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An Investigation Of The Factors Associated With Community Ambulation In Chronic Stroke

Sarah Durcan

Royal College of Surgeons in Ireland, sarahdurcan@rcsi.ie

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AN INVESTIGATION OF THE FACTORS ASSOCIATED WITH COMMUNITY AMBULATION IN CHRONIC STROKE

Sarah Durcan, B.Sc. (Physio)

A dissertation submitted in partial fulfillment of the requirements for the degree of MSc in Neurology & Gerontology.

School of Physiotherapy,
Faculty of Medicine and Health Sciences,
Royal College of Surgeons in Ireland.

September 2014

Supervisor: Dr Frances Horgan
Declaration

I declare that this thesis, which I submit to RCSI for examination in consideration of the award of a higher degree MSc 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.

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SUMMARY

Introduction

Loss of independent community ambulation is one of the most disabling consequences of stroke. While the relationship between gait speed and community ambulation has been well established, other underlying factors that may influence return to independent community ambulation post stroke are not clearly understood.

Aims and Objectives

The aim of this research was to investigate the factors associated with community ambulation in patients between one and three years post stroke. More specifically, it examined the association of multiple personal and post stroke factors with community ambulation and which factors were independently associated with community ambulation.

Methods

A cross-sectional study design was used. Forty community-dwelling stroke patients, between one and three years post stroke were recruited into the study. Each participant attended Baggot Street Hospital for one assessment. The primary outcome measure was a Community Ambulation Questionnaire. Other outcome measures included: 10 Metre Walk Test, Timed-Up and Go Test, Activities-Specific Balance Confidence Scale, Fatigue Severity Scale, Hospital Anxiety and Depression Scale, Trail-Making Test-Part B and Single Letter Cancellation Test. Demographic information was also recorded.
**Results**

Age, number of medications and use of a walking aid were found to be significantly associated with community ambulation (p ≤ 0.05). Gait speed, walking balance and balance self-efficacy were also found to be significantly associated with community ambulation (p ≤ 0.05). Balance self-efficacy was the only factor independently associated with community ambulation post stroke.

**Conclusion**

Balance self-efficacy may be a significant determinant in the attainment of independent community ambulation post stroke. This suggests that physical aspects such as gait speed and walking balance should not be considered in isolation when addressing community ambulation post stroke.

**Implication of Findings**

Clinically, the results support the need for assessment and treatment of balance self-efficacy when addressing community ambulation post stroke. Also, the role of balance self-efficacy should be considered when developing future outcome measures and interventions for community ambulation post stroke.
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I would like to my colleagues in the Stroke Rehab Team and Physiotherapy colleagues for their advice and support throughout this project.

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INTRODUCTION

Stroke is the third most common cause of death and the most common cause of acquired major disability in Ireland (Irish Heart Foundation Stroke Guidelines, 2009). It is estimated that only 50% of stroke patients regain independent walking ability by the end of standard rehabilitation (Jorgensen et al. 1995), with many patients still experiencing motor impairment and difficulty with activities of daily living (Schaechter, 2004). A common sequelae of stroke is the loss of independent community ambulation. It has been reported that only 20-66% of patients manage to walk independently in the community again following a stroke (Perry et al. 1995, Lord et al. 2004, Viosca et al. 2005). Loss of independent community ambulation has been found to be associated with poor quality of life, decreased satisfaction and mood disorders in stroke patients (Pound et al. 1998).

The attainment of independent community ambulation has not been well researched in the literature to date, therefore it is unclear what factors play a significant role in the ability to walk independently in the community following stroke. In the absence of a validated outcome measure to assess community ambulation post stroke, many studies have focussed on gait speed as a proxy measure for community ambulation. Gait speed has been found to be a useful and discriminate measure of different ambulation levels (Perry et al. 1995). Walking distance has also been reported as a useful predictor of community walking activity in high functioning people with stroke (Fulk et al. 2010). However, physical ability does not always predict the ability to walk in the community following stroke. Lord et al. (2004) found that although 80% of patients regained independent gait and scored highly on mobility
outcomes, nearly one third were unable to walk unsupervised in their own community. It has been suggested in the literature that other physical, psychological and cognitive factors may also be significantly associated with community ambulation post stroke.

Community ambulation is a complex task requiring the ability to adapt gait to diverse and complex conditions, including walking on varying terrains, in diverse ambient conditions, with attentional demands and while performing additional tasks such as carrying a load, changing directions, avoiding obstacles and engaging in social interactions (Shumway-Cook et al. 2007). Given the demands of the task, it is possible other factors such as walking balance, endurance, balance self-efficacy and patient motivation may be influencing factors. Also, the high prevalence of deficits such as post stroke fatigue, anxiety and depression, executive dysfunction and visual neglect make it likely that they may play a key role in return to independent community ambulation post stroke.

Only a few studies to date have examined what other physical, psychological and cognitive factors are associated with community ambulation following stroke. Robinson et al. (2011) found balance self-efficacy and depression to be associated with participation in community walking in chronic stroke patients. Similarly, Van de Port et al. (2008) found that the ability to walk in the community is determined by several underlying factors such as balance, motor function, endurance and use of an assistive device. There is no consensus to date on what factors are most important in predicting those who will return to independent community ambulation. Given the
paucity of research which has been carried out in this area and the importance of community ambulation to quality of life and level of disability of stroke patients, identifying factors affecting community ambulation following stroke is vital.

This current study will aim to investigate the association of personal and stroke-specific factors with the ability to ambulate independently in the community following stroke. If a better understanding of the factors underlying return to community ambulation post stroke is gained, this will allow more specific interventions for community ambulation to be developed and tested, with the aim of maximising functional outcomes for patients.
CHAPTER 1        LITERATURE REVIEW

1.1 Introduction

Community ambulation has been defined as independent mobility outside the home, which includes the ability to confidently negotiate uneven terrain, private venues, shopping centres and other public venues (Lord et al. 2004). It has been reported that approximately 80% of patients regain independent gait following a stroke (Lord et al. 2004, Veerbeek et al. 2011), however only a smaller proportion manage to walk independently in the community again. Loss of independent community ambulation is one of the most disabling consequences of stroke. It has been found to be associated with poor quality of life, decreased satisfaction and mood disorders in stroke patients (Pound et al. 1998). Lord et al. (2004) found that the ability ‘to get out and about’ in the community was considered to be either essential or very important by 75% of the 115 stroke patients they questioned. Considering the importance of community ambulation to quality of life post stroke, it is necessary for clinicians to gain a better understanding of the factors associated with community ambulation, so they can develop more specific rehabilitation programs to maximise patient outcome.

1.2 Prevalence of Community Ambulation after Stroke

The prevalence of independent community ambulation following stroke has varied in the literature. Perry et al. (1995) recruited a sample of 147 stroke patients, greater than three months post stroke and found that only 50% were able to walk in the community, as measured by the Hoffer Functional Ambulation Scale. Similarly,
Viosca et al. (2005) reported that 48% of stroke patients regained independence in community ambulation, as measured on the five-point Functional Ambulation Category (FAC) scale. In contrast, Hill et al. (1997) reported that only 7% of the 109 patients in their study met the criteria for independent community ambulation, which included minimal thresholds for gait velocity and endurance, as well as independence on the FAC measure and the locomotion domain of the Functional Independence Measure (FIM).

Much of this variability between the studies can be explained by differences in the characteristics of the stroke patients included, differences in sample size, as well as the use of different measures to define community ambulation. In the study by Perry et al. (1995), they had a relatively young cohort of stroke patients (average age 55.5 ±12.2 years), in comparison to Hill et al. (1997) who recruited an older patient cohort (average age 72 ±10.4 years). This age difference may be an important factor in explaining the large variance in community ambulation levels between these studies. Also, both Perry et al. (1995) and Viosca et al. (2005) used similar Functional Ambulation Categories for measuring community ambulation, which may explain the similarity in reported ambulation levels for these studies. In contrast, Hill et al. (1997) applied a more stringent criteria, with subjects required to meet certain targets in all four categories (gait speed, endurance, FAC and FIM scores), in order to be classified as being independent in community ambulation. This may account for only 7% of stroke patients in this study being classified as independent community ambulators.
1.3 Measurement of Community Ambulation

Currently, there is no reliable and validated measure of community ambulation for people with stroke. Researchers have focused on mobility variables such as gait speed and walking endurance as proxy measures for community ambulation. Gait speed is a reliable, objective measure of walking ability and walking performance following stroke (Salbach et al. 2001). A study by Lord et al. (2004) found gait speed to be a useful and discriminate measure for the different categories of community ambulation. The categories were classified as 1) not ambulant outside the home, 2) ambulant as far as the letterbox, 3) ambulant in the immediate environment and 4) ambulant in a shopping centre and/or places of interest. They reported a cut off value for community ambulators of a gait velocity of at least 49.2 m/min. A cut off gait velocity of 48 m/min has also been reported by Perry et al. (1995) and Hill et al. (1997), as a measure of distinguishing between community ambulators and those unable to achieve independent community ambulation. However, walking ability alone does not always reflect ability to walk unsupervised in the community. In that same study by Lord et al. (2004), approximately 80% of patients had regained independent gait and scored highly on gait speed, however, nearly one third were not able to walk unsupervised in their own community again after their stroke. The authors suggest that there may be other underlying factors that may influence return to community ambulation post stroke, however they do not hypothesise as to what those other factors might be.

A later study by Van de Port et al. (2008) examined the strength of the association between gait speed and community ambulation and whether this association was
significantly confounded by other variables. This was a cross-sectional study of 102 patients who were three years post stroke. The results found that while gait speed was significantly related to community ambulation, this association was confounded by balance, motor function, endurance and use of an assistive device. While these results concur with the previous studies that gait speed is an important measure of community ambulation, they also suggest that other underlying factors may influence stroke patients’ ability to return to independent community ambulation. Potential underlying factors may include walking distance, walking balance and balance self-efficacy, fatigue, anxiety and depression, executive function and visual neglect of extrapersonal space.

1.4 Walking Distance and Community Ambulation

Dean et al. (2001) carried out a study examining both 10 metre comfortable walking speed and 6-minute walking distance in 14 stroke patients, who were at least three months post stroke. They found that gait speed measured over 10 metres can overestimate the locomotor capacity of stroke patients, suggesting that walking distance might be a better predictor for community walking than gait speed. This hypothesis was further examined in a cross-sectional study by Fulk et al. (2010), which investigated the ability of the 6-minute walk test (6MWT) and other outcome measures such as self-selected gait speed, Berg Balance Scale (BBS), the lower limb section of the Fugl-Meyer Assessment and the Stroke Impact Scale, to predict home and community walking in 32 chronic stroke patients. Accelerometers were used to measure the average steps taken per day over a seven day period. The 6MWT was found to be the only predictor of average steps taken per day and they concluded that
walking endurance may be a useful measure to predict community walking in higher functioning people with stroke.

A more recent study by Bijleveld-Uitman et al. (2013) investigated whether gait speed or walking distance is a better predictor of community ambulation post stroke. They examined 241 chronic stroke patients of varying levels of stroke severity, using the 5-metre timed walk to measure gait speed and the 6MWT to assess walking distance. The results of this study found that both gait speed and walking distance were equally appropriate predictors of community ambulation levels after stroke. In contrast to the previous two studies, Lord et al. (2004) found endurance to be less discriminating than gait speed in determining community ambulation. Once again, differences in measures of community ambulation and characteristics of the study participants, as well as how gait speed is measured, limit the comparability of the studies and definite conclusions cannot be drawn.

1.5 Complexity of Community Ambulation

It is evident from the previous studies that gait speed and endurance are important factors related to community walking, however in isolation, they are not always reflective of independent community ambulation and may not capture the complexity of the task. A qualitative study by Corrigan and McBurney (2012) aimed to establish what abilities, skills and factors physiotherapists considered important in enabling patients to return to independent community ambulation post stroke. They interviewed 10 physiotherapists, who were working with stroke patients in both rural
and regional communities and who had greater than 3 years experience as a physiotherapist. Six key themes were identified which included; the ability to walk at speed and physical fitness, the ability to negotiate different terrains, ambient conditions, the ability to reason and monitor the environment, to have support of a person or aid and to have the motivation to walk in the community. This suggests that numerous factors other than mobility variables should be taking into account when developing rehabilitation programmes for return to community ambulation. To date, there have been no focus groups carried out with stroke patients regarding community ambulation and more specifically, what factors they feel are important or influence their ability to walk independently in the community.

Patla and Shumway-Cook (1999) developed an operational definition of community mobility that considered eight environmental domains. These domains included 1) terrain, 2) postural transitions, 3) loads, 4) attention, 5) ambient conditions, 6) crowds, 7) time constraints, and 8) distance. This was further examined by Shumway-Cook et al. (2002) who observed 17 older adults with mobility disability walking in the community and compared them to 19 older adults without disability. They concluded that community ambulation requires the ability to adapt gait to diverse and complex conditions, including walking on varying terrains, in diverse ambient conditions, with attentional demands and while performing additional tasks such as carrying a load, changing directions, avoiding obstacles or engaging in social interactions. Considering the complexity of the task, it is likely that a number of other physical, psychological and cognitive factors are associated with the ability to participate in community ambulation following stroke.
1.6 Walking Balance and Balance Self-Efficacy

Walking balance refers to the ability to control the centre of mass within the base of support to remain upright while walking (Pollock et al. 2011). Balance impairment is a common difficulty post stroke, with falls occurrence reported to be as high as 73% in ambulatory people post stroke, who are living in the community (Mackintosh et al. 2006). Balance impairment has also been found to be associated with poor ADL and mobility recovery (Tyson et al. 2006), as well as being associated with poor quality of life in chronic stroke patients (Schmid et al. 2013). Balance self-efficacy refers to a person’s belief in their ability to undertake activities of daily living without losing their balance (Salbach et al. 2005). Balance self-efficacy may influence a person’s ability to carry out functional tasks and participate in community activities. Hellstrom et al. (2003) found that balance self-efficacy was a stronger predictor than balance capacity of the ability to perform ADL’s at 10 months post stroke, in a sample of 37 community-dwelling stroke patients.

