA other than walking. These findings are in agreement with Fini et al. (2014) who undertook a review of PA measurement methods used for patients after stroke.

The proposed solution for the current study therefore was to design a new customised outcome measure for effective PA measurement after stroke by making use of upcoming innovative technological systems with the application of advanced software applications in Health Informatics.

2.6 Health information systems for remote activity monitoring

Health information systems are being used in a continuous way to provide quick efficient and accurate data regarding patients and hospital processes. They utilise health information technology along with computer science software (Marschollek, 2009). With the increasing use of BWS, wireless health technology is being integrated with these wearables sensors to monitor many different aspects of patient health ranging from patient identification and correct drug administration in hospitals to remote monitoring of physiological measures such as heart rate or blood glucose levels at home (Dobkin and Dorsch, 2011). There has been a slow and steady increase in the application of the 'sensor enhanced health information systems' (Marschollek, 2009). Evidence of wireless transmission of sensor signals to computers and the use of algorithms to quantify PA has been discussed previously (Fulk et al., 2012, Zhang et al., 2008, Prajapati et al., 2011). Another technology which has been used in combination with sensors has been real time location

systems in healthcare environment (Harrow, 2006). RTLS utilise RFID technology in combination with ubiquitous computing to monitor or track assets or merchandise (Chao et al., 2007, Roy et al., 2009). RFID is a tagging technology with which any object or person can be identified using radio-frequency waves. A direct line of sight between the person or object and the device is not required (Harrow, 2006). A system based on RFID technology consists of passive or active RFID tags and readers which collect data from the tags. Active tags are used for tracking purposes while passive tags can be used to identify objects or people based on their ID code. A software known as 'middleware' which is connected to the reader is used to store and process information from several tags at once. The middleware can be integrated with computer systems used within hospitals (Yao et al., 2012).

There is strong evidence observed regarding the growing use of health informatics integrated with RFID technology in the healthcare setting (Lin et al., 2007, Yao et al., 2012, Fosso Wamba, 2012, Matic et al., 2012). In fact it has been reported that between 1991 and 2005 the number of publications on RFID technology increased by 116 publications in retail sectors. More studies where RFID enabled healthcare systems were used have been reported between 1997 and 2011. Moreover between 2009 and 2012, the number of papers published on RFID technology rose by 13 studies (1 in 2009, 14 in 2012) (Fosso Wamba, 2012). With particular emphasis on its application in healthcare, the number of studies where RFID was used was divided into 3 main categories. These were: use of RFID technology for asset management, patient management and staff management respectively. Most studies were related to patient management (n=13) followed by staff management (n=11) and then asset management (n=5). With respect to patient management RFID technology was used for correct identification of patients, safe drug and medication

provision in hospitals and quantifying waiting times in OPD clinics (Stahl et al., 2011, Wu et al., 2012). In a healthcare setting RFID based applications have been used for easy tracking and location of medical equipment to save time, keeping track of costly instruments as well tracking patients in a nursing home (Yao et al., 2012, Holzinger et al., 2008). Holzinger et al. (2008) evaluated the use of an RFID based ubiquitous system for safe monitoring of patients with dementia. In a memory clinic which was a 22 bedded unit, physically mobile patients having dementia were given an RFID tag which could be sewn on the clothes or worn around the wrist or at the collar. The area within the unit was installed with a wireless local area network infrastructure such that information from the RFID tags was continuously processed by the system. There was an alarm system placed at a point where the unit ended and the outside area began. If a patient crossed into an unsafe area, the alarm picked up the tag information and the relevant staff members were alerted via the server. The authors report that although the system was efficient its acceptability in the healthcare environment was limited as it was seen as 'electronic surveillance'. However the study highlights the utility of RFID based systems for patient management.

In another study RFID tags were used to detect correct dressing activity by healthy subjects in combination with a vision processing system (Matic et al., 2012). The aim of the study was to correctly identify 'dressing failures' in a non-intrusive manner. RFID tags were placed on different items of clothing such as shirts, T-shirts, sweaters, jackets and trousers. In a specifically designed dressing booth, RFID antenna were placed such that the tags from both sets of clothes for the upper body and the lower body will transmit the information without interfering with each other's signals. Eleven participants between the age of 28 and 40 were involved in the study and a total of 52 dressing activities were undertaken. All participants were asked

initially to undertake a dressing activity involving 3 garments, shirt, sweater and trousers. They were then instructed to execute a 'dressing failure' 2 out of 3 times based on researchers' instructions. Video recording was also undertaken for comparison with RFID reported dressing order. Vision processing was also used where an image of the patient was taken as they entered the dressing area and as they left. The images were compared and clustering of images was performed based on colour and a rule based system was applied to identify dressing failures. The tag ids were used for detecting the sequence of clothes put on while dressing. Dressing tasks that were tested included putting garments on correctly, wearing clothes on in wrong order (T-shirt after wearing a jacket), wearing too many or too few layers (in contrast to the weather) and wearing clothes the other way around. RFID technology was able to correctly detect wearing clothes the other way around or in a wrong order while vision processing could accurately identify garment put on partially or on the wrong part of the body. When the two systems were used together the overall accuracy of identifying correct dressing as well as dressing failure events was found to be 93% accurate.

As RFID based healthcare applications is a new emerging technology, a search was undertaken for the present literature review to look for evidence regarding the use of RFID based systems specifically as an objective method for PA measurement.

One study was identified where RFID technology was used for activity monitoring in healthy subjects. Barman et al. (2012) used a sensor enabled RFID based system to measure arm activity in daily life. In the study the system was designed and tested on healthy subjects and the authors report that the ultimate goal is to use the system to measure the type of upper limb ADL undertaken by patients after stroke in the community. Called as the '**S**ensor **E**nabled **R**FID **S**ystem for **M**onitoring **A**rm

Activity' (SERSMAA) system™, the following equipment was used in combination. An active RFID tag was worn by participants on their wrist. The everyday objects such as cups, books, hairbrush or remote controls were fitted with a movement sensor (5 cmx5cmx1.7cm) weighing 37 grams and a proximity sensor transmitter (7.8cmx3.8cmx2cm) weighing 50 grams. The receiver component of the proximity sensor was attached to the RFID tag on the wrist and had the following dimensions; 7.4cmx6.1cmx2.4cm; and weighed 95 grams. A LAN was setup between the RFID reader and the computer via an Ethernet switch. As the arm approached an object to simulate an activity such as lifting a coffee mug, the proximity sensor receiver on the arm received the signal and the RFID tag transmitted the radio-frequencies to the reader. If objects were lifted then the motion sensor consisting of a bi-axial accelerometer recorded the movement. The sensitivity and specificity were both rigorously tested for the proximity sensor as well the movement sensor. The range of the proximity sensor was assessed by moving the arm closer and away from the coffee mug from a distance of 24 cm to 20 cms in the X, Y and Z axis of the mug. The RFID reader distance was also increased to test the range of signals such that the reader was placed in different rooms with walls in between. Different everyday objects were used for testing as well. Similarly movement sensor was tested the same way by moving the mug from one position to another along the 3 axes of the mug. To test the specificity of both sensors, the sensors were activated and set next to the tag and the transmitter for a period of 24 hours. Each movement trial was repeated 200 times. The proximity sensor range was 23cms or less from the receiver. The results showed that no signals were received by the proximity sensor transmitter if the distance was more than 23cms. Out of 200 approaches testing approach of hand, grasp and withdrawal of hand, the proximity was detected with an

error of only 4 counts. Similar results were found with different objects and in different directions.

The movement sensor was found to be equally sensitive with 99% accuracy in movement detection of the mug. Based on the initial benchmark testing, reliability and validity was undertaken in a lab based setting subsequently. Healthy subjects (n=35) with an age range of 17 to 46 years were recruited for the study. Each wore the RFID tag on the right wrist. The proximity sensor transmitter and the movement sensor were fixed to 5 objects (mug, hairbrush, book, remote control and telephone. Three tests were undertaken and the first 2 tests consisted of moving the objects in succession at slow, medium and fast pace from the starting position and back firstly with the right hand (test1) and then alternately using the right and left hand (test2). The slow pace was repeating 6 movements in 18 seconds, medium pace was 12 repeated movement s in 18 seconds and high pace was 18 movements in 18 seconds. In test number 3, the 5 objects at random were lifted by participants and placed 150 cms away at a target location. The unit of measurement was the time duration for which an object was held in with the right arm. The mean error was reported by the system was 2.5%. As the amount of time for which an object was handled depending the pace, a significant (p=0.0001) increase or decrease in handling time was also reported by the RFID based system. Similar the system correctly identified the objects lifted by participants at random in test 3.This study was first of its kind to test an RFID based system for PA measurement for the upper limb. The results obtained by the system can be expected due to the meticulous nature of the testing. The authors reported that further work needs to be carried out to assess the system's utility with patients after stroke.

The results of the studies by Matic et al. (2012) and Barman et al. (2012) strongly suggested that there was high potential of utilising RFID technology in combination with other sensors or systems to design novel systems in the field of healthcare and rehabilitation. Therefore the results of these studies were considered as relevant as there was an opportunity to use an RFID technology based Real time Location system which could be developed successfully for long term continuous PA measurement in the early stages of recovery after stroke. Moreover so far all the evidence regarding different methods of PA measurement provided in the summary above (section 2.4) strongly supported this decision. Using RTLS based on RFID technology could not only overcome the limitations of the current methods of measurement, but could also be designed such that a combination of parameters were measured together using one method. The system could be used to measure activity continuously and without intrusion in both a rehabilitation setting and also at home. Activity in an environmental context could be recorded using other compatible sensors (Catarinucci et al., 2012, Barman et al., 2012) which again was an advantage over use of OBM. The conclusion from the review led to the formation of the objectives of the study given below to meet the aims of this study

2.7 Study aims and objectives

The aim of this study was to explore functional recovery in the early stages of rehabilitation after stroke.

The primary objectives were:

- To measure patient physical activity in a rehabilitation setting and at home using a system that was capable of doing so in a continuous and unobtrusive manner with minimal disruption of clinical routine (provided that secondary objectives are successfully met).
- To determine the relationship of relevant physical activity variables with measures of functional recovery.

The secondary objectives were:

- To co-design a new measurement system by making use of a real time location system based on RFID technology and sensor enabled information systems.
- To evaluate the reliability, validity and acceptability of this new automated measurement system.

The study hypotheses are as follows:

- **H_a1:** The new measurement system will be a reliable, valid and acceptable tool for PA measurement post stroke.
- **H_01:** The new measurement system will not be a reliable, valid and acceptable tool for PA measurement post stroke.

- **H_a2:** There will be moderate significant correlation between relevant physical activity variables and measures of functional recovery (correlation coefficients ≥0.50, p≤0.05).

- **H_02:** There will not be moderate significant correlation between relevant physical activity variables and measures of functional recovery (correlation coefficients ≤0.50, p≥0.05).

3. Methodology

The purpose of this chapter is to describe the overall study design and the approach undertaken to meet the study objectives. Explanation regarding the inter-disciplinary collaborative approach used for the research framework development have been presented first followed by the description and installation of equipment at the **R**egional **S**troke **U**nit **(RSU)**. Subsequently, details of prototype testing and ethical considerations has been presented.

3.1 Overall study design

The time frame was 3 years and the overall project was an observational study which was conducted in 2 stages (Figure 3.1). The feasibility of the newly developed system was tested first followed by the longitudinal study where it was used for PA measurement.

Phase One-Developmental Phase: In this phase, the psychometric properties of the new system were investigated. After initial proto-type testing, two sub studies were undertaken; the reliability study and., the validity study. Reliability study was undertaken to explore the extent to which measurements taken by the system via the RFID tags were free from measurement error when a certain set of fixed activities were performed by participants wearing the tag (Bruton et al., 2000). For any outcome measure or equipment to be reliable, the scores obtained must be as close to the true score as possible with minimal error (Atkinson and Nevill, 1998, Bruton et al., 2000). Also, in order for the system to be used repeatedly by the same rater or by different raters, the variation or the measurement error needs to be minimal. Other than reliability, an equally important criterion for evaluating the psychometric

properties of a measurement system is testing its validity. Comparison of the measurement obtained with the new system against those obtained using other credible PA measurement methods was investigated in the validity study.

the focus of this research was on *criterion related validity* to check if the RMMS tool could be used instead of another well-established system to measure the same variables (Portney and Watkings, 2009). Therefore the aim was to validate the system with a gold standard method of activity monitoring.

The findings from the sub studies in the first phase were also used to refine the methodology for the sub studies undertaken in stage two.

Phase Two- Longitudinal Study and Acceptability Study: In this stage PA measurement from admission into the stroke unit until discharge was conducted in the longitudinal study. Further analysis was then undertaken to explore functional recovery in the early stages of rehabilitation. Participants' views on user friendliness of wearing the tag and on long term measurement were explored in the acceptability study.

 A smaller pilot study was undertaken where PA was measured in the home environment using the same automated system.

Figure 3. 1 Sequence and time scale of the 2 stages of the current study

Phase One	Phase Two
Equipment Installation, Testing and Calibration May 2011-Nov 2012	Longitudinal study in RSU May 2012-May 2013
Reliability Study Nov 2011 -Feb 2012	Acceptability Study Jan 2012-Jul 2013
Validity Study Feb 2012-Jun 2012	Home Pilot Study Aug 2012-Jul 2013
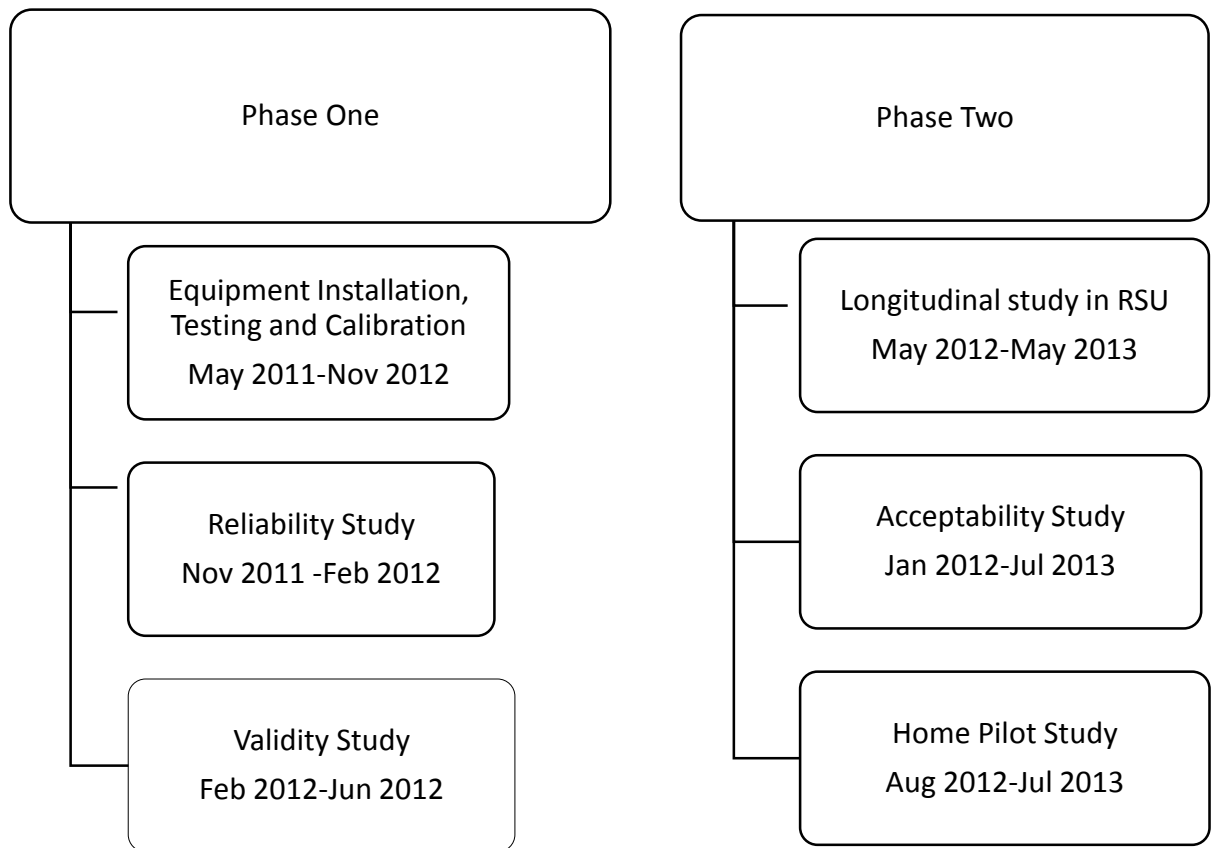
3.2 Collaborative approach and research framework

"Good design begins with honesty, asks tough questions, comes from collaboration and from trusting your intuition." --Freeman Thomas (ThinkExist, 1999)

This section of the chapter aims to elaborate on the collaborative aspects of the research project and the research framework which was developed as a result. The research project is the result of joint working between two disciplines; Healthcare Sciences and Computer Science and Informatics. A three member supervisory team guided two candidates who were working on their respective PhDs in the field of

Computer Science and in the field of Physiotherapy. The supervisors were Prof Robert van Deursen, Prof Alun Preece and Dr Allison Cooper. Prof Robert van Deursen has expertise in rehabilitation science particularly activity measurement and movement analysis. He has worked with different types of activity monitors and is also highly skilled with MATLAB programming to visually display movement analysis data. For the project the expertise in both fields meant that the potential areas for collaboration could be identified and maximised. From the School of Computer Science and Informatics, Prof Alun Preece was in the research group. His research focuses on techniques for information provision and decision-support in complex environments. Having specialist knowledge in working with different sensor based technologies and their application in real life environments led to relevant input regarding the future direction of the research and the long term application of this technology. Dr Allison Cooper is a stroke research fellow who is a neuro-physiotherapist by background. She has extensive clinical and research experience and thus was able to give the clinicians' perspective on the research outcomes in the context of stroke rehabilitation. Long term involvement in stroke research also helped in designing the project such that it met with the current needs and directions of stroke research within the NHS.

Mr. Przemyslaw Woznowski was the other PhD student at the start of the project whose PhD focused on the implementation of semantic systems for sensors for activity monitoring. Since the completion of this thesis, Mr. Woznowski has obtained his doctorate (January 2014). The research objectives of the current project and his project were aligned. Although the two research projects were potentially connected they were designed as individual PhD level projects in their own merit. This section focuses on the research framework from the point of view of the author's thesis. The

detailed explanations of Dr Woznowski's study can be referred to separately

(Woznowski, 2013)**.**

The main objective of this collaboration was to work together to convert the idea and the availability of RTLS equipment into an efficient computerised system to ultimately generate a better understanding of the functional recovery after stroke. For this, inter-disciplinary meetings were held every month during the course of the research. Essentially called 'supervisory meetings', it emerged very early on in the process that these meetings were a valuable brainstorming platform where expert knowledge from all the collaborators could be converged. This led to the formation of a conceptual framework which served as a tool for meeting the individual PhD objectives as well as for collaborative decision making. This framework consisted of three broad interconnected concepts. These concepts were *'Activity Detection'*, *'Sensor Information Processing'* and *'Early Stroke Rehabilitation'* after stroke. Figure 3.2 represents the inter-relation between the three concepts and the explanation is given below.

Figure 3. 2 Research themes and conceptual framework
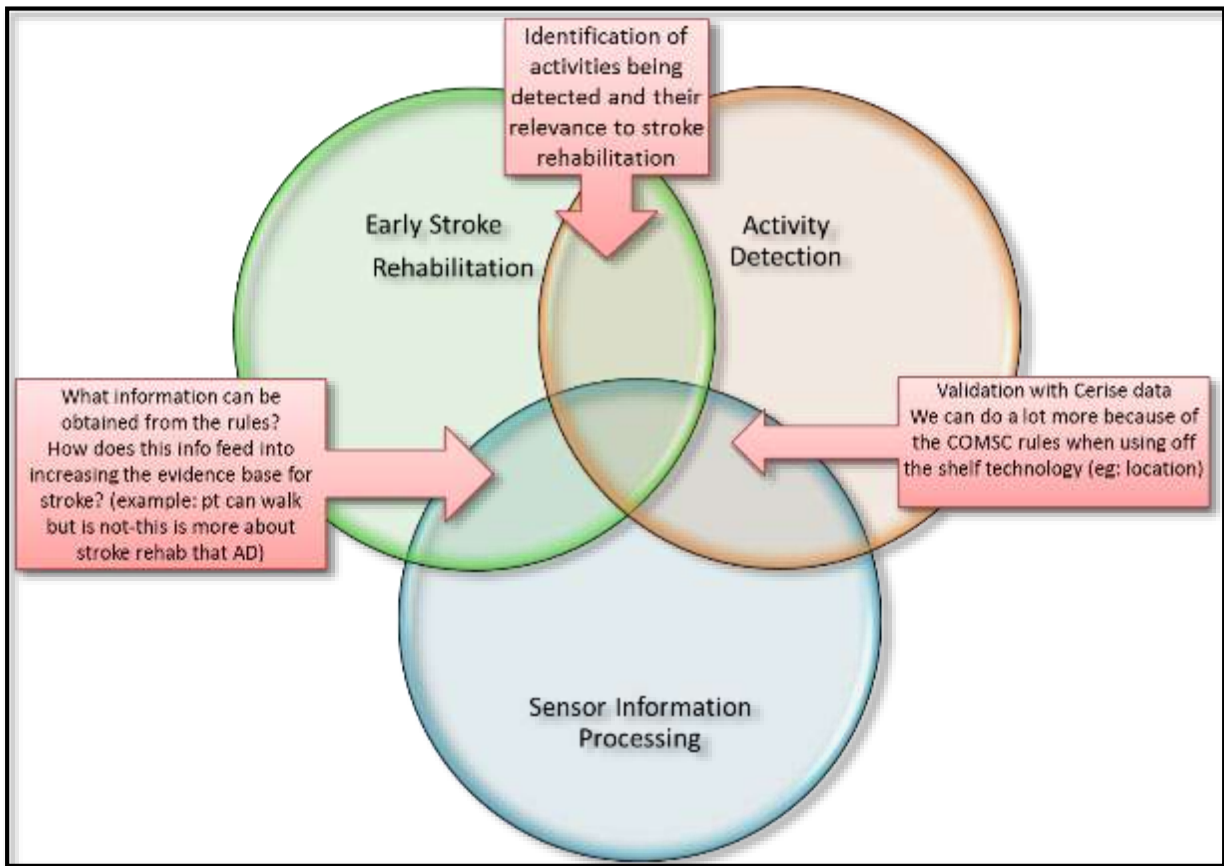
The field of '*Activity Detection'* specifically referred to measurement of movement using the sensor based computerised system. From the healthcare professionals' perspective it was necessary to be able to identify all activities that could be detected by the system. However the more important information was the area where the knowledge from this area overlapped with knowledge generated from the area of *'Early Stroke Rehabilitation'*. The information from this intersection would help with the selection of those activities whose measurement would lead to information about early stages of recovery after stroke. Once these activities were finalised, the aim was to use them as parameters to reliably measure patient activity and ultimately generate more knowledge and further research strategies in stroke rehabilitation. Information about the ability of the system for measuring PA included in the field of *'Sensor Information Processing'* was also equally important for the computer

114

scientists. Their primary research exploration was in the field of sensor informatics which looks at the possibility of improving information from basic sensors by setting certain logic based conditions known as 'rules'. These rules are a representation of real-world situations in a computer programming language and are used to instruct the computer how it needs to process the data for a particular situation. The exact nature of this field and its use in research is explained in detail in Dr Woznowski's thesis (Woznowski, 2013) . For this research project, discussion focuses on the common knowledge generated by the overlap of this component with the field of '*Activity Detection*'. The objective was to determine the extent to which the activity detection could be improved by using computer science programming, rules and applications. While a considerable proportion of the sensor informatics input would improve patient activity detection, other features would potentially add to the evidence base of Early Stroke Rehabilitation. These could be in the form of applications or feedback tools which could give healthcare professions and patients more information about recovery.

Research Framework: Once the interrelation between the conceptual themes was finalised and agreed upon, the individual study design for the project was formed. In Chapter 2, section 2.1 the variables that needed to be measured to quantify PA were identified. Hence a research framework for the project was designed using the ICF model to meet the project objectives (WHO, 2001).

This new RTLS based system was named as the **R**ehabilitation **M**obility **M**easurement **S**ystem **(RMMS)** and it became clear that in order to use RMMS for longitudinal PA measurement, it essentially needed to function as an OM incorporating software programs to automatically score individuals on a continuous or categorical scale.

After further discussion during the course of the project, the CERISE tool used for BM was reviewed for the patient PA measurement using the RMMS (De Wit et al., 2006). Appendix 5 depicts the 3 main components of the CERISE tool and the items under each of them. Like RMMS, the CERISE tool uses time as a main unit of measurement which was a distinct advantage. When matched against the conceptual framework, the CERISE tool could be used to detect activity during early stroke rehabilitation as well as had great potential to be modified using computer programming code for the sensor based system. The kind of non-therapeutic activities measured using the CERISE tool could be explicitly linked to the ICF Mobility category (WHO, 2001). Based on these points the CERISE tool was unanimously selected as the most appropriate OM that could be used the project. Following the selection, the modification of the CERISE tool and the conditions set for forming the rule based approach for analysis were undertaken during the interdisciplinary meetings. Some items were removed whilst others were added to measure PA in the RSU setting (Appendix 6). The study design and data analysis for the validity study and the studies undertaken in stage 2 subsequently used the modified CERISE tool items and were based on the ICF category of mobility (WHO, 2001). The details of the same are given in the next section 3.8. The results of the sub studies will be presented in the next chapter and it is anticipated that the results will also help in drawing attention to the importance of the collaborative working process and its benefits.

3.3 Equipment selection

Project requirements

Following the discussion of PA measurement methods in Chapter two, it emerged that to develop and use an automated measurement tool based on real time location technology in the stroke rehabilitation unit, two key requirements needed to be fulfilled. Firstly, the system needed to be able to measure early phase of recovery post stroke with strong emphasis on the measurement of important aspects of functional recovery such as mobility and PA levels. Secondly the system had to be capable of measuring these aspects continuously over weeks or months without disrupting the clinical routine. This also meant that practical issues namely; network connectivity, electricity consumption, battery life, equipment size, installation and storage needed to be considered carefully. Attention also had to be paid to the frequency of manual input that would be needed to operate the computer based system as well as the type of software under consideration. At the time when this study was started, although RTLS and RFID system were being used, there was no ready-made system available that met the study requirements. Thus a bespoke system was developed based on off the shelf hardware components and software products from the company RF code (RF-CODE, 2015) collaboratively between the School of Healthcare Sciences and the School of Computer Sciences and Informatics at Cardiff university as explained in section 3.2. Originally based in Texas, USA, the company provides IT equipment and software for environment monitoring and asset management. These are also used in hospital environments. For application of this system in the RSU, the plan was to use a large number of tags worn by the patients and rehabilitation staff. Tags were also to be placed on essential equipment such as mobility aids. The combined information would be used

to draw conclusions about patient PA. However, for this additional customised software development was required.

Three main hardware products selected from RF code were body-worn sensor tags, room locators and readers. The tags, room locators and readers work in synchrony to produce data which is collected using Zone manager, the main software program. The product details followed by how they work together to give relevant data is explained below.

Radio-Frequency Identification (RFID) tag

Amongst the various asset tags available, the tag considered most appropriate for use in the study was the **M163-i Infra-red wristband tag™**. This tag, designed like a watch is small in size (measuring 48 millimeters long and wide with a height of 14.5 mm) and weighs only 14 grams. It can be worn on the wrist using a simple strap or be attached like a badge using a clip. It is water resistant, heat resistant and operates via a coin sized battery which can last up-to 3 years. Each tag is enabled with 2 sensors; an in-built motion sensor and an **I**nfra-**R**ed **(IR)** sensor. The IR sensor monitors the environment for the IR signals transmitted by room locators. This feature along with its ability to detect movement via the motion sensor means that when worn by a person around the wrist, information about where the person is and whether they are moving or not moving can be suitably gathered.

Each tag has a serial number printed on its surface which is its unique identification code (Figure 3.3). The tag transmits this number along with the location code that it picks up from the room locator and its movement information via motion sensor, at regular intervals of 2 to 10 seconds. This information is in the form of Radio-Frequency (RF) signals having the operating frequency of 433 megahertz which is

significantly less than the signal emitted by a mobile phone. RF signal transmitted by the tag is received by the M250 fixed reader.

Figure 3. 3 M-163 infra-red wrist band RFID tag

Room Locator

It is a unit fitted with IR transmitters which produce IR beams at regular intervals of 2 seconds. The A750 **R**oom **L**ocator™ **(RL)** was considered the most appropriate type to use. The A750 RL can be configured with a unique three digit location code continuously transmitted as IR pulses which cover a distance of approximately 10.66 meters (35 feet); a size of a large room. The IR output intensity can be set in the range of 10% to 100%. The RL works indoors only and the IR beam intensity emitted can be affected by sunlight or other lighting in the room making it necessary to adjust the output intensity. Each RL is divided into 9 sections having 1 light emitting diode (LED) each (Figure 3.4). Individual sections can be disabled such that the RL emits IR beams in a specific direction (Figure 3.5). An exact protocol to configure the settings is provided in the manual by the company RFCODE, Austin, Texas, USA. The RL can be easily mounted on a wall or a ceiling. The infra-red beams (carrying the location code) then reflect off surfaces and cover the whole room. It can work in

stand-alone mode as well as in series where two or more RLs can be configured with the same location code. The IR location codes sent out are picked up the RFID tags and transmitted to the RF code reader.

Figure 3. 4 Configuration of the infra-red room locator (RF-CODE, 2015)
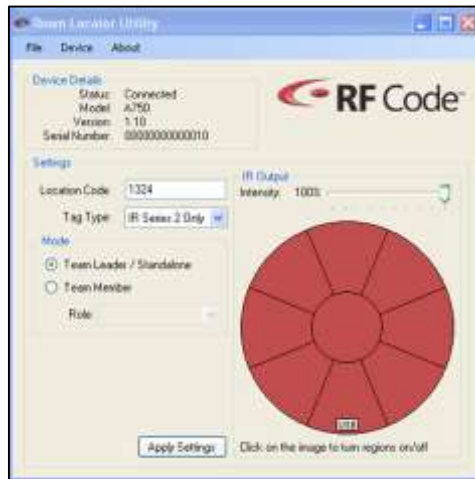
Figure 3. 5 Setting the IR output and intensity of room locator (RF-CODE, 2015)
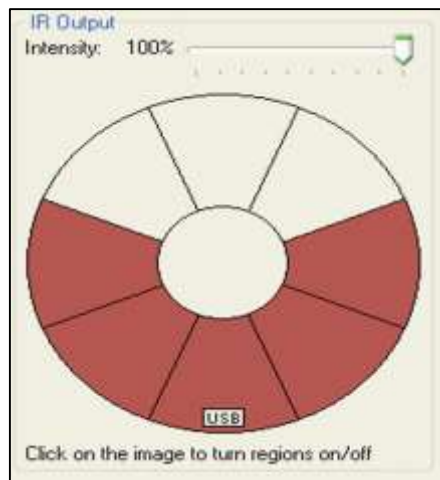
The M250 fixed reader

The M250 reader™ can interpret and process movement and location radio frequency signals from the RFID tags in real time. This reader has the capacity to simultaneously process information from up to 1400 tags every 10 seconds or 140 **T**ag **R**eports **P**er **S**econd **(TRPS).** Moreover as it runs on electricity, it is more appropriate for continuous reporting over months instead of using a battery operated mobile reader which needs to be recharged every 8 to 10 days. The reader has two channels for radio receiving operating at a frequency of 433.92 megahertz and two short antennae for receiving signals (Figure 3.6). The maximum range can be configured depending on the software, location and installation. The range of coverage with a single omni-angle reader is 91meters (300 feet). Portable antennae strategically placed with the help of cables can be connected instead of the short antennae to increase the range of coverage. The M250 readers come in two models; one which can connect with Ethernet via a wire and the other which is equipped with Wi-Fi to subsequently connect to a computer which has the software installed on it. For the study, the model which could be connected via Ethernet was used (Figure 3.7 and Figure 3.8). At the time of undertaking the study in the RSU, the NHS Wi-Fi or network via Ethernet connection could not be accessed due to hospital regulations. Hence a router was used to connect the reader and the recording computer to work as a self-contained system where the NHS internet connection would not be accessed. These radio frequency data are received by the software program on the computer called 'Zone Manager'.

Figure 3. 6 M250 reader
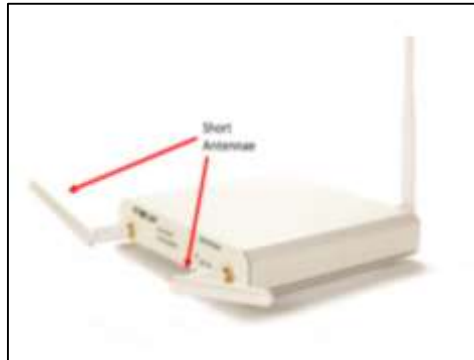
Figure 3. 7 Front view of the reader

Figure 3. 8 Back view of the reader

Zone manager™

Zone manager™ software is a real time location engine which is used with RTLS hardware. This software installed on a computer can display data from all tags within range and the function status of the readers being used. The zone manager can be used online to access current tag information. It gets information from the readers in an *exception mode* which means that the reader sends tag information only if there is a change in the tags location or movement status. Two other types of information relayed to the zone manager are detection of a new tag in the location (tag online) and if a tag disappears out of location (tag offline). A major feature of the zone manager is that it can be used to see very basic information about tags which could potentially be used for rehabilitation. However it cannot on its own interpret data about the asset on which the tag is placed and thus its open Application Programming Interface is very useful for development of bespoke applications (Cickusic et al., 2011). This means that other computer applications can be integrated with the zone manager's interface and computer programming code can be written to convert RTLS equipment data to end-user requirements. The interaction between the various components of the RTLS which ultimately gives the desired information is represented in Figure 3.9 .Room locators transmit their location code signals as IR waves every 2-10 seconds. The RFID tags present in the same room pick up these IR signals. Thus their location along with their movement and their unique identification codes is transmitted via RF waves to a reader. The reader processes the RF signals and sends them to the zone manager location engine installed on a computer. The information that is displayed on the zone manager in real time is each tag number present in the vicinity, where each tag was based on room locator code and whether it was moving or not.

Figure 3. 9 How the Real Time Location System works
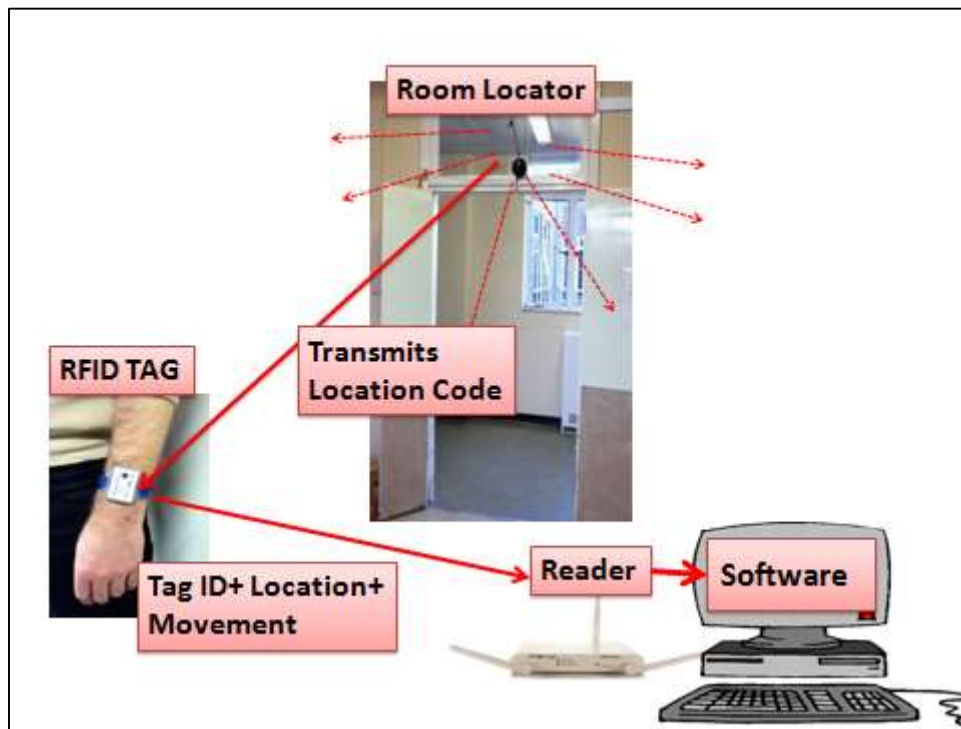
Advantages and challenges of RTLS equipment

Advantages of RTLS

It was very evident from the way in which the RTLS works that it could provide continuous real time information about the tag wearer's identification, location, change of location and movement. Moreover due to the collective features of the equipment it could also be said that developing a new automated tool based on the RTLS could potentially meet the important requirements for the study that were previously mentioned. The sensor tags were small, light-weight, durable with a long battery life (3 years) and could be worn around a wrist or attached to clothing. The installation of RLs was easy and the tags could be located in an indoor setting where technology like GPS tracking could not be used. Moreover there was no need to connect to a server using Ethernet connection as the system worked as a standalone system capable of bypassing integration with the hospital network connection. The equipment could be permanently installed as it was not bulky and

could be plugged into regular sockets. Also, the reader was very capable of processing information from multiple tags simultaneously. These points highlight that an RTLS based system could be used for continuous long term objective patient activity measurement in a rehabilitation setting without disruption of the day to day ward routine. The RTLS uses technology that has passed stringent criteria for use in hospitals. It has been tested and approved for compliance with US and International standards that pertain to electromagnetic interference including the requirements in Europe. Radio emissions when using RTLS are in the range of 0.00314µWatt to 0.0028 µWatt and these are substantially less than mobile phones which emit peak powers of 2 Watt, ± 70,000 greater. Signals in 27 µ bursts are sent every 2 or 10 seconds so that actual transmission time is less than 1 minute per day. Overall, the equipment appeared safe to use within the RSU without interference with other medical equipment or pacemakers (RF-CODE, 2008).

Challenges of the RTLS

Although it met the main requirements for the study, there were some challenges associated with using the RTLS system, particularly with respect to software and analysis. These needed to be resolved before the feasibility of the system as a PA measurement tool could be investigated**.**

Data storage and retrieval: The zone manager engine displays information on the screen as long as the system is active and running. This information cannot be saved or retrieved at a later time. Hence additional software was required to integrate with the zone manager to make raw RTLS data collection easily retrievable. Moreover it was essential that this data was stored securely in line with the ethical considerations and in a format that would ease its processing.

Obtaining information in the relevant context: The tag location, id and movement information processed by the reader and displayed on screen is in numerical codes. One of the main requirements was the ability to obtain meaningful information in rehabilitation context which could then be analysed in the later stages.

Data reduction: Lastly, large volumes of data need to be stored over a long period of time. For example if 100 tags were used over a period of 24 hours, 6 million data points (or tag reports per second) would be obtained and would need to be stored. Hence any software designed for data processing needed to exhibit considerable data reduction properties.

In order to meet the challenges associated with the development of this sensor based system, a good collaboration developed between the Schools of Healthcare Sciences and School of Computer Science and Informatics of Cardiff University. In this study the designated end-users were researchers from the School of Healthcare Sciences and the software programming was developed by collaborating with computer scientists. The collaborative working and the resultant research framework which led to the developed system will be described in section 3.7 in this chapter. Once the basic challenges were met, the equipment was installed in the stroke unit after which system testing and calibration began prior to stage one project data collection.

3.4 System installation

RSU, Cardiff was a 24 bedded hospital specially admitting patients post stroke for rehabilitation (Figure 3.10). The unit was self-contained and occupied the entire 3rd floor. RSU layout, the detailed installation of the equipment and the configuration of the software system will be explained in this section. The initial testing carried out prior to the start of the first phase of the study will be explained in the next section.

Layout of the Regional Stroke Unit

Reception Area: On entering the RSU, reception was located on the right hand side

Patient rooms: there were 8 single occupancy rooms called 'single rooms' and two 8 bedded units called the 'bay rooms'. These were termed the left bay and the right bay. Each bay was further divided into two cubicles by a wooden partition and each cubicle had 4 beds in it.

Therapy areas: Opposite the main entrance was the open area for Physiotherapy. The Occupational therapy area which also included a kitchen was adjacent to the Physiotherapy room. Along the far end of the corridor to the left was a door leading to the other offices including the speech and language therapy rooms and rooms for clinical psychologists.

Day room: Between the two bays was a common area called the Day Room where patients socialised or watched TV. Sometimes patients had their meals here and occasionally, this room was also used for speech and language therapy and for group sessions.

Offices: The office for the medical staff and the nurse in-charge were located opposite single rooms 6 and 7. The other offices were located in the area down the end of the corridor on the left side.

127

Toilets were located opposite single room 3 and single room 7. Two more were located adjacent to the left and the right bay rooms. Two baths were located inside each bay next to the toilets.

Other rooms: Storage rooms, laundry rooms and kitchen were also present in the unit.

Figure 3. 10 Layout of Regional Stroke Unit
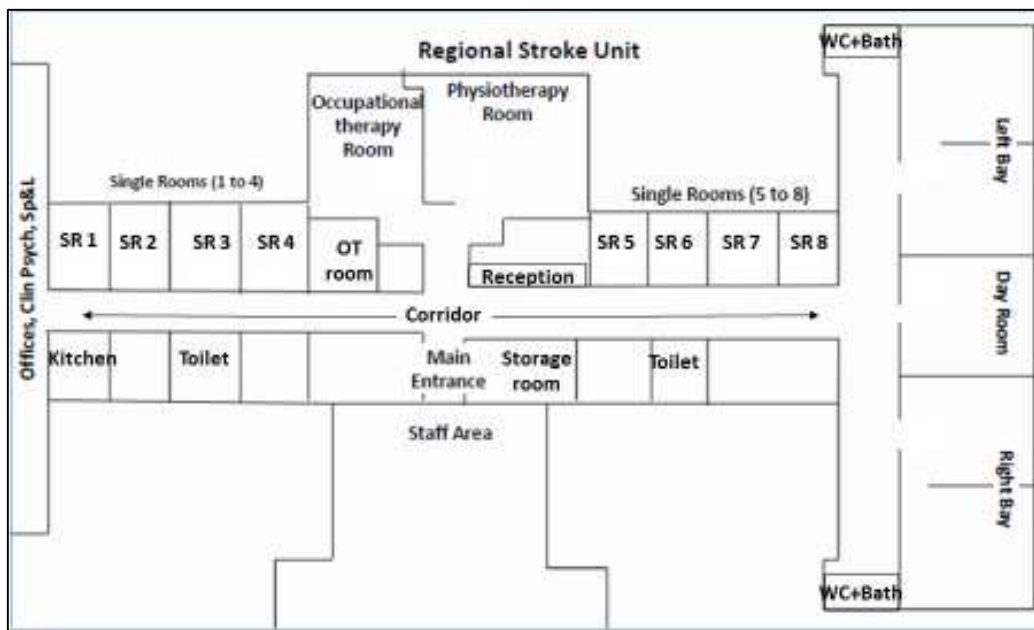
3.4.1 Tag placement

A hundred and fifty RFID tags, 13 room locators, 1 reader with 2 Omni-angle antennae and a router were all set up in the RSU.

RFID tags

The 150 tags were divided into 4 categories; patient tags, staff tags, patient related object tags and equipment tags. All tags were placed such that they were in the best possible position to pick up the IR location codes from the RLs.

Patients Tags: Participants wore the tag with a hospital band around their unaffected wrist and ankle. The strap used to tie the tag was a type of a simple

wristband provided and used by the NHS to identify patients. These hospital bands could be tied around the wrist as well as around the ankle (Figure 3.11).

Figure 3. 11 Placement of patient tag (wrist) and walking aid tag

Staff tags: Participating staff members were asked to wear the tag on their uniforms using a badge clip. The staff members could clip the tags on when they came to work and take them off when they finished (Figure 3.13). The ethical protocol followed for staff recruitment has been explained further in on in sections 3.6 and 4.1

Patient related object tags: Equipment that was personally used by the individual patients was termed as patient related objects. These were mainly patients' beds, their bedside armchairs and specific walking aids which were solely for their use. Using cable ties, 1 tag was placed underneath the patients' beds and on the arm of their bedside chairs respectively. If they used a walking aid such as a Zimmer frame or a stick, one tag was also tied around these. (Figure 3.12).

Figure 3. 12 Tag placement on bedside chair

Figure 3. 13 Tag worn by staff

Figure 3. 14 Placement of tags on equipment (steady and hoist)

Equipment tags: Other equipment generally used for rehabilitation and transfers were also tagged. One tag each was tied around all equipment used for transferring or transporting patients. These included sling hoists, standing hoists and all the 'steadies' provided by Sara Stedy^{TM} (ArjoHuntleigh UK, Bedfordshire, UK). Common equipment used for physiotherapeutic rehabilitation such as Oswestry standing frame, stationary cycles and the Golvo hoist were also tagged. Wheelchairs that were assigned to patients were also tagged and one of the front wheel spoke was fitted with tag using a cable tie (Figure 3.14).

Room locator tags: One tag was placed on each installed RL. This was to efficiently check if it was working or not as the specific tag would report no signal if the RL was accidently switched off or was not working.

3.4.2 Room Locator placement and configuration

Thirteen RLs in total were installed in all areas accessed by patients using a hook similar to one used to hang a wall clock. Toilets, staff offices and meeting rooms were not fitted with RLs (Figure 3.15 to 3.18). The exact location of the room locator

was chosen such that for each room it was convenient, near enough to the electricity and did not interfere with clinical activities.

Each RL was configured with an individual 3-digit code. Table 3.1 represents the rooms where the RLs were installed and their respective location codes. It is important to mention here that two extra codes were used for the software programming. '000' was defined as 'lack of location' for those scenarios when the patient was either in a room not installed with the RL (toilet or the offices) or if the installed room locator was switched off. The tags would also report a '000' location code if there was no direct line of sight between the tag and IR waves transmitted by the RL for instance when the patient's hand was under a pillow or blanket. Code '999' was used when the patient was out of the range of the reader if they left the unit for reasons such as practicing car transfers, going on a home visit or for medical tests.

Table 3. 1 Placement of room locators and the numeric codes assigned to each room locator

Room	Location code
Single room 1	500
Single room 2	700
Single room 3	300
Single room 4	501
Single room 5	759
Single room 6	702
Single room 7	704
Single room 8	102
Physiotherapy room	100
Occupational Therapy room	200
Day room	400
Outside range	999
Lack of location	000

Figure 3. 15 Room locator placement in RSU
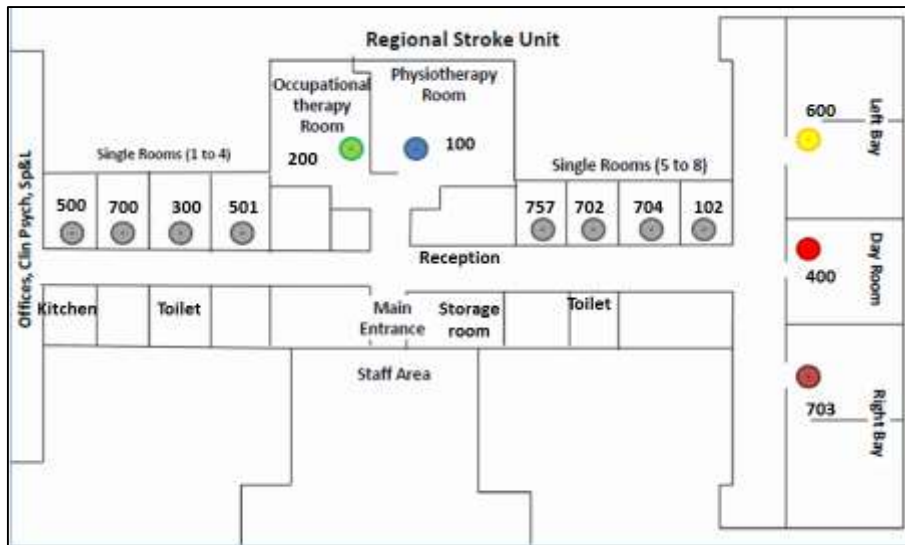
Figure 3. 16 Room locator placement in Physiotherapy area

Figure 3. 17 Room locator in Day room
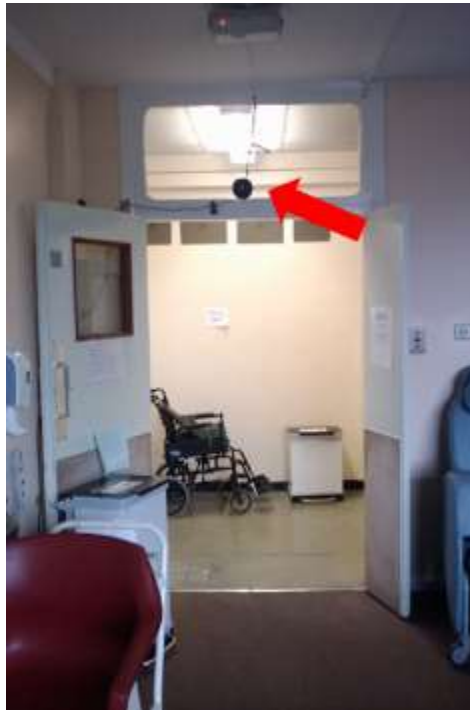
Figure 3. 18 Room locator in Bay room

3.4.3 Installation of Reader and the Computer

The reader and the computer (with the installed zone manager) were placed safely out of the way on a shelf in a storage room next to the entrance. Long cables (> 20 meters) connected the two omni-angle antennae which were suspended securely from the ceiling on the opposite sides of the corridor (Figure 3.19).

Figure 3. 19 Omni-angle antenna connected to reader

Coding of tags for data collection and storage

SAll tags were identified according to their unique serial numbers and were given alpha numeric codes according to the category to which they belonged. The information displayed on CSV sheets was in the same format in which the tags were coded. The method for coding is explained in Appendix 4.

3.4.4 Additional software program development

To deal with the challenges relating to the raw data obtained from the RTLS mentioned in section 3.3, computer software programs were also being developed collaboratively with computer scientists. Software programs were built to store online tag data from the zone manager in a secure database. A 'user interface' was designed to start and stop this software program. Another feature built in was to separately save stored data as 'comma separated value' sheets (CSV) which are similar to Microsoft Excel spreadsheets. The CSV data files could be transferred to an encrypted USB stick as data analysis was off site. In the software, there was also provision to add or edit tag details in case an additional tag was added to new equipment. Thus the process for data collection, storage and retrieval was sufficiently in place with the help of software programs. Separate customised software for data processing and analysis were additionally designed for each phase of the study and these will be discussed in the relevant sections of Chapters 4 and 5.

