A feasibility study to identify attitudes, determine outcome measures and develop an intervention to inform a definitive trial that will determine the effectiveness of adapted cardiac rehabilitation for sub-acute stroke and TIA patients.

Thesis submitted for the degree of Doctor of Philosophy at the University of Leicester

by

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Abstract

Title - A feasibility study to identify attitudes, determine outcome measures and develop an intervention to inform a definitive trial that will determine the effectiveness of adapted cardiac rehabilitation for sub-acute stroke and TIA patients.

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Stroke leads to reduced cardiorespiratory fitness (CRf) and increased risk of future cardiovascular events. Cardiac rehabilitation (CR), has been shown to reduce the risk of future cardiovascular events in cardiac patients. The use of CR for the stroke population has only been explored in one study in England. This study provided CR for stroke patients for 30 weeks and focussed on people with very mild severity stroke.

The overall aim of this thesis was to establish the feasibility of conducting a definitive study investigating the effect of six weeks of adapted CR on CRf, blood pressure, heart rate, activity levels, quality of life, fatigue, tone, falls, body mass index, anxiety and depression for people with mild to moderate stroke in the sub-acute stage of recovery. Feasibility was determined by: acceptability, ability to recruit, adherence to the programme, identifying outcome measures and adverse events. This mixed-methods thesis reports firstly on the attitudes and knowledge of healthy lifestyles in people post stroke and their thoughts on attending CR. Secondly, it identifies the attitudes of stroke and CR teams towards people with stroke attending CR and the adaptations that would be needed. These two phases informed the design of the final cohort study by identifying the CR adaptations needed and the recruitment strategies to be used.

The third phase of this thesis reports on the results of a validity and reliability study which aimed to identify the most valid and reliable clinical test of CRf in people with mild-to-moderate severity stroke. The Incremental Shuttle walk test (ISWT) was shown to have modest validity ($r=0.58$, 95% confidence intervals (CI) 0.34-0.75, $p=0.001$) and strong reliability (ICC of 0.99, 95% CI 0.96-0.99) for measuring CRf in people post-stroke and this measure was used in the final phase of the thesis. Finally, this thesis reports on the results of a mixed-methods cohort study that integrated people with stroke into CR programmes in the sub-acute phase of recovery.

It was found that adapted CR: was acceptable to people with NIHSS <3, the stroke and cardiac teams if suitable support and training provided, and the cardiac patients; had acceptable recruitment; had high adherence and only one adverse event; and identified outcome measures that could measure change. It concludes that a definitive study to explore CR for a very mild stroke population (NIHSS <3) is feasible with appropriate adaptations and support.
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List of Abbreviations

6MWT Six minute walk test
BI Barthel Index
CPET Cardiopulmonary exercise test
CR Cardiac Rehabilitation
CRf Cardiorespiratory fitness
CVA Cerebrovascular Accident
HADS Hospital Anxiety and depression scale
ICT Incremental Cycle test
ISWT Incremental Shuttle Walk test
MAS Modified Ashworth Scale
MFIS Multidimensional Fatigue Inventory Score
MHR Maximum Heart Rate
RER Respiratory Exchange ratio
RPEs Rating of perceived exertion
SAKQ Stroke Attitude and Knowledge questionnaire
SF36 Short Form Health Survey - 36
TIA Transient Ischaemic Attack
Definitions

**Adverse Event (AE)** - Any untoward medical occurrence in a patient or clinical investigation participants, which does not necessarily have to have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the study, whether or not considered related to the study (European Medicines Agency, 1995).

**Adverse Reaction (AR)** - All untoward and unintended responses related to the study. All cases judged by either the reporting medically qualified professional or the sponsor as having a reasonable suspected causal relationship to the study qualify as adverse reactions (European Medicines Agency, 1995).

**Cardiac Rehabilitation** – Cardiac rehabilitation is a complex intervention offered to patients diagnosed with heart disease, which includes components of health education, advice on cardiovascular risk reduction, physical activity and stress management (Dalal, 2015).

**Cardiorespiratory exercise** – exercises to promote improved capacity of the cardiovascular system. The contraction of major muscle groups must be repeated often enough to elevate the heart rate to a target level determined during testing (Medical dictionary, 2016).

**Cardiorespiratory fitness** - is conferred by the central capacity of the circulatory and respiratory systems to supply oxygen, and the peripheral capacity of the skeletal muscle to utilise oxygen (Mead and van Wijck, 2013).

**Cerebrovascular Accident (CVA) or Stroke** – a clinical syndrome consisting of rapidly developing clinical signs of focal (and at times global) disturbance of cerebral function, lasting more than 24 hours or leading to death with no apparent cause other than that of vascular origin (WHO, 1978)

**Collaborative analysis** - processes in which there is joint focus and dialogue among two or more researchers regarding a shared body of data, to produce an agreed interpretation (Cornish et al., 2013).
**High tone** - is described as a motor disorder characterised by a velocity dependent increase in tonic stretch reflexes (muscle tone) with exaggerated tendon jerks, resulting from hyperexcitability of the stretch reflex, as one component of the upper motor neuron syndrome (Thibaut et al., 2013).

**Maximum Heart Rate (MHR)** – the age-related number of beats per minute of the heart when working at it’s maximum measured as 220 – age or 206.9 - (0.67 x age) (Medical dictionary, 2016).

**Member checking or Respondent validation** – suggests that researchers should go back to the subjects with the tentative results and refine them in the light of the subjects’ reactions (Silverman, 2002).

**Mild severity stroke** – National Institutes of Health Stroke Scale (NIHSS) (National Institutes of Health, 2016) quantifies this with a score between 0 and 4 out of 42. 0 indicates no stroke symptoms and 42 indicates a severe stroke.

**Mixed methodology** – Mixed methods designs are used for collecting, analysing and mixing both quantitative and qualitative data in a single study or series of studies to both explain and explore specific research problems (Rauscher and Greenfield, 2009).

**Moderate severity stroke** – National Institutes of Health Stroke Scale (NIHSS) (National Institutes of Health, 2016) quantifies this with a score between 5 and 15 out of 42. 0 indicates no stroke symptoms and 42 indicates a severe stroke.

**Reflection** - process of acknowledging the changes brought about in themselves as a result of the research process and how these changes have affected the research process (Palaganas, 2017).

**Reliability** – Reliability is the degree to which an assessment tool produces stable and consistent results (Phelan and Wren, 2005).

**Respiratory Exchange ratio** - The ratio of the net output of carbon dioxide to the simultaneous net uptake of oxygen at a given site, both expressed as moles or STPD volumes per unit time (Medical dictionary, 2016).
**Serious Adverse Event or Serious Adverse Reaction (SAR)** - A serious adverse event or reaction is any untoward medical occurrence that at any dose: results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect (European Medicines Agency, 1995).

**Severe Adverse Events (SAE)** - To ensure no confusion or misunderstanding of the difference between the terms "serious" and "severe", which are not synonymous, the following note of clarification is provided: the term "severe" is often used to describe the intensity (severity) of a specific event (as in mild, moderate, or severe myocardial infarction); the event itself, however, may be of relatively minor medical significance (such as severe headache). This is not the same as "serious," which is based on patient/event outcome or action criteria usually associated with events that pose a threat to a participant's life or functioning. Seriousness (not severity) serves as a guide for defining regulatory reporting obligations (European Medicines Agency, 1995).

**Subacute phase of stroke recovery** – Patients between 1-6 months post-stroke are identified as in sub-acute stage of recovery (Canadian Partnership for Stroke Recovery, 2018)

**Suspected Unexpected Serious Adverse Reactions (SUSAR)** - A serious adverse reaction, the nature or severity of which is not consistent with the applicable product information (European Medicines Agency, 1995).

**Transient ischaemic attack (TIA)** – an acute loss of focal cerebral or ocular function with symptoms lasting less than 24 hours and which is thought to be due to inadequate cerebral or ocular blood supply as a result of low blood flow, thrombosis or embolism associated with diseases of the blood vessels, heart, or blood (Hankey and Warlow, 1994).

**Triangulation** – refers to the attempt to get a ‘true’ fix on a situation by combining different ways of looking at it or different findings (Silverman, 2002)

**VO₂ max** - oxygen uptake attained during maximal exercise intensity that could not be increased despite further increases in exercise workload, thereby defining the limits of
the cardiorespiratory system. It is measured in millilitres per kilogramme of body weight per minute (Hawkins et al., 2007).

**VO$_2$ peak** - the highest value of VO$_2$ attained on a particular test, most commonly an incremental or other high intensity test, designed to bring the subject to the limit of tolerance. It defines the highest VO$_2$ that was attained during the test it does not necessarily define the highest value attainable by the subject (Whipp, 2014)

**Validity** – the extent to which an instrument measures what it purports to measure (Kimberlin and Winterstein, 2008).
Chapter 1  Introduction

1.1  Prevalence and pathophysiology of stroke

Stroke is defined by the World Health Organisation (WHO) as “a clinical syndrome consisting of rapidly developing clinical signs of focal (at times global) disturbance of cerebral function, lasting more than 24 hours or leading to death with no apparent cause other than that of vascular origin” (WHO, 1978, p.1). A stroke can be as a result of an emboli or thrombus occluding cerebral blood vessels, that is an ischaemic stroke, or as a result of a haemorrhage. Ischaemic strokes make up 85% of all strokes and 15% are haemorrhagic (The Stroke Association, 2016). The American Heart Association and American Stroke Association (2011) state that “the classic categories of ischaemic stroke have been defined as large-artery atherosclerotic infarction, which may be extracranial or intracranial; embolism from a cardiac source; small-vessel disease; other determined cause such as dissection, hypercoagulable states, or sickle cell disease; and infarcts of undetermined cause” (Furie et al., 2011, p.578). Haemorrhagic strokes can be subdivided into: Intracerebral haemorrhage (ICH), that is, bleeding within the brain or Subarachnoid haemorrhage (SAH), bleeding on the surface of the brain (The Stroke Association, 2016).

Each year 17 million people worldwide will suffer a stroke, one third of whom will remain permanently disabled (World Health Federation, n.d.). Stroke is the leading cause of disability in England (National Audit Office, 2010) and the second leading cause of mortality in the world (The Stroke Association, 2016). The Stroke Association's report, State of the Nation, stated that there are approximately 152,000 cases of stroke in the UK per year, of which about 25–33% are recurrent strokes. About 1.2 million people in the UK live with the effects of stroke, and over a third of these are dependent on other people (Stroke Association, 2016).

A Transient ischaemic attack (TIA) is traditionally defined as an acute loss of focal cerebral or ocular function with symptoms lasting less than 24 hours and which is thought to be due to inadequate cerebral or ocular blood supply as a result of low blood flow, thrombosis or embolism associated with diseases of the blood vessels, heart, or blood (Hankey and Warlow, 1994). TIAs affect 35 people per 100,000 of the
population each year and are associated with a very high risk of stroke in the first month after the event and up to 1 year afterwards (Royal College of Physicians, 2016).

1.2 Disability post-stroke

People post-stroke demonstrate a range of disabilities, which vary in severity and can include: sensory deficit, muscle weakness or tightness, ataxia, speech difficulties, visual changes, cognitive and perceptual difficulties which can all lead to the inability to walk, balance and carrying out activities of daily living. Stroke can also lead to physiological changes to the musculoskeletal, cardiorespiratory and endocrine systems.

1.3 Treatment and provision of stroke care.

Stroke treatment requires urgent Computerised Tomography (CT) or Magnetic Resonance Imaging (MRI) to determine the type of stroke, assess suitability for urgent treatment and to assist in the exclusion of stroke mimics. Recent advances in stroke care have seen a significant improvement in response rates allowing urgent MRI/CT scans to be conducted within hours of the signs and symptoms; the latest UK Royal College of Physicians National Stroke Guidelines recommended that diagnostic scanning is undertaken within one hour of hospital admission (Royal College of Physicians, 2016). The immediate medical treatment for an ischaemic stroke includes thrombolysis and/or thrombectomy in selected patients within 4.5 and 6 hours, respectively. The Stroke Sentinel Audit (2014) identified that 99% of trusts now provide thrombolysis compared to only 50% in 2012. In all ischaemic stroke patients, assessment of the underlying cause with institution of appropriate secondary prevention therapy, including antiplatelet or anticoagulation, statin, antihypertensive therapy, and carotid endarterectomy, where appropriate, is also important. The immediate medical treatment for an intracerebral haemorrhage includes: medication to reverse anticoagulation, where appropriate, intensive blood pressure reduction, and surgery in selected patients (Royal College of Physicians, 2016).

Due to the range of disabilities caused by a stroke, the rehabilitation process can involve doctors, nurses, physiotherapists, occupational therapists, speech and language therapists, dieticians and psychologists. The Royal College of Physicians Stroke guidelines state that “All patients with any impairment at 24 hours should receive a full
multidisciplinary assessment using an agreed procedure or protocol within 5 working days” (Royal College of Physicians, 2016, p.55) and they recommend that “Patients with stroke should be offered a minimum of 45 minutes of each appropriate therapy that is required, for a minimum of 5 days a week” (Royal College of Physicians, 2016, p.80). The Stroke Sentinel Audit (2014) found, however, that only 28% of hospitals provide physiotherapy seven days a week and only 74% have access to a stroke specialist early supported discharge team. The role of the stroke team is to maximise the recovery of the patient, and to prevent complications and further cardiovascular events through risk factor management.

1.4 Risk factor management

The Royal College of Physicians (2016) state that the incidence of recurrence of stroke is “26% within 5 years of a first stroke and 39% by 10 years” (Royal College of Physicians, 2016, p.61); though the risk is front-loaded after TIA and minor ischaemic stroke. Table 1.1 illustrates recognised risk factors for stroke and the medical secondary prevention related to that risk factor (Royal College of Physicians, 2016).

Table 1.1 Risk factors for Stroke and medical secondary prevention

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Secondary Prevention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carotid artery stenosis</td>
<td>Carotid endarterectomy (stenosis &gt; 50%) or Carotid angioplasty and stenting (unsuitable for open surgery)</td>
</tr>
<tr>
<td>Hypercholesterolaemia</td>
<td>Statin drug therapy unless contraindicated.</td>
</tr>
<tr>
<td>Hypertension</td>
<td>Ace-inhibitors, Calcium blockers and/or diuretics. Aim to reduce systolic BP to below 130mmHg.</td>
</tr>
<tr>
<td>Thrombus</td>
<td>Anti-platelets - Aspirin plus modified-release dipyridamole or clopidogrel monotherapy. Anti-coagulants – warfarin or non-vitamin K oral anticoagulants (NOACs) - for patients with AF</td>
</tr>
</tbody>
</table>
All stroke guidelines also recognise the importance of lifestyle changes to reduce the risk of future stroke, although the link between lifestyle changes and reducing the incidence of further stroke has not been fully established. “Long-term adherence to cardio-protective diets, together with other lifestyle modifications such as smoking cessation, increased physical activity and reduced alcohol intake, may have a beneficial effect on stroke recurrence” (Royal College of Physicians, 2016, p.63). Table 1.2 lists evidence for lifestyle interventions for stroke prevention.

Table 1.2 Evidence for Lifestyle intervention for stroke prevention

<table>
<thead>
<tr>
<th>Lifestyle intervention</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular exercise</td>
<td>Moderately intense physical activity compared with inactivity, showed a protective effect on total stroke (Wendel-Voss et al., 2004. Relative risk (RR) = 0.64, 95% Confidence Interval (CI):0.48–0.87). If doing physical activity more than four times a week there is a small reduction in risk (McDonnell et al., 2013. Hazard Ratio (HR) = 1.20).</td>
</tr>
<tr>
<td>Smoking cessation</td>
<td>Systematic review – limited number of smoking intervention studies, more studies needed (Edjoc et al., 2012)</td>
</tr>
<tr>
<td>Weight reduction</td>
<td>Meta-analysis – overweight and obesity associated with increased risk of stroke but no intervention studies reported (Strazzullo et al., 2010)</td>
</tr>
<tr>
<td>Dietary interventions</td>
<td>Dairy consumption reduces the risk of stroke (de Goede et al., 2016. RR = 0.93; 95% CI: 0.88–0.98)</td>
</tr>
<tr>
<td></td>
<td>A decreased risk of stroke was shown for the highest compared with the lowest categories of healthy dietary</td>
</tr>
</tbody>
</table>
| Pattern | Cochrane review - reduced salt diet leads to small decreases in BP but link with reduced mortality not established (Adler et al., 2014)  
Cochrane review - Mediterranean diet – small reductions in LDL and total cholesterol (Rees et al., 2013) |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Stress reduction</td>
<td>Long working hours are associated with increased risk of stroke (Kivimaki et al., 2015. RR = 1·33, CI: 1·11–1·61). No intervention studies reported.</td>
</tr>
<tr>
<td>Alcohol consumption</td>
<td>Increase in the risk of stroke in the highest compared with lowest alcohol-drinking pattern. Reduced risk with low alcohol levels (Zhang et al., 2015. OR = 1.25, 95% CI: 1.17-1.33)</td>
</tr>
</tbody>
</table>

### 1.4.1 Cardiovascular exercise to reduce cardiovascular risk

It is recommended that “For adults over the age of 19 years, activity should add up to at least 150 minutes of moderate intensity, over a week, in bouts of 10 minutes or more” (Royal College of Physicians, 2016, p.63), that is, cardiovascular exercise. In order for it to be effective cardiovascular exercise needs to be maintained at 60-70% of the maximum heart rate (MHR: measured as 220 – age or 206.9 - (0.67 x age)).

Cardiovascular exercise is defined as exercises to promote improved capacity of the cardiovascular system. The contraction of major muscle groups must be repeated often enough to elevate the heart rate to a target level determined during testing (Medical dictionary, 2016).

This can be exercise such as walking, cycling, jogging and swimming and should lead to cardiovascular or cardiorespiratory fitness. Cardiovascular or cardiorespiratory fitness “is conferred by the central capacity of the circulatory and respiratory systems to supply
oxygen, and the peripheral capacity of the skeletal muscle to utilise oxygen” (Mead and van Wijck, 2013, p.78).

Cardiovascular exercise is thought to reduce cardiovascular risk by: 1) promoting weight reduction; 2) reducing high blood pressure; 3) reducing low-density lipoprotein [LDL] level, as well as total cholesterol, and potentially raising high-density lipoprotein level [HDL]); 4) increasing the body’s ability to use insulin to control glucose levels in the blood (Myers, 2003); 5) increasing a chronic anti-inflammatory effect which relates to improved blood vessel function, anti-inflammation of the arteries and reductions in vascular adhesion (Mora et al., 2007).

1.4.2 Normal cardiovascular and metabolic responses to exercise and changes post-stroke

In a healthy body, the heart, blood vessels, blood and lungs respond in a predictable way to exercise. In order to meet the increased oxygen demands of the body during exercise, the respiratory rate and tidal volume of the lungs are increased, stimulated by the respiratory centres in the brainstem of the central nervous system. The oxygen is transported from the lungs into the blood vessels and the heart pumps the blood around the body. The cardiac output of the heart is the amount of blood pumped by the left ventricle of the heart per minute, this increases during exercise until it reaches its maximum capacity. Cardiac output is a result of the heart’s stroke volume and heart rate, the maximum capacity of the cardiac output is governed by the limitations of the stroke volume rather than the limits of heart rate.

During exercise the blood flow changes so that the muscles receive a 60% increase due to the increased cardiac output and redirection of blood. Mean arterial blood pressure also increases due to the increase in cardiac output and a lesser reduction in peripheral resistance of the arteries. Blood flow through the coronary arteries supplying oxygen to the heart increases, due to increases in heart rate, systolic blood pressure and myocardial oxygen consumption.

In the long term, there are a number of changes that occur in many systems of the body with sustained cardiovascular exercise. In the cardiorespiratory systems, the lungs display a permanent increase in tidal volume, pulmonary diffusion rates and pulmonary
blood flow partly due to changes in the efficiency of the diaphragm and intercostal muscles (Åstrand and Rodahl, 1986). The cardiac output of the heart increases due to a permanent increase in stroke volume. Stroke volume increases due to: hypertrophy of the left ventricle and increased plasma volume leading to an increased stretch of the left ventricle wall. Arterial blood pressure at rest and at submaximal and peak levels of exercise reduces partly due to an increase in the number of capillaries in the skeletal muscles leading to less peripheral resistance from the blood vessels. Also, the platelets become less adhesive leading to less risk of clotting and hormonal changes produce a chronic anti-inflammatory effect. In the endocrine system, there is an increase in insulin sensitivity reducing the storage of glucose and a rise in the breakdown of glucose (Smith and Fernhall, 2011).

Post stroke in the musculoskeletal system, the muscle fibres can change from slow twitch to fast twitch fibres with a reduced ability to exercise for long periods of time (Landin et al., 1977). There is also evidence of more fat within the muscle fibres (Ryan et al., 2002) and a reduced capillary network (Prior et al., 2009). In the cardiorespiratory systems, damage to the brainstem can affect the electrical control of the heart and lungs, respiratory muscles can become weak affecting lung volumes and exercise capacity (Anoni et al., 1990). The blood flow into the affected limb is reduced due to an increased arterial wall thickness and reduced capacity to vasodilate and pro-inflammatory markers are increased post-stroke (Castellanos et al., 2002). Finally, endocrine function specifically insulin control is affected leading to an increase in insulin resistance (Vermeer et al., 2006). All of these changes will significantly affect the physiological response to exercise.

1.4.3 Cardiorespiratory fitness after stroke

Literature suggests that cardiorespiratory fitness (CRf) after stroke is reduced by as much as 50% compared to age-matched individuals (Mackay-Lyons et al., 2002 and Macko et al., 1997). This could be due to impaired balance and coordination, changes in muscle physiology and inflammation, impaired haemodynamic response, altered metabolic health and, to a lesser extent, respiratory dysfunction (Billinger et al., 2012). However, research has established that cardiovascular exercise can improve CRf for people with stroke (Meek et al., 2003, Pang et al., 2006, Stoller et al., 2012, Smith et al.,
2012, NICE 2013, Goncalves et al., 2016, Saunders et al., 2016). Table 1.3 summarises the research for cardiovascular exercise for chronic stroke patients (see search strategy in Appendix 1) and Table 1.4 summarises the research for cardiovascular exercise for sub-acute stroke patients (see search strategy in Appendix 1). The Canadian Partnership for Stroke Recovery (2018) define the sub-acute phase of recovery as “patients between 1-6 months post-stroke” and the chronic phase of recovery as “patients longer than 6 months post-stroke” (Canadian Partnership for Stroke Recovery, 2018).
<table>
<thead>
<tr>
<th>Author and country</th>
<th>Study</th>
<th>Intervention</th>
<th>Subjects</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potempa et al 1995 (USA)</td>
<td>Pilot RCT</td>
<td>I – 3 x per week for 10 weeks. Cycle. C – passive ROM</td>
<td>42. Age range 21 – 77 years</td>
<td>Increase in VO(_2) peak in intervention group only (p= 0.022) Adverse events – not reported</td>
</tr>
<tr>
<td>Macko et al., 2001 (Canada)</td>
<td>Cohort study</td>
<td>3 x 40 mins sessions on treadmill, per week for 6 months</td>
<td>23. Mean age 67 years</td>
<td>Increased VO(_2) peak at 3 months (P&lt;0.02) No adverse events</td>
</tr>
<tr>
<td>Eng et al, 2003 (Canada)</td>
<td>Cohort study</td>
<td>8 weeks community group programme. 60 mins, 3 times per week</td>
<td>25. Mean age 63 years</td>
<td>Significant Improvements in 12 min walk test in intervention group (p&lt;0.05) Adverse events – not reported</td>
</tr>
<tr>
<td>Chu et al., 2004 (Canada)</td>
<td>Pilot single blind RCT</td>
<td>I – 8 weeks water-based programme/3 times per week C – UL function programme</td>
<td>12. Mean age 61.9 years</td>
<td>Significant improvement in VO(_2) max in intervention group (p&lt;0.05) No adverse events</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Intervention (I)</td>
<td>Control (C)</td>
<td>Findings</td>
</tr>
<tr>
<td>-----------------------</td>
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</tr>
</tbody>
</table>
| Pang et al., 2005 (Canada) | Pilot single blind RCT | I – community-based fitness programme  
19 weeks/3 x 1 hr sessions a week. | C – UL programme.  
19 weeks/3 x 1 hr sessions a week. | 63. Mean age 65 years  
Significant improvement VO$_2$ max in the intervention group (p=0.034)  
Adverse events – 5 falls, no injuries | | |
| Macko et al., 2005 (Canada) | Pilot RCT | I – 3x/week for 6 months treadmill  
C – stretching and low intensity training | 45. Mean age 64 years  
Increased VO$_2$ peak in intervention group (p<0.005)  
No adverse events | | |
| Mudge et al., 2009 (NZ) | Single blind RCT | I – 12 sessions circuit training, 3x /week for 4 weeks  
C – social and education classes | 60. Mean age 71 years  
Improved distance on 6MWT (p=0.03)  
Adverse events – not reported | | |
| Michael et al., 2009 (USA) | Non-controlled pilot | 3 x week for six months – group sessions | 7. Mean age 71 years  
Increased VO$_2$ peak (p=0.03)  
Adverse events – not reported | | |
| Moore et al., 2010 (UK) | Pilot RCT – single blind | I - 19 weeks/ 3x per week/group work  
C - stretching | 40. Age > 50 years  
Improved VO$_2$ Peak (p<0.01)  
No adverse events | | |
| Jorgensen et al., 2010 (Denmark) | Cohort study | 12 weeks (5 days a week) treadmill training | 14. Mean age 58.4 years  
Significant improvement in 6MWT (p<0.001) no sign in VO$_2$ peak (p=0.08) | | |
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Intervention</th>
<th>Control</th>
<th>Adverse events</th>
</tr>
</thead>
</table>
| Globas et al., 2012 | Pilot RCT – single blind | I - Treadmill for 3 months (39 sessions)  
C – Physiotherapy  
(1-3 sessions of 1 hour each/week) | 38. Age > 60 years  
Improved VO$_2$ peak in intervention group (p<0.001)  
Adverse events – 2 falls |
| Askim et al., 2014  | Feasibility study | 6 weeks, high intensity training 2 x per week                              | 15. Mean age 70 years  
No improvement in peak oxygen uptake (p=0.189)  
Adverse events – 1 fall |
| Jin et al., 2012    | Pilot RCT       | I – 8 weeks (5x per week) aerobic cycle training  
C- 8 weeks overground walking | 133. Mean age 58 years  
Improved peak VO$_2$ in intervention group (p<0.001)  
Adverse events – not reported |
| Al-Jarrah et al., 2014 | Cohort study   | 3 months (3 times a week) treadmill and strength training                   | 30. Mean age 58 years  
Improved 6MWT at 3 months (p<0.001) and six months (p=0.008)  
Adverse events – not reported |

RCT – Randomised Controlled Trial. I – Intervention group, C – Control group.
Table 1.4  Studies using cardiovascular training in the subacute stroke population

<table>
<thead>
<tr>
<th>Author and country</th>
<th>Study</th>
<th>Intervention</th>
<th>Subjects</th>
<th>Results</th>
</tr>
</thead>
</table>
| Duncan et al., 1998 (USA) | Pilot RCT | I – 12 weeks strength, balance and cycle leg ergometry. 3 x per week  
C – usual care no endurance training | 20 (66 days post stroke). Mean age 67.6 years | Sign. increase in 10 metre walk test (P=0.05)  
Adverse events – not reported |
| da Cunha et al., 2002 (USA) | Pilot RCT | I – Supported treadmill plus physiotherapy/ 3 weeks  
C – usual physiotherapy | 11 (9 – 28 days post stroke). Mean age 58.4 years. | No difference in VO₂ – 5minute walk  
Adverse events -not reported |
| Duncan et al., 2003 (USA) | RCT | I – Over 900 mins/12 weeks/3 days per week/20-30mins/cycle  
C – usual care | 92 (mean 77.5 days post stroke). Mean age 69 years | Intervention group greater gains in VO₂ peak (p<0.01)  
Adverse events – 3 re-stroked and 1 hospitalised |
| Katz-Leurer et al., 2003 (Israel) | RCT | I – cycle ergometer/28 sessions/ 8 weeks/ 3 x per week  
C – usual care | 92 (mean 30 days post stroke). Mean age 63.5 years | Significantly improved peak work rate in intervention group (p<0.01)  
Adverse events – not reported |
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Intervention (I) Details</th>
<th>Outcome Measures</th>
<th>Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eich et al., 2004 (Germany)</td>
<td>Pilot RCT</td>
<td>I – Treadmill/over 900 mins/6 weeks/5 days per week/30 mins</td>
<td>6MWT improved in intervention group (p=0.002)</td>
<td>No adverse events</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C – usual physiotherapy</td>
<td>Mean age 63.2 years</td>
<td></td>
</tr>
<tr>
<td>Tang et al., 2009 (Canada)</td>
<td>Pilot RCT</td>
<td>I – Over 400 mins/4 weeks/3 days per week/30 mins/cycle</td>
<td>Significant changes in VO$_2$ peak in intervention group (p=0.004)</td>
<td>No adverse events</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C – usual care</td>
<td>Mean age 65.2 years</td>
<td></td>
</tr>
<tr>
<td>Letombe et al., 2010 (France)</td>
<td>Pilot RCT</td>
<td>I – 4 weeks leg cycle ergometry, treadmill or stepper. 4 x per week</td>
<td>Significant increase in VO$_2$ peak in intervention group (p&lt;0.05)</td>
<td>Adverse events – not reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C – usual care</td>
<td>Mean age 60 years.</td>
<td></td>
</tr>
<tr>
<td>Outermans et al., 2010 (Germany)</td>
<td>Pilot RCT</td>
<td>I – 4 weeks/3 times per week, task-oriented training</td>
<td>6MWT improved in intervention group (p&lt; 0.02)</td>
<td>Adverse events – not reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C – low intensity physiotherapy</td>
<td>Mean age 57 years.</td>
<td></td>
</tr>
<tr>
<td>Toledano-Zarhi et al, 2011 (Israel)</td>
<td>Pilot RCT</td>
<td>I – supervised training 2 x per week for six weeks</td>
<td>Significant change in 6MWT in intervention group (p&lt;0.001)</td>
<td>Adverse events – not reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C – no supervised training</td>
<td>Mean age 65.0 years</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Interventions</td>
<td>Duration</td>
<td>Population</td>
</tr>
<tr>
<td>-------------------------------</td>
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<td>-------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Billinger et al., 2012 (USA)</td>
<td>Cohort</td>
<td>Stepper 3 x per week for 8 weeks.</td>
<td>9</td>
<td>Mean 66 days post stroke. Mean age 61 years</td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
<td>Mackay-Lyons et al., 2013 (Canada)</td>
<td>Pilot RCT</td>
<td>I – Treadmill – 48 sessions – 20 – 30 mins</td>
<td>50</td>
<td>Average 23 days post stroke. Mean age 60 years</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C – no CV training, usual care</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biasin et al., 2014 (Canada)</td>
<td>Prospective cohort</td>
<td>Inpatient programme – 3 x per week, mean 4 sessions. Max 20min session.</td>
<td>31</td>
<td>25 days post stroke. Mean age 69.1 years</td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
<td>Floel et al., 2014 (Germany)</td>
<td>RCT</td>
<td>I – treadmill training 5 days a week/4weeks</td>
<td>215</td>
<td>5 – 45 days post stroke.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C - relaxation sessions 5 days a week/4weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boss et al., 2014 (The Netherlands) MotiveS</td>
<td>RCT</td>
<td>I – 12 weeks aerobic programme plus physiotherapy visits plus usual care</td>
<td>120</td>
<td>&lt; 1 month.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C – usual care</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| MoveIT  
| (ongoing trials) | Sandburg et al., 2016 (Sweden) | Pilot RCT | I – Cycle ergometer – 2 x per week for 12 weeks  
| | | | C – usual care  
| | | | 56 (mean 22 days post stroke). Mean age 70.8 years  
| | | | No significant change in peak work rate in intervention group  
| | | | No adverse events  

RCT – Randomised Controlled Trial. I – Intervention group, C – Control group.
Table 1.3 and 1.4, show that CV training for the stroke population in all stages of recovery varies significantly. For chronic studies, the duration of treatments varied from 4 weeks to 6 months. This compares to studies in the sub-acute phase with much shorter durations ranging from 19 days to 12 weeks. In chronic studies, the frequency of training varied from three to five times a week, although mostly occurred three times a week. In the sub-acute studies there were two studies that provided twice weekly interventions but most were three times a week. Treadmill training and group training were the most common techniques used in the chronic phase of recovery, although three studies used cycle training and one used aquatic training. In the sub-acute phase, however, treadmill training and cycle training were the most common approaches with three studies using stepper training. Session durations ranged from 20 – 60 minutes.

The National Institute of Health and Clinical Excellence (2013) states that “Cardiorespiratory training for people with stroke should be started by a physiotherapist with the aim that the person continues independently” (NICE, 2013, p.3). However, the guidelines do not provide any specific advice for physiotherapists in terms of the optimum treatment. As is clear from the variety of studies outlined above, more research is needed to determine the optimum duration, frequency and type of CV training. One form of cardiovascular training that has not been fully explored for stroke patients is the existing programmes for cardiac patients, that is, cardiac rehabilitation (CR). The Cardiovascular Disease Outcomes Strategy (DoH, 2013) suggested the use of existing CR programmes for Transient Ischaemic Attack (TIA) patients and mild disability stroke patients.

1.5 Cardiac rehabilitation (CR)

“Cardiac rehabilitation is a complex intervention offered to patients diagnosed with heart disease, which includes components of health education, advice on cardiovascular risk reduction, physical activity and stress management” (Dalal, 2015, p.1). CR is well-established as part of the recovery process for most people with cardiac conditions. The NICE guidelines (2013) recommend CR for people post myocardial infarction alongside medication, lifestyle changes and advice. Anderson and Taylor (2014) conducted an
overview of Cochrane Systematic reviews and concluded that “Exercise-based cardiac rehabilitation is an effective and safe therapy to be used in the management of clinically stable people following myocardial infarction or percutaneous coronary intervention or who have heart failure” (Anderson and Taylor, 2014, p.2). Established CR programmes have been shown to reduce mortality by 18% and readmissions by 31% for certain cardiac patients (DoH, 2013).

However, The National Audit of Cardiac Rehabilitation (British Heart Foundation 2016) found that only 44% of patients with myocardial infarction, percutaneous coronary intervention and coronary artery bypass graft took part in CR (NACR, 2012) indicating that there were a high percentage of patients not engaging in CR (NACR, 2012). Karmali et al (2014) conducted a systematic review to identify successful methods to increase uptake and adherence to CR but found only weak evidence that interventions were effective at increasing uptake and they were unable to recommend a specific approach. They did recommend that further research was needed to explore this topic. It is also unclear how to motivate patients to continue with their healthy lifestyles after CR is completed, that is, how to maintain their healthy lifestyles.

1.6 Cardiac rehabilitation in the stroke population

All six studies investigating CR for stroke patients have been feasibility studies and only one study has used existing CR programmes in England (Kirk et al., 2014). This study was conducted over 18 weeks and focussed on a stroke population with mild disability (stroke severity) post-stroke. Table 1.5 summarises the studies that have used CR for people with stroke (see Appendix 1 for search strategy).
Table 1.5 Studies using CR for the stroke population

<table>
<thead>
<tr>
<th>Author and country</th>
<th>Study</th>
<th>Intervention</th>
<th>Subjects</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chronic stage of recovery</strong></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Lennon et al., 2008 (Ireland)</td>
<td>Pilot RCT</td>
<td>I - 10 weeks/16 cycle ergometry sessions C – usual care</td>
<td>48 (&gt;1 year post stroke) Functional ambulatory category – 0-2 – physical help (17%), 38 independently mobile. Mean age 60 years</td>
<td>Improved VO$_2$ peak in I group (p&lt;0.001) Improved cardiac risk score in I group (p&lt;0.05) Adverse effects – not reported</td>
</tr>
<tr>
<td>Tang et al., 2010 (Canada)</td>
<td>Feasibility</td>
<td>6 months CR – once weekly, 90 minute session.</td>
<td>41 (30 months post stroke). Mild to moderate stroke patients Chedokee-Mcmaster – 4.4 arm, 5.1 leg. Mean age 65 years</td>
<td>Improved VO$_2$ peak (p=0.06) No serious adverse effects</td>
</tr>
<tr>
<td>Marzolini et al., 2014 (Canada)</td>
<td>Cohort</td>
<td>6 months CR – once weekly,</td>
<td>120 (25 months post-stroke).</td>
<td>Improved VO$_2$ peak (p&lt;0.001).</td>
</tr>
<tr>
<td>Subacute</td>
<td>90 minute session</td>
<td>Chedokee-McMaster – 4 (6 and 7 normal). Mean age 63.8 years</td>
<td>Sign. Improvements in 6MWT (p&lt;0.001) Adverse effects – not reported</td>
<td></td>
</tr>
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</tr>
<tr>
<td><strong>Prior et al., 2011 (Canada)</strong></td>
<td>Feasibility – no control</td>
<td>6 months CR – twice weekly, 50 sessions</td>
<td>Improved METS (p&lt;0.001) Improved CV risk factors – lipids (p&lt;0.001), BMI (p=0.003), reduction in smoking. Adverse events – 3 recurrent strokes</td>
<td></td>
</tr>
<tr>
<td><strong>Kirk et al., 2014 (England)</strong></td>
<td>Pilot RCT</td>
<td>18 weeks (6 weeks phase 3 and 12 sessions phase 4)</td>
<td>Significant reduction in cardiovascular disease risk score (p=0.042) Improved SF 36 – Physical functioning (p=0.012)</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Intervention Details</td>
<td>Participants</td>
<td>Outcomes</td>
<td>Adverse Events</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>--------------------------------------</td>
<td>--------------</td>
<td>---------------------------------------------------------------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>Marzolini et al., 2016 (Canada)</td>
<td>Cohort – no control 6 months CR – 5 aerobic sessions per week.</td>
<td>85 TIA patients. Mean age 67.5 years</td>
<td>Improved VO$_2$ peak (p&lt;0.001), Improved waist and hip circumference (p&lt;0.001), depression (p=0.04)</td>
<td>Adverse events – not reported</td>
</tr>
</tbody>
</table>

Three of the studies were conducted with a chronic stroke population (Tang et al., 2010, Marzolini et al., 2014, Lennon et al., 2008), two with the sub-acute stroke population (Prior et al., 2011, Kirk et al., 2014) and one study with TIA patients (Marzolini et al., 2016). Four studies were conducted in Canada (Prior et al., 2011, Tang et al., 2010, Marzolini et al., 2014, Marzolini et al., 2016), one in Ireland (Lennon et al., 2008), and one in England (Kirk et al., 2014). Two were pilot, feasibility studies (Lennon et al., 2008 and Kirk et al., 2014) and four were feasibility, cohort studies (Marzolini et al., 2014 and Marzolini et al., 2016, Tang et al., 2010, Prior et al., 2011).

All studies showed improvements in the main outcomes: CRf (Lennon et al., 2008, Tang et al., 2010, Marzolini et al., 2014 and Marzolini et al., 2016) and Cardiovascular risk (Prior et al., 2011, Kirk et al., 2014), but as all these studies were feasibility or pilot studies it is not possible to provide a definitive conclusion. In addition, all of the Canadian studies carried out six month interventions (Tang et al., 2010, Marzolini et al., 2014, Prior et al., 2011 and Marzolini et al., 2016) which is unfeasible in the UK system. As well as the length of programmes outside the UK, the results from studies conducted outside the UK are not readily transferrable to the UK due to: private insurance-based medical care compared to the NHS; potentially different staff providing the interventions; varying stroke services in different countries; patients experiences and attitudes may be very different in each country.

Typically phase three CR in the UK lasts six weeks and provides once or twice weekly intervention, patients are then offered a phase four programme in the community led by trained exercise professionals. In the only study for people post-stroke conducted in the English CR system, Kirk et al (2014) provided 6 weeks of phase three CR and 18 weeks phase four intervention in the community and included people post stroke less than 2 on the NIHSS stroke severity scale. The study in this thesis (Chapter 6) aimed to recruit people post-stroke who had a more severe stroke (up to 15 on the NIHSS) to explore what level of severity of stroke could be included in the present CR system. Also the present study only provided six week phase three CR to determine the effect of a short term CR intervention on people post-stroke.
1.7 Attitudes to Cardiac rehabilitation and Exercise post-stroke

1.7.1 Staff attitudes

There are no previous studies exploring attitudes of staff towards people with stroke taking part in CR (see Appendix 1 for search strategy). However, there are a number of studies that have explored the attitudes of physiotherapists and exercise professionals towards the use of exercise schemes in the community after the sub-acute phase of rehabilitation for people post-stroke. Lau et al (2016) conducted a cross-sectional e-survey of 186 physical therapists in Canada, and found that 90% of physical therapists provided advice about the health benefits of exercise. However, only 36% provided advice about community programmes due to a lack of programmes. Wiles et al (2008) conducted 30 interviews with people post-stroke, exercise professionals and physiotherapists and found that attitudes of physiotherapy staff in the United Kingdom towards exercise on prescription schemes was positive. Nonetheless, concerns were raised about the level of stroke knowledge and limited monitoring of the instructors, and recommended that training opportunities on stroke needed to be developed for exercise professionals.

Condon and Guidon (2018) conducted a cross-sectional study using an online survey with 87 exercise professionals in Ireland. They found that exercise professionals are interested in working with people with stroke, but had limited experience and knowledge. Furthermore, Marsal and colleagues (2017) conducted a survey of physiotherapy staff (n = 129) and students (n = 248) and medical staff (n = 65) in France about self-rehabilitation, and found that ‘the strategy of asking patients to perform exercises alone, in the practice or at home, is still not accepted by a large proportion of physical therapy professionals, as compared with students or with physicians’ (Marsal et al, 2017). These studies indicate that although stroke physiotherapists encourage exercise and on-going exercise programmes they are reluctant to refer onto programmes where there is limited expertise. In addition, they are reluctant to allow self-management making it very difficult for people post-stroke to continue with their exercise regimes.
1.7.2 Attitudes of people post stroke to CR and exercise

Previous qualitative research exploring attitudes towards exercise in people with stroke has mainly focussed on the identification of barriers and facilitators to exercise post stroke. Nicholson et al (2012) conducted a systematic review of five qualitative and one quantitative study that explored barriers and facilitators to exercise. Four of the studies were conducted in the USA, one in Australia and one in the UK. The authors concluded that lack of motivation, environmental factors and stroke impairments were the main barriers to engaging in exercise post stroke, and that the main motivators were the desire to return to independence, and support from family and professionals. One further study in Canada (Simpson and Eng, 2011) found similar results, and stated the main barrier for patients with chronic stroke was self-efficacy. Table 1.6 illustrates these studies. This study and the systematic review mainly focused on patients with chronic stroke. It is debateable whether barriers and facilitators to exercise will be the same at all stages of post-stroke recovery and with different levels of stroke severity.

Table 1.6 Facilitators and Barriers to exercise post stroke

<table>
<thead>
<tr>
<th>Author</th>
<th>Study</th>
<th>Subjects</th>
<th>Facilitators</th>
<th>Barriers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rimmer 2004 (USA)</td>
<td>Telephone survey</td>
<td>83 (time post stroke not reported) Mean age 54</td>
<td>Not reported</td>
<td>Health promotion activity – environmental and personal including motivation</td>
</tr>
<tr>
<td>Hammel 2006 (USA)</td>
<td>Qualitative</td>
<td>20 (time post stroke not reported) mean age 55.5</td>
<td>Not reported</td>
<td>Assessing venues - Individual, environmental and policy barriers</td>
</tr>
<tr>
<td>Study</td>
<td>Method</td>
<td>Sample</td>
<td>Activity</td>
<td>Motivators</td>
</tr>
<tr>
<td>-------</td>
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</tr>
<tr>
<td>Damush 2007 (USA)</td>
<td>Focus groups</td>
<td>13 chronic (&lt;12 months) mean age 59</td>
<td>Taking part in physical activity study. Finding motivators, social support</td>
<td>Stroke impairments, motivation and environmental factors</td>
</tr>
<tr>
<td>Resnick 2008 (USA)</td>
<td>Focus groups and interviews</td>
<td>29 chronic (minimum 6 months post stroke) mean age 64</td>
<td>Related to 6 months treadmill training they had participated in – social, physical and psychological</td>
<td>Not reported</td>
</tr>
<tr>
<td>Patterson 2009 (Australia)</td>
<td>Interviews</td>
<td>10 (time post stroke not reported) mean age 59</td>
<td>Related to programme they were involved in – social, motivational and confidence builder</td>
<td>Not reported</td>
</tr>
<tr>
<td>Robison 2009 (UK)</td>
<td>Interviews</td>
<td>19 chronic (&gt;12 months post stroke) mean age 70</td>
<td>Support from professionals and significant others</td>
<td>Physical, cognitive and environmental</td>
</tr>
<tr>
<td>Simpson and Eng 2011 (Canada)</td>
<td>Focus groups</td>
<td>11 chronic (8 years post stroke)</td>
<td>Support from others</td>
<td>Low self-efficacy</td>
</tr>
</tbody>
</table>

In relation to stroke patient’s attitudes towards CR post stroke, Marzolini et al. (2016) conducted a questionnaire-based study with 61 people post-stroke who had taken part in a six-month programme of CR in Canada. They found that the four greatest barriers
influencing attendance were severe weather, transportation problems, health problems, and travelling distance. People who were more disadvantaged socioeconomically (language, finances), and physically (stroke-related deficits) were more affected by these barriers. As this was a questionnaire-based study it lacked the in-depth analysis that an interview-based study would provide. This reflected what was seen as barriers to exercise post stroke.

Hillsdon et al., (2013) conducted 22 semi-structured interviews with people post-stroke who had attended 18 weeks of non-adapted CR in England. They found that CR had a positive effect on motivation to exercise, however, people post-stroke did not recall information given and risk factors specific to them. As this study assessed attitudes towards non-adapted CR, the themes identified may be different to the attitudes of people post-stroke who attend an adapted CR programme.

1.8 Outcome measures for measuring Cardiorespiratory fitness in the stroke population

In order to determine the effect of CR on CRf in the stroke population it is important to use valid and reliable outcome measures.

1.8.1 Qualities of Outcome Measures – validity and reliability

An outcome measure is “an objective test that is used to determine the baseline function of a patient at the beginning of treatment. Once treatment has commenced, the same instrument can be used to determine progress and treatment efficacy” (Physiopedia, 2018). Outcome measures are an essential part of treatment and research, to determine the effectiveness of a treatment or intervention. Outcome measures should be valid and reliable, the validity of an outcome measure relates to how much the measure reflects the truth or “the extent to which an instrument measures what it purports to measure” (Kimberlin and Winterstein, 2008, p.2278). There are different types of validity including face validity, content validity and criterion validity which is divided into concurrent and predictive validity. Criterion validity is the extent to which an outcome measure is related to an outcome, so predictive validity relates a measure to a future outcome whereas concurrent validity compares the
accuracy of measurement of one outcome measure to another gold standard outcome measure and is the type of validity tested within this project.

Reliability is the degree to which an assessment tool produces stable and consistent results (Phelan and Wren, 2005). There are a number of different types of reliability. Inter-rater reliability tests the accuracy of an outcome measure when recorded by a number of different measurers and intra-rater reliability measures the accuracy of an outcome measure when recorded by one measurer a number of times. Test–retest reliability examines the stability of a measure when tested on the same group of people on two separate occasions, this is the type of reliability tested within this project.

1.8.2 Measurement of Cardiorespiratory fitness (CRf)

Cardiovascular or cardiorespiratory fitness “is conferred by the central capacity of the circulatory and respiratory systems to supply oxygen, and the peripheral capacity of the skeletal muscle to utilise oxygen” (Mead and van Wijck, 2013, p. 78). Cardiopulmonary Exercise tests (CPET) on a treadmill or bike ergometer are considered to be the most valid tests of CRf fitness. They measure VO$_2$ max, which is the maximum volume of oxygen a person can use and is measured in millilitres per kilogramme of body weight per minute (ml/kg/min). During the CPET, the amount of oxygen inhaled and exhaled is recorded. The average untrained healthy male will have a VO$_2$ max of approximately 35–40 mL/kg/min and the average untrained healthy female will record a VO$_2$ max of approximately 27–31 mL/kg/min (Heyward, 1998).

The CPET measuring VO$_2$ max, however, could be too challenging for non-healthy populations so sub-maximal tests (VO$_2$ peak) have been designed using the same equipment but setting limits for their heart rate (HR) and blood pressure (BP) and reducing the incremental demands. These laboratory-based exercise tests require a significant amount of expensive equipment and therefore cannot be used extensively in the clinical setting. Therefore, field exercise tests have been devised to attempt to replicate the demands of the VO$_2$ max/peak tests, these clinical tests include the Incremental Shuttle Walk Test (ISWT) (Singh et al., 1992) and the 6minute Walk Test (6MWT) (Balke, 1963). The primary clinical measure used in CR throughout the UK is the ISWT (British Heart Foundation, 2018) and the second most commonly used measure of
CRf in the cardiac population is the 6MWT. The 6MWT is, however, the most commonly used test for measuring CRf in the stroke population (Physiopedia, 2018) and the ISWT is not commonly used for the stroke population.

1.8.2.1 Incremental shuttle walk test (ISWT)
The ISWT was described by Singh et al. (1992) for patients with chronic airways obstruction. The purpose was to produce an incremental test that challenged the subject’s cardiovascular system so as to produce a maximum effort. The test has been found to be valid (0.67 to 0.95, P < .01) and reliable (ICC = 0.76 to 0.99) for respiratory patients (Parreira et al., 2014) and cardiac populations (ICC = 0.99) (Hanson et al., 2016). However, there is limited evidence of its validity and reliability with stroke patients (see Appendix 1 for search strategy).

Two studies have been identified that investigated the use of the ISWT in the stroke population. The first study compared the ISWT to the 6MWT (van Bloemendaal et al., 2012) and found that there was a moderate correlation between the two tests (r= 0.65, p<0.01) for high speed walking in 75 stroke patients. They reported that test retest was good (ICC= 0.961). However, this study was conducted with non-disabled, chronic stroke patients and did not compare the ISWT with the gold standard of the CPET. A second study compared the ISWT with a cycle ergometer and measured VO$_2$ peak using a portable metabolic cart (Dunn et al., 2014). Eighteen subjects completed both tests and it was found that there was no significant difference between both tests (p=0.728) for VO$_2$ peak. They concluded that both the cycle test and ISWT were appropriate for measuring CRf in a sub-acute to chronic stroke population. However, their sample size was small and the population were only mildly disabled post stroke. The ISWT is not routinely used in the stroke services so it is necessary to determine reliability of this test with the stroke population and to compare with the 6MWT, which is more routinely used to measure CRf in the stroke population.

1.8.2.2 Six-minute walk test (6MWT)
The 6MWT was devised by Balke (1963) to produce a measure of physical fitness for healthy adults. The test has since been shown to be moderately valid and reliable for a
number of populations including cardiac (Pollentier et al., 2010, Adnan et al., 2011), respiratory (Casanova et al., 2007), elderly (Harada et al., 1999) and spinal cord injury populations (Lam et al., 2007 and van Hedel et al., 2005). In the *chronic* stroke population, the 6MWT has been shown to be moderately reliable and valid (Outermans et al., 2015). Table 1.7 summarises the evidence for the studies investigating the validity and reliability of the 6MWT with the chronic stroke population (see Appendix 1 for search strategy). However, there is less evidence in the *sub-acute and acute* population and few studies compare the 6MWT with the CPET. Table 1.8 summarises the evidence for the validity and reliability of the 6MWT in the sub-acute/acute stroke population (See Appendix 1 for search strategy).
Table 1.7 Summary of studies showing the validity and reliability of the 6MWT in the chronic stroke population

<table>
<thead>
<tr>
<th>Author and country</th>
<th>Study</th>
<th>Subjects</th>
<th>Outcome measures</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eng et al., 2001</td>
<td>Validity</td>
<td>25 (4 years post stroke). Mean age 62.6 years</td>
<td>12MWT/6MWT/8MWT</td>
<td>Moderate correlation with other walk tests (r&gt;0.90)</td>
</tr>
<tr>
<td>(Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eng et al., 2004</td>
<td>Validity and reliability</td>
<td>12 (3.5 years). Mean age 62.5 years</td>
<td>Treadmill / Cycle (VO₂ max)/6MWT</td>
<td>r=0.37, p&gt;0.05</td>
</tr>
<tr>
<td>(Canada)</td>
<td></td>
<td></td>
<td></td>
<td>ICC = 0.99</td>
</tr>
<tr>
<td>Pang et al., 2005</td>
<td>Validity</td>
<td>72 (5.5 years). Mean age 65.3 years</td>
<td>CPET – cycle (VO₂ max)/6MWT</td>
<td>r=0.4, p&lt;0.05</td>
</tr>
<tr>
<td>(Canada)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Courbon et al., 2006</td>
<td>Validity</td>
<td>21 (24 months). Mean age 53.48 years</td>
<td>CPET - cycle (VO₂ peak)/6MWT</td>
<td>r=0.6, p&lt;0.0032</td>
</tr>
<tr>
<td>(France)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patterson et al., 2007</td>
<td>Validity</td>
<td>74 (48 months). Mean age 64 years</td>
<td>CPET - Treadmill (VO₂ peak)/6MWT</td>
<td>r=0.64, p&lt;0.001</td>
</tr>
<tr>
<td>(USA)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carvalho et al., 2008</td>
<td>Validity</td>
<td>34 (62 months). Mean age 60 years</td>
<td>CPET - cycle (VO₂ peak)/6MWT</td>
<td>r=0.34, non-significant</td>
</tr>
<tr>
<td>(Norway)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Type</td>
<td>Duration</td>
<td>Mean Age</td>
<td>Test Method</td>
</tr>
<tr>
<td>------------------------------</td>
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</tr>
<tr>
<td>Tseung et al., 2009 (USA)</td>
<td>Validity</td>
<td>9 (47.6 months)</td>
<td>56.8 years</td>
<td>CPET - cycle (VO2 peak)/ 6MWT</td>
</tr>
<tr>
<td>Ovando et al., 2011 (Brazil)</td>
<td>Validity</td>
<td>8 (18 months)</td>
<td>53 years</td>
<td>CPET - Treadmill (VO2 peak)/ 6MWT</td>
</tr>
<tr>
<td>Calmels et al., 2011 (France)</td>
<td>Validity</td>
<td>14 (12 months)</td>
<td>53.7 years</td>
<td>CPET - cycle (VO2 peak)/ 6MWT</td>
</tr>
<tr>
<td>Wevers et al., 2011 (The Netherlands)</td>
<td>Reliability</td>
<td>27 (266 days)</td>
<td>60.7 years</td>
<td>6MWT</td>
</tr>
<tr>
<td>Severinsen et al., 2011 (Denmark)</td>
<td>Validity</td>
<td>48 (18 months)</td>
<td>68 years</td>
<td>CPET – cycle (VO2 peak)/ 6MWT</td>
</tr>
<tr>
<td>Marzolini et al., 2016 (Canada)</td>
<td>Validity</td>
<td>60 (13.5 months)</td>
<td>64.5 years</td>
<td>CPET - cycle (VO2 peak)/6MWT</td>
</tr>
</tbody>
</table>
Table 1.8 Summary of studies showing the validity and reliability of the 6MWT in the subacute population

<table>
<thead>
<tr>
<th>Author and country</th>
<th>Study</th>
<th>Subjects</th>
<th>OMs</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kelly et al., 2003 (Australia)</td>
<td>Validity</td>
<td>17 (30 days). Mean age 66 years</td>
<td>CPET - Semi-recumbent bike (VO₂ peak)/ 10MTWT and 6MWT</td>
<td>r=0.84, p value not given</td>
</tr>
<tr>
<td>Kosak and Smith, 2005 (USA)</td>
<td>Reliability and validity</td>
<td>18 (28 days). Mean age 77 years</td>
<td>6MWT/2MWT and 12MWT</td>
<td>Reliability of 6MWT - ICC = 0.78, p&lt;0.0007  Validity of 6MWT/2MWT - r=0.997, p&lt;0.001</td>
</tr>
<tr>
<td>Tang et al., 2006 (Canada)</td>
<td>Validity</td>
<td>36 (&lt;3 months). Mean age 64.6 years</td>
<td>CPET – cycle (VO₂ peak)/6MWT</td>
<td>r=0.56, p&lt;0.001</td>
</tr>
<tr>
<td>Fulk et al., 2008 (USA)</td>
<td>Reliability</td>
<td>35 (34.5 days). Mean age 67.4 years</td>
<td>6MWT</td>
<td>ICC = 0.86 (95%CI)</td>
</tr>
</tbody>
</table>
It can be seen that the ISWT has only been used twice with a stroke population to measure CRf. As a clinical test regularly used in CR for the cardiac population it needs to be established if it is valid and reliable in the stroke population. This is because it has the potential to measure CRf more accurately than other walking tests due to the incremental nature of the test. It has also been shown that the 6MWT has been used widely to measure CRf in the chronic and sub-acute stroke population and has been shown to be reliable. However, in both the chronic and sub-acute stroke population it did not closely correlate with CPET (VO₂ peak). The 6MWT and ISWT have also not been directly compared to the CPET so it is not clear which test would be the most valid and reliable clinical test to measure CRf in people post-stroke in the sub-acute phase of recovery.

