Integrating Survivors of Stroke Into Cardiac Rehabilitation

Elizabeth Wherley Regan

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INTEGRATING SURVIVORS OF STROKE INTO CARDIAC REHABILITATION

by

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Submitted in Partial Fulfillment of the Requirements
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University of South Carolina
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DEDICATION

I would like to dedicate my dissertation to my kids, Evann and David, and my partner, Bryan Lynip. I would also like to honor my brother, David Wherley, and my parents Ann Wherley and David Wherley. My parents taught me to believe I could be anything I wanted if I worked hard enough, and emphasized the importance of service to others. My brother, my first friend and constant childhood companion, taught me to not take myself too seriously. My kids gave me resilience in the face of sorrow and continue to help me be a better parent, teacher and person every day. I hope they learn that you are never too old to learn something new, and the pursuit of knowledge, especially to help others, is a worthwhile endeavor. To Bryan, I thank you for coming on this unexpected ride with me, steadfast and supportive right from the beginning and into our future together.
ACKNOWLEDGEMENTS

Without the following exceptional individuals, this dissertation would not have been possible. I would like to acknowledge and thank first, my mentor, Stacy Fritz, for her expertise, leadership, flexibility, enthusiasm and humor. You restored my faith in how good leadership sparks success. Without your appreciation of the challenges of pursuing a PhD as a non-traditional student with family demands, I would not be writing this today. To my secondary mentor, Jill C. Stewart, thank you for your guidance and sharing your knowledge with patience and kindness. I would also like to thank the remaining members of my dissertation committee, Sarah Wilcox and Lee Pearson, for your support to shape my project into its successful completion.

I am grateful for the hard work and dedication of the men and women who participated in my study and the team at Novant Health Cardiac Rehabilitation.

I thank my co-author and co-conspirator Reed Handlery for supporting this project and me with enthusiasm and shared excitement for physical activity.

To my friends on this PhD journey with me, Kelly Hawkins, Kait Crosby, Jen Kline and Alicia Flach, for sharing the highs and lows, the challenges and successes, I thank you. To my aunts, Clare Wherley and Jane Kircher, I appreciate you for blazing the trail as successful strong women for my generation. Finally, to my friend Kathy Ferguson for her copy-editing skills, and to her and Brandi Coco for family support. You all are amazing examples of what smart women can accomplish while supporting other women.
ABSTRACT

Stroke is the leading cause of disability in the United States (U.S.). Impairments after stroke typically result in reduced physical activity which increases the risk for stroke recurrence and the development or worsening of comorbid health conditions. Physical activity and exercise behaviors can reduce cardiovascular risk factors and improve endurance for survivors of stroke. Despite these known significant benefits, survivors of stroke face barriers to participating in regular physical activity due to limited self-efficacy, safety concerns, environmental restrictions and lack of accessible community programs.

Cardiac Rehabilitation (CR) is a structured exercise and behavior modification program for people with cardiovascular disease that is prevalent in health care systems in the U.S. Participation in CR has been shown to increase functional exercise capacity, lower risk of hospital readmissions, and improve health related quality of life for traditional participants. Despite similar cardiovascular risk factors, stroke is not among the covered diagnoses for CR services.

The purpose of this mixed methods pilot intervention study was to examine the feasibility and participant impact of integrating survivors of stroke into an existing hospital-based CR program in the southeast U.S. Chapter two assessed feasibility through quantitative assessments of recruitment, uptake, retention, adherence, fidelity, acceptability and safety, and a qualitative evaluation of participant
perception of the program. Chapter three evaluated participant impact through pilot effectiveness measures for physical function and other health impacts, and through qualitative evaluation of participant perception of outcomes and future exercise plans.

A mixed methods design combined a single group, pre-post, follow-up design, pilot feasibility study with a pragmatic qualitative inquiry. Survivors of stroke were recruited through hospital system providers and the community into a standard 12-week, 36 visit CR program. Fifty-three survivors were referred, 29 started the program and 24 completed the program. Participants were evaluated in effectiveness outcome measures at three timepoints: pre-program, post-program and six-month follow-up. Qualitative interviews occurred at the post-program evaluation. Process variables and feasibility measures were recorded and analyzed throughout the study.

Results suggest CR is feasible for survivors of stroke who were able to meet dosage and intensity goals, and perceived the program as needed regardless of their mobility limitations or previous exercise experience. Participants enjoyed the camaraderie and positive environment and felt safe and attended to by staff. CR had significant impacts on cardiovascular endurance and functional strength, which were maintained at six-month follow-up. Most participants continued to exercise in the follow-up period. Challenges focused primarily on managing referral and uptake of the program. Using an existing structured exercise program, that is widely available in the U.S., feasible for stroke survivors, and supported by qualified licensed professionals, has the potential to improve cardiovascular endurance, health status and quality of life for survivors of stroke.
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<table>
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<th>Definition</th>
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<tbody>
<tr>
<td>6MWT</td>
<td>Six-Minute Walk Test</td>
</tr>
<tr>
<td>ABC</td>
<td>Activities-Specific Balance Confidence</td>
</tr>
<tr>
<td>AHA</td>
<td>American Heart Association</td>
</tr>
<tr>
<td>ANOVA</td>
<td>Analysis of Variance</td>
</tr>
<tr>
<td>BPM</td>
<td>Beats Per Minute</td>
</tr>
<tr>
<td>CR</td>
<td>Cardiac Rehabilitation</td>
</tr>
<tr>
<td>EP</td>
<td>Exercise Physiologist</td>
</tr>
<tr>
<td>FSS</td>
<td>Fatigue Severity Scale</td>
</tr>
<tr>
<td>FTSS</td>
<td>Five Times Sit to Stand</td>
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<tr>
<td>FWS</td>
<td>Fast Walking Speed</td>
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<tr>
<td>HR</td>
<td>Heart Rate</td>
</tr>
<tr>
<td>IQR</td>
<td>Inter-Quartile Range</td>
</tr>
<tr>
<td>IRB</td>
<td>Institutional Review Board</td>
</tr>
<tr>
<td>m</td>
<td>meters</td>
</tr>
<tr>
<td>METs</td>
<td>Maximum Metabolic Equivalents</td>
</tr>
</tbody>
</table>
MHR ................................................................. Maximum Heart Rate

PA ................................................................. Physical Activity

PHQ-9 ............................................................. Patient Health Questionnaire-9

PI ................................................................. Primary Investigator

PTs ............................................................... Physical Therapists

RPE .............................................................. Rating of Perceived Exertion

s ......................................................................... seconds

SD ................................................................. Standard Deviation

SIS ................................................................. Stroke Impact Scale

SOEE ................................................................ Short Outcomes Expectations for Exercise

SSEE ................................................................ Short Self-Efficacy for Exercise

SSWS ............................................................. Self-Selected Walking Speed

U.S. ................................................................. United States

USC ............................................................... University of South Carolina
CHAPTER 1

INTRODUCTION

Stroke is the leading cause of disability in the United States (U.S.). Impairments after stroke typically result in a sedentary lifestyle which increases the risk for stroke recurrence and the development or worsening of comorbid health conditions such as coronary artery disease, hypertension, hyperlipidemia, and diabetes mellitus. Studies support the feasibility and safety of exercise training for survivors of stroke and suggest that such behavior can improve their cardiovascular risk factors and endurance while reducing their disabilities. Despite these known benefits, survivors of stroke face barriers to participating in regular physical activity (PA) due to limited self-efficacy, safety concerns, environmental restrictions and lack of accessible community programs.

