

Chapter 1

The Literature Review

Introduction.

It is the governments intent to modernise the NHS. One of the methods in which this can be achieved is through evidence based practice. The current climate within the NHS has clear manifestations of such practice, the most visible perhaps being the increase in audit within practice. The facilitation of high quality care also requires practitioners to partake in multiprofessional treatment planning and embrace such plans into their every day practice. In line with the above it is essential that during the emergence of such practice audit occurs to measure the effectiveness of such approaches.

One of the areas that could greatly benefit from such practice is that of Cerebral Palsy. Management of children with cerebral palsy is the focus of considerable resources in many countries so that the evaluation of the efficacy of new and established treatments is imperative (Boyd 2001).

Cerebral Palsy is a lifelong condition with a significant impact on the individual and their carers. Most subjects with mild or moderately severe CP survive into adult life and have a normal life expectancy (Bhusan 1993). Although the brain pathology that underlies the clinical manifestations of CP is non-progressive, the functional abilities of the individuals and their health and social needs usually change (Bakheit 2001).

With the above philosophy of evidence based practice in mind and the current need for valid and reliable tools to achieve this goal, it is the aim of this thesis to validate an activity monitor, the activPAL, for use with cerebral palsy (CP). It will establish whether or not the activPAL activity monitor is a valid and reliable tool with which to measure this population. A review of existing activity monitor research shall take place and outcome measures currently adopted within cerebral palsy studies shall be reviewed.

It is proposed that the activPAL activity monitor could be used as an alternative outcome measure within treatment regimes. This may

prove to provide a potential improvement over current outcome measures, as it collects real world data, collected in the community outwith the remit of laboratory conditions.

1.1 CEREBRAL PALSY

Aetiology

Cerebral Palsy (CP) is the most common cause of physical disability in children, with a reported incidence of 2.0-2.5 per 1000 live births (Stanley 2000). It is also the most common motor disorder originating in childhood (Molnar 1991). CP results from a permanent static lesion of the cerebral motor cortex that occurs before, at, or within two years of birth (Dabney 1997). Even though the lesion itself does not change, the clinical manifestations of the lesion change as the child grows and develops (Essex 2003). Functional capacity is reduced due to a reduction in central control and co-ordination. The lack of central control is evidenced clinically by the presence of spasticity (spasticity is velocity dependent resistance of a muscle when stretched), which may lead to muscle contractures and resultant joint deformity. Weakness and loss of selective motor control manifests itself through poor co-ordination. The presence of all, or combinations of the above have a profound effect on the individual's ability to walk, evidenced in varying degrees of spatial and temporal changes in the gait cycle. Flett 2003 summarises the above by stating that CP is not the result of a recognised progressive or degenerative brain disease and is characterised by aberrant control of movement or posture appearing early in life secondary to central nervous system damage or dysfunction. The motor skills of most children with CP improve as they grow, but the rate of improvement is slower in children with CP than in unaffected children (Essex 2003).

Classification of Cerebral Palsy

Cerebral Palsy can be classified in three distinct ways, motor type, topographical distribution and functional severity (Stanley 2000).

Motor Disorder

1) Spastic Paresis-High tone that results in restriction in range of movement of joints.

- 2) Ataxic Paresis – results in balance difficulties and uncoordinated movements.
- 3) Athetoid – fluctuation of tone which results in difficulties in control of speech and breathing.
- 4) Mixed- a combination of two or more of the above.

Difficulties lie in the fact that many children have mixed motor types and changing motor types that do not lie perfectly within the categories above.

Topographical – the area of the body affected (Flett 2003, Levitt 1982).

- 1) Monoplegia – only one extremity/limb involved
- 2) Diplegia – all four limbs involved the two lower limbs affected the most.
- 3) Paraplegia – involvement of the lower limbs.
- 4) Hemiplegia – one lower and one upper limb involved on the same side.
- 5) Triplegia – three limbs involved with inclusion of the trunk.
- 6) Quadraplegia – all four limbs involved with the trunk.
- 7) Double Hemiplegia/Spastic Tetraplegia – involvement of all four limbs where the involvement of the upper limbs is more severely affected than the lower limbs.

The distribution of the most common clinical patterns is difficult to assess because specific diagnoses are not available. National registries identify CP with the code 343.9 from the International Classification of Diseases ninth revision (ICD9). Rumeau- Rouquette et al (1997) identified the distribution of clinical patterns as, hemiplegia 21%, diplegia 17% and quadriplegia 40%. The gross motor functional classification system was employed by Kennes et al (2002) and found the following distribution; level 1 27.5%, level 2 11.5%, level 3 19.9%, level 4 20.1 % and level 5 21.1%. Level 1 indicates a few limitations and level 5 severe impairments within this classification system.

Motor type and topographical classifications lack reliability despite being widely used and clinically significant. Topographical classification using the terms, monoplegia, diplegia, quadraplegia is widely employed (Howard 2005) however confusion may exist even when observers are experienced due to a lack of clarity in definition, particularly between the less commonly used terms of double hemiplegia and spastic tetraplegia (Blair et al 1985). It is thought that the best way to classify children with CP is with a combination of motor type, topography and gross motor function (GMF) (Howard 2005). It has also been stated that the GMF has strong correlations with musculoskeletal problems (Kennes et al 2002).

1.2 Gait Classification in Cerebral Palsy.

"Gait patterns in spastic motor disorders have been described by a number of authors but only two classifications are widely used," (Rodda et al 2001).

According to Winters et al 1987 there are four differentiable gait patterns within hemiplegia when the limb as a whole is considered and according to Sutherland et al (1993) there are four definable categories within spastic diplegia in relation to the knee motion that occurs. As this study is only concerned with the validation of the activPAL activity monitor for hemiplegic gait, Winters classification shall be employed within the study. There is widespread use of this classification and it is frequently referenced within literature (Rodda et al 2001).

Winters and Gage classifications are more accurately referred to as postural patterns rather than gait patterns. The postural patterns are most clearly seen in the middle to end of stance phase and are largely based on sagittal plane observations except where referring to type 4 hemiplegia and also in diplegia and quadriplegia where coronal and transverse plane observations are also required. Of the four types of Winters and Gage hemiplegia the study will look at type 2 hemiplegia. Type two hemiplegia can be further classified into type 2a and 2b where;

Type 2a Equinus plus neutral knee and extended hip.

Type 2b Equinus plus recurvatum knee and extended hip.

Type 2 hemiplegia is by far the most common type in clinical practice, it is characterised by a variable degree of plantarflexion during swing phase due to the impaired function of tibialis anterior and true equinus as a result of spasticity and/or contracture during the stance phase of gait (Rodda et al 2001).

Apart from the rare exceptions of youngsters with severe damage to the brain, children with congenital hemiplegia are generally 4 to six months behind in early motor achievements. Attainment of walking may be delayed somewhat longer, but the majority can walk by 2 years and virtually all by the age of 3. Along with the delay in motor achievements underdevelopment of the extremity (size and length discrepancy) often exists due to a cortical sensory deficit (Gage 1991). The recent development of the Gross Motor Function Classification System (GMFCS) that was designed for the measure of function has increasingly become used as a classification system (Howard J et al). This will be discussed in greater detail within the following chapters.

1.3 Gait Analysis Descriptors and their relevancy to activity monitoring.

In previous research to validate an activity monitor D J Walker et al (1997) stated that, "analysis of output from the machine in terms of steps counted has caused some problems of definition as shown by the inter-observer differences in viewing the video. At some point a shuffle has to be defined as a step or not. Our definition of a step has proved reasonably robust for the populations we have tested. The above comments made by Walker et al (1997) draws attention to the fact that inter-observer differences may exist in the way in which a step is defined. The above point will need to be taken into account in the research trial protocol.

The challenge of defining abnormal walking patterns was raised as early as 1987 by Wall. The paper considers the applicability of standard gait descriptives as applied within the normal gait cycle when addressing the many variants observed within pathological gait cycles. It highlights some of the major difficulties encountered.

The above paper has implications towards this study. It is apparent that the parameters that the activity monitor uses to identify a step may not be relevant when considering a person with a hemiplegic gait pattern resultant from C.P. The idea that the parameters and the

algorithms will have to be tuned for a specific clearly defined pattern of gait may become apparent. On further reflection on the paper and the pathological patterns described within. It is easy to see how the written word in subjective descriptions of pathological gait patterns can be misleading. The subjective commentary alone is not sufficient to accurately transfer a true representation of the anomalies existing. The terminology used can be interpreted in many different ways when unsupported. However when supported by diagrams and video data for example the standard terminology can convey the gait pattern with more accuracy or can be less open to misinterpretation.

1.4 OUTCOME MEASUREMENTS IN CEREBRAL PALSY.

A major challenge to for those working with young disabled children is how to assess the effectiveness of various intervention programmes (Bax 1985). On looking further it became evident that many of the theories used in the treatment of CP were indeed just that, and very little if any research to validate particular treatment regimes was available. Pearson (1982) states that parents and professionals invest time and costly resources in diverse therapy and educational endeavors, but there is a lack of scientific evidence about the influence of various approaches on outcome. This comment was made some time ago now but still holds true. This is an increasing source of frustration for many health care professionals who recognise this as being the case yet find themselves without the time or the resources to alter the course of this historical situation. The call for more refined research was made by Shonkoff and Hauser-Cram (1987), to identify clearly what were important programme components. Anyone who has worked amongst the plethora of treatment modalities within the area of C.P. alone will appreciate the magnitude of this request. Due to the long standing history of poor funding within this area very little research has occurred and the quality of existing research, or perhaps the relevancy of research to actual clinical practice is debatable. Helder in 2001 stated that, "The focus of paediatric rehabilitation is increasingly changing. The emphasis on outcome measurement is the driving force for redesigning service provision, as outcome tells us 'what', while service provision 'how' is to be provided."

With the advent of the modern day activity monitor the possibility of real world outcome measurement and resultant intervention assessment may become a reality.

One of the most recent treatment advances for cerebral palsy has occurred through the administration of botulinum toxin A. Botulinum toxin is injected locally into a specific muscle or muscle groups to lower the spasticity within that specific injection site. This being a recent treatment modality it was thought pertinent to review the most recent (1990 – 2005) research literature to ascertain what outcome measures have been employed.

A systematic review in 2001 by Boyd et al revealed that much research has occurred within this area over the last 15 years. However out of 156 papers relating to the lower limb, reviewed from the last 10 years, only ten were randomised studies. Out of the 156 papers only five considered functional improvement as one of the outcome measures. This could be potentially due to the fact that a valid or reliable measurement tool doesn't exist or that the existing measurement tools are impractical and time consuming in their deployment. Or is it due to functional improvement still not being seen as a relevant clinical indicator?

Outcome Measures Employed in the Treatment of CP with Botulinum Toxin A.

Gross Motor Function Classification system (GMFCS)

The most useful development in the classification of CP in recent years has been the Gross Motor Function Classification system (GMFCS) (Palisano 1997). It has been shown to be both valid and reliable and clinically relevant for children with CP between the ages of 2 and 12 years (Wood E. 2000). The GMFCS relies on the assessment of self-initiated movement with specific emphasis being placed upon function during sitting standing and walking. There are five levels of distinction within the scale based upon functional limitations, such as the ability to walk with and without aids and quality of movement. According to Howard et al 2005, children with spastic hemiplegia will usually be in levels one and two, whilst children with spastic diplegia will be in

levels 2, 3 and 4 and those with quadriplegia will be in levels 3, 4 and 5.

The gross motor function measure (GMFM)

The gross motor function measure (GMFM) is a standardised observational instrument designed to measure changes in functional tasks (Russel et al 1989), it must not be confused with the qualitative measure of functional skills such as the gross motor performance measure (Palisano et al 1997). Limitations however exist with the use of GMFM. Damiano et al 1996 reported a ceiling effect when measuring outcomes in children with hemiplegia and mild diplegia. This effectively meant that the GMFM indicated greater improvement in function than was the case within this trial that looked at the relationship of gait analysis to GMF. In a later study in 2000, it was proposed by Nordmark et al that a floor effect was exhibited in groups with severe impairment (GMFCS 4 and 5) when measured with GMFM. Also younger children may be less likely to co-operate with the demanding testing protocol of the GMFM where 5 years is recommended as the suitable age for assessment (Russell et al 1993). Russell improved the scaling of the GMFM and provided evidence for its reliability and validity in 2000 (Russell 2000).

Other Outcome Measurements Employed in Botulinum Toxin A Studies includes the physicians rating scale and kinematic studies that gain objective measures of gait.

Measurements that quantify impairment have also been used such as the Modified Tardieu Scale (Boyd and Graham 1999) and the Modified Ashworth Scale (Corry et al 1998).

Questionnaire based activity monitoring designs have also been employed, examples of which include the Rivermead Mobility Index. This involves questions such as, 'do you walk around outside without help?' The weakness with this question is that it ignores the frequency or the duration of the activity.

1.5 METHODS OF ASSESSMENT FOR CHILDREN WITH CEREBRAL PALSY.

Static Assessment

One of the simplest ways the clinician has to assess CP is the static examination. Range of movement and muscle power are mainly of concern within this assessment. In a recent study (Noonan 2003) it was found that the average variability in static range of motion from physical examination ranged from 25 degrees to 50 degrees.

Simple Dynamic Assessment

In the simplest form a dynamic assessment will consist of the clinician simply observing the patient as they walk up and down (Coleman 1999). This technique when performed by a skilled clinician can be useful, however the accuracy of observations made becomes more and more questionable as the complexity and number of gait deviations increase. This is also a problematic technique as the recording of the information is reliant on the subjective reporting of the clinician. Observational gait analysis can be greatly enhanced by the use of two dimensional video recording, especially if there is the facility for slow motion replay (Boyd et al 1999). The gait pattern can then be observed at a later date in greater detail. This recording could also be used for comparative purposes after treatment interventions and provide a simple form of outcome measure.

Gait Laboratory Assessment.

As an adjunct to the static assessment, some clinical centers may have the added benefit of gait laboratory analysis, although this is not commonly the case.

A gait laboratory provides the clinician with the possibility of greater accuracy of measurements. It also enables the measurement of parameters that would otherwise not be available, such as ground reaction vectors and centre of mass.

Research has been undertaken to study the consistency of results gained through gait analysis. The average variability in sagittal,

coronal and transverse plane kinematic motions averaged 12, 7 and 20 degrees respectively (Noonan 2003). From this it was concluded that substantial variations in raw data exist when the same CP patient is evaluated at different gait centers. Also the data do not yield the same treatment recommendations in the majority of patients (Noonan 2003). The above findings perhaps point to the use of alternative technology as an adjunct to refine the data obtained from gait labs. It could also be implied that such laboratories are still complex in their usage and lead to erroneous results and misinterpretation, except to those who regularly use such equipment. This being the case a less complex tool is still required to help the clinician decide upon the validity of their treatment.

When studies within gait labs use a univariate approach, where only one variable is measured (such as peak knee flexion) one has to understand that there are shortcomings in terms of specificity and interdependence. Variables that are specific give information about an isolated aspect of gait, but fail to adequately explain the whole picture (Novacheck et al 2004). Researchers may try to provide a more comprehensive picture by taking multiple and simultaneous univariate measures, however may fail to take into account possible interdependence of the recorded gait measures. As a result the same variable is effectively counted twice which may enhance the outcome artificially. Clearly great care is required when both undertaking and using univariate studies to draw conclusions upon treatment effects. This effect can be overcome by using the normality index (NI), a figure resultant from multivariate analysis of the variables, which provides a valuable measure for overall gait pathology based on quantitative gait analysis.

1.6 ACTIVITY MONITORING

1.6.1 Method of Activity Monitoring Previous to the Advent of Activity Monitors.

In 1999 Coleman stated that, "the extent to which a person is able or willing to move around the world is often a strong indicator of his/her condition," and as such can be taken as an assertion that activity is

worthy of assessment and an indicator of the condition and hence a potential outcome indicator. Quantitative evaluation of function, in relation to children with physical disabilities, has to date been mainly focused upon laboratory-based measures. However a more direct relationship with physical function, health and well-being may be found through the measurement of activity in the community (Pirpiris et al 2004). Previous to the advent of activity monitors this has been done by the employment of diaries and the employment of activity scales.

The Employment of Diaries for the Recording of Activity.

Before the advent of the modern activity monitor which produces quantitative data, physical activity was measured using various qualitative procedures. Subjects were asked to keep diaries of their activities over a period of time. This qualitative reporting was then examined to provide an indicator of the subjects real world activity. The accuracy of the information provided from the subject is questionable. This is more so the case, where patient diaries are kept and used by the healthcare professional, as an indicator towards a treatment modalities success.

The Employment of Activity Scales for the Assessment of Activity.

These assessments can be categorised as clinimetry and have their origin in clinical practice and commonly have a degree of subjectivity (Bussmann et al 1998). They include activity scales which have been devised for the measurement of physical ability/activity. All such activity scales are instruments and as such need to be evaluated for their validity and reliability.

1.6.2 The measurement of activity in children.

Functional assessment of a child is an effort to systematically describe and measure a child's abilities and limitations when performing the activities of daily living. It is imperative that the tool effectively defines and measures the relevant construct that is function rather than development (McCabe et al 1990). The need to assess physical activity

in any population is based on the desire to determine the current activity status of that population. Some of the most widely used children's activity measures are described below.

The Paediatric Functional Independence Scale (WeeFIM) was designed by McCabe and is a direct descendent of the (FIM), the Adult Functional Independence Scale. Within this research, the scale failed within the third phase of 'conceptual adequacy of its subdomains, according to the method of indexing content validity described by Lynn (1986). Its validity as a scale is therefore questionable.

The gross motor function measure (GMFM) as discussed earlier is a standardised observational instrument designed to measure changes in functional tasks (Russel et al 1989) and as such does not quantify the frequency of activity that occurs in the real world. Such a scale exists in the Childrens Activity Scale (CARS).

The Children's Activity Rating Scale (CARS) is a rating scale that was developed to provide an activity score representative of energy expenditure in young children (Puhl, J et al 1990). Common activities by preschool aged children are classified into five levels according to a rating system developed by Puhl et al. The level 1 activities are sedentary. The level 2 activities are sedentary but include movement of the limbs or torso. Level 3 to 5 activities are labeled as translocation (moving the body from one location to another). The speed or intensity of the activities determines the level. By using the coding rules by Puhl et al a level of physical activity observed for 3-s duration or repeated in brief duration (<3 s) at least three times within 15 s are recorded using a standard score sheet. Only one activity at each level is recorded, with up to five scores being recorded within each mm. All levels within the minute were then averaged, and the mean minute CARS score was recorded. It has been used successfully to describe physical activity in young children from different ethnic groups, although direct observation is accepted as the standard in this age group. Due to the high level of observation required the assessment is costly and there is a possibility of observer error due to the lengthy observation periods.

The 'Activites Scale for kids (ASK)' is a self report measure of childhood disability in the community, that has excellent reliability (ICC = 0.97) Young (2000). It is valid and responsive for children in the age range of 5 to 15 years old and is assessed by mail. Rasch analyses confirmed that all items measured the same construct and supported aggregation of a summary score. A correlation of 0.92 ($p < 0.0001$) was demonstrated against the Childhood Health Assessment Questionnaire scores.