3.5 Prototype testing and calibration

Once the computer and the reader were installed in RSU, several tests were conducted to make sure that all the equipment was working for effective and continuous data collection in both stages of the study. With respect to the hardware, the main focus of these tests were to check the range of the reader via the antennae, room locator coverage in each room and the appropriate tag placement to make sure that the tag could pick up both, object movement as well as the location signal.

Reader range

After installing the antennae, the range of the reader was tested to determine that signals could be processed from the farthest most areas of the RSU. Select tags were placed in the corners of both Bay rooms, in the offices down the far end of the corridor, in the corner of the Physiotherapy area and just outside the main entrance. The zone manager was checked to see the status of these tags. If the strength of the reader was weak then the RF signals sent by the tags would not be read by the reader and the tags would not appear on screen of the zone manager software. If the tags were displayed on screen it meant that the reader was effectively receiving the RF signals from the tags. During the initial testing all tags were displayed as online hence it was determined that the reader range was strong and covered the entire stroke unit.

Room Locator coverage

The optimal position of each RL was tested by placing tags at different locations in each room and checking if the RL code was displayed onscreen.

Tag motion sensor and IR sensor testing

The sensitivity of the motion sensor built in the tag was tested first. Positioning of the tags under the bed and on the armchair was checked and it was ascertained that when the patient was lying in bed or sitting in a chair, the motion sensors were adequately sensitive and picked up low amplitude movement immediately. The 'settlement time' that is the time taken for the tags to report that the tag had stopped moving was 30 seconds.

The testing of the tag IR sensor was undertaken next. The IR sensor could accurately pick up and relay the room locator code when the tag remained in the room continuously. Tests were conducted to check the ability of the tag to report the

change in location code if the object or person wearing the tag moved from one room to another. The time taken by the tag sensor to stop reporting the previous location code and start reporting the new location code was calculated. It was found that when the tag was moved from a room covered by a room locator into an area with no room locator, it continued to report the old location code for 2 to 10 seconds. However if the tag was moved to another room which had a room locator in it, the sensor reported the new location in 2 to 4 seconds.

From the initial sensor testing time taken by the sensors to report the movement and location codes was considered highly satisfactory.

Having meticulously investigated and confirmed efficient functioning of both the hardware and the software components of the RTLS based system; the sub studies in the first stage of the project were started. During the course of the research project, further improvement to the software were made and these will be discussed in Chapter 4 and 5 in the thesis.

3.6 Ethical consideration

Ethical approval was obtained from the South-East Wales Research Ethics Committee, Panel B (research reference number 10/WSE/02/25). NHS site specific information approval was obtained from the NHS Research and Development office.

Data storage and protection

All information was securely stored in a password protected computer (Data protection act 1998). No participant was identified in any document that was shared with people outside of the research group. Core members of the research team had approved 'research passports' from the Research and Development department at

Cardiff and Vale University Health Board which officially allowed them to access to specific patient information. No personal data was stored on databases designed by computer scientists. If research participants were photographed for presentations or teaching purposes prior consent was obtained and their faces were blurred in the photograph to protect privacy.

Patient identification, screening and recruitment

All patients with the onset of stroke are admitted in the acute stroke unit at the University Hospital of Wales, Cardiff, UK from where patients who are deemed medically stable for further rehabilitation are transferred to the specialised stroke rehabilitation centers in Cardiff. The RSU, West Wing, Cardiff Royal Infirmary was one such specialised rehabilitation units. It was selected as the main site for the study and all patients for this project were recruited when they were transferred to RSU.

A member of the RSU staff was requested to make first contact with the patients and/or their relatives or carers. If they were willing to know more about the study, the researcher discussed the information sheet with them and their relatives. If the patients agreed to participate they were requested to give written informed consent (Appendix 2). In situations where the patient was unable to fully comprehend the information given or unable to consent due to cognitive, speech or physical impairments, informed assent was obtained from their family members (Mental Capacity Act 2005).

Staff identification and recruitment

A separate information sheet and consent form was given to staff members (Appendix 3).

The researcher explained the study to the staff members and obtained their consent if they chose to participate. The main reason for the inclusion of staff members in the study was to identify and measure the amount of time patients spent interacting with those staff members who were likely to have most face to face contact with patients and who were directly involved in the patients' rehabilitation. All staff members from the following disciplines were included in the study: Medical Registrar, Nursing staff, Physiotherapy staff and students, Occupational therapy staff and students, Speech and Language Therapy staff and students, Clinical Psychologists and receptionists.

Any specific protocol that was followed for recruiting patients and staff for each sub study as well as the ethical guidelines that were used have been mentioned alongside the relevant inclusion-exclusion criteria presented in sections 4.1.1, 4.1.2, 5.1, section 6.1 and 6.2

4. Phase One: Developmental Phase

Once the RTLS based equipment was installed and calibrated, sub studies that comprised of stage one of the project were undertaken to investigate the feasibility of the RMMS being developed. The reliability and the initial validity study were done together first followed by the main validity study. In this chapter the methods for the reliability and validity study are given first followed by the results. The discussion and the implication of the results on the main longitudinal study are presented subsequently.

4.1 Methods

4.1.1 Study design: Reliability and initial validity

Reliability Study

The aim of this sub study was to determine the reliability of the new rehabilitation tool to measure select tasks performed by the patients in the RSU when the testing conditions were controlled or standardised.

Based on the objectives of the project, a 'script' consisting of a sequential order of simple movements chosen by the researcher was created and consisted of 33 steps as in Table 4.1 given below.

Table 4. 1 Script for the reliability study

1. Pt supine lying
2. **H**ealth**C**are **S**taff **(HCS)** enters room (trigger event)
3. HCS positions chair
4. Pt starts to get up (lying to sitting initiated)
5. Pt sits at the edge of the bed (sitting completed)
6. Pt stands (stand to sit initiated)
7. Pt sits in chair (stand to sit completed)
8. HCS leaves the room
9. Pt in chair-inactive

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10. Wheelchair brought into patient's room (trigger event)*
11. Pt starts to get up from chair (Sit to stand initiated)
12. Pt stands (sit to stand completed)
13. Pt sits in wheelchair (stand to sit completed)
14. Pt leaves own room
15. Pt enters Day room
16. Pt starts to get up from wheelchair(Sit to stand initiated)
17. Pt stands (sit to stand completed)
18. Pt sits in chair (stand to sit completed)
19. Wheelchair moved out of Day room
20. TUG test started
21. TUG test ends
22. Pt in chair-inactive

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23. Therapist enters the Day room with walking aid *(trigger event)*
24. Therapist positions walking aid
25. Pt starts to get up from chair(Sit to stand initiated)
26. Pt stands (sit to stand completed)
27. Walking with aid initiated (Toe off)
28. Pt enters corridor
29. 10MWT started
30. 10MWT ends
31. Pt enters therapy room
32. Pt sits in chair/bed (stand to sit completed)
33. Walker moved to the side
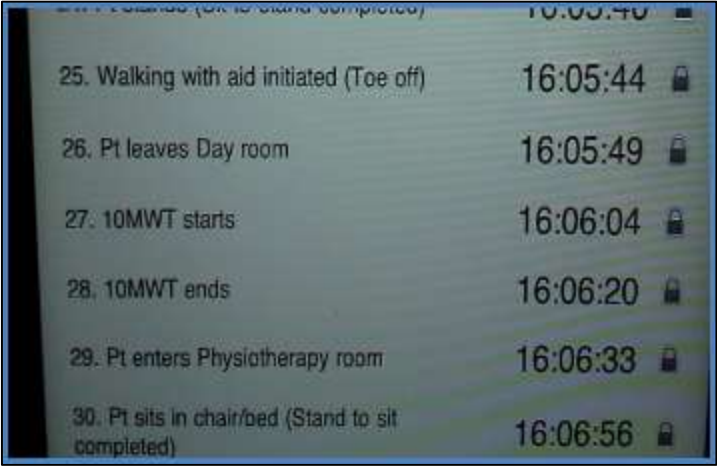
These simple movements were chosen such that specific variables of the mobility components relating to the ICF framework were incorporated in the script. These are; walking short distances (steps 27 to 31), changing body position (steps 4 to 7 and 11 to 1), maintaining body position (step 1, 9 and 18) and moving around (27 to 31). Through these steps the aim was to capture most factors which change during the early rehabilitation stages such as use of wheelchair or walking aid, sitting in bed

or chair and walking. The presence of staff member indicating supervision or assistance for mobility could be captured through steps 2 and 8 and also though steps 22 and 33. It was hypothesised that if the system could reliably detect these movements, then the changes in these activities could be measured in the second stage of the project.

Initial validity study

The initial validation was done together with the main reliability study**. For this study the aim was to determine the accuracy of the time taken by patients to perform certain movements obtained via the tags by correlating it with the time recorded manually via observation for the same activities**. The activity script designed for data collection included steps which would help with consecutive data collection for the initial validation specifically the timed **10 M**eter **W**alk **T**est **(10MWT)** (steps 28 and 29). The 10MWT has been used routinely and is a reliable and valid OM used to assess walking speed in patients after stroke (Mudge and Stott, 2009, Tyson and Connell, 2009). The equipment used remained the same and a specific area was measured and marked in the corridor for the 10MWT as seen in Figure 4.2. An iPad was used for the project (I-pad 2, Apple Inc, California, USA). An application was designed by Prof Alun Preece, School of Computer Sciences which served as a stopwatch for measuring time taken to perform each activity by the participants according to the activity script that was created for the reliability study as explained above. (Figure 4.1). The start and stop time for each event automatically recorded and stored as a CSV file was used for analysis. The stopwatch App can be accessed via this link http://users.cs.cf.ac.uk/A.D.Preece/sohcs/timer.php

Figure 4. 1 Stopwatch ipad app used for initial validity study data collection

Inclusion-exclusion criteria

The inclusion criteria for the reliability study and the initial validity study was as follows:

Diagnosis of a Cerebro-vascular accident (CVA)

- Either ischemic stroke or haemorrhagic stroke

-Able to:

- transfer with help of 2 people

- sit independently in a specific chair (having a backrest and arm support) for maximum 5 minutes

- walk for minimum 10 meters with/without walking aid and with assistance of another person

-Functional Ambulation Category (FAC) score of 2 or above (Mehrholz et al., 2007).-

The exclusion criteria for the reliability and the initial validity study was as follows:

Previous history of stroke

- Other factors like cerebral palsy, Parkinson's disease or mental illness such as schizophrenia

-Severe cognitive deficit causing inability to follow simple instructions

-Poor standing balance

-Brainstem/ pontine lesion with a Glasgow Coma Scale score of 3.

Sample size calculation and recruitment

Reliability study : Sample size calculation was done based on the method described by (Walter et al., 1998). In the method number of subjects 'K' can be calculated when the number of replicates 'n' is fixed. On selecting the minimally acceptable level of reliability (p0) and the anticipated level of reliability (p1), type 1 and type 2 errors also need to be set. For the current study, with 'n' set as 3, α or type I error value was selected as 0.05 and β or type II error was selected as 0.20. Based on the literature and previous research undertaken with healthy subjects, $\rho0$ and p1 values were selected as 0.40 and 0.80 respectively (Chinn, 1991, Wuest, 2010). Hence the number of subjects required was 10 (K = 9.6).

Initial Validity Study: As the initial validity study was undertaken alongside the reliability study the same patients were used, i.e. 10.

Recruitment: Patients were identified in RSU and those who matched the inclusion criteria were approached to participate in the study as described in section 3.6. One qualified physiotherapist who was external to RSU was recruited to participate in the study. Informed consent was obtained from the therapist in advance.

Data collection for reliability study and initial validity study

Pilot testing was initially undertaken in the school of Healthcare Sciences where RTLS equipment was placed in physiotherapy lab areas. Using beds and chairs to replicate the RSU environment, 2 healthy subjects were asked to wear tags and undertake activities according to the script in Table 4.2 while the researcher gave instructions and noted the time with the ipad app. This helped standardise the protocol and design the visual display tool (Figure 4.3) that was eventually used to process the data. Following this, the researcher also undertook initial testing with two patients in the RSU using the activity script and ipad while the other PhD student from the school of Computer Science and Informatics tested the effectiveness of the data collection via the automated RMMS prototype.

After pilot testing to ensure smooth running of the procedure in the RSU environment, data collection was started in the RSU. Protocol standardisation is undertaken to minimise the external sources of variation and reduce the chances of random error (Portney and Watkins, 2009). Details of standardisation for the reliability and the initial validity study are as follows:

- The same rater (PhD student) took all the measurements for all patients.
- The same tags were used for data collection with all participants.
- The location where tags were placed on objects such as beds and chairs remained fixed.

- The chair in the day room was positioned at the same distance each time from the door of the Day room.

- The events in the script were followed strictly and all patients received the same instructions.

Tags were placed on the following patient related objects: under the bed mattress, on the seat of the bedside chair, on the walking aid (if used) and the wheelchair. Each participant was either assisted or supervised by the qualified physiotherapist. The physiotherapist wore the tag clipped on the uniform. Ten patients wore 3 tags each around their unaffected wrist and ankle.

The researcher gave instructions to the patients and the physiotherapist according to the script that was designed on the ipad as an app. All participants and the accompanying physiotherapist were asked to perform these actions in the exact sequence during data collection. The participants carried out the sequence of activities once.

As participants undertook tasks according to the script, data was automatically collected by the RMMS based on the tag signals. This data was used for the reliability study analysis. The patients wore 3 tags each on the wrist and the ankle, data from each tag was considered as one observation, thereby giving a total of 30 observations each for the wrist tags and the ankle tags respectively from 10 patients. For the initial validity study, as the participants undertook the tasks according to the script, the researcher observed and recorded the start time and finish time for each step on a stopwatch ipad app. The data automatically collected by the system and that from the stopwatch app was used for the initial validity study analysis (Figure 4.2)

Figure 4. 2 Data collection procedure for the initial validity study
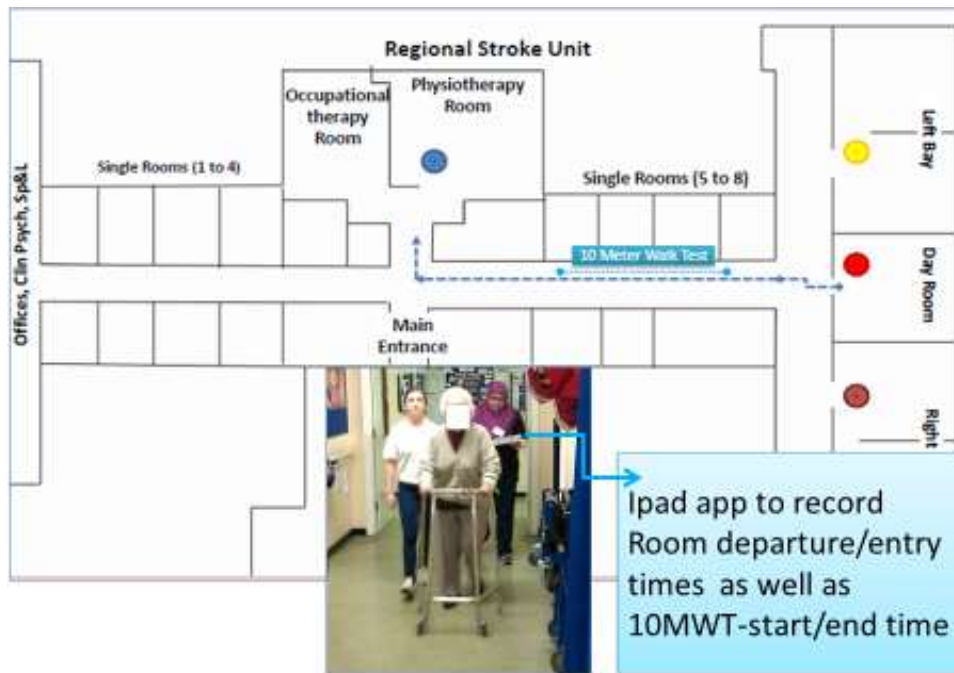
Data processing and parameter selection

Reliability Study

A customised software program was developed by computer scientists to visually

display the data collected and help with initial data processing.

The data displayed by the tool gave accurate information about tag motion and

location status in 2 second timeframes similar to a 'Gannt chart' (Figure 4.3).

Figure 4.3 represents a screen shot of the display tool that was used for data

processing. The tags are listed on the left hand side and the timeline is at the top

and bottom. Each location is colour coded with red for Day room, blue for

Physiotherapy room and black for those locations where no room locator signal was

present (corridor). The gaps between two locations reflect the time lag between the

tag losing the previous location code and picking up the new location code (between

2-4 seconds). The 3 wrist tags are UL1, UL2 and UL3 where UL means upper limb.

Similarly the 3 ankle tags are LL1, LL2 and LL3 where LL means lower limb. Tag

motion is represented as the thick blocks (examples; UL, LL, walking aid and staff

tags) while no motion is a thin line as seen for bed and chair and wheelchair tags.

Figure 4. 3 Screenshot of the display and processing tool used for reliability study data analysis
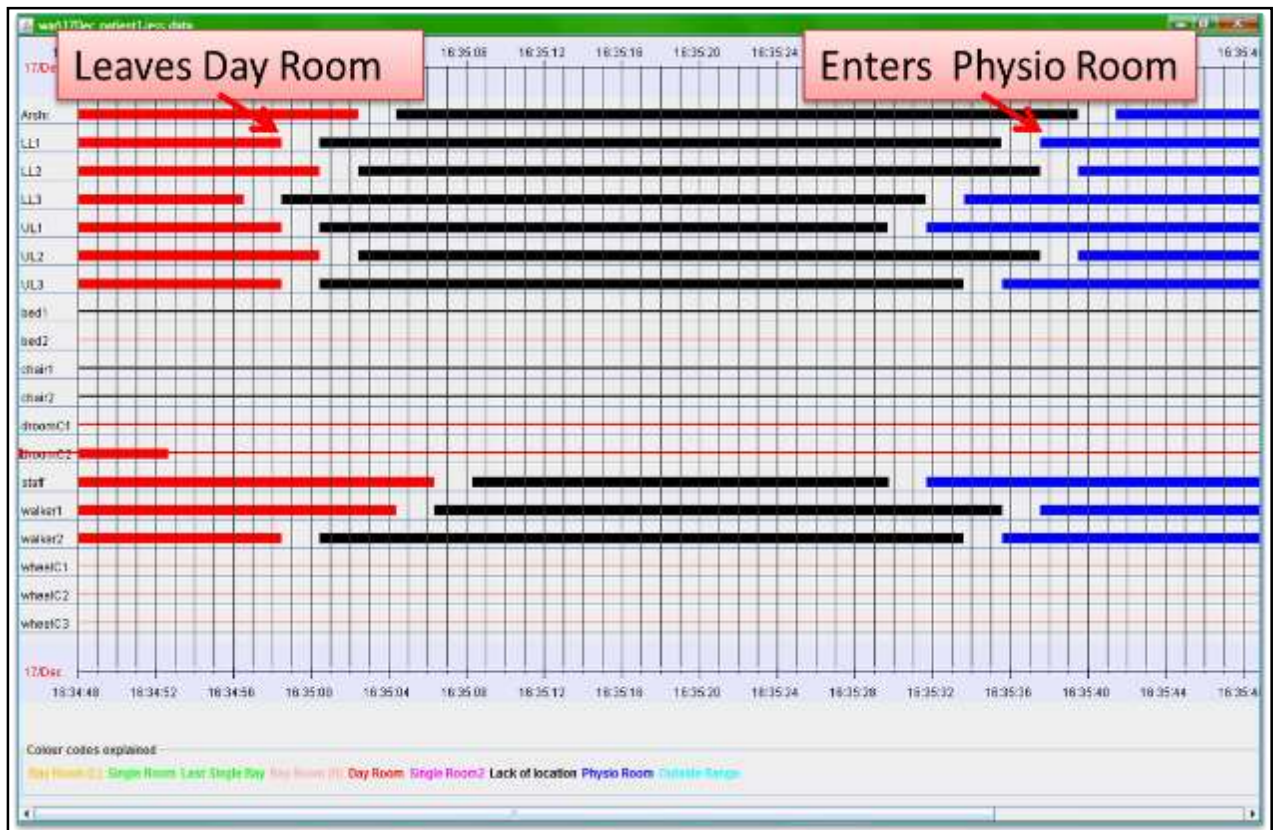
The time in HH:MM:SS reported by the tags when each activity started and stopped

was noted down using the display tool. The difference between the start and end

times was calculated to obtain the total time taken by the various tags when patients

undertook a certain movement or activity.

The first activity was the patients being transported from their **O**wn **R**oom (**OR)** to the

Day **R**oom **(DR)** in a wheelchair. The agreement between the time reported by

patient tags and wheelchair tags for this journey was evaluated as the 1st variable.

As the patients were sitting in the wheelchair, it was anticipated that the time points

of the tags when the wheelchair and patients entered and exited a room would overlap thereby making it possible to detect the use of wheelchair by the patient for mobility. To be able to quantify the accuracy of the system to detect this, the total time taken by the respective tags was used for statistical analysis. The same rationale was used for detecting use of walking aid by patients and detection of supervision/assistance by staff.

The next activity was patients walking from the **D**ay **R**oom **(DR)** to the **Phy**siotherapy **R**oom **(PhyR)** using a walking aid. They were assisted or supervised by the **H**ealth**C**are **S**taff (**HCS**). Based on the time taken to walk, 3 parameters were considered.

1. The reliability of the time reported by the wrist and ankle tags when walking from the DR to the PhyR.

2. Agreement between the time reported by the patient tags and the staff tag.

3. Agreement between the time reported by the patient tags and the walking-aid tags.

Initial Validity Study

Time in seconds reported by the rehabilitation mobility measurement system was compared to the time reported by manual observation for the select activities.

The variables used for analysis along with the related data obtained from RMMS and the ipad app stopwatch is given in Table 4.2 below.

Table 4. 2 Parameters selected for initial validation of RMMS

Parameter for analysis	Data from RMMS (via tag)	Data from ipad app stopwatch
1) **SSWS** in the corridor when walking from the DR to the PhyR (RMMS vs Observation) Calculated as: Distance (20 meters)/ Time in seconds taken to walk from DR to PhyR	Time when patient tag started to report PhyR location code minus the time when tag lost the DR location code.	Time when patient entered the PhyR minus Time when patient entered corridor. (Step 31 minus step 28).
2) SSWS by RMMS vs 10MWT speed	Same as above	Time when 10MWT ended minus time when 10MWT started (step 30 minus step29)
3) Time spent by healthcare staff in patient's room (RMMS vs observation)	Time when the staff's tag stops reporting OR location code minus time when the staff's tag starts reporting OR location code.	Time when healthcare staff leaves OR minus time when healthcare staff enters OR (step 8 minus step 2)
4) Time spent inactive in bedside chair by patient (RMMS vs observation).	Time when patient's tag stops reporting motion minus time when patient's tag starts to report motion	Time when therapist enters patient's room with wheelchair minus time when patient sits inactive in bedside chair (step 9 minus step 10).

4.1.2 Study design: Main validity study

The study was aimed at the determination of the validity of the RMMS as an automated tool for behaviour mapping of patients after stroke.

The main criterion related validity study was undertaken next. The RTLS based computerised system was compared with Behaviour Mapping; a known measurement of PA. Current evidence regarding this method has been reviewed in Chapter 2 section 2.4.6; hence it can be said that it functioned as a gold standard for comparison. The BM checklist used for this study was developed by (De Wit et al., 2005) called the **CERISE** tool. The collaborative work which led to the utilisation of the modified version of the CERISE tool has been discussed in section 3.2.

Inclusion and Exclusion Criteria

The inclusion criteria as follows:

-Diagnosis of a Cerebro-vascular accident (CVA)

- Either ischemic stroke or haemorrhagic stroke

The exclusion criteria was as follows:

-Previous history of stroke

- Other factors like cerebral palsy, Parkinson's disease or mental illness such as schizophrenia

Sample size calculations and recruitment

Criterion related validity of the new system was determined by comparing it with 'OBM' as a gold standard. BM is usually undertaken for 8 hours a day over a period of several days with many subjects as seen in Chapter 2 section 2.4.6. However the aim of this study was to use OBM as a gold standard method *for comparison* rather than for PA measurement. Hence it was decided that 10 subjects would be a sufficient sample size for the comparison as a total of 120 hours (7200 minutes) of data would be obtained in total for data analysis.

Recruitment: Patients were recruited from RSU following the same protocol as described in section 3.6.

Staff recruitment**:** Staff members from the RSU were recruited for the main validity study. All staff members were approached by the researcher and the study was explained. They were all given an information sheet and if willing to participate, they were asked to sign a consent form. After they had given written consent, they were asked to wear a tag on their uniform during working hours. More details about how their anonymity was maintained has been presented in Appendix 3. Staff members who were not willing to take part were not asked to wear the tag.

Data Collection

Standardisation of protocol was undertaken for the validity study.

One thing that needed to be done early on was to minimise ambiguity of observation and to record activity in its context as accurately as possible. It was decided that 'ground- rules' needed to be developed beforehand to record activity in its context and could also be followed during data collection and processing. Previous studies done by the CERISE authors were reviewed to help with this standardisation.

Additionally the authors of the CERISE tool were contacted to further understand the decision making behind noting down each observation. The idea was to obtain a manual which could provide the instructions as to how activity being observed should be interpreted in its context. This would help record observations in such a way that the subsequent data processing would be standardised and the observer's subjective bias could be minimised. Based on the CERISE manual and the instructions certain ground rules were created to standardise the protocol. These are given below:

- If the patient is involved in an Activity (active and/or passive), score the activity. If the patient is not involved in any activity, then score the position of the patient.

- The presence of the staff within the same room as a patient would be noted as 'supervised' Activity.

- Walking with a physiotherapist or a nurse would be categorized as 'physiotherapy' or 'nursing care'.

- The activity recorded would the one observed as soon the researcher observed the patient. The example used was one of a photograph. The question asked to record the observations appropriately was 'if a photograph was taken at this moment, how would you record what was in the photograph?'

- When location is therapy room, Activity is therapeutic and Activity type would always be recorded as supervised or assisted.

- When interaction is with staff (e.g. nurse)-Activity type would be recorded as supervised or assisted and Activity would be recorded as therapeutic (nursing care). This will be done for any location.

- Smoking would be recorded as passive leisure

- Dressing and hygiene includes bedside toileting

- Ask staff later about patient Activity if patient not visible at the time or if curtains were drawn around the bed

- Use 'other' category minimally

The time period selected for BM was 12 hours over two days between 7:00 am and 7:00pm. The 12 hours were sub-divided in four periods lasting 3 hours each. The observer walked along a fixed route every 10 minutes noting down observations on an ipad application designed to record observations. The CERISE tool was replicated as an Ipad application for data collection (Figure 4.4). The researcher undertook all the observations and manually input data into the CERISE app. It was then saved regularly and uploaded to a 'dropbox' folder. Dropbox, Inc is an internet based file hosting service where documents can be uploaded online using a personal account. Specific folders can be created on PCs or tablets to access and synchronise these documents. These files can be shared with other users as well. The data could be processed as a CSV data file as required. Initial piloting was done to refine the app and develop and test the ground rules. CERISE Tool App can be accessed using the link given below

http://users.cs.cf.ac.uk/A.D.Preece/sohcs/CerisePlus/

Figure 4. 4 Screenshots of the CERISE tool ipad app used for main validity study data collection
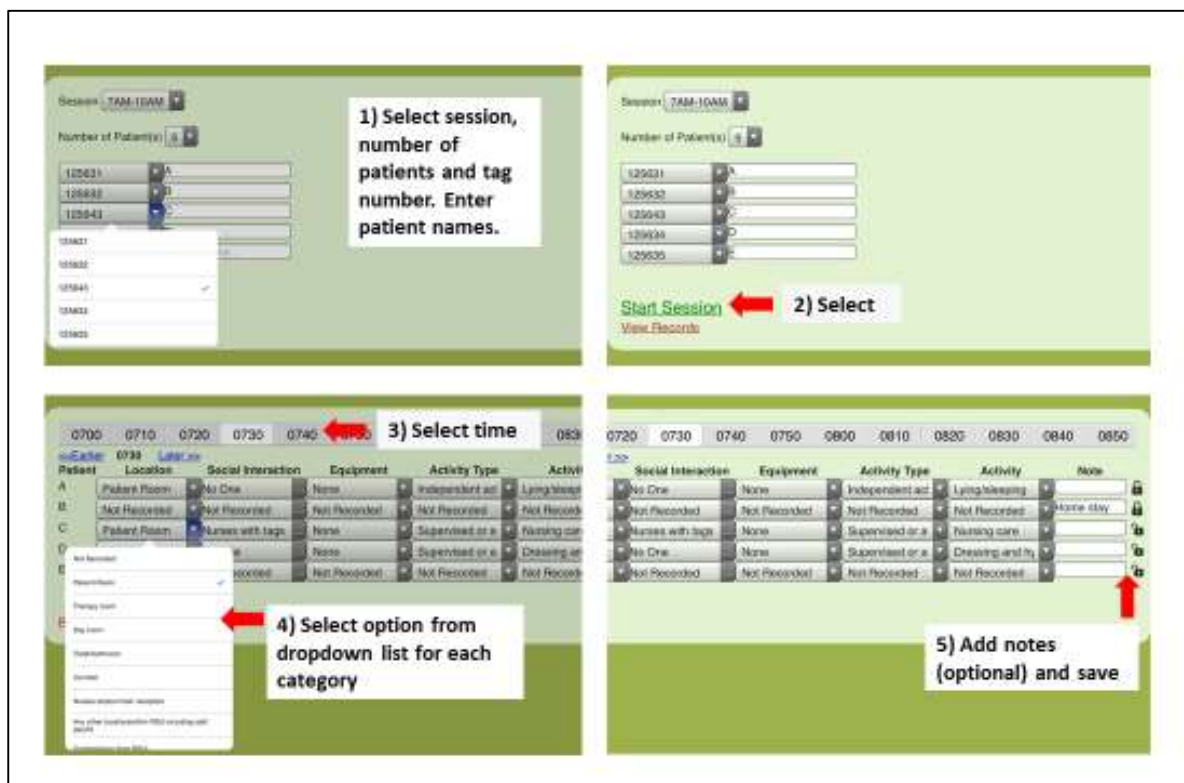
The data from RMMS was collected automatically via tags and was used for analysis.

Data processing and parameter selection

Total time taken for BM was 12 hours (720 minutes) per person. The variables selected for comparison with results from BM were based on the 2 main categories; Location and Activity.

Two variables were selected for the Location category; Percentage of time spent in physiotherapy room and percentage of time spent in patient's own room. The percentage was calculated as: Total time (in minutes) spent in room/ 720 minutes*100.

Three variables were selected for the Activity category. The first variable was frequency of ambulation events (covering short distances) which included walking independently or with a walking aid. Six observations were made every hour and a total of 72 observations were made per person over 12 hours. The frequency of walking reported via BM was compared against the frequency of change of location reported via tags. The second and third variables were percentage of time spent lying in bed and time spent sitting in bedside chair. For these measurements, the idea was to use the information from the motion sensors in the bed and chair tags along with that of patient tags to detect when the patient was in bed or sitting in bedside chair.

Additional software programs were created for data processing from the automated system. A customised rule based semantic system was created by computer scientists. In this system, raw data from the various tag sensors were combined and certain conditions or rules were set. These needed to be met for the correct interpretation of data. To simplify, these rules were analogous to 'if- then' statements. For example, for the calculation of time spent walking, certain criteria had to be met to derive the conclusion that the patient was walking. These conditions were; movement recorded from patient tag, movement recorded from the tag on a walking aid assigned for that patient and consecutive change in location which was identical for the patient as well as the walking aid tag. Hence in simple language it can be explained as:

"**IF** for a given time frame, patient tag was moving

AND IF the location of the tag changed from 600 to 400 to 703

AND IF the walking aid tag (belonging to patient) was moving

AND IF the location of the walking aid tag changed from 600 to 400 to 703
at the same time as the patient tag,

THEN interpret as walking for xyz seconds in duration"

For calculating the time spent lying in bed, the conditions that needed to be met were: movement recorded from patient tag, movement recorded from the tag on the bed, no movement of walking aid assigned for that patient, no movement of bedside chair and no change in location of any of the mentioned objects. Hence in simple language it can be explained as

"**IF** for a given time frame, patient tag was moving

AND IF the bed tag was moving

AND IF the walking aid tag (belonging to patient) was not moving

AND IF the bedside chair tag was not moving

AND IF the above occurred at the same time with no change in location

THEN interpret as lying in bed for xyz seconds in duration"

For calculating the time spent sitting in bedside chair, the conditions that needed to be met were: movement recorded from patient tag, movement recorded from the tag on the bedside chair, no movement of walking aid assigned for that patient, no movement of tag on bed and no change in location of any of the mentioned objects. Hence in simple language it can be explained as

"**IF** for a given time frame, patient tag was moving

AND IF the bedside chair tag was moving

AND IF the walking aid tag (belonging to patient) was not moving

AND IF the bed tag was not moving

AND IF the above occurred at the same time with no change in location

THEN interpret as sitting in bedside chair for xyz seconds in duration"

Software programs were developed for all parameters that needed to be analysed. A user-interface was designed to obtain the processed data. At first the software was designed for processing data to calculate time spent by patients in different rooms within the RSU i.e. from the location category. The user–interface allowed for selection of the date, timeframe, and the CSV sheet for that particular date and the specific patient tag. The results were displayed as a grid as seen in Figure 4.5.

Alongside the display grid, a location by location trace for the tag regarding its movement and location data was also displayed. The room locator signals from the single rooms dispersed into the corridor. This was almost like an electronic trail that could be followed as patients walked or were transported. Looking at the sequence of location codes displayed, an individual patient's walking behaviour could be mapped automatically and with ease. Any change in the location and movement status of the tag could be seen clearly as shown in Figure 4.6.

Figure 4. 5 Screen shots of the user interface designed for the main validity study data processing
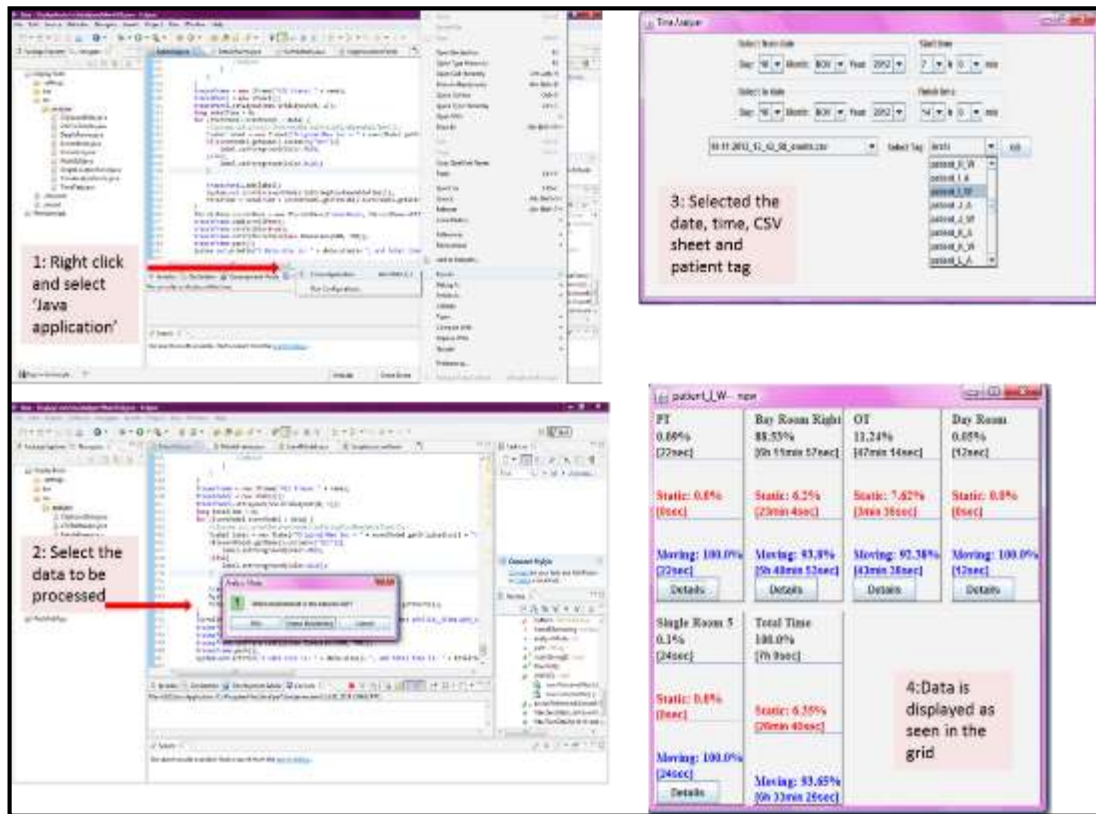
Figure 4. 6 Screenshot display of the results obtained post data processing for the main validity study
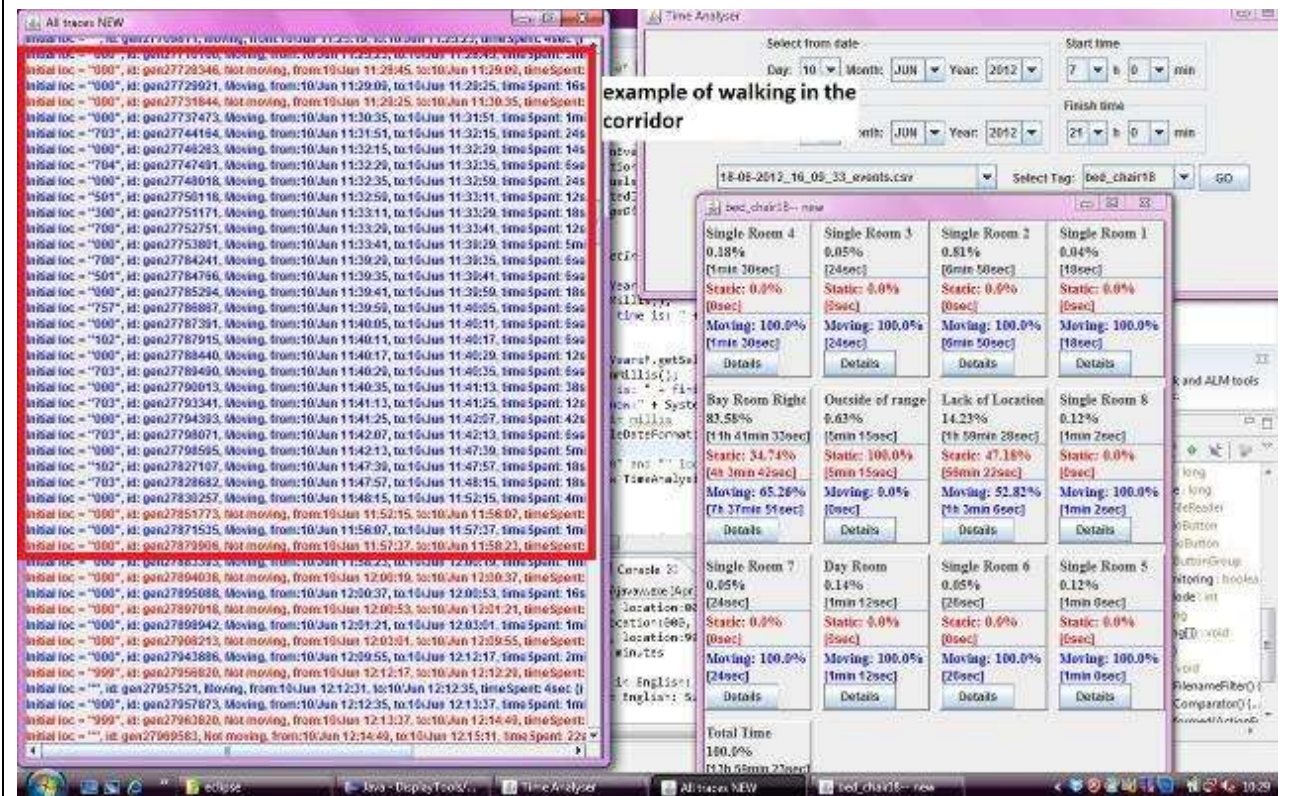
The second column refers to the sequential location codes that were reported by the wrist tag. The 4th column gives the movement status of the tag where movement is reported by the word 'moving' in blue and the stationary status is reported by the word 'not moving' in red. The start date and time at a particular location is displayed in the 5th and 6th columns respectively. The end date and time at that particular location is displayed in the 7th and 8th columns respectively. Finally the time spent in movement or no movement at that location is given in the last column.

The IR waves (and the location codes) from the RL that dispersed out into the corridor are seen in the Figure 4.7. With respect to the example given above by coordinating the sequence of location codes displayed it can be deduced that the patient started walking from the right bay, going all the way down the corridor to the opposite end and then coming back into the right bay.

Figure 4. 7 Example of the dispersion of IR waves from the room locators into the corridors
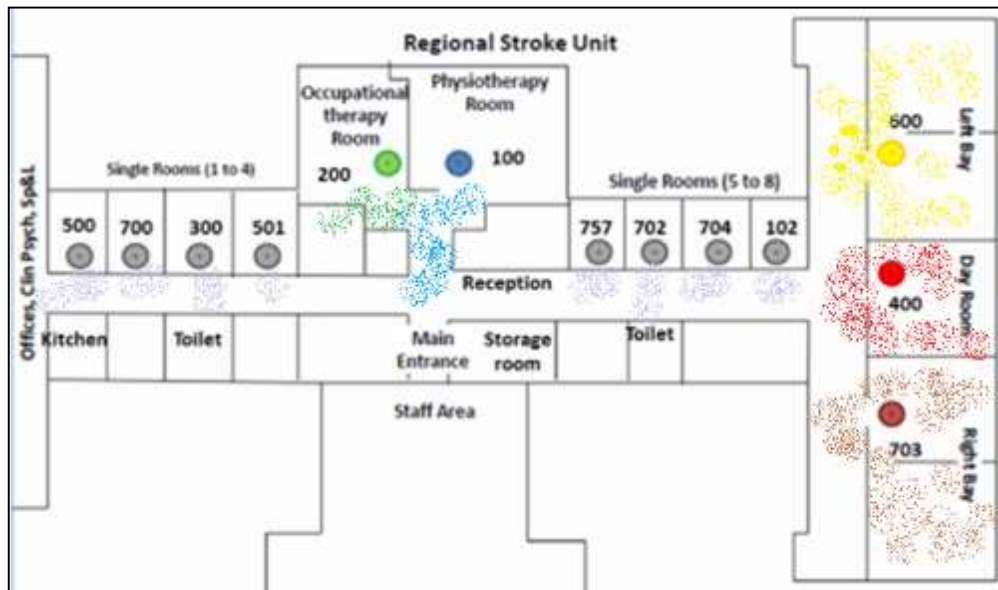
703 Right bay;600 Left bay; 400 Day room;
100 Physiotherapy Room; 200 Occupational Therapy room;
500 Single room 1; 700 Single room 2; 300 Single room 3; 501 Single room 4;
757 Single room 5; 702 Single room 6; 704 Single room 7; 102 Single room 8

4.2 Data analysis

Graphs and charts were plotted in Microsoft Excel except B&A plots which were made using IBM SPSS statistics version 20. The other statistical analysis was undertaken with SPSS.

Reliability Study

Relative reliability was tested to determine the system's ability to effectively differentiate between the scores for each subject and determine the subjects' positions in relation to each other from those with the highest scores to those with the lowest scores. ICC $_{(3, 3)}$ a two way mixed models of consistency were used for

relative reliability analysis. The values set for ICC were based on the guidelines in the literature (Walter et al., 1998, Portney and Watkings, 2009).Portney and Watkins (2009) also suggest that an ICC value of above 0.60 represents good reliability. These are displayed in Table 4.3

Absolute reliability was tested using standard error of measurements to know the exact variation between scores on repeat measurements. To obtain the value of SEM, a repeat measures ANOVA was calculated for the 3 wrist and 3 ankle tags. The mean square error (MSE) value was noted and the SEM was calculated as square root of MSE value. SEM was the most appropriate test to obtain measurement error when 3 or more scores are being used (Weir, 2005).

For reporting agreement between patient tags and staff tags which were only two scores, B&A plots were obtained as it is also sensitive to systematic bias or heteroscadicity in the data (Bland and Altman, 2010). 95% LOA were calculated using the equation

95% LOA = Mean difference±2 standard deviation of the difference.

Validity study (initial validity study and main validity study)

Pearson's Correlation Coefficients were used to determine the strength and direction of the relationship between the scores obtained by two systems of measurement. The closer the PCC value is to 1, the stronger is the correlation. As per Portney and Watkins (2009), the criteria for interpretation of values is set as shown in Table 4.4 To compare the automated system with gold standard methods for activity monitoring B&A 95% LOA method was chosen. This method was specifically designed to look if one method of measurement could replace another.

Table 4. 3 Intraclass Correlation Coefficient values and their interpretation

ICC values	Interpretation

0.2 to 0.4	Fair reliability
0.41 to 0.60	Moderate reliability
0.61 to 0.80	Substantial reliability (good)
0.81 to 1.00	Almost perfect (excellent)

Table 4. 4 Pearson's Correlation Coefficient values and their interpretation

Values (positive or negative)	Interpretation
0.0 to 0.25	Little or no relationship
0.25 to 0.50	Fair relationship
0.50 to 0.75	Moderate to good relationship
> 0.75	Good to excellent relationship

4.3   Results: Phase one

The 1st study in the developmental phase of this 2 staged project included the reliability study investigating the ability of the RMMS to measure patient PA in a rehabilitation unit. The results from the 3 sub-studies; the reliability study, the initial validity study and the main validity study are presented in this chapter.

All sub-studies for the developmental phase and the main parameters selected for analysis are displayed in Figure 4.8. The parameters' link with the individual items under the ICF category of mobility are given in Table 4.5**.**

Figure 4. 8 Summary of the parameters used in stage 1 sub studies for analysis
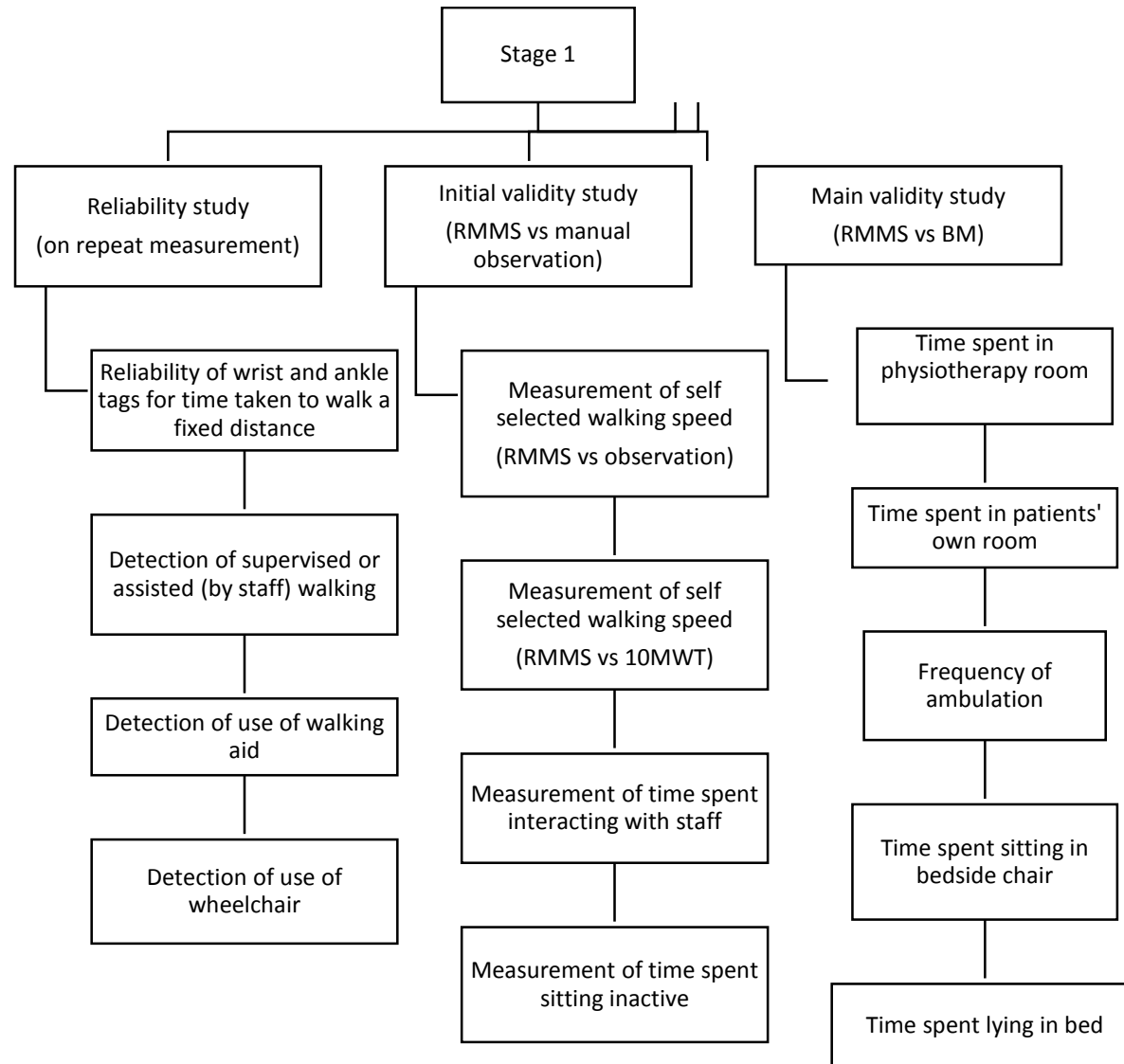
Table 4. 5 Link of stage 1 study parameters with ICF-mobility categories and the representative CERISE categories

	Parameters	Link with ICF 'mobility' category	CERISE category represented
Reliability Study	Time taken to walk a fixed distance	D450*	Activity
	Detection of use of walking aid use of wheelchair	D465 Moving around using equipment	Activity
	Detection of supervised or assisted (by staff) walking	N/A	Activity/Interaction
Initial Validity Study	Measurement of SSWS: system vs observation system vs 10MWT	D450 D4601 Moving around within buildings other than home	Activity
	Time spent sitting inactive (system vs observation)	D415 Maintaining body position	Activity
	Time spent by staff in patient's room (system vs observation)	N/A	Activity/Interaction
Main Validity Study	Ambulation Frequency (system vs BM)	D460** D4601 Moving around within buildings other than home D410 Changing basic body position	Activity
	Time spent sitting in bedside chair (system vs BM) Time spent lying in bed (system vs BM)	D415 Maintaining body position	Activity
	Time spent in Physiotherapy room (system vs OBM) Time spent in own room (system vs OBM)	D460	Location
	*D450 Walking **D460 Moving around different locations		

4.3.1 Reliability study

Ten patients participated in the reliability study; male and female participants in equal numbers (Table 4.6). Seven patients used a walking aid while 3 could walk independently.