1.9 Summary of Background

Stroke leads to reduced CRf and potentially increased cardiovascular risk. Risk factor management includes lifestyle management such as dietary changes, smoking cessation and cardiovascular exercise. Sustained cardiovascular exercise has been shown to produce a range of positive cardiovascular and metabolic changes. Cardiovascular exercise is exercise that challenges the cardiorespiratory system, for example, cycling, swimming and running and in order to be effective, needs to be maintained at 60-70% of the target heart rate for 150 minutes a week. There are numerous studies that demonstrate the effectiveness of cardiovascular exercise for people with stroke to increase their CRf both in the sub-acute and chronic stage of recovery. However, it is not clear what is the optimum dose, frequency and type of cardiovascular exercise for people with stroke.

CR is a form of cardiovascular exercise originally applied to the cardiac population and has been shown to be effective in this population to reduce mortality rates. There are six feasibility studies that have applied CR to the stroke population, however, only one has been conducted in the English CR system and all of the studies have had interventions longer than 10 weeks long. These studies have all included patients with low levels of stroke severity so it is not clear what level of disability (stroke severity) can be included in the English CR programmes. This thesis employs a mixed-method approach to examine the feasibility of just six weeks of adapted CR for people with mild
to moderate severity stroke in the sub-acute phase of recovery. Firstly, exploring the perceptions of people with stroke (Chapter 3 and Chapter 6), stroke and cardiac rehabilitation teams (Chapter 4 and Chapter 6) and cardiac patients (Chapter 6) towards cardiovascular exercise and healthy lifestyles in people with stroke and their acceptability to CR. Secondly, examining the clinical measurement of cardiorespiratory fitness in people with mild-to-moderate severity stroke in the sub-acute phase of recovery (Chapter 5) and finally attempting to determine the intervention, recruitment strategy, adherence and outcome measures for a larger definitive trial (Chapter 6).

1.10 Aim of definitive study

The overall aim of the definitive study is to determine if adapted CR is an effective treatment to increase CRf and improve activity levels, QOL, fatigue, tone, falls, BMI, anxiety and depression for people post-stroke with a mild to moderate stroke severity in the sub-acute phase of recovery.

1.11 Aim of thesis

The overall aim of this research is to establish the feasibility of conducting a definitive study investigating the effect of six weeks of adapted CR on CRf, BP, HR, activity levels, QOL, fatigue, tone, falls, BMI, anxiety and depression for people with mild to moderate stroke in the sub-acute stage of recovery.

1.12 Objectives of Thesis

1. To conduct a literature review to identify and summarise the qualitative literature that relates to the experiences of people post-stroke and their attitudes to and knowledge of exercise, healthy lifestyles and CR post-stroke.

2. To conduct a qualitative interview-based study with people post-stroke who have a mild-to-moderate stroke severity who are in the subacute stage of recovery to explore experiences and knowledge of and attitudes to healthy lifestyles and CR.
3. To conduct a literature review to identify and summarise the literature that relates to healthcare professionals’ attitudes to healthy lifestyles, particularly exercise and CR in people post-stroke with mild to moderate severity in the sub-acute phase of recovery.

4. To conduct a qualitative focus group study with healthcare professionals who work in CR and stroke care to explore experiences and knowledge of and attitudes to healthy lifestyles and CR post-stroke.

5. To conduct a systematic review to identify and summarise the literature related to the use of the 6MWT and ISWT to measure CR in people post-stroke.

6. To conduct a quantitative study to measure the concurrent validity of the ISWT, 6MWT with the ICT and to test the test-retest reliability of the ISWT and the 6MWT.

7. To conduct a systematic review to identify and summarise the literature related to cardiovascular exercise and CR for people post-stroke.

8. To conduct a cohort study to identify the acceptability, recruitment strategy, adherence, outcome measures and adaptations needed for adapted CR for people post-stroke with a mild-to-moderate severity stroke in the sub-acute stage of recovery.

9. To conduct a review of literature to identify and summarise the literature related to experiences of and attitudes to CR post-stroke from the patient and staff perspectives.

10. To conduct a qualitative interview-based study with people post-stroke and people post cardiac event who took part in CR and with people post-stroke who did not take part in CR to explore experiences of CR and attitudes to healthy lifestyles after stroke and cardiac events.

11. To conduct a qualitative focus group study with healthcare professionals who work in CR and stroke to explore experiences of CR for people post-stroke and their attitudes to healthy lifestyles post-stroke.
Chapter 2  Method

2.1 Complex interventions

The Medical Research Council (MRC)(2008) stated that “complex interventions are built up from a number of components” (Craig et al., 2008, p.2) and in order to evaluate their effectiveness it is necessary to assess a number of individual components. CR would be classed as a complex intervention as it involves exercise classes managed by a multidisciplinary team; an education programme; lasts for six weeks and can be conducted once or twice a week. There are, therefore, a number of variables that could have an impact on the effectiveness of the intervention. For CR, the effectiveness of the programme may be determined by, for example, changes in physical or psychological measures or by changes in behaviour and so on. The MRC originally proposed a linear framework for the development of trials of complex interventions which was subsequently updated to a cyclical sequence (Craig et al., 2008) (see figure 2.1).

Figure 2.1 Key elements of the development and evaluation process (Craig et al., 2008)

As identified in the diagram there are four key elements in the development and evaluation of a complex intervention. All four stages have been examined for CR with the cardiac population and it has been comprehensibly established and shown to be effective for this population (Anderson and Taylor, 2014). However, using CR for a stroke population remains at the development and feasibility stages. Therefore, the studies described in this thesis support: identifying the evidence, designing or modelling
the process, determining the outcome measures and estimating recruitment and retention.

2.2 Mixed method methodology

As is seen with most feasibility studies, the methodologies required for this thesis were both qualitative and quantitative in nature, therefore, in order to achieve the objectives a mixed method approach was deemed to be the most appropriate approach. Rauscher and Greenfield (2009) stated that “Mixed methods designs are used for collecting, analysing and mixing both quantitative and qualitative data in a single study or series of studies to both explain and explore specific research problems” (Rauscher and Greenfield, 2009, p.91). They identified that the advantages are that mixed methods “reveal the complexity of disablement, rehabilitation, and recovery processes” (Rauscher and Greenfield, 2009, p.91).

Rauscher and Greenfield (2009) commented that the three main types of mixed method design are Sequential explanatory, Sequential exploratory and Concurrent Triangulation. Sequential explanatory design is where the quantitative data takes priority over the qualitative data and the data is collected in a sequential way. Sequential exploratory design is where the data is again collected in distinct phases but the qualitative data takes priority. Concurrent Triangulation design means that both qualitative and quantitative data are collected together and build on the previous findings. As the objectives of the present study were both qualitative and quantitative in nature this led to a mixed method design. The four phases of the study are distinct from each other and therefore could be described as sequential. As the overall aim was to inform a definitive quantitative study then the focus is more quantitative in purpose, therefore the mixed method design of this present study is a sequential explanatory design. Figure 2.2 outlines a flowchart depicting the four phases of this thesis.
Phase I – Qualitative study (Chapter 3)

Interviews with 20 people post stroke and TIA with mild to moderate severity in the subacute stage of recovery – experiences of and attitudes to healthy lifestyles particularly exercise

Phase II – Qualitative study (Chapter 4)

Seven focus groups with CR and stroke staff – experiences and attitudes to people post-stroke taking part in exercise and CR

Phase III – Quantitative study (Chapter 5)

To determine the Validity and Reliability of the ISWT and 6MWT compared to the CPET for measuring CRf in people post stroke and TIA with mild to moderate severity in the sub-acute phase of recovery. 40 patients.

Phase IV – Mixed method study (Chapter 6)

Quantitative Cohort study – 32 people post stroke and TIA with mild to moderate severity in sub-acute phase of recovery. All take part in 6 weeks of twice weekly CR. Outcome Measures taken at baseline and after the intervention.

Qualitative studies – five focus groups with CR and stroke staff – experiences and attitudes towards people post-stroke taking part in CR.

Interviews with 30 stroke patients and 12 carers post CR – experiences and attitudes to CR.

Interviews with 5 people post-stroke who did not want to take part in CR.

Interviews with 5 people post cardiac event who took part in the CR programme with stroke patients.
2.3 Methods used

2.3.1 Recruitment

For all phases of this thesis, except the focus group studies, patients were purposively chosen if they had had a mild to moderate severity stroke (0 – 15 on the NIHSS scale) (National Institute of Health, 2016) or TIA. They were recruited from a large single-centre UK University teaching hospital trust within one week to six months (sub-acute) post stroke or TIA. All patients were able to walk 10 metres with or without an aid and provided written consent. Exclusion criteria were based on cardiac contraindications and included: heart disease class III and upwards (Yancy et al., 2016), Class C and D exercise risk (Heath, 2005), uncontrolled arrhythmias (causing symptoms), angina on exercise and uncontrolled hypertension (>180/110mmHg at rest). For the qualitative interview studies, patients were purposively selected to represent a range of ages, gender and ethnicities. For the focus group studies in this thesis, the staff members were conveniently sampled, that is all levels of staff were approached to take part in the focus group but only those that were able to be released attended the groups.

As previously mentioned, the present study employed both quantitative and qualitative methods. The following sections will outline the main quantitative approaches used in this thesis, however a more detailed explanation of the data analysis will be included in each quantitative experimental chapter as the analysis varied for each study. The qualitative methods will be explained in detail here and referred to in each qualitative experimental chapter, as the philosophy, process of data collection and analyses were similar for each qualitative chapter.

2.3.2 Quantitative philosophies and methodologies

Quantitative research is “Explaining phenomena by collecting numerical data that are analysed using mathematically based methods (in particular statistics)” (Aliaga and Gunderson, 2002). Quantitative research is based on the positivist assumption that knowledge is based on natural phenomena and interpreted through logic and reason. There are four main types of quantitative research: Descriptive, Correlational, Quasi-Experimental, and Experimental Research. Descriptive research measures and defines a phenomenon but does not have a hypothesis. Correlational research explores the
relationship between different variables using statistical methods. Quasi-experimental research attempts to establish a causal relationship between a dependent and independent variable but the study has not been controlled or randomised. Experimental research also attempts to establish a causal relationship and is considered the gold standard as the variables are controlled and participants are randomised into groups (Sacramento State University Library, 2018).

The quantitative studies in this thesis employed correlational and quasi-experimental designs. Chapter 5 reports on a validity and reliability study which aimed to determine the correlation between three different measures of CRf. Chapter 6 outlines a quasi-experimental study that aimed to identify the feasibility of conducting a definitive study to determine the effect of CR on CRf and other quantitative outcome measures in a group of patients post-stroke. These two types of research, “use deductive reasoning, where the researcher forms a hypothesis, collects data in an investigation of the problem, and then uses the data from the investigation, after analysis is made and conclusions are shared, to prove the hypotheses not false or false” (BCPS, 2018).

2.3.3 Quantitative data collection

All research starts with a research question and in quantitative research this is transformed into a hypothesis. An alternative hypothesis postulates that there will be a difference or correlation between two variables whereas a null hypothesis “is a general statement or default position that there is no relationship between two measured phenomena, or no association among groups” (Everitt, 1998). Once a hypothesis is established, quantitative data can be collected using outcome measures (see Section 1.8.1 for an explanation of outcome measures). In the correlational study in Chapter 5, data from three measures of CRf were collected, controlling for fatigue and the learning effect. In the quasi-experimental study in Chapter 6, data were collected before and after patients took part in a six-week CR programme. The primary outcome measure was CRf, however, a number of other outcome measures were also taken to measure the effect of CR on depression, anxiety, fatigue, tone, pain, quality of life, stroke knowledge and activity levels.
Bias can be introduced into a quasi-experimental or experimental study during data collection if the outcome measures are not valid and reliable (see Section 1.8.1) and if: the individual collecting the data is not blinded to the intervention; the participants are not blinded to the intervention or the therapists providing the intervention are not blinded. For the quasi-experimental study in Chapter 6, bias was reduced by using valid and reliable outcome measures, however, it was not possible to blind the patients or therapists providing the treatment or assessing the treatment as there was only one treatment provided.

2.3.4 Quantitative data analysis

Once the data have been collected, descriptive statistics are conducted to determine the mean and standard deviations (SDs) or median and interquartile ranges (IQRs) for the data and these data can be presented in graphs. Levels of data collected can range from nominal data (eg. Male or female), ordinal data (eg. Likert rating scale), interval data (exact difference between the points eg. Temperature) or ratio data (as for interval data but has an exact zero such as height). If nominal or ordinal data are collected then median values and IQRs are calculated and presented as bar charts or pie charts, if ratio or interval data are collected then mean values and SDs are calculated and presented as histograms or box plots. In Chapter 5, the data are presented as means and SDs as the data collected were interval level data but in Chapter 6 the data are presented as both mean and SDs and median and IQRs as some outcomes are interval level data (eg. CRf) and some are ordinal level data (eg. Fatigue).

Once descriptive statistics have been completed, inferential statistics may be carried out to determine if the data confirms the alternative hypothesis or the null hypothesis. If the research question relates to a correlation then a Pearson’s or a Spearman’s correlation test will be conducted (see decision chart, figure 2.3). Which test is chosen is dependent on whether the data collected are ordinal or nominal level data leading to a non-parametric test or ratio or interval level data meaning that a parametric test can be conducted. In Chapter 5, the correlation between the three measures (validity) was tested using a Pearson’s correlation test as the data collected were ratio level data. Choosing a parametric test also relies on the data being normally distributed and this requires further statistical analysis as explained in Chapter 5. Testing the reliability of
the measures in Chapter 5 used an Intraclass correlation coefficient (ICC) as the same outcome measures were repeated so the repeated tests have exactly the same unit of measurement. It is not appropriate to use a Pearson’s or Spearman’s test with these type of data. In addition, Bland Altman plots were constructed to demonstrate the range of repeatability across the range of population values.

The result of an inferential test produces a p value, the p value gives the probability of any observed difference having happened by chance. $P = 0.5$ means that the probability of the correlation or difference having happened by chance is 0.5 in 1 or 50:50. The lower the p value the less likely that the difference has occurred by chance so the higher the significance of the finding. $P=0.05$ means that the probability of the correlation or difference having happened by chance is 0.05 in 1 or 1 in 20. For this thesis, $p=0.05$ is taken as the level of significance, so any p values equal to or below 0.05 were considered statistically significant and the alternative hypothesis was accepted and the null hypothesis rejected.

If the research question relates to a difference between two measures then there are a number of statistical tests that can be used dependent on the number of variables, number of experimental conditions and groups of participants (see figure 2.3).

However, because the study in Chapter 6 of this thesis, was a feasibility study it was not relevant to conduct inferential tests as the study was too small to statistically answer a research hypothesis and establish a causal relationship. If inferential tests were conducted on these data, this could lead to a type I error, that is, the rejection of a true null hypothesis (or identifying a difference of correlation when there was none) or a type II error: failing to reject a false null hypothesis (or identifying no difference or correlation when there was one).
Figure 2.3 Statistical inferential decision-making chart (Greene and D'Oliveira, 1982)
2.3.5 Qualitative philosophies and methodologies

Denzin and Lincoln (2011) identified a number of phases in the development of qualitative research from post-positivism in the 1950s to critical theory and experimental ethnography in the 1990s. Savin-Baden and Howell Major (2012) summarised present qualitative philosophies as: Critical social theory, Pragmatism, Post-modernism/structuralism, Social constructionism, Constructivism and Phenomenology. Critical social theory is based on power relationships and ideologies such as Marxism, Pragmatism focuses on observation of natural behaviour in a natural context, Post-modernism is related to literary texts and their interpretation, Social constructionism interprets social interaction, Constructivism suggests that individuals make and construct their own meaning, and Phenomenology focuses on the human experience.

All these philosophies employ different methodologies, the most common methodologies are: Grounded Theory, Ethnography, Participatory Action Research and Phenomenology. With a Phenomenological methodology, researchers will explore a phenomenon and collect data based on previous understanding of that phenomenon. The data will be described (Descriptive phenomenology) or interpreted (Interpretive phenomenology) using phenomenological reduction, but a theory will not be the end product. The present thesis used a phenomenological philosophy and approach, and attempted to identify the human experience of CR, exercise and healthy lifestyles for people with stroke, through the use of interviews and focus groups.

2.3.6 Interview data collection

Interviews are the main form of data collection for qualitative research. “The goal is to replicate the elements of a natural conversation...the interviewer guides the conversation and strives to understand the participants views as well as the meaning...” (Savin-Baden and Howell Major, 2013, p.357). There are different types of interviews: structured, semi-structured and unstructured. Structured interviews are limited in that they do not allow for a change in order of questions or a deeper exploration of the
topic, however, they do allow for comparisons across different interviewees. For semi-structured interviews, an interview schedule is used but allows for additional comments and responses. If time is limited these interviews allow for some focused interaction but may be limited because of that. Unstructured interviews only have an initial goal or plan and most questions arise from the conversation. These interviews require a number of interviews with one person to allow the topic to be explored in-depth and therefore can be very time-consuming.

For the present thesis, semi-structured interviews were used (as described in Chapters 3 and 6.5) as the topic required an in-depth discussion of the patients’ experiences and thus structured interviews were not appropriate. In addition, time did not allow a number of interviews per patient, a requirement for the use of unstructured interviews. Chapter 3 outlines Phase I of the present thesis, interviews with people who had a stroke, and who were exploring the experience of having a stroke and their thoughts on exercise and healthy lifestyles before and after their stroke. Chapter 6.5 outlines part of Phase IV of the thesis and explores the experiences of people who had a stroke and who attended CR, and people who had had a cardiac event who attended CR.

Interview schedules for both phases of the research are included in Appendix 2 and 4. It can be seen that the interviews started with general initial questions with probes, and then progressed to more in-depth questions to explore the experiences in more detail. Questions were open and aimed to identify emotions and feelings, as well as thoughts, beliefs and experiences. Question development was aided by four members of the study Patient and Public Involvement group (PPI); two people who had had a stroke over ten years previously and their wives. The main author had experience of conducting 24 semi-structured interviews as part of her MPhil study, however, she conducted a pilot interview with two of the PPI and discussed the transcript and recording with an expert qualitative researcher (CC).

All interviews were conducted in the patients’ home to allow them to ‘open up’ (Shuy, 2002) and allowed the interviewer to understand the context in which the patient provided their answers, that is, the socio-economic situation, in order to aid
interpretation of the data (Elwood and Martin, 2000). Face-to-face interviews also allow observation of non-verbal information, and in the present thesis this was also recorded after each interview (See Appendix 2 for an example of one of these observations). Interviews in the present thesis, were audio-recorded using digital recorders in order to record detailed responses rather than rely on interviewer recall, and therefore allowed for more in-depth questioning.

The philosophical approach of the research determines the number of interviews; for example, a grounded theory approach may have up to thirty interviews, whereas a phenomenological approach and philosophy may have only two to four participants (Carpenter and Suto, 2008). As the present thesis used a phenomenological methodology, potentially only a few interviews would have been required, however, as the patients had a wide range of perspectives, purposive recruitment continued until people with a range of ages, socio-economic and ethnic backgrounds were represented. Data collection was continued until it was perceived that data saturation had been reached, that is, the “point at which no new themes are being uncovered” (Savin-Baden and Howell Major, 2013, p.25). The purpose of qualitative research is not to generalise to the larger population, that is, transferability, however, the present thesis aimed to explore as many perspectives as possible, as can be seen in the results in Chapters 3 and 6.5.

2.3.7 Focus group data collection

A focus group differs from a group interview in that it encourages interaction of group members (Savin-Baden and Howell Major, 2013); the aim being usually to understand a new area and to explore a group understanding rather than individual interpretation. There are different types of focus groups: Exploratory, Clinical, Storyline, Issue development and Phenomenological (Savin-Baden and Howell Major, 2013). An exploratory focus group explores an issue and helps to develop a question, a clinical focus group is usually employed in action research in the medical field, a storyline focus group involves a storyline with a missing component that the group discusses, issue
development is where the group discusses a presentation, and finally a phenomenological focus group explores a groups’ views and experiences.

The present thesis used a phenomenological focus group approach to explore the experience of CR for people with stroke from the perspective of CR and stroke staff (Chapter 6.4) and also to explore the experience of stroke, exercise and healthy lifestyles from the perspective of CR and stroke staff (Chapter 4). Open interview schedules were designed (See Appendix 3) with initial general questions leading to more in-depth questions and probes. The main author was the facilitator and moderator, and each focus group had an observer who made notes and summarised the discussion at the end to prompt any final comments. All focus groups took place in a hospital setting to take into account the work pressures on the clinical teams. Each focus group took approximately one hour, the maximum number of attendees was six and the minimum was four. Patients were purposively selected from the stroke and CR teams to represent a range of abilities and professions. All of the focus groups were recorded using a digital auditory recorder. It was decided that videotaping the group was not beneficial as this may have significantly impacted on the openness of the discussions (Jewitt, 2012).

2.3.8 Strategies for rigour

When conducting any research, whether quantitative or qualitative, it is important to ensure that the methods used are as rigorous as possible to ensure valid and reliable data. Shenton (2004), however, commented that the terms validity and reliability cannot be directly used when considering qualitative research. He suggested that Guba’s (1981) constructs of: a) credibility (in preference to internal validity); b) transferability (in preference to external validity/generalisability); c) dependability (in preference to reliability); and d) confirmability (in preference to objectivity) are used instead. In order to ensure credibility, it is important to use triangulation, peer review, collaborative analysis, member checking and reflexivity; for transferability, the background of the study and the participants’ backgrounds need to be considered. Dependability can be encouraged through the use of in-depth methodological
description, and confirmability needs the use of triangulation, reflexivity and a clear audit trail. Yardley (2000) added that there should be: a sensitivity to context, that is, the awareness of social context and relationships between the researcher and participant; commitment to rigour, that is, does the size and nature of the sample address the research question; transparency and coherence, that is, is there sufficient detail of the methods used, and finally impact and importance, that is, will the results have practical and theoretical relevance.

All of these concepts were taken into account when conducting the qualitative research in the present thesis. Triangulation is defined as “using multiple data sources in an investigation to produce understanding” (Robert Wood Johnson Foundation, 2018), and in the present thesis, this was achieved through the combination of focus groups and semi-structured interviews, as well as through the use of different participant groups, that is, those post-stroke and post cardiac event, as well as CR therapists and nurses, and stroke therapists, nurses and doctors. Peer review and collaborative analysis refers to more than one researcher analysing the data and reviewing the process. In the present thesis, there were four main qualitative researchers, the primary author, two research assistants (SD and AH) and expert qualitative researcher (CC), all of whom had different backgrounds and represented different perspectives on the research topic. This ensured a varied analysis of the data and a thorough interpretation of the results.

Member checking or member validation involves asking the participants to read the transcripts of the interviews to confirm content or interpretation. In the present thesis, two patients were asked to read their transcripts, they agreed on the content and did not add any additional points.

Malterud (2001) stated that “A researcher's background and position will affect what they choose to investigate, the angle of investigation, the methods judged most adequate for this purpose, the findings considered most appropriate, and the framing and communication of conclusions” (Malterud, 2001, p.483-484). The present thesis reduced the effect of the researcher’s background by using peer review and collaborative analysis. The primary author also used a reflexive diary (see Appendix 2 for an excerpt of a reflective diary) and bracketing (see Appendix 2) to ensure an
awareness of her influences so that her data collection and analysis could be as honest and credible as possible. She consistently reflected on how her own personal and professional assumptions, and beliefs about exercise and maintaining a healthy lifestyle could influence the data collection and analysis processes. She has been a neurological physiotherapist for 28 years and a university lecturer for 13 years. She made every effort throughout the study implementation to make explicit her positive attitudes towards exercise and the importance of healthy living. During the interview process, where possible, she did not identify herself as a physiotherapist in case that knowledge influenced the patients’ responses.

2.3.9 Qualitative data analysis

“Data analysis is the process of moving from raw interviews to evidence-based interpretations...Analysis entails classifying, comparing, weighing and combining material to extract the meaning and implications” (Rubin and Rubin, 2005, p.201). The process of data analysis can vary depending on the methodology undertaken, for example, Grounded Theory uses a constant comparative analysis, whereas Phenomenology involves a thematic analysis (Braun and Clarke, 2006). Social Constructionism uses conversational analysis to explore social interaction and involves “examining conversations and analysing what was said, why it was said and how it was said” (All about Linguistics, 2019). Finally, content analysis “allows a researcher to take qualitative data and to transform it into quantitative data (numerical data)” (Tutor2u, 2019). Using coding units, the frequency of phrases or words or themes can be counted and quantified although this does not establish causality and cannot provide in-depth, deeper meanings.

As the present thesis used a phenomenological approach, a thematic analysis was employed based on the Braun and Clarke model (2006) (see Appendix 2). They break down the process into the following steps, as undertaken in the qualitative analysis of the results of this thesis:

1. Familiarisation with the data.
In the present study, the audio-recordings were transcribed by a professional transcriber. It was acknowledged that this was not the most ideal way of managing the data, but due to time-restraints this was the only way to ensure timely analysis. The transcripts were not transcribed verbatim, however, in order to maintain an in-depth description and analysis, the author read the transcripts and listened to the recordings simultaneously. Any additional pauses or sounds were added to the transcript, and after each interview or focus group the author recorded any significant non-verbal communication.

2. Generation of codes

For each interview and focus group, the transcripts were read and re-read, and quotes that related to the aims of that part of the study were highlighted and coded by the main author and the two research assistants (SD and AH)(See Appendices 2, 3, 4 and 5). For parts of the thesis additional researchers helped to identify codes, including University of Leicester Physiotherapy staff (Sundeep Nagi - SN), University of Leicester NHS trust staff member (Ross Dixey - RD) and Coventry University staff (CC). Codes were identified by each researcher individually according to common subjects identified. Each transcript was reviewed to determine if the codes were similar, and to identify other codes if necessary. Mind maps were developed to help make sense of the codes emerging. It was decided not to use software to assist with this process, as the author found it easier to use longhand to work with the data. Appendix 2 demonstrates an example of a mind map developed during the interview analysis process.


Once the codes had been identified, an attempt was made to produce themes that captured the essence of these codes. See Appendix 2 for an example of how themes were identified from codes. These processes were independently completed by three researchers (main author, SD and AH) and the themes identified were discussed and compared. The main author finalised the themes following these discussions and defined and named the themes.
In addition to thematic analysis, in this thesis content analysis was also employed with the analysis of interviews in Chapter 3 and Chapter 6 to attempt to collate the number of responses to certain questions and identify common categories.

2.4 Safety reporting /adverse events

See definitions section for explanation of AE, AR, SAE, SAR and SUSAR. All Adverse events (AEs) occurring during the study observed by the investigator or reported by the participant, whether or not attributed to study, were recorded on the CRF. The following information was recorded: description, date of onset and end date, severity, assessment of relatedness to study, other suspect device and action taken. Follow-up information was provided as necessary. AEs considered related to the study as judged by a medically qualified investigator or the sponsor were followed until resolution or the event was considered stable. All related AEs that resulted in a participant’s withdrawal from the study or were present at the end of the study, were followed up until a satisfactory resolution occurs. It was left to the investigator’s clinical judgment whether or not an AE was of sufficient severity to require the participant’s removal from treatment. A participant was also able to voluntarily withdraw from treatment due to what he or she perceived as an intolerable AE.

All Serious Adverse Events (SAEs) were reported to the University Hospitals of Leicester Research and Development office (UHL R&D) within one working day of discovery or notification of the event. UHL R&D performed an initial check of the information and ensured that it was reviewed at the next R&D management meeting. All SAE information was recorded on an SAE form and faxed to UHL R&D. There were no Suspected Unexpected Serious Adverse Reactions (SUSARs). In addition to the expedited reporting above, the main author submitted a report once a year throughout the study or on request an Annual Report to the Ethics Committee which listed all SAEs /SUSARs that had occurred during the preceding 12 months.

2.5 Ethics

Prior to recruitment and data collection, ethical approval was gained from the Northampton Ethics Committee (Reference: 14/EM/1067) (see Appendix 6). All team
members completed Good Clinical Practice (GCP) training and Consent training. Anonymity of the patients was achieved throughout the study by assigning a study number to each patient on consenting. Confidentiality was ensured by the use of study patient numbers and only one screening sheet with participant details securely stored on an NHS trust password-protected database. All patients were given at least 24 hours to consider the study information sheets (See Appendix 6), and informed consent (see Appendix 6) was obtained from all patients at all stages of the study. Data collected was anonymous and securely stored on an NHS trust password-protected database. Data were retained for the required five years.
Chapter 3  Experimental Chapter – Phase I - Semi-structured, in-depth interviews with people post-stroke and TIA in the subacute phase of recovery

A version of this chapter has been published in the International Journal of Therapy and Rehabilitation (see Appendix 8). Additionally, the information in this chapter was presented at the Physiotherapy UK 2015 conference, the European region – World Confederation for Physical Therapy (ER-WCPT) conference 2016, the Physiotherapy Research Society conference 2017 and a poster presented at the UK Stroke Forum 2015 with associated abstract published in the International Journal of Stroke. It is acknowledged that the article and abstracts had contributions from all of the co-authors but the majority of the work was written by the main author.

3.1  Introduction

A search of the literature was conducted to identify relevant previous qualitative research that explored the experiences of people post stroke, and their attitudes and beliefs about exercise after having a stroke. The search strategy can be found in Appendix 1. The main studies identified have been highlighted in Chapter 1.7.2. To summarise this research the literature mainly focused on barriers and facilitators towards exercise in people post stroke and identified that environmental barriers were the main difficulties for people in the chronic phase of recovery post stroke. Personal barriers such as lack of confidence and motivation were also found to be barriers for exercise post stroke. Once the analysis for this section of the thesis had been conducted a new search was carried out in relation to knowledge of stroke and healthy lifestyles as this theme emerged from the data during discussions. A search strategy in relation to knowledge of healthy lifestyles can be seen in Appendix 1.

3.1.1  Understanding of healthy lifestyles in people with stroke

Previous research exploring the understanding of healthy lifestyles of people with stroke has focussed mainly on the provision and delivery of advice. A survey of people with stroke conducted by the Healthcare Commission (2006) found that 43% of respondents were not given any information about dietary changes, and one in three were not given any information about physical exercise. In the same year, the Stroke
Association (2006) conducted an audit of stroke units and patients and found that only 46% of patients were given any information about future stroke prevention.

A Cochrane review conducted in 2012 (Forster et al, 2012) found that active information provision, where the participants were able to ask questions and relate the information to their experience, was more successful than a passive approach in improving knowledge. However, all the studies measured knowledge using a variety of structured questionnaires, and no qualitative studies were identified. Assessment of knowledge was a component of research studies that explored the effect of information provision, and, as Hillsdon et al (2013) commented, “future research should explore views of people not included in a trial” (Hillsdon, Kersten and Kirk, 2013, p.7).

It is also important to assess not just knowledge of healthy lifestyles, but the application of healthy lifestyle messages or the effect on behaviour change. Lennon et al (2015) are completing their final analysis of the ‘Cardiac rehabilitation adapted to transient ischaemic attack and stroke’ (CRAFTS) trial which compared an intervention group of chronic stroke patients and TIA patients, who received advice and exercise intervention post stroke, to a control group who did not receive this intervention. Preliminary results showed that secondary prevention improves compliance of lifestyle changes in the short term (Lennon, 2015).

It can be seen that there is limited qualitative research that explores the experiences of people post-stroke in relation to healthy lifestyles and in particular exercise. The research that exists has mainly focussed on identification of barriers and has mainly recruited people in the chronic phase of recovery post-stroke. The aim, therefore, of the first phase of the research programme reported in this thesis was to explore the experiences of and attitudes to healthy lifestyles particularly exercise, of people who have had a mild to moderate stroke or TIA in the sub-acute phase. As the people recruited were not part of any other trial, their experiences may better reflect a typical stroke population and everyday clinical practice.
3.2 Method

A qualitative phenomenological approach (Dowling, 2005) was chosen as most appropriate to gain an in-depth understanding of individuals’ perceptions of the topic of interest. An in-depth explanation of qualitative methodologies has been discussed in Chapter 2.4.5.

3.2.1 Patients

Twenty patients with a range of mild to moderate stroke in the sub-acute phase of recovery, were recruited from stroke units, early supportive discharge teams, community teams and TIA clinics at a large University teaching hospital. Patients were purposively chosen if they had had a mild to moderate stroke (defined as scores of 0 to 15 using NIHSS scale) (National Institute of Health, 2016) or TIA, were within six months of their stroke and could walk 10 metres. Seven of the patients had carers present who contributed to the discussions.

3.2.2 Procedure

An interview schedule (see Appendix 2) (Sample questions in Table 3.1) was developed by the main author and research team, and was piloted with a patient representative, who met the broad inclusion criteria, and his carer. The pilot interview offered the opportunity to refine the questions and enhance the main author’s qualitative interviewing skills. Thereafter, semi-structured in-depth interviews, approximately 45-90 minutes in length, were conducted with 20 patients in their homes. In seven of the interviews the carers were present, however, the questions were primarily directed to the individuals with stroke during the interviews. The carers were involved at the patients' request and their comments were audiotaped and probing questions asked as necessary.

Fourteen interviews were conducted by the author and six by two research assistants (AH and SD), who had previously received guidance in qualitative interviewing from the author and were supervised by the author. Field notes were written after each interview, recording details, such as, the patient’s level of disability (stroke severity),
home environment, body language and other observations. Data collection, and the initial stages of data analysis, occurred concurrently, and the interviews were continued until it was considered that data saturation had been achieved. All interviews were audiotaped and transcribed by a professional transcriber. The patients were offered the opportunity to review their interview transcripts in order to add or delete content if they wished, however only two patients chose to be involved at this stage.

Table 3.1 Example questions for Phase I

<table>
<thead>
<tr>
<th>Question:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can you explain what happened to you over the last few months/weeks?</td>
</tr>
<tr>
<td>How would you describe the experience of being at home or going home after a stroke/TIA?</td>
</tr>
<tr>
<td>How active were you before your stroke/TIA?</td>
</tr>
<tr>
<td>Before the stroke, what did you consider to be the appropriate amount of activity to keep someone your age healthy?</td>
</tr>
<tr>
<td>What have you been told by health professionals about exercising after having stroke/TIA?</td>
</tr>
<tr>
<td>How would you describe the benefits to YOU of exercising after a stroke/TIA?</td>
</tr>
<tr>
<td>Do you think there are any negative effects of exercise?</td>
</tr>
<tr>
<td>What do you think would help you exercise now after your stroke/TIA?</td>
</tr>
<tr>
<td>What do think might make it (or makes it) difficult for you to exercise after your stroke/TIA?</td>
</tr>
<tr>
<td>Why do you think you had a stroke/TIA?</td>
</tr>
<tr>
<td>Do you know the risks factors that lead to a stroke?</td>
</tr>
<tr>
<td>Question</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>What changes would you like to make to your lifestyle and if so how confident are you that you can make those changes?</td>
</tr>
<tr>
<td>How confident are you that you can make those changes?</td>
</tr>
<tr>
<td>How important is it to you that you make these changes?</td>
</tr>
<tr>
<td>Is there anything else you would like to say about your stroke/TIA or exercise or healthy lifestyle?</td>
</tr>
</tbody>
</table>

### 3.2.3 Data analysis

Thematic analysis was conducted according to the analytic framework developed by Braun and Clarke (2006) (see Appendix 2). The data were analysed by the author and a colleague (CC) who has extensive experience in qualitative approaches, and the research assistants (AH and SD) contributed additional insights. Open inductive coding through line-by-line reading of the transcripts of patient interviews was undertaken. See Method Chapter 2.4.9. for a more detailed explanation of the data analysis process. See Appendix 2 for an illustration of how the quotes were reduced to categories and then themes for these data. Some content analysis was also employed to determine the number of responses for certain themes.

### 3.3 Results

Twenty volunteers participated in the study, 12 men and eight women who ranged in age between 30 and 88 years. Their ethnicity reflected the local population, with 14 Caucasian, four Asian and two Afro-Caribbean patients. The average length of time post stroke was 59 days (range 14 – 124). Three people identified themselves as ‘mothers’, eight people were retired, four were employed as managers or engineers, two people were employed in manual unskilled work, two in manual skilled work and one non-manual skilled work. In seven interviews, patients’ carers were present and contributed to the discussion.

Data analysis identified three core themes: Perceptions related to exercise, Perceptions related to other lifestyle factors, and Understanding of stroke and healthy lifestyles.
3.3.1 Perceptions related to exercise

Sub-categories contributing to perceptions related to exercise were: Activity or Exercise, Benefits of Exercise, Motivators and Difficulties

3.3.1.1 Activity or exercise.

Most patients were active prior to their stroke. Some stated that they were very active at work or getting to and from work, or around the home doing housework or working in the garden. Some patients engaged in more formal exercise regimes or sporting activities:

“I play bowls a lot…that keeps me very active as regards sport because I like sport” (P12)

However, when the frequency, time and intensity of exercise were discussed only five patients appeared to be achieving the recommended level of cardiovascular training of 150 minutes a week at a moderate intensity (World Health Organisation, 2010). Some were achieving the duration required but not the intensity.

3.3.1.2 Benefits of activity

Patients identified a number of benefits of activity such as social benefits: “we just went for the social aspect of it” (P1), psychological benefits: “I think it gives you a positive outlook” (P2) and physical benefits such as weight control: “I joined the gym about 10 weeks before I had the stroke and I’d lost about three quarters of a stone…I looked at it that I’m going to lose weight and that’s it.” (P14)

Being independent was clearly very important to the patients and associated with ‘getting stronger,’ and ‘doing exercise’. As one patient said “it [exercise] helps you to become a bit more independent” (P1). The patients functioned independently before having a stroke and were keen to achieve independence again. As one carer said: “because she [P20] was very independent before it, she feels bad that somebody has to give her a shower or bath.” (P20). This desire for independence also linked with an
overwhelming need to be ‘normal’ again. Exercise was seen as a way to achieving normality:

“It will make me feel normal again, the more I can do the more I feel I am just back to normal and it’s gone away.” (P13)

However, the patients did not identify the benefits of reducing their cardiovascular risk factors, such as decreasing blood pressure and cholesterol levels, or the relationship of these with a decreased risk of future cardiovascular events. The link between exercise and risk prevention or reduction were clearly not understood by the patients.

3.3.1.3 Motivators
Patients identified a number of factors they felt would motivate or facilitate their involvement with exercise post stroke. Using Social – Cognitive Theory (Bandura, 2004) facilitators of exercise engagement can be divided into personal, social and environmental. The personal facilitators the patients in this study identified included: the fear of having another stroke, the fear of being dependent, religious guidance, and enjoy being competitive. In other words, patients did not “want to be beaten by the stroke” (P13). The social facilitators of exercise included: religious beliefs, support from friends and families, walking groups, and support from therapists and exercise professionals. The patients in this study did not identify any environmental facilitators that might encourage them to exercise post stroke.

3.3.1.4 Difficulties
A number of personal difficulties or barriers were identified related to exercise post stroke. First, a number of patients identified pain and the existence of multi-pathologies as difficulties to exercise post stroke:

“I used to be very active before the arthritis started taking over… I get a lot of pain in my back it’s putting the mockers on it a bit.” (P1). 

Secondly, patients identified fear of falling and having a fall as factors preventing them from participating in exercise, in particular, because their confidence was undermined and the experience of falling was difficult to overcome. As with the general falls
population (Jung et al., 2009), patients’ fear of falling was not necessarily associated with having fallen. As one patient explained: “The negativity is constantly thinking I might fall” (P3). Some patients commented that other peoples’ attitudes contributed to their fear of falling: for example, one patient pointed out that “it’s the blame culture, if I fall over then it will be them (the nurses) that’s blamed not me” (P2) or one carer said: “I don’t let her walk on her own because she’s had a couple of falls” (P20).

Thirdly, patients also identified fatigue as a personal difficulty to participating in exercise post stroke. Fatigue in long-term conditions has been described as “decreased mental and physical endurance” (Krupp, 2003, p.12). As one patient explained “it is an overwhelming problem that is constant - I am always tired” (P9) and “It’s not that I want to go to sleep, it’s my body says it wants to have a rest” (P16).

Fourthly, a number of patients expressed concerns about ‘overdoing it’: “Yes my main concern is it’s going to be a sudden shock to the system to all of a sudden be bouncing around” (P3) and “I think you can take exercise to the extreme” (P11). This perhaps highlights a lack of knowledge and understanding of appropriate exercise programs and progression and the potential risks of exercise. Other personal difficulties included a degree of embarrassment associated with the physical aspects of stroke: “You’re embarrassed to be like this” (P14). Interestingly, a lack of motivation was not identified as a difficulty to exercise post stroke.

Only one social difficulty to exercise after a stroke was identified in the interviews. For one patient (P7) religion was a barrier to exercise as she was unable to exercise with a mixed gender group and with male instructors. In the local area this issue has been addressed with some facilities providing female only group swimming with female lifeguards. However, many exercise facilities do not offer these options.

In addition, a number of environmental difficulties were discussed including inadequate or lack of accessible transportation. “Well the first obstacle is how do I get there and back” (P10). This patient lived in the countryside without public transportation although others lived in the city and still had problems; for example, “The problem is the gym is the other side of town” (P3). Finally, some patients were constrained by insufficient
finances: “Financially it’s [living with a stroke] crippled me” (P3) and “I think the only thing that worries me…is that I am always worrying about money” (P9).

3.3.2 Perceptions related to Other Lifestyle factors

Sub-categories contributing to Perceptions related to Other Lifestyle factors were: Changes to Lifestyle, and Doubts and disagreements.

3.3.2.1 Changes to lifestyle

Most of the patients wanted to achieve a healthy lifestyle by improving their diet after the stroke: for example, “Cut down on the eating and start doing more exercise.” (P3), or stopping smoking: “No I stopped it, after this, completely I have stopped.” (P7) or losing weight: “I could do with losing 2 or 3 stone.” (P11). Although they were unable to articulate any definite plans or details about how they were going to instigate this lifestyle change or maintain the change. The patients recognised the importance of changing their lifestyles in order to improve and maintain their health, but they did not appear to have the information necessary to support these changes.

3.3.2.2 Doubts and disagreement

Some patients expressed doubts about the positive benefits of a healthy lifestyle. Despite their belief that they had lived a healthy lifestyle, they still had the stroke or they cited other people they knew, who they believed were healthy but who still had developed significant health problems: “I know people who exercise regularly have had heart attacks as well” (P1), “When you think that the guy who started jogging died jogging apparently…he had a heart attack” (P9), “My wife died of lung cancer and she stayed in a ward and everyone on that ward had lung cancer and only one smoked” (P11), and “I did a lot of exercise and it didn’t do me any good” (P19). Some even disagreed with the concepts of benefits and risks, and the preventative advantages associated with maintaining a healthy lifestyle, for example, “are you trying to tell me having low cholesterol is a good thing – I don’t think so!” [P18]. One patient simply felt that exercise was not part of life before the stroke: “It wasn’t an important part of my life…I couldn’t be bothered” (P6) making it very unlikely that he would participate in exercise after the stroke.
3.3.3 Understanding of Stroke and Healthy lifestyles

Sub-categories that contributed to understanding of stroke and healthy lifestyles were: Role of exercise, Risk factors for stroke, Cause of Stroke, and Lack of information or recall.

3.3.3.1 Understanding the role of exercise

When asked about their understanding of the recommended levels of exercise for their age only two patients offered explanations of the recommended dose: “I probably do three lots of cardio a week at least 40 minutes at a time” (P6) and “Everyone should do at least 10,000 strides a day” (P5). Other patients’ knowledge was clearly hazy and several incorrect interpretations of the recommendations were articulated, for example: “It’s not recommended to go every day” (P1) and “You’ve got to listen to your body” (P12). Most of the patients had not given the issue of exercise after a stroke much thought: for example, when asked ‘did you think about the appropriate amount of activity’, Patient 2 stated: “No definitely not”. Others made comments like: “I didn’t think about it, I didn’t realise that exercise could help with a stroke” (P3), “I didn’t really think about it if I am honest (P7)” and “I don’t really think about it much, I am just aware the more walking I can do the better” (P11).

3.3.3.2 Risk factors associated with stroke

Some patients were able to discuss some of the risk factors associated with stroke, for example, “it’s important to keep the weight down...have a sensible diet” (P1), “I don’t think it’s my diet because I am not a great eater of fried things and fatty stuff, and I am not obese” (P9), “oh yes like high blood pressure, high cholesterol, high blood sugars, smoking which I have stopped now” (P13), and “I’m not a smoker, I’m not diabetic, I don’t have high stress...” (P14). However, over half the patients were, rather worryingly, not aware of the risk factors that could lead to a stroke. As one patient who had diabetes said: “No I didn’t know there were any risks” (P15).

3.3.3.3 Cause of stroke

Over half the patients were unable to discuss what might have contributed to them having a stroke, for example, “Nobody has been able to tell me’’ (P2), “I don’t know
how- do you get a blood clot” (P6), “No I don’t know, nobody has explained to me about that” (P15), “I don’t know really must have been some weakness in the brain” (P16), and “I haven’t a clue, I haven’t a clue” (P19).

A number of the patients did understand that knowing what might have caused the stroke would enable them to target the changes they made in their lifestyle and recognised the importance of such knowledge.

“And because they don’t know why it happened that worries me a bit because it could happen again.” (P13)

“I don’t know what the root cause was which is somewhat unnerving because it could happen again unless I know what to do to prevent it...if they could determine the cause of the stroke for me because I can’t tell you whether I need to change anything because I don’t know.” (P14).

### 3.3.3.4 Lack of information or recall

When asked about any advice they had been given about exercise the main response was that they had been given specific strengthening and stretching exercises by the physiotherapist but very few talked about advice they had been given about maintaining their fitness:

“They don’t mention it [lifestyle issues]...nothing positive in terms of longer term options” (P2), “They didn’t talk about general fitness” (P6), “I haven’t been told anything” (P9), “Nobody has mentioned there is a benefit to exercise- that hasn’t been covered” (P14), “I was simply told I should only do so much and not overdo things” (P15) and “No - they said continue doing the things you’ve been doing” (P16).

One patient remembered being given advice about exercise post-stroke by the doctor:

“The doctor let me do anything really he just said don’t lift weights ...He didn’t really say one way or another, he didn’t say a lot to be honest.” (P13).

The patients’ responses, with respect to their understanding of the more general issues of healthy living and the importance of addressing these post-stroke, were cause for
concern as they reflected a lack of information, for example: “Well they [health professionals] don’t go into great detail about it” (P5), “I haven’t been told anything” (P9), “Not a lot of information has been provided in all honesty” (P11), “Nobody’s said anything” (P12), and “Nobody has told us anything useful really, we’ve been using Google” (P20). As the last comment suggests some patients, particularly younger ones, did use and value the internet as a source of obtaining information. However, a majority of the patients, those aged over 60 years, felt they did not have adequate computer skills or were comfortable effectively accessing the internet, for example: “I am not an online person” (P5), “No don’t know how to use a computer” (P7), “I’m not computer literate” (P9), “I don’t have a computer” (P16), and “No I only just about know how to use my phone” (P18).

Printed leaflets providing information about stroke and common risk factors were given by health professionals to some of the patients, but these did not seem to have significantly contributed to their understanding. As one patient (P17) said: “there was a lot of information leaflets at both hospitals. I just took them but I have not had a chance to read them. They were useful but perhaps if someone did actually say well look if you have this or do that”. It would appear that the patients were not given consistent or relevant information or advice about maintaining a healthy lifestyle or CRf.

3.4 Discussion

This present study explored patients’ experiences and perceptions of healthy lifestyles before and after having a stroke. The patients discussed a number of personal, environmental and social factors that prevented or made it difficult for them to engage in exercise and these findings replicate what have been found in other studies with the chronic stroke population (Forster et al., 2012, Nicholson et al., 2012). These factors need to be considered when designing long-term interventions for exercise and healthy lifestyle interventions for people post-stroke, for instance, providing transport to attend the programmes. Fatigue appears to be a major barrier to exercise post-stroke in the acute and chronic phase of stroke recovery, however, it is unclear what effect exercise has on fatigue. More research is needed in this field as it is possible that exercise may
improve fatigue as has been seen in other populations for example the chronic fatigue population (White et al., 2011). In contrast to previous studies with the chronic stroke population (Nicholson et al., 2012 and Simpson and Eng, 2011), a lack of motivation was not identified as a barrier to exercise at this sub-acute stage of recovery from stroke. It seems that it is important to work with people with stroke in the early stages of their recovery to encourage activity and to prevent perceived motivational barriers developing.

Patients in the present study identified a number of benefits of exercise that the Health Belief Model (Rosenstock, 1974) suggests could be beneficial to support their attempts to achieve a healthy lifestyle. The patients, however, did not discuss the benefits of fitness or prevention of future cardiovascular events, which suggests that they did not consider this to be part of the role of exercise after stroke. More research is needed to find the best way to support people with stroke in their efforts to understand and maintain a healthy lifestyle and explore the long-term benefits of a healthy lifestyle after a stroke.

An area of concern, highlighted in the present study, was the doubts and lack of agreement expressed by some patients about the healthy lifestyle messages they had been given. This was also highlighted in previous studies (Forster et al., 2012 and Hillsdon et al., 2013) and emphasises the need for clear and consistent healthy lifestyle messages. Perhaps, more importantly, some patients appeared to welcome a chance to discuss their beliefs in order to address any doubts they had about the advice they were being given. This reinforces Forster et al.’s (2012) recommendations that active information provision, such as, integrating the use of workbooks into experiential classes was much more effective than passive approaches, such as, the provision of information packs for use at home.

It appears that patients did not fully understand the factors that contribute to having a stroke. They were able to discuss some lifestyle risk factors but did not seem to make the link between these and having a stroke. This was also identified in a recent study by Hillsdon et al (2013) who found that “some disregarded information about known risk
factors for minor stroke or that lifestyle changes can reduce such factors” (Hillsdon et al., 2013, p.7). Effective health behaviour change relies on people taking ownership of their health behaviours, that is, switching from an ‘external locus of control’ (Rotter, 1966) to an ‘internal locus of control’. If, as illustrated in this study, people are unable to make the link between lifestyle risk factors and having a stroke then they are less likely to make lifestyle changes.

The American Stroke Association (2011) states that “patients with ischaemic stroke or TIA ...should be managed according to NCEP III guidelines, which include lifestyle modification, dietary guidelines, and medication recommendations” (Furie et al, 2011, p.230). In order to modify their lifestyle, people with stroke need to be aware of exercise and dietary guidelines and recommendations, however, only two people with stroke in the present study were aware of the recommendations for CRf. This is not altogether surprising as a survey by the National Obesity Observatory (2016) found that only 6% of men and 9% of women in the general population had any idea about the recommended levels of exercise.

The present study also found that very few patients had been given healthy lifestyle advice. This mirrors the results of previous studies (Healthcare Commission Survey of patients, 2006, The Stroke Association, 2006, Furie et al., 2011, Forster et al., 2013) although, as with these studies, it is not clear whether this information was given but not fully absorbed and recalled by people with stroke. More research is needed to determine how to provide essential information, at what stage of stroke recovery it should be provided, and how to ensure that lifestyle changes are made and maintained as a result of receiving the information. People with stroke vary in their opinions about how relevant information could be provided. In the present study, only the younger patients expressed a preference for online information, the majority preferred to speak to someone to get advice. An associated unpublished study (Clague-Baker et al, 2015), conducted by the author, used focus groups in which the timing of lifestyle advice was discussed by a range of healthcare professionals working in stroke rehabilitation. It was found that most patients considered it was too early to provide lifestyle advice to people with stroke while they were still receiving care in an acute stroke unit and the
team members, who provided care to people in the later stages of stroke recovery, felt that specific training would help them in effectively delivering accurate and relevant lifestyle information.

Finally, it has been theorised (Rosenstock and Strecher, 1998 and Bandura, 1977) that people wanting to make changes in their lives need to believe in the importance of those changes and feel confident that they can achieve the desired changes. In the present study, it appeared that over half the patients did not know any of the risk factors that could lead to a stroke and did not know why they had had a stroke. Without this knowledge it is doubtful that they would understand the importance of any lifestyle changes and have the confidence to make any change.

3.5 Limitations

One limitation of the study was that patients who agreed to take part were keen to talk about healthy lifestyles and exercise and their interest in adapting their lifestyle after having had a stroke. As a result, these findings may not reflect a broad range of perspectives and experiences. Future research would benefit from actively engaging those people who are not as positive towards healthy lifestyles. A second limitation is that the average length of time after stroke varied from 14 days to 124 days and people’s perceptions may have varied over this time period. A third limitation is the potential bias of healthcare professionals as interviewers and data analysers. Although bracketing was employed and an experienced qualitative supervisor was involved throughout the data collection and analysis, it is recognised that there will always be an element of influence and bias due to the education, beliefs and opinions of each healthcare professional involved. Finally, interpretive thematic analysis can be seen as subjective and lacking in consistency and cohesion. Although the study employed collaborative analysis, it needs to be acknowledged that the themes identified were similar to the themes identified in the interview schedule and that perhaps further analysis and interpretation might have identified other themes.
3.6 Conclusion

In the sub-acute phase of stroke recovery, barriers to exercise such as lack of motivation do not appear to be an issue although fatigue, falls and lack of transport are seen as significant barriers. People with stroke in the sub-acute phase of recovery have a lack of understanding of healthy guidelines, risk factors and cause of their stroke. It is not clear if this is due to a lack of information provision or a lack of recall. They also do not appear to make the link between lifestyle choices and the cause of their stroke.

3.7 Key aspects that contributed to the rest of the study

This phase of the study identified that in order to:

1. Recruit patients for further stages of the study it was important to stress the benefits of exercise particularly the benefits of health promotion and a potential for a reduction in further CV risk. It was also important to reduce the personal and environmental barriers by providing extra specialist therapy support and transport for Phase III and Phase IV of the study.

