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Does Self-Reported Physical Activity Correlate With Objective Measurement In People Post Discharge Following Stroke?

Edel Hennessy

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DOES SELF-REPORTED PHYSICAL ACTIVITY CORRELATE WITH OBJECTIVE MEASUREMENT IN PEOPLE POST DISCHARGE FOLLOWING STROKE?

A dissertation submitted in partial fulfilment of the requirements for the degree of MSc in Neurology and Gerontology

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September 2016

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Dr Rose Galvin (University of Limerick)
I declare that this thesis, which I submit to RCSI for examination in consideration of the award of a higher degree in Neurology and Gerontology, is my own personal effort. Where any of the content presented is the result of input or data from a related collaborative research programme this is duly acknowledged in the text such that it is possible to ascertain how much of the work is my own. I have not already obtained a degree in RCSI or elsewhere on the basis of this work. Furthermore, I took reasonable care to ensure that the work is original, and, to the best of my knowledge, does not breach copyright law, and has not been taken from other sources except where such work has been cited and acknowledged within the text.

Signed _______Edel Hennessy______________

RCSI Student Number ___14106850____________

Date _________5th September 2016____________
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<td>TIA</td>
<td>Transient Ischaemic Attack</td>
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<td>AHA</td>
<td>American Heart Association</td>
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<td>Metabolic Equivalent Tasks</td>
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<td>AVERT</td>
<td>A Very Early Rehabilitation Trial</td>
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STROBE  STrengthening the Reporting of OBservational studies in
Epidemiology.
SUMMARY

Aims and objectives: To quantify self-reported and objective levels of physical activity in people post discharge following a stroke.

Methods: Every patient admitted at the Acute Stroke Unit (ASU) in University Hospital Limerick was considered for recruitment to this descriptive cohort study. Participants wore an accelerometer for the first seven days post discharge home from the ASU. The data from this was compared to self-reported physical activity (PA) levels as measured by the International Physical Activity Questionnaire using the Spearman rank correlation coefficient. Secondary measures of age, cognition, balance, self-efficacy, function, anxiety and depression were examined using a mixed linear regression model to determine whether they influenced levels of physical activity following a stroke.

Results: A total of 21 participants were recruited during the study period from 1/10/15 to 29/2/16. Analysis demonstrated that no participant reached the recommended 10,000 steps per day. The median number of steps taken per day as measured by the accelerometer was 4023 with an interquartile range (IQR) of 2724 steps (minimum 1745 – maximum 9824 steps/day).

The median MET’s per day as measured by the accelerometer was 30.53 (IQR 1.45, minimum 26.83 – maximum 102.55).
Conclusions: Following discharge home from the ASU patients do not meet the recommended levels of physical activity. There is a poor correlation between self-reported and objective levels of physical activity in this cohort. This study did not establish a relationship between any of the secondary measures and physical activity.

Implications of findings: Stroke survivors are largely inactive in the acute period following discharge home from the ASU. Improved identification of barriers to PA and effective interventions are required to improve outcomes for patients post stroke to reduce the risk of stroke recurrence and optimise their outcome.
ACKNOWLEDGEMENTS

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My fiancéé, Ken, who has supported me throughout this process and has been unflinching in his patience.
INTRODUCTION

Approximately 10,000 people experience a stroke in Ireland every year and it is the third greatest cause of death in Ireland and the leading cause of acquired disability (Irish Heart Foundation, 2008). It has been demonstrated that about 10% of people who have a stroke will have another in the first 12 months (Irish Heart Foundation, 2008). Between 2-4% of the total Irish health expenditure was spent on stroke in 2007, which at conservative estimates equates to between €489 and €805 million (Irish Heart Foundation, 2010).

The advent of the National Clinical Programme in Stroke has resulted in significantly better outcomes for people with stroke in Ireland. There is reduced inpatient mortality (14% in 2015 compared to 19% in 2008) and fewer patients are being discharged to residential care (8% in 2015 compared to 15% in 2008) (Irish Heart Foundation/Health Service Executive, 2015). However, there is a projected increased trend of stroke in Ireland of 50% by 2021 with a projected increased cost of 50% (Irish Heart Foundation, 2010). With an ageing population and rising socioeconomic costs for the treatment of stroke, it is essential that strategies are introduced to optimise outcome for patients following stroke and reduce the risk of recurrence.

Decreased physical activity (PA) has been recognised as a risk factor for stroke (O’Donnell et al, 2010) and exercise prescription should be incorporated into stroke secondary prevention (American Heart Association, 2014). Despite this, it has been found that only 41% of patients were counselled in exercise prescription as a
secondary prevention measure in a recent national audit (Irish Heart Foundation/Health Service Executive, 2015).

Early mobilisation has become standard care and a hallmark of acute stroke care (AVERT [A Very Early Rehabilitation Trial] Trial Collaboration Group, 2015) although it has been found that there are long periods of inactivity in the ASU environment (Bernhardt et al, 2008). These trends of inactivity have also been demonstrated in the long term period post stroke with patients not meeting the recommended levels of PA (Paul et al, 2015). It has also been demonstrated that stroke survivors are less active than their healthy peers, despite those having the physical ability to participate in regular PA (Dhamoon et al, 2006). Current stroke guidelines recommend that adults participate in 150 minutes of moderate intensity PA per week or 10,000 steps per day (American Heart Association, 2014).

To date, there have been no studies to quantify the levels of PA of patients who are discharged directly home from the ASU and who are independently mobile. Additionally, to the author’s knowledge this will be the first study to establish the correlation between self-reported and objective measurement (by use of the International Physical Activity Questionnaire) of PA in the cohort of patients who are independently mobile and being discharged directly home from the ASU.

The primary aim of this study was to quantify self-reported and objective levels of PA in people post discharge following a stroke. Additionally, the study aims to determine if self-reported and objective levels of PA correlate in this cohort and to determine if cognition, self-efficacy, balance, age, functional ability, depression or anxiety have an association with PA post-acute stroke.
CHAPTER 1 – LITERATURE REVIEW

1.0 Stroke epidemiology and cost

Approximately 10,000 people experience a stroke in Ireland every year and it is the third leading cause of death in Ireland and leading cause of acquired disability (Irish Heart Foundation, 2008). Approximately 2,500 people are assessed in Irish hospitals annually with suspected transient ischaemic attack (TIA) and the risk of stroke is higher in people who have previously had a stroke or TIA (Azarpazhooh et al, 2008). About 10% of people who have a stroke will have another in the first 12 months (Irish Heart Foundation, 2008). Between 2-4% of the total health expenditure was spent on stroke in 2007 which at conservative estimates equates between €489 and €805 million (Irish Heart Foundation, 2010). There is a projected increased trend of stroke in Ireland of 50% by 2021 with a projected increased cost of 50% (Irish Heart Foundation, 2010).

1.1 Burden of stroke

In high income countries from 1990 to 2010 the age-standardised incidence of stroke has decreased by 12% and mortality by 37% (Feigin et al, 2014). However, Feigin et al (2014) also demonstrated that the life-years lost worldwide to disability had increased by 12% between 1990 and 2010. Therefore, the economic and social costs of stroke are high as more individuals are surviving stroke but may acquire a disability.
The largest proportion of costs for stroke in Ireland has been attributed to nursing home and indirect costs which consider lost productivity from mortality and morbidity (Smith et al, 2010). Of those who survive a stroke, approximately 40% are left with a functional disability and require some form of care (Young and Forster, 2007). The need for support in activities of daily living can impact upon the life of the stroke survivor and their relatives, who can be their informal caregiver. Caregiver burden can have an impact upon a stroke survivors recovery and its’ prevalence is reported between 25-54% (Rigby et al, 2009). It has been demonstrated that higher functional disability, older stroke survivor age and poor mental health are factors that contribute to carer burden (Rigby et al, 2009).

Reducing stroke frequency and recurrence through primary and secondary prevention is essential to minimise the burden of stroke in an ageing population. Additionally the promotion of evidence based, efficient rehabilitation is necessary to optimise stroke survivor’s outcomes.

1.2 Secondary prevention

The five risk factors which account for 80% of ischaemic stroke risk are hypertension, current smoking, increased waist-hip ratio, diet and decreased PA (O’Donnell et al, 2010). The combination of appropriate secondary preventative medications along with lifestyle modifications may reduce vascular events by 80% over five years in patients with cerebrovascular event (Hackman and Spence, 2007). However, a study by Brewer et al (2015) reported suboptimal control of many risk factors post ischaemic stroke in an Irish cohort. They found that patients with a history of hypertension at baseline assessment were less likely to have optimal
control six months later. They reported that 67% of patients were categorised at overweight or obese and although the proportion of smokers had reduced from 28%, at six months post stroke 16.4% were still smoking. PA was not measured as a risk factor or addressed in the interventions. These results demonstrate the potential to improve stroke secondary prevention.

The American Heart Association (AHA) highlights the importance of lifestyle interventions for blood pressure reduction post stroke. These include: weight loss; a diet that is high in fruits and vegetables, a diet that uses low fat dairy products, a diet that has reduced salt intake; regular PA; and limited alcohol consumption (Kernan et al, 2014). The AHA guidelines on stroke prevention in stroke survivors also recommend that all patients should be screened for obesity and be referred to a comprehensive, behaviourally orientated PA program (Kernan et al, 2014). As cigarette smoking is an independent risk factor for primary stroke and passive (second-hand) smoking also a risk factor for stroke, all stroke survivors should be counselled on smoking cessation (Kernan et al, 2014).

Hypertension is the single biggest risk factor for all types of stroke with the odds of stroke in those with hypertension reported to be almost three times that of those without the risk factor (odds ratio 2.64, confidence interval 2.26 – 3.08) (O’ Donnell et al, 2010). Hypertension is recognised as a modifiable risk factor (Gallanagh et al, 2011). PA (in the form of endurance, strength and isometric training) has been demonstrated to have a positive effect upon hypertension (Pederson and Saltin, 2015). Participants demonstrating uncontrolled hypertension (BP >180/105) require medical clearance before embarking upon regular PA. Participants who are regularly physically inactive and have clearance to partake in PA, it is recommended they start
at a low to moderate intensity and monitor for signs of exertional symptoms (Riebe et al, 2015).

Physical inactivity and a sedentary lifestyle have been shown to place individuals at a higher risk of cardiovascular disease, obesity and diabetes (Darden et al, 2013). Stroke survivors are less physically active than their peers and are at an 18.3% higher risk of recurrent stroke within five years of initial stroke (Dhamoon et al, 2006). It is recommended that all patients following a stroke should take part in regular PA and that PA and exercise prescription should be incorporated into the management of stroke survivors (American Heart Association, 2014).

1.3 Physical activity post stroke

1.3.1 Physical activity in acute stroke unit

Mobilising within 24 hours of admission to an ASU has now become standard care (The AVERT Trial Collaboration Group, 2015). The promotion of early mobilisation in the acute phase of stroke is now a factor which differentiates an ASU from a general medical ward (Indredavik et al, 1999). However, there is a lack of evidence to demonstrate the PA patterns of those patients who are discharged directly home from the ASU, who have relatively mild deficits post stroke and do not require the intensity of an inpatient rehabilitation facility.

Despite the introduction of early mobilisation policies within ASUs, PA patterns in the acute stroke setting have been investigated and demonstrate that stroke patients are largely inactive one week post stroke (Bernhardt et al, 2008). In the ASU Kramer
et al (2013) demonstrated by objective PA measurement (via accelerometer and behavioural mapping) that patients (n=16) spend 2% of the day in dynamic activity (standing and walking). Kunkel et al (2015) demonstrated that patients (n=61) spent 2% of recorded time walking. However, the accelerometer was only attached to participants for six to seven hours/day. In a behavioural observational study Skarin et al (2013) demonstrated that participants (n=104) spent on average 13% of the observed time in standing or walking. The higher percentage of PA compared to other studies may be in response to the investigators presence and may have resulted in performance bias. To measure PA in the first seven days following stroke and TIA Strommen et al (2014) used a cohort observational study design. Their recruitment selection was unclear and could have led to recruitment bias. The authors demonstrated that there was a significant relationship with PA and increasing stroke severity, as measured by the Scandinavian Stroke Scale (p<.0001) and increasing age (p=.0002). As age and stroke severity increased, total activity counts decreased. However, of the 126 patients included in the study, 57 had an ischaemic stroke and only 11 participants had accelerometer recordings for a full six to seven days. No reason was given for this but it was reported that participants wore the activity monitor until discharge and the mean recording time was 47 hours (range 2 – 167 hours).

1.3.2 Physical activity in sub-acute stroke

Within the first month following a stroke, Kramer et al (2013) demonstrated that stroke patients do not increase their level of PA. At two time points (median 5.5 and 27 days post stroke) the authors demonstrated by objective PA measurement (dual
axial accelerometer) that the median difference in percentage time spent in dynamic activity was only 2%. In the same time period the mean difference in time spent sitting was -2%. However, the generalisability of the results is poor due to the small numbers (n=16) that had data from both time points, heterogeneity of participants with regards stroke type (haemorrhagic n=5, ischaemic n=11), stroke severity as measured by NIHSS (mild n=9, moderate n=5, severe n=2) and discharge location from the ASU (home n=2, rehabilitation facility n=14). The level of therapy patients received was not recorded nor their cognitive status which would influence a patients level of PA. It is not known whether discharge location had an impact upon PA levels.

It has been noted that stroke patients expend higher amounts of energy than matched non stroke peers possibly due to pre-existing cardiovascular disease, spasticity or mechanical inefficiency (Daniellson et al, 2007; Billinger et al, 2014). Moore et al (2013) demonstrated that 31 individuals, one week post stroke took 5040 less steps than age, sex and body mass index matched controls. When energy expenditure was expressed as Metabolic Equivalent of Task (METs) it was found that stroke patients expended 23% less energy that their matched peers. Therefore, despite having an increased energy requirement for walking, stroke patients expend less energy than their peers.

### 1.3.3 Physical activity in chronic stroke

Despite having the ability to mobilise independently, it has been shown that stroke patients with mild deficits post stroke are not physically active in the community (Rand et al, 2009). Upon converting accelerometer data into energy expenditure,
Rand et al (2009) found that only 18% participants (n=4) included in the study reached the higher levels of recommended intensity of PA (286kcal/day). However this study did not adjust for independent variables such as age or cognitive deficits post stroke, which may have had an influence upon PA. The sedentary trend for stroke patients discharged from hospital was also highlighted by Tieges et al (2015) who used accelerometers to measure PA in a total of 31 participants at one, six and twelve months post stroke. It was demonstrated that the median time per day spent in sedentary behaviour at the three time points were: 19.9 hours (IQR 18.4 – 22.1 hours), 19.1 hours (IQR 17.8 – 20.8 hours) and 19.3 hours (IQR 17.3 – 20.9 hours). They also demonstrated that sedentary bout lengths were longer for every year increase in age (p=.02). However, it was not stated how much rehabilitation participants received (if any).

When monitoring the same patients over three years Kunkel et al (2015) demonstrated that there was a small but significant increase in time spent walking (p=.028) and a significant decrease in time spent sitting (p=.001), as measured by uniaxial accelerometer over a period of six to seven hours/day. Due to methodological flaws, only 15 of the 86 participants recruited had data for the four time points throughout the study. The four time points were: in-hospital; and at one; two and three years post-stroke. Examination of the raw data of the 15 completed data sets revealed heterogeneity between participants. The percentage of active time increased between in-hospital and year one assessment for 14 participants. While there was a significant (p=.03) increase in the overall percentage of time active between the four time points only four participants had increased the amount of active time between year one and year three. For the 37 participants with data at year three, the mean percentage of time spent in lying or sitting was 73%, standing was
9% and walking was 9%. The authors did not identify inclusion/exclusion criteria or stroke severity which may have accounted for the heterogeneity of participants.

1.3.4 Steps per day post stroke

Chronic stroke survivors are less physically active than recommended. A total of 10,000 steps per day is the recommended number of steps an adult should take to benefit health (Tudor-Locke et al, 2011). In a small (n=11), heterogeneous post-stroke population Haeuber et al (2004) demonstrated that none of the participants reached 10,000 steps/day. The average number of steps/day over a 48 hour period was 3021 +/- 2042 in the study. However, the generalisability of the findings is limited due to the variability of results (as seen in the large standard deviation) and small sample size. Although measured, the authors did not identify whether there was a correlation between cognitive status (as measured by Mini Mental State Examination), depression (Centre for Epidemiologic Studies-Depression screen) and PA. Paul et al (2015) found that chronic (more than four years post stroke) survivors took an average of 4035 steps/day. Their sample of 22 participants had variable levels of gait ability. Three required a wheelchair for longer distances and it was not stated whether any participants required assistance or supervision to mobilise. This variable may place limitations on an individual’s freedom to mobilise. Low step count was reiterated by Moore et al (2013) who demonstrated that patients (n=25) six months post stroke took an average of 5927 +/- 4091 steps/day. This was despite all participants having the ability to mobilise independently.
1.3.5 Exercise intensity post stroke

It has been demonstrated that stroke survivors have low endurance for exercise as shown by decreased VO2max of between 26 – 87% of matched healthy peers (Smith et al, 2012). This poor cardiovascular fitness often results in higher levels of disability (Darden et al, 2013). A meta-analysis of 11 randomised controlled trials by Stoller et al (2012) concluded that cardiovascular exercise results in significant improvements for stroke survivors. The pooled results favoured the cardiovascular exercise intervention group rather than the control for improving walking endurance (as measured by the Six Minute Walking Test) and aerobic capacity (as measured by VO2peak data). The control group received “usual care” which did not include any endurance training. Due to the heterogeneity of functional measures used across the studies it was not possible to pool functional outcomes. Two studies used the Barthel Index to measure for functional improvements but found no significant difference between groups. Nine of the 11 studies used cycle ergometry or treadmill training as the method for aerobic exercise which may account for the lack of improvement in function. This highlights the importance of including task orientated functional exercises in a rehabilitation programme.