Evidence of a relationship between walking balance and balance self-efficacy with both functional ability and participation in acute and chronic stroke populations has been identified. A cross-sectional study by Ng (2011), with 78 subjects who were greater than one year post stroke, found that both balance ability and subjective balance confidence were independently associated with functional ability, as measured by the Timed Up and Go (TUG). Schmid et al. (2012) found that balance self-efficacy, as measured by the Activities-Specific Balance Confidence Scale (ABC), was independently associated with post-stroke activity and participation in a sample of 77 stroke patients, over six months post stroke. Similarly, a study by Pang
et al. (2007) found balance self-efficacy (measured by ABC scale) to be an independent predictor of community reintegration in 63 older adults, greater than one year after their stroke. While it is evident from the research that balance and balance self-efficacy play an important role in return to functional activity and participation following stroke, only a few studies have examined their relationship specifically with community ambulation.

One such study by Robinson et al. (2011) examined the association between personal factors such as age and sex, and measures such as the ABC scale, Fatigue Severity Scale and the Centre for Epidemiologic Studies Depression Scale (CES-D), with participation in community walking in 50 community dwelling stroke survivors. They found that balance self-efficacy was strongly associated with both subjective and objective measures of participation in community walking. Similarly, Van de Port et al. (2008) found that the ability to walk in the community is determined by several underlying factors, which included balance ability. This suggests that mobility factors other than gait speed and endurance need to be considered as having an importance influence on community ambulation post stroke and the extent of their contribution requires further investigation.

1.7 Fatigue and Physical Activity Post Stroke

Fatigue is a common and often severe sequelae of stroke, which patients may experience for months and years post stroke (Glader et al. 2002). Fatigue can be defined as ‘a feeling of lack of energy, weariness and aversion to effort’ (Staub and
Bogousslavsky, 2001). The prevalence of post stroke fatigue has varied in the literature. Stein et al. (1996) found that 78% of patients at eight months post stroke reported suffering from fatigue. A large prospective cohort study by Glader et al. (2002), which recruited 3667 stroke patients, found that at two years post stroke, 40% of patients reported that they were ‘always’ or ‘often’ fatigued. Fatigue may be an important factor associated with reduced physical activity post stroke; however to date, research is limited. In other neurological conditions such as Parkinsons Disease, fatigue has been found to be strongly linked to deficit severity and functional capacity (Garber and Friedman, 2003). Similarly, in Multiple Sclerosis, fatigue has been shown to have a negative effect on the performance of activities of daily living (Krupp and Christodoulou, 2001). Michael et al. (2006) reported that in patients with chronic stroke, fatigue is associated with cardiovascular deconditioning and results in reduced ambulatory activity at home and in the community.

The association of fatigue with participation in community ambulation following stroke has not been well investigated to date. Robinson et al. (2011) found fatigue was not associated with number of trips or walking related activities in the community in a sample of 50 community dwelling stroke survivors. Similarly, Bijleveld-Uitman et al. (2013) found fatigue not to be a significant confounder in the relationship between gait speed and community walking. However, these were both small studies and they used different criteria and definitions of both fatigue and community ambulation, therefore definite conclusions cannot be drawn. Considering the high prevalence of post stroke fatigue and the association of fatigue with ADL performance and physical activity in stroke and other neurological conditions, the
relationship between community ambulation and post-stroke fatigue warrants further exploration.

1.8 Depression and Anxiety

Depression is another prevalent symptom post stroke. A systematic review by Hackett et al. (2005) estimated that the prevalence of post stroke depression was 33%, however this has varied in the research from 25% to 79% (Gordan and Hibbard, 1997). In more recent years, there has also been a focus on post stroke anxiety in the literature, with prevalence ranging from 4% to 28% (Astrom, 1996; House et al. 1991). A relationship between depression, physical activity and functional ability in patients post stroke has been reported in the literature. A study by Chemerinski et al. (2001) examined the effect of post stroke depression on recovery of ADL function in a sample of 55 stroke patients, at three and six months post stroke. The results found post-stroke depression, as measured by the Hamilton Depression Scale (HDS), to be significantly associated with impaired recovery of ADL function. Similarly, a study by Goodwin and Devanand (2008) examined the association of post-stroke depression with functional health outcomes. They found a significant association existed between depression and greater limitations in activities of daily living, walking and stair climbing. Post-stroke depression may also result in reduced participation levels. Feibel and Springer (1982) reported that patients suffering depression at six months post stroke, had greater difficulties in returning to their prior social activities compared with non-depressed patients.
Given the association between depression and activity levels post stroke, it is possible that depression may have an influential effect on community ambulation also. Only one study to date has examined the relationship between depression and participation in community ambulation post stroke. Robinson et al. (2011) looked at the association between depression (as measured by the CES-D) with participation in community walking. The results demonstrated that depression was significantly correlated with reduced participation in community walking, increased perceived difficulty and reduced satisfaction with walking. However, this was a small cross-sectional study, with a convenience sample of 50 community-dwelling stroke patients, which limits the generalisability of the results. Further research is needed to investigate the relationship between community ambulation and post-stroke depression and anxiety.

1.9 Executive Function

In recent years, the role of executive function in gait has been increasingly reported in the literature. Executive function is defined as the cognitive ability to independently perform complex, goal-directed and self-serving behaviours (Malloy and Richardson, 1994). Executive function includes multiple cognitive tasks such as planning, tracking, judgement, initiation, scanning, sequencing, problem solving and cognitive flexibility (Royall et al. 2002). Impairment of executive function may impact one’s ability to walk efficiently and safely (Yogeve et al. 2008). A number of studies have been carried out examining the relationship between physical performance and executive function in older adults. A large cross-sectional study by Ble et al. (2005) investigated the relationship between performance on tests of
executive function and performance of mobility tasks of varying attentional demands, in a sample of 926 older adults. The results found that executive function was independently associated with lower extremity tasks which require high attentional demands. Similarly, Mc Gough et al. (2011) found slower gait speed to be significantly associated with lower executive function performance in 201 sedentary older adults.

Donovan et al. (2008) reported that up to 65% of stroke patients demonstrate new onset or worsening of cognitive impairments, including executive dysfunction, which may interfere with their physical recovery. Only a few studies to date have examined the effect of executive dysfunction post stroke on physical performance outcomes. Liu-Ambrose et al. (2007) investigated the association of executive function with performances of balance and mobility in 63 community-dwelling stroke patients, greater than one year post mild-stroke. They found that cognitive flexibility was independently associated with better performance on balance and mobility measures. A pilot study by Hayes et al. (2013), with a sample of 20 stroke patients, reported that poor performance in measures of executive function was more frequently associated with poor performance in complex gait tests compared to basic gait tests. Currently, the relationship between executive function and community ambulation following stroke has not been examined specifically in the research. Considering the results of the previous studies and the complexity of the task of community ambulation in terms of both physical and cognitive demands, the association of community ambulation with executive function post stroke should be investigated.
1.10 Visual Neglect of Extrapersonal Space

Visual neglect of the extrapersonal space is another factor which may be associated with community ambulation post stroke. Patients with extrapersonal neglect cannot avoid obstacles such as a doorway or may be unable to look to the contralesional side when crossing the street (Kim et al. 2010). Visual inattention has been reported to be associated with poor functional outcomes and reduced physical activity levels post stroke. Jehkonen et al. (2000) investigated whether visual neglect was predictive of poor functional recovery at one year post stroke, in a sample of 57 stroke patients. The results demonstrated that visual neglect was the best single predictor of poor functional outcome at one year post stroke and residual neglect restricted patients real-life activities and hobbies. Similarly, Pahlman et al. (2012) reported that visual neglect was an important factor associated with low physical activity levels at one year post stroke. Considering these difficulties, it is likely that visual inattention may play a role in the ability to community ambulate following stroke; however this has not been examined to date.

1.11 Conclusion

Community ambulation is a very important and meaningful activity for people following stroke. It is evident from the literature that mobility variables such as gait speed and endurance play an important role in the ability to walk in the community; however they don’t always accurately predict those who return to community walking. It is important to establish what other physical, psychological and cognitive variables are associated with community ambulation after stroke. Factors such as balance, balance self-efficacy, fatigue, depression, executive function and visual
neglect have been shown to be associated with physical performance outcomes post stroke, however their relationship to community ambulation requires further investigation. This will enable clinicians to predict more accurately those who will return to community ambulation after stroke. It will also help inform interventional strategies for community ambulation to be further tested in research. This in turn would allow clinicians to deliver more focussed and specific treatment programmes, maximising patient outcomes.

The aim of this current study is to examine the association between multiple personal and post stroke factors and community ambulation, in patients between one and three years post stroke. More specifically, it will examine whether personal factors are significantly associated with community ambulation, as well as whether impairments in gait speed, balance, fatigue, depression, balance self-efficacy, executive function and visual inattention are associated with community ambulation post stroke. Finally, it will investigate which post-stroke variables are independently associated with community ambulation post stroke.
CHAPTER 2   METHODOLOGY

2.1 Aim
The aim of this study was to examine the association between multiple personal and post stroke factors and community ambulation in patients between one and three years post stroke.

2.2 Objectives
The objectives of this study were:

- To examine whether personal factors are significantly associated with community ambulation post stroke
- To examine whether impairments in gait speed, balance, fatigue, depression, balance self-efficacy, executive function and visual inattention are associated with community ambulation post stroke.
- To determine which post stroke-variables are independently associated with community ambulation post stroke.

2.3 Study Design
This was a cross-sectional observational study, with measurements taken at one single time point.

2.4 Subjects
Study participants were recruited from the database of the Stroke Rehabilitation Team in Baggot Street Hospital. A sample size of 40 participants was calculated. According to Conroy (2009), in studies investigating relationships between variables
of clinical interest, a correlation of less than 0.45 is unlikely to have clinical significance. Conroy (2009) has produced a table to assist with sample size calculation for correlation studies (Appendix 1). For the current study, based on finding a correlation between 0.45 and 0.55 for a study powered at 90%, a sample size of 40 was calculated, which falls between 30 and 48.

All patients who were between one and three years post stroke were selected from the database of the Stroke Rehabilitation Team. Their names were entered into a Microsoft Excel spreadsheet. A random number table was used to place the names in a random order and then the top 100 names were selected. This was to account for a proposed response rate of 40%, which has been reported in other studies with community dwelling stroke survivors (Lloyd et al. 2010).

2.5 Inclusion Criteria

The inclusion criteria for the study were as follows:

- Diagnosed with a stroke, as defined by the World Health Organisation definition, 'a stroke is clinical syndrome characterised by rapidly developing clinical symptoms and / or signs of focal, and at times global, loss of cerebral function, with symptoms lasting more than 24 hours or leading to death, with no apparent cause other than that of vascular origin (Hatano, 1976.)'

- Greater than 18 years of age, community-dwelling

- Between one and three years post stroke
• Able to walk at least 10 metres, with/without a walking aid and independently

• Able to give informed written consent

2.6 Exclusion Criteria

The exclusion criteria for this study were as follows:

• Aphasia- unable to complete the pen and paper tests or questionnaires secondary to communication difficulties

• Parkinsons Disease

• Multiple Sclerosis

• Traumatic brain injury/other brain injury of non-vascular origin

• Recent lower limb fracture (within previous six months)

• Uncontrolled cardiac conditions

• Cognitive impairment (a score of \( \leq 6 \) on the Abbreviated Mental Test Score [AMTS]). For patients where there was a concern regarding reduced cognitive ability/memory, the AMTS (Appendix 2) was administered by the lead researcher prior to the consenting process. Patients with cognitive impairment were excluded from this project as they would have reduced cognitive ability to follow instructions, in particular for the physical tests, which would be a safety hazard.
2.7 Recruitment of Participants

The subjects who were selected from the database were sent a letter inviting them to participate in the study by the gatekeeper, Ms. Evelyn Flavin, Physiotherapy Manager (Appendix 3). The purpose of the gatekeeper was to minimise recruitment bias, as many of the clients were previously known to the lead researcher. They also received a participant information leaflet with the contact details, if they wished to participate in the research study (Appendix 4).

2.8 Ethical Considerations

Ethical approval for this research study was obtained from the RCSI Research Ethics Committee on 15th October, 2013 (Appendix 5). Permission to carry out the research on site in the Stroke Rehabilitation Team in Baggot Street Hospital was also obtained from Physiotherapy Manager Ms Evelyn Flavin and Primary Care Manager, Ms Helen Deely (Appendix 6).

All participants who volunteered to take part in the research study were asked to complete a written consent form (Appendix 7). Participants were informed that their participation in the study was voluntary and that they could withdraw at any time and it would not affect their future treatment. They were also informed that all information received about them would remain confidential. Each participant was allocated a study I.D. number to identify them. All the data collected was coded and entered into a file, which was securely stored and password protected on the RCSI server V: drive. All written documentation with subject’s name or I.D. number was stored in a locked metal filing cabinet, which only the lead researcher had access to. All documentation from this research study will be stored safely in RCSI for 5-7 years and will then be destroyed.
2.9 Procedure

Testing was carried out in the Physiotherapy Gym in Baggot Street Hospital. Prior to commencement of the study, a pilot study with four stroke patients was conducted, to inform the length of time required for administration of the outcome measures and to highlight any difficulties with their administration. Data collected in the pilot study was excluded from the statistical analyses. Standardised instructions were given for each of the outcome measures and they were administered by the lead researcher.

2.10 Measures

2.10.1 Demographic information

Basic demographic information was collected. This included age, sex, marital status, race, education, living status, medications, use of assistive device and number of co-morbidities.

Data on stroke characteristics were also collected. This included time since stroke, side of hemiparesis, type of stroke and Modified Rankin Score (Appendix 8). Participants were also asked if they had fallen in the previous six months and if so, how often.

All information collected was inputted into the data collection sheet (Appendix 9).

2.10.2 Primary Outcome Measure

- Community Ambulation Questionnaire (CAQ)

This is a short, self administered questionnaire that was developed by Lord et al. (2004). It categorises patients into 4 categories of community ambulation: (i) the
patient is unable to walk outside, (ii) the patient can walk outside as far as the front of the house without physical assistance or supervision, (iii) the patient can walk in the immediate environment (e.g. down the road) without physical assistance or supervision, (iv) the patient can walk to shops, friends’ houses or activities in the vicinity without physical assistance or supervision (Appendix 10). This questionnaire has been used in previous community ambulation studies with people after stroke (Van de Port et al. 2008, Bijleveld-Uitman et al. 2013).

2.10.3 Other Outcome Measures

- **10 Metre Walk Test (10MWT)**

This was administered as a measure of gait speed (Appendix 11). In this test, the individual walks without assistance for 10 metres and the time is measured for the intermediate six metres, allowing for acceleration and deceleration. The use of a walking aid is allowed and this was recorded. Three trials of the test were carried out and the average of the three was calculated. This has been found to be a reliable measure of gait speed after stroke (ICC = 0.95-0.99) (Collen et al. 1990).