Other childrens scales exist such as The Childhood Health Assessment Questionnaire (CHAQ) which was designed for children with arthritic conditions and the Paediatric Evaluation of Disability Inventory (PEDI) Feldman (1990).

1.6.3 Theory of Pedometers and Accelerometers used in Activity Monitoring.

One of the earliest forms of commercial activity monitor was the pedometer. Pedometers were found to have large errors in accuracy, they employed a gear driven mechanical technology and were designed to measure distance walked (Montoye 1988). Later pedometers became more complex employing a horizontal, spring levered pendulum arm that moves up and down with vertical accelerations to measure the number of steps. Where displacement of the arm is sufficient it makes an electrical contact with a sensor and registers a step. Pedometers have been shown to underestimate the number of steps by approximately 50 – 90% at the slowest walking speeds of between 50-54m/min or approximately 1.8- 2.0mph (Schneider 2003). As early as 1976 Morris describes using accelerometers to measure human body movements.

1.6.4 Activity Monitors and the Assessment of Activity.

McDonald et al (2000) have demonstrated how the activity monitors have progressed to the stage where they can be used to gain effective objective data from children with disabilities undergoing treatment. The technology has moved forwards steadily to the point where the physical size of the activity monitor is small enough and light enough to capture data without affecting the daily routine, being the size of an

average pager. The data can also be stored “onboard” for periods up to 4 days and then downloaded conveniently onto a pc or laptop.

Activity monitors have many advantages over existing forms of activity monitoring, being able to measure ‘real world activity’ as opposed to activity that occurs within the confines of the laboratory. The collection of data occurs over days rather than minutes, or at best hours as in previous methods. Their uses include assessing compliance within treatment regimes and as outcome measures in the evaluation of treatment. A description of the activity monitor to be validated within this study follows below and descriptions of other commercially available monitors can be seen in appendix 1.

The activPAL activity monitor.

The activPAL activity monitor is an extremely small, slim and hence unobtrusive device. It can thus be attached to a patient without affecting their usual daily activities (see fig 1 below).



Specifications.

- measurements are 35mm x 53mm x 7mm
- Weight 20g
- Sampling frequency 10Hz
- Memory capacity: 4Mbytes

(Figure 1 The activPAL activity monitor activaPAL information booklet)
The activPAL activity monitor is worn on the mid line of the thigh halfway between the knee and the top of the leg, it is orientated as indicated by a figure on the front panel of the device. The device can be secured with Medipore tape. The device will record up to 110 hours with a maximum of eight sessions in the recording period. On completion of testing the device is switched off and attached to the USB port of a laptop or computer via a docking port with cable interface. The docking port allows for the recharging of the monitor. The computer communicates with the monitor via custom written

software which is supplied with the activity monitor. The interface and software make the downloading of the information an extremely easy and efficient process. The software displays the information in excel format and also provides two further formats to convey the data in a clear and accurate way. An example of the output can be seen below. Summaries of the activity record are given at the top of the window (total time sitting/lying, standing and stepping and the total number of steps). The data is also displayed in a series of bars, yellow for sitting, green for standing and red for stepping. This information is presented for 15s intervals, one hour per line. The height of the stepping data (red) represents the stepping frequency (cadence). See appendix 2 for examples of output from the activPAL software.

1.6.5 Validation of Activity Monitors

Previously the question has been asked, whether or not the subjective quantifiable data that is recorded by activity monitors reveals similar results to those of the existing subjective models that have been used to assess activity levels previous to the existence of activity monitors. As early as 1985 Klesges and Klesges reported in a validation study that the hourly readings of the Caltrac activity monitor correlated with observer scores using the Fargo Activity Time-Sampling Survey (FATS) observational system.

In a more recent study by Finn et al (2000), the (CARS) Childrens Activity Rating Scale (as described earlier in section 5.1.5) was used in direct observation of physical activity within children. The results obtained by this subjective lens were compared against the more objective readings gained from the Actiwatch activity monitor. The conclusions state that, 'the activity monitor was found to be an accurate means of assessing children's activity levels (pre school age) with high correlation between the two measures being obtained.' They found the correlation coefficients were higher in those children who were more active, probably due to the larger ranges in the CARS scores. The activity monitor therefore appears to provide accurate information that is easily interpreted and provides information that is comparable to more subjective studies. The quantitative data obtained agrees with the qualitative data within this particular research. The

activity monitor would be favored due to its low long term costs, and increased accuracy over longer periods of time.

The results indicate that the motion sensor counts determined by the Actiwatch are correlated with direct observation of activity as assessed by the CARS. It was concluded that these results would favor the use of the Actiwatch in the assessment of activity in preschool-aged children because obtaining a valid observational score requires extensive training and personnel requirements.

Further studies that have shown activity monitors to be valid methods of recording activity in adults include Sanders 1980, White et al 1992, van den Berg-Emons et al 2000, Walker et al 1997,

If this result is repeatable across such studies the activity monitor will provide an accurate efficient means of measuring specific treatment outcomes and negate the necessity for time consuming methodologies of a subjective nature where the patient and professionals record activity within diaries or by other means.

1.6.6 Outcome Measurement Studies Employing Activity Monitors.

Community physical activity levels in disabled and non disabled children were measured with the SAM (step activity monitor) by McDonald et al (2000). Participants included 20 boys with Duchenne muscular dystrophy, 10 children with cerebral palsy, 10 children with spina bifida and a controlled convenience sample of 75 able bodied children. The SAM was worn on right ankle for 3 days.

Quantitative daily physical activity profiles of, low activity level (LAL), medium activity level (MAL) and high activity level (HAL) were categorized. Where;

LAL= low activity levels (steps per min. = 1-15) intermittent steps/daily living

MAL = moderate activity levels. (Steps per min. = 16 -30) slow/walking moderate activity

HAL = high activity levels. (Steps per minute > 30) continuous walking/ running.

The conclusions were made that children with physical disabilities spent considerably less time HAL. The measurements provide quantitative data profiles that represent functional output levels for

both disabled and non disabled children. It was stated that, the above categories represent new functional outcome measures for disabled and non-disabled children. These outcomes can be used as a measure for children undergoing surgery, orthotic or any other treatment.

1.6.7 Previous Studies Employing Activity Monitors to Analyse Childrens Activity Levels.

One study that falls into this category has been described earlier in section 6.4.2 above McDonald et al (2000).

Klesges and Klesges (1987) validated a single-plane accelerometer, the Caltrac personal activity computer against the Fargo Activity Time Sampling Survey (FATS). Within this study they also investigated sources of error in the activity monitor. They found that the correlations were higher for females and overweight children were higher than males and normal weight children, respectively. They state that using this accelerometer to assess physical activity of young children may be ill-advised. They state that future investigations where a large sample is not possible should ensure the sample is sufficiently homogeneous to reduce potential variability that may reduce the correlations between the assessment methods and the criterion under investigation. This is the case within the research sample chosen for my study, the sample being reduced to type 2 hemiplegic gait patterns.

1.6.8 Previous Studies Using activPAL

A previous study, the GAPS (Glasgow Augmented Physiotherapy after Stroke) Study used the activPAL activity monitor to investigate outcomes after stroke.

The activPAL has been used to inform upon materials used within design of hip replacements. A private company DTX Materials Technology researched outcomes after hip-replacement. Thirteen hip-replacement patients and eight non-impaired subjects were monitored over one day.

Unpublished research has occurred at Salford University Mickelborough et al (2004) that has looked at whether or not the activPAL activity monitor is a valid and reliable tool to use at differing walking speeds in normal gait patterns. The first study analysed the accuracy of the monitor to count the number of steps over different speeds. Early indications from the data obtained within this pilot study indicate that for speeds between 0.3 and 1.2 metres per second the monitor is valid. However at speeds of 0.2 metres per second the monitor has a tendency to over count the number of steps, in some instances to a considerable degree. An activity monitor was worn on both legs to give an indicator towards the reliability of the device. It was shown that there was no significant difference between the monitors – $p < 0.6$ at a confidence interval of 95% (-1.545 and 2.717). When the slowest trial speed of 0.2 ms sq $p < 0.8$ (95% confidence intervals -0.706 and 0.862).

The second study, analysed whether there was any difference in the number of step counts, dependent on which leg the monitor was placed. This study occurred on subjects with gait difficulties. Early indications from this data suggest that variations in step counts do occur between which leg the monitor is placed (there are no statistics that quantify this as yet). Suggestions for future work from these pilot studies state that longer/more varied structured walk should occur in the trials and that a greater sample size should be researched. It was also stated that variability in subjects will occur from day to day on their ability to carry out activity.

The above findings have had implications for the protocol within this study. The activities carried out have been over a greater time interval and are more varied than the above study. The activities have also been set out in line with studies that have informed upon children's activity patterns to simulate similar patterns of activity. The question of whether to apply a monitor on both legs is one of contention within this study. It is indicative of the hemiplegic gait pattern that the affected lower limb will have a differing pattern of movement to the contra-lateral limb. This in affect implies that the activPAL may record differences in step counts between the two limbs. However there may be some overlay effect within the gait pattern of the 'unaffected' limb resultant from the CP. There will also be compensatory movements

that occur in the unaffected limb again causing subtle changes to its pattern of movement.

1.6.9 Activity within able bodied children

It is important to understand the activity patterns of the able bodied child before measuring and commenting on the activity levels of disabled children. "Central to the understanding of accurate assessment of any population is a clear understanding of the nature of the individual or individuals being studied," Welk et al (2000).

There are reviews that have assessed different approaches of physical activity measurements for children including Baranowski et al (1992) and Eston and Ingledew (1997). The area of activity monitoring of children has specific challenges due to the unique way in which children's activity patterns vary from those of adults. This is apparent to an even greater degree for the youngest of children. One reason for this difference in activity patterns, may be a child's need to hone their central nervous system with stimulation gained through activity Rowland (1998). Bailey et al (1995) gives a clear insight into the nature of a child's activity, typically children exhibit short intermittent bouts of vigorous physical activity with frequent rest periods. The rest periods are generally of a longer duration however the results indicate that a child does not stay inactive for extended periods of time. The point is made that children's patterns of activity are different and as such require different intervals of assessment and outcome measures to be used to assess their levels of activity. The above stated distinct differences between the nature of children's activity and adult activity are of relevance to this study and must be taken into account in the methodology of the validation. To monitor children's activity levels appropriately the tool must be able to monitor intermittent activity that occurs for short durations, but also must have the capacity to record the frequency and length of the rest periods. The tool must have the ability to record both sets of data consistently over long periods of time (preferably days rather than hours) to capture the true nature of the activity.

CHAPTER 2

METHOD

2.1 Design

The data collected from the activPAL activity monitor is numerical. Specifically, counts of the number of steps taken, the number of times sit to stand occurs and the time elapsed for the activities of, sitting/lying, standing and walking. The nature of this data and its presentation lends itself to a quantitative style of analysis.

It is the priority of this methodology to establish the validity of the activPAL activity monitor, however trials were also undertaken to establish the reliability. The proviso shall also exist, that all instruments/scales used for measuring or comparative purposes against the active-pal activity monitor must themselves have been evaluated primarily for their validity. It is proposed that to ensure this, tried and tested methods of validation are employed that have been used successfully within previous studies, where validation of instruments for specific gait patterns resultant from various pathologies have occurred.

The Protocol.

There are two protocols to be adhered to within the research.

Protocol 1 which details the trial for the validity of the activPAL monitor and Protocol 2 which details the reliability trial of the activPAL monitor.

Protocol 1 - The Validity Trial.

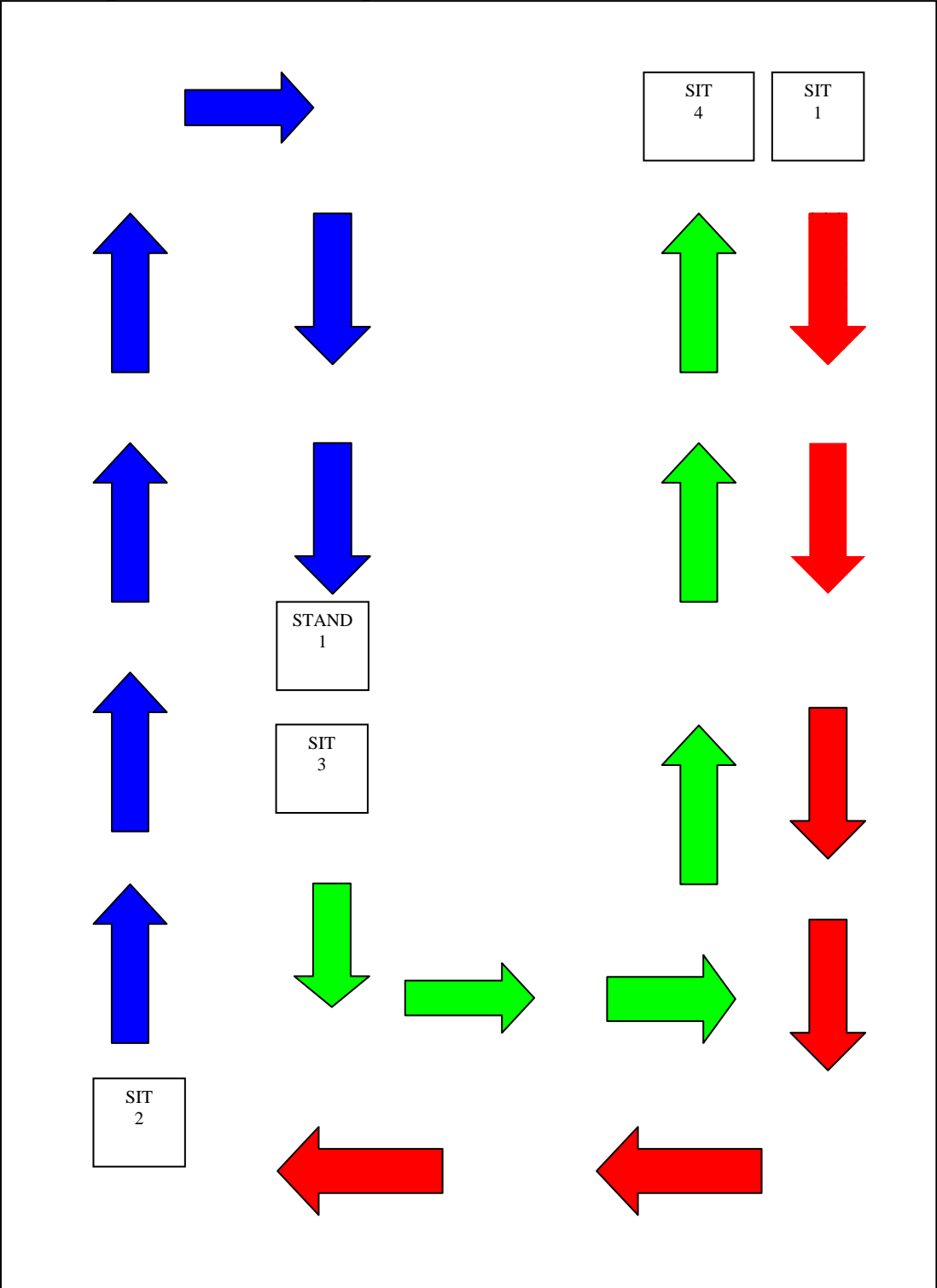
The method shall involve the direct comparison of readings taken by the activity monitor against observations analysed from a video recording taken at that time. Investigations examining the results of two tests are referred to as method comparison studies Ottenbacher (1993). Direct observation can be highly accurate and provide useful validation criteria for other assessment methods, specifically instruments for recording activity, when the problems associated with it are controlled Cone et al (1982). *The problems that are associated*

with direct observation are observer reliability, observer drift and reactivity. To reduce the possibility of experimental errors the two video observers shall undertake training for footstep recognition. This is seen as essential due to the complexities of gait patterns within CP. Specific guidelines will be detailed (see appendix number 5) and practice sessions held to try to ensure accurate foot step recognition as classified within this research. Through this approach an increase in the intra-rater reliability of this aspect of the research protocol should be ensured. Correlation statistics and t-tests shall be carried out to test the reliability of the observations between the two observers.

Children will be recruited for the study from schools within the local Salford and Trafford areas. Two other healthcare professionals input will be required to ensure that candidates within the study are graded accurately as being type 2 hemiplegia. The children recruited for the study will be asked to attend The Centre for Rehabilitation and Human Performance Research. They will attend with their parent/guardian and/or physiotherapist. The total time of attendance at the university will be approximately one hour, of which 25 minutes shall be spent with familiarization of the activities to be carried out, attaching the activity monitor to the patient and ensuring that the equipment is set up correctly. The remainder of the time taken will be dedicated to collecting the data (see appendix number 2 for data collection protocol).

The participant shall be asked to undertake a set activity course. This will involve a set period of sitting for thirty seconds (sit 1), followed by a sit to stand movement, and followed by a set distance of walking (walk 1). The participant will then sit down for a further thirty seconds (sit 2) before standing to walk for a second time (walk 2) followed by a period of standing for thirty seconds (stand 1). After standing the subject will sit down for thirty seconds (sit 3). The subject will then sit to stand and immediately walk back (walk 3) to the original chair he/she started from and sit down (sit 4) for a further thirty seconds. This will conclude the activities required of the participant during the trial (*see diagram 1 below*). It will be ensured that the distances to be walked are not beyond the abilities of the participants and will be no further than 10 meters, the distance set out in the patient criteria.

Diagram 1 The Activity Course.



KEY
WALK 1
WALK 2
WALK 3

The operation of a digital video recorder shall be used to store the activity occurring during the trials. A stop clock will be employed to ensure that the pre selected time intervals of sitting and standing occur accurately.

The activPAL activity monitor shall be attached to the participant to measure and log the activities undertaken. Once the activity trial is completed, the data from the activPAL monitor shall be downloaded to a laptop.

Two professionals will be chosen because of their expertise in gait observation. They will both be given the same information/training to enable them to know what observations they are required to record. They shall both be given the same recording chart to record their data upon (*see appendix number 9*). The data to be recorded shall fall into two categories. The timing of the events in minutes and seconds shall be noted, this information will be drawn from the digital video recorders own runtime clock displayed on the recording. Secondly the number of steps during walking shall be counted and recorded. The two observers shall be trained as to what is defined as a step for the purposes of this study (*see appendices number five for step training protocol*). This will ensure that they are observing the type 2 hemiplegic pattern and identifying and recording the number of steps from the same theoretical basis. As noted earlier this will increase observer intra-rater reliability. To decrease the risk of observer drift whilst observing the video data the two observers will observe the data whilst at the University of Salford and will be provided with a quiet room to minimize the possibility of any interruptions. Two healthcare professionals will be chosen who are specialised in observing pathological gait patterns, this will further help to ensure observer intra-rater reliability of the data collected from the video analysis. They will be asked to analyze the video data and record the activities of interest. Correlation statistics will be carried out upon the two sets of data obtained from the video observation and will help to determine the intra-rater reliability of the two observers.

The observation results from the video will then be compared to the data that has been gained from the activPAL activity monitor. Correlation and t-test statistical analysis was undertaken to prove

whether the monitor was a valid instrument (see introduction for details of the null and alternative hypotheses).

The method to be used, as described above, has been used in previous validation studies for activity monitoring devices (van den Berg-Emons et al 2000; Walker et al 1997).

Protocol 2 – The Reliability Trial.