2. To provide effective education for the patients it would be necessary to ensure: clear healthy lifestyle messages and provide national guidelines; clear links between healthy lifestyles and future risk of stroke for each individual; interactive education sessions repeated regularly at different stages of their recovery. They also need to be helped to recognise the importance of healthy lifestyles and have the confidence to make changes in order to ensure long-term behaviour change.
Chapter 4  Experimental Chapter – Phase II - Focus groups with CR and Stroke staff

The information in this chapter was presented as a poster at the UK Stroke Forum 2015 with an associated abstract published in the International Journal of Stroke 2015. A version of this chapter, in combination with the results from the focus groups in Phase IV was presented as a poster at the BACPR 2017, Society of Research in Rehabilitation 2018 and the UK Stroke Forum 2018, and published as an abstract in Clinical Rehabilitation 2018.

4.1 Introduction

A search of the literature was conducted to identify relevant previous qualitative research that explored the experiences of therapy and medical staff providing care for people post stroke. The search focussed initially on exploring the literature on attitudes towards exercise and CR post-stroke but after the focus groups were carried out further searches were conducted to explore attitudes towards healthy lifestyle provision especially exercise. The search strategy can be found in Appendix 1. The literature related to attitudes towards CR and exercise can be found in Chapter 1.7.1., in summary there was no identified literature exploring staff’s attitudes towards people post stroke attending CR, and limited research exploring attitudes to exercise post-stroke. The studies focussed on the lack of provision of exercise programmes post-stroke, and the lack of training and support for exercise professionals to provide these programmes. In relation to attitudes towards healthy lifestyle provision, the research is outlined in the next section.

4.1.1 Attitudes of staff towards Healthy Lifestyle provision

Wang et al (2001) conducted a questionnaire-based study in China designed to gather information on the stroke knowledge, attitude and behaviour (KAB) of Chinese health professionals. They found that health professionals’ KAB was low, and only 28% suggested and helped people post-stroke to exercise. As this was a questionnaire-based study, there was a lack of in-depth analysis of the responses, but there appeared to be a need for more training of health professionals in relation to healthy lifestyles particularly exercise. Esposito and Fitzpatrick (2011) also conducted a questionnaire-
based study with nurses in the United States but the aim was to identify correlations
between beliefs, behaviours and recommendations in relation to exercise. They found
that there was a strong positive correlation between positive beliefs of the benefits of
exercise, exercise behaviours and exercise recommendations to patients. As with Wang
et al (2001), the limitations of this study were that it was a questionnaire-based study
and therefore lacked the in-depth analysis of nurses’ attitudes and perceptions, but
indicated that health professionals’ own exercise beliefs strongly influenced their
behaviours towards patients.

4.1.2 Attitudes of healthcare professionals compared to carers and people with stroke

Two studies have explored the differences between the attitudes and beliefs of health
professionals, carers and people with stroke. Choi et al (2005) conducted a survey with
50 people post stroke, 31 doctors and 57 nurses, attempting to identify essential
aspects for patient education. Patients gave high rankings to 'possibility to cure with
drug treatment' (P < 0.01), 'stress management' (P < 0.01), and most items concerning
'general medical knowledge' and 'post-stroke diet management,' whereas doctors gave
higher rankings than patients for most items concerning risk factor management and
treatment with surgery. Younger patients gave higher rankings than older patients for
items concerning 'medical knowledge regarding stroke,' 'exercise,' and 'post-stroke
sexual activities' (P < 0.01 for each). These results identify that healthcare professionals
have different priorities to patients, and different patient age groups have different
priorities post stroke. As this was a survey design, again the topic lacked in-depth
exploration.

Morris et al (2015) conducted a qualitative study exploring patient, carer and
physiotherapist beliefs about physical activity. They carried out 38 interviews with
community-dwelling people post-stroke, 2 focus groups with carers, and 2 focus groups
with physiotherapists with the aim of identifying beliefs about physical activity. They
found that carers and people with stroke used physical activity to participate in valued
activity, whereas physiotherapists prioritised physical and functional activities. Also
physiotherapists and carers influenced physical activity post-stroke, but they varied in
how this was done, and neither group matched the priorities of people post-stroke. As this study involved two focus groups with therapists, it had the potential to identify more in-depth attitudes and beliefs, but only results on beliefs about exercise were highlighted.

In summary, although research has explored attitudes of healthcare professionals to exercise there is no research exploring attitudes towards CR for people post-stroke. Also attitudes towards healthy lifestyle interventions in people post-stroke, the studies have been mainly survey-based. Therefore, interview or focus group-based studies with staff are needed to explore attitudes and beliefs towards CR, and the broader topic of exercise, healthy lifestyles and health behaviour change. Thus, Phase II of this thesis aimed to explore the attitudes of stroke and CR staff towards healthy lifestyle interventions including exercise and CR, through the use of focus groups.

4.2 Methods

A qualitative interpretive approach (Dowling, 2005) was chosen as most appropriate to gain an in-depth understanding of individuals’ perceptions of the topic of interest (See Chapter 2.4.5 for more detail about qualitative philosophies). The research aim was to understand healthcare professionals’ attitudes to healthy lifestyles, particularly exercise and CR, for individuals with mild-to-moderate severity stroke and TIA.

4.2.1 Participants

The managers acted as the gatekeeper to approach their staff to see who was interested in taking part and who was available to attend. Seven focus groups were conducted across three hospital sites. Participants were recruited using purposive and convenience sampling. Inclusion criteria included working in the CR or stroke teams, as a therapist or therapy assistant, nurse or doctor. Any level of experience and banding were included, and a range of professions and ages was encouraged. CR and stroke team managers were approached and the project explained. Those that expressed an interest were sent the information sheet via email (see Appendix 6) to read prior to the focus group session.
4.2.2 Procedures

A schedule of questions was developed (see Appendix 3 for the detailed schedule) with the help of the wider research team to guide the focus group discussions; sample questions are provided in Table 4.1. The questions were open in order to develop discussion and address the research aim. A pilot focus group was carried out with therapy staff at the University of Leicester. No significant changes were made to the questions, but the pilot allowed the researchers to develop their skills in relation to group facilitation. Focus groups were arranged on times and days that were convenient to the staff and clinical service to reduce its impact, and were undertaken in hospital meeting rooms to encourage attendance. It was decided to conduct separate speciality focus groups, that is, focus groups with only CR staff and focus groups with only stroke staff due to the practicalities of bringing the two specialities together on the same hospital sites. However, it was also felt that mixing staff from two specialities might restrict the discussions as the staff would be unfamiliar with each other and therefore perhaps less vocal with their opinions.

At the beginning of the focus groups, participants completed a consent form (see Appendix 6). Focus groups were facilitated by the author, with the assistance of one or two research physiotherapists. Discussions were summarised at the end of each focus group to allow the participants to add any final observations. Field notes were written after each focus group (See Appendix 3), recording details, such as: openness of the group, ease of facilitation, and cohesiveness of the group. All focus groups were audiotaped and transcribed verbatim by a professional transcriber. Data collection, and the initial stages of data analysis, occurred concurrently, and the schedule of questions were expanded after each focus group as more topics were explored.
<table>
<thead>
<tr>
<th>Question:</th>
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<tbody>
<tr>
<td>Please introduce yourself and state what exercise you do yourself.</td>
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<tr>
<td>Based on your experience how do patients participate in exercise before and after a stroke or TIA?</td>
</tr>
<tr>
<td>What do you see as the positives of patients exercising after a stroke or TIA?</td>
</tr>
<tr>
<td>Do you think there are any negatives of patients exercising after a stroke or TIA?</td>
</tr>
<tr>
<td>What do you see as the barriers to patients exercising after a stroke or TIA?</td>
</tr>
<tr>
<td>What do you think are the barriers for stroke and TIA patients attending cardiac rehabilitation programmes?</td>
</tr>
<tr>
<td>How useful do you think cardiac rehabilitation programmes are for individuals who have had a stroke or TIA?</td>
</tr>
<tr>
<td>How would you describe your role and responsibility in influencing patients to take up a healthy lifestyle after a stroke or TIA?</td>
</tr>
<tr>
<td>In your experience what are patients’ attitudes to health behaviour change after a TIA or stroke?</td>
</tr>
<tr>
<td>Do you have any other thoughts about stroke and TIA patients and exercise, cardiac rehabilitation or healthy lifestyles?</td>
</tr>
</tbody>
</table>
4.2.3 Data analysis

Thematic analysis was conducted according to the analytic framework developed by Braun and Clarke (2006) involving five qualitative researchers. These researchers included the thesis author, two research physiotherapists (AH and SD), and specialist qualitative researchers from Coventry University and University of Leicester. See Chapter 2.4.9 for more detailed explanation of the data analysis process.

4.3 Results

4.3.1 Participant information

Seven focus groups were conducted with ten CR and stroke nurses (9 females, 1 male), 13 CR and stroke physiotherapists (11 females, 2 male), six consultants/medical staff (3 females, 3 males), three stroke occupational therapists (3 females), two physiotherapy assistants (2 males), and one speech therapist (female). The grade of staff was dependent on availability, but ranged from Band 2 physiotherapy assistants to medical consultants. The mean number of participants in each focus group was 5 (range 4 to 7). Themes identified included: Attitudes to exercise and CR; Experiences of stroke compared to cardiac patients; Attitudes to healthy lifestyle provision; and Attitudes to Behaviour change.
4.3.2 Attitudes to exercise and CR for the stroke population

Subcategories identified were: activity levels before and after stroke; activity versus exercise; benefits of exercise and CR; negatives of exercise and CR; barriers to exercise and CR; and adaptations needed for CR. See Table 4.3 for quotes related to these subcategories.

Table 4.2 Quotes related to Exercise and CR for stroke population

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Quote</th>
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</table>
| Activity levels before and after stroke | Before - “some of the elderly their concept is that they shouldn’t be exercising, it’s almost like an age limit” (SFG3), 
“(patients say) I go for a dog walk or walking down to the shops...that’s about as active as you get” (SFG2),
“I would say gardening is the most common activity” (SFG2),
“They haven’t seen that exercise is an important part of keeping yourself healthy” (SFG2)
“a lot of patients don’t do any exercise before stroke, some of them are really elderly and perhaps that’s why” (SFG2), “I think the patients that I feel could be doing exercise...it doesn’t seem to be on their radar” (SFG2) |
<table>
<thead>
<tr>
<th>Activity versus exercise</th>
<th>“attitude to exercise varies with age...I think the generation now are more into doing exercise” (SFG3), “It’s almost a complete reversal in the generations”, and “older generations wouldn’t have so much TV so were generally more active” (SFG3).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benefits of exercise and CR</td>
<td>Social – “It’s about joining a group and seeing other people and talking to them. So there are a lot of things going on apart from just the exercise” (CRFG1), “socialising...that feeling of there are other people here who have had a stroke as well so actually I am not on my own” (SFG3). Psychological - “exercise makes you feel good” (SFG3), “It’s good for your mood” (SFG5), “a lot of it is confidence-building”, “a sense of well-being” and “depression...we all know if you do a bit of exercise it makes you, gives you a sense of high” (CRFG1), “Well I think as people start to exercise you get the psychological benefits” (SFG2) Physical – “reduces falls doesn’t it” (SFG6), “Blood pressure control I would have thought” (SFG5), “reduce their risk factors hopefully” (CRFG4), “Gain their independence” (CRFG4), “more independent” (SFG2), “prevent a stroke happening again” (SFG2)</td>
</tr>
<tr>
<td>Negatives of exercise and CR</td>
<td>Physical - “we would need to know that the BP was well controlled because exercise is going to raise their BP” (CRFG1), “they have had a vascular event so there is some vascular risk” (SFG2), “I think one thing would be symmetry.....increasing tone” (CRFG1), “because you can get associated reactions...so I think it does take careful management” (SFG2), and “From my aspect it’s the tone” (SFG2).</td>
</tr>
<tr>
<td>Barriers to exercise and CR</td>
<td>Psychological – “quite scary to join a group of people that are established” (CRFG1), “might find it quite demoralising if everyone else is...” (SFG5), “I think some people are reluctant to exercise after an event because they think it’s going to happen again” (CRFG1)</td>
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<tr>
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<tr>
<td>Physical – “falls risk” (SFG5), “Blood pressure, how controlled their diabetes is” (SFG3), “Physical ability” (SFG3), “inattentive to one side” (SFG2), “cognitive ability to follow instructions” (SFG2)</td>
<td>Psychological – “motivation, depression those kind of things” (SFG7), “self-awareness as well, some patients are really quite conscious of how they might be moving differently” (SFG7), “There are issues with body image” (SFG6),</td>
</tr>
<tr>
<td>Environmental – “Accessible environment, accessible equipment” (SFG5),</td>
<td>Environmental – “accessible environment, accessible equipment” (SFG5),</td>
</tr>
<tr>
<td>CR team knowledge and confidence - “I would be worried about giving them too many weights” (CRFG1), “I was just thinking from a knowledge point of view that’s what I would worry about a bit more” (CRFG1), “I think I need more knowledge, more training really” (CRFG4), “We are cardiac trained and we know the cardiovascular system, I would say my knowledge of stroke is not as good as it could be” (CRFG1), “what worries me is my lack of knowledge in dealing with these patients” (CRFG1) and “I think exercising at that kind of level might bring up questions for the patient that a cardiac specialist nurse would struggle to answer” (SFG2).</td>
<td></td>
</tr>
<tr>
<td>Adaptations needed for CR</td>
<td>Staff - “I think from the educational point of view they would need a slightly modified package, I don’t think it’s that different” (SFG6), “you do need someone who has more experience dealing with strokes there for the patients’ benefit”, they were concerned “about the level of understanding of the impact a stroke could have”, and “the patient might bring up questions that a cardiac specialist nurse would struggle to answer” (SFG2), “I think there is an education need because</td>
</tr>
</tbody>
</table>
it’s 20 odd years since I properly looked after stroke patients and that was back in my training”, and “I am quite outdated probably, I have got a basic idea, but it would be good to be updated on what is the best way” (CRFG1).

Class - “we are getting a bike now, it’s not got a thing in the middle so they don’t have to get over it”, “whether they can actually physically get on a treadmill and walk on a treadmill ...and if they are going to be doing weights can they manage on their weak side” (CRFG1)

Education - “education around stroke and medication” (CRFG4), “it would be worth talking about education about strokes and how long it could take people to improve, the dips and the plateaus and the challenges they could face” (SFG7)
4.3.2.1 Activity levels before and after stroke

Overall, CR teams were unsure about usual levels of pre-stroke activity as they lacked experience with stroke patients. However, stroke teams were consistent with their thoughts on stroke patients’ previous activity levels; most stroke staff felt that the majority of people with stroke had low pre-stroke activity levels, particularly elderly patients. Nonetheless, stroke staff also recognised that some patients were very active: “we have had marathon runners (who) had a stroke”, “they don’t particularly like not being able to exercise”, “younger ones are the marathon runners...harder for them to come to terms with it” (SFG3).

Following stroke, staff described different patient reactions: some people increased activity and some decreased. Another important sub-category in this area was distinguishing between activity and exercise. Teams felt that the older generation were used to undertaking activity rather than exercise, but that the younger generation undertook exercise but not activity.

4.3.2.2 Benefits of exercise and CR

Both stroke and CR teams identified social, psychological and physical benefits of CR such as: blood pressure control, muscle improvement, improved independence and functional capacity, and decreased risk of recurrent cardiovascular events. However, stroke teams appeared to be more reluctant to encourage the use of the term ‘exercise’, preferring the term ‘activity’: “I don’t ever use the term exercise when I am talking to a patient...because if you say exercise patients assume that’s going for a run or going to the gym” (SFG2). CR teams recognised the importance of exercise rather than activity: “people think some of their activities are exercise when it’s not” (CRFG4).

4.3.2.3 Negatives of exercise and CR

Both CR and stroke teams highlighted negatives to people exercising and attending CR post-stroke, such as, cardiovascular risks and quality of movement. Interestingly, the concept of tone and associated reactions was only expressed by physiotherapists in the CR teams and not other CR team members. Stroke teams also mentioned a number of other negatives, not raised by the CR teams, such as, increasing fatigue: “perhaps over-stretch themselves, to the point where they are extremely fatigued” (SFG2); shoulder damage: “you do get people who damage their shoulders because they are doing their...
bench press on their weak shoulder” (SFG6); and frail elderly considerations: “frail and elderly who do more than they are meant to do from therapy ...and increase their fall risk” (SFG6).

4.3.2.4 Barriers and facilitators to exercise and CR

Both teams identified personal physical and psychological barriers to exercise and CR, including tone, lack of movement, asymmetry and cognition. However, again the stroke teams identified more personal barriers including, inattention: “if they are inattentive to one side ...can cause quite a lot of problems” (SFG2); comorbidities: “pre-morbid condition is really important” (SFG2); communication difficulties: “where they don’t feel confident in what they are saying or what they are thinking” (SFG7); fatigue: “their fatigue is another massive barrier” (SFG3); motivation and depression: “Motivations and depression those kind of things” (SFG7); confidence: “patients own confidence of how they are going to cope with the situation and how they are going to cope with the exercise” (SFG7); and “body image” (SFG6).

CR and stroke teams identified that carers can be both a social barrier and facilitator to exercise and CR. In particular, carers can sometimes be too protective of their relative: “If the patient has got a mild stroke and they want to feed the patient and do everything for them” (SFG5). Both teams also identified environmental barriers, including lack and cost of transport. An additional barrier identified by both teams was lack of knowledge and confidence of CR teams to include stroke patients in CR classes.

4.3.2.5 Adaptations needed for CR with the stroke population

It was identified by both teams that adaptations would need to be made to the staffing, class and education programme for the current CR programme to be suitable for a stroke population. In relation to the staff adaptations, both teams recognised the importance of a specialist stroke physiotherapist in the class, as well as the need for more education about stroke for existing CR class professionals. In addition, both teams identified that the number of staff would need to be increased to improve the patient-to-staff ratio. With respect to class adaptations, both teams felt that there may be a need for specialist equipment or an awareness of how to adapt existing CR class equipment. Additionally, the CR teams commented that the classes may need to be slightly longer. Considering adaptations to the education programme, both teams
agreed on changes to content and who provided the information. Finally, the stroke teams wondered whether the name would need to be changed from Cardiac Rehabilitation so that people with stroke felt it was more relevant to them (SFG5).

4.3.3 Experiences of stroke compared with cardiac patients

4.3.3.1 Differences between people who have a stroke and people who have a cardiac event

CR staff were aware of the different ability levels between patients, whether cardiac or stroke, and that the level of residual disability may be different. CRFG1 “cardiac patients haven’t lost their independence” and CRFG1 “after a stroke it depends on what ability they get post stroke”. However, they did not appreciate the potential range of disability post-stroke compared to cardiac patients, and the impact that this might have. They anticipated difficulties with confidence and falls, CRFG1 “might not be as confident because they are probably at high risk of falls”, but did not mention difficulties with speech, fatigue, inattention and continence that the stroke teams identified.

4.3.3.2 Similarities between people who have a stroke and people who have a cardiac event

Overall, it was felt that there were more similarities than differences between the two patient groups. CR teams identified that in relation to cardiac patients: “patients (are) quite sedentary prior to the event” (CRFG4), and “people who do quite a bit of exercise beforehand they are more determined afterwards” (CRFG1). This confirmed the views of Stroke teams, as previously discussed in Section 4.3.2.1. CR teams felt that the cardiovascular event was motivating for both post stroke and cardiac patients: “it’s a wake-up call...that’s similar with cardiac patients” (CRFG1), and that both patient populations feared a recurrent event: “I think some people are reluctant to exercise after an event because they think it’s going to happen again” (CRFG1), “lots of misconceptions...people in the gym using heavy weights when they had a heart attack and then they daren’t pick up a weight again” (CRFG1), “some people get quite cautious of it because they worry it’s going to happen again” (SFG2), and “the younger ones are a bit more cautious...more worried about it happening again” (SFG2).
4.3.4 Attitudes towards healthy lifestyle provision for the stroke population

Table 4.3 Quotes related to Attitudes towards healthy lifestyle provision for the stroke population

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Quote</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timing of advice</td>
<td>“difficult in the early stage to get them to understand why because they are drowsy...ESDS maybe the pressure will be on those guys to try and highlight the importance of exercise” (SFG3).</td>
</tr>
<tr>
<td></td>
<td>“they just haven’t got their head in the right place to know what is going on” (SFG3), “ESDS is almost the best point to be handing out information (about exercise classes) because you want to give something that’s relevant to their ability” (SFG2).</td>
</tr>
<tr>
<td>Type of advice</td>
<td>“persuasion”, “goalsetting” and “see beyond these four walls” (SFG2) “helping someone to be motivated while they are here...is one of the key things that we can do” (SFG2)</td>
</tr>
<tr>
<td>Difficulties</td>
<td>“I think people are being discharged quite quickly these days...they are not then getting the message from anybody to get active” (SFG3)</td>
</tr>
</tbody>
</table>

CR teams felt that providing healthy lifestyle education was a major part of their role, for patients: “as healthcare professionals should be encouraging everyone to exercise” (CRFG1), “we can take the time with them...we can review all the other risk factors” (CRFG4). Though stroke teams also highlighted the importance of healthy lifestyle education, they considered that the timing of this was important. For example, they considered that an in-patient setting was too early and an ESDS setting more ideal. However, the ESDS teams highlighted the importance of training for ESDS healthcare professionals: “I personally feel that’s a training need for me” (SFG7), and “I think there
needs to be a bigger focus on healthy lifestyles and the educating of patients ....(but) I feel I don’t have enough training to talk about it” (SFG7).

Both CR and stroke teams emphasised the importance of engaging carers in this process, though appreciated the time constraints:

“big benefit...we get an opportunity to talk to the carers” (CRFG4),

“I wouldn’t normally seek them (carers) out to say by the way your husband/wife needs to do this...I don’t have the time unfortunately” (SFG2).

4.3.5 Attitudes to behaviour change

Table 4.4 Quotes related to Behaviour change for the stroke population

<table>
<thead>
<tr>
<th>Subcategories</th>
<th>Quote</th>
</tr>
</thead>
<tbody>
<tr>
<td>No changes</td>
<td>“small amount of people that whatever you say they are not going to make any difference” (CRFG4) and “I don’t know maybe it’s just the way I read it but I don’t think they are going to do a lot of change” (SFG2).</td>
</tr>
<tr>
<td>Barriers to behaviour change</td>
<td>“a lot of patients have not exercised because they have thought it’s not for them...they think it’s for the superfit...we say this is actually for you there is no particular type of person” (CRFG4), “don’t understand the importance of a warm-up and cool-down” (CRFG1), “don’t have a clue about pacing” (CRFG1), “I think motivation is a big factor particularly people with an external locus of control where they are expecting people to do things for them” (SFG2), “better education, what we actually mean by exercise” (SFG2), “confidence building...we used to be able to do that (but now) rushing patients out of here” (SFG2).</td>
</tr>
<tr>
<td>Techniques used</td>
<td>“Giving them a lot more confidence” (CRFG1), “they think they have been exercising safely for years and actually they haven’t...” (SFG2).</td>
</tr>
</tbody>
</table>
got a clue” (CRFG1), “trying to give them a different slant...without piling pressure on people” (CRFG4), “setting goals, quite short term...and exercise will be the longer term thing” (SFG5), “we have tried other options, web-based programmes” (CRFG1), ”depends on the age and how many of them are computer literate” (SFG3).

Maintenance “and regressing as well, 6 -12 months down the line” (CRFG1).

Both teams identified that there are some people post stroke or post cardiac event that will not change their health behaviours, “The ones that continue to smoke...they are not intending to change their life...some people are just not interested in the group” (CRFG1). They identified a number of barriers that impacted on change behaviour, including financial pressures, stress, anxiety, and faulty beliefs about exercise: “they are unemployed and they have money problems...they can’t give up smoking because of that...stress levels and anxiety” (CRFG4),

However, it appeared that the CR team were more familiar with the process of health behaviour change, identifying key factors to support this, such as: confidence-building, education and goal-setting “We do try and influence them to have goals based upon the information that we have...personalise it...based on information about their cholesterol, weight or exercise” (CRFG4). The CR teams recognised the need to provide different forms of education and support, such as computer-based online options. Though the stroke teams were aware of the importance of confidence-building, motivation and education, they considered it the patient’s responsibility, rather than the healthcare professional’s role in supporting health behaviour change: “You can give all the information in the world and it’s down to them if they are going to act on it” (SFG2).

Nonetheless, some focus group members recognised the importance of the level of competence of the therapist in supporting patient health behaviour change: “it’s down to individual therapists and how accomplished they are at counselling” (SFG2).

CR teams also commented on the difficulty in maintaining behaviour change: “they (patients) sometimes think it’s 6 weeks they have done their rehab that’s it tick that box
"I can go back to doing nothing" (CRFG1). They were aware of the importance of positive and negative influences of referrers towards behaviour change and the positive influence of patient volunteers: “some of our medical consultants are very good and they refer a lot of patients...GPs aren’t so good” (CRFG1), and “we have got volunteers in most of our classes, who have been through CR” (CRFG1). Stroke teams also commented that “some people tend to listen when the message comes from the doctors” (SFG6), though the doctors identified that “we don’t really give them much information about exercise” (SFG6). The stroke team also acknowledged that the importance of the expert patient: “...you can completely empathise with the person” (SFG3).

4.4 Discussion

The present thesis explored CR and stroke healthcare professionals’ attitudes to healthy lifestyles, particularly exercise and CR, for individuals with mild-to-moderate severity stroke and TIA. Four main themes were identified; attitudes to exercise and CR, experiences of stroke compared to cardiac patients, attitudes to healthy lifestyle provision, and attitudes to behaviour change.

In relation to attitudes to exercise and CR, subcategories included; activity levels, benefits, negatives, barriers and adaptations. The stroke teams identified that most people with stroke tend to be inactive before their stroke and this was reflected in what the CR teams reported of the cardiac patients’ behaviours before their cardiac event. Both teams felt that the patients, whether post-stroke or post-cardiac event, are more positive towards activity after their event although some patients expressed anxiety about exercise. This indicates a need for more education about the appropriate approach to exercise post-stroke, and is important to consider when attempting behaviour change, as anxiety will have a significant effect on confidence and thus impact on any change in behaviour (Bandura, 1977).

CR and stroke teams agreed on the physical, psychological and social benefits of exercise and CR for the stroke population, but differed in the terminology used, with stroke teams being reluctant to use the word ‘exercise’. It could be argued that the stroke teams are more aware of the needs of the stroke population and know how to
motivate them, that is, by discussing activity rather than exercise. This reflects the latest campaign by the Chartered Society of Physiotherapy (CSP) (2018) ‘Love Activity, Hate Exercise?’ where the CSP recognises the difficulties some people have with exercise and are encouraging people to find an activity that can keep them fit instead of traditional exercise programmes.

The results identified that both teams were aware of some of the negatives of exercise and CR for people with stroke, but the stroke teams were more aware of additional aspects such as fatigue, falls and shoulder damage. As up to 85% of stroke patients suffer fatigue (Cumming et al., 2016), up to 73% fall post-stroke (Rensink et al., 2009) and up to 90% suffer shoulder pain post-stroke (Allison et al., 2016), it is imperative that everyone treating stroke patients is aware of these difficulties and knows how to manage them. Also, it appeared that only the physiotherapists, not the nursing staff, in the CR teams were aware of and concerned about asymmetry and tonal changes with exercise. This lack of awareness is an important consideration if CR programmes were to support people with stroke in CR classes, especially as the British Association for Cardiovascular Prevention and Rehabilitation (BACPR) national audit (2012) identified that only 63% of programmes had physiotherapists on their staff. It also highlights the need to consider the different levels of ability before placing people with stroke in CR programmes.

Using Social – Cognitive Theory (Bandura, 2004), the identified barriers to CR and exercise can be divided into personal, social and environmental barriers. Both teams identified social and environmental barriers, which would need to be considered when designing CR programmes for the stroke population. Both teams also identified adaptations that could be made to support people attending the programmes, such as providing transport and physical support in the classes. This reinforces the recommendations identified by Mead and van Wijck (2013). The stroke teams, however, identified more personal barriers to people post-stroke exercising and attending CR. This could indicate a lack of knowledge of the stroke population in the CR teams which was highlighted by the CR teams themselves. This point is important to consider when determining whether people post-stroke can attend existing CR programmes. The Cardiovascular Disease Outcomes Strategy (DoH, 2013) suggested the
use of existing cardiac rehabilitation programmes for Transient Ischaemic Attack (TIA) patients and mild disability stroke patients, however, this did not take into account the concerns and levels of training needed for the existing CR teams.

The ‘attitudes to healthy lifestyle’ and ‘attitude to behaviour change’ themes identified that the two teams had a different awareness of their roles in relation to healthy lifestyle advice and behaviour change. The CR teams saw this as a key aspect of their role, however, the stroke teams did not have the time, opportunity and some felt, the knowledge, to do this, which reflects what was seen in previous research by Wang et al (2001). Provision of training for stroke healthcare professionals related to healthy lifestyles may be indicated. There is also a clear need to address healthy lifestyle messages with the stroke population, as a number of studies have found that people post-stroke are not recalling the healthy lifestyle messages given post-stroke (Lawrence et al., 2010, Hillsden et al., 2013 and Clague-Baker et al., 2017).

Understanding healthy lifestyles is part of the process for behaviour change. One theory of behaviour change, the Trans-Theoretical Model (Prochaska et al., 2005), identifies that people go through five stages of change from pre-contemplation, contemplation, preparation, action and maintenance. Both teams appeared to be aware of the range of acceptability to change post-stroke, with some patients being ready for action whereas some patients were in the pre-contemplation stage. However, the stroke teams identified that early provision of information on the acute stroke unit would be too soon to address needs post stroke. This was also identified by Lawrence et al., (2010) who discussed the importance of providing essential information in the community. Lawrence et al (2010) and Smith et al (2008) both demonstrated that providing written information was not enough and that the patient and their family need to be actively involved in the learning process. CR provides this opportunity for people post-stroke.

The COM-B system (Michie et al, 2011) is another theory of health behaviour, it identifies that behaviour relates to the physical and psychological capability, the opportunity (environment) and the motivation (conscious and unconscious) to exercise. This thesis found that CR and stroke healthcare professionals had varying perceptions of the capabilities of people post-stroke to exercise but they agreed most people post-stroke were motivated to be active in the sub-acute phase of recovery. The opportunity
to exercise appears to be the main barrier post-stroke, previous research has found that there is a lack of physical activity programmes for people post-stroke (Lau et al., 2016, Mead and van Wijck, 2013) and lack of training for exercise professionals (Wiles et al., 2008, Condon and Guidon, 2018). CR may provide a solution to this lack of opportunity as long as CR teams are trained and supported by specialist stroke physiotherapists.

4.5 Limitations

One limitation of this phase of the thesis was that not all members of the stroke and CR teams were represented. The research team endeavoured to recruit a wide range of staff but it is evident that there were few stroke nurses represented and they may have expressed different perspectives on healthy lifestyles post-stroke. It could also be suggested that focus groups do not allow participants to expand on their own viewpoints due to the range of individuals involved. However, it was felt that the advantages of the focus group paradigm, particularly the ability to stimulate conversation, outweighed this limitation.

4.6 Conclusion

CR and stroke staff attitudes to exercise and CR for people with stroke were similar in relation to adaptations needed, benefits, negatives, social and environmental barriers, and facilitators to exercise. However, the stroke team identified more negatives and personal barriers for people with stroke and the CR team identified their own knowledge as a barrier, which needs to be considered when adapting CR programmes for people with stroke. Provision of healthy lifestyle advice and health behaviour change methods were evident in the CR team approach but not in the stroke team due to knowledge, time and opportunity. CR may provide an opportunity for people post-stroke to address their exercise and behaviour change needs as long as the CR teams are trained and supported by specialist stroke physiotherapists.

4.7 Key aspects that contributed to the rest of the study

This phase of the study identified that in order to:

1. Enhance recruitment for Phase IV of this study it was important to reassure the stroke teams that each CR session would have a specialist stroke physiotherapist
assisting the participants to reduce risks and enhance the benefits of the CR programme.

2. Improve the quality of the CR service for the stroke population it was important to make minor changes in the class content and educational programme to address the needs of the stroke population.

3. Reassure the CR teams that the introduction of the stroke population into the CR classes would be safe and effective and that they would have a specialist stroke physiotherapist in each class, who additionally contributed to the education programme.
Chapter 5  Experimental Chapter – Phase III – Concurrent Validity of the ISWT and 6MWT with the ICT and test-retest reliability of the ISWT and 6MWT

A version of this chapter, has been published in Physiotherapy; was presented as a poster at the UK Stroke Forum 2016 and BACPR conference 2017, and presented at the PRS conference 2017. Additionally, the information in this chapter was published as an abstract in the International Journal of Stroke 2016 (See Appendix 8 for a copy of the article in press).

5.1  Introduction

A comprehensive review of the literature related to the validity and reliability of the ISWT and the 6MWT can be found in Section 1.8 of this thesis, however, the following introduction provides a concise summary. Laboratory measures of CRf are the gold standard but are expensive and not readily available for clinical practice. Therefore, field-based exercise tests offer a potential alternative, for example the ISWT and 6MWT. The use of the ISWT in a stroke population to measure CRf has only been published twice. Van Bloemendaal et al. (2012) compared the ISWT and the 6MWT in a non-disabled chronic (>6 months) stroke population, and reported modest correlation between the ISWT and 6MWT (r=0.65, p<0.01) with strong test/retest reliability of the ISWT (ICC=0.96), but the authors did not compare the ISWT with a CPET measuring VO₂ peak. The second study compared the peak oxygen uptake on the ISWT using a portable metabolic cart with an incremental cycle ergometer measuring VO₂ peak (Dunn et al., 2014). It was found that there was no significant difference between the measures of VO₂ peak (p=0.73). However, the sample size was small, and the population were only mildly disabled post stroke. As a clinical test regularly used in CR for the cardiac population, the ISWT needs further testing to establish if it is valid and reliable in the stroke population.

As reported in Chapter 1 of this thesis, the 6MWT has been widely used to measure CRf in both chronic and sub-acute stroke populations, and has been shown to have test-retest reliability (Kosak and Smith, 2005) (ICC = 0.78) and validity when compared to an ICT (Tang et al., 2006)(r=0.56, p<0.001). However, in both chronic and sub-acute stroke populations, it did not closely correlate with CPET (VO₂ peak). The 6MWT and ISWT...
have also not been tested simultaneously or directly compared to a CPET, so it is not clear which test would be the most valid and reliable one with which to measure CRf in people post-stroke in the sub-acute phase of recovery.

Overall, there has been limited research of these field-based assessments of CRf in the sub-acute (1 week to 6 months) stroke population (Canadian Partnership for Stroke recovery, 2018).

5.2 Method

5.2.1 Aims

The study presented in this chapter aimed to compare the performance on the ISWT and 6MWT with the VO$_2$ peak measured using an Incremental cycle test (ICT) in a sub-acute stroke population with mild-to-moderate stroke severity. This study also aimed to determine the test-retest reliability for both the ISWT and 6MWT in this population. Given the variability in residual disability following stroke, an additional objective was to identify whether the level of residual neurological impairment impacted on patients that were able to complete the test.

5.2.2 Hypotheses

In order to determine the validity of the ISWT and 6MWT, two null hypotheses were tested: (1) the distance measured during the ISWT shows no significant positive correlation with the VO$_2$ peak measured with an ICT; and (2) the distance measured during a 6MWT shows no significant positive correlation with the VO$_2$ peak measured with an ICT.

5.2.3 Patients

Patients were recruited from a large single-centre UK University teaching hospital within one week to six months (sub-acute) of mild-to-moderate stroke, defined by a National Institutes of Health Stroke Scale (NIHSS) (Brott et al., 1989) score of 0 to 15 (Tseng and Chang, 2006). All patients were able to walk 10 metres with or without an aid and provided written informed consent. Exclusion criteria were based on cardiac contraindications and included: heart disease class III and upwards (Yancy et al., 2016),
Class C and D exercise risk (Heath, 2005), uncontrolled arrhythmias (causing symptoms), angina on exercise and uncontrolled hypertension (>180/110mmHg at rest).

5.2.4 Procedure

All patients attended the exercise laboratory and after consenting to the study, the following information was recorded from the medical record: details about the stroke, relevant past medical history, drug history and social history. In addition, the following baseline assessments were undertaken: NIHSS, Fugl-Meyer scale (Sullivan et al., 2011) and lower limb strength. Height and weight (body mass index (BMI)) were also recorded. Finally, routine cardiovascular parameters were measured to determine maximum heart rate (MHR) as defined by 220 minus age (years), and to set safety parameters for exercise, as follows: HR limit as 90% of MHR, and maximum blood pressure (MBP) of 200/110mmHg for ischaemic and 180/100mmHg for haemorrhagic stroke patients. HR limits were not set for those on betablockers, but BP limits were adhered to.

Each patient completed an ICT to establish VO$_2$ peak, with breath-by-breath analysis, followed by two ISWTs and two 6MWTs in a randomised order following standard operating procedures (Holland et al., 2014). VO$_2$ peak is the highest value of VO$_2$ attained on a particular test, most commonly an incremental or other high intensity test, designed to bring the subject to the limit of tolerance. It defines the highest VO$_2$ that was attained during the test it does not necessarily define the highest value attainable by the subject (Whipp, 2014). This compares to the VO$_2$ max which is the oxygen uptake attained during maximal exercise intensity that could not be increased despite further increases in exercise workload, thereby defining the limits of the cardiorespiratory system. It is measured in millilitres per kilogramme of body weight per minute (Hawkins et al., 2007).

All tests were carried out on one day, rest times between tests varied between 30 and 40 minutes (as recommended) due to the availability of the testing site. Randomisation was achieved using random number tables and allocation concealment with sealed envelopes. Routine haemodynamic monitoring was undertaken throughout the exercise tests; BP was measured at two-minute intervals and the electrocardiogram was
monitored continuously during the ICT, and HR was recorded at minute intervals during the ISWT and 6MWT. In addition, BP and HR were recorded prior to and at the end of each test, in addition the Borg perceived exertion and breathlessness scales were recorded.

Two ICT protocols were used to accommodate a range of patient abilities. Programme one had a two-minute warm-up at 10 watts at a target cadence of 50 revs per minute (rpm), followed by a 5 watts increment every minute (Tang et al., 2006). Programme two had a two-minute warm-up at 10 watts at a target cadence of 50rpm, followed by a 10 watts increment every minute, based on the pilot tests that indicated that some patients may need a greater challenge to reach their peak VO$_2$. To identify which programme the patient attempted, a formula was used based on Wasserman et al. (2011):

\[
\text{Work Rate Intensity (WRI)} = \frac{\text{Peak VO}_2 - \text{VO}_2 \text{ unloaded}}{100}
\]

Where:

- \(\text{Peak VO}_2 = (\text{height} - \text{age}) \times 20 \) (males) or
- \(\text{Peak VO}_2 = (\text{height} - \text{age}) \times 14 \) (females) and

where:

- \(\text{VO}_2 \text{ unloaded} = 150 + (6 \times \text{weight})\).

If the WRI was less than seven, the patient completed the 5 watt programme, if the WRI was more than seven, the patient completed the 10 watt programme aiming for the patients to exercise between eight and nine minutes (Tang et al., 2006). The end of the test was determined when the HR or BP reached maximum limits so was stopped by the therapist or if the patient reached symptomatic limitations.

Both the ISWT and 6MWT were conducted twice as recommended by Holland et al. (2014) to account for the learning effect, that is, patients become more familiar with the test which can improve performance so carrying out two tests reduces this error.
The ISWT is an externally paced maximum exercise test using two cones, nine metres apart. The speed of walking is controlled by a pre-recorded set of bleeps, and the number of laps around the cones are recorded and measured in metres. The 6MWT used a thirty metre course marked out by two cones. The distance achieved in six minutes was recorded to the nearest metre. Standard instructions were used and the use of walking aids was consistent between the two tests as recommended by Holland et al. (2014).

5.2.5 Data and statistical analysis

VO$_2$ peak was determined when either: Respiratory Exchange Ratio (RER) was greater than 1.01 (Van Bloemendaal et al., 2012) or the subject had reached 90% of their maximum age-predicted MHR. As the data collected were interval level data, and the data were normally distributed and equally spread around the mean, parametric tests were used. Pearson’s correlation coefficients were used to determine the correlation of the ISWT and 6MWT compared to the ICT when comparing VO$_2$ peak with distance walked, with a value of 0.20 to 0.39 indicating a weak correlation, 0.4 to 0.69 indicating a modest correlation, 0.70 to 0.90 indicating a strong correlation, and 0.90 to 1.00 indicating a very strong correlation (Fowler, 2002). A Pearson’s correlation coefficient was also used to calculate the correlation between the maximum heart rates for each test. Bland Altman plots were used to determine the test re-test reliability of the ISWT and 6MWT, and intraclass correlation coefficients (ICC) calculated; ICC >0.7 indicating good reliability. An ICC is used to assess agreement when there are two or more independent raters or outcomes and the outcome is measured at a continuous level (Psychometrics, 2019). Pearson’s correlations between the different measures, were also calculated for those with no (NIHSS=0) or mild-to-moderate (NIHSS<15) neurological severity. Statistical significance was taken at p<0.05. A power calculation determined that 30 patients were needed to test the validity of each measure if $r=0.8$, with 80% power at the 5% significance level (Singh et al., 1994).
5.3 Results

Forty patients (27 male) of mean age 68.3 (SD: 13.4) years were recruited a mean of 84 (SD: 41) days following stroke onset. Median NIHSS was 1.2 (range 0 – 8), and other baseline demographic data are shown in Table 5.1.
Table 5.1 Patient demographics

| Age (years) | Mean (SD) | 68.28 (13.48) |
| Gender (male) | n (%) | 27 (68%) |
| Ethnicity | n (%) | Caucasian: 36 (90%)  
Asian: 3 (7.5%)  
Afro-Caribbean: 1 (2.5%) |
| Ischaemic stroke | n (%) | 38 (95%) |
| Side of body affected (left) | n (%) | 19 (48%) |
| Length of time post stroke (days) | Mean (SD) | 84.7 (41.19) |
| NIHSS* - Median (range) | 1.0 (0 – 8) |
| NIHSS – score of 0 – n (%) | 17 (43%) |
| NIHSS – score > 0 – n (%) | 23 (57%) |
| Fugl-Meyer | Mean (SD) | 113.6 (16.5) |
| Current Smokers | n (%) | 4 (10%) |
| Diabetes mellitus | n (%) | 11 (28%) |
| Hypertension | n (%) | 17 (43%) |
| Atrial Fibrillation | n (%) | 3 (8%) |
| Ischaemic Heart Disease | n (%) | 6 (15%) |
| No. of co-morbidities | | 2.25 (1.41) |
Data are presented as mean (SD) or n (%), unless stated. NIHSS: National Institute of Health Stroke Scale. *Median (Range) NIHSS scores presented; score of 1 to 5 classified as mild, 6 to 15 classified as moderate [8]. For this study, the population was divided into those that had no disability post stroke (NIHSS = 0) and those that had disability post-stroke (NIHSS >0).

127 patients were screened and of those 87 were excluded giving a 30% recruitment rate. See figure 5.1 consort diagram for reasons for exclusion.

<table>
<thead>
<tr>
<th>Mean (SD)</th>
<th>No. with pain</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>20 (50%)</td>
</tr>
<tr>
<td>Body Mass Index</td>
<td>Mean (SD)</td>
<td>28.63 (4.63)</td>
</tr>
<tr>
<td>No. on betablockers</td>
<td>n (%)</td>
<td>10 (25%)</td>
</tr>
</tbody>
</table>

Data are presented as mean (SD) or n (%), unless stated. NIHSS: National Institute of Health Stroke Scale. *Median (Range) NIHSS scores presented; score of 1 to 5 classified as mild, 6 to 15 classified as moderate [8]. For this study, the population was divided into those that had no disability post stroke (NIHSS = 0) and those that had disability post-stroke (NIHSS >0).

All 40 patients completed the incremental cycle protocol; 13 completed the 10 watt, and 27 the 5 watt increment programme. The peak RER was 1.25 (mean 1.05, range 0.76 - 1.27) and peak HR was 150bpm (mean 112bpm, range 75 – 150). 31 patients achieved an RER>1.0, indicating that they were nearing exhaustion. Of the nine patients who did not achieve an RER>1.0, three stopped the test due to fatigue, and six were stopped by the therapist due to reaching MHR (1), reaching MBP (4) or not keeping up...
the required speed (1). In total, 19 of the incremental tests were stopped by the therapist and 19 by the patient, with two patients completing the end of the programme, that is, cycling for 16 minutes.

Only six patients achieved the target of 90% maximum HR but they did not achieve >80% VO₂ peak indicating a cardiovascular limitation to exercise (four had documented high BP and one had AF). Four patients achieved >80% VO₂ peak but did not achieve 90% maximum HR (one was on betablockers). Two of these patients stopped the test themselves due to weakness and fatigue and two were stopped by the therapist due to reaching maximum BP. Of the 30 patients who did not achieve either >80% VO₂ peak or 90% maximum HR: 16 were stopped by the therapist due too high BP (10), dropped revs (2), dropped BP (2) and reached end of programme (2); and 14 stopped by the patient due to breathing (2), leg pain or fatigue (11), seat uncomfortable (1).

One 6MWT was stopped by the therapist due to BP issues, no ISWTs were stopped by the therapist. The tests stopped by the therapist were due to cardiac precautions and had the potential to reduce the peak VO₂ and maximum results on the 6MWT achieved by the patient but this was felt to be appropriate due to the potential risks involved.

5.3.1 Test re-test reliability of 6MWT and ISWT

Results of the first and repeat ISWT and 6MWTs are shown in Table 5.2. Increased distances were covered in both repeat tests (Table 5.2).
Table 5.2 Test retest results for the Incremental Shuttle and 6-minute Walk Tests

<table>
<thead>
<tr>
<th></th>
<th>First test</th>
<th>Second test</th>
<th>Mean difference (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ISWT (m)</strong></td>
<td>243.3 (174.0)</td>
<td>263.1 (171.2)</td>
<td>19.7 (29.1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>95% CI 10.3 to 29.2</td>
</tr>
<tr>
<td><strong>6MWT (m)</strong></td>
<td>356.9 (134.1)</td>
<td>373.2 (145.6)</td>
<td>16.2 (42.9)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>95% CI 1.7 to 30.8</td>
</tr>
</tbody>
</table>

Data are shown as mean (standard deviation). ISWT: incremental shuttle walk test; 6MWT: 6-minute walk test.

The difference between the two tests is significant when the test of interest is first and non-significant when it is second (Table 5.3). Test-retest correlations were large as reflected by an ICC of 0.99 (95% CI 0.96-0.99) for the ISWT, and 0.97 (95% CI 0.94-0.98) for the 6MWT.

Table 5.3 Order effect of ISWT and 6MWT

<table>
<thead>
<tr>
<th></th>
<th>ISWT</th>
<th>6MWT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean difference (SD)</td>
<td>Mean difference (SD)</td>
</tr>
<tr>
<td><strong>ISWT first test (n=20)</strong></td>
<td>27.0 (26.6)</td>
<td>0.8 (39.3)</td>
</tr>
<tr>
<td></td>
<td>95% CI 14.6 to 39.4</td>
<td>95% CI -18.7 to 20.3</td>
</tr>
<tr>
<td><strong>6MWT first test (n=20)</strong></td>
<td>12.1 (30.3)</td>
<td>31.7 (41.8)</td>
</tr>
<tr>
<td></td>
<td>95% CI -2.5 to 26.7</td>
<td>95% CI 10.9 to 52.5</td>
</tr>
</tbody>
</table>
Bland Altman plots for the ISWT and 6MWT are shown in Figures 5.2 and 5.3, respectively. Given the limits of agreement, and the fact that both plots show a fairly even scatter of data points across all values of test results, repeatability is not influenced by whether the test results are at the lower or higher range of the population values. For the ISWT where patient values ranged between 0 and 600m, on 95% of occasions a patient would score between 70m higher and 40m lower on the second occasion than they did on the first. For the 6MWT where patient values ranged between 50m and 580m, on 95% of occasions a patient would score between 100m higher and 80m lower on the second occasion than they did on the first. Figures 5.2 and 5.3 also show the difference between people who had an NIHSS score of 0 and those that had an NIHSS score >0. Four patients were unable to complete a second 6MWT test due to fatigue and one patient was unable to complete a second ISWT due to fatigue.
Figure 5.2 Bland Altman plot demonstrating the relationship between the first and second Incremental Shuttle Walk test.

Purple line - mean difference line, blue line - upper confidence limit, orange line - lower confidence limit, red dots - participants with NIHSS >0, purple cross - participants with NIHSS=0.
5.3.1.1 Adverse events

No adverse events were recorded, however, two patients were excluded just prior to testing due to: identification of a 2cm aneurysm on MRI scan, and left ventricular abnormality on ECG.

5.3.1.2 Patient comments

Six patients complained of pain during the ICT: hip pain (1), knee (1), ‘leg pain’ (2), and pain from the seat (2). When asked which test was preferred, 23 (60%) indicated the ICT due to: ‘easier to push yourself’, ‘walking was limited by speed’, ‘leg fatigue with walking’, ‘dizziness with walking tests’, ‘gets the knee bending’, ‘walking tests limited by
moving legs quickly enough’ and ‘leg stiffened with walking tests’.

5.3.2 Construct Validity between ICT (VO₂ Peak), ISWT and 6MWT

Mean values for ICT (VO₂ peak), and the best performance (m) of each of the two ISWTs and two 6MWTs were significantly reduced compared to % predicted values (Table 5.4). The Pearson correlation coefficients between the maximum HRs for each test was ICT (VO₂ Peak) and ISWT (r=0.60, p=0.001, 95% CI 0.34-0.86), ICT (VO₂ Peak) and 6MWT (r=0.61, p=0.001, 95% CI 0.43-0.91), and ISWT and 6MWT (r=0.83, p=0.001, 95% CI 0.55-0.97). ICT (VO₂ peak) had a modest correlation with both the ISWT (Figure 5.6; r=0.58, 95% confidence intervals (CI) 0.34-0.75, p=0.001) and 6MWT distance (Figure 5.7; r=0.55, 95% CI 0.35-0.71, p<0.001). It is acknowledged that the CIs are relatively large for both tests making it difficult to conclude the magnitude of both relationships. In addition, a very strong correlation was observed between the ISWT and 6MWT distance (r=0.93, 95% CI 0.88-0.97, p<0.001).
Table 5.4 Results of the Incremental Cycle, Incremental Shuttle and 6-minute Walk Test

<table>
<thead>
<tr>
<th></th>
<th>ICT (mL/min/kg)</th>
<th>ISWT (m)</th>
<th>6MWT (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All (Mean (SD))</td>
<td>12.1 (3.1)</td>
<td>261.4 (177.3)</td>
<td>365.0 (142.5)</td>
</tr>
<tr>
<td>Males</td>
<td>13.2 (3.1)</td>
<td>301 (180.1)</td>
<td>397 (138.7)</td>
</tr>
<tr>
<td>Females</td>
<td>9.9 (1.7)</td>
<td>179 (144.8)</td>
<td>298 (130.9)</td>
</tr>
<tr>
<td>% predicted</td>
<td>58%</td>
<td>54%</td>
<td>66%</td>
</tr>
<tr>
<td>Peak HR (bpm)</td>
<td>112 (20.3)</td>
<td>98 (20.2)</td>
<td>94 (18.4)</td>
</tr>
<tr>
<td>Peak Borg breathlessness scale (Median (range))</td>
<td>2 (0-7)</td>
<td>2 (0-5)</td>
<td>2 (0-4)</td>
</tr>
<tr>
<td>Peak Borg Perceived exertion scale (Median (range))</td>
<td>12 (7-17)</td>
<td>11 (7-17)</td>
<td>12 (7-15)</td>
</tr>
<tr>
<td>Predominant limiting symptom</td>
<td>Leg pain and weakness</td>
<td>Speed of test particularly on turning</td>
<td>High tone in leg leading to leg fatigue</td>
</tr>
</tbody>
</table>

Figure 5.4 Scatter plot demonstrating the correlation between the maximum HR achieved during the Incremental Cycle test and Incremental Shuttle Walk test

Figure 5.5 Scatter plot demonstrating the correlation between the maximum HR achieved during the Incremental Cycle test and Six minute walk test
Figure 5.6 Scatter plot demonstrating the correlation between the Incremental Cycle test (VO\textsubscript{2 peak}) and the Incremental Shuttle Walk test.

Figure 5.7 Scatter plot demonstrating the correlation of VO\textsubscript{2} peak (ICT) and distance walked (6MWT) between the Incremental Cycle test and 6 minute Walk test.
When patients were grouped by NIHSS scores into those with no neurological impairment (NIHSS = 0) and those with mild-to-moderate neurological impairment (NIHSS <15), and the relationship between ISWT and 6MWT with ICT was explored, differences in the strength of agreement were noted. In 17 patients with no neurological impairment, a significant strong correlation between the ISWT (r=0.80, p<0.001) and 6MWT (r=0.83, p<0.0001) with ICT (VO₂ peak) was observed (see Figures 5.8 and 5.9), but only a modest correlation was reported in those with residual mild-to-moderate stroke severity (NIHSS 1-15) (ISWT: r=0.45, p=0.03, 6MWT: r=0.38, p=0.08) (see Figures 5.10 and 5.11).
Figure 5.8 Scatter plot demonstrating the correlation of the distance walked (ISWT) and VO2 peak (ICT) for patients with no residual deficit post stroke.

Figure 5.9 Scatter plot demonstrating the correlation between the distance walked (6MWT) and VO2 peak (ICT) for patients with no residual deficit post stroke.
Figure 5.10 Scatter plot demonstrating the correlation between the distance walked (ISWT) and VO\textsubscript{2} peak (ICT) for patients with mild to moderate stroke severity

Figure 5.11 Scatter plot demonstrating the correlation between the distance walked (6MWT) and VO\textsubscript{2} peak (ICT) for patients with mild to moderate stroke severity
5.4 Discussion

With increasing importance being given to secondary prevention and healthy lifestyle in this population, it is important to have a reliable and valid measure of CRf in order to measure the effectiveness of treatments to improve CRf. Laboratory tests can be expensive and time consuming, and therefore cheap alternatives have been validated in many disease groups (Singh et al., 1994, Singh et al., 2014, Hanson et al., 2016, Pollentier et al., 2010 and Casanova et al., 2007). This study aimed to determine the construct validity of the ISWT and 6MWT compared to the gold standard measure of CRf in a post-stroke population of mild-to-moderate stroke severity in the subacute recovery period. It was found that both the ISWT and 6MWTs correlated significantly with the gold standard of VO₂ peak, although the association was modest. The thesis also aimed to determine the test-retest reliability for the ISWT and the 6MWT, and found that there was variability between the first and second tests. This was different to previous studies for the ISWT that found the test to be reliable with respiratory (Singh et al., 2014), cardiac (Hanson et al., 2016) and chronic stroke patients (Van Bloemendaal et al., 2012), and previous results for the 6MWT with cardiac (Pollentier et al., 2010), respiratory (Casanova et al., 2007) and chronic stroke patients (Eng et al., 2004). As with previous studies, it was found that there was a learning effect with both tests, and therefore the recommendation would be that two ISWTs and two 6MWTs are completed, with the results of the second test used.