- **Timed-Up and Go (TUG)**

This was used to assess walking balance (Appendix 12). In this test, subjects were asked to stand up from a chair with arms, walk up to a line on the floor 3 metres away, turn around and walk back to the chair and sit down. The time taken to complete the test was recorded. Each participant was given a practice trial that was not timed prior to testing. Flansbjer et al. (2005) demonstrated that this is a reliable
measure in chronic stroke patients. It is strongly associated with the Berg Balance Scale (BBS) in community-dwelling stroke survivors ($\rho = -0.70$, $p < 0.001$) (Knorr et al. 2010).

- **Activities-Specific Balance Confidence Scale (ABC Scale)**

This was administered to assess balance confidence in carrying out everyday activities (Appendix 13). Participants were asked to rate on a scale from 0% (no confidence) to 100% (completely confident) how confident they were that they would not lose their balance or become unsteady carrying out a range of 16 functional activities. It has been found to be a reliable measure for use with stroke patients ($\text{ICC} = 0.85; 95\% \text{ CI} 0.68-0.93$) (Botner and Miller, 2005).

- **Fatigue Severity Scale (FSS)**

This was used to assess the impact of fatigue (Appendix 14). It is a 9-item self-report scale, which measures the severity of fatigue and how much it affects the person’s activities and lifestyle. It contains 9 questions with scores ranging from 1 (strongly disagree) to 7 (strongly agree). It has been shown to be a reliable and valid measure of fatigue in a stroke population (Lerdal and Kottorp, 2011). It has been previously used in studies to assess fatigue in stroke patients (Choi-Kwan et al. 2005).
• **Hospital Anxiety and Depression Scale (HADS)**

This was used as a measure of anxiety and depression (Appendix 15). It contains two 7-item scales, one for anxiety and one for depression. It has been shown to be reliable, valid and sensitive to change in the screening for depression (Zigmond and Snaith, 1983).

• **Trail-Making Test-Part B (TMT-B)**

This was used as a measure of executive function (Appendix 16). It evaluates the components of executive function that represent complex visual scanning, speed, attention and ability to shift sets (Greenlief et al. 1985). The test consists of 25 circles numbered 1 to 13 and lettered A-L, randomly distributed over a page of paper. Participants were asked to connect the circles as quickly as possible, alternating between numbers and letters (e.g. 1A, 2B, 3C…). It has been previously used in studies examining associations between gait and executive function (Ble et al. 2005). It has been shown to have excellent test-retest reliability in patients with stroke (ICC = 0.86) (Goldstein and Watson, 1989).

• **Single Letter Cancellation Test**

This was used to measure unilateral spatial neglect of the near extrapersonal space (Appendix 17). The test consists of one A4 sheet of paper containing 6 lines with 52 letters per line. The subject was asked to put a line through each H that is found on the page. The score is calculated by subtracting the number of omissions from the possible perfect score of 104. It has been found to have strong psychometric
properties, (including reliability and validity), in identifying unilateral spatial neglect in the near extrapersonal space (Menon and Korner-Bitensky, 2004).

2.11 Data Collection

All data was collected from each participant during one 45-60 minute session. The data was inputted into the data collection form. This data was then coded and transferred to a Microsoft Excel Spreadsheet.

2.12 Statistical methods

Data was analysed using SPSS software (Version 18.0; SPSS Inc, Chicago, Illinois). Descriptive statistics were used to describe the characteristics of the participants and their levels of community ambulation. The mean and standard deviation or median and interquartile range were calculated for each of the variables, following tests for normality. Data has been presented using a variety of tables and graphs. Binary logistic regression analysis was carried out to examine for associations between community ambulation and the personal and post-stroke factors. Multivariate logistic regression was used to examine whether any of the factors were independently associated with community ambulation post stroke.
CHAPTER 3 RESULTS

The aim of this study was to examine the association of multiple personal and post stroke variables with community ambulation in patients between one and three years post stroke.

The objectives were to:

- To examine whether personal factors are significantly associated with community ambulation post stroke
- To examine whether impairments in gait speed, balance, fatigue, depression, balance self-efficacy, executive function and visual inattention are associated with community ambulation post stroke.
- To determine which post stroke-variables are independently associated with community ambulation post stroke.

3.1 Participant Recruitment

All study participants were recruited between October 2013 and January 2014. Letters of invitation to participate in this study were sent to 100 stroke patients, who were randomly selected from the Stroke Rehabilitation Team database. There were 40 patients who volunteered to participate in the study and who met the inclusion criteria. This was a response rate of 40%. The flow of participants into this study is shown in Figure 3.1.
Letters of invitation were sent to 100 stroke patients

40 patients responded and met the inclusion criteria for the study

Patients who did not participate in the study (n=60)

No Response (n=50)

Did not wish to participate (n=6)

In hospital (n=3)

RIP (n=1)

Figure 3.1: Flow of participants in the study
3.2 **Baseline Demographics**

The average age of the participants in this study was 66 years ± standard deviation (SD) 13.4 years. There were 22 male participants (55%) and 18 female participants (45%). The average length of time since stroke was 22.3 months ± SD 6.9 months. The majority of the participants had suffered a right hemispheric lesion (62.5%) and 90% of participants had suffered a stroke of ischaemic origin. Full details of all the baseline characteristics of this study population are provided in Table 3.1.

3.3 **Levels of Community Ambulation**

Based on the responses to the Community Ambulation Questionnaire, participants were classified as being:

- Level 4- independent community walkers, able to walk to shops, friends’ houses or activities in the vicinity without physical assistance or supervision (n = 23).

- Level 3- limited community walkers, able to walk in their immediate environment without physical assistance or supervision (n = 14).

- Level 2- Non-community walkers, able to walk outside as far as the front of the house without physical assistance or supervision (n = 3).

This information is represented graphically in Figure 3.2. The study participants were dichotomised into two groups as has been done in previous studies (Van de Port et al. 2008, Bijeveld-Uitmann et al. 2013). Participants in Level 4 were classified as independent community walkers, whilst those in Level 2 and Level 3 were classified as non-community walkers.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), Mean (SD)</td>
<td>66 (13.4)</td>
</tr>
<tr>
<td>Gender, n (%) male</td>
<td>22 (55)</td>
</tr>
<tr>
<td>Marital Status, n (%)</td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>25 (62.5)</td>
</tr>
<tr>
<td>Single</td>
<td>10 (25)</td>
</tr>
<tr>
<td>Widowed</td>
<td>5 (12.5)</td>
</tr>
<tr>
<td>Race, n (%) Caucasian</td>
<td>40 (100)</td>
</tr>
<tr>
<td>Education, n (%), ≤ Secondary school</td>
<td>28 (70)</td>
</tr>
<tr>
<td>Living status, n (%)</td>
<td></td>
</tr>
<tr>
<td>Alone</td>
<td>8 (20)</td>
</tr>
<tr>
<td>With someone</td>
<td>32 (80)</td>
</tr>
<tr>
<td>Use of walking aid, n (%), yes</td>
<td>12 (30)</td>
</tr>
<tr>
<td>No. of medications, median (IQR)</td>
<td>5 (4)</td>
</tr>
<tr>
<td>No. of Co-morbidities, median (IQR)</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Time since stroke (months), Mean (SD)</td>
<td>22.3 (6.9)</td>
</tr>
<tr>
<td>Lesion side, n (%)</td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>25 (62.5)</td>
</tr>
<tr>
<td>Left</td>
<td>15 (37.5)</td>
</tr>
<tr>
<td>Type of stroke, n (%)</td>
<td></td>
</tr>
<tr>
<td>Ischaemic</td>
<td>36 (90)</td>
</tr>
<tr>
<td>Haemorrhagic</td>
<td>4 (10)</td>
</tr>
<tr>
<td>MRS, n (%)</td>
<td></td>
</tr>
<tr>
<td>≤ 2</td>
<td>33 (82.5)</td>
</tr>
<tr>
<td>&gt;2</td>
<td>7 (17.5)</td>
</tr>
<tr>
<td>No. of falls, n (%)</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>29 (72.5)</td>
</tr>
<tr>
<td>Once</td>
<td>6 (15)</td>
</tr>
<tr>
<td>&gt; 1</td>
<td>5 (12.5)</td>
</tr>
</tbody>
</table>
Figure 3.2  Community ambulation levels of the participants (n = 40)

<table>
<thead>
<tr>
<th>Community ambulation levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>57.5% Level 2</td>
</tr>
<tr>
<td>35%  Level 3</td>
</tr>
<tr>
<td>7.5% Level 4</td>
</tr>
</tbody>
</table>

Level 2- Non-community walkers
Level 3- Limited community walkers
Level 4- Independent community walkers

3.4 Normality Testing

Each of the continuous outcome measures were examined for normality, using the Shapiro-Wilks test for normality. These included gait speed, TUG, ABC scale, FSS, HADS, TMT-B and SLCT. Also, other continuous variables such as age and time since stroke were assessed for normality. Table 3.2 displays the normality scores.

Results indicated that the TUG, ABC scale, TMT-B and SLCT were not normally distributed for both the community walkers and non-community walkers. Also, on visual inspection of the histograms and QQ plots, it was evident that the distributions were skewed. These variables were therefore treated as non-normal and median and interquartile range values are given in the summary statistics.
### Table 3.2 Testing for Normality

<table>
<thead>
<tr>
<th>Measure</th>
<th>Independent community walkers</th>
<th>Non-community walkers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gait Speed *</td>
<td>p = 0.308 *</td>
<td>p = 0.229 *</td>
</tr>
<tr>
<td>TUG</td>
<td>p = 0.294 *</td>
<td>p = 0.000</td>
</tr>
<tr>
<td>ABC Scale</td>
<td>p = 0.046</td>
<td>p = 0.615 *</td>
</tr>
<tr>
<td>FSS *</td>
<td>p = 0.369 *</td>
<td>p = 0.513 *</td>
</tr>
<tr>
<td>HADS-A *</td>
<td>p = 0.429 *</td>
<td>p = 0.236 *</td>
</tr>
<tr>
<td>HADS-D *</td>
<td>p = 0.059 *</td>
<td>p = 0.356 *</td>
</tr>
<tr>
<td>TMT-B</td>
<td>p = 0.001</td>
<td>p = 0.028</td>
</tr>
<tr>
<td>SLCT</td>
<td>p = 0.000</td>
<td>p = 0.000</td>
</tr>
<tr>
<td>Age *</td>
<td>p = 0.310 *</td>
<td>p = 0.202 *</td>
</tr>
<tr>
<td>Time since Stroke *</td>
<td>p = 0.140 *</td>
<td>p = 0.078 *</td>
</tr>
</tbody>
</table>

* Normal distribution statistical significance p ≥ 0.05

### 3.5 Outcome Measures

The group was divided into independent community walkers (n = 23) and non-community walkers (n = 17) for the descriptive statistics. The descriptive statistics for each of the individual outcome measures is provided in Table 3.3.
Table 3.3 Summary statistics for outcome measures

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Independent Community Walkers (n=23)</th>
<th>Non-Community Walkers (n=17)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gait Speed (m/s), Mean (SD)</td>
<td>1.33 (0.2)</td>
<td>0.76 (0.3)</td>
</tr>
<tr>
<td>TUG (secs), Median (IQR)</td>
<td>9.43 (1.8)</td>
<td>15.3 (14.1)</td>
</tr>
<tr>
<td>ABC Scale, Median (IQR)</td>
<td>86.25 (15)</td>
<td>56.25 (14.1)</td>
</tr>
<tr>
<td>FSS, Mean (SD)</td>
<td>32.87 (14)</td>
<td>36.35 (10.2)</td>
</tr>
<tr>
<td>HADS-A, Mean (SD)</td>
<td>6.39 (4.4)</td>
<td>6.24 (3.4)</td>
</tr>
<tr>
<td>HADS-D, Mean (SD)</td>
<td>4.09 (2.7)</td>
<td>5.41 (2.7)</td>
</tr>
<tr>
<td>TMT-B (secs), Median (IQR)</td>
<td>106 (114)</td>
<td>165 (187)</td>
</tr>
<tr>
<td>SLCT, Median (IQR)</td>
<td>104 (1)</td>
<td>102 (5)</td>
</tr>
</tbody>
</table>

3.6 Binary Logistic Regression

3.6.1 Relationship between community ambulation and personal factors

Binary logistic regression analysis was used to examine the association between level of community ambulation and personal factors. A two-tailed significance level of 0.05 was used for all tests. Gender, living status, marital status, education, use of walking aid, type of stroke, side of lesion and history of falls were treated as dichotomous variables for the purpose of the analyses. All other personal factors were treated as discrete variables. There was a significant association between community ambulation and age (p = 0.04), use of a walking aid (p = 0.001) and number of medications (p = 0.02). Patients who were older and with polypharmacy were less likely to be community walkers, whilst those who used a walking aid were
more likely to be community walkers. All the results of the analyses are presented in Table 3.4.

**Table 3.4**  Binary logistic regression analyses for relationship between community ambulation and personal factors

<table>
<thead>
<tr>
<th>Variable</th>
<th>Regression Co-efficient</th>
<th>S.E.</th>
<th>P-Value</th>
<th>EXP(B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>-0.06</td>
<td>0.03</td>
<td>0.04 *</td>
<td>0.94</td>
</tr>
<tr>
<td>Gender</td>
<td>-0.56</td>
<td>0.65</td>
<td>0.39</td>
<td>0.57</td>
</tr>
<tr>
<td>Living status</td>
<td>-1.02</td>
<td>0.82</td>
<td>0.21</td>
<td>0.36</td>
</tr>
<tr>
<td>Marital status</td>
<td>-0.27</td>
<td>0.66</td>
<td>0.68</td>
<td>0.76</td>
</tr>
<tr>
<td>Education</td>
<td>1.10</td>
<td>0.77</td>
<td>0.15</td>
<td>3.00</td>
</tr>
<tr>
<td>Use of walking aid</td>
<td>3.70</td>
<td>1.14</td>
<td>0.001 *</td>
<td>40.33</td>
</tr>
<tr>
<td>Time since stroke</td>
<td>0.02</td>
<td>0.05</td>
<td>0.62</td>
<td>1.02</td>
</tr>
<tr>
<td>Type of stroke</td>
<td>0.88</td>
<td>1.20</td>
<td>0.47</td>
<td>2.40</td>
</tr>
<tr>
<td>Side of lesion</td>
<td>-0.71</td>
<td>0.66</td>
<td>0.29</td>
<td>0.49</td>
</tr>
<tr>
<td>No. of medications</td>
<td>-0.39</td>
<td>0.16</td>
<td>0.02 *</td>
<td>0.68</td>
</tr>
<tr>
<td>No. of co-morbidities</td>
<td>-0.46</td>
<td>0.24</td>
<td>0.06</td>
<td>0.63</td>
</tr>
<tr>
<td>Modified Rankin Score</td>
<td>-22.04</td>
<td>15192</td>
<td>0.99</td>
<td>0.00</td>
</tr>
<tr>
<td>History of falls</td>
<td>-0.17</td>
<td>0.71</td>
<td>0.82</td>
<td>0.85</td>
</tr>
</tbody>
</table>

*S.E = Standard Error  
P-Value = Significance value  
EXP(B) = Odds ratio
3.6.2  

*Relationship between community ambulation and outcome measures*

Binary logistic regression analysis was used to examine the association between level of community ambulation and the individual outcome measures. A two-tailed significance level of 0.05 was set for all tests. A significant association was found between community ambulation and gait speed (p =0.001), the TUG (p= 0.004) and the ABC scale (0.001). The results of all the analyses are presented in Table 3.5. Patients with higher scores for gait speed and balance self-efficacy were more likely to be community walkers. Also, patients who took less time to complete the TUG were more likely to be community walkers.