The reliability methodology uses the same activity course. However one participant will be required to complete the course twice, run 1 and run 2. The activPAL data output from run 1 was compared against the data from run 2. The two sets of data obtained were correlated against each other and t-tests undertaken to establish whether the activPAL monitor was reliable.

(Please see appendix number 9 for the timetable of events)

2.2 Apparatus

Hardware

activPAL activity monitor

Monitor docking station.

Monitor 'stickies'.

Stop watch

Laptop

Digital video camera with on screen timer.

Designated activity course area.

Software.

SPSS statistical software.

activPAL data software.

Microsoft excel

2.3 The Participants taking part in the trial.

2.3.1 Sample Size

It is standard practice now that a researcher should calculate the sample size and these calculations should reveal indicative estimates rather than unrealistically precise figures. Nomograms give sufficient precision. Along with this a sensitivity analysis should show the effects of varying the initial requirement of the study. Where trials are small they should be clearly stated as hypotheses forming (1995 Fayers and Machin). Fowler (1993) states that the need to consider the absolute size of the sample rather than the proportion of the population.

The Population Sample Size Calculation.

The number of participants was decided upon by carrying out correlation coefficient power calculations.

A confidence interval of 95% around the mean of the primary outcome measure was used.

A power of 0.8 was used within the calculation.

A correlation coefficient under the Null Hypothesis of 0.2 was used and a correlation coefficient under the alternative hypothesis of 0.8 was used.

Using the above power calculation it was revealed that a sample size of 12 would satisfy a power of 0.8.

Sensitivity Analysis

Varying the sample size to 8 (if the population size stated could not be acquired) would lower the power of the study to 0.6

However if a sample size of 20 were to be obtained this would maximize the power to a value of 0.976

2.3.2 The type of cerebral palsy to be studied within the validation.

Many research protocols within the area of CP fail to categorize or fail to state clearly the population that is being studied. Due to the complexity of presentations within CP this can make such studies difficult to interpret and sometimes render them meaningless.

In research by R. Boyd in 1999 studying children with CP, energy expenditure was found to be higher in those with diplegia than in those with hemiplegia. They also found relatively high oxygen cost values within the hemiplegic group studied, due to the large numbers of Winters and Gage type 4 hemiplegic subjects within this population studied. Children with Winters and Gage type 1 and 2 hemiplegia, have only mildly elevated or normal values of mean oxygen cost, it was stated. Various papers discussed within the literature review substantiate that spatial and temporal parameters within hemiplegic gait may vary significantly from one another (Gage 1991, Rodda 2001, Walker 1997, Winters 1987, Wall 1987).

The changes in energy consumptions in type 4 compared to type 1 and 2 hemiplegia belie the discrepancies in gait patterns between the four classifications. Strict criteria were therefore set for the population that was studied to ensure that the accuracy of the research would not be compromised by looking at a population whose gait characteristics were dissimilar. For clarity it was therefore decided to study a particular level of hemiplegia according to Winter and Gage (1987) classification scale. It was decided to focus upon type 2 hemiplegic patterns to ensure that the resultant research output was valid for a particular gait classification.

It is accepted that this will result in a limitation of the usage of the activPAL to type 2 hemiplegic gait in cerebral palsy, this is however necessary to ensure the validity of the trial. However Type 2 hemiplegia is by far the most common type in clinical practice (Rodda et al 2001), so the tool would provide coverage for the most common presentation. Children with spastic hemiplegia will usually be in levels one or two of the GMFCS.

The activPAL activity monitor will have to be validated separately for each of the other types of gait patterns within future studies.

The population age to be studied.

The age of the population to be studied within the validation of the activity monitor is seen as highly relevant. If a positive validation of activPAL is gained it is proposed that it first be used to assess the activity levels within the age range of 7 to 16 yrs old. This is seen to be the age group where the multiprofessional team is most active in its clinical management and it is therefore most relevant the activPAL is validated for the type of gait patterns associated at this age. This is important even though the subset of hemiplegic gait has been decided upon, as the clinical effects of CP are progressive and it is therefore paramount that the tool is valid and sensitive to the type of hemiplegic gait patterns present within this age group.

The Inclusion Criteria for the Sample

1. Cerebral Palsy resulting in hemiplegia.
2. Hemiplegia type: Gage Type 2.
3. Gross Motor Function Classification Scale (GMFCS) levels 1 and 2.
4. Aged between 7 and 16 years old.
5. Ability to walk a distance of 10m - The usage of walking aids is permissible.
6. Sufficient cognitive ability to allow the subject to follow instruction of what activities are required.

The above inclusion criteria were arrived at to represent the population it is believed will benefit the most from the validation of the activity monitor. The management of cerebral palsy is at its most cohesive whilst the person is still attending school. This is due to the input of a multidisciplinary team at this point. The interventions that occur at this time will have long term implications for the patient. It is therefore imperative, that clinicians and researchers have an effective means of measuring outcomes of treatment plans at this stage.

2.4 Procedure

2.4.1 Ethical Procedures.

An information sheet will be provided to the parents of the children participating in the trial. This shall detail what will be required of themselves and their child during the trial (*Please see appendix number 7*).

The inconvenience associated with partaking in the trial is low, as stated above only one visit is required to Salford University. The potential risks associated with the study are minimal and the long term potential benefits, to the cerebral palsy patient group are substantial, if the activity monitor proves to be a valid tool. Feedback as to the outcome of the validation shall be sent to the participants of the study. Great care has been taken to ensure that all ethical considerations have been met. The research protocol was first verified by the University of Salford Ethics Committee and once ratified passed through the strict procedures of the Central Office Ethics Committee (COREC). After submission of the digital COREC form official confirmation was to be verified through Oldham Local Research Ethics Committee. I attended a meeting at Oldham ethics committee where clarification was sought on various issues and procedures within the trial. Minor alterations to the parent/guardian and children's information sheets were required. The committee also insisted that a reply slip was placed in the initial correspondence with potential subjects. This reply slip had to be signed and returned to the research centre before any direct verbal communications occurred between the researcher and the subjects for the trial. These amendments were made and a positive decision was taken by Oldham Local Ethics Committee for the research to proceed.

2.4.2 Procedure for the Recruitment of Participants.

Initial contact for the recruitment of individuals shall be through a physiotherapist who practices within schools in the local Salford area. The physiotherapist shall receive a, "Subject Identification Sheet" that outlines the purpose of the study and lists inclusion criteria for suitability within the study. After the physiotherapist identifies potential candidates a letter of invitation upon the study will be sent. Along with the letter of invitation, an information sheet will be attached detailing the auspice of the study. Within this, the information sheet will detail exactly what will be undertaken during the trial and what length of time is required to complete the trial. It will also explain any possible risks of taking part in the trial and any potential benefits of the trial. It will be made clear in the letter, that the parents may withdraw their child, at any time from the study. There will be a reply slip attached to the letter of invitation which the parents must sign and return to the researcher before direct communication can occur. Only after this point can a telephone call be made to the parents of the child to arrange an appointment. Confidentiality of any correspondence shall remain at all times. Any correspondence shall be kept separate from other documentation and it will be ensured that only those party to the research have access to any such information.

Please see appendix number 7 for the documentation listed below;
Subject Identification Sheet.
Information Sheet for Participant Advice.
Letter of Invitation to Take Part in the Study.

2.4.3 Procedures for the observers.

The definition of a step

It was also apparent from the literature, that guidance upon the definition of a step was required for the professionals observing the video data within this study. The stride in conventional gait pattern is described as the distance between two consecutive points of contact of the same foot. The stride is made up of two steps, defined as the distance that the left foot is placed in front of the right foot, using the same anatomical point of contact. Contact usually occurring with the most proximal part of the heel.

Within hemiplegic gait patterns, classified within Gage types 1 and 2 heel contact may not be the first point of contact with the ground. Often the forefoot is placed on the ground first, followed by the rearfoot. In some hemiplegic gait patterns the heel may never come into contact with the ground, for instance where a limited degree of ankle extension exists. Due to this deviation from the norm, the definition of a step for the purposes of this study was defined as follows. The point of initial contact of the foot where mass is transferred to the next consecutive point of contact of that foot where mass is transferred (the consecutive point of contact of the foot does not necessarily have to be the same part of the foot).

The following clarification was also provided to the observers. If the hemiplegic gait pattern resulted in a drop foot, so that during swing phase the foot scuffed the ground, this would not be regarded as the next consecutive point of contact as mass is not being transferred at this point.

CHAPTER 3

RESULTS.

The raw data tables can be seen in appendix 8

8.1 The intra-rater data tables for the observers

8.2 The reliability data tables from the activPAL and the observer.

8.3 The validity data tables from the activPAL and observers.

The results output from the activPAL software is generated in an excel spreadsheet output which can be seen in appendix number

8.1 The reliability output.

8.2 The validity output.

It was from the excel sheet 8.2 that the activPAL data was drawn to be correlated against the observer outputs within the validity aspect of the trial.

The statistical analysis was performed using SPSS statistics software, the outputs of which can be seen in their totality in appendix number 13.

3.1 The intra rater results for the observer 1 and observer 2.

The data from the observers was used for comparative purposes against the data obtained from the activPAL monitor. It was therefore important to ensure that the observer data was reliable.

To evaluate the reliability of the observers data Pearson correlation and t-tests were carried out, the results of which can be seen below.

8.1.1 Correlation and t-test for the sit timings.

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	S	30.87	15	1.407	.363
	M	31.33	15	.900	.232

Paired Samples Test

		Paired Differences				t	df	Sig. (2-tailed)	
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	S- M	-.467	.743	.192	-.878	-.055	-2.432	14	.029

Correlation results;

Pearson correlation (0.844) was statistically significant at the 0.01 level.

T – test results;

Mean = -0.467

Standard error from the mean = 0.192

t = -2.432

df = 14

Significance (2 - tailed) = 0.029

$t(14) = -2.43, p < 0.029$

From the t-test it can be concluded that the mean time recorded by the observer 'S' (30.87) was significantly different from the mean recorded by the observer 'M' (31.33).

The reliability of the two observer's data in respect of the sit timings recorded is therefore questionable. Any conclusions within the validity section in respect of the sit timings will also be inconclusive as a result of this. The reliability conclusions will not be affected as they were not compared to the observer data set analysed above.

8.1.2 Correlation and t-test results for the stand timings.

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	S	30.60	5	1.140	.510
	M	32.00	5	3.391	1.517

Paired Samples Test

		Paired Differences				t	df	Sig. (2-tailed)	
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
							Lower	Upper	
Pair 1	S - M	-1.400	2.608	1.166	-4.638	1.838	-1.200	4	.296

Correlation results;

Pearson correlation (0.776) was not statistically significant at the 0.01 level.

T – test results;

Mean = -1.400

Standard error from the mean = 1.166

t = -1.200

df = 4

Significance (2 - tailed) = 0.296

$t(4) = -1.4, p < 0.296$

From the t-test it can be concluded that the mean time recorded by the observer S (30.60) is not significantly different from the mean recorded by the observer M (32.00).

The observations made by observer S and observer M in respect of the number of the stand timings can be taken to be reliable.

8.1.3 Correlation and t-test for walk timings

Correlations

T-Test

Paired Samples Statistics

	Mean	N	Std. Deviation	Std. Error Mean
Pair 1 S	28.93	15	4.758	1.228
M	28.47	15	4.454	1.150

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Pair 1 S - M	.467	1.457	.376	-.340	1.274	1.240	14	.235

Correlation results;

Pearson correlation (0.952) was statistically significant at the 0.01 level.

T – test results;

Mean = 0.467

Standard error from the mean = 0.376

t = 1.240

df = 14

Significance (2 - tailed) = 0.235

t(14)= 1.24, p<0.235

From the t-test it can be concluded that the mean time recorded by observer S (28.93) is not significantly different from the mean recorded by the activPAL (28.47).

The observations made by observer S and observer M in respect of the number of the walk timings can be taken to be reliable.

8.1.4 Correlation and results for the number of steps taken.

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	S	26.93	15	5.837	1.507
	M	27.20	15	5.685	1.468

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	S - M	-.267	.594	.153	-.595	.062	-1.740	14	.104

Correlation results;

Pearson correlation (0.955) was statistically significant at the 0.01 level.

T – test results;

Mean = -0.267

Standard error from the mean = 0.153

t = -1.740

df = 14

Significance (2 - tailed) = 0.104

$t(14) = -1.74, p < 0.104$

From the t-test it can be concluded that the mean time recorded by the observer 'S' (26.93) is not significantly different from the mean recorded by the observer 'M' (27.20).

The observations made by observer S and observer M in respect of the number of steps taken can be taken to be reliable.

8.1.5 Correlations and t-test for total observation data observer 'S' and observer 'M'

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	S	30.04	28	3.616	.683
	M	30.21	28	3.775	.713

Paired Samples Test

		Paired Differences				t	df	Sig. (2-tailed)	
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower				Upper
Pair 1	S - M	-.179	1.701	.321	-.838	.481	-.556	27	.583

Pearson's correlation (0.895) was statistically significant at the 0.01 level.

T – test results;

Mean = -0.179

Standard error from the mean = 0.321

t = -0.556

df = 27

Significance (2 - tailed) = 0.583

$t(27) = -0.56, p < 0.583$

From the t-test it can be concluded that the mean time recorded by the observer 'S' (30.04) is not significantly different from the mean recorded by the observer 'M' (30.21).

When the observations were statistically analysed in their totality, it could be concluded that there is good agreement between the two observers. However poor agreement was revealed for the sit time data when analysed on its own.

Comments upon the intra rater data.

The t-test showed that there was no significant difference between the two observer's data at the 0.05 level, for the walk timings, the stand timings and the number of steps taken.

However the t-test showed that there was a significant difference at the 0.05 level between the observers recorded data for the sit timings.

8.2 The Reliability of the activPAL monitor.

One participant (who was not one of the five included in the validity trial) was asked to repeat the activity course seven times. Readings were taken on all seven runs and then statistical analysis applied as described within the methodology. Pearson correlation and t-tests were performed and the output is shown below.

The SPSS output can be seen in their entirety in appendix number 9.2

The Reliability of the activPAL to count the Number of Steps.

Paired Samples Statistics

	Mean	N	Std. Deviation	Std. Error Mean
Pair 1 run1	23.67	3	3.786	2.186
run2	24.00	3	4.359	2.517

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1 run1 - run2	-.333	.577	.333	-1.768	1.101	-1.000	2	.423

Pearson's correlation (1.00) was statistically significant at the 0.01 level.

T – test results;

Mean = -0.33

Standard error from the mean = 0.333

t = -1.00

df = 2

Significance (2 - tailed) = 0.423

t(2)=-1.00, p<0.423

There was high correlation between the recordings of the number of steps by the activPAL monitor as determined by Pearsons correlation. From the t-test it can be concluded that the mean number of steps recorded by the activPAL (23.67) on run1 is not significantly different from the mean recorded by the activPAL (24.00) on run 2.

The activPAL was deemed to be a reliable instrument for the measurement of the number of steps taken.

The Reliability of the activPAL to time the Activities.

Paired Samples Statistics

	Mean	N	Std. Deviation	Std. Error Mean
Pair 1 run1	28.83	6	2.927	1.195
run2	28.67	6	3.204	1.308

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Pair 1 run1 - run2	.167	.753	.307	-.623	.957	.542	5	.611

Pearson's correlation (0.974) was statistically significant at the 0.01 level.

T – test results;

Mean = -0.167

Standard error from the mean = 0.307

t = 0.542

df = 5

Significance (2 - tailed) = 0.611

t(2)=-1.00, p<0.423

There was high correlation between the timing recordings as determined by Pearsons correlation.

From the t-test it can be concluded that the mean timing recorded by the activPAL (28.83) on run1 is not significantly different from the mean recorded by the activPAL (28.67) on run 2.

The activPAL was deemed to be a reliable instrument for the measurement of time spent sitting, standing and walking.

Comments upon the reliability of the activPAL monitor.

There was a high degree of correlation between the data obtained from the activPAL for the timings of the activities and the number of steps taken which was confirmed by Pearsons correlation.

The t-test showed that there was no significant difference between the data obtained from the activPAL monitor at the 0.05 level for the stand timings, the sit timings and the walk timings collectively and the number of steps taken.

The activPAL activity monitor is therefore found to be reliable at timing the activities and counting the number of steps.

The Validity results for the activPAL monitor

The statistical results for the step data shall be shown for clarity. The remainder of the statistical output can be seen in the appendices.

8.3.1 Correlation and t-test for the sit timings.

8.3.2 Correlation and t-test results for the stand timings.

8.3.3 Correlation and t-test for the walk timings.

8.3.4 Correlation and results for the number of steps taken.

8.3.1 Correlation and t-test for the sit timings.

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	activPAL	34.20	10	9.247	2.924
	observer	34.00	10	8.869	2.805

Paired Samples Test

		Paired Differences				t	df	Sig. (2-tailed)	
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	activPAL - observer	.200	1.476	.467	-.856	1.256	.429	9	.678

Pearson's correlation (0.988) was statistically significant at the 0.01 level.

T – test results;

Mean = 0.200

Standard error from the mean = 0.467

t = 0.429

df = 9

Significance (2 - tailed) = 0.678

$t(9)=0.429, p<0.678$

From the t-test it can be concluded that the mean time recorded by the activPAL (34.20) is not significantly different from the mean recorded by the observer 'M' (34.00).

The activPAL was deemed to be a valid instrument for the measurement of time spent sitting. However this is questionable to some degree as low intra-rater agreement occurred between the observers sit timing data.

8.3.2 Correlation and t-test results for the stand timings.

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	activPAL	31.20	5	1.924	.860
	observer	32.00	5	3.391	1.517

Paired Samples Test

		Paired Differences				t	df	Sig. (2-tailed)	
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	activPAL - observer	-.800	4.712	2.107	-6.650	5.050	-.380	4	.723

Pearson's correlation (-0.537) was not statistically significant at the 0.01 level.

T – test results;

Mean = -0.800

Standard error from the mean = 2.107

t = -0.380

df = 4

Significance (2 - tailed) = 0.723

$t(4) = -0.38, p < 0.678$

Although the Pearson correlation proved not statistically significant, the t-test reveals that the mean time recorded by the activPAL (31.20) is not significantly different from the mean recorded by the observer 'M' (32.00).

The activPAL monitor was found to be a valid instrument to measure the time standing.

8.3.3 Validity Correlations and t-test for walk data.

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	activPAL	29.87	15	7.249	1.872
	observer	29.27	15	6.475	1.672

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	activPAL - observer	.600	3.180	.821	-1.161	2.361	.731	14	.477

Pearson's correlation 0.899 was statistically significant at the 0.01 level.

t – test results;

Mean = -0.600

Standard error from the mean = 0.821

t = 0.731

df = 14

Significance (2 - tailed) = 0.477

$t(4) = -0.73, p < 0.477$

The t-test reveals that the mean time recorded by the activPAL (29.87) is not significantly different from the mean recorded by the observer 'M' (29.27).

The activPAL was therefore found to be a valid instrument for the measurement of time spent walking.