Mobility impairments and accompanying lack of PA are major health concerns for many of the seven million survivors of stroke in the U.S. With a large number of survivors of stroke living with disability and at a higher risk for stroke reoccurrence and other diseases, there is an urgent need to reduce disability and modify cardiovascular risk factors. Many survivors of stroke receive rehabilitation care which is focused on recovery of function with limited or no focus on aerobic fitness. While some traditional rehabilitation activities can induce cardiovascular training effects, research has shown that during these programs patients spend little time at the intensity levels required
for endurance changes: only 24% of time at > 40% maximum heart rate (MHR) in one study, and 4.8% of time at > 60% MHR in another.\textsuperscript{12,13} As the reimbursement climate changes, rehabilitation stays are declining in length, potentially compounding the deconditioning remaining when rehabilitation is complete.\textsuperscript{14,15} At completion of supervised rehabilitation, therapists sometimes educate patients on the health benefits of exercise and PA and prescribe home exercise programs. \textsuperscript{16} The lack of availability of appropriate group exercise programs for survivors of stroke impedes continuation of supervised activity.\textsuperscript{17} Without support or guidance, most survivors of stroke do not continue exercise or engage in PA post-rehabilitation. Daily step counts for community dwelling survivors of stroke are commonly less than 3000, well below a 6025 step cutoff for predicting new vascular events.\textsuperscript{18-20} In addition to insufficient community programs, breaking the cycle of inactivity is complicated by barriers to PA and exercise.\textsuperscript{5,7,14,21} Barriers common to people with disability include lack of motivation, cost, accessibility and transportation difficulties.\textsuperscript{22} Barriers specific to survivors of stroke include their physical impairments, performance apprehension (low exercise self-efficacy), fear of falling and belief that exercise will not impact their health conditions.\textsuperscript{21,23,24} As a result, a large gap exists in the transition from rehabilitation patient to community PA participant, potentially leaving survivors of stroke to remain at suboptimal health and function.\textsuperscript{21}

Multidisciplinary cardiac rehabilitation (CR) programs are an integral part of recovery after cardiac events for the secondary prevention of cardiovascular disease. CR services in the U.S. are defined by Medicare guidelines for reimbursement and typical include up to 36 sessions (2-3 sessions a week for 12-18 weeks).\textsuperscript{25} Components of the program must include at least 31 minutes of aerobic exercise, as well as cardiac and risk
factor modification services through individually tailored plans measured by outcome and psychosocial assessments. The American Heart Association (AHA) further details core components of CR programs to include cardiovascular endurance activities, resistance and stretching exercises, educational programs, and stress reduction efforts. These programs are widely available, staffed by experienced health care professionals and are well established in the medical infrastructure. Currently, these beneficial programs are offered to individuals with acute myocardial infarction, chronic stable angina, and those post-cardiac surgery. While survivors of stroke face similar deficits in cardiovascular health with an increase in risk factors, stroke is not among the recommended or covered diagnoses for CR services.

Integrating survivors of stroke into existing CR programs is an opportunity to bridge the gap between formal rehabilitation and community PA participation, to break the cycle of inactivity, and to reduce the risk for developing or worsening cardiovascular and comorbid conditions. Participation in CR has been shown to increase functional exercise capacity, lower risk of hospital readmissions, and improve health related quality of life for traditional cardiovascular disease participants. Previous studies of cardiovascular training in survivors of stroke have demonstrated that they can safely perform aerobic programs and achieve health benefits. Research studies, primarily outside of the U.S., have implemented cardiac rehabilitation programs exclusively for survivors of stroke as well as including survivors of stroke within cardiac diagnosis specific programs. One example is a program in Canada that provided a stroke specific program for survivors of stroke with remaining mobility deficits post-rehabilitation and integrated those without mobility deficits into a traditional CR
program. The stroke-specific program was a once weekly 90 minute class including aerobic exercise, resistance training and health education. While this and other studies outside the U.S. support feasibility and benefit for survivors of stroke, several limitations exist. Limitations include a focus on mild stroke and transient ischemic attack (TIA) diagnoses, variation in duration of program and number of sessions, limited evaluation of functional outcomes and limited external validity. Additionally, it is difficult to apply these findings to settings in the U.S. due to differences in frequency and duration of programs with different costs and insurance structures. As a result, a knowledge gap exists for feasibility and efficacy of CR for survivors of stroke with a large range of impairments within programs in the U.S. that follow Medicare guidelines for dosage and components. Finally, there is insufficient evaluation of functional measures and quality of life after CR which are vital components to health after stroke. Understanding the impact of supervised exercise for survivors after rehabilitation has the potential to improve health, reduce risk for future cardiac events and enable self-regulated habitual exercise.

The current pilot rehabilitation intervention study examined the feasibility of integrating survivors of stroke into an existing hospital-based CR program at Novant Health in Charlotte, NC. The use of an existing structured CR program leveraged the efficiency and availability of an established care network. Survivors of stroke were recruited through hospital system medical and rehabilitation providers, and directly from support groups for entry into a multidisciplinary, three-month CR program. This program consisted of three sessions per week (1 to 2 hours) of supervised cardiovascular endurance and resistance training, relaxation and education. Nutrition and psychological
counseling consultations were included as part of the program as needed. Participants completed formal physical and occupational rehabilitation and obtained medical provider approval prior to the program.\(^{40}\)

The project challenged the existing paradigm of clinical practice post-stroke which discontinues formal exercise training after one-on-one rehabilitation ends. The goal of the project was to examine the ability to integrate survivors of stroke into an existing medically supervised group exercise program (CR) and to evaluate the participant impact. Key knowledge expansion areas included: (1) determining if an existing program infrastructure and staffing was able to absorb additional participants with potentially unique movement, speech and cognition deficits; (2) evaluating efficacy of the program for survivor’s health and well-being; (3) assessing whether participants with stroke adhered to and completed the program, perceived the program as beneficial, and changed their beliefs and habits (Figure 1.1). Study results and future phases of the project will determine the possibility and impact of CR becoming a standard practice for survivors of stroke. \(^{41-43}\)

**Primary Aim (Chapter 2):**

Examine the feasibility of integrating survivors of stroke into an existing, hospital-based CR program in the southeastern U.S.\(^{41-43}\) through an assessment of (1) recruitment, uptake and retention, (2) adherence and fidelity, (3) acceptability, (4) safety, and (5) effectiveness.
Figure 1.1: Conceptual Model of Cardiac Rehabilitation Programs for Survivors of Stroke
Secondary Aim (Chapter 3):

Evaluate participant impact of an existing hospital-based CR program through (1) pilot effectiveness measures for physical function (cardiovascular endurance, functional strength, walking speed), and for other health impacts (quality of life, balance confidence, depression, fatigue, exercise habits) and (2) a qualitative evaluation of participant perception of program impact on physical function, health and future exercise plans.
CHAPTER 2
FEASIBILITY OF INTEGRATING SURVIVORS OF STROKE INTO CARDIAC REHABILITATION: A MIXED METHODS PILOT STUDY

Introduction

Stroke is the leading cause of disability in the United States (U.S.). Impairments after stroke typically result in reduced physical activity which increases the risk for stroke recurrence and the development or worsening of comorbid health conditions, such as coronary artery disease, hypertension, hyperlipidemia, and diabetes mellitus. Studies support the feasibility and safety of exercise training for survivors of stroke and suggest that such behavior can improve their cardiovascular risk factors and endurance while reducing their disabilities. Despite these known significant benefits, survivors of stroke face barriers to participating in regular physical activity (PA) due to limited self-efficacy, safety concerns, environmental restrictions, and lack of accessible community programs.

With a large number of survivors of stroke living with disability and at a higher risk for stroke reoccurrence and other diseases, there is an urgent need to reduce disability and modify cardiovascular risk factors. Many survivors receive rehabilitation care immediately after a stroke, which focuses on the recovery of function with limited or
no focus on cardiovascular endurance.\textsuperscript{10,11} While some traditional rehabilitation activities can induce cardiovascular training effects, research has shown that during these programs, patients spend little time at the intensity levels required for endurance changes: only 24\% of time at > 40\% maximum heart rate (MHR) in one study, and 4.8\% of time at > 60\% MHR in another.\textsuperscript{12,13} As the insurance reimbursement climate changes, rehabilitation stays are declining in length, potentially compounding the deconditioning remaining when rehabilitation is complete.\textsuperscript{14,15} At the completion of supervised rehabilitation, therapists may educate patients on the health benefits of exercise and PA and prescribe home exercise programs.\textsuperscript{16} The lack of appropriate exercise programs available for survivors impedes continuation of supervised activity.\textsuperscript{17} Without support or guidance, most survivors do not continue exercise or engage in PA post-rehabilitation. Daily step counts for community-dwelling survivors are commonly less than 3000, well below a 6025 step cutoff for predicting new vascular events.\textsuperscript{18-20} In addition to insufficient community programs, breaking the cycle of inactivity is complicated by barriers to PA and exercise.\textsuperscript{5,7,14,21} Barriers common to people with disability include lack of motivation, cost, accessibility, and transportation difficulties.\textsuperscript{22} Barriers specific to survivors of stroke include their physical impairments, performance apprehension (low exercise self-efficacy), fear of falling, and a belief that exercise will not impact their health conditions.\textsuperscript{21,23,24} As a result, a large gap exists in the transition from rehabilitation patient to community PA participant, potentially leaving survivors of stroke to remain at suboptimal health and function.\textsuperscript{14}
Since 1994 the American Heart Association (AHA) has recommended multidisciplinary cardiac rehabilitation (CR) programs as an integral part of recovery after cardiac events for the secondary prevention of cardiovascular disease. CR programs improve participants’ health through cardiovascular endurance activities, resistance and stretching exercises, educational programs, and stress reduction efforts. These programs are widely available, staffed by experienced health care professionals, and are well-established in the medical infrastructure. Currently, these beneficial programs are offered to individuals with acute myocardial infarction, chronic stable angina, and those post-cardiac surgery. While survivors of stroke have similar deficits in cardiovascular health with an increase in cardiac risk factors, stroke is not among the recommended or covered diagnoses for CR services.