Table 4. 6 Patient demographics for the reliability study

F=5,M=5	Mean	Std. Dev	Min	Max
Age in years	77.90	10.22	64	91
Days since stroke	46.70	38.69	6.00	139

The first event used for analysis was time taken to walk from one room to another when using a walking aid and accompanied by a staff member.

1) Reliability of the patient tags

The times (in seconds) reported by the wrist and ankle tags when walking from DR to PhyR are given in Table 4.7.

Table 4. 7 Time taken (in seconds) to walk from the Day room to the Physiotherapy room

Tags	Mean	Std. Dev	Min	Max
ankle1	64.80	49.30	22.00	190.00
ankle2	61.10	48.48	16.00	180.00
ankle3	60.70	53.23	.00	173.00
wrist1	57.60	52.00	14.00	194.00
wrist 2	55.80	42.87	14.00	160.00
wrist 3	55.30	46.62	14.00	172.00

Table 4. 8 Reliability of patient tags

Tags (time taken to walk from DR to PhyR)	ICC $_{(3,3)}$ with 95%CI	SEM (seconds)
Wrist Tags(3)	0.98 (0.99 to 0.94)	± 6.79
Ankle Tags (3)	0.90 (0.97 to 0.76)	± 15.76
Wrist and ankle	0.99 (0.99 to 0.92)	± 14.37

Almost perfect reliability was obtained for all tags (ICCs≥ 0.90). The SEM appeared to be within acceptable limits with the wrist tags more accurate than the ankle tags (Table 4.8).

2) Agreement of patient tags with staff tags and with walking aid tags

The times taken by the various tags are given in Table 4.9.

Table 4. 9 Descriptive statistics for patient tags, staff tags and walking-aid tags

Tags	Mean (secs)	Std. Dev	Min	Max
Ankle tag average	62.20	48.71	21.33	181.00
Wrist tag average	56.23	46.99	14.00	175.33
Staff tag	46.20	40.90	20.00	154.00
Walking aid tag average	52.81	40.01	19.00	143.00

All PCCs were ≥ 0.98 indicating excellent significant correlation ($p<0.01$) for time taken to walk from the DR to the PhyR. It appeared in the B&A plots (Figures 4.9, 4.10) that the patients took longer than staff as well as the walking aids to walk the distance. This may be due the staff and equipment tags being in a better position to pick up PhyR location code signals. This along with the probable outliers could account for the larger 95% LOA.

Figure 4. 9 B&A plot for agreement between patient tags and staff tags

Yaxis: Difference(wrist tag time-staff tag time) ;Xaxis: Average (wrist tag+stafftag/2)
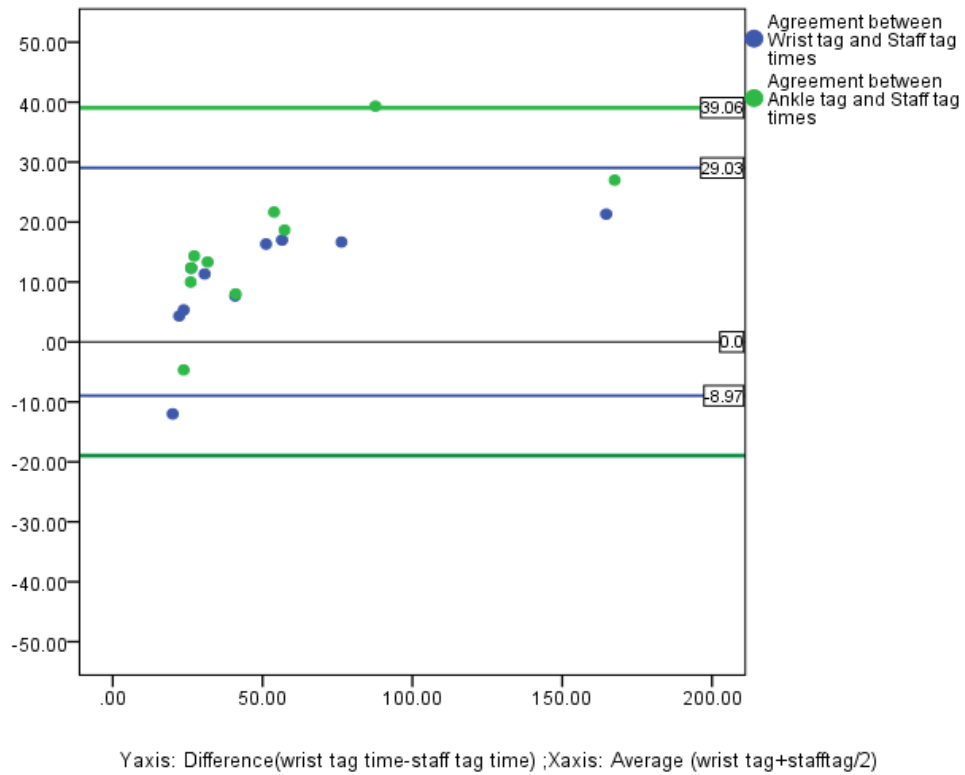
Figure 4. 10 B&A plot for agreement between patient tags and walking aid tags

Y axis: Difference (wrist tag - walk.aid tag); X axis: Average (wrist tag+walk.aid tag/2)
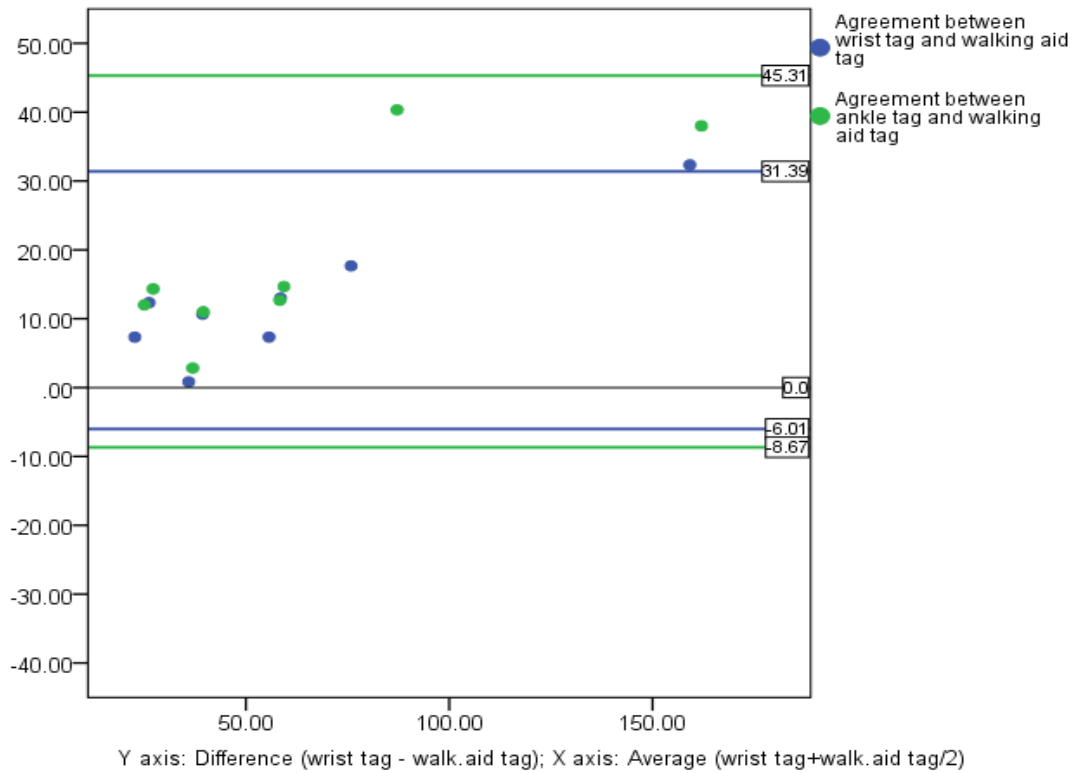
3) Agreement between patient tags and wheelchair tags

The time taken by the patient tags and the wheelchair tags to travel from OR to the DR was analysed. The PCC value was 0.99 (p=0.01) and the 95% LOA were between + 3 seconds and -7 seconds. Therefore it could be said that there was excellent significant correlation between the patient and wheelchair tags with narrow 95% LOA.

4.3.2 Initial validity study

Based on the time taken to walk from DR to PhyR, SSWS were calculated and used for analysis (Table 4.10).

Table 4. 10 SSWS in the corridor and the 10MWT

Speed in m/sec	Mean	Std. Dev	Min	Max
SSWS RMMS	0.55	0.37	0.11	1.41
SSWS observation	0.38	0.21	0.09	0.86
10 MWT speed	0.48	0.25	0.11	0.96

Walking speed comparisons

1) Corridor SSWS

Excellent significant correlation was obtained between the RMMS and observation speeds (PCC = 0.99; p value significant at 0.01 level) which was significant at 0.01 level. There appeared to be systematic bias observed in the B&A plot (Figure 4.11) where SSWS by RMMS was greater than that by observation. Moreover there was a trend observed wherein the bias increased as the average speed increased.

On further exploration it was found that the systematic bias was due to the RL signal dispersions. The time taken to walk from the DR to the PhyR reported by the system was less than that reported through observation. As the IR waves from RLs have a tendency to disperse outside the rooms into the corridor (Figure 4.12), the patient tags continued to report the Day room location code *after* the patient had crossed the door of the Day room and started to report the Physiotherapy room location code *before* the patient had walked up to the Physiotherapy room door. In comparison, the

leaving and entry times recorded by manual observation were the time points when

the person was observed exactly at the doors of the Day room and the

Physiotherapy room respectively. As the distance variable remained the same for

SSWS calculations, the decrease in the time variable led to an increase in the

system measured SSWS.

Figure 4. 11 B&A plot for agreement between RMMS and observation for corridor SSWS
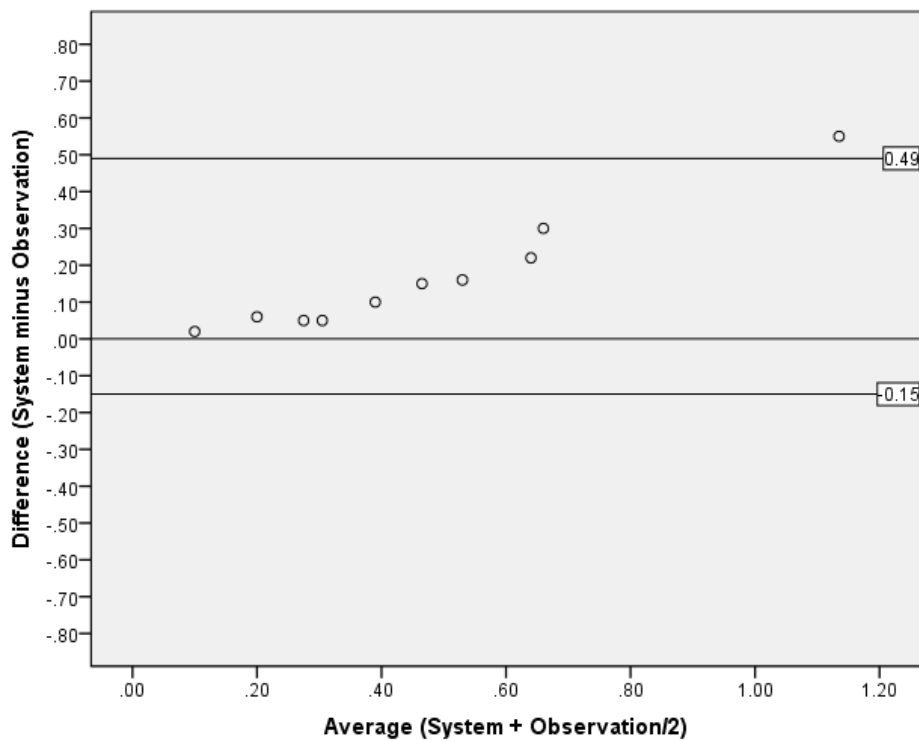
Figure 4. 12 Example of dispersion of IR waves outside Physiotherapy room and Day room
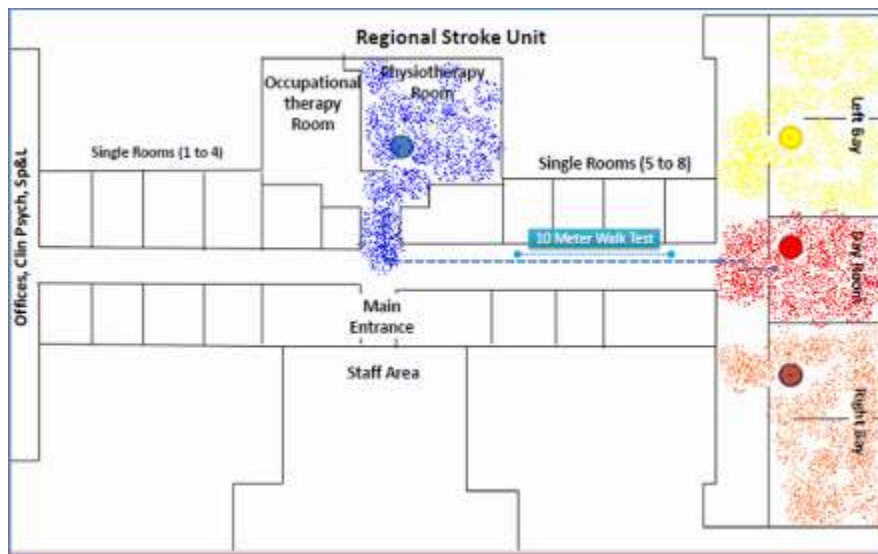
2) SSWS via RMMS with 10MWT

Average speed and the standard deviations obtained from the system and via 10MWT were similar (Table 4.6). The PCC was 0.96 (p=0.01) suggesting excellent correlation between the measurements obtained by both methods. The B&A plot appeared to show minimal dispersion with narrow 95% LOA (Figure 4.13).

Figure 4. 13 B&A plot for agreement between SSWS via RMMS and 10MWT speed
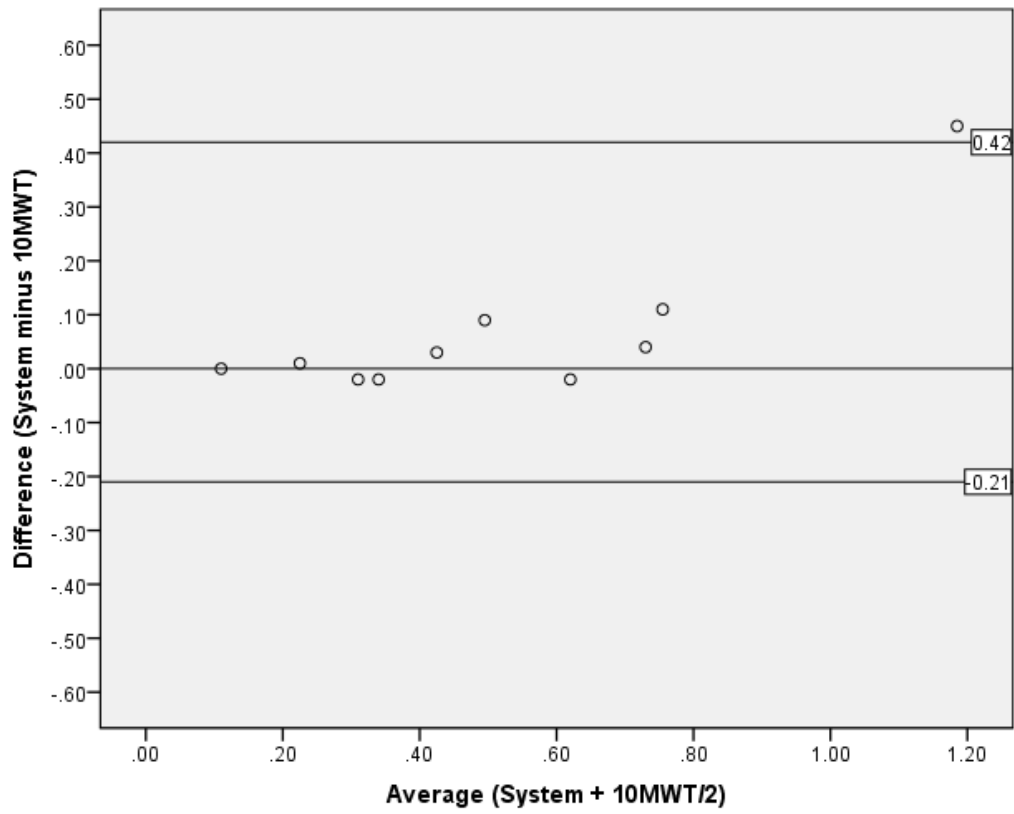
3) Time spent by healthcare staff in patient room

Table 4. 11 Time (in seconds) spent by staff in patient room

Method	Mean (seconds)	Std. Dev	Min	Max
RMMS	58.50	28.70	22.00	119.00
Observation	63.10	20.14	30.00	100.00

The mean difference between the methods of measurement for this variable was 5 seconds (Table 4.11). The PCC value was 0.37 (p >0.05) suggesting fair non-significant correlation between the methods. The 95% LOAs appeared wide (Figure 4.14). Hence it cannot be said accurate measurement of time spent interacting with HCS was obtained by RMMS.

4) Time spent sitting inactive in chair

Table 4. 12 Time (in seconds) spent sitting inactive in chair

Method	Mean (seconds)	Std. Dev	Min	Max
RMMS	57.33	34.27	15.00	131.00
Observation	93.10	23.77	69.00	139.00

The difference between the measurements obtained by the 2 methods was 36 seconds (Table 4.12).The correlation seemed fair (PCC= 0.46) with p> 0.01. The inactive time measured through the system was consistently less than that measured through observation (Figure 4.15). The bias may be systematic and was because of the motion sensor within the tag was extremely sensitive. Hence though the patients were not doing any activity, even a simple flicker of the wrist was picked up by the

motion sensor and recorded. This could explain the weak insignificant correlation

and low level of agreement between the two methods.

Figure 4. 14 B&A plot for agreement between RMMS and observation for time spent by staff in patient rooms
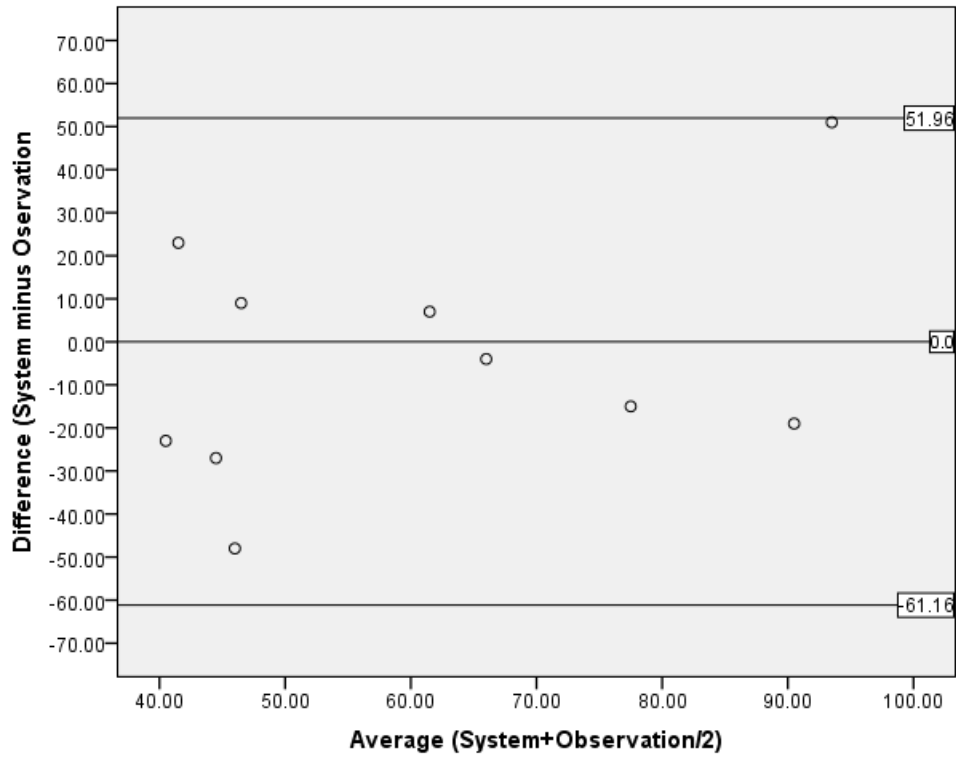
Figure 4. 15 B&A plot for agreement between RMMS and observation for time spent sitting inactive in chair
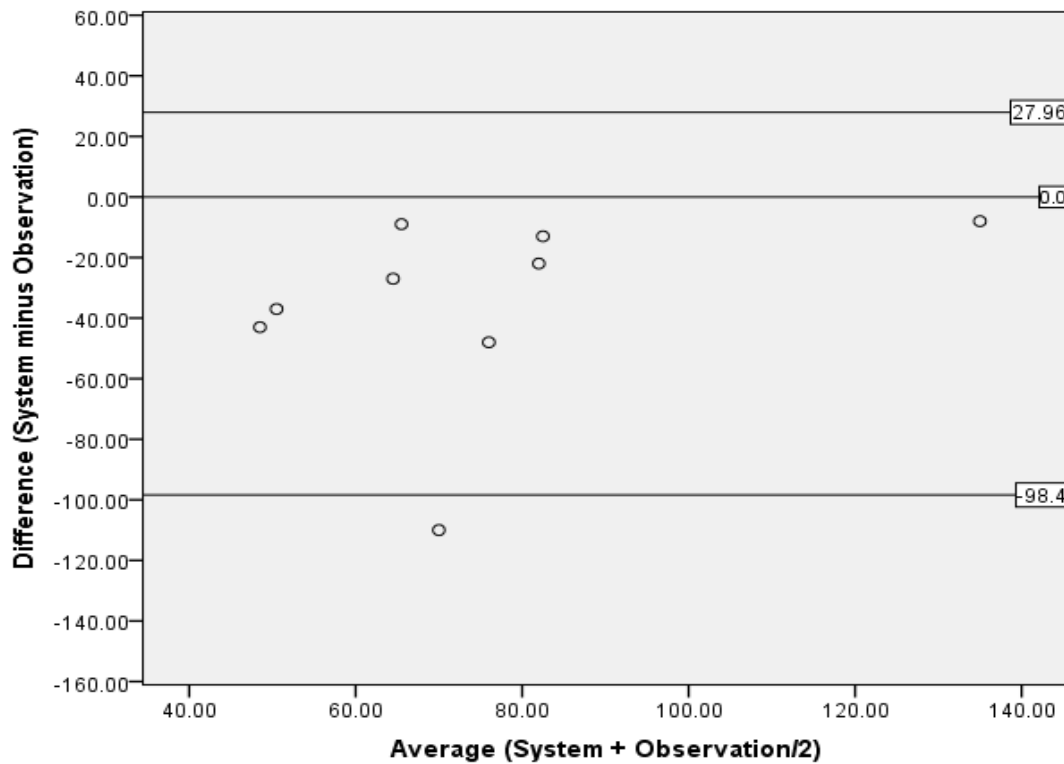
4.3.3 Main validity study

10 patients were included in the study (Table 4.13). Their FAC scores ranged between 0 and 4 and both the median and the mode were 0. For data processing, the patient wrist tags were selected as the reliability study suggested that the wrist tag was more accurate.

Table 4. 13 Patient demographics for the validity study

F=4,M=6	Mean	Std. Dev	Min	Max
Age (years)	66.50	16.46	32.00	87.00
Days after stroke	81.60	66.91	20.00	255.00

The data from the RMMS was obtained on a day to day basis for each patient as explained in section 4.1.2. The data from BM was also saved as CSV files and

179

duration for time spent in each location was calculated from the sheet. An example
of the output obtained for BM is given in Figure 4.16.

Figure 4. 16 Example of the raw data obtained from BM undertaken in main validity study

Results for the 'Location' category

Total time spent in Physiotherapy room

The mean difference between RMMS and BM measurements was <1 minute
(RMMS=48.90$\pm$42.80, BM=48$\pm$39.94). The PCC was 0.99 with p= 0.01. The 95%
LOA were +10.24 to - 8.44 minutes.

Total time spent in patient's own room

On calculating the total time patients in their own room, there was a mean difference
of 87 minutes noted between the two systems (RMMS=482.40$\pm$181.47,
BM=569$\pm$139.55). The PCC was 0.53 and it was not significant. The B&A 95% LOA
ranged from +405.78 to - 232.58 indicating fair correlation and low agreement
between methods.

Consequently the data obtained for both methods were explored and it was found that there were occasions when according to BM records patients were observed in their own rooms while the tags reported a '000' location code for the same patients at the same time. The location code of '000' stood for 'lack of location' (or unidentifiable location). '000' is reported when the patients are still within RSU but on scanning the environment for RL signals, the tags do not pick up any IR location code signals from a RL. This can happen in two circumstances; a) if the patients are in an area not covered by a RLs such as toilets or staff offices or b) if there is an obstruction between the RFID tags and the IR waves from the RL. For example; if the wrist tag is hidden under a blanket or if the patient is asleep with the hand under the pillow, the tag would be unable to pick up the infra-red signals and subsequently report a location code of '000'. For the validity study data, the time for which the patient tags reported a lack of location signal was fragmented, with each event not lasting more than 1 minute. Moreover it was also interspersed with the patient wrist tag reporting the location code of the patient's own room. As most of these patients had an FAC score of ≤1, any ambulation out of the patient's room would have required assistance from one or more staff members and it was anticipated that such an activity would take longer than a few seconds. It was therefore concluded that the lack of location time was due to the absence of a direct line of sight between the tag and room locator rather than the patients being in an office or a toilet.

The initial computer science rule written for data processing for time spent in each location can be simply explained as follows

IF tag reports location code '000' from (12:27:00) to (12: 29:00)

THEN display 'lack of location' for 2mins (End time – start time) in HH:MM:SS'

The above code was modified to ensure that the location code of '000' which was interspersed with other location codes was appropriately dealt with and that the lack of location category was accurately defined. It was decided that if the patient tags reported the location code 000 for some seconds and the preceding and subsequent location codes represented another room such as their own room, then the code 000 will be replaced by the same code as the previous one.

The revised code can be explained as follows

> **IF** tag reports location code '000' from (12:27:00) to (12:29:00)
> **AND IF tag reports location code '600'* from (12:25:00) to (12:27:00)**
> **AND IF tag reports location code '600' from (12:29:00) to (12:35:00)**
> **THEN** display 'left bay' for 10mins (12:35:00 – 12:25:00) in HH:MM:SS'
> * location code for left bay

Additionally an exception to the above code was defined. This rule was to be followed for all location codes except when the location code was '999' and when the time duration for which the tags reported '999' was for more than 20 minutes. Location code of '999' stands for when the tags are out of range of the reader and if patients were out of range for more than 20 minutes, it would be because they had left RSU. This logic based software programming code was implemented for the data processing and analysis software for all location categories.

Following the application of this rule the data was reanalysed. The 95% LOAs for time spent in PhyR further improved and were -6.7 to +9.7.and the PCC remained the same. For time spent in patient's own room, the mean difference between the

systems was 1 minute and there was excellent significant correlation between them (PCC=0.99, p=0.01) with narrow 95%LOA ($\pm$34 minutes)

Results for the 'Activity' category

Three parameters were considered for analysis; frequency of ambulation, time spent sitting in bedside chair and time spent in bed

Frequency of ambulation

From the RMMS data (obtained in a Microsoft Excel format) the number of times patients walked was counted (Table 4.14) where each 'walking' event seen in the first column was counted as 1. From the BM data, change in location between two successive observations was counted as 1. The rationale was that patients have to walk or be transported if a change in their location was recorded for a subsequent observation (Table 4.15).

Table 4. 14 RMMS data: select timeframes when patient was measured as walking (columns 1, 5 and 6)

	location	Patient	equipment	Start time	End time	Total time	secs
Walking	**600 000 102**	patient_O_W	nil	**15/May 07:50:17**	**15/May 07:51:25**	1min 8sec	68
Walking	**102 702 704**	patient_O_W	walk_aid_O	**15/May 09:20:33**	**15/May 09:23:17**	2min 44sec	164
Walking	102 000 702 757 000 100	patient_O_W	walk_aid_O	15/May 09:48:21	15/May 09:53:19	4min 58sec	298

Table 4. 15 Behaviour mapping data: select time frames when patient was observed changing location (4th Column)

Tag	date	Time	Location	Interaction	Equipment	Activity type	Activity
125 643	15/05/12	730	**Patient Room**	No One	None	Independent activity	Sitting
125 643	15/05/12	740	**Toilet/bathroom**	Nurses with tags	Not Detectable	Supervised or assisted activity	Dressing and hygiene
125 643	15/05/12	750	**Toilet/bathroom**	Nurses with tags	Not Detectable	Supervised or assisted activity	Dressing and hygiene
125 643	15/05/12	800	**Patient Room**	No One	None	Independent activity	Dressing and hygiene
████							
125 643	15/05/12	920	**Patient Room**	No One	None	Independent activity	Sitting
125 643	15/05/12	930	**Toilet/bathroom**	No One	Walker	Independent activity	Dressing and hygiene
125 643	15/05/12	940	**Patient Room**	No One	Walker	Independent activity	Standing

The frequencies obtained from both methods were compared. To further confirm the accuracy walking events recorded from RMMS the second by second trail of patient's movement and location signals were also examined (explained in Chapter 4, Figure 4.7) following which the results were obtained.

Table 4.16 below gives the number of ambulation events recorded. Six patients out of 10 were found to walk or be transported during the time of data collection for the validity study.

Table 4. 16 Frequency of ambulation

Patients	System	Observation	Ambulation events undetected By	
			System	Observation
1	19	14	0	5
2	2	2	0	0
3	5	5	0	0
4	2	2	0	0
5	5	5	0	0
6	4	2	0	2
Total	**37**	**30**	**0**	**7**

It appears that there were a total of 7 ambulation events which were undetected by BM the reasons for which can be explained. In BM, the observations were undertaken and recorded every 10 minutes and it is possible that the more mobile patients could have walked a short distance within this period such as walking from the Day room to the left bay and back. However these events may not have been observed by the researcher if the researcher was in another area of RSU. It is also possible that these events although observed could not be recorded due to the 10 minute restriction. The automated system however was free from these restrictions as tags automatically would have reported the change in location. Moreover, the data obtained was cross-checked with a second by second history of the tag traces. It is also important to point out that the reliability of the system had been sufficiently and rigorously investigated by then. Hence the difference of 7 events was accepted

with ease. It can also be said that for detecting ambulation, the automated system seemed not only comparable *but better than* BM.

Time spent sitting in chair and lying in bed

Data analysis for these variables was not undertaken as the collected data could not be processed with accuracy.

4.4 Discussion - phase one

Reliability study

The results indicated that the reliability of RMMS via tags was almost perfect (ICC>0.90) for reporting the time taken to walk from one room to another. The wrist tags were more accurate than the ankle tag based on the ICC and SEM values. Wrist tag data was used for further analysis.

On comparison of patient tags with staff and walking aid tags, PCC values were also almost perfect (r ≥0.98) and the 95% LOAs were wide which could be due to tag location and outliers. Although the reliability study was undertaken within a short period, continuous data collection for the main longitudinal study was to be processed over weeks and months and hence these 95% LOAs were considered acceptable.

Thus it was concluded that the system was able to reliably measure and detect activities such as supervised/assisted ambulation, use of walking aids and use of wheelchairs. All tags could reliably detect and report motion and location signals and the tags could be used on objects effectively.

Based on the findings all further analysis was undertaken using data from the wrist tags.

The results indicated that the presence of healthcare staff and use of walking aids and wheelchair could be reliably detected, parameters for the initial validity study and the main validity study were selected accordingly. For the initial validity study, time spent by staff in patient's room was selected as a parameter. For the main validity

study time spent in various rooms in RSU and the frequency of ambulation was selected.

Initial validity study

The results obtained from the initial validity study suggested that RMMS is able to measure SSWS. The large LOA could be attributed to the presence of outliers, the protocol for manual observation and the nature of the equipment used. It could be said that different aspects of gait recovery could be potentially measured. Moreover dispersion of IR signals outside of rooms needed to be managed or utilised as an advantage.

For the parameter 'time spent by staff in patient's room' there was poor agreement noted between the time measured by RMMS and observation using stopwatch app (PCC r=0.37, B&A 95%LOA=±60 seconds) where the average duration of time spent by staff in patient room was 63 seconds. This was due to the dispersion of IR waves into the neighbouring areas from the room locators placed in patient rooms. Therefore the patient tags started to report the patient room location codes before they entered the door and continued to report the patient room location code even after they had left the particular room. The error of 60 seconds out of a total of 63 seconds was considered as too large to be able to use RMMS for quantification of patient –staff interaction time over a complete waking day. Also it became obvious that in Bay rooms which were 8 bedded units it would be practically impossible to pin point exactly which patient was interacting with the staff member. This could also get more complicated if more than one staff member was present at a time. Therefore although it was possible to detect patient-staff presence in the same area as seen in

the reliability study, duration of interaction with staff (including supervision or assistance by staff for ADL) could not be measured.

Similarly time spent sitting inactive in chair was not sufficiently correlated (PCC r= 0.46 B&A 95%LOA= -98 to +27 seconds) where the average duration of time spent sitting inactive was 93 seconds. It can be said that RMMS could not accurately measure this parameter as well as the OBM.

One of the main reasons for analysing these parameters in the 1st stage was to get to know the system in greater detail and judge its ability to detect such activities. These results were therefore considered relevant for the planning and execution of the subsequent studies.

As the tag motion sensor was very sensitive, it was decided that the information bed and bedside chair tags could be utilised to determine whether the amount of time spent lying in bed or sitting in chair could be used as a parameter for the main validity study instead of quantifying time spent sitting inactive which was not accurately detected.

Also, it was decided that parameters related to 'Interaction' such as time spent alone or time spent in presence of HCS could not be used for the main validity study and therefore parameters related to 'Location' and 'Activity' were used instead.

Validity study:

The RMMS was comparable to BM for detection of 'Location' parameters. On comparison with BM a high level of agreement was obtained for measurement of time spent by patients in therapy room and in their own room (PCC r=0.99) with narrow B&A 95%LOA. The development of new computer program codes that were

used for further analysis enabled the correct processing of the data and helped fine tune the system to be used as an outcome measure. This emphasises the need to use computer science generated sensor-based programming code in order to work efficiently with RMMS. The dispersion of RL codes in the corridor was utilised as an additional feature of the automated system to get beneficial information to map activity patterns of patients in the RSU environment.

With respect to the parameters for the 'Activity' category, RMMS appeared to very accurately quantify the frequency of ambulation. Time period selection was such that activity was observed at different times over an entire day. Thus it can be said that the signalling and the data collection by system was tested at different time points and remained unaffected by factors such as the number of people around during busy periods and the location of patients in different areas of RSU.

However the amount of time spent in bed or bedside chair was not easily measurable by the system. This was because of the high sensitivity of the tags to motion as mentioned previously (section 4.3.2). For the software development, the motion information from the bed tag was used. The notion was that when the tag under the bed or the bedside chair would cease to report movement once the patient had transferred out of them. However due to low movement detection threshold , the tags under the vacant bed or chair continued to report very low intensity of motion throughout which in turn made it difficult to detect whether someone was using them or if there was just 'noise'. Therefore it could not be interpreted whether the patient was sitting in bed or lying in bed when both objects were moving and these variables were not used for the longitudinal study. Thus RMMS needs to be used in combination with other sensors such as pressure sensors to detect better when the patient is using a bed or chair.

4.4.1 Implication of results on longitudinal study

All the results obtained from the reliability study and validity study were used to inform the studies in phase 2 which were the longitudinal study, the acceptability study and the home pilot study. Therefore 'valid and reliable detection' and 'frequency of occurrence' became factors based on which the longitudinal study parameters could be prioritised for data processing and analysis.

Frequency of occurrence: Data collected using the CERISE tool during the main validity study was examined. The most frequently occurring Activity, Location and Interaction were noted down. This also ensured that the software codes that were being developed could be validated against observed data to confirm that accurate interpretations were being made by RMMS.

From Figure 4.17 it can be seen that out of a total of 720 observations in the Activity category, sitting and lying were most frequent, but they were ruled out for data processing as they could not be effectively measured by the RMMS in its current form. Frequency of 'transfers' which also made use of data from bed and chair was ruled out for similar reasons.

Location could be measured with most precision and all parameters were retained (Figure 4.18). It was important to focus on time in patient's own room and out of 720, the number of times patients were observed in their own room was 573.

With respect to Interaction, although it could be seen that during the time of BM patients spent a lot of time on their own (Figure 4.19) it was noted that variables related to Interaction could not be sufficiently validated in the 1st stage of the study. Hence these parameters were not selected for further analysis.

Figure 4. 17 Frequency of occurrence of each activity from CERISE BM in validity study
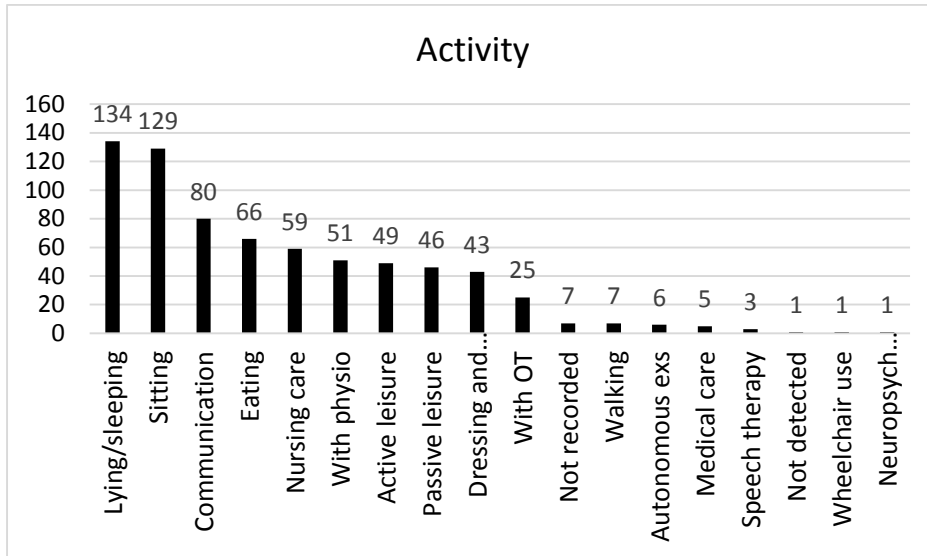
Figure 4. 18 Frequency of time spent in each location from CERISE BM in validity study
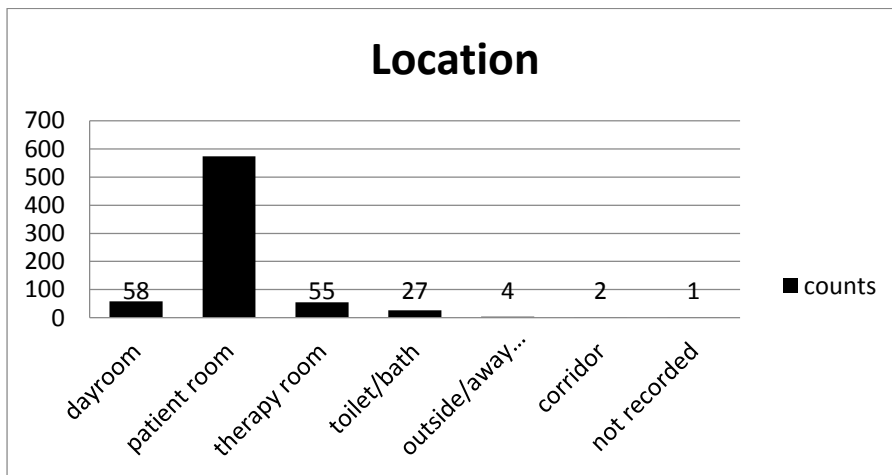
Figure 4. 19 Frequency of interaction from CERISE BM in validity study
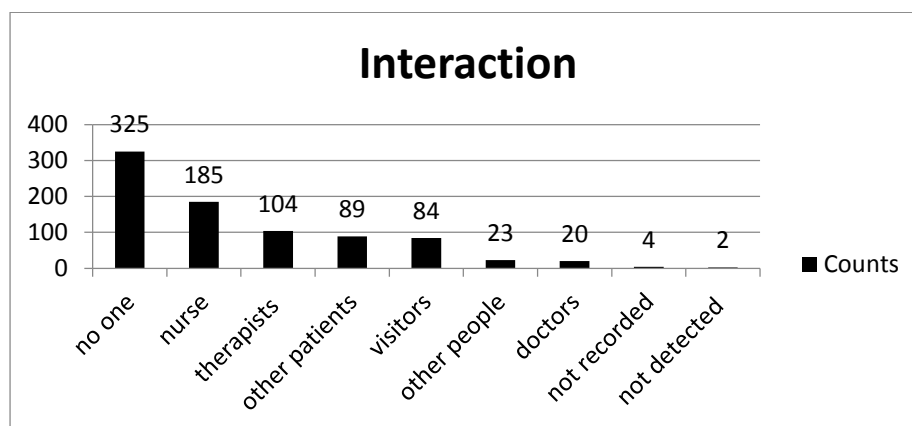
Reliable and valid detection: Results from stage one sub studies were also taken into account to prioritise parameters for longitudinal study data processing. Table 4.17 shows the results from the sub studies.

Table 4. 17 Characteristics of Phase 1 study variables

Study	Parameters	Link with ICF 'mobility' category	CERISE category representation	Reliable/valid detection with RMMS
Reliability Study	Time taken to walk a fixed distance	Y	Y (Activity)	Y
	Detection of use of walking aid and wheelchair	Y	Y (Activity)	Y
	Detection of supervised or assisted (by staff) walking	N/A	Y (Interaction)	Y
Initial Validity Study (RMMS versus Observation)	Measurement of SSWS	Y	Y (Activity)	Y
	Measurement of time spent sitting inactive	Y	Y (Activity)	N
	Measurement of time spent by staff in patient's room	N/A	Y (Interaction)	N
Main Validity Study	Frequency of ambulation	Y	Y (Activity)	Y

(RMMS versus BM)	Time spent sitting in bedside chair and time spent lying in bed	Y	Y (Activity)	N
	Time spent in Physiotherapy room Time spent in own room	Y	Y (Location)	Y

Software advancement

As opposed to the reliability and the main validity study where data processing was less time consuming and was undertaken with 10 subjects, for the longitudinal study, data processing for variables needed to be undertaken repeatedly for 52 patients and therefore efficiency was important.

During the joint meetings between collaborators, it was decided that the data processing software had to be advanced and 3 main user requirements were addressed as follows: the ability to query the database in such a way that raw data for multiple patients on one given day could be obtained, the ability to process data for more than one parameter at a time and the ability to directly save the raw data as CSV files.

Therefore an advanced user interface was created where data for multiple patients could be obtained for many parameters simultaneously (Figure 4.20). Moreover as opposed to processing data for single days or some hours per day, data could be collectively processed for weeks or months at a time which made further analysis highly efficient.

Figure 4. 20 Screenshot of advanced user interface designed for subsequent longitudinal study data processing
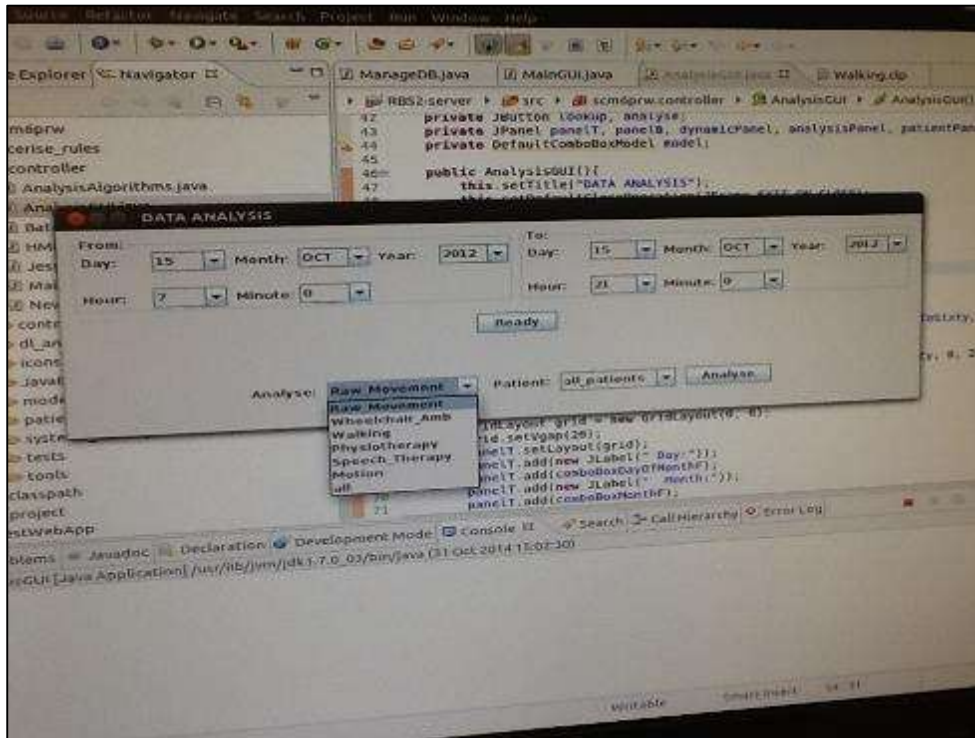
5. Phase Two: Longitudinal Study

In this stage of the project the main longitudinal study was undertaken in the RSU to measure PA from admission to discharge.

Participants' views on user friendliness of wearing the tag and on long term measurement were explored in the acceptability study. Subsequently a smaller pilot study was conducted to measure patient PA post discharge when they went home. Both these are presented in Chapter 6. The longitudinal study design and protocol along with the data collection and processing methods are given below. This is followed by the results.

5.1 Study design: Longitudinal Study

The aim of this study was to measure physical activity levels of patients using RMMS.

The main longitudinal study was undertaken subsequent to the developmental phase where the systems reliability and validity had been sufficiently determined. This meant that the developed tool was capable of continuous, repeated measurement of PA in the RSU. For the longitudinal study, the main focus of measurement was the tags worn by the recruited patients. The information from these tags along with the information from the other tags (equipment tags, staff tags) in the patients' environment was collected with RMMS

Routine clinical OMs were also used at admission and discharge and post discharge to measure mobility and activity levels of patients. The intention was to obtain

primary information from the system and use the clinical OM scores to gain a better in-depth understanding of functional recovery in a rehabilitation setting.

Inclusion-Exclusion Criteria

The inclusion criteria was as follows:

-The study included all patients with:

-Diagnosis of a Cerebro-vascular accident (CVA)

- Either ischemic stroke or haemorrhagic stroke

The exclusion criteria was as follows:

-Previous history of stroke

- Other factors like cerebral palsy, Parkinson's disease or mental illness such as schizophrenia

Sample Size calculation and recruitment

The aim was to determine a sample size which would enable exploration of changes over time thereby indicating recovery rather than to achieve statistical significance. To meet this aim, a sample of 50 patients was deemed realistic and appropriate for the longitudinal study. The RSU is a 24 bedded unit and it was possible to achieve the required sample size over an 18 month period. Following discussions with RSU staff it was determined that per annum 100-200 patients were admitted and over 66% of these were discharged home. Anticipating that 5% of these patients would be lost, to achieve a sample size of 50 patients for the main longitudinal study, a participation rate of ± 30% was needed.

Recruitment

Patient recruitment: Patients were recruited at RSU following the protocol mentioned in section 3.6.

Staff recruitment: Staff members who were working at RSU during the time of undertaking the main validity study and were recruited for the main validity study continued to participate in the longitudinal study if they were willing. New staff members were approached by the researcher and information was given to them about the project. They were recruited for the longitudinal study after informed consent was obtained from them.

Data collection

A cohort of participants was followed and measured continuously over an extended period of time.

Patients were recruited and data collection was started within 3 to 7 days of the patients being admitted into the unit. Data was automatically collected using RMMS via tags placed on equipment and worn by patients and staff members as described in Chapter 3 section 3.4.

During the period of data collection, the researcher visited RSU twice a week regularly (Mondays and Thursdays). The following tasks were carried out on these days to minimise data loss and ensure smooth functioning of data collection:

- Check the system was working and data was being collected.
- Save previous weeks data as a CSV file every Monday and restart the system
- Check via the room locator tag signals that all room locators were switched on.

- Speak with RSU staff regarding new admission or potential discharge due in that week. Ask if there were any concerns regarding the project.

- Examine the tags worn by the patients to ensure that they were not tight and there was no skin damage or circulatory problems.

- In case a walking aid was assigned to a patient it was tagged and the date was noted.

- If the patient was moved to another room, the approximate date of this transfer was noted for record keeping.

Apart from that, their demographic details and co-morbidity factors were noted. OMs were used and scores noted for assessment of the patients.

There were 2 clinical OMs, the Functional Ambulation Category (FAC) and the Motor Assessment Scale (MAS) that were used by physiotherapists in the RSU and apart from those a set of other OMs were chosen to assess the patients (Holden et al., 1984). Three main points considered for selection of the OMs were their psychometric properties, whether they were used in UK and their link with ICF framework. The selected OMs and the exact point of time when they were used is given in Table 5.1.

Table 5. 1 Other clinical measures and outcome measures used for patient assessment at different time points from admission to post discharge

Time Scale	Measurements Collected
Within 72 hours of admission into RSU	• Type and severity of stroke • Co-morbidity factors, • Time in acute care in days • Demographic details: age and sex • Outcome measures: modified Rankins scale, FAC, Motor Assessment Scale (MAS), BI(Collin et al., 1988), mRMI (Lennon and Johnson, 2000)
Within 72 hours before discharge	Length of stay, discharge destination • Outcome measures: modified Rankins scale ,FAC, MAS, BI, mRMI, Timed up and go test (TUG) (Podsiadlo and Richardson, 1991),10MWT, Hospital Anxiety and Depression scale (HADS) (Zigmond and Snaith, 1983)
4 weeks post discharge home	• Outcome measures: BI, mRMI, TUG, 10MWT, Nottingham Extended activities of daily living Scale (Nouri and Lincoln, 1987) (NEADL), HADS
6 months post stroke at home Or End of 4 months if still in RSU	• Outcome measures: BI, TUG, 10MWT,NEADL,

Data collection software: A user interface was created by the PhD student from the School of Computer Science and Informatics. The user interface was used to manually start or stop the system, retrieve the data collected and save it as a CSV file. In order to regularly check the data being collected, to minimise any data loss and to have sufficient internal memory space, the decision was taken to restart the system on a weekly basis. Having a purpose-designed dashboard on the screen meant that this could be done efficiently by the researcher without disrupting the data collection for more than 10 minutes. This is seen in Figure 5.1.