A step rate greater than 80 steps/minute is considered a moderate intensity of PA (Paul et al, 2015; Manns & Baldwin, 2009). While sedentary activity is detrimental to health, the intensity of PA is an important consideration in exercise prescription (Billinger et al, 2014). Either 20 – 60 minute sessions on at least three days per week or shorter (10 – 15 minute) repeated bouts of moderate intensity sessions are recommended to improve cardiovascular fitness in stroke survivors – see Table 1.0 reproduced from Billinger et al (2014). When compared to age and gender matched controls Paul et al (2015) found that stroke survivors spent significantly less time
moderately or vigorously physically active. The stroke survivors spent significantly more of their time at low intensity levels of PA.

Table 1.0 Summary of Exercise/Physical Activity Recommendations for Stroke Survivors (Billinger et al, 2014).

<table>
<thead>
<tr>
<th>Setting/mode of exercise</th>
<th>Goals/Objectives</th>
<th>Prescriptive Guidelines: Frequency/Intensity/Time</th>
</tr>
</thead>
</table>
| Hospitalisation and early convalescence (acute phase)        | • Prevent deconditioning, hypostatic pneumonia, orthostatic intolerance, and depression  
  • Evaluate cognitive and motor deficits  
  • Stimulate balance and coordination | 10 – 20 bpm increases in resting HR; RPE =11 (6 – 20 scale); frequency and duration as tolerated, using an interval or work-rest approach |
| • Low-level walking, self-care activities                    |                                                                                  |                                                                                         |
| • Intermittent sitting or standing                           |                                                                                  |                                                                                         |
| • Seated activities                                          |                                                                                  |                                                                                         |
| • Range of motion activities, motor challenges               |                                                                                  |                                                                                         |
| Inpatient and outpatient exercise therapy or “rehabilitation” | • Increases walking speed and efficiency  
  • Improve exercise tolerance (functional capacity)  
  • Increase independence in activities of daily living (ADL’s)  
  • Reduce motor impairment and improve cognition  
  • Improve vascular health and induce other cardioprotective benefits (e.g. vasomotor reactivity, decrease risk factor) | 40-70% VO2 reserve or HR reserve; 55-80% HR max; RPE 11-14 (6-20 scale)  
  • 3-5 days per week  
  • 20-60 minute session (or multiple 10 minute sessions)  
  • 5 – 10 minute of warm-up and cool-down activities  
  • Complement with pedometers to increase lifestyle physical activity |
| Aerobic                                                       |                                                                                  |                                                                                         |
| • Large-muscle activities (e.g. walking, graded walking, stationary cycle ergometry, arm-leg ergometry, functional activities seated exercises, if appropriate) |                                                                                  |                                                                                         |
### Muscular strength/endurance
- Resistance training of UL extremities, trunk using free weights, weight-bearing or partial weight-bearing activities, elastic bands, spring coils, pulleys
- Circuit training
- Functional mobility
- Increase muscle strength and endurance
- Increase ability to perform leisure-time and occupational activities and ADL’s
- Reduce cardiac demands (i.e. RPP) during lifting or carrying objects by increasing muscular strength, thereby decreasing the percentage MVC that a given load represents
- Increase range of movement of involved segments
- Prevent contractures
- Decrease risk of injury
- Increase ADL’s
- Improve balance, skill reacquisition, quality of life, and mobility
- Decrease fear of falling
- Improve level of safety during ADL’s

### Flexibility
- Stretching (trunk, upper and lower extremities)
- Static stretches; hold for 10-30 seconds
- 2-3 days per week (before or after aerobic or strength training)

### Neuromuscular
- Balance and coordination activities
- Tai chi
- Yoga
- Recreational activities using paddles/sports balls to challenge hand-eye coordination
- Active-play video gaming and interactive computer games
- Use as a complement to aerobic, muscular strength/endurance training, and stretching activities
- 2-3 days per week

### Legend:
BPM: beats per minute; RPE: rate of perceived exertion; ADL’s: activities of daily living; HR: heart rate; Max: maximum; Min: minutes; UL: upper limb; RPP:
rate pressure product; MVC: maximum voluntary contraction; 1RM: 1 repetition maximum; ROM: range of movement.

1.4 Barriers to physical activity post stroke

1.4.1 Medical instability post stroke

Prolonged bed rest is no longer advocated for the management of acute stroke due to the deleterious effects on many body systems (Harper and Lyles, 1988). However, cardiovascular instability, such as cardiac arrhythmia’s, angina or systolic blood pressure >250mmHg or diastolic >115mmHg would terminate any PA and require medical assistance (Billinger et al, 2014). The results of the A Very Early Rehabilitation Trial (AVERT) study demonstrated that very early mobilisation may be harmful for patients following a large stroke or haemorrhage (The AVERT Trial Collaboration Group, 2015). Therefore only patients with mild ischaemic stroke were considered for inclusion in this study.

It has been recommended that stroke survivors who may be at risk of exertion-related cardiovascular event undergo exercise testing before embarking upon a vigorous exercise program. Otherwise it is recommended that stroke survivors exercise at 11 – 12 on the Borg Scale of Perceived Exertion, or at the patient’s resting heart rate plus 20 bpm and electrocardiogram (ECG) monitoring (Billinger et al, 2014). Due to the lack of exercise testing in this study, participants were advised to exercise at a moderate intensity and to stop if feeling unwell. All participants were seen by their consultant and deemed appropriate to participate in PA. They were
recommended to undertake short (ten minute) bouts initially, repeated throughout the
day, and to increase if tolerated to 30 minutes. It was also recommended that they
should be an increase in daily lifestyle activity and spend less time sedentary, as per
recent guidelines (Billinger et al, 2014).

1.4.2 Non-physical barriers

Non-physical post stroke symptoms may limit a stroke survivor’s ability to
participate in PA. Reports of fatigue post stroke range from 38% to 77% and it may
be a self-perpetuating cycle of physical deconditioning generated by inactivity
(Saunders et al, 2014). To date there have been no trials which have demonstrated
meaningful interventions for the management of fatigue but it is a necessary
consideration in exercise prescription (Wu et al, 2015).

Depression occurs in ≥30% of the post stroke population (Hackett et al, 2014). A
Cochrane review of physical fitness post stroke was inconclusive in making
recommendations for exercise to treat depression post stroke due to a paucity of
good quality trials and further research is recommended (Saunders et al, 2013). A
total of ten trials assessed the benefit of cardiorespiratory training, resistance training
or both in their studies. However pooled results were not possible due to the
heterogeneity of interventions and outcome measures (Saunders et al, 2013). Using
the Hospital Anxiety and Depression Scale (HADS) White et al (2014) assessed
anxiety and depression at four time points (three, six, nine and 12 months) in the first
year following stroke. Anxiety was more prevalent (47% of cases) at initial
assessment (while in hospital post stroke) but lessened over time. Although the rate
of depression was lower (22% at initial assessment) it was more likely to persist one
year post stroke, and was associated with baseline anxiety, low social support and limited community participation (White et al, 2014). These findings were reiterated by Nicholson et al (2014) who, in their qualitative study reported that stroke survivors’ negative beliefs about their capabilities and the influence of social interactions presented as barriers to PA.

Other reported barriers to PA and exercise training post stroke include poor health, lack of motivation, fear (of falling or recurrent stroke), reduced self-efficacy and lack of resources or support (accessing or paying for classes) (Simpson et al, 2011). These findings were also reported in a qualitative study by Nicholson et al (2014) which used 1:1 interviews to evaluate barriers to PA post stroke. They reached data saturation after 13 participants. As participants were volunteers to the study, recruitment bias may have led to poor generalisability. It was not stated the amount of rehabilitation each participant had received post stroke or their level of PA upon recruitment to the study. All participants could mobilise independently and were a median of 345 days post stroke (IQR 316 – 366). The barriers to PA that emerged as themes in the study were: lack of support from either professionals or family, reduced self-efficacy and the feelings of fear, fatigue or pain following PA.

A review of six qualitative studies by Nicholson et al (2012) identified environmental factors such as access, transport and cost as barriers to participation in PA post stroke. Stroke related impairments, embarrassment and fear of recurrent strokes were also highlighted as barriers to participation in PA. Highlighting the importance of appropriate education from health professionals, a lack of knowledge about how to exercise and the benefits of PA post stroke were also identified. Data from 174 participants was used in the review although it was not reported the levels
of impairments participants had acquired from their stroke. Only three of the six articles reviewed reported time since stroke which was greater than six months.

Many of these non-physical barriers to participation to PA can be addressed through a comprehensive rehabilitation programme that encompasses health education, PA and health education for self-management and lifestyle modification. Early results from a trial that compares such a comprehensive rehabilitation programme over eight weeks with a one-off two hour didactic stroke education class has reported improvement in compliance with exercise compared to the control group (p=.005). Data at one-year follow up is currently being analysed (Lennon et al, 2015). This will establish whether this comprehensive rehabilitation program is effective at making long-term change to the lives of stroke survivors.

### 1.4.3 Pre-stroke comorbidities

Pre-existing cardiovascular comorbidities in addition to physiological changes in body tissues and organs in the elderly may present as barriers to PA in stroke survivors (Chodzko-Zajko, 2009). As the incidence of stroke increases with age more patients may be older and have more difficulty engaging in PA. At 80 plus years of age the rate of stroke in the American population is 15.8% for men and 14% for women. This compares with a rate of 6.1% of men and 5.2% of women in the 60-79 year old age category (Mozaffarian et al, 2015). A review of 132 studies involving 5987 community dwelling participants who were over 60 years of age reported a major theme of physical limitations as a barrier to PA. The limitations reported included muscle aches, concerns about falling and comorbidities including urinary incontinence (Franco et al, 2015). As the review by Franco et al (2015) also
highlighted in their study that participants were not aware of the benefits of PA, it is important that patients are counselled in its’ benefits. Advancing age is not a contraindication for appropriate PA and a mixture of aerobic and resistance exercise is recommended for the older adult to minimise the effect of the physiological ageing process and increase life expectancy (Chodzko-Zajko, 2009).

1.5 Do self-reported and objective measurement of physical activity correlate?

A disconnect between self-reported and objective measures of PA has been demonstrated (Schuna et al, 2013). There tends to be a pattern of overestimation of PA with self-reporting questionnaires (Mozaffarian et al, 2015). Secondary analyses of data from 3,725 participants in an American longitudinal study showed that participants who self-reported >150 minutes of moderate to vigorous PA per week in reality accumulated 57 minutes. However, the study demonstrated that participants who reported higher levels of PA engaged in more PA than those in the less active category (Schuna et al, 2013). In healthy Swedish adults Ekelund et al (2006) found the IPAQ over-estimated time spent in PA although demonstrated 77% specificity of those who met the PA guidelines of 30 minutes/day when compared with accelerometer measurement. Despite this, when walking was included in the analysis of their results, Ekelund et al (2006) demonstrated that there was significant difference between self-reported and objective levels of PA. Therefore while it has been established that the IPAQ can detect recommended levels of PA and is useful for categorising individuals into activity categories, it lacks agreement with objective measurement for total PA levels.
1.6 Summary of review

Stroke places a significant emotional, financial and physical burden on stroke survivors and the wider society. In an ageing population it is imperative that rehabilitation and secondary prevention for stroke survivors are optimised. Decreased PA is in itself a risk factor for stroke and participation in regular PA is recommended to reduce the risk of many of the most common stroke risk factors such as hypertension and increased waist-hip ratio. It is widely documented that stroke survivors are less active than their peers and even those that have the ability to be regularly physically active are not. This study will address the time period when patients are admitted directly home from the ASU and those who have minimal deficits post stroke. A number of barriers to PA post stroke have been identified and physical ability is only one facilitator. A disconnect exists between an individuals perceived level of PA and their measured level in non-stroke groups. This study will establish whether this disconnect exists in a stroke population.

To the authors knowledge the correlation between the IPAQ and objective measurement of PA has not been established in this cohort. This study will aim to bridge this gap in the literature. The overall aim of this study is to quantify levels of PA in individuals with acute stroke following discharge from hospital. This study will establish the relationship between self-reported and objective levels of PA. The study also aims to identify whether age, cognition, balance, depression, anxiety, self-efficacy or functional ability have an influence upon PA post stroke.
CHAPTER 2 – METHODS

2.0 Aim of the study

The aim of the study is to quantify self-reported and objective levels of PA in people post discharge following a stroke.

2.0.1 Secondary aims

- To establish levels of self-reported and objective PA after acute stroke following discharge from hospital.
- To determine if self-reported measures of PA correlate with objective measurement of PA.
- To determine if age, cognition, balance, self-efficacy, function, anxiety and depression influence levels of PA following a stroke.

2.1 Study design

This is a descriptive cohort study and the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) (Vandenbroucke et al, 2007) standardised reporting guidelines were used to conduct and report the study.
2.2 Participants

Every patient admitted to University Hospital Limerick (UHL) with a confirmed diagnosis (by treating consultant) of ischaemic stroke was considered for inclusion in the study. It was intended that stroke severity be measured by the National Institutes of Health Stroke Scale (NIHSS) upon admission. A medical chart review revealed that this was not routinely carried out by the admitting doctor, therefore, stroke location was described and a measure of dependency was included – the Barthel Index.

2.2.1 Participant recruitment

Participants were recruited by consecutive admissions of stroke to the ASU in UHL. To select appropriate participants inclusion and exclusion criteria were applied. Of those deemed eligible by the inclusion/exclusion criteria the study gatekeeper approached those patients and provided them with an outline of the study’s aims and objectives. The patient information leaflet was issued to potential participants at this time (Appendix 1). The gatekeeper was the Clinical Nurse Specialist in Stroke who routinely reviews every patient admitted to UHL following a stroke. The gatekeeper agreed to the role and was fully informed of the research project. This enabled the gatekeeper to provide an outline of the study to all potential participants.

Once agreeable at that point the primary investigator (PI) (EH) approached the patient and provided any further details of the study which were required. The patient was offered a 24 hour cooling off period to consider their participation. Once the patient agreed to participate and signed the consent form, the PI carried out the
initial assessment. If the patient did not consent to participate in the study they received routine treatment from the treating physiotherapist. The treating physiotherapist was either the PI or a staff grade physiotherapist working in the area of stroke. The caseload of patients in the ASU was distributed between both physiotherapists on a daily basis.

2.2.2 Inclusion criteria

• Informed written consent.
• Aged 18 years or older.
• Confirmed diagnosis of ischaemic stroke by their treating consultant.
• Medically stable (systolic blood pressure <250mmHg or diastolic <115mmHg; resting heart <100bpm).
• Independently mobile with or without a walking aid.
• For discharge directly home from the ASU.
• Mini Mental State Examination Score (MMSE) greater than 23 out of 30.

2.2.3 Exclusion criteria

• Haemorrhagic stroke.
• Symptoms attributable to diseases other than ischaemic stroke (e.g. brain tumour, dementia).
• Ulcers or skin diseases in the area of accelerometer placement.
• Allergic skin reactions to the accelerometers.
Unable to achieve informed consent from the patient due to diminished capacity or communication deficits.

- Resident in a nursing home prior to the stroke.

### 2.3 Sample size estimation

There were no similar studies identified that reported levels of correlation between objective measures and self-reported measures of PA in people with acute stroke. Therefore, the sample size estimation was based on outputs provided by a similar study in community dwelling adults with chronic stroke, where moderate correlations (Pearson correlations ranging from 0.6 to 0.73) were reported between objective step counts and other measures of PA (Rand et al, 2009). A moderate correlation (r=0.6) was estimated between step counts and self-reported levels of PA in this study population. Using a two sided test, 5% significance level test (α=0.05) with 80% power (β=0.2), the required sample size was approximately 37 individuals with acute stroke (n=37). Accounting for an expected 20% attrition, the final sample size was increased to 44 participants.

### 2.4 Ethical considerations

The study was submitted to the UHL Research Ethics Committee for approval on the 8th June 2015 (Appendix 2). Approval was granted on the 22nd June 2015 (Appendix 3). This ethics approval was accepted by the Royal College of Surgeons in Ireland (RCSI) Ethics Committee on the 4th November 2015 (Appendix 14). Recruitment commenced on the 1st October 2015. All consultants whose patients may be
participants in the study were informed of the study (Appendix 4). All participants General Practitioner’s (GPs) were also informed of their patient’s participation in the study (Appendix 4).

Informed signed consent was obtained from every participant. All participants were informed that their involvement was voluntary and that they could withdraw from the study at any point and it would not affect their rehabilitation.

There was no identifiable personal information on any data collection forms or outcome measures. Every participant was issued with an identification number which identified each outcome measure and data sheet. Participant’s names, identification number, date of birth and telephone number were stored on a password protected spreadsheet to which only the PI had access. All written documentation, unused and returned activity monitors were kept in a locked filing cabinet in the physiotherapy department to which only the PI had the key.

There was a slight risk of a fall during the assessment as participants balance was challenged. All assessments were carried out by a qualified senior physiotherapist (the PI) who maintained close supervision throughout. In the event that a participant felt unwell during the assessment, a medical review was requested if the symptoms persisted on stopping the assessment. As participants were advised to undertake regular PA, they were informed regarding the effects of exercise (sweating and increased heart rate). They were advised to build up their levels of PA and stop if feeling unwell and seek medical assistance. No adverse incidents were reported during the study.
2.5 Procedure

As per standard physiotherapy care post stroke patients were seen on the ASU by the treating physiotherapist. A standard neuromuscular assessment was carried out, any impairment was identified and patients were issued with a personalised home exercise plan which included advice regarding recommended levels of PA. The home exercise program was based on the findings of the neuromuscular assessment and the PA recommendations from The American Heart Association Guidelines (Billinger et al, 2014) (See summary table in Appendix 5). As standard care all patients were issued with the Irish Heart Foundation information booklet on PA (Appendix 6).