Research studies, primarily outside of the U.S., have implemented cardiac rehabilitation programs exclusively for survivors of stroke as well as have included survivors of stroke within cardiac-diagnosis specific programs. While these studies support feasibility and benefit for survivors of stroke, several limitations exist. Limitations include a focus on mild stroke and transient ischemic attack diagnoses, variation in duration of program and number of sessions, limited evaluation of participant perception and limited external validity. Additionally, it is difficult to apply these findings to U.S. settings due to differences in frequency and duration of programs with different costs and insurance issues unique to the U.S. As a result, a knowledge gap exists for the feasibility and efficacy of CR for survivors of stroke with a large range of impairments within U.S. programs that follow Medicare guidelines for dosage and components.
This purpose of this pilot intervention study was to examine the feasibility of integrating survivors of stroke into an existing, hospital-based CR program in the southeastern U.S.\textsuperscript{41-43} through an assessment of (1) Recruitment, Uptake and Retention, (2) Adherence and Fidelity, (3) Acceptability, (4) Safety, and (5) Effectiveness.

**Materials and Methods**

A mixed methods design combined a single group, pre-post design, pilot feasibility study with a pragmatic, qualitative inquiry of participant perception. The study was a registered clinical trial through the United States National Library of Medicine (ClinicalTrials.gov ID: NCT03706105). The health system Institutional Review Board (IRB) approved this study, and the University of South Carolina’s IRB acknowledged it. The health system CR program had an existing protocol for non-cardiac diagnoses to participate in the program. The study program was modeled after phase II cardiac rehabilitation requirements and documentation.\textsuperscript{28} Hospital system providers (medical and rehabilitative), community support groups, and word of mouth recruited survivors of stroke for this 12-week, 36 session CR program.

The following inclusion criteria determined eligibility for the study program:

(1) a diagnosis of stroke at least 3 months prior;

(2) completion of physical and occupational therapy rehabilitation, if applicable;

(3) clearance by treating medical provider (physician or nurse practitioner) to participate;

(4) ability to walk at least 40 meters with or without an assistive device;

(5) ability to transfer from sit to stand without external assistance; and
(6) ability to follow instructions and to communicate exertion, pain and distress.

Potential participants were excluded from the study for any of the following:

(1) acute medical problem rendering exercise unsafe;

(2) significant pain that prevented standing or interferes with movement; or

(3) history of additional, non-stroke, neurologic condition.

Study Procedures:

Consecutive sampling from referral sources and community interest identified potential participants. Twenty-two participants were required based on the efficacy power calculation (see Chapter 3). Referrals from health system sources used standard referral procedures through electronic medical records. Outside referrals were accepted from physicians and with the following information: participant name, date of birth, stroke diagnosis code, date of stroke and a notation of referral to CR-stroke. Once initial eligibility and interest were determined, participants completed an evaluation at the CR site. The evaluation included informed consent, a physical therapy screen, basic demographic data, and a battery of outcome measures. The primary investigator (PI), a licensed physical therapist, performed the screen to verify eligibility and determine any modifications required for CR equipment or activities. The primary efficacy outcome measure was the six-minute walk test (6MWT), which is a measure of cardiovascular endurance and community walking capacity.45-47 In addition, the 6MWT is a standard outcome measure and indicator of initial fitness levels in many CR programs including
the study CR program. Further details of the effectiveness methods and results are presented in Chapter 3.

The physical therapy screen and outcomes informed modifications to the standard CR program which were shared with the primary Exercise Physiologist (EP) and documented in a plan of care for all intervention staff to review. Participants were scheduled to begin CR upon completion of the initial evaluation. Aside from modifications provided by the participant evaluation, the intervention did not differ from the standardized program. The program began with an analysis by the EP to determine baseline levels of exercise intensity in metabolic equivalents (METs) based on participant’s 6MWT results. METs are a standard measure of exercise tolerance and functional capacity in cardiac rehabilitation programs. Target heart rate (HR) was estimated from resting HR and HR at the completion of the 6MWT. Target exercise rating of perceived exertion (RPE) levels were set from 11-14 (somewhat hard to hard) on a scale of 6 - 20. Sessions were scheduled three times a week for 12 weeks with a target of 31-50 minutes of aerobic activity each session. Participants chose their days and times based on their schedule and program availability: Monday, Wednesday and Thursday at scheduled blocks between 6:30am and 5:30pm and Friday between 6:30am and 11:30am. Training sessions were individualized based on the plan of care and the recommendations. While components varied by session and individual, the general format was 8 to 10 minutes of warm up, 10 to 40 minutes of cardiovascular endurance activities (treadmill, recumbent step machine, recumbent bike, over ground walking) and strength-building (resistance exercises), and a 5 to 10 minute cool down followed by optional activities. Optional activities included strengthening, stretching, and/or
relaxation, depending on the individual needs and goals. Optional wellness education was provided weekly in approximately 30-minute blocks after scheduled session times. Wellness topics included cardiovascular health, exercise options and safety, nutrition, medication compliance, and stress relief. Progression in the program was determined through participant response, including HR and blood pressure (pre and post exercise) and RPE. If RPE was consistently rated ≤ 11, METs level effort was increased to reach an RPE of 14. Regular monitoring was completed both pre- and post-session for blood pressure, HR, and as needed, blood sugar and heart rhythms. Discontinuation of a session occurred if blood pressure exceeded 170/100 or by clinical expertise of the EP or staff nurses. During the 12-week exercise period, the PI was available to consult both in person and by phone with EPs and participants as needed to address any mobility impairment issues.

Psychosocial and nutritional consultation were available to participants with stroke as part of the program but were not required. The PI discussed these options with participants at the initial evaluation, and participants were instructed to discuss their interest with the primary EP. Interest was recorded on the plan of care.

The CR program was free for study participants; the per participant cost ($237) was covered by the study. At the end of the three-month CR program, all participants who began the program were re-assessed using the study outcome measures.
Feasibility Quantitative Measures and Analysis:

Demographic data was collected on all participants starting the program using a standardized intake form (Appendix A) and then means, standard deviations and ranges were calculated.

Process variables and feasibility measures were recorded and analyzed throughout the study. (Figure 2.1) The following categories were analyzed for feasibility, with details in Table 2.1: (1) recruitment, uptake and retention, (2) adherence and fidelity, (3) acceptability, (4) safety, and (5) effectiveness. Descriptive statistics for program intensity fidelity included means and standard deviations for minimum and maximum HR, minimum and maximum target HR, % of time below, in, and above target heart rate ranges. Intensity fidelity measures also included calculations for median minimum and maximum RPE for each session, each participant and the entire sample.

Qualitative Procedures and Analysis:

A pragmatic, qualitative approach evaluated participant perspectives. Participants who had previously participated in CR or had verbal communication limitations were excluded from the qualitative portion. All others who had started the program were invited to participate. Those participating completed informed consent and received a $20 gift card as an incentive. Semi-structured interviews were conducted after participants completed or left the program. Table 2.1 presents key areas of evaluation, and the interview guide is attached in Appendix B. Interviews were recorded and transcribed verbatim. The number of participant interviews was determined by voluntary
Figure 2.1: Flow Diagram of Study with Feasibility Outcomes

Abbreviation: CR, Cardiac Rehabilitation; MD, Medical Doctor; SD, Standard Deviation.
Table 2.1: Feasibility Measures and Qualitative Interview Topics