In relation to the validity of the tests, one of the reasons why there was only a modest correlation between the tests appeared to be due to the range of residual neurological impairment studied from 0 (none) to 8 (moderate) on the NIHSS scale. A strong correlation was seen between the ICT and both clinical tests in patients with no residual neurological impairment. Therefore, the ISWT or 6MWT could be used to measure CRf or cardiovascular capacity in such patients. In those with residual neurological impairment, there was only a modest correlation. However, it needs to be acknowledged that the study was not powered for these sub-group analyses. In addition, this may in part be because some patients found it difficult to complete the walking-based tests compared to the cycle test. Nonetheless, the majority of patients
completed the ICT without assistance; only two patients needing their affected foot strapped to the pedal and support with their arm, and one patient help to initiate pedalling. Furthermore, the majority of patients preferred the cycle-based test (60%). This indicates that further research is needed to explore the most valid measure of CRf in people with residual neurological impairment post-stroke in order to inform guidelines (Best et al., 2010 and Mackay-Lyons et al., 2013).

However, additional questions need to be addressed in respect of the use of a cycle-based test. First, whether a conventional or recumbent cycle should be used. Tang et al (2006) used a semi-recumbent position for testing, but found that this “may not help to address the potential problems arising from local limb fatigue related to motor dyscontrol or asymmetry” (Tang et al., 2006, p.1104). Although six of the patients in this study complained of pain with the cycle test, only two were related to the seat of the cycle and the rest were due to leg pain that occurred with all of the tests. Secondly, it is still important that stroke patients can achieve VO$_2$ peak even if it is as a cycle-based test. Cycle-based VO$_2$ testing measures 10% to 15% lower than treadmill-based tests in healthy adults because a treadmill test “permits a larger muscle mass to be brought to bear ...and more work against gravity is done, leading to greater stress on the organ systems mediating the exercise response” (ATS, 2003, p.218), but Tang et al (2006) highlighted the importance of measuring VO$_2$ peak as accurately as possible to ensure that the exercise prescription is appropriate. Therefore, clinical incremental cycle-based tests need to be devised to measure the CRf of sub-acute stroke patients with a stroke severity greater than 0 on the NIHSS.

The exclusion criteria and termination of testing procedures were based on ACSM guidelines (Heath, 2005) and are all based on cardiac contraindications. These enabled a safe and acceptable level of testing for the stroke population studied. It is recommended that BP limits for ischaemic stroke patients are set at 200/110mmHg and for haemorrhagic stroke at 180/100mmHg, as although ten tests were stopped by the therapist due to hypertension, six of those patients achieved an RER over one. Indeed, compared to previous studies with subacute stroke patients, where only 44% of patients achieved RER (Tang et al., 2006), a high percentage of patients in this study (78%) achieved RER. It is also recommended that the MHR is set at 90% of the age-
predicted MHR, as only five patients were stopped due to maximum HR limits and three of those achieved an RER over one. However, it may be necessary to add more stroke-specific exclusion criteria for testing based on some issues identified. One patient had a 2 cm brain aneurysm, and another patient had greater than 50% bilateral carotid stenosis; both of these patients were excluded by their treating stroke consultant. It is therefore, recommended that cerebral aneurysms and >50% carotid stenosis should be added to the list of exclusion criteria for future studies investigating VO$_2$ peak with stroke patients. Further investigation of stroke specific contraindications should be considered, such as post-stroke epilepsy and tonal issues.

As has been seen in other studies (Tang et al., 2006 and Kelly et al., 2003), VO$_2$ peak values were significantly lower than age-related data. Indeed, the mean values of 12.1 mL/kg/min reported for sub-acute recovery stroke patients in this thesis were lower than the 15mL/kg/min required for independent living (Mackay-Lyons and Makrides, 2004). This further supports the need for cardiovascular training for sub-acute, mild-to-moderate stroke patients as recommended by the NICE guidelines (Dworzynski et al., 2013).

5.5 Limitations

All tests were conducted on the same day due to funding limitations, this may have impacted on the patients’ ability to complete all the tests to the best of their ability. Ideally, the tests would have been completed across two days to reduce the impact of fatigue on the results.

The preferred duration of an incremental exercise test is between eight and nine minutes (Tang et al., 2006), however, the mean length of time for the test reported here was 10.2 minutes. This was because four patients managed to reach the end of the testing (16 minutes with the 10 watt increments). In future studies it might be necessary to set the peak power according to a predictive equation based on age, height and gender as a minimum.

In relation to the statistical analysis, it is acknowledged that conducting a correlation test such as Pearson’s correlation coefficient or Spearman’s correlation coefficient for testing the validity of the different tests will only measure whether the two tests
correlate with each other. As Bland and Altman (2010) explained, these correlation tests will not calculate the agreement between the measures. It could be that the two tests correlate but there may be a large difference in the size of the values collected for each test. Therefore, it would have been advantageous to conduct a Bland Altman plot for the validity data as well as the reliability data.

In addition, Bland Altman (2010) also recommended calculating the precision of the Limits of Agreement (LOA). The calculation uses the standard errors and confidence intervals to see how precise the estimates are. This calculation is valuable as it is recognised that two measures might have a large variation of differences but still appear to have agreement. The calculation of the precision of limits of agreement would resolve this issue. In future studies this method will be employed.

A minimal detectable change (MDC) is defined as “a statistical estimate of the smallest amount of change that can be detected by a measure that corresponds to a noticeable change in ability” (Shirley Ryan AbilityLab, 2019). In future studies it would be beneficial to calculate the MDC for the ISWT in people post-stroke so that the size of change can be determined in order to relate to changes in functional ability.

Though it would have been interesting to measure oxygen consumption during the walking tests in the present study, in order to make a true comparison of the level of oxygen consumed in each walking test compared to the ICT, the equipment was not available for this study. However, it is acknowledged that the ISWT and 6MWT are submaximal clinical tests of CRf and so true VO\textsubscript{2} peak may not have been reached. In order to determine VO\textsubscript{2} peak during ISWT and 6MWT testing, future studies need to attempt to use portable oxygen consumption devices, perhaps with a small pilot study to determine if people post-stroke can use these devices.

Future studies also need to identify a cycle-based, clinical test that would adequately measure CRf in this sub-acute, mild-to-moderate stroke population and need to test this measure against the VO\textsubscript{2} peak measured with an ICT in order to establish the validity of a cycle-based clinical test.
5.6 Conclusion

The ISWT and 6MWT have a significant, modest correlation with the ICT for stroke patients in the sub-acute recovery phase. The ISWT and 6MWT are not strongly correlated with ICT (VO\textsubscript{2} peak) in a stroke population that is disabled and the best way to determine cardiorespiratory fitness requires further investigation, but may be with a cycle-based test. BP and HR limits have been identified for people who have had haemorrhagic and ischaemic strokes, and additional contraindications to testing have also been established. The test-retest reliability of the ISWT and 6MWT indicated a difference between the first and second tests with a better performance on the second test indicating that two tests may be needed to accurately assess an individual’s capabilities.

5.7 Key aspects that contributed to the rest of the study

This phase of the study identified that in order to:

1. Measure CRf in the stroke population, the ISWT or the 6MWT can be used (although for people with moderate severity neither of these tests are ideal). It was decided that the primary outcome measure for further studies presented in this thesis would be the ISWT, as this test is routinely used for cardiac patients attending the CR service and there was no funding to use the ICT.

2. Ensure a reliable ISWT for further studies presented in this thesis, two tests were taken before and after the patients took part in CR, with the second test result being used.

3. Ensure a safe testing procedure for further studies presented in this thesis, patient HR was monitored throughout the ISWT, with BP taken before and immediately after the ISWT. Also the identified contraindications to testing were observed.
Chapter 6  Experimental Chapter – Phase IV – Feasibility study to explore cardiac rehabilitation for people with mild-to-moderate stroke in the sub-acute phase of recovery

A platform presentation of some of these results was presented at the UK Stroke Forum 2017 and at the BACPR conference 2018, with an associated abstract published in the International Journal of Stroke 2017. In addition, posters of this data were presented at the Society of Rehabilitation Research conference 2019 and PhysiotherapyUK 2019. The focus group data, in combination with the results from the focus groups in Phase II, was presented as a poster at the BACPR conference 2017, the Society of Research in Rehabilitation conference 2018, UK Stroke Forum 2018 and PhysiotherapyUK 2019 conference and published as an abstract in Clinical Rehabilitation 2018. For the interview data an abstract of this chapter has been presented as a poster at the UK Stroke Forum 2018, and platform presentations at the Society of Rehabilitation Research 2019 and PhysiotherapyUK 2019.

6.1  Introduction

6.1.1  Previous research related CR and stroke population

For a detailed discussion of the evidence for the use of CR for the stroke population please refer to Chapter 1.6. However, in brief, routine stroke therapy focuses on improving function and quality of movement but does not address CR or reducing cardiovascular risk factors (Mackay-Lyons and Makrides, 2004). In the United Kingdom, the Cardiovascular Disease Outcomes Strategy (Department of Health, 2013) suggested the use of existing cardiac rehabilitation (CR) for transient ischaemic attack (TIA) and mildly disabled stroke patients in order to address secondary prevention and potentially reduce cardiovascular risk. There have been a number of previous feasibility studies (Prior et al., 2011, Tang et al., 2010, Marzolini et al., 2014, Marzolini et al., 2016, Lennon et al., 2008, Kirk et al., 2014) exploring the use of the CR paradigm for people post stroke. However, most of the studies were conducted in different healthcare systems with only one taking place in the English system (Kirk et al., 2014), so it is unclear what level of disability (stroke severity) can be accommodated within existing CR classes in
the sub-acute phase of stroke recovery. It is also unclear if six weeks of CR are as effective as the longer programmes seen in other feasibility studies.

Furthermore, the outcomes measured in previous studies have focussed on cardiovascular risk reduction, including various measures of CRf, obesity, blood pressure, physical activity levels, lipid profiles and blood glucose. In addition, some of the studies measured depression, quality of life, function, cognition and walking ability. However, the effect of a CR programme on issues important to stroke therapists, including tone, fatigue and incidence of falls, and any potential detrimental effects have not been reported.

Importantly, CR is designed to include “components of health education, advice on cardiovascular risk reduction, physical activity and stress management” (Dalal, 2015, p.1), and has been shown to “reduce mortality by 18% and readmissions by 31% for certain cardiac patients” (Department of Health, 2013). These outcomes are equally important in the stroke population, but have not been formally assessed in this population undergoing CR. Therefore, a feasibility study is needed to investigate whether a definitive study could use an adapted CR programme for stroke patients across a range of stroke severity (National Institutes of Health Stroke Scale score <15) (Brott et al., 1989) in the sub-acute phase of recovery. A feasibility study is also needed to see if it is acceptable to patients and staff for people post-stroke to attend adapted CR for six weeks and also to assess the use of additional outcome measures to determine the effect of adapted CR on tone, fatigue and falls incidence. Finally a feasibility study is needed to identify the recruitment strategy and adherence of people post-stroke to adapted CR.

6.1.2 Attitudes of staff

A search of the literature was conducted to identify relevant previous qualitative research that explored the attitudes of therapy and medical staff towards stroke patients attending CR. The search strategy can be found in Appendix 1. There was no previous research identified exploring the attitudes and experiences of therapy and medical staff. However, as was seen in Chapter 4, there were a number of studies identified that: explored staff attitudes to healthy lifestyle provision; physiotherapist
attitudes to exercise provision; and healthcare professional attitudes compared to carers and people with stroke. These studies were expanded on in Section 4.1.1, but a brief summary is provided below.

Although research has explored attitudes of healthcare professionals to healthy lifestyle interventions in people post-stroke, most of these studies have been survey-based and have not explored the attitudes of CR or stroke staff. Interview-based or focus group-based studies with physiotherapists have focussed on attitudes to exercise post-stroke, and not explored attitudes and beliefs towards the broader topic of healthy lifestyles or health behaviour change or involvement in CR. This phase of the study, therefore, aimed to explore the attitudes of CR staff who took part in adapted CR for people post-stroke and attitudes of the stroke teams who referred into the programme.

6.1.3 Attitudes of people post-stroke and cardiac patients

A search of the literature was conducted to identify relevant previous qualitative research that explored the experiences of people post stroke and their attitudes and beliefs about CR post stroke. The search strategy can be found in Appendix 1. This was discussed in Chapter 1.7.2. and in summary there was limited research found related to experiences of CR for the stroke population. The main focus was barriers and facilitators to attending CR and was questionnaire-based. There was no studies exploring the attitudes of cardiac patients to people post-stroke taking part in CR.

6.2 Method

6.2.1 Aims

In order to conduct a definitive study exploring these aspects of CR a feasibility study was needed to determine: the acceptability of a 6 weeks adapted CR programme; the outcome measures; recruitment strategy and adherence to inform a definitive study.

The aims of this feasibility study were therefore:

1. to determine the recruitment strategy for a definitive study
2. to determine the acceptability of adapted CR for people post-stroke with mild to moderate severity stroke from the perspectives of the stroke and cardiac participants and the CR and stroke staff
3. to determine the adherence to the CR programme
4. to determine the suitability of outcome measures

6.2.2 Patients

Patients were recruited from a large single-centre UK University teaching hospital within one week to six months (sub-acute) of a mild-to-moderate stroke, defined by an NIHSS (Brott et al., 1989) score of 0 to 15. All patients were over 18 years old, able to walk 10 metres with or without an aid and provided written consent. Exclusion criteria were based on cardiac contraindications and included: heart disease class III and IV (New York Heart Association, NYHA) (Yancy et al., 2016), Class C and D exercise risk (American College of Sports Medicine, ACSM)(Heath, 2005), uncontrolled symptomatic arrhythmias, exertional angina and uncontrolled hypertension (>180/110mmHg at rest). As this was a feasibility study a power calculation was not completed, though the aim was to recruit 30 patients over eight months.

6.2.3 Procedure

Study research staff were notified about potential patients by treating clinicians from the acute stroke unit and early supported discharge services. Eligible patients were provided with the study information sheet and given 48 hours to consider participation. Following consent, the following information was recorded from the medical record and patient: details about the stroke; past medical, drug and social history; and lifestyle behaviour, including self-reported physical activity, smoking, alcohol intake, diet and stress levels. The following baseline assessments were also undertaken: blood pressure (BP) and heart rate (HR), weight, height, body mass index (BMI), NIHSS (Brott et al., 1989), quality of life (SF36) (Ware et al., 1994), tone using the Modified Ashworth Scale (MAS) (Bohannon and Smith, 1987), fatigue (Multidimensional Fatigue Inventory scale, MFIS) (Smets et al., 1995), anxiety and depression (Hospital Anxiety and Depression Scale, HADS) (Zigmond and Snaith, 1983), Stroke Knowledge and Healthy lifestyle
attitude (Stroke Attitude and Knowledge Questionnaire, SAKQ) using a questionnaire specifically designed for the study, and functional ability (Barthel Index, BI) (Mahoney and Barthel, 1965). Patients also completed two incremental shuttle walk tests (ISWT) (Singh et al., 1992), with the Borg exertion scale (Borg, 1970) and maximum BP recorded at the end of the test, and HR taken at one-minute intervals during the test. Finally, patients were given an ActiGraph wGT3X-BT accelerometer (ActiGraph, Pensacola, FL, USA), able to detect physical activity intensities from slow walking to moderate running, on the right anterior hip during waking hours for seven days to measure their activity levels for a week prior to starting the programme, and were asked to fill out a falls diary (See Appendix 7) during the six weeks of the CR programme.

A week after the baseline assessment, patients commenced an adapted and supervised CR programme, twice weekly for six weeks (Table 6.1), delivered by members of the CR team, but including a specialist stroke physiotherapist. A maximum of three stroke patients were included in each class of up to 14 (cardiac) patients. At the end of the 6-week programme, the outcome measures undertaken at baseline were repeated, and an accelerometer was provided to measure activity levels for a further week.
| **Education morning**  
| (3 hours) | First half of session (stroke patients only) – what is a stroke, types of stroke, causes of stroke, stroke prevention and rehabilitation.  
| | Second half of session (including cardiac patients) – risk factors and healthy lifestyle advice including diet, cholesterol, weight reduction, exercise, smoking, alcohol and stress management. |  
| **Content of classes** | **Health check** before each exercise session – BP, HR, changes in medication, blood sugar (for known diabetics)  
| | **Warm up** (15 mins) – walking, standing on spot exercises to gradually increase HR. Use of chair support for some stroke patients and closer supervision needed.  
| | **Main Aerobic exercise training** (30 mins) – circuit training including side steps, back steps, step ups (all progressed with the use of arm weights), treadmill (progressed with speed and then gradient), static bike (progressed by adding wattage), use of a motormed bike instead of static bike when necessary (eg. needing assisted pedalling); HR check every 5mins to maintain HR at 50 – 70% (maximal HR calculated using the Karvonen formula (Karvonen, 1988)). Intensity was also monitored every five minutes using the Borg exertion scale with patients aiming to achieve a level between ‘somewhat hard’ and ‘hard’.  
| | **Cool down** (10 mins) – slow walking, arm weights in standing and stretches in sitting for some stroke patients.  
| | **Discussion** After each session there was a ten-minute discussion each week, topics included: medications, goal-setting, phase IV programme, diet and rating of perceived exertion (RPEs). |
Finally, a semi-structured, in-depth interview was undertaken in the patient’s home. Additional interviews were undertaken with eligible stroke patients who did not want to undertake the CR programme, and with people who had had a cardiac event and took part in the CR programmes. A qualitative interpretive approach (Dowlings, 2005) was chosen as most appropriate to gain an in-depth understanding of individuals’ perceptions of the topic of interest. (See Chapter 2.4.5 for more detail about qualitative philosophies).

Three interview schedules (see Appendix 4) were developed by the main author and research team. One interview schedule for people post-stroke who took part in CR (Sample questions in Table 6.2), one interview schedule for the cardiac patients (Table 6.3), and one for the people with stroke who did not want to take part in CR (Table 6.4). Thereafter, semi-structured in-depth interviews, approximately 45-90 minutes in length, were conducted with patients. In twelve of the interviews the carers were present, though the questions were primarily directed to the individuals with stroke during the interviews. The carers were involved at the patients’ request, their comments were audiotaped and probing questions asked as necessary.

Field notes were written after each interview, recording details, such as, the patient’s level of disability, home environment, body language and other observations. Data collection, and the initial stages of data analysis, occurred concurrently, and the interviews were continued until it was considered that data saturation had been achieved. All interviews were audiotaped and transcribed professionally.
Table 6.2 Sample questions for Phase IV stroke patients

<table>
<thead>
<tr>
<th>Question:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>How are you feeling after all the experiences you have been through over the last few months?</td>
<td></td>
</tr>
<tr>
<td>How would you say you are coping with life after having had a stroke/TIA?</td>
<td></td>
</tr>
<tr>
<td>How active were you before your stroke?</td>
<td></td>
</tr>
<tr>
<td>What did you consider to be the appropriate amount of activity to keep someone your age healthy?</td>
<td></td>
</tr>
<tr>
<td>What effect has cardiac rehab had on your activity levels?</td>
<td></td>
</tr>
<tr>
<td>Do you think there are any benefits to exercise?</td>
<td></td>
</tr>
<tr>
<td>Do you think there are any negative effects of exercise?</td>
<td></td>
</tr>
<tr>
<td>Have your thoughts changed since you have taken part in cardiac rehab?</td>
<td></td>
</tr>
<tr>
<td>What are your thoughts about attending cardiac rehab?</td>
<td></td>
</tr>
<tr>
<td>Prompts - Cardiac patients/Staff/Content of exercise programme/Leisure centre or home/Content of educational programme</td>
<td></td>
</tr>
<tr>
<td>Did you consider yourself healthy before your stroke?</td>
<td></td>
</tr>
<tr>
<td>Do you consider yourself healthy now?</td>
<td></td>
</tr>
<tr>
<td>Are there any changes you would like to make to your lifestyle and if so how confident are you that you can make those changes?</td>
<td></td>
</tr>
<tr>
<td>Is there anything else you would like to say about your stroke/TIA or exercise or cardiac rehabilitation or healthy lifestyle?</td>
<td></td>
</tr>
</tbody>
</table>
### Table 6.3 Sample questions for Phase IV cardiac patients

<table>
<thead>
<tr>
<th>Question:</th>
</tr>
</thead>
<tbody>
<tr>
<td>How are you feeling after all the experiences you have been through over the last few months?</td>
</tr>
<tr>
<td>How would you say you are coping with life after having had a heart problem?</td>
</tr>
<tr>
<td>How active were you before your heart problems?</td>
</tr>
<tr>
<td>What did you consider to be the appropriate amount of activity to keep someone your age healthy?</td>
</tr>
<tr>
<td>Do you think this has changed now you have had a heart problem?</td>
</tr>
<tr>
<td>Do you think there are any benefits to exercise?</td>
</tr>
<tr>
<td>Do you think there are any negative effects of exercise?</td>
</tr>
<tr>
<td>Have your thoughts changed since you had your heart problems?</td>
</tr>
<tr>
<td>What are your thoughts about attending cardiac rehabilitation?</td>
</tr>
<tr>
<td>Prompts - Staff/Content of exercise programme/Leisure centre or home/Content of educational programme</td>
</tr>
<tr>
<td>Did you consider yourself healthy before your heart problem?</td>
</tr>
<tr>
<td>Do you consider yourself healthy now?</td>
</tr>
<tr>
<td>Are there any changes you would like to make to your lifestyle and if so how confident are you that you can make those changes?</td>
</tr>
<tr>
<td>Is there anything else you would like to say about your heart problem or exercise or cardiac rehabilitation or healthy lifestyle?</td>
</tr>
</tbody>
</table>
Table 6.4 Sample questions for Phase IV stroke non-patients

<table>
<thead>
<tr>
<th>Question:</th>
</tr>
</thead>
<tbody>
<tr>
<td>How are you feeling after all the experiences you have been through over</td>
</tr>
<tr>
<td>the last few months?</td>
</tr>
<tr>
<td>How would you say you are coping with life after having had a stroke/TIA?</td>
</tr>
<tr>
<td>How active were you before your stroke/TIA?</td>
</tr>
<tr>
<td>What did you consider to be the appropriate amount of activity to keep</td>
</tr>
<tr>
<td>someone your age healthy?</td>
</tr>
<tr>
<td>Do you think this has changed now you have had a stroke/TIA?</td>
</tr>
<tr>
<td>Do you think there are any benefits to exercise?</td>
</tr>
<tr>
<td>Do you think there are any negative effects of exercise?</td>
</tr>
<tr>
<td>Have your thoughts changed since you had your stroke/TIA?</td>
</tr>
<tr>
<td>What are your thoughts about attending cardiac rehab? Can I ask why you</td>
</tr>
<tr>
<td>decided not to take part in CR?</td>
</tr>
<tr>
<td>Prompts – Personal/social/environmental</td>
</tr>
<tr>
<td>Did you consider yourself healthy before your stroke/TIA?</td>
</tr>
<tr>
<td>Do you consider yourself healthy now?</td>
</tr>
<tr>
<td>Are there any changes you would like to make to your lifestyle and if so</td>
</tr>
<tr>
<td>confident are you that you can make those changes?</td>
</tr>
<tr>
<td>Is there anything else you would like to say about your stroke/TIA or</td>
</tr>
<tr>
<td>exercise or cardiac rehabilitation or healthy lifestyle?</td>
</tr>
</tbody>
</table>
Focus groups were conducted with CR and stroke staff after the adapted CR programme. A schedule of questions was developed (see Appendix 5, some sample questions in Table 6.5) by the main author and research team, to guide the group discussions. Focus groups were arranged on times and days that were convenient to the staff and the service to reduce the impact on the service. They took place in meeting rooms in hospital settings. At the beginning of each focus group each participant completed the consent form (see Appendix 6). The main author facilitated all the focus groups with the assistance of one or two research physiotherapists. The research physiotherapists summarised the discussion at the end of each focus group to allow the participants to add any final observations. Field notes were written after each focus group (see Appendix 5), recording details, such as, openness of the group, ease of facilitation, and cohesiveness of the group. Data collection, and the initial stages of data analysis, occurred concurrently, and the question schedule was expanded after each focus group as more topics were explored. All focus groups were audiotaped and transcribed verbatim by a professional transcriber. Using a qualitative interpretive approach with three researchers, five focus groups were conducted. Group discussions were audiotaped and transcribed verbatim.
### Table 6.5 Sample questions for focus groups with CR and stroke staff

<table>
<thead>
<tr>
<th>Question:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please introduce yourself and state what exercise you do yourself.</td>
</tr>
<tr>
<td>Based on your experience how do patients participate in exercise before and after a stroke or TIA?</td>
</tr>
<tr>
<td>What do you see as the positives of patients exercising after a stroke or TIA?</td>
</tr>
<tr>
<td>Do you think there are any negatives of patients exercising after a stroke or TIA?</td>
</tr>
<tr>
<td>What do you see as the barriers to stroke or TIA patients exercising after a stroke or TIA?</td>
</tr>
<tr>
<td>Inclusion and exclusion criteria for trial – any thoughts?</td>
</tr>
<tr>
<td>Do you think the cardiac rehabilitation programmes had a positive or negative effect on the patients who have had a stroke or TIA?</td>
</tr>
<tr>
<td>Do you have any concerns about people with stroke attending CR?</td>
</tr>
<tr>
<td>How would you describe your role and responsibility in influencing patients to take up a healthy lifestyle after a stroke or TIA?</td>
</tr>
<tr>
<td>Do you think you have enough knowledge to provide the healthy lifestyle messages?</td>
</tr>
<tr>
<td>In your experience what are patients’ attitudes to health behaviour change after a TIA or stroke?</td>
</tr>
<tr>
<td>Do you have any other thoughts about stroke and TIA patients and exercise, cardiac rehabilitation or healthy lifestyles?</td>
</tr>
</tbody>
</table>
6.2.4 Data analysis

As this was a feasibility study, inferential tests were not completed on the quantitative data but descriptive analysis was undertaken for all quantitative data.

For the qualitative data, auditory recordings were transcribed and then analysed using the thematic framework devised by Braun and Clarke (2016). Collaborative analysis was carried out by the author and four other researchers (SD, AH and specialist researchers from University of Leicester). Categories were combined into themes. Please see Section 2.4.9 for a more detailed discussion of the qualitative data analysis process.

6.3 Results

Thirty-two patients (the target number) (21 male) of mean age 64.4 (SD 14.4) years were recruited a mean of 88 (SD 30.9) days following stroke onset. Median NIHSS was 2 (IQR 1-3); other baseline demographic data are shown in Table 6.6.

Table 6.6 Patient demographics

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>64.4 (14.4)</td>
</tr>
<tr>
<td>Gender (male)</td>
<td>21 (66%)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
</tr>
<tr>
<td>Caucasian:</td>
<td>27 (84%)</td>
</tr>
<tr>
<td>Asian:</td>
<td>3 (9%)</td>
</tr>
<tr>
<td>Afro-Caribbean:</td>
<td>2 (7%)</td>
</tr>
<tr>
<td>Ischaemic stroke</td>
<td>24 (75%)</td>
</tr>
<tr>
<td>Side of body affected (left)</td>
<td>15 (47%)</td>
</tr>
<tr>
<td>Length of time post stroke (days)</td>
<td>87.97 (30.9)</td>
</tr>
<tr>
<td>Body Mass Index</td>
<td>27.9 (5.01)</td>
</tr>
<tr>
<td>Current smoker</td>
<td>5 (16%)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>5 (16%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>21 (66%)</td>
</tr>
<tr>
<td>Atrial Fibrillation</td>
<td>0</td>
</tr>
<tr>
<td>Ischaemic Heart Disease</td>
<td>1 (3%)</td>
</tr>
<tr>
<td>No. of co-morbidities</td>
<td>2.38 (1.45)</td>
</tr>
<tr>
<td>-----------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>No. with pain</td>
<td>11 (34%)</td>
</tr>
</tbody>
</table>

Data are presented as mean (SD) or n (%).

In relation to CVD risk factors, 15 patients had a history of cardiac problems, 6 had a history of neurological events, 5 were diabetic, 22 were overweight or obese, 6 were smokers or had given up smoking since the stroke, 14 did not meet the healthy exercise guidelines (WHO, 2010), and 5 had an anxiety score greater than 8 indicating clinical anxiety. The mean number of CVD risks was 2 with a range of 0 to 5.

30 of the 32 stroke patients (19 men, ranging in age between 35 and 89 years) and 12 of their carers were interviewed, one patient who dropped out was not interviewed and one patient lost contact with the researchers. The patients and their carers were therefore purposively selected. Also five people post-stroke who had not wanted to take part in CR (3 men, ranging in age between 59 to 79 years) and five people post cardiac event (3 men, ranging in age between 35 and 80 years) were interviewed (Table 6.15). The inclusion criteria for this final group of patients were that they had had a cardiac event, and they had taken part in the adapted CR. A range of ages, gender and ethnicity were purposively selected.

In relation to the staff focus groups, five focus groups were conducted with 8 CR and stroke nurse specialists, 7 CR and stroke physiotherapists, two stroke occupational therapists, two stroke generic workers, two exercise professionals and one speech therapist. The grade of staff was dependent on availability but ranged from Band 3 generic workers to Band 7 nurses and therapists. The size of each focus group varied but ranged from 4 to 5 participants.

6.3.1 Acceptability

The majority of stroke patients found the CR programme acceptable with a number saying; “It was really, really good” (P7) and “it gave me confidence” (P9). Some of the more disabled patients were embarrassed by their disability “I think it’s
embarrassment...how your arm is and all that” (P16). The five cardiac patients interviewed also considered it acceptable for stroke patients to participate in the programme saying: “I don’t see a real difference” (CP1) and “I didn’t mind at all, I thought it was good” (CP4). In the five CR staff focus groups, all the CR staff felt “they (stroke patients) get a lot out of it” (CRFG5) and they have a “positive effect on other people in the room” (CRFG4), although they reflected the comments of the more disabled patients, “self-conscious...and feel should I be here” (CRFG5). The CR teams also felt that the staff needed extra support from specialist stroke physiotherapists and more training if more disabled stroke patients were to be included in the programme, ‘I would agree, having done 20 years in cardiology I wouldn’t want to mislead them, we don’t have the background’ (CRFG5).

6.3.2 Additional data from interviews

All the stroke patients felt that CR was a positive experience: “the team has been absolutely excellent” (P3), “It was really really good” (P7), and “I looked forward to doing it” (P25).

The main themes identified were: benefits of CR, knowledge, behaviour change, barriers to CR, adaptations to CR and fatigue. For the people post cardiac event, the themes identified were: benefits of CR, knowledge of exercise, barriers to CR and behaviour change. For the stroke patients who did not want to participate in CR the themes identified were: reasons for non-participation, activity levels pre-stroke, stroke knowledge, exercise knowledge, healthy lifestyle knowledge and provision.

6.3.2.1 Benefits of CR

Table 6.7 Quotes related to Benefits of CR

<table>
<thead>
<tr>
<th>Subcategories</th>
<th>Quotes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical</td>
<td>“strength improved” (P5), “getting fitter”(P12), “I feel energetic” (P1), “getting moving” (P16), and “I walk better” (P24).</td>
</tr>
</tbody>
</table>
All patients identified a number of benefits of attending CR and these could be divided into: physical; psychological; social; early return to work; and education about exercise and healthy lifestyles (see table 6.7 for example quotes). Of the thirteen people still at working age, two felt that the CR assisted them to get back to work. Some of the carers also felt that they had learnt from the exercise and education sessions: “We both learnt something...well the whole thing we were learning all the while’ (P24), and ‘I learnt a lot from it...he wouldn't have been able to take it all on board” (P10).

### 6.3.2 Knowledge

One of the aims of CR is to increase knowledge of healthy guidelines and stroke. When questioned on their knowledge of the recommended levels of cardiovascular exercise over half of patients were able to remember the guidelines. However, despite attending a three-hour education programme and regular after-class short advice sessions, six patients could not remember the exercise guidelines, three did not think about it, and four could not remember the intensity needed for successful CRf. Some of this lack of

| Psychological | “increased confidence” (P10) or reduced fear (P2, P8, P9, P24, P26, P27), increased motivation (P5, P8, P9, P14,P24, P26, P31), “it’s very hard to have the willpower to do something on your own” (P31), and “it helped me cope with my stroke” (P25). |
| Social | “shared experiences” (P12, P26, P28, P31), and “I’m going to get back to my social life” (P24). |
| Return to work | “without CR I would have been sitting, it would have taken me a while before going back to work, but because of the CR I went back to work quite early” (P12). |
| Education | “how to exercise safely” (P7, P9, P16, P17, P24, P29), and to improve their diet, “I have cut an awful lot of silly things out...it’s really taught me how I’ve been doing some things I shouldn’t have been doing” (P3). |
knowledge could be explained due to memory, cognitive and speech difficulties. Knowledge of healthy dietary advice appeared to increase, however, a number of patients still had doubts about the effectiveness of a healthy lifestyle to reduce the incidence of stroke: “I know we can’t prevent it” (P22), “Can have another one at any time” (P30), and “it’s in your genes and the traffic” (P31).

Patients’ knowledge of what caused their stroke was very limited, over half of the patients had no idea what could have caused their stroke, “totally unexpected” (P28), and “don’t know, a bolt out of the blue” (P29), though two of the six smokers attributed the cause of their stroke to smoking. Of those that gave a specific cause to their stroke over half felt the cause was related to stress. In terms of understanding what a stroke is and the risk factors that can lead to a stroke, most people had an increased awareness of the types of stroke but some “still don’t know what a stroke is” (P21). One young stroke patient who was very informed about his stroke said, “I am amazed how little people knew about their stroke” (P27).

6.3.2.3 Behaviour change

Twenty-two of the thirty patients interviewed stated that they had made changes in their lifestyles. Nine of these made reported changes to their exercise regimes post stroke, “I’m doing a lot more than I would of...before I didn’t used to enjoy exercise but now...” (P14). Although two of the nine appeared to be active before their stroke, they did not achieve the recommended levels of moderate to vigorous exercise. Fifteen patients commented on changes they had made to their diet including: “the sugary stuff was bad for me...so I don’t touch it now” (P3), “I still eat and do what I want but I cut right down” (P16), and “now I don’t put any salt on at all” (P17). Of the six smokers, all stated that they had either stopped smoking or reduced their smoking: “well being in hospital and the first week I was in and I have never started” (P13), “I’ve now packed cigarettes and cigars in” (P21), and “it’s been difficult sometime, I have one of those things (vaporisers)...I have panic attacks when it doesn’t work” (P29). Of the eight people who did not make any changes, most felt that they had a healthy lifestyle before the stroke: “I’ve always been conscious about what I eat...I’ve never drunk a lot. I used to smoke a bit” (P27), or felt that the stroke was out of their control, “They did say it could happen to anyone at any time” (P24).
### 6.3.2.4 Barriers to CR

The main barriers to CR were physical disabilities, psychological and environmental barriers (see Table 6.8). No one mentioned that spasticity or tightness of their limbs was a barrier. In fact, those that had increased tone felt that classes helped reduce their tightness: “(the classes) actually loosened up, the tightness loosened right up” (P5), and “(the class) made it better I think because I felt it loosened up” (P24).

#### Table 6.8 Quotes related to Barriers to CR

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Quote</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical</td>
<td>“I couldn’t do the gym or anything because I’ve got two new knees” (P18), or after the stroke: “my biggest difficulty is probably my balance” (P8), “well really it’s just the leg and arm…the movement and pain” (P24), and “The difficulty for me was of course this painful hip… and I got tired too quickly” (P28).</td>
</tr>
<tr>
<td>Psychological</td>
<td>“I think it’s embarrassment...how your arm is and all that” (P16), “You’ve got to feel so mentally ready. You’ve got to really push yourself to do it” (P21), and also concern about having another stroke (P17, P20, P28) or overdoing it (P23, P31, P32).</td>
</tr>
<tr>
<td>Environmental</td>
<td>“I’d have to get a bus...then another bus...it would have been two and a half hours travelling a day” (P27), and “I was going to be getting a bus which would have cost me I don’t know how much, it’s very expensive” (P12).</td>
</tr>
</tbody>
</table>

Though some patients reported that their tightness increased during CR, there appeared to be no long-term effect on the tightness: “No the tightness didn’t get any worse with the class” (P29). Transport was the main environmental barrier with over half of the patients saying that without the transport they would not have been able to get to the classes in the early stages of their stroke.
### 6.3.2.5 Adaptations to CR

Table 6.9 Quotes related to Adaptation to CR

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Quotes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education programme</td>
<td>“I have learnt, I didn’t know about the drugs...the drugs I give at work I know what they do” (P17), and “it’s like reminding you that this is what you’re supposed to be doing” (P12). However, some patients felt “there were bits that were more relevant to cardiac patients” (P8), with some preferring “more about my stroke” (P5), and inclusion of stress education (P8, P9, P14, P16).</td>
</tr>
<tr>
<td>Specialist staff</td>
<td>“helping me (with step ups)” (P13), “helped having (stroke physio) there to talk to if you have a question” (P5), “knew our backgrounds” (P8), “It was more individual” (P9), “know more about a stroke than a heart person would.” (P22), “for fine tuning” (P21), and “we are special aren’t we, every stroke is different I think” (P29).</td>
</tr>
<tr>
<td>With cardiac patients</td>
<td>“I couldn’t move, couldn’t do this, couldn’t do that and that felt a bit disheartening really” (P5), and “Yes it did (bother me) a little bit, yes, they could talk and I can’t” (P13).</td>
</tr>
</tbody>
</table>

Patients were asked about the content of the classes and education programme, the staff and other patients attending the sessions, and the timing, frequency and duration of the programme. The patients felt that the content of the classes was appropriate, the warm-up, main exercises and cool down were manageable on-the-whole, though some of the patients found the treadmill speed difficult (P9, P28), the bike seat difficult to get on to (P5), and the weights difficult to use (P16) (not all patients used the hand weights.
due to shoulder pain or hand weakness). Most of the patients found the education sessions informative. In relation to the staff and other patients in the CR programme, all stroke patients agreed that attending the programme with cardiac patients was not a problem, although a few more disabled patients felt “self-conscious occasionally when I couldn’t do anything with this arm” (P27). Half of the patients felt that they needed a stroke specialist physiotherapist in the class.

Half of the patients also felt that twice a week classes for six weeks was enough, though four patients only came once a week and felt that was better due to fatigue issues: “he spent the next day in bed not doing much...It would have been too much for him” (P30). Six patients would have come more often and for longer “I think another couple of weeks would have helped me personally” (P21). Although the patients were not able to choose between a class and individual treatment they were asked which they would have preferred. The majority of patients felt that they would prefer a group setting as it is more motivating and social, “at home I don’t do it” (P28), and “the social point of view the classes is definitely better” (P23).

6.3.2.6 Fatigue

Fatigue was described by patients as “I have felt tired, very tired and very achy” (P31), and “This was a wall where I’ve got to sleep, I can’t move, I physically can’t move, I’ve got to rest” (P21). Whilst all patients had stroke-related fatigue, over half felt that exercise reduced their fatigue: “it would build you up and I won’t be as tired next time” (P14), and “I could sleep more once I’d been exercising” (P22). Only two patients felt that exercise made their fatigue worse: “it makes me more tired when I do exercise” (P10), and “It made it worse just because I had to have a sleep every day” (P5). Other factors that made the fatigue worse included: time of day (P1, P25), heat (P16), cold (P1), and not sleeping (P12, P24, P26). Aspects that reduced their fatigue included: Pacing (P2, P7), and “pushing through it” (P27).

6.5.3.8 Results of the non-participant interviews

Three themes were identified: Reasons for not participating, Knowledge and Healthy lifestyles.
Table 6.10 Quotes illustrating all themes for non-participants

<table>
<thead>
<tr>
<th>Theme</th>
<th>Quote</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reasons for not participating</td>
<td>The non-participants did not want to take part in CR mainly due to the time commitment: “the time factor…it’s the commitment” (SNP2), “it’s a big commitment...I felt because I was exercising…” (SNP3), although some patients also declined due to other reasons: “wasn’t feeling good about myself” (SNP1), “wife’s not very well” (SNP2), and “I’m frightened. I can’t breathe when I leave the house” (SNP4).</td>
</tr>
<tr>
<td>Knowledge of cause of stroke</td>
<td>“something to do with heating and overheating” (SNP1), “doing too much physically” (SNP2), and medication “(the doctor) he said that they’d found in research that indapamide hadn’t been beneficial in preventing strokes” (SNP3).</td>
</tr>
<tr>
<td>Healthy Lifestyles</td>
<td>“I hope it doesn’t happen again but it’s not in my hands is it, maybe our mate upstairs has got something to do with it, who knows…” (SNP2).</td>
</tr>
</tbody>
</table>

In relation to non-participation, most were limited by time and a few patients acknowledged that they felt because they were exercising anyway they did not need to take part. However, when the level of exercise they were doing was explored it was found that over half were not doing enough to challenge their cardiovascular system.

Patients knowledge of exercise guidelines was limited and sometimes wrong; patient 2 saying that a possible cause of his stroke was “doing too much physically” (SNP2), though his level of exercise was quite limited. The majority were not given any advice about how to exercise: “(the nurse) said well do as much as you think” (SNP2), and “(the
doctor) her words of wisdom were as good as any when I was in there and she said that you need to rest more than you have ever rested before” (SNP1).

In relation to advice about healthy lifestyles, most of the patients felt that they had not received much advice: “they just said carry on with what you’re doing” (SNP2), and “no nothing more than watching the programme and the three women there, they are doing a programme all to do with diets” (SNP1). They appeared to have a general idea about the lifestyle risk factors when questioned but linking the risks to their specific situation was limited. Stress seemed to be a major risk factor in a number of patients’ lives; one patient having a number of traumatic events leading up to her stroke, and admitting that she was very anxious, depressed and fearful of another stroke: “And I have got very, very anxious, I get very anxious about things, sometimes worse than others, and there again sometimes...oh the anxiety... And then there was this dreadful fear, especially when I came out of hospital, I thought I daren’t go to sleep. I thought what if I wake up and it happens again or I wake up and it’s worse, because I realise it could have been far worse.” (SNP3)

However, there was no psychological support or advice to manage this stress and depression.

Interestingly, one non-participant who attended the TIA clinic had a completely different experience. His consultant spent time discussing his lifestyle risk factors: “well basically looking at diet, looking at fitness. Looking at lifestyle basically” (SNP5). Subsequently he and his wife made significant changes: “I would say we were biased towards red meat”, but now “we eat more fish and stuff like that”, “Cheese was a big one, wasn’t it...I love cheese...so we’re into the low fat cheese now”, and “I’ve joined a gym”. Previously, he had not undertaken any activity, and finally he said that over the prior six weeks “I’ve lost, since the incident I’ve lost a stone” (SNP5).

6.3.2.7 Results of the cardiac interviews
The themes that emerged from the cardiac interviews were: Benefits of CR, Knowledge, Barriers and Behaviour change. Cardiac patients all agreed that CR was beneficial for social, psychological and physical reasons as identified by the stroke patients: “it was lovely to meet all them people, we had a laugh” (C3), “It made me feel better, yes” (C2),
and “It does help to keep you mobile” (C1). They appeared to have increased knowledge of exercise guidelines as was seen with the stroke patients: “now I realise you have actually got to push it” (C1), and “I need to do that 30 minutes every day” (C3).

However, in keeping with stroke patients, there were some cardiac patients who said: “I am not going to say I learnt anything” (C2), implying that they knew a lot already.

Like stroke patients, cardiac patients also appeared to have an unclear idea of what had caused their cardiac event, and how to link lifestyle risk factors to their event: “They never said, no probably diet or something I have eaten. But they have not said you shouldn’t eat some things” (C1), and “when you get het up that causes your blood pressure to go high don’t it, but no not really” (aware of cause of high BP) (C2).

In contrast to stroke patients, most cardiac patients did not identify personal, social or environmental barriers to attending CR. However, one patient did identify fear of another event as a barrier: “it’s all ‘what if’, all the while in your head and it overtakes you, you just can’t you know, it’s not very nice” (C3), which was also identified as a barrier by some stroke patients.

Most cardiac patients had also made some changes in their behaviour mainly related to diet and exercise: “Not eating salami…changed to low salt…haven’t had a crisp since” (C1), and “I am cutting down, I don’t have salt, I am trying to cut all the junk food out” (C3).

6.3.3 Additional data from focus groups

The main themes identified in these focus groups were: 1. CR for people post stroke: subcategories: positive impact, progress, negative effect, referral considerations, barriers; 2. Confidence; 3. Knowledge; 4. Adaptations for CR; and 5. Healthy lifestyles and behaviour change.

6.3.3.1 Effect of CR on people post stroke
Table 6.11 Quotes related to CR for people post-stroke

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Quote</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive impact</td>
<td>“they (stroke participants) get a lot out of it” (CRFG5), “great improvement in confidence” (CRFG5), “they fitted in really well” (CRFG5). “positive effect on other people in the room” (CRFG2), “stroke patients put a lot more effort into the classes than a lot of cardiac patients do” (CRFG5).</td>
</tr>
<tr>
<td>Progress</td>
<td>“there has been a big physical change in a lot of the patients...so that has been really surprising” (CRFG5), and “they have improved physically and confidence wise more than I expected” (CRFG5)</td>
</tr>
<tr>
<td>Negative effect</td>
<td>“self-conscious...and feel should I be here” (CRFG5), particularly the younger participants who “wouldn’t normally mix with these older people” (CRFG5).</td>
</tr>
<tr>
<td>Referral considerations</td>
<td>“I think maybe presenting it as a positive thing did help” (SFG4), “It does leave a hole when we pull out and yes it was great to be able to offer them something else” (SFG3).</td>
</tr>
<tr>
<td>Barriers</td>
<td>“their anxiety and their self-consciousness” (CRFG5), “transport issues, motivational issues” (CRFG2), “funding as well as transport” (SFG3) and “some people don’t want to be seen out in the community if they look different” (SFG3).</td>
</tr>
</tbody>
</table>

From the two CR team focus groups, all the CR staff felt that CR had a positive influence on the stroke patients, and stroke patients had a positive impact on the cardiac patients. The CR teams were surprised at the progress of the stroke patients. However, the CR staff did identify that sometimes the stroke patients felt self-conscious, particularly the more disabled and younger patients.
In the three Stroke team focus groups, it was clear that most of the stroke therapists and nurses had not seen the stroke patients after they had participated in CR so it was difficult to comment on the effect of CR. Prior to CR, stroke therapists were concerned about the negative effect that CR could have on high tone leading to more asymmetry and poor functional ability. However, the therapists who saw the patients after CR found that their concerns were lessened, “it was the tonal issues...very high tone...is it going to affect her...And then it (CR) certainly didn’t make her tone worse...if it’s done right and if we are monitoring it closely...I think it really helped her emotionally as well” (SFG1).

The stroke teams were instrumental in identifying and referring stroke patients for CR. They felt that the patients were particularly keen to get involved if the therapists were positive about CR and that it provided more therapy after the Early Supported Discharge teams finished.

Both teams were aware of the psychological and environmental barriers to people with stroke attending CR and doing exercise. However, the stroke teams were aware of more physical and cognitive barriers, “pre-existing cardiac problems, uncontrolled diabetes, blood pressure” (SFG1), “their communication...and also their cognitive skills” (SFG4), and “communication difficulties it’s the social aspect is a big barrier” (SFG4).

6.3.3.2 Confidence

Confidence was a major theme for CR and stroke staff. Stroke teams lacked confidence in the CR teams; some commented that “I would feel uncomfortable if (the tone) wasn’t closely monitored” (SFG4), “I think it’s important to have a stroke specialist in there because we see people every day that have had strokes but they’re not the same as each other” (SFG3), and “I was reassured by the fact there was a stroke physio there” (SFG1). The CR staff initially lacked confidence with stroke patients saying: “It’s just a massive learning curve” (CRFG4), and “We didn’t know what we didn’t know” (CRFG4). However, by the end of the research study, some of the CR staff felt “I am more confident now I think than at the start” (CRFG5). Confidence appeared to be connected to experience and knowledge.
### 6.3.3.3 Knowledge

Table 6.12 Quotes related to Knowledge

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Quote</th>
</tr>
</thead>
<tbody>
<tr>
<td>Of stroke (CR teams)</td>
<td>“I would like to do it again but with a bit more background to help the stroke patients more than I could really” (CRFG5), “now we know that there are some issues out there which we didn’t know” (CRFG2), “I didn’t have a clue did I and I felt very vulnerable there (related to splint)” (CRFG2), “maybe not knowing as much as I thought I should know about stroke patients really” (CRFG5), and “because of our lack of knowledge we wouldn’t have even picked that up (quality of movement)” (CRFG2).</td>
</tr>
<tr>
<td>Of healthy lifestyles (Stroke teams)</td>
<td>“I just give general advice and point them in the direction of the Stroke Association leaflet on healthy eating and exercise” (SFG3), and “am I qualified to do that (provide advice). Am I overstepping...” (SFG4), “I don’t think we have enough experience or confidence in giving that advice (healthy lifestyle)” (SFG1), “I don’t think it’s something that we’re taught very well” (SFG1).</td>
</tr>
<tr>
<td>Of CR (Stroke teams)</td>
<td>“I don’t exactly know what they do when they go there. I know they do exercise” (SFG4), and “I’m not sure I fully knew what was involved in CR...I didn’t know what happens” (SFG4).</td>
</tr>
</tbody>
</table>

The CR teams identified that they had limited knowledge of people with stroke and some of the stroke teams also felt they had a lack of knowledge of healthy lifestyle and CR. It also appeared that some stroke team members had a lack of knowledge of the importance of CV exercise saying, “That’s why I like the active lifestyle exercise referrals ...sitting doing some tai chi or a chair-based exercise” (SFG3). When asked how they recommend people post-stroke build up their fitness, one response was “class-based
exercise...there’s lots of seated exercise groups” (SFG1), indicating a lack of knowledge of the intensity needed to increase CRf. Stroke teams that treated stroke patients in the acute phase of recovery felt that exercise and getting fit was not a priority at this stage, “priorities up to that point was not about getting fit, it’s been about getting out of bed” (SFG1), and they felt that discussing exercise at this stage was “almost a bit insensitive” (SFG1).

6.3.3.4 CR adaptations

Table 6.13 Quotes related to adaptations of CR

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Quote</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training of staff</td>
<td>“I would agree, having done 20 years in cardiology I wouldn’t want to mislead them, we don’t have the background” (CRFG5), “I think I would need a lot more training before I felt capable of doing a talk on different strokes. Because they would ask questions and I probably wouldn’t know the answers to be fair” (CRFG5), “I think you definitely need a stroke nurse or stroke physio” (CRFG2). “it is beneficial to have a stroke physio I think from a monitoring point of view...I would still feel uncomfortable if it wasn’t closely monitored” (SFG1) and “There’s a whole lot more to look at with a stroke patient than with a cardiovascular patient” (SFG1).</td>
</tr>
<tr>
<td>Specialist staff</td>
<td>“it would have been a very difficult class to manage as CR nurses and physios without the support of the stroke physios” (CRFG2), “they can have feedback to get the best movement pattern” (SFG1), “another thing about having a stroke physio around, they can keep an eye on are they sticking to what they should be doing” (SFG1),</td>
</tr>
</tbody>
</table>

Both teams were very clear that in order for people post stroke to attend CR the main adaptation was having a specialist stroke physiotherapist in the class and providing specialist education for the stroke population.
6.3.3.5 Healthy lifestyles and behaviour change

CR teams were very clear that education about healthy lifestyle and behaviour change was a definite part of their role, “we all have a role” (CRFG2), “we’re the foundations” (CRFG2), and “we’re sowing the seeds” (CRFG2). They felt that the stroke patients were positive towards healthy lifestyle messages, “I think they’re interested in healthy eating” (CRFG2), and “have a good attitude to changing lifestyles to get better” (CRFG2). Stroke teams in the later stage of rehabilitation also appeared to acknowledge their role in healthy lifestyle advice: “I certainly do use the leaflets and there is information about healthy diet” (SFG3), and “I do all the diet things and weigh the patients, advice on not smoking or if they’re drinking...” (SFG3). However, they felt that “because you are in their home you can’t really, it’s difficult to turn around and preach to them.” (SFG3), and “you’ve got to be careful because that’s not our main role, although it’s important we need to make sure that we are not breaking down that rapport that we’ve built with a patient” (SFG3).

Acute stroke teams stated that “we don’t probably sit down and talk to anybody about lifestyle” (SFG1), and they felt they do not have the time or opportunity “it’s just unfortunately the environments that we work in within an acute trust, we don’t necessarily always get those opportunities (to influence exercise behaviour)...the main focus was going home” (SFG1). They also appeared more negative towards patients taking up behaviour change: “I don’t think it’s high on their agenda” (SFG1), and “I don’t think I see many that make that change” (SFG1). In the stroke teams, only certain professions seemed to provide healthy lifestyle messages, which was reflected in a comment by one of the speech and language therapists, “I think it hasn’t been that high on my list of things that I’m thinking about and it should be being part of a stroke team...maybe I should be bringing that in as part of my role” (SFG4).
6.3.4 Ability to recruit

Seventy-eight patients were screened, 32 (57%) consenting over a ten-month period, providing an actual recruitment rate of three per month, compared to an anticipated rate of four (Figure 6.1). Importantly, recruitment was expanded to neurology outpatient services and community hospitals to help meet targets. Reasons for non-participation were explored in interviews with non-consenting patients and outlined in Section 6.5.3. Reasons given to recruiting therapists included: partner not willing, not interested, holidays, and work commitments. It was particularly difficult to recruit TIA patients due to time and work commitments, and moderate-to-severe stroke patients, as they failed to fulfil the eligibility criteria of walking 10 metres within six months of stroke onset.

6.3.5 Adherence

Adherence to the CR programme, a mean of 9.6 classes were attended; 80% of target. Those patients not achieving all 12 classes over 6 weeks, cited fatigue and class timing as the most common reasons. Six patients (19%) stopped attending for medical
reasons: vertigo (1 patient), pneumonia (3), cardiovascular (1 tachycardia, 1 hypertension).

6.3.6 Outcome measures

All of the patients (except dropouts) were able to undertake the ISWT pre and post rehabilitation, showing an increase from baseline to six weeks of 200 (SD 191) to 234 metres (SD 193), a mean change of 34 metres (SD 31.9, 95% CI 46.96 to 21.19) (Figure 6.2). Other changes in the tested outcome measures are displayed in Table 6.14 and Table 6.15.