Figure 5. 1 Screenshot of the 'dashboard' used for longitudinal study data collection
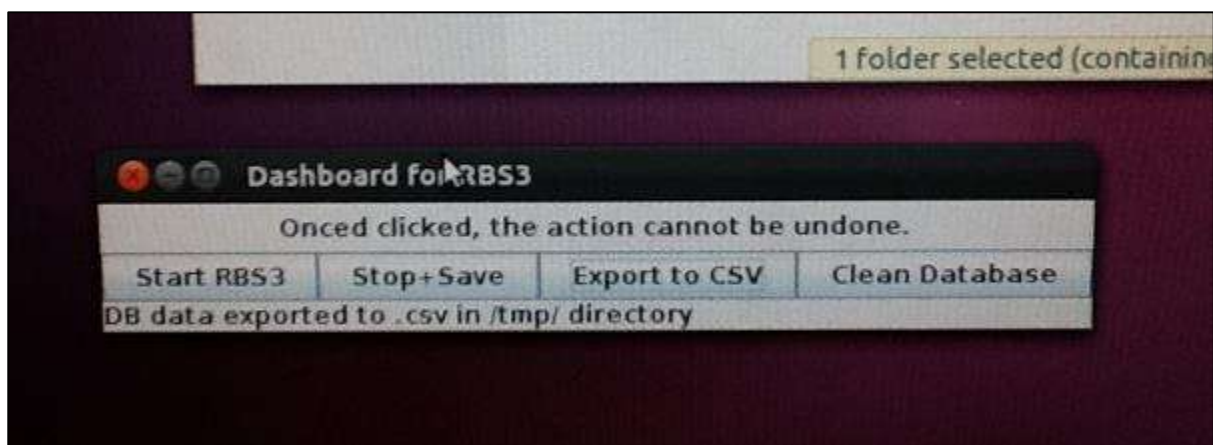
More features were added to this dashboard to ensure accurate tag assignment. The database contained the ID numbers of all tags allocated to people and equipment and if other tags were used to replace missing or lost tags, the new tag ids could be easily changed using the features of the dashboard.

Parameter selection

The longitudinal study was the major part of the research project and the results obtained would be key in answering the original research question for this project.

Much thought was given to the selecting the variables for data processing and several points needed to be considered for making this selection.

The parameters had to be related to the ICF component of Activity especially those that comprised of the 'Mobility' category. Due to the fact that s stroke recovery is a complex process and differs for every individual the variables needed to be generic and measurable on all patients *regardless* of the severity of stroke and related clinical factors.

Their ability to reflect the milestones of functional recovery was also an important factor and he parameters needed to have some level of hierarchy with respect to recovery of functional activity after stroke.

For example from lying in bed for long periods of time the next stage would be progression to sitting, and finally to walking.

Additionally the selected variables needed to be   related to those that would be measured for the home pilot study.

The parameters that were selected initially as categorised using the CERISE categories are given in (Table 5.2).

Table 5. 2 Longitudinal study parameters and the representative CERISE categories

Parameters	Cerise Category

1) Time spent lying/sleeping in bed
 	
2) Time spent sitting out of bed
 	
3) Transfers (bed to chair)
 	
    3a.With hoist (turn disc)
 	
    3b.Independent
 	
4) Gait recovery
 	
    4a.Walking : Walking with aid/Walking independently
 	
    4b.Wheelchair mobility
	Activity

4c.Transport	
5)Time spent in patient's own room 6) Time spent out of room 7)Time spent in therapy room 8) Time spent in Day room	Location
9) Time spent alone 10)Time spent with healthcare staff	Interaction

As mentioned in Chapter 4, section 4.4, the final list of parameters for the longitudinal study was informed by the results of the studies undertaken in the developmental phase. Consequently, out of 12, 7 parameters were retained for the longitudinal study data analysis (Table 5.3).

Table 5. 3 Parameters shortlisted for longitudinal study

Cerise Category	Parameters
Location	1. Time spent in patient's own room 2. Time spent in other areas of RSU 3. Time spent in Physiotherapy room 4. Time spent in Occupational therapy room 5. Time spent in Day room
Activity	6. Walking with aid/ independently 7. Wheelchair mobility 8. Transport

Standardisation of protocol

This was undertaken primarily for data reduction and data simplification by **a)** accurately defining the 'monitoring frame' which refers to the number of days required for accurate measurement of activity and **b)** by deciding to exclude certain days of measurement to improve accuracy and to efficiently process data. The various decisions made for standardisation and the justification behind the same are described below.

Use of weekly average scores for analysis: In order to measure parameters from admission to discharge, it was decided that scores will be processed on a weekly basis for the patients instead of on a daily basis. This type of data reduction was important as the average number of days on which measurements were made for the 52 subjects was 64 days and change in data over weeks would be easier to measure and provide more meaningful results rather than on a day to day basis.

Use of weekday scores: It was also decided that data from working days only (Monday to Friday) would be used for analysis as therapeutic rehabilitation was not undertaken on weekends and this could affect the duration and frequency of activities such as walking and use of other rooms apart from patient's own room. Also, as patients sometimes either went home for the weekend or were away on day leave, it would have been necessary to exclude those weekends from analysis to prevent their effect on the weekly average. The task to identify these particular weekend days manually would be time consuming and not practical for future studies.

Determination of monitoring frame: For weekly average score to be used it was important to determine the number of days required per week to reliably measure mobility parameters (Tudor-Locke et al., 2002). The amount of time (in minutes) spent in patient's own room over a 14 hour period was the selected parameter. To include a sample that adequately represented different patient groups, 8 subjects each were chosen from 3 categories; patients discharged home (n=8), patients discharged to a nursing/residential home (n=8) and patients who spent less than 10 days in RSU (n=8). Data from working days for week 1 and week 5 respectively was selected for analysis. ICC $_{(3, 1)}$ with a two way mixed model of consistency was used.

The average age of these 24 patients (male=4, female=19) was 81±7 years.

The ICC values for both weeks were ≥0.80 as seen in Table 5.4.

Table 5. 4 Within week reliability of time spent by patients in their own room for week 1 and 5 (descriptive statistics and ICC values)

Week	Mean	Standard Dev	ICC (with 95% CI)
Week 1	87.69	17.92	0.92 (0.85 to 0.96)
Week 5	89.75	13.31	0.80 (0.66 to 0.91)

The repeatability of scores across 5 days is substantially reliable as the ICC scores obtained are above 0.75. This could mean that across a given week the percentage of time spent in patient's own room from one day to the next is repeatable. Based on the analysis, scores obtained from any one day of the week were considered representative of the weekly average of time spent in own room. Therefore, in case of missing data or exclusion of certain days analysis could still be undertaken without compromising the accuracy of the weekly average scores.

Exclusion of days based on tag movement: It was determined in the first stage that the data collection software used for RMMS data could be undertaken over months in a rehabilitation setting. There were however practical issues with wearing the tags. There were incidences when the tag on the wrist came off and was put on the side table near the patient's bed. In such cases, the tag continued to report the location code for the patient's own room however the movement reported was less in duration. When data was being processed retrospectively, it was difficult to determine whether the low movement duration was because the tag had been taken or fallen off the wrist or if the patient had been inactive for the day(s) due to other medical reasons which is why the tag reported less movement. The fact that location

code for their own room was being reported throughout, it was very plausible that if they were unwell the patients had remained in their own rooms for the whole time. Moreover RMMS is an automated system and it was not possible to subjectively distinguish between the two conditions; one being that the tag had come off and the other being that the patient was very inactive. To resolve this issue and standardise the approach for analysing all future parameters, a minimum acceptable limit was set for duration of movement based on the data already collected. If the total duration of movement was found to be below this value, the day would be excluded for analysis. Exclusion of days was appropriate because it has been seen above that a minimum of 1 day was representative of the week. Hence even if certain days were excluded, the reliability of the data for the week would remain uncompromised.

The smallest acceptable duration of movement was established based on the data analysis as described. Out of 52, 11 patients were identified where it could be confirmed from the observational notes that their wrist tags were not worn for a certain number of days. The duration of movement reported by the tags for the specific days when the tags were not worn was calculated in hours and minutes. The duration of movement form the wrist tags from the same 11 patients was calculated when the tags were worn by them and descriptive statistics were obtained for comparison. The average movement reported by the 11 wrist tags when they were not worn was 41.3±36.8 minutes (minimum=5 minutes, maximum=158 minutes). The total number of days used for these calculations was 41. The average movement reported by the same 11 wrist tags when the same patients were wearing them was 597±104 minutes (minimum = 233, maximum= 796). The number of days used for these calculations was 98. It can be seen that the maximum time reported by the tags when they were not worn was 158 minutes (2 hours 30 minutes) whereas the

minimum duration of movement when tags were worn was 233 minutes (3 hours 53 minutes) (Figures 5.2 and 5.3).

Figure 5. 2 tag movement when not worn   **Figure 5. 3 tag movement when worn**
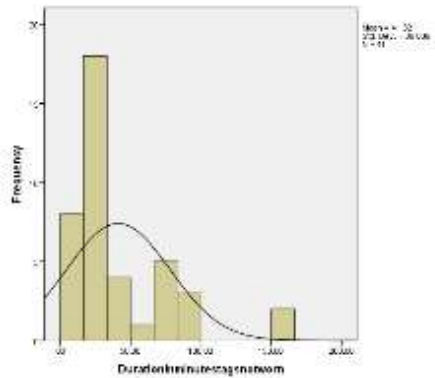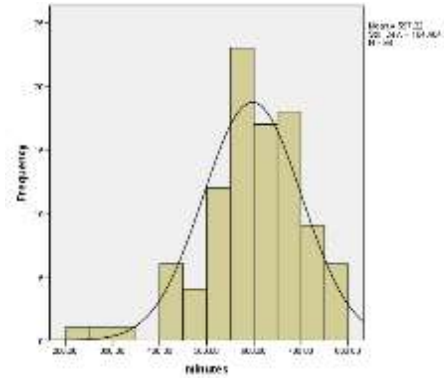
Therefore it was decided that if the tag motion was ≤2 hours for a certain day, the day would be excluded from the analysis. Hence the smallest acceptable duration of movement was set as 2 hours or 120 minutes.

Data processing for longitudinal study

Time period selected for analysis was 7:00am to 9:00pm (14 hours) per day. Data from the first and last day of measurement in the RSU were ignored because it was difficult to note down the exact times when the tags were assigned or taken off.

For any specific variable, total time per day was noted down and percentage was calculated out of 840 minutes.

Programming codes were developed by the School of Computer Science and Informatics to be written for each parameter selected for the longitudinal data processing.

Specific data processing techniques for each parameter of the longitudinal study are given in sections 5.2.1 to 5.2.3 before the results.

Data analysis

Descriptive statistics were used for initial inferential data analysis. Kolmogorov-Smirnov and Shapiro-Wilk tests were used to check if the data met the assumption of normality and the p value was greater than 0.05. If the data were normally distributed, paired samples dependent t-test was used for comparison between admission and discharge scores, otherwise the non-parametric equivalent which is the Wilcoxon Matched-Pairs Test was used (Field, 2009).

5.2 Results: Longitudinal Study

The longitudinal study data collection was undertaken over a one year period. Data was continuously collected 24 hours a day, 7 days a week from the point of admission to discharge for 52 patients. More details are presented in Figure 5.4 and Table 5.5

Figure 5. 4 Flowchart depicting patient participation in longitudinal study
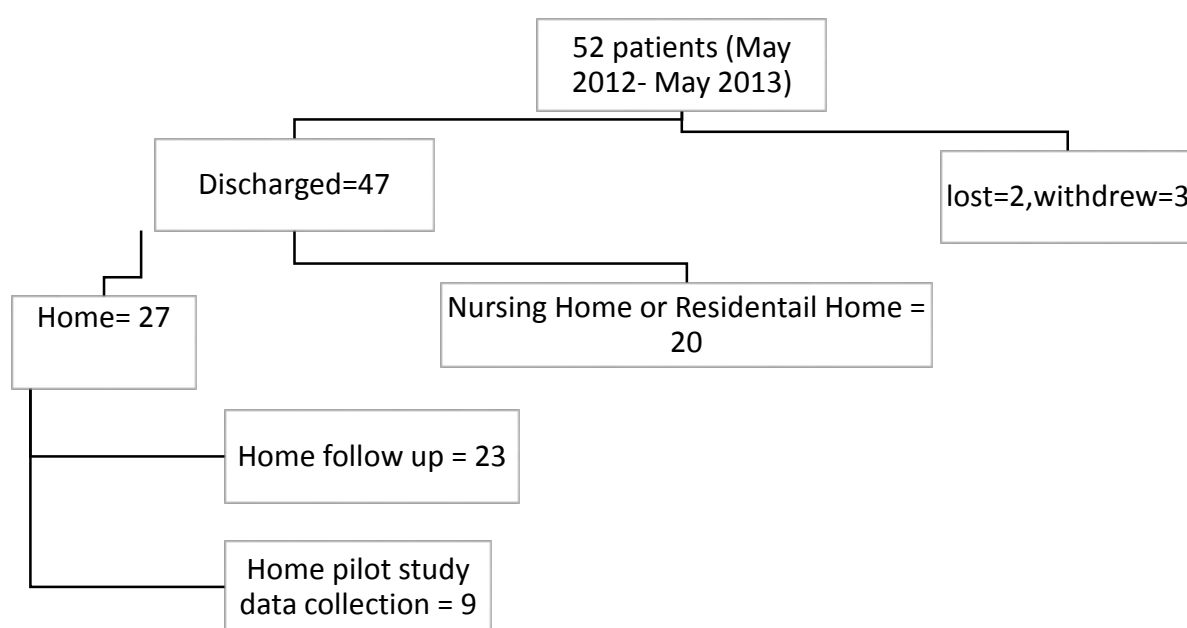
Table 5. 5 Patient demographics for longitudinal study

Females = 41, Males = 11	Mean	Std Dev	Min	Max
Age in years	78	11.4	32	93
Days post stroke	17	15.2	1	69
Length of stay in RSU	94	77.28	7	462
Follow up days	64	53.62	6	260

The main results related to PA measurement given below are average duration of mobility and exploration of functional recovery.

5.2.1 Duration of mobility

Duration of mobility consisted of time spent in being transported using steadies, using a wheelchair, and walking. The 3 variables are inter-linked and changes in any one of them could have an effect on the other two. For example as the ability to walk improves, it can be expected that the use of wheelchair and/or transport using a steady could decrease. Another possibility can be that a patient may be able to walk distances of less than 10 meters and therefore uses the wheelchair for longer distances. In this case although walking duration remains the same, passive transport may be expected to decrease as wheelchair use increases. These examples illustrate that recovery of function can vary for patients after stroke. Also, PA is influenced by demographic details, nature of stroke and other co-morbidity factors. Hence, all 3 parameters were studied in relation to each other to get a better understanding of recovery of mobility. The analysis was undertaken with formulae given below.

> The time frame of 14 hours (7:00 am to 9:00 pm) was selected for data processing and working days (Monday to Friday) were used.
>
> Average daily walking duration = Total seconds spent walking in that week **/** the number of days walking was observed in that week.
>
> Average daily duration of transport =Total seconds spent in transport in that week **/** the number of days transport was observed in that week.
>
> Average daily duration of wheelchair mobility = Total seconds spent in wheelchair mobility in that week **/** the number of days wheelchair mobility was observed in that week.

Higher level sensor-based programming codes:

The key conditions required to enable correct detection, measurement and interpretation of variables that involved patients changing locations and moving around were laid down to interpret and measure duration of walking, of wheelchair mobility and of transport for analysis in the next chapter. The main objective of this action was to make the computer programming codes maximally robust and limit the number of alternative interpretations of events.

Hence the following conditions were set for making of sensor-based programming code.

1) Walking with walking aid would be interpreted only if the specific walking aid that was assigned to the patient was being used. The walking aid for each patient was coded as 'Walk_aid_patient alphabet' and belonged to the group of tags called as Patient Related Objects (Chapter 3 section 3.4.1 & Appendix 4).

2) Wheelchair use would be interpreted by RMMS only if the wheelchair was specifically assigned to the patient. During data collection, tags were put around wheelchairs that were designated to individual patients. These tag numbers were noted down for each patient during data collection. A feature was added in the user – interface software where the assigned wheelchair information could be entered into the database before data processing. Hence, duration of wheelchair use was obtained from the RMMS.

3) The computer program rule would be activated to process data only if the change in location involved 3 or more location codes. As the IR wave dispersed and reflected room locator signals from the adjacent room could be misinterpreted as

walking. Hence 3 successive location codes had to be detected before it could be interpreted that a patient was moving around. The exception to this condition was the location code of the Day room (400). Therefore if the change in location involved 2 locations and one of them was the Day room, it would be interpreted that the patient was moving around. This exception was laid down due to the location of the Day room which made it highly unlikely that the Day room location code signals would disperse into neighbouring rooms.

4) If the patient tag was reporting change of 3 or more location but there were no corresponding wheelchair tags or walking aid tags reporting the exact sequence of location change at the exact time as the patient tags, then the activity would be interpreted as 'transport'. This could mean that patient was being transported using a steady or was using a walking-aid or wheelchair that was for general use.

It was seen during observation that this occurred only when patients were in transient stage of recovery where they were not considered capable of using a walking aid or sitting in wheelchair safely outside of therapy time. Hence interpreting these occurrences as time spent in 'transport' was acceptable.

While on the other hand patients were assigned a personal walking aid or wheelchair only when they were capable of using it safely outside of therapy time. Hence time spent in moving around using a designated walking aid or wheelchair was considered as a significant milestone in functional recovery.

And if there were cases where the patient did not use a walking aid at all and walked independently, the information regarding this would be present in their demographic details that were taken at the time of recruitment. Hence data could be analysed correctly.

5) To further strengthen the interpretation, Functional Ambulation Category scores (that were recorded by RSU staff) were correlated with the type of mobility (walking, wheelchair or transport) measured by RMMS. As the scores from FAC became higher it could be assumed that the ambulation capability of patients were better. Data from the longitudinal study was processed subsequently and the results obtained are presented in the next chapter.

Classification of Patients:

Different ways to group patients according to a certain characteristic were explored to determine potential predictive factors of recovery. Subdividing patients according to other demographic details was ruled out due to heterogeneous representation of stroke and the co morbid factors. Also, recovery of mobility was different with respect to use of walking equipment, LOS and mobility milestones. Some patients were walking with a walking aid on admission and on discharge while others were completely non-mobile and remained wheelchair users. As seen clinically during rehabilitation, most patients who are non-mobile at the onset of stroke and are passively transported with a steady before progressing to walking with a walking aid during their rehabilitation. Others have an intermittent stage where they are able to sit safely in a wheelchair before they ultimately walk. It was hypothesised from the preliminary data processing that grouping patients according to the type of progression or recovery of walking function was possible. Hence, patients were categorised depending on the manner in which they were mobile when data collection was started with them as explained below.

1) Transport only: Patients were passively transported using a steady or a generic wheelchair and did not progress to walking. Transport duration also included use of those wheelchairs which did not have a tag and were not assigned to any particular patient. These were used generically for all patients in RSU.

2) Wheelchair use only: Patients were passively transported using a specific wheelchair assigned at the time of recruitment and did not progress to walking.

3) Wheelchair use and walking Patients were passively transported using a specific wheelchair assigned at the time of recruitment and progressed to walking.

4) Transport and wheelchair use: All 3 modes of mobility were detected and in some weeks walking, wheelchair use and transport occurred simultaneously.

5) Transport and walking: Most of them were observed being transported as well as walking when measurements started and the others were initially being transported and then started to walk or vice-versa depending on the recovery.

6) Transport, wheelchair use and walking: Patients were observed moving around either by walking or using the other two types of equipment.

7) Walking only: Patients either progressed to walking during their recovery or were already walking when recruited into the study. Patients were detected walking with or without their assigned walking aid as well as with or without assistance.

Duration of mobility

Data from 47 patients out of the total of 52 was analysed. Data was unavailable for 3 patients as the raw data files were not readable (patient number1, number 11 and number 19). Patient number 8 wore the tag on the shoe for most of the time in the rehabilitation unit and another patient (number 6) was recruited primarily for the validity study and the longitudinal monitoring was started 7 months after stroke onset. Therefore these patients were excluded from analysis.

Schematic Representation of results

These results obtained for the mobility parameters are given below from section 6.11 to Section 6.18. When the main analysis was undertaken and graphs were plotted according to the total number of patients in each category, the weekly average duration of mobility was found to vary for each individual. Moreover when patients used 2 or more methods of mobility, the combination changed per week. Therefore a combination of plots and tables were used along with the narrative description to present the results in each category. Stacked bar graphs represent the average daily mobility over LOS and in the week before discharge. The LOS was plotted on the secondary vertical axis (on the right hand side). Under each category individual graphs have also been presented and discussed which highlight the change in the recovery patterns of individual mobility as well the differences in the recovery between two patients belonging to the same category.

Only 2 individual graphs per category have been discussed as presenting individual profiles of all 47 patients was beyond the scope of this thesis. In the individual graphs, the number of weeks of stay, the week when patient were admitted and discharged in RSU as well as the week when measurements with RMMS were started and stopped were displayed on the X axis. Time in HH:MM:SS was displayed on the primary Y axis (on the left hand side of graph).The secondary Y axis (on the right hand side of graph) was used to display the Functional Ambulation Category score that was recorded from the patient files. The difference in the rate and type of mobility recovery could be distinguished in the individual plots.

Category 1: Transport only

Table 5.6 shows the demographic details of these patients. Their FAC scores on admission **(adm)** and discharge **(d/c)** were 1.

Table 5. 6 Patient demographics for category 1 (Transport only)

F=3,M=0	Mean	Std Dev	Min	Max
Age	85	5.19	79	88
Days post stroke	11.66	5.13	6	13
Length of stay	101	45.76	63	152
Follow up days	89	38.74	60	133

Patient 17 spent the minimum duration in transport and patient 27 was transported the most (Figure 5.5 and Table 5.7). In the week before discharge, patient 27 was not transported and data for patient 30 was missing (Figure 5.6). However the BI score for all 3 either remained 0 or 1 at admission and discharge. Similarly the mRMI scores for patients 17 and 27 remained 1 while that for patient 30 changed from 4 at admission to 9 at discharge indicating that these patients are low functioning patients and were highly dependent with an MRS score of 5 on admission. All 3 patients were discharged to a **N**ursing **H**ome **(NH).**

Table 5. 7 Descriptive statistics for category 1

Transport (n=3)	Mean/day	Std Dev	Min	Max	Sum
Week post-admission	00:01:05	00:00:56	00:00:25	00:01:44	00:02:09
Week pre-discharge	00:00:08	00:00:12	00:00:00	00:00:16	00:00:16
Average over stay	00:01:42	00:00:39	00:01:02	00:02:20	00:02:20

Figure 5. 5 Mobility duration over stay: category 1 (Transport only)

Tranport duration over stay

Transport ■   Weeks of Measurement ◆
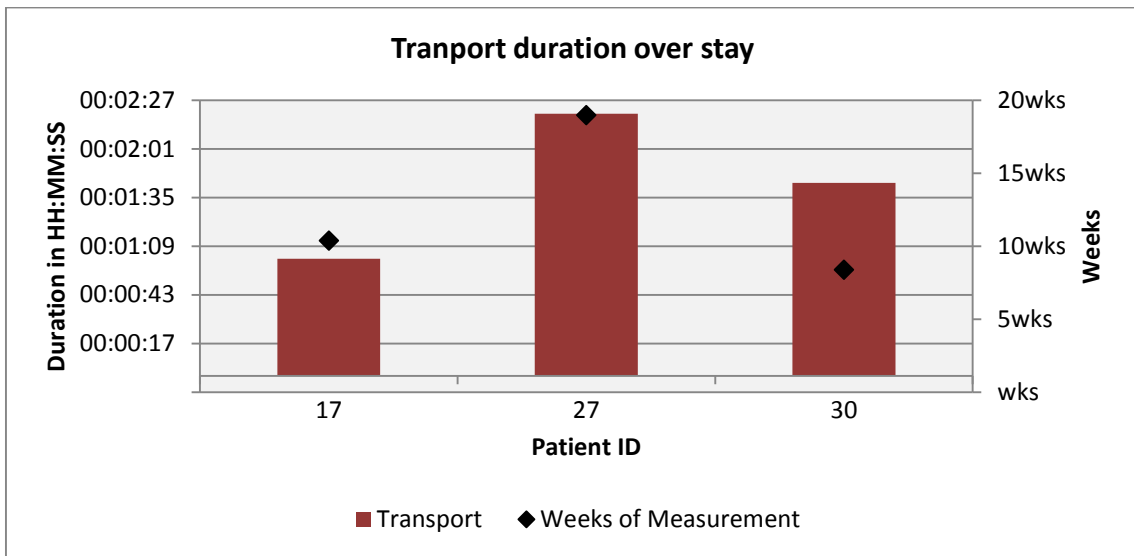
Figure 5. 6 Mobility duration in week before discharge: category 1 (Transport only)

Week before discharge

Transport ■   Weeks of Measurement ▲
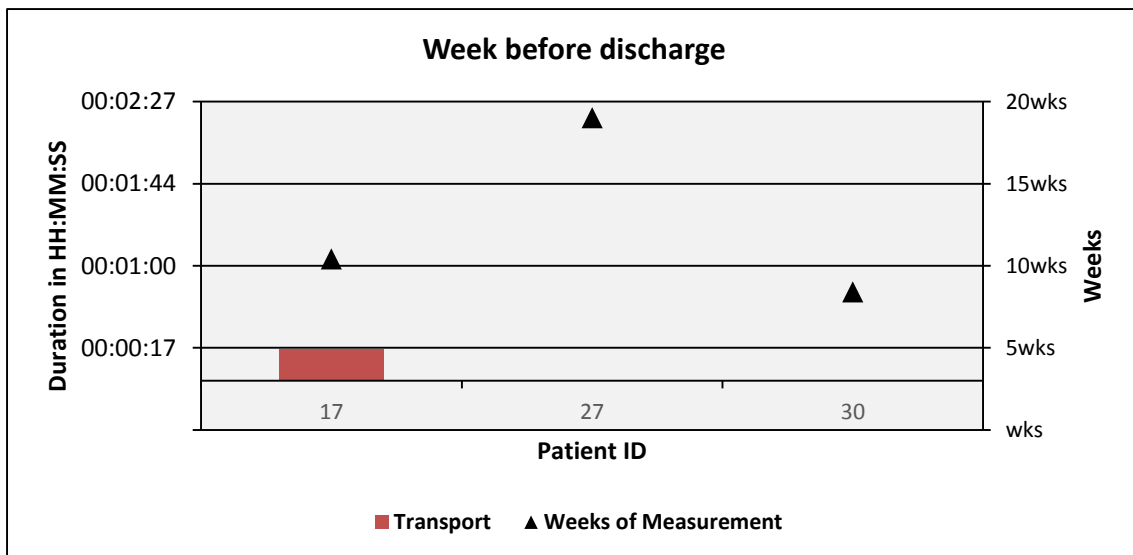
Category 2: Wheelchair use only

One patient (age= 85, LOS=20, FAC score at admission/discharge= 1) used an assigned wheelchair. The patient was admitted 10 days post stroke and PA was measured for 19 days. The average daily wheelchair mobility was 7 minutes and from Figure 5.7 it can be observed that this time decreased progressively over weeks. This could be due to medical co-morbid factors. The patient had diabetes mellitus and pancreatic cancer which could have caused complications affecting mobility. The BI score was 6 and 9 and the mRMI score was 17 and 20 on admission and discharge respectively. The patient spent 91% of time in their own room. The MRS score on admission was 4 however recovery was minimal and the patient was ultimately transferred to a palliative care unit.

Figure 5. 7 Mobility duration over stay: category 2 (Wheelchair use only)
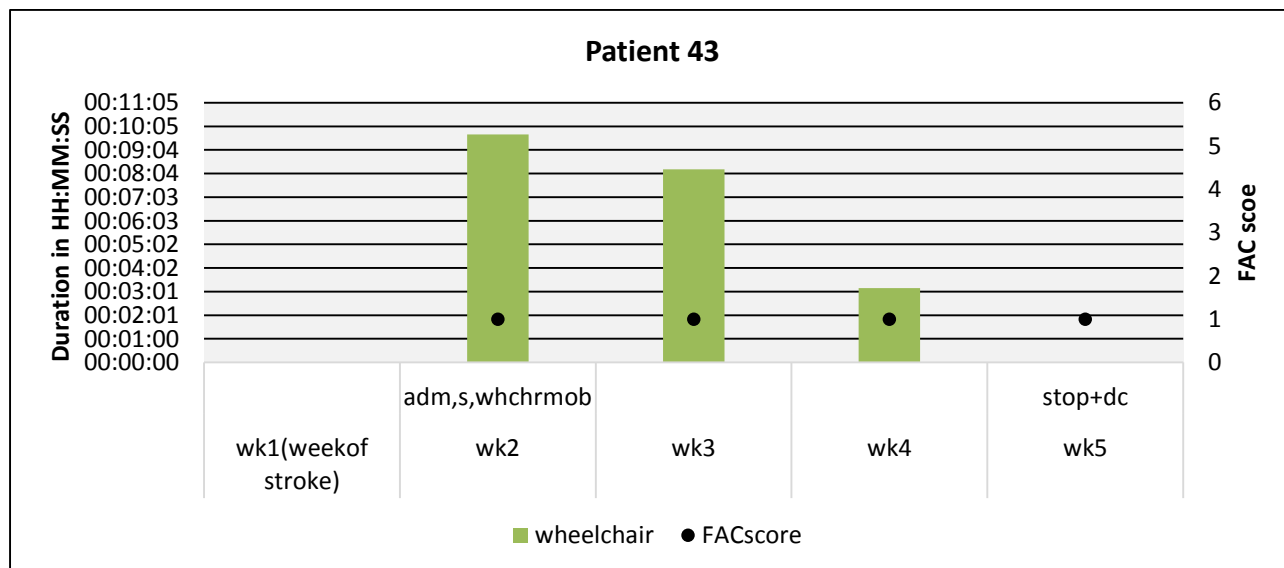
Key: FAC = Functional Ambulation Category Score. Wk= week,
Adm= admission, s=measurement started, whchrmob= wheelchair mobility, stop+dc= measurement stopped and discharge

Category 3: Transport and Wheelchair use

Twelve patients used an assigned wheelchair or other equipment for mobility. Of the 12, 6 patients progressed from being transported in the first week of measurement to using assigned wheelchairs later (patient numbers 5,18,31,35,40 and 49) while 4 were observed using both modes of mobility right from the start (patient numbers 26,38,44 and 46). Two patients were observed using only a wheelchair at the beginning (patient numbers 12 and 48). **The average patient age was less than that for patients in category 1 and their FAC score remained 1 at admission and discharge** (Table 5.8).

Table 5. 8 Patient demographics for category 3 (Transport and Wheelchair)

Female=10,Male=2	Mean	Std Dev	Min	Max
Age	77.5	11.58	55	90
Days post stroke	19.4	21.9	4	69
LOS (Length of Stay)	124	42.64	55	200
Follow up days	155	32.36	87.66	54

The average time spent using a wheelchair or other transport equipment was less than 5 minutes a day. In comparison to the duration of transport there was more variability in the amount of time spent in wheelchair mobility as observed in the standard deviation values (Table 5.8). Apart from patients 5, 31 and 48, all patients appear to spend less than 4 minutes a day using wheelchairs irrespective of the number of weeks of measurement (Table 5.9). Wheelchair mobility one week prior to discharge for patient number 31 was exceptionally high (76 minutes) while the average mobility over stay was 11 minutes (Table 5.10). Wheelchair use data was missing for 4 weeks. This could be either because the original wheelchair which had a tag on was changed mid-way and the correct wheelchair was tagged later on

hence no data was recorded or because the patient did not use the wheelchair for 4 weeks. Data collection for patient number 40 and 44 was discontinued early due to ill-health and withdrawal from study respectively. Only 4 other patients were found to be mobile in the week of discharge (5, 12, 18, and 26). Patient numbers 35,38,46,48 and 49 showed no mobility in the week before discharge (Figure 5.9). The average BI scores at admission and discharge were 1.5 and 3 respectively and the change in the average BI score for all patients from admission to discharge was 1 (range -5 to +7). Similarly the average mRMI score for all patients at admission was 6.2 and at discharge was 8.2 and the average change in mRMI score was 1.5 (range -6 to +13). Thereby it can be said that patients in this category were variable in their function and mobility and recovery was observed in few of them only. While some reasons such as ill health can explain the decline in function, overall, patients' dependence for ADL and their mobility levels were slightly better than those in category 1. Most patients (7/12) were discharged to a NH while 3 were discharged home. Unfortunately 2 patients were lost to follow up.

Table 5. 9 Descriptive statistics for category 3

Time spent	Mean/day	Std Dev	Min	Max
Transport	00:01:40	00:01:34	00:00:31	00:06:25
Wheelchair use	00:04:12	00:03:38	00:01:40	00:11:54

Table 5. 10 Category 3: mobility in week post- admission, pre-discharge and over stay

Total (transport and wheelchair) N=12	Mean/day	Std Dev	Min	Max	Sum (n=12)
Week post-admission	00:03:22	00:02:03	00:00:07	00:06:32	00:37:07
Week pre-discharge	00:10:07	00:30:29	00:00:00	01:46:35	02:01:23
Average over stay	00:05:53	00:04:16	00:02:40	00:14:10	01:10:32

Figure 5. 8 Mobility duration over stay: category 3 (Transport and Wheelchair)
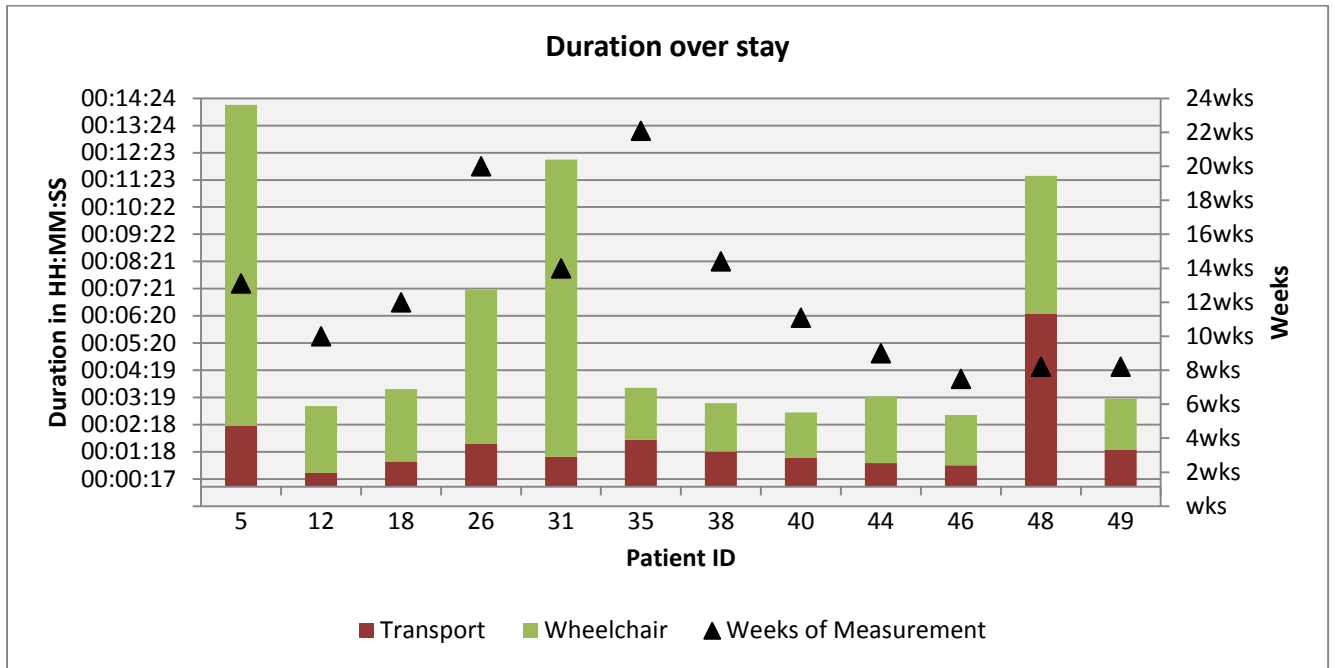
Figure 5. 9 Mobility duration in week before discharge: category 3 (Transport and Wheelchair Use)
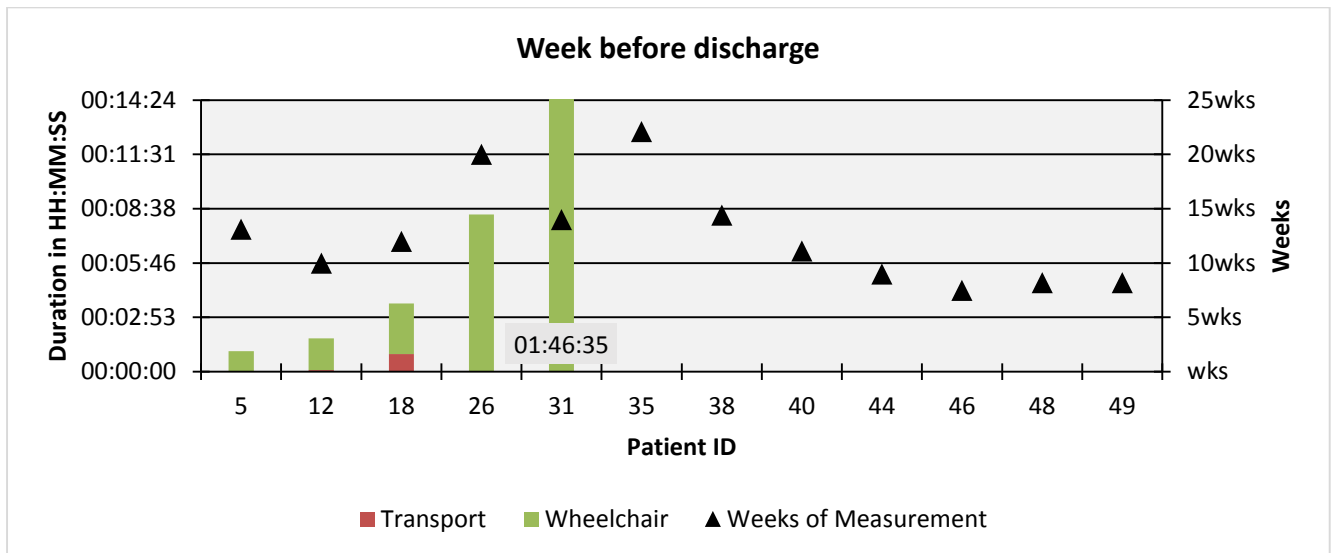
Individual mobility profiles

Profiles of patient numbers 18 and 26 were chosen to represent this category (Figure 5.10 and 5.11). Both patients spent 20 weeks or more in the RSU. Their FAC scores remained unchanged however the duration of transport and wheelchair mobility appears quite different. For patient 18, wheelchair use was seen in the 3rd week of measurement and decreased over stay while for patient 26 it was seen in the 1st week of measurement and tended to increase over stay as transport duration decreased. The change in mobility for the 2 patients reflected the change in their OM scores. For patient number 18, the decline in mobility from admission to discharge coincided with decline in mRMI score (admission=9; discharge=5). In contrast, the change in mRMI score from admission to discharge was 13 points (admission=7; discharge=20) and that in BI was 7 points (admission=2; discharge=9) for patient number 26. Another point to note from the graph belonging to patient 26 is that the duration of wheelchair mobility in certain weeks was more than 10 minutes a day but not in all weeks suggesting that although this patient was capable of using a wheelchair over 10 minutes this duration was not maintained consistently. The duration of wheelchair mobility for patient 26 can be considered as exceptionally high in comparison to other patients in the group.

Figure 5. 10 Individual mobility profile 1: category 3
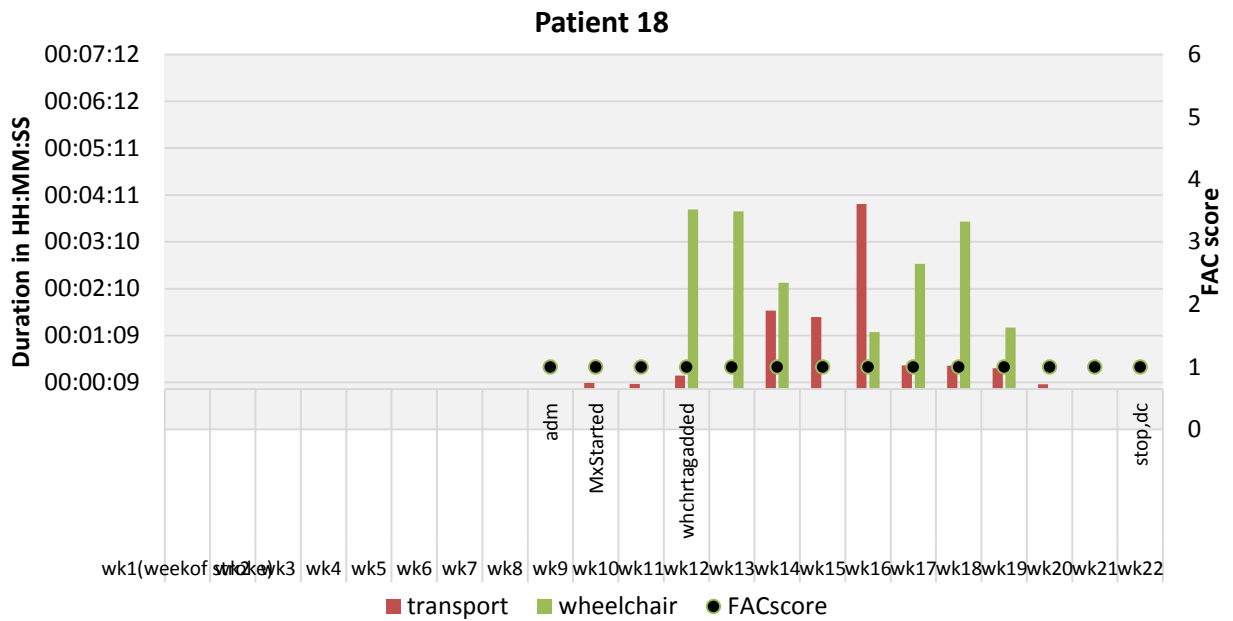
Patient 18

Figure 5. 11 Individual mobility profile 2: category 3
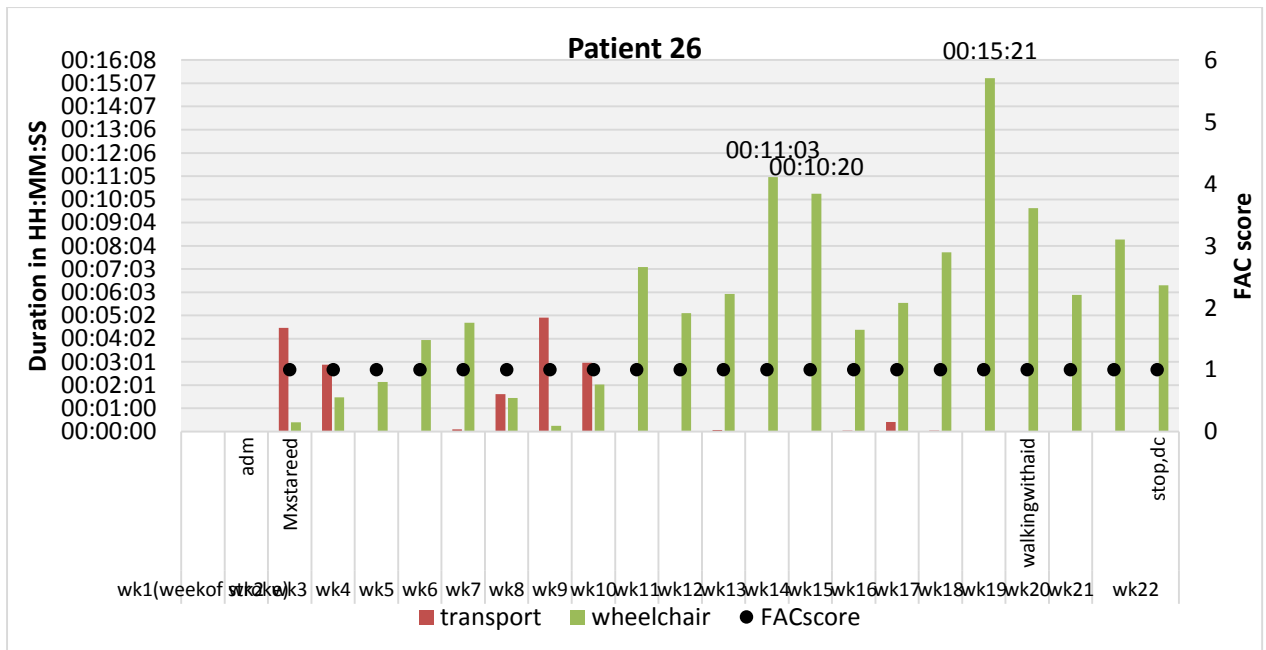
Patient 26

Category 4: Wheelchair use and Walking

No patients were included in this category for the present study.

Category 5: Transport, Wheelchair use and Walking

Four patients were in this category and the demographic details are given in (Table 5.11). Their mean age was similar to patients in the first two categories, however the average LOS (75 days) was less than those of categories 1 (101 days) and 3 (124 days). Three of them were being transported at the beginning following which wheelchair use and walking was observed (patient numbers 13, 37 and 47) and patient number 21 was being transported and using the assigned wheelchair in the first week of measurement. It appears from Figure 5.12 that all 4 were quite varied in their capacity to move around and had different LOS as reflected by the weeks of measurements. This is also seen in Table 5.13 as average daily mobility was 10 minutes with wide standard deviations. Note that this variability was sensitively detected and measured by RMMS.

It is observed from Figure 5.13 and Table 5.13 that mobility improved for all 4 patients on discharge. Either an increase in the duration and/or progression from being transported to walking with an aid (patient 13) was observed. The mode and median FAC value at admission and discharge were 1 and 2 respectively. The BI scores showed a mean change of 8.5 points between admissions (0.5) to discharge (9). Similarly the change is mRMI score was 14 points between admission (11.7) and discharge (25.7). The average scores are better than those in all 4 categories so far especially the mRMI scores which were <20 on discharge. Moreover all patients were discharged home unlike patients in the above categories where all or most of

them were discharged to a NH. Although no mobility was observed for patient 37 in the week before discharge, the overall profile is discussed below.

Table 5. 11 Patient demographics for category 5 (Transport, Wheelchair and Walking)

F= 4 M=0	Mean	Std Dev	Min	Max
Age	84.5	5.25	77	89
Days post stroke	12.25	6.29	5	18
LOS	75	26.83	45	105
Follow up days	59.5	26.68	41	98

Table 5. 12 Descriptive statistics for category 5

Time spent	Mean	Std Dev	Min	Max
Transport	00:03:30	00:02:50	00:00:44	00:07:12
Wheelchair use	00:03:32	00:02:23	00:00:43	00:06:32
Walking	00:02:55	00:03:43	00:00:32	00:08:27

Table 5. 13 Category 5: mobility in week pre-admission, post-discharge and over stay

Total (transport, wheelchair and walking) N=4	Mean	Std Dev	Min	Max	Sum
Week post-admission	00:05:31	00:03:04	00:02:31	00:08:28	00:22:04
Week pre-discharge	00:11:39	00:14:09	00:00:00	00:30:58	00:46:36
Average over stay	00:09:57	00:06:13	00:05:53	00:19:10	00:39:49

**Figure 5. 12 Mobility duration over stay: category 5 (Transport, Wheelchair use and Walking)**
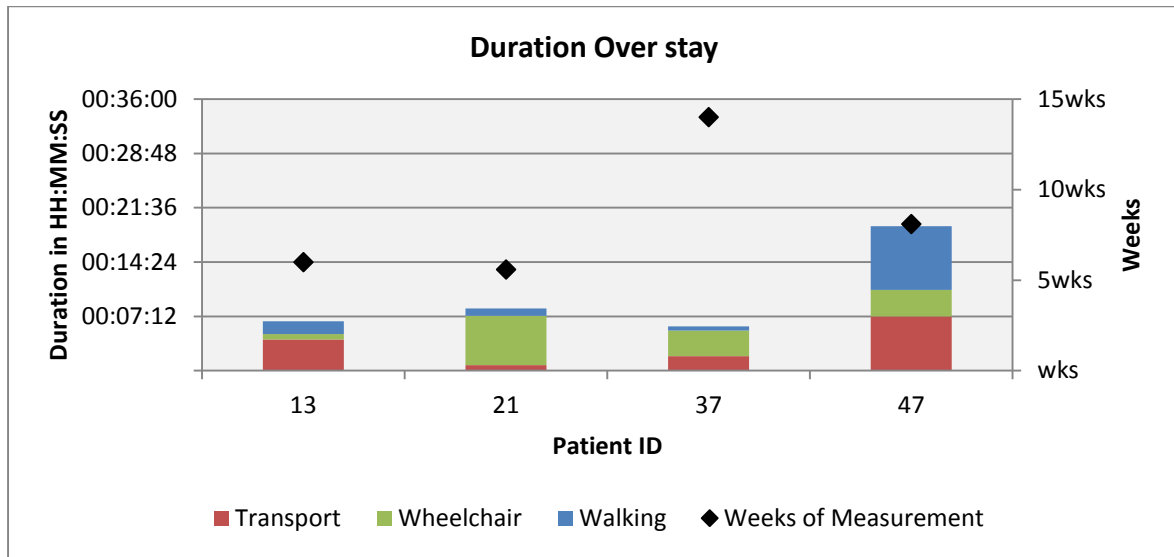
**Figure 5. 13 Mobility duration in week before discharge: category 5 (Transport, Wheelchair use and Walking)**
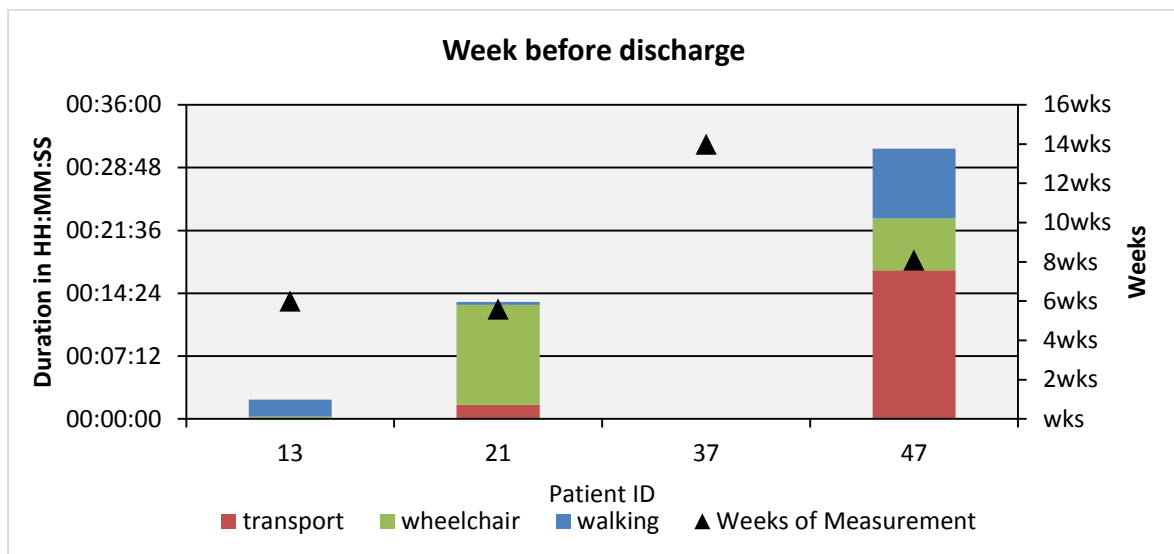
Individual mobility profiles

Figure 5.14 shows the mobility pattern for patient number 21. It can be said that the patient recovered very well as the BI score increased to 16 at discharge from 1 at admission and the mRMI score increased to 36 at discharge from 10 at admission. The FAC scores also suggested that the ambulatory capability increased over weeks however it appears that the actual mobility per day did not adequately reflect the increase. Passive transport decreased and use of wheelchair increased over stay. Although the duration of walking does not appear to increase any qualitative change in terms of support required, balance and type of gait cannot be commented on as the RMMS is not capable of measuring such changes. The recovery chart for patient number 37 (Figure 5.15) suggests a slower process of recovery. It is seen that as this patient started to use the assigned wheelchair more, transport became negligible and walking started towards the end of stay in RSU and this pattern is consistent with the recovery model after stroke. The overall duration of wheelchair mobility seemed less than 6 minutes.