<table>
<thead>
<tr>
<th>Topic</th>
<th>Feasibility Measures</th>
<th>Qualitative Interview Topics</th>
</tr>
</thead>
</table>
| Recruitment, Uptake and Retention | • Number of referrals from each source  
• Number phone screened  
• Number evaluated  
• Number eligible to participate, number eligible refusing participation,  
• Descriptions of limitations  
• Number completing program  
• Number dropping out of program  
• Number completing qualitative interviews  
• Uptake rate (recruitment to program start)  
• Program completion rate (start to completion) | • Recruitment (source, initial motivation for attending)  
• Participation Barriers  
• Participation Facilitators                                                                                                                                 |
| Adherence and Fidelity         | • Average number of sessions  
• Total completing at least 18 of 36 visits  
• Average nutrition and exercise consultations  
• Number attending weekly education sessions  
• Number consulting psychologist  
• Frequency of each exercise activity (% of sessions)  
• Frequency of optional activity (% of sessions)  
• Average session exercise minutes  
• Average exercise minutes spent at target intensities  
• Number of PI-participant communications |                                                                                                                                                                      |
| Acceptability                 |                                                                                                                                                                                                                     | • Capability, components, dosing  
• Relationships (staff, other participants)  
• Modification recommendations and preferences                                                                                                                                 |
| Safety \(^b\)                 | • Number and type of serious and non-serious events  
• Number and type of mobility impairments  
• Mobility and safety consultations | • Factors that promoted safety  
• Participant’s perception of their safety                                                                                                                                                                                                 |
| Effectiveness                 | • Six-Minute Walk Test (primary outcome measure)                                                                                                                                                                    |                                                                                                                                                                      |

\(^a\) Minimum standard for Medicare guidelines of cardiac rehabilitation.  
\(^b\) Serious safety events were defined as any injury or medical issue requiring absence > one week from the program.
participation. In addition to interviews, the PI completed monthly structured observations to provide supplementary data (Appendix C) and to add to qualitative rigor.\textsuperscript{52}

Deductive and inductive thematic analysis were completed using NVivo software (version 12, QSR International).\textsuperscript{53} The PI completed the first round of open coding using in vivo style to stay close to participant phrasing; initial coding was completed for all transcripts and structured observations.\textsuperscript{53} A codebook was created during this process based on study questions and initial codes. The codebook was reviewed in committee with another researcher. The codebook included broad categories for recruitment, barriers and facilitators, program delivery (safety, gym environment, interaction with staff, dosing, socialization, activity preferences, adherence, and recommendations for changes to program), and other. (Appendix D) All codes related to outcomes were separated for distinct review (Chapter 3). Both researchers independently completed the second round of coding categorizing results into the codebook’s broad categories. Results were reviewed, compared and discrepancies resolved by consensus. PI completed the third round of coding to create subcategories under each broad category. Data conflicting with primary themes were highlighted to present alternative viewpoints.\textsuperscript{53} Results were reviewed, codes refined and finalized with a committee of researchers including a mentor.

**Results**

A flow diagram presents a summary of study flow and feasibility findings. (Figure 2.1) The study recruitment period lasted for 12 months from August 2018 through August 2019. The first participant began in October 2018, and the final participant finished in November 2019. A total of 29 participants began the program, 24
completed the program (attended at least part of the program with final outcome measures available\textsuperscript{54}). Demographic details are presented in Table 2.2.

Eleven completers and one non-completer participated in the qualitative interviews. Of the remaining 13 completers, 10 did not qualify for qualitative inclusion, one declined, one had unusable audio, and one left the country after program completion. The remaining non-completers either did not qualify or were unable to be reached.

Recruitment, Program Uptake, and Retention:

Recruitment:

Over a 12-month recruiting period, 53 potential participants were referred. The largest number of referrals came from local stroke survivor support groups the PI visited and provided education on the benefits of post-stroke exercise and the details of the program. Clinicians (rehabilitation providers, nurses and physicians), CR staff, and community referrals provided the remaining referrals. (Figure 2.1)

Qualitative responses revealed participants found out about the study because of a local support group (n=5), through a health system medical provider (n=4) or through a community contact (n=4). Participants were initially motivated to join the program because of desire for structured exercise, goals for health or symptom improvement, and altruism to support other stroke survivors and the researcher.

Participant 3: “Well, I remember what you said in the presentation about, um, stroke survivors do not do enough aerobics. And um, I
Table 2.2: Demographic Details of Cardiac Rehabilitation Program Completers (n=24) and Non-Completers (n=5)

<table>
<thead>
<tr>
<th>Gender, % (number)</th>
<th>Age, mean (SD)</th>
<th>Race / Ethnicity, % (number)</th>
<th>Time Since Stroke, mean (SD)</th>
<th>Work Status, % (number)</th>
<th>Walk Aid, % (number)</th>
<th>Initial 6MWT Distance, mean (SD)</th>
<th>Initial Self-Selected Walking Speed, mean (SD)</th>
<th>Pre-Program Exercise Level, % (number)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completers</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>79% (19) Male</td>
<td>62.2 (12.4)</td>
<td>71% (17) White</td>
<td>29.7 (29.9) Months</td>
<td>8% (2) Full Time</td>
<td>75% (18) None</td>
<td>397.8 (119.2) meters</td>
<td>1.17 (0.21) m/s</td>
<td>12.5% (3) None</td>
</tr>
<tr>
<td>21% (5) Female</td>
<td></td>
<td>25% (6) African American</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>4% (1) Asian</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Completers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>60% (3) Male</td>
<td>68.4 (15.0)</td>
<td>60% (3) White</td>
<td>37.0 (41.8) Months</td>
<td>20% (1) Part Time</td>
<td>60% (3) None</td>
<td>279.7 (147.1) meters</td>
<td>0.67 (0.28) m/s</td>
<td>40% (2) None</td>
</tr>
<tr>
<td>40% (2) Female</td>
<td></td>
<td>40% (2) African American</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>20% (1) Walker</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviation: SD, standard deviation; m/s, meters per second.
have never been enthralled by aerobics (laughing). And I thought this might just be the time for me to check it out.”

Participant 5: “Well, I was initially coming because I was trying to build up my stamina and everything because I had a long-term goal. The long-term goal is in September to go to [foreign country].”

Participant 12: “I've always wanted to kind of find a way to either somehow help people who've had strokes or somehow give back to [health system] because you guys, they've been so amazing.”

Uptake:

Program uptake rate (referral to start of program) was 55% and completion rate (start to finish of program) was 83%. Twenty referrals did not move forward to phone screen because of inability to contact, disinterest, conflicts or ineligibility. (Figure 2.1) All of the 33 referrals who were phone screened advanced to initial participant evaluation. Four participants did not start the program: two failed the in-person screening - one had significant back pain with movement (physical therapy was recommended) and the other was not independent on and off equipment. Two participants qualified but declined after the participant evaluation - one was unable to commit to three weekly visits, and the other was unable to obtain a referral from their out-of-system physician.

Twenty-nine participants began the program. Most walked unaided (n=21), with the remaining using a single point cane (n=6) or a hemi-walker/walker (n=2). Participants described remaining deficits related to their stroke as weakness (n=13), walking (n=10), balance (n=9), coordination (n=7), speech (n=6), cognitive (n=5), vision
(n=4) and memory (n=4), with several individuals reporting multiple complaints.

Nineteen participants had some sort of mobility impairment, and 15 participants received recommendations for modifications to the CR program. Recommendations due to mobility limitations were primarily related to limitations or cautions on treadmill use or track-walking with an assistive device only. There were a few limitations of upper extremity overhead motion due to shoulder pain. Other recommendations were safety related, such as expressive speech limitations requiring pointing or writing numbers for exertion, and orthostatic hypotension requiring slow and gradual transitions.

Five participants did not complete the program either by choice, due to medical complications, or both. (Figure 2.1) Two self-selected to discontinue the program; one cited transportation and other medical issues (two sessions) while the other cited increasing headaches, knee pain and medical uncertainty (nine sessions). (Figure 2.1) Three other participants did not complete the program due to safety concerns related to cognitive issues (one session), ineligibility after second stroke (11 sessions), and complications due to recurrent bronchitis (23 sessions). (Figure 2.1)

Retention:

Barriers to starting the program are listed above in the Uptake section. The remaining barriers and facilitators to continuing in the program and participating regularly were identified by the qualitative responses. Barriers included medical complications, competing time demands, financial concerns, transportation difficulties (including long distance to site), and disinterest in gym exercise. Facilitators to study participation
included availability of social support, perceived benefits of exercise, intrinsic motivation and sense of commitment, and ease of transportation.

**Medical Complications:** Medical complications impacted a few of the participants’ attendance in the program. Perceived impairments impacted specific activities, minor illness or sleep disruption caused missed sessions, and for one participant, significant knee pain and headaches caused him to leave the program.

Participant 15: “Yes. I ah, ah...two or three times [missed sessions]. I had bouts of coughing at night and ah, um not being able to stop coughing ah resulting in not sleeping and ah, not going to work the next day or, and in a couple cases ah, um missed a couple days. Um, vomiting and ah, um just being tired probably.”

Participant 25 (non-completer): “So it [headache and knee pain symptoms] was makin’ my work out here more difficult. Even though I would puff through it, umm, it was still more overbearing for me than, I probably shouldn’t have done it but.”