Figure 6.2 Bar chart illustrating the change in ISWT after CR
Table 6.14 Changes in cardiovascular, anthropometric and accelerometer parameters from baseline to six week follow-up

<table>
<thead>
<tr>
<th></th>
<th>Pre CR</th>
<th>Post CR</th>
<th>Mean change (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max systolic BP post exercise</td>
<td>148.0 (21.4)</td>
<td>155.9 (22.9)</td>
<td>7.9 (-0.8 to -14.9)</td>
</tr>
<tr>
<td>(mmHg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resting BP (mmHg)</td>
<td>129.1 (17.6)</td>
<td>133.0 (13.7)</td>
<td>3.8 (10.8 to -3.2)</td>
</tr>
<tr>
<td>Max HR post exercise (bpm)</td>
<td>101.9 (17.2)</td>
<td>101.0 (16.8)</td>
<td>-0.88 (6.2 to -7.9)</td>
</tr>
<tr>
<td>Resting HR (bpm)</td>
<td>72.8 (12.8)</td>
<td>68.4 (10.2)</td>
<td>-4.4 (0.2 to -9.3)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>80.5 (19.5)</td>
<td>80.7 (18.7)</td>
<td>0.23 (1.3 to -1.7)</td>
</tr>
<tr>
<td>BMI</td>
<td>28.2 (5.4)</td>
<td>28.3 (4.9)</td>
<td>0.06 (-0.6 to 0.5)</td>
</tr>
<tr>
<td>Step count (per day)</td>
<td>3255 (2864)</td>
<td>3908 (3399)</td>
<td>653 (-1026.1 to -325.9)</td>
</tr>
<tr>
<td>LPA (min/day)</td>
<td>204.5 (75.9)</td>
<td>218.8 (81.3)</td>
<td>14.3 (-5.3 to 33.9)</td>
</tr>
<tr>
<td>MVPA (min/day)</td>
<td>11.1 (19.5)</td>
<td>16.3 (24.5)</td>
<td>5.2 (0.4 to 10.0)</td>
</tr>
<tr>
<td>Sedentary (min/day)</td>
<td>503.9 (95.7)</td>
<td>483.3 (87.5)</td>
<td>-20.6 (-60.3 to 19.1)</td>
</tr>
</tbody>
</table>

Data are presented as mean (SD). BP: blood pressure; HR: heart rate; BMI: body mass index; MVPA: moderate-to-vigorous physical activity; LPA, light physical activity.

Of the 32 patients who took part, 26 completed the study and 24 provided valid physical activity data at both time points (92% of completers). The invalid data were due to providing less than 8 waking hours of wear time on more than 1 day.
<table>
<thead>
<tr>
<th>Measure</th>
<th>Pre CR</th>
<th>Post CR</th>
<th>Mean change (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BI</td>
<td>91.7 (88.7-100)</td>
<td>92.5 (88.7-100)</td>
<td>1.1 (-3.1 to 0.7)</td>
</tr>
<tr>
<td>SF36 - Physical function</td>
<td>51.4 (32.5-61.3)</td>
<td>51.5 (33.7-70)</td>
<td>0.1 (-16.3 to 15.9)</td>
</tr>
<tr>
<td>SF36 - Physical health</td>
<td>0 (0-0)</td>
<td>0 (0-50)</td>
<td>18.9 (33.9 to 3.9)</td>
</tr>
<tr>
<td>SF36 - Emotional health</td>
<td>66.7 (33.3-100)</td>
<td>83.3 (33.3-100)</td>
<td>8.9 (21.3 to -3.4)</td>
</tr>
<tr>
<td>SF36 - Energy</td>
<td>55 (38.7-66.2)</td>
<td>57.5 (43.7-81.2)</td>
<td>4.0 (-19.5 to 11.4)</td>
</tr>
<tr>
<td>SF36 – Emotional wellbeing</td>
<td>78 (56-89)</td>
<td>78 (66-93)</td>
<td>0.0 (-14.4 to 14.4)</td>
</tr>
<tr>
<td>SF36 - Social Functioning</td>
<td>62.5 (50-75)</td>
<td>75 (62.5-100)</td>
<td>13.5 (23.3 to 3.5)</td>
</tr>
<tr>
<td>SF36 - Pain</td>
<td>77.5 (45-100)</td>
<td>78.7(57.4-90)</td>
<td>1.2 (-11.1 to 8.6)</td>
</tr>
<tr>
<td>SF36 - General Health</td>
<td>60 (43.7-81.3)</td>
<td>62.5 (50-81.3)</td>
<td>2.5 (-11.9 to 13.8)</td>
</tr>
<tr>
<td>MAS</td>
<td>0 (0-3.2)</td>
<td>0 (0-3.2)</td>
<td>0.4 (-0.2 to 1.1)</td>
</tr>
<tr>
<td>MFIS</td>
<td>11 (-2-29.7)</td>
<td>4 (-8-17.7)</td>
<td>-7.1 (-1.35 to -12.8)</td>
</tr>
<tr>
<td>HADS – overall score</td>
<td>11.5 (5.7-16)</td>
<td>8.9 (4.7-13.5)</td>
<td>-2.6 (-0.30 to -4.8)</td>
</tr>
<tr>
<td>HADS – anxiety</td>
<td>4.9 (3.5)</td>
<td>3.9 (3.6)</td>
<td>-1.0 (-2.4 to 0.4)</td>
</tr>
<tr>
<td>HADS - depression</td>
<td>6.6 (4.3)</td>
<td>4.9 (3.5)</td>
<td>-1.7 (-3.0 to -0.4)</td>
</tr>
<tr>
<td>SAKQ – stroke knowledge</td>
<td>6 (1-10)</td>
<td>10 (6-11)</td>
<td>4.0 (4.1 to 1.4)</td>
</tr>
<tr>
<td>SAKQ – weight knowledge</td>
<td>1 (1-1)</td>
<td>1 (1-1)</td>
<td>0.0 (-0.3 to 0.2)</td>
</tr>
<tr>
<td>SAKQ – diet knowledge</td>
<td>2.0 (1-4)</td>
<td>3.0 (2-4)</td>
<td>1.0 (1.2 to 0.0)</td>
</tr>
<tr>
<td>SAKQ – Activity knowledge</td>
<td>1.0 (1-2)</td>
<td>3.0 (2-3)</td>
<td>0.9 (1.5 to 0.4)</td>
</tr>
</tbody>
</table>
Higher scores indicate better results for Barthel Index (BI), Short Form 36 (SF36) and Stroke Attitude and Knowledge Questionnaire (SAKQ). Lower scores indicate better results for Modified Ashworth Scale (MAS), Multidimensional Fatigue Inventory Score (MFIS) and Hospital Anxiety and Depression scale (HADS). Data are presented as median (IQR).

Overall the proposed OMs were feasible to complete by all patients. A number of the measures indicated a positive change after 6 weeks of CR (ISWT, fatigue, anxiety, depression, MVPA, step count, and stroke and physical activity knowledge) although this needs to be interpreted with caution as this was a feasibility study. Tone, falls rate and fatigue did not appear to be adversely affected by CR.

6.3.7 Adverse events

The falls diaries indicated that no one had a fall during the six-week programme. Only one serious adverse event was reported; a patient collapsing during the warm-up of one class. This patient was admitted to hospital and monitored. No cardiac or stroke symptoms were observed and he was discharged home the next day.

6.4 Discussion

This study aimed to determine the feasibility of an adapted six-week CR programme for people with mild-to-moderate severity stroke in the sub-acute phase of recovery. It was possible to recruit patients who scored up to six on the NIHSS but patients with moderate neurological severity (up to 15 on NIHSS) were not recruited, as they were not able to walk ten metres within the six-month recruitment window. This meant that a significant number of people who have a moderate severity stroke were not eligible for the CR programme and so these people are missing the opportunity to potentially improve their CR and reduce their risk of further stroke unless a suitable programme is provided for them.

It was possible to recruit three patients per month and the recruitment rate was high with people post-stroke, on-the-whole, being positive about the opportunity to attend CR. However, people post-TIA were difficult to recruit identifying that they had
difficulties attending due to time and work commitments. This reflects results found by Kirk et al (2014). It could be argued that a greater emphasis needs to be given to supporting this group of people to attend to prevent subsequent further events as it has been shown that “4% to 20% of patients with transient ischemic attacks (TIAs) progress to stroke within 90 days” (Ivey et al., 2008).

The subacute stage of recovery was defined as between one and six months post-stroke. Most patients were recruited after they had taken part in the early supported discharge service so therefore the average time post-stroke was nearly three months post-stroke. It was felt by the stroke staff and patients that they could not cope with CR during active treatment and the CR provided an opportunity to extend the patients treatment. This meant that the effect of earlier CR was not identified. However, as they had received therapy input up until this time their functional abilities had been maximised. The CR was designed to increase CRf but future studies could also aim to measure functional ability using other scales not the BI as this scale was not sensitive enough to measure change in functional ability.

The programme was found to be acceptable to people post-stroke and post-cardiac event, as well as to stroke and CR teams. However, patients with a more severe stroke (classed as over two on the NIHSS) were identified by staff and by the patients themselves, as being embarrassed and self-conscious of their disabilities and in need of more support from specialist stroke physiotherapists. Additionally, CR staff felt they needed more support and training if CR programmes were to include a more disabled stroke population. The NIHSS normally classes stroke patients six and under as mild stroke (Johnston, 2007), so the recommendation by the Cardiovascular Disease Outcomes Strategy (Department of Health, 2013) that existing CR could be used for Transient Ischaemic Attack (TIA) patients and mild disability stroke patients, may need to be reviewed. The programme was found to have good adherence with 80% of classes attended and only six drop-outs due to medical reasons. This compares favourably with the adherence for cardiac patients of 77% (British Heart Foundation, 2016), and again confirms the findings of Kirk et al (2014).

The ISWT was an acceptable outcome measure for most stroke patients in this study. However, as reported in Chapter 5 of this thesis, the ISWT was found to be a valid
measure for measuring CRf for stroke patients with no residual neurological impairment, but an alternative cycle-based clinical test may be needed for stroke patients with neurological deficit. The ISWT is often reported as a submaximal test for CRf so for a definitive trial, it may be advantageous to use an ICT to measure VO₂ peak to determine the effect of CR on CRf.

Allowing for the fact that this was a feasibility study and compared to other feasibility studies of similar size, most measures showed a positive change indicating that a six week programme may be as effective as a ten (Lennon et al., 2008) or twelve week (Kirk et al., 2014) programme at improving CRf, quality of life and fatigue. Importantly, there were no detrimental effects on tone or number of falls, in this population so a CR programme does not appear to cause the negative changes on these outcomes that might be anticipated by stroke teams. The more disabled patients showed positive changes in most measures and interestingly showed a greater change in the ISWT, BI and Stroke knowledge compared to the less disabled patients. This is perhaps because they had lower scores at the beginning of the study so had more potential to increase their scores. The less disabled patients had more positive changes in the quality of life measures perhaps indicating that the more disabled patients need more support to address their quality of life. More research is needed to explore these topics.

Not surprisingly, the results showed that there was no effect on BMI, in keeping with other studies using the CR approach with people post-stroke (Kirk et al., 2014) and post-cardiac events (Joliffe et al., 2001). As CR is designed to reduce risk factors for further cardiovascular events it seems that the content of CR programmes might need to be reviewed in order to address the needs of people who are overweight or obese. As people post-stroke, in particular, have reduced mobility this would be a key adaptation of the CR programmes.

As was found with Kirk et al (2014) the effect of the programme on BP was limited, and as identified in the associated cardiac research (Joliffe et al., 2001, Taylor et al., 2004, Clark et al., 2005) may need significantly larger studies to determine an effect. The sample size identified by the present study, for a definitive study based on the ISWT was 146, however, if the definitive trial aimed to determine an effect of CR on mortality rates or recurrence risk the sample size would rise significantly (Kirk et al., 2014).
Activity levels improved over the six-week period of CR as measured by the increased step count, MVPA and decreased sedentary behaviour. It is known that the activity levels of people post-stroke are significantly lower than people without neurological disease (Butler, 2014), and sedentary behaviour is increased to 80% of their day (Tieges et al., 2015). However, there is limited research in this population to determine the effect of interventions on this behaviour. The present study, therefore identifies promising novel insights into the possible effect of adapted CR on activity levels and sedentary behaviour post-stroke.

CR teams were very positive towards stroke patients taking part in adapted CR. They identified a number of benefits for both stroke and cardiac patients. This contrasts to concerns that the CR teams had before stroke patients took part in CR, as was seen in Chapter 4. On the whole, stroke teams were unable to comment about the impact of CR on stroke patients, as they did not see them after their involvement. This identifies a need to feedback to the stroke teams about the positive impact of adapted CR for people with stroke, as stroke teams will be the main referrers into the programme. As has been found in previous CR and pulmonary rehabilitation (PR) studies, the positive attitude of referrers to CR programme has had a beneficial impact on the attendance levels to CR and PR programmes (Bulley et al., 2007 and Dalal et al., 2015).

It was identified that one negative effect of the CR programme was the psychological impact on more severely disabled stroke patients who were self-conscious and embarrassed about their disabilities. This needs to be taken into account when deciding on the level of stroke severity that can be included into existing CR programmes. Whilst NIHSS scores of 0 to 5 are considered mild severity strokes, this could still include individuals with neurological impairments, so it might be more acceptable to people post-stroke to only include people with an NIHSS score of 2 or less in existing CR classes to reduce the potential psychological impact of class participation. Another negative of exercise and CR was considered by the stroke teams to be the impact on high tone. It is identified that 17% to 43% of people post-stroke develop post-stroke spasticity (Urban et al., 2010), and traditionally it was thought that increased activity and effort can increase the tightness experienced by people post-stroke. However, the teams did not
find a long-term increase in tone due to the CR programmes, and so stroke teams were less concerned about referring patients into the programmes.

Both teams identified the main barriers to CR and exercise were environmental barriers, such as lack of funds and transport. This needs to be considered when providing CR, as all stroke patients are unable to drive within a month of stroke. Further research is necessary to identify the cost benefits of providing transport for the stroke population to attend ongoing CR. As was found with the focus groups in Chapter 4, CR teams did not identify as many physical and cognitive barriers for people with stroke attending CR, compared to stroke teams. However, having taken part in the adapted programmes, some of the CR teams had an increased awareness of the specific needs of stroke patients, such as fatigue and tonal needs. Interestingly, the focus groups conducted prior to the CR intervention (see Chapter 4) identified motivation and confidence as barriers to stroke patients taking part in CR, though these were not subsequently identified.

CR teams identified a lack of knowledge of stroke and felt they would need more education and support if stroke patients were to be included in the CR programmes even after taking part in the CR for stroke patients. Stroke teams recognised a lack of knowledge of CR, which potentially impacted on their ability to understand the importance of specific CV training for the stroke population. The research therefore highlighted that both teams need more education before CR can be provided for the stroke population. Stroke teams also felt that they could improve their knowledge of healthy lifestyles, so that the whole team can provide the healthy messages as is seen with staff involved with CR services.

Providing healthy lifestyle messages was not seen as a priority for the acute stroke teams and this contrasted with the attitudes of the CR teams. The acute stroke teams felt that in the early stages of stroke recovery this was too soon to provide healthy messages. However, CR services provide these messages in the early stages of cardiac recovery. Indeed, the British Association for Cardiovascular Prevention and Rehabilitation states that two of the seven core components of CR are lifestyle risk management and health behaviour change (BACPR, 2012). Behaviour change models, such as the Transtheoretical model (Prochaska et al., 2005), have identified that there
are five stages of behaviour change: pre-contemplation, contemplation, pre-preparation, action and maintenance. People immediately post-stroke may be more likely to contemplate behaviour change, so the sooner the messages are provided to them and their families the more likely behaviour change will occur. However, Mauk et al (2006) suggests a different model post-stroke that patients may be more likely to take on advice in the later stages of recovery. This would indicate the importance of stroke teams, particularly early supported discharge teams, receiving more education on how to provide healthy lifestyle messages and how to facilitate behaviour change.

In relation to adaptations, similar to the focus groups that were conducted prior to the CR intervention (and reported on in Chapter 4), the teams identified the need for a specialist physiotherapist in the classes. Both teams expressed the need for a specialist stroke physiotherapist to attend the CR programmes to advise on appropriate adaptations to exercise, and to provide specialist advice and education for stroke patients and CR staff. This was particularly for stroke patients who had more physical and cognitive difficulties, and highlights again the importance of identifying the appropriate level of disability (stroke severity) to include in existing CR programmes.

Overall, individuals with a mild severity stroke in the sub-acute phase of recovery enjoyed adapted CR. It was found that there were physical, psychological and social benefits to attending the classes, and this reflected the findings of Hillsdon et al. (2013). The present study additionally reported that one major benefit of adapted CR for stroke patients was the increased knowledge of exercise and dietary guidelines, and stroke; in keeping with Hillsdon et al. (2013) and the author’s findings in Chapter 3. Hillsdon et al. (2013) reported that their patients did not recall information that they had been given about stroke and risk factors for stroke during regular stroke treatment. The results in this section of the thesis also showed a lack of knowledge post CR classes too, which may reflect problems linked to memory, communication and cognitive deficits post-stroke, in keeping with the findings of Hillsdon et al. (2013).

The results from the interviews also found that people post-stroke were not able to identify a cause of their stroke and to link risk factors to stroke. This mirrors observations made in Chapter 3 with a group of people post-stroke who were not part of any intervention study, over half could not identify a cause for their stroke and could
not identify risk factors. In order to reduce stroke recurrence, Lawrence (2011) identified that there should be a multimodal approach of medical, surgical and lifestyle interventions. Deijle et al. (2017) conducted a systematic review and found that lifestyle interventions are effective in lowering systolic blood pressure. However, it is unlikely that people with stroke will participate in lifestyle interventions if they do not perceive these as the cause of their stroke.

The main barriers to CR found in the interviews were past and present physical disabilities, psychological barriers such as fear of another stroke and embarrassment, and environmental barriers particularly transport issues. These replicate the environmental barriers seen in the study of Marzolini et al. (2016), and the environmental and personal barriers to exercise previously reported in this thesis (Chapter 3). Marzolini et al (2016) did not identify embarrassment as a barrier, perhaps because they had a less disabled population. Unlike the results found in Chapter 3 which identified additional barriers such as fatigue and falls in a group of stroke patients who did not attend CR, the results in this section of the thesis identified that fatigue and falls were not a concern after taking part in CR. Perhaps the stroke patients who took part in CR reduced their fear of falling by taking part in CR. This would need to be examined using the Falls Efficacy Scale (Yardley et al., 2005) in subsequent studies. In relation to fatigue, the results in this section of the thesis identified that all patients suffered from fatigue though this was not seen as a barrier to exercise, in contrast to the findings reported in Chapter 3 and Nicholson et al. (2012). Only two patients found CR to increase their fatigue, this reflects research in other populations that identified exercise as a solution to fatigue (White et al., 2011). However, overall, more research is needed to explore the effect of CR and exercise on fatigue levels in the stroke population.

The majority of patients had made changes to their behaviour, especially to exercise and diet, over the six weeks following the adapted CR programme, although whether these changes are sustained requires further investigation. Heron et al. (2017) conducted a systematic review of lifestyle intervention studies in the sub-acute stage of stroke and following TIA. They found that the main behaviour change techniques used in the four studies reviewed were goal setting and instructions about how to perform
given behaviours. The present study employed these methods in CR to encourage behaviour change. The COM-B model of behaviour change (Michie et al., 2014) identifies six key factors that affect behaviour change: physical and psychological capability, social and physical opportunity, and automatic and reflective motivation. As mentioned above the barriers related to CR were physical, psychological (capabilities) and environmental (opportunities), so these need to be considered when attempting to assist people with post-stroke change behaviour. In relation to automatic and reflective motivation, the present study found that CR increased motivation (automatic motivation) and encouraged changes in behaviours (reflective motivation), so adapted CR has the potential to increase behaviour change. However, as McManus et al. (2009) found, the long-term effects of behaviour change interventions have yet to be established.

People post stroke were happy to attend a CR programme with cardiac patients, and considered the content and structure of the programme acceptable. They did, however, feel that the education programme could be more stroke specific, similar to findings from Hillsdon et al. (2013). The present study also found that people post-stroke felt they needed a specialist stroke physiotherapist to attend their sessions particularly if they were more disabled. It is imperative that stroke physiotherapists have the time and opportunity to support the CR staff and patients in order to achieve long term exercise interventions, as identified by Morris and Williams (2009) ‘physiotherapists need to take a leading role...with other exercise professionals and services to address the transition from rehabilitation to an active lifestyle following stroke’ (Morris and Williams, 2009).

The stroke patients who did not want to take part in CR identified the main reason as time commitments. Potentially some of them would have taken part if the programme was just once a week and this could be considered for a future definitive trial. Lebris et al (2006) found that exercise tolerance was the same with both a low and high frequency CR programme with cardiac patients, so the frequency potentially could be reduced without a significant effect on results. As was found in Chapter 3 of this thesis, the non-participants had limited knowledge of stroke, exercise and healthy lifestyle guidelines and how to link to their stroke.
As was found with the stroke patients, cardiac patients identified: similar benefits of CR; had an increased knowledge of exercise guidelines; had made changes in their behaviour in relation to exercise and diet; and did not appear to make the link between lifestyle risk factors and the cause of their cardiac event. However, the majority of cardiac patients did not identify any barriers to attending CR, unlike cardiac patients in the review by Daly et al (2002), perhaps because the selected patients were driving and did not have any other significant co-morbidities.

6.5 Limitations

The main limitation of this study is the lack of a control group. As this was a feasibility study the aim was not to compare groups, however, it may have provided more pilot information for a definitive study if a control group had been recruited. As there was no control group it was not possible to understand the change in the control group so therefore it was not possible to calculate the sample size for a definitive study. The change in the ISWT needs to be that of a meaningful difference either known to be associated with an important health outcome or important to an individual. This study did not provide this information.

In relation to recruitment, it was hard to recruit people from the TIA clinics as they were through the system very quickly so the numbers assessed for eligibility could have been a lot larger as a result. Also the stroke staff on the wards initially spoke to the potential participants and could have introduced selection bias if they did not believe the patient would be able to take part in the CR programme. This is reflected in the small numbers that were identified for screening seen in the consort diagram.

Although the OMs used in this study were shown to be acceptable for this study there are limitations to these measures. As has been discussed in Chapter 5 of this thesis, the ISWT is a sub-maximal measure of CRf and so a definitive study may need to use an ICT to determine CRf or employ portable VO\textsubscript{2} measurements to determine the effect of CR on CRf. Also basing the sample size on this measure might be seen as a limitation, as cardiovascular risk might be a better final outcome.

One limitation of the focus groups was that not all members of the stroke and CR teams were represented. The research team endeavoured to recruit a wide range of staff but
it is evident that there were few stroke nurses and CR physiotherapists represented and they may have expressed different perspectives on CR post-stroke. It could also be suggested that focus groups do not allow participants to expand on their own viewpoints due to the range of individuals involved. However, it was felt that the advantages of the focus group paradigm, particularly the ability to stimulate conversation, outweighed this limitation.

In relation to the interviews, it is recognised that the main author knew the stroke patients and they knew that she was a stroke physiotherapist as she had attended all of the initial assessments and a number of the CR classes. This needs to be acknowledged as the patients may have been influenced by this knowledge, for example, providing answers that they felt were required. However, the author identified this prior to the interviews and where possible identified that CR was not part of her routine practice and therefore attempted to maintain a distance from the CR programme.

Another limitation of the study was that patients who agreed to take part were keen to exercise and extend their treatment for another six weeks. As a result, the interview findings may not reflect a broad range of perspectives and experiences. Future research would benefit from actively engaging those people who are not as positive towards healthy lifestyles. A final limitation is that the average length of time after stroke varied from 38 days to 135 days and people’s perceptions may have varied over this time period.

6.6 Conclusion

A definitive study to determine the effect of six weeks of adapted CR on CRf in people with mild severity stroke (NIHSS < 3) is feasible in relation to acceptability, recruitment, retention and identified outcome measures. Positive changes were seen in CRf, activity levels, fatigue, stroke knowledge and attitudes. There were no significant adverse events and no negative effects on fatigue, falls or tone. However, people with mild to moderate severity stroke (NIHSS >2) may need a more specialist programme, more research is needed in this population.
It is important that there is effective communication, education and support between stroke and CR teams to provide adapted CR for people with stroke. Stroke and CR teams feel that small numbers of people with mild stroke (NIHSS < 3) can be included in existing CR programmes, where CR staff have increased stroke knowledge and confidence, and the programme is adapted and supported by specialist stroke staff.

People with a mild severity stroke in the sub-acute phase of recovery enjoy and benefit from adapted CR although cognitive, communication and memory deficits may limit educational benefits. More disabled patients may benefit from a separate programme due to physical difficulties leading to psychological barriers. Environmental barriers such as transport, and frequency of the programme need to be considered when designing adapted CR programmes for people post-stroke. CR programmes need to be adapted particularly in relation to specific stroke education and support from specialist stroke physiotherapists. People post stroke and cardiac events attending adapted CR can increase their knowledge of healthy lifestyles and can change their behaviour, unlike non-participants, but long-term behaviour change needs to be investigated.
Chapter 7  Discussion

The overall aim of this research was to establish the feasibility of conducting a definitive study investigating the effect of six weeks of adapted CR on CRf, BP, HR, activity levels, QOL, fatigue, tone, falls, BMI, anxiety and depression for people with mild to moderate stroke in the sub-acute stage of recovery.

The objectives of the thesis were:

1. To conduct a literature review to identify and summarise the qualitative literature that relates to the experiences of people post-stroke and their attitudes to and knowledge of exercise, healthy lifestyles and CR post-stroke.

2. To conduct a qualitative interview-based study with people post-stroke who have a mild-to-moderate stroke severity who are in the subacute stage of recovery to explore experiences and knowledge of and attitudes to healthy lifestyles and CR.

3. To conduct a literature review to identify and summarise the literature that relates to healthcare professionals’ attitudes to healthy lifestyles, particularly exercise and CR in people post-stroke with mild to moderate severity in the sub-acute phase of recovery.

4. To conduct a qualitative focus group study with healthcare professionals who work in CR and stroke care to explore experiences and knowledge of and attitudes to healthy lifestyles and CR post-stroke.

5. To conduct a systematic review to identify and summarise the literature related to the use of the 6MWT and ISWT to measure CRf in people post-stroke.

6. To conduct a quantitative study to measure the concurrent validity of the ISWT, 6MWT with the ICT and to test the test-retest reliability of the ISWT and the 6MWT.

7. To conduct a systematic review to identify and summarise the literature related to cardiovascular exercise and CR for people post-stroke.

8. To conduct a cohort study to identify the acceptability, recruitment strategy, adherence, outcome measures, sample size, and adaptations needed adapted CR for
people post-stroke with a mild-to-moderate severity stroke in the sub-acute stage of recovery.

9. To conduct a review of literature to identify and summarise the literature related to experiences of and attitudes to CR post-stroke from the patient and staff perspectives.

10. To conduct a qualitative interview-based study with people post-stroke and people post cardiac event who took part in CR and with people post-stroke who did not take part in CR to explore experiences of CR and attitudes to healthy lifestyles after stroke and cardiac events.

11. To conduct a qualitative focus group study with healthcare professionals who work in CR and stroke to explore experiences of CR for people post-stroke and their attitudes to healthy lifestyles post-stroke.

7.1 Objectives 1 and 2

Objectives 1 and 2 are addressed in Chapters 1, 2 and 3 reporting on the background literature, method and results of a qualitative interview study that explored the experiences and knowledge of and attitudes to healthy lifestyles and CR in people post-stroke in the sub-acute phase of recovery.

This study found that the patients discussed a number of personal, environmental and social factors that prevented or made it difficult for them to engage in exercise and these findings replicate what have been found in other studies with the chronic stroke population (Forster et al., 2012, Nicholson et al., 2012). These factors need to be considered when designing the definitive study, for instance, providing transport to attend the programmes. Fatigue appeared to be a major barrier to exercise post-stroke in the acute and chronic phase of stroke recovery, however, it is unclear what effect exercise has on fatigue. More research is needed in this field as it is possible that exercise may improve fatigue as was seen in phase IV of this thesis and has been seen in other populations for example the chronic fatigue population (White et al., 2011). In contrast to previous studies with the chronic stroke population (Nicholson et al., 2012 and Simpson and Eng, 2011), a lack of motivation was not identified as a barrier to
exercise at this sub-acute stage of recovery from stroke. It seems that it is important to work with people with stroke in the early stages of their recovery to encourage activity and to prevent perceived motivational barriers developing.

Patients in the present study identified a number of benefits of exercise that the Health Belief Model (Rosenstock, 1974) suggests could be beneficial to support their attempts to achieve a healthy lifestyle. The patients, however, did not discuss the benefits of fitness or prevention of future cardiovascular events, which suggests that they did not consider this to be part of the role of exercise after stroke. More research is needed to find the best way to support people with stroke in their efforts to understand and maintain a healthy lifestyle and explore the long-term benefits of a healthy lifestyle after a stroke and this could be incorporated into the definitive study.

An area of concern, highlighted in this study, was the doubts and lack of agreement expressed by some patients about the healthy lifestyle messages they had been given. This was also highlighted in previous studies (Forster et al., 2012 and Hillsdon et al., 2013) and emphasises the need for clear and consistent healthy lifestyle messages. Perhaps, more importantly, some patients appeared to welcome a chance to discuss their beliefs in order to address any doubts they had about the advice they were being given. This reinforces Forster et al.’s (2012) recommendations that active information provision, such as, integrating the use of workbooks into experiential classes was much more effective than passive approaches, such as, the provision of information packs for use at home.

It appears that patients did not fully understand the factors that contribute to having a stroke. They were able to discuss some lifestyle risk factors but did not seem to make the link between these and having a stroke. This was also identified in a recent study by Hillsdon et al (2013) who found that “some disregarded information about known risk factors for minor stroke or that lifestyle changes can reduce such factors” (Hillsdon et al., 2013, p.7). Effective health behaviour change relies on people taking ownership of their health behaviours, that is, switching from an ‘external locus of control’ (Rotter, 1966) to an ‘internal locus of control’. If, as illustrated in this study, people are unable to make the link between lifestyle risk factors and having a stroke then they are less likely to make lifestyle changes.
The American Stroke Association (2011) states that “patients with ischaemic stroke or TIA ...should be managed according to NCEP III guidelines, which include lifestyle modification, dietary guidelines, and medication recommendations” (Furie et al, 2011, p.230). In order to modify their lifestyle, people with stroke need to be aware of exercise and dietary guidelines and recommendations, however, only two people with stroke in the present study were aware of the recommendations for CRf. This is not altogether surprising as a survey by the National Obesity Observatory (2016) found that only 6% of men and 9% of women in the general population had any idea about the recommended levels of exercise.

This study also found that very few patients had been given healthy lifestyle advice. This mirrors the results of previous studies (Healthcare Commission Survey of patients, 2006, The Stroke Association, 2006, Furie et al., 2011, Forster et al., 2013) although, as with these studies, it is not clear whether this information was given but not fully absorbed and recalled by people with stroke. More research is needed to determine how to provide essential information, at what stage of stroke recovery it should be provided, and how to ensure that lifestyle changes are made and maintained as a result of receiving the information. People with stroke vary in their opinions about how relevant information could be provided. In the present study, only the younger patients expressed a preference for online information, the majority preferred to speak to someone to get advice. An associated unpublished study (Clague-Baker et al, 2015), conducted by the author, used focus groups in which the timing of lifestyle advice was discussed by a range of healthcare professionals working in stroke rehabilitation. It was found that most patients considered it was too early to provide lifestyle advice to people with stroke while they were still receiving care in an acute stroke unit and the team members, who provided care to people in the later stages of stroke recovery, felt that specific training would help them in effectively delivering accurate and relevant lifestyle information.

Finally, it has been theorised (Rosenstock and Strecher, 1998 and Bandura, 1977) that people wanting to make changes in their lives need to believe in the importance of those changes and feel confident that they can achieve the desired changes. In the present study, it appeared that over half the patients did not know any of the risk
factors that could lead to a stroke and did not know why they had had a stroke. Without this knowledge it is doubtful that they would understand the importance of any lifestyle changes and have the confidence to make any change.

7.2 Objectives 3 and 4

Chapters 1, 2 and 4 report on the background literature, method and results of a qualitative focus group study with healthcare professionals who work in CR and stroke care to explore experiences and knowledge of and attitudes to healthy lifestyles and CR post-stroke.

The study identified four main themes: attitudes to exercise and CR, experiences of stroke compared to cardiac patients, attitudes to healthy lifestyle provision, and attitudes to behaviour change. In relation to attitudes to exercise and CR, subcategories included; activity levels, benefits, negatives, barriers and adaptations. The stroke teams identified that most people with stroke tend to be inactive before their stroke and this was reflected in what the CR teams reported of the cardiac patients’ behaviours before their cardiac event. Both teams felt that the patients, whether post-stroke or post-cardiac event, are more positive towards activity after their event although some patients expressed anxiety about exercise. This indicates a need for more education about the appropriate approach to exercise post-stroke, and is important to consider when attempting behaviour change, as anxiety will have a significant effect on confidence and thus impact on any change in behaviour (Bandura, 1977).

CR and stroke teams agreed on the physical, psychological and social benefits of exercise and CR for the stroke population, but differed in the terminology used, with stroke teams being reluctant to use the word ‘exercise’. It could be argued that the stroke teams are more aware of the needs of the stroke population and know how to motivate them, that is, by discussing activity rather than exercise. This reflects the latest campaign by the Chartered Society of Physiotherapy (CSP) (2018) ‘Love Activity, Hate Exercise?’ where the CSP recognises the difficulties some people have with exercise and are encouraging people to find an activity that can keep them fit instead of traditional exercise programmes.
The results identified that both teams were aware of some of the negatives of exercise and CR for people with stroke, but the stroke teams were more aware of additional aspects such as fatigue, falls and shoulder damage. As up to 85% of stroke patients suffer fatigue (Cumming et al., 2016), up to 73% fall post-stroke (Rensink et al., 2009) and up to 90% suffer shoulder pain post-stroke (Allison et al., 2016), it is imperative that everyone treating stroke patients is aware of these difficulties and knows how to manage them. Also, it appeared that only the physiotherapists, not the nursing staff, in the CR teams were aware of and concerned about asymmetry and tonal changes with exercise. This lack of awareness is an important consideration if CR programmes were to support people with stroke in CR classes, especially as the British Association for Cardiovascular Prevention and Rehabilitation (BACPR) national audit (2012) identified that only 63% of programmes had physiotherapists on their staff. It also highlights the need to consider the different levels of ability before placing people with stroke in CR programmes.

Using Social – Cognitive Theory (Bandura, 2004), the identified barriers to CR and exercise can be divided into personal, social and environmental barriers. Both teams identified social and environmental barriers, which would need to be considered when designing CR programmes for the stroke population. Both teams also identified adaptations that could be made to support people attending the programmes, such as providing transport and physical support in the classes. This reinforces the recommendations identified by Mead and van Wijck (2013). The stroke teams, however, identified more personal barriers to people post-stroke exercising and attending CR. This could indicate a lack of knowledge of the stroke population in the CR teams which was highlighted by the CR teams themselves. This point is important to consider when determining whether people post-stroke can attend existing CR programmes. The Cardiovascular Disease Outcomes Strategy (DoH, 2013) suggested the use of existing cardiac rehabilitation programmes for Transient Ischaemic Attack (TIA) patients and mild disability stroke patients, however, this did not take into account the concerns and levels of training needed for the existing CR teams.

The ‘attitudes to healthy lifestyle’ and ‘attitude to behaviour change’ themes identified that the two teams had a different awareness of their roles in relation to healthy
lifestyle advice and behaviour change. The CR teams saw this as a key aspect of their role, however, the stroke teams did not have the time, opportunity and some felt, the knowledge, to do this, which reflects what was seen in previous research by Wang et al (2001). Provision of training for stroke healthcare professionals related to healthy lifestyles may be indicated. There is also a clear need to address healthy lifestyle messages with the stroke population, as a number of studies have found that people post-stroke are not recalling the healthy lifestyle messages given post-stroke (Lawrence et al., 2010, Hillsden et al., 2013 and Clague-Baker et al., 2017).

Understanding healthy lifestyles is part of the process for behaviour change. One theory of behaviour change, the Trans-Theoretical Model (Prochaska et al., 2005), identifies that people go through five stages of change from pre-contemplation, contemplation, preparation, action and maintenance. Both teams appeared to be aware of the range of acceptability to change post-stroke, with some patients being ready for action whereas some patients were in the pre-contemplation stage. However, the stroke teams identified that early provision of information on the acute stroke unit would be too soon to address needs post stroke. This was also identified by Lawrence et al., (2010) who discussed the importance of providing essential information in the community. Lawrence et al (2010) and Smith et al (2008) both demonstrated that providing written information was not enough and that the patient and their family need to be actively involved in the learning process. CR provides this opportunity for people post-stroke.

The COM-B system (Michie et al, 2011) is another theory of health behaviour, it identifies that behaviour relates to the physical and psychological capability, the opportunity (environment) and the motivation (conscious and unconscious) to exercise. This thesis found that CR and stroke healthcare professionals had varying perceptions of the capabilities of people post-stroke to exercise but they agreed most people post-stroke were motivated to be active in the sub-acute phase of recovery. The opportunity to exercise appears to be the main barrier post-stroke, previous research has found that there is a lack of physical activity programmes for people post-stroke (Lau et al., 2016, Mead and van Wijck, 2013) and lack of training for exercise professionals (Wiles et al., 2008, Condon and Guidon, 2018). CR may provide a solution to this lack of opportunity as long as CR teams are trained and supported by specialist stroke physiotherapists.
7.3 Objectives 5 and 6

Chapters 1, 2 and 5 report on the background literature, method and results of a quantitative study that aimed to measure the concurrent validity of the ISWT, 6MWT with the ICT and to test the test-retest reliability of the ISWT and the 6MWT.

The study found that both the ISWT and 6MWTs correlated significantly with the gold standard of VO$_2$ peak, although the association was modest. The study also aimed to determine the test-retest reliability for the ISWT and the 6MWT, and found that there was variability between the first and second tests. This was different to previous studies for the ISWT that found the test to be reliable with respiratory (Singh et al., 2014), cardiac (Hanson et al., 2016) and chronic stroke patients (Van Bloemendaal et al., 2012), and previous results for the 6MWT with cardiac (Pollentier et al., 2010), respiratory (Casanova et al., 2007) and chronic stroke patients (Eng et al., 2004). As with previous studies, it was found that there was a learning effect with both tests, and therefore the recommendation would be that two ISWTs and two 6MWTs are completed, with the results of the second test used.

In relation to the validity of the tests, one of the reasons why there was only a modest correlation between the tests appeared to be due to the range of residual neurological impairment studied from 0 (none) to 8 (moderate) on the NIHSS scale. A strong correlation was seen between the ICT and both clinical tests in patients with no residual neurological impairment. Therefore, the ISWT or 6MWT could be used to measure CRf or cardiovascular capacity in such patients. In those with residual neurological impairment, there was only a modest correlation. However, it needs to be acknowledged that the study was not powered for these sub-group analyses. In addition, this may in part be because some patients found it difficult to complete the walking-based tests compared to the cycle test. Nonetheless, the majority of patients completed the ICT without assistance; only two patients needing their affected foot strapped to the pedal and support with their arm, and one patient help to initiate pedalling. Furthermore, the majority of patients preferred the cycle-based test (60%). This indicates that further research is needed to explore the most valid measure of CRf in people with residual neurological impairment post-stroke in order to inform guidelines (Best et al., 2010 and Mackay-Lyons et al., 2013).
However, additional questions need to be addressed in respect of the use of a cycle-based test. First, whether a conventional or recumbent cycle should be used. Tang et al (2006) used a semi-recumbent position for testing, but found that this “may not help to address the potential problems arising from local limb fatigue related to motor dyscontrol or asymmetry” (Tang et al., 2006, p.1104). Although six of the patients in this study complained of pain with the cycle test, only two were related to the seat of the cycle and the rest were due to leg pain that occurred with all of the tests. Secondly, it is still important that stroke patients can achieve VO$_2$ peak even if it is as a cycle-based test. Cycle-based VO$_2$ testing measures 10% to 15% lower than treadmill-based tests in healthy adults because a treadmill test “permits a larger muscle mass to be brought to bear ...and more work against gravity is done, leading to greater stress on the organ systems mediating the exercise response” (ATS, 2003, p.218), but Tang et al (2006) highlighted the importance of measuring VO$_2$ peak as accurately as possible to ensure that the exercise prescription is appropriate. Therefore, clinical incremental cycle-based tests need to be devised to measure the CRf of sub-acute stroke patients with a stroke severity greater than 0 on the NIHSS.

The exclusion criteria and termination of testing procedures were based on ACSM guidelines (Heath, 2005) and are all based on cardiac contraindications. These enabled a safe and acceptable level of testing for the stroke population studied. It is recommended that BP limits for ischaemic stroke patients are set at 200/110mmHg and for haemorrhagic stroke at 180/100mmHg, as although ten tests were stopped by the therapist due to hypertension, six of those patients achieved an RER over one. Indeed, compared to previous studies with subacute stroke patients, where only 44% of patients achieved RER (Tang et al., 2006), a high percentage of patients in this study (78%) achieved RER. It is also recommended that the MHR is set at 90% of the age-predicted MHR, as only five patients were stopped due to maximum HR limits and three of those achieved an RER over one. However, it may be necessary to add more stroke-specific exclusion criteria for testing based on some issues identified. One patient had a 2 cm brain aneurysm, and another patient had greater than 50% bilateral carotid stenosis; both of these patients were excluded by their treating stroke consultant. It is therefore, recommended that cerebral aneurysms and >50% carotid stenosis should be
added to the list of exclusion criteria for future studies investigating VO2 peak with stroke patients. Further investigation of stroke specific contraindications should be considered, such as post-stroke epilepsy and tonal issues.

As has been seen in other studies (Tang et al., 2006 and Kelly et al., 2003), VO2 peak values were significantly lower than age-related data. Indeed, the mean values of 12.1 mL/kg/min reported for sub-acute recovery stroke patients in this thesis were lower than the 15mL/kg/min required for independent living (Mackay-Lyons and Makrides, 2004). This further supports the need for cardiovascular training for sub-acute, mild-to-moderate stroke patients as recommended by the NICE guidelines (Dworzynski et al., 2013).

7.4 Objectives 7, 8, 9 and 10

Chapters 1, 2 and 6 report on the background literature, method and results of a mixed method cohort study that aimed to identify the acceptability, recruitment strategy, adherence, outcome measures and adaptations needed for adapted CR for people post-stroke with a mild-to-moderate severity stroke in the sub-acute stage of recovery. In addition, the aim was to conduct a qualitative interview-based study with people post-stroke and people post cardiac event who took part in CR and with people post-stroke who did not take part in CR to explore experiences of CR and attitudes to healthy lifestyles after stroke and cardiac events. The final aim was to conduct a qualitative focus group study with healthcare professionals who work in CR and stroke to explore experiences of CR for people post-stroke and their attitudes to healthy lifestyles post-stroke.

7.4.1 Acceptability

Phase IV identified that people post-stroke found CR to be acceptable and even enjoyable. However, the stroke population with persistent neurological deficit (NIHSS >2) commented that they felt embarrassed and self-conscious and would have preferred a stroke only service, this was also observed by the CR staff. The staff also identified that these patients needed more physical support and specialist advice from the stroke physiotherapists. The cardiac patients in the CR groups also found it acceptable for the stroke patients to take part in the CR programmes. The CR teams
initially lacked confidence with this population and the stroke teams lacked confidence in the CR teams.

This is the first study that has explored the acceptability of CR for the stroke population from a number of different perspectives. Hillsden et al. (2013) identified that a group of TIA and minor stroke patients (NIHSS <3) who took part in a non-adapted CR programme were satisfied with the programme, but would have preferred a more stroke-specific education programme. They did not, however, explore the perspectives of the cardiac patients and the staff conducting the programme. For a future definitive study, it would be advantageous to only include patients with an NIHSS <3, this would reduce the negative impact on the more disabled stroke population and increase the confidence of the CR team to provide the support this population would need.

7.4.2 Ability to recruit people post-stroke for CR

It was possible to recruit people post-stroke who had an NIHSS score up to six but due to the inclusion criteria requiring the ability of the patients to walk 10 metres this excluded people with more stroke severity. Previous research with CR and stroke have only recruited mild disability stroke patients or TIA patients (Lennon et al., 2008, Tang et al., 2010, Marzolini et al., 2014, Prior et al., 2011, Kirk et al., 2014, Marzolini et al., 2016), there has been a limited amount of research exploring the use of CR for a more severely disabled stroke population. Stoller et al. (2012) conducted a small study with patients who had severe motor deficit within 23 days post-stroke, they found that treadmill walking with body weight support was feasible and safe. More research is needed with this more severe population.

It was also difficult to recruit people post-TIA due to the patients wanting to get back to work and not being able to find time to fit the sessions in to their life. This was also observed by Kirk et al. (2014), although Marzolini et al. (2016) did not report difficulties recruiting TIA patients for their CR study in Canada. For a future definitive study, the target population would ideally be people with a mild severity stroke (NIHSS <3) in the sub-acute phase of recovery as this population was the easiest to recruit. People post TIA and more severe strokes may need studies that focus specifically on their needs, for
example, web-based programmes for TIA patients as has been successful for cardiac populations (Houchen-Wolloff et al., 2018).

7.4.3 Adherence to CR

Phase IV of this thesis also identified that 80% of classes were attended. There were six dropouts due to medical reasons, and two of the patients preferred to come only once a week due to fatigue and timing of the classes. This compares favourably to other CR programmes with cardiac patients of 77% adherence (British Heart Foundation, 2016), and previous studies of CR with TIA patients, with an adherence of almost 73% (Marzolini et al., 2016).

7.4.3.1 Barriers to attendance and recruitment into CR

1. Motivation

Some of the barriers to attendance of CR and to exercise post-stroke, identified in Phase I and Phase IV of this thesis, showed that people post-stroke in the sub-acute recovery stage, had environmental, personal and social barriers to exercise but these did not include motivation. This differed to findings from Nicholson et al (2012) who found that people in the chronic stage of recovery lacked motivation to exercise. Behaviour change models such as the COM-B model (Michie et al., 2014) identify the importance of motivation, both reflective and automatic, to establish behaviour change. If people post stroke are initially motivated to exercise but then lose this motivation in the chronic stage of recovery it suggests that there needs to be more opportunity for people post-stroke to take part in exercise. CR appears to provide one avenue to increase this opportunity.

2. Fatigue

Interestingly, in comparison to the cohort in Phase I who did not take part in CR, the group in Phase IV who took part in CR did not identify fatigue or falls as personal physical barriers to exercise. In fact, over half the patients felt that CR reduced their fatigue over the six week intervention. This links to findings in other populations where exercise was found to be beneficial for fatigue in chronic fatigue patients (Larun et al., 2017), MS patients (Heine et al., 2015) and people with cancer (Kessels et al., 2018). The prevalence of fatigue in people post stroke has been reported as between 43%
(Drummond et al., 2017) to 57% of the stroke population (Choi-Kwon et al., 2005). O’Connell and Stokes (2007) reported that “Post-stroke fatigue has been demonstrated to be related to poor neurological recovery, reduced functional ability, decreased quality of life and, possibly, high mortality” (O’Connell and Stokes, 2007: p.321). It also appears to be related to low mood and poor mobility (Drummond et al., 2017).

Research exploring the effect of exercise on fatigue in people post-stroke is limited, Flynn and Stube (2010) identified the incidence and impact of fatigue, and reported that for some people post-stroke exercise was beneficial. Duncan et al. (2012) concluded in their systematic review that “there is very limited evidence regarding associations between exercise, fitness, and fatigue after stroke. It still remains highly plausible that exercise can have a positive influence on fatigue. Future research should be longitudinal in design” (Duncan et al., 2012, p.157).

3. Tone

The effect of exercise on tone was seen as a barrier for the stroke teams. They were reluctant to refer patients to a CR programme as they felt that this would increase their tone and result in further asymmetry and potential for falls. This did not prove to be the case. A future study would therefore need to consider perceived personal barriers such as fatigue, falls and tone, and provide reassurance to patients and stroke staff that CR may not have a negative effect on any of these aspects in fact may have a positive effect on fatigue.

4. Environmental

Environmental barriers were consistently identified by Phase I and Phase IV patients, and reflect previous research with the stroke population (Nicholson et al., 2012). A definitive study will need to anticipate the environmental barriers such as cost and transport issues and therefore aim to provide transport for the patients.

7.4.4 Outcome measures for measuring the effectiveness of CR

7.4.4.1 Questionnaires

The questionnaires used in Phase IV of this thesis were easy to complete, although time-consuming particularly for patients with cognitive and speech deficits. The questionnaires used provided important information on fatigue (MFIS), anxiety,
depression (HADS), quality of life (SF-36), function (BI), stroke knowledge and healthy lifestyle attitudes (SAKQ), and falls. All questionnaires demonstrated changes over time except the falls diaries. The BI, HADS and SF36 are well-known questionnaires for measuring function, anxiety, depression and quality of life, respectively, but the MFIS for measuring fatigue is less well-known. There are over 50 scales for measuring fatigue but the Fatigue Severity Scale (Krupp et al., 1989) appears to be the more popular fatigue scale used with the stroke population so for the definitive trial further review of fatigue scales may be necessary. 

The Stroke Attitude and Knowledge questionnaire

The Stroke Attitude and Knowledge questionnaire (SAKQ) was specifically designed for this study, and needs further validation and reliability testing before it can be used for a definitive study. There is a lack of standardised measures for measuring knowledge of stroke and attitudes towards healthy lifestyles in people post stroke. Forster et al., (2012) conducted a Cochrane review to assess the effectiveness of information provision strategies in improving the outcome for stroke patients. Of the ten trials that assessed stroke knowledge, all used different questionnaires and only three of those questionnaires were validated. For a definitive study, further work will need to be completed to determine the most effective, valid and reliable measure of stroke knowledge and attitudes.

Falls diaries

Finally, the incidence of falls in the stroke population has been reported as nearly 40% in inpatient settings (Nyberg and Gustafson, 1995), and up to 70% in community settings (Weerdesteyn et al., 2008). The documentation of falls is easier in the inpatient setting as staff can document these on incidence forms, however, in the community settings recall can be a problem. As has been seen with general falls research, the accuracy of self-reported falls without diaries is poor (Mackenzie et al., 2006), so prospective falls diaries are important to determine the effect of CR on the incidence of falls. Falls diaries were used for this thesis and gathered information about the number of falls the patients experienced over the six weeks of CR. All patients managed to complete the diaries sometimes with help from their carers. For a
definitive study use of falls diaries will be important to prompt accurate recall of falls in the patients.

7.4.4.2 Physical measures

ISWT

The physical outcome measures used in this thesis included the ISWT, BP, HR, weight, height, BMI, Modified Ashworth Scale (MAS) and accelerometry. The ISWT showed positive changes over time for people in the mild severity category (NIHSS <3) and moderate severity category (NIHSS >2). However, as was seen in Phase III of this thesis, the correlation of the ISWT with the VO\textsubscript{2} peak measured with the ICT was only modest for people with a measurable post stroke neurological deficit (NIHSS >0). In addition, it needs to be acknowledged that a number of the subjects in the validity study had physical limitations such as cardiac, pain and fatigue which restricted their ability to achieve a peak VO\textsubscript{2}. For a definitive study that includes people with stroke severity NIHSS <3, it needs to be acknowledged that the ISWT may not be measuring VO\textsubscript{2} peak, and that a cycle-based test might be the best way to measure cardiorespiratory fitness in a stroke population with a measurable post stroke neurological deficit (NIHSS >0).

Cardiovascular risk

BP and HR changes were limited over the six week intervention, but this was to be expected and was seen in previous studies with stroke (Kirk et al., 2014) and cardiac patients (Joliffe et al., 2001, Taylor et al., 2004 and Clark et al., 2005). A definitive study would need a significantly larger study population to determine an effect on BP and HR. This highlights a significant dilemma with these studies, that is, should the main outcome be CRf or cardiovascular risk profiles? Previous studies using CR with the stroke population have either had CRf as their main outcome (Tang et al., 2010, Marzolini et al., 2014 and Marzolini et al., 2016) or cardiovascular risk (Lennon et al., 2008, Prior et al., 2011, Kirk et al., 2014). Cardiovascular risk profiles collect: lipid profile; C-reactive protein (measured with a high sensitive assay), fibrinogen levels and blood glucose. The Framingham Risk score (Levy and Wang, 2013) has been used in cardiac studies to calculate the risk of developing cardiovascular disease (CVD) over ten years based on age, gender, cholesterol levels, smoking status, diabetic status and systolic BP. The QRisk algorithm (2016) also calculates the risk of developing CVD.
However, both measures require that the subject does not already have CVD. The patients in a future definitive study will already have CVD so these risk scores would not be appropriate.

Other measures of risk include MRI/CT scans and ultrasound scans to detect the presence of atherosclerosis. Muntendam et al. (2010) used CT scans and MRI scans to assess the presence of atherosclerosis in coronary arteries and carotid arteries over time in asymptomatic individuals, and Hollander et al. (2003) used ultrasound scans of carotid and aortic arteries to determine the risk of stroke in healthy volunteers. These measures may be potential outcomes for a definitive study, however, it is not clear if six weeks of CR would have an impact on these factors and the size of the study cannot be determined without pilot study data. Therefore, a definitive study of the effect of CR based on the present thesis would need to focus on measuring CRf.

Obesity measures
Measuring weight, height and BMI is important to determine the effect of CR on obesity as a risk factor for stroke. The measures showed some change over time but it could be argued that six weeks will not demonstrate a significant change in weight over time. In fact, successful weight loss is seen as losing 10% of body weight and maintaining this over one year (Wing and Phelan, 2005). It is also important where the fat is lost as the presence of abdominal fat is significantly correlated to increased CV risk (Lee et al, 2016). So a definitive study might benefit from measuring skin folds or waist circumference as well as BMI.

Tone measures
The incidence of high tone or spasticity post stroke has been documented between 17% to 43% of people post stroke (Urban et al., 2010). Measurement of high tone varies from the use of quick assessment measures, such as the Modified Ashworth Scale (MAS) used in this thesis, and the Modified Tardieu Scale, to functional tests and electrophysiological measures. The present study in this thesis found that the MAS did measure change in tone over the six weeks of CR, however, two assessors varied in their measurement of tone. This has been seen in previous research, Thibaut et al., (2013) found that the MAS had poor inter-rater reliability, but moderate to good intra-
rater reliability. Therefore, for a definitive trial the Modified Ashworth scale could be used to measure change in tone but other measures might be more appropriate. If the MAS was used only one therapist should collect the data to improve the reliability of the results (Thibaut et al., 2013).

Measurement of Activity levels
Phase IV of this thesis used tri-axial accelerometry to measure physical activity and sedentary behaviour post-stroke and post CR. Physical activity has been shown to be significantly reduced and sedentary behaviour increased post-stroke (Butler and Evenson, 2014). Measuring physical activity post-stroke can be achieved using questionnaires or accelerometry. Accelerometry has been shown to be superior to self-reported questionnaires, although Skender et al. (2016) recommend the use of both to obtain complete physical activity data. For the definitive study, as the patients are completing a number of questionnaires, physical activity would be best measured with accelerometry.

Measures of stress
Finally, over half of the patients in the interviews in Phase IV of this thesis identified stress as a significant contributor to their stroke. This replicates findings from a meta-analysis (Booth et al., 2015) which found that “perceived psychosocial stress was independently associated with the risk of stroke” (Booth et al., 2015: 1). Phase IV of this thesis used the HADS and could be seen to be measuring stress through the anxiety questions, however, a definitive study may consider other measures of stress. These can include questionnaires such as the Perceived Stress Scale (Cohen et al., 1983) or physical measures such as using saliva to measure the level of the hormone, cortisol (Centre for studies on human stress, 2007). Further work would need to be completed to determine the most appropriate measure of stress with the stroke population.