8.3.4 Correlation and results for the number of steps taken.

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	activPAL	26.40	15	6.197	1.600
	observer	27.20	15	5.685	1.468

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	activPAL - observer	-.800	1.740	.449	-1.764	.164	-1.780	14	.097

Pearson's correlation 0.961 was statistically significant at the 0.01 level.

t – test results;

Mean = -0.800

Standard error from the mean = 0.449

t = -1.780

df = 14

Significance (2 - tailed) = 0.097

$t(14) = -1.780, p < 0.097$

The t-test reveals that the mean time recorded by the activPAL (26.40) is not significantly different from the mean recorded by the observer 'M' (27.20).

The activPAL monitor was therefore found to be valid for the measurement of the number of steps taken.

Overall Results Comments on the Validity and Reliability of the activPAL activity monitor.

The activPAL activity monitor was found to be valid and reliable for the measurement of the number of steps taken, the time spent sitting, time spent standing and time spent walking.

When the outcome reaches statistical significance the null hypotheses (H_0) is rejected. In this instance, the possibility of correlation between the data obtained from the video and the activity monitor being down to chance would be rejected if the results prove statistically significant. Statistical significance was conclusively proved for all of the activities that the activPAL measures. The null hypothesis could therefore be rejected. The alternative hypotheses (H_1 - that the correlation between the results obtained from the activity monitor and the video capture are of statistical significance) was accepted for all of the activities measured.

Further comment upon these results can be found within the discussion section that follows.

CHAPTER 9

DISCUSSION

Interpretation of the Statistical Results for this Pilot Study.

The activPAL activity monitor was found to be valid and reliable for the measurement of the number of steps taken, the time spent sitting, time spent standing and time spent walking.

It has to be borne in mind that this is the result of a pilot study with a small sample size. A power calculation was undertaken that stated the number of participants required to provide a power of 0.8 was eight. For a power of 0.9 eighteen subjects would be required. Sample size directly effects the confidence we can have, in the assumption that, our sample is representative of the population as a whole. The central limit theory states that a minimum of thirty subjects are required in the smallest sub groupings, if parametric tests are to be employed.

The above points must be taken into account when conclusions are drawn from this pilot study. It is the intention of the author to continue to recruit further participants and to apply the same hypotheses and analysis.

Suitability of the activPAL for use with children

Only preliminary research has occurred to date that reports upon the measurement of uptime (time spent upright) in a paediatric population (2001 Eldridge). There are aspects of the activPAL that make it ideal for activity monitoring of the disabled/child. The less developed cognitive skills of the child results in a lesser ability to effectively use self report questionnaires (Welk 2000). The activPAL monitor requires no reliance upon the subject's cognitive skills and as such is suitable for children or other subjects where cognitive ability may be affected. Children with lower limb disabilities will potentially have a slower walking speed. The number of steps is broken down by the cadence. Normal walking cadence is between 80 -150 steps per minute (Whittle 2002). The results from the participants fall without these bounds. From the table in appendix number 10 it can be seen that the cadence varies between 45.4 and 58.5 steps per minute. This is well below the

range of normal walking speeds. Previous studies have shown activity monitors to be affected by low levels of cadence (Crouter 2003).

Earlier unpublished data (Kenney L, Miclelborough J 2001) tends to suggest that the activPAL activity monitor is not affected to any great degree by reductions in the levels of cadence. The resultant reduction in cadence that is present in the children with type 1 hemiplegia within this study has been shown not be a source of error when using the activPAL monitor.

Previous methods of measuring activity levels have had flaws within them that preclude them from measuring across the whole age range of children. The monitor does not exhibit any ceiling (Damiano 1996), or floor effect (Nordmark 2000) as exhibited by the GMFM. The deployment of the activPAL monitor will result in no such methodological weakness in this respect. Issues arise with conventional activity assessments such as the CARS around the cost of deploying health care professionals as observers of activities (Puhl 1990). Lengthy and costly observation is not required from the healthcare professional when using the activPAL monitor to observe children in the community.

Discussion upon aspects within the research trial
Weaknesses within the methodology of the research.

Weaknesses were identified within the study. Cone et al (1982), state that direct observation can be highly accurate and provide useful validation criteria for other assessment methods, specifically instruments for recording activity. However this is only when the problems associated with it are controlled. The problems that are associated with direct observation are observer reliability, observer drift and reactivity. The protocol took steps to reduce the possibility of errors due to the above. The correlation and t-tests that occurred to identify any discrepancies between the two observer's data testify that these protocols were not entirely successful, producing good correlation between the two observers for the walk and stand timings and the number of steps taken. However, producing poor intra rater results in respect of the sit timings. The protocol ensured that the observers were trained at the same time both being given identical written support instructions to identify the activities from the video

recordings and enter the timing data within the excel calculation sheets. In respect of the sit timing data the definition between when sitting starts and finishes may not have been clearly defined leading to a significant intra rater error. The measures in the protocol could not ensure the observers accuracy in stopping the video at exactly the correct point and some degree of reaction time error would affect all the timings taken for the activity events. So some degree of error is inherently built into the study design from this aspect. This source of error has to be taken into consideration when looking at the raw data and the statistical data.

Amendments to the trial protocol.

The protocol for the trial had to be amended on two counts to avoid built in errors within the study. The timings of the periods of sitting had to be reduced from one minute to thirty seconds. This became evident after the first participants trial run. It was clear from this run that the younger participants within the trial would find it difficult to sit still for the full sixty second duration stated. The sitting events were therefore reduced to thirty seconds to reduce the likelihood of the younger participants getting up from the chair too early.

An amendment to the protocol occurred relating to the data taken by the two observers of the video. The switching on and off of the monitor requires the insertion of a male six pinned switch into the female counterpart at the base of the monitor. This operation made it difficult to accurately switch on and off the monitor and made for an unclear start point and finish point to the trial. It was particularly difficult to ensure that the observers would record these points correctly from the video output. It was therefore decided that for observation purposes the trial would start at 'walk 1' this being a more clearly identifiable point for the observers of the video. The trial would be terminated at the end off walk 3. The switching has been designed in this manner to prevent the accidental switching off of the monitor whilst being worn in the community. The accuracy of the time off switching on and off the monitor to the exact second is not an issue in respect of its clinical application within the community.

Amendments for future trial protocols.

In future trial protocols it will be ensured a clear definition of what defines the start and the ending of the sit activities. This should resolve the lower intra rater affect that occurred within this specific part of the trial.

In line with the above ensure that the reliability aspect of the trial procedure carries the same rigorous standards as the validity aspect of the trial. Act in accordance with all other aforesaid amendments that were made within the current trial procedure.

Failure to tightly define the words and terms that we use within research studies can lead to serious misinterpretations of results and hence inappropriate treatment may result form this. It is therefore imperative that we define what we mean by activity and the term being active. For instance, in a previous study heart rate has been used to measure activity (Armstrong 1990) and cut off values below and above certain heart rate values have been used to interpret when that individual has been deemed to be active. Depending on the level of this cut off value serious variations in activity output can be drawn from the data. This has occurred in past studies, where heart rate levels relevant to adult activity have been applied to studies into childrens activity levels. No such methodological potential for error exists when using an activity monitor, making it superior to non-direct measurements of activity.

Weaknesses within the statistical analysis.

The outcomes of investigations such as this are dependent upon the statistics employed being both suitable for the nature of the study and their accurate interpretation. Sanchez (1999) states, "In the process of designing a clinical trial, the accuracy and precision of an endpoint is of critical importance in being able to determine valid results. In the creation and subsequent testing of the validity of the endpoint, it is desirable to show that on repeated measurements the endpoint can be measured precisely, and that it is reproducible with not only itself but with any gold standard that can assess accuracy. Short of having this gold standard, we rely on showing that the end point is reliable."

Correlation coefficients have been used within the statistics of this study, however their application is questionable when undertaking a validity trial between two instruments. Two measures may correlate highly, yet there could be substantial differences in the two measures across their range of values (Hopkins W 2004). To reduce the possibility of inaccuracies in respect of this, t-tests were also carried out in this study, where the differences between the means of the two sets of data would be highlighted.

Bland (1986) states that validity investigations are often analysed inappropriately, notably by using correlation coefficients. The use of correlation is misleading. An alternative approach to this study would have been to use a graphical technique that employs simple calculations. This can be interpreted together with an assessment of repeatability. Several researchers have argued that the Pearson r is a measure of linear association (co-variation) between variables and does not provide accurate estimates of direct agreement (Ottenbacher 1993). Within the study several commonly used quantitative methods to establish agreement were compared it was demonstrated that the Pearson r is not appropriate for use in studies where the purpose is to determine whether two instruments are interchangeable. The procedure recommended is referred to as the limits of agreement method, this emphasizes the clinical comparability of two instruments (or raters), instead of focusing solely upon the statistical relationship. Agreement with the above is also stated in a paper by Indrayan A et al, it is also stated that intra-class correlation coefficient may be employed, both statistical methods having their own merits and demerits. Hopkins in 2004, disagrees with the limits of agreement theory, in favour of using regression when comparing measures. He argues that the Bland-Altman plot can lead to inaccurate conclusions about the validity of the measure as a systematic proportional bias in the instrument to be validated is recorded even though none is present.

Putting the statistical approaches into some context Bland and Altman (1986) state, "we want to know by how much the new method is likely to differ from the old; if this is not enough to cause clinical problems in clinical interpretation we can replace the old method by the new or use the two interchangeably. How far apart

measurements can be without causing difficulties will be a question of judgement." The correct statistical methodology to be employed in such trials is still debatable as can be seen from the above evidence. A means of estimating what may be an acceptable difference, for a given data set would provide a more scientific end point to such studies.

The Application of the activPAL Monitor.

Within this study the main aim was to provide evidence towards whether or not the activPAL activity monitor is a valid and reliable tool for the measurement of community activity in children with type 2 hemiplegia (as classified by Winters 1987) resultant from cerebral palsy. In the first half of the thesis relevant literature was reviewed to enlighten the reader as to the current need to develop and validate activity measurement tools. This would enable productive research into current and future treatment modalities and hence the facilitation of evidence based practice. To enable this, literature was cited to inform upon current assessment and measurement techniques, applied within research and clinical practice in the area of cerebral palsy. The past and current nature of activity monitoring was also considered.

The context for the clinical application of the activity monitor is perhaps clearer after considering certain factors within the current educational system for children with disabilities. Over the past decade there have been changes within the educational system that have moved progressively towards the integration and inclusion of children, with both learning and physical disabilities, within mainstream schools. As this occurred the role of the health care professionals caring for these children has had to change, producing new challenges on improving the quality of lives of the children in their care. The multiprofessional team, consisting of the Orthotist and Physiotherapist, have found it difficult to maintain the same level of contact with the population they treat, as it has become increasingly dispersed throughout the educational system. This has meant that conventional routine observations that would occur within the setting of the special needs schools now occur with reduced frequency in the setting of main stream education.

Traditionally, within schools that are created for the sole purpose of educating children with special needs, the physiotherapist would be able to treat and hence observe the children throughout the whole of the week. The Orthotist could then gain feedback from the physiotherapist on any Orthotic intervention that may have occurred and hence effect future treatment actions. One result of the inclusion policy was a decrease in the actual contact time between the physiotherapist and the child, and hence a crucial feedback mechanism was lost. This decrease in accurate feedback may have lead to a reduction in the effectiveness of Orthotic intervention.

Where careful selection procedures are in place, there are many advantages to be gained from children with disabilities partaking in mainstream education and there exists a need to facilitate inclusion at all levels. The activPAL has been shown during the trials to produce data with minimum impact to the child. This may enable children to continue their education within the mainstream school environment, without a serious compromise to their Orthotic treatment programme. Thus the activPAL has real scope to be implemented as a clinical tool as well as a research tool, potentially reducing the negative impact upon the clinical needs of the child.

Due to its ease of use the implementation of activPAL within current clinical and community settings could readily occur. It will create an increase in research opportunities for practicing clinicians, once again, due to its ease of use. To employ the activPAL monitor there is no technical knowledge relating to the electronics required. It therefore provides a user friendly medium which is simplistic in its nature. The time required to both set up a monitor on the patient and to download the information is minimal and could be built into the clinicians schedule without too much difficulty. As seen within this study the software produces data in excel and graphical format that enables easy interpretation. These factors are of major importance if such emerging technologies are to be successful in changing our procedures of practice for the better.

Such future deployment of the activPAL may prove effective within the facilitation of Audit Procedures. Strategies for future treatment plans could then be based on objective data and the strategies once implemented measured by the same objective tool. This may result in the fine tuning of current treatment or in some cases where the

results proved a specific treatment to have no conclusive benefits the treatment procedure could be revised. If no measurable improvements occurred after revising the procedures then the treatment would be dropped from the overall treatment plan.

The above scenario is one that does not occur within many areas of conservative medicine relating to CP due to the lack of measuring tools that are both valid and reliable and easy to employ. Accurate data that can be used for further interpretation is therefore scarce. Due to this fact evidence cannot then be pooled together from different centres around the world to have any bearing on future treatment regimes. Hence it is difficult for specific global and national guidelines to be formulated to guide treatment within departments at a more local level.

The obvious advantage for the clinician of the activPAL activity monitor is that it obtains data with minimum input of time being required for both collection and retrieval of data. Thus in the current climate, where evidence of good clinical practice is becoming more and more important, could provide the means to achieve the required outcome measures. These measurements would be efficiently taken and would not result in clinicians having to significantly reduce their patient contact time undertaking core responsibilities. This would be a realistic method to employ within the NHS Trust hospitals and within the community setting where clinician time is of a premium.

It should be noted the possibility that activity may correlate with a child's developmental status or degree of disability can only be explored once a normative database for the measurement of activity in children has been established (Eldridge B et al 2003). In respect of this the activPAL monitor could be used to build a normative database for activity in the different classifications of cerebral palsy. This could then be used for comparative purposes after differing treatment regimes.

The study has highlighted the need for future research into the design and application of activity monitors. It has highlighted that the activity monitor has the potential to become a useful tool producing valid and reliable outcome data. The robustness of the activPAL as an

assessment tool will only be improved as successive validation studies occur within the field of cerebral palsy. Only when further validation studies have occurred for diplegic and mixed walking patterns could the device be termed robust.

CONCLUSION

A major challenge still exists for those professionals treating disabled children in how to assess the effectiveness of various intervention programmes (Bax 1985). Many of the methods that the different disciplines employ appear to be effective to some degree and wherever possible new ways of treating patient groups are deployed in clinical practice. It became evident in my recent years of clinical practice and as evidenced within the literature search of this thesis, that many of these practices, although of benefit, were very rarely measured in terms of their outcomes. On looking further it became evident that many of the theories used within conservative disciplines were indeed just that and the need for high quality research and evidence to validate particular treatment regimes is required. Pearson (1982) states that parents and professionals invest time and costly resources in diverse therapy and educational endeavours, but there is a lack of scientific evidence about the influence of various approaches on outcome. This is an increasing source of frustration for many HCP's who recognise this as being the case yet find themselves without the time or the resources to alter the course of this historical situation. The call for more refined research was made by Shonkoff and Hauser-Cram (1987), to identify clearly what were important programme components. Anyone who has worked amongst the plethora of treatment modalities within the area of C.P. alone will appreciate the magnitude of this request. Due to the long standing history of poor funding within this area very little research has occurred and the quality of existing research, or perhaps the relevancy of research to actual clinical practice is debatable.

The need therefore for increased accuracy in measuring activity is required if activity monitoring is to be used both within research as an outcome measure to further evidence based practice and within the clinical setting to monitor on going treatment and thus help to fill the existing gap of knowledge within the area of CP treatment.

In conclusion from the results of this trial the activPAL activity monitor has many of the attributes that are required from a tool specifically required to measure activity within the community. The data gained within this pilot study gave an early indication as to the accuracy of

the monitor. It has to be borne in mind that this is the result of a pilot study with a small sample size and further trials are required with a larger population before any of the above conclusions are verified. To substantiate this beyond any doubt the author intends to recruit further participants to increase the size of the population. Further statistical analysis may then occur.

Following this, further research will verify whether the activPAL monitor is a suitable instrument for other classifications of CP and gross motor classification. Liaison with activity monitor companies will occur as required to highlight findings that may be relevant to future design specifications.

REFERENCES

Armstrong, N, Balding J, Gentle P, Kirby B. Patterns of physical activity among 11-16 year old British children. *British Medical Journal*. 1990 (301) 203-205.

Bakheit A.M.O, Bower E, Cosgroves A, Fox M, Morton R, Phillips S, Scrutton D, Shrubbs V, Yude C. 'Opinion statement on the minimal acceptable standards of healthcare in cerebral palsy.' Disability and Rehabilitation, 2001; vol 23, no 13, 578-582

Bailey RC, Olsen J, Pepper SL, Porszaz J, Barstow TL, Cooper DM. The level and tempo of childrens physical activities: an observational study. Medicine and science in sports and exercise. (1995) 27, 1033-1041.

Baranowski T, Bouchard C, Bar-Or O, Bricker T, Heath G, Kimm SYS,, Malina R, Obarzenek E, Pate R, StrongWB, Truman B, Washington R, Assessment and prevalence of and cardiovascular benefits of physical activity and fitness in youth. Medicine and Science in Sports and Exercise, 24(suppl) 237-247.

Barrett P.S. Research Grant Applications; Full economic costing. Contracts Office, Research and Graduate College, Salford University. Accessed on 16th October 2005 www.rgc.salford.ac.uk/pages/index

Bhusan V, Paneth N, Kiely J. 'Impact of improved survival of very low birth weight infants on recent secular trends in the prevalence of cerebral palsy.' Pediatrics 1993; (91) 1094-1100

Black N, Brazier J, Fitzpatrick R, Reeves B. Health Services Research Methods A guide to best practice. BMJ Books BMJ Publishing Group. 1998

Blair E, Stanley F. Interobserver agreement in the classification of cerebral palsy. *Dev. Med. Child Neurol.* 1985; 27 615-622

Bland, J.M, Altman, D.G. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet* 1986; Vol 1 307-310.

Boyd. R, High or low technology measurements of energy expenditure in clinical gait analysis? *Developmental Medicine and Child Neurology* 1999, 41: 676-682

Boyd R N, Graham H K. Objective measurement of clinical findings in the use of botulinum toxin type A for the management of children with cerebral palsy. Eur J Neurol 1999;(6) (Suppl 4) 23-35.

Boyd R N, Hays R M. Current evidence for the use of botulinum toxin A in the management of children with cerebral palsy: a systematic review. European Journal of Neurology 2001(8)(supplement 5)1-20.

Bussmann JBJ, Stam HJ. Techniques for the measurement and assessment of mobility in rehabilitation: a theoretical approach. Clinical Rehabilitation 1998;Vol 12 455-464

Coleman K.L. Step Activity Monitor: long term, continuous recording of ambulatory function. Journal of Rehabilitation Research and Development. 1999; Vol 36 No 1, 8-18.

Cone J.D, Foster D.L. Direct observation in clinical psychology. Methods in Clinical Psychology, P Kendall and J Butcher (Eds.). NY:John Willey and Sons, 1982, 311-354

Cornfield J. Randomisation by group: a formal analysis. American Journal of Epidemiology. 1978;108:100-2

Cory IS, Cosgrove RP, Duffy CM, Taylor TC, Graham HK. Botulinum Toxin A in hamstring spasticity. *Gait and Posture* 1999 (10): 206-210

Crouter SE, Schneider PL, Karabulut M, Bassett DR. Validity of 10 electronic pedometers for measuring steps, distance and energy cost. *Medical Science Sports Exercise*.