Potential participants who met the inclusion criteria were approached by the gatekeeper and recruited as soon as possible into their admission to hospital as some patients may have been discharged home once their medical investigations were completed. If they agreed to participate following the cooling off period a one-off assessment was completed by the PI as illustrated in Figure 1.
2.6 Assessments

Figure 2.1 illustrating the sequence of assessment to ensure ease of repeatability.

- Standard neuromuscular assessment
- International Physical Activity Questionnaire
- Stroke Self-Efficacy Questionnaire
- Barthel Index
- Berg Balance Scale
- Hospital Anxiety and Depression Scale
- Mini Mental State Examination

The PI completed the assessment and it took approximately 45 minutes.

2.6.1 Demographics

A medical chart analysis was conducted to ascertain the demographic details of participants. Participant date of birth, gender, stroke site, pre-stroke mobility status was collected and added to the data collection sheet.
2.6.2 Primary research measure

2.6.2.1 Activity monitor/accelerometer

The primary outcome measurement tool was an activity monitor/accelerometer (ActivPAL) (Figure 2.0). It weighs 15 grams and is 7mm thick. It measures 53 x 35mm in length and width. Using proprietary algorithms, (Intelligent Activity Classification™), it classified an individual's free-living activity into periods spent sitting, standing and walking. It was worn on the thigh of the non-affected leg for seven days using a waterproof dressing. The activity monitor was applied to the non-affected leg by the PI on the participant’s day of discharge home. Participants were instructed to wear the activity monitor at all times during the first seven days on discharge home from hospital, moving without consideration for the equipment. Participants were issued with additional waterproof dressings on discharge should the original dislodge and participant’s were taught how to apply the waterproof dressing. The activity monitors were supplied by the University of Limerick.
Accelerometers are objective measurement tools which can be uniaxial, biaxial or triaxial depending upon their sensitivity to one, two or three orthogonal planes, respectively (Gebruers et al, 2010). Accelerometers have been used in stroke research to investigate upper limb function (Uswatte et al, 2006), motor recovery (Siekierka-Kleiser et al, 2006), PA patterns (Strommen et al, 2014), sedentary behaviour (Moore et al, 2013) and function (Gebruers et al, 2010). However, some of these studies (Kramer et al, 2013; Moore et al, 2013) used uniaxial or biaxial accelerometers which have been shown to be less sensitive than triaxial (Gebruers et al, 2010).

In a reliability study of a triaxial accelerometer in a community dwelling stroke population Rand et al (2009) demonstrated excellent day to day reliability. Thirty-seven of the 40 participants had a mild deficit post stroke. As a result they found no difference in reliability when the accelerometer was placed on either hip. However, it has been recommended (Gebruers et al, 2010), that the accelerometer be placed on
the unaffected leg due to the asymmetrical gait post stroke or in the case of sensory disturbance (Kramer et al, 2013).

2.6.3 Secondary measures

Other outcome measures were employed to establish the participant’s status across the domains of impairment, disability and function (World Health Organisation, 2002). The Berg Balance Scale (BBS) assessed balance. To screen for cognitive impairment the Mini Mental State Examination (MMSE) was used. To screen for depression/anxiety the Hospital Anxiety and Depression Scale (HADS) was used and the Stroke Self-Efficacy Questionnaire (SSEQ) evaluated the participant’s degree of confidence in their ability to perform tasks following stroke. The Barthel Index (BI) was completed as a measure of functional ability.

2.6.3.1 International Physical Activity Questionnaire (IPAQ)

The IPAQ (Appendix 7) is a self-reported measure of physical activity and relies on user recall over the previous seven days. It has been shown to be as reliable as other self-reported measures of physical activity (Craig et al, 2003). As the second IPAQ was completed via telephone, the IPAQ telephone version was used which has been shown to demonstrate very high agreement with face to face measurement (Hallal et al, 2010).

Data collected from the IPAQ is converted to METs (Metabolic Equivalent Tasks) using a formula. Each subcategory on the IPAQ uses a different formula to calculate the METs. To calculate METs for walking the following formula is used:
“walking MET-minutes/week = 3.3 * walking minutes * walking days”.

This provides a continuous score which allows comparison with objective measurement (Institut Ferran, 2004). One MET is the amount of oxygen consumed while sitting at rest and is equal to 3.5ml O2 per kg body weight/minute (Jette et al, 1990).

There is no gold standard self-reporting PA questionnaire and to the author’s knowledge, none designed for the stroke population. Self-reported PA questionnaires rely upon the recall, honesty and insight of the patient (Craig et al, 2003). They are used in large-scale cohort studies due to their low cost and accessibility (Lee et al, 2011). The IPAQ-short form was developed and validated across 12 countries and is widely used which allows comparison with other studies. The short and long versions display reasonable agreement ($\rho=0.67$ CI 0.64 - 0.70) and the reliability of the telephone administered versus the self-administered version is similar (Craig et al, 2003). As it breaks PA down into vigorous, moderate and walking it can account for leisure and domestic PA. Other commonly used PA questionnaires available but were unsuitable for this study include: Physical Activity Scale for the Elderly (not suitable for <65 years of age) (Washburn et al, 1993); Yale Physical Activity Survey (for adults <65 years of age) (Young et al, 2001); Stanford Seven-day Physical Activity Recall (not validated for telephone administration) (Young et al, 2001); Human Activity Profile questionnaire (It consists of 94 items asks respondents to indicate if they are still doing the activity, if they have stopped or whether they have ever completed the task. The large number of items was deemed excessive participant burden) (Teixeira-Salmela et al, 2007).
Each participant completed the IPAQ while in hospital to establish pre-hospital admission level of PA and it was repeated on the final day of wearing the activity monitor.

2.6.3.2 Mini Mental State Examination (MMSE)

The MMSE (Appendix 8) was chosen as an assessment of cognitive function as it has been shown to be sensitive and specific to screen for cognitive impairment in post-stroke dementia, multi-domain impairments and any degree of cognitive impairment. It takes ten minutes to complete, is freely available and minimal training is required to complete it. A cut off score of 23/30 has been shown to detect cognitive impairment and was used as the cut off point for this study (Burton and Tyson, 2015).

2.6.3.3 Hospital Anxiety and Depression Scale (HADS)

The HADS (Appendix 9) screens for mood disorders in non-psychiatric patients. It has 14 items in two subscales: anxiety and depression. Each item can be scored from 0 - 3. In each subsection a total score of 21 is available. A score of 0 – 7 indicates normal level of anxiety or depression, 8 – 10 is borderline abnormal and 11 – 21 is abnormal. It is a self-administered questionnaire which takes two to five minutes to complete and is validated in stroke patients (Turner et al, 2012).


**2.6.3.4 Berg Balance Scale (BBS)**

The BBS (Appendix 10) measures the patient’s ability to maintain balance while performing various functional movements. It is a 14-item scale that takes ten minutes to complete and has demonstrated excellent internal consistency (Cronbachs α=0.92 – 0.98) (Mansfield et al, 2013). Items are scored from 0 – 4 and a score of four represents independence with the task. The maximum available score is 56 and scores of 42- 56 represent good balance (Blum and Korner-Bitensky, 2008).

**2.6.3.5 Barthel Index (BI)**

The BI (Appendix 11) was used as a baseline measurement of functional ability. This 10 item measure is widely used in stroke rehabilitation and includes tasks such as stair climbing and transfers. It has been demonstrated excellent reliability and validity in measuring functional ability of patients with acute stroke. A score of 100 indicates independence with functional tasks and a score of 0 indicates maximum dependency (Hseuh et al, 2002).

**2.6.3.6 Stroke Self-efficacy Questionnaire (SSEQ)**

The SSEQ (Appendix 12) is a 13-item self-report questionnaire which has shown good internal consistency (ICC >0.87) and criterion validity and is recommended for use in stroke research as it gives an indication as to whether the participant believes they can take part in rehabilitation (Riazi et al, 2014). It asks the participant to rate their confidence in completing 13 functional tasks (e.g. walking indoors, outdoors...
and exercising) on a scale of one to ten, with a score of 10 indicating full confidence in the task (Mansfield et al, 2013).

2.7 Data collection

At the point of recruitment to the study each participant was assigned an identification number. All data forms contained this code pertaining to that individual. The participant was only identifiable by this code during data input and analysis.

2.7.1 Data storage

Hard copies of the assessment forms (demographics, BBS, IPAQ, HADS, BI, SSEQ) and the activity monitor data were retained for the duration of the study and the results were transferred to electronic data and stored on an encrypted file. Upon completion of the study all hard copies were shredded.

All hard copies of data forms were stored in a secure locked filing cabinet by the PI in the Physiotherapy Department, UHL. Data was entered to a study data file. Computer files were stored on the hard drive of a password protected desktop computer by the PI.

2.8 Statistical methods

Activity monitoring data was converted into time spent sitting/lying, standing and walking. MET’s per day were also used from the activity monitor to allow
comparison with the IPAQ. Walking was converted into steps to allow comparison to other studies. Shapiro-Wilk normality test was used to test the normality of data. Descriptive statistics were used to describe the study population and the output of the outcome measures using means and standard deviations when relevant. Levels of objective PA were compared to the IPAQ using the Spearman Rank Correlation coefficient. The association between the dependent variable (activity levels in minutes) and predictors: age, HADS (anxiety and depression) score, BBS score, function (BI) and self-efficacy were examined using a mixed linear regression model. Significance was set at p<0.05. Data was analysed using SPSS (version 22.0, Chicago, Illinois).
CHAPTER 3: RESULTS

3.0 Introduction

The primary aim of the current study was to quantify self-reported and objective levels of PA in people post discharge following a stroke. Additionally, the study aimed to identify the correlation between objective and self-reported measures of PA in the acute stroke population who are discharged home directly from the ASU. It was hypothesised that there would be a moderate correlation between the accelerometer data and the International Physical Activity Questionnaire (IPAQ). The study also aimed to identify factors which may have had an impact upon PA in the acute stroke population.

3.1 Recruitment

Twenty-one subjects were recruited to the study. Recruitment commenced on the 1st October 2015 and finished on the 28th February 2016. Over the period of the study, 164 consecutive patients were admitted to UHL with a primary diagnosis of stroke. Of those, 31 suffered a haemorrhagic stroke, 133 suffered an ischaemic stroke, 12 died as a result of the stroke, 73 were transferred to a rehabilitation facility or another hospital for ongoing care, two declined to participate in the study and 6 were discharged home on days when the PI was unavailable to recruit.

A total of 43 patients were discharged directly home from the ASU. Of these 14 did not meet the inclusion criteria. Two patients recorded an MMSE score of <23/30, three patients underwent carotid endoarterectomy surgery and were discharged directly
home by the surgical doctors, five patients suffered haemorrhagic strokes, two patients displayed cardiovascular instability and were not appropriate to engage in regular PA until their review with their cardiologist, one patient did not speak English and could not provide informed consent and one patient was discharged home with the care of the palliative care team. Therefore 21 participants were included in the study. Figure 3.1 displays the flow of participants through the study.
Figure 3.1 Flow diagram to illustrate participants included and the reasons for exclusion.

164 patients admitted to UHL with acute stroke

- 31 suffered haemorrhagic stroke
- 133 suffered an ischaemic stroke

- 12 died as a result of their stroke
- 73 transferred to another hospital

- 36 were discharged directly to a nursing home
- 6 were discharged on days that the PI was unavailable to recruit

- 2 declined to participate
- 43 were discharged directly home from the ASU

- 14 did not meet the inclusion criteria
  - 2 had MMSE <23/30
  - 3 underwent carotid endocardectomy surgery
  - 5 suffered haemorrhagic stroke
  - 2 had cardiovascular instability
  - 1 was discharged home with palliative care
  - 1 did not speak English and could not provide informed consent

21 participants were recruited to the study

- 20 participants were included for analysis.
3.2 Description of the study group

The median age of the group was 65 years; the interquartile range (IQR) was 28 years. There were 17 males and four females recruited to the study. The median age for females was significantly younger; 47 years, (IQR 23 years) than the median for males; 72 years, (IQR 19 years).

Prior to their stroke 18 participants were living with family and three were living alone. This remained unchanged on discharge from the ASU. All female participants were living with family and 14 males lived with family. Three males were living alone. Prior to their stroke all participants (n=21) were independently mobile. Table 3.1 displays the baseline demographic variables among the group.

Table 3.1. Summary of baseline demographics (n=21)

<table>
<thead>
<tr>
<th></th>
<th>Median</th>
<th>IQR</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Total n=21)</td>
<td>65</td>
<td>28</td>
<td>36</td>
<td>85</td>
</tr>
<tr>
<td>Age (Female n=4)</td>
<td>47</td>
<td>23</td>
<td>36</td>
<td>65</td>
</tr>
<tr>
<td>Age (Male n=17)</td>
<td>72</td>
<td>19</td>
<td>39</td>
<td>85</td>
</tr>
<tr>
<td>Total n=21</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Living alone</td>
<td>3</td>
<td></td>
<td>With family</td>
<td>18</td>
</tr>
<tr>
<td>Male</td>
<td>17</td>
<td></td>
<td>Female</td>
<td>4</td>
</tr>
<tr>
<td>Independently mobile</td>
<td>21</td>
<td></td>
<td>Mobile with assistance</td>
<td>0</td>
</tr>
</tbody>
</table>
3.3 Stroke details

Sixteen participants had a left hemispheric ischaemic stroke and five had a right hemispheric ischaemic stroke. The stroke location was classified using the Oxford Stroke Classification (Smith et al, 2001). This classification breaks down cerebral infarction into total anterior circulation stroke (TACS), partial anterior circulation stroke (PACS), posterior circulation stroke (POCS) and lacunar syndromes (LACS). The breakdown of stroke types identified is detailed in Figure 3.2.

Figure 3.2. Stroke classification for all participants.

3.4 Physiotherapy intervention

While in hospital, all participants received routine care from their treating physiotherapist. This included a tailored exercise programme and advice regarding PA. For some participants this was a one off brief (45 minute) intervention. It was
not within the scope of this study or within the scope of the resources available to provide more regular interventions aimed at engaging patients more in PA while in hospital. When required, participants were referred to their local Primary Care Team for ongoing management of their impairments upon discharge.

3.5 Activity monitor/accelerometer

Of the 21 participant’s, one participant (participant ID 1) lost the accelerometer and therefore had no data. Another three participants’ accelerometers did not gather data for the full seven days due to insufficient battery. Seventeen participants’ accelerometers recorded data for seven days. Activity monitor data has been broken down into steps per day and MET’s per day for the remaining 20 participants.

The median number of steps taken per day as measured by the accelerometer was 4023 with an interquartile range (IQR) of 2724 steps (minimum 1745 – maximum 9824 steps/day). See Figure 3.3 for median steps per day for all participants who returned data on the accelerometer. Data from participant number 1 is not presented as there was no data available.

The median MET’s per day as measured by the accelerometer was 30.53 (IQR 1.45, minimum 26.83 – maximum 102.55).
3.6 Time spent sitting/lying, standing and stepping

The time spent in sitting/lying, standing and stepping was obtained from the activity monitors. The average time spent per day in each position, over a 24 hour period is displayed in Figure 3.4.

The median time spent in sitting or lying per day was 19 hours (IQR 2 hours), the median time per day spent standing was 2.76 hours (IQR 1.2 hours) and the median time spent stepping was one hour per day (IQR .56 hours).
Figure 3.4 Time spent per day sitting/lying, standing and walking for all participants

### 3.7 International Physical Activity Questionnaire

#### 3.7.1 IPAQ pre – stroke

In the week prior to their admission to the ASU the 21 participants reported median METs per day of 225 (IQR 761.79). Six participants self-reported vigorous PA on at least one day pre-stroke. Seventeen participants reported that between five and seven days pre-stroke they undertook moderate levels of PA (light lifting or housework) for at least ten minutes. Six participants reported walking at least five times per week pre stroke. Ten participants reported that they did not walk on any day for longer than ten minutes.
### 3.7.2 IPAQ seven days post discharge from ASU

Upon telephoning participants on day seven post discharge from the ASU, the median METs per day was reported as 118.93 (IQR 345.70). On day seven post discharge, four participants reported that they had not undertaken any walk for longer than ten minutes in the previous week. No participants reported undertaking any vigorous PA in the seven days post discharge from the ASU. Thirteen participants reported at least 30 minutes of moderate intensity PA or walking for longer than ten minutes over the previous seven days.

### 3.7.3 IPAQ pre-stroke and seven days post stroke

The median total MET’s for seven days pre-stroke was 1680 MET’s (IQR 5446). The median total MET’s for seven days post stroke was 840 MET’s (IQR 2243). A Wilcoxon Signed Rank Test revealed a statistically significant reduction (z=-1.96, p=0.05) in PA from pre-stroke self-reported levels of PA compared with seven days post discharge from the ASU. Fourteen participants reported engaging in less PA upon discharge home when compared to their pre-stroke levels of PA. Seven participants reported an increase in their levels of PA post stroke.
3.8 Secondary measures

3.8.1 Mini Mental State Examination

The Mini Mental State Examination was used as an assessment of cognition and as a screening tool to exclude participants who could not provide informed consent. The median score was 28 out of a maximum of 30 (IQR 3), indicating that all participants had a high level of cognitive function. Table 3.2 summarises median and IQR for all secondary measures.

3.8.2 Hospital Anxiety and Depression Scale

The Hospital Anxiety and Depression Scale (HADS) was used as a screening tool for mood disorders in the participants post stroke. It has two subsections: anxiety (HADS A) and depression (HADS D). A score of 0 – 7 indicates normal levels of anxiety or depression, 8 – 10 is borderline abnormal and 11 – 21 is abnormal. The median anxiety score was five (IQR 5) and the median depression score was four (IQR 5).