7.4.5 Adverse events during CR
There was one adverse event associated with the warm-up in one class. However, there were no changes needed to be made to the class as a result of this, the patient was subsequently withdrawn from the study due to HR issues.
7.4.6 Adaptations to CR for people post-stroke

7.4.6.1 Staff adaptations

Specialist stroke staff

Interviews with patients in Phase IV of this thesis identified that a significant number of them felt that they needed the support of specialist stroke physiotherapists due to the stroke physiotherapists knowledge of stroke and how to treat people post-stroke. This was also reflected in the focus groups with CR and stroke staff before and after the CR programmes. Both the CR and stroke teams were aware of the environmental and social barriers to attending CR for people post-stroke, but the stroke teams were more aware of the range of physical and cognitive personal barriers. This highlighted a lack of knowledge of stroke in the CR teams which they acknowledged themselves. In fact, this lack of knowledge led to a lack of confidence in the CR teams to provide a CR service for people post-stroke. This has not been identified in previous research, although a study with exercise professionals by Condon and Guidon (2018) found that exercise professionals are interested in working with people with stroke despite their limited experience and knowledge. Wiles et al (2008) also found that attitudes of physiotherapy staff in the United Kingdom towards exercise on prescription schemes was positive. However, they were also concerned about the level of stroke knowledge and limited monitoring of the instructors.

Specialist training of non-stroke staff

Despite this obvious lack of knowledge and experience of exercise professionals and other staff in ongoing exercise programme such as CR, training programmes are limited. Only two sources of accredited training are available in the UK for exercise professionals; Laterlife training (Laterlife training, 2018) and The ARNI Institute (ARNI Institute, 2018). The Stroke Association (2018) is conducting a pilot ‘Moving Forward After Stroke’ programme across the UK to provide neuro-physiotherapy with some sessions provided by specialist Exercise Professionals for 12 weeks after discharge from early therapy. People post-stroke are divided into high, medium and low levels of ability and referred for the appropriate level of exercise. The results of this pilot are still to be analysed. This programme highlights the importance of identifying which people post-stroke need more specialist input from physiotherapy and who can be seen by exercise...
professionals. The present study also identified this need with CR teams identifying that support from specialist stroke physiotherapists for the more disabled people post-stroke is important. It appears that with extra training and support, CR staff could provide CR for people post-stroke who have low levels of disability, defined in this thesis as people with an NIHSS score less than 3.

7.4.6.2 Educational programme adaptations

Further adaptations needed

The adapted CR education programme in Phase IV of this thesis provided education on stroke and living a healthy lifestyle. The weekly discussions after each exercise class provided advice and support in relation to: medications, goal-setting, phase IV programme, diet, and rating of perceived exertion (RPEs). The stroke patients felt that the information provided about stroke by the specialist stroke physiotherapists, was appropriate and informative. However, they felt that the healthy lifestyle messages and weekly discussions were not always targeted or relevant to them. It appears that there would need to be further adaptations to the education programme in order to address the needs of the stroke patients. Some of these adaptations include: changing the name of the CR programme to make it more stroke specific, discussing causes of stroke and how it relates to their specific situation, and how to make specific changes in their lifestyle if necessary.

7.4.7 Additional discussion points

7.4.7.1 CR increases knowledge

Phase I of this thesis identified that people post-stroke in the sub-acute phase of recovery appear to have limited knowledge of: stroke and the causes of stroke; the link between lifestyle risk factors and stroke occurrence; healthy lifestyles and how to change their lifestyles; and benefits of exercise for cardiorespiratory fitness. Phase IV nonparticipants also lacked this knowledge. In both groups there appeared to be a lack of provision of healthy lifestyle advice. Phase IV of this thesis, however, showed that adapted CR could increase knowledge of all of these aspects except cause of stroke, in patients with no cognitive deficit.
**7.4.7.2 Stroke education for those with cognitive difficulties**

Those patients with cognitive deficit had problems recalling the information they had been given. This adds to findings from Hillsden et al (2013) who found that there appeared to be a lack of knowledge in people post-stroke but they did not link this to cognitive deficits. This indicates a need for more research into the most effective way to provide healthy lifestyle information to people post stroke particularly people with cognitive deficits.

**7.4.7.3 Stress and incidence of stroke**

In relation to knowledge of cause of stroke, a significant number of both stroke cohorts (Phase I and Phase IV) were unable to identify the cause of their stroke. Stress was identified by over half the people who could identify a cause of their stroke in the Phase IV cohort. A meta-analysis conducted by Booth et al., (2015) found that “Current evidence indicates that perceived psychosocial stress is independently associated with increased risk of stroke” (Booth et al., 2015: p.233), and a systematic review by Backé et al., (2011) also found that work related stress was significantly correlated with an increased risk of cardiovascular disease. Return to work programmes post-stroke need therefore, to take into account that returning a person back to the same work environment could place them at increased risk of further events. There is a lack of research that explores the impact of stress reduction strategies on the incidence of stroke or risk factors. More research, therefore, is needed to determine the effect of stress management programmes, which could include exercise, on the incidence of stroke and risk factors for stroke.

**7.4.7.4 Education and Behaviour change**

The CR programme aims to encourage behaviour change through: motivating patients to change; and providing the opportunity and capability (through changing knowledge, attitudes and skills) to change. In order to motivate the patients, the CR programme discusses the benefits of healthy lifestyles. During the focus groups in Phase IV of this thesis both CR and stroke teams were positive about the benefits of exercise post-stroke, and identified that people post-stroke in the sub-acute phase of recovery were motivated to exercise. Interestingly, it appeared that the stroke teams had limited time to focus on cardiovascular exercise and team members other than physiotherapists had
a limited knowledge of CRf. So providing adapted CR has the potential to support people post-stroke by providing the opportunity and motivation to change behaviour.

CR also has the potential to offer the capability to change behaviour through education and advice on goal-setting. The patients in Phase I and Phase IV identified that they had not been given any advice about keeping fit and maintaining a healthy lifestyle. Healthy lifestyle advice and behaviour change were key aspects of the roles of the CR teams, however, the stroke teams identified a lack of time and some had a lack of knowledge of healthy lifestyle. This links with a previous study by Wang et al (2001) who identified a lack of knowledge about stroke in Chinese health professionals leading to only 28% of people post-stroke being encouraged to exercise. More research is needed to identify the most effective ways to encourage healthy lifestyles post-stroke and behaviour change.

Therefore, a definitive study of CR for people post-stroke needs to identify the most effective way to educate people post-stroke about: stroke and the causes of stroke; the link between lifestyle risk factors and stroke occurrence; and healthy lifestyles and how to change their lifestyles in order to produce behaviour change.

7.4.7.5 Class adaptations
It was found that the existing class warm-up, exercises and stations and cool-down were appropriate for the stroke patients although certain adaptations were needed: close supervision and chair support in warm-up standing activities; assistance and support with step ups, side-steps and step backs; motormed machines for those that could not get on a static bike or treadmill; use of mirrors for visual feedback; support of arm on static bike; and not using the treadmill for the more disabled patients.

7.4.8 Completion of Objectives
All objectives of the thesis have been met, it is possible to progress to a definitive trial although some questions still remain. The following chapter provides a conclusion of the thesis and recommendations for the future definitive study and areas still to be addressed.
Chapter 8 Conclusion, Strengths, Limitations and Future research

8.1 Conclusion

A definitive study investigating the effect of CR on people post-stroke in the sub-acute phase of recovery is acceptable. It has been found that adapted CR for people post-stroke is acceptable to cardiac patients and CR teams for people with very mild severity stroke (NIHSS <3). However, the more disabled stroke population felt they needed a more specialist service, and the CR and stroke teams felt that specialist stroke physiotherapists would be needed for people with a measurable post stroke neurological deficit (NIHSS >2). It was possible to recruit people post-stroke with an NIHSS score up to six but due to the inclusion criteria requiring the ability of the patients to walk 10 metres, within six months of a stroke, this excluded people with a greater stroke severity. People post-TIA were not easy to recruit due to time issues and the need to return to work. Therefore, a definitive study should aim to recruit people post stroke with a stroke severity measured on the NIHSS of <3.

Adherence to the programme was equivalent to other CR programmes, with 80% of the classes attended. There were six dropouts due to medical reasons and one adverse event. Barriers to attending were identified as environmental, personal and social barriers, but these did not include motivation, fatigue and falls. Environmental barriers need to be considered for a definitive study and transport provided. Some of the outcome measures used in this feasibility study demonstrated change over time and were easy to use and complete (SF36, BI, HADS, accelerometry, falls diary), but some outcome measures needed further consideration due to: acceptability of the measure (MFIS); and validity and/or reliability of the measure (SAKO, ISWT, MAS). Additional measures that might be considered for a definitive study might include: cardiovascular risk profiles; skin fold measurements; and measures of stress. Adaptations needed for a definitive trial included: specialist stroke physiotherapists; a more specific stroke education programme and specialist equipment in the classes.
8.2 Strengths

This thesis used a mixed method approach to explore the use of CR for people post-stroke. The advantages of mixed method approaches are that they “reveal the complexity of disablement, rehabilitation, and recovery processes” (Rauscher and Greenfield, 2009, p.91). The use of interviews before and after CR with people post-stroke provided valuable insight into the barriers to CR, and the knowledge and attitudes towards CR and healthy lifestyles. This helped to inform the recruitment and retention of patients in Phase IV of the thesis, and the composition of the intervention. Focus groups with the CR teams and stroke teams provided important information about barriers to recruitment, adaptations needed for CR, and potential limitations of CR for this population. Also interviews with non-participants and cardiac patients provided additional insights into acceptability, recruitment and barriers to attendance. Phase III (Chapter 5) and Phase IV (Chapter 6) employed quantitative methodologies to collect data related to the validity and reliability of the ISWT and to test the feasibility of CR for people post-stroke. Both qualitative and quantitative methods are essential in rehabilitative research to fully understand the complexity of the patient’s experience and understand the relationships between variables.

A second strength of this thesis is the thoroughness of the methodology of both the qualitative and quantitative studies. The qualitative research methods in Phase I (Chapter 3), II (Chapter 4) and IV (Chapter 6) incorporated numerous strategies to ensure trustworthiness of the data. These included: purposive sampling, triangulation of data collection and analysis, reflexivity, positionality, peer review, collaborative analysis, member checking, prolonged engagement, and data saturation. The quantitative studies, Phase III (Chapter 5) and Phase IV (Chapter 6) benefitted from the support of a statistician and experienced researchers to ensure a reliable and valid method from question and hypothesis formation through data collection, recruitment to data analysis. The small dropout rate in Phase IV and successful recruitment rate throughout, demonstrate this strength.

The attempt to recruit a range of abilities post-stroke can be seen as a strength as it helps to explore the difficulties that people post-stroke with more disability (stroke severity) may have taking part in CR and similar programmes. The involvement of
former stroke patients throughout the project is also a strength, this helped to: identify inclusion and exclusion criteria, establish methods, and support the data collection and analysis.

As Phase IV is one of only two feasibility studies in the UK exploring CR for the stroke population, it adds to the evidence-base exploring CR for people post-stroke and helps to determine more detail needed for the design of a definitive study in particular the inclusion criteria, the intervention and the outcome measures. Although the implications to clinicians and policymakers is limited due to the feasibility nature of Phase IV, the results seem to indicate that CR could benefit a number of aspects of stroke recovery including CRf, fatigue, anxiety and depression, stroke knowledge and attitudes, QOL, and activity levels.

8.3 Limitations

Limitations for individual phases of this thesis have been identified in the individual experimental chapters, these included:

8.3.1 Recruitment strategy

Patients who agreed to take part were keen to take part in an exercise study post-stroke and talk about healthy lifestyles and exercise and their interest in adapting their lifestyle after having had a stroke. As a result, these findings may not reflect a broad range of perspectives and experiences. In addition, it was hard to recruit people from the TIA clinics as they were through the system very quickly so the numbers assessed for eligibility could have been a lot larger as a result. Also the stroke staff on the wards initially spoke to the potential participants and could have introduced selection bias if they did not believe the patient would be able to take part in the CR programme.

People were recruited up to six months post-stroke but the average length of time after stroke varied from 14 days to 124 days. This could have affected the participants’ responses to interview questions as people’s perceptions may have varied over this time period. Most participants were recruited after the Early Supported Discharge service (ESDS) had completed their treatments as it was felt by the stroke staff and patients that they could not cope with CR during active treatment and the CR provided
an opportunity to extend the patients treatment. This meant that the effect of earlier CR was not identified.

Recruitment for focus groups; not all members of the stroke and CR teams were represented. The research team endeavoured to recruit a wide range of staff but it is evident that there were few stroke nurses represented and they may have expressed different perspectives on healthy lifestyles post-stroke.

8.3.2 Design of the qualitative studies

It could be suggested that focus groups do not allow participants to expand on their own viewpoints due to the range of individuals involved. However, it was felt that the advantages of the focus group paradigm, particularly the ability to stimulate conversation, outweighed this limitation.

There was a potential bias using healthcare professionals as interviewers and data analysers. Although bracketing was employed and an experienced qualitative supervisor was involved throughout the data collection and analysis, it is recognised that there will always be an element of influence and bias due to the education, beliefs and opinions of each healthcare professional involved.

Qualitative data analysis using interpretive thematic analysis can be seen as subjective and lacking in consistency and cohesion. Although the study employed collaborative analysis, it needs to be acknowledged that the themes identified were similar to the themes identified in the interview schedule and that perhaps further analysis and interpretation might have identified other themes.

8.3.3 Design of cohort study

The main limitation of this study was the lack of a control group. As this was a feasibility study the aim was not to compare groups, however, it may have provided more pilot information for a definitive study if a control group had been recruited. As there was no control group it was not possible to understand the change in the control group so therefore it was not possible to calculate the sample size for a definitive study. The change in the ISWT needs to be that of a meaningful difference either known to be associated with an important health outcome or important to an individual. This study
did not provide this information. In addition, the cohort feasibility study could have collected data over a longer period of time to identify the effects of the intervention on readmissions, falls rates etc. This, however, was not possible due to funding restraints.

Although the OMs used in this study were shown to be acceptable for this study there are limitations to these measures. As has been discussed in Chapter 5 of this thesis, the ISWT is a sub-maximal measure of CRf and so a definitive study may need to use an ICT to determine CRf or employ portable VO$_2$ measurements to determine the effect of CR on CRf. Also basing the sample size on this measure might be seen as a limitation, as cardiovascular risk might be a better final outcome.

The following limitation relate to the thesis as a whole:

### 8.3.4 Mixed method designs

Bergman (2011) identified the following difficulties with mixed method designs: the merging of different philosophies; the demarcation of the two approaches in the study; the differing questions and sampling methods; and the complexity of the combination of the results. Bryman (2007) explored other difficulties related to mixed method studies, and found that the main difficulties with mixed methodologies were the analysis and integration of the results. He identified that mixed method researchers analysed the data separately, and published the data in different journals due to journal preferences and researcher expertise. To reduce this difficulty, in the present thesis the qualitative data was analysed separately from the quantitative data but where possible was combined with the quantitative data to provide a richer analysis.

### 8.4 Future research

The present thesis identifies that a definitive study would need to recruit a mild stroke population (NIHSS <3) between one week and six months post-stroke. The participants would have baseline measures taken prior to attending adapted CR and immediately after the six week programme. These baseline measures have been identified as: HR, BP, BMI, ICT to measure CRf, Accelerometry to measure activity levels, HADS to measure anxiety and depression and the SF36 to measure quality of life.
The CR would need to be adapted so that the classes had a specialist stroke physiotherapist available and specialist equipment available such as motormed machines and slow treadmills. A maximum of three people post-stroke could attend the classes. The education programme would need to include information about stroke types and incidence and relate healthy lifestyles to the stroke population as well as the cardiac population. The CR teams will need to be trained to support people post-stroke with the assistance of the stroke physiotherapists, so that they can support people with cognitive deficit, communication deficits, sensory changes, painful shoulders, balance and gait difficulties, awareness of orthotics etc. In addition, transport would need to be provided so that people post-stroke could attend the classes.

The present study raises further questions about how to measure: functional ability, CV risk, muscle tone, stress, fatigue, stroke knowledge and behaviour change, all of which would be valuable to measure in a definitive study. In addition, the sample size of the study remains unanswered and the length of the follow-up needs to be addressed. Finally, the need for health economic evaluations would need to be added to a definitive study.

Future studies are also needed to explore the effect of reducing the length of programmes and even explore online programmes as has been developed for cardiac patients. It is also important to investigate how CRf can be increased and cardiac risk can be reduced in a more severe stroke population (NIHSS >2), and to determine what is the earliest that CV training can be introduced post-stroke. It is recommended that future rehabilitation research is more specific to the level of ability (stroke severity) of the people post-stroke, as some rehabilitation research attempts to generalise treatments to all levels of ability. People post-stroke with different levels of ability may require different rehabilitation interventions. Finally, studies need to be devised that explore the impact of CR and CV training on carers of people post-stroke, and the best way to support carers throughout this traumatic time.
Appendices

Appendix 1 – Search strategies

Appendix Table 1  Search strategy for cardiovascular exercise for people with stroke

Databases: CINAHL, AMED and MEDLINE (date: 3/4/2019)

<table>
<thead>
<tr>
<th>Query</th>
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<td>Interface - EBSCOhost Research Databases</td>
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<td>cardiovascular AND fitness</td>
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<td>a/a</td>
</tr>
<tr>
<td>S2</td>
<td>stroke or CVA</td>
<td>a/a</td>
<td>a/a</td>
</tr>
<tr>
<td>S1</td>
<td>Cardiovascular fitness and stroke or CVA</td>
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Appendix Table 2 Search strategy for CR and stroke

Databases: CINAHL, AMED and MEDLINE (date: 3/4/2019)

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Appendix Table 3  Search strategy for OMs for CRf and stroke

Databases: CINAHL, AMED and MEDLINE (date: 3/4/2019)

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<td>---------------------------------------------------</td>
</tr>
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Appendix Table 4 Search strategy for attitudes to and knowledge of Healthy lifestyles and stroke

Databases: CINAHL, AMED and MEDLINE (date: 3/4/2019)
feelings or beliefs

<table>
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<td>S1</td>
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</table>

Appendix Table 5 Search strategy for attitudes to exercise and healthy lifestyles post-stroke in health-care professionals

Databases: CINAHL, AMED and MEDLINE (date: 3/4/2019)

<table>
<thead>
<tr>
<th>Query</th>
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### Appendix Table 6

Search strategy for attitudes to people post-stroke taking part in cardiac rehabilitation

Databases: CINAHL, AMED and MEDLINE (date: 3/4/2019)

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</tr>
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<td>a/a</td>
</tr>
<tr>
<td>S3</td>
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<td>a/a</td>
<td>a/a</td>
</tr>
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<td>S2</td>
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<td>a/a</td>
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<td>Limiters/Expanders</td>
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<td>-------</td>
<td>-------------------</td>
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<td>---------</td>
</tr>
<tr>
<td>S5</td>
<td>(stroke patients) AND</td>
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</table>

Appendix Table 7 Search strategy for experiences of CR

Databases: CINAHL, AMED and MEDLINE (date: 3/4/2019)

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</thead>
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</tr>
<tr>
<td>S3</td>
<td>attitudes or perceptions or opinions or thoughts or feelings or beliefs</td>
<td>a/a</td>
<td>a/a</td>
</tr>
<tr>
<td>S2</td>
<td>stroke or cerebrovascular accident or cva</td>
<td>a/a</td>
<td>a/a</td>
</tr>
<tr>
<td>S1</td>
<td>cardiac rehabilitation or cardiac rehab</td>
<td>a/a</td>
<td>a/a</td>
</tr>
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<td></td>
<td>(S1 AND S2 AND S4)</td>
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</tr>
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</table>
### Appendix 2 – Phase I

Appendix Table 8.1 Bracketing for all qualitative work

<table>
<thead>
<tr>
<th>Personal characteristics</th>
<th>Personal beliefs</th>
<th>Effect on the research</th>
</tr>
</thead>
<tbody>
<tr>
<td>White middle class</td>
<td>People from Asian cultures may have less opportunity and motivation to exercise particularly females. People who work in manual jobs may have less knowledge of healthy lifestyles and less opportunity to exercise.</td>
<td>Awareness of these beliefs and ensure my questioning of people from different cultures and different socioeconomic backgrounds is fair and open. Ensure that my body language does not indicate that I have different views or knowledge of the subject, remain neutral. Ensure that collaborative analysis is completed for all of the data.</td>
</tr>
<tr>
<td>50 year old female</td>
<td>Older females are less likely to exercise than males although younger females may exercise to the same level as males.</td>
<td>Recognise this belief and question this assumption. Make sure the recruitment strategy is open to everyone and that the questioning allows all patients to explain their beliefs without prompting. Ensure that my body language does not indicate that I have different views or knowledge of the subject, remain neutral. Ensure that collaborative analysis is completed for all of the data.</td>
</tr>
<tr>
<td>Physiotherapist with 30 years of practice</td>
<td>Exercise is positive and people should be encouraged to exercise and live a healthy lifestyle.</td>
<td>Recognise this belief and ensure that people who are less positive about exercise are recruited. Ensure that the questioning allows all patients to explain their beliefs without prompting. Ensure that my body language does not indicate that I have different views or knowledge of the subject, remain neutral. Avoid wearing clothes that identify me as a physiotherapist, introduce</td>
</tr>
<tr>
<td>Healthy with no medical conditions</td>
<td>It is possible for most people with stroke and other medical conditions to exercise with support. It may be that people post-stroke could be afraid of exercise and need support.</td>
<td>Recognise this belief and ensure that the recruitment process allows an open selection of patients within the exclusion criteria. Ensure that the questioning allows all patients to explain their beliefs without prompting. Ensure that my body language does not indicate that I have different views or knowledge of the subject, remain neutral. Ensure that collaborative analysis is completed on all the data.</td>
</tr>
<tr>
<td>Specialist Neurological physiotherapist</td>
<td>Beliefs about the need for specialist stroke physiotherapists to treat people post-stroke</td>
<td>Recognise this belief and ensure that this perception does not influence the questioning in the focus groups. Ensure that collaborative analysis is completed on all the data.</td>
</tr>
</tbody>
</table>
Interview schedule for Phase I

Thanks for agreeing to take part

This study is about the experiences and thoughts of people who have had a stroke. I’m going to ask you some questions which will help us to understand your ideas in particular about your attitudes to exercise after having a stroke.

I would just like to remind you that I will be taping this conversation but as soon as it is typed up the information will be anonymous. The recording and typed transcript will be kept securely on an encoded memory stick.

Do you have any questions before we start?

How are you feeling now you are at home/going home?

How was your experience in hospital?

How would you say you are coping with life after having had a stroke/TIA?

Is there anything that you have found that has helped you cope?

What thoughts do you have about your future?

Do you consider yourself a positive or negative person?

Has this changed since you had a stroke?

Did you used to feel that you had control over your life?

Do you feel that you now have control over your future?

How active were you before your stroke?

Prompts – Formal/Informal

What did you consider to be the appropriate amount of activity to keep someone your age healthy?

Do you think this has changed now that you have had a stroke?
Do you plan to do more or less activity now you have had a stroke?
Why?

Does your partner/spouse/family take part in exercise?
Does this affect your attitude to exercise?

What did your stroke doctor tell you about exercise?
Has this affected your decision-making?

What did the therapists tell you about exercise?
Has this affected your decision-making?

Do you think there are any benefits to exercise?
Have your thoughts changed since you had your stroke?

Do you think there are any negative effects of exercise?
Have your thought changed since you had your stroke?

What helped you to exercise before your stroke?
What might help you exercise more now you have had a stroke?

Prompts – Group/Individual/Transport/Home/leisure centre/hospital
Independent or guided

What can make it difficult for people who have had a stroke to exercise?

Prompts – Fatigue/Transport

Do you have any thoughts about exercising with others who had not had a stroke?

-
Would you have any thoughts about attending a cardiac rehabilitation programme that was designed to improve your cardio-respiratory fitness but had mainly cardiac patients attending?

Would you have any thoughts about attending these programmes and being guided by an exercise professional or nurse or physiotherapist?

If you were part of a research study looking at the effect of CR and other exercise for stroke patients would you have any thoughts about attending the hospital twice a week for six weeks?

-----------------------------------------------

Did you consider yourself healthy before your stroke?

Do you consider yourself healthy now?

What do you think will affect how healthy you are in the future?

Are there any changes you would like to make to our lifestyle and if so how confident are you that you can make those changes?

Is there anything else you would like to say about your stroke or exercise or healthy lifestyle?

-----------------------------------------------

Thank you for all your answers. I will be typing them all out would you be happy to have a read of your responses and check that I have recorded what you said appropriately?

If you have any concerns as a result of this discussion I am happy to answer any questions about exercise and refer you to your GP for further advice.
Excerpt from a Reflexive diary for Phase I interviews

First patient interviewed. Older lady who has a number of medical issues which affected her ability to exercise after the stroke. Her partner was quite protective so did not fully encourage the patient to exercise after her stroke. Both of them seem to want to exercise more but perhaps felt they were too old and that they couldn’t do what they used to. The only exercise she is managing is with a zimmer frame and around the ground floor of the small semidetached house. Both of the ladies were former nurses and their knowledge of the guidelines for exercise was incorrect so made me think about other people’s knowledge and understanding of exercise. Maybe this is an angle to explore more, peoples understanding of exercise as well as their attitudes towards exercise.
### Appendix Table 8.2 Stages of Thematic Analysis (adapted from Braun and Clarke, 2006)

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description of Analysis process</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Familiarising myself with the data</td>
<td>a) Narrative preparation ie. Transcribing data</td>
</tr>
<tr>
<td></td>
<td>b) Reading and re-reading data and noting down initial ideas</td>
</tr>
<tr>
<td>2. Generating initial codes</td>
<td>a) Coding interesting features of the data in a systematic fashion across entire data set</td>
</tr>
<tr>
<td></td>
<td>b) Collating data relevant to each code</td>
</tr>
<tr>
<td>3. Searching for themes</td>
<td>a) Collating codes into potential themes</td>
</tr>
<tr>
<td></td>
<td>b) Gathering all data relevant to each potential theme</td>
</tr>
<tr>
<td>4. Reviewing themes</td>
<td>a) Checking the themes work in relation to the coded extracts</td>
</tr>
<tr>
<td></td>
<td>b) Checking the themes work in relation to the entire data set</td>
</tr>
<tr>
<td></td>
<td>c) Reviewing data in search of additional themes</td>
</tr>
<tr>
<td></td>
<td>d) Generating a thematic map of the analysis</td>
</tr>
<tr>
<td>5. Defining and naming themes</td>
<td>a) Ongoing analysis to define the specifics of each theme and the overall story of the analysis</td>
</tr>
<tr>
<td></td>
<td>b) Generating clear definitions and names for each theme</td>
</tr>
<tr>
<td>6. Producing the report</td>
<td>a) Selection of vivid and compelling extracts</td>
</tr>
<tr>
<td></td>
<td>b) Final analysis of selected extracts</td>
</tr>
<tr>
<td></td>
<td>c) Relating the analysis back to the research question, objectives and previous literature</td>
</tr>
</tbody>
</table>
Appendix Figure 8.1 Excerpt of interview transcript - Patient 1 - Stage 1 and 2 thematic analysis (Familiarising myself with the data and generating initial codes)

So how do you keep yourselves active now?

(A) I manage to take the dog for a walk, I drive to the arboretum and either Mary comes with me or one of the neighbours and I walk with Brin. You can walk down the paths and he will gallop off on his own roll about in the grass and keep nipping back to see you.

And until this year I did Aqua Tone and Anne did her version of Aqua Tone, but then because she'd had a bad fall you started having panic attacks didn't you, couldn't get her out of the pool. So she stopped doing that but she still uses the two bikes at the gym.

So you go to the gym quite regularly?

(A) Yes David Lloyd.

So have you started, it's a bit early since being out the hospital.

We can't go until she can drive.

(A) And the physio says don't rush it, she realises about the arthritis, she says don't rush it.

I keep her mobile in the house, she does the drinks and I carry them through and she does the toast to get that exercise, things like that. I don't let her just sit.

(A) I don't want to just sit and fester no.

I think we have answered some of these questions as we have talked, before the stroke what did you consider to be an appropriate amount of activity to keep somebody your age healthy? Or did you not think about it?

(A) Walking is a good activity.

But you can't do much of that before your back goes.

(A) And going to the gym.

Did you do it every day?

(A) Oh no

Two or three times a week.

(A) It's not recommended to go every day, folks think they ought to but it's not the sort of thing they recommend.

Do you know what the national recommendations are now about exercise?
Appendix Figure 8.2 Identifying themes from quotes for patients 1 - 6 - Stage 3 - thematic analysis (searching for themes)
Appendix Figure 8.3 Use of mindmap to check and review themes - Stage 4 - thematic analysis
Appendix 3 – Phase II

Interview Schedule for Phase II

Based on your experience how do patients participate in exercise before and after a stroke or TIA?

Do people who have had a stroke or TIA change their attitude to exercise after a stroke or TIA?

(Decreased/increased/personality)

What do you see as the positives of patients exercising after a stroke or TIA?

(Group/individual/BP/strength/fitness)

Do you think there are any negatives of patients exercising after a stroke or TIA?

(psychoolgical/tone/pain/falls/balance/fatigue)

What do you see as the barriers to stroke or TIA patients exercising after a stroke or TIA? (cardiac/cognition/asymmetry/sensation/carers/costs/transport)

How do you think these barriers can be overcome? (education/exercise facilities)

What do you think are the barriers for stroke patients and TIA patients attending cardiac rehabilitation programmes? (transport/continence issues)

How can these be overcome?

How useful do you think cardiac rehabilitation programmes are for individuals who have had a stroke or TIA?

Do you think any changes need to be made to the programmes?

(risk stratification- what guidelines do they use/OM/education/size/ratio/equipment)

Do you have any concerns about patients exercising after a stroke or TIA?
How would you describe your role and responsibility in influencing patients to exercise and participate in cardiac rehabilitation after stroke or TIA? Do you think you have a role?

How would you describe your role and responsibility in influencing patients to take up a healthy lifestyle after a stroke or TIA?

(Any training needed)

How effective do you think lifestyle changes are in preventing further strokes or TIAs compared to medication changes?

In your experience what are patients’ attitudes to health behaviour change after a TIA or stroke?

Do you think advice given by other patients or non-healthcare professionals would be useful for health behaviour change?

Do you think online advice would be useful?

Do you have any other thoughts about stroke and TIA patients and exercise, cardiac rehabilitation or healthy lifestyles?
Reflexive diary for Phase II focus groups

After Focus group 1:

The group of CR nurses and PTs were all keen to explore the use of CR for people post-stroke but they were obviously concerned about their knowledge and understanding of stroke. They identified a number of adaptations that would need to be made and this is useful to think about the classes in phase IV. Will be interesting to see what the stroke therapists feel about including stroke patients in CR. The CR staff identified that the educational needs maybe different and this needs to be discussed with the stroke teams. The CR teams identified a very definite role for themselves about providing healthy lifestyle advice, I wonder if the stroke teams feel the same.
Appendix Figure 8.4 Excerpt of focus group transcript - Focus group 5 - Stage 1 and 2 thematic analysis (Familiarising myself with the data and generating initial codes)

pushed to the exercise limit I would say.

Any cognition problems that would be a barrier to exercise?

Huge.

What sort of things would you class as a barrier to exercise

There is the whole insight side of things, if they are not aware of what the dangers are and you are pushing them to do exercise and they think they can do it on their own and they can’t, so that whole awareness of what is going on, that puts them in danger. We did have a gentlemen recently who got up and walked because he had done it with the physio and two people and he gave it a go. But he is not meant to be cognitively challenged!

So do you think that was a memory thing or more of a ..

I think he just wanted to ?? and I want to give it a try.

Personality perhaps, motivation.
Quite stubborn I think. I think you have interviewed him actually.

?? carry over from session to session, so if someone comes to you with a memory issue do you tend to predict, as it were, that they may not necessarily improve so much because they carry over??

I don’t think we have predicted but we notice that it’s not happening, the memory might be ok but they have still got carry over physically.

Do you mean muscle memory?

Yes so that does return or come back.

So we have looked at the barriers for exercising, do you think there are anyways we can overcome some of these barriers? We have talked about it as we have gone along to a certain extent in terms of cognitive problems, physically cardiac problems, epilepsy. And other solutions to barriers that we haven’t suggested?

What about staffing, if you had more time you could broach subjects like that and do more if we had time.

We used to run a HC programme where we would set up a programme and then support staff could carry some of them out. But that stopped.

Just because of lack of staff and lack of time?

Yes

And falls risk as well, do you find as a nurse that you sometimes find the culture is to
Appendix Figure 8.5 Identifying themes from quotes for focus groups 6 and 7 - Stage 3 - thematic analysis (searching for themes)
Appendix Figure 8.6 Use of mindmap to check and review themes - Stage 4 - thematic analysis
Appendix 4 – Phase IV - Interviews

Interview Schedules for Phase IV interviews – Stroke patients

Thanks for agreeing to take part

You have attended Cardiac Rehabilitation over the last six weeks and now we would like to ask you about your experiences and thoughts about Cardiac Rehabilitation and exercise after having had a stroke.

I would just like to remind you that I will be taping this conversation but as soon as it is typed up the information will be anonymous. The recording and typed transcript will be kept securely on an encoded memory stick.

Do you have any questions before we start?

How are you feeling after all the experiences you have been through over the last few months?

How would you say you are coping with life after having had a stroke/TIA?

Is there anything that you have found that has helped you cope?

What thoughts do you have about your future?

Do you consider yourself a positive or negative person?

Has this changed since you had a stroke?

Did you used to feel that you had control over your life?

Do you feel that you now have control over your future?

How active were you before your stroke?

Prompts – Formal exercise/Informal exercise

What did you consider to be the appropriate amount of activity to keep someone your age healthy?
Do you think this has changed now that you have had a stroke?

What effect has cardiac rehab had on your activity levels?

Why?

Does your partner/spouse/family take part in exercise?

Prompt – Effects

Do you think there are any benefits to exercise?

Have your thoughts changed since you had your stroke?

Have your thoughts changed since you have taken part in cardiac rehab?

Do you think there are any negative effects of exercise?

Have your thoughts changed since you had your stroke?

Have your thoughts changed since you have taken part in cardiac rehab?

What helped you to exercise before your stroke?

What might help you exercise more now you have had a stroke?

Prompts – Group or individual/Independent or guided

What can make it difficult for people who have had a stroke to exercise?

Prompts- Transport/Effort/Fatigue

----------------------------------------------------------------------------------------------------------------------------------------

What are your thoughts about attending cardiac rehab?

Prompts – Cardiac patients/Staff/Content of exercise programme/Leisure centre or home/Content of educational programme

----------------------------------------------------------------------------------------------------------------------------------------

Did you consider yourself healthy before your stroke?

Do you consider yourself healthy now?

What do you think will affect how healthy you are in the future?
Are there any changes you would like to make to your lifestyle and if so how confident are you that you can make those changes.

-----------------------------------------------

Is there anything else you would like to say about your stroke or exercise or cardiac rehabilitation or healthy lifestyle?

Prompts – Cardiac rehab for stroke patients?

-----------------------------------------------

Thank you for all your answers. I will be typing them all out would you be happy to have a read of your responses and check that I have recorded what you said appropriately?

If you have any concerns as a result of this discussion I am happy to answer any questions about exercise and refer you to your GP for further advice.
**Interview Schedules for Phase IV interviews – Stroke non-patients**

How are you feeling after all the experiences you have been through over the last few months?

How would you say you are coping with life after having had a stroke/TIA?

Is there anything that you have found that has helped you cope?

What thoughts do you have about your future?

Do you consider yourself a positive or negative person?

Has this changed since you had a stroke?

Did you used to feel that you had control over your life?

Do you feel that you now have control over your future?

---------------------------------------------------------------------------------------------------------------

How active were you before your stroke?

Prompts – Formal exercise/Informal exercise

What did you consider to be the appropriate amount of activity to keep someone your age healthy?

Do you think this has changed now that you have had a stroke?

Does your partner/spouse/family take part in exercise?

Prompt – Effects

Do you think there are any benefits to exercise?

Have your thoughts changed since you had your stroke?

Do you think there are any negative effects of exercise?

Have your thoughts changed since you had your stroke?

Have your thoughts changed since you have taken part in cardiac rehab?

What helped you to exercise before your stroke?
What might help you exercise more now you have had a stroke?

Prompts – Group or individual/Independent or guided

What can make it difficult for people who have had a stroke to exercise?

Prompts- Transport/Effort/Fatigue

--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

You decided not to take part in CR, which is absolutely fine, can I ask why?

Prompts – Individual/environmental

--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Did you consider yourself healthy before your stroke?

Do you consider yourself healthy now?

What do you think will affect how healthy you are in the future?

Are there any changes you would like to make to your lifestyle and if so how confident are you that you can make those changes.

--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Is there anything else you would like to say about your stroke or exercise or cardiac rehabilitation or healthy lifestyle?

--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Thank you for all your answers. I will be typing them all out would you be happy to have a read of your responses and check that I have recorded what you said appropriately?

If you have any concerns as a result of this discussion I am happy to answer any questions about exercise and refer you to your GP for further advice.
Interview Schedules for Phase IV interviews – Cardiac patients

How are you feeling after all the experiences you have been through over the last few months?

How would you say you are coping with life after having had a cardiac event?

Is there anything that you have found that has helped you cope?

What thoughts do you have about your future?

Do you consider yourself a positive or negative person?

Has this changed since you had your cardiac event?

Did you used to feel that you had control over your life?

Do you feel that you now have control over your future?

How active were you before your cardiac event?

Prompts – Formal exercise/Informal exercise

What did you consider to be the appropriate amount of activity to keep someone your age healthy?

Do you think this has changed now that you have had a cardiac event?

Does your partner/spouse/family take part in exercise?

Prompt – Effects

Do you think there are any benefits to exercise?

Have your thoughts changed since you had your cardiac event?

Do you think there are any negative effects of exercise?

Have your thoughts changed since you had your cardiac event?

Have your thoughts changed since you have taken part in cardiac rehab?
What helped you to exercise before your cardiac event?

What might help you exercise more now you have had a cardiac event?

Prompts – Group or individual/Independent or guided

What can make it difficult for people who have had a cardiac event to exercise?

Prompts- Transport/Effort/Fatigue

What are your thoughts about attending cardiac rehab with people that have had a stroke?

Prompts – Content of exercise programme/Leisure centre or home/Content of educational programme

Did you consider yourself healthy before your cardiac event?

Do you consider yourself healthy now?

What do you think will affect how healthy you are in the future?

Are there any changes you would like to make to your lifestyle and if so how confident are you that you can make those changes.

Is there anything else you would like to say about your cardiac event or exercise or cardiac rehabilitation or healthy lifestyle?

Thank you for all your answers. I will be typing them out would you be happy to have a read of your responses and check that I have recorded what you said appropriately?

If you have any concerns as a result of this discussion I am happy to answer any questions about exercise and refer you to your GP for further advice.
Excerpt from a Reflexive diary for Phase IV interviews

After interviewing patient 12:

This patient has significant physical disabilities including expressive dysphasia, high tone and difficulties walking. Up until this point most of the patients have been positive about their experiences of CR but this patient really did not enjoy it at first as he was embarrassed and found it difficult. He said by the end he found it ok but would prefer to have been in a group with similar difficulties. He would like to continue to exercise but will find it very difficult as he can’t drive and his daughters all work and have family commitments. Despite all his difficulties he remains up-beat and positive. He was a smoker and has given up as he realises the significant impact that smoking has had on his stroke.
Appendix Figure 8.7 Excerpt of interview transcript - Patient 32 - Stage 1 and 2 thematic analysis (Familiarising myself with the data and generating initial codes)

On a day like this wouldn't you rather be outside breathing great gulps of fresh air than in a gym with sweaty people basically. It's fine but I'd rather be out in a field somewhere walking and listening to birds and watching, all that, rather than in a gym listening to some crap music.

So let's move on to thinking about cardiac rehab. So you did it for six weeks didn't you.
Yes.

And you managed to come twice a week I think most of the time.
Yes.

So do you think six weeks twice a week is enough to offer people after a stroke?
Initially, because when I had the early stroke, the team that came out, that was every day so I think that was really good but obviously I understand it takes a lot of people to do that. But then, yes, working out a couple of times a week is, but it has to be done in conjunction with, you can't just go to the gym twice a week and think ah that's great and then do nothing. You've got to do something every day.

What was your overall thoughts about cardiac rehab after having had a stroke, did you find it useful?
Yes I found it very useful, yes it was good to... It's one thing exercising at home but it is good when you're with a group of people as well.

How is it different do you think working out with other people?
I just think it makes it more interesting, it helps you motivate, and also it stops you getting into bad habits because you can be doing exercises at home and think oh this is great and you're not doing it right so you're not really getting the full benefit.

Obviously you've got quite a distance to travel to get from here to the hospital, it must take you about what, 40 minutes or something?
Yes 45 minutes.

If the transport hadn't been provided would you have been able to get there do you think?
Initially no. I could now. I could drive in, but initially I wouldn't have been able to. Also, I don't know whether I'd want that, take a whole different thing as well, whether I'd want to drive in.

Because of the effort, yes.

Yes, the effort of driving on a Monday morning through rush hour to get there. It's one thing being driven because I could do other things, you know, on the phone or whatever, but yes if I was driving or didn't have a taxi or something then, yes, probably not.
Appendix Figure 8.8 Identifying themes from quotes for patients 29 - 32 - Stage 3 - thematic analysis (searching for themes)
Appendix Figure 8.9 Use of mindmap to check and review themes - Stage 4 thematic analysis
Appendix 5 – Phase IV – focus groups

Interview schedule – CR and stroke teams

Based on your experience how do patients participate in exercise before and after a stroke or TIA?

Do people who have had a stroke or TIA change their attitude to exercise after a stroke or TIA?

(Decreased/increased/personality)

What do you see as the positives of patients exercising after a stroke or TIA?

(Group/individual/BP/strength/fitness)

Do you think there are any negatives of patients exercising after a stroke or TIA?

(psychological/tone/pain/falls/balance/fatigue)

What do you see as the barriers to stroke or TIA patients exercising after a stroke or TIA?

(cardiac/cognition/asymmetry/sensation/carers/costs/transport)

How do you think these barriers can be overcome?

(education/exercise facilities)

How useful do you think cardiac rehabilitation programmes are for individuals who have had a stroke or TIA?

What do you think are the barriers for stroke patients and TIA patients attending cardiac rehabilitation programmes?

(transport/continence issues)

How can these be overcome?

Do you think any changes need to be made to the programmes?

(risk stratification- what guidelines do they use/OM/education/size/ratio/equipment)
Do you have any concerns about patients exercising after a stroke or TIA?

How would you describe your role and responsibility in influencing patients to exercise and participate in cardiac rehabilitation after stroke or TIA? Do you think you have a role?

How would you describe your role and responsibility in influencing patients to take up a healthy lifestyle after a stroke or TIA?

(any training needed)

How effective do you think lifestyle changes are in preventing further strokes or TIAs compared to medication changes?

In your experience what are patients’ attitudes to health behaviour change after a TIA or stroke?

Do you think advice given by other patients or non-healthcare professionals would be useful for health behaviour change?

Do you think online advice would be useful?

Do you have any other thoughts about stroke and TIA patients and exercise, cardiac rehabilitation or healthy lifestyles?
Reflexive diary for Phase IV focus groups

After focus group 1 with stroke therapists:

*Only one of the therapists had seen a patient after they had taken part in the CR and they were pleasantly surprised that they enjoyed it and that there was no negative impact on her tone. Made me think that this is a major difficulty with the stroke teams referring into the CR programmes as they are not aware of the results of the CR. The stroke teams are concerned about tone and fatigue but are not provided with the positive results of the CR programme. Will explore this more with other focus groups. The stroke teams also seem to have a very protective nature towards their patients and maybe this is impacting on the ability of the patients to be self-managing.*
Appendix Figure 8.10 Excerpt of focus group transcript - Focus group 2 - Stage 1 and 2 thematic analysis (Familiarising myself with the data and generating codes)

I think it’s knowledge again. Just listening to you talking there about the overextending and stuff like that, as a cardiac nurse that’s something I, and I think one of you said it, I’m totally not aware of. So that’s a training issue for us.

I think when we started this I think we were all open minded about it but we kind of felt that the responsibility was all on you, at the end of the day. Whereas perhaps say if we had a teaching session about what the main issues are, hyperextension etc, that would actually, when we watch you we’d actually say ah, that’s why you’re doing that and that’s what’s going on there. There are even things about what kind of stroke it was as well and I think we didn’t quite understand. There were questions about medication but they didn’t always seem particularly consistent, you know, things like blood pressure medication, things like that didn’t always seem to add up and make sense to us. And so that might have made a difference. But I think we were open minded but at the same time we thought well, at the end of the day they’re your problem. And there was a bit of that. It’s not that we would kind of run out of the room if something happened, we would obviously do our best to help, and there are some things that perhaps we knew a little bit more at home with, very occasionally. So I kind of think how we were primed made a difference. But I don’t think anybody thought, you know, this is a terrible idea. I don’t think anybody thought that, I think everybody was very open minded.

I would like to learn more from this exercise. For me it’s just been a massive learning curve and I’ve already asked what courses I can do.

And we can make it a better experience for them as well.

Well I think you’re right. I think there’s lots we can teach you and we can share that. If it’s going to happen we can share our knowledge as much as possible and it’s whether ultimately you feel that you can do it yourselves but I think that’s perhaps a bit further down the line.

Yes, I think it’s a confidence thing because there’s not a lot of classes that I’ve been where I think oh they can’t deal with this.

We definitely need more staff, I wouldn’t like to do it with three.

There’s no class that I’ve been in where I’ve thought no they can’t deal with this, I need to deal with it.

But from our point of view we didn’t know what we didn’t know and now we know that there are some issues out there which we didn’t know. And then we could step in if we had a bit more knowledge or be more supportive of you.

No that’s fine. How would you describe your role and responsibility in influencing patients to exercise and participate in cardiac rehab after stroke or TIA? Do you think you have a role? This question probably more relates to longer term, not just in the cardiac rehab setting.

Yes.

I would say we all do don’t we, we all have a role.
Appendix Figure 8.11 Identifying themes from quotes for focus group 1 - Stage 3 - thematic analysis (searching for themes)
Appendix Figure 8.12 Use of mindmap to check and review themes - Stage 4 - thematic analysis
Appendix 6 – Ethics, Consent forms and PIS

Ethics approval letter

Re-issue FIFO, 14 August 2014 – Removal of ‘not highlighted’ documents

Health Research Authority
NRES Committee East Midlands - Northampton
Royal Standard Place
Nottingham
NG1 8FS
Telephone: 0115 883 9440

11 August 2014

Professor Sally Singh
Department of Respiratory Medicine
University Hospitals of Leicester
Leicester
LE3 9QP

Dear Professor Singh,

<table>
<thead>
<tr>
<th>Study title:</th>
<th>A feasibility study to identify attitudes, determine outcome measures and develop an intervention to inform a definitive trial that will determine the effectiveness of adapted cardiac rehabilitation for sub-acute stroke patients.</th>
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Thank you for your letter of 04 August 2014, responding to the Committee’s request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Rebecca Mortedge, NRESCommittee.EastMidlands-Northampton@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.
Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at [http://www.rdforum.nhs.uk](http://www.rdforum.nhs.uk).

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett ([catherineblewett@nhs.net](mailto:catherineblewett@nhs.net)), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).
Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

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<tr>
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Re-issue FIFO, 14 August 2014 – Removal of 'not highlighted' documents

| Summary CV for Chief Investigator (CI) [CV - CI] | 1 | 28 May 2014 |
| Summary CV for student [CV - student] | 1 | 28 May 2014 |
| Summary CV for supervisor (student research) [CV - Supervisor] | 1 | 28 May 2014 |
| Validated questionnaire [Part IV - HAD] | 1 | 28 May 2014 |
| Validated questionnaire [Part IV - SF36] | 1 | 28 May 2014 |
| Validated questionnaire [Part IV - MAS] | 1 | 28 May 2014 |
| Validated questionnaire [Part IV - MFSI] | 1 | 28 May 2014 |
| Validated questionnaire [Part IV - SIS ] | 1 | 28 May 2014 |

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

14/EM/1067 Please quote this number on all correspondence

With the Committee’s best wishes for the success of this project.
Re-issue FIFO, 14 August 2014 – Removal of ‘not highlighted’ documents

Yours sincerely,

[Signature]

Mr Ken Willis
Chair

Email: NRESCommittee.EastMidlands-Northampton@nhs.net

Enclosures: “After ethical review – guidance for researchers”

Copy to: Mrs Carolyn Maloney
Consent form – Phase I

Version 2. 29/7/2014.
Part I – Interview study
Original – kept in site file. Copy – to patient and in Medical notes.

General Hospital
Gwendolen Road
Leicester
LE5 4PW

Chief Investigator: Professor Sally Singh
Contact: Nicola Clague-Baker, Research Physiotherapist. Tel: 07912950671

Part I – Interview study - Exploring attitudes to exercise in people who have had a stroke or TIA

Please initial boxes

1. I confirm that I have read and understood the information sheet (Part I – Interview study. 29/7/14 version 2) for the above study. I have had time to think about whether or not I would like to take part in this study and have had the opportunity to ask questions.

2. I understand that my participation in this study is voluntary and that I am free to withdraw from the study at any time, without giving any reason and without my medical care or legal rights being affected.

3. I give permission for the researcher to make written notes of her thoughts during the interview.

4. I give permission for the interview to be audiotaped.

5. I am aware that the results of this study will be published and I give permission for anonymised quotes from my interview to be printed in the published report.

6. I give permission for anonymous data to be shared outside of UHL

7. I give permission for my GP to be informed of my participation in the study.
8. I understand that relevant sections of my medical notes and/or data may be looked at by responsible individuals from the study team, the Sponsor, Research Ethics Committee, NHS Trust or from regulatory authorities where it is relevant to my taking part in the research. I give permission for these individuals to access my records.

9. I agree to take part in this study.

Name of Participant ___________________ Date ____________ Signature ___________________

Name of Researcher ___________________ Date ____________ Signature ___________________
Consent form – Phase II

Version 2, 29/7/2014.

Part II – Focus groups

Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW

Chief Investigator: Professor Sally Singh
Contact: Nicola Clague-Baker, Research Physiotherapist. Tel: 07912950671

Part II – Focus groups - Exploring healthcare professionals’ attitudes to exercise and Cardiac Rehabilitation in individuals with mild to moderate stroke and TIA

Please initial boxes:

1. I confirm that I have read and understood the information sheet (Part II – Focus groups 29/7/14 version 2) for the above study. I have had time to think about whether or not I would like to take part in this study and have had the opportunity to ask questions.

2. I understand that my participation in this study is voluntary and that I am free to withdraw from the study at any time, without giving any reason and without my medical care or legal rights being affected.

3. I give permission for the researcher to make written notes of her thoughts during the focus group.

4. I give permission for the focus group to be audiotaped and am aware of and will adhere to the ground rules.

5. I am aware that the results of this study will be published and I give permission for anonymised quotes from this focus group to be printed in the published report.

6. I give permission for anonymous data to be shared outside of UHL.
7. I understand that relevant sections of my medical notes and/or data may be looked at by responsible individuals from the study team, the Sponsor, Research Ethics Committee, NHS Trust or from regulatory authorities where it is relevant to my taking part in the research. I give permission for these individuals to access my records.

8. I agree to take part in this study.

__________________________  __________________________  __________________________
Name of Participant          Date                        Signature

__________________________  __________________________  __________________________
Name of Researcher           Date                        Signature
Consent form – Phase III

Version 2. 29/7/2014.
Part III – Validity study
Original – place in Site File. Copy – to Patient and in Medical notes

Physiotherapy Department
Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW

Chief Investigator: Professor Sally Singh
Contact: Nicola Clague-Baker, Research Physiotherapist. Tel: 07912950671

Part III – Validity study - A study to test three clinical measures of cardiovascular fitness in stroke and TIA patients

Please initial in box

1. I confirm that I have read the information sheet (Part III – Validity study.Version 2. 29/7/2014) for the above study. I have had the opportunity to consider the information, ask questions and had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

3. I consent for the research team and the study physiotherapist to look at my medical records

4. I understand that relevant sections of the data collected during the study may be looked at by individuals involved in the study for analysis and discussion. I permit these individuals access to my records.

5. I consent to the research team holding the contact details I have previously sent them so that they can contact me for follow up information or if they need to check the information I have given them. I understand these details will be held securely and destroyed after a letter telling me the results of the study has been sent to me.

6. I agree to my GP being informed of my participant in the study

7. I am aware that the results of the study may be presented in research reports, scientific conferences and/or journals. However, the information I provide for the study will remain
Consent Form
Part III – Validity study

conferences and/or journals. However, the information I provide for the study will remain confidential.

8. I give permission for anonymous data to be shared outside of UHL

9. I understand that relevant sections of my medical notes and/or data may be looked at by responsible individuals from the study team, the Sponsor, Research Ethics Committee, NHS Trust or from regulatory authorities where it is relevant to my taking part in the research. I give permission for these individuals to access my records

10. I agree to take part in the above study

______________________________  ______________________________  ______________________________
Name of Participant                Date                             Signature

______________________________  ______________________________  ______________________________
Name of Researcher                Date                             Signature
Consent forms – Phase IV

Version 2. 29/7/2014.
Part IV - Cohort study
Original – kept in Site file. Copy – to patient and in Medical records

Physiotherapy Department
Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW

Chief Investigator: Professor Sally Singh
Contact: Nicola Clague-Baker, Research Physiotherapist. Tel:07912950671

Part IV – Cohort Study - A study to determine if cardiac rehabilitation is acceptable for patients who have had a stroke or TIA in order to inform a larger study.

Please initial in box

1. I confirm that I have read the information sheet (Part IV – cohort study. Version 2. 29/7/2014) for the above study. I have had the opportunity to consider the information, ask questions and had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

3. I consent for the research team and the study physiotherapist to look at my medical records.

4. I understand that relevant sections of the data collected during the study may be looked at by individuals involved in the study for data analysis and discussion. I permit these individuals access to my records.

5. I consent to the research team holding the contact details I have previously sent them so that they can contact me for follow up information or if they need to check the information I have given them. I understand these details will be held securely and destroyed after a letter telling me the results of the study has been sent to me.

6. I agree to my GP being informed of my participant in the study.

7. I am aware that the results of the study may be presented in research reports, scientific conferences and/or journals. However, the information I provide for the study will remain confidential.
8. I understand that relevant sections of my medical notes and/or data may be looked at by responsible individuals from the study team, the Sponsor, Research Ethics Committee, NHS Trust or from regulatory authorities where it is relevant to my taking part in the research. I give permission for these individuals to access my records.

9. I agree to take part in the above study.

Name of Participant ___________________________ Date ___________ Signature ___________________________

Name of Researcher ___________________________ Date ___________ Signature ___________________________
Part I – Interview study - Exploring attitudes to exercise in people who have had a stroke or Transient Ischaemic Attack (TIA)

INFORMATION LEAFLET
You are invited to take part in a stroke/TIA study. Before you decide whether or not to take part, we would like to explain why the study is being done and what it will involve. Please read the following information and ask us if anything is not clear, or if you would like more information, using one of the contact options listed above.

What is the purpose of this study?
It is well known that exercise forms part of a healthy lifestyle and that exercise can contribute to better health outcomes. It is also known that people who have experienced a major physical event such as a stroke or TIA may find it more difficult to participate in exercise. The purpose of this study is to explore people’s experiences of exercise before and after having a stroke or TIA. We hope that by speaking with you we can gain information that will allow us to provide better care for people with stroke or TIA. The project is also gathering information for an educational qualification.

Why have I been invited?
You have been invited because you have had a stroke or TIA and we believe, therefore, that you may be eligible to participate in the study.