Dabney KW, Lipton GE, Miller F. Cerebral Palsy. *Curr Opin Pediatrics* 1997 (9) 81-88

Donner A, Brown KS, Brasher P. A methodological review of non-therapeutic intervention trials employing cluster randomisation. *International Journal of Epidemiology* 1990 (19) 795-800.

Eastlack, M.E., Arvidson, J., Snyder-Mackler, L., Danoff, J.V. McGarvey, C.L. 'Interrater reliability of videotaped observational gait analysis assessments' Physical Therapy 1991 (71) 465-72

Eldridge B, J, McCoy AT, Wolfe R, Graham H, K, Galea M. Remote activity monitoring by the uptimer in normal children. Developmental Medicine in Child Neurology 43 (suppl.88):41 (Abstract).

Eldridge BJ, Galea M, McCoy A, Wolfe R, Graham HK. Uptime normative values in children aged 8 to 15 years. Developmental medicine and Child Neurology 2003 45: 189-193.

Essex C. Hyperbaric oxygen and cerebral palsy: no proven benefit and potentially harmful. Developmental Medicine Child Neurology 2003 (45) 213-215.

Fayers, PM, Machin D. Sample size: How many patients are necessary? (editorial). Br J Cancer 1995 (72) 1-9

Finn K.J, Specker B. Comparison of Actiwatch activity monitor and Children's Activity Rating Scale in Children. Medicine and Science in Sports and Exercise 2000 Jan 1794-1797.

Feldman A.B, Haley S.M, Coryell J. Concurrent and Construct Validity of the Paediatric Evaluation of Disability Inventory. Physical Therapy 1990 (70) 602-610

Flett, P.J., Rehabilitation of spasticity and related problems in childhood cerebral palsy. Journal of Paediatrics and Child Health 2003 (39)6.

Fowler F.J. Survey Research Methods (1993) (2nd edition) London Sage.

Gage J R Gait analysis in cerebral palsy Clinics in developmental medicine No 121 1991 MacKeith Press Blackwell Scientific Publications Ltd, New York, Cambridge University Press.

Helders, P.J.M. 'To be and to become: the changing focus of developmental paediatrics. (2001); vol 23, No 13, 583-585

Howard J, Soo B, Kerr Graham H, Boyd R N, Reid S, Lanigan A, Wolfe R, Reddihough S. Cerebral Palsy in Victoria: Motor types, topography and gross motor function. Journal of Paediatrics and Child Health 2005 vol41 issue9-10, 479-483.

Indrayan A, Chawla R. Clinical agreement in quantitative measurements. The national medical journal of India 1994 229-234

Kennes J, Rosenbaum P, Hanna S E. Health status of school aged children with cerebral palsy: Information from a population based sample. Developmental Medicine Child Neurology.2002;44:240-247

Klesges L.M, Klesges R.C, Swenson A,M, Pheley A.M. A validation of two motion sensors in the prediction of child and adult physical activity levels. American Journal of Epidemiology 1985;122:400-410

Krebs, D.E., Edelstein J.E., Fishman S. (1985): 'Reliability of observational kinematic gait analysis', Physical Therapy 1985 65 1027-33

Lynn M. Determination and quantification of content validity. Nursing Research 1986 (35) 382-385

Mantha S, Roizen M.F, Fleisher L.A, Thisted R, Foss J. Comparing methods of clinical measurement: Reporting standards for Bland and Altman analysis. Anesthesia and Analgesia 2000; 90 (3) 593-602

McCabe M., Granger, C.V. (1990) 'Content Validity of a Paediatric Functional Independence Measure.' Applied Nursing Research 1990 (3) 120-122

McDonald C.M., Walsh D.D., Widman L.A., Walsh S.A., Abresch, R.T. (2000): Quantitative Assessment of Community Physical Activity Levels in Disabled Children with the Step Activity Monitor. Arch Phys Med Rehabilitation 2000 (81) 1273-

Molnar G E, (1991) Rehabilitation in Cerebral Palsy. Western Journal of Medicine; 154(5): 569-572

Montoye H,J. Use of movement sensors in measuring physical activity. Journal of Sports Science 1988 (3) 223-236

Morris JWR. Accelerometry – a technique for the measurement of human body movements. J Biomechanics 1973 (6): 729-736

*National institute for Health (07/09/2004)
www.grants.nih.gov/grants/funding/sbir_successes/158*

Noonan, K. 2003 Interobserver Variability of Gait Analysis in Patients with Cerebral Palsy. J Pediatric Orthopaedics 2003 (3): 279-287

Norbeck, J. (1985) 'What constitutes a publishable report of instrument development? Nursing Research 1985 (34) 380-382

Novacheck TF, Schwartz M. Chapter 23 Functional assessment of outcomes pp 406-421. The treatment of gait problems in cerebral palsy. Edited by James R Gage 2004 Mac Keith Press. ISBN 1 898683 379

Ottenbacher K.J, Stull G.A. The analysis and interpretation of method comparison studies in rehabilitation research. American Journal of Physical Medicine and Rehabilitation. 1993; 266-271.

Palisano R, Rosenbaum P, Walter S, Russell D, Wood E, Galuppi B. Development and reliability of a system to classify gross motor function in children with cerebral palsy. Dev. Med. Child Neurology. 1997; 39:214-23

Pirpiris M, Graham H,K. Uptime in Children with Cerebral Palsy. Journal of Pediatric Orthopedics. 2004 24 (5):521-528

Rodda J, Graham H,K. Classification of gait patterns in spastic hemiplegia and spastic diplegia: a basis for a management algorithm. European Journal of Neurology 2001(8)(Suppl.5)98-108.

Rumeau-Rouquette C, Grandjean H, Cans C, du MC, Verrier A. Prevalence and time trends of disabilities in school-age children. International Journal of Epidemiology 1997 (26) 137-145.

Rowland TW. The biological basis of physical activity. Medicine and Science in sports and Exercise 1988 (30) 392-399.

Rowlands AV, Eston RG, Ingledew DK. Measurement in children with particular referance to the use of heart rate and pedometry. Sports Medicine 1997 (4) 258-272)

Russell D, Rosenbaum P, Gowland C. The Gross Motor Function Measure, 2nd edition. Hugh McMillan Rehabilitation Centre, McMasterUniversity, Toronto, Canada.

Russell D, Avery L M, Rosenbaum PL, Raina PS, Walter S D, Palisano RJ. Improved scaling of the gross motor function measure for children with cerebral palsy: evidence for reliability and validity. Physical Therapy 2000 (80):873-885.

Ruud W. Selles, PhD, Margriet A.G. Formanoy, MSc, Johannes B.J. Bussmann, PhD, Henk J. Stam, PhD, MD. Automated detection of heel strike and toe-off timing using accelerometers; development and validation in transtibial amputees and controls. Medical and Biological Engineering and Computing.

Sanchez M.M, Bruce S.B. Guidelines for measurement validation in clinical trials. Journal of biopharmaceutical statistics 1999; 9 (3) 417-438.

Schneider P,L, Crouter S,E, Lukajic O, Bassett D,R. Accuracy and Reliability of 10 Pedometers for measuring steps over a 400m walk. Medical Science Sports Exercise 2003; 35 (10) 1779-84.

Stanley F, Blair E, Alberman E. Cerebral Palsies: Epidemiology and Causal Pathways. (2000) Clinics in Developmental Medicine No. 151. Mac Keith Press, London.

Sutherland DH, Davids JR. Common gait abnormalities of the knee in cerebral palsy. Clinical Orthopaedics 1993;288:139-47.

van den Berg-Emons H.J, Bussman JB, Balk A.H, Stam H.J. Validity of ambulatory accelerometry to quantify physical activity in heart failure. Scandinavian Journal of Rehabilitation Medicine 2000; 32(4):187-192

Walker D.J, Heslop P.S, Plummer C.J, Essex T, Chandler S. A continuous patient activity monitor: validation and relation to disability. Physiol Meas 1997;18(1):49-59

Wall J.C, Charteris M.S, Turnbull G.I: Two steps equals one stride equals what? The applicability of normal gait nomenclature to abnormal walking patterns. Clinical Biomechanics 1987; 2 No3: 119-125

Welk GJ, Corbin CB, Dale D. Measurement issues in the assessment of Physical Activity in Children. Research Quarterly for Exercise and Sport 2000, (71) 2 59-73.

Whittle MW Normal Ranges for Gait Parameters in Gait Analysis: an introduction, 3rd edition (2002), Butterworth-Heinemann, Oxford, ISBN 0 7506 5262 4, Appendix 1.

Whiting-O'Keefe Q.E., Henke C, Simborg DW. Choosing the correct unit of analysis in medical care experiments. Med Care 1984;22:1101-14

Winters T, Hicks TSR, Gage J. Gait patterns in spastic hemiplegia in children and young adults. Journal of Joint and Bone Surgery; 1987 69-A: 437-441.

Wood E, Roseburn P. The Gross Motor Function Classification System for cerebral palsy: A study of reliability and stability over time. Dev. Med. Child Neurology 2000;42: 292-6

Young N.L, Ivan J, Williams D.E, Yoshida K.K and James G.Wright. Measurement Properties of the Activities Scale for Kids. Journal of Clinical Epidemiology 2000 53 (2): 125-137

APPENDIX

Appendix 1

Current Commercially Available Activity Monitors.

During the literature search the monitors below were found to be the most frequently used.

The StepWatch Activity Monitor (SAM)

This is a highly adjustable, computer programmable instrument that is worn on the ankle and records the number of steps taken every minute for up to 2 months between downloads. It is unobtrusive, waterproof, maintenance free and extremely durable. Accuracy typically exceeds 98% regardless of walking style, from completely functional to highly impaired. (Cyma 2004)

The Actiwatch® (registered trademark of Mini Mitter Company, Inc., Sunriver)

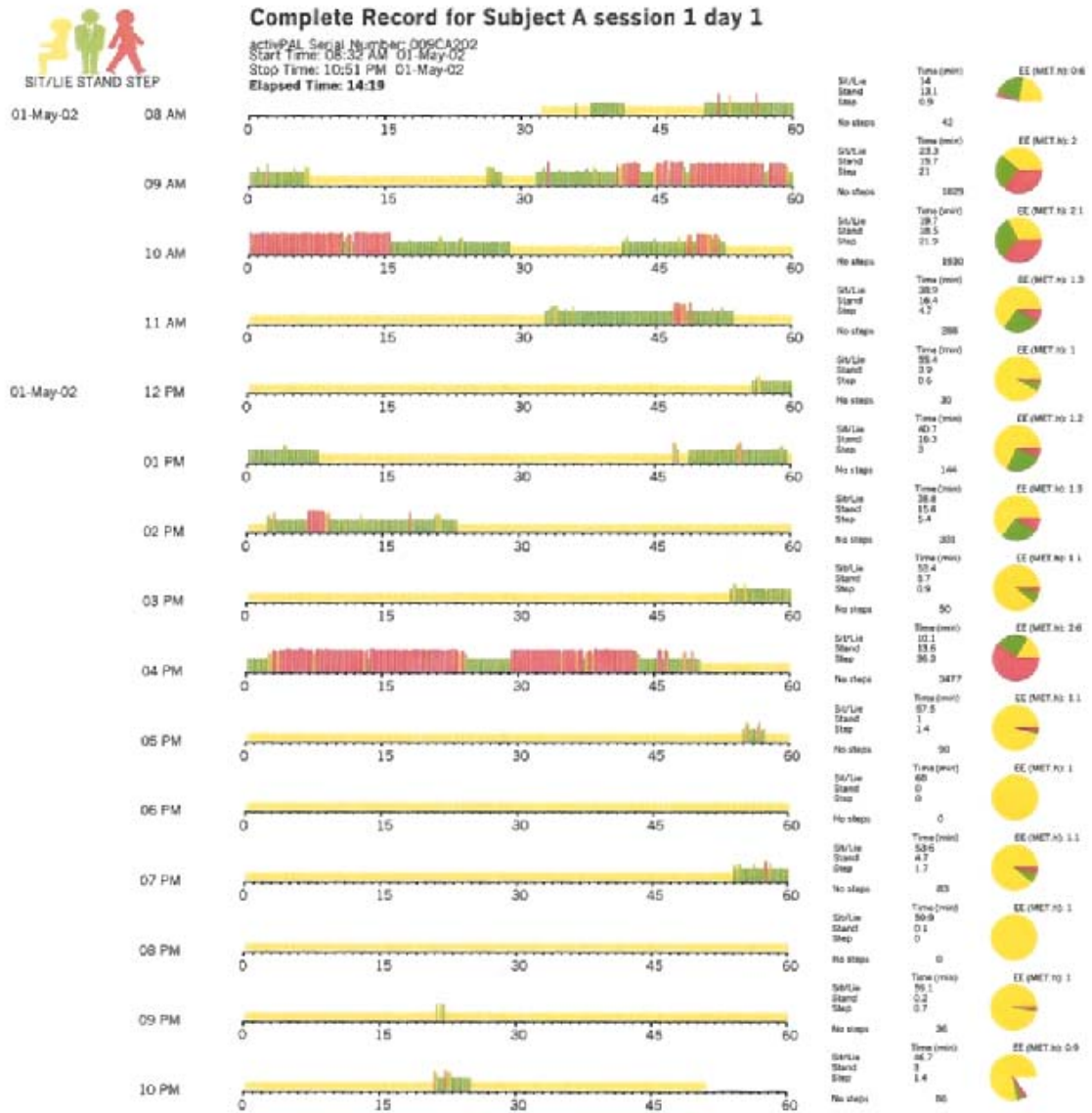
The Actiwatch is a long-term activity monitoring device that can be worn on the limb(s) or the torso without discomfort. The compact size (27 mm X 26 mm x 9 mm) of the device is suitable for use in children, although it has not been validated for assessing physical activity in preschool-aged children. Actiwatch activity monitor. The Actiwatch activity monitor contains an omni-directional sensor capable of detecting acceleration in two planes. Sensitive to 0.01g (0.098 ms) this type of sensor integrates the degree and speed of motion and produces an electrical current that varies in magnitude. An increased degree of speed and motion produces an increase in voltage. The monitor stores this information as activity counts. The maximum sampling frequency is 32 Hz. The device has been used in sleep studies and is beginning to be used in energy expenditure studies.

A recent comparison of activity monitors worn during treadmill walking has provided strong correlations with energy expenditure. This method is useful for validating motion sensors for adult activities; however, it may be inappropriate for validating sensor counts in children due to the intermittent nature of the child's activity patterns. Simultaneous observational data are needed to compare with the Actiwatch activity counts to evaluate it as a useful instrument of physical activity for preschool aged children.

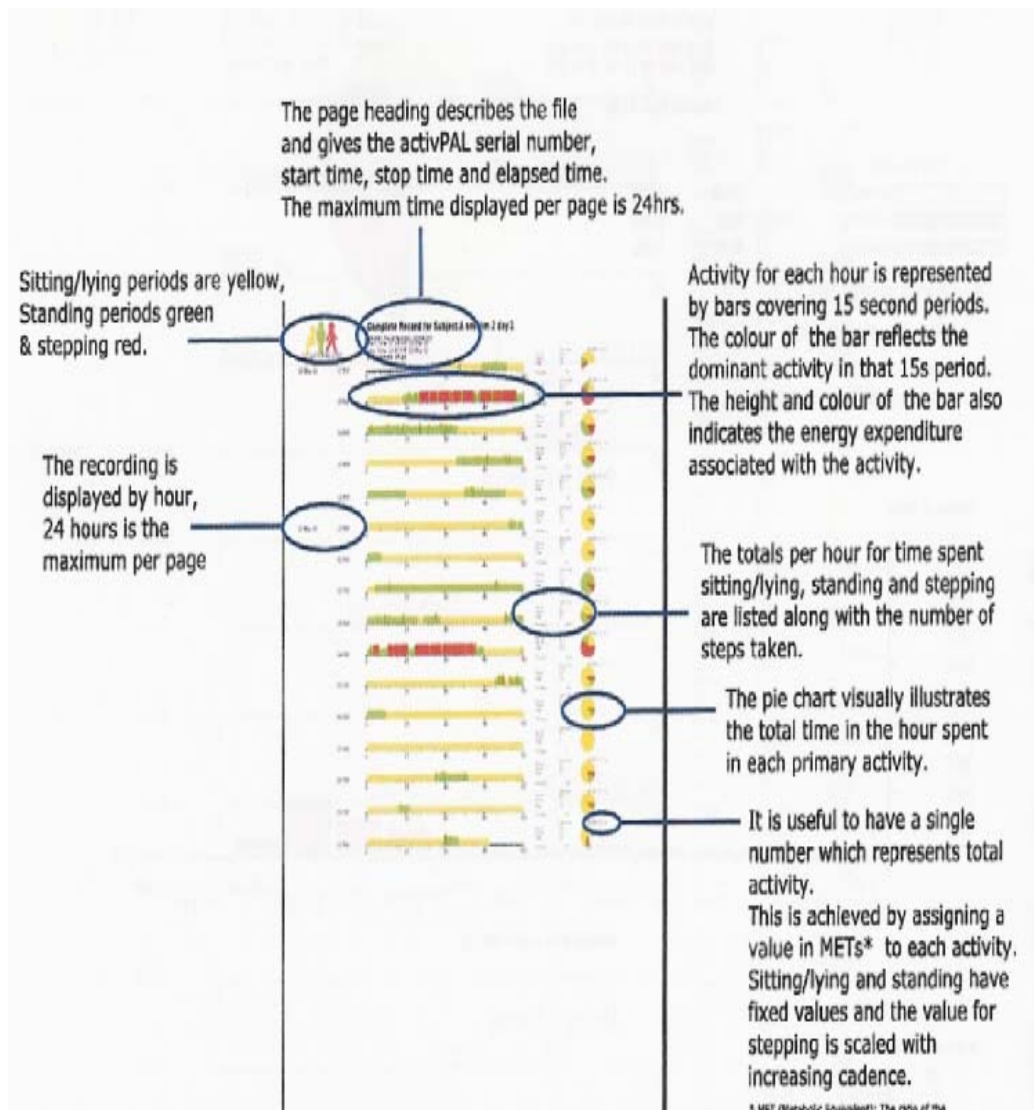
The NUMACT ambulatory monitor.

This activity monitor was developed at Freeman Hospital, Newcastle upon Tyne. The NUMACT enables the logging of an individual's activity for a period of twenty four hours. Activity is recorded as time spent sitting, standing and lying down. During walking the number of steps and their timing is recorded. The weakness of this particular activity monitor is its relatively small amount of on-board memory which only allows the recording of data for one day.

Appendix 2 Example of graphical data output from activPAL.