Figure 5. 14 Individual mobility profile 1: category 5
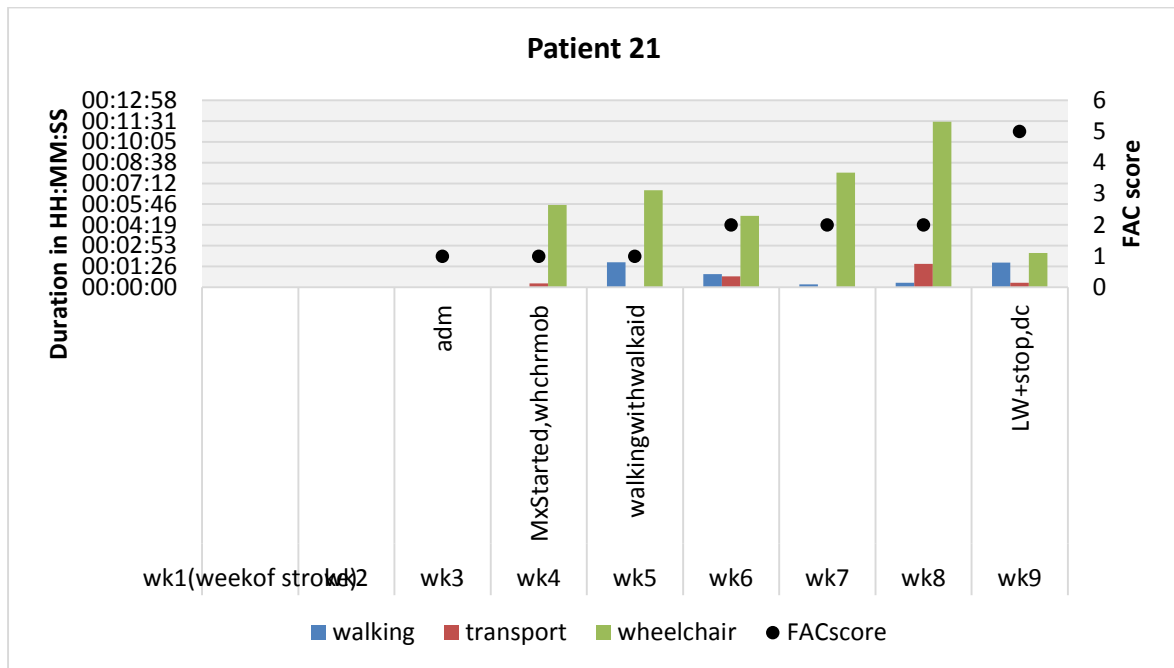
Figure 5. 15 Individual mobility profile 2: category 5
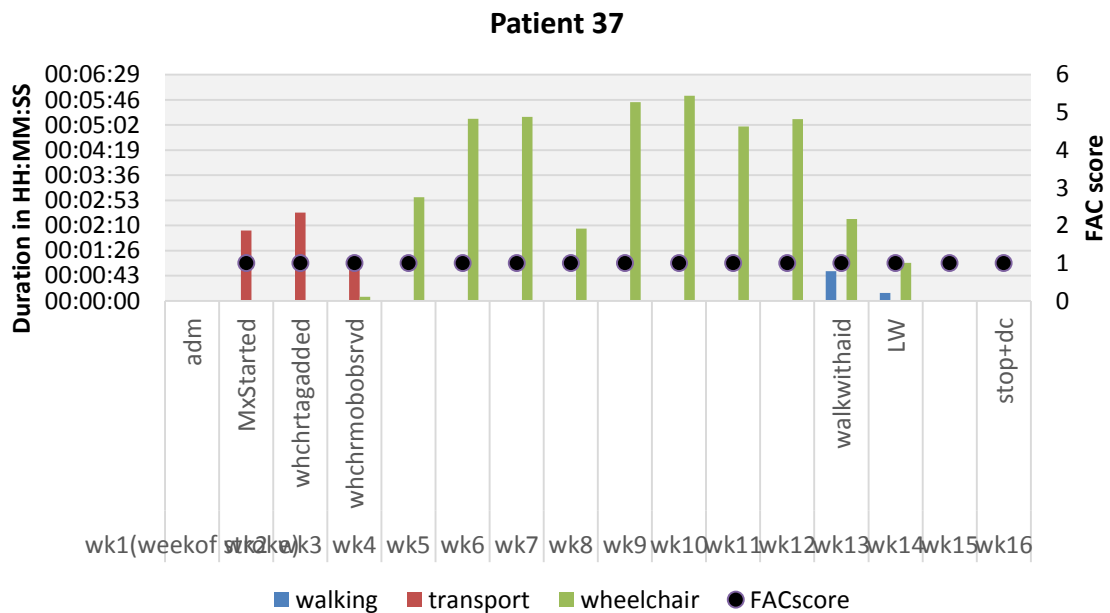
Category 6: Transport and Walking

Twenty one of the 47 patients were in this category and it can be said that most of patients were moving around either by walking or were being transported. Walking and transport seemed to occur simultaneously for 12 patients as soon as PA measurement started (patient numbers 2, 3, 4, 9,14,22,25,28,29,33 and 45). Seven patients were being transported in the week after measurement started (patient numbers 20, 23, 32,34,36,41 and 51) and walking occurred later during rehabilitation and patient number 7 was able to walk when measurement started and passive transport was detected later in the rehabilitation phase. No mobility was recorded for patient numbers 15 and 39 for the week after measurement started and their average mobility over stay has been given in the graph below. It is observed that the patients' LOS was shorter than the other categories so far (Table 5.14). The median and mode FAC values at admission and discharge were 1 and 4 respectively indicating good ambulation capability.

Table 5. 14 Patient demographics for category 6 (Transport and Walking)

M=4,F=17	Mean	Std Dev	Min	Max
Age	76.90	13.81	32	90
Days post stroke	18.90	15.59	1	54
LOS	75	52.06	8	194
Follow up days	47.95	39.43	6	147

As seen in patients in category 5, the standard deviation of average transport and walking duration suggests variability in their individual mobility pattern (Table 5.15). However the average daily duration of mobility is much longer than those who were wheelchair users or were transported as their the average duration was < 5 minutes (Table 5.16)

Table 5. 15 Descriptive statistics for category 6

Time spent	Mean	Std Dev	Min	Max
Transport	00:07:16	00:14:15	00:00:25	01:07:55
Walking	00:08:19	00:06:04	00:00:46	00:34:40

Apart from patient number 2, daily transport duration for all patients appeared to be less than 7 minutes (Figure 5.16). Also, the average daily walking duration was 8 minutes and only 3 patients were observed walking for more than 17 minutes (Patient numbers 4, 33 and 39). In the week prior to discharge, the duration of total mobility for some patients has not been displayed in Figure 5.17. For patient numbers 2, 3 and 7 there was missing data as measurement was discontinued early to allow for software improvements. Patient number 33 took the wrist tag off before measurement could be completed and number 39 stayed for only one week. However for patient numbers 22, 32 and 41 the score of zero minutes of mobility is their true score and it appears that their mobility declined over time. Hence the lower group average mobility prior to discharge in comparison to the group average over stay could be due to missing data or no mobility undertaken (Table 5.16). On comparing mobility duration after admission and before discharge the pattern of recovery for 9 patients was similar to the recovery model where either the duration of mobility increased and/or more walking than transport was undertaken at discharge. For 3 patients the duration remained the same but recovery was reflected in their

OM scores. The BI and mRMI scores for 6 patients were missing and therefore were excluded for analysis. Therefore based on a sample size of 15 out of 21, the average change in BI scores was 7 points (admission=6.4; discharge=13.2) and change in mRMI scores was 11 points (admission=19; discharge=30). In comparison to other patients so far, it is observed that these patients were fairly high functioning to begin with and improved more in their mobility over stay. Sixteen patients were discharged home while 4 went to a NH. From Figures 5.16 and 5.17, it can be said that the duration of transport seemed less than the duration of walking. The group FAC scores at admission was 1 and at discharge was 4 which also suggest that the ambulation capacity was better than that observed for patients belonging to categories 1 to 3.

Table 5. 16 Category 6: mobility in week post-admission, pre-discharge and over stay

Total (transport and walking) N=21	Mean/day	Std Dev	Min	Max	Sum
Week post-admission	00:16:45	00:29:25	00:01:38	01:59:30	05:18:10
Week pre-discharge	00:06:30	00:06:16	00:00:00	00:19:04	02:16:21
Average over stay	00:14:23	00:15:55	00:01:44	01:15:17	05:02:08

Figure 5. 16 Mobility duration over stay: category 6 (Transport and Walking)
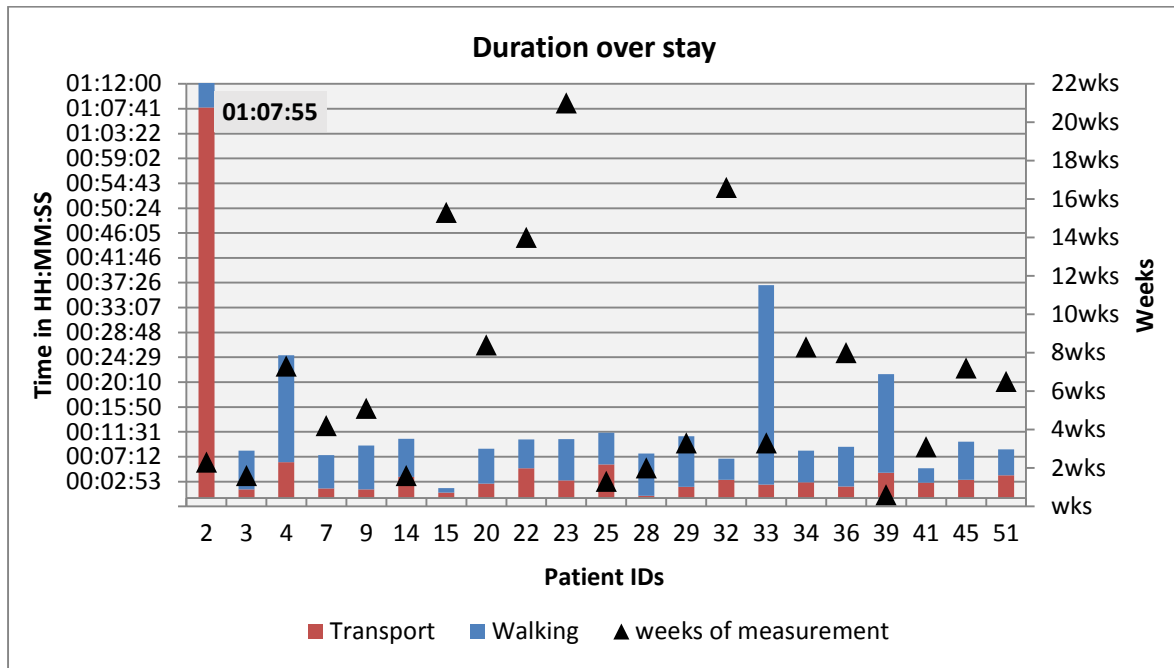

Figure 5. 17 Mobility duration in week before discharge: category 6 (Transport and Walking)
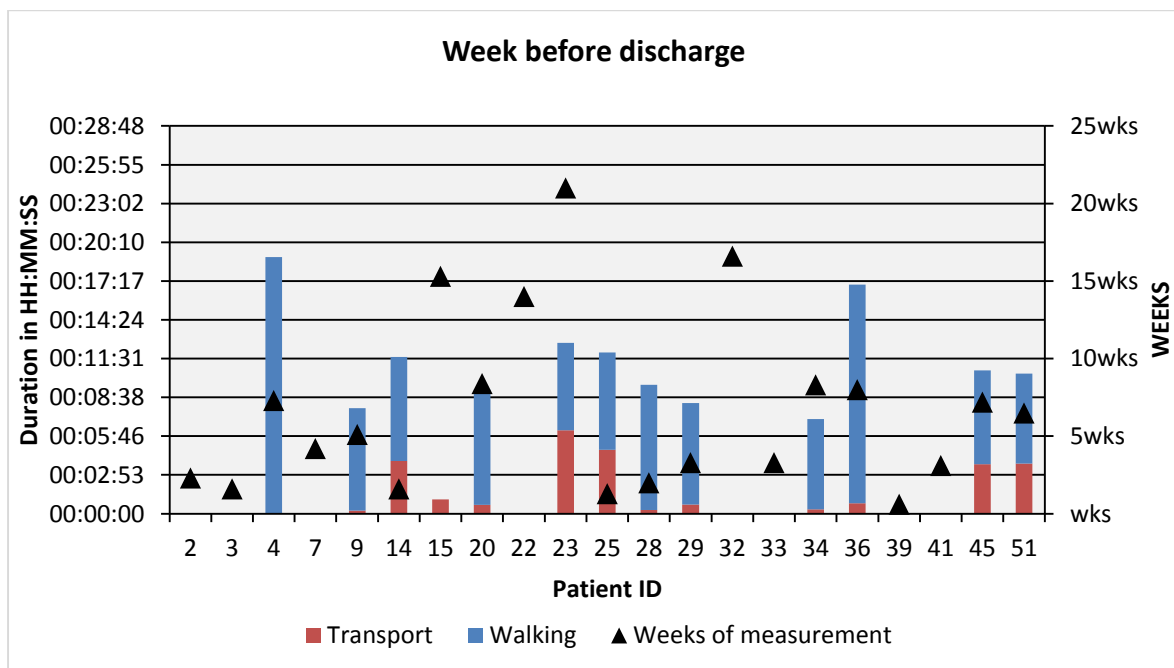
Individual mobility profiles:

Patient number 4 started to walk with an assigned walking aid in the 4th week after stroke as opposed to patient number 34 who was assigned a walking aid in the 7th week (Figures 5.18 and 5.19). It can be observed in both cases that as walking duration increased, the duration of transport decreased. Both had an FAC score of 1 at admission and improved to 4 and 5 respectively on discharge. Furthermore the mRMI score for patient number 34 was 4 on admission and improved by 23 points at discharge. The OM scores for patient number 4 were missing as the patient was discharged before they could be obtained.

It is important to note that for patient number 34, the duration of transport in 6th week was higher than those measured in the preceding weeks. Moreover the FAC score recorded in that week was 3 which meant that patient was judged to be able to ambulate on level surfaces with intermittent or continuous assistance of one person. Therefore the patient was able to walk and may not have needed to be transported passively. Hence a sudden improvement from transport to walking within a week was considered as an anomaly due to the following reason. One of the conditions set for the software coding for walking was that the co-location of the wrist tag *along* with the assigned walking aid was essential (as explained on page 211-212). Hence if the patient was detected as changing their location but there was no assigned walking aid being detected simultaneously, it would be coded as 'transport'. To guard against this limitation of the RMMS tool, other factors such as the FAC were also plotted alongside so that the correct interpretations regarding walking or transport could be made. Therefore it can be suggested that patient number 34 may have been walking throughout.

Figure 5. 18 Individual mobility profile: category 6
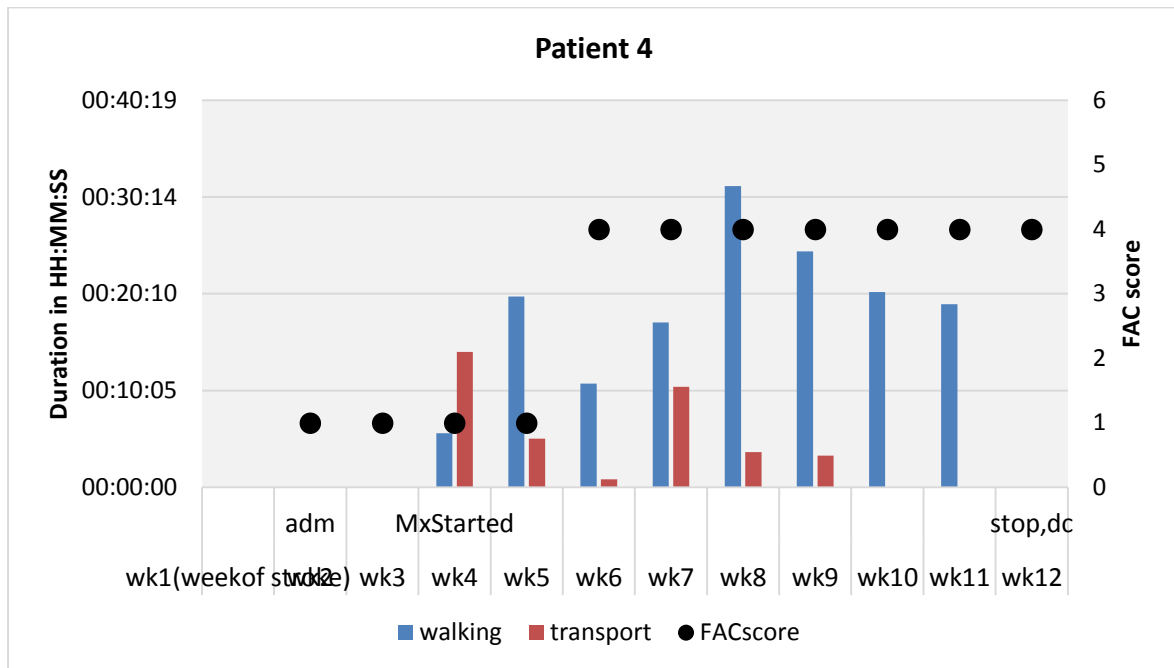
Patient 4

Figure 5. 19 Individual mobility profile 2: category 6
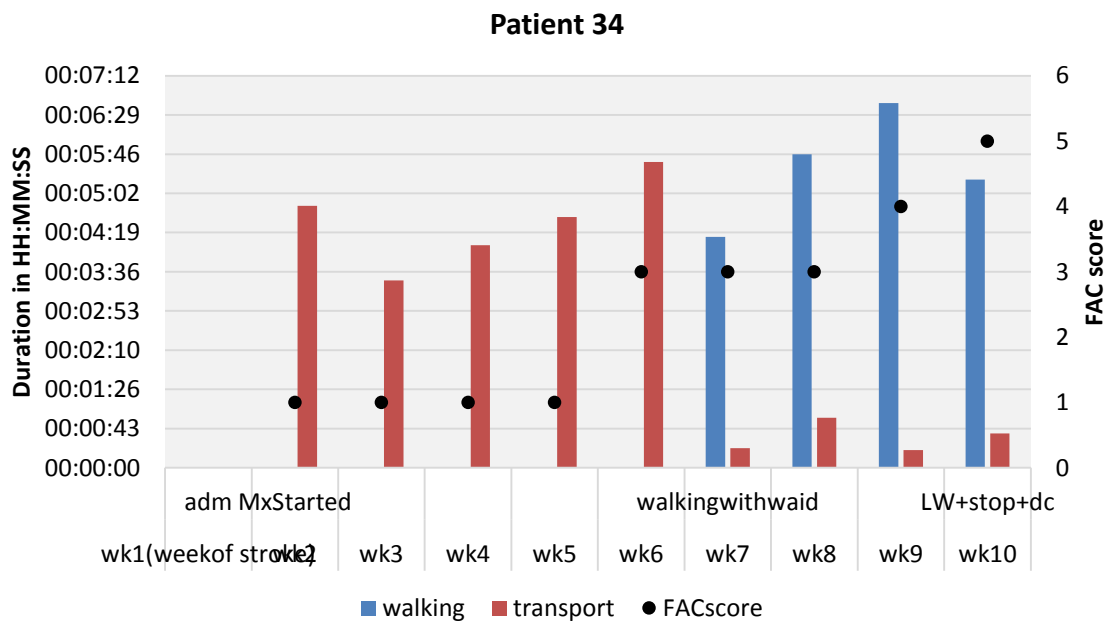
Patient 34

Category 7: Walking only

Six patients walked around in the RSU without using a wheelchair or being transported. Four patients at the time of recruitment were able to walk and 2 patients progressed to walking during their stay. Their overall LOS was shorter than those for categories 1 to 6 and less than half the LOS of patients in categories 1 and 3 (LOS = 101 days and 124 days respectively) (Table 5.17). Similarly the FAC scores at admission and discharge were 4 and 5 which are higher than those observed in the categories 1 to 5. The average weeks of measurement was also just under 3 weeks and 3 out of 6 patients were measured for 2 weeks or less.

Table 5. 17 Patient demographics for category 7 (Walking only)

F=4,M=2	Mean	Std Dev	Min	Max
Age	75.83	5.91	67	84
Days post stroke	9.5	7.14	3	20
LOS	51	37.89	7	105
Follow up days	20.16	12.81	6	36

The mean time spent walking was 14±11 minutes. The minimum walking observed was 2 minutes and the maximum walking more than 1 hour, 23 minutes. As 3 patients were measured for 2 weeks or less it was difficult to compare their mobility for a week after admission and for the week before discharge. Patient numbers 24 and 52 withdrew from the study while patient number 10 took the wrist tag off before measurements could be completed hence the mobility at discharge was not recordable (Figures 5.20 and 5.21). Table 5.18 shows duration of walking at admission and discharge. With respect to OMs, BI at admission and discharge was 12.7 and 16.5 respectively (change =3) and mRMI was 30 on admission and 34 on discharge with a change in score of 4 points. Scores for two patients were

unavailable. Overall OMs scores for these patients suggest that their functional and mobility capacity was better than those in every other category so far (Table 6.13). All patients in this category went home on discharge except one who was discharged to a residential home because of other economic factors rather than dependence in ADL.

Table 5. 18 Category 7: mobility in week pre-admission, post-discharge and over stay

Total Walking N=6	Mean	Std Dev	Min	Max	Sum
Post-admission	00:19:45	00:29:14	00:00:00	00:53:20	00:59:16
Pre-discharge	00:10:22	00:12:25	00:00:00	00:29:55	01:02:10
Average over stay	00:13:59	00:11:50	00:01:56	00:36:46	01:23:55

Figure 5. 20 Mobility duration over stay: category 7 (Walking only)
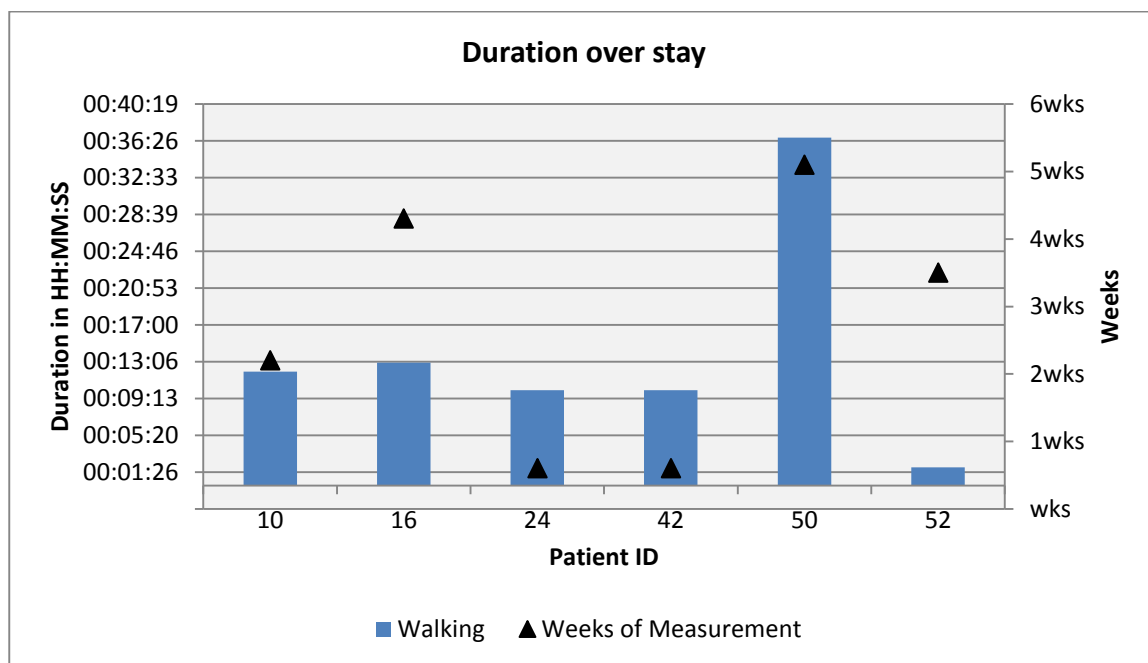
Figure 5. 21 Mobility duration in week before discharge: category 7 (Walking only)
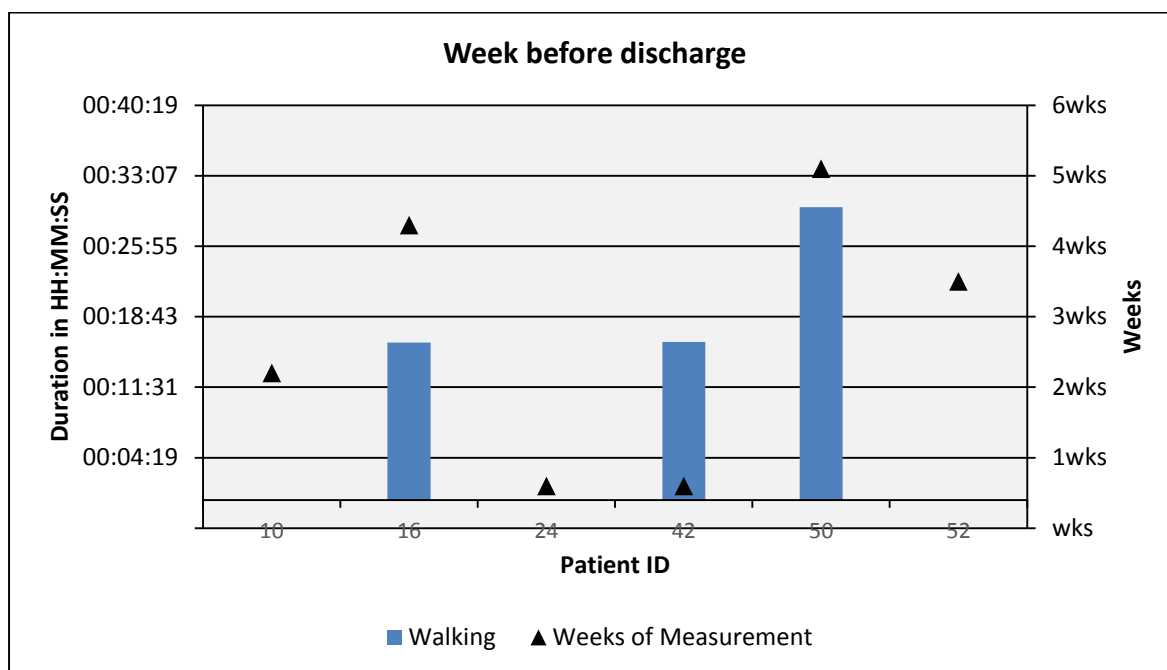
Individual mobility profiles

Walking duration for patient number 42 in week 2 was 5 times more than that in week 1 but in contrast walking decreased from just under an hour to less than 20 minutes for patient number 50 during the stay (Figures 5.22 and 5.23). This is of interest as their FAC scores were similar and neither used a walking aid. Moreover their BI and mRMI at admission and discharge were above 18 and above 39 respectively which indicates that patient number 50 was physically high functioning to begin with. However the decrease in mobility over the stay does not appear to be linked to functional limitations. The reasons why the duration of walking was not maintained seem unclear for this patient as it is also seen that the patient spent on average of 29% of time in their own room over stay and most of their time out of their own room.

Figure 5. 22 Individual mobility profile 1: category 7
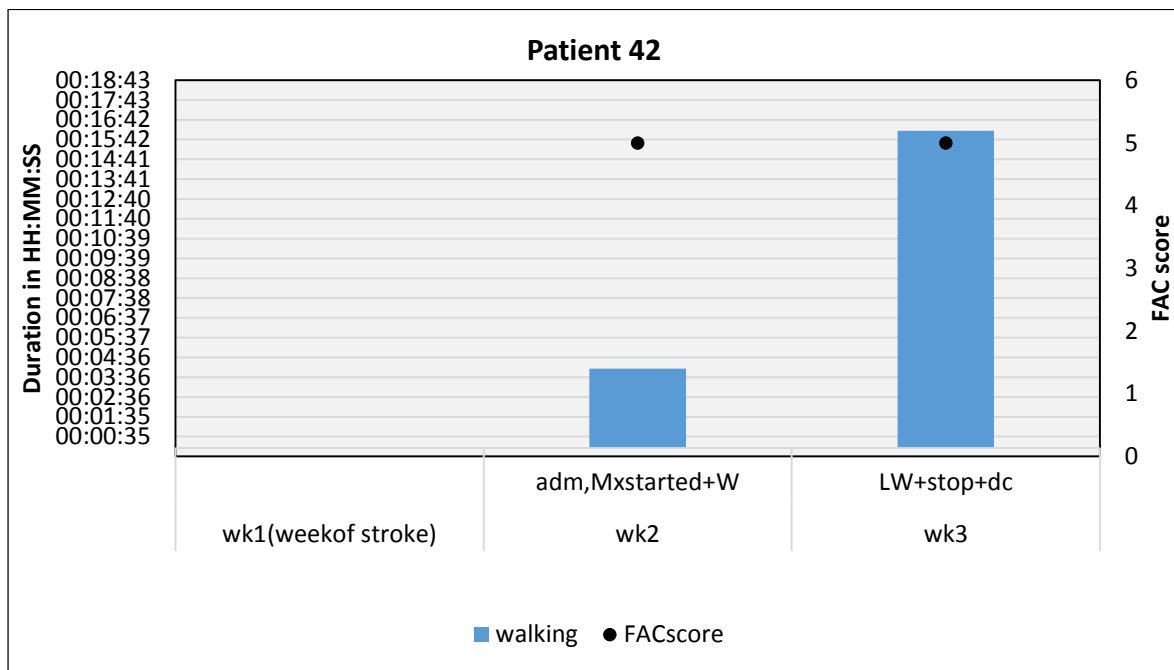
Patient 42

Figure 5. 23 Individual mobility profile 2: category 7
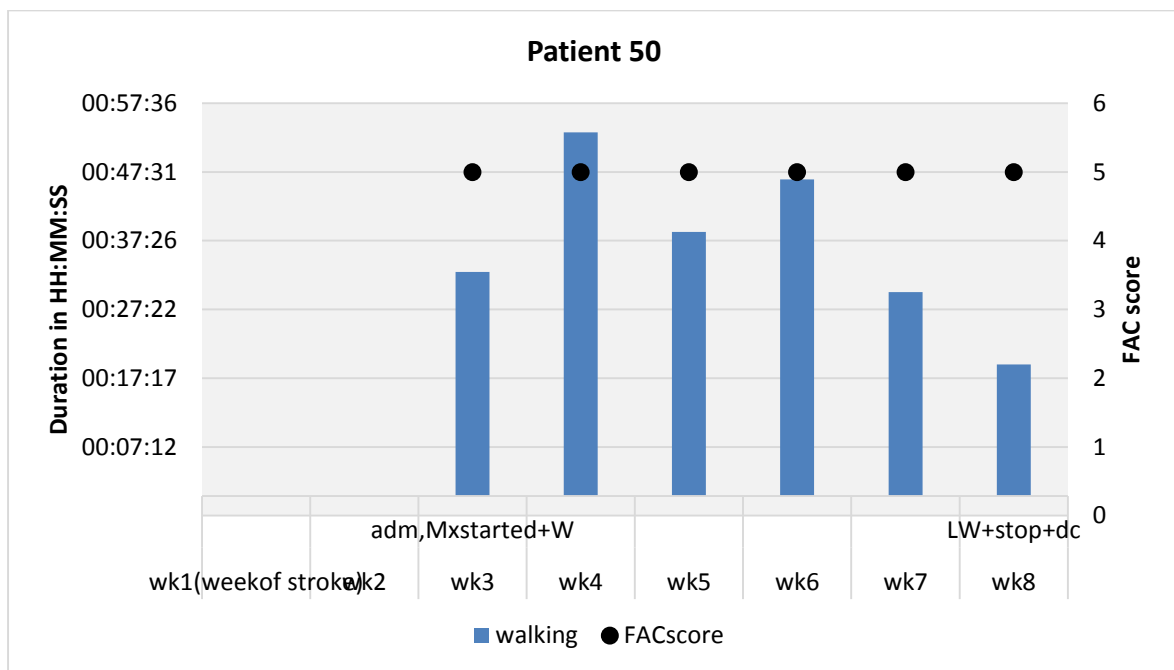
Patient 50

Duration of mobility: overview

The overview of the results obtained for mobility measurements undertaken in the early stages of recovery when patients were in a rehabilitation unit are given in Table 5.19. It can be said that on an average, patients were moving around or changing location for a maximum of 14 minutes, 23 seconds per day, irrespective of the mode used (walking, transport or wheelchair). Table 5.20 represents the group average of mobility in week before discharge.

Figure 5.24 represents the mobility measurements for all patients over their stay. It is evident in the stacked bars that 41 out a total of 47 patients were moving around RSU for less than 14 minutes a day. A point to note is that the 6 other patients whose average mobility was more than 14 minutes were all capable of walking with the exception of patient number 2. However the patient was capable of using the wheelchair on their own and was able to transfer independently from bed to wheelchair. Their mRMI scores were also high with the lowest being 23 on admission and the highest being 40 on discharge although it should be noted that the OM scores were not available for patients 2 and 4. Similarly the BI scores were more than 9 on admission and up to 20 on discharge. The OM scores indicate that these patients could move around for either a longer duration during the day and/or also more frequently including trips to use the toilet or bath rather than being confined to their rooms. It is also important to note that patient number 50 spent as much as 71% of her time outside of her own room during the day. Also the average number of times the patient was observed walking on any given week was 18. Similar walking frequency (14 times per week) was also observed for patient number 33. During the researcher's time on the wards, it was observed that relatives of patient number 4 and patient number 47 practiced walking in the corridor with these

patients outside of Physiotherapy sessions. Hence better mobility and functional

independence at the onset, ability to walk and additional walking outside of therapy

sessions could have contributed to increased overall mobility.

Table 5. 19 Group average duration of mobility over stay for categories 1-7 (except category 4 wheelchair use)

Category	No of Patients	Transport	Wheelchair mobility	Walking	Total group average of daily mobility
Transport only	3	00:01:42	----	----	00:01:42
Wheelchair only	1	----	00:07:03	----	00:07:03
Transport and Wheelchair	12	00:01:40	00:04:12	----	00:05:53
Transport, Wheelchair and Walking	4	00:03:30	00:03:32	00:02:55	00:09:57
Transport and Walking	21	00:06:04	-----	00:08:19	00:14:23
Walking only	6	----	----	00:13:59	00:13:59

Table 5. 20 Group average duration of mobility in week before discharge for categories 1-7 (except category 4 wheelchair use)

Category Week before discharge	No of Patients	Transport	Wheelchair mobility	Walking	Total group average of daily mobility
Transport only	3	00:00:08	----	----	00:00:08
Wheelchair only	1	----	00:08:14	----	00:08:14
Transport and Wheelchair	12	00:00:05	00:10:02	----	00:10:07
Transport, wheelchair and Walking	4	00:04:40	00:04:25	00:02:34	00:11:39
Transport and Walking	21	00:01:27	-----	00:06:07	0:07:35
Walking only	6	----	----	00:10:22	00:10:22

From Figure 5.25 it can be seen that the mobility in the last week before discharge is not recorded for 20 patients. It is important to note that 9 were not mobile in the week prior to discharge while for the other 11, data could not obtained due to several reasons. Table 5.21 gives the details

Table 5. 21 Patient IDs for whom mobility data for week before discharge was unavailable

Reason	Missing data	Ill health	Tag came off	LOS less than 2 weeks	Withdrew	**Not mobile**
Patient ID	2,3,7,30	40	10,33	39	25,44,32	15,27,32,35,38,39,46, 48,49

Figure 5. 24 Mobility duration over stay for all patients (n=47)

Average mobility over stay
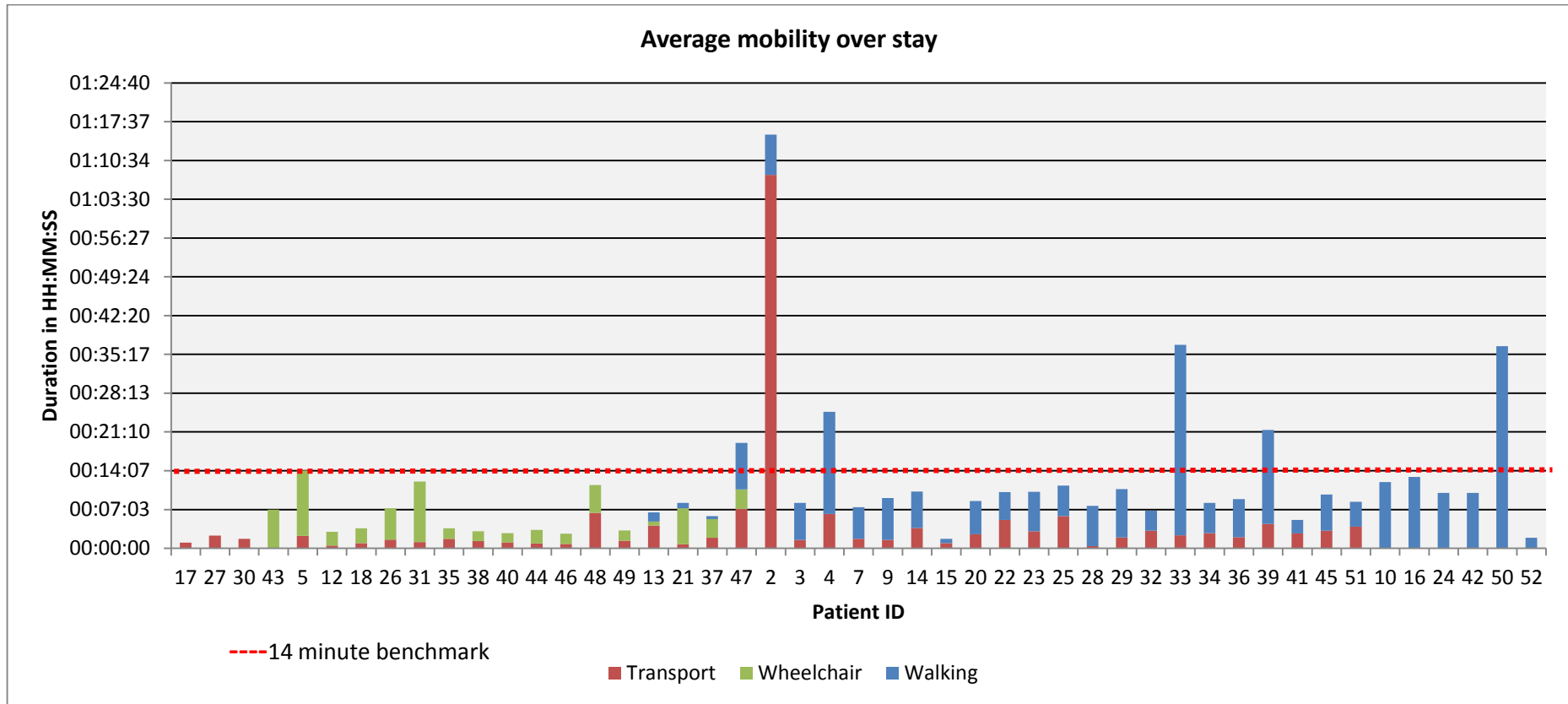
Figure 5. 25 Mobility duration in week before discharge for all patients (n=47)
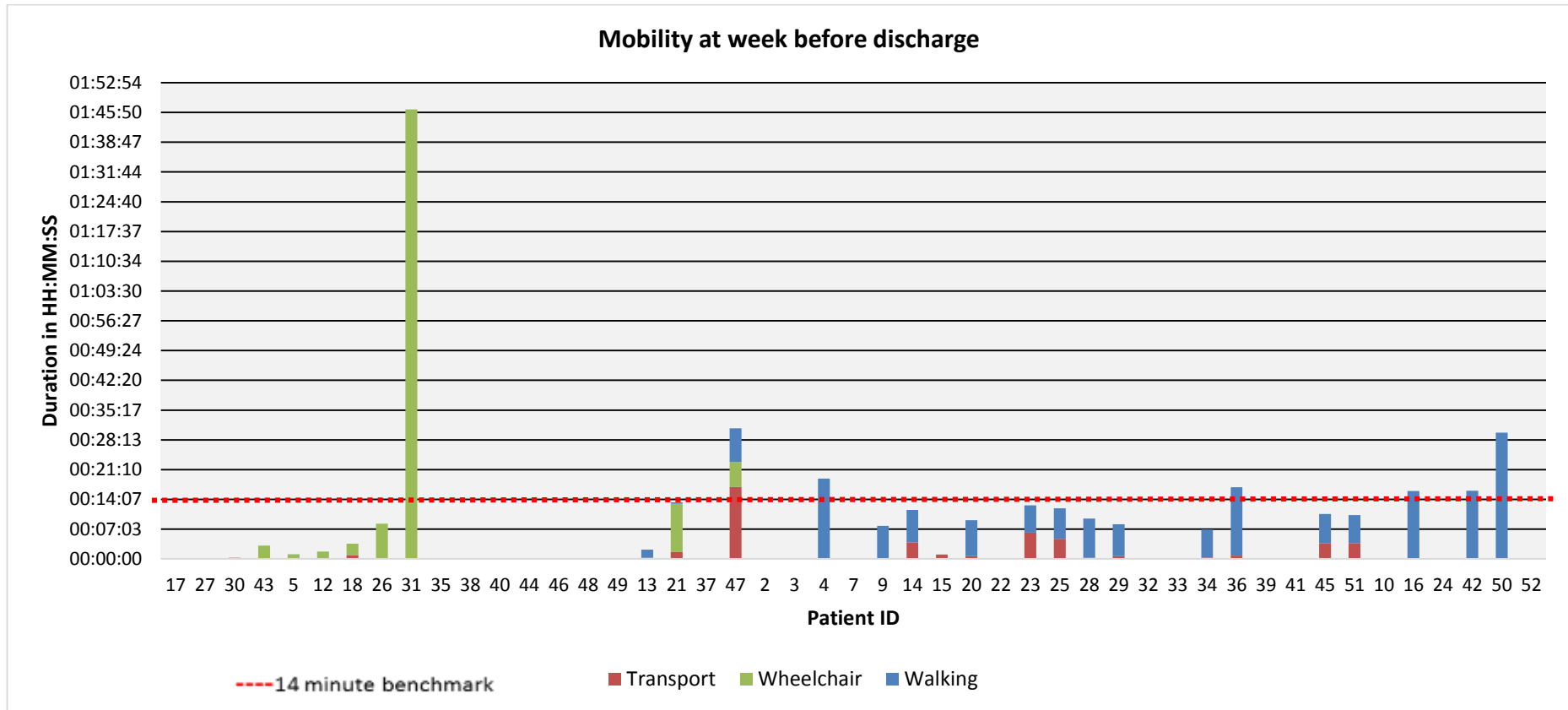
It can be seen (Figure 5.24) that patients belonging to those categories which included walking (categories 4 to 7) tended to be more mobile than those patients who were being transported or used a wheelchair. Likewise, when the OMs of those patients whose mobility was 14 minutes or more in the week prior to discharge were examined, it was found that alongside the scores of patients 4, 47 and 50 the mRMI admission and discharge scores of patients 16, 36 and 42 were also above 36. These patients were independent in ADL as the BI score was 20 on discharge and 11 or more on admission. The walking ability was better as compared to the other categories at admission as seen in the FAC scores and the weeks over which they were measured during the stay was also less in comparison to the other categories. The proportion of time spent by patients in their own rooms was plotted for patients according to the mobility categories (Figure 5.26). There is some suggestion of a slight trend for patients who were walking to spend slightly less proportion of time in their own rooms however more robust analysis needs to be undertaken before more definitive interpretations can be made.

Figure 5. 26 Distribution of average daily time patients spent in their own rooms across the 7 mobility categories

Average percentage of time spent in patients' own room

1: Transport only 2: Wheelchair only 3: Transport & Wheelchair 4: Wheelchair & Walking
5: Transport, Wheelchair & Walking 6: Transport & Walking   7: Walking only
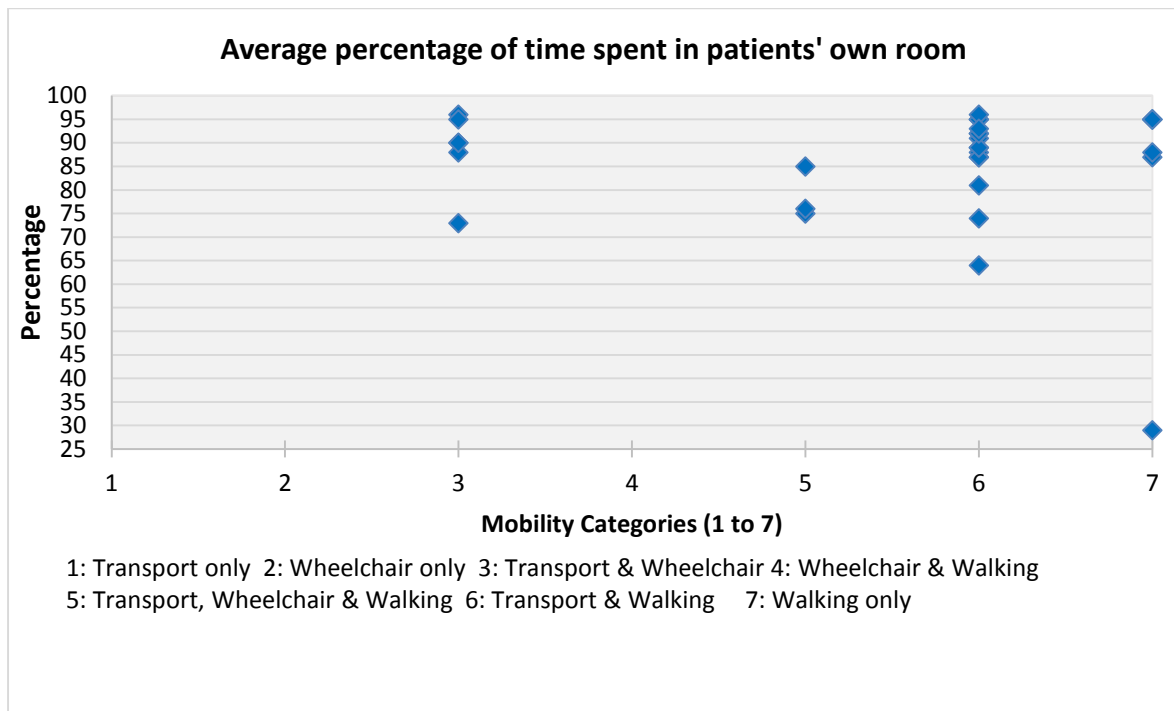
Exploration of Functional recovery

The aim of the current study was to gain a better understanding of aspects of functional recovery in the early stages after stroke. Moreover the above results also highlighted the need to determine the relationship between mobility duration and the relevant OMs reflecting functional recovery which were BI, mRMI and FAC. It was also deemed necessary to explore the change in all these parameters from admission to discharge to ascertain how patients recovered functionally after stroke during their stay in the rehabilitation unit. The following analysis was undertaken.

1) The relationship between mobility duration and OMs was determined using PCC and simple regression analysis

2) Change in the patient recovery from admission to discharge was determined with t-tests.

3) Relationship between mobility duration with other factors (age and MRS score) was determined with PCC.

The analysis for 1 and 2 was undertaken with a sample of 23 out of 47 patients as mobility scores in the week after measurement was started were not available for all patients. This is because some patients were recruited more than 2 weeks after admission and correlation analysis with OM scores such as BI, FAC and mRMI at admission was considered inappropriate. Hence those patients whose measurements started more than 2 weeks after discharge were excluded from analysis. Similarly for some patients, mobility scores for the week before discharge were not available and were excluded. The demographic details, average mobility and the OM scores are given in Tables 5.22, 5.23 and 5.24 respectively.

Table 5. 22 Patient demographics for subsequent exploratory study with mobility data (n=23)

F= 21 M=2	Mean	Std Dev	Min	Max
Age	79.82	8.82	58	90
Days post stroke	15.86	17.71	1	69
Length Of Stay	72.95	46.92	17	167
Follow up days	58.52	41.78	10	155

Table 5. 23 Mobility data for subsequent exploratory study (n=23)

Mobility	Mean/day	Std Dev	Min	Max	Sum
Week post-admission	00:07:18	00:10:23	00:00:00	00:53:20	02:47:29
Week pre-discharge	00:09:23	00:08:22	00:00:00	00:30:58	03:35:40

Table 5. 24 Patient outcome measure scores for subsequent exploratory study

N=23	Mean	Std. Dev	Min	Max
BI admission	4.60	5.33	.00	19.00
BI discharge	10.56	7.53	.00	20.00
mRMI admission	15.30	12.69	.00	40.00
mRMI discharge	25.00	13.74	3.00	40.00
FAC admission	1.78	1.47	.00	5.00
FAC discharge	3.00	1.93	.00	5.00

1) Relationship between mobility duration and OMs

There appeared to be a moderate correlation between mobility duration and OMs at admission and discharge (Table 5.25). The highest correlation was noted between mobility duration and mRMI score at discharge (0.77**). There was a moderate but significant correlation between change in duration of mobility and change in mRMI score. Simple regression analysis was undertaken with duration of mobility as the independent factor to determine if it could predict improvement in the following OM discharge scores: mRMI, BI and FAC thereby predicting functional recovery. The R^2

values for BI, mRMI and FAC discharge scores were 0.43, 0.49 and 0.21 respectively and the individual model significance values were ≤0.01.