What will happen if I decide to take part?
If you decide to take part you will be visited at home by one of the research team at a time convenient for you. They will go through the information sheet with you and then ask you to complete a consent form. They will then conduct the interview which will take up to one hour. You will be asked questions about your thoughts and attitudes to exercise before and after your stroke or TIA. The interview will be recorded and the data transcribed and analysed by the research assistants. The recorded data and the transcript of that information will be securely stored and kept for five years. The data will be anonymous and confidential and will not be shared with anyone other than the two research assistants and the expert qualitative advisor. You might be asked to review the transcript of your interview to confirm if that is what you said.
Do I have to take part?
Only if you want to. Participation is voluntary, you may refuse to participate or withdraw from the study at any time. You do not need to tell us why you do not want to take part. If you choose to withdraw or not to participate, your decision will in no way affect your future treatment. It may be that the investigator or sponsor of the study consider that it is in your interests to withdraw you or stop the study altogether.

What are the possible disadvantages and risks of taking part?
There are no risks or side effects from taking part in this study.

Are there any costs involved?
No. The researcher will come to your house to talk to you so there will be no costs incurred by yourself.

Confidentiality
The records will identify you only by a number (not your hospital number) and your initials. All information in your notes will be treated in strict confidence. A copy of the Informed Consent Form will be kept and you will be given a copy. The information from this study will be retained for five years. If you agree to participate in this study, your General Practitioner will be informed, unless you state otherwise.

Your rights
Your participation in this study is entirely voluntary and refusal will not affect any other medical treatment. You may, without giving reason, refuse to take part in the trial, and this will not in any way affect your continuing treatment by your doctor or therapist.

Who is organising and funding the research?
This study is being conducted by a team of experts at UHL NHS Trust, University of Leicester, Coventry University and Loughborough University. It is being funded by The Stroke Association.

Are there any benefits of taking part in this study?
There may be no benefits to taking part. However, the aim of the study is to help determine the attitudes to exercise of people who have had a stroke to help provide better care for people with stroke in the future. Personally you will be able to discuss your exercise and your future healthy lifestyle with a chartered physiotherapist.

What if there is a problem?
In the very unlikely event of you being harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone’s negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms would be available to you. If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [tel:07912950671]. If you remain unhappy and wish to complain formally, you can do this. Details can be obtained from the Patient Information and Liaison Service: Free phone line: 08081 788337. Email: pils@uhl-tr.nhs.uk.

Who has reviewed the study?
The Northampton Research Ethics committee has reviewed this study.

What do I do now?
If you agree to take part, please telephone the contact number on the attached letter to arrange your appointment or return the enclosed reply slip.

Thank you.
Information sheet - Part II

Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW

Chief Investigator – Professor Sally Singh
Contact: Nicola Clague-Baker, Research Physiotherapist
Tel: 0116 252 3305 mobile: 07912950671
email: Njc36@le.ac.uk

Part II - Exploring healthcare professionals’ attitudes to exercise and Cardiac Rehabilitation in individuals with mild to moderate stroke

INFORMATION LEAFLET
You are invited to take part in a stroke/TIA study. Before you decide whether or not to take part, we would like to explain why the study is being done and what it will involve. Please read the following information and ask us if anything is not clear, or if you would like more information, using one of the contact options listed above.

What is the purpose of this study?
It is well known that exercise forms part of a healthy lifestyle and that exercise can contribute to better health outcomes. It is also known that people who have experienced a major physical event such as a stroke or TIA may find it more difficult to participate in exercise. The purpose of this study is to explore healthcare professionals’ attitudes to exercise and cardiac rehabilitation in individuals with mild to moderate stroke or TIA. We hope that by speaking with you we can gain information that will allow us to provide better care for people with stroke and TIA. The project is also gathering information for an educational qualification.

Why have I been invited?
You have been invited because you are a healthcare professional with expertise in either stroke rehabilitation or cardiac rehabilitation and we believe, therefore, that you may be eligible to participate in the study.

What will happen if I decide to take part?
If you decide to take part you will be asked to attend a focus group in a convenient location to your workplace. You will be asked to read the information sheet and consent form and then you will be asked to complete a consent form. The focus group will take up to one hour. You will be asked to discuss questions exploring the subject of exercise after stroke/TIA. It will be audio-recorded and the data transcribed and analysed by the research assistants. The recorded data and the transcript of that information will be securely stored and kept for five years. The data will be anonymous and confidential and will not be shared with anyone other than the two research assistants and the expert qualitative advisor. You might be asked to review the transcript of the focus group to confirm if that is what you said.

Do I have to take part?
Only if you want to.
Participation is voluntary, you may refuse to participate or withdraw from the study at any time. You do not need to tell us why you do not want to take part. It may be that the investigator or sponsor of the study consider that it is in your interests to withdraw you or stop the study altogether.

**What are the possible disadvantages and risks of taking part?**
There are no risks or side effects from taking part in this study.

**Are there any costs involved?**
No. The focus group will take place in your workplace and in your work time so no costs will be incurred by yourself.

**Confidentiality**
The records will identify you only by a number (not your hospital number) and your initials. A copy of the Informed Consent Form will be kept and you will be given a copy. The information from this study will be retained for five years. Only your name and profession will be recorded. All information which is collected about you for the purpose of the research will be kept strictly confidential. Information will be stored on separate secure computer databases, to which only members of the study team have access. Various regulatory bodies oversee clinical research projects to ensure research quality and to protect study participants. Individuals from the NHS Health Board of your area, representatives from the regulatory bodies may see the data collected about you, where it is relevant to your taking part in this research, as part of their routine monitoring, to ensure the trial meets the appropriate quality assurance and data confidentiality standards.

**Your rights**
Your participation in this study is entirely voluntary. You may, without giving reason, refuse to take part in the trial.

**Who is organising and funding the research?**
This study is being conducted by a team of experts at UHL NHS Trust, University of Leicester, Coventry University and Loughborough University. It is being funded by The Stroke Association.

**Are there any benefits of taking part in this study?**
There may be no benefits to taking part. However, the aim of the study is to help determine the attitudes to exercise and cardiac rehabilitation of people who work with patients that have had a stroke or cardiac problems. Ultimately this will help to provide better care for people with stroke in the future.

**What if there is a problem?**
In the very unlikely event of you being harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone’s negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms would be available to you. If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [tel:07912950671]. If you remain unhappy and wish to complain formally, you can do this. Details can be obtained from the Patient Information and Liaison Service: Free phone line: 08081 788337. Email: pilis@uhl-tr.nhs.uk.

**Who has reviewed the study?**
The Northampton Research Ethics committee has reviewed this study.

**What do I do now?**
If you agree to take part, please telephone the contact number on the attached letter to arrange your appointment or return the enclosed reply slip.

Thank you.
Information sheet – Part III

Physiotherapy Department
Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW

Chief Investigator – Professor Sally Singh
Contact: Nicola Clague-Baker, Research Physiotherapist
Tel: 0116 258 4072 mobile: 07912950671
email: Njc36@le.ac.uk

Part III - A study to test three clinical measures of cardiovascular fitness in stroke and Transient Ischaemic Attack (TIA) patients

INFORMATION LEAFLET
You are invited to take part in a stroke/TIA study. Before you decide whether or not to take part, we would like to explain why the study is being done and what it will involve. Please read the following information and ask us if anything is not clear, or if you would like more information, using one of the contact options listed above.

What is the purpose of this study?
It is well known that exercise forms part of a healthy lifestyle and that exercise can contribute to better health outcomes. It is also known that people who have experienced a major physical event such as a stroke or TIA may find it more difficult to participate in exercise. The purpose of this study is to test three measures of cardiovascular fitness to determine which one would be the most appropriate to measure cardiovascular fitness with people who have had a stroke or TIA. The project is also gathering information for an educational qualification.

Why have I been invited?
You have been invited because you have had a stroke or TIA and we believe, therefore, that you may be eligible to participate in the study.

What will happen if I decide to take part?
If you decide to take part you will be asked to attend the Glenfield Hospital on a date and time convenient to you. Transport will be provided. When you arrive you will be met by one of the research assistants who will discuss the trial again with you and ask you to fill out the consent form. After you have consented to be on the trial you will be asked to complete three measures of your fitness – the six minute walk test, the shuttle walk test and a bike test (VO2 peak test).

The six minute walk test is a measure that involves walking between two cones for six minutes and the distance you walk is recorded. You can go at your own speed and rest as many times as you like with this test. You will do this test twice with at least 30 minutes rest between.
The shuttle walk test involves walking between two cones, the speed that you walk is progressively increased and the distance you manage to walk is recorded. If you cannot manage the speed required we will stop the test. You can stop at any time during this test if you cannot go any further and the test will be ended. You will do this test twice with at least a thirty minute rest between.

The bike test (VO2 peak test) involves cycling on a static bike with a mask on so that the oxygen you take in and breathe out is recorded. The settings on the bike will gradually be changed, that is, the resistance will be increased to challenge your fitness. You will be required to cycle at a set speed. If you cannot manage the set speed then we will stop the test. If at any time you need to stop this is fine. You will do this test once. There will be plenty of time allowed to rest between each test.

You will do the bike test first but the order of the other two tests will be randomised so some people will complete the six minute walk test next and some people will complete the shuttle walk test next. You will be constantly monitored by trained staff to ensure safe procedures and during the bike test (VO2 peak test) your heart will be monitored using an ECG, your blood pressure will also be recorded, and your breathing will be measured using a pulse oximeter where a small probe is placed onto your finger. A doctor will be available if necessary.

Do I have to take part?
Only if you want to.
Participation is voluntary, you may refuse to participate or withdraw from the study at any time. You do not need to tell us why you do not want to take part. If you choose to withdraw or not to participate, your decision will in no way affect your future treatment. It may be that the investigator or sponsor of the study consider that it is in your interests to withdraw you or stop the study altogether.

What are the possible disadvantages and risks of taking part?
These tests are regularly used for patients who have had cardiac events and respiratory disease without complications. Stroke patients have also completed the VO2 peak and six minute walk tests without complications. The Shuttle walk test has not been completed with stroke patients before but presents no additional risks compared to the VO2 peak or the six minute walk test.

Are there any costs involved?
No. Transport will be provided so you will not be required to pay for transport to or from the Glenfield Hospital. While you are at the hospital we will pay for any refreshments you need.

Confidentiality
The records will identify you only by a number (not your hospital number) and your initials. All information in your notes will be treated in strict confidence. A copy of the Informed Consent Form will be kept and you will be given a copy. The information from this study will be retained for five years. If you agree to participate in this study, your General Practitioner will be informed, unless you state otherwise. Information will be stored on separate secure computer databases, to which only members of the study team have access. Various regulatory bodies oversee clinical research projects to ensure research quality and to protect study participants. Individuals from the NHS Health Board of your area, representatives from the regulatory bodies may see the data collected about you, where it is relevant to your taking part in this research, as part of their routine monitoring, to ensure the trial meets the appropriate quality assurance and data confidentiality standards.

Your rights
Your participation in this study is entirely voluntary and refusal will not affect any other medical treatment. You may, without giving reason, refuse to take part in the trial, and this will not in any way affect your continuing treatment by your doctor or therapist.

Who is organising and funding the research?
This study is being conducted by a team of experts at UHL NHS Trust, University of Leicester, Coventry University and Loughborough University. It is being funded by The Stroke Association.
Are there any benefits of taking part in this study?

There may be no benefits to taking part. However, the aim of the study is to help determine the most appropriate test to measure cardiovascular fitness in stroke and TIA patients. Your involvement will therefore help future stroke and TIA patients determine their physical fitness. Personally you will be able determine your cardiovascular fitness and will be able to discuss your exercise and your future healthy lifestyle with a chartered physiotherapist.

What if there is a problem?

In the very unlikely event of you being harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone’s negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms would be available to you. If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [tel:07912950671]. If you remain unhappy and wish to complain formally, you can do this. Details can be obtained from the Patient Information and Liaison Service: Free phone line: 08081 788337. Email: pils@uhl-tr.nhs.uk.

Who has reviewed the study?

The Northampton Research Ethics committee has reviewed this study.

What do I do now?

If you agree to take part, please telephone the contact number on the attached letter to arrange your appointment or return the enclosed reply slip.

Thank you.
Part IV - A study to determine if cardiac rehabilitation is acceptable for patients who have had a stroke or Transient Ischaemic Attack (TIA) in order to inform a larger study

INFORMATION LEAFLET
You are invited to take part in a stroke/TIA study. Before you decide whether or not to take part, we would like to explain why the study is being done and what it will involve. Please read the following information and ask us if anything is not clear, or if you would like more information, using one of the contact options listed above.

What is the purpose of this study?
It is well known that exercise forms part of a healthy lifestyle and that exercise can contribute to better health outcomes. It is also known that people who have experienced a major physical event such as a stroke or TIA may find it more difficult to participate in exercise. The purpose of this study is to include stroke and TIA patients in cardiac rehabilitation programmes to determine if stroke and TIA patients find cardiac rehabilitation acceptable and whether enough stroke and TIA patients would attend and complete the programme in order to determine if a larger trial can be conducted. The project is also gathering information for an educational qualification.

Why have I been invited?
You have been invited because you have had a stroke or TIA and we believe, therefore, that you may be eligible to participate in the study.

What will happen if I decide to take part?
If you decide to take part you will be asked to attend the Glenfield hospital to take part in cardiac rehabilitation twice a week for six weeks. Cardiac rehabilitation involves an hour exercise session each visit plus an education programme. You will also be asked to complete various physical and questionnaire-based measures at the start and end of the programme. The physical measures will determine your physical fitness and they will include either the six minute walk test or the shuttle walk test. The six minute walk test is a measure that involves walking between two cones for six minutes and the distance you walk is recorded. You can go at your own speed and rest as many times as you like with this test.

The shuttle walk test involves walking between two cones, the speed that you walk is progressively increased and the distance you manage to walk is recorded. If you cannot manage the speed required we will stop the test. You can stop at any time during this test if you cannot go any further and the test will be ended. Your blood pressure, height, weight, body mass index and tone will also be measured. The questionnaires measure your quality of life, your fatigue levels and your levels of anxiety and depression. Transport will be provided for all sessions.

When you first arrive you will be met by one of the research assistants who will discuss the trial again with you and ask you to fill out the consent form. After you have consented to be on the trial you will take part in the initial measures. You will then attend twice weekly sessions of cardiac rehabilitation. You will be constantly monitored during the rehabilitation by chartered physiotherapists.
The shuttle walk test involves walking between two cones, the speed that you walk is progressively increased and the distance you manage to walk is recorded. If you cannot manage the speed required we will stop the test. You can stop at any time during this test if you cannot go any further and the test will be ended. Your blood pressure, height, weight, body mass index and tone will also be measured. The questionnaires measure your quality of life, your fatigue levels and your levels of anxiety and depression. Transport will be provided for all sessions.

When you first arrive you will be met by one of the research assistants who will discuss the trial again with you and ask you to fill out the consent form. After you have consented to be on the trial you will take part in the initial measures. You will then attend twice weekly sessions of cardiac rehabilitation. You will be constantly monitored during the rehabilitation by chartered physiotherapists.

Over the six weeks of the trial you will also be asked to fill out a falls diary that records whether you have fallen over the six weeks. You will also be asked to wear a small watch-like piece of equipment (accelerometer) which measures your activity levels for the first week of the programme and the last week of the programme.

Finally, we would like to ask you about your experiences of being involved in cardiac rehabilitation so we would like to interview you for up to an hour about your thoughts on exercise and cardiac rehabilitation.

Do I have to take part?
Only if you want to. Participation is voluntary, you may refuse to participate or withdraw from the study at any time. You do not need to tell us why you do not want to take part. If you choose to withdraw or not to participate, your decision will in no way affect your future treatment. It may be that the investigator or sponsor of the study consider that it is in your interests to withdraw you or stop the study altogether.

What are the possible disadvantages and risks of taking part?
Cardiac rehabilitation is regularly used for patients who have had cardiac events without complications. Stroke patients have also completed other forms of cardiovascular training without any complications. You will be constantly monitored throughout any testing and exercise training by suitably trained individuals.

Are there any costs involved?
No. Transport will be provided for all the sessions to bring you to and from the hospital for the cardiac rehabilitation sessions and testing sessions so no costs will be incurred by yourself.

Confidentiality
The records will identify you only by a number (not your hospital number) and your initials. All information in your notes will be treated in strict confidence. A copy of the Informed Consent Form will be kept and you will be given a copy. The information from this study will be retained for five years. If you agree to participate in this study, your General Practitioner will be informed, unless you state otherwise. All information which is collected about you for the purpose of the research will be kept strictly confidential. Information will be stored on separate secure computer databases, to which only members of the study team have access. Various regulatory bodies oversee clinical research projects to ensure research quality and to protect study participants. Individuals from the NHS Health Board of your area, representatives from the regulatory bodies, may see the data collected about you, where it is relevant to your taking part in this research, as part of their routine monitoring, to ensure the trial meets the appropriate quality assurance and data confidentiality standards.

Your rights
Your participation in this study is entirely voluntary and refusal will not affect any other medical treatment. You may, without giving reason, refuse to take part in the trial, and this will not in any way affect your continuing treatment by your doctor or therapist.
Who is organising and funding the research?
This study is being conducted by a team of experts at UHL NHS Trust, University of Leicester, Coventry University and Loughborough University. It is being funded by The Stroke Association.

Are there any benefits of taking part in this study?
There may be no benefits to taking part. However, it has been shown that people who have a stroke or TIA can improve their physical fitness after a stroke or TIA by doing various forms of exercise. Taking part in cardiac rehabilitation may improve your physical fitness and may also reduce your risk of subsequent strokes or TIs through helping you identify and establish lifestyle changes. You will be able to discuss your exercise and your future healthy lifestyle with a chartered physiotherapist and specialist nurses and psychologists. The results of this trial will also help to establish if a larger trial can be conducted to determine the effect of cardiac rehabilitation compared to other forms of cardiovascular fitness training. Thus future stroke and TIA patients may benefit from your involvement in this trial.

What if there is a problem?
In the very unlikely event of you being harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms would be available to you. If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [tel:07912950671]. If you remain unhappy and wish to complain formally, you can do this. Details can be obtained from the Patient Information and Liaison Service: Free phone line: 08081 788337. Email: pilts@uhl-tr.nhs.uk.

Who has reviewed the study?
The Northampton Research Ethics committee has reviewed this study.

What do I do now?
If you agree to take part, please telephone the contact number on the attached letter to arrange your appointment or return the enclosed reply slip.

Thank you.
Appendix 7 – Outcome measures and SOPs

Standard Operating Procedure – Incremental Shuttle Walking Test (ISWT)

Scope and Purpose

The original purpose of the ISWT was to develop a standardised, externally paced, incremental field walking test to assess the functional capacity in patients with chronic airways obstruction. The ISWT is a valid symptom limited maximal test of functional capacity that relates strongly to VO2max during cardio-pulmonary exercise testing on a treadmill. The test is companioned with the endurance shuttle walking test (ESWT). This is a validated field test that has proven sensitive to changes in pulmonary rehabilitation and bronchodilator therapy.

Equipment

- Two small cones to mark the turnaround points 9 meters apart with a 0.5 inset for turning.
- One chair, one at one end of the walking course
- BORG Scale (Appendix 1)
- RPE Scale (Appendix 2)
- Clipboard with an ISWT Proforma and a pen (Appendix 3)
- Automated blood pressure machine
- Pulse oximeter
- Stopwatch
- Pre-measured marks along the track/corridor
- Access to oxygen and telephone in case of an emergency
- Supplemental oxygen if required to perform exercise test by patient

The test should be conducted along a quiet corridor/physiotherapy gym/ or dedicated exercise testing room. If there is a dedicated exercise testing facility air conditioning would be optimal.

Precautions

Absolute contraindications for the ISWT include:
- unstable angina.
- myocardial infarction during the previous month.

Relative contraindications for the ISWT include:
- resting heart rate of more than 120
- a systolic blood pressure of more than 180 mm Hg
- diastolic blood pressure of more than 100 mm Hg

Subjects with any of these findings should be referred to the physician ordering or supervising the test for individual clinical assessment and a decision about the conduct of the test. The results from a resting electrocardiogram done during the previous 6 months should also be
reviewed before testing. Stable exertional angina is not an absolute contraindication for an ISWT, but subjects with these symptoms should perform the test after using their anti-angina medication, and rescue nitrate medication should be readily available.

Safety Issues

1. Testing should be performed in a location where a rapid, appropriate response to an emergency is possible. The appropriate location of a crash cart should be determined by the physician supervising the facility.
2. Supplies that must be available include oxygen, sublingual nitroglycerine, aspirin, and Salbutamol (metered dose inhaler or nebuliser). A telephone or other means should be in place to enable a call for help.
3. The technician should be certified in cardiopulmonary resuscitation with a minimum of Basic Life Support. Advanced cardiac life support certification is desirable. Training, experience, and certification in related health care fields (e.g. registered nurse, registered respiratory therapist, or certified pulmonary function technician) are also desirable. A certified individual should be readily available to respond if needed.
4. Physicians are not required to be present during all tests. The physician ordering the test or a supervising laboratory physician may decide whether physician attendance at a specific test is required.
5. If a patient is on long term or ambulatory oxygen therapy, oxygen should be given at their standard rate or as directed by a physician or a protocol.

Stop the Test in the Event of Any of the Following
- Chest pain suspicious for angina.
- Evolving mental confusion or lack of coordination/staggering.
- Evolving light-headedness.
- Intolerable dyspnoea.
- Leg cramps or extreme leg muscle fatigue.
- Excessive sweating
- Persistent \( \text{SpO}_2 < 85\% \) (if this is unusual for the subject)
- Pale or ashen appearance that occurs during the test
- Any other clinically warranted reason

Technicians must be trained to recognise these problems and the appropriate responses. If a test is stopped for any of these reasons, the patient should sit or lie supine as appropriate depending on the severity of the event and the technician’s assessment of the severity of the event and the risk of syncope. The following should be obtained based on the judgment of the technician: blood pressure, pulse rate, oxygen saturation, and a physician evaluation. Oxygen should be administered as appropriate.

Preparation

Establishment of a Walking Track
• The course should be identified by 2 cones with an inset of 0.5 m from either end, thus avoiding abrupt changes in direction.

• The track should be flat, with minimal blind turns or obstacles.

The walking track should be in an area with a maintained comfortable ambient temperature and humidity.

**Patient Preparation**
- Take into account any precautions or contraindications prior to performing the walk test.
- Instruct the subject to dress comfortably and wear appropriate footwear.
- Where possible/appropriate, the subject should be advised to avoid eating a heavy meal for two hours before the test as well as drinking tea and coffee (caffeinated drinks).
- Any prescribed inhaled bronchodilator medication should be taken within one hour of testing.
- The subject should rest for at least 15 minutes before beginning the ISWT.
- A ‘warm up’ should not be performed.

**Encouragement:** Only the standardised phrases for encouragement (as specified in the procedure below) must be used during the test. Encouragement significantly increases the distance walked.

**Supplemental Oxygen:** If oxygen supplementation is needed during the walks and serial tests are planned, then during all walks by that subject oxygen should be delivered in the same way with the same flow. If the flow must be increased during subsequent visits due to worsening gas exchange, this should be noted on the worksheet and considered during interpretation of the change. Measurements of pulse and SpO2 should be made after waiting at least 10 minutes after any change in oxygen delivery.

The type of oxygen delivery device should also be noted on the report: for instance, the subject carried liquid oxygen or pushed or pulled an oxygen tank, the delivery was pulsed or continuous. Technicians should avoid walking behind the subject with the oxygen source, however if the subject is not able to control/carry/manage their own oxygen cylinder, the technician should try to walk slightly behind the subject to avoid setting the walking pace. It should be clearly documented how the technician has assisted with the transport of the oxygen, so any subsequent walk tests with the same subject can be performed in the same manner.
**Medications:** The type of medication, dose, and number of hours taken before the test should be noted. Significant improvement in the distance walked, or the dyspnoea scale, after administration of bronchodilators has been demonstrated in patients with COPD.

**Procedure**

- The ISWT must initially be performed on two occasions to account for a learning effect. The best distance walked in metres is recorded, to the nearest 10 as completed lengths.
- If the two tests are performed on the same day, at least 20 minutes rest should be allowed between tests.

1) Set the CD to the start and play the standardised instructions to the individual. Patients are advised to:

   "Walk at a steady pace, aiming to turn around when you hear the signal. You should continue to walk until you feel that you are unable to maintain the required speed without becoming unduly breathless."

2) After the subject has been at rest for 15 minutes, obtain and record measurements of blood pressure, heart rate, oxygen saturation and Borg dyspnoea and RPE scores (Appendices 1 & 2).
3) Direct the subject to the ‘starting cone’ of the walking track.
4) Describe the walking track to the subject.
5) Give the patient the following instructions:

   "Are you ready? Remember that the object is to walk AS LONG AS POSSIBLE, but don’t run or jog."

6) The speed at which the patient should walk is directed by an audio signal played on a CD player.
7) Once the first triple bleep plays the test has started.
8) Monitor the subject for any untoward signs and symptoms throughout the duration of the test.
9) Watch the patient. Do not get distracted and lose count of the laps. Ensure you keep count of the number of lengths as the subject completes them, throughout the duration of the test. It is advisable to time the performance as an additional measure to confirm manual recording of the number of shuttles completed.
10) At every increase in speed, at the end of every minute, indicated by a triple bleep advise the patient ‘you now need to increase your speed of walking’
11) During the test only one verbal cue can be used to encourage the patient to pick up their speed ‘you need to increase their speed to keep up with the test’ (see below).
12) The test is terminated when either 1) the subject indicates that they are unable to continue, 2) if the operator determines that the subject is not fit to continue, or, 3) the operator assess that the subject was unable to sustain the speed and cover the distance to the cone prior to the beep sounding (see below for more details)
13) Allow the subject to sit down or, if the subject prefers, allow to them to stand.
14) Immediately record oxygen saturation, heart rate, Borg dyspnoea and RPE Score on the proforma. Measure and record the subject’s blood pressure.

15) Congratulate the patient on good effort and offer a drink of water.

16) Total up the number of lengths walked in meters (to the last 10 completed), and record on the proforma.

17) The subject should remain in a clinical area for at least 15 minutes following an uncomplicated test, or be allowed to rest for at least 30 minutes if performing the second walk test on the same day.

Operator termination of the test

The operator will be required to terminate the test if the participant fails to reach the cone/marker in the time allowed. This is defined as the individual being more than 0.5m away from the cone when the bleep sounds on a second successive 10 length. When the individual is just outside the 0.5m marker, they are, if they fail to do so the test is terminated and the distance recorded.

The test should be discontinued by the operator if SpO₂ falls below 80% as per ATS guidelines for cardiopulmonary exercise testing (ATS 2003).

Participant termination of the test

The patient may indicate to terminate the test if they indicate they are unable to do so. In respiratory disease the common reason for terminating the test is due to excessive dyspnoea, however other non-respiratory reasons may cause termination of the test, these include fatigue (commonly leg fatgue) or pain (knee/hip/low back pain).

A sample scoring sheet is included in the appendix.

Quality assurance

It is important that all operators are familiar with the test procedures, as the test requires clear processes to be followed. It is important the operator can walk exactly at the first speed of walking to pace the patient, this is particularly important for patients with a higher functional capacity who’s natural speed of walking is faster than the first very slow speed of walking. It is recommended that anyone unfamiliar with test procedures completes 10 observed ISWTs, which are performed to the standards identified above. A competent operator will be responsible for signing off satisfactory completion of the tests. Ideally quality assurance testing should require the operator to conduct the test on participants with a range of functional exercise capacity.
Standard Operating Procedure – Six Minute Walk Test (6MWT)

Version 1

Scope and Purpose

The original purpose of the six minute walk test was to assess exercise tolerance in patients with chronic respiratory disease and heart failure. The test has since been used as a performance-based measure of functional exercise capacity in other populations. As with other measurements used for clinical and research purposes, it is important to standardise procedures, describe required preparation, and outline safety measures. This document is based on the ATS and the Australian Lung Foundation/Australian Physiotherapy Association guidelines.

Equipment

- Stopwatch or countdown timer
- Lap counter
- Two small cones to mark the turnaround points
- A chair that can be easily moved along the walking course
- Clipboard with a 6MWT proforma and a pen
- BORG Scale
- Automated blood pressure machine
- Pulse oximeter
- Trundle wheel, or pre-measured marks along the track/corridor
- Access to oxygen and telephone in case of an emergency

Precautions

Absolute contraindications for the 6MWT include:
- unstable angina
- myocardial infarction during the previous month.

Relative contraindications for the 6MWT include:
- resting heart rate of more than 120
- a systolic blood pressure of more than 180 mm Hg
- diastolic blood pressure of more than 100 mm Hg

Subjects with any of these findings should be referred to the physician ordering or supervising the test for individual clinical assessment and a decision about the conduct of the test. The results from a resting electrocardiogram done during the previous 6 months should also be reviewed before testing. Stable exertional angina is not an absolute contraindication for a 6MWT, but subjects with these symptoms should perform the test after using their anti-angina medication, and rescue nitrate medication should be readily available (ATS 2002).
Safety Issues

1. Testing should be performed in a location where a rapid, appropriate response to an emergency is possible. The appropriate location of a crash cart should be determined by the physician supervising the facility.

2. Supplies that must be available include oxygen, sublingual nitroglycerine, aspirin, and Salbutamol (metered dose inhaler or nebuliser). A telephone or other means should be in place to enable a call for help.

3. The technician should be certified in cardiopulmonary resuscitation with a minimum of Basic Life Support by Resuscitation Council (UK)–approved cardiopulmonary resuscitation course. Advanced cardiac life support certification is desirable. Training, experience, and certification in related health care fields (e.g. registered nurse, registered respiratory therapist, or certified pulmonary function technician) are also desirable. A certified individual should be readily available to respond if needed.

4. Physicians are not required to be present during all tests. The physician ordering the test or a supervising laboratory physician may decide whether physician attendance at a specific test is required.

5. If a patient is on chronic oxygen therapy, oxygen should be given at their standard rate or as directed by a physician or a protocol.

Stop the Test in the Event of Any of the Following
- Chest pain suspicious for angina.
- Evolving mental confusion or lack of coordination/staggering.
- Evolving light-headedness.
- Intolerable dyspnoea.
- Leg cramps or extreme leg muscle fatigue.
- Excessive sweating
- Persistent SpO₂ < 85% (if this is unusual for the subject)
- Pale or ashen appearance that occurs during the test
- Any other clinically warranted reason

Technicians must be trained to recognise these problems and the appropriate responses. If a test is stopped for any of these reasons, the patient should sit or lie supine as appropriate depending on the severity of the event and the technician’s assessment of the severity of the event and the risk of syncope. The following should be obtained based on the judgment of the technician: blood pressure, pulse rate, oxygen saturation, and a physician evaluation. Oxygen should be administered as appropriate.

Preparation
Establishment of a Walking Track

- The track may be a continuous track (oval or rectangular) or a point-to-point track.
- In the case of a point-to-point track, the walking course must be 30m in length, with the turnaround points marked with a cone. A starting line, which marks the beginning and end of each lap, should be marked on the floor using brightly coloured tape, unless one of the cones marks the start.
- The track should be flat, with minimal blind turns or obstacles.
- The minimum recommended length for a centre-based walking track is 25m, though 30m is preferred. The track could be marked in 1-metre or 3-metre increments to assist in calculation of partial lap completion at the end of the test.

   *Note: If you do not have access to at least a 25m track, make sure you use the same track for all tests and be aware that the distance walked may be less due to the patient having to slow down and turn more often in the six minutes.*

The walking track should be in an area with a maintained comfortable ambient temperature and humidity.

Patient Preparation

- Take into account any precautions or contraindications prior to performing the walk test
- Instruct the subject to dress comfortably and wear appropriate footwear
- Where possible/appropriate, the subject should be advised to avoid eating a heavy meal for two hours before the test
- Any prescribed inhaled bronchodilator medication should be taken within one hour of testing
- The subject should rest for at least 15 minutes before beginning the 6MWT
- A ‘warm up’ should not be performed

Quality Assurance

*Technician Training and Experience*: Technicians who perform 6MWTs should be trained using the standard protocol and then supervised for several tests before performing them alone. They should also have completed cardiopulmonary resuscitation training.

*Encouragement*: Only the standardised phrases for encouragement (as specified in the procedure below) must be used during the test. Encouragement significantly increases the distance walked.
**Supplemental Oxygen:** If oxygen supplementation is needed during the walks and serial tests are planned, then during all walks by that subject oxygen should be delivered in the same way with the same flow. If the flow must be increased during subsequent visits due to worsening gas exchange, this should be noted on the worksheet and considered during interpretation of the change noted in 6MWD. Measurements of pulse and SpO\textsubscript{2} should be made after waiting at least 10 minutes after any change in oxygen delivery. The type of oxygen delivery device should also be noted on the report: for instance, the subject carried liquid oxygen or pushed or pulled an oxygen tank, the delivery was pulsed or continuous. Technicians should avoid walking behind the subject with the oxygen source, however if the subject is not able to control/carry/manage their own oxygen cylinder, the technician should try to walk slightly behind the subject to avoid setting the walking pace. It should be clearly documented how the technician has assisted with the transport of the oxygen, so any subsequent walk tests with the same subject can be performed in the same manner.

**Medications:** The type of medication, dose, and number of hours taken before the test should be noted. Significant improvement in the distance walked, or the dyspn\textsubscript{o}ea scale, after administration of bronchodilators has been demonstrated in patients with COPD.

**Procedure**

- The 6MWT must initially be performed on two occasions to account for a learning effect. The best distance walked in metres is recorded.
- If the two tests are performed on the same day, at least 30 minutes rest should be allowed between tests. Some individuals may require tests to be performed on separate days, preferably less than one week apart.

1) Set the lap counter to zero, and the timer to 6 minutes (or stopwatch to zero)
2) After the subject has been at rest for 15 minutes, obtain and record measurements of blood pressure, heart rate, oxygen saturation and Borg dyspnoea and fatigue scores.
3) Direct the subject to the ‘start line’ of the walking track.
4) Describe the walking track to the subject, and then demonstrate by walking one lap yourself. Walk and pivot around a cone briskly (if applicable).
5) Give the patient the following instructions:

"The object of this test is to walk as far as possible for 6 minutes. You will walk back and forth in this hallway. Six minutes is a long time to walk, so you will be exerting yourself. You will probably get out of breath or become exhausted. You are permitted to slow down, to stop, and to rest as necessary. You may lean against the wall while resting, but resume walking as soon as you are able.

You will be walking back and forth around the cones. You should pivot briskly around the cones and continue back the other way without hesitation. Now I'm going to show you. Please watch the way I turn without hesitation."

Demonstrate by walking one lap yourself. Walk and pivot around a cone briskly.
"Are you ready to do that? I am going to use this counter to keep track of the number of laps you complete. I will click it each time you turn around at this starting line. Remember that the object is to walk AS FAR AS POSSIBLE for 6 minutes, but don’t run or jog.

Start now, or whenever you are ready."

6) Start the timer when the patient begins to walk
7) Monitor the subject for any untoward signs and symptoms throughout the duration of the test
8) Do not talk to anyone during the walk. Use an even tone of voice when using the standard phrases of encouragement. Watch the patient. Do not get distracted and lose count of the laps. Ensure you keep count of the number of lengths or laps as the subject completes them throughout the duration of the test. Each time the participant returns to the starting line, click the lap counter once (or mark the lap on the worksheet). Let the participant see you do it – exaggerate the motion if necessary.
9) Use the following standard encouragements during the test, using an even tone of voice:
   - At minute one: “You are doing well. You have five minutes to go.”
   - At minute two: “Keep up the good work. You have four minutes to go.”
   - At minute three: “You are doing well. You are halfway done.”
   - At minute four: “Keep up the good work. You have only two minutes left.”
   - At minute five: “You are doing well. You have only one minute to go.”

10) If the subject stops during the six minutes:
   - Do NOT stop the timer
   - Allow the subject to sit in a chair if they wish.
   - Measure and record the oxygen saturations and heart rate.
   - Ask patient why they stopped, and record the reason.
   - Record the time the subject stopped (but keep the stop watch running).
   - If the patient stops, give the following instruction “You can lean against the wall if you would like; then continue walking whenever you feel able.”
   - If the patient refuses to continue (or you decide that they should not continue), discontinue the walk, and note on the worksheet the distance, the time stopped, and the reason for stopping prematurely.

11) When the timer is 15 seconds from completion, say: “In a moment I’m going to tell you to stop. When I do, just stop right where you are and I will come to you.”
12) When the time reaches exactly 6 minutes, say: “Stop!”. Consider taking a chair over to the subject if they look exhausted. Mark the spot where they stopped by placing a marker on the floor.
13) Allow the subject to sit down or, if the subject prefers, allow them to stand. Note: The measurements taken before and after the test should be taken with the subject in the same position.
14) Immediately record oxygen saturation, heart rate, Borg dyspnoea and fatigue rating on the proforma. Measure and record the subject’s blood pressure.
15) Total up the number of lengths/laps walked, and measure the excess distance with a trundle wheel/tape measure/marks along track or corridor. Tally up the total distance walked by the subject, rounded to the nearest metre, and record on the proforma.

16) Congratulate the patient on good effort and offer a drink of water.

17) The subject should remain in a clinical area for at least 15 minutes following an uncomplicated test, or be allowed to rest for at least 30 minutes if performing the second walk test on the same day.

Reference


Author: C Smith
Reviewed: M Polkey
Date: 26th May, 2011
How old are you?  
Are you male or female?  
Did you have a stroke or TIA?  
What side of your body did it affect?

---

Section 1. Stroke Knowledge

1. What is a stroke?

2. What are the two main types of stroke?

3. What type of stroke did you have?

4. What can cause a stroke ie. what are the risk factors for a stroke?

5. What caused your stroke?

6. Do you think you can do anything about preventing another stroke?
Section 2. Weight – knowledge and attitudes

7. Would you consider yourself:

Underweight    Healthy weight    Overweight    Obese

8. Do you want to change your weight?

9. How confident are you that you can change your weight? (0 – not confident, 10 – very confident)

   1  2  3  4  5  6  7  8  9  10

10. How important is it for you on a scale of 0 – 10 (0 being not important, 10 being very important)

    1  2  3  4  5  6  7  8  9  10

11. What is the best way to lose weight?

12. What difficulties might you have with losing weight?

13. What would encourage you to lose weight?

Section 3. Diet – knowledge and attitudes

14. What do you consider to be a healthy diet?
16. What changes would you make to your own diet?

17. How confident are you that you can make those changes? (0 – not confident, 10 – very confident)

    0  1  2  3  4  5  6  7  8  9  10

18. How important is it to you that you make these changes? (0 – not important, 10 – very important)

    0  1  2  3  4  5  6  7  8  9  10

19. What difficulties might you have with eating more healthily?

20. What would encourage you to change your diet?

21. Which statements do you agree with?

   a) Healthy foods are enjoyable          agree/disagree
   b) I really care about what I eat     agree/disagree
   c) It's confusing – what foods are healthy?  agree/disagree
   d) If you do enough exercise you can eat what you want agree/disagree
   e) I try to eat only at meal times    agree/disagree
   f) I eat more when I am depressed or worried agree/disagree
   g) I eat more if I am upset            agree/disagree

Section 4: Smoking - Knowledge and attitudes

22. Are you a smoker?
23. Do you want to give up smoking?

24. How confident are you that you can give up? [0 – not confident, 10 – very confident]

25. How important is it for you on a scale of 0 – 10 (0 being not important, 10 being very important)

26. What is the best way to give up smoking?

27. What difficulties might you have trying to give up smoking?

28. What would encourage you to give up smoking?

Section 2. Physical activity – knowledge and attitude

29. What is the recommended level of physical activity for adults?

30. How many minutes of activity/exercise do you do a week?

31. What type of activity?
32. What changes would you make to your activity levels?

33. How confident are you that you can make these changes? (0—not confident, 10—very confident)

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
---|---|---|---|---|---|---|---|---|---|---|

34. How important is it for you on a scale of 0—10 (0 being not important, 10 being very important)

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
---|---|---|---|---|---|---|---|---|---|---|

35. What is the best way to change your activity levels?

36. What difficulties might you have changing your activity levels?

37. What would encourage you to change your activity levels?

38. Which statements do you agree with?

a) Exercise should be avoided in hot weather           agree/disagree
b) I really enjoy exercise                              agree/disagree
c) Exercise reduces your risk of developing type-2 diabetes agree/disagree
d) If you watch what you eat you don’t have to exercise agree/disagree
e) You should be at least comfortably short of breath when exercising agree/disagree
f) Vigorous exercise increases the risk of stroke agree/disagree
g) Over time exercise reduces your resting blood pressure and heart rate agree/disagree

Thank you for your comments
Falls diary

Please fill in this falls diary every day over the next six weeks. A fall is described as 'unintentionally coming to rest on the ground or at some other level'. Thank you for your efforts.

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<th>Injury? Did you contact anyone?</th>
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<td>39</td>
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<td>42</td>
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</tbody>
</table>

Please bring with you on your last visit.

Thank you
National Institute of Health Stroke Scale (NIHSS)

NIH STROKE SCALE

Interval: [ ] Baseline  [ ] 2 hours post treatment  [ ] 24 hours post onset of symptoms ± 20 minutes  [ ] 7-10 days  [ ] 3 months  [ ] Other __________ (______)

Time: _______ _____ [ ] am  [ ] pm

Person Administering Scale

Administer stroke scale items in the order listed. Record performance in each category after each subscale exam. Do not go back and change scores. Follow directions provided for each exam technique. Scores should reflect what the patient does, not what the clinician thinks the patient can do. The clinician should record answers while administering the exam and work quickly. Except where indicated, the patient should not be coached (i.e., repeated requests to patient to make a special effort).

Instructions

<table>
<thead>
<tr>
<th>Scale Definition</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a. Level of Consciousness: The investigator must choose a response if a full evaluation is prevented by such obstacles as an endotracheal tube, tracheostomy, or other severe uncooperative state. A score of 3 is given only if the patient makes no movement (other than reflexive pulling) in response to noxious stimulation.</td>
<td>G = Alert; lanely responsive.</td>
</tr>
<tr>
<td>1b. LOC Question: The patient is asked the number and correct age. The answer must be correct - there is no partial credit for being close. Aphasics and stuporous patients who do not comprehend the question will score 0. Patients unable to speak because of endotracheal intubation, tracheostomy, severe dysarthria from any cause, language barrier, or other problem not secondary to aphasia are given a 1. It is important that only the initial answer be graded and that the examiner not &quot;help&quot; the patient with verbal or non-verbal cues.</td>
<td>0 = Answers both questions correctly.</td>
</tr>
<tr>
<td>1c. LOC Commands: The patient is asked to open and close the eyes and then to grasp and release the non-paretic hand. Substitute another one-step command if the hands cannot be used. Credit is given if an unequivocal attempt is made but not completed due to weakness. If the patient does not respond to command, the task should be demonstrated to him or her (passive move), and the result scored (i.e., follows none, one or two commands). Patients with coma, unresponsiveness, or other physical impediments should be given suitable one-step commands. Only the first attempt is scored.</td>
<td>0 = Performs both tasks correctly.</td>
</tr>
<tr>
<td>2. Best Gaze: Only horizontal eye movements will be tested. Voluntary or reflexive (oculocerebellar) eye movements will be scored, but voluntary testing is not done. If the patient has conjugate deviation of the eyes that can be overcome by voluntary or reflexive activity, the score will be 1. If a patient has an isolated peripheral nerve paresis (CN III, IV or VI), score a 1. Gaze is testable in all aphasis patients. Patients with outer trauma, head injuries, pre-existing blindness, or other disorders of visual acuity or fields should be tested with roentgen movement, and a clinical aphasis by the investigator. Establishing eye contact and then moving about the patient from side to side will occasionally clarify the presence of a partial gaze palsy.</td>
<td>0 = Normal.</td>
</tr>
</tbody>
</table>

Rev 10/1/2003

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### NIH Stroke Scale

#### Interval:
- [ ] Baseline
- [ ] 2 hours post treatment
- [ ] 24 hours post onset of symptoms ± 20 minutes
- [ ] 7-10 days
- [ ] 3 months
- Other: ____________________________

#### Item 3: Visual Field
- 0 = No visual loss.
- 1 = Partial hemianopia.
- 2 = Complete hemianopia.
- 3 = Bilateral hemianopia (blind including cortical blindness).

#### Item 4: Facial Palsy
- 0 = Normal symmetrical movements.
- 1 = Minor paralysis (flattened nasolabial fold, asymmetry on smiling).
- 2 = Partial paralysis (total or near-total paralysis of lower face).
- 3 = Complete paralysis of one or both sides (absence of facial movement in the upper and lower face).

#### Item 5: Motor Arm
- 0 = No drift; limb holds 90 (or 45) degrees for full 10 seconds.
- 1 = Drift; limb holds 90 (or 45) degrees, but drifts down before full 10 seconds; does not hit bed or other support
- 2 = Some effort against gravity; limb cannot get to or maintain (if used) 90 (or 45) degrees, drifts down to bed, but has some effort against gravity.
- 3 = No effort against gravity; limb falls.
- 4 = No movement.
- UN = Amputation or joint fusion, explain:

  5a. Left Arm
  5b. Right Arm

#### Item 6: Motor Leg
- 0 = No drift; leg holds 90 degree position for full 6 seconds.
- 1 = Drift; leg holds 90 degree position for the end of the 6-second period but does not hit bed.
- 2 = Some effort against gravity; leg falls to bed by 5 seconds, but has some effort against gravity.
- 3 = No effort against gravity; leg falls to bed immediately.
- 4 = No movement.
- UN = Amputation or joint fusion, explain:

  6a. Left Leg
  6b. Right Leg

---

**284**
<table>
<thead>
<tr>
<th>Interval:</th>
<th>Baseline</th>
<th>2 hours post treatment</th>
<th>24 hours post onset of symptoms</th>
<th>5-10 days</th>
<th>3 months</th>
<th>Other</th>
</tr>
</thead>
</table>

7. Limb Ataxia: This item is aimed at finding evidence of a unilateral cerebellar lesion. Test with eyes open. In case of visual defect, ensure testing is done in a direct visual field. The finger-to-nose and heel-to-shin tests are performed on both sides, and ataxia is scored only if present in one hemisphere. Ataxia is scored absent in the patient who cannot understand or is paralysed. Only in the case of amputated or joint fusion, the examiner should record the score as untestable (UN), and clearly write an explanation of this choice. In cases of bilateral test by having the patient touch nose from extended arm position.

8. Sensory: Sensation or grimmance to pinch when touched, or withdrawal from noxious stimulus in the obtunded or aphasic patient. Only sensory loss attributed to stroke is scored as abnormal and the examiner should test as many body areas (arms, legs, face, lower, upper) as needed to accurately check for hemisensory loss. A score of 2, "severe or total sensory loss," should only be given when a severe or total loss of sensation can be clearly demonstrated. Unconscious and aphasic patients will, therefore, probably score 1 or 0. The patient with a brainstem stroke who has bilateral loss of sensation is scored 2. If the patient does not respond and is quadraplegic, score 2. Patients in a coma (item 9c) are automatically given a 2 on this item.

9. Body Language: A great deal of information about comprehension will be obtained during the preceding sections of the examination. For this scale item, the patient is asked to describe what is happening in the attached picture, to name the items on the attached naming sheet and to read from the attached list of sentences. Comprehension is judged from the responses here, as well as to all of the commands in the preceding general neurological exam. If visual loss interferes with the test, ask the patient to identify objects placed in the hand, repeat, and produce speech. The intubated patient should be asked to write. The patient in a coma (item 9c) will automatically score 3 on this item. The examiner must choose a score for the patient with stupor or limited cooperation, but a score of 3 should be used only if the patient is told and follows no one-step commands.

10. Dysarthria: If patient is thought to be normal, an adequate sample of speech must be obtained by asking patient to read or repeat words from the attached list. If the patient has severe aphasia, the clarity of articulation of spontaneous speech can be raised. Only if the patient is intubated or has other physical barriers to producing speech, the examiner should record the score as untestable (UN), and clearly write an explanation for this choice. Do not tell the patient why he or she is being tested.

---

**NIH Stroke Scale**

**Patient Information:**

- **Patient Identification:**
- **Pl. Date of Birth:**
- **Hospital:**
- **Date of Exam:**

**Interval:**

- Baseline
- 2 hours post treatment
- 24 hours post onset of symptoms
- 5-10 days
- 3 months
- Other

**0 = Absent.**

1 = Present in one limb.

2 = Present in two limbs.

UN = Amputated or joint fusion, explain:

**0 = Normal; no sensory loss.**

1 = Mild-to-moderate sensory loss; patient feels pinch is lean or is dull on the affected side, or there is a loss of superficial pain with pinprick, but patient is aware of being touched.

2 = Severe to total sensory loss; patient is not aware of being touched in the face, arm, and leg.

**0 = No aphasia; normal.**

1 = Mild-to-moderate aphasia; some obvious loss of fluency or facility of comprehension, without significant limitation on ideas expressed or form of expression. Reduction of speech and/or comprehension, however, impairs conversation about provided materials difficult or impossible. For example, in conversation about provided materials, examiner can identify picture or naming card content from patient's response.

2 = Severe aphasia; all communication is through fragmentary expressions; great need for inference, questioning, and passing by the listener. Range of information that can be exchanged is limited; listener cannot be understood. Examiner cannot identify resources provided from patient's response.

3 = Mutism, global aphasia; no usable speech or auditory comprehension.

**0 = Normal.**

1 = Mild-to-moderate dysarthria; patient slurs at least some words and, at worst, can be understood with some difficulty.

2 = Severe dysarthria; patient's speech is so slurred as to be unintelligible in the absence of or out of proportion to any dysphasia, or is mute/aphonic.

UN = Intubated or other physical barrier, explain.
| Interval: | [] Baseline | [] 2 hours post treatment | [] 24 hours post onset of symptoms ±20 minutes | [] 7-10 days | [] 2 months | [] Other |

11. Extinction and Inattention (formerly Neglect): Sufficient information to identify neglect may be obtained during the prior testing. If the patient has a severe visual loss preventing visual or tactile simultaneous stimulation, and the cutaneous stimuli are normal, the score is normal. If the patient has aphasia but does appear to attend to both sides, the score is normal. The presence of visual spatial neglect or anosognosia may also be taken as evidence of anosognosia. Since the abnormality is scored only if present, the item is never understated.

0 = No abnormality.
1 = Visual, tactile, auditory, spatial, or personal inattention or extinction to bilateral simultaneous stimulation in one of the sensory modalities.
2 = Profound hemi-inattention or extinction to more than one modality; does not recognize own hand or objects to only one side of space.
Modified Ashworth Scale (MAS)

Modified Ashworth Scale Instructions

General Information (derived Bohannon and Smith, 1987):
- Place the patient in a supine position
- If testing a muscle that primarily flexes a joint, place the joint in a maximally flexed position and move to a position of maximal extension over one second (count "one thousand one")
- If testing a muscle that primarily extends a joint, place the joint in a maximally extended position and move to a position of maximal flexion over one second (count "one thousand one")
- Score based on the classification below

Scoring (taken from Bohannon and Smith, 1987):

0  No increase in muscle tone
1  Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is moved in flexion or extension
1+ Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the ROM
2  More marked increase in muscle tone through most of the ROM, but affected part(s) easily moved
3  Considerable increase in muscle tone, passive movement difficult
4  Affected part(s) rigid in flexion or extension

Patient Instructions:
The patient should be instructed to relax.
Modified Ashworth Scale Testing Form

Name: ___________________________ Date: __________

<table>
<thead>
<tr>
<th>Muscle Tested</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>
SF-36 QUESTIONNAIRE

Name: ___________________________ Ref. Dr: ___________________________ Date: ________
ID#: ___________________________ Age: ________ Gender: M / F

Please answer the 36 questions of the Health Survey completely, honestly, and without interruptions.

GENERAL HEALTH:
In general, would you say your health is:
☐ Excellent ☐ Very Good ☐ Good ☐ Fair ☐ Poor

Compared to one year ago, how would you rate your health in general now?
☐ Much better now than one year ago
☐ Somewhat better now than one year ago
☐ About the same
☐ Somewhat worse now than one year ago
☐ Much worse than one year ago

LIMITATIONS OF ACTIVITIES:
The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.
☐ Yes, Limited a lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf
☐ Yes, Limited a Lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Lifting or carrying groceries
☐ Yes, Limited a Lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Climbing several flights of stairs
☐ Yes, Limited a Lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Climbing one flight of stairs
☐ Yes, Limited a Lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Bending, kneeling, or stooping
☐ Yes, Limited a Lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Walking more than a mile
☐ Yes, Limited a Lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Walking several blocks
☐ Yes, Limited a Lot ☐ Yes, Limited a Little ☐ No, Not Limited at all

Walking one block
☐ Yes, Limited a Lot ☐ Yes, Limited a Little ☐ No, Not Limited at all
Bathing or dressing yourself
○ Yes, Limited a Lot ○ Yes, Limited a Little ○ No, Not Limited at all

PHYSICAL HEALTH PROBLEMS:
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

Cut down the amount of time you spent on work or other activities
○ Yes ○ No

Accomplished less than you would like
○ Yes ○ No

Were limited in the kind of work or other activities
○ Yes ○ No

Had difficulty performing the work or other activities (for example, it took extra effort)
○ Yes ○ No

EMOTIONAL HEALTH PROBLEMS:
During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

Cut down the amount of time you spent on work or other activities
○ Yes ○ No

Accomplished less than you would like
○ Yes ○ No

Didn't do work or other activities as carefully as usual
○ Yes ○ No

SOCIAL ACTIVITIES:
Emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?
○ Not at all ○ Slightly ○ Moderately ○ Severe ○ Very Severe

PAIN:
How much bodily pain have you had during the past 4 weeks?
○ None ○ Very Mild ○ Mild ○ Moderate ○ Severe ○ Very Severe

During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?
○ Not at all ○ A little bit ○ Moderately ○ Quite a bit ○ Extremely
ENERGY AND EMOTIONS:

These questions are about how you feel and how things have been with you during the last 4 weeks. For each question, please give the answer that comes closest to the way you have been feeling.

Did you feel full of pop?
- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little bit of the time
- None of the time

Have you been a very nervous person?
- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little bit of the time
- None of the time

Have you felt so down in the dumps that nothing could cheer you up?
- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little bit of the time
- None of the time

Have you felt calm and peaceful?
- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little bit of the time
- None of the time

Did you have a lot of energy?
- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little bit of the time
- None of the time
Have you felt downhearted and blue?
☐ All of the time
☐ Most of the time
☐ A good bit of the time
☐ Some of the time
☐ A little bit of the time
☐ None of the time

Did you feel worn out?
☐ All of the time
☐ Most of the time
☐ A good bit of the time
☐ Some of the time
☐ A little bit of the time
☐ None of the time

Have you been a happy person?
☐ All of the time
☐ Most of the time
☐ A good bit of the time
☐ Some of the time
☐ A little bit of the time
☐ None of the time

Did you feel tired?
☐ All of the time
☐ Most of the time
☐ A good bit of the time
☐ Some of the time
☐ A little bit of the time
☐ None of the time

SOCIAL ACTIVITIES:
During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?
☐ All of the time
☐ Most of the time
☐ Some of the time
☐ A little bit of the time
☐ None of the time

GENERAL HEALTH:
How true or false is each of the following statements for you?