**Table 3.5  Binary logistic regression analyses for relationship between community ambulation and outcome measures**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Regression Co-efficient</th>
<th>S.E.</th>
<th>P-Value</th>
<th>EXP(B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gait Speed</td>
<td>9.27</td>
<td>2.91</td>
<td>0.001 *</td>
<td>10596</td>
</tr>
<tr>
<td>TUG</td>
<td>-1.04</td>
<td>0.36</td>
<td>0.004 *</td>
<td>0.35</td>
</tr>
<tr>
<td>ABC Scale</td>
<td>0.13</td>
<td>0.04</td>
<td>0.001 *</td>
<td>1.15</td>
</tr>
<tr>
<td>FSS</td>
<td>-0.02</td>
<td>0.02</td>
<td>0.38</td>
<td>0.98</td>
</tr>
<tr>
<td>HADS-A</td>
<td>0.01</td>
<td>0.08</td>
<td>0.90</td>
<td>1.01</td>
</tr>
<tr>
<td>HADS-D</td>
<td>-0.18</td>
<td>0.12</td>
<td>0.14</td>
<td>0.834</td>
</tr>
<tr>
<td>TMT-B</td>
<td>-0.01</td>
<td>0.003</td>
<td>0.06</td>
<td>0.99</td>
</tr>
<tr>
<td>SLCT</td>
<td>0.112</td>
<td>0.08</td>
<td>0.16</td>
<td>1.12</td>
</tr>
</tbody>
</table>

_S.E = Standard Error  
EXP(B) = Odds ratio  
P-Value = Significance value_
3.7 Multivariate Logistic Regression

Multivariate logistic regression was carried out to examine which post-stroke variables were independently associated with community ambulation post stroke. Four variables which were found to be significantly associated (p ≤ 0.05) with community ambulation on the binary logistic regression analysis were entered into the analysis. Age was entered into the analysis as a biological factor and as it had been shown to be significantly associated with community ambulation in the binary logistic regression analysis (p = 0.04). Gait speed, TUG and the ABC scale were also included in the analysis. A two-tailed significance level of 0.05 was used for all tests. The ABC Scale was the only variable found to be independently associated with community ambulation post stroke when age, gait speed and walking balance were also taken into account. The results of this analysis are presented in Table 3.6.

Table 3.6 Multivariate logistic regression for community ambulation

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>S.E</th>
<th>Wald</th>
<th>df</th>
<th>Sig</th>
<th>Exp(B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>-0.13</td>
<td>0.10</td>
<td>1.64</td>
<td>1</td>
<td>0.20</td>
<td>0.87</td>
</tr>
<tr>
<td>Gait Speed</td>
<td>13.06</td>
<td>9.56</td>
<td>1.87</td>
<td>1</td>
<td>0.17</td>
<td>470017</td>
</tr>
<tr>
<td>TUG</td>
<td>-0.03</td>
<td>0.48</td>
<td>0.004</td>
<td>1</td>
<td>0.95</td>
<td>0.97</td>
</tr>
<tr>
<td>ABC</td>
<td>0.17</td>
<td>0.09</td>
<td>3.90</td>
<td>1</td>
<td>0.05*</td>
<td>0.05</td>
</tr>
<tr>
<td>Constant</td>
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<td>17.80</td>
<td>0.80</td>
<td>1</td>
<td>0.40</td>
<td>0.00</td>
</tr>
</tbody>
</table>

*B = Regression co-efficient  df = degrees of freedom
S.E = Standard Error        Sig = Significance level
Wald = Wald statistic       Exp(B) = Odds ratio
3.8 Summary

The main results of this study suggest that personal factors such as age, use of a walking aid and polypharmacy are significantly associated with community ambulation post stroke. Similarly, gait speed, walking balance and balance self-efficacy are significantly associated with community ambulation levels. Balance self-efficacy was the only factor found to be independently associated with community ambulation post stroke. The results of this study will be discussed in greater detail in the discussion chapter.
CHAPTER 4    DISCUSSION

4.1 Introduction

The aim of this current study was to investigate what factors are associated with return to independent community ambulation in patients between one and three years post stroke. The main finding of this study was that while gait speed is a significant factor associated with independent community ambulation post stroke, a fact that has previously been well established, other factors may also play a significant role in return to independent community walking. These include personal factors such as age, use of a walking aid and polypharmacy, as well as deficits in walking balance and reduced balance self-efficacy. The key finding of this study was that balance self-efficacy was the only factor independently associated with community ambulation, with those scoring higher on the Activities-Specific Balance Confidence (ABC) Scale more likely to be independent community walkers.

4.2 Prevalence of Community Ambulation

In this study, independent community ambulation was defined as ‘the ability to confidently negotiate uneven terrain, private venues, shopping centres and other public venues without physical assistance or supervision’ (Lord et al. 2004). Based on this criteria, 57.5% of the subjects were classified as independent community walkers. The prevalence of independent community ambulation post stroke has varied in the literature, depending on the measure used to define community ambulation. The Community Ambulation Questionnaire (CAQ) which was used in this study was originally developed by Lord et al. (2004), who found 61% of the
subjects in their study to be unlimited community walkers, a similar finding to this current study. Other studies by Van de Port et al. (2008) and Bijleveld-Uitman et al. (2013) also used the same criteria to define community ambulation and found the prevalence of independent community ambulation to be 74% and 79% respectively. This difference may be explained by the higher subject numbers in these studies, as well as differences in the subject characteristics.

The average age of the participants in the study by Bijleveld-Uitman et al. (2013) was 58.1 years compared to 66 years in this study and 68 years in the study by Lord et al. (2004). Considering age has been found to be associated with community ambulation, this may explain in part the variance in reported levels of community ambulation. Time since stroke may also be another factor which may explain these differences in community ambulation levels. In this study, the average time since stroke was 22.3 months compared to 8.7 months in the Bijleveld-Uitman et al. (2013) study. A previous prospective cohort study by Van de Port et al. (2006) found that mobility outcomes in chronic stroke survivors significantly deteriorated between one and three years post stroke, in particular in patients with poor levels of activity, cognitive problems, fatigue and depression. This may infer that community ambulation levels may decline in a similar manner, the longer the timeframe post stroke, with some patient subgroups more susceptible to decline than others.
4.3 Gait Speed

Gait speed was found to be significantly associated with community ambulation in this patient group, with those who walk at faster speeds more likely to be independent community walkers. The association between gait speed and community ambulation has been previously well established in the literature. Gait speed has been found to be a reliable, objective measure of walking ability and walking performance following stroke (Salbach et al. 2001). In the absence of a validated outcome measure for community ambulation post stroke, gait speed, as measured by a 10 metre walk test (10MWT), has been found to be a useful and discriminative measure for different community ambulation levels (Lord et al. 2004). However, in this current study, gait speed was not found to be an independent predictor of community ambulation post stroke, which suggests that the task of community walking requires more complex attributes than gait speed alone. This is in keeping with the findings of the study by Lord et al. (2004), who reported that while approximately 80% of patients had regained independent gait and scored highly on gait speed, nearly one third were not able to walk unsupervised in their own community after their stroke.

The mean gait speed for the independent community walker group was 1.33 m/s in comparison to a mean speed of 0.76 m/s in the non community walker group. In previous literature, threshold gait speeds for community ambulation have varied between 0.8 m/sec to 1.2 m/s (Perry et al, 1995, Hill et al. 1997). In these studies, gait speed was recorded within three months of stroke onset, when there may have still been potential to make further mobility gains. This may explain in part why the
independent community walker group in this study scored higher on gait speed. The subjects in this study also had mild to moderate disability levels, with 87.5% of the patients scoring two or less on the Modified Rankin Score (MRS), which indicates they had no significant disability or slight disability. This may explain their ability to achieve higher gait velocities.

Other studies by Van de Port et al. (2008) and Bijleveld-Uitman et al. (2013), who examined community ambulation in chronic stroke patients, reported cut-offs for independent community ambulation as 0.66 m/sec and 0.78 m/sec respectively. A possible explanation for these lower gait speeds is that these studies used a 5-meter walk test (5MWT) to measure gait speed as opposed to the 10MWT used in this current study.

4.4 Walking Balance and Balance Self-Efficacy

Walking balance, as measured by the Timed-Up and Go (TUG) tests was found to be significantly associated with community ambulation in this patient group, with those who took less time to complete the TUG more likely to be community walkers. Walking balance was not however found to be independently associated with community ambulation in the multivariate logistic regression analysis ($p = 0.95$). The median score for the TUG in the independent community walker group was 9.43 seconds compared to 15.3 seconds in the non-community walker group. The cut-off time for older adults with stroke is 14 seconds or less, with those who score higher than 14 seconds at greater risk of falls (Andersson et al. 2006). The non-community
walker group were above this threshold, therefore placing them at a higher risk of falls. This may explain in part why they were less likely to have returned to ambulating independently in the community. While the TUG has been less commonly used than the Berg Balance Scale (BBS) for assessing balance impairment in stroke ambulation studies, it has been shown to be strongly associated with the BBS in community-dwelling stroke survivors ($\rho = -0.70$, $p < 0.001$) (Knorr et al. 2010).

The results of this study are supported by previous research which has examined the relationship between balance and community ambulation. Robinson et al. (2011) examined the association of physical factors with participation in community walking following stroke, by comparing 30 individuals with and without stroke. They found that while balance impairment was significantly associated with participation in community walking in stroke patients, when considered in isolation, it explained very little of the variance in participation. Similarly, Van de Port et al. (2008) found that balance impairment was a significant confounder in the relationship between gait speed and community ambulation, however other factors such as use of an assistive device and motor function were also found to be significant confounders. The results of these studies suggest that while clinicians should be aware of the relationship between balance and community ambulation, other significant factors should also be considered when formulating treatment plans for return to community ambulation post stroke.
The key finding of this study was that balance self-efficacy, as measured by the ABC Scale was independently associated with community ambulation post stroke, when gait speed, walking balance and age were also taken into consideration. The median score on the ABC Scale for the independent community walker group was 86.25 compared to 56.25 in the non-community walker group. A score of 80 or more is indicative of a high level of physical functioning, while a score of between 50 and 80 indicates a moderate level of physical functioning. The non-community walker group had much lower levels of balance self-efficacy than the independent community walkers, which appeared to be the most significant factor affecting their ability to ambulate independently in their own community.

Previous research has also identified balance self-efficacy as a significant factor associated with community ambulation and participation levels following stroke. Schmid et al. (2012) reported that balance-self efficacy was independently associated with post-stroke activity and participation in chronic stroke patients. Similarly, Pang et al. (2007) found balance self-efficacy to be an independent predictor of community reintegration in older adults with chronic stroke. The authors of this studied hypothesised that fear of falling is a major psychological barrier, which may lead to self-imposed avoidance of certain activities, which in turn may result in further deterioration in function and low levels of community reintegration. In relation to community ambulation post stroke, Robinson et al. (2011) found that balance self-efficacy was the only personal factor which was strongly associated with both subjective and objective measures of participation in community walking, which concurs with the findings of this current study.
Balance self-efficacy refers to a person’s belief in their ability to undertake activities of daily living without losing their balance (Salbach et al. 2005). Considering the complex nature of community ambulation and the skills and attributes required, it is understandable that stroke patients with low levels of balance confidence may be less likely to attain independent community ambulation. It is possible that in a chronic stroke population, patients may have learned to manage their physical limitations, however the fear of having a fall may prevail. This may result in limitations in activity and participation in everyday activities, including community ambulation. Also, physiotherapy intervention following stroke tends to focus on the recovery of the physical aspects such as gait and balance, with little input addressing balance self-efficacy. Future interventions addressing return to community ambulation post stroke should consider methods of improving balance self-efficacy in the chronic stroke population. One example is the use of self-management programmes following stroke, which can promote changes in behaviour and self management skills, which in turn have a positive effect on self-efficacy (Jones and Riazi, 2011).

4.5 Personal Factors

A number of personal factors were analysed in this study to examine for associations with community ambulation. Age, number of medications and use of a walking aid were all found to be significantly associated with community ambulation level ($p \leq 0.05$). Patients with increasing age and polypharmacy were less likely to be community walkers, while those who used a walking aid were more likely to be community walkers. This may imply that as stroke patients get older and suffer from more co-morbidities, requiring multiple medications, they may become frailer and
less likely in engage in community ambulation activities. Given the small sample size in this study, these factors could not be included in the multiple logistic regression analysis, therefore it could not be established if they were significant determinants of community ambulation.

Increasing age has previously been found to be associated with participation outcomes (Gardner et al. 2006). Similarly, polypharmacy has been shown to be a significant predictor of impaired mobility in an elderly population (Frazier 2005). Van de Port et al. (2008) found that use of an assistive device was a significant confounder in the relationship between gait speed and community ambulation, similar to the findings of this current study. It is possible that use of a walking aid increases the ability to walk in the community. A randomised controlled trial by Logan et al. (2004) found that provision of a walking aid can increase outdoor mobility post stroke.