Table 5. 25 Correlation between mobility duration and outcome measure scores

Parameter	BI	mRMI	FAC (Spearman's)
Mobility duration at admission	0.50**	0.56**	0.42**
Mobility duration at discharge	0.704**	**0.77****	0.51*
Mobility change (admission to discharge)	0.49*	**0.52****	0.46
**. Correlation significant at the 0.01 level (2-tailed). *. Correlation significant at the 0.05 level (2-tailed).			

2) Change in the patient recovery from admission to discharge

Paired samples t- tests were used to determine if the mobility duration and OM scores changed from admission to discharge. There was no significant increase noted in duration of mobility from admission to discharge (p=0.29). All 3 outcome measures showed a significant increase in scores from admission to discharge (p≤0.03).

3) Relationship between mobility duration with other factors

This involved exploring the relationship of patients' mobility measured by RMMS with their demographics namely age and Modified Rankin's Score which reflects a patients' level of dependency for ADL after stroke (van Swieten et al., 1988). Data was available for all 47 patients for this step.

PCC value of -0.50 (p<0.001) was obtained for correlational analysis between average mobility duration and age indicating fair relationship. There was a strong significant negative correlation between MRS scale score and average mobility as observed by Spearman's rho analysis (r= -0.73; p<0.001).

The results will be discussed at length in Chapter 7.

5.2.2 Time spent and movement detected

Percentage of time spent by patients in their own rooms was the second variable that was analysed for the longitudinal study. It is important to state that the analysis for this variable was undertaken *before* the analysis and results for the variables 'duration of mobility' previously presented in section 5.2.1 and 'sustained activity in RSU' which will be presented in section 5.2.3. The analysis was undertaken in two stages for this variable.

These sub analysis and the results are given below.

Sub analysis 1

The main aim of this stage was to quantify where patients spent time during their stay in RSU and how active they were in each area.

This study consisted of a sample of 20 patients. A decision was taken to primarily include those patients whose length of stay was an average of 6 weeks for this data analysis**.** This was because the targeted length of stay for patients undergoing rehabilitation in RSU is 6 weeks.

 Data processing software:

The data processing software was very similar to the one used for the validity study. Data processing for time and movement in various locations were being processed on a day by day basis for one patient at a time. The results from the display tool (Figure 4.5) were being manually entered onto a Microsoft Excel sheet.

The following scores were used for analysis

1) Average percentage time spent in select locations from admission to discharge

2) Average percentage of time spent moving in select locations from admission to discharge

3) Percentage of time spent active in each location.

The detailed approach used for data processing and analysis is described below

Raw data in minutes was obtained from the data processing software for time spent in each location and the time spent moving in each location for each day between 7:00 am and 9:00 pm. The locations selected for measurement were as follows: Patient's Own room, Day room, Physiotherapy room, Occupational therapy room, other areas (including toilets, offices, corridor) and away from the unit. Time spent in other areas included the time spent in areas defined under the category lack of location (Chapter 3 section 3.5). It also included minutes where location codes from other single rooms were picked up by the tags as the patient passed through the corridor due to the dispersion of IR waves outside the rooms.

In order to calculate the time spent in other areas accurately, the following formula was used:

Time in other areas = Total time (840 minutes) - (time in own room+ time in Day room+ time in Physiotherapy room + time in Occupational therapy room + time away from RSU).

If the time in other areas was 30 minutes or more per day, the data was rechecked to find out in which room the time was spent. The idea was to identify other rooms within the RSU that may have been of relevance for that individual patient. For example if a patient in the bay room was spending more than 30 minutes in another single room, there was a possibility that the patient may have been visiting another patient and this could be considered important from the point of view of interaction.

Daily percentage of time spent in each location was obtained as follows

Percentage of time spent in location= Time spent in location / Total time (840)* 100

Time spent moving each of the above mentioned location was also calculated from the data display software for each day and percentages were obtained.

Percentage of movement in each location= Time spent moving in location / Total time (840) *100

And finally percentage of time active in each location was also determined as follows

*Percentage of time active in location = Time spent moving at the location/ Total time spent at that location *100*

Sub analysis 1: results

Demographic details of these patients is given in Table 5.26 and it can be seen that their **M**odified **R**ankin's **S**core **(MRS)** ranged from 2 to 5. Moreover looking at the range for the OMs seen in Table 5.26, the sample of patients selected for the sub study can be considered as a good representative of the patients admitted in the rehabilitation unit.

Table 5. 26 Patient demographics for sub analysis 1

Females = 13, Males = 7	Mean (std dev)	Minimum	Maximum
Age in years	78 (9.8)	58	94
Number of days of monitoring	25 (16.6)	6	59
Length of stay	50 (83)	7	105
FAC score	Median/Mode=3	0	4
BI admission BI discharge	9 15	0 7	18 20
mRMI admission mRMI discharge	24 32	4 19	39 39
Key: FAC=Functional ambulation Category score (maximum score out of 6); BI = Barthle Index (maximum score out of 20); mRMI = modified Rivermead Mobility Index (maximum score out of 40)			

Percentage of time spent and movement detected in select locations

The average percentage (from admission to discharge) for each variable was obtained by dividing the total minutes by number of days the patients were measured with the RMMS. From Table 5.27, it can be seen that an average of 85% of their day or 11 hours a day (between 7:00am and 9:00pm) was spent in their own rooms where the movement measured by the wrist tag was 8 hours (61%). The amount of time spent in Physiotherapy and in the Day room was on average of 2% or 35 minutes a day where the movement measured was between 25 to 30 minutes. The low percentage of time spent in the Occupational area can be accepted as accurate as not all patients were referred for Occupational therapy and some of the sessions on dressing and hygiene can be undertaken in the bathroom which may have been identified as time spent in other areas.

Table 5. 27 Descriptive statistics for percentage of time spent by patients in different locations of RSU and the wrist tag movement detected in each room

Location	Daily average	Mean%	Std. Dev	Min%	Max%
Patient's own room	Time spent	85.29	8.95	56.60	94.90
	Movement	61.18	11.99	29.82	81.49
Physiotherapy room	Time spent	2.57	1.38	0	4.59
	Movement	2.30	1.22	0	4.48
Occupational therapy	Time spent	0.38	0.56	0	2.16
	Movement	0.36	0.53	0	1.95
Day room	Time spent	2.28	2.82	0	9.63
	Movement	1.92	2.31	0	6.66

Other areas	Time spent	4.51	3.16	0.87	10.20
	Movement	2.38	2.19	0	6.37
Outside RSU	Time spent	4.94	7.33	0	26.57
Total movement in RSU		72.84	10.92	54.74	94.94

The individual percentages for the 20 patients are displayed as stacked-cluster bars in Figure 5.27 and provide information about where patients were moving around within the RSU. While all 20 patients spent time in their own rooms and in other areas which included toilets and corridor, the number of patients who spent time in the Day room and therapy rooms varied. The exact number of patients who spent time in each location during their stay in RSU is given in Table 5.28 which indicates that some patients did not go to the Day room at all.

Table 5. 28 Number of patients (out of 20) spending time in each location of the RSU

Location	Number of patients who spent time there	Percentage (%)
Own room	20	100
Physiotherapy room	19	95
Occupational therapy room	12	60
Day room	14	70
Other areas	20	100
Outside RSU	15	75

Figure 5. 27 Sub analysis 1: percentage of time spent and movement detection in each location
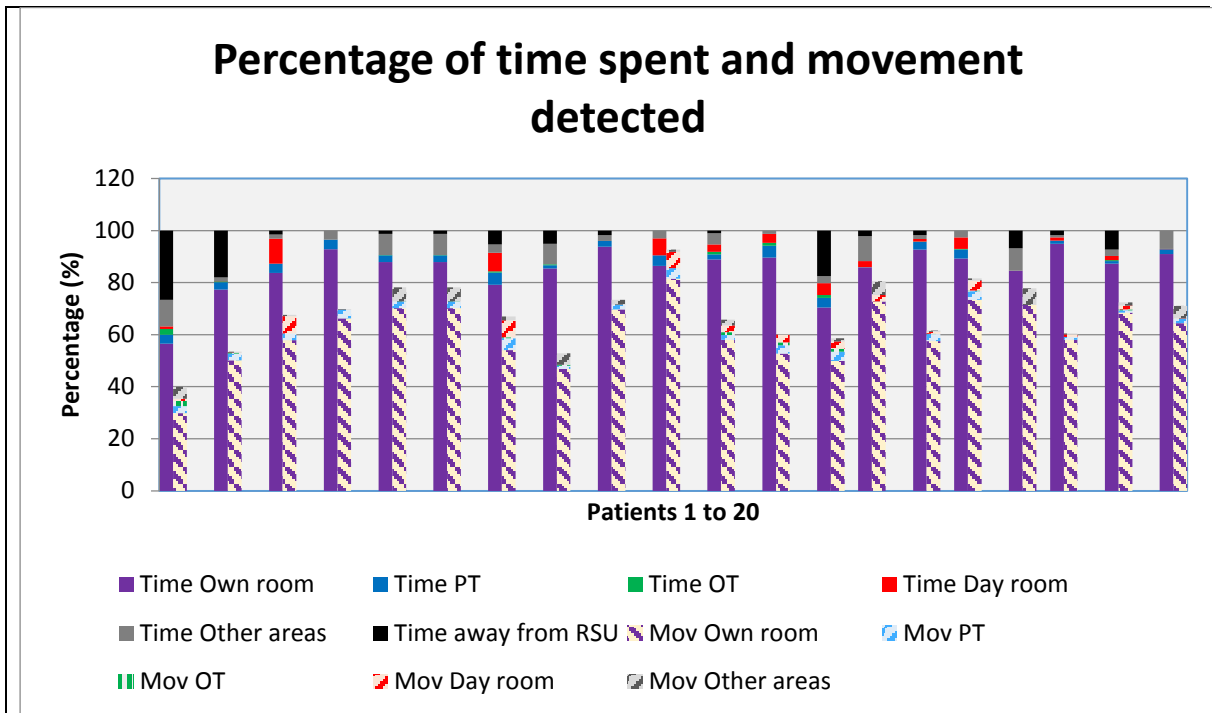
The graphs displays the percentage of time spent in each location and the wrist tag movement detected for each of the 20 patients. Location data and movement data are displayed in pairs of stacked column charts for each patient. The first column (solid coloured stacks) displays the percentage of time spent by the patient in different locations. The second column (striped coloured stacks) displays the percentage of movement in each location. It can be seen that patients spent most time in their own rooms (purple solid colour stack) and the therefore the corresponding movement is the most in their own room (striped purple stack)

Percentage of time active in each location: Based on the average time and movement in each location the percentage of time for which patients were active in each location was calculated and the details are presented in Table 5.29. It is important to highlight that not all 20 subjects spent time in the therapy areas and the Day room; hence the analysis has been performed taking this into account. It can be seen that when patients spent time in the therapy rooms they were most active (>91%). This is a reasonable finding as therapeutic activities are undertaken in these areas as compared to the other locations. However it is also important to note that

the amount of time spent in therapy areas and the Day room was 30 to 35 minutes as compared to that spent in patient's own room which was 11 hours. Hence it may be possible that patients also spent time resting in their own rooms which would account for the 30% of inactive time.

Table 5. 29 Percentage of time spent active by patients at each location

Location	Mean	Std. Deviation	Min	Max
Patient's own room	71.42	10.90	52.69	94.28
Physiotherapy	**91.01**	8.84	61.83	100
Occupational therapy	**95.26**	3.69	90.20	100
Day room	87.54	11.57	65.43	100
Other areas	44.47	22.46	0	87.27

Sub analysis 2

The 2nd sub analysis was undertaken with the following variables; Time and movement spent in patient's own room as well as total movement in RSU.

Looking at the results obtained from the 1st sub analysis, it was apparent that patients spent most of their time in their own rooms during the day were most active during therapy sessions. However the previous analysis was undertaken using the total number of days of stay in RSU for averaging in the early stages of the project and it was decided that these variables needed to be studied longitudinally. It was hypothesised that as patients recovered, they would begin to move around other areas of the RSU and spend less time in their own rooms. In this case it was important to determine whether the above mentioned variables changed significantly from admission to discharge. This would thereby suggest that percentage of time

spent in own room, movement detected in own room and overall movement detected in RSU could be used to explore functional recovery in the early stages after stroke.

The following analysis was undertaken in this phase with three variables at two time points, week of admission (first week) and week of discharge (last week).

1) Investigation of significant difference in time spent in patient's own room from admission to discharge.

2) Investigation of significant difference in time spent moving in patient's own room from admission to discharge.

3) Investigation of significant difference in overall movement in RSU from admission to discharge.

A sub set of 25 patients were selected based on the data with minimal data loss due to technical error such as tags taken off or vibration artefacts.

Weekly averages were obtained for the said variables. Descriptive statistics and t-tests were used for analysis.

Sub analysis 2: results

Table 5.30 gives the patients demographic details.

Table 5. 30 Patient demographics for sub analysis 3

N= 25 (female=18,male=7)	Mean	Std. Dev	Min	Max
Age (years)	77	9.0	56	93
Follow up days	30	18.23	6	60
Length of stay	53	35.5	7	156

1) Investigation of significant difference in time spent moving in patient's own room from admission to discharge

2) Investigation of significant difference in overall movement in RSU from admission to discharge.

Table 5. 31 Descriptive statistics of percentage of time in own room and movement (wrist tag) in the first and last week of stay

Variable	Week	Mean	Std. Dev	Min	Max
Time in patient's own room	First	86.34	15.59	23.21	100
	Last	81.20	16.52	28.31	99.22
Movement in patient's own room	First	60.03	17.17	16.40	81.49
	Last	58.14	15.54	20.27	89.15
Overall movement in RSU	First	70.61	14.11	37.57	94.94
	Last	73.09	13.59	40.15	94.94

Figure 5. 28 Sub analysis 2: Weekly group averages for percentage of time spent and movement in their own rooms and overall movement in RSU
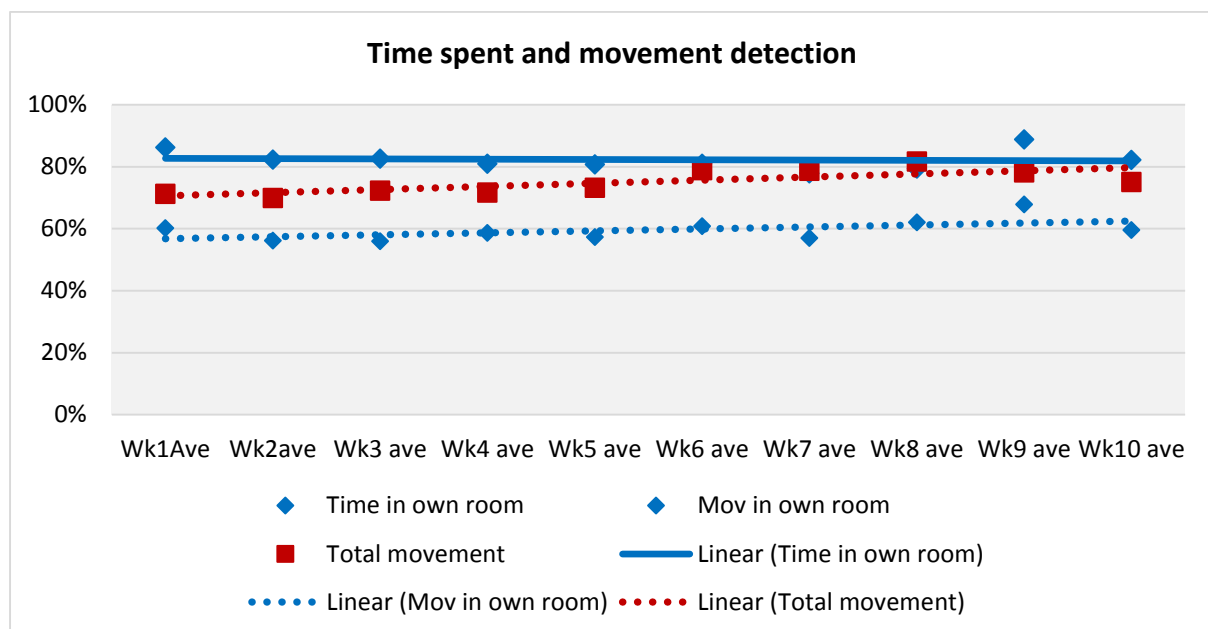
It is observed that the amount of time patients spent in their own rooms in the last week of stay was 5.14% less than that observed in the first week of stay. It is also

observed that between the week of discharge and week of admission the movement in own room decreased by 1.87% while the overall movement in RSU increased by 2.48% (Table 5.31).The movement and time proportions tended to remain the same over weeks (Figure 5.28). Paired samples t-tests were used to determine the difference in these variables over time.

For the percentage of time spent in patients' own room the assumptions of normality was not met (p=0.00) therefore, non-parametric tests were undertaken. There was no significant difference between the movement measured for the first and last week of stay for both variables (Table 5.32).

For the percentage of movement in patients' own room and overall movement in RSU. The assumptions of normality were met, parametric tests were undertaken. There was no significant difference between the movement measured for the first and last week of stay for both variables (Table 5.32).

Table 5. 32 Difference between first and last week of stay for movement in patient's own room and total movement in RSU

Dependent variable	Independent variable	Paired samples t-tests
Movement in patient's own room	First week vs last week	p = 0.60
Overall movement in RSU	First week vs last week	p = 0.49
Time in own room	First week vs last week	p = 0.18
p>0.05 hence no significant difference between weeks		

Besides the above results, change in the percentage of time spent in patient's own room for individual patients could be obtained via RMMS. The line graphs for patients discharged is shown in Figure 5.29. From the graph it can be seen that increase (patient L050) or decrease (patient L047) in the time spent could be detected by RMMS and demonstrated with ease.

Figure 5. 29 Sub analysis 2: Time spent by individual patients in their own rooms (n=20) over weeks
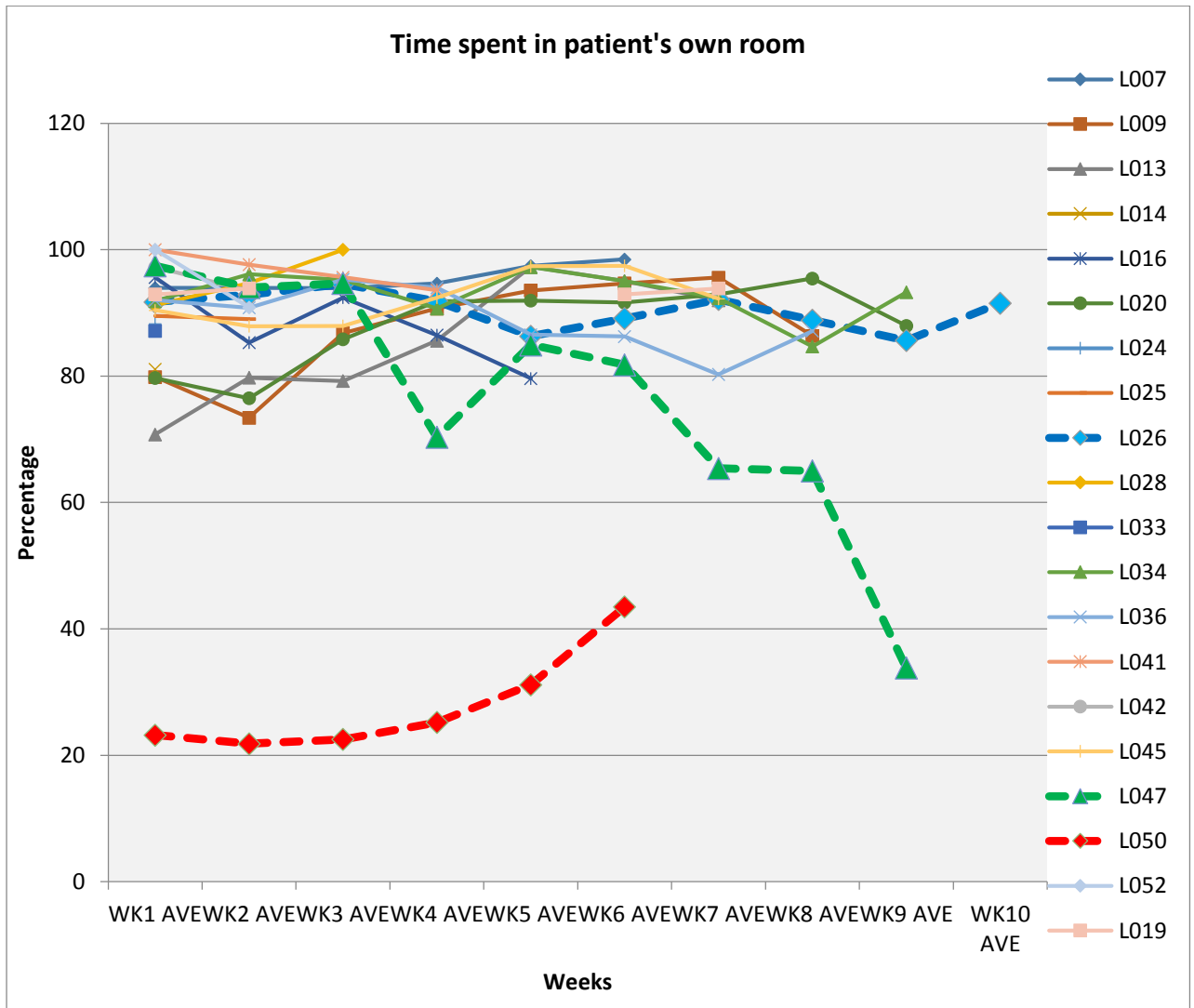
5.2.3 Percentage of sustained activity

Percentage of time spent in undertaking sustained activity was the last parameter used from the longitudinal study to gain a better understanding of the functional tasks undertaken by patients.

Although the overall movement did not appear to change significantly from admission to discharge as seen in section 5.2.2, an average of 70% movement (10 hours) was still considered as high and there was a need to separate functional movement from the non-functional movement which could be due to the low threshold of the tag motion sensor.

The most suitable way for this differentiation was to categorise the raw movement data based on the length of time for which each bout of movement occurred. It was hypothesised that for patients to be undertaking an activity that was functional such as dressing or upper limb exercises, the activity would last for at least 10 minutes. Therefore with duration of wrist tag movement was considered as the unit of measurement based on which intensity of activity could be calculated. Total duration of movement recorded, was subdivided according to duration of movement in each episode. The categorisation that was used is given below (Table 5.33)

Table 5. 33: Classification of activity based on wrist tag movement

Categories	Duration of each bout of movement
Twenty minutes or more of activity	> 20 minutes
Higher duration of activity	> 10 up to 20 min
High duration of activity	> 5 up to 10min
Medium duration of activity	more than 3 up to 5min

Raw movement data output was obtained as CSV sheets and an example is given in

Figure 5.30.

Figure 5. 30 Screenshot of the CSV sheet with the output of movement data for wrist tags

The category of activity, the room it which it occurred and the specific patient involved are given in columns A, C and D respectively.

The start and end times and dates are displayed from columns J to K

Total duration of each activity bout in minutes and seconds is in column M and in total seconds is given in column N.

Only the first two categories were used for analysis and data was analysed as explained below.

Weekdays selected for analysis from 7:00 am to 9:00 pm.

Total number of weekdays over which patients were monitored with RMMS was noted down for each patient.

At the rate of 14 hours a day, the total hours over which measurements were undertaken during their stay was calculated as follows

Total hours of measurement= Total number of weekdays *14 hours.

Time obtained in hours was converted into seconds as follows

Total time of measurement in seconds = Total hours of measurement * 3600

Total percentage of time spent by each patient in bouts of activities which belonged to the category '20 minutes or more' were calculated as follows

Total time in seconds for '20 minutes or more of activity' / Total time of measurement in seconds*100

Total percentage of time spent by each patient in bouts of activities which belonged to the category 'Higher level of activity' (between 10 to 20 minutes) were calculated as follows

Total time in seconds for 'Higher level of activity'/ Total time of measurement in seconds * 100

Percentage of sustained activity: Results

Raw data from all 47 patients was used for analysis and their demographic details have been presented below (Table 5.34).

Table 5. 34 Patient demographics for percentage of sustained activity analysis

Female = 39, Male =8	Mean	Std Dev	Min	Max
Age	78.25	11.44	32	90
Days post stroke	16.61	15.66	1	69
Length Of Stay	85	51.12	7	200
Follow up days	57.53	40.17	6	155

Patients spent 15% of their time undertaking PA that lasted 20 minutes in duration and most of their time was spent in activities that lasted 10 minutes or less (Table 5.35). The individual profiles are presented in Figure 5.31 where the patients have been arranged in decreasing order with regards to the percentage of time spent in activity bouts lasting 20 minutes or more. The total number of days over which measurement was undertaken is displayed on the secondary Y axis (vertical axis on the right hand side of graph)

Table 5. 35 Percentage of time spent in category of activity

Activity category	Mean%	Std. Deviation	Min%	Max%
> 20 minutes	14.67	13.50	0.05	55.34
10 to 20 minutes	9.96	5.18	0.30	19.29
< 10 minutes	75.36	17.12	31.06	99.64

Figure 5. 31 Percentage to sustained activity over stay
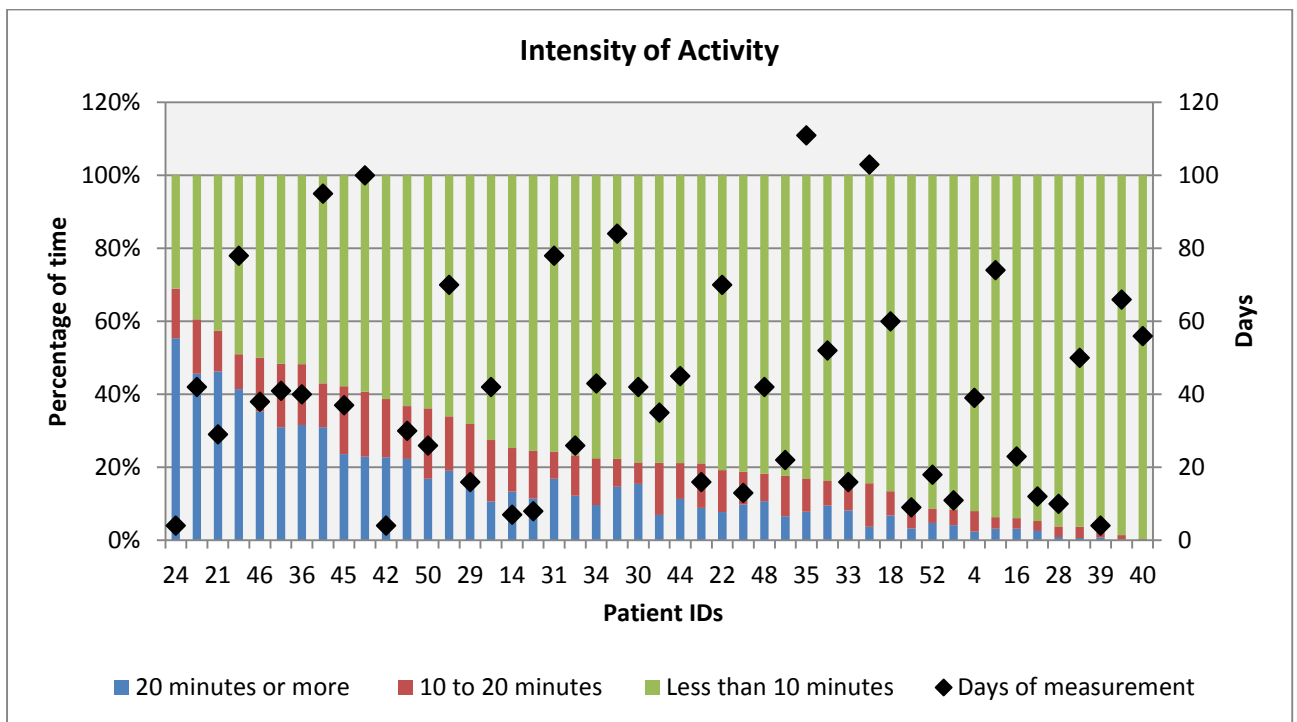
Out of 47, there were 12 patients who spent ≥ 20% of their time engaged in activity bouts that lasted over 20 minutes (Table 5.36). OM scores, mobility data and field observation records made by the researcher (self) were reviewed to determine if there were any overt explanations for the increased intensity of movement. While the OM scores and mobility status of these patients did not indicate any conclusive explanation, subjective observation records did indicate some reasons that could explain the increased intensity of movement. Patient 13 had a history of movement disorder which affected her upper limbs while patient 27 was given sedatives as she was reported to be agitated. Both these causes could have led to increased wrist movement which were non-functional. Additional activities such as solving crossword puzzles (patient 21) and practising therapeutic exercises with relative outside of therapy time (patient 47) also explain increase in percentage of activity. It was also noted that 9 out of the 12 patients did not represent any major speech and language or cognitive impairment and were alert and communicating most of the time. This

could have led to increased wrist movement due to hand gestures while communicating. However objective outcome measure scores are warranted to further support these findings.

Table 5. 36 Details of patients spending more than 20% of time in sustained activity

Patient ids	20 minutes or more of activity	10 minutes to 20 minutes of activity	Less than 10 minutes of activity	Days of measurement
13	22%	15%	63%	30
15	41%	10%	49%	78
21	46%	11%	43%	29
24	55%	14%	31%	4
26	23%	18%	59%	100
27	31%	12%	57%	95
36	32%	17%	52%	40
42	23%	16%	61%	4
45	24%	19%	58%	37
46	35%	15%	50%	38
47	31%	17%	52%	41
49	46%	15%	39%	42

It was observed that the standard deviation for the number of days for which measurement was undertaken was large. As percentages were calculated using the number of weekdays, there was a possibility that percentage of 20 minutes of activity would be more for patients who were measured for less number of days as opposed to those who stayed longer. To examine the extent of relationship between number of days and percentage of activity, Spearman's correlation coefficient was used. The correlation coefficient value was 0.04 and it was not significant (p=0.80) suggesting that there was negligible correlation between the number of days of measurement

and the intensity of activity. The relationship between the average duration of mobility undertaken by these 47 patients and the average intensity of movement was explored and there was very poor correlation between mobility duration and percentage of 20 minutes or more of wrist tag movement (PCC = -0.085, p=0.56).

Preliminary exploration of the functional movement type

In order to identify the kind of functional activities that patients were doing that lasted longer than 20 mins in duration; preliminary exploration was attempted by using the BM data obtained in the first phase of the project (Chapter 4 Section 4.3.3). From BM, the kind of activity that being undertaken every 10 minutes was recorded via the CERISE tool app. Data from RMMS detailing the date and time when sustained activity of more than 20 minutes was undertaken was extracted for those patients who were recruited for the main validity study. The time periods from the RMMS activity data when 20 minutes of activity was undertaken was matched against the time period when the BM activity was recorded for each patient. Examples of how the observations from the two studies were compared for exploration are given below.

Example 1: RMMS data for one patient is given in the Figure A. Under the name column, the category of activity is displayed as 'twenty plus'. The start and finish time and date show that the activity was undertaken on 15th May 2012 between 11:43 and 12:04.

BM data is displayed in Figure B. It can be seen that for the 3 observations made between 11:40 and 12:00, that the type of activity (last column) was with a therapy staff member.

Thus by matching the time frames of both sets of data, it was deduced that for this patient, the type of activity being performed when the sustained movement of tag was 20 minutes or more was therapeutic and that therapists were present.

Figure A: RMMS data

RMMS Data							
Name	Location	InvolvedAgent	Start(time)	Start(date)	Finish(time)	Duration	Duration(sec)
TwentyPlusM	100	patient_N_W	11:43:35	15/May/2012	12:04:53	21min 18sec	1278

Figure B: OBMT data

OBMT data							
patient tag	Date	Time	Location	Interaction	Equipment use	Supervised or assis	Type of Activity
125632	15-5-12	1140	Therapy room	Therapist with	Other	Supervised or assis	Individual with occupational therapist
125632	15-5-12	1150	Therapy room	Therapist with	None	Supervised or assis	Individual with physiotherapist
125632	15-5-12	1200	Therapy room	Therapist with	Other	Supervised or assis	Individual with physiotherapist

Example 2: RMMS data for another patient is given in the Figure A. Under the name column, the category of activity is displayed as 'twenty plus'. The start/finish time and date show that the activity was undertaken on 6ᵗʰ June 2012 between 17:02 and 17:531.

BM is displayed in Figure B. It can be seen between for the 5 observations made between 17:00 and 17:50 that the type of activity (last column) was eating and sitting. Moreover the patient was alone as seen from the 'Interaction' column.

Thus by matching the time frames of both sets of data, it was deduced that for this patient, the type of activity being performed when the sustained movement of tag was 20 minutes was eating or sitting.

Figure A: RMMS data

RMMS Data							
Name	Location	InvolvedAgent	Start(time)	Start(date)	Finish(time)	Duration	Duration(sec)
TwentyPlusM	500	patient_A_W	17:02:45	06/Jun/2012	17:51:07	48min 22sec	2902

Figure B: OBMT data

OBMT data							
patient tag	Date	Time	Location	Interaction	Equipment use	Supervised or assis	Type of Activit
125631	06-Jun	1700	Patient Room	No One	None	Independent activi	Sitting
125631	06-Jun	1710	Patient Room	No One	None	Independent activi	Eating
125631	06-Jun	1720	Patient Room	No One	None	Independent activi	Eating
125631	06-Jun	1730	Patient Room	No One	None	Independent activi	Sitting
125631	06-Jun	1740	Patient Room	Other persons	None	Independent activi	Sitting
125631	06-Jun	1750	Patient Room	No One	None	Independent activi	Eating

Out of 10 patients, there is no data available for two patients (pt1 and pt8) and two

patients did not perform any activity that lasted for 20 minutes or more (pt 4 and 5).

Hence there were 88 observations in total from 6 patients from the validity study

On comparison with BM data, all events where the activity was 20 minutes or more

in duration could be mapped against the RMMS data for the time frames.

Out of a total of 88; for 42 comparisons, the activities were performed alone and for

46 comparisons patients were either supervised or assisted by a member of staff (to

put it simple someone was present in the same room as the patient) (See Tables 5.37 and 5.38)

Table 5. 37 Type of activities undertaken when alone

Type of activity undertaken when patient was alone	Number of observations out of 42
Sitting	18
Eating	18
Autonomous exercises	1
Passive leisure	2
Dressing and hygiene	2
Wheelchair propulsion	1

Table 5. 38 Type of activity undertaken when supervised

Type of activity undertaken when patient was supervised/assisted by staff	Number of observations out of 46
Active leisure newspaper	1
Communication	4
Sitting	7
Eating	1
Dressing and hygiene	4
Patient with therapists, or nursing care	28

Most of the activities that were undertaken were either in the presence of staff which meant that they were therapeutic. When patients were alone, patients were either eating or sitting. Moving around or change of position was not observed. The implication of these findings are discussed in Chapter 7 subsequently.

The next section of this chapter focuses on the results of the pilot study that was undertaken at home.

6. Phase Two: Acceptability study

The acceptability study was undertaken continuously alongside the other studies in both stages of this project to determine compliance from the end users, in this case, the patients as well the healthcare professionals in RSU. Unlike the reliability and the validity studies which were quantitative in nature, there was a qualitative element involved in the acceptability study design.

6.1 Study design: Acceptability study

The main aim of this study was to investigate the user-friendliness and comfort of wearing the tag as well as to and the secondary aim was to explore the experience of participants being remotely measured using real time location technology in a rehabilitation setting.

For many ubiquitous, sensor based devices user acceptance and comfort have been sought from participants mainly through questionnaires and focus groups (Allen et al., 2009, Demers et al., 2002, Kramer et al., 2013, Hale et al., 2008). For this study a paper based questionnaire was selected over focus groups or interviews keeping in mind the type of participants and the underlying cognitive or speech and language impairments that may be present. The questionnaire contained 11 statements requiring scaled responses that ranged from 'highly disagree to highly agree'. (Appendix 6). Feedback on clarity of questions and the language was obtained from a service user who was recruited from the organisation 'Involving People'. She was stroke survivor and provided feedback as an 'expert patient'. A clinical psychologist working within the RSU also provided feedback on the questions before the final version was created.

Apart from this a qualitative approach known as the participant-observation method was used to explore the perspectives of patients and staff on being monitored by the system via wearing a device (Fitzpatrick and Boulton, 1994). The participant observation method was selected because the author was present on the unit 2-3 times a week over the whole duration of data collection. This fitted with the conditions of the researcher being able to observe and be involved in the subject of the study yet record their findings as objectively as possible from the point of view of an 'outsider'. The author's presence on the unit during working and non-working hours enabled the recording of events regarding compliance, the practical issues of wearing the tags and the perception of the staff and patients (Kawulich, 2005).

Inclusion-Exclusion Criteria

The inclusion criteria was as follows:

-Diagnosis of a Cerebro-vascular accident (CVA)

- Either ischemic stroke or haemorrhagic stroke

The exclusion criteria was as follows:

-Previous history of stroke

- Other factors like cerebral palsy, Parkinson's disease or mental illness such as schizophrenia

Sample size and recruitment

With the focus being on the 'richness' of data obtained instead of achieving 'statistical significance' all 50 patients taking part in the longitudinal study were recruited by default into this study. Therefore the sample size was 50.

Data collection

Questionnaire protocol: The questionnaires were given to the patients before discharge when the tag was taken off. The same verbatim explanation regarding the purpose of the questionnaire and how to fill it was given to all staff and patients to ensure standardisation. If writing or reading was a difficulty, the researcher read out the questions and ticked the answer. Each patient was asked if they had any additional comments and these were noted down after checking with them that the researcher's interpretation was accurate. The questionnaires were also given to the staff in the unit to obtain their feedback on the acceptability of wearing the tag.

Participant-Observation protocol: The author as the main researcher was the participant –observer in this study. Field notes were made during the course of the research from March 2012 to March 2013. The field notes were shared with the research team on a (3-6) monthly based on what was observed. This helped check that the observations were being recorded as objectively as possible and individual bias was minimal. Any relevant theme information that seemed to emerge from the observations were discussed with some members of staff and patients to probe further. These were done in casual conversations either in the ward or when accompanying a staff member on home visits. The author's experience and reflections were also used to draw upon the conclusions from the study.

Data analysis, Data processing and themes selection

Themes were selected to explore the data from the questionnaire and the field notes. In order to select the themes, existing relevant literature was reviewed and priori themes were selected based on the research undertaken previously (Ryan and

Bernard, 2003) (Braun and Clarke, 2006). The relevant articles that were used to select the themes for the current study are discussed here.

The Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST) is an outcome measure that evaluates user satisfaction with assistive technology (Demers et al., 2002). The questions in this measure are divided into two headings which are 'device' and the 'service'. The characteristics such as comfort, weight, safety and simplicity of use are some items that the QUEST consists of under the heading 'device'. A user feedback questionnaire was designed by Simone et al. (2007) to gauge the participant experience and user comfort of a wearable finger flexion monitor developed to evaluate hand function and similarly Kramer et al. (2013) also gauged acceptability of wearing PAL2 where participants were asked to rate statements relating to comfort and experience on a 5-point Likert scale. Hale et al 2008 also designed a utility questionnaire to evaluate participant's opinion of using RT3 which is a tri-axial accelerometer which accelerometer that measures PA. The questions in their study addressed issues such as; acceptability of wearing the device every day, remembering to wear it daily, interference with ADL and whether they would wear it in the future.

Staff members' compliance with wearing the tags and perception of activity monitoring were also important themes to explore based on the initial discussions with the staff at the beginning of the project to gauge their initial reaction to wearing the tags.

Depending on features evaluated in the literature mentioned above the questions from the questionnaire were divided into 3 themes to gauge participants' responses. These themes and the related questions are given in **Table 6.1.** Apart for these, participants' compliance with wearing the tag and their perception of remote activity

monitoring were also explored as additional themes using this approach (Braun and

Clarke, 2006).

Subsequently, theoretical thematic analysis to process the data from the field note

data was fit into the pre-existing themes.

Table 6. 1 Themes and related questions for acceptability study

Theme	Questions
Acceptability	I found the tag to be acceptable
	I found it acceptable to wear it in front of other people
	I would find it acceptable to wear the tag for one month
Comfort level	I forgot I was wearing the tag
	I experienced discomfort while wearing the tag
	I found that the tag restricted my arm or leg movements
	The tag did not interfere with my daily activities
	I found it simple to take it on/off on my own
Dimension and safety	I found the tag too big.
	I found the tag too heavy
	I have concerns about its safety

 Apart for these, compliance with wearing the tag and perception of being monitored

were also explored additionally.

These were as follows: Tag acceptability, Experience and comfort and Tag

dimensions and safety. Additionally, preference and compliance with wearing the

tags were also determined.

Scaled responses in the questionnaire were coded from 5 to 1 with strongly agree

being coded as 5. Data was analysed using descriptive statistics and Pie charts were

obtained.

Data triangulation and methodological triangulation was undertaken in order to

validate interpretations made for observations recorded in the field notes (Bloor,

2006, Creswell, 2007). Data from all three sources; the field notes, the questionnaire

and relevant quantitative data from the longitudinal study were amalgamated for

obtaining the results for the acceptability study. With respect to exploring user

acceptability of patients as participants, the categorical data from the questionnaire responses was the primary source of information. It was supplemented with data from the field notes and relevant quantitative data from the longitudinal study (table 6.2). For exploring user acceptability of staff as participants, the main source of data were field notes from participant-observation for the themes of compliance and perception of activity monitoring whereas for the other themes, the main source of information was categorical data from the questionnaire (Table 6.3).

Patient data analysis

Table 6. 2 Amalgamation of data from patients

Themes	Questionnaire	Participant Observation	Longitudinal study data
Acceptability	Responses to questions Any specific comments?		Number of days for which tags were worn by patients. Number of participants who withdrew from the study.
Comfort	Responses to questions Any specific comments?	When tags were checked every week, was anything observed that was relevant? Did the patients or the relatives report anything to the researcher?	How many wore the tag throughout their stay in RSU? Did any patient ask the tags to be removed due to reasons such as discomfort?
Dimensions and safety	Responses to questions Any specific comments?	Any adverse reactions reported? Or observed?	
Compliance	Responses to questions Any specific comments?	Any patients who were not wearing the tag when seen during weekly visits?	Number of patients who withdrew or asked the tag to be removed? Or removed it themselves?
Perception of AM	Any specific comments?		
Patient preference (wrist or ankle)	Responses to question Any specific comments?	Any adverse reactions observed during weekly visits?	Number of patients in the longitudinal study who wore the tag on the wrist and/or ankle

Table 6. 3 Amalgamation of data from staff

	Questionnaire	Participant Observation Field Notes	Longitudinal study data
Acceptability	Responses to questions Any specific comments?		Number of participants who withdrew from the study?
Comfort	Responses to questions Any specific comments?	When tags were checked every week, was anything observed that was relevant? Did staff report anything to the researcher?	
Dimensions and safety	Responses to questions Any specific comments?	Any adverse reactions reported or observed?	
Compliance		Any staff member observed not wearing the tag during weekly visits? Any discussion with staff members regarding wearing the tags?	
Perception of AM		Discussion with staff during meetings. Informal conversations with staff during weekly visits. Observation field notes (number of staff members wearing the tag)	

6.2 Results: Acceptability study

The acceptability study was undertaken to explore primarily the user-friendliness and comfort of wearing a tag. Along with questionnaires, field observations were made by the researcher and these were used for analysis and for confirmation of questionnaire data with regards to acceptability of the automated system. The main results for the acceptability study are divided into 2 parts. The acceptability results from patients are presented first followed by results from staff members.

1) Patients' data analysis

User feedback questionnaire:

Out of 52, 17 patients completed the questionnaire thus the response rate was 32%. The reasons for non-completion are given in Table 6.4. More demographic details are given Table 6.5**.** Total time taken to fill the questionnaire was 15 minutes at the most. 10 patients wore the tags on their wrists and ankle while 7 wore it only on the wrist. The number of participants wearing the tag on the left or right side was almost equal.

Table 6. 4 Percentage of questionnaire non completion

Reason	Total%	Number
Speech and/or cognitive impairment	27%	14
Lost to follow up/ withdrew	11%	6
Language barrier	4%	2
Discharged before questionnaire given	21%	11
Medically unwell	2%	1
Did not return questionnaire	2%	1

Table 6. 5 Patient demographics for acceptability study

N=17 (f=14,m=3)	Mean	Std. Dev	Min	Max
Age in years	74.7	15.19	32	93
No of days tag worn for	35.82	31.11	9	118

Questions were categorized into 3 themes as described in section 6.1. Based on the number of responses under each category, pie charts depicting the patients' responses were obtained. The relevant observations from the field notes were analysed and used to supplement the questionnaire data results for the same 3 themes. Finally to further validate the questionnaire data and to confirm the subjective interpretation of observational notes, descriptive data from the longitudinal study was used to arrive at the final results regarding acceptability.

Theme 1: Tag acceptability

More than 70% of the patients said that they found the tag acceptable and were willing to wear it in front of other people (Figure 6.1).

During the course of the study 3 participants chose to withdraw for the study however apart from that there were no known cases where patients or their family members objected to this method of monitoring after providing informed consent. The longitudinal study records also showed that the patients wore the tags for 64 days on an average with a maximum of 260 days. All this indicates that the tags could be an acceptable form of a BWS for unobtrusive activity measurement.

Theme 2: Tag comfort and experience

Majority of the patients (70% to 80%) found the tag comfortable to wear and this is further supported by the fact that 76% of them agreed that they forgot that they were wearing the tag. It also appears that most of them were able to perform their daily

activities with ease (Figure 6.2). However only 19% of participants found the tag easy to wear and take off. While some patients wore it comfortably for over 6 months, there were two cases where patients asked if it could be taken off after wearing the tag for over 4 months. It was also observed that the hospital band used to tie the RFID tag needed to be adjusted quite carefully. If it was too loose, the band slipped up the arm which could cause some discomfort and could also catch on cardigan or knitwear while dressing. As the tags were on the non-affected side, patients could find it difficult to use the affected hand while dressing the unaffected side. Sometimes the tag rested on the plantar aspect of the hand and could get in the way of writing. However, if the band holding it was tied appropriately, this could be avoided. As the main researcher was present twice a week for the entire duration of data collection, all patients, their relatives as well as the staff had ample opportunities to inform the researcher in case patients found the tag uncomfortable. Moreover the researcher regularly enquired from the patients or staff regarding the comfort of the tags. Hence it can be said that overall the tags were comfortable to wear and did not restrict upper limb or lower limb movement while patients were in RSU.

Theme 3: Tag dimensions and safety

Most participants (69%) found the tags safe however few (≤25%) had concerns about the weight and size of the tags (Figure 6.3).

There were no bruises or any reactions noted on the wrist or ankle during the weekly inspections. The tags were sturdy and there were no complaints of them breaking or causing any injury. The feedback comments regarding the weight and the bulk of the tag were taken on board as there may be other devices that may be lighter than the tag. However for the requirements of the project this RFID tag was found most

feasible. It should also be noted that the weight of the tag (14 grams) was less than half the weight of the SAM™ (38 grams) and also smaller in size (SAM™= 70 x 50 x 20 mm and tag = 48 x 48 x 14.5 mm). Overall the tags and RMMS can be considered safe to use.

Additional feedback was given by patients regarding their experience of wearing the tag. Their comments are given below which gives some insight into the comfort levels of the tags.

"Little heavy"

"Ankle tag was uncomfortable/ got in the way of putting socks on and off otherwise no problem"

"Got in the way of writing"

"Uncomfortable on the leg"

"Make it prettier!"

"Irritation on moving the arm"

"When there is another tag to be worn can the two be integrated?"

"It was a relief to take it off"

"Bulk was annoying sometimes"

Patient preference: Patients were asked whether they would like to wear the tags around their wrist or ankle. Out of 17, 10 (58%) patients said they would prefer to wear on the wrist, 3 preferred to wear it around the ankle, and 3 patients said it did not matter (17%). One participant said they would like to wear it on the ankle instead of the wrist *but only* when going out of the house or RSU. Observation notes also suggested that most patients at the time of recruitment preferred to wear the tag around their wrist. There were incidences when the ankle tags were taken off after a few days in case of swelling around the ankle which caused the band to become tight. For the longitudinal study data all 52 patients wore the tag on their wrist out of which 19 patients additionally wore it on their ankle, while the remaining 3 wore it on

their shoe instead of the ankle. No patient preferred to wear it around the ankle only. This strongly suggests that patients preferred to wear the tag around the wrist.

Previous experience: Only 4 (23%) patients could confirm that they had worn another monitoring device (e.g. step counter or pedometer) previously; however more explanations regarding these were not obtained.

Compliance and perception of activity monitoring

On the whole patients were very compliant with wearing the tags. There were no events where tags were taken off without a good reason. The patients and their relatives seemed positive about PA being measured in this way. They would often enquire about the results obtained from their tag and how active patients were.

Figure 6. 1 Pie charts depicting patient responses for theme 1 statements (tag acceptability)

Figure 6. 2 Pie charts depicting patient responses for theme 2 statements (tag user comfort and experience)

Figure 6. 3 Pie charts depicting patient responses for theme 3 statements (tag dimensions and safety)
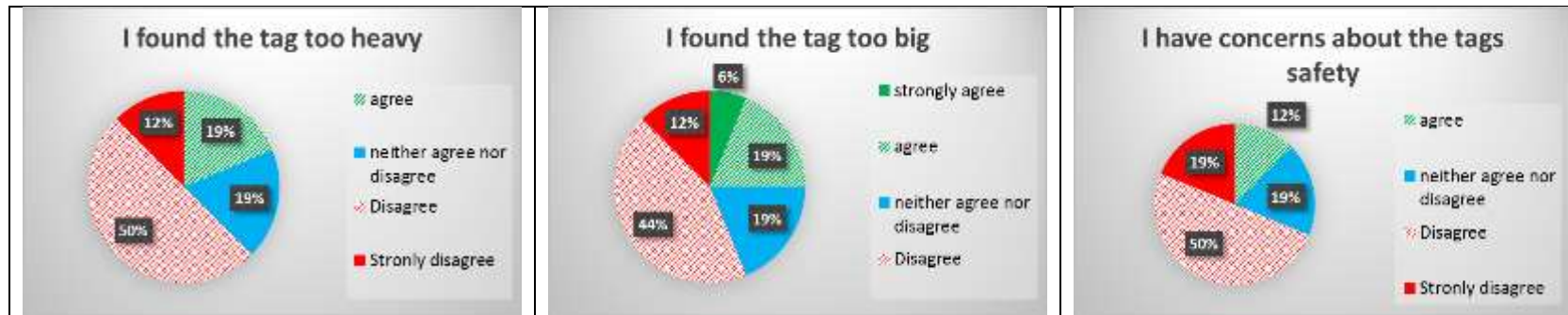
2) Results from staff members' data analysis

User feedback questionnaire: staff

Staff members were given similar questionnaires which were completed by 14 of them. They included nurses, physiotherapists, occupational therapists, speech and language therapists, clinical psychologist and the main receptionist. All of them wore the tag with a badge clip either on their waist or on the collar of the uniform during working hours.