I seem to get sick a little easier than other people
☐ Definitely true ☐ Mostly true ☐ Don't know ☐ Mostly false ☐ Definitely false

I am as healthy as anybody I know
☐ Definitely true ☐ Mostly true ☐ Don't know ☐ Mostly false ☐ Definitely false

I expect my health to get worse
☐ Definitely true ☐ Mostly true ☐ Don't know ☐ Mostly false ☐ Definitely false

My health is excellent
☐ Definitely true ☐ Mostly true ☐ Don't know ☐ Mostly false ☐ Definitely false
Hospital Anxiety and Depression Scale (HADS)

Chart I — Hospital Anxiety and Depression Scale

This questionnaire will help your physician 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. Mark only one answer for each question.

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

D (6) I feel as if I am slowed down:
   3( ) Nearly all the time
   2( ) Very often
   1( ) From time to time
   0( ) Not at all

A (5) I get a sort of frightened feeling like butterflies in the stomach:
   3( ) Not at all
   1( ) From time to time
   2( ) Quite often
   3( ) Very often

A (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 (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 (9) 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

A (3) Worrying thoughts go through my mind:
   3( ) Most of the time
   2( ) A lot of times
   1( ) From time to time
   0( ) Only occasionally

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

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

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

D (14) I can enjoy a good TV or radio program or book:
   0( ) Often
   1( ) Sometimes
   2( ) Not often
   3( ) Hardly at all
# Multidimensional Fatigue Symptom Inventory – Short Form (MFSI)

**MFSI-SF**

Below is a list of statements that describe how people sometimes feel. Please read each item carefully, then circle the one number next to each item which best describes how true each statement has been for you in the past 7 days.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Not at all</th>
<th>A little</th>
<th>Moderately</th>
<th>Quite a bit</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I have trouble remembering things</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. My muscles ache</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. I feel upset</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. My legs feel weak</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5. I feel cheerful</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6. My head feels heavy</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>7. I feel lively</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>8. I feel nervous</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>9. I feel relaxed</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>10. I feel pooped</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>11. I am confused</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>12. I am worn out</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>13. I feel sad</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>14. I feel fatigued</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>15. I have trouble paying attention</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>16. My arms feel weak</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>17. I feel sluggish</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>18. I feel run down</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>19. I ache all over</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>20. I am unable to concentrate</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>21. I feel depressed</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>22. I feel refreshed</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>23. I feel tense</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>24. I feel energetic</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>25. I make more mistakes than usual</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>26. My body feels heavy all over</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>27. I am forgetful</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>28. I feel tired</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>29. I feel calm</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>30. I am distressed</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

Multidimensional Fatigue Symptom Inventory-Short Form, Moffitt Cancer Center and University of South Florida, Tampa, FL. ©1998
**Barthel Index**

**FEEDING**
- 0 = unable
- 5 = needs help cutting, spreading butter, etc., or requires modified diet
- 10 = independent

**BATHING**
- 0 = dependent
- 5 = independent (or in shower)

**GROOMING**
- 0 = needs help with personal care
- 5 = independent (face, hair, teeth, shaving (implements provided))

**DRESSING**
- 0 = dependent
- 5 = needs help but can do about half unaided
- 10 = independent (including buttons, zips, laces, etc.)

**BOWELS**
- 0 = incontinent (or needs to be given enemas)
- 5 = occasional accident
- 10 = continent

**BLADDER**
- 0 = incontinent, or catheterized and unable to manage alone
- 5 = occasional accident
- 10 = continent

**TOILET USE**
- 0 = dependent
- 5 = needs some help, but can do something alone
- 10 = independent (on and off, dressing, wiping)

**TRANSFERS (BED TO CHAIR AND BACK)**
- 0 = unable, no sitting balance
- 5 = minor help (one or two people, physical), can sit
- 10 = minor help (verbal or physical)
- 15 = independent

**MOBILITY (ON LEVEL SURFACES)**
- 0 = immobile or < 50 yards
- 5 = wheelchair independent, including corners, > 50 yards
- 10 = walks with help of one person (verbal or physical) > 50 yards
- 15 = independent (but may use any aid; for example, stick) > 50 yards

**STAIRS**
- 0 = unable
- 5 = needs help (verbal, physical, carrying aid)
- 10 = independent

**TOTAL (0-100):**
Appendix 8 – copies of articles

A qualitative study exploring patients’, with mild to moderate stroke, and their carers’ perceptions of healthy lifestyles

Nicola Clague-Baker, Christine Carpenter, Thompson Robinson, Annegret Hagenberg, Sophie Drewry, Sally Singh

Abstract

Background/Aims: To explore patients’, with mild to moderate stroke, and their carers’ experiences after a stroke and to explore their perceptions of healthy lifestyles.

Methods: A qualitative study using semi-structured interviews was undertaken with 20 people (12 males and 8 females) with mild to moderate stroke or transient ischaemic attack (1 week to 6 months’ post event) and seven of their carers. Each interview was transcribed and a thematic analysis approach guided the analytic process.

Results: Patients with sub-acute, mild to moderate stroke were positive about healthy lifestyles and their ability to achieve them post-stroke. Three core themes were identified: perceptions related to exercise; perceptions related to other lifestyle factors; and understanding of stroke and healthy lifestyles.

Conclusions: In the sub-acute phase of stroke recovery, barriers to exercise such as lack of motivation do not appear to be an issue. People with stroke have a lack of understanding of healthy guidelines, risk factors and cause of their stroke. It is not clear if this is due to a lack of information provision or a lack of recall. They also do not appear to make the link between lifestyle choices and the cause of their stroke.

Key words: Cardiovascular fitness, Healthy lifestyles, Perceptions, Physiotherapy, Stroke

Submitted 28 July 2016; accepted following double blind peer review: 13 June 2017

Stroke is the primary cause of disability in England (National Audit Office, 2010) and leads to reduced physical activity and cardiorespiratory fitness, which, in turn, are associated with increased cardiovascular risk (Ivey et al., 2005). Following a stroke, patients are at risk of recurrent stroke (approximately 25% within five years) and other vascular events (Raffone et al., 2006). Risk factors that lead to recurrent vascular events include lifestyle risks such as poor diet, obesity, lack of exercise and smoking (Lawrence et al., 2009).

Previous qualitative research exploring perceptions towards healthy living in people with stroke has been mainly focused on the identification of barriers and facilitators to exercise post stroke. Nicholson et al. (2012) conducted a systematic review of five qualitative and one quantitative study that explored barriers and facilitators to exercise. Four of the studies were conducted in the US, one in Australia and one in the UK. The authors concluded that lack of motivation, environmental factors and stroke impairments were the main barriers to engaging in exercise post stroke, and that the main motivators were the desire to return to independence, and support from family and professionals. One further study in Canada (Simpson and Eng, 2011) found similar results and stated the main barrier for patients with chronic stroke was self-efficacy. This study and the systematic review mainly focused on patients with chronic stroke. It is debatable whether barriers and facilitators to exercise will be the same at all stages of post-stroke recovery and with different levels of stroke severity. The present study, therefore, aimed to focus on perceptions of healthy living of patients with sub-acute, mild to moderate stroke rather than a discussion of barriers and facilitators to exercise.

Previous research exploring the understanding of healthy lifestyles of people with stroke has focused mainly on the provision and delivery of advice.

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A survey of people with stroke conducted by the Healthcare Commission (2006) found that 43% of respondents were not given any information about dietary changes and one in three were not given any information about physical exercise. In the same year, the Stroke Association (2006) conducted an audit of stroke units and patients and found that only 46% of patients were given any information about future stroke prevention. The American Stroke Association (Furie et al, 2011) recommended cardiovascular training and lifestyle modification to reduce the risk of further stroke.

A Cochrane review exploring intervention provision for stroke patients and their caregivers (Forster et al, 2012) found that active information provision, where the participants were able to ask questions and relate the information to their experience, was more successful than a passive approach in improving knowledge. The review aimed to assess the effectiveness of information provision strategies for stroke patients and their caregivers; however, all the studies included measured knowledge using a variety of structured questionnaires, and no qualitative studies were identified. Assessment of knowledge was a component of the design of all of the studies in the review. As Fillis et al (2013) commented: “future research should explore views of people not included in a trial”.

Therefore, the aim of the present study was to explore the perceptions of healthy lifestyles in individuals following a sub-acute stroke who were not involved in other studies.

METHODS

A qualitative phenomenological approach (Dowling, 2007) was chosen as the most appropriate to gain an in-depth understanding of individuals’ perceptions of the topic of interest.

Ethics

Prior to recruitment and data collection, ethical approval was gained from the Northampton Ethics Committee (Reference: 14/EM/067). Anonymity and confidentiality were ensured and informed consent obtained from a participant.

Participants

Twenty participants with a range of sub-acute, mild to moderate stroke were recruited from stroke units, early supportive discharge teams, community teams and transient ischaemic attack (TIA) clinics at a large university teaching hospital. Participants were purposively chosen if they had had a mild to moderate stroke (using the National Institutes of Health Stroke Scale (NIHSS): mild: <5; moderate: 6–15) (National Institute for Health, 2016) or TIA, were within 6 months of their stroke and could walk 10 metres. Seven of the participants had carers present who contributed to the discussions.

Procedure

An interview schedule (Table 1) was developed by the principal investigator (NCB) and research team, and was piloted with a patient representative who satisfied inclusion criteria, and his carer. The pilot interview offered the opportunity to refine the questions and enhance the principal investigator’s qualitative interviewing skills. Therefore, semi-structured in-depth interviews, approximately 45–90 minutes in length, were conducted with 20 participants in their homes. In seven of the interviews, the carers were present; however, the questions were primarily directed to the individuals with stroke during the interviews. The carers were involved at the participants’ request and their comments were audio taped and probing questions asked as necessary. Fourteen interviews were conducted by NCB and six by research assistants (AAI and SD), who had previously received guidance in qualitative interviewing from NCB. Field notes were taken after each interview, recording details, such as the participant’s level of disability, home environment, body language and other observations. Data collection, and the initial stages of data analysis, occurred concurrently and the interviews were continued until it was considered that data saturation had been achieved. All interviews were audio taped and transcribed verbatim by a professional transcriber. The participants were offered the opportunity to review their interview transcripts in order to add or delete content if they wished; however, only two participants chose to be involved at this stage.

Data analysis

Thematic analysis was conducted according to the analytic framework developed by Braun and Clarke (2006). The data were analysed by NCB and colleagues (CC) with experience in qualitative approaches, and the research assistant contributed additional insights. Open inductive coding, through line-by-line reading of the transcripts of participant interviews was undertaken. In each transcript, participants’ statements that appeared to inform the study purpose were highlighted and codes assigned that represented the key message or concept of these statements. The coded data were gradually abstracted from the transcript and condensed until a number of core categories were identified that provided an in-depth description of participants’ perceptions of healthy lifestyles. These core categories were then used to develop key messages.

NCB consistently reflected on her own personal and professional assumptions and beliefs about
exercise and maintaining a healthy lifestyle could influence the data collection and analysis processes. She has been a neurological physiotherapist and university lecturer for 26 years. She made every effort throughout the study implementation to make explicit her positive attitudes towards exercise and the importance of healthy living. During the interview process she did not identify herself as a physiotherapist in case that knowledge influenced the participants’ responses. One research assistant, who was less positive of the benefits of exercise post-stroke, was specifically asked to contribute to the analytic process.

RESULTS

Twenty volunteers participated in the study: 12 men and eight women who ranged in age between 50 and 88 years. Their ethnicity reflected the local population, with 14 Caucasian, four Asian and two Afro-Caribbean participants. The average length of time post stroke was 59 days (range 14–124) (see Table 2). In seven interviews, participants’ cases were present and contributed to the discussion.

Data analysis identified three core themes:

- Perceptions related to exercise
- Perceptions related to other lifestyle factors
- Understanding of stroke and healthy lifestyles.

**Perceptions related to exercise**

Sub-categories contributing to perceptions related to exercise were:
<table>
<thead>
<tr>
<th>Participant</th>
<th>Gender</th>
<th>Age</th>
<th>Occupation</th>
<th>Ethnicity</th>
<th>Time after stroke (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F</td>
<td>78</td>
<td>Retired Nurse</td>
<td>Caucasian</td>
<td>59</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>67</td>
<td>Manager</td>
<td>Caucasian</td>
<td>69</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>35</td>
<td>Security guard</td>
<td>Black Afro-Caribbean</td>
<td>109</td>
</tr>
<tr>
<td>4</td>
<td>F</td>
<td>45</td>
<td>Shop worker</td>
<td>Caucasian</td>
<td>38</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>68</td>
<td>Shop fitter</td>
<td>Caucasian</td>
<td>14</td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>53</td>
<td>Manager</td>
<td>Asian</td>
<td>87</td>
</tr>
<tr>
<td>7</td>
<td>F</td>
<td>76</td>
<td>Mother</td>
<td>Asian</td>
<td>64</td>
</tr>
<tr>
<td>8</td>
<td>F</td>
<td>75</td>
<td>Retired Farmer's wife</td>
<td>Caucasian</td>
<td>72</td>
</tr>
<tr>
<td>9</td>
<td>F</td>
<td>58</td>
<td>Cleaner</td>
<td>Caucasian</td>
<td>22</td>
</tr>
<tr>
<td>10</td>
<td>M</td>
<td>45</td>
<td>Mechanic and mother</td>
<td>Caucasian</td>
<td>29</td>
</tr>
<tr>
<td>11</td>
<td>M</td>
<td>64</td>
<td>Retired Carpenter</td>
<td>Caucasian</td>
<td>35</td>
</tr>
<tr>
<td>12</td>
<td>M</td>
<td>71</td>
<td>Retired Graphic designer</td>
<td>Caucasian</td>
<td>29</td>
</tr>
<tr>
<td>13</td>
<td>M</td>
<td>30</td>
<td>Manager</td>
<td>Caucasian</td>
<td>19</td>
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<tr>
<td>14</td>
<td>M</td>
<td>53</td>
<td>Engineer</td>
<td>Caucasian</td>
<td>74</td>
</tr>
<tr>
<td>15</td>
<td>M</td>
<td>60</td>
<td>Retired Bus driver</td>
<td>Black Afro-Caribbean</td>
<td>64</td>
</tr>
<tr>
<td>16</td>
<td>M</td>
<td>71</td>
<td>Retired lecturer</td>
<td>Caucasian</td>
<td>109</td>
</tr>
<tr>
<td>17</td>
<td>M</td>
<td>65</td>
<td>Retired car salesman</td>
<td>Caucasian</td>
<td>36</td>
</tr>
<tr>
<td>18</td>
<td>M</td>
<td>59</td>
<td>Taxi driver</td>
<td>Asian</td>
<td>77</td>
</tr>
<tr>
<td>19</td>
<td>F</td>
<td>62</td>
<td>Mother</td>
<td>Caucasian</td>
<td>68</td>
</tr>
<tr>
<td>20</td>
<td>F</td>
<td>68</td>
<td>Mother</td>
<td>Asian</td>
<td>124</td>
</tr>
</tbody>
</table>

*I joined the gym about 10 weeks before I had the stroke and I'd lost about three quarters of a stone... I looked at it that I'm going to lose weight and that's it.* (P14)

Being independent was clearly very important to the participants and associated with 'getting stronger,' and ‘doing exercise’. As one participant said:

*‘It [exercise] helps you to become a bit more independent.’* (P1)

The participants functioned independently before having a stroke and were keen to achieve independence again. As one carer said:

*‘Because she [P20] was very independent before it, she feels bad that somebody has to give her a shower or bath.'* (C1)

This desire for independence also linked with an overwhelming need to be ‘normal’ again. Exercise was seen as a way to achieving normality: *‘It will make me feel normal again, the more I can do the more I feel I am just back to normal and it’s gone away.’* (P13)

However, the participants did not identify the benefits of reducing their cardiovascular risk factors, such as decreasing blood pressure and cholesterol levels or the relationship of these with a decreased risk of future cardiovascular events. The link between exercise and risk prevention or reduction were clearly not understood by the participants.

**Motivators**

Participants identified a number of factors they felt would motivate or facilitate their involvement with exercise post stroke. Using social cognitive theory (Bandura, 2004), facilitators of exercise engagement can be divided into personal, social, and environmental.

The personal facilitators that the participants in this study identified included: the fear of having another stroke; the fear of being dependent; religious guidance; and enjoying being competitive. In other
words, participants did not “want to be bazoned by the stroke” (P13).

The social facilitators of exercise included religious beliefs; support from friends and family; walking groups; and support from therapists and exercise professionals. The personal and social facilitators identified in the literature highlight the importance of people with chronic stroke attributes to the support of family, friends and professionals in encouraging them to establish and achieve their exercise goals. The participants in this study did not identify any environmental facilitators that might encourage them to exercise post stroke.

Difficulties

A number of difficulties or barriers were identified related to exercise post stroke. Personal difficulties associated with exercising included pain, fear or experience of falling, and fatigue. A number of participants identified pain and the existence of multiple pathologies as difficulties in exercise post stroke:

“I used to be very active before the arthritis started taking over ... I get a lot of pain in my back... it’s putting the morders on it a bit.” [ie, stopping the participant from enjoying activities] (P9)

The participants identified fear of falling and having a fall as factors preventing them from participating in exercise, particularly because their confidence was undermined and the experience of falling was difficult to overcome. As with the general falls population (Jung, et al, 2009), participants’ fear of falling was not necessarily associated with having fallen. As one participant explained:

“The negativity is constantly thinking I might fall.” (P3)

Some participants commented that other peoples’ attitudes contributed to their fear of falling. For example, one participant pointed out that:

“It’s the blame culture, if I fall over then it will be them (the nurses) that’s blamed not me.” (P2)

One carer said:

“I don’t let her walk on her own because she’s had a couple of falls.” (C1)

Participants also identified fatigue as a personal difficulty to participating in exercise post stroke. Fatigue in long-term conditions has been described as “decreased mental and physical endurance” (Krupp, 2003: 12). Participants explained:

“It’s an overwhelming problem that is constant—I am always tired.” (P9)

“It’s not that I want to go to sleep, it’s that my body says it wants to have a rest.” (P16)

This problem has also been identified in the literature in relation to the chronic stroke population (Forster, et al, 2012).

Interestingly, in the chronic fatigue population (White, et al, 2011), exercise has been shown to improve fatigue for people with chronic fatigue; however, this was not something that the participants in this study identified or discussed.

A number of participants expressed concerns about ‘overdoing it’:

“Yes my main concern is it’s going to be a sudden shock to the system to all of a sudden be bouncing around.” (P9)

“I think you can take exercise to the extreme.” (P11)

This perhaps highlights a lack of knowledge and understanding of appropriate exercise programmes and progression and the potential risks of exercise. Other personal difficulties included a degree of embarrassment associated with the physical aspects of stroke:

“You’re embarrassed to be like this.” (P14)

Interestingly, a lack of motivation were not identified as difficulties to exercise post stroke. Only one social difficulty to exercise after a stroke was identified in the interviews. For one participant (P7), religion was a barrier to exercise as she was unable to exercise with a mixed gender group and with male instructors. In the local area, this issue has been addressed with some facilities providing female only group swimming with female lifeguards. However, many exercise facilities do not offer these options.

Finally, a number of environmental difficulties were discussed, including inadequate or lack of accessible transportation.

“Well the first obstacle is how do I get there and back?” (P10)

This participant lived in the countryside without public transportation, although others lived in the city and still had problems—for example:

“The problem is the gym is the other side of town.” (P3)
Some participants were constrained by insufficient finances:

- ‘Financially it’s [living with a stroke] crippled me.’ (P9)
- ‘I think the only thing that worries me is that I’m always worrying about money.’ (P9)

These difficulties have previously been identified in research with people in the chronic stage of stroke recovery (Nicholson et al., 2012) and identify the need to provide facilities that support people who have had a stroke to exercise in the long term.

**Perceptions related to other lifestyle factors**

Sub-categories contributing to perceptions related to lifestyle changes were:

- Changes to lifestyle
- Doubts and disagreements

**Changes to lifestyle**

Most of the participants wanted to achieve a healthy lifestyle by improving their diet after the stroke, stopping smoking, or losing weight:

- ‘Cut down on the eating and start doing more exercise.’ (P3)
- ‘No I stopped it [smoking], after this, completely I have stopped.’ (P7)
- ‘I could do with losing 2 or 3 stone.’ (P11)

However, they were unable to articulate any definitive plans or details about how they were going to instigate this lifestyle change or maintain the change. The participants recognized the importance of changing their lifestyles in order to improve and maintain their health, but they did not appear to have the information necessary to support these changes.

**Doubts and disagreement**

Some participants expressed doubts about the positive benefits of a healthy lifestyle as despite their belief that they had lived a healthy lifestyle, they still had the stroke or they cited other people they knew who they believed were healthy, but who had still developed significant health problems:

- ‘I know people who exercise regularly have had heart attacks as well.’ (P1)
- ‘When you think that the guy who started jogging died jogging apparently ... he had a heart attack.’ (P9)
- ‘My wife died of lung cancer and she stayed in a ward where everyone on that ward had lung cancer and only one smoked.’ (P11)
- ‘I did a lot of exercise and it didn’t do me any good.’ (P19)

These perceptions could be interpreted as examples of confirmation bias, defined as ‘seeking or interpreting of evidence in ways that are partial to existing beliefs, expectations, or a hypothesis in hand’ (Nickerson, 1998: 175). It indicates that behaviour change for some participants might be difficult if they tend to select negative messages or even disagree with the concepts of benefits and risks and the preventative advantages associated with maintaining a healthy lifestyle, for example:

- ‘Are you trying to tell me having low cholesterol is a good thing—I don’t think so!’ (P18)

One participant simply felt that exercise was not part of his life before the stroke, making it very unlikely that he would participate in exercise after the stroke:

- ‘It wasn’t an important part of my life ... I couldn’t be bothered.’ (P6)

**Understanding of stroke and healthy lifestyles**

Sub-categories that contributed to understanding of stroke and healthy lifestyles were:

- Role of exercise
- Risk factors for stroke
- Cause of stroke
- Lack of information or recall

**Understanding the role of exercise**

When asked about their understanding of the recommended levels of exercise for their age, only two participants offered explanations of the recommended dose:

- ‘I probably do three lots of cardio a week at least 40 minutes at a time.’ (P6)
- ‘Everyone should do at least 10 000 strides a day.’ (P5)

Other participants’ knowledge was clearly hazy and several incorrect interpretations of the recommendations were articulated, for example:

- ‘It’s not recommended to go every day.’ (P1)
You've got to listen to your body.' (P12)“

Most of the participants had not given the issue of exercise after a stroke much thought; for example, when asked ‘Did you think about the appropriate amount of activity’, Participant 2 stated: ‘No definitely not’. Others made comments including:

‘I didn’t think about it, I didn’t realise that exercise could help with a stroke.’ (P3)“

‘I didn’t really think about it if I am honest.’ (P7) ‘I don’t really think about it much, I am just aware the more walking I can do the better.’ (P11)“

Risk factors associated with stroke

Some participants were able to discuss some of the risk factors associated with stroke, for example:

‘It’s important to keep the weight down ... have a sensible diet.’ (P1)“

‘I don’t think it’s my diet because I am not a great eater of fried things and fatty stuff. And I am not obese.’ (P9)“

‘Oh yes like high blood pressure, high cholesterol, high blood sugars, smoking which I have stopped now.’ (P13)“

‘I’m not a smoker, I’m not diabetic, I don’t have high stress...’ (P14)“

However, over half the participants were, rather worryingly, not aware of the risk factors that could lead to a stroke. As one participant who had diabetes said:

‘No I didn’t know there were any risks.’ (P15)“

Cause of stroke

Over half the participants were unable to discuss what might have contributed to them having a stroke, for example:

‘Nobody has been able to tell me.’ (P2)“

‘I don’t know, how do you get a blood clot?’ (P6)“

‘No I don’t know, nobody has explained to me about that.’ (P15)“

‘I don’t know really, must have been some weakness in the brain.’ (P16)“

I haven’t a clue.’ (P19)“

A number of the participants did understand that knowing what might have caused the stroke would enable them to target the changes they made in their lifestyle and recognised the importance of such knowledge:

‘And because they don’t know why it happened that worries me a bit, because it could happen again.’ (P13)“

‘I don’t know what the root cause was, which is somewhat unnerving because it could happen again unless I know what to do to prevent it ... if they could determine the cause of the stroke for me because I can’t tell you whether I need to change anything because I don’t know.’ (P14)“

Lack of information or recall

When asked about any advice they had been given about exercise, the main response was that they had been given specific strengthening and stretching exercises by the physiotherapist, but very few talked about advice they had been given about maintaining their fitness:

‘They don’t mention it [lifestyle issues ... nothing positive in terms of longer-term options.’ (P2)“

‘They didn’t talk about general fitness.’ (P6)“

‘I haven’t been told anything.’ (P9)“

‘Nobody has mentioned there is a benefit to exercise—that hasn’t been covered.’ (P14)“

‘I was simply told I should only do so much and not overdo things!’ (P15)“

‘No, they said continue doing the things you’ve been doing.’ (P16)“

One participant remembered being given advice about exercise post-stroke by the doctor:

‘The doctor let me do anything really he just said don’t lift weights... He didn’t really say one way or another; he didn’t say a lot to be honest.’ (P13)“

‘The participants’ responses, with respect to their understanding of the more general issues of healthy living and the importance of addressing these post-stroke, were cause for concern as they reflected a lack of information, for example:”
"Well they [health professionals] don't go into great detail about it." (P5)

"I haven't been told anything." (P9)

"Not a lot of information has been provided in all honesty." (P11)

"Nobody's said anything." (P12)

"Nobody has told us anything useful really, we've been looking online." (P20)

As the last comment suggests, some participants, particularly younger ones, did use and value the Internet as a source of obtaining information. However, a majority of the participants, those aged over 60 years, felt they did not have adequate computer skills or were comfortable effectively accessing the Internet, for example:

"I am not an online person." (P5)

"No, I don't know how to use a computer." (P7)

"I'm not computer literate." (P9)

"I don't have a computer." (P16)

"No, I only just about how to use my phone." (P18)

Printed leaflets providing information about stroke and common risk factors were given by health professionals to some of the participants, but these did not seem to have significantly contributed to their understanding. As one participant said:

"There was a lot of information leaflets at both hospitals. I just took them but I have not had a chance to read them. They were useful but perhaps if someone did actually say "well look, if you have this or do this!"." (P17)

It would appear that the participants were not given consistent or relevant information or advice about maintaining a healthy lifestyle or cardiovascular fitness. As Hillson et al (2013) found in their study exploring patients' experiences of standard care or cardiac rehabilitation post minor stroke and TIA, it is not always clear whether participants are able to recall the advice or information they are given. This raises issues of the nature, relevance and timing of health information and these require further research to ensure the effectiveness of these interventions for individual patients.

**DISCUSSION**

**Barriers and benefits**

The participants discussed a number of factors that prevented or made it difficult for them to engage in exercise, but these did not include a lack of motivation. This is in contrast to previous studies (Simpson and Eng, 2011; Nicholson et al, 2012) that focused on exploring the barriers and facilitators of exercise in the later stages of stroke recovery. It seems that it is important to work with people with stroke in the early stages of their recovery to encourage activity and to prevent perceived motivational barriers developing.

Participants in the present study identified a number of benefits of exercise that the Health Belief Model (Rosenstock, 1974) suggests could be beneficial to support their attempts to achieve a healthy lifestyle. The participants, however, did not discuss the benefits of illness or prevention of future cardiovascular events, which suggests that they did not consider this to be part of the role of exercise after stroke. More research is needed to find the best way to support people with stroke in their efforts to understand and maintain a healthy lifestyle and explore the long-term benefits of a healthy lifestyle after a stroke.

**Factors contributing to stroke**

It appears that participants did not fully understand the factors that contribute to having a stroke. They were able to discuss some lifestyle risk factors but did not seem to make the link between these and having a stroke. This was also identified in a study by Hillson et al (2013), who found that ‘some disregarded information about known risk factors for minor stroke or that lifestyle changes can reduce such factors’.

Effective health behaviour change relies on people taking ownership of their health behaviours, that is, switching from an ‘external locus of control’ to an ‘internal locus of control’ (Roter, 1966). If, as illustrated in this study, people are unable to make the link between lifestyle risk factors and having a stroke, then they are less likely to make lifestyle changes.

The American Stroke Association states that ‘patients with ischemic stroke or TIA... should be managed according to NCEP III guidelines, which include lifestyle modification, dietary guidelines, and medication recommendations’ (Parisi et al, 2011). In order to modify their lifestyle, people with stroke need to be aware of exercise and dietary guidelines and recommendations; however, only two people with stroke in the present study were aware of the recommendations for cardiovascular fitness. This is not altogether surprising, as a survey by the National...
Obesity Observatory (2016) found that only 5% of men and 9% of women in the general population had any idea about the recommended levels of exercise.

**Healthy lifestyle messages and advice**

An area of concern, highlighted in the present study, was the doubts and lack of agreement expressed by some participants about the healthy lifestyle messages they had been given. This was also highlighted in previous studies (Forster et al., 2012; Hillston et al., 2013) and emphasizes the need for clear and consistent healthy lifestyle messages. Perhaps more importantly, some participants appeared to welcome a chance to discuss their beliefs in order to address any doubts they had about the advice they were being given. This reinforces Forster and colleagues’ (2012) recommendations that active information provision, such as integrating the use of workbooks into experiential classes, was much more effective than passive approaches, such as the provision of information packs for use at home.

The present study also found that very few participants had been given healthy lifestyle advice. This mirrors the findings of previous studies (Healthcare Commission, 2006; The Stroke Association, 2006; Forster et al., 2011; Forster et al., 2013) although, as with these studies, it is not clear whether this information was given but not fully absorbed and recalled by people with stroke.

More research is needed to determine how to provide essential information, at what stage of stroke recovery it should be provided, and how to ensure that lifestyle changes are made and maintained as a result of receiving the information. People with stroke vary in their opinions about how relevant information could be provided.

In the present study, only the younger participants expressed a preference for online information, the majority preferred to speak to someone to get advice. An online version of the Lifestyle Coaches (Clutton-Brock et al., 2015), conducted by the present research team, used focus groups in which the timing of lifestyle advice was discussed by a range of health care professionals working in stroke rehabilitation. It was found that most participants considered it was too early to provide lifestyle advice to people with stroke while they were still receiving care in an acute stroke unit and the team members, who provided care to people in the later stages of stroke recovery, felt that specific training would help them in effectively delivering accurate and relevant lifestyle information.

It has been theorised (Bandura, 1977; Rosenstock et al., 1990) that people wanting to make changes in their lives need to believe in the importance of those changes and feel confident that they can achieve the desired changes. In the present study, it appeared that over half the participants did not know any of the risk factors that could lead to a stroke and did not know why they had had a stroke. Without this knowledge, it is doubtful that they would understand the importance of any lifestyle changes and have the confidence to make any change.

**Limitations**

This study explored participants’ experiences and perceptions of healthy lifestyles before and after having a stroke.

One limitation of the study was that participants who agreed to take part were keen to talk about healthy lifestyles and exercise and their interest in adapting their lifestyle after having had a stroke. As a result, these findings may not reflect a broad range of perspectives and experiences. Future research would benefit from actively engaging those people who are not as positive towards healthy lifestyles. A second limitation is that the average length of time after stroke varied from 14 days to 124 days and people’s perceptions may have varied over this time period.

**Future research**

Future research needs to explore different types, durations and frequencies of exercise programmes that can provide cardiovascular training for people with sub-acute, mild to moderate stroke. Research is also needed to explore the best way to provide individual healthy lifestyle advice for the sub-acute stroke population in order to help them make individual changes and maintain change throughout their lifetime to help prevent future cardiovascular events.

**CONCLUSIONS**

In the sub-acute phase of stroke recovery, barriers to exercise such as lack of motivation do not appear to be an issue. People with stroke have a lack of understanding of healthy guidelines, risk factors and cause of their stroke. It is not clear if this is due to a lack of information provision or a lack of recall. They also do not appear to make the link between lifestyle choices and the cause of their stroke.

Acknowledgements: We are grateful to the participants for giving their time to this study and to Professor Acres’ funders for providing feedback on the transcript. Thanks also to the stroke teams at UHNL NHS Trust and LFT NHS Trust for their help with recruitment.

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Conflict of interest: The authors declare that there is no conflict of interest.
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The validity and reliability of the Incremental Shuttle Walk Test and Six-minute Walk Test compared to an Incremental Cycle Test for people who have had a mild-to-moderate stroke

Nicola Clague-Baker, Thompson Robinson, Annegret Hagenburg, Sophie Drewry, Clare Gillies, Sally Singh

Objective To determine the construct validity and test-retest reliability of the Six-minute Walk Test (6MWT) and Incremental Shuttle Walk Test (ISWT) in the sub-acute recovery phase following mild-to-moderate severity stroke.

Participants 40 stroke patients (mean age: 68.27 years, SD: 13.48) of median National Institutes of Health Stroke Scale (NIHSS) score 1.2 (range: 0 to 8) within six months of stroke.

Method Each participant completed one Incremental Cycle Test (ICT) followed by two ISWT and two 6MWT in a randomised order. Pearson’s Correlation Coefficients were used to determine the validity and Bland Altman plots were used to determine the test-retest reliability.

Results The Incremental Cycle Test (ICT) was positively correlated with the ISWT ($r = 0.39, 95\%$ confidence interval $0.25$ to $0.70$, $P = 0.001$) and the 6MWT ($0.25$, $0.35$ to $0.71$, $P < 0.001$). The correlation of the ICT with the ISWT and 6MWT was highest for the 17 patients with no residual ISWT ($r = 0.79$, $P < 0.001$, $6MWT: 0.825$, $P < 0.001$) compared to mild-to-moderate neurological impairment ($ISWT: r = 0.45$, $P = 0.01$, $6MWT: r = 0.39$, $P = 0.08$). Test-retest reliability for both the ISWT and the 6MWT showed there was some variability between the first and second tests with a better performance on the second test.

Conclusion The ISWT and 6MWT have a significant, modest correlation with the ICT for stroke patients in the sub-acute recovery phase. The ISWT and 6MWT are not strongly correlated with ICT (VO2 peak) in a stroke population that is disabled. The test-retest reliability of the ISWT and 6MWT indicated that two tests may be needed to accurately assess an individual’s capabilities.

Keywords: Exercise test, Physiotherapy; Rehabilitation; Stroke

Acknowledgements: 6MWT, Six minute Walk Test; ISWT, Incremental Shuttle Walk Test; NIHSS, National Institute of Health Stroke Scale; VO2, peak, peak oxygen uptake; WBI, maximum oxygen uptake; ICT, Incremental Cycle Test; CI, confidence interval; CBF, cerebral blood flow; NYHA, New York Heart Association; ACSM, American College of Sports Medicine; BMI, Body Mass Index; MHR, maximum heart rate; MABP, maximum blood pressure; Rcm, cm2/m2; WRW, work rate intensity; B3R, Respiratory Exchange Ratio.

* Study performed in Centre for Exercise and Rehabilitation Science (CERS), NHRI Leicester Biomedical Research Centre, University Hospitals of Leicester NHS Trust, Leicester.

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Introduction

Improved cardiopulmonary fitness can be linked to a reduction in cardiovascular risk [1] so it is essential to have a reliable and valid measure of cardiopulmonary fitness (CPF) in order to measure the effectiveness of treatments to improve CPF. Laboratory measures of CPF are the gold standard, but are expensive and not readily available for clinical practice. Therefore, field-based exercise tests offer a potential alternative, for example, the Incremental Shuttle Walk Test (ISWT) and Six-minute Walk Test (6MWT). To our knowledge, only one study [2] has compared these tests, albeit in a non-disabled chronic (>6 months) stroke population, and reported a strong correlation between the ISWT and 6MWT (r = 0.63, P < 0.01) with strong test-retest reliability (ICC = 0.961), but the authors did not compare the ISWT with an incremental exercise test reporting VO2 peak. Performance on the 6MWT has been shown to have test-retest reliability [3] (ICC = 0.990 and validity [4] (r = 0.64, P < 0.001), when compared with the VO2 peak in acutely stroke population. However, Marzini et al. [5] found that the 6MWT underestimated the exercise intensity in this population, when determining the target exercise training intensity. Overall, there has been limited research of these field-based assessments in the sub-acute (1 week to 6 months) [6] stroke population.

Accordingly, the aim of the present study was to compare the performance on the ISWT and 6MWT with the VO2 peak measured using an ICT in a sub-acute, mild-to-moderate (<15 on NIHSS) [7] stroke population. The study also aimed to determine the test-retest reliability for both the ISWT and 6MWT in this population. As the level of disability post-stroke is so variable, the aim was also to identify which participants could complete the tests dependent on their level of acrological impairment.

Hypotheses

In order to determine the validity of the ISWT and 6MWT, two null hypotheses were identified: (1) the distance measured during the ISWT shows no correlation with the VO2 peak measured with an ICT, and (2) the distance measured during a 6MWT shows no correlation with the VO2 peak measured with an ICT.

Methods

Participants

Participants were recruited from a large single-centre UK University teaching hospital within one week to six months (sub-acute) of mild-to-moderate stroke, defined by a National Institute of Health Stroke Scale (NIHSS) [7] score of 0 to 15 [8]. All participants were able to walk 10 metres with or without an aid, and provided written consent. Exclusion criteria were based on cardiac contraindications and included: heart disease class III and upwards [9], Class C and D exercise risk [10], uncontrolled arrhythmias (causing symptoms), angina on exercise and uncontrolled hypertension (>180/110 mmHg at rest).

The study was approved by the National Research Ethics Service NRES Committee East Midlands – Northampton 14/EM/0067.

Procedure

All participants attended the exercise laboratory and after consenting to the study, the following information was recorded from the medical record: details about the stroke, relevant past medical history, drug history and social history. In addition, the following baseline assessments were undertaken: NIHSS, Fogel-Meyer scale [11] and lower limb strength. Height and weight (Body Mass Index (BMI)) were also recorded. Finally, routine cardiovascular parameters were measured to determine maximum heart rate (MHR) as defined by 220 minus age, and to set safety parameters for exercise, as follows: HR limit at 90% of MHR, and maximum blood pressure (MBP) of 200/110 mmHg for ischaemic and 180/100 mmHg for haemorrhagic stroke participants. HR limits were not set for those on beta-blockers, but BP limits were adhered to.

Each participant completed an ICT to establish VO2 peak, with breath-by-breath analysis, followed by two ISWTs and two 6MWTs in a randomised order following standard operating procedures [12]. All tests were carried out on one day, rest times between tests varied between 30 and 40 minutes due to the availability of the testing site. Randomisation was achieved using random number tables and allocation concealed with sealed envelopes. Routine haemodynamic monitoring was undertaken throughout the exercise tests; BP was measured at two-minute intervals and continuous electrocardiogram monitoring during the ICT, and HR was recorded at minute intervals during the ISWT and 6MWT. In addition, BP and HR were recorded prior to and at the end of each test, and the Borg perceived exertion and Borg breathlessness scales were recorded.

Two ICT protocols were used to accommodate a range of participant abilities. Programme one had a two-minute warm-up at 10 W at a target cadence of 50 revs per minute (rpm), followed by a 5 W increment every minute [13]. Programme two had a two-minute warm-up at 10 W at a target cadence of 50 rpm, followed by a 10 W increment every minute, based on the pilot tests that indicated that some subjects may need a greater challenge to reach their peak VO2. To identify which programme the patient attempted, a formula was used based on Wasserman et al. [14]:

\[
\text{Work Rate Intensity (WRI)} = \frac{\text{Peak VO2} - \text{VO2 unloaded}}{100}
\]

where: Peak VO2 = (height - age) x 30 (males) or
Peak VO₂ = (height – age) × 14 (female) and where VO₂ unloaded = 150 + (6 × weight).

If the WR6 was less than seven, the participant completed the 5W programme; if the WR6 was more than seven, the participant completed the 1W programme.

Both the ESWT and 6MWT were conducted twice as recommended by Holland et al. [12] to account for the learning effect, that is, participants became more familiar with the test which can improve performance so carrying out two tests reduces this error. The ISWT is an externally paced maximum exercise test using two cones, nine metres apart. The speed of walking is controlled by a pre-recorded set of beeps and the number of laps around the cones are recorded and measured in metres. The 6MWT uses a thirty metre cone marked out by two cones. The distance achieved in six minutes is recorded to the nearest metre. Standard instructions were used and the use of walking aids was consistent between the two tests as recommended by Holland et al. [12].

Data and statistical analysis

VO₂ peak was determined when either: Respiratory Exchange Ratio (RER) was greater than 1.0 [13] or the participant had reached 95% of their maximum age-predicted MHR. Pearson’s correlation coefficients were used to determine the correlation of the ISWT and 6MWT compared to the ICT, with a value of 0.20 to 0.39 indicating a weak correlation; 0.4 to 0.69 indicating a modest correlation; 0.70 to 0.89 indicating a strong correlation and 0.90 to 1.00 indicating a very strong correlation [15]. Bland Altman plots were used to determine the test re-test reliability of the ISWT and 6MWT. Pearson’s correlations between the different measures were also calculated for those with no neurological impairment (NIHSS=0) or mild to moderate (NIHSS <15) neurological impairment. Statistical significance was taken at P < 0.05. A power calculation determined that 30 subjects were needed to test the validity of each measure if r = 0.8, with 80% power at the 5% significance level [16].

Results

Forty participants (27 male) of mean age 68.3 (SD: 13.48) years were recruited a mean of 84 days (SD: 41.1) following stroke onset. Median NIHSS was 1.2 (range 0 to 8) and other baseline demographic data are shown in Table 1.

Construct validity between VO₂ Peak, ISWT and 6MWT

All 40 participants completed the incremental cycle protocol, 13 completed the 1W and 27 the 5W incremental programme. Of these participants, 31 achieved an RER > 1.0, indicating that they were nearing exhaustion. Of the non-participants who did not achieve an RER > 1.0, three stopped the test due to fatigue, and six were stopped by the therapist due to reaching MHR (1), reaching MBP (4) or not keeping up the required speed (1). In total, 19 of the incremental tests were stopped by the therapist and 19 by the participant, with two participants completing the assigned programme.

Table 1

<table>
<thead>
<tr>
<th>Participant demographics.</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>10.2 (9.1, 15.6)</td>
</tr>
<tr>
<td>Mean(SD)</td>
<td>23 (9.0)</td>
</tr>
<tr>
<td>Gender (male) n (%)</td>
<td>27 (68)</td>
</tr>
<tr>
<td>Ethnicity n (%)</td>
<td>25 (62)</td>
</tr>
<tr>
<td>Caucasian: 36 (90)</td>
<td></td>
</tr>
<tr>
<td>Asian: 3 (8)</td>
<td></td>
</tr>
<tr>
<td>Afro-Caribbean: 1 (2)</td>
<td></td>
</tr>
<tr>
<td>Ischaemic stroke n (%)</td>
<td>39 (95)</td>
</tr>
<tr>
<td>Side of body affected left (60) n (%)</td>
<td>10 (42)</td>
</tr>
<tr>
<td>Length of time post stroke (days)</td>
<td>19 (60)</td>
</tr>
<tr>
<td>Mean(SD)</td>
<td>1.0 (1.3)</td>
</tr>
<tr>
<td>NIHSS &lt;15 (n = 30)</td>
<td>23 (62)</td>
</tr>
<tr>
<td>NIHSS &gt;15 (n = 10)</td>
<td>4 (40)</td>
</tr>
<tr>
<td>NIHSS &gt;15 median (range)</td>
<td>1.0 (0 to 4)</td>
</tr>
<tr>
<td>NIHSS &lt;15 median (range)</td>
<td>17 (4)</td>
</tr>
<tr>
<td>NIHSS &lt;15 interval (n = 30)</td>
<td>3 (8)</td>
</tr>
<tr>
<td>NIHSS &gt;15 interval (n = 10)</td>
<td>64 (15)</td>
</tr>
<tr>
<td>No. of co-morbidities</td>
<td>2 (6)</td>
</tr>
<tr>
<td>Mean(SD)</td>
<td>2.25 (1.48)</td>
</tr>
<tr>
<td>No. with pain n (%)</td>
<td>29 (75)</td>
</tr>
<tr>
<td>Body Mass Index</td>
<td>28.63 (6.63)</td>
</tr>
<tr>
<td>Mean(SD)</td>
<td>19 (25)</td>
</tr>
<tr>
<td>% Bodyfat (n = 29)</td>
<td>4.04 (0.04)</td>
</tr>
</tbody>
</table>

Data are presented as mean (SD) or n (%) unless stated. NIHSS: National Institute of Health Stroke Scale.

Mean values for ICT (VO₂ peak), and the best performance (m) of each of the two ISWTs and two 6MWTs were significantly reduced compared to normative values for an age-matched healthy cohort (Table 2). ICT (VO₂ peak) had a modest correlation with both the ISWT (r = 0.59, 95% confidence interval CI 0.34 to 0.76, P = 0.001) and 6MWT distance (r = 0.55, 95% CI 0.35 to 0.71, P = 0.001). It is acknowledged that the CIs are relatively large for both tests making it difficult to conclude the magnitude and both relationships. In addition, a very strong correlation was observed between the ISWT and 6MWT distance (r = 0.55, 95% CI 0.39 to 0.71, P < 0.001).

When participants were grouped by NIHSS scores into those with no neurological impairment (NIHSS = 0) and those with mild to moderate neurological impairment (NIHSS <15) and the relationship between ISWT and 6MWT with ICT was explored, differences in the strength of agreement were noted. In 17 participants with no neurological impairment, a significant strong correlation between the ISWT (r = 0.80, P < 0.001) and 6MWT (r = 0.83, P < 0.001) with ICT (VO₂ peak) was observed. However, only a modest correlation was reported in those with residual mild-to-
Table 2
Results of the Incremental Cycle Test, Incremental Shuttle and 6-minute Walk Tests.

<table>
<thead>
<tr>
<th></th>
<th>ICT (SD)</th>
<th>ISWT (SD)</th>
<th>6MWT (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>11.1 (1.1) m/min/Hz</td>
<td>261 (177) m</td>
<td>365 (143) m</td>
</tr>
<tr>
<td>Male</td>
<td>11.2 (1.1) m/min/Hz</td>
<td>261 (177) m</td>
<td>395 (160) m</td>
</tr>
<tr>
<td>Female</td>
<td>10.9 (1.1) m/min/Hz</td>
<td>244 (144) m</td>
<td>334 (108) m</td>
</tr>
<tr>
<td>Non-marital aged matched data*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>29 to 12 m/min/Hz</td>
<td>408 m</td>
<td>572 m</td>
</tr>
<tr>
<td>Female</td>
<td>29 to 12 m/min/Hz</td>
<td>408 m</td>
<td>572 m</td>
</tr>
<tr>
<td>Mean Peak HR (SD) BPM</td>
<td>122 (20)</td>
<td>98 (20)</td>
<td>24 (8)</td>
</tr>
</tbody>
</table>


Fig. 1. Scatter plot demonstrating the correlation between Incremental Cycle Test and Incremental Shuttle Walk Test.

Fig. 2. Scatter plot demonstrating the correlation between the Incremental Cycle Test and 6-minute Walk Test.

Adverse events
No adverse events were recorded, however, two participants were excluded just prior to testing due: identification of a 2 cm aneurysm on MRI scan, and left ventricular abnormality on ECG.

Participants comments
Six participants complained of pain during the ICT: hip pain (1), knee (1), ‘leg pain’ (2), and pain from the seat (2). When asked which test was preferred, 23 (60%) indicated the ICT due to: ‘easier to push yourself’, ‘walking was limited by speed’, ‘leg fatigue with walking’, ‘difficulties with walking tests’, ‘gets the knee bending’, ‘walking tests limited by moving legs quickly enough’ and ‘leg stiffened with walking tests’.

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https://doi.org/10.1016/j.physio.2018.12.005
Table 3
Test results for the Incremental Shuttle and 6-minute Walk Tests.

<table>
<thead>
<tr>
<th></th>
<th>First test</th>
<th>Second test</th>
<th>Mean difference (limits of agreement)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISWT (m)</td>
<td>243.3 (174.0)</td>
<td>265.0 (171.1)</td>
<td>19.7 (–7.5 to 46.7)</td>
</tr>
<tr>
<td>6MWT (m)</td>
<td>355.9 (134.1)</td>
<td>372.2 (145.5)</td>
<td>16.2 (–67.9 to 110.4)</td>
</tr>
</tbody>
</table>

Data are shown as mean (SD). ISWT: Incremental Shuttle Walk Test; 6MWT: 6-minute Walk Test.

Fig. 3. Bland Altman plot demonstrating the relationship between the first and second Incremental Shuttle Walk Test. Purple line – mean difference line, blue line – upper confidence limit, orange line – lower confidence limit, red dots – participants with NIBIS > 0, purple cross – participants with NIBIS = 0.

Discussion

With increasing importance being given to secondary prevention and healthy lifestyle in this population, it is important to have a reliable and valid measure of CRF in order to measure the effectiveness of treatments to improve CRF. Laboratory tests can be expensive and time consuming and therefore cheap alternatives have been validated in many disease groups [16,19–22]. This study aimed to determine the construct validity of the ISWT and 6MWT compared to the gold standard measure of cardiorespiratory fitness in a post stroke population of mild-to-moderate stroke severity in the subacute recovery period. We found that both the ISWT and 6MWT demonstrated a modest correlation with the VO2 peak measured with the ICT. The study also aimed to determine the test–test reliability for the ISWT and the 6MWT, and found that there was some variability between the first and second tests. This was different to previous studies for the ISWT that found the test to be reliable with respiratory [19], cardiac [20] and chronic stroke patients [2], and previous results for the 6MWT with cardiac [21], respiratory [22] and chronic stroke patients [3]. As with previous studies, it was found that there was a learning effect with both tests, and therefore the recommendation would be that two ISWTs and two 6MWTs are completed, with the results of the second test used.

In relation to the validity of the tests, one of the reasons why there was only a modest correlation between the tests appears to be due to the range of residual neurological impairment studied from none, 0 on the NIBIS scale, to moderate, 8 on the NIBIS scale. A strong correlation was seen between the ICT and both clinical tests in participants with no residual neurological impairment (NIBIS = 0). Therefore, the ISWT or 6MWT could be used to measure CRF or cardiovascular capacity in such patients. In those with residual neurological impairment there was only a modest correlation. However, it needs to be acknowledged that the study was not powered for these sub-group analyses. In addition, this may in part be because some participants found it difficult to complete the walking-based tests compared to the cycle test. The

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majority of subjects completed the ICT without assistance; only two participants needed their affected foot strapped to the pedal and support with their arm, and one participant helped to initiate pedaling. Furthermore, the majority of participants preferred the cycle-based test (60%). This indicates that further research is needed to explore the most valid measure of CRI in people with residual neurological impairment post stroke in order to inform guidelines [23,24].

However, additional questions need to be addressed in respect of the use of a cycle-based test. First, whether a conventional or recumbent cycle should be used. Tang et al. [13] used a semi-recumbent position for testing, but found that this "may not help to address the potential problems arising from initial fatigue related to motor dyscontrol or asymmetry" [13, p. 1004]. Although six of the participants in the present study complained of pain with the cycle test, only two were related to the seat of the cycle and the rest were due to leg pain that occurred with all of the tests. Secondly, it is still important that stroke participants can achieve V̇O₂ peak even if it is a cycle-based test. Cycle-based V̇O₂ testing measures 10% to 15% lower than treadmill-based tests in healthy adults [23] but Tang et al. [13] highlighted the importance of measuring V̇O₂ peak as accurately as possible to ensure that the exercise prescription is appropriate. Therefore, clinical cycle-based tests need to be devised to measure the CRI of people who have had a stroke in the sub-acute phase of recovery.

The exclusion criteria and termination of testing procedures were based on ACSM guidelines [10] and are all based on cardiac contraindications. These enabled a safe and acceptable level of testing for the stroke population studied. It is recommended that BP limits for people who had an ischemic stroke are set at 130/80 mmHg and for people who had a hemorrhagic stroke, set at 180/100 mmHg, as although ten tests were stopped by the therapist due to hypertension, six of these participants achieved an RER over one. Indeed, compared to previous studies with subacute stroke participants, where only 44% of participants achieved RER [13], a high percentage of participants in the present study (79%) achieved RER. It is also recommended that the MHR is set at 90% of the age-predicted MHR, as only five participants were stopped due to maximum HR limits and three of those achieved an RER over one. However, it may be necessary to add more stroke-specific exclusion criteria for testing based on issues identified in this present study. One participant had a 2 cm brain aneurysm, and another potential participant had greater than 50% bilateral carotid stenosis; both of these participants were excluded by their treating stroke consultant. It is therefore recommended that cerebral aneurysms and >50% carotid stenosis should be added to the list of exclusion criteria for future studies investigating V̇O₂ peak with stroke participants. Further investigation of stroke specific contraindications should be considered, such as post stroke epilepsy and renal issues.
As has been seen in other studies [13,24], VO\textsubscript{2} peak values were significantly lower than age-related data, that is, in the sub-acute phase of stroke recovery the mean values found in this study, 12.1 ml/kg/minute, were lower than the 15 ml/kg/minute required for independent living [25]. This further supports the need for cardiovascular training for people with mild-to-moderate stroke in the sub-acute phase, as recommended by the NICE guidelines [26].

**Study limitations**

The preferred duration of an incremental exercise test is between eight and nine minutes [13], however, the mean length of time for the test in the present study was 10.2 minutes. This was because four participants managed to reach the end of testing (16 minutes). In future studies it might be necessary to set three test protocols to accommodate participants at the higher end of the physical ability scale.

Though it would have been interesting to measure oxygen consumption during the walking tests in the present study, in order to make a true comparison of the level of oxygen consumed in each walking test compared to the ICT, it was anticipated that using the portable equipment required would be too cumbersome for the stroke participants. However, it is acknowledged that the ISWT and 6MWT are submaximal clinical tests of CRF and so true VO\textsubscript{2} peak may not have been reached. In order to determine VO\textsubscript{2} peak during ISWT and 6MWT testing, future studies need to attempt to use portable oxygen consumption devices, perhaps with a small pilot study to determine if people post-stroke can use these devices.

Future studies also need to identify a cycle-based, clinical test that would adequately measure CRF in this sub-acute, mild-to-moderate stroke population and need to test this measure against the VO\textsubscript{2} peak measured with an ICT.

**Conclusion**

The ISWT and 6MWT have a significant, modest correlation with the ICT for stroke patients in the sub-acute recovery phase. The ISWT and 6MWT are not strongly correlated with ICT (VO\textsubscript{2} peak) in a stroke population that is disabled and the best way to determine cardiovascular fitness may be with a cycle-based test with this population. BP and HR limits have been identified for people who have had haemorrhagic and ischaemic strokes, and additional contraindications to testing have also been established. The test–test reliability of the ISWT and 6MWT indicated a difference between the first and second tests with a better performance on the second test indicating that two tests may be needed to accurately assess an individual’s capabilities.

**Key messages**

1. The ISWT and the 6MWT are both valid clinical measures to measure cardiorespiratory fitness in people with no neurological impairment post stroke, however, people with neurological impairment post stroke may need alternative measures such as a cycle-based test, to determine their cardiorespiratory fitness.
2. The ISWT and 6MWT both had differences in their first and second tests.
3. This adds to the limited knowledge on the validity and reliability of the 6MWT and ISWT with a stroke population in the sub-acute as opposed to the chronic stage of recovery.

**New knowledge**

The ISWT has not been tested against the ICT and 6MWT in people with stroke in the sub-acute phase of stroke recovery. The ISWT is important as it is an incremental test that has the potential to challenge the cardiorespiratory system more than the 6MWT. The study identifies that routine field-based tests of CRF such as the ISWT and 6MWT both have limitations for measuring CRF in a stroke population.

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**Conflict of interest** TR is an NIHR Senior Investigator.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.physci.2018.12.005.

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