**Competing Time Demands:** Participants cited other life demands such as work, complications in home life, and travel for holidays and vacations as impacting session participation over the 12-week period.

Participant 4: “So my, not being able to here three times a week um, work came into play.”
Participant 11: “I’ve had glitches where I like missed a day because of chaos in my personal life.”

Financial concerns: While most participants did not mention financial concerns, the no-cost factor facilitated a few enrolling in the study, because alternatives such as personal training were too expensive. Additionally, a few participants cited financial concerns as barriers to continuing to participate as self-pay clients at CR after the study ended.

Transportation difficulties including long distance to site: A few participants cited distance from their house as being difficult. Another had some limitations in driving due to vision loss and did not like to drive in the rain.

Disinterest in gym exercise: Participant comments revealed that for a few participants, gym machine exercise is not their preferred activity. One participant preferred riding her horse or dancing, which she perceived as more fun. Another had never exercised regularly in a gym and had to get adjusted in the beginning of the program. The other two simply did not like to exercise at all. All of these participants overcame this barrier and believed exercise was important to their health.

Participant 16: “It's somewhat monotonous, and I don't like feeling fatigued and uncomfortable and tired.”

Interviewer: “But you do it anyway?”

Participant 16: “I do it anyway, and I do feel better when it's all over.”
Availability of social support: Participants noted social support as a facilitator to their program participation. Whether that be from a spouse, family member, staff, or other CR participants, having someone to encourage them and notice their progress was a key facilitator.

Participant 11: “Yes, my husband is supportive. He wants me to continue doing it, he says that he’s seen tremendous change and tremendous improvement. So, um you know, I maybe don’t see it or feel it as much because I’m the one participating, but he, and he said that in terms of my stamina and overall like, you know.”

Participant 12: “My wife, you know, she's always been supportive of me getting out there and trying you know, she knows everything that going on in my brain, unfortunately. She gets to hear it all the time. Um, but she's uh, extremely supportive about and, and pushing me and to, to you know kind of get involved in stuff like this.”

Participant 19: “You know, if you get alone, and maybe somebody who's paying a little bit more attention to you, then you think they're paying attention to somebody else because they like to talk, or the subjects that you talk about are interesting to them and yourself. That motivates you to show up. "Oh, I'm gonna see [staff EP] today because we're talking [topics of mutual interest]. Well, so, you know, we have, we've always had interesting conversations. So that motivates you to come.”
**Perceived benefits of exercise:** Most participants acknowledged that exercise was important to their health. Many also either had previous positive experiences with exercise or noted program results contributed to their on-going participation.

Participant 5: “Because I know that exercise is very, very beneficial. I know that. I just have to be motivated to do it that’s all (laughing).”

Participant 16: “Because I... I had a stroke and I don't want that to happen again. And everyone says exercise is good.”

**Intrinsic motivation and sense of commitment:** Most participants noted either an ability to push themselves towards their goals and/or a sense of following through on obligations that helped facilitate their on-going participation. They felt accountable to themselves, to the staff at CR, and to the study PI.

Participant 5: “I um am kinda a little bit self-motivated, but then when you get here you get extra motivation too.”

Participant 11: “Well my personality is such that if I commit to do something, I’m gonna do it. Even if it sucks, even if I hate it, even if I feel terrible, I’m gonna. I, I, my life is the suck it up principle. You suck it up and you [expletive] do it.

Participant 19: “So there was an accountability to myself, accountability to the trainers that are here, and accountability to [PI].”
Ease of transportation or close distance to site: Living or working close to the CR facility was a facilitator for some of the participants. Being close was convenient for participants, which made it easier to fit in sessions with their other obligations. Being nearby also allowed one participant to drive to the site even though she was uneasy driving, and another participant was able to walk to sessions and easing his burden of getting rides from friends and family.

Participant 3: “It was very easy for me to get here, you know its ten minutes away. And um once I found the place, I could get here very easily. Um, and so that was good. I’ve driven myself which is very odd for me. I drive very little and only in the daytime and you know only in the neighborhood.”

Adherence and Fidelity:

The average number of sessions attended by program completers was 25.25 (SD 5.82) of 36 possible sessions with a range of 12-36 sessions. Participants averaged 38.93 (SD 5.64) exercise minutes per session with a range of 29.25 to 51.41 minutes. HR and RPE targets, HR averages and RPE medians are presented in Table 2.3 and Figures 2.2 and 2.3. While HR goals were not met, the calculations included warm-up and cooldown periods which were not intended to be in the target range. While medications may blunt HR response, RPE provides another measure of intensity, and RPE target goals were met. Twenty-one participants (87.5%) completed at least 18 sessions, with the remaining three completing 12, 17, and 17 sessions respectively. The participant who completed only 12 sessions cited demand for work as a barrier to more regular attendance. Education of participants was primarily informal and included nutrition and exercise consultation and
Table 2.3: Target and Actual Aerobic Exercise Minutes, Rating of Perceived Exertion and Heart Rate Ranges

<table>
<thead>
<tr>
<th>Measure</th>
<th>Target</th>
<th>Session Results, Mean (SD) or Median (IQR)&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Session Results, Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minutes of Aerobic exercise</td>
<td>&gt; 31 minutes total: 8-10 minutes warm up 10-40 minutes moderate activity 5-10 minutes cooldown</td>
<td>38.93 (5.64) minutes total</td>
<td>29.25 - 51.41 minutes total</td>
</tr>
<tr>
<td>RPE Minimum</td>
<td>9 (warm up and cooldown) 11 (moderate activity goal)</td>
<td>11 (0.625)&lt;sup&gt;a&lt;/sup&gt;</td>
<td>8-15</td>
</tr>
<tr>
<td>RPE Maximum</td>
<td>11 (warm up and cooldown) 14 (moderate activity goal)</td>
<td>13 (1.000)&lt;sup&gt;a&lt;/sup&gt;</td>
<td>11-16</td>
</tr>
<tr>
<td>HR Session Minimum, BPM</td>
<td>97.74 (12.16)</td>
<td>90.57 (10.06)</td>
<td>65.92 - 103.5</td>
</tr>
<tr>
<td>HR Session Maximum, BPM</td>
<td>115.14 (11.71)</td>
<td>108.45 (12.02)</td>
<td>75.42 - 129.19</td>
</tr>
<tr>
<td>% of session time in or above target HR range</td>
<td>57.63 (27.36)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>13.28 - 98.87</td>
<td></td>
</tr>
<tr>
<td>% of session time below target HR range</td>
<td>38.91 (25.18)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% of session time unrecorded HR range</td>
<td>3.46 (7.58)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviation: SD, standard deviation; IQR, interquartile range; RPE, rating of perceived exertion; HR, heart rate; BPM, beats per minute.

<sup>a</sup> Median (IQR)

<sup>b</sup> Total time includes warm up and cool down times which are intended to be lower than target ranges.
Figure 2.2: Heart Rate Fidelity: Average of Total Session Time Spent Below, At, or Above Target Heart Rate Ranges for each Participant
Figure 2.3 Session Minimum and Maximum Rating of Perceived Exertion Medians
Abbreviation: RPE, rating of perceived exertion. Shaded area indicates target RPE zone, warm up or cool down between 9-11 (very light to light) and moderate intensity activity between 11 (light) to 14 (somewhat hard).
advice. Staff noted on exercise logs discussions based on participant request for information or just general information sharing from supervising staff (EP, nurse, dietitian) during exercise sessions and recorded in notes on exercise logs. Detailed nutritional plans were sometimes provided. Both exercise and nutrition consultations often included an accountability component where participants were asked about their home food intake or exercise. Nutrition consults occurred on average of 2.04 (SD 1.52) times per participant (range 0-5 times), and exercise consultations occurred on average of 1.54 (SD 1.47) times per participant (range 0-4 times). None of the participants attended the weekly formal education sessions or consulted a psychologist.

Qualitative results reveal that participants didn’t know about the availability of the psychologist or formal education sessions (despite information provided at the initial evaluation).

Participant 8: “I didn’t know that was an option to meet with her/him [psychologist], but I will.

Participant 19: “I wasn't as informed about the sessions that took place when and where and all of that. So I don't know if that's a negative or, you know, a positive, but if it's something that, if they're looking for participants to go and listen to these talks, especially for the sake of the speaker, I wasn't, you know, I don't ever remember being informed, "Oh, tomorrow there's a talk on X."”