Sixteen participants displayed normal levels of anxiety, two participants were in the borderline category and three participants displayed abnormal levels of anxiety. In the depression subsection, one participant displayed borderline levels of depression and one participant abnormal levels of depression. The two participants with higher levels of depression displayed normal levels of anxiety. Table 3.2 summarises median and IQR for all secondary measures.
3.8.3 Berg Balance Scale

The Berg Balance Scale (BBS) was used to assess participants balance while carrying out functional tasks. A score of >45/56 indicates that an individual is physically capable of mobilising independently. The median score was 56/56 (IQR 4). Twelve participants recorded a maximum score of 56. No participant recorded a score of 45 or less. Table 3.2 summarises median and IQR for all secondary measures.

3.8.4 Barthel Index

The Barthel Index (BI) was used as a measure of participants’ functional ability. A maximum score of 100 indicates independence with functional tasks. The median score was 100 (IQR 3). Five participant’s needed minimal assistance with functional tasks. In all five of these cases the participant’s needed assistance on the stairs and one participant also needed some assistance in dressing tasks. Table 3.2 summarises median and IQR for all secondary measures.

3.8.5 Stroke Self-Efficacy Questionnaire

The Stroke Self-Efficacy Questionnaire (SSEQ) asked participants to report how confident they felt carrying out functional tasks post stroke. They were 13 items and participants ranked how confident they felt completing each item on a Likert scale of one to ten. A maximum score of 130 indicated that participants were fully confident in completing the named tasks. The median score was 128 (IQR 12). Table 3.2 summarises median and IQR for all secondary measures.
Table 3.2: Summary of secondary measures for all participants (n=21) with maximum available scores.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Median</th>
<th>IQR</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>MMSE</td>
<td>28</td>
<td>3</td>
<td>23</td>
<td>30</td>
</tr>
<tr>
<td>(Max 30, score range 0-30)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HADS A</td>
<td>5</td>
<td>5</td>
<td>0</td>
<td>17</td>
</tr>
<tr>
<td>(Max 21, Score range 0-21)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HADS D</td>
<td>4</td>
<td>5</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>(Max 21, Score range 0-21)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SSEQ</td>
<td>128</td>
<td>12</td>
<td>95</td>
<td>130</td>
</tr>
<tr>
<td>(Max 130, Score range 0-130)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BBS</td>
<td>56</td>
<td>4</td>
<td>47</td>
<td>56</td>
</tr>
<tr>
<td>(Max 56, Score range 0-56)</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>BI</td>
<td>100</td>
<td>3</td>
<td>85</td>
<td>100</td>
</tr>
<tr>
<td>(Max 100, Score range 0-100)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3.9 Objective versus self-reported physical activity

The relationship between objective levels of PA (as measured by accelerometer) and self-reported PA (as measured by IPAQ) was investigated using Spearman ranked correlation coefficient as the data were not normally distributed. There was a weak, inverse correlation between the two variables, \( r = -0.25 \), \( n=20 \), \( p=0.30 \) with higher levels of self-reported PA compared to objective measurement.

3.10 Predictors of physical activity

Upon univariable linear regression it was found that none of the secondary measures had a significant effect upon PA. No significant \( (p<0.05) \) association was found between the dependent variable (PA) and predictor variables: age \( (p=0.11) \); cognitive status \( (p=0.64) \); balance \( (p=0.12) \); function \( (p=0.54) \); pre-stroke PA \( (p=0.86) \); self-efficacy \( (p=0.39) \); anxiety \( (p=0.45) \) or depression \( (p=0.81) \). Table 3.3 summarises the results of the univariable linear regression.
Table 3.3 Summary of univariate linear regression results

<table>
<thead>
<tr>
<th>Independent variable</th>
<th>Beta</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>-.37</td>
<td>.11</td>
</tr>
<tr>
<td>Cognitive status (MMSE)</td>
<td>.11</td>
<td>.64</td>
</tr>
<tr>
<td>Balance (BBS)</td>
<td>.36</td>
<td>.12</td>
</tr>
<tr>
<td>Function (BI)</td>
<td>.15</td>
<td>.54</td>
</tr>
<tr>
<td>Pre-stroke PA (IPAQ)</td>
<td>.04</td>
<td>.86</td>
</tr>
<tr>
<td>Self efficacy (SSEQ)</td>
<td>.20</td>
<td>.39</td>
</tr>
<tr>
<td>Anxiety (HADS A)</td>
<td>.18</td>
<td>.45</td>
</tr>
<tr>
<td>Anxiety (HADS D)</td>
<td>.06</td>
<td>.81</td>
</tr>
</tbody>
</table>

3.11 Multivariate analysis

The two predictors (age and balance) that demonstrated a p value of <0.15 were entered into a multivariable model to examine if they displayed significance (McCowan et al, 2011).

The regression model demonstrated that the independent variables, age and balance (as measured by the BBS), were not found to significantly predict the dependent variable (PA) in this study, F(2, 17) = 2.27, p=0.13.
3.12 Summary of findings

Twenty-one participants were recruited to the study. All participants were physically capable of mobilising independently and did not display any sign of cognitive impairment. This study demonstrated that the median number of steps taken per day in an acute stroke cohort is 4023 steps. The study identified a weak inverse relationship between self-reported and objective measurement of PA. The study did not identify any variables that could predict levels of PA in this cohort.

The results of this study will be discussed in Chapter 4.
CHAPTER 4: DISCUSSION

4.0 Statement of principal findings

The aim of the current study was to quantify self-reported and objective levels of physical activity (PA) in people post discharge following a stroke. It was estimated that there would be a moderate correlation between self-reported and objective levels of PA. Objective measurement of PA demonstrated that individuals who, following a stroke are physically capable of PA do not partake in the recommended levels of PA. Additionally it was found that there is a poor correlation between self-reported levels of PA and objective levels of PA. The secondary aims of the study were to establish whether there were independent factors that affected participant’s level of PA post stroke. This study did not identify any factors which may have had an impact upon participant’s level of PA.

Twenty-one participants were recruited to the study over a five month period from a total number of 164 patients that were admitted to the ASU at University Hospital Limerick (UHL) with a primary diagnosis of stroke. Exclusion criteria eliminated 143 potential participants as the cohort of patients who were independently mobile and being discharged directly home were the focus of the study.

Eighty-one percent of the participants recruited to the study were male and most participants (n=18) were living with a spouse or family. This is higher than the rate of males admitted to the ASU at UHL, which is 56%. This may reflect the traditional role that female partners take in the care-giver role and make them available to care for their spouse on discharge home. The higher ratio of men to women is reflected in
a national audit where 57% of strokes nationally are male and 43% are female (Irish Heart Foundation/Health Service Executive, 2015). The median age in this study is lower than the national mean age of 73.3 years of stroke patients (Irish Heart Foundation/Health Service Executive, 2015). Older stroke patients carry additional comorbidities and may make them unsuitable to discharge directly home from hospital (Mozaffarian et al, 2015).

The age range of the participants ranged from 36 to 85 years with a median age of 65 years and no participant displayed any early signs of dementia or cognitive decline. The large age range may reflect recent research which reported that 24% of stroke cases are under 65 years which is an increase from 19% in 2008 (Irish Heart Foundation/Health Service Executive, 2015). Although age is a significant predictor of stroke (Mozaffarian et al, 2015), stroke is no longer an event suffered in old age and there have been significant improvements in stroke care through the National Stroke Program. The National Stroke Programme has facilitated the establishment of 26 Stroke Unit’s nationwide, which is an increase from one in 2008 and there are now 22 hospitals providing a 24/7 thrombolysis service (Irish Heart Foundation/Health Service Executive, 2015). There is less mortality associated with stroke, people are living longer following a stroke and suffering less disability (Irish Heart Foundation/Health Service Executive, 2015). This highlights the importance of secondary prevention in stroke and the importance of community reintegration and the fulfilment of an individual’s life following stroke.

Participants’ mobility status was unchanged following the stroke. All participants were independently mobile pre-stroke and remained so post-stroke. The median score for the Berg Balance Scale was 56/56. This indicates that all participants were physically capable of participating in PA without assistance. One participant
mobilised with the aid of a stick, all others did not use any aid. The median Barthel Index score was 100/100. These high scores indicate that the participants were high functioning and although not recorded, suffered strokes that left them with minimal (if any) physical deficits.

It was intended to record stroke severity via the National Institutes of Health Stroke Scale (NIHSS). This was not routinely administered on admission by the admitting Doctor so could not be accurately recorded. Therefore the level of medical intervention in the initial management of the stroke which may have had an impact upon the patients’ recovery is unknown. Interventions such as thrombolysis or thrombectomy may place a higher burden on patient’s recovery and make them more susceptible to fatigue due to the invasive nature of the interventions. Additionally the intensive monitoring of patients in the first 24 hours following thrombolysis may increase anxiety levels.

In this study, it was investigated whether age, previous level of PA, depression, anxiety, cognitive status, functional ability or balance had an impact upon PA post stroke. No association was found between the independent variables and PA. However due to the small sample size and heterogeneous population caution must be applied to the interpretation these findings.

4.1 Results in the context of current literature

The median steps per day (n=4023) in this study were lower than that of large group (n=849) of healthy adults. Schuna et al (2013) demonstrated that adults who reported that they were mostly sitting in their occupational and domestic time took a mean
number of 4909 steps per day and overestimated their self-reported PA. The results of this study demonstrate that following mild stroke, individuals are not as active as non-stroke adults.

The results of this study are similar to other studies which investigated PA in stroke. The median steps per day (n=4023) identified in this study were aligned to a meta-analysis performed by Field et al (2013) which generated an estimate of 4355 steps per day in high functioning adults post stroke. This meta-analysis included 26 studies which recruited 1105 participants from a mean time of three months to 8.5 years post stroke. Although those participants were longer post stroke, the trend towards low PA post stroke in high functioning adults is relevant. Moore et al (2013) demonstrated in 31 high functioning (Barthel Index 93±10) adults that at one week, three months and six months post stroke participants took 2956 (±2224), 5763 (±3026) and 5927 (±4091) steps per day respectively. While there was an increase at three and six months, the improvement plateaued at six months and the range of steps also increased. Another study by Paul et al (2015) demonstrated that individuals (n=22), a mean 4.2 years post stroke took an average of 4035 steps per day, as measured by accelerometers. The results from the current study demonstrate low levels of engagement in PA in the acute period following stroke and the evidence base indicates that stroke survivors will potentially remain relatively physically inactive in the years following stroke.

Medical management of risk factors for stroke such as hypertension, atrial fibrillation, hypercholesterolaemia, smoking, diabetes and carotid stenosis are managed by a patient’s medical team. Through a series of investigations a patient’s risk profile is identified and appropriate secondary prevention is instigated (Sarikaya et al, 2015). The American Heart Association recognises decreased PA as a risk
factor in stroke (Goldstein et al, 2011). However, only 41% of Irish patients were counselled in exercise prescription as a secondary prevention measure in a recent national audit (Irish Heart Foundation/Health Service Executive, 2015). This highlights that there is not enough education on the importance of exercise in stroke recovery and secondary prevention in Irish hospitals. Early results from a trial by Lennon et al (2015) have demonstrated improved compliance with moderate exercise following an eight week lifestyle modification and exercise programme. However, the long term effects on mortality and cardiovascular risk factor reduction from lifestyle modification and exercise programmes post stroke are not yet established and further research is necessary (Lennon et al, 2014).

The current study did not identify any variables that were independently associated with the levels of PA. However, other studies have demonstrated that increasing age accounted for a significant decrease in objectively measured PA in 100 participants admitted to an ASU (Strommen et al, 2014). This was not demonstrated in the current study; however due to the large age range in the participant group it is difficult to eliminate such a relationship.

In their qualitative study Nicholson et al (2014) reported that self-efficacy could be a barrier or a facilitator to PA. Many participants reported that they lacked control over what they could do and had low beliefs regarding their own capabilities. This was not demonstrated in the current study as the median score on the SSEQ was 128/130. However, in the study by Nicholson et al (2014) participants were a median of 345 days post stroke and may have had more time to adjust to life post stroke whereas in the current study participants were still in hospital and had not returned to their pre-stroke environment.
The brief intervention delivered to participants while in the ASU may not have been adequate for them to engage in self-management of their PA and may not have accounted for the emotional effects of the stroke. For some participants in this study they met the PI on only one occasion. During the brief intervention they were issued with advice regarding PA and reducing sedentary behaviours and advised that PA is an important component of stroke secondary prevention. During the 45 minute intervention participants were invited to ask questions which were answered by the PI or directed to their medical team, as appropriate. Every stroke patient admitted to UHL was also counselled by the Stroke Clinical Nurse Specialist who advises all patients regarding stroke secondary prevention. However, these brief interventions may not have provided ample time to facilitate lifestyle modification.

All participants displayed high levels of physical ability but there was a significant drop in their self-reported levels of PA pre and post stroke \((z=-1.96, p=0.05)\). The high level of physical ability in this cohort may not have coincided with high community integration. Participants may have felt anxiety about participating in PA outside their own home as they may have felt stigmatised by their broader community after suffering a stroke and may have found community integration challenging. More participants demonstrated higher levels of anxiety than depression as measured by the HADS. Twenty-four percent of participants displayed borderline or abnormal levels of anxiety post stroke. Although not significant a larger sample size may have identified more meaningful trends and it is recommended that this patient cohort is monitored for anxiety post stroke.

A qualitative meta-analysis identified numerous factors which affects community integration following a stroke (Walsh et al, 2015). Non-physical symptoms such as fatigue, loss of control, reduced confidence and reduced self-esteem were identified
as limiting an individual’s integration. Other personal factors which are difficult to measure but impact upon how well an individual copes with a life-changing event such as stroke include their perseverance and adaptability (Walsh et al, 2015). The acute period following a stroke can be an emotional and life-altering time and individuals will cope with this differently. Those who lack the perseverance and adaptability to change may struggle with behaviour modification and psychological consequences of stroke and require additional support from the appropriate health professional. This highlights the importance of a psychology service within the Stroke MDT which is recommended by current stroke guidelines (Intercollegiate Stroke Working Party, 2012).

Environmental factors may have been a barrier to PA for the participants. Participants were recruited from October 2015 to February 2016. Although not measured, numerous participants reported bad weather as a limiting factor in engaging in PA outside the home. The catchment area for UHL spans three counties and serves a population of 400,000 (HSE, 2016). Following stroke the Road Safety Authority (RSA) in Ireland does not permit individuals to drive for a minimum of one month post stroke (RSA, 2015). This may have led to social isolation and restricted community access. Accessing alternative facilities may have been difficult for this cohort as the median age was 65 and they may not be accustomed to attending gyms or leisure centres. Professionals working in these environments may lack confidence or the knowledge to work with people following stroke and this may create barriers to participation in PA and exercise (Rimmer et al, 2004). These environmental issues were also demonstrated by Nicholson et al (2014) as being barriers to PA post stroke.
The relationship with professionals has been identified as a potential barrier to community integration after stroke. Walsh et al (2015) reported that the relationship between the patient and the professional may act as a facilitator or a barrier to community integration. Knowledge that PA was beneficial to stroke recovery has been identified as a facilitator to PA and conversely a lack of knowledge has been identified as a barrier (Nicholson et al, 2014). This highlights the importance of providing a positive experience of early stroke care for patients and facilitating recovery by providing clear information and advice to empower the patient to take the necessary steps in their recovery.

In studies in patients with coronary artery disease it has been demonstrated that interventions with integrated health education, exercise and behavioural modification results in decreased secondary end points like cardiovascular mortality, nonfatal myocardial infarction and stroke (Maasland et al, 2011). In an Irish setting it has been demonstrated that an eight week exercise, lifestyle counselling and a risk factor education class improved compliance with moderate intensity exercise and smoking cessation in a community dwelling stroke population more than one year post stroke (Lennon et al, 2015). However, cardiovascular risk scores did not significantly improve and the prescribed levels of recommended PA was 20 minutes, three days per week which is less than the recommended levels (Lennon et al, 2015). The results of the current study correlate with the findings that brief, education information interventions are not sufficient to engage in lifestyle modifications that are necessary in stroke secondary prevention. Further research is recommended in the promotion of self-management where the patient acquires the skills and knowledge to influence their health.
Patients may have anxiety regarding cardiac instability or stroke recurrence with increasing heart rate and the exertion associated with exercise (Nicholson et al, 2012). Individualised exercise testing has been recommended (Billinger et al, 2014). However, following their review of 112 studies involving 5008 participants post stroke Gaverth et al (2015) reported that symptom-limited exercise stress testing is safe during submaximal PA. In the current study all participants were deemed suitable for PA by their medical team in hospital and were advised on engaging in moderate intensity exercise.

Although not measured, anecdotally a number of participants reported fatigue being a limiting factor on their PA post stroke. Prevalence of post-stroke fatigue has been reported to range from 29 to 70% (Mohanasuntharaam and Goh, 2015). Like many aspects to stroke recovery stroke survivors can exhibit different strategies in the management of fatigue. A qualitative study by Kirkevold et al (2012) found that fatigue is a significant problem for people post stroke and many approach its’ management differently. Some face fatigue as a challenge to be managed; others describe a process of coming to terms with fatigue while others do not attempt to restore pre-stroke energy levels. This highlights the importance of health professionals engaging with patients to ascertain their individual coping strategies and providing them with the appropriate guidance to recover from the effects of stroke and participate in PA. Exercise has been shown to decrease fatigue post mild stroke and TIA (Faulkner et al, 2015) although a review by Wu et al (2015) found low quality evidence to recommend strategies in the management of post-stroke fatigue and more research in this area is warranted.
4.2 Strengths of the study

- To the authors' knowledge this is the first study examining PA in this patient cohort. The findings that patients are relatively inactive in the first week of discharge from the ASU are particularly important to inform and plan clinical and social interventions to improve PA and stroke recovery in the acute period post discharge home. Early Supported Discharge teams are ideally placed to facilitate the transition home and their establishment in all ASU’s is recommended.
- Every consecutive patient admitted to the ASU was considered for recruitment to the study which reduced selection bias. A robust methodology was conducted throughout the study to ensure consistency and reliability.
- The activity monitors provided accurate, meaningful data on the PA levels in this cohort. There were relatively non-invasive and no participant reported any issues while wearing them. Donning the activity monitors for 24 hours per day for seven days clearly demonstrated the trends of PA reducing the effect of performance bias.
- To the author’s knowledge this is the first study to assess the correlation between the IPAQ and objective measurement in a stroke population. Given the poor correlation with objective measurement, the IPAQ cannot be recommended for use in this cohort which is a useful finding of this study. As participants significantly overestimated their levels of PA, greater examination of self-reported levels of PA needs to be completed by healthcare professionals when prescribing PA.