Theme 1: Tag acceptability

More than 90% of the staff members replied that they found the tag acceptable and were willing to wear it in front of other people (Figure 6.4).

Theme 2: Tag comfort and experience

Over 90% of staff members said that the tag was comfortable and did not restrict their movement or interfered with their work (Figure 6.5).

Theme 3: Tag dimensions and safety

Most participants (69%) found the tags safe (Figure 6.6).

Previous experience: Eight staff members confirmed that they had worn another BWS previously however more explanations regarding these were not obtained.

Additional feedback was given by 2 staff members regarding their experience of wearing the tag as given below

"It made me aware of the amount of steps taken during my working shift"

"It sounds a really interesting project and it has been no trouble wearing the tag - as long as I remember to put it on. I look forward to hearing the results. Good luck."

There were no specific observations that were recorded on-sight with respect to staff members regarding comfort and user friendliness of tags. As the tags were worn with a badge clip, it can be said that largely the tags were comfortable and considered safe to use by the staff. However for the factors of compliance and perception of continuous activity monitoring, participant-observation notes, conversations with staff in RSU as well as formal meetings with them generated valuable data that was used for analysis for these two factors.

Compliance: Compliance in the first stage of the project especially for the validity study was extremely good. All HCS ensured that they were wearing the tags. All therapy based professionals consistently wore the tags throughout the data collection for the project. Most of them wore it on their uniform or along with their ID tags. Compliance achieved from the nursing staff was comparatively less. Initially the researcher would remind them to wear the tags or hand one over to them however this practice was later stopped as it could have had a detrimental effect. The main reason behind this decision was that it was important for the participants to *'forget'* that they were wearing the tag. There was a strong possibility that continuously requesting them to wear the tags would serve as a constant reminder that their PA was being measured which could lead them to alter their routine behaviour. Measures were taken to involve all the consenting staff members in wearing the tags. On approaching the nurse(s)-in-charge they proposed that the tags could be put in the key rings that were handed over every day when the nurses changed shifts. On the whole it can be said that compliance from the therapy staff was better than that from the nursing staff. This finding is further corroborated by the observation that when the researcher visited RSU, all Physiotherapists and most Occupational therapists were consistently found to be wearing the tags. The

physiotherapy staff members also requested for extra tags in case students on placements consented to participate in the study. However difference in compliance could also be due to changing shift patterns for nursing staff.

Perception about activity monitoring: The project was undertaken in January 2010 and after obtaining ethical approval an initial meeting was held in March 2010 with all current RSU staff members. The project design, aims and objectives were explained. The idea of the project and the use of the RTLS based system were received cautiously by staff. Their initial perception regarding automated measuring system was that it was a way of 'performance management' and the individual staff members could be singled out. This was also because of the nature of data recorded especially location data from individual tags. It was explained that the focus of the project was to explore the activity levels of patients and the only reason why staff members were requested to wear the tag was to detect and measure variables such as supervised or assisted walking and more importantly, the frequency and duration of patient interaction with staff. Hence the only time the data from the staff tags will be used was to ascertain if they were in an area where patients were present as well. Further emphasis was made on the fact that the sheer volume of data collected and the numerical raw data would make it impossible to single out any individual members.

Over the course of the study, up to date findings were shared with the staff on a 6 monthly basis and their initial concerns seem to be allayed. Their perception of being monitored by technology was more positive as the study progressed and results were shared. It is thought that the staff members were habituated to wearing the tag. This may also be reflected by a statement (given below) by a staff member made in November 2012 saying that it had become second nature to them by then

"We (staff) come in the morning—pen goes in, badge goes on and tag goes on"

More importantly, the physiotherapists quite approved of the idea of getting more information about patient PA that the project aimed to measure. Moreover all staff members co-operated with the researchers in a busy environment the best they could. The tags if misplaced or taken off when patients were discharged they were kept aside and given back to the researcher on the next visit.

Towards the end of the project staff members were asked to give their opinion on the role of RMMS as an objective measure of PA measurement in the future and some of the comments are given below.

"Would be beneficial as a live system to motivate patients. Sometimes they need very black and white evidence that they are improving."

"(can be used for) feedback delivery in MDT and goal planning meetings for relatives. Educating families about abilities of patient"

The above constructive comments again appear to indicate that staff acceptability greatly improved as the project progressed.

On the whole it can be said that the staff members' perspectives on the concept of remote activity monitoring was less sceptical than at the start of the project.

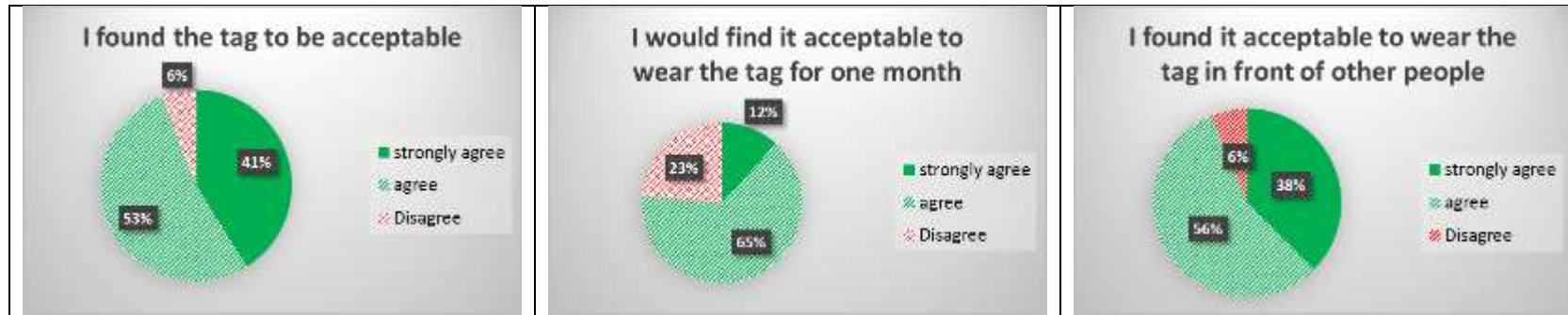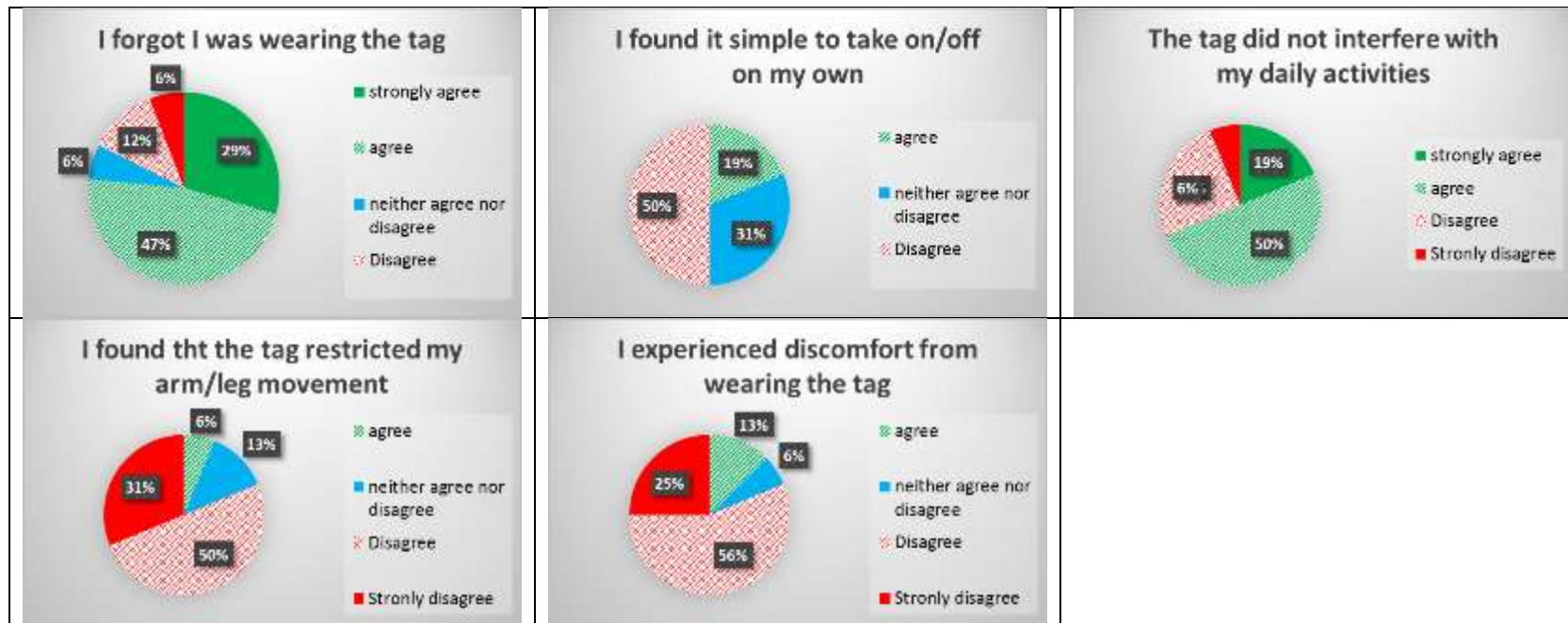**Figure 6. 4 Pie charts depicting staff responses for theme 1 statements (tag acceptability)**
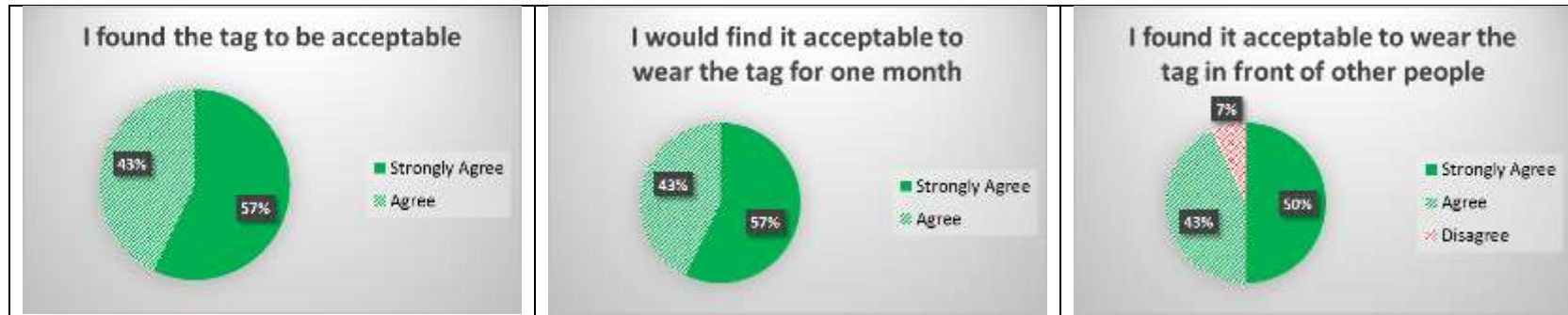
Figure 6. 5 Pie charts depicting staff responses for theme 2 statements (tag user comfort and experience)

Figure 6. 6 Pie charts depicting staff responses for theme 3 statements (tag dimensions and safety)
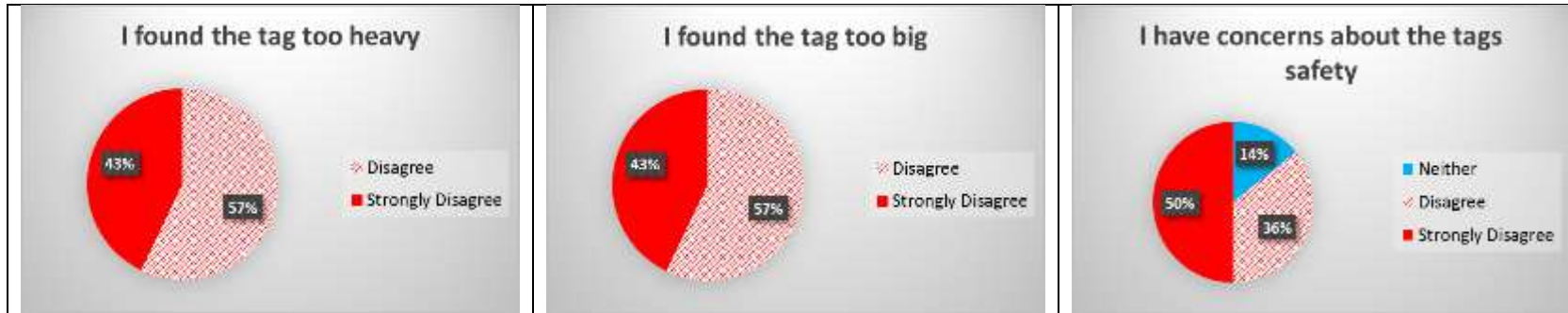
6.3 Home pilot study

In order to observe the subsequent recovery of function post discharge with the system, a pilot study was conducted to measure activity levels at home. This was again an observational study and the same automated system was used in individual homes. Patients who were a part of the longitudinal study were followed up at home where their PA levels were measured with RMMS.

Study design

The focus of the home measurements was to investigate any changes in patient PA levels post discharge within their home environment. The activity levels of patients while admitted in the RSU were compared to those after patients were discharged home. PA measurement was undertaken once sufficient weeks had elapsed since the discharge so that they were able to settle down at home and could form a regular routine. Patients were measured for a period of 14 days at home.

System Installation for home pilot testing

For data collection in patients' homes, RLs were installed in the living room and the kitchen and coded as "104" and "103" respectively (Figures 6.7 and 6.8). Patients wore the tags on their unaffected wrist and ankle using Velcro wristwatch style straps. The reader along with the router and the computer were placed in the living room out of the way.

Figure 6. 7 Room locator placement in kitchen

Figure 6. 8 Room locator placement in living room

Coding of tags for the home system was similar to that done for the RSU tags (Appendix 4). Software system was similar to the one used in hospital and was replicated onto the computer used for the home monitoring project. The initial testing and calibration was undertaken in the RSU in the first stage of the project and by the time the system was used for the home pilot study in stage 2, it was running smoothly.

Inclusion-Exclusion criteria

The criteria for inclusion and exclusion was the same as the criteria for the longitudinal study.

However only those patients who were discharged either to their own homes or to the home of a family member were included in the home pilot study.

Additional exclusion criteria were

Presence of leg ulcers or Oedema

Poor memory, severe cognitive impairment

Sample size calculation and recruitment

Fifty patients were recruited for the longitudinal study and participants were chosen from these for the home study. The smaller MSc project was undertaken alongside the home pilot study for the current project and a convenience sample of 10 subjects was chosen for the study.

Recruitment

All participants were recruited for the longitudinal study and had therefore signed the consent form. Once a decision was made regarding discharge date and destination, those patients who were discharged home were approached in RSU and asked whether they would still consent to participating in the home pilot study. If they had already been discharged, then the researcher contacted them at home via telephone and enquired if they would still agree to participate in the home pilot study. If they agreed, a date and time to visit them at home was set up.

Data collection

All patients were visited at home 3 times on prearranged dates and times. In the 1st visit the system was installed and data collection was started. The patients were given the tags to wear along with a written sheet of instructions containing frequently asked questions**.** The 2nd visit was after 7 days, during which the system was checked and the data was saved as CSV file for that week. Finally in visit 3, the system was uninstalled after data collection was completed.

Data processing and parameter selection

In line with the parameters selected for the main longitudinal study, comparison of total time moving between home and last week at RSU were selected based mainly on the tag motion signals. The time frame selected for analysis was 12 hours (9:00 am to 9:00 pm) and percentages were calculated for the variable.

Data analysis

Descriptive statistics and line graphs were used for initial data exploration. Paired samples) dependent t-tests were used as the test for detecting significant difference between activity at home and RSU. Kolmogorov-Smirnov and the Shapiro- Wilk test was used to test whether the data met the assumption of normality. The difference between the scores (time spent moving in RSU – time spent moving at home) was calculated and tests for normality were undertaken on the difference. If assumptions of normality were not met ($p \leq 0.05$), then the equivalent non-parametric test which is the Wilcoxon Matched Pairs Test will be used (Field, 2009).

Results: Home pilot study

Home pilot study was undertaken to measure patients' mobility levels post discharge using the RMMS. Home measurements were undertaken on an average of 5 months after discharge from RSU (Table 6.6). The average NEADL score for the 9 participants at 6 months after stroke was 9.7 (min 3 max =20) out of a total of 22 with the median and mode value of 6.

Table 6. 6 Patient demographics for home pilot study

F=7;M=2	Mean	Std Dev	Min	Max
Age	76	11.79	56	93
Length Of Stay in RSU	50	47.21	7	151
Days post discharge	160	86.16	60	300
FAC score on discharge	Median =4	Mode=4	1	5

The variable selected for analysis was based on the wrist movement. Data for the 'movement' category was considered for analysis instead of 'Location' category because room locators were not installed in the bedrooms at home to respect patient privacy.

1) Percentage of time spent moving in the house

Based on the raw wrist tag motion, percentage of time spent moving was calculated over a 12 hour period; between 9:00 am and 9:00 pm when patients were at home. The average time patients were moving around per day at home was 19% which is approximately 3 hours a day out of 12 hours (Table 6.7).

2) Comparison of time spent moving (Home versus RSU)

On comparison with the movement undertaken in the last week of stay in RSU, the mean difference between the two percentages was 54.11% (Table 6.7). The average number of days used for analysis were 6 days for RSU and 7 days for home. It appeared from Figure 6.9 that patients were moving a lot more in RSU than at home (9 hours a day in RSU versus 3 hours a day at home).

Table 6. 7 Average percentage of time spent moving

Movement	Mean %	Std Dev	Min %	Max %
RSU Discharge	72.93	7.98	56.56	82.57
Home	18.82	12.90	7.40	48.91

Figure 6. 9 change in percentage of activity when measured in RSU and measured at home
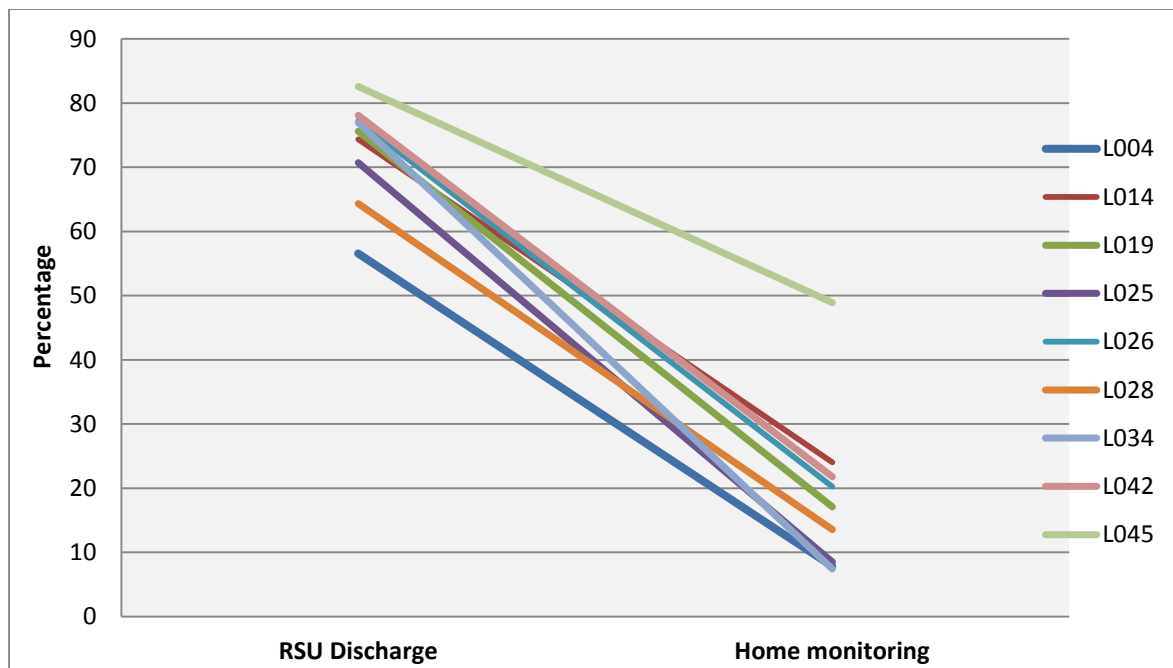
Paired samples t-test was used to look for significant difference between the mean percentages of movement of patients when discharged from RSU and when measured at home. Assumptions of normality through the Shapiro-Wilk test was met (p>0.05). The p value obtained via the t- test statistical analysis was p<0.001.Hence

it can be said that the percentage of time spent moving when patients were in the RSU was significantly less than the percentage at home.

Results from both Chapters 5 and 6 have been presented to illustrate the exploration undertaken with a set of different parameters to give information about functional recovery after stroke as well as to identify the most appropriate parameters which can be accurately measured using RMMS in a rehabilitation environment. The final discussion regarding all the results obtained and their implications have been discussed in the next chapter followed by the final conclusions in Chapter 8.

7. Discussion

In this chapter the results from the two phases of the study will be discussed within the context of functional recovery and how they relate to studies undertaken up until now. Further on, the strengths and limitations of the study will be highlighted and lastly implications of results for rehabilitation and future recommendations will be presented.

The aim of this study was to explore functional recovery in the early stages of rehabilitation after stroke in a hospitalised setting and at home. This was undertaken by measurement of PA on a continuous basis using a new computerised system of measurement known as RMMS. The results of the longitudinal study demonstrated that patients spent limited time walking or moving around when admitted in the RSU. The amount of time spent in their own rooms was 50% of their waking day and this remained constant from admission to discharge.

Optimal recovery of function post stroke especially regaining independent activities of daily living and walking are primary aims of clinicians and patients alike. The long-term consequences of low PA levels may lead to increased risk of stroke recurrence, decreased functional task independence, limitation in activity, restricted community participation and social isolation. Initiating rehabilitation early after stroke and decreasing time spent in sedentary has been found to increase recovery of function and mobility (Jorgensen et al., 1995, Langhorne et al., 2011, Kwakkel et al., 2004). However there is mounting evidence that patients are undertaking limited high level PA irrespective of the stage of rehabilitation (hospitalised or community). Several studies results state that patients spend 4% or less of their time in upright activities

or walking. Moreover self-directed activity constitutes just 4% of the daily time (West and Bernhardt, 2012, Bernhardt et al., 2004).

Measurement of PA is an integral part of rehabilitation clinically as well as for research purposes. It has been used to make discharge destination decisions, in goal planning meetings and as indicators of recovery post stroke (Reiser and Schlenk, 2009, Bussmann et al., 1998).

A review of literature was undertaken to search for current methods of continuous PA measurement post stroke. On evaluation, while most methods were found to be valid and reliable, long term monitoring over the entire length of stay in a rehabilitation setting was not effectively undertaken with these methods. Battery life as well as the underestimation of steps taken while walking for accelerometer based methods and the manual input required for continuous OBM were other constraints limiting their use. Apart from research based activity monitors, commercial activity monitors were also reviewed. Limited number of studies investigating the psychometric properties of these devices were found during the literature search. Therefore at this stage it is difficult to comment whether any of these devices can be used for longitudinal PA measurement post stroke.

As a result, newer methods of activity monitoring were reviewed to design a new system for the present study. Real time location technology along with radio-frequency identification tags were initially used to track and identify medical equipment (Najera et al., 2010). RFID tag based technological applications have diversified since then and are being utilised more for direct patient care and rehabilitation purposes such as in nursing homes for safe monitoring of patients and until more recently for monitoring arm activity of patients post stroke (Holzinger et al., 2008, Barman et al., 2012).

Collaborative working between healthcare professionals and computer scientists was a significant feature of this project which led to the formation of the conceptual framework consisting of the fields of 'Activity Detection', 'Early Stroke Rehabilitation' and 'Sensor Information Processing'. The main aim of the collaboration was to find a way such that off the shelf hardware and software products could be maximally utilised to develop a PA measurement system for stroke rehabilitation with the help of customised software programs and applications designed by computer scientists. Consequently the RMMS tool was successfully developed.

The study was undertaken in an iterative manner in two phases. The RMMS tool was developed as an outcome measure and its reliability and validity were evaluated in the first stage called the developmental phase. Following this, the tool was used to measure key variables related to patient activity especially mobility after stroke in the second stage which was the longitudinal study. Acceptability of the system by patients and staff was evaluated in a mixed design study.

7.1 Developmental phase

The first objective of the study was to identify the important aspects of PA which indicate functional recovery and to determine whether the RMMS tool could measure these aspects. Therefore the reliability and validity testing were undertaken simultaneously to make sure that RMMS was accurate as well as relevant for PA measurement.

The reliability of RMMS tool for measuring detection of moving around between two rooms was almost perfect (ICC>0.90) with low SEM (6 seconds). These results are similar to those studies where reliability of BWS such as SAM™ and Actigraph™

have been determined. Haeuber et al. (2004) examined the reliability of the SAM™ across a 48 hour period in their home settings and found almost perfect reliability for step counts (ICC=0.96). In contrast to the present study, 17 patients with stroke at least 6 months post onset were recruited in the study. Similarly Patterson et al. (1993) found almost perfect (r=0.96) between day test retest reliability for Actigraph™ for quantifying the duration of time spent in sedentary activities in sitting and upright physical tasks like walking and stair climbing. However they used only 4 healthy participants for the testing as opposed to the present study where10 patients post stroke were recruited. Moreover ICC and SEM used in the present study are more robust forms of reliability testing than PCC because the variance between measures can be determined rather than just the association. As opposed to studies with most BWS, reliability of RMMS was undertaken with even those participants who required manual support of 2 individuals to walk 20 meters rather than including selective patients who could walk independently. As the aim was to study recovery of mobility over stay, RMMS being a reliable tool for measuring early stage mobility is a distinct advantage.

Similarly, RMMS was highly comparable with other known observation based methods for measurement of variables related to PA measurement. When walking duration as well as self-selected walking speed was measured using RMMS and stopwatch based methods, excellent correlations (PCC≥0.96) as well as high level of agreement were obtained between the two systems. These results also depict the advantage of RMMS over other systems such as the pedometer and ActivPAL™. It has been reported that both these devices have a tendency to underestimate step counts at slow gait speed (<0.6m/sec) (Maddocks et al., 2010, Grant et al., 2008, Dahlgren et al., 2010). The average speed of the participants in this study was

0.48m/s (mean days post onset=47) and it can be expected that patients in the early stages of recovery are likely to walk even slower. Therefore it can said that RMMS is a reliable and valid system for measuring duration of walking and SSWS for patients in the early stages of recovery even when they walk at slow speeds.

Apart from walking duration and speed, RMMS appeared to be a valid tool for the quantitative measurement of the duration of time spent in different areas of the stroke rehabilitation unit (Location) as well as the frequency of ambulation (Activity). The results obtained by RMMS for time spent by patients in different areas in RSU were strongly correlated with those obtained by the gold standard (BM) with narrow 95%LOA which makes the results relevant for research and clinical use. Moreover the results obtained for time spent in two main areas (patient's own room and Physiotherapy room) appeared to be highly accurate. For the Activity category it was clear that frequency of ambulation measured by RMMS was more accurate than that measured by BM and this in particular highlights the advantages of using RMMS over BM. Using RMMS for longitudinal PA measurement planned in stage two would ensure that all ambulation would be detected with high accuracy irrespective of factors such as the time, the day or the room of the patient.

On the contrary, accuracy of the RMMS to measure time spent sitting inactive in a chair was poor in the present validity study. On comparison with the duration measured using an observation method, a mean difference of 36 seconds (Observation = 93 seconds; RMMS= 57seconds) was obtained between the two systems. The correlation between the two systems was fair (PCC r=0.46) and the 95%LOA suggested that RMMS could underestimate the inactive time by as much as 98 seconds. This is due to the high sensitivity of the motion sensor in the RFID tag. The motion sensor comprises of a simple omni-directional tilt and vibration

sensor which is sensitive to low threshold motion or vibration (Signalquest, 2015).Therefore while the patients were observed sitting inactive, the RMMS tool recorded movement which could be vibrational artefacts or 'noise' due to the high sensitivity of the motion sensor. In comparison, better accuracy has been reported for the device ActivPAL™ for duration of time spent in positions such as sitting/lying where the percentage error was reported as < 2% (Godfrey et al., 2008, Taraldsen et al., 2011). However ActivPAL™ consists of a uniaxial accelerometer to detect posture and movement based on frequency of movement. Therefore accelerometer frequency (in Hertz) can be categorised based on which 'inactive time' can be differentiated from 'active time'. This could be responsible for better accuracy for posture detection by ActivPAL™ and is something which could not be undertaken with the motion sensor in the tag. At this stage it is important to point out that as explained earlier in Chapter 2, it was not considered appropriate to consider ActivPAL™ for PA measurement in the current study. Besides that ActivPAL™ needs to be worn in direct contact with the skin on the mid-thigh and it is highly unlikely that patients could have worn such a device for an average of 64 days which was the average time frame for longitudinal data collection for the study (Chapter 5 section 5.2). Therefore acceptability of such a device was questionable.

Time patients spend sitting idly in a chair or lying in bed are important indicators of recovery of mobility apart from walking and ambulation. It can be anticipated that as patients recover, the amount of time sitting inactive in the bedside chair would decrease over time replacing it with other high level PA (West and Bernhardt, 2012). Therefore it has to be acknowledged that in its current form the RMMS is not appropriate and valid measure to detect this milestone in the process of recovery of function post stroke and is a limitation of the study.

Similarly it was not possible to accurately quantify the amount of time patients spent in the presence of HCS in patients' own room using RMMS in its current form. The present study was the first of its kind to investigate whether contextual factors were measurable in a rehabilitation unit as interaction with staff or the level of independence with ADL at different points in time also contribute towards a better understanding of patients' functional recovery after stroke. It is recognised therefore that although potential of using RMMS for the purpose exists, the above mentioned limitations need to be resolved before it can be used for further research. Perhaps RMMS needs to be used in combination with other sensors such as pressure sensors to detect better when the patient is using a bed or chair.

The reliability and validity results provided crucial information about the current capability of RMMS and the potential improvements that were required to make RMMS fit for the purpose of measuring PA after stroke especially the important aspects of mobility.

User friendliness of the tags and overall patient perspective on PA monitoring with RMMS was tested in the acceptability study apart from the reliability and validity testing. Other than a questionnaire which has been the most common approach to gauge user comfort and compliance with BWS participation observation method was used to explore acceptability of RMMS for remote PA measurement (Hale et al., 2008, Carroll et al., 2012, Bussmann et al., 2009). From the questionnaire responses it was clear that patients preferred to wear the tags around the wrist and this was also supplemented with participation-observation data as well demographic data from the longitudinal study. Reasons why few patients found it uncomfortable were related more to tags straps rather than the RFID tag itself. Patient compliance with wrist tags was found to be better than with ankle tags and this is in line with

previously reported evidence where other BWS have been placed around the wrist in order to increase compliance (Esliger et al., 2011). What appears to make the acceptability study more comprehensive than other studies in the literature is that staff members' perception towards continuous PA monitoring was also examined with the sole aim of detecting patient-staff interaction and assistance with ADL. However although perception of staff with continuous activity monitoring changed over time user-burden may need to be considered when planning continuous activity monitoring using a system such as RMMS.

From the acceptability study it was also clear that wrist tags were more useful than ankle tags for observations and the data from the wrist tags only were used for further analysis.

Three main findings from the studies in the developmental phase and from the acceptability study that informed the project were as follows; firstly, the variables d460 *'moving around in different locations'* and d4500 'walking short distances' were most relevant for the present study. Secondly although important, variables d410 'changing basic body position' and d415 'maintaining *body position'* under the domain of 'mobility' did not appear to be directly detectable. Nonetheless d410 could be inferred from d460 because in order to move around or change rooms, it could be expected in some cases that a change in position would have to occur. And finally, the parameters under the 'Interaction' category (time spent with staff members and time spent alone) was also not feasible to record largely due to nature of the equipment used but also due to some variability in compliance by staff members **Therefore the first null hypothesis for the present study given below can be rejected.**

- **H_01:** The new measurement system will not be a reliable, valid and acceptable tool for PA measurement post stroke.

In the second phase the main point of focus of the study was to examine each patient's recovery pattern to draw conclusions about the impact of current functional recovery for rehabilitation and generate a better understanding of the organisation of healthcare services post stroke. This approach was in line with the conceptual framework that was designed for the collaborative project. On a practical level it was necessary to focus on those parameters that were accurately and directly detectable for measuring PA from the longitudinal study data. Therefore in order to meet the second objective of the project, instead of measuring variables outlined in the CERISE tool, 3 parameters related to the CERISE 'Activity' category were excluded from further analysis (Chapter 5 section 5.1). This can be justified because even with a set of 3 parameters that were selected, relevant   information about patients' recovery in the early stages of rehabilitation in a hospitalised environment was obtained as discussed below.

7.2   Longitudinal measurement of physical activity

The main objective of the longitudinal study was to explore functional recovery after stroke by measuring parameters related to PA. Although the data from the longitudinal study were analysed stage wise, results were obtained for 3 main variables related to patient activity; the amount of time spent moving around the RSU, the time patients spent in their own room while in RSU, and the amount of time spent in sustained activity.

Duration of mobility

In the study, patients moved around the unit using different modes of mobility which changed from admission to discharge depending on their motor ability. Therefore in order to study their mobility over time patients were grouped based on three different modes of mobility; using transport, using wheelchairs or walking with/without a walking aid. Most of the patients i.e. 44% (21/47) belonged to category number 6 in which patients were detected as either being transported using equipment such as a steady or were walking around with a walking aid. Irrespective of the mobility mode, the average daily duration of moving around the rehabilitation unit appeared to be 15 minutes or less over stay. This could explain the consistently high duration of time spent in patient's own room because on correlational analysis, there was significant negative correlation observed between duration of mobility and time spent in own room for a sub group of 25 participants (PCC= -0.72, p=0.00).There was also some suggestion that those patients who were able to walk may be spending less time in their own rooms (Figure 5.26) which emphasises the need for more research before accepting the results completely. An average duration of walking of 15 minutes or less over 14 hours amounts to 1.7% of the day spent moving around; a remarkably low proportion of time per day. On examining mobility graphs at admission and in the week before discharge, there appeared very little change in the duration of mobility over patients' stay. Moreover when individual categories were examined it also appeared that the average daily mobility of those patients who were able to walk even a little was more than that of those patients who were not able to walk at all. In case of those patients who were using wheelchair and/or transport aids, the daily average mobility did not exceed 8 minutes a day (1%).

Similar findings have also been reported by other researchers. Bernhardt et al. (2004) report that patients were observed walking for 6.8% of time over 9 hours a

day which is equal to an average of 35 minutes a day. In the study, 66 patients were observed over 20 days between 8 am and 5 pm. Following which, Bernhardt et al. (2008) also reported slightly better findings with 23% and 12% time spent walking over a 9 hour period in 2 stroke units across Australia with a total of 95 patients. In contrast, in another rehabilitation across UK, 40 patients when observed for 15 hours per day over 30 random weekdays were found to spend just 1.2% (11 minutes a day) being transported or moving around (De Wit et al., 2005). In the review by West and Bernhardt (2012) patients spent a median of 21% of time in moderate to high PA which included transfer without hoist, sitting unsupported, walking and standing and Skarin et al. (2013) also stated that 104 patients spent 13% of the day between 8 am and 5 pm (70 minutes a day) engaged in activities such as walking or standing. It has to be noted that BM is usually undertaken in 10 minute intervals which can lead to over or under estimation of activities depending on the time point when patients are observed. But even then, the percentage of walking that patients undertake during the day appears to be very limited. Results from a more recent study by Kunkel et al. (2015) further reinforce this outcome and also validate the findings of the present study. In their study *physical inactivity* of 61 participants in a rehabilitation unit was measured 23 days post stroke. On using ActivPAL™ rather than BM authors reported that patients spent an average of 2% of their time walking over 6 to 7 hours a day which is less than 10 minutes per day. The study by Kunkel et al. (2015) is the only study where another BWS has been used to measure PA after stroke and the walking duration measured in their study is highly comparable to the walking duration of 15 minutes reported in the present study.

There are some factors that may have perhaps accounted for the low walking and ambulation duration observed in the present study. Increased fatigue has been

known to occur quite commonly after stroke (Ingles et al., 1999, Snaphaan et al., 2011). It is possible that some patients may have found additional ambulation after a rehabilitation session quite tiring as it has been observed that patients were highly active in the therapy sessions (Chapter 5 section 5.2.2). Mobility duration may also have been limited in patients with severe stroke or with those who required assistance with walking which in a busy environment is not always easily available. However although it can be expected that the above may occur with some patients or in the early stages of recovery, the low mobility duration was seen for all patients irrespective of their stroke severity and number of days post stroke onset. Therefore the likelihood of this occurring can be said to be low. Another influencing factor may have been the tool itself. While RMMS has been established as an accurate method, one limitation encountered with mobility measurement was that 'walking' could be interpreted by the computer program code only when the patient was using the walking aid that was assigned and tagged for them. Therefore in the event where a patient walked independently or used an unassigned walking aid, it could be mistaken for 'transport'. However the data was used in combination with FAC scores and regular checks were made by the researcher to ensure that appropriate walking aids were tagged which greatly minimised the chance of this happening.

Contrary to patient fatigue and non-tagged walking aids, a bigger factor which could have contributed to low mobility is the *infrastructure* of the Regional Stroke Unit itself. RSU was a compact unit on the second floor with one main corridor where patients could walk. Patients often expressed that they had nowhere to walk to once they left their room. The lack of outdoor and indoor space may have deterred patients from walking around which resulted in them spending excessive amounts of time in their own rooms. In fact mobility duration of 15 minutes a day could just be walking to and

from patient's own room to therapy area and back as the average speed of walking is slow in patients anyway. This can also suggest that apart from two bouts of walking in the corridor, patients did not move around at all.

Duration of time spent and movement detected in patient's own room

The initial results demonstrated that   that out of all accessible areas, patients spent most of the daytime hours in their own rooms (85% average). For a time period of 14 hours (7:00 am to 9:00 pm) that amounts to 11 hours a day. It was also evident that patients spent an average of 3% of time in therapy areas and in the Day room which amounts to 25(±10) minutes a day. On further analysis it was observed that the time patients spent in their own room did not change significantly from admission to discharge. This was corroborated by using the *related samples Wilcoxon's test* to look for difference in this time between week of admission and week of discharge. No significant difference in the amount of time spent in patient's own room ($p > 0.27$) was observed. The results also suggest that the lack of change in the percentage of time spent over weeks is not due to the lack of sensitivity of RMMS but due to patient behaviour. Another aspect that supports this finding is the individual patient graphs observed in Figure 5.29 which suggest that RMMS could capably detect decrease or increase in the duration of time for which patients were in their own room on a week to week basis.

The proportion of time spent by the participants in their own rooms in the present study is very similar to other evidence reported in the literature which further strengthens the study results. In fact it can be said that this proportion was comparatively higher. In a systematic review undertaken by West and Bernhardt (2012), 22 studies between 1989 and October 2010 were identified where time spent

309

by patients in their own room was measured for hospitalised patients after stroke using BM. The median amount of time spent in own room by these patients was 56.5% (minimum 12%, maximum 95%) and the median proportion of time in therapy areas was reported as 6.4%. The number of participants in the studies included in the review ranged from a total of 7 to 58 and these patients were observed in stroke units across Europe and Australia. It was observed that patients in these studies were measured for a maximum of 5 days at a given time (Keith, 1980, Mackey et al., 1996) and that the largest time frame for measurement was over 15 hours. In contrast RMMS was used to measure time spent in own room for an average of 64± 53 days continuously over a 24 hour period although data was analysed over 14 hours. Also only weekdays were included in analysis as no therapy occurs over weekends and patients tend to go home over weekends as well. Even though the number of patients selected for this parameter was less (n=25) the subjects chosen for analysis were representative of the patients that were being admitted in the RSU. The theory behind the selection of this parameter was that as patients recovered, the amount of time spent in patient's own room may decrease steadily with the expectation that they would leave the room more and more. Therefore 'time in patient's own room' could be an important indicator of functional recovery. While the results of this parameter suggested that patients were spending large amounts of time in their own room, there was very little direct evidence to suggest that patients were *inactive* or sedentary in their own room. Besides that sometimes therapy is undertaken in patients' own room as well (West and Bernhardt, 2012). After the results of the first parameter were obtained, the direction of the research was focused on two other main factors; the determination of time spent moving around (recovery of mobility) and the type of sustained activity undertaken. Recovery of

mobility where duration of walking, transport and wheelchair ambulation was measured longitudinally is discussed first followed by the duration of sustained activity.

he results from two main aspects of PA measured strongly suggested that patients were moving around out of their rooms for a very limited period of time each day and were spending large amounts of time in their own room . Based on these results, the measurement of duration of time patients spent in sustained movement in their own rooms can be justified. Sustained movement as a variable was considered important in order to potentially determine the kind of activities patients undertook in their own rooms so that subsequently the activities could be classified as high level or low level categories (West and Bernhardt, 2012). It was therefore anticipated that quantifying the percentage of sustained movement would help ascertain how they recovered functionally after stroke since the results so far seemed to suggest that very little therapeutic activity was being undertaken outside of their own rooms.

Intensity of sustained movement

The movement data from the motion sensor of the RFID tag was captured and utilised to quantify wrist movement duration. It was observed in the initial analysis (Chapter 5 section 5.2.2) that for a cohort of 25 patients the proportion of the *total wrist movement* was high throughout their length of stay; 71% at admission and 73% at discharge. As it was important to identify how much of that movement constituted of functional tasks the duration of each individual bout of wrist movement was considered to differentiate between intensity of activity undertaken by patients. When the percentage of time spent by patients in performing activities was categorised according to the duration of each bout of movement, the results revealed that the

study participants spent 15% of their time in performing activity bouts that lasted 20 minutes of more in duration in the rehabilitation unit. Each activity bout which was sustained for 20 minutes or more in duration was considered as a representative of a functional task or an ADL as patients after stroke are slower to complete ADL tasks in comparison to adults without a stroke making it unlikely that a therapeutic activity or functional activity could be performed in less than 20 minutes (de Niet et al., 2007, Cirstea and Levin, 2000). Moreover they wore the tag on their unaffected wrists and it has been observed that patients use their unaffected arm for undertaking ADL more than the affected arm. This again raises questions regarding task practice with the affected upper limb or bi-manual activities (Michielsen et al., 2012).

The limited time spent in high intensity activity bouts therefore also resulted in patients spending 75% of their time engaged in tasks that were less than 10 minutes in duration which suggests that most of the time they undertook low level PA. This again is in line with findings from a review mentioned previously where non-therapeutic or low PA accounted for 24% to 98% of the time with a median value of 48% (West and Bernhardt, 2012). In the current study, there is a possibility that patient could have been performing higher level tasks such as moving around or exercising in their own rooms for the sustained 20 minute movement bouts as there were no manual observations made during longitudinal PA measurement. Conversely there is also the possibility that the 20 minute sustained movement was the result of the high sensitivity of the tag motion sensor to vibrations as discussed in section 7.1 of this chapter.

To gain some understanding of type of functional tasks patients could have undertaken lasting 20 minutes or more in duration, further exploration was undertaken with the validity study data. Out of a total of 88 observations, patients

were found engaged in nursing care or therapeutic care (with a staff member) for 28 observations (31%). When they were alone, patients were observed passively sitting or eating for 20 observations each (40%). Other activities such as leisure or dressing and hygiene accounted for the remaining 12 observations (29%). All the tasks that patients carried out for a large proportion of the time were those activities which can be classified as low level activities (West and Bernhardt, 2012). The results can be accepted as accurate because BM was undertaken by actual observation of patients using a valid and reliable data mapping tool. According to the CERISE tool guidelines, if patients were involved in any sort of passive or active leisure such as reading or watching TV while in a seated position, the researcher would have recorded the activity (passive/active leisure) rather than the position (sitting).Therefore any observation under the 'Activity' category which was recorded as 'sitting' means that the patient was in a sedentary seated position. With respect to the results for the 47 patients who were measured in the longitudinal study these results therefore suggest that sustained activity undertaken in RSU involves sedentary sitting rather than walking or moving around in rooms. When correlation analysis was also undertaken to explore whether length of stay had an effect on the percentage of sustained activity there was a non-significant fair relationship observed (PCC=0.04, p=0.80). It can be expected that patients who recovered faster would undertake more sustained activity in their own rooms than those patients who recovered at a slower rate. However this was not observed in the correlational analysis which means that whether patients were discharged within 6 weeks or stayed for longer than 6 weeks their sustained activity duration appeared to remain the same. Also, the duration of mobility did not appear to have any impact of the proportion of sustained movement that patients performed in their own rooms

(PCC=-0.08, p=0.5). It can therefore again be anticipated patients spent large amounts of time engaged in low level sedentary type activity in their own rooms. The last point to note is that presence of a therapist or a staff member is often a driving factor for patients to be physically active (Ada et al., 1999). Patients were seen to be most physically *inactive* when they were alone (59%) and spent most time sitting out of bed when interacting with each other rather than doing any therapeutic activity (Skarin et al., 2013). Moreover other studies have also reported that patient activity during non-therapy time consists of passive sitting and observing other people (Esmonde et al., 1997, Bernhardt et al., 2004).

The results regarding sustained patient activity do need to be accepted with slight caution till a better version of RMMS is developed. Nonetheless when seen in combination with the low mobility undertaken by these patients as well the literature evidence, these results and the interpretation appear robust. Another element of the current project which involved the use of total wrist movement was the home pilot study as discussed below.

Home pilot study

The home study was focussed on the change in activity levels based on the wrist tag movement in the last week of stay in RSU and that with one week post discharge at home. These measurements were undertaken on an average of 3 months post discharge. From a rehabilitation point of view PA measurement at home could give an idea of the longer term functional recovery pattern of patients in the community and the outcome of in-patient rehabilitation on patients' ability to be independent at home. The results show that on average the recorded wrist movement at home dropped by 54% which can suggest that patient activity decreased substantially once

patients were discharged home. It has been observed that when patients' sustained activity was measured in the RSU for an average of 41 days, patients were spending on average 15% of their time in sustained activity of 20 minutes or more (range 0 to 55%) and an average of 10% in sustained activity bouts of 10-20 minutes (range 0 to 19%) over a 14 hour period (7:00am to 9:00pm). On that basis it is not entirely unexpected that these sustained bouts of activity were either missing or limited when measured at home. It was also observed from the NEADL scores in the present study that patients appear to be limited in undertaking extended ADL (mean score 9 out of 22). In a study undertaken by Alzahrani et al. (2011), 14 community dwelling stroke survivors were observed in their homes over 5 hours to measure the kind of activities they undertook. They found that patients were engaged in some form of activity for 255 minutes out of a total of 300 minutes. However 48% of this time was made up of solitary leisure activities such as knitting, watching TV or reading followed by intrinsic domestic tasks such as eating and dressing. Extrinsic domestic activities (e.g. food preparation, washing up) as well as leisure activities with contact (e.g. phone calls, shopping, visiting) made up of 15% or less of their activities. Similarly Kunkel et al. (2015) report that when physical activity was measured at the end of one year post stroke, 77% of the time was spent sitting/lying and patients were walking for 7% of the time. Moreover the time spent in sitting or lying remained above 73% when measured at 2 year and 3 years after stroke onset The results of the study by Alzahrani et al. (2011) and by Kunkel et al. (2015) appear to be in agreement with the present study thus strengthening the finding that patient activity at home tends to decrease over time.

On the other hand a 50% decrease in activity post discharge may not be an entirely accurate representative of the patients' activity at home. Activities such as personal

hygiene and dressing undertaken in the mornings may not have been adequately captured as patients took their tags off for the night and may not have worn it first thing in the morning. There is a possibility that patients may have worn the tags after their carers had helped them in the morning with dressing. This would mean that not all sustained activity at home was recorded by RMMS.

Moreover it can be the case that visits outside the house involved activities that required walking around. This in-turn could mean less activity at home due to fatigue. Another plausible explanation could be that as patients recovered, functional tasks such as eating became easier and took less time which in turn would reduce the overall activity or wrist movement duration. And finally while NEADL scores were low, it is a categorical outcome measure and includes items such as ability to manage money while outside, ability to drive a car and ability to manage own garden and these may not completely reflect mobility within the house. Therefore it can be said that while there is a strong possibility that patient activity levels did indeed tend to decrease post discharge, more research is needed before the results can be accepted without any caution.

It is important to note that use of RMMS to unobtrusively measure PA in a home environment seems to be a novel approach with advantages over other methods that are currently used. Pedometers have been used for a community based walking programme to examine and improve walking and mobility in participants 6 months after stroke (Sullivan et al., 2014, Robinson et al., 2011). Apart from that several sensors making use of global positioning system technology are also being assessed to measure activity outside of home (Evans et al., 2012, McCluskey et al., 2012). However none of these studies have focused on activities that can be undertaken within the patient's home. The value of using RMMS in a home setting is

that in the future, potential research could involve measuring the amount of time spent in kitchen and other areas of the house. It can be supposed that if patients are spending more time in the kitchen and the wrist tag shows constant movement, the kind of tasks undertaken could be related to cooking and household chores. If this duration increases over time, it could again indicate an increase in patients undertaking more extended ADL and consequently better functional recovery. Therefore as opposed to other measures of PA, activity in 'context' could be measured with more ease as evidence suggests that patient tend to recover better when discharged home because they undertake ADL in a familiar environment (von Koch et al., 1998) . With the introduction of early supported discharge services (Teasell et al., 2003, Langhorne et al., 2011, Langhorne et al., 2007) by using RMMS to measure PA in the home settings, further research can be undertaken to explore the relevance of 'familiar context' on physical activity (von Koch et al., 2000).

.The discussion around the study findings presented so far raised questions about how patients recover functionally after stroke and these were further explored as given below.