Walking the track was the most regular included session activity (91.42% of sessions) and often was the warmup and/or cool down activity. Other equipment included
in sessions were NuStep (67.49% of sessions), upper body ergometer (48.68%), aerodyne bike (41.09%), recumbent bike (39.77%), treadmill (37.79%), and elliptical (36.96%). Optional exercise components included weekly guided relaxation, chair strengthening exercises and yoga after regular exercise sessions. Relaxation was the only optional session recorded on exercise logs and averaged 2.71 (SD 2.42) times per participant or 10.73% of sessions.

Opinions on the types of exercise equipment they liked and did not like varied widely among participants. Several liked the recumbent or upright bike or the NuStep. The most disliked pieces of equipment were the elliptical and the upper body ergometer/arm bike. For each piece of equipment one participant disliked, another liked. Participants highlighted their enjoyment of the variety of machines, being encouraged to try several different types and having some influence on what equipment to use regularly.

Participant 15: “[I liked] machines that ah involved my legs ah I...bicycle for all my life and uh so yeah, it was good to get back on something that uh either reclining bike or upright bikes.

Participant 11: “I mean there are a couple machines that I knew I did not like to use and that did not work for me. And they were nice about saying, ‘okay well you don’t have to’. They made me try everything, but there were ones that I just was not going to continue using.”

Relaxation was mentioned by several of the participants as an enjoyable and positive aspect of the program.
Participant 3: “I really liked it. I attempted to do relaxation on my own but not been so successful. Um, so the group setting where everybody is quiet, and eyes are closed and there is this very gentle voice leading us through. Um, was very very good. And um, I felt like um you know, I didn’t go to sleep but I felt sort of drowsy. And then when she brought us back into the present um, I just felt peaceful. It was good.”

Participant 4: “I really love the relaxation sessions… the um relaxation I give a lot of thumbs up. That was new to me.”

Non-safety related consultations by PI with participants came at the request of the primary EP. If participants were missing for more than two weeks, EP requested PI contact by phone to determine concerns and encourage return (four - one returned to the program after contact and the other three left the program).

Acceptability:

Program acceptability was evaluated using qualitative responses. Resultant themes included the perceived benefits of an individualized program in a group setting, correct dosing with a desire for more scheduling options, positive interactions with staff who were qualified, and a supportive, energetic gym environment with opportunities for socialization and connection.

*Perceived benefits of an individualized program in a group setting:* Participants noted that although there was structure to the program, they were able to customize it to their abilities, interests and plan. Participants were individually monitored and
encouraged to challenge themselves. Staff modified activities or provided support when necessary, such as using Velcro to support a weak limb on the NuStep and assisting another participant who wanted to work on strengthening with the leg press machine.

Participant 4: I’m, I’m gonna come to say (pause) for the most part it was the right level. And that’s another thing that your staff was doing, is, is no one was pushing anyone to do anything that they were not comfortable with. And uh, you also, I mean, I, I’d be asked what would you like to do next? Where would you like, you know, what exercise would you prefer? Where would you like to be? And so, so it’s pretty much left to the individual and I shouldn’t be speaking for everybody else. So for me, I did what I was comfortable with.”

Participant 5: “Uh, this is a very good, nice atmosphere. I mean because it’s not like I am over here pumping iron or I am do this right here to outdo this person over here. Everyone is working at their own pace and I love that.”

Participant 11: “Well, um I think it was really good, I really liked it. I liked that once I figured out what I was supposed to do, I could kind, it was kind of self-guided. You know, I was monitored but I could kind of control what I was doing. And liked that I wasn’t um, I could kind of zone out and do my own thing.”
**Acceptable frequency with a desire for more exercise day options:** All participants thought that three times weekly was an appropriate frequency. All except one participant thought the 12-week duration was also appropriate; one wished it was longer because of the benefits she was seeing. Three (25%) participants noted that they would prefer Tuesday or Friday afternoon options to get in three sessions a week.

Participant 5: “Three times a week is good. Um, the other thing I would do is every other day, Monday, Wednesday, Friday.”

Participant 25 (non-completer): “Three, three times for an hour is like, like, no big deal.”

Participant 12: “I like it just because it gave me uh you know it wasn't I didn't feel like oh, we got to get this whole crammed into a week or a month. But at the same time it gave me time to kind of get used to it all. You know, yeah, I mean, now it's it is, ahh except for [non-health life change event], I mean it was becoming a habit.”

Participant 16: “It was nice in that I could see a finish line. You know I was going three times a week, working out hard but I knew there was an end point and I'm going to continue to workout, I'm going to go to the Y, maybe just call it a milestone rather than an endpoint.”

*Positive Interactions with Staff who were qualified:* Participants report regular, repeated, appropriate interaction with staff throughout their sessions.
Participant 3: “I think the individual attention here is as good as the one on one stuff at the hospital [rehabilitation]. Because whoever was assigned to me would get me started with, set the machine and time me and they would almost to a person would come back at exactly the right time and ask how it went. And then do all the, you know, how hard was it? I really felt cared for.”

Participant 15: “Ah, [nurse] was ah attentive. Ah, that's a...they all were if they took up the slack if uh, uh, uh [Primary EP] wasn't available. [Nurse 2] was very helpful and uh, um, uh and remembering what ah was my particular uh weakness and so on.”

Participants described the staff as encouraging, caring, and enthusiastic. There was a team approach to supporting the participants. Study participants regularly mentioned the primary EP had a fun and energetic personality but also was skilled and attentive to their efforts and exercise responses.

Participant 19: “If there is 10 trainers here at one time, everybody helps everybody. So it isn't, you know, "Just wait for [primary EP], I can't help you." The next person would recognize that, okay, this guy's done or are you okay? Constantly being checked on by all of the team, and if I needed help, I wasn't afraid to ask then, you know, somebody else other than [primary EP], because at other times [primary EP] was in, into, involved with, you know, helping somebody else. So, very team oriented in that sense.
Participant 5: “I mean, [head exercise physiologist] makes it fun. [Head exercise physiologist] keeps me, I mean he tells so many jokes that keep you going and then you concentrating on, trying to concentrate and not because you are listening to him or laughing at him. And um, you forget what you are doing, and you look, and you have done more than you thought you was going to do.”

Participant 3: “I thought [head exercise physiologist] was particularly skilled in reading me. You know I would be walking around the track he would come next to me and say I think you ought to stop now. And I would say well why? Well your right leg is dragging a little bit but I didn’t know that. Or he will, I’ll have ten minutes set on a machine and he will say let’s just stop at five and he really read me in terms of fatigue and um uneven heartbeat.”

Supportive Energetic Gym Environment with Opportunities for Socialization and Connection: All participants commented positively on the gym environment. Participants described the environment as welcoming to all regardless of age or abilities. Others noted a comfort in knowing that those around them had experienced something similar. Some were inspired by the effort of everyone around them.

Participant 3: “Most people were very concentrated on what they were doing. A few people would say hello, but that was kind of it. And we were just all concentrating on what we were doing. And it
was kind of nice to see the level of energy and the people were working so hard. And that was kind of inspirational.”

Participant 19: “Um, gym atmosphere is very, very loose. Um, it looks like the participants all understand the personalities of the different people working here. And so, I think it puts them at ease to be here because the age group of the people that are here are all over the place you have people that could be in their twenties to people that could be in their eighties and I've seen both ends of the spectrum and I've seen both, both sets of people very comfortable in what they're doing.”

One contrary opinion on the gym environment came from a participant with sensory sensitivities secondary to her stroke. She reported difficulty, but also how she was able to overcome the barriers to participate.

Participant 11: “The only thing I would say specifically is, is the like I said, the conditions for stroke people and you know, I guess different strokes might have different needs. But, but the lights and sounds, that kind of thing, that surprised me that that was like a really big thing for me.”

Participant 11: “…So, um I, when I would come, I would wear my sunglasses and I would put earbuds in and sometimes I would put earbuds in with no, with no music just to block out the sound. And I
realized that if I did that, it could, it would calm me down and I could function.”

Socialization opportunities varied from casual interactions to connections and friendships. Several participants noted casual, encouraging conversation with others while at CR. Several of the same participants and others noted opportunities for deeper connections because of shared experiences and re-connecting with old friends or making new ones.

Participant 3: “I found myself believe it or not looking forward to coming here. And I got. I saw several people that I had known from past lives here. [notes several personal connections from the past] … And I was thinking gosh this is my crowd you know. And of course, [head exercise physiologist] is just wonderful. Um, so there were people that I could talk to and say hello to. Um, so it was a nice kind of minimal but a very nice social time. And I needed that.”