4.3 Weaknesses of the study

- A larger sample size may have identified greater trends and more meaningful information. The data gathered was found not to be normally distributed which
required a more conservative approach in statistical analysis. The heterogeneity of
the group may have accounted for this but the pragmatic approach in recruitment
limited bias. Further restrictions in exclusion criteria may not have accurately
reflected this cohort.

- No independent factors were identified as predictive of PA post stroke. The median
  scores for two of the secondary measures were the maximum score (BBS 56/56 and
  BI 100/100). The median score of the SSEQ was 98% of the total score (128/130)
  and the MMSE was 93% of the total score (28/30). Although routinely used in this
  patient cohort they may not be sensitive enough to detect impairments and
  alternatives are recommended in future research. The number of comorbidities for
each participant was not noted and this may have been a factor which may have had
an impact upon levels of PA.

- This study was focussed on individuals with mild stroke and the findings cannot be
  extrapolated to individuals with more severe stroke. Additionally, participants with
  severe cognitive impairment were not considered for inclusion to the study. This
  may have resulted in selection bias and these individuals may have been
  underrepresented in this study.

- It was found that there was a poor correlation between self-reported and objective
  levels of PA. Participants significantly overestimated their levels of PA. This may be
  because participants completed the second questionnaire via the telephone to the PI;
it may be that they lacked insight into their levels of PA or that the IPAQ is not
  sensitive enough to detect sporadic, spontaneous, low intensity PA which
  participants may have engaged in.
### 4.4 Clinical policy implications

Reducing the risk of recurrent stroke requires a multifaceted approach to target multiple risk factors. A stroke-specific rehabilitation programme aimed at community dwelling patients is recommended. This programme should incorporate behaviour modification education, psychological support, an exercise programme and education on stroke secondary prevention. To measure the effectiveness of this programme a large scale, multi-centre randomised controlled trial comparing it to standard care is recommended. As the baseline levels of PA have been established in this cohort, initially it is recommended that a pilot study to examine the feasibility of an exercise class for community dwelling adults post stroke be implemented.

While early mobilisation is recognised as a cornerstone of the ASU, functional mobility must be encouraged and facilitated. Once mobilised upon admission, care must be taken to continue mobility practice at a ward level for stroke patients. Avoiding prolonged periods in bed and dressing in day clothes (when appropriate) should be encouraged to minimise patients post stroke adopting a dependent role. This will require a higher nurse to patient ratio than a general medical ward and this is reflected in current standards of stroke care (Intercollegiate Stroke Working Party, 2012).

When required, participants were referred to their local Primary Care Team for ongoing management of their impairments. However, these teams are not stroke specific and patients may be faced with a long waiting list prior to their review. A report on rehabilitation post stroke found that over half of 256 patients referred for community therapy post stroke reported delays in accessing the therapy (ASPIRE-S, 2014). Rapid access, stroke specific teams like Early Supported Discharge (ESD)
Teams are recommended to facilitate rehabilitation in the patient’s own environment. ESD has been demonstrated to be effective in improving the odds of functional independence compared to standard rehabilitation at three, six and 12 months post discharge (Fisher et al, 2016). An MDT with access to all required therapies and psychology is of upmost importance to facilitate a patient taking ownership of their PA and secondary prevention. Twenty-eight percent of patients who survived their stroke were discharged home from UHL in the five month recruitment period. This is compared to the national average of 54% (Irish Heart Foundation/Health Service Executive, 2015). The presence of an ESD team in UHL would facilitate speedier and more efficient discharges home and avoid transfers to rehabilitation facilities.

Behaviour change at all levels of society is necessary to adopt less sedentary lifestyles. Thirty-nine percent of Irish adults over the age of 50 (45% of men; 33% of women) are overweight and it is reported that obesity levels are rising in Ireland (Leahy et al, 2014). The association between decreased levels of PA and obesity is also highlighted. It is reported that 47% of obese women report low levels of PA compared to 30% of normal weight women (Leahy et al, 2014). At every point of contact healthcare professionals should be promoting PA through advice and demonstration. GPs and Public Health Nurses are often the main point of contact for community dwelling adults to access healthcare. A widespread education campaign is recommended to enable these healthcare professionals to confidently prescribe the latest safe, recommended levels of PA for their patients and through review to monitor compliance and provide support.
4.5 Recommendations for future research

- To facilitate PA post stroke, predictors of PA post stroke need to be identified. Although no independent predictors were identified in this study, an increased number of participants may identify more significant trends.

- Although complex, measurement of fatigue post stroke needs further investigation and management. Further studies in the assessment of PA post stroke should incorporate a measure of post stroke fatigue.

- It is also recommended that a qualitative component be included in future research of PA post stroke. Examining the process of recovery from the patients’ perspective may provide valuable insights to facilitate service planning and delivery.

- Stroke can be a serious and life-changing event for individuals, irrespective of residual disability. This is reflected in the higher levels of anxiety detected using the HADS in this study. It has been shown that stroke survivors with poor social support and lacking in community participation are more likely to suffer from depression post stroke (Pearce et al, 2015). A more intensive rehabilitation program which encourages participation and community integration is recommended. ESD teams would be ideally placed to facilitate this community reintegration and optimisation of outcome. The provision of therapy in the patient’s home would translate tasks into meaningful activities for the patient which may facilitate greater compliance with therapy.

- There may be a role for a physiotherapy review in medical outpatient clinics that patients attend post discharge from hospital. In UHL these clinics are attended by the medical team only and review secondary prevention strategies. As decreased PA is a risk factor in stroke, the role of the physiotherapist in secondary prevention should not be overlooked in service planning. These reviews would provide an opportunity
to engage in exercise sessions with patients, review exercise programmes and identify barriers to participation in PA.

- A randomised controlled trial which compared standard care and an eight week program that included exercise classes and an education program demonstrated that patients with a mild stroke maintain improvements in perceived health and well-being over a 12 month period (Faulkner et al, 2015). To determine the long-term benefits of such a programme, a large scale, multi-site randomised controlled trial is recommended.

- Difficulties accessing facilities to participate in PA have been highlighted. Novel solutions are required which negate the need to travel long distances to sports and exercise facilities. Technology may offer a solution and internet based or telephone programs may be used to promote PA in patients own homes. Such programs could be tailored to individuals and provide the support which many require to facilitate lifestyle modification.
CONCLUSION

The primary aim of this study was to quantify the self-reported and objective levels of PA in people post discharge following a stroke from an ASU. Additionally, the study aimed to determine if there was a correlation between self-reported and objective levels of PA and determine whether cognition, balance, self-efficacy, function, age, anxiety or depression influenced levels of PA.

This study has established the baseline levels of PA in the acute period following a stroke in those with a mild stroke. It has demonstrated that patients are relatively inactive in this time period and do not meet the recommended levels of PA. Additionally, it was found that patients significantly overestimate their levels of PA. These are important findings in service planning and delivery for this cohort. No independent variables were identified as having an impact upon levels of PA but due to the small sample size caution must be applied to this finding and further research is recommended in this area.

Physical activity post stroke is a complex process. There are many factors which may facilitate or act as a barrier to engagement in the recommended levels of PA and in the reduction of sedentary behaviour. An individual stroke survivor’s personality and resilience is tested following a stroke and support in their recovery and lifestyle modification is recommended, irrespective of stroke severity. This support should be delivered by health professionals, their family and the wider community who have an understanding of the complex recovery process from stroke and the lifelong management of stroke secondary prevention.

Word count: 14,103
REFERENCES


Saunders DH, Sanderson M, Brazzelli m, Greig CA, Mead GE (2013) Physical fitness training for stroke patients. *Cochrane Database of Systematic Reviews* Issue 10. Art No.: CD003316.


APPENDIX

Appendix 1 - Patient Information Leaflet

Patient Information Leaflet

Physical activity after stroke; Does self-reported physical activity correlate with objective measurement in people with stroke post discharge?

Principal Investigator’s Name: Edel Hennessy
Principal Investigator’s Title: Senior Physiotherapist in Neurology (University Hospital Limerick)
Telephone No. of Principal Investigator: 061 482151

Co-investigator Name: Dr Peter Boers
Co-investigator Title: Consultant Neurologist, University Hospital Limerick
Contact details: 061 301111

Academic Supervisor Name: Dr Frances Horgan
Academic Supervisor Title: Senior Lecturer in Physiotherapy, RCSI
Contact details: 01 402 2472

Academic Supervisor Name: Dr Rose Galvin
Academic Supervisor Title: Lecturer in Physiotherapy, University of Limerick
Contact details: 061 233721

You are invited to take part in a research study about physical activity following a stroke which is being carried out in the Physiotherapy Department at University Hospital Limerick. The purpose of this information leaflet is to give you all the information you need to help you to decide if you would like to take part in the study and to make sure that you know what is involved.
You are not obliged to take part in this study and if you decide not to take part this will not affect your treatment in any way. Likewise, if you decide to take part now, and then change your mind later on, this is also fine and will not affect your treatment in any way.

Before you decide to take part, you should read this information leaflet carefully and if you wish, discuss it with your family, friends or doctor. You can also ask the researcher questions about the study.

**WHY ARE WE DOING THIS STUDY?**
Physiotherapists treat people following a stroke and provide them with exercises and advice regarding physical activity. Some people following a stroke are less active than people who have not had a stroke. This study involves measuring the amount of physical activity a participant carries out in their first week home following a stroke. The study will also investigate what factors may influence the amount of physical activity a participant undertakes in the first week home from hospital following a stroke. This information will help us to recommend more appropriate physiotherapy treatment and appropriate follow up for people following a stroke.

**WHO IS ORGANISING THIS STUDY?**
Edel Hennessy, a Senior Physiotherapist in University Hospital Limerick is carrying out this study with Dr Peter Boers in University Hospital Limerick, Dr. Frances Horgan in the Royal College of Surgeons in Ireland and Dr Rose Galvin in the University of Limerick.

**HOW WILL THE STUDY BE CARRIED OUT?**
The study will start in October 2015 and will continue for six months. We are aiming to measure the amount of physical activity 44 participants undertake in the first week home following a stroke. If you agree to take part in the study you will be asked to complete an assessment, much of which is part of a standard physiotherapy assessment and wear an activity monitor for one week. This assessment will take place in the hospital and take no longer than 45 minutes. The activity monitor weighs 15 grams and is 7mm thick. It measures 53 x 35mm in length and width. It will be attached to your upper leg using a waterproof dressing.

**WHAT WILL HAPPEN TO ME IN THE STUDY?**
While in hospital you will be asked to complete an assessment, which will take approximately 45 minutes. Your balance will be assessed and you will also be asked questions about your mood, your memory, your usual level of physical activity and your confidence carrying out tasks. On the day you are going home, you will be asked to wear an activity monitor on your leg for the following seven days. On the seventh day, Edel Hennessy will telephone you and ask you to return the activity monitor in an envelope she will have provided for you. The investigator will also ask you to repeat a questionnaire regarding physical activity on the telephone. This will take 5 minutes. If you are interested in the data from the activity monitor Edel Hennessy will contact you once the study is finished and the data has been analysed.

WHAT OTHER TREATMENTS ARE AVAILABLE?
If you decide not to take part in the study, this will not affect your current treatment.

BENEFITS:
The physical activity monitoring will provide detailed feedback on your level of physical activity.

RISKS:
There is a very slight risk that you might lose your balance and fall during assessment. However, we feel that this is a very low risk as you will be supervised at all times by an experienced physiotherapist, in a safe environment.
You may develop skin irritation from wearing the activity monitor. If this happens you should remove the monitor and contact Edel Hennessy.
You may experience some fatigue during the assessment but breaks will be provided if necessary.

WHAT IF SOMETHING GOES WRONG IN THE STUDY?
If you experience any problems when you are in the study or if we discover any health issue, Edel Hennessy will be responsible for contacting your General Practitioner (GP) and Consultant to inform them.

WILL THERE BE ANY COSTS INVOLVED?
There will be no cost incurred to any participants in the study. Edel Hennessy will provide you with a stamped and addressed envelope to return the activity monitor once the seven days is over.

**WHAT ARE YOUR RESPONSIBILITIES AS A PARTICIPANT**

As a participant in the study it is important that you follow the instructions provided to ensure your safety. You should also tell the physiotherapist about any changes in your health that may affect your ability to participate.

**WHAT ARE THE RESEARCHER’S RESPONSIBILITIES TO YOU**

The researcher (Edel Hennessy) should be professional and courteous at all times, and conduct the study in the manner approved by the Ethics committee.

**CONFIDENTIALITY ISSUES**

We are obliged to tell your Consultant and General Practitioner (GP) that you are taking part in this study, but if you do not want us to contact your GP this is fine. The research physiotherapist will look at your medical chart and will place a copy of your consent form in the chart.

Your results will be coded; this means your name will not appear on the assessment forms. Edel Hennessy will have access to this code. The study records will be kept in a safe secure location at the Physiotherapy Department in University Hospital Limerick, and the computer records will be stored on a password protected computer. The information will be destroyed after 5 years. We may contact you again following the study to see how you are, but this has not yet been decided.

**IF YOU NEED MORE INFORMATION**

If you have any other questions about the study you can contact the main researchers:

Edel Hennessy, Physiotherapy Department, University Hospital Limerick.
Phone number: 061 482151
Dr. Frances Horgan, Senior Lecturer in Physiotherapy, Royal College of Surgeons in Ireland, 123 St. Stephen’s Green, Dublin 2.
Phone No: 01 4022472

Dr Rose Galvin, Lecturer in Physiotherapy, Clinical Therapies, University of Limerick.
Phone number: 061 233721
STANDARD APPLICATION FORM

For the Ethical Review of Health-Related Research Studies, which are not Clinical Trials of Medicinal Products For Human Use as defined in S.I. 190/2004

DO NOT COMPLETE THIS APPLICATION FORM IF YOUR STUDY IS A CLINICAL TRIAL OF A MEDICINAL PRODUCT

Title of Study: Does self reported physical activity correlate with objective measurement in people post discharge following stroke?

Application Version No: ____________________________

Application Date: _______8th June 2015____________________________

For Official Use Only – Date Stamp of Receipt by REC:
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This Application Form is divided into Sections.

*Sections A, B, C, D, E, J and K are Mandatory.

(Sections F, G, H, I and L are optional. Please delete Sections F, G, H, I and L if these sections do not apply to the application being submitted for review.)

**IMPORTANT NOTE:** Please refer to Section I within the form before any attempt to complete the Standard Application Form. Section I is designed to assist applicants in ascertaining if their research study is in fact a clinical trial of a medicinal product.

**IMPORTANT NOTE:** This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying Guidance Manual for more in-depth advice prior to deleting any question.
PLEASE ENSURE TO REFER TO THE ACCOMPANYING GUIDANCE MANUAL WHEN COMPLETING THIS APPLICATION FORM.

SECTION A  GENERAL INFORMATION

SECTION A IS MANDATORY

A1 Title of the Research Study:

Does self-reported physical activity correlate with objective measurement in people post discharge following stroke?

A2 (a) Is this a multi-site study?  **No**

If you chose 'yes' please delete questions A2 (e) and (f). If you chose 'no' please delete Questions A2 (b) (c) and (d)

A2 (e) If no, please name the principal investigator with overall responsibility for the conduct of this single-site study.

**Title:** Ms  
**Name:** Edel Hennessy  
**Qualifications:** BSc (Hons) Physiotherapy  
**Position:** Senior Physiotherapist in Neurology  
**Dept:** Physiotherapy  
**Organisation:** HSE West  
**Address:** Physiotherapy Department, University Hospital Limerick, Dooradoyle, Limerick  
**Tel:** 061482151  
**E-mail:** neurophysiorhd@hse.ie

A2 (f) For single-site studies, please name the only site where this study will take place.

**University Hospital Limerick**

A3. Details of Co-investigators:

**Name of site (if applicable):** Not applicable  
**Title:** Dr. / Ms. / Mr. / Prof.  
**Name:** Answer  
**Qualifications:** Answer  
**Position:** Answer  
**Dept:** Answer  
**Organisation:** Answer  
**Address:** Answer  
**Tel:** Answer  
**E-mail:** Answer  
**Role in Research e.g. statistical / data / laboratory analysis:** Answer

A4. Lead contact person who is to receive correspondence in relation to this application or be contacted with queries about this application.