(activPAL information brochure 2005)



(activPAL information brochure 2005)



Summary for Subject A session 1 day 1

activPAL Serial Number: 009CA202
 Start Time: 08:32 AM 01-May-02
 Stop Time: 10:51 PM 01-May-02

Elapsed Time: 14:19



TIME (hrs:min)	State	Time (hrs:min)	Percentage
10:31	Sitting/Lying	10:31	73%
02:08	Standing	02:08	15%
01:39	Stepping	01:39	12%

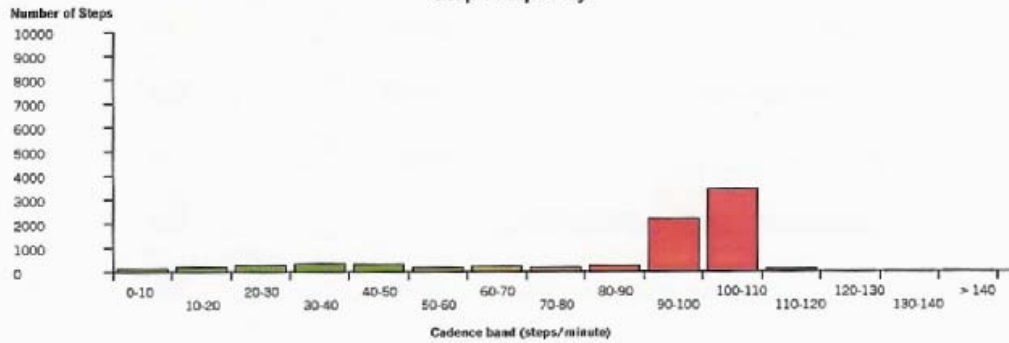
TOTAL NUMBER OF STEPS: 8416

Energy Expenditure: 19.3 MET.h

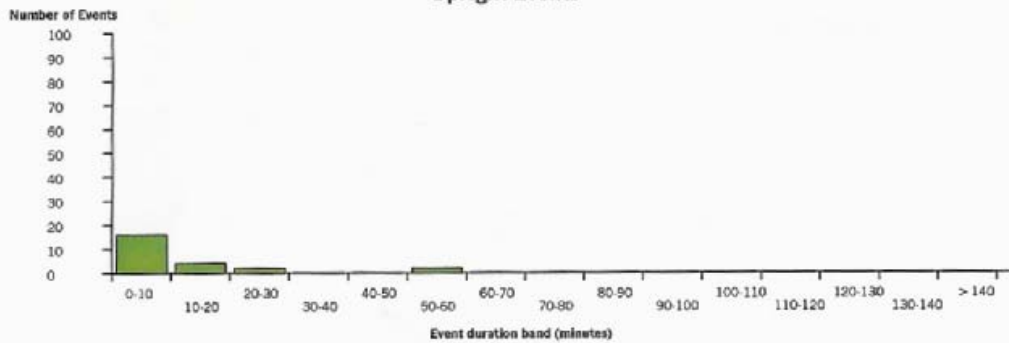
NUMBER OF UPRIGHT EVENTS: 24

NUMBER OF SEATED/LYING EVENTS: 24

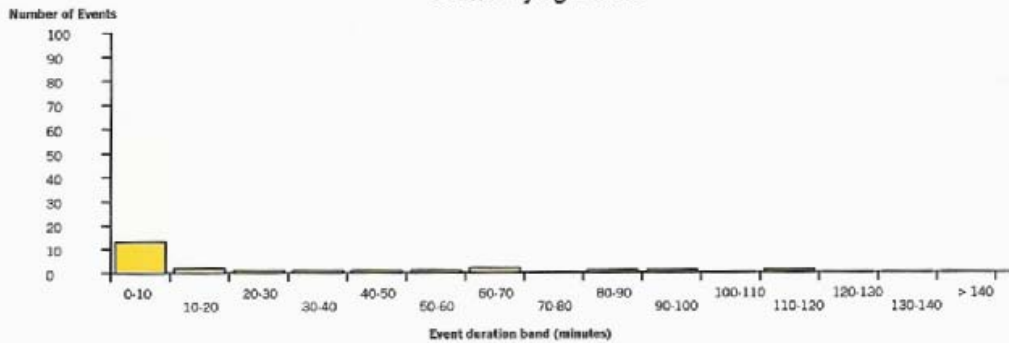
Step Frequency



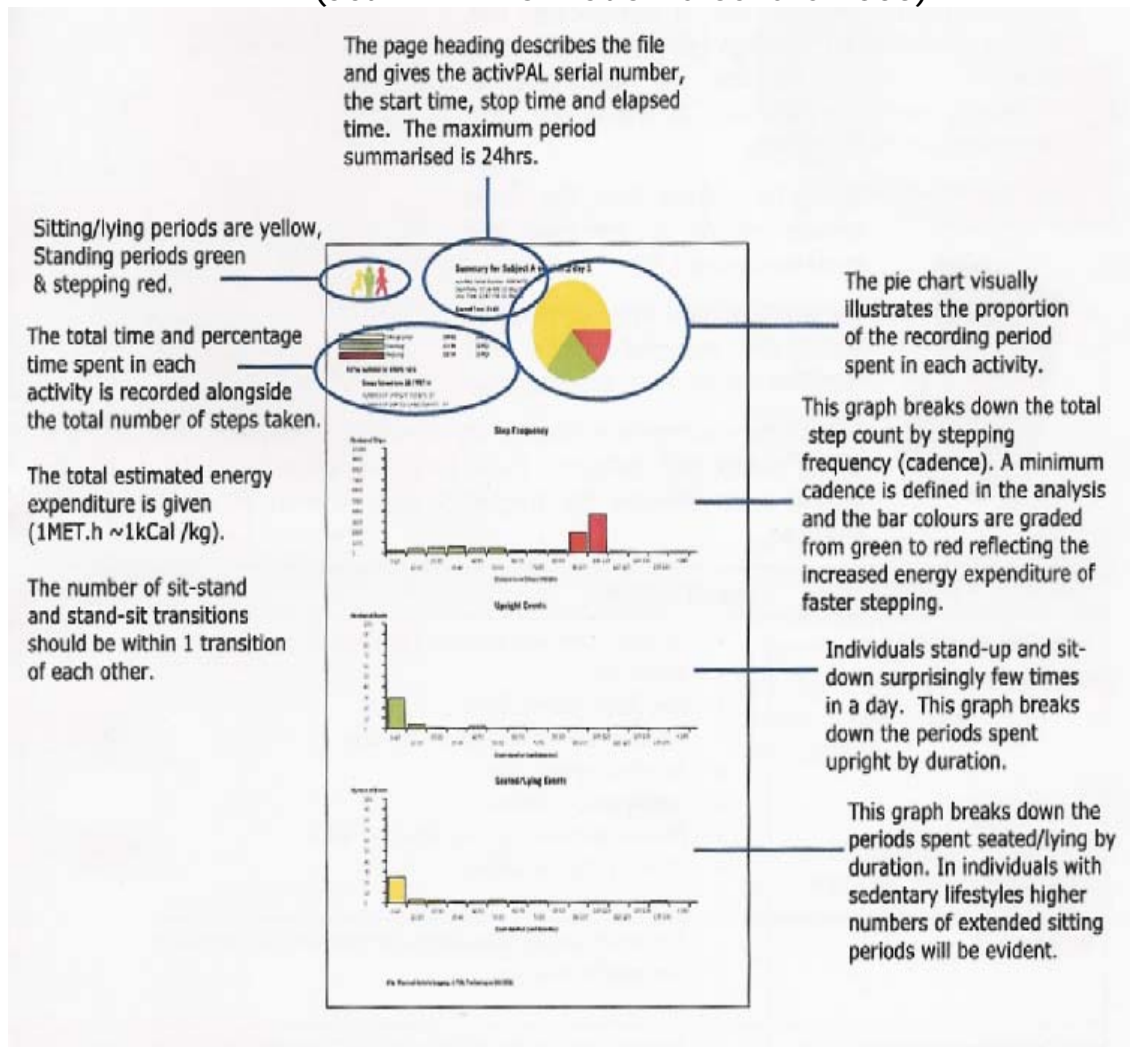
Upright Events



Seated/Lying Events



(activPAL information brochure 2005)



(activPAL information brochure 2005)

Appendix 3 Data Collection Protocol for activPAL.

Procedure for the collection of data.

- 1 First make sure that any old data has been purged from the memory card of the activPAL monitor.
- 2 Affix the monitor to the subject's thigh using 'stickies provided' or similar, **ensuring the device is the correct way up** (guided by picture of man on monitor, see picture below).
- 3 Using the tool provided, switch on the monitor.
At the same time start the video recorder.
- 4 Start the sequence of activities as described in the activities protocol.
- 5 Switch off the monitor once the activities have been completed.
- 6 Take the activPAL monitor off the subject's leg.

The device will record up to 110 hours with a maximum of eight sessions in the recording period. NB THIS WILL MEAN THAT THE MAXIMUM NUMBER OF SUBJECTS TO ATTEND THE TRIAL IN ANY ONE DAY WILL BE 8. IF MORE THAN EIGHT SUBJECTS ATTEND IN ONE SESSION THE DATA WILL HAVE TO BE DOWNLOADED FROM THE MONITOR TO THE LAPTOP BEFORE THE NINTH SUBJECT.

Procedure for the downloading/purging of data from the activPAL monitor.

- 1 First switch on the laptop then start the activPAL software.
- 2 Connect monitor download lead to a USB port on the laptop.
- 3 Now connect the activPAL monitor to the download lead.

4 Start the activPAL monitor with a pin (a constant red light will be displayed on the monitor).



5 Click settings / port/ and select the correct port that the monitor is connected to.

6 Press connect icon (far left on the activPAL menu bar).

To purge the memory;

To clear old data that may be held in the right hand box, click program and clear memory', then answer 'yes' to the prompt.

To download the data;

First tick the 'process data' box (default).

Click on required data file (in the box on the right hand side of the screen).

Save the file into a separate folder (initials/session number/date, eg. MMcA2-14-03-06).

Repeat this for all files.

Backup the data on another hard drive.

Purge memory once the data are saved separately.

Disconnect the monitor.

Appendix 4

Procedure for identification of subjects for the trial;

All subjects will be assigned an identification code prior to taking part in the trial. This is in accordance with the procedures ratified by Bolton ethics committee to ensure subject anonymity. The code assigned will be random and consist of two numbers and two letters eg 1A7H.

ALWAYS identify the subject on the video using a notice with the subjects identification code and the date of the trial.

ALWAYS attach the activPAL to the affected leg (the side of the hemiparesis).

ALWAYS use the same activity monitor for all of the trials.

Run the video continuously from BEFORE switch on until AFTER the final switch off of the monitors.

Appendix 5

The activity course procedure.

Equipment Required.

One appropriately labeled activPAL activity monitor.

One monitor 'switch device' to switch the monitor on and off.

One set of 'stickies' to adhere the monitor to the subject.

One stop watch

One digital video recorder with video time capture display switched on.

Participant information file (with 'agreement to participate form' as pre signed by parent or guardian of the child before attendance).

Activity course arranged as diagram below with two chairs in positions as marked.

Signs to inform research centre staff that a trial is occurring and between which hours this will occur.

There shall be two researchers required for this part of the trial.

One will be required to video the participant around the course ensuring that the lower limbs and feet are visible at all times (this must occur to ensure that the observers can count the number of steps accurately).

The second will be in charge of a stop watch to ensure the pre determined times of sitting and standing occur accurately.

The participant shall be asked to undertake a set activity course. This will involve periods of sitting, standing and walking. It will be ensured that the walking distance is not beyond the abilities of the participants and will be no further than 10 meters, the distance set out in the patient criteria. See below;

1 Start sitting in the chair 'sit 1' in area A (sitting for a period of thirty seconds).

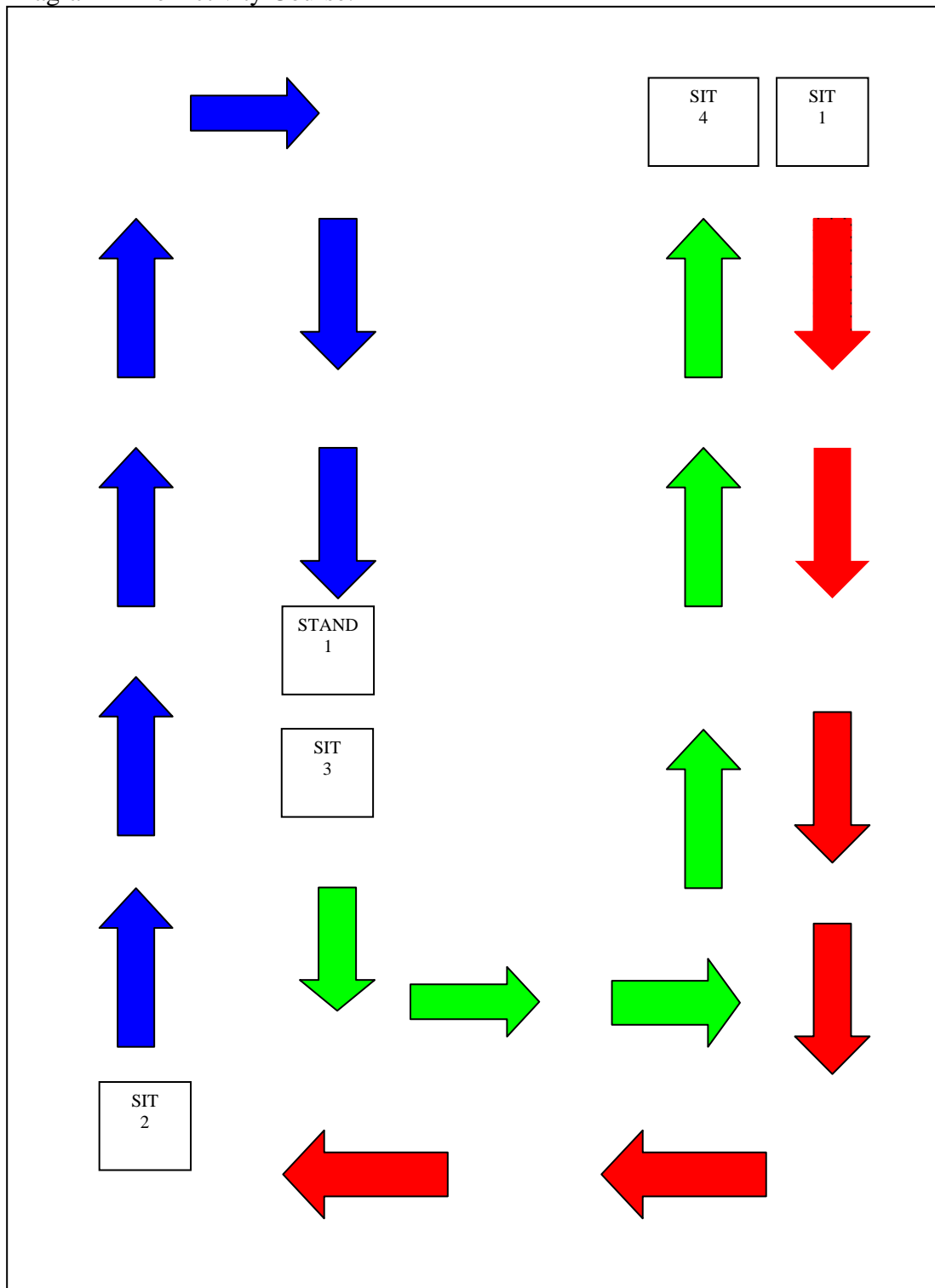
2 Stand and walk down the corridor then sit down 'sit 2' in the chair for 30 seconds.

3 Stand and walk to the top of the corridor then turn around and stand by the window 'stand 1' for 30 seconds, then sit down in the chair for a further thirty seconds 'sit 3'

4 Stand and walk to the chair in area A and sit down 'sit 4' for 30 seconds.

Refer to the diagram below.

Diagram - The Activity Course.



KEY
WALK 1
WALK 2
WALK 3

Appendix 6

The results file procedure.

The results are stored in folder;
D:\TaughtMRes\MResDissertation\TrialResults
A back-up is stored on;
H:\MResDissertation\TrialResults

The data falls into two categories;

1 The step data;

The step data taken from the video.

The step data taken from the activPAL monitor.

2 The timing data;

The timing data taken from the video.

The timing data taken from the activPAL monitor.

STEP DATA

The data for the steps is taken from the video by the two observers (M=Martin, T=Steve) and the results placed in the appropriate box.

The Step Data.

This data includes; the number of steps taken after the first sit phase (walk 1), the number of steps taken before the first stand phase (walk 2) and the number of steps taken before the fourth and final sit phase (walk 3).

A single figure is placed into one of the appropriate three rows and can then be summed automatically.

The Timing Data.

Timings are noted by the observers from the video for the intervals;

1 Initial sitting time (sit 1).

2 Sit to stand – 1st walk – to beginning of sit (sit 2).

3 Start of sit 2 until start of walk 2

4 Walk (walk2) to the beginning of stand (stand 1)

- 5 Start of stand 1 until start of sit (sit 3).
- 5 Start of sit 3 until walk (walk 3)
- 6 Start of walk 3 to start of sit (sit 4).
- 5 Start of sit until end of sit (sit 4)

Appendix Number 7.

Guidance for observers of the video.

The stride in conventional gait pattern is described as the distance between two consecutive points of contact of the same foot. The stride is made up of two steps, defined as the distance that the left foot is placed in front of the right foot, using the same anatomical point of contact. Contact usually occurring with the most proximal part of the heel.

Within hemiplegic gait patterns, classified within Gage types 1 and 2 heel contact may not be the first point of contact with the ground. Often the forefoot is placed on the ground first, followed by the rearfoot. In some hemiplegic gait patterns the heel may never come into contact with the ground, for instance where a limited degree of ankle extension exists.

The definition of a step for this research.

Due to this deviation from the norm the definition of a step for the purposes of this study shall be, ***the point of initial contact of the foot where mass is transferred, to the next consecutive point of contact of that foot where mass is transferred*** (the consecutive point of contact of the foot does not necessarily have to be the same part of the foot – for instance the forefoot or midfoot could be the point of weight transfer).

The additional proviso applies; if the hemiplegic gait pattern resulted in a drop foot, so that during swing phase the foot scuffed the ground, this would not be regarded as the next consecutive point of contact, as mass is not being transferred at this point.

Appendix Number 8

Order of Participants on the digital video capture.

Participant 2

Participant 3

Participant 4

Participant 5

Participant 1

Order of Events

Sit 1 – walk 1 – sit 2 – walk 2 – stand 1- sit 3 – walk 3 – sit 4

Ignore sit1 event – no need to time

All other events time

The sitting timings.

Start of sit time is when the participant's buttocks strike the seat.

End of sit time is when the participant's buttocks leave the seat.

Sit 4 – stop the clock when the on/off pin is pulled out of the activPAL monitor.

Appendix Number 9 Correspondence/Information to the Trial Participants.

9.1 Letter of Invitation to Take Part in the Trial;

A study to test the suitability of a device that measures activity for usage with people with cerebral palsy.

Dear Parent/Guardians,

Thank you for showing an interest, with the possibility of your child taking part in the above research. I have included a detailed outline of what taking part in this trial will involve. A brief outline is shown below.

The activPAL activity monitor is a small device that attaches to the body so that activity levels can be measured. Your child will be required to wear either shorts or a skirt whilst carrying out the tasks as the monitor is required to be attached to your thigh. The activity that we measure will be that of sitting, standing and walking. The venue for the research is Salford University, at The Centre for Rehabilitation and Human Performance Research.

The goal of the research is to make sure that the device measures these activities accurately, for people with cerebral palsy.

Please remember that if at any time you wish to withdraw your child from the study you are at will to do so.

I will be contacting you within the next week, so that you can ask any further questions that may arise. Thank you for considering your child's participation within this study.