Other personal factors such as gender, time since stroke, living status, number of co-morbidities and history of falls were not found to be significantly associated with community ambulation in this sample of stroke patients. Given that this group of patients were relatively young, high functioning, had low levels of co-morbidities (median = 2) and a low number of fallers (27.5%), this may explain in part why these personal factors were not found to be significantly associated with community ambulation.
4.6 Fatigue and Depression/Anxiety

Fatigue was not found to be significantly associated with community ambulation in this current study \( (p = 0.38) \), as measured by the Fatigue Severity Scale (FSS). The mean score on the FSS for the independent community walker group was 32.87 compared to 36.35 in the non-community walker group. A score of 36 or more on this scale suggests that a patient may be suffering from fatigue, therefore the non-walker group were slightly above this cut-off. Robinson et al. (2011) also found that fatigue was not significantly associated with number of trips or walking related activities in the community in a chronic stroke population. Similarly, Bijleveld-Uitman et al. (2013) reported that fatigue (also measured by the FSS) was not a significant confounder in the relationship between gait speed and community ambulation.

It is possible that in a chronic stroke population, between one and three years post stroke, patients may have learned to adapt to fatigue levels and have received advice and guidance regarding pacing, therefore not allowing fatigue to significantly impact on their ability to get out and about in the community. Also, the CAQ used in this study only examines what places a person can get out to in their community but not how often they go out or how long they stay out for. It is possible the endurance component of community ambulation may be affected by post stroke fatigue given the previously reported association between fatigue and cardiovascular deconditioning in chronic stroke (Michael et al.2006). This aspect of community ambulation was not measured in this current study however. Similarly, in the absence of a stroke-specific assessment for fatigue, the FSS was used in this study.

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This measure was originally developed for use in Multiple Sclerosis (Krupp et al. 1989), although has been frequently used with stroke patients. It is possible however, that it may not capture fully the aspects of fatigue most relevant and specific to stroke patients.

Depression and anxiety were also found not to be significantly associated with community ambulation post stroke. Both groups scored similarly on the anxiety scale of the Hospital Anxiety and Depression Scale (HADS), with a mean score of 6.39 for the independent community walker group and 6.24 for the non-community walker group. The independent community walker group had a mean score of 4.09 on the depression scale of the HADS compared to a score of 5.41 for the non-community walker group. A score of eight or above on either scale may indicate that a patient is suffering with anxiety or depression. Both groups had relatively low mean scores on each of the scales, indicating low levels of depression and anxiety in this patient group. Previous research has demonstrated an association between anxiety associated with fear of falling and gait and balance control, which may result in gait disruptions (Gage et al. 2003). Given the low levels of anxiety and the higher levels of balance self-efficacy in the independent community ambulation group, these findings further support the link between anxiety/self-efficacy and mobility outcomes.

To date, a significant association between depression and anxiety and community ambulation post stroke has not been established. Robinson et al. (2011) found depression was significantly correlated with reduced participation in community
walking, increased perceived difficulty and reduced satisfaction with community walking, however it was not found to be independently associated with participation in community walking. In the studies by Van de Port et al. (2008) and Bijleveld-Uitman et al. (2013), depression and anxiety were found to be weak confounders in the relationship between gait speed and community ambulation. As this current sample of stroke clients were relatively high functioning and with low levels of depression and anxiety, this may explain why no significant relationship with community ambulation was identified.

4.7 Executive Function

Executive function was not found to be significantly associated with community ambulation in this patient group. There was large variability in the scores on the Trail-Making Test Part B (TMT-B) in both the independent community walker group and the non-community walker group. The median score in the independent group was 106 seconds, with an interquartile range (IQR) of 114 seconds, while the median score in the non-community walker group was 165 seconds, with an IQR of 187 seconds. A score of greater than 273 seconds is indicative of a deficit in executive function. The majority of this patient group completed the test within this time suggesting low levels of executive dysfunction.

Previous research has shown that executive function is associated with performances of balance and mobility (Liu-Ambrose et al. 2007) and with the ability to complete complex gait tests in stroke patients (Hayes et al. 2013). These studies however have
used a battery of tests to assess executive function. A relationship between executive function and community ambulation has not yet been established. The TMT-B used in this study evaluates the components of executive function that represent complex visual scanning, speed, attention and ability to shift sets (Greenlief et al. 1985), however it does not provide a comprehensive assessment of executive function. Future research examining the relationship between executive function and community ambulation may need to use a larger battery of tests to obtain a comprehensive assessment of executive function. This may provide more definitive results for whether executive function is significantly associated with community ambulation post stroke.

4.8 Visual Neglect of Extrapersonal Space

Visual neglect was not found to be associated with community ambulation in this study (p = 0.16). Both groups scored very highly on the Single Letter Cancellation Test (SLCT), with a median score of 104 for the independent community walkers and a median score of 102 for the non-community walkers. A score of less than 100 has been found to be indicative of impaired visual perception (Zoccolotti et al. 1989). Similarly, Bijleveld-Uitman et al. (2013) also found that hemi-neglect was not significantly associated with community ambulation post stroke. Both that study and this current study used letter cancellation tests to measure visual neglect. The SLCT has been reported to have strong psychometric properties in identifying unilateral spatial neglect in the near extrapersonal space. It is possible however, that deficits in the far extrapersonal space may be more significant for community ambulation. Far extrapersonal space has been defined as the space outside the hand.
reaching distance (Berti and Frassinetti, 2000). Currently, there are very few visual perceptual assessments that assess the far extrapersonal space. The Catherine Bergego Scale (Azouvi et al. 1996) and the Occupational Therapy-Adult Perceptual Screening Test (Cooke et al. 2005) both contain components that assess for neglect in the far extrapersonal space but not in isolation. Considering the complex nature of community ambulation and the various environments and terrains that must be negotiated, visual neglect of the far extrapersonal space should be considered as a significant factor in future research.

4.9 Limitations of the Study

There were several limitations of this current study, which are outlined below and would need to be taken into account when considering the external validity and generalisability of the study findings.

- The cross-sectional study design used in this study meant that any causal relationships between any of the variables and community ambulation could not be established.

- The small sample size was a limitation, as it limits the external validity and generalisability of the findings to the wider stroke population. Also, it meant that the multivariate logistic regression analysis could only include a small number of variables. Other factors which were found to be significantly associated with community ambulation in the binary logistic regression analysis, such as number of medications and use of walking aid had to be omitted from the multivariate analysis.
• The sampling method used in this study was another potential source of bias as it was not a truly random selection. Also, as only patients between one and three years post stroke and who had previously attended a Community Stroke Rehab Team were included in the sample, this limits the generalisability of the results.

• The study population was relatively young (average age 66 years) and high functioning, with mild to moderate levels of disability as measured by the MRS. Therefore, they may not be representative of the wider stroke population and the prevalence of independent community ambulation may have been over-estimated.

• The use of the self-administered questionnaire by Lord et al. (2004) may have resulted in reporting bias. The classification of community walkers based on a questionnaire requires further validation.

• Although a gatekeeper was used to limit selection bias in this study, this may still have arisen as the majority of the subjects were previously known to the Principle Investigator, therefore may have felt more inclined to participate in the study.

• The exclusion of patients with severe communication problems and cognitive impairment may have affected the results of this study and limit the external applicability of the findings.

• There was no record of previous physiotherapy input or whether the subjects were still attending physiotherapy, which may have influenced the study findings.
The Single Letter Cancellation Test was used as a measure of visual neglect, however it can only measure visual neglect in the near extrapersonal space, as opposed to the far extrapersonal space, which may be a more important factor in community ambulation. Also, the use of the TMT-B test to measure for executive dysfunction is limited as it only captures one component of executive function.

Due to time constraints, only a limited number of factors could be considered in this study. Other factors such as walking endurance, dual task ability, patient motivation and lower limb strength which may influence community ambulation, were not measured. Also, environmental factors were not considered in this study.

4.10 Recommendations for Future Research

Following on from this research, there are a number of recommendations for future research in the complex area of community ambulation post stroke.

- A larger scale prospective cohort study, following up patients from baseline to three years post stroke so that causal relationships between community ambulation and certain factors can be examined for.

- The development of a validated outcome measure of community ambulation, which takes into account the broader dimensions of community ambulation post stroke. It should incorporate the physical aspects such as gait speed, walking endurance and balance and well as other key factors such as balance
self-efficacy, patient motivation and dual/multiple attention ability. Also, different environmental conditions would need to be taken into account.

- Future research should include stroke patients with moderate to severe aphasia, through the development and use of more aphasia-friendly outcome measures.

- Qualitative research should be conducted, such as focus groups or semi-structured interviews with stroke patients, to establish what they feel are the barriers and facilitators to return to community ambulation following stroke.

- Research is needed to identify effective treatment approaches that maximise patients’ potential to return to independent community ambulation post stroke. Treatment approaches should address the key factors that have been found to be associated with independent community ambulation post stroke such as gait speed, dynamic balance, balance self-efficacy, as well as considering the attentional demands of the task. Randomised controlled trials would need to be conducted to assess the effectiveness of such interventions.
CONCLUSION

The results of this study found that certain personal and physical factors were significantly associated with return to independent community ambulation in patients between one and three years post stroke. Stroke patients with increasing age and polypharmacy were less likely to be independent in the community, while those who used a walking aid were more likely to be independent community walkers. Patients with higher gait speeds were more likely to be independent in the community, as were those with lower TUG scores. The key finding was that balance self-efficacy was the only factor found to be independently associated with community ambulation post stroke, with patients with higher levels of balance self-efficacy more likely to have returned to ambulating independently in their own community.

The results highlight the important role that balance confidence may play in attainment of independent community ambulation in chronic stroke patients. Despite this group of patients being relatively young, high functioning and with good mobility outcomes, 42.5% of patients were still not able to be fully independent in their own community. Clinically, these findings support the need to incorporate subjective balance confidence into the assessment and treatment of outdoor mobility post stroke. Improving balance self-efficacy, in combination with physical interventions addressing gait speed and walking balance may be crucial in maximising patients’ ability to attain independent community ambulation post stroke. The integration of self-management programmes for chronic stroke patients, which promote self-management skills, self-efficacy and problem solving may be one method of addressing balance self-efficacy.
Considering the complex nature of community ambulation post stroke and its importance to the quality of life of stroke patients, it is vital that continued research is carried out in this area to further establish the significant determinants of community ambulation post stroke. This will enable a more specific outcome measure to be developed and validated, as well as the development of more effective interventions for community ambulation post stroke, which in turn should maximise functional outcomes for stroke patients.

Word Count: 12936
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  (Accessed 8th April, 2014).


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Appendix 1

*Table 1: Table of sample size for correlations between two variables (Conroy, 2009)*

<table>
<thead>
<tr>
<th>% Shared Variation</th>
<th>Correlation</th>
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<th>Sample size 95% power</th>
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<td>121</td>
</tr>
<tr>
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<tr>
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</tr>
<tr>
<td>50%</td>
<td>0.71</td>
<td>16</td>
<td>20</td>
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</tbody>
</table>
Appendix 2

**Abbreviated Mental Test Score**

**Patient’s details:**

**Date of test:**

*Scoring* Each correctly answered question scores 1 point.

*Interpretation* Scores ≤ 7 is indicative of likely cognitive impairment.

**Comment on alertness level:**

<table>
<thead>
<tr>
<th>Alert/normal</th>
<th>Vigilant</th>
<th>Lethargic</th>
<th>Stupor</th>
<th>Coma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncertain</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Instrument**

1. **Age**

2. **Time (to nearest hour)**

3. **Address (for recall at end of test)** Say to patient: I am going to say an address: ‘42 West Street’ Can you say that address please? I am going to ask you to repeat it for me in a few minutes.

4. **Year**

5. **Name your home address**

6. **Recognition of two persons/objects**

7. **Date of birth**

8. **Year of First/Second World War**

9. **Name of current Taoiseach**

10. **Count backwards 20-1**

**TOTAL SCORE**

<table>
<thead>
<tr>
<th></th>
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</thead>
</table>

**Signature of Examiner**

Appendix 3

Letter of invitation to study participants

Date:
Patient Name:
Address:
Address:
Address:

Re: Invitation to participate in a physiotherapy research study.
‘An investigation of the factors associated with community ambulation in chronic stroke’

Dear Sir/Madam,

I am writing to you to invite you to participate in the above named study which will be carried out in the Stroke Rehabilitation Team in Baggot Street Hospital. I have enclosed an information leaflet explaining the research study. This research is being carried out by Physiotherapist, Sarah Durcan as part of her Masters Degree in Neurology and Gerontology, through the Royal College of Surgeons in Ireland.

Please take the time to read the enclosed information leaflet carefully. If you have any questions about the research study or if there is anything that is not clear, please feel free to contact project supervisor Frances Horgan or Sarah to discuss it prior to making any decisions.

If you are interested in participating in this research study, please contact Sarah on 01-6699389. She will discuss the study further with you and arrange a suitable time for you to come in for testing.

Thank you for taking the time to consider this research study.

Yours sincerely,

______________________________________
Evelyn Flavin MISCP
Physiotherapy Manager
Ph. No: (01) 2680322
Appendix 4

School of Physiotherapy
Royal College of Surgeons in Ireland
123, St Stephen’s Green, Dublin 2

Participant information leaflet
(Version 2  Date: 09/10/2013)

Study title: An investigation of the factors associated with community ambulation in chronic stroke

Principal investigator: Sarah Durcan
Principal investigator’s title: Physiotherapist, Stroke Rehab Team, Baggot St Hospital
Phone Number: (01) 6699389

You are being invited to take part in a research study being carried out in the Stroke Rehabilitation Team in Baggot Street Hospital.

Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family and friends. Take time to ask questions – do not feel rushed or under pressure to make a quick decision. You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as ‘Informed Consent’.

You do not have to take part in this study and a decision not to take part will not affect your future medical care. You can change your mind about taking part in the study at any time. Even if the study has started, you can still opt out without giving a reason. If you do opt out, it will not affect the quality of treatment you get in the future.

Why is this study being done?

The aim of this study is to determine the ability of people, who are greater than a year after their stroke, to walk outdoors and in their own community again. It will examine to what extent difficulties with walking, balance, fatigue, depression, balance confidence, planning ability and awareness of your surroundings affect return to outdoor walking after stroke.
Who is organising and funding this study?

This research study is being carried out by Physiotherapist, Sarah Durcan, as part of a Master of Science Degree in Neurology and Gerontology at the Royal College of Surgeons in Ireland.

Why am I being asked to take part?

You are being asked to take part in this study as you have had a stroke and have previously attended the Stroke Rehabilitation Team in Baggot Street Hospital.