**Name:** Edel Hennessy  
**Position:** Senior Physiotherapist in Neurology  
**Organisation:** HSE West
A5 (a) Is this study being undertaken as part of an academic qualification? **Yes**

If answer is **No**, please delete remaining questions in Section A

A5 (b) If yes, please complete the following:

**Student Name(s):** Edel Hennessy  
**Academic Course:** MSc Neurology and Gerontology  
**Academic Institution:** Royal College of Surgeons in Ireland

A5 (c) Academic Supervisor(s):

**Title:** Dr  
**Name:** Frances Horgan  
**Qualifications:** BSc (Physiotherapy); MSc (Research); PhD  
**Position:** Course Director MSc Neurology and Gerontology  
**Dept:** Physiotherapy Department  
**Organisation:** Royal College of Surgeons in Ireland  
**Address:** 123 St Stephen’s Green, Dublin 2  
**Tel:** 01 4022472  
**E-mail:** fhorgan@rcsi.ie

**Title:** Dr  
**Name:** Rose Galvin  
**Qualifications:** BSc (Physiotherapy); PG Dip Stats, PhD  
**Position:** Lecturer in Physiotherapy  
**Dept:** Clinical Therapies  
**Organisation:** University of Limerick  
**Address:** Castletroy, Limerick  
**Tel:** 061 233721  
**E-mail:** rose.galvin@ul.ie

**SECTION B STUDY DESCRIPTORS**

**SECTION B IS MANDATORY**

B1. What is the anticipated start date of this study?

**28/9/2015**

B2. What is the anticipated duration of this study?

**6 months**

B3. Please provide a brief lay (plain English) description of the study. Please ensure the language used in your answer is at a level suitable for use in a research participant information leaflet.

Approximately 10,000 people experience a stroke in Ireland every year and it is third greatest cause of death in Ireland and the leading cause of acquired
disability. Approximately 2,500 people are assessed in Irish hospitals annually with suspected transient ischaemic attack (TIA) and the risk of stroke is higher in people who have previously had a stroke or TIA. About 10% of people who have a stroke will have another in the first 12 months. There is a projected increased trend of stroke in Ireland of 50% by 2021 with a projected increased cost of 50%. This trend highlights the importance of preventative measures for a disease that has identifiable and modifiable risk factors.

The combination of appropriate secondary preventative medications along with lifestyle modifications may reduce vascular events by 80% over five years in patients with cerebrovascular event (Hackman and Spence, 2007). It is recommended that all patients following a stroke should take part in regular physical activity and that physical activity and exercise prescription should be incorporated into the management of stroke survivors (Billinger et al, 2014).

In stroke rehabilitation, physiotherapists identify physical problems through assessment and formulate treatment plans to restore motor control and improve functional performance. They play a key role in the multi-disciplinary team in aiding the patient’s recovery from stroke. Physiotherapists address physical activity in the acute management of stroke patients by acting as drivers for early mobilisation from bed. They continue this drive for physical activity through the prescription of exercise to work on specific deficits or to improve physical fitness.

To date, there is a dearth of research that examines levels of physical activity following discharge from hospital in individuals with acute stroke. The aim of this study is to examine levels of physical activity (PA) in the first week following discharge from hospital using an objective activity monitor. A secondary aim of the study is to ascertain whether an objective measure of PA correlates with self-report levels of PA. Furthermore, this study will explore if cognition, function, balance, self-efficacy or depression influence levels of physical activity following stroke.

**B4. Provide brief information on the study background.**

Stroke is the leading cause of acquired disability in Ireland. It has been demonstrated that stroke patients are less active than their age matched controls. In an effort to optimise outcome physiotherapists educate patients on appropriate physical activity post stroke but there is limited research on objective levels of physical activity in community dwelling people with acute stroke. Physical activity is essential for improving recovery, function and fitness post stroke. Therefore the purpose of this study is to explore the physical activity levels of patients who are discharged directly home from the acute stroke unit using subjective and objective measures of physical activity. A secondary aim of the study is to examine if participants are adhering to physical activity guidelines in the first week following discharge from hospital.

**B5. List the study aims and objectives.**

Research question and main aims of the study:
What levels of physical activity do people with acute stroke engage in in the first week following discharge from hospital?

Objectives
To establish levels of physical activity after acute stroke following discharge from hospital
To determine if self-reported levels of physical activity correlate with an objective measure of physical activity
To determine if cognition, function, balance, self-efficacy or depression influence levels of physical activity following stroke
To examine if participants are adhering to physical activity guidelines in the first week following discharge from hospital

B6. **List the study endpoints / measurable outcomes (if applicable).**

| Physical activity using objective (activity monitor) and subjective measurement (patient self-reported levels of PA) |

B7. **Provide information on the study design.**

This is a descriptive cohort study. The STROBE standardised reporting guidelines will be followed to ensure the conduct and reporting of the research.

B8. **Provide information on the study methodology.**

<table>
<thead>
<tr>
<th>Participants</th>
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<tr>
<td>Every patient admitted to University Hospital Limerick (UHL) with a confirmed diagnosis (by treating Consultant) of ischaemic stroke will be considered for inclusion in this study. Stroke severity will be measured by the National Institutes of Health Stroke Scale (NIHSS).</td>
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<tr>
<th>Recruitment strategy</th>
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<tr>
<td>Participants deemed eligible for inclusion to the study based on the inclusion/exclusion criteria (See section C1.3 and C1.4) will be approached by the study gatekeeper and provided with an outline of the study. The Gatekeeper is a stroke Clinical Nurse Specialist who routinely reviews every patient admitted to UHL with a stroke. The Gatekeeper has agreed to the role and is fully informed of the research project. This will enable her to provide an outline of the study to all potential participants. If agreeable at that point the primary investigator (PI) (EH) will approach the patient and provide them with a detailed outline of the study and an information leaflet. See attached. The patient will be offered a 24 hour cooling off period to consider their participation in the study. Once they consent and sign the consent form, the PI (EH) will carry out the initial assessment. If the patient does not consent to participate in the study they will receive routine treatment from the treating physiotherapist.</td>
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<th>Outcome measurement</th>
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<tr>
<td><strong>Primary outcome</strong></td>
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<td>The primary outcome measurement tool will be an activity monitor/accelerometer (ActivPAL). It weighs 15 grams and is 7mm thick. It measures 53 x 35mm in length and width. Using proprietary algorithms, (Intelligent Activity Classification™), it classifies an individual's free-living activity into periods spent sitting, standing and walking. It will be worn on the thigh of the non-affected leg for seven days using a Velcro strap. Participants will be issued with an activity monitor and instructed to wear for the first seven days on discharge home from hospital. Participants will be permitted to remove the activity monitor when in bed and instructed to wear at all times during the day, moving without consideration for the equipment. The ActivPAL has been widely used in healthcare research and validated for use with stroke patients. It has been shown to be unobtrusive and comfortable to wear.</td>
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| Secondary outcomes (see attached) |
| International Physical Activity Questionnaire (IPAQ) |
To measure self-reported physical activity over the seven days post discharge from hospital the IPAQ will be used. This nine item questionnaire relies on participant recall and records physical activity at four levels: vigorous (e.g. aerobics), moderate (e.g. leisure cycling), walking and sitting. The IPAQ will be administered at two time points: during the initial assessment in hospital and repeated on the seventh day following discharge from hospital. The second measurement will take place via telephone when the PI (EH) telephones the participant to request the return of the activity monitor.

As part of the initial assessment there will be measures of cognitive impairment (Mini Mental State Examination), depression (Hospital Anxiety and Depression Scale), function (Barthel Index), balance (Berg Balance Scale) and self-efficacy. These measures will constitute the initial assessment and should take no longer than 45 minutes.

**Mini Mental State Examination (MMSE)**
The MMSE has been shown to be sensitive and specific to screen for cognitive impairment in post-stroke dementia, multi-domain impairments and "any degree of cognitive impairment". It takes ten minutes to complete, is freely available and minimal training is required to complete it. A cut off score of 23/30 has been shown to detect cognitive impairment and will be used as the cut off point for this study (Burton and Tyson, 2015).

**Hospital Anxiety and Depression Scale (HADS)**
The HADS screens for mood disorders in non-psychiatric patients. It has 14 items in two subscales: anxiety and depression. It is a self-administered questionnaire which takes two to five minutes to complete.

**Berg Balance Scale (BBS)**
The BBS is routinely used in physiotherapy practise and measures the patient’s ability to maintain balance while performing various functional movements. It is a 14-item scale that takes ten minutes to complete. A score of >45/56 will be used as a cut off point for participation as below this a patient would be deemed a “falls risk” if mobilising alone.

**Barthel Index (BI)**
The BI will be used as a baseline measurement of functional ability. This 10 item measure is widely used in stroke rehabilitation and includes tasks such as stair climbing and transfers.

**Stroke Self-efficacy scale**
The SSEQ is a 13-item self-reporting questionnaire which has been shown to have good internal consistency and criterion validity and is recommended for use in stroke research as it will give an indication as to whether the participant believes they can take part in rehabilitation.

**Duration of follow-up**
Baseline assessments will be carried out in hospital. Participants will be issued with an appropriate personalised home exercise plan to focus on any specific deficits identified post stroke. As routine care they will be issued with the Irish Heart Foundation booklet “Physical Activity” and instructed on the recommended physical activity levels (see attached). As routine practise they will be reviewed in hospital by their treating physiotherapist as necessary. On discharge they will be instructed to wear the activity monitor for the following seven days. On the seventh day the PI (EH) will telephone the participant, request the return of the activity monitor and repeat the IPAQ.

B9. Provide information on the statistical approach to be used in the analysis of your results (if appropriate) / source of any statistical advice.
Activity monitoring data will be converted into time spent sitting/lying, standing and walking. Walking will be converted into steps to allow comparison to other studies. Shapiro-Wilk normality test will be used to test the normality of data. Descriptive statistics will be used to describe the study population and the output of the outcome measures using means and standard deviations when relevant. Levels of objective physical activity will be compared to the IPAQ using the Pearson Product Moment Correlation coefficient. The association between the dependent variable (activity levels in minutes) and predictors: HAD score, Berg Balance score, Barthel index, depression and self-efficacy will be examined using a mixed linear regression model. Significance will be set at P<0.05. Data will be analysed using SPSS.

B10 (a) Please justify the proposed sample size and provide details of its calculation (including minimum clinically important difference).

There are no similar studies that report levels of correlation among objective measures of physical activity versus self-reported measures of physical activity in people with acute stroke. Therefore our sample size is based on outputs provided by a similar study in community dwelling adults with chronic stroke, where moderate correlations (Pearson correlations ranging from 0.6 to 0.73) were reported between objective step counts and other measures of physical activity (Rand et al, 2009). We estimate a moderate correlation (r=0.6) between step counts and self-reported levels of physical activity in our population also. Using a two sided test, 5% significance level test (α=0.05) with 80% power (β=0.2), the required sample size is approximately 37 individuals with acute stroke (n=37). Accounting for an expected 20% attrition, the sample size has been inflated to 44 participants.

B10 (b) Where sample size calculation is impossible (e.g. it is a pilot study and previous studies cannot be used to provide the required estimates) then please explain why the sample size to be used has been chosen.

Not applicable

B11. How many research participants are to be recruited in total?

44

B12 (a) How many research participants are to be recruited in each study group (where applicable)? Please complete the following table (where applicable).

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<tr>
<th>Name of Study Group:</th>
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NA
B12 (b) Please provide details on the method of randomisation (where applicable).

Not applicable – this is an observational study

B13. How many research participants are to be recruited at each study site (where applicable)? Please complete the following table.

<table>
<thead>
<tr>
<th>Site:</th>
<th>Number of Research Participants at this site:</th>
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<tbody>
<tr>
<td>NOT APPLICABLE</td>
<td></td>
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</tbody>
</table>

SECTION C  STUDY PARTICIPANTS

SECTION C IS MANDATORY

C1 PARTICIPANTS – SELECTION AND RECRUITMENT

C1.1 How will the participants in the study be selected?

Consecutive admissions of stroke to the Acute Stroke Unit (ASU) in UHL. See inclusion and exclusion criteria in section C1.3 and C1.4.

C1.2 How will the participants in the study be recruited?

Participants will be recruited from the Acute Stroke Unit. The gatekeeper (CNS Stroke) who will be aware of the study details will approach each potential study participant on the Acute Stroke Unit. If they consent she will provide them with the information leaflet (see attached). If at this point the potential participant consents the PI (EH) will approach the individual and provide them with further details of the study. Once consent is achieved and the consent form is signed the participant will be offered a 24 hour cooling off period.

C1.3 What are the inclusion criteria for research participants? (Please justify, where necessary)

- Informed consent
- >18 years age
- Confirmed diagnosis of ischaemic stroke by Consultant
- Medically stable
- Independently mobile +/- walking aid
- For discharge directly home from ASU
- MMSE >23

C1.4 What are the exclusion criteria for research participants? (Please justify, where necessary)

- Haemorrhagic stroke (due to possible detrimental rise in blood pressure with exercise)
Symptoms attributable to diseases other than ischaemic stroke
- Ulcers of skin diseases in the area of accelerometer placement
- Allergic skin reactions to the accelerometers
- Unable to achieve informed consent from the patient
- Resident in a nursing home pre stroke

C1.5 Will any participants recruited to this research study be simultaneously involved in any other research project? Not to my knowledge

C2 PARTICIPANTS – INFORMED CONSENT

C2.1 (a) Will informed consent be obtained? Yes

C2.1 (b) If no, please justify. You must provide a full and detailed explanation as to why informed consent will not be obtained.

Not applicable

C2.1 (c) If yes, please outline the consent process in full. (How will consent be obtained, when, by whom and from whom etc.)

The Gatekeeper will approach each potential participant and inform them of the study. She will issue them with the information leaflet (see attached). If they consent to participate, the PI (EH) will approach the patient and provide them with information about the study. This will happen as soon as possible into their admission to hospital as some patients may be discharged home once their medical investigations are completed.

C2.2 (a) Will participants be informed of their right to refuse to participate and their right to withdraw from this research study? Yes

C2.2 (b) If no, please justify.

Answer

C2.3 (a) Will there be a time interval between giving information and seeking consent? Yes

C2.3 (b) If yes, please elaborate.

Yes – a cooling off period of 24 hours will be provided to participants to consider their involvement in the research project.

C2.3 (c) If no, please justify and explain why an instantaneous decision is reasonable having regard to the rights of the prospective research participants and the risks of the study.
### C3  ADULT PARTICIPANTS (AGED 18 OR OVER) - CAPACITY

C3.1 (a) Will all adult research participants have the capacity to give informed consent?  **Yes**

### C4  PARTICIPANTS UNDER THE AGE OF 18

C4.1 (a) Will any research participants be under the age of 18 i.e. Children?  **No**

If answer is **No**, please delete remaining questions in Section C4

### C5  PARTICIPANTS - CHECKLIST

C5.1 Please confirm if persons from any of the following groups will participate in this study. This is a quick checklist to assist research ethics committee members and to identify whether study participants include persons from vulnerable groups and to establish what special arrangements, if any, have been made to deal with issues of consent. It is recognised that not all groups in this listing will automatically be vulnerable or lacking in capacity. Please refer to the HSE’s National Consent Policy, particularly Part 3, Section 5.

Committees are particularly interested to know if persons in any of these groups are being targeted for inclusion, as per the inclusion criteria.

(a) Healthy Volunteers  **No**

(b) Patients  **Yes**

- Unconscious patients  **No**
- Current psychiatric in-patients  **No**
- Patients in an emergency medical setting  **No**

(c) Relatives / Carers of patients  **No**

(d) Persons in dependent or unequal relationships  **No**

- Students  **No**
- Employees / staff members  **No**
- Persons in residential care  **No**
- Persons highly dependent on medical care  **No**

(e) Intellectually impaired persons  **No**

(f) Persons with a life-limiting condition  **No**
(g) Persons with an acquired brain injury  Yes

C5.2 If yes to any of the above, please comment on the vulnerability of the research participants, and outline the special arrangements in recognition of this vulnerability (if any).

Patients: all patients’ hospital Consultants will be informed of the study (see attached letter) and all participants will receive standard care, irrespective of their participation in the study. The gatekeeper will inform the patients of the study, they will receive information about the study, if they agree to participate fully informed consent will be obtained. Patients will also be screened for cognitive impairment.

Persons with an acquired brain injury: a stroke can be considered an acquired brain injury. The same inclusion and exclusion criteria will apply.

C5.3 Please comment on whether women of child-bearing potential, breastfeeding mothers, or pregnant women will be included or excluded in this research study.

no

SECTION D  RESEARCH PROCEDURES

SECTION D IS MANDATORY

D1 (a) What activities, procedures or interventions (if any) are research participants asked to undergo or engage in for the purposes of this research study?

As standard physiotherapy care following stroke patients will be issued with advice regarding physical exercise and where appropriate, an individualised exercise program by their treating physiotherapist. Additionally they will be asked to complete an activity questionnaire while in hospital and repeat it on the last day of wearing the activity monitor.

The International Physical Activity Questionnaire (IPAQ) will be used as the self-reported measure of physical activity.

Other outcome measures which are routine practise in physiotherapy assessment and intervention will be completed by each patient. To assess balance the Berg Balance Scale (BBS) will be used. To screen for cognitive impairment the Mini Mental State Examination (MMSE) will be used. To screen for depression/anxiety the Hospital Anxiety and Depression Scale (HAD scale) will be used and the Stroke-self Efficacy Questionnaire will evaluate the participant’s degree of confidence in their ability to perform tasks without falling.

As standard physiotherapy care following stroke patients will be issued with advice regarding physical exercise and where appropriate, an individualised exercise program by their treating physiotherapist. Additionally they will be asked to complete an activity questionnaire while in hospital and repeat it on the last day of wearing the activity monitor.