Yours Sincerely,

Mark McAloon
Orthotics and Prosthetics Lecturer,
Centre for Rehabilitation and Human Performance Research
University of Salford
Frederick Road
Salford
M6 6PU

9.2 CONSENT FORM FOR PARTICIATION IN RESEARCH

Title of Research Project.

A Research Study to Validate an Activity Monitor for Usage with Cerebral Palsy.

Name of Researcher: Mark McAloon

1. I understand that my childs participation in this research is voluntary and I am free to withdraw him/her at any time, without giving any reason, without their medical care or legal rights being affected.

2. I confirm that I have received and understand the information sheet for the above study and have had the opportunity to ask questions on any terms or issues that may have been unclear.

3. I agree to my child being videoed as part of this study on the understanding that the video will be erased at the completion of this research. The video will not be used for any other purpose other than this research project.

4. I agree to take part in the research as titled above.

Name of Parent/Guardian

Date

Signature

Name of researcher

Date

Signature

9.3 Information Sheet for Participant Advice.

A study to test the suitability of a device that measures activity for usage with people with cerebral palsy.

Introduction

A device called an activity monitor measures and records various forms of activity. One such device is activPAL activity monitor. This device measures the length of time that a person is inactive or active. It also records when a person changes their posture, for instance, when a person moves from sitting to standing and during walking will record the number of steps taken. Such information can be useful to help decide whether treatments that people undergo are being effective. This information would be particularly helpful in some treatment areas of cerebral palsy.

Why do we need participants to take part in this trial?

We need participants to take part in this trial to ensure the accuracy of the activPAL. In this way we can ensure that any future research undertaken with the activPAL activity monitor will be correct and result in improvements in the way in which we treat our patients.

What participation in the trial involves.

Your child will be required to partake in one testing session only. The whole process will take place in the University of Salford and will take no longer than 1 hour.

During this time the researcher will ask your child to undertake a number of activities, such as walking and sitting for a set amount of time. The distance your child will be expected to walk will be a distance within their ability. However, if at any time your child feels that they are unable to complete any of the tasks, they may stop.

Whilst your child is undertaking the activities he/she will have an activity monitor attached to them. This will be attached to the thigh with tape. He/she will be required to wear shorts or a skirt during the trial due to this fact.

Your child will also be videotaped whilst carrying out the set tasks. The video will be used to show that the activPAL is recording your movements accurately. At the end of the research study the video recording will be erased. The time for your child to complete this part of the study will be approximately 20 minutes.

Are there any possible risks in taking part in the study?

There are no risks in taking part in the study as the activPAL activity monitor is a safe and approved battery-operated device. At all times during the activities there will be a researcher next to you to assist as necessary.

Are there any benefits of taking part in the study?

There are no immediate benefits to your child partaking within this study. However, if the activPAL proves to be successful, as a tool to monitor activity in people with cerebral palsy, you will be notified.

What will happen now?

I will contact you in the next few days to organise when would be a suitable time for you and your child to partake in the trial. If you would like to talk to me before then, please contact me on the telephone number below.

Remember, taking part in this trial is voluntary and if at any time you wish to withdraw your child from the trial, for whatever reason, it will not be a problem.

Mr Mark McAloon (Lecturer at the University of Salford/ Post Grad Research Student); Telephone Number: 0161 2952270

Appendix number 10 Section of the observer excel spreadsheet data form.

THE VIDEO DATA

A) The timing data

Subject 1						
		time(secs)		time(secs)		time(secs)
	sit 1		walk 1		stand1	
	sit 2		walk 2			
			walk 3			
Total		0		0		0

Subject 2						
		time(secs)		time(secs)		time(secs)
	sit 1		walk 1		stand1	
	sit 2		walk 2			
			walk 3			
Total		0		0		0

B) The Step Count Data.

Subject 1		
		Number of steps
	walk 1	
	walk 2	
	walk 3	
Total		0

Subject 2		
		Number of steps.
	walk 1	
	walk 2	
	walk 3	
Total		0

Appendix number 11

Timetable of stages within the research.

7TH December Obtain Ethical Approval.

9th January Complete and write up the literature search.

9th January-27th February Completion of the trials.

27th February-17th April Analysis and presentation of the data.

17th April-26th May Discussion and conclusion write up.

Appendix Number 9 The activPAL excel spreadsheet data.

12.1 The reliability spreadsheets

12.1.1 Activity run 1

Activity profile for Euan run 3 324DG404 03Apr06 01-44-45 PM - 03Apr06 01-48-09 PM - Day 1

activPAL Serial Number: 324DG404

Start Time: 01:44 PM 03-

Apr-06

Stop Time: 01:48 PM 03-

Apr-06

Elapse 00:03

d Time:

Date	Hour	Sit/Lie (min)	Stand (min)	Step (min)	sit/stand movements	stand/sit movements	No steps	EE (MET.h)
03-Apr-06	1:00 PM	1.3	0.7	1.2	2	2	124	0.117

15s data for Activity profile for Euan run 3 324DG404 03Apr06 01-44-45 PM - 03Apr06 01-48-09 PM - Day 1

activPAL Serial Number: 324DG404

Start Time: 01:44 PM 03-

Apr-06

Stop Time: 01:48 PM 03-

Apr-06

Elapsed 00:03

Time:

Time	Sittin g (s)	Standin g (s)	Steppin g (s)	Steps	Energy Expenditure (MET.h)
13:44:45	0	0.2	14.8	14	0.0106
13:45:00	1.5	1.5	12	22	0.014
13:45:15	15	0	0	0	0.0052
13:45:30	13.9	1.1	0	0	0.0053
13:45:45	0	1.1	13.9	26	0.0151
13:46:00	0	9.2	5.8	10	0.0095
13:46:15	0	15	0	0	0.0058
13:46:30	6.5	8.5	0	0	0.0056
13:46:45	15	0	0	0	0.0052
13:47:00	7.5	1.9	5.6	12	0.0093
13:47:15	0	0	15	28	0.0161
13:47:30	5.4	2.2	7.4	12	0.0103
13:47:45	15	0	0	0	0.0052

12.1.2 Activity run 2

Activity profile for 324DG404 Euan run 4 03Apr06 01-49-10 PM - 03Apr06 01-52-32 PM - Day 1

activPAL Serial Number: 324DG404

Start Time: 01:49 PM 03-Apr-06

Stop Time: 01:52 PM 03-Apr-06

Elapsed 00:03

Time:

Date	Hour	Sit/Lie (min)	Stand (min)	Step (min)	sit/stand movements	stand/sit movements	No steps	EE (MET.h)
03-Apr-06	1:00 PM	1.4	0.7	1.2	2	2	122	0.118

15s data for Activity profile for 324DG404 Euan run 4 03Apr06 01-49-10 PM - 03Apr06 01-52-32 PM - Day 1

activPAL Serial Number: 324DG404

Start Time: 01:49 PM 03-Apr-06

Stop Time: 01:52 PM 03-Apr-06

Elapsed 00:03

Time:

Time	Sitting (s)	Standing (s)	Stepping (s)	Steps	Energy Expenditure (MET.h)
13:49:15	0	0	15	24	0.0143
13:49:30	8.7	2.2	4.1	6	0.0082
13:49:45	15	0	0	0	0.0052
13:50:00	6.7	1.9	6.4	14	0.01
13:50:15	0	1.9	13.1	22	0.0144
13:50:30	0	15	0	0	0.0058
13:50:45	0	15	0	0	0.0058
13:51:00	14.6	0.4	0	0	0.0052
13:51:15	15	0	0	0	0.0052
13:51:30	0.9	1.9	12.2	24	0.0141
13:51:45	0	0	15	28	0.0157
13:52:00	11	1.9	2.1	2	0.0067
13:52:15	15	0	0	0	0.0052

PAL: Physical Activity Logging. © PAL Technologies Ltd 2005

12.2 The validity output from the activPAL monitor in excel format.

12.2.1 Participant no.1

Activity profile for 324DG404 25Apr06 02-15-30 PM - 25Apr06 02-18-47 PM - Day 1

activPAL Serial Number: 324DG404

Start Time: 02:15 PM 25-Apr-06

Stop Time: 02:18 PM 25-Apr-06

Elapsed Time: 00:03

Date	Hour	Sit/Lie (min)	Stand (min)	Step (min)	sit/stand movement	stand/sit movement	No steps	EE (MET.h)
25-Apr-06	2:00 PM	0.8	0.9	1.5	1	1	148	0.127

15s data for Activity profile for 324DG404 25Apr06 02-15-30 PM - 25Apr06 02-18-47 PM - Day 1

activPAL Serial Number: 324DG404

Start Time: 02:15 PM 25-Apr-06

Stop Time: 02:18 PM 25-Apr-06

Elapsed Time: 00:03

Time:

no sit 1 period recorded during trial due to trial error not activity monitor error.

Time	Sitting (s)	Standing (s)	Stepping (s)	Steps	Energy Expenditure (MET.h)	
14:15:30	0	1.9	13.1	16	0.0112	- start walk 1 14:15:30
14:15:45	0	0	15	28	0.0162	
14:16:00	0	2.9	12.1	2		end walk 1 14:16:15 start sit 2
14:16:15	0	15	0	0	0.0058	registers standing in this sit 2 period
14:16:30	0	0.3	14.7	30	0.0163	end sit 2 14:16:30 start walk 2
14:16:45	0	6.8	8.2	16	0.0119	end walk 2 14:16:53 start stand 1
14:17:00	0	15	0	0	0.0058	
14:17:15	5.3	9.7	0	0	0.0056	end stand 1 14:17:25 start sit 3
14:17:30	15	0	0	0	0.0052	
14:17:45	8.8	1.4	4.8	10	0.0091	end sit 3 14:17:54 start walk 3
14:18:00	0	0	15	32	0.0174	
14:18:15	6.4	1.9	6.7	14	0.0106	end walk 3 14:18:23 start sit 4
14:18:30	15	0	0	0	0.0052	end sit 4 14:18:45

12.2.2 Participant no. 2

Activity profile for participant 2 run 2 324DG404 19Apr06 10-24-56 AM - 19Apr06 10-29-13 AM - Day 1

activPAL Serial Number: 324DG404

Start Time: 10:25 AM 19-Apr-06

Stop Time: 10:29 AM 19-Apr-06

Elapsed

Time: 00:04

Date	Hour	Sit/Lie (min)	Stand (min)	Step (min)	sit/stand movements	stand/sit movements	No steps	EE (MET.h)
19-Apr-06	10:00 AM	0.6	1.6	1.9	1	1	222	0.174

15s data for Activity profile for participant 2 run 2 324DG404 19Apr06 10-24-56 AM - 19Apr06 10-29-13 AM - Day 1

activPAL Serial Number: 324DG404

Start Time: 10:25 AM 19-Apr-06

Stop Time: 10:29 AM 19-Apr-06

Elapsed

Time: 00:04

Time	Sitting (s)	Standin g (s)	Steppin g (s)	Steps	Energy Expenditure (MET.h)
10:25:00	15	0	0	0	0.0052
10:25:15	8.5	2.9	3.6	6	0.0069
10:25:30	0	0	15	34	0.0178
10:25:45	0	2.8	12.2	26	0.0155
10:26:00	0	15	0	0	0.0058
10:26:15	0	15	0	0	0.0058
10:26:30	0	1.8	13.2	32	0.0169
10:26:45	0	0	15	36	0.0187
10:27:00	0	1.8	13.2	4	0.0078
10:27:15	0	15	0	0	0.0058
10:27:30	0	11.5	3.5	4	0.0073
10:27:45	0	15	0	0	0.0058
10:28:00	0	11.3	3.7	8	0.0086
10:28:15	0	0	15	34	0.0182
10:28:30	0	0	15	30	0.0164
10:28:45	8.7	1.1	5.2	10	0.0094

PAL: Physical Activity Logging. © PAL Technologies Ltd 2005

12.3.3 Participant no.3

Activity profile for 324DG404 Participant 3 run 1 03Apr06 04-05-54 PM - 03Apr06 04-17-39 PM - Day 1

activPAL Serial Number: 324DG404

Start Time: 04:06 PM 03-

Apr-06

Stop Time: 04:17 PM 03-

Apr-06

Elapsed 00:11

Time:

Date	Hour	Sit/Lie (min)	Stand (min)	Step (min)	sit/stand movements	stand/sit movement s	No step s	EE (MET.h)
03-Apr-06	4:00 PM	3.9	3.6	4.1	4	4	394	0.403

15s data for Activity profile for 324DG404 Participant 3 run 1 03Apr06 04-05-54 PM - 03Apr06 04-17-39 PM - Day 1

activPAL Serial Number: 324DG404

Start Time: 04:06 PM 03-Apr-

06

Stop Time: 04:17 PM 03-Apr-

06

Elapsed 00:11

Time:

Time	Sitting (s)	Standing (s)	Stepping (s)	Step s	Energy (MET.h)	Expenditure
16:06:00	0	15	0	0	0.0058	
16:06:15	0	15	0	0	0.0058	
16:06:30	0	8.9	6.1	10	0.0088	
16:06:45	0	12.1	2.9	2	0.0072	
16:07:00	0	7.2	7.8	14	0.0108	
16:07:15	0	7.9	7.1	14	0.011	
16:07:30	0	6.3	8.7	18	0.0122	
16:07:45	0	0	15	30	0.0163	
16:08:00	0	14.1	0.9	0	0.0064	
16:08:15	0	15	0	0	0.0058	
16:08:30	0	10.5	4.5	8	0.0082	
16:08:45	0	0	15	30	0.0168	
16:09:00	0	0	15	28	0.0157	
16:09:15	4.9	2.6	7.5	6	0.0084	
16:09:30	15	0	0	0	0.0052	
16:09:45	15	0	0	0	0.0052	
16:10:00	15	0	0	0	0.0052	
16:10:15	15	0	0	0	0.0052	
16:10:30	15	0	0	0	0.0052	
16:10:45	15	0	0	0	0.0052	
16:11:00	15	0	0	0	0.0052	
16:11:15	15	0	0	0	0.0052	
16:11:30	3.5	1	10.5	18	0.0121	
16:11:45	0	0	15	26	0.0152	
16:12:00	0	6.1	8.9	12	0.0103	
16:12:15	0	15	0	0	0.0058	

16:12:30	0	14.9	0.1	2	0.0059
16:12:45	0	0	15	24	0.0145
16:13:00	0	0	15	24	0.0146
16:13:15	0	12.8	2.2	2	0.0071
16:13:30	0	15	0	0	0.0058
16:13:45	9.1	5.9	0	0	0.0055
16:14:00	15	0	0	0	0.0052
16:14:15	6.8	1.4	6.8	10	0.0089
16:14:30	0	0	15	16	0.0119
16:14:45	0	0	15	22	0.0132
16:15:00	0	0	15	20	0.0135
16:15:15	9.6	1.1	4.3	6	0.0078
16:15:30	15	0	0	0	0.0052
16:15:45	15	0	0	0	0.0052
16:16:00	4.5	2.9	7.6	4	0.0068
16:16:15	3.8	0.9	10.3	14	0.0111
16:16:30	15	0	0	0	0.0052
16:16:45	10.1	0.9	4	8	0.0082
16:17:00	0	1.6	13.4	26	0.0146
16:17:15	0	15	0	0	0.0058

PAL: Physical Activity Logging. © PAL Technologies Ltd
2005

12.4.4 Participant no.4

Activity profile for Participant number 4 324DG404 05Apr06 10-47-59 AM - 05Apr06 10-54-51 AM - Day 1

activPAL Serial Number: 324DG404

Start Time: 10:48 AM 05-Apr-06

Stop Time: 10:54 AM 05-Apr-06

Elapsed 00:06

Time:

Date	Hour	Sit/Lie (min)	Stand (min)	Step (min)	sit/stand movements	stand/sit movements	No steps	EE (MET.h)
05-Apr-06	10:00 AM	3	1.6	2.2	4	4	218	0.228

15s data for Activity profile for Participant number 4 324DG404 05Apr06 10-47-59 AM - 05Apr06 10-54-51 AM - Day 1

activPAL Serial Number: 324DG404

Start Time: 10:48 AM 05-Apr-06

Stop Time: 10:54 AM 05-Apr-06

Elapsed 00:06

Time:

Time	Sitting (s)	Standing (s)	Stepping (s)	Steps	Energy Expenditure (MET.h)	
10:48:00	0	15	0	0	0.0058	
10:48:15	0	15	0	0	0.0058	
10:48:30	8.4	3.3	3.3	6	0.0077	sit 1 starts here
10:48:45	15	0	0	0	0.0052	
10:49:00	15	0	0	0	0.0052	
10:49:15	13.7	1.3	0	0	0.0053	
10:49:30	0	0.6	14.4	32	0.0169	
10:49:45	5	1.7	8.3	16	0.0119	
10:50:00	15	0	0	0	0.0052	
10:50:15	10.5	1.3	3.2	8	0.0079	
10:50:30	0	0	15	32	0.0175	
10:50:45	0	14.7	0.3	0	0.0061	
10:51:00	0	15	0	0	0.0058	
10:51:15	11.1	3.9	0	0	0.0054	
10:51:30	15	0	0	0	0.0052	
10:51:45	5.8	1.3	7.9	14	0.0106	
10:52:00	0	0	15	34	0.0175	
10:52:15	9.3	1	4.7	8	0.009	
10:52:30	15	0	0	0	0.0052	
10:52:45	15	0	0	0	0.0052	
10:53:00	15	0	0	0	0.0052	
10:53:15	11.4	2.4	1.2	4	0.0062	
10:53:30	0	0	15	10	0.0096	
10:53:45	0	0	15	24	0.0146	
10:54:00	0	0	15	16	0.0119	
10:54:15	0	2.6	12.4	14	0.0102	
10:54:30	0	15	0	0	0.0058	

PAL: Physical Activity Logging. © PAL Technologies Ltd 2005

12.5.5 Participant no.5

Activity profile for 324DG404 19Apr06 11-23-46 AM - 19Apr06 11-27-42 AM - Day 1

activPAL Serial Number: 324DG404

Start Time: 11:24 AM 19-Apr-06

Stop Time: 11:27 AM 19-

Apr-06

Elapsed

Time: 00:03

Date	Hour	Sit/Lie (min)	Stand (min)	Step (min)	sit/stand movements	stand/sit movements	No steps	EE (MET.h)
19-Apr-06	11:00 AM	1.8	0.7	1.2	3	3	136	0.132

15s data for Activity profile for 324DG404 19Apr06 11-23-46 AM - 19Apr06 11-27-42 AM - Day 1

activPAL Serial Number: 324DG404

Start Time: 11:24 AM 19-Apr-06

Stop Time: 11:27 AM 19-

Apr-06

Elapsed

Time: 00:03

Time	Sitting (s)	Standing (s)	Stepping (s)	Steps	Energy Expenditure (MET.h)
11:24:00	15	0	0	0	0.0052
11:24:15	8.2	2.3	4.5	8	0.0083
11:24:30	0	0	15	28	0.0157
11:24:45	9.8	1.2	4	6	0.008
11:25:00	15	0	0	0	0.0052
11:25:15	6.1	1.2	7.7	16	0.0107
11:25:30	0	0	15	22	0.0144
11:25:45	0	13.9	1.1	2	0.0066
11:26:00	0	15	0	0	0.0058
11:26:15	14.2	0.8	0	0	0.0052
11:26:30	15	0	0	0	0.0052
11:26:45	0.6	1.6	12.8	28	0.0153
11:27:00	0	0.8	14.2	26	0.0158
11:27:15	12.7	2.3	0	0	0.0053

PAL: Physical Activity Logging. © PAL Technologies Ltd 2005

Appendix Number 13 Analysis of the Data.