7.3 Exploration of functional recovery

As the results demonstrated that the most important aspect of recovery which was measured with RMMS was duration of mobility in rehabilitation stay, this section aims to primarily discuss the significance of mobility for functional recovery. Patients moved around or were mobile for an average of 15 minutes a day and even less if they were being transported or used a wheelchair. This duration remained unchanged from admission to discharge irrespective of mode of mobility (p= 0.29). In

contrast, there were significant changes (p≤0.03) from admission to discharge in the scores for mRMI and BI; the two performance related outcome measures used for assessing mobility and ADL respectively.

So what could be the potential factors that cause change in recovery as measured by the OMs which is not reflected in the actual duration of mobility?

It is a possibility that recovery of non-motor functions such as continence, grooming, and eating improved to a larger degree than the mobility which would explain the change in BI score at discharge. Similarly in the mRMI scores, improvement in scores related to transfers and sitting unsupported could have led to an increase in mRMI discharge score but actual *duration* of walking and moving around did not change. Although the recovery of these aspects is important, lack of the ability to move around effectively can lead to limited ability to further undertake domestic tasks and lead an independent life. Another point to note is that as spontaneous recovery and functional recovery co-exist, there is also the possibility that the overall recovery observed was more due to the neurological recovery rather than rehabilitation assisted recovery which means that further optimisation of time spent in rehabilitation unit may be necessary. Correlational analysis revealed that duration of mobility was strongly and significantly related to both BI and mRMI at discharge (Spearman's rho=0.70, p< 0.001). Therefore patients who walked more and who moved around more may have shown better improvement in their ADL and mobility performance than those who were less mobile. This implies that the amount of time spent moving around and walking leads to better functional recovery in hospitalised stroke patients. Other studies have also made similar interpretations. (Alzahrani et al., 2011) found that walking performance (capability, speed and stair climbing) was strongly correlated to community based activities in patients after stroke Likewise,

Kunkel et al. (2015) stated that apart from mobility and balance, ADL independence measured with BI, walking capacity measured using FAC and mood measured with HADS had an impact on physical activity levels of patients after stroke. The results obtained in the present study are very closely aligned with those reported by Kunkel et al. (2015), however they refrained from mentioning any causal relationships between activity levels and performance OMs due to variability of individual patients and small sample size (n=15/74). While the present study also had limitations regarding complete sample sets, the overall number of patients included in the analysis was more (n=23/47) than in the study mentioned above. Moreover all patients were measured during the early rehabilitation phase and their average LOS was 72±46 days as opposed to the study by Kunkel and colleagues (2015) where complete data sets included patients who were followed up in the community at 1,2 or 3 years after stroke for a single day. Thus, patient variability may not have been a very big issue in the present study. In contrast to the two studies which looked at PA in the community, Janssen et al. (2014a) found that there was strong correlation between change in physical activity and change in level of independence measured through Functional Independence Measure (PCC= 0.80) when BM was carried out in a mixed rehabilitation unit with 14 patients 23 days after stroke onset. In their study 'physical activity' included tasks other than just walking and ambulation such as eating and personal ADL making it difficult to determine the specific relationship between mobility and independence as seen in the present study. However the findings from both studies are similar. The current study is the first of its kind where correlational analysis has been supplemented by simple regression analysis. The predictive value of duration of mobility on the level of independence was explored in the study. The results revealed that duration of mobility could be accountable for as

319

much as 43% and 49% of variation in the BI and mRMI scores at discharge further emphasising the important role of patients walking and moving around on ADL performance for functional recovery after stroke.

Based on the above discussion, the second null hypothesis for the present study given below can be rejected.

- **H$_0$2:** There will not be moderate significant correlation between relevant physical activity variables and measures of functional recovery (correlation coefficients ≤0.50, p≥0.05).

7.4 Strengths of the study

Several strengths of the present study can be identified. This thesis gives information about the rehabilitation parameters which can not only enable insight in functional recovery but are also reliably measurable with an automated system. The parameters selected are based on the ICF framework and have been considered as relevant for measurement in stroke recovery by healthcare professionals as well as patients (WHO, 2001). There is a need for the Activity parameters to be measured over a long period of time using continuous variables (rather than categorical variables/OMs) as it gives relevant information about the weekly recovery patterns of individual patients. The presented study simultaneously measured multiple items of mobility after stroke and the inter-link between the variables highlighted different aspects of functional recovery. The interaction between the variables that were chosen to explore functional activity for patients shows a different combination (with each factor either increasing or decreasing) for each patient. Hence individual patient profiles can be studied over time but grouping patients according to a certain

common parameter may also be possible. This aspect is favourable because how stroke affects a certain individual's brain is different and each patient recovers differently after stroke. There is the ability to get information per day or a time slot during the day and also per month or over the entire length of stay depending on the requirements of the researcher or the rehabilitation team.

RMMS can be considered more useful than SAM™ for early stroke rehabilitation. The present study has looked at activity monitoring of patients having severe, moderate as well as mild stroke according to the modified Rankin's scale which is better than some known BWS where PA measurement has been undertaken with patients mild to moderate stroke (Shaughnessy et al., 2005). Another advantage is that PA measurement was neither based on recall nor tested under lab conditions where there is likelihood that patient performance may be better (Bussmann et al., 2009). Besides that Activity via RMMS is observed behaviour and not a self-reported measure.

The RMMS was found to be sensitive enough to pick out exceptions. These can potentially be further investigated when required. For example, if a person stops walking in a particular week, the reasons behind the same can be investigated. For example, the tag was taken off, the patient was unwell or was away from RSU etc. As the analysis strategy became clearer, the main analysis was undertaken with all patients. The final selection of parameters can be considered as appropriate because till date, no study was found that has focused on mobility measurement of patients using a wheelchair. Also, the underestimation of step counts in the early stages of gait recovery has been mentioned in various studies found till date (Manns

et al., 2007, Fulk et al., 2014). Quantifying the duration of moving around in a wheelchair *as well as* of walking is a strength of the RMMS.

The longitudinal study was undertaken continuously every day for an average of 64 days for 47 patients. The automated data collection was advantageous as the PA monitoring could be measured over 14 hours a day. Till date, the largest time frame found in the literature for PA measurement has been 15 hours (De Wit et al., 2005). However in the present study PA was monitored from 7:00 am to 9:00 pm which encompasses most of the patients' waking hours. Another advantage of this study is that the resultant substantial amount of data was effectively managed with RMMS as manual collection and processing of this sort of data would not have been practically possible. Besides that, the fact that the environment of study was a working hospital, it can be said that the mobility measurements have been undertaken with minimal hindrance to staff and patients and with minimal calibration required for data collection.

From the main discussion in this chapter it is evident that variables related to patient mobility provided a better understanding of functional recovery of patients during rehabilitation. Daily walking duration has the potential to be combined with other factors to further explore recovery after stroke. It can be combined with variables such as distance walked, walking frequency, location and equipment used to obtain milestones of gait recovery during stay in a rehabilitation unit. Thus it can be said that the variable of mobility is multi-factorial. Measurement of sustained activity as a standalone parameter was less useful than the measurement of mobility duration however a combination of total movement, time in patient's own room and duration of mobility has provided valuable information with which better, more organised stroke rehabilitation services may be developed across Wales and globally.

7.5 Limitations of the study

It is necessary to acknowledge that like many automated systems, the RMMS is not absolutely perfect.

The reliability and validity of the RMMS has been undertaken with a small number of participants. The sample size was appropriately calculated but study participants included in the reliability study were more active that those participants who were subsequently included in the main validity study. Moreover, for the validity study, a modified version of the CERISE tool has been used as the criterion measure. Therefore it would have been better to validate the modified CERISE tool before using it as a criterion measure for the current project.

It can therefore be said that reliability and validity of RMMS needs to be further investigated including patients with different levels of activity to address the weaknesses mentioned above before RMMS can be considered as a completely robust tool to use for future studies.

One of the he main limitation was the low threshold of the motion sensor in the RFID tag which at present restricts its utility for the adequate detection of activities such as transfers, sitting and lying down and these have been discussed in section 7.1 above. Vibration artefact has been reported by Patterson et al. (1993) when people wearing Actigraph™ were travelling in the car. Maddocks et al. (2010) also reported that PALite detected false steps when travelling in a car. Therefore increased sensitivity of the motion sensor of the RFID tag to pick up vibration and low threshold movement has been seen in other devices as well. Moreover it can be said that detecting patient positions with a BWS may be practically difficult when gathering

data over 2 months in a working rehabilitation unit as opposed to detecting these positions for less than 2 weeks under experimental conditions or in lab settings as seen with the use of ActivPAL™. There may be potential for the RMMS to be developed to accommodate for this limitation in the future as mentioned in section 7.1.

Results regarding the sustained activity point out that movement data obtained via RMMS needs to be interpreted in the context of its occurrence. To do this, background knowledge is required which may be subjective in nature. This suggests that the RMMS is not purely a computerised system; however accelerometry based BWS also have the same limitation. The main reason for this is that physical activity is a characteristic of human behaviour which exists in combination with emotional and cognitive factors and is therefore difficult to predict accurately (Bussmann et al., 2009). It can also be said that by including location and using sensors within the environment, this study may be a step closer to solving this limitation.

Acceptability study for the project was undertaken following a mixed methodology where user-friendliness of RMMS as a BWS has been investigated more in depth than for other devices (Sullivan et al., 2014, Kramer et al., 2013, Barak et al., 2014). Participation-observation method was used and the theoretical approach followed for analysis where themes were selected after reviewing the literature rather than following an inductive approach where themes that emerge from the data are used for analysis. Therefore instead of coding the data first, identifying themes from the collected data and checking for sub themes, themes were selected beforehand (Braun and Clarke, 2006, Ryan and Bernard, 2003)..This can be considered as a limitation as prior theorising can inhibit forming fresh ideas (Ryan and Bernard, 2003). However keeping in mind the overall research design, the decision to make

this approach was undertaken pragmatically. It can be recommended that in the future, inductive analysis can be used to extensively study perception and acceptability of remote activity monitoring using recommended guidelines for thematic qualitative analysis.

The results from the acceptability study demonstrate that patients find the tag acceptable to wear and perception of remote activity monitoring is positive, staff perception of activity monitoring was less positive. This can considered as a weakness for the study especially when equipment such as multiple RFID tags were used. Although cost effective and light, involvement of staff in stroke unit needs to be considered carefully in the future. It is important to identify ways that requires less demand on staff and minimises staff effort if they need to wear the tags themselves.

There was loss of data however it was minimal. Over a 1 year, data was lost only on 4 occasions; twice when the RMMS crashed during the early stages of testing (July 2012 and October 2012) and twice due to human error (once when the researcher forgot to restart the data collection software and once when the staff member accidently switched off the main power supply to the computer in the storage room). This can be considered as minimal thus making it feasible for long term monitoring. When the repeatability study was conducted to determine the number of days for which measurements needed to be taken such that the scores were representative of the week, the results obtained suggested that measurement taken on any one day could represent the scores for that week, a finding similar to that obtained for pedometers (Tudor-Locke et al., 2002). Therefore it can be rationalised that loss of data over 3 days in a particular week could not influence the results. In fact, there is evidence that 7 days in a month is representative of the monthly step counts using a pedometer (Clemes and Griffiths, 2008) since the average number of days of

measurement with RMMS was 64±53 days, it can further be said that loss of data did not have repercussions on the results.

7.6 Implications of study

The main aim of rehabilitation services is to enable patients to attain the best possible level of physical and psychological performance and subsequently counteract the dependence on others for ADLs and prevent social isolation (Kwakkel et al., 1999, Kollen et al., 2006). This aim is also shared by patients and their main goal is *functional independence* in order to return home and resume everyday activities. In fact specialised stroke units were established with the aim of providing organised, rehabilitation focused care for patients which could be delivered by healthcare professionals from different specialities who worked together as a team (Keith, 1980, Lincoln et al., 1989, Kwakkel et al., 1999).

In neuro-rehabilitation, from a physiotherapy point of view, a combination of several treatment approaches have been used to promote recovery after stroke namely Bobath technique and motor learning approach along with fundamental techniques such as muscle strengthening and stretching (Langhorne et al., 2011). Research examining the suitable dose and intensity of therapy for hospitalised stroke patients has been undertaken. Although accurate quantification for the same does not appear to exist, there appears to be a consensus that starting rehabilitation as early as possible after stroke onset is beneficial (Langhorne et al., 2011). Moreover there has been evidence in support of high intensity training and repetitive task practice to enhance motor recovery after stroke. This can also lead to maximised performance of ADL and aid reorganisation of the brain (Carr and Shepherd, 2011).

On the one hand the existing evidence that suggests that repetitive task practice can improve functional activities and rehabilitation needs to be undertaken as early as possible, on the other hand the results from the current study and other studies indicate that the overall PA levels of patients maybe insufficient as discussed below.

The results of the present study show that overall PA of patients is very limited which has been noted in other studies as well (Bernhardt et al., 2004, De Wit et al., 2005, West and Bernhardt, 2012). There was no significant increase found in important aspects of physical activity from admission to discharge during the entire rehabilitation stay which means that the important phase to optimise recovery after stroke onset does not seem to be utilised effectively.

From the results (individual mobility graphs) it is also evident that patients were moving around for longer durations in some weeks than in other weeks and the duration of moving around was not consistently maintained throughout their stay in the rehabilitation unit (Figures 5.11 & 5.18). Nor was there a steady consistent increase in mobility duration noted in successive weeks. In some cases (Figures 5.14 & 5.23) their FAC scores illustrated that that these patients were *capable* of moving around however the actual duration of mobility did not reflect this. Therefore measures need to be taken to reduce the discrepancy between patient capability and performance of PA which was not only observed in the current study but also has been evidenced in the literature (Rand and Eng, 2012).

Another issue that may deter the progression of functional recovery is the reduced daily wheelchair or transport mobility (≤5 mins) reported in Table 5.19. After stroke there are instances where some patients remain wheelchair users or exhibit little ambulatory capability. But in most patients, using a wheelchair is an interim stage in

the gait rehabilitation process before patients' progress to walking with assistance. The extremely low percentage of this type of ambulation seems to suggest that more focus needs to be placed on their recovery.

The ability to be able to move around outside of own rooms can encourage social interaction within the rehabilitation unit especially for those patients who stay in single rooms. Besides giving patients a chance to communicate, time spent in social activities is evidenced to correlate with patient's mood measured using HADS (Janssen et al., 2014a). It can also be suggested that once patients start walking, wheelchair use can be continued alongside walking practice in the initial stages to ensure that daily mobility duration remains consistently high and is not affected by fatigue.

The study findings also appear to have other implications for instance the 'Early Supported Discharge' schemes (Touillet et al., 2010).There is evidence supporting early discharge from hospital as it reduces the LOS and long term dependency in patients (Langhorne et al., 2007). The increased amount of time spent in patient's own room and limited mobility undertaken by patients during rehabilitation stay seen in the present study results could be considered as a cause of concern. It can be said that for maximal recovery to occur, PA levels need to be enhance while they are hospitalised and need to be maintained if not increased once discharged home. Otherwise lack of activity after being discharged early may result in further deterioration in performance of ADL, more isolation and less integration into the community. Evidence shows that low level PA after stroke, like the occurrence of stroke itself is linked with reduced mobility, reduced balance, decreased aerobic fitness and can cause depression (Field et al., 2013) . Moreover, as the subsequent

number of patients returning to the community is growing, the decreased activity levels at discharge could result in lack of upright or standing activities. This could further reduce participation and emotional wellbeing which in turn could adversely impact patients' families and the healthcare system (Egan et al., 2014, Kollen et al., 2006, Mayo et al., 2002).

It can therefore be suggested that by having a more structured rehabilitation routine on a day to day basis could lead to increased PA post stroke in a rehabilitation unit. Having a specific time slot outside of therapy session, during the patient's waking hours for specific task practice, wheelchair ambulation or walking can be considered in the future. Recommendations that relate to this suggestion are further discussed in section 7.7.

Software implications

The present study results also have implications related to the data collection, processing and analysis software. Some of these have already been discussed in Chapters 4 and 5 and the others are discussed here. Unlike other BWS where data has to be transferred manually (SAM™, ActivPAL™) data collection for RMMS was automatic. Moreover data from multiple sources could be combined together. In the present study manual resources required for data processing was reduced as the study progressed. A software system using logical rules written by computer scientists led to automated data processing. Raw data collected using the RTLS hardware could be processed in multiple ways by changing the rules written by computer scientists. The contribution of the study was to inform computer scientists of those variables which were relevant from a patient rehabilitation point of view to gain a better understanding of recovery. The present data can be explored later on

to ascertain if there are areas that patients prefer to move around in and also the frequency of undertaking mobility per day which will generate more in-depth information about their walking ability. However these aspects can be easier to analyse if the data processing software was further automated and required less manual input and that can be considered as a challenge for computer scientists to take on board and work towards in the future. A distinct advantage of using a system such as RMMS is that the sensor middleware software can be used with other types of sensors in addition to RTLS. The information from other sensors such as pressure sensors or thermal sensors can be integrated with RMMS data which can be used to obtain different information as required.

7.7 Recommendations for the future

Based on the discussion around PA and the evidence presented so far not just from the current study results but also noted in previous research in the field, certain recommendations can be made to further optimise post stroke rehabilitation and advance research in this area. The present study results demonstrate that patients appear to be most physically active when engaged in therapy sessions and high activity level was hardly observed at other times during the rest of their waking day. It is therefore important to increase mobility and physical activity levels of patients in the early stages of rehabilitation as soon as patients are admitted into the rehabilitation unit and continuing to do so not only till discharge but also post discharge in the community. Moreover as duration of mobility does not appear to be consistent across weeks as seen previously (Chapter 5 section 5.2.1), it is necessary to measure PA continuously from admission to discharge instead of measuring

activity at certain time points over stay. This would ensure that the correct pattern of recovery can be obtained.

It can be recommended that other approaches must be utilised apart from increasing intensity and dose of therapy for optimal functional recovery of patients. Early rehabilitation for inpatients is planned and provided by a specialised multi-disciplinary team (Barman et al., 2012). It can be suggested that a patient's waking day is more organised and better structured to encourage high level activity throughout the day rather than in therapy sessions only. Some of the methods that can be considered for doing this are detailed below.

It is observed that most rehabilitation centres have dedicated times for meals, drug rounds and even visiting hours. This can be further extended to officially include specific time frames for task practice and undertaking therapeutic activities outside of therapy sessions. Group exercises can also be encouraged to maximise limited staff resources (Ada et al., 1999). With regards to the current study, RMMS data can be explored further to identify timeframes and locations where percentage of time spent active is as high as observed in therapy sessions. These locations and timeframes can then be exploited to encourage rehabilitation oriented activities outside of therapy time. The use of robot assisted training and video games are already being used to encourage task practice and one of their advantages is that they help the patients focus on the task or goal attainment rather than on the impairment (Lange et al., 2009, Holden, 2005). A similar approach can be also be recommended for the in-patient setting where patients can be encouraged to actively serve themselves a meal rather than it being delivered to their bedside which is what they would need to do if discharged home.

It was observed in this study that with certain patients such as patient number 4 and patient number 47 the overall duration of mobility was higher in comparison to other similar patients (Figures 5.12 and 5.18). This could be attributed to the involvement of family members in the patient's rehabilitation. Family members were observed (by the researcher) practising therapeutic exercises and walking with the patients in the corridor during visiting hours. Therefore it can be suggested that family members and visitors can play a bigger role in patients' rehabilitation and in enhancing PA after stroke. They can be further guided by the therapy team to ensure that family can assist with transport and walking during visiting hours in a safe manner rather than sitting with the patients by their bedsides.

Seven day working is currently also being explored for stroke rehabilitation services in the NHS (NHS-Improving-Quality, 2013a, NHS-Improving-Quality, 2013b). On the one hand, the additional resources required for a 7 day service needs to be considered but on the other hand there is trend for patients to be up to 5% less active on weekends (Janssen et al., 2014a). One way proposed to utilise time spent on weekends to increase PA is to appoint therapy assistants or activities co-ordinators who can do functional activities or task oriented activities with patients on the weekend. As visiting hours are generally increased on weekends, family members can also be involved on weekends. In the present study PA measurement was undertaken only on weekdays and in the future, measurement of PA on weekends can be advocated to look for differences between weekends and weekdays. As the RMMS tool is automated and unobtrusive, PA measurement can be undertaken on weekends with ease.

Stroke severity was found substantially and negatively correlated with mobility in the present study (PCC= -0.73, p<0.001) but not all patients were completely dependent

for ADL. Several patients were more active than others and future research could potentially focus on exploring motivational and predictive factors for patients who recover more efficiently than others. Additionally in collaboration with psychologists, efficacy of motivational strategies can be investigated to influence patients' behaviour to undertake self-directed activities. This will further add to the 'patient centred' rehabilitation approach that is followed by stroke services.

The above are some recommendations that can be made to enable optimal functional recovery of patients after stroke.

One of the aspects of human behaviour is physical activity and another one is the external environment. To bring about a change in behaviour, the physical environment in the hospital or rehabilitation unit needs to be conducive for undertaking more mobility and PA than what patients are currently undertaking. In the present study patients who were able to walk, commented on the lack of places for them to go to without leaving the unit and as the unit of a 24 bedded unit, the point is justified. There has been evidence that an 'enriched environment' can facilitate increase in PA of patients after stroke (Janssen et al., 2014b). An 'enriched environment' is known as creating physical surroundings of patients such that it can encourage physical, social and cognitive tasks that they can undertake on their own volition. Its benefit has been advocated by other studies in the literature (Johansson, 2000, Nithianantharajah and Hannan, 2006). Encouraging group activities, providing opportunities on the weekends for task practice and allowing patients to actively undertake ADL according to their capability are all aspects that can be considered as components of an enriched environment. Apart from the above, it can be recommended that all staff members encourage patients to be more active when communicating with the patients while not appearing to be forceful. If the same

consistent message is communicated by all staff members not just the therapy team, it may become a motivational method in itself.

One major advantage of a system such as RMMS is that it comprises of real time location technology.

Therefore it has potential to be used to provide live feedback for end users regarding duration of mobility undertaken on a weekly or daily basis. The end users can be patients and relatives and/or therapy staff. Providing quantitative feedback can be used to motivate patients and also help them to set targets for the subsequent duration of their recovery. Another important recommendation which links in with the implications of the findings for the field of Computer Science and Informatics is that further research with other types of sensors could be undertaken to complement the strengths of the RMMS and compensate for some of its current limitations.

It can be said that the present study results have provided some understanding of current PA activity levels and the related functional recovery in the early stages of stroke. Based on the work done so far, future studies can be undertaken to identify other predictive factors that contribute to functional recovery of patients apart from duration of mobility. Exploring the relationship of PA variables with OMs related to cognition and mood as well as demographic details such as type of stroke can also be recommended.

8. Conclusion

The following conclusions can be made from this study:

- A new system making use of real time location technology was successfully developed and evaluated. The system was designed to overcome the limitations of the current subjective and objective PA monitoring methods.

- RMMS was found to be very reliable for detecting the use of equipment such as walking aids and wheelchair. Its reliability to detect change in location from one room to another was almost perfect and the RMMS was found better than the criterion BM technique for detecting the frequency of ambulation. The agreement between RMMS and BM for measuring the duration of time spent by patients in their own rooms was high.

- However, accurate quantification of time spent in sitting in chair, lying in bed, and time spent by patients interacting with healthcare staff was not readily possible. While the tag's dimensions and prolonged battery life are advantageous, its current technical limitation which is low motion threshold needs to be addressed. Resolving other issues such as decreasing staff user effort and evaluating reliability and validity more comprehensively could help develop an advanced version of the RMMS tool.

- None the less longitudinal measurement of early stage PA was undertaken continuously with RMMS and unobtrusively with minimal disruption of clinical routine and with limited patient burden.

- The longitudinal study results demonstrate that patients spend very little time moving around and/or walking during the day. Besides that, they were spending large amounts of time in their own rooms and appeared to be doing very little functional tasks which could be classed as high level physical

activity. Moreover, there was no significant change in their mobility or time spent in their own room duration from admission to discharge.

- On further exploration, duration of mobility as a variable was strongly correlated to both Barthel Index and modified Rivermead Mobility Index scores and could account for up to 49% of variation in recovery. The results indicate that mobility duration is a key variable to explore longitudinally.

- These results are in line with literature findings published over two decades which report that patients spend almost half their time in their own rooms and undertake limited high level physical activity such as walking or therapeutic task practice outside of formal therapy sessions.

- Also, 'Mobility' can be considered as multi-factorial parameter as apart from daily duration, frequency or speed can also be obtained to further understand functional recovery in the early stages.

- This implies that it is crucial to prevent low PA from becoming norm to improve patients' functional recovery post stroke and optimise their rehabilitation. This could perhaps be achieved by better organisation of patient routine which would also be in line with relevant healthcare strategies and guidelines that have been developed.

- Creation of an enriched environment in the rehabilitation setting along with the use of an efficient system such as RMMS to provide live feedback about mobility for patients and clinicians can be recommended.

It can be said that the aim of this study has been achieved and that it has generated significant knowledge regarding functional recovery and rehabilitation after stroke making a valuable contribution to the existing evidence in this field for research and clinical practice.

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Appendices

<u>Appendix 1: Example of literature search with the device 'Pedometer'.</u>

	Search terms	Number of articles
1	Pedometer	4128
2	Stroke	457444
2	Post stroke	16269
4	Reliability	307268
5	Accuracy	745883
6	Test retest	45589
7	Reproducibility	484598
8	Validity	311209
Combination of search terms with 'AND'		
	1,2	53
	1,4	133
	1,5	171
	1,6	0
	1,7	85
	1,8	184
	1,2,4	7
	1,2,5	11
	1,2,7	6
	1,2,6	0
	1,2,8	3
	1,3,4	0
	1,3,6	1
	1,3,7	0

A novel system of activity monitoring to measure functional recovery from stroke during rehabilitation in the Cardiff Stroke Unit and home environment

PATIENT INFORMATION SHEET
Version 1.4 January 2012

> A large-print version or Welsh translation of this sheet is available on request.

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, and discuss it with your family and friends if you wish. Please ask us if there is anything that is not clear, or if you would like more information.

- Part 1 tells you the purpose of this study and what it will include.

- Part 2 gives you more detailed information about the conduct of the study.

- Part 3 gives information to carers who are considering this study on behalf of the patient (carer assent).

Take time to decide whether you wish to take part.

Thank you for reading this information sheet.

Part 1

What is the purpose of the study?

Stroke rehabilitation is a complex process. During recovery from a stroke there are many stages to go through before returning to normal walking and other activities of daily living. Furthermore, a whole team of healthcare staff is involved in supporting this recovery. Measuring the level of activity at every stage of recovery is not easy. Neither is it easy to measure how much interaction occurs between healthcare staff and people recovering from a stroke. New equipment which is very lightweight and can be worn like a watch can be used to measure these aspects all the time whilst at the Cardiff Regional Stroke Unit. This is a promising opportunity to develop a research tool that will allow us to do more research into the rehabilitation process and how to make improvements. First we need to investigate how best to use this new equipment and develop computer software specifically for this purpose.

Why have I been chosen?

You have been invited to help us with this study as you have been admitted to hospital with a stroke. We will be asking people who are admitted with a stroke to the University Hospital of Wales and the Regional Stroke Unit in a 2 year period. You are one of 110 patients that we hope will take part in the study.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive. If you are unable to sign the consent form due to problems following your stroke we will ask one of your relatives to sign the form on your behalf. We may ask you to sign the form at a later date if your recovery means that you are able to do that. If you consent to take part in this study but, due to the sometimes fluctuating nature of stroke you lose the capacity to consent during the study, as long as you or your family do not indicate that you do not want to continue to take part, you will continue to be included in the research.

What will happen to me if I take part?

You will be asked to wear a small device, the size of a watch, on your non-affected wrist and ankle. Staff in the unit will also wear the same device which will detect when people are moving, where they are and who they are with on a continuous basis. You may be asked to leave the device on your wrist and ankle at all times. After you have worn it, the researcher may also request you to complete a questionnaire to get some feedback from you about the comfort and acceptability of wearing the device. The questionnaire will take no more than 10 minutes to complete.

Other information will be collected such as clinical scoring lists and tests to identify which activities you are able to do at the different stages of your recovery.

In addition to that, the researcher will also record some observations manually. On certain days ,the researcher will walk around the stroke unit during the day .The researcher will observe and record your activity; your location and your interaction with other people present at that time, every 10 minutes. Events such as using the toilets, dressing, bath times or when the curtains around the bed are closed will not be observed.

After being discharged you may be requested to continue to be measured for another 4 weeks at home. The measurements whilst you are at home will require that we set up recording equipment and a small computer in your house. You will be reimbursed for the cost of the electricity that this equipment will consume.

Information collected will relate to the amount of time and how often you are moving your (arm) /leg and how much you are recovering from your stroke. Time spent during the day

356

with therapists and other healthcare workers and the effect this has on how much activity you do will be measured as well. This information will be compared with other clinical measures to identify which ones best relate to improvements in walking and activities of daily living.

What are the possible disadvantages and risks of taking part?

We do not expect there will be any additional risk in taking part.

What are the possible benefits of taking part?

There will be no benefit for you but the information we get from this study will help us to provide care and support to people who may have a stroke in the future.

Will my taking part in the study be kept confidential?

Yes. All the information about your participation in this study will be kept confidential. The details are included in Part 2.

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering taking part, please continue to read the additional information in Part 2 before making any decision.

Part 2

What will happen if I do not want to carry on with the study?

If you withdraw consent from further participation in the study, the information collected from you for the study will remain on file and will be included in the final study analysis. At the end of the study, your information will be securely stored for a minimum of 10 years. If you withdraw consent for your information to be used, it will be confidentially destroyed.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions (Dr Robert van Deursen on 02920 687704 or 02920 687685; Dr Allison Cooper on 07717 576108). If you wish to complain formally you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

There are no special compensation arrangements in place for this study. You may have grounds for legal action for compensation as a result of someone's negligence but you may have to pay for it. The normal NHS complaints mechanisms will still be available to you (if appropriate).

Will my taking part in this study be kept confidential?

If you decide to take part in this study, all information collected about you during the course of the research will be kept <u>strictly confidential</u>. This information will be securely stored by the research team at your hospital on paper and electronically, under the provisions of the 1998 Data Protection Act.

If you join the study, some parts of your medical records and the data collected for the study will be looked at by authorised persons from Cardiff University (the study Sponsor) and Cardiff and Vale University Local Health Board They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Your hospital and the research team will hold a copy of the consent form that you sign, which will have your name on it. You will be given a unique study number and this will be used as a code to identify you on all study forms. Only the research team and your hospital will be able to identify you from this number.

Involvement of the General Practitioner /Family Doctor (GP):
Your GP will be been informed that you are taking part in this study.

What will happen to the results of the research study?

We will share our findings with people who have had a stroke by means of a newsletter and a local conference. Meetings with healthcare professionals and publications in professional and scientific journals will allow us to share our information with interested parties in healthcare practice and research. Furthermore, we will set up a project Web site so that people can read about our study online. By the end of the study the evolved equipment and computer software will help us to carry out further studies into stroke rehabilitation to compare different therapeutic approaches or ways of organising rehabilitation services to improve the quality of care and to achieve that people can go home sooner.

Who is organising and funding the research?

This research is being organized by the Department of Physiotherapy, Cardiff University in collaboration with the College of Human Health and Sciences, Swansea University and Cardiff and Vale University Local Health Board.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by South East Wales Research Ethics Committee. It has also been approved by Cardiff and Vale University Local Health Board R&D Department.

This completes Part 2 of the Information Sheet.

If you are a carer considering participation in this study on behalf of a patient please continue and read Part 3.

Part 3 Carer Assent

Your relative/friend is unable to provide consent to participate in this research therefore you have been identified as a person who we can consult about whether or not they would want to be involved. You are known as the consultee and have been provided with the same information about the research project as your relative/friend. If you are unsure you may seek independent advice about this role and what is expected of you or if you do not feel able to take on this role, you may identify someone else to take your place.

As consultee you should set aside your own views and provide advice on the participation of your relative/friend in the research, taking into consideration their wishes and interests. Advance decisions made by your relative/friend about their preferences and wishes will always take precedence.

If you decide that your relative/friend would want to be involved, you will be asked to sign **an assent** form.

If you decide that your relative/friend would not wish to take part in this study this will not affect the standard of care they receive in anyway.

Contacts for further information:

Please discuss any questions that you may have with your research study contact:

   Name: Dr Robert van Deursen

Job title: Director of Physiotherapy, Department of Physiotherapy, Cardiff University
Contact phone number: 02920 687704 or 02920 687685

Independent advice about taking part in research studies can be obtained from Involving People. For all enquiries, please contact:

Involving People

Wales Council for Voluntary Action

Baltic House

Mount Stuart Square

Cardiff Bay

CF10 5FH

Involvingpeople@wcva.org.uk

Tel no: 029 2043 1700

If you decide you would like to take part, please read and sign the **assent** form. You will be given a copy of this information sheet and the signed **assent** form to keep.

If you need more time to consider this, please feel free to think this over.

Thank you for taking the time to read this information sheet

Patient ID:	Initials:
Date of Birth:	Hospital Number:

PATIENT CONSENT FORM Version 1.4 January 2012

1. I confirm that I have read and understand the Information Sheet dated 11th January (Version 1.4) for the above study and have had the opportunity to ask questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my medical care or legal rights being affected.

3. I understand that my medical notes and social service records may be looked at by responsible individuals from the research team, regulatory bodies or Sponsor where it is relevant to my taking part in the research; I give permission for these individuals to have access to my records.

4. I understand that my medical data will be collected for this study and may be used to evaluate safety and help develop new research, and that data protection regulations will be observed, and strict confidentiality maintained.

5. I understand that even if I withdraw from the above study, the data already collected from me will be used in analysing the results of the trial, unless I specifically withdraw consent for this. I understand that my identity will remain anonymous.

6. I understand that if I consent to take part in this study but then lose the capacity to consent during the study, as long as I or my family does not indicate that I want to withdraw from the study then I will continue to be included in the research.

7. I understand that my GP may be aware of my participation in this study.

361

8. I agree to take part in the above study

_____   _____   _____

Name of Patient   Date   Signature

_____   _____   _____

Name of Person   Date   Signature

Taking Consent

_____   _____   _____

Name of Witness   Date   Signature

(1 copy for the patient; 1 for filing in the patients' medical records;
Original stored in Investigator Site File)

Patient ID:	Initials:
Date of Birth:	Hospital Number:

CARER ASSENT FORM Version 1.4 January 2012

1. I confirm that I have read and understand the Information Sheet dated 5th October 2011 (Version 1.3) for the above study and have had the opportunity to ask questions.

2. I understand the purpose of the study and know what I and my relative/friend's involvement will be.

3. I understand that my and my relative/friend's participation is voluntary and that I and my relative/friend are free to withdraw our assent/consent for participation at any time without giving any reason and without my relative/friend's medical care or legal rights being affected.

4. I understand that my relative/friend's medical notes and social service records may be looked at by responsible individuals from the research team, regulatory bodies or Sponsor where it is relevant to my relative* taking part in the research; I give permission for these individuals to have access to my relative/friend's records.

5. I understand that my relative/friend's medical data will be collected for this study and may be used to evaluate safety and help develop new research, and that data protection regulations will be observed, and strict confidentiality maintained.

6. I understand that even if I and my relative/friend withdraw from the above study, the data already collected from me and my relative/friend will be used in analysing the results of the trial, unless me and my relative/friend specifically withdraw consent for this. I understand that my and my relative/friend's identity will remain anonymous.

7. I understand that my relative/friend's GP may be aware of my relative/friend's participation in this study.

8.   I agree to my relative/friend taking part in the above study

[ ]

_____   _____   _____

Name of Relative/Friend   Date   Signature

_____   _____

Name of Patient   Relationship to Patient

_____   _____   _____

Name of Person   Date   Signature

Taking Consent

_____   _____   _____

Name of Witness   Date   Signature

(1 copy for the relative; 1 for filing in the patients' medical records;
Original stored in Investigator Site File)

A novel system of activity monitoring to measure functional recovery from stroke during rehabilitation in the Cardiff Stroke Unit and home environment

STAFF INFORMATION SHEET
Version 1.3 January 2012

A large-print version or Welsh translation of this sheet is available on request.

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, and discuss it with your family friends or anyone else if you wish. Please ask us if there is anything that is not clear, or if you would like more information.

- Part 1 tells you the purpose of this study and what it will include.
- Part 2 gives you more detailed information about the conduct of the study.

Take time to decide whether you wish to take part.

Thank you for reading this information sheet.

Part 1

What is the purpose of the study?

This study aims to measure functional activity in patients recovering from stroke in a Regional Stroke Unit (RSU) by measuring their physical activity using new automatic tracking equipment. One of the important aims in rehabilitation is to restore walking activity to regain independence. To understand the stroke rehabilitation process thoroughly, better measurement tools are required that effectively provide information about functional activities from the early stages to full recovery effectively.

Moreover a whole team of healthcare staff is involved in supporting this recovery and it is not easy to measure how much interaction occurs between people recovering from a stroke and healthcare staff.

New equipment which is very lightweight and can be worn like a watch can be used to measure these aspects all the time whilst at the Cardiff Regional Stroke Unit. This is a promising opportunity to develop a research tool that will allow us to do more research into the rehabilitation process and how to make improvements. First we need to investigate how best to use this new equipment and develop computer software specifically for this purpose.

Why have I been chosen?

You have been invited to help us with the study as you are a member of the healthcare staff at the stroke unit who has a role in the patients' recovery and with whom they interact.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason.

What will happen to me if I take part?

You will be asked to wear a small device the size of a watch on your uniform during your working hours at the unit. Although the device will record data throughout your working hours, the only time the data from device worn by you will be used for the research is when you interact with those patients who have agreed to take part in the study and are wearing the devices themselves. After you have worn it, the researcher may also request you to complete a questionnaire to get some feedback from you about the comfort and acceptability of wearing the device. The questionnaire will take no more than 10 minutes to complete.

The patients will wear the same device on their non-affected wrist and ankle which will then detect when they are moving, where they are and who they are interacting with.

The patients may be asked to leave device on at all times.

In addition to that, the researcher will also record some observations manually. On certain days, the researcher will walk around the stroke unit during the day. The researcher will observe and record the patients' activity; their location and their interaction with other people present at that time every 10 minutes. Events such as using the toilets, dressing, bath times or when the curtains around the bed are closed will not be observed.

Information collected from the patients will relate to the amount of time and how often they are moving their arm and leg and how much they are recovering from their stroke. Time spent during the day with therapists and other healthcare workers and the effect this has on how much activity they do will be measured as well. This information will be compared with other clinical measures to identify which ones best relate to improvements in walking and activities of daily living.

What are the possible disadvantages and risks of taking part?

We do not expect there will be any additional risk in taking part.

What are the possible benefits of taking part?

There will be no benefit for you but the information we get from this study will help us to provide care and support to people who may have a stroke in the future.

Will my taking part in the study be kept confidential?

Yes. All the information about your participation in this study will be kept confidential. The details are included in Part 2.

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering taking part, please continue to read the additional information in Part 2 before making any decision.

Part 2

What will happen if I do not want to carry on with the study?

If you withdraw consent from further participation in the study, the information collected from you for the study will remain on file and will be included in the final study analysis. At the end of the study, your information will be securely stored for a minimum of 10 years. If you withdraw consent for your information to be used, it will be confidentially destroyed.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions (Dr Robert van Deursen on 02920 687704 or 02920 687685; Dr Allison Cooper on 07717 576108). If you wish to complain formally you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

There are no special compensation arrangements in place for this study. You may have grounds for legal action for compensation as a result of someone's negligence but you may have to pay for it. The normal NHS complaints mechanisms will still be available to you (if appropriate).

Will my taking part in this study be kept confidential?

If you decide to take part in this study, all information collected about you during the course of the research will be kept <u>strictly confidential</u>. This information will be securely stored by the research team at your hospital on paper and electronically, under the provisions of the 1998 Data Protection Act.

If you join the study, some parts of the data collected for the study will be looked at by authorised persons from Cardiff University (the study Sponsor) and Cardiff and Vale University Local Health Board They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Your hospital and the research team will hold a copy of the consent form that you sign, which will have your name on it. You will be given a unique study number and this will be used as a code to identify you on all study forms. Only the research team and your hospital will be able to identify you from this number.

What will happen to the results of the research study?

We will share our findings with people who have had a stroke by means of a newsletter and a local conference. Meetings with healthcare professionals and publications in professional and scientific journals will allow us to share our information with interested parties in healthcare practice and research. Furthermore, we will set up a project Web site so that people can read about our study online. By the end of the study the evolved equipment and computer software will help us to carry out further studies into stroke rehabilitation to compare different therapeutic approaches or ways of organising rehabilitation services to improve the quality of care and to achieve that people can go home sooner.

Who is organising and funding the research?

This research is being organized by the Department of Physiotherapy, Cardiff University in collaboration with the College of Human Health and Sciences, Swansea University and Cardiff and Vale University Local Health Board.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by South East Wales Research Ethics Committee. It has also been approved by Cardiff and Vale University Local Health Board R&D Department.

This completes Part 2 of the Information Sheet.

Contacts for further information:

Please discuss any questions that you may have with your research study contact:

> Name: Dr Robert van Deursen
> Job title: Director of Physiotherapy, Department of Physiotherapy, Cardiff University
> Contact phone number: 02920 687704 or 02920 687685

If you decide you would like to take part, please read and sign the consent form. You will be given a copy of this information sheet and the signed consent form to keep.

If you need more time to consider this, please feel free to think this over.

Thank you for taking the time to read this information sheet

Participant ID:	Initials:
Date of Birth:	

PARTICIPANT CONSENT FORM Version 1.3 January 2012 1. I confirm that I have read and understand the Information Sheet dated 011th January 2012(Version 1.3) for the above study and have had the opportunity to ask questions 2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my medical care or legal rights being affected. 3. I understand that even if I withdraw from the above study, the data already collected from me will be used in analysing the results of the trial, unless I specifically withdraw consent for this. I understand that my identity will remain anonymous 4. I agree to take part in the above study	Please initial the boxes ☐ ☐ ☐ ☐

_____   _____   _____

Name of Participant   Date   Signature

_____   _____   _____

Name of Person

Taking Consent   Date   Signature

_____   _____   _____

Name of Witness   Date   Signature

(1 copy for the participant;
Original stored in Investigator Site File)

Appendix 4: Details of tag coding

Patient tags and patient related object tags: 15 sets of tag were created and named alphabetically from set A to set O. Each set consisted of 5 tags; 2 patient tags (1 for the wrist and 1 for the ankle) and 3 patient related object tags; for the bed, for the bedside chair and for the walking aid tag respectively. The whole bundle of tags could be used again for another patient once the former patient was discharged. **Table** below displays an example of tag coding for patient and patient related object tags for set B.

Example of Patient and Patient Related Tag Coding

Tag Category	Tag Number	'asset'/object type	Tag code (e.g.set B)
Patient tags	IRCODE00125632 IRCODE00125638	Wrist tag Ankle tag	Pt_B_W* Pt_B_A**
Patient related object tags	IRCODE00097942 IRCODE00097962 IRCODE00097982	Bed tag Bedside chair tag Walking aid tag	Bed_B*** Bed_chair_B Walk_aid_B
Further explanation of the code *Pt_B_W : 'Pt' stands for patient; 'B' is the corresponding alphabet for the set (from set A to Set O)and 'W' stands for wrist ** Pt_B_A: Code for the ankle tag where 'A' stands for ankle *** Bed_B : Bed was the type of object the tag was on and B referred to the alphabetical set (from Set A to set O)			

Staff tags: A total of forty tags were allocated to be used as staff tags. The maximum number of staff present in one shift for each profession was calculated after discussion with RSU staff. Based on the professional roles a specific number of tags were allocated to each profession as follows: 16 tags for nurses, 8 for physiotherapists, 6 for occupational therapists, 4 for speech and language therapists, 2 for clinical psychologists, 2 for medical staff and 1 for the clinical receptionist. The researcher also wore a tag when in RSU. The tags were placed in individual boxes marked by the professional roles and these boxes were kept in accessible places with in the unit. The number of tags assigned to each professional role was more than the actual number of staff present at any given time of day. This was done deliberately so that the staff members had a choice of tags instead of being compelled to wear the same tag every day in which case a particular staff member could be singled out. The possibility of losing data was also minimised in this way because if a tag was lost or misplaced staff members could wear another one. Staff members were instructed to pick up any tag out of the box of tags when they came on duty and take it off when they left. It was not necessary for them to wear the same tag everyday as the idea was to gather information about patient-staff interaction based on their professional roles instead of gathering data

about an individual member of staff. More details regarding this aspect is explained in the relevant sub study protocols **(section 4.1.2).**

Examples of how the staff tags were labelled is given in the **Table below**. In the actual software, the tag code as well as the staff member role was displayed.

Example of Staff Tag Coding

Category	Tag serial number	Role	Tag code
Staff Member tags	IRCODE00125651	Physiotherapist	Staff_1
	IRCODE00125658	Occupational Therapist	Staff_8
	IRCODE00125663	Nurse	Staff_14

Equipment tags were coded based on their function and some of these examples are given in the **Table below.**

Example of Equipment Tag Coding

Category	Tag serial number	Object Type	Tag code
Equipment tags	IRCODE00090104	Sling hoist	Equipment_17
	IRCODE00090105	Standing hoist	Equipment_18
	IRCODE00090077	Steady	Equipment_22
	IRCODE00098009	Turn disc	Equipment_23
	IRCODE00098022	O standing frame	Equipment_25
	IRCODE00098023	Treadmill	Equipment_26
	IRCODE00098028	Patient Wheelchair	Wheelchair_1

As one home monitoring data collection was undertaken at a time, one set of tags was used. The tags and the coding are given in the **Table below**.

Tag Coding For Home Pilot Project

Tag category	Tag serial number	Tag type	Tag code
Patient tags	IRCODE00155704 IRCODE00155703	Ankle Wrist	Pt_1_ankle Pt_1_wrist
Equipment tags	IRCODE00155689 IRCODE00155688 IRCODE00155677	Walking aid Stair lift Wheel chair	Walk_aid Stair_lift Pt_Wheelchair

Appendix 5: Original CERISE tool (De Weerdt et al., 2000)

Activity	**Therapeutic activities** Physiotherapy Individual with physiotherapist Group therapy Occupational therapy Individual with occupational therapist Group therapy Speech therapy Neuropsychological training Nursing care Medical care Sports activities Swimming Fitness Other (e.g. Horse riding,etc.) Autonomous exercising and/or training Other activities	**Non- therapeutic activities** Sitting Eating Transport (covering distances) Lying or sleeping Communication Dressing and hygiene Active leisure (reading a book, walking in garden etc.) Passive leisure (watching tv, listening to music, etc.) Other activities
Location	Patient's room Therapy room Corridor Dining room Day room Toilet or bathroom Cafeteria Outside Any other location	
Social Interaction	Doctors and/or specialists Therapists Nurses Other patients Visitors Other persons (e.g. Cleaning personnel, etc.) No-one	

Modified CERISE tool for present study

CERISE CATEGORY	Items retained from original tool	Items discarded from original tool	Items added or modified
Activity (therapeutic)	Physiotherapy Individual with physiotherapist Group therapy Occupational therapy Individual with occupational therapist Group therapy Speech therapy Neuropsychological training Nursing care Medical care	Sports activities Swimming Fitness Other (e.g. Horse riding,etc.)	Group physio therapy Group occupational therapy
Activity (Non-therapeutic) Termed as : activities outside of therapy time	Sitting Eating Transport (covering distances) Lying or sleeping Communication Dressing and hygiene Active leisure (reading a book, walking in garden etc.) Passive leisure (watching tv, listening to music, etc.) Other activities	None	Wheelchair ambulation Walking Standing Getting into the bed Getting into the chair Getting into the wheelchair
Location	Patient's room Therapy room Corridor Day room Toilet or bathroom	Cafeteria Dining room	Nurses station/main reception Outside (away from RSU) Any other location (within RSU including SALT/Psych)
Social Interaction	Doctors and/or specialists Therapists Nurses Other patients Other persons (e.g. Cleaning No-one	None	Visitors (relatives/carers) personnel/catering staff/dietician)
Additional category added Activity Type	Assisted activity/Supervised activity Independent Activity		
Additional category added Equipment	None Walker Stick Steady Hoist wheelchair Other		

Stroke Patient Activity Project-User Feedback Questionnaire

Covering Letter

Dear Participant,

As a part of your involvement in our study, you have been wearing the RFID tag over the last few days. We would like to thank you for the same.

We would like to gather some additional information regarding your experience of wearing the RFID tag. Attached please find a questionnaire that we would request you to complete.

The questionnaire will take no more than 10 minutes to fill out. Once you have completed the questionnaire, the researcher will collect it from you.

Information obtained from you will help us improve our research project in the future. All information will be kept strictly confidential

If you have any questions or concerns about the questionnaire, please contact the researchers. (Dr Robert van Deursen on 02920 687704 or 02920 687685; Dr Allison Cooper on 07717 576108)

Thank you once again for your participation.

Yours sincerely,

Arshi Samar Iqbal

PhD student

School of HealthCare Studies, Cardiff University

Ph no:

Email:

Questionnaire

Date: Tag worn on: Right wrist/Left
wrist/Right ankle/left ankle/uniform

Please tick one box for statements 1 to 10 below

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
1. I found the tag to be acceptable					
2. I forgot I was wearing the tag					
3. I have concerns about the tag's safety					
4. The tag did not interfere with my daily activities					
5. I experienced discomfort while wearing the tag					
6. I found that the tag restricted my arm/leg movements					
7. I found it acceptable to wear the tag in front of other people					
8. I found the tag too big					
9. I found the tag too heavy					
10. I found the tag simple to take on/off on my own					
11.I would find it acceptable to wear the tag for one month					

12. For how many days did you wear the tag? (E.g. 2 days, 14 days etc.)

----

13. In the past, have you ever worn any other device that measures your

activity? (e.g. a step counter or a pedometer)

(Please Tick One Box)

☐ **Yes**

☐ **No**

14. Is there anything else you would like to tell us about your experience

of wearing the tag? If YES, please write below

End of Questionnaire

Thank you for Taking the Time to Answer the Questions

COOPER, A., IQBAL, A., WOZNOWSKI, P., PREECE, A. & VAN DEURSEN, R. 2014. Effective measurement of early stage functional recovery after stroke with a new sensor based automated system. International Journal of Stroke, 9, 48.

IQBAL, A. S., WOZNOWSKI, P. R., COOPER, A., PREECE, A. D. & VAN DEURSEN, R. 2013. A new computerised system can continuously measure functional activities of patients in a stroke rehabilitation unit. Cerebrovascular Diseases, 35, 204.

IQBAL, A. S., WOZNOWSKI, P. R., COOPER, A., PREECE, A. D. & VAN DEURSEN, R. 2012. Measuring functional activities of patients in a stroke unit: Comparison of a sensor based real time location system with the observational behaviour mapping technique. International Journal of Stroke, 7, 48.