How will the study be carried out?

This study will commence in October 2013. It is hoped to recruit 40 participants to this study, which will take place in the Physiotherapy Gym of the Stroke Rehabilitation Team in Baggot Street Hospital.

If you agree to participate, you will be asked to attend Baggot Street Hospital on one occasion to complete 2 walking tests, 2 pen and paper tasks and some short questionnaires.

What will happen to me if I agree to take part?

Your participation in the study is entirely voluntary.

Sarah Durcan (Physiotherapy investigator) will invite you to attend Baggot Street Hospital on one occasion at a time that is suitable for you. You will be asked to sign a consent form and you will have an opportunity to ask the researcher any questions you may have about the study.

Initially, you will be asked some questions about your stroke, past medical history and current walking ability. Two physical tests of your walking speed and your balance will be carried out. You will be asked to complete 2 timed pen and paper tasks, which will look at your planning and visual scanning abilities. Finally, you will be asked to complete 3 short questionnaires about balance confidence, fatigue and depression. Testing should take approximately 45-60 minutes.

What are the benefits?

There are no direct benefits from participating in this study, other than an in-depth assessment.

It is hoped that the information obtained from this study will help clinicians who work with people after stroke, to better understand the factors that can affect return to outdoor walking. This, in turn, should help them deliver more specific treatment programmes.
What are the risks?

There is a minimal risk of a fall during the walking tests, however they will be carried out in a safe environment and you will be closely supervised at all times to minimise this risk.

If any of the questions in the questionnaires cause you any distress/upset or if they produce any concerns for you, you will be referred to your GP.

Will it cost me anything to take part?

Travel expenses for taking part in this study will not be covered.

Is the study confidential?

You will be assigned a study number which will be used to identify you so your name will not appear on any documents. Any information that you provide will be kept private and confidential. Coded data that will not identify you will be accessed by Dr. Frances Horgan (Research Project Supervisor) at the Royal College of Surgeons in Ireland. On completion of the study, all data related to the study will be retained securely in the Royal College of Surgeons for five years and then destroyed.

Where can I get further information?

If you have any further questions about the study or if you want to opt out of the study, you can rest assured it won't affect the quality of treatment you get in the future.

If you need any further information now or at any time in the future, please contact:

Name: Sarah Durcan  
Address: Stroke Rehabilitation Team, Baggot Street Community Hospital, Dublin 4  
Phone No: (01) 6699389

Supervisor: Dr. Frances Horgan, Lecturer in Physiotherapy, RCSI.  
E-mail: fhorgan@rcsi.ie
### Appendix 5 Ethics Application Form

<table>
<thead>
<tr>
<th>REC Number:</th>
<th>REC - 000860</th>
</tr>
</thead>
</table>

#### SECTION 1 – DETAILS OF APPLICANT(S)

<table>
<thead>
<tr>
<th>1</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short Title of Project:</td>
<td>Factors associated with community ambulation in chronic stroke</td>
</tr>
<tr>
<td>Full Title of Project:</td>
<td>An investigation of the factors associated with community ambulation in chronic stroke</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2</th>
<th>Contact Details of Applicant (All correspondence will be sent to this address unless indicated otherwise.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family Name</td>
<td>Durcan</td>
</tr>
<tr>
<td>Forename</td>
<td>Sarah</td>
</tr>
<tr>
<td>Title</td>
<td>Ms</td>
</tr>
<tr>
<td>Present Appt of Applicant:</td>
<td>Physiotherapist, Stroke Rehabilitation Team, Baggot Street Community Hospital</td>
</tr>
<tr>
<td>Qualifications:</td>
<td>BSc Hons (Physio)</td>
</tr>
<tr>
<td>Address (for correspondence regarding application):</td>
<td>School of Physiotherapy, Royal College of Surgeons in Ireland, 123 St Stephens Green, Dublin 2</td>
</tr>
<tr>
<td>Tel:</td>
<td>0861599781</td>
</tr>
<tr>
<td>Fax:</td>
<td>N/A</td>
</tr>
<tr>
<td>Email:</td>
<td><a href="mailto:sarahdurcan@rcsi.ie">sarahdurcan@rcsi.ie</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3</th>
<th>Name and contact details of Principal investigator (PI) on this project</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Frances Horgan, Senior Lecturer/Academic Supervisor, School of Physiotherapy, Royal College of Surgeons in Ireland, 123 St Stephen’s Green, Dublin 2. E-mail: <a href="mailto:fhorgan@rcsi.ie">fhorgan@rcsi.ie</a> Direct line: 01 402 2472</td>
<td></td>
</tr>
<tr>
<td>Other Individuals/Departments involved:</td>
<td>Ms Evelyn Flavin, Physiotherapy Manager, Baggot Street Community Hospital</td>
</tr>
</tbody>
</table>

#### SECTION 2 – DETAILS OF PROJECT

| 5 | Aims and Objectives of the Project (i.e., what is the intention of the project?) | The aim of this project will be to examine the association of multiple post stroke variables with community ambulation in patients between one and three years post stroke. Using a cross-sectional study design, the study is intended to determine the prevalence of independent community ambulation in an Irish sample of stroke patients. The objectives are to; 1. Examine whether personal factors are significantly associated with community ambulation after stroke and whether impairments in gait speed, balance, fatigue, depression, balance self-efficacy, executive function and visual inattention are associated with reduced ability to walk unsupervised in the community. 2. Determine which post stroke-variables are independently associated with community ambulation. Study endpoints: It is proposed that the study endpoints will be the establishment of the association between the various personal factors and post-stroke variables with community ambulation in people with chronic stroke. |
|---|---|
| Summary of practical benefits/improvements in patient care which are envisaged: | A common sequelae of stroke is the loss of independent community ambulation. Only 20-66% of patients manage to walk independently in the community again following a stroke (Lord et al. 2004). Loss of independent community ambulation is associated with poor quality of life, decreased satisfaction and mood disorders in stroke patients (Pound et al. 1998). If clinicians have a better understanding of the factors that influence return to independent community ambulation following stroke, it will enable them to better predict those who will return to community walking. It will also allow them to deliver more focussed and specific treatment programmes addressing all the relevant impairments which, in turn, may result in better rehabilitation outcomes and improved quality of life for patients following stroke |
**SCIENTIFIC BACKGROUND TO STUDY**

Loss of independent community ambulation is one of the most disabling consequences of stroke. Despite a substantial proportion of stroke patients regaining independent gait (Jorgensen et al. 1995), only a smaller proportion manage to walk independently in the community again. Lord et al. (2004) found that the ability ‘to get out and about’ in the community was considered to be either essential or very important by 75% of stroke patients. Gait speed has been shown to be a useful and discriminate measure for the different categories of community ambulation (Lord et al. 2004). Similarly walking endurance has been shown to be a useful predictor of community walking in high functioning people after stroke (Fulk et al. 2010). However, walking ability alone does not always reflect ability to walk unsupervised in the community (Lord et al. 2004). Community ambulation is a complex task requiring the ability to adapt gait to diverse and complex conditions, including walking on varying terrains, in diverse ambient conditions, with attentional demands and while performing additional tasks such as carrying a load, changing directions, avoiding obstacles or engaging in social interactions (Shumway-Cook et al. 2002). Considering the complexity of the task, it is likely that a number of other physical, psychological and cognitive factors are associated with the ability to participate in community ambulation following stroke. Robinson et al. (2011) found that balance self-efficacy was strongly associated with both subjective and objective measures of participation in community walking and that personal factors explained 27% to 55% of the variability in community walking. Similarly, Van de Port et al. (2008) found that the ability to walk in the community is determined by several underlying factors such as balance, motor function and use of assistive devices. This suggests that gait speed and endurance should not be considered in isolation as predictors of community ambulation following stroke. Other possible factors include fatigue, depression, executive function and visual inattention, however to date, the association of these factors with community ambulation has not been established. The aim of this study is to investigate the association of these physical, psychological and cognitive factors with community ambulation in chronic stroke.

**BRIEF OUTLINE OF PROJECT**

What do you intend to do?

This study will be a cross-sectional study and will examine the association of multiple post stroke variables with community ambulation in patients between one and three years post stroke. 40 participants will be recruited from the database of the Stroke Rehabilitation Team in Baggot Street Hospital. A sample of 80 patients will be randomly selected from the database using a random number table in Excel. This is to account for a proposed response rate of 50% which has been reported in other studies with community dwelling stroke survivors (Lloyd et al. 2010).

The participants will be sent a letter of invitation from the study gatekeeper (Physiotherapy Manager), inviting them to participate in the study. The purpose of the gatekeeper is to minimise recruitment bias as many of the clients will be previously known to the principal investigator.

Patients will also receive a participant information leaflet with details of the study and how to contact the principal investigator if they wish to partake in the study.

Each participant will attend on one occasion to complete two physical tests, two pen and paper tasks and to complete three questionnaires. Prior to testing, they will be asked to sign a written consent form. Basic demographic information, stroke characteristics and current walking ability will also be obtained from the participants and from their medical charts. The following outcome measures will be administered:

**Primary Outcome Measure:**
Community ambulation questionnaire, which is a short, self administered questionnaire that was developed by Lord et al. (2004).

**Other outcome measures**
- 10 metre walk test- to assess gait speed
- Timed-up and go- to assess dynamic balance
- Activities-Specific Balance Confidence Scale- to assess balance self-efficacy
- Fatigue Severity Scale- to assess the impact of fatigue.
The testing will be carried out by the principal investigator in the Physiotherapy Gym of the Stroke Rehabilitation Team in Baggot Street Community Hospital. Testing will take between 45-60 minutes for each participant and participants will receive standardised instructions for each of the tests.

A pilot study with approx 4-5 stroke patients will be conducted to inform the timing of the tests and to highlight any difficulties with their administration.

8 STUDY DESIGN (eg. COHORT, CASE CONTROL) Cross sectional study design

9i HOW WAS THE SIZE OF THE STUDY DETERMINED? A sample size of 40 participants will be recruited. According to Conroy (2009), in studies investigating relationships between variables of clinical interest, a correlation of less than 0.45 is unlikely to have clinical significance. Conroy (2009) has produced a document to assist with sample size calculation for correlation studies. Based on finding a correlation of 0.45, for a study powered at 90%, the recommended sample size is 48 participants. Based on finding a correlation of 0.5, for a study powered at 90%, the recommended sample size is 30. For the current study, based on finding a correlation between 0.45 and 0.55 for a study powered at 90%, a sample size of 40 has been calculated, which falls between 30 and 48.

9ii IS THERE FORMAL STATISTICAL INPUT INTO THE OVERALL STUDY DESIGN? No

9iii WHAT METHOD OF ANALYSIS WILL BE USED? (The statistical software package used for the analysis is not sufficient details on what statistical method will be used and why are needed).

Data will be analysed using SPSS software (Version 18.0; SPSS Inc, Chicago, Illinois). Descriptive statistics will be used to describe the characteristics of the participants and their levels of community ambulation, using parametric and nonparametric methods as appropriate. Data will be presented using a variety of tables and graphs. Pearson correlation coefficients (or Spearman Rank coefficients for non-parametric data) will be used to explore for associations between the variables and community ambulation. Multiple linear regression will be used to examine what proportion of the variability in community ambulation can be explained by the post stroke variables.

10i DOES THE STUDY FALL INTO ANY OF THE FOLLOWING CATEGORIES?

| Pilot | No |
| Multi-centre study | No |
| If Multi Centre Study: Name of Centre(s): | N/A |
| Undergraduate student project | No |
| If student project: | N/A |
| Name of Course: | N/A |
| Name of Institution: | N/A |

10ii WHICH ETHICS COMMITTEES HAVE BEEN APPROACHED, AND WHAT IS THE OUTCOME TO DATE? Name of Ethics Committee: N/A Outcome: N/A

10iii WHO WILL HAVE OVERALL RESPONSIBILITY FOR THE STUDY? Principal Investigator Sarah Durcan and her supervisor Dr Horgan

10iv WHO HAS CONTROL OF THE DATA GENERATED? Sarah Durcan and Dr Horgan

10v HOW WILL YOU PROTECT IT UNDER THE DATA PROTECTION GUIDELINES? Each participant will be allocated a study ID number which will identify them. All the data collected will be coded and entered in a file which will be securely stored and password protected on the RCSI server V: drive. All written documentation with subject's name or ID number will be stored in a locked metal filing cabinet that only Sarah Durcan will have access to. After the research is completed, all documentation will be stored safely in RCSI for 5 - 7 years and will then be destroyed.

11 WHERE WILL THE STUDY TAKE PLACE AND IN WHAT SETTING? (E.G., DUBLIN/GEN PRACTICE/HOME) The study will take place in the Physiotherapy Gym of the Stroke Rehabilitation Team in Baggot St.
### Section 3 - Recruitment of Participants and Control Groups

#### 14a How Will the Participants in the Study Be Selected, Approached, and Recruited?

40 participants will be recruited from the database of the Stroke Rehabilitation Team in Baggot Street Hospital. Only patients who are within 1-3 years after their stroke will be contacted. This database is updated on a weekly basis by the rehabilitation assistant. Some of these patients may be still attending the service and those who are no longer attending the service would have been contacted within the past 3 years. There is a small possibility that some of these patients may have died. We will cross reference patient details with resources such as www.rip.ie and any recent hospital episodes to ensure that we are aware if the patient identified is recently deceased.

Assuming a response rate of 50%, 80 patients will be randomly selected using a random number table in Excel. They will be sent a letter of invitation inviting them to participate in the study from the study gatekeeper (Physiotherapy Manager). They will also receive a participant information leaflet. They will be provided with details to contact the Principal Investigator if they wish to partake in the study or would like more information about it. If they are interested and they meet the inclusion/exclusion criteria, they will be invited to attend the Stroke Rehabilitation Team in Baggot Street Hospital on one occasion at a suitable time.

#### 14b What Inclusion and Exclusion Criteria Will Be Used?

**Inclusion Criteria**
- Diagnosed with a first stroke, as defined by the World Health Organisation definition of stroke
- Greater than 18 years of age, community-dwelling
- Between one and three years post stroke
- Able to walk at least 10m with/without a walking aid independently
- Able to give informed written consent

**Exclusion Criteria**
- Aphasia - Unable to complete the pen and paper tests or questionnaires secondary to communication difficulties
- Parkinsons Disease
- Multiple Sclerosis
- Traumatic brain injury/other brain injury of non-vascular origin
- Recent lower limb fracture (within last 6 months)
- Uncontrolled cardiac conditions
- Cognitive impairment (a score of ≤ 6 on the Abbreviated Mental Test Score (AMTS)). The AMTS will be administered by the lead researcher SD who is an experienced senior physiotherapist in stroke care. An AMTS score of 6 or less is indicative of cognitive impairment. Patients with cognitive impairment are to be excluded as they would have reduced cognitive ability/memory to follow the instructions for the physical tests which would be a safety hazard. They would also have reduced capacity to follow the instructions or to complete the pen and paper tests which are primarily cognitive tasks.