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The Berg Balance Scale (BBS) will be used to quantitatively assess the patients balance and risk for falls. It is a 14-item measure which takes approximately 10 minutes to complete and is used routinely in physiotherapy practise to measure a patient’s ability to maintain equilibrium while performing various functional tasks. It has been shown to have excellent reliability for measuring balance in stroke patients, high (Cronbach alphas, ranging from .92 to .98) internal consistency and excellent correlation with measures of function (e.g. Barthel Index) (Blum and Kornr-Bitensky, 2008).
The MMSE has been shown to be sensitive and specific to screen for cognitive impairment in post-stroke dementia, multi-domain impairments and "any degree of cognitive impairment". It takes ten minutes to complete, is freely available and minimal training is required to complete it. A cut off score of 23/30 has been shown to detect cognitive impairment and will be used as the cut off point for this study (Burton and Tyson, 2015). The SSEQ is a 13-item self-reporting questionnaire which has been shown to have good internal consistency and criterion validity and is recommended for use in stroke research as it will give an indication as to whether the participant believes they can take part in rehabilitation (Riazi et al, 2014). The HAD Scale yields good psychometric data for depression and has been demonstrated to accurately identify anxiety in patients following stroke (Burton and Tyson, 2015). Copies of all outcome measures are included.

D1 (b) What other activities (if any) are taking place for the purposes of this research study e.g. chart review, sample analysis etc?

Chart analysis will be conducted to ascertain the demographic details of participants as well as the details of stroke. See data collection sheet.

D2. Please provide details below of any potential harm that may result from any of the activities, procedures, interventions or other activities listed above.

Participants may experience a little fatigue during the assessment process. The majority of the assessments are conducted as part of routine physiotherapy. There will be additional breaks to minimise fatigue.

D3. What is the potential benefit that may occur as a result of this study?

Participants will benefit from detailed feedback about their levels of physical activity. As physical activity and exercise prescription is recommended in the treatment of stroke patients the results of this study will guide future care of this group of patients. It will identify whether the current model of exercise prescription is effective in facilitating stroke patients to exercise independently once discharged home from the ASU in the acute stage post stroke.

D4 (a) Will the study involve the withholding of treatment? No

D4 (b) Will there be any harms that could result from withholding treatment? No

D4 (c) If yes, please elaborate.

Not applicable

D5 (a) How will the health of participants be monitored during the study, and who will be responsible for this?
The PI (EH) will conduct the assessments pre discharge and on day seven following collection of the activity monitor information. The patients will also be referred to community services e.g. physiotherapy and occupational therapy as appropriate and will be scheduled to attend their hospital outpatient clinic with their consultant.

D5 (b) How will the health of participants be monitored after the study, and who will be responsible for this?

The patients will be referred to community services as appropriate. Following their discharge from hospital their Consultant will schedule the patient with a review in their outpatient clinic in the following four to six weeks. Additionally a discharge summary will be sent to the patients GP from their hospital consultant. The participants GP will be informed of their participation in the study (see attached letter).

D6 (a) Will the interventions provided during the study be available if needed after the termination of the study?  
Not applicable

D6 (b) If yes, please state the intervention you are referring to and state who will bear the cost of provision of this intervention?

Not applicable

D7. Please comment on how individual results will be managed.

All study participants will be asked if they wish to receive a summary of their study results. They will be assured that their information will be anonymous and not identified to anyone. At the time of their assessment pre discharge and at the completion of the seven days of activity monitoring, the results will be explained to each study participant.
Data from each individual patient will be transferred from paper copy to SPSS for data screening and cleaning.

D8. Please comment on how aggregated study results will be made available.

This study forms part of an MSc in Neurology and Gerontology. The aggregate results will be presented in thesis format and will be disseminated through peer review publication, the local stroke team and presentation at relevant stroke conference. Additionally if the study participant wishes to receive a summary of the study results, this will be forwarded by post by the study PI (EH).

D9. Will the research participant’s general practitioner be informed that the research participant is taking part in the study (if appropriate)?  
Yes

D10. Will the research participant’s hospital consultant be informed that the research participant is taking part in the study (if appropriate)?  
Yes

SECTION E IS MANDATORY
E1 DATA PROCESSING - CONSENT

E1.1 (a) Will consent be sought for the processing of data? Yes

E1.1 (b) If no, please elaborate.
Not applicable

E2 DATA PROCESSING - GENERAL

E2.1 Who will have access to the data which is collected?
The study PI (EH) and co-investigators (Drs Boers, Galvin and Horgan).

E2.2 What media of data will be collected?
Hard copies of the assessment forms (demographic, Berg, IPAQ, HADS, Barthel, self-efficacy) and the activity monitor data will be retained and the results will be transferred to electronic data and stored on an encrypted file.

E2.3 (a) Would you class the data collected in this study as anonymous, irrevocably anonymised, pseudonymised, coded or identifiable data?
Coded

E2.3 (b) If ‘coded’, please confirm who will retain the ‘key’ to re-identify the data?
The PI (EH) will retain the “key” in a secure locked cabinet in the physiotherapy department in University Hospital Limerick. The “key” will be kept in a separate office and cabinet from all other data relating to the study within the Physiotherapy Department.

E2.4 Where will data which is collected be stored?
Paper copies will be stored in a locked filing cabinet in the physiotherapy department at University Hospital Limerick where the PI (EH) is a hospital employee. At the point of recruitment to the study each participant will be assigned an identification code. All data forms will contain this code pertaining to that individual. During data input and analysis the participant will only be identifiable by this code.

E2.5 Please comment on security measures which have been put in place to ensure the security of collected data.
All hard copies of data forms will be stored in a secure locked filing cabinet by the PI (EH) in the physiotherapy department at UHL. Data will be entered to a study data file, computer files will be stored on the hard drive of a password protected desktop computer by the study PI (EH).
E2.6 (a) Will data collected be at any stage leaving the site(s) of origin?  
Yes

E2.6 (b) If yes, please elaborate.

An encrypted copy of the data file may be forwarded to the academic supervisors Drs Galvin and Horgan to assist with data analysis.

E2.7 Where will data analysis take place and who will perform data analysis (if known)?

Drs Galvin and Horgan will assist with data analysis at UL and RCSI.

E2.8 (a) After data analysis has taken place, will data be destroyed or retained?

Data will be retained for 5 years and then destroyed.

E2.8 (b) Please elaborate.

As per E2.8(a)

E2.8 (c) If destroyed, how, when and by whom will it be destroyed?

Paper files will be destroyed using confidential hospital paper waste disposal services after all results are verified and published. Computer based files will be destroyed after 5 years in consultation with the IT department to ensure that they are not recoverable.

E2.8 (d) If retained, for how long, for what purpose, and where will it be retained?

Data will be retained for 5 years until all results are verified and published.

E2.9 Please comment on the confidentiality of collected data.

Participants will be assigned an identification code on entry to the study. All data files will link to this code and no participant will be identifiable.

E2.10 (a) Will any of the interview data collected consist of audio recordings / video recordings?  
No

E2.10 (b) If yes, will participants be given the opportunity to review and amend transcripts of the tapes?

Not applicable

E2.11 (a) Will any of the study data collected consist of photographs/ video recordings?  
No

E2.11 (b) If yes, please elaborate.

Not applicable
E3 ACCESS TO HEALTHCARE RECORDS

E3.1 (a) Does the study involve access to healthcare records (hard copy / electronic)? **Yes**

If answer is **No**, please delete remaining questions in Section E3

E3.1 (b) If yes, please elaborate.

The study PI (EH) may need to access the participants’ medical records to verify some demographic details or medications.

E3.1 (c) Who will access these healthcare records?

The study PI only, Edel Hennessy, who is a physiotherapist at UHL.

E3.1 (d) Will consent be sought from patients for research team members to access their healthcare records? **Yes**

If answer is **Yes**, please delete remaining questions in Section E3

SECTION F HUMAN BIOLOGICAL MATERIAL

F1 BODILY TISSUE / BODILY FLUID SAMPLES - GENERAL

F1 1 (a) Does this study involve human biological material? **No**

If the answer is **No**, please delete Section F

SECTION G RADIATION

G1 RADIATION – GENERAL

G1.1 (a) Does this study/trial involve exposure to radiation? **No**

If answer is **No**, please delete remaining questions in Section G

SECTION H MEDICAL DEVICES

H1 (a) Is the focus of this study/trial to investigate/evaluate a medical device? **No**
If answer is No, please delete remaining questions in Section H.

SECTION I  MEDICINAL PRODUCTS / COSMETICS / FOOD AND FOODSTUFFS

I.1  NON-INTERVENTIONAL TRIALS OF MEDICINAL PRODUCTS

I1.1 (a) Does this study involve a medicinal product? No

If the answer is No, please delete remaining questions in subsection I1

I.2  COSMETICS

I2.1 (a) Does this study involve a cosmetic? No

If the answer is No, please delete remaining questions in subsection I2

I.3  FOOD AND FOOD SUPPLEMENTS

I3.1 (a) Does this study involve food or food supplements? No

If the answer is No, please delete remaining questions in subsection I3

SECTION J  INDEMNITY AND INSURANCE

SECTION J IS MANDATORY

J1 Please confirm and provide evidence that appropriate insurance/indemnity is in place for this research study at each site.

The PI (EH) is covered by hospital indemnity as an employee of the hospital.

J2 Please confirm and provide evidence that appropriate insurance/indemnity is in place for this research study for each investigator.

As a member if the Irish Society of Chartered Physiotherapy the PI (EH) has the appropriate indemnity for this research study.

J3.1 Please give the name and address of the organisation / or individual legally responsible for this research study?

Edel Hennessy, Physiotherapy Department, University Hospital Limerick, Dooradoyle, Limerick
J3.2 Where an organisation is legally responsible, please specify if this organisation is:

A pharmaceutical company  
Yes / No

A medical device company  
Yes / No

A university  
Yes  Royal College of Surgeons in Ireland

A registered charity  
Yes / No

Other  
Yes  If yes, please specify:  University Hospital Limerick

J3.3 Please confirm and provide evidence of any specific additional insurance / indemnity arrangements which have been put in place, if any, by this organisation / or individual for this research study?

Not applicable

SECTION K  COST AND RESOURCE IMPLICATIONS, FUNDING AND PAYMENTS

SECTION K IS MANDATORY

K1  COST AND RESOURCE IMPLICATIONS

K1.1 Please provide details of all cost / resource implications related to this study (e.g. staff time, office use, telephone / printing costs etc.)

The PI (EH) will fund the cost of telephone calls to the participants on day seven to request the return of activity monitors and complete the IPAQ. Additionally the PI (EH) will fund the cost of the stamped and addressed envelopes to return to accelerometers following the seven days of measurement.

K2  FUNDING

K2.1 (a) Is funding in place to conduct this study?  
No

K2.1 (b) If no, has funding been sought to conduct this study? From where? Please elaborate.

Not applicable; the PI will fund costs.

K2.1 (c) If yes, please state the source of funding (industry, grant or other), the name of the funder, the amount of funding and duration of funding.

<table>
<thead>
<tr>
<th>Source of funding (industry, grant or other):</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Funder:</td>
<td>Answer</td>
</tr>
<tr>
<td>Amount of Funding:</td>
<td>Answer</td>
</tr>
<tr>
<td>Duration of Funding</td>
<td></td>
</tr>
</tbody>
</table>
K2.1(d) Please provide additional details in relation to management of funds.

Not applicable

K2.1(e) Is the study funded by a ‘for profit’ organisation? No

K2.2 (a) Do any conflicts of interest exist in relation to funding or potential funding? No

K2.2 (b) If yes, please elaborate.

Not applicable

K3 PAYMENTS TO INVESTIGATORS

K3.1 (a) Will any payments (monetary or otherwise) be made to investigators? No

K3.1 (b) If yes, please provide details of payments (including amount).

Not applicable

K4 PAYMENTS TO PARTICIPANTS

K4.1 (a) Will any payments / reimbursements (monetary or otherwise) be made to participants? No

K4.1 (b) If yes, please provide details of payments / reimbursements (including amount).

The PI will provide a stamped and addressed envelope for the return of the accelerometers.

SECTION L ADDITIONAL ETHICAL ISSUES

L1 (a) Does this project raise any additional ethical issues? No

If answer is No, please delete remaining questions in Section L.

L1 (b) If yes, please identify any particular additional ethical issues that this project raises and discuss how you have addressed them.

Not applicable

PLEASE ENSURE THIS APPLICATION FORM IS FULLY COMPLETED AS INCOMPLETE SUBMISSIONS WILL NOT BE REVIEWED.
Appendix 3 – UHL Research Ethics Committee Approval Letter

Ospidéal na hOllscoile, Luimneach
University Hospital Limerick

9th July, 2015.

Ms. Edel Hennessy,
Senior Physiotherapist in Neurology,
Physiotherapy Department,
University Hospital Limerick,
Doora Professional,
Limerick.

Re/ Protocol Title
Does Self-Reported Physical Activity Correlate with Objective Measurement in People Post Discharge Following Stroke?

Dear Ms. Hennessy,

The Research Ethics Committee at the University Hospital Limerick has received a submission for ethical approval for the above study.

The following documents were reviewed and approved by the Research Ethics Committee:

Application to the Research Ethics Committee
Study Protocol
Patient Information Leaflet
Letter to Consultant and GP
Data Sheet
International Physical Activity Questionnaire
Mini Mental State Examination
Hospital Anxiety and Depression Scale
Berg Balance Scale
The Barthel Index
The Stroke Self Efficacy Questionnaire
Consent Form

Approved
Approved
Approved
Approved
Approved
Approved
Approved
Approved
Approved
Approved

From an insurance perspective, please note that cover does not extend to those parties not employed by the Health Service Executive (HSE), or non-HSE Institutions.

Yours sincerely,

Brian McKeon,
Planning, Performance & Business Information Manager,
(For and on behalf of the Research Ethics Committee & the QPS Department).

ULH
Caring, Courteous and Professional

Health Service Executive
Physiotherapy Department,  
University Hospital Limerick,  
Dooradoyle,  
Limerick  
neurophysiorhd@hse.ie

Date xxx

Dear Doctor,

As part of my MSc in Neurology and Gerontology in RCSI I am conducting a piece of research on physical activity in patients following a stroke. Physical inactivity is highly prevalent after stroke which leads to physical deconditioning and sedentary lifestyles. It has been shown that stroke patients are less active than their age matched controls and even stroke patients who are capable of mobilising independently spend 33% of the working day in bed during the first month following stroke.

As standard practise physiotherapists instruct patients on the appropriate amount of physical activity which is 30 minutes of moderate intensity, five days per week. Physiotherapists also assess and provide personalised exercise plans for patients to focus on any physical deficits identified following a stroke.

To date, there is a dearth of research that examines levels of physical activity following discharge from hospital in individuals with acute stroke. The aim of this study is to examine levels of physical activity (PA) in the first week following discharge from hospital using an objective activity monitor. A secondary aim of the study is to ascertain whether an objective measure of PA correlates with self-report
levels of PA. Furthermore, this study will explore if cognition, function, balance, self-efficacy or depression influence levels of physical activity following stroke.

Every patient admitted to UHL with a confirmed diagnosis of stroke (by Consultant) will be considered for inclusion. Patients will be included if they are >18 years of age, have a confirmed diagnosis of ischaemic stroke, are independently mobile (+/- walking aid), are for discharge directly home from the Acute Stroke Unit, are medically stable and have an Mini Mental State Examination score >23/30.

Every participant will receive standard physiotherapy care and any patient who does not participate will also receive standard care, once they are referred for physiotherapy.

If you wish, I will provide you with the results of the study once completed. The study will begin in October 2015 and run for six months.

Kind regards,

Edel Hennessy MISCP

Senior Physiotherapist in Neurology
### Appendix 5 – Physical Activity Recommendations for Stroke Survivors (Billinger et al, 2014)

<table>
<thead>
<tr>
<th>Setting/mode of exercise</th>
<th>Goals/Objectives</th>
<th>Prescriptive Guidelines: Frequency/Intensity/Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitalisation and early convalescence (acute phase)</td>
<td>• Prevent deconditioning, hypostatic pneumonia, orthostatic intolerance, and depression</td>
<td>10 – 20 bpm increases in resting HR; RPE =11 (6 – 20 scale); frequency and duration as tolerated, using an interval or work-rest approach</td>
</tr>
<tr>
<td>• Low-level walking, self-care activities</td>
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<tr>
<td>• Intermittent sitting or standing</td>
<td>• Evaluate cognitive and motor deficits</td>
<td></td>
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<tr>
<td>• Seated activities</td>
<td>• Stimulate balance and coordination</td>
<td></td>
</tr>
<tr>
<td>• Range of motion activities, motor challenges</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inpatient and outpatient exercise therapy or “rehabilitation”</td>
<td>• Increases walking speed and efficiency</td>
<td>40-70% VO2 reserve or HR reserve; 55-80% HR max; RPE 11-14 (6-20 scale)</td>
</tr>
<tr>
<td>Aerobic</td>
<td>• Improve exercise tolerance (functional capacity)</td>
<td>3-5 days per week</td>
</tr>
<tr>
<td>• Large-muscle activities (e.g. walking, graded walking, stationary cycle ergometry, arm-leg ergometry, functional activities seated exercises, if appropriate)</td>
<td>• Increase independence in activities of daily living (ADL's)</td>
<td>20-60 minute session (or multiple 10 minute sessions)</td>
</tr>
<tr>
<td></td>
<td>• Reduce motor impairment and improve cognition</td>
<td>5 – 10 minute of warm-up and cool-down activities</td>
</tr>
<tr>
<td></td>
<td>• Improve vascular health and induce other cardioprotective benefits (e.g. vasomotor reactivity, decrease risk factor)</td>
<td>Complement with pedometers to increase lifestyle physical activity</td>
</tr>
<tr>
<td>Muscular strength/endurance</td>
<td>• Increase muscle</td>
<td>1-3 sets of 10-15 repetitions of 8-10 exercises involving the major muscle groups at 50-80% of 1RM</td>
</tr>
<tr>
<td>• Resistance training of UL extremities, trunk using free weights, weight-</td>
<td></td>
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<td></td>
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<tr>
<td>Physical Activities</td>
<td>Benefits</td>
<td></td>
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<td>---------------------</td>
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</tr>
<tr>
<td>Weight-bearing activities, elastic bands, spring coils, pulleys, circuit training, functional mobility.</td>
<td>Strength and endurance, increase ability to perform leisure-time and occupational activities and ADL’s, reduce cardiac demands (i.e., RPP) during lifting or carrying objects by increasing muscular strength, thereby decreasing the percentage MVC that a given load represents.</td>
<td></td>
</tr>
<tr>
<td>Flexibility: stretching (trunk, upper and lower extremities).</td>
<td>Increase range of movement of involved segments, prevent contractures, decrease risk of injury, increase ADL’s.</td>
<td></td>
</tr>
<tr>
<td>Neuromuscular: balance and coordination activities, Tai chi, yoga, recreational activities using paddles/sports balls to challenge hand-eye coordination, active-play video gaming and interactive computer games.</td>
<td>Improve balance, skill reacquisition, quality of life, and mobility, decrease fear of falling, improve level of safety during ADL’s.</td>
<td></td>
</tr>
</tbody>
</table>

- 2-3 days per week
- Resistance gradually increased over time as tolerance permits
- Static stretches; hold for 10-30 seconds
- 2-3 days per week (before or after aerobic or strength training)
- Use as a complement to aerobic, muscular strength/endurance training, and stretching activities
- 2-3 days per week
Appendix 6 – Irish Heart Foundation information booklet on physical activity
Appendix 7 – International Physical Activity Questionnaire

International Physical Activity Questionnaire

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the last 7 days. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the vigorous activities that you did in the last 7 days. Vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

1. During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, digging, aerobics, or fast bicycling?

______ days per week

☐ No vigorous physical activities  ➔ skip to question 3

2. How much time did you usually spend doing vigorous physical activities on one of those days?

______ hours per day

______ minutes per day

☐ Don’t know/not sure

Think about all the moderate activities that you did in the last 7 days. Moderate physical activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3. During the last 7 days, on how many days did you do moderate physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

______ days per week

☐ No moderate physical activities  ➔ skip to question 5

4. How much time did you spend doing moderate physical activities on one of those days/

______ hours per day

______ minutes per day
Think about the time you spent walking in the last 7 days. This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure.