Participant 25 (non-completer): “I don’t remember anybody’s names that I talked to. The one we, they’d walk like my speed around the track or whatever. But there’d be people that I’d see that we just kinda, like, clicked, just from seein’ each other, right? Or we’d be workin’ next to each other… it was just talkin’ about regular things in life.”

Participant 18: “I feel like people were just here doing their best. And that was good enough for me. Like there’s … that vibe makes
me feel like that's where I want to, uh, be in. And I- I- I have a home [exercise routine], but I like being around people. There's something about knowing other people are dealing with looking struggle in the face, and you're in a camaraderie about that.”

Safety:

One serious safety event occurred during CR. One participant with a known atrial fibrillation diagnosis had an episode with a new rhythm. (Figure 2.1) The CR staff put the participant on hold until she had permission from her cardiologist to return. CR staff contacted the cardiologist’s office (outside of the health system) with information on the episode, and the participant returned to the program two weeks later, after an appointment with her cardiologist and a medication change.

Three serious safety events occurred outside of CR during the program period. One participant was in a car accident and missed three weeks due to his chiropractor’s recommendation. Another participant had an ocular stroke and was discharged due to eligibility but returned after a three-month waiting period and restarted the program. The third participant lost consciousness while playing golf and was hospitalized. He returned to the program one week later with reduced intensity and was eventually diagnosed with a medication dosage issue which was corrected.

Non-serious events are presented in Table 2.4. Pain complaints occurred 45 times (7.4%) aggregated over all sessions for all participants. The average pre-session pain on a scale of 0-10 was 0.51(SD 0.87) with a range 0-9. The average post-session pain was 0.43 (SD 0.94) with a range of 0-8.
Table 2.4: Non-serious Safety Events

<table>
<thead>
<tr>
<th>Non-Serious Safety Event</th>
<th>Number of episodes recorded across all participants (% of 606 total sessions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Falls at CR without injury</td>
<td>1&lt;sup&gt;a&lt;/sup&gt; (0.17%)</td>
</tr>
<tr>
<td>Falls outside of CR without injury</td>
<td>3 (0.50%)</td>
</tr>
<tr>
<td>Soreness</td>
<td>12 (2.00%)</td>
</tr>
<tr>
<td>Pain</td>
<td>45 (7.40%)</td>
</tr>
<tr>
<td>Numbness</td>
<td>2 (0.33%)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>12 (2.00%)</td>
</tr>
<tr>
<td>Shortness of Breath</td>
<td>4 (0.66%)</td>
</tr>
<tr>
<td>Low Blood Sugar</td>
<td>1 (0.17%)</td>
</tr>
<tr>
<td>High Blood Pressure at start</td>
<td>9 (1.50%)</td>
</tr>
<tr>
<td>Low Blood Pressure at start</td>
<td>3 (0.50%)</td>
</tr>
<tr>
<td>Atrial Fibrillation</td>
<td>4&lt;sup&gt;b&lt;/sup&gt; (0.66%)</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>4 (0.66%)</td>
</tr>
</tbody>
</table>

Abbreviation: CR, Cardiac Rehabilitation

<sup>a</sup> One participant had a fall without injury at the post-program evaluation appointment where a stroke-related spatial relations issue caused the participant to miss a chair and sit on the floor. Participant was evaluated by CR staff and continued post-assessment.

<sup>b</sup> One of these atrial fibrillation events occurred in a patient who had been previously undiagnosed. CR staff and participant spoke to health system cardiologist, medication was prescribed, and participant returned to CR program the same week.
Consultations occurred between the PI and EP due to mobility concerns (n=4) and safety concerns (n=4). Mobility consultations included three joint study eligibility evaluations (both the PI and primary EP): related to cognitive issues (n=1) and assistance required for participants with hemiplegia getting on and off equipment (n=2). One additional mobility consultation occurred during the program between the PI and EP addressing gait and strength deficits. The PI consulted with the primary EP related to the four safety issues that required physician visits, including the participant who had the second stroke, the two atrial fibrillation episodes, and the participant who was hospitalized after loss of consciousness. The PI reported all safety events with physician visits to the health system and university IRBs; neither IRB considered any as sentinel events.

Safety themes from qualitative evaluation include regular monitoring and staff attentiveness promoting feelings of safety and participants’ perceptions of impairments impacting activity safety.

*Regular monitoring and staff attentiveness promoting feelings of safety:* Many participants explicitly stated they never felt unsafe during the program. For most participants that sense of safety was due to the monitoring and staff attentiveness. Participants noted the staff was regularly focused on issues with blood pressure or heart rate (high or low) and responded quickly to atrial fibrillation episodes that the participants themselves did not recognize as anything problematic. Staff evaluated irregular heart rhythms, gave clear instructions to participants on findings, and contacted medical providers with detailed information. Additionally, staff monitored heart rates and
blood pressure after sessions and had participants wait, drink water, or relax to normalize before they released them to leave.

Participant 19: “I felt very comfortable that God forbid I lost my balance and fell over and hit my head, or if my blood pressure was too high or too low, I feel very confident in the ability of the people that work here to react because I’ve seen accidents where anyone, another participant that had fallen and they jump faster than a cricket jumps. They just all of a sudden converge to the person that fell and they are on top of it.”

Participant 4: “And so, I called [head exercise physiologist] over because I wanted to explain to him that the machine I was on was broken. Because it’s reading my heart rate as 165. Okay. And of course, he took my pulse and um, said there’s nothing wrong with the machine would you please come and sit over here. And uh, that’s the very first time I was aware that I had had an a-fib and what an a-fib was. And um, (clearing throat) [head exercise physiologist] and [nurse], they both and everyone else spent all of the next forty-five minutes taking care of me.”

Participant 3: “I think it was the checking of my heart beat and then using the strip and they were showing AFib and then really kind of wild variation. … Um, and so I called my doctor and got an appointment…. And he made a minor medication change for me, and I think it’s really helped. So, my blood pressure is more
predictable, and it’s not crazy. And the dizziness is somewhat better. Um, so this was like a great service that this program did for me is to help me figure out that I needed some more attention and got it.”

Participant 15: “And then at the end of the day there were three or four days that uh, I had to drink uh volumes of water and eat crackers before they would release me and uh I felt that was uh caring and thoughtful and although it was frustrating to, um, not be able to uh to just get on the way.”

Participant’s perceptions of impairments impacting activity safety: A few participants had safety concerns about specific activities at CR. One felt the treadmill and the rower were not safe because of her leg weakness. Another attributed a fall without injury at study post-assessment as related to stroke proprioceptive and cognitive processing deficits. The same participant worried about getting on and off the treadmill as well. Finally, another participant’s dizziness, headache, vision symptoms, and knee pain made him feel less safe on the equipment.

Participant 3: “I have these stroke related things that are somewhat subtle but made it really impossible for me to do um the treadmill. That I would just fall. I didn’t. I mean [head exercise physiologist] was with me, and I didn’t fall but it was such a risk and then rowing machine I also had a hard time getting up and getting down.”
Effectiveness:

Participants walked an average of 397.8m (SD 119.2m) in the pre-program 6MWT, and an average of 459.7m (SD 118.5m) post-program, a statistically significant improvement of 61.9m (p<0.0001). More details on effectiveness and secondary outcome measures are presented in Chapter 3.