If a potential participant expresses an interest in the study and is subsequently deemed to be cognitively impaired by the
researcher (SD) and excluded from the study, they will be invited to complete the Community Ambulation Questionnaire and the ABC Balance Confidence Scale to estimate their current level of community ambulation and self efficacy, and the patient and carer will be advised regarding safety and maintenance of current activity levels. This will minimise potential upset to the participant and their carer, while upholding the study criteria and in particular safety during completion of the full battery of study assessments.

<table>
<thead>
<tr>
<th>15</th>
<th>HOW MANY PARTICIPANTS WILL BE RECRUITED AND OF WHAT AGE?</th>
<th>40 participants will be recruited, all of whom will be greater than 18 years of age.</th>
</tr>
</thead>
<tbody>
<tr>
<td>16a</td>
<td>HOW WILL THE CONTROL GROUP (IF USED) BE SELECTED, APPROACHED, AND RECRUITED?</td>
<td>N/A</td>
</tr>
<tr>
<td>16b</td>
<td>CONTROL GROUP: WHAT INCLUSION AND EXCLUSION CRITERIA WILL BE USED?</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>HOW MANY CONTROLS WILL BE RECRUITED AND OF WHAT AGE?</td>
<td>N/A</td>
</tr>
<tr>
<td>18</td>
<td>ARE THE PARTICIPANTS INCLUDED IN THIS STUDY INVOLVED IN ANY OTHER RESEARCH INVESTIGATION AT THE PRESENT TIME?</td>
<td>Not Known</td>
</tr>
<tr>
<td></td>
<td>If yes, please provide details:</td>
<td>N/A</td>
</tr>
<tr>
<td>19</td>
<td>WILL PARTICIPANTS RECEIVE ANY PAYMENT OR OTHER INCENTIVE TO PARTICIPATE?</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>If yes, please give details of incentive per participant:</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>If yes please indicate the source of the incentive:</td>
<td>N/A</td>
</tr>
<tr>
<td>20</td>
<td>IS WRITTEN CONSENT TO BE OBTAINED?</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Copy of the Consent Form to be used</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If No, please justify:</td>
<td>N/A</td>
</tr>
<tr>
<td>21</td>
<td>DOES THE STUDY INCLUDE PARTICIPANTS FOR WHOM:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>English is not a first language</td>
<td>Not Known</td>
</tr>
<tr>
<td></td>
<td>Children under 16</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>People with learning difficulties</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Other vulnerable groups (e.g. psychological disorders, dementia)</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>1. What special arrangements have been made to deal with the issues of consent and assent, e.g. is parental or guardian agreement to be obtained, and if so what form?</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>2. In what way, if any can the proposed study be expected to benefit the individual who participates?</td>
<td>N/A</td>
</tr>
<tr>
<td>22</td>
<td>ARE WOMEN OF CHILDBEARING POTENTIAL INCLUDED?</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>If Yes, does this study plan any invasive or other interventions that could be a risk to pregnancy?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. Scientific justification,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Negative teratogenic studies,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Warning participant that foetus may be damaged,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Initial negative pregnancy test,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5. Forms of contraception defined,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6. Duration of use to exceed drug metabolism,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7. Exclude those unlikely to follow contraceptive advice,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8. Notify investigator if pregnancy suspected?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If NO, Please explain:</td>
<td></td>
</tr>
<tr>
<td>23</td>
<td>WILL THE PARTICIPANT BE GIVEN A WRITTEN INFORMATION SHEET OR LETTER?</td>
<td>Yes</td>
</tr>
</tbody>
</table>
SECTION 5 - DETAILS OF INTERVENTIONS

26 WHAT INVESTIGATIONS AND/OR INTERVENTIONS WILL PARTICIPANTS AND/OR CONTROLS HAVE OVER AND ABOVE ROUTINE CARE?

<table>
<thead>
<tr>
<th>Investigation</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self completion questionnaires</td>
<td>Yes</td>
</tr>
<tr>
<td>Interviews/interview administered questionnaires</td>
<td>No</td>
</tr>
<tr>
<td>Video/audio tape recording</td>
<td>No</td>
</tr>
<tr>
<td>Physical examination</td>
<td>Yes</td>
</tr>
<tr>
<td>Internal physical examination</td>
<td>No</td>
</tr>
<tr>
<td>Venepuncture*</td>
<td>No</td>
</tr>
<tr>
<td>Arterial puncture*</td>
<td>No</td>
</tr>
<tr>
<td>Biopsy material*</td>
<td>No</td>
</tr>
<tr>
<td>Imaging investigations (not radiation)</td>
<td>No</td>
</tr>
<tr>
<td>Other investigations not part of normal care</td>
<td>No</td>
</tr>
<tr>
<td>Additional outpatients attendances</td>
<td>Yes</td>
</tr>
<tr>
<td>Longer inpatient stays</td>
<td>No</td>
</tr>
<tr>
<td>Local anaesthetsia</td>
<td>No</td>
</tr>
<tr>
<td>General anaesthetsia</td>
<td>No</td>
</tr>
<tr>
<td>Other</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Details:

Participants will complete three self-completion questionnaires (ABC Balance Confidence Scale, Fatigue Severity Scale, Hospital Anxiety and Depression Scale). Participants will complete 2 walking tests for gait speed and balance (Timed Up and Go and 10m walk test). Participants will complete 2 pen and paper tests assessing executive function and visual neglect (Trail Making Test Part B and Single Letter Cancellation Test).

Participants will be required to attend for one outpatient appointment for the tests and questionnaires to be administered. Testing will take approx 45-60 minutes.

SECTION 6 – RISKS AND ETHICAL PROBLEMS

27a ARE THERE ANY ETHICAL PROBLEMS OR CONSIDERATIONS THAT THE INVESTIGATORS CONSIDER TO BE IMPORTANT OR DIFFICULT WITH THE PROPOSED STUDY?

Yes

If yes, please give details of incentive per participant:

If a potential participant expresses an interest in the study and is subsequently deemed to be cognitively impaired by the researcher (SD) following completion of the AMTS and is excluded from the study (AMTS <6), they will only be invited to complete the Community Ambulation Questionnaire and the ABC Balance Confidence Scale to estimate their current level of community ambulation and self-efficacy. The patient and carer will be advised regarding safety and maintenance of current activity levels. This will minimise potential upset to the participant and their carer, while upholding the study criteria and in particular safety during completion of the full battery of study assessments. Refer also to Q14.b.

27b WILL TREATMENTS PROVIDED DURING THE STUDY BE AVAILABLE IF NEEDED AT THE END OF THE STUDY?

N/A

27c IF NOT IS THIS MADE CLEAR IN THE PATIENT INFORMATION SHEET?

N/A

28 ARE THERE ANY POTENTIAL HAZARDS TO PARTICIPANTS OR PATIENTS?

Yes

If Yes, please give details, and give the likelihood and details of precautions taken to minimise them, and arrangements to deal with adverse events, including reporting to the relevant authorities:

There is a minimal risk that a participant could fall during the walking tests. To minimise this risk, participants will be screened for the exclusion criteria. Cognition will be assessed using the abbreviated mental test score to ensure they would understand
all the instructions. All participants will be supervised during the assessments and the environment will be kept clear to minimise risk of trips/falls. If any participant sustains an injury during the assessments, the GP or an ambulance will be called as necessary. Any adverse events will be reported to the Physiotherapy Manager and to the project supervisor, Dr. Frances Horgan.

<table>
<thead>
<tr>
<th>29</th>
<th>IS THIS STUDY LIKELY TO CAUSE DISCOMFORT OR DISTRESS TO PARTICIPANTS/PATIENTS?</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>If Yes, estimate the degree and likelihood of discomfort or distress entailed and the precautions to be taken to minimise them:</td>
<td>There is a minimal risk that some of the questions in the Hospital Anxiety and Depression Score may cause some distress to participants or highlight feelings of concern for them. If any participant becomes distressed or receives a high score on the anxiety/depression subscales, they will be advised to discuss it with their GP and advised about counselling services, psychological supports and support groups/helplines that are available to them, as per normal protocol for the Stroke Rehabilitation Team.</td>
</tr>
</tbody>
</table>

**SECTION 7 – INDEMNITY AND CONFIDENTIALITY**

Product liability and consumer protection legislation make the supplier and producer (manufacturer) or any person changing the nature of a substance, e.g. by dilution, strictly liable for any harm resulting from a consumer’s use of a product.

| 30a | WHAT ARRANGEMENTS HAVE BEEN MADE TO PROVIDE INDEMNIFICATION AND/OR COMPENSATION IN THE EVENT OF A CLAIM BY, OR ON BEHALF OF, A PARTICIPANT FOR NEGLIGENT HARM? | All research activity will be covered by HSE insurance- see attached Research permission letter. Bernie Dardis and Jim Millard from Marsh Insurance were both consulted regarding indemnity for this research project and advised that as it will be covered by HSE insurance, there is no need to advise RCSI insurers of this research activity. |
| 30b | WHAT ARRANGEMENTS BEEN MADE TO PROVIDE INDEMNIFICATION AND/OR COMPENSATION IN THE EVENT OF A CLAIM BY, OR ON BEHALF OF, A PARTICIPANT FOR NON-NEGLIGENT HARM? | All research activity will be covered by HSE insurance-see attached Research permission letter. Bernie Dardis and Jim Millard from Marsh Insurance were both consulted regarding indemnity for this research project and advised that as it will be covered by HSE insurance, there is no need to advise RCSI insurers of this research activity. |
| 30c | WILL AN UNDERGRADUATE STUDENT BE INVOLVED DIRECTLY IN CONDUCTING THE PROJECT? | No |

| 31 | IN CASES OF EQUIPMENT OR MEDICAL DEVICES, HAVE APPROPRIATE ARRANGEMENTS BEEN MADE WITH THE MANUFACTURER? (PLEASE INDICATE NA IF NOT APPLICABLE.) | N/A |
|     | If Yes, give details. | N/A |

| 32 | WILL THE STUDY BE HELD ON A COMPUTER? | Yes |
|     | If Yes, will the data be held so that participants cannot be identified from computer files (i.e. no name, address, medical chart number or other potential identifier such as GMS or RSI number)? | Yes |
|     | If No, give reasons. | N/A |
|     | Will records (preferably paper records) linking study participant ID numbers with identifying features be stored confidentially? | Yes |
|     | If not please explain why not? | N/A |

| 33 | WILL THE PATIENT’S MEDICAL RECORDS BE EXAMINED? | Yes |
|     | If Yes, will information relevant to this study be extracted | Yes |
|     | If extra information is extracted, please justify | Information about the participants date of stroke, type of stroke and past medical history will be extracted from the medical charts. |
|     | What, if any, additional steps have been taken to safeguard confidentiality of personal records? | Each participant will be allocated a study ID number which will identify them. All the data collected will be coded and stored on a password protected computer. All written documentation with subject’s name or ID number will be stored in a locked metal filing cabinet that only Sarah Durcan will have access to. After the research is completed, all documentation will be stored safely for 5 years and then destroyed. |

<p>| 34 | WILL THE STUDY INCLUDE THE USE OF ANY OF THE FOLLOWING? | Audio/videotape recording: No |
|     | Observation of participants: No | 83 |</p>
<table>
<thead>
<tr>
<th>If “Yes” to either:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How are confidentiality and anonymity to be ensured?</td>
</tr>
<tr>
<td>2. What arrangements have been made to obtain consent?</td>
</tr>
<tr>
<td>3. What will happen to the tapes at the end of the study?</td>
</tr>
<tr>
<td>[Note: they should be stored for data verification or transcribed]</td>
</tr>
</tbody>
</table>

| 35  | WILL MEDICAL RECORDS BE EXAMINED BY RESEARCH WORKER(S) OUTSIDE THE EMPLOYMENT OF THE RCSI? | No |

**SECTION 8 – ANNEXE A, B & C**

| 36  | Does the study involve the use of a new medicinal product or medical device, or the use of an existing product outside the terms of its product licence? | No |
| 37  | Does the study include the use of ionising or non-ionising radiation, radioactive substances or X rays. Requires printing and posting? | No |
| 38  | For research conducted in a general practice setting all GPs whose patients will be involved must sign to indicate that they are aware of and in agreement with the planned project. Is this applicable? | No |
Ms Sarah Durcan
School of Physiotherapy,
Royal College of Surgeons in Ireland,
123 St Stephens Green,
Dublin 2

<table>
<thead>
<tr>
<th>Ethics Reference No:</th>
<th>REC860</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Title:</td>
<td>Factors associated with community ambulation in chronic stroke</td>
</tr>
<tr>
<td>Researchers Name (lead applicant):</td>
<td>Ms Sarah Durcan</td>
</tr>
<tr>
<td>Principle investigator of the project</td>
<td>Dr Frances Horgan, School of Physiotherapy, RCSI</td>
</tr>
<tr>
<td>Other Individuals Involved:</td>
<td>Ms Evelyn Flavin, Physiotherapy Manager, Baggot Street Community Hospital</td>
</tr>
</tbody>
</table>

Dear Ms Durcan

Thank you for your Research Ethics Committee (REC) application. We are pleased to advise that ethical approval has been granted by the committee for this study.

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 15th August 2014.

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,

[Signature]

PP Dr. Niamh Clarke (Convenor)
Dr David Smith (Acting Chair)
03/10/2013

Study title: Factors associated with community ambulation in chronic stroke

Researcher: Sarah Durcan, Physiotherapist, Stroke Rehabilitation Team

Project Supervisor: Dr. Frances Horgan, Lecturer in Physiotherapy, Royal College of Surgeons

To whom it may concern,

I give permission for the above named research project being carried out by Sarah Durcan, Physiotherapist to be conducted in the Stroke Rehabilitation Team in Baggot Street Hospital.

All research activity will be covered by HSE insurance, Mary Brennan in HSE Estate Management will be informed of this research.