5. During the last 7 days, on how many days did you walk for at least 10 minutes at a time?

______ days per week

☐ No walking ➔ skip to question 7

6. How much time did you usually spend walking on one of those days?

______ hours per day

______ minutes per day

☐ Don’t know/not sure

The last question is about the time you spent sitting on weekdays during the last 7 days. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7. During the last 7 days, how much time did you spend sitting on a week day?

______ hours per day

______ minutes per day

☐ Don’t know/not sure

This is the end of the questionnaire, thank you for participating.
## Mini-Mental State Examination (MMSE)

**Participant number:**

**Date:**

**Instructions:** Ask the questions in the order listed. Score one point for each correct response within each question or activity.

<table>
<thead>
<tr>
<th>Questions</th>
<th>Maximum score</th>
<th>Patient's Score</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Year? Season? Date? Day? Month?”</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The examiner names three unrelated objects clearly and slowly, then asks</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>the patient to name all three of them (apple, table, penny). The patient’s</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>response is used for scoring. The examiner repeats them until patient learns</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>all of them, if possible. Number of trials:_________________________</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“I would like you to count backward from 100 by sevens.” (93, 86, 79, 72,</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>65, …) Stop after five answers. Alternative: “Spell WORLD backwards.”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(D-L-R-O-W)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Earlier I told you the names of three things. Can you tell me what</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>those were?”</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name a pencil and watch.</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Repeat the phrase: ‘No ifs, ands, or buts.’”</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Place index finger of right hand on your nose and then on your left ear”.</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Please read this and do what it says.” (Written instruction is “Close</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>your eyes.”)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Make up and write a sentence about anything.” (This sentence must contain</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a noun and a verb.)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Please copy this picture.” (The examiner gives the patient a blank</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>piece of paper and asks him/her to draw the symbol below. All 10 angles</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>must be present and two must intersect.)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total** /30
Appendix 9 – Hospital Anxiety and Depression Scale

<table>
<thead>
<tr>
<th>Item</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>I feel tense or wound up</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Most of the time</td>
<td>3</td>
<td>Nearly all the time</td>
<td>Very often</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>A lot of the time</td>
<td>2</td>
<td>Occasionally</td>
<td>1</td>
<td>Sometimes</td>
<td></td>
</tr>
<tr>
<td>From time to time, occasionally</td>
<td>1</td>
<td>Not at all</td>
<td>0</td>
<td>Not at all</td>
<td></td>
</tr>
<tr>
<td>I still enjoy the things I used to enjoy</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Definitively as much</td>
<td>0</td>
<td>Not at all</td>
<td>1</td>
<td>Occasionally</td>
<td></td>
</tr>
<tr>
<td>Not quite so much</td>
<td>2</td>
<td>Not at all</td>
<td>0</td>
<td>Not at all</td>
<td></td>
</tr>
<tr>
<td>Only a little</td>
<td>3</td>
<td>Very Often</td>
<td>2</td>
<td>Quite Often</td>
<td></td>
</tr>
<tr>
<td>Hardy at all</td>
<td>2</td>
<td>Very Often</td>
<td>3</td>
<td>Not at all</td>
<td></td>
</tr>
<tr>
<td>I get a sort of frightened feeling as if something awful is about to happen</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Very definitely and quite badly</td>
<td>3</td>
<td>Not at all</td>
<td>1</td>
<td>I may not take as much care as I should</td>
<td></td>
</tr>
<tr>
<td>Very, but not too badly</td>
<td>2</td>
<td>Not at all</td>
<td>0</td>
<td>I may not take as much care as I should</td>
<td></td>
</tr>
<tr>
<td>Occasionally</td>
<td>1</td>
<td>Not at all</td>
<td>0</td>
<td>I take just as much care as ever</td>
<td></td>
</tr>
<tr>
<td>I can laugh and see the funny side of things</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Very much as I always could</td>
<td>3</td>
<td>Very much</td>
<td>2</td>
<td>Quite a lot</td>
<td></td>
</tr>
<tr>
<td>Not quite so much</td>
<td>2</td>
<td>Not very much</td>
<td>1</td>
<td>Very much</td>
<td></td>
</tr>
<tr>
<td>Not at all</td>
<td>3</td>
<td>Not at all</td>
<td>0</td>
<td>Not at all</td>
<td></td>
</tr>
<tr>
<td>Worrying thoughts go through my mind</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Very much as I ever did</td>
<td>3</td>
<td>Not at all</td>
<td>1</td>
<td>Not very much</td>
<td></td>
</tr>
<tr>
<td>Rather less than I used to</td>
<td>2</td>
<td>Very often</td>
<td>0</td>
<td>Not at all</td>
<td></td>
</tr>
<tr>
<td>Definitely less than I used to</td>
<td>1</td>
<td>Not at all</td>
<td>0</td>
<td>Not at all</td>
<td></td>
</tr>
<tr>
<td>I feel cheerful</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Very often indeed</td>
<td>3</td>
<td>Not at all</td>
<td>1</td>
<td>Not very often</td>
<td></td>
</tr>
<tr>
<td>Not often</td>
<td>2</td>
<td>Not at all</td>
<td>0</td>
<td>Not at all</td>
<td></td>
</tr>
<tr>
<td>I can sit at ease and feel relaxed</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Seldom</td>
<td>3</td>
<td>Very often</td>
<td>2</td>
<td>Not often</td>
<td></td>
</tr>
<tr>
<td>I can enjoy a good book or radio or TV program</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Seldom</td>
<td>3</td>
<td>Very often</td>
<td>2</td>
<td>Not often</td>
<td></td>
</tr>
</tbody>
</table>
## Appendix 10 – Berg Balance Scale

<table>
<thead>
<tr>
<th>Balance Item</th>
<th>Score (0-4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Sitting unsupported</td>
<td></td>
</tr>
<tr>
<td>2. Change of position: sitting to standing</td>
<td></td>
</tr>
<tr>
<td>3. Change of position” standing to sitting</td>
<td></td>
</tr>
<tr>
<td>4. Transfers</td>
<td></td>
</tr>
<tr>
<td>5. Standing unsupported</td>
<td></td>
</tr>
<tr>
<td>6. Standing with eyes closed</td>
<td></td>
</tr>
<tr>
<td>7. Standing with feet together</td>
<td></td>
</tr>
<tr>
<td>8. Tandem standing</td>
<td></td>
</tr>
<tr>
<td>9. Standing on one leg</td>
<td></td>
</tr>
<tr>
<td>10. Turning trunk (feet fixed)</td>
<td></td>
</tr>
<tr>
<td>11. Retrieving objects from floor</td>
<td></td>
</tr>
<tr>
<td>12. Turning 360 degrees</td>
<td></td>
</tr>
<tr>
<td>13. Stool stepping</td>
<td></td>
</tr>
<tr>
<td>14. Reaching forward while standing</td>
<td></td>
</tr>
</tbody>
</table>

TOTAL (0–56): _____
## Appendix 11 – Barthel Index

**THE BARTHEL INDEX**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FEEDING</strong></td>
<td></td>
</tr>
<tr>
<td>0 = unable</td>
<td></td>
</tr>
<tr>
<td>5 = needs help cutting, spreading butter, etc., or requires modified diet</td>
<td></td>
</tr>
<tr>
<td>10 = independent</td>
<td></td>
</tr>
<tr>
<td><strong>BATHING</strong></td>
<td></td>
</tr>
<tr>
<td>0 = dependent</td>
<td></td>
</tr>
<tr>
<td>5 = independent (or in shower)</td>
<td></td>
</tr>
<tr>
<td><strong>GROOMING</strong></td>
<td></td>
</tr>
<tr>
<td>0 = needs help with personal care</td>
<td></td>
</tr>
<tr>
<td>5 = independent face, hair, teeth, shaving (implements provided)</td>
<td></td>
</tr>
<tr>
<td><strong>DRESSING</strong></td>
<td></td>
</tr>
<tr>
<td>0 = dependent</td>
<td></td>
</tr>
<tr>
<td>5 = needs help but can do about half unaided</td>
<td></td>
</tr>
<tr>
<td>10 = independent (including buttons, zips, laces, etc.)</td>
<td></td>
</tr>
<tr>
<td><strong>BOWELS</strong></td>
<td></td>
</tr>
<tr>
<td>0 = incontinent (or needs to be given enemas)</td>
<td></td>
</tr>
<tr>
<td>5 = occasional accident</td>
<td></td>
</tr>
<tr>
<td>10 = continent</td>
<td></td>
</tr>
<tr>
<td><strong>BLADDER</strong></td>
<td></td>
</tr>
<tr>
<td>0 = incontinent, or catheterized and unable to manage alone</td>
<td></td>
</tr>
<tr>
<td>5 = occasional accident</td>
<td></td>
</tr>
<tr>
<td>10 = continent</td>
<td></td>
</tr>
<tr>
<td><strong>TOILET USE</strong></td>
<td></td>
</tr>
<tr>
<td>0 = dependent</td>
<td></td>
</tr>
<tr>
<td>5 = needs some help, but can do something alone</td>
<td></td>
</tr>
<tr>
<td>10 = independent (on and off, dressing, wiping)</td>
<td></td>
</tr>
<tr>
<td><strong>TRANSFERS (BED TO CHAIR AND BACK)</strong></td>
<td></td>
</tr>
<tr>
<td>0 = unable, no sitting balance</td>
<td></td>
</tr>
<tr>
<td>5 = major help (one or two people, physical), can sit</td>
<td></td>
</tr>
<tr>
<td>10 = minor help (verbal or physical)</td>
<td></td>
</tr>
<tr>
<td>15 = independent</td>
<td></td>
</tr>
<tr>
<td><strong>MOBILITY (ON LEVEL SURFACES)</strong></td>
<td></td>
</tr>
<tr>
<td>0 = immobile or &lt; 50 yards</td>
<td></td>
</tr>
<tr>
<td>5 = wheelchair independent, including corners, &gt; 50 yards</td>
<td></td>
</tr>
<tr>
<td>10 = walks with help of one person (verbal or physical) &gt; 50 yards</td>
<td></td>
</tr>
<tr>
<td>15 = independent (but may use any aid, for example, stick) &gt; 50 yards</td>
<td></td>
</tr>
<tr>
<td><strong>STAIRS</strong></td>
<td></td>
</tr>
<tr>
<td>0 = unable</td>
<td></td>
</tr>
<tr>
<td>5 = needs help (verbal, physical, carrying aid)</td>
<td></td>
</tr>
<tr>
<td>10 = independent</td>
<td></td>
</tr>
</tbody>
</table>

**TOTAL (0–100): ____**
Appendix 12 – Stroke Self-Efficacy Questionnaire

Stroke Self Efficacy Questionnaire

These questions are about your confidence that you can do some tasks that may have been difficult for you since your stroke.

For each of the following tasks, please circle a point on the scale that shows how confident you are that you can do the tasks now in spite of your stroke.

Where 0 = not at all confident and 10 = very confident

How confident are you now that you can

1. Get yourself comfortable in bed every night
   Not confident at all
   Very confident

   0 5 10

2. Get yourself out of bed on your own even when you feel tired
   Not confident at all
   Very confident

   0 5 10

3. Walk a few steps on your own on any surface inside your house
   Not confident at all
   Very confident

   0 5 10

4. Walk about your house to do most things you want
   Not confident at all
   Very confident

   0 5 10

5. Walk safely outside on your own on any surface
   Not confident at all
   Very confident

   0 5 10

6. Use both your hands for eating your food
   Not confident at all
   Very confident

   0 5 10
7. Dress and undress yourself even when you feel tired

8. Prepare a meal you would like for yourself

9. Persevere to make progress from your stroke after discharge from therapy

10. Do your own exercise program every day

11. Cope with the frustration of not being able to do some things because of your stroke

12. Continue to do most of the things you liked to do before your stroke

13. Keep getting faster at the tasks that have been slow since your stroke
CONSENT FORM

Protocol Title:

Does self-reported physical activity correlate with objective measurement in people with stroke post discharge?

Please tick the appropriate answer.

I confirm that I have read and understood the Patient Information Leaflet dated ___________ attached, and that I have had ample opportunity to ask questions all of which have been satisfactorily answered. □Yes □No

I understand that my participation in this study is entirely voluntary and that I may withdraw at any time, without giving reason, and without this decision affecting my future treatment or medical care. □Yes □No

I understand that my records may be viewed by individuals with delegated authority from ___________________ □Yes □No
I understand that my identity will remain confidential at all times.  ✔Yes  ❌No

I am aware of the potential risks of this research study.  ✔Yes  ❌No

I have been given a copy of the Patient Information Leaflet and this Consent form for my records.  ✔Yes  ❌No

**FUTURE USE OF ANONYMOUS DATA:**

I agree that I will not restrict the use to which the results of this study may be put. I give my approval that unidentifiable data concerning my person may be stored or electronically processed for the purpose of scientific research and may be used in related or other studies in the future. (This would be subject to approval by an independent body, which safeguards the welfare and rights of people in biomedical research studies - the University Hospital Limerick Ethics (Medical Research) Committee.)  ✔Yes  ❌No

Patient ____________________  ____________________

Signature and dated   Name in block capitals
To be completed by the Principal Investigator or his nominee.

I the undersigned have taken the time to fully explain to the above patient the nature and purpose of this study in a manner that he/she could understand. I have explained the risks involved, the experimental nature of the treatment, as well as the possible benefits and have invited him/her to ask questions on any aspect of the study that concerned them.

_________________________  ________________________  ____________  _________

Signature: Name in Block Capitals: Qualification: Date:

3 copies to be made: 1 for patient, 1 for PI and 1 for hospital records.
Appendix 14 – RCSI REC Approval letter

Royal College of Surgeons in Ireland
The Research Ethics Committee
121 St. Stephens Green, Dublin 2, Ireland.
Tel: +353 1 402209 Email: recadmin@rcsi.ie

Dr David Smith, Acting Chair
Dr Niamh Clarke, Convener

4th November 2015

Ms Edel Hennessy
Physiotherapy Department,
University Hospital Limerick,
Doonadolye,
Limerick.

<table>
<thead>
<tr>
<th>Ethics Reference No:</th>
<th>REC 1142 (accepted: University Hospital, Limerick)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Title:</td>
<td>Does self-reported physical activity correlate with objective measurement in people post discharge following stroke?</td>
</tr>
<tr>
<td>Researchers Name (lead applicant):</td>
<td>Ms Edel Hennessy (Physiotherapy, University Hospital Limerick)</td>
</tr>
<tr>
<td>Principal investigator/RCSI academic supervisors:</td>
<td>Dr Frances Horgan (RCSI School of Physiotherapy) and Dr Rose Galvin (Dept of Clinical Therapies, University of Limerick)</td>
</tr>
<tr>
<td>Other individuals involved:</td>
<td>Dr Peter Boers (Neurology, University Hospital Limerick)</td>
</tr>
</tbody>
</table>

Dear Ms Hennessy,

Thank you for your Research Ethics Committee (REC) application. The RCSI HREC accepts the ethical approval granted by University Hospital Limerick REC for the research study (details above) submitted by Ms Edel Hennessy

This letter provides approval for data collection for the time requested in your application and for an additional 6 months. This is to allow for any unexpected delays in proceeding with data collection. Therefore this research ethics approval will expire on 4th November 2016.

Where data collection is necessary beyond this point, approval for an extension must be sought from the Research Ethics Committee.

This ethical approval is given on the understanding that:

- All personnel listed in the approved application have read, understand and are thoroughly familiar with all aspects of the study.
- Any significant change which occurs in connection with this study and/or which may alter its ethical consideration must be reported immediately to the REC, and an ethical amendment submitted where appropriate.
- Please submit a final report to the REC upon completion of your project.

We wish you all the best with your research.

Yours sincerely,

Niamh Clarke
PP Dr Niamh Clarke (Convener)
Dr David Smith (Acting Chair)