Intra observer reliability

Before the correlation between the data output from the activPAL monitor and the video occurs it must be ensured that the observer data is reliable.

To ensure that the data gained from the video by the two observers was reliable, statistical analysis for intra observer reliability was carried out, between the two sets of observer results:

- 1) The steps.
- 2) The times taken for each event.

The data from observer 1 and observer 2 for the number of steps were correlated against each other using Pearson's Correlation and paired t-test. The data from observer 1 and 2 for each of the individual events were also correlated against each other using Pearson's Correlation and paired t-test. (sit 2; sit 3; walk 1;walk 2; walk 3; stand 1).

Reliability of the activPAL monitor.

The reliability of the monitor was assessed by, the same monitor being used with the same subject, repeating the course seven times. *Pearson's Correlation and t-tests were then carried out on the number of steps undertaken for walk1, walk2 and walk3. Secondly Pearson's correlation and t-tests occurred for the timings of the activities undertaken.*

The Validity of the activPAL monitor.

To examine the validity, the data obtained from the activPAL monitor was correlated against the data obtained from observer 1 and a t-test was undertaken. The intra correlation between the observers was high indicating that the discrepancies between the data obtained from observer 1 and observer 2 were minimal. This being the case it was decided to correlate the activPAL data against the data obtained from observer 1. The data obtained for the number of steps from the activPAL was also correlated against the data obtained from observer 1.

Appendix 14 The raw data tables

12.1 The intra-rater data tables for the observers

Observer timings and counts comparison.

Subject 1									
		Steve	Martin		Steve	Martin		Steve	Martin
		time (secs)	Time (secs)		Time (secs)	time (secs)		Time (secs)	Time (secs)
	sit 1			walk 1	00:00:26	00:00:26	stand1	00:00:31	00:00:31
	sit 2	00:00:32	00:00:32	walk 2	00:00:28	00:00:28			
	sit 3	00:00:30	00:00:31	walk 3	00:00:31	00:00:32			
	sit 4	00:00:31	00:00:31						
	Total	00:02:04	00:02:05		00:01:25	00:01:26		00:00:31	00:00:31

Subject 2									
		Steve	Martin		Steve	Martin		Steve	Martin
		time (secs)	Time (secs)		Time (secs)	Time (secs)		Time (secs)	Time (secs)
	sit 1			walk 1	00:00:30	00:00:31	stand1	00:00:32	00:00:38
	sit 2	00:00:35	00:00:34	walk 2	00:00:34	00:00:30			
	sit 3	00:00:31	00:00:31	walk 3	00:00:41	00:00:40			
	sit 4	00:00:32	00:00:32						
	Total	00:01:38	00:01:37		00:01:45	00:01:41		00:00:32	00:00:38

Subject 3									
		Steve	Martin		Steve	Martin		Steve	Martin
		time (secs)	Time (secs)		Time (secs)	time (secs)		Time (secs)	Time (secs)
	sit 1			walk 1	00:00:26	00:00:26	stand1	00:00:29	00:00:30
	sit 2	00:00:31	00:00:31	walk 2	00:00:27	00:00:27			
	sit 3	00:00:29	00:00:31	walk 3	00:00:32	00:00:31			
	sit 4	00:00:30	00:00:31						
	Total	00:01:30	00:01:33		00:01:25	00:01:24		00:00:29	00:00:30

Subject 4									
		Steve	Martin		Steve	Martin		Steve	Martin
		time (secs)	time(sec)		Time (secs)	time (secs)		Time (secs)	Time (secs)
	sit 1			walk 1	00:00:26	00:00:27	stand1	00:00:31	00:00:31
	sit 2	00:00:30	00:00:30	walk 2	00:00:21	00:00:20			

	sit 3	00:00:31	00:00:32	Walk 3	00:00:30	00:00:30			
	sit 4	00:00:31	00:00:31						
Total		00:01:32	00:01:33		00:01:17	00:01:17		00:00:31	00:00:31

Subject 5									
		Steve	Martin		Steve	Martin		Steve	Martin
		time (secs)	Time (secs)		Time (secs)	time (secs)		Time (secs)	Time (secs)
	sit 1			walk 1	00:00:29	00:00:26	stand1	00:00:30	00:00:30
	sit 2	00:00:30	00:00:31	walk 2	00:00:23	00:00:24			
	sit 3	00:00:30	00:00:31	walk 3	00:00:30	00:00:29			
	sit 4	00:00:30	00:00:31						
Total		00:01:30	00:01:33		00:01:22	00:01:19		00:00:30	00:00:30

Participant 1			
		S	M
		No.Steps	No. steps
	walk 1	22	23
	walk 2	21	21
	walk 3	30	29
Total		73	73
Participant 2			
		S	M
		No.Steps	No. steps
	walk 1	33	33
	walk 2	32	33
	walk 3	41	41
Total		106	107
Participant 3			
		Steve	Martin
		No.Steps	No. steps
	walk 1	24	24
	walk 2	24	24
	walk 3	29	29

Total		77	77
-------	--	----	----

Participant 4			
		Steve	Martin
		No.Steps	No. steps
	walk 1	26	27
	walk 2	21	22
	walk 3	31	31
Total		78	80

Participant 5			
		Steve	Martin
		No.Steps	No. steps
	walk 1	22	23
	walk 2	20	20
	walk 3	28	28
Total		70	71

14.2 The reliability data tables from the activPAL and the observer.

The sit timings

sit 2		
Trial no.	observer	activPAL
1	00:00:30	00:00:32
2	00:00:30	00:00:31
3	00:00:32	00:00:31
4	00:00:30	00:00:31
5	00:00:31	00:00:33
6	00:00:32	00:00:33
7	00:00:31	00:00:31

sit 3		
Trial no.	observer	activPAL
1	00:00:29	00:00:29
2	00:00:30	00:00:31
3	00:00:30	00:00:30
4	00:00:28	00:00:29
5	00:00:30	00:00:30
6	00:00:31	00:00:30
7	00:00:31	00:00:31

The walk timings

walk 1		
Trial no.	observer	activPAL
1	00:00:27	00:00:27
2	00:00:27	00:00:21
3	00:00:28	00:00:12
4	00:00:26	00:00:24
5	00:00:26	00:00:24
6	00:00:26	00:00:24
7	00:00:25	00:00:25

walk 2		
Trial no.	observer	activPAL
1	00:00:24	00:00:22
2	00:00:23	00:00:23
3	00:00:23	00:00:22
4	00:00:25	00:00:27
5	00:00:25	00:00:24
6	00:00:24	00:00:23
7	00:00:25	00:00:23

walk 3		
Trial no.	observer	activPAL
1	00:00:32	00:00:29
2	00:00:32	00:00:29
3	00:00:32	00:00:20
4	00:00:35	00:00:35
5	00:00:33	00:00:24
6	00:00:34	00:00:31
7	00:00:34	00:00:37

The stand timings

stand 1		
Trial no.	observer	activPAL
1	00:00:31	00:00:33
2	00:00:30	00:00:30
3	00:00:31	00:00:32
4	00:00:33	00:00:31
5	00:00:31	00:00:32
6	00:00:30	00:00:32
7	00:00:29	00:00:31

The number of steps

walk 1		
Trial no.	observer	activPAL
1	22	18
2	22	15
3	21	11
4	22	22
5	22	21
6	22	21
7	23	22

walk 2		
Trial no.	observer	activPAL
1	21	18
2	21	18
3	21	19
4	22	22
5	21	19
6	21	19
7	22	20

walk 3		
Trial no.	observer	activPAL
1	28	26
2	29	27
3	28	26
4	30	31
5	29	21
6	30	31
7	30	30

14.3 The validity data tables from the activPAL and observers.

All walk data		
	activPAL	Observer
walk 1	00:00:45	00:00:46
walk 2	00:00:23	00:00:23
walk 3	00:00:30	00:00:29
walk 1	00:00:33	00:00:31
walk 2	00:00:41	00:00:30
walk 3	00:00:39	00:00:40
walk 1	00:00:25	00:00:26
walk 2	00:00:26	00:00:27
walk 3	00:00:32	00:00:31
walk 1	00:00:24	00:00:27
walk 2	00:00:19	00:00:20
walk 3	00:00:32	00:00:30
walk 1	00:00:26	00:00:26
walk 2	00:00:25	00:00:24
walk 3	00:00:28	00:00:29

All sit data		
	activPAL	Observer
sit 2	00:01:00	00:00:59
sit 3	00:00:29	00:00:30
sit 2	00:00:35	00:00:34
sit 3	00:00:29	00:00:31
sit 2	00:00:31	00:00:30
sit 3	00:00:31	00:00:32
sit 2	00:00:33	00:00:30
sit 3	00:00:32	00:00:32
sit 2	00:00:32	00:00:31
sit 3	00:00:30	00:00:31

All stand data		
	activPAL	Observer
stand 1	00:00:32	00:00:31
stand1	00:00:29	00:00:38
stand1	00:00:31	00:00:30
stand1	00:00:34	00:00:31
stand1	00:00:30	00:00:30

All number steps data		
walk 1	23	23
walk 2	23	21
walk 3	28	29
walk 1	33	33
walk 2	36	33
walk 3	41	41
walk 1	23	24
walk 2	21	24
walk 3	28	29
walk 1	24	27
walk 2	20	22
walk 3	28	31
walk 1	21	23
walk 2	20	20
walk 3	27	28

Appendix No 15 THE SPSS ANALYSIS STATISTICS OUTPUT

15.1 Intra-rater observer statistics

13.1.1 Correlation and t-test for all sit timings

Correlations

Correlations

		Steve	Martin
Steve	Pearson Correlation	1	.884(**)
	Sig. (1-tailed)		.000
	N	15	15
Martin	Pearson Correlation	.884(**)	1
	Sig. (1-tailed)	.000	
	N	15	15

** Correlation is significant at the 0.01 level (1-tailed).

T-Test

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Steve	30.87	15	1.407	.363
	Martin	31.33	15	.900	.232

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	Steve & Martin	15	.884	.000

Paired Samples Test

		Paired Differences				95% Confidence Interval of the Difference	t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean					
Pair 1	Steve - Martin	-.467	.743	.192	Lower: -.878 Upper: -.055	-2.432	14	.029	

15.1.2 Correlation and t-test for all stand timings.

nb not statistically significant as more than 0.05 – however t-test below reveals that there is not a significant difference between the means of 30.50 and 32.25

Correlation

Correlations

		Steve	Martin
Steve	Pearson Correlation	1	.886(**)
	Sig. (1-tailed)		.000
	N	12	12
Martin	Pearson Correlation	.886(**)	1
	Sig. (1-tailed)	.000	
	N	12	12

** Correlation is significant at the 0.01 level (1-tailed).

T-test

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Steve	30.83	12	1.528	.441
	Martin	31.33	12	.985	.284

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	Steve & Martin	12	.886	.000

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Steve - Martin	-.500	.798	.230	-1.007	.007	-2.171	11	.053

15.1.3 Correlation and t-test for walk timings

Correlations

Correlations

		Steve	Martin
Steve	Pearson Correlation	1	.952(**)
	Sig. (1-tailed)		.000
	N	15	15
Martin	Pearson Correlation	.952(**)	1
	Sig. (1-tailed)	.000	
	N	15	15

** Correlation is significant at the 0.01 level (1-tailed).

T-Test

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Steve	28.93	15	4.758	1.228
	Martin	28.47	15	4.454	1.150

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	Steve & Martin	15	.952	.000

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Steve - Martin	.467	1.457	.376	-.340	1.274	1.240	14	.235

15.1.4 Correlations and t-test for step count data

Descriptive Statistics

	Mean	Std. Deviation	N
S	26.93	5.837	15
M	27.20	5.685	15

Correlations

		S	M
S	Pearson Correlation	1	.995**
	Sig. (1-tailed)		.000
	N	15	15
M	Pearson Correlation	.995**	1
	Sig. (1-tailed)	.000	
	N	15	15

** . Correlation is significant at the 0.01 level

T-Test

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	S	26.93	15	5.837	1.507
	M	27.20	15	5.685	1.468

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	S & M	15	.995	.000

Paired Samples Test

		Paired Differences				t	df	Sig. (2-tailed)	
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower				Upper
Pair 1	S - M	-.267	.594	.153	-.595	.062	-1.740	14	.104

15.1.5 Correlations and t-test for observer S and observer M for total observation data.

Descriptive Statistics

	Mean	Std. Deviation	N
S	30.04	3.616	28
M	30.21	3.775	28

Correlations

		S	M
S	Pearson Correlation	1	.895**
	Sig. (1-tailed)		.000
	N	28	28
M	Pearson Correlation	.895**	1
	Sig. (1-tailed)	.000	
	N	28	28

** . Correlation is significant at the 0.01 level

T-Test

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	S	30.04	28	3.616	.683
	M	30.21	28	3.775	.713

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	S & M	28	.895	.000

Paired Samples Test

		Paired Differences				t	df	Sig. (2-tailed)	
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower				Upper
Pair 1	S - M	-.179	1.701	.321	-.838	.481	-.556	27	.583

15.1.6 Comment on intra rater statistics.

The statistical output reveals without doubt that there is a close correlation between the observations made by observer 'M' and observer 'S'. Only the stand timings correlation output is not statistically significant, however the t-test reveals that there is not a significant difference between the means of 30.50 and 32.25. It can be concluded that the observations are accurate. Due to the excellent correlation of the observations it was decided to correlate the activPAL data against observer 'M' data when determining the reliability of the activPAL monitor.

15.2 The Reliability Statistics

15.2.1 The reliability of the Activity Timing.

Correlations

Correlations

		run1	run2
run1	Pearson Correlation	1	.974**
	Sig. (1-tailed)		.001
	N	6	6
run2	Pearson Correlation	.974**	1
	Sig. (1-tailed)	.001	
	N	6	6

** . Correlation is significant at the 0.01 level

T-Test

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	run1	28.83	6	2.927	1.195
	run2	28.67	6	3.204	1.308

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	run1 & run2	6	.974	.001

Paired Samples Test

		Paired Differences				t	df	Sig. (2-tailed)	
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
								Lower	Upper
Pair 1	run1 - run2	.167	.753	.307	-.623	.957	.542	5	.611

15.2.2 The Reliability of the Step Counts

Correlations

Correlations

		run1	run2
run1	Pearson Correlation	1	1.000**
	Sig. (1-tailed)		.006
	N	3	3
run2	Pearson Correlation	1.000**	1
	Sig. (1-tailed)	.006	
	N	3	3

** . Correlation is significant at the 0.01 level

T-Test

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	run1	23.67	3	3.786	2.186
	run2	24.00	3	4.359	2.517

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	run1 & run2	3	1.000	.011

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	run1 - run2	-.333	.577	.333	-1.768	1.101	-1.000	2	.423

15.3 The Validity Statistics.

13.3.1 Validity Correlations All Sit Data.

Descriptive Statistics

	Mean	Std. Deviation	N
activPAL	34.20	9.247	10
observer	34.00	8.869	10

Correlations

		activPAL	observer
activPAL	Pearson Correlation	1	.988**
	Sig. (1-tailed)		.000
	N	10	10
observer	Pearson Correlation	.988**	1
	Sig. (1-tailed)	.000	
	N	10	10

** . Correlation is significant at the 0.01 level (1-tailed).

T-Test

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	activPAL	34.20	10	9.247	2.924
	observer	34.00	10	8.869	2.805

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	activPAL & observer	10	.988	.000

Paired Samples Test

		Paired Differences				t	df	Sig. (2-tailed)	
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower				Upper
Pair 1	activPAL - observer	.200	1.476	.467	-.856	1.256	.429	9	.678

15.3.2 Pearson Correlation and t-test for all stand data.

Descriptive Statistics

	Mean	Std. Deviation	N
activPAL	31.20	1.924	5
observer	32.00	3.391	5

Correlations

		activPAL	observer
activPAL	Pearson Correlation	1	-.537
	Sig. (1-tailed)		.176
	N	5	5
observer	Pearson Correlation	-.537	1
	Sig. (1-tailed)	.176	
	N	5	5

T-Test

[DataSet0]

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	activPAL	31.20	5	1.924	.860
	observer	32.00	5	3.391	1.517

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	activPAL & observer	5	-.537	.351

Paired Samples Test

		Paired Differences				t	df	Sig. (2-tailed)	
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower				Upper
Pair 1	activPAL - observer	-.800	4.712	2.107	-6.650	5.050	-.380	4	.723

15.3.3 Correlations for Validity All walk Data

Descriptive Statistics

	Mean	Std. Deviation	N
activPAL	29.87	7.249	15
observer	29.27	6.475	15

Correlations

		activPAL	observer
activPAL	Pearson Correlation	1	.899**
	Sig. (1-tailed)		.000
	N	15	15
observer	Pearson Correlation	.899**	1
	Sig. (1-tailed)	.000	
	N	15	15

** . Correlation is significant at the 0.01 level (1-tailed).

T-Test

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	activPAL	29.87	15	7.249	1.872
	observer	29.27	15	6.475	1.672

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	activPAL & observer	15	.899	.000

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	activPAL - observer	.600	3.180	.821	-1.161	2.361	.731	14	.477

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	activPAL	29.87	15	7.249	1.872
	observer	29.27	15	6.475	1.672

15.3.4 Validity Correlations and t-test for all step data.

Descriptive Statistics

	Mean	Std. Deviation	N
activPAL	26.40	6.197	15
observer	27.20	5.685	15

Correlations

		activPAL	observer
activPAL	Pearson Correlation	1	.961**
	Sig. (1-tailed)		.000
	N	15	15
observer	Pearson Correlation	.961**	1
	Sig. (1-tailed)	.000	
	N	15	15

** . Correlation is significant at the 0.01 level (1-tailed).

T-Test

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	activPAL	26.40	15	6.197	1.600
	observer	27.20	15	5.685	1.468

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	activPAL & observer	15	.961	.000

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	activPAL - observer	-.800	1.740	.449	-1.764	.164	-1.780	14	.097

Appendix Number 16.

The calculations of the cadence of participants 1 to 5

CALCULATIONS FOR CADENCE OF PARTICIPANTS 1 - 5

Participant 1 Cadence (Steps per minute)
time No steps
(secs)

45	23
23	23
30	28

98 second = 1.63 minutes

Cadence = $74/1.63 = 45.40$ steps/minute

Participant 2 Cadence (Steps per minute)
time No steps
(secs)

33	33
41	36
39	41

Cadence = No steps /minutes = $110/1.88 = 58.51$

Participant 3 Cadence (Steps per minute)
time No steps
(secs)

25	23
26	21
32	28

Cadence = No steps/minute = $72/1.38 = 52$

Cadence ranges from 45.4 to 58.5 steps per minute

Participant 4 Cadence (Steps per minute)
time No
(secs) Steps

24	24
19	20
32	28

Cadence = No steps/minute = $72/1.25 = 57.6$

Participant no 5 Cadence (Steps per minute)
time No steps
(secs)

26	21
25	20
28	27

Cadence = No steps/minute = $68/1.32 = 51.5$