Yours sincerely,

[Signature]
Evelyn Flavin
Physiotherapy and Stroke Rehab Team Manager DSE

[Signature]
Helen Deely
A/Primary Care Operations Manager DSE/W
Title of Study: An investigation of the factors associated with community ambulation in chronic stroke

Researcher: Sarah Durcan, Stroke Rehab Team, Bagot St Hospital
Supervisor: Dr. Frances Horgan, School of Physiotherapy, RCSI
Phone No: (01) 6699389
E-mail Address: sarahdurcan@rcsi.ie

I have read and understood the Information Leaflet about this research project. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction. ☐ Yes ☐ No

I understand that I don’t have to take part in this study and that I can opt out at any time. I understand that I don’t have to give a reason for opting out and I understand that opting out won’t affect my future medical care. ☐ Yes ☐ No

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

I give permission for researchers to look at my medical records to get information. I have been assured that information about me will be kept private and confidential. ☐ Yes ☐ No

I have been given a copy of the Information Leaflet and this completed consent form for my records. ☐ Yes ☐ No

Storage and future use of information:
I give my permission for information collected about me to be stored or electronically processed for the purpose of scientific research and to be used in related studies or other studies in the future but only if the research is approved by a Research Ethics Committee. ☐ Yes ☐ No

Participant Name (Block Capitals): __________________________
Participant Signature: __________________________ Date: ________________

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 they could understand. I have explained the risks involved as well as the possible benefits. I have invited them to ask questions on any aspect of the study that concerned them.

Name (Block Capitals): __________________________ Qualifications: __________________________
Signature: __________________________ Date: ________________
Appendix 8

MODIFIED RANKIN SCALE (MRS)

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No symptoms at all</td>
</tr>
<tr>
<td>1</td>
<td>No significant disability despite symptoms; able to carry out all usual duties and activities</td>
</tr>
<tr>
<td>2</td>
<td>Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance</td>
</tr>
<tr>
<td>3</td>
<td>Moderate disability; requiring some help, but able to walk without assistance</td>
</tr>
<tr>
<td>4</td>
<td>Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance</td>
</tr>
<tr>
<td>5</td>
<td>Severe disability; bedridden, incontinent and requiring constant nursing care and attention</td>
</tr>
<tr>
<td>6</td>
<td>Dead</td>
</tr>
</tbody>
</table>

TOTAL (0–6): __________

References

Rankin J. “Cerebral vascular accidents in patients over the age of 60.” *Scott Med J* 1957;2:200-15


*Provided by the Internet Stroke Center — www.strokecenter.org*
Appendix 9  
Data Collection Form

- Subject Number: ________  Date of testing: ____________
- Age: ______  D.O.B.: ____________
- Male □  Female □
- Marital Status: ______________
- Race: ______________
- Education: ______________
- Living status: ______________
- Use of assistive device  Yes □  No □  If yes, what type? ______________
- Medications: __________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
- Co-morbidities: _______________________________________________________
_____________________________________________________________________
_____________________________________________________________________
- Time since Stroke: ________ months
- Side of lesion: Right □  Left □
- Type of stroke: Ischaemic □  Haemorrhagic □
Subject Number: ________

- Modified Rankin Score:___________
- Have you fallen in the past six months? Yes □ No □ If yes how often? Once □ 2-4 □ > 4 falls □

Outcome measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Community Ambulation Questionnaire</td>
<td></td>
</tr>
<tr>
<td>Gait Speed (m/s)</td>
<td></td>
</tr>
<tr>
<td>Timed up and go (secs)</td>
<td></td>
</tr>
<tr>
<td>ABC Scale</td>
<td></td>
</tr>
<tr>
<td>Fatigue Severity Scale</td>
<td></td>
</tr>
<tr>
<td>Hospital Anxiety and Depression Scale</td>
<td></td>
</tr>
<tr>
<td>Trail-making test-B</td>
<td></td>
</tr>
<tr>
<td>Single letter cancellation test</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 10  Community ambulation questionnaire

1. How important is it for you to be able to get out of the home?
Not important □  Mildly important □  Important □  Very important □  Essential □

2. Which places outside the home did you like to get to before your stroke?
(Please list a maximum of 3 types of places, in order of preference)
1.___________________  2.___________________  3.___________________

3. Are you able to get out and about, by yourself, without physical assistance or supervision from anyone?
   • No □  (Go to question 5)
   • Outdoors (eg, as far as the letterbox) but no farther □  (go to question 5)
   • Yes □  (Give up to 3 examples.)
1.___________________  2.___________________  3.___________________

4. Do you require special equipment to achieve this?  Yes □  No □
   If yes, please state type of equipment, for example, wheelchair, scooter, type of walking aid.
________________________________________________________________________

5. Does the assistance you require to get out and about cause any problems to you or your carers? (If yes, please identify)  Yes □  No □
________________________________________________________________________

6. Do you have any other comments you would like to make regarding getting out of the home?
________________________________________________________________________

Based on the answers supplied, subjects are classified as
i)  Unable to walk outside
ii) Can walk outside e.g. as far as the car/post box without assistance or s/v
iii) Can walk in immediate environment
iv) Can walk to shops/friends houses or activities in community
Appendix 11

Timed 10-Meter Walk Test

General Information:

Individual walks without assistance 10 meters (32.8 feet) and the time is measured for the intermediate 6 meters (19.7 feet) to allow for acceleration and deceleration

- start timing when the toes of the leading foot crosses the 2-meter mark
- stop timing when the toes of the leading foot crosses the 8-meter mark
- assistive devices can be used but should be kept consistent and documented from test to test

if physical assistance is required to walk, this should not be performed can be performed at preferred walking speed or fastest speed possible
documentation should include the speed tested (preferred vs. fast)
collect three trials and calculate the average of the three trials

Set-up (derived from the reference articles):

- measure and mark a 10-meter walkway
- add a mark at 2-meters
- add a mark at 8-meters

Patient Instructions (derived from the reference articles):

- Normal comfortable speed: “I will say ready, set, go. When I say go, walk at your normal comfortable speed until I say stop”

- Maximum speed trials: “I will say ready, set, go. When I say go, walk as fast as you safely can until I say stop”
Appendix 12

Timed Up and Go (TUG) Test$^{1,2}$

1. Equipment: arm chair, tape measure, tape, stop watch.

2. Begin the test with the subject sitting correctly in a chair with arms, the subject's back should resting on the back of the chair. The chair should be stable and positioned such that it will not move when the subject moves from sitting to standing.

3. Place a piece of tape or other marker on the floor 3 meters away from the chair so that it is easily seen by the subject.

4. Instructions: "On the word GO you will stand up, walk to the line on the floor, turn around and walk back to the chair and sit down. Walk at your regular pace.

5. Start timing on the word "GO" and stop timing when the subject is seated again correctly in the chair with their back resting on the back of the chair.

6. The subject wears their regular footwear, may use any gait aid that they normally use during ambulation, but may not be assisted by another person. There is no time limit. They may stop and rest (but not sit down) if they need to.

7. Normal healthy elderly usually complete the task in ten seconds or less. Very frail or weak elderly with poor mobility may take 2 minutes or more.

8. The subject should be given a practice trial that is not timed before testing.

9. Results correlate with gait speed, balance, functional level, the ability to go out, and can follow change over time.

10. Interpretation

   \[ \leq 10 \text{ seconds} = \text{normal} \]

   \[ \leq 20 \text{ seconds} = \text{good mobility, can go out alone, mobile without a gait aid.} \]

   \[ \leq 30 \text{ seconds} = \text{problems, cannot go outside alone, requires a gait aid.} \]

A score of more than or equal to fourteen seconds has been shown to indicate high risk of falls.


$^{2}$ Shumway-Cook A, Brauer S, Woollacott M. Predicting the Probability for Falls in Community-Dwelling Older Adults Using the Timed Up & Go Test. Physical Therapy 2000 Vol 80(9): 906-913

Saskatoon Falls Prevention Consortium. Falls Screening and Referral Algorithm, TUG. Saskatoon Falls Prevention consortium, June, 2005
Appendix 13

The Activities-specific Balance Confidence (ABC) Scale*

Instructions to Participants:
For each of the following, please indicate your level of confidence in doing the activity without
losing your balance or becoming unsteady from choosing one of the percentage points on the
scale from 0% to 100%. If you do not currently do the activity in question, try and imagine how
confident you would be if you had to do the activity. If you normally use a walking aid to do the
activity or hold onto someone, rate your confidence as it you were using these supports. If you
have any questions about answering any of these items, please ask the administrator.

The Activities-specific Balance Confidence (ABC) Scale*
For each of the following activities, please indicate your level of self-confidence by choosing a corresponding number from the following rating scale:

0% 10 20 30 40 50 60 70 80 90 100%
no confidence completely confident

“How confident are you that you will not lose your balance or become
unsteady when you…
1. walk around the house? ___%  
2. walk up or down stairs? ___%  
3. bend over and pick up a slipper from the front of a closet floor ___%  
4. reach for a small can off a shelf at eye level? ___%  
5. stand on your tiptoes and reach for something above your head? ___%  
6. stand on a chair and reach for something? ___%  
7. sweep the floor? ___%  
8. walk outside the house to a car parked in the driveway? ___%  
9. get into or out of a car? ___%  
10. walk across a parking lot to the mall? ___%  
11. walk up or down a ramp? ___%  
12. walk in a crowded mall where people rapidly walk past you? ___%  
13. are bumped into by people as you walk through the mall? ___%  
14. step onto or off an escalator while you are holding onto a railing? ___%  
15. step onto or off an escalator while holding onto parcels such that you
cannot hold onto the railing? ___%  
16. walk outside on icy sidewalks? ___%  

Appendix 14

Fatigue Severity Scale (FSS)

The Fatigue Severity Scale (FSS) is a method of evaluating the impact of fatigue on you. The FSS is a short questionnaire that requires you to rate your level of fatigue.

The FSS questionnaire contains nine statements that rate the severity of your fatigue symptoms. Read each statement and circle a number from 1 to 7, based on how accurately it reflects your condition during the past week and the extent to which you agree or disagree that the statement applies to you.

- A low value (e.g., 1) indicates strong disagreement with the statement, whereas a high value (e.g., 7) indicates strong agreement.
- It is important that you circle a number (1 to 7) for every question.

### FSS Questionnaire

<table>
<thead>
<tr>
<th>During the past week, I have found that:</th>
<th>Disagree</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. My motivation is lower when I am fatigued.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>2. Exercise brings on my fatigue.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>3. I am easily fatigued.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>4. Fatigue interferes with my physical functioning.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>5. Fatigue causes frequent problems for me.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>6. My fatigue prevents sustained physical functioning.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>7. Fatigue interferes with carrying out certain duties and responsibilities.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>8. Fatigue is among my three most disabling symptoms.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>9. Fatigue interferes with my work, family, or social life.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td></td>
</tr>
</tbody>
</table>

Total Score: _

### Scoring your results

Now that you have completed the questionnaire, it is time to score your results and evaluate your level of fatigue. It’s simple: Add all the numbers you circled to get your total score.

### The Fatigue Severity Scale key

A total score of less than 36 suggests that you may not be suffering from fatigue.

A total score of 36 or more suggests that you may need further evaluation by a physician.

### Your next steps

This scale should not be used to make your own diagnosis.

If your score is 36 or more, please share this information with your physician. Be sure to describe all your symptoms as clearly as possible to aid in your diagnosis and treatment.

---

Fatigue Severity Scale ©Lauren B. Knupp. Reproduced with permission from the author.
Appendix 15

Chart 1 – Hospital Anxiety and Depression Scale

This questionnaire will help your physician to know how you are feeling. Read every sentence. Place an “X” on the answer that best describes how you have been feeling during the LAST WEEK. You do not have to think too much to answer. In this questionnaire, spontaneous answers are more important.

A 1) I feel tense or wound up:
   3 ( ) Most of the time
   2 ( ) A lot of the time
   1 ( ) From time to time
   0 ( ) Not at all

D 2) I still enjoy the things I used to enjoy:
   0 ( ) Definitely as much
   1 ( ) Not quite so much
   2 ( ) Only a little
   3 ( ) Hardly at all

A 5) I get a sort of frightened feeling as if something awful is about to happen:
   3 ( ) Very definitely and quite badly
   2 ( ) Yes, but not too badly
   1 ( ) A little, but it doesn’t worry me
   0 ( ) Not at all

D 4) I can laugh and see the funny side of things:
   0 ( ) As much as I always could
   1 ( ) Not quite as much now
   2 ( ) Definitely not so much now
   3 ( ) Not at all

A 5) Worried thought goes through my mind:
   3 ( ) A great deal of the time
   2 ( ) A lot of the time
   1 ( ) From time to time but not too often
   0 ( ) Only occasionally

D 6) I feel cheerful:
   3 ( ) Not at all
   2 ( ) Not often
   1 ( ) Sometimes
   0 ( ) Most of the time

A 7) I can sit at ease and feel relaxed:
   0 ( ) Definitely
   1 ( ) Usually
   2 ( ) Not often
   3 ( ) Not at all

D 8) I feel as I am slowed down:
   3 ( ) Nearly all the time
   2 ( ) Very often
   1 ( ) Sometimes
   0 ( ) Not at all

A 9) I get a sort of frightened feeling like butterflies in the stomach:
   0 ( ) Not at all
   1 ( ) Occasionally
   2 ( ) Quite often
   3 ( ) Very often

D 10) I have lost interest in my appearance:
   3 ( ) Definitely
   2 ( ) I don’t take so much care as I should
   1 ( ) I may not take quite as much care
   0 ( ) I take just as much care as ever

A 11) I feel restless, as if I had to be on the move:
   3 ( ) Very much indeed
   2 ( ) Quite a lot
   1 ( ) Not very much
   0 ( ) Not at all

D 12) I look forward with enjoyment to things:
   0 ( ) As much as I ever did
   1 ( ) Rather less than I used to
   2 ( ) Definitely less than I used to
   3 ( ) Hardly at all

A 13) I get sudden feeling of panic:
   3 ( ) Very often indeed
   2 ( ) Quite often
   1 ( ) Not very often
   0 ( ) Not at all

D 14) I can enjoy a good TV or radio program or book:
   0 ( ) Often
   1 ( ) Sometimes
   2 ( ) Not often
   3 ( ) Very seldom
Appendix 16

Trail Making Test Part B

Patient's Name: ___________________________ Date: ____________
CANCELLATION SHEET

Test Date: _____________________


Number of Errors: __________

Test 1 Scanning Score: __________

Test 2 Spatial Neglect Score: __________