Discussion

CR using Medicare guidelines for dosage and components appears to be a feasible, acceptable, safe and effective exercise opportunity for survivors of stroke. CR improved cardiovascular endurance with progressive, moderate-intensity exercise adjusted to the individual, and the staff provided motivation and expert monitoring. Survivors of stroke were able to meet the intensity demands of the CR program which they perceived as appropriate. Participants were encouraged to work hard but never pushed in a way that made them uncomfortable. A frequency of three times a week for 12 weeks was acceptable to most participants. They liked the different time options throughout the day for sessions but would have liked a full five-day week to consistently meet three times weekly. A 2020 systematic review and meta-analysis evaluated the effects of exercise program dosage, intensity, and supervision on walking capacity for stroke survivors. The results suggest that three days a week is the best frequency, greater than 12 weeks (versus less than or equal to 12 weeks) is the best duration, supervision is superior to self-management, and moderate and high intensities are equal in impact. These findings generally support the standard CR model dosing for stroke survivors and are consistent with the findings of the current pilot study.
Participant recruitment was the largest barrier to the present study. It is a common problem in traditional CR, with a 2018 report noting a 60-85% referral rate for common cardiac diagnoses, and of those referred, a 50% uptake. The AHA, along with the Centers for Disease Control and Prevention, have initiated the Million Hearts Initiative which includes strategies to impact these statistics. In the present study, targeted referring providers demonstrated enthusiasm for the program and its potential benefit to their patients. Still, referrals and uptake from the health system providers were low, and enrollment for those referred from the health system was also low. Clinicians were anticipated to be the largest referral source and this result was unexpected. Electronic referrals could only be completed by a limited number of targeted providers and the process was time consuming which may have influenced the low number of referrals. Survivors of stroke were interested, as demonstrated by their self-referrals through support groups and community members. Participants highlighted the importance of exercise to improve their health (either through existing knowledge or education at support group) and the value of a recommendation from a trusted source as motivation to participate. In one study by Anderson et al., stroke survivors preferred referrals for health system and community programs because they didn’t understand the rules for access or qualifications for specific programs. This ambiguity was especially true for survivors with mild to moderate impairments. For example, one participant in this study qualified for a research-based exercise program because she had more severe mobility deficits; another was too high level for the same program, but was also deemed unsafe at a community exercise facility. In another survey-based study of 312 stroke survivors, the majority wished they performed more exercise, and 84% indicated interest in an exercise
program if available. In the same study, participants reported that recommendations from a healthcare provider directly influenced their exercise behaviors, yet only 45% received an exercise recommendation. In traditional CR, a recommendation by the physician and endorsement by supporting healthcare providers increases the likelihood of CR participation. An easy electronic referral process and prompts in electronic medical records to consider referral to these programs would reduce process burden on healthcare providers. Readily available educational materials for patients and training of healthcare providers could also influence referral and uptake. These methods are supported for traditional cardiac participants through a task force from the American College of Cardiology and the AHA. Community outreach and education through support groups is another potential recruitment tool that allows for education directly to the stroke survivor outside of the stressful health care environment which can impact information processing and retention. Community outreach was a successful recruitment tool in the present study. Educational interventions using evidence-based strategies may positively influence survivors of stroke without exercise self-efficacy, a key driver of participation. These types of interventions have been shown to influence both stroke survivors and traditional CR participants to exercise. Physical Therapists (PTs) have a unique opportunity for these education and referral interactions, because they have touchpoints with almost all stroke survivors.

There are several studies and programs outside the U.S. that support the use of CR for stroke survivors. However, these programs often do not provide the same dosage or create an entirely new program just for survivors of stroke. Canadian programs have shown effectiveness and feasibility, but vary greatly from U.S. programs in dosage, with
a six-month duration and once weekly frequency. Programs in Canada separate stroke survivors with mobility impairments for a stroke-specific CR program, while those without mobility impairments attend standard CR, yet the stroke specific programs are not widely available. While other research has examined modified CR in the U.S. and found it to be effective and feasible, these studies have not presented why programs separate from the standard CR programs are required or desired. Utilizing existing CR programs, which are widely available in the U.S., has potential implementation advantages over creating new programs. In a study by Cuccurullo et al. in 2019, stroke survivors worked in groups using a NuStep recumbent stepper only while monitored by PTs and PT assistants. Reasons for modifications were not provided in the study and there was no mention of mobility concerns that supported the utilization of PTs. Another study, Biasin et al, executed the cardiac program concurrently with inpatient rehabilitation and also only used a NuStep recumbent stepper, even for ambulatory participants. This program had suboptimal dosage with less than eight sessions and only 11.3 minutes per session spent in the target heart rate range. PTs supervised the Biasin study with non-licensed trained assistants. No adverse events occurred in either study, supporting feasibility. However, in the Biasin study, those with cardiovascular co-morbidities were excluded which would not be required in a standard CR setting. The current study demonstrates that stroke survivors with a variety of mobility and other limitations can meet CR standards with prescribed intensities, and that they value the variety of activities available. CR staff (EPs and nurses) are qualified to monitor the cardiovascular system as was well demonstrated in the current study. PT touchpoints in the current study were at referral, at initial evaluation for program modification, and
during the program for consultation. Few activity restrictions were recommended; those identified could be accomplished through referral from a PT with specifications, or if coming from another source, a PT screening could be required for those with mobility impairments prior to starting the standard program. Finally, there were only four mobility related consultations during the program. These types of consultations could be generally handled by email or phone and staff training for common stroke-related mobility impairments. The current study results support the use of standard CR staff personnel with PT support needed only for referral, consultation, and staff training.

Barriers and facilitators to program participation in the current study are consistent with the existing literature for traditional CR participants and the general exercise literature for survivors of stroke. Commonly identified facilitators for both groups are high exercise self-efficacy, belief that exercise is beneficial for their health, flexible times, making exercise a priority, and social support.66-69 Program completers in the present study were an intrinsically motivated group of primarily previous exercisers. Generally, they knew exercise was important for their health, wished to avoid further strokes and health complications, and wanted to improve themselves. Often, they felt like they did not have the proper tools to do this on their own or lacked the accountability piece that the CR program provided. Participants had support and encouragement from family to participate in CR. Sometimes this support was practical through transportation provided by family, and sometimes it was psychological support through motivation or encouragement. For example, one participant’s mother found out about program and encouraged her to attend, two participant’s spouses supported them by reflecting on their achievements, and another’s spouse drove him to the facility and encouraged his regular
attendance. Once attending the program, social support through shared experiences with other participants, encouragement and ongoing evaluation from staff, and relationships with both other participants and staff encouraged continued participation. Social connection and support is one of the most recognized traditional CR participant adherence facilitators and the survivors in this study reflect that. Being surrounded by others with similar experiences is a powerful motivator for survivors of stroke.

Barriers to the program for pilot participants were related to other time obligations including work, transportation or distance to the site, and impairments related or unrelated to their stroke deficits. Return to work conflicts are a common barrier for traditional CR participants. Transportation issues, poor health and low exercise self-efficacy are shared common barriers for traditional CR participants and stroke survivors. Physical impairments and their impact on accessibility, balance and ability to perform exercise are unique to survivors of stroke. Portions of the current sample reflected this concern despite general high mobility in the group.

Safety, through monitoring and staff experience identifying and handling adverse cardiac events, was an important finding in the pilot study. CR staff was trained and experienced in identifying blood pressure, blood sugar and heart rhythm issues and swiftly addressing them. Exercise was impacted where necessary, but simple interventions such as water or nutrition and retesting, allowed participants to continue with their exercise routine. Several of the issues efficiently identified and handled in the CR environment, including identifying atrial fibrillation episodes (both new and chronic) and low and high blood pressure and blood sugar readings, would not have been monitored or easily identified in a standard fitness facility. As a result, a CR facility
promotes safety and helps address underlying medical issues that can affect exercise tolerance, safety and risk. In the current study, one participant had unusually high blood pressure and an intolerance for medications. Due to a documented history of medication trials in the health system record and staff comfort with unusual readings, the participant was able to exercise, and blood pressure readings reduced during activity. Atrial fibrillation, both diagnosed before and after stroke, is common in survivors. One study found for adults with first-ever, acute ischemic stroke, 24% had post-stroke atrial fibrillation, suggesting the incidence of atrial fibrillation episodes was not an unexpected occurrence.\textsuperscript{75} CR staff quickly recognized these atrial fibrillation episodes, confirmed them with heart monitoring, educated the patient and contacted their medical providers. For one participant, atrial fibrillation was suspected, but had not been officially diagnosed. For another with known atrial fibrillation, an unexpected rhythm precipitated a medication change. The participants recognized the focus on safety and the staff’s ability to handle adverse occurrences as a major benefit of the program. Promoting safe exercise for a population with cardiovascular co-morbidities like the current sample supports the safety and benefit of CR as a transitional program for stroke survivors.

Strengths of the present study include application of standard U.S. based CR program dosage and intensity, including measures of intervention fidelity and including an analysis of qualitative responses for participant program acceptability. Limitations in the present study include the evaluation of only one health system CR site in the Southeast U.S., limiting generalizations to other areas and programs. While the inclusion-exclusion criteria were broad with desires of reaching a varied sample, most of the pilot
participants were Caucasian men who were already exercising and had few mobility limitations.

Future research can expand on these findings through studies aimed at increasing participation by individuals with limited exercise experience, more women, and more diverse racial and ethnic backgrounds to reflect the overall population of the community more directly. Additionally, more exploration of health system barriers to program referral and uptake is suggested.

Conclusion

CR is feasible for survivors of stroke who are able to meet dosage and intensity goals and perceive the program as needed, regardless of their mobility limitations or previous exercise experience. Participants enjoyed the comradery and positive environment, felt safe and attended to by staff, and improved their endurance. Challenges focused primarily on managing referral and uptake of the program. Providers need an easy way to refer and educate patients on the importance of exercise. Survivors need positive exercise beliefs and to overcome scheduling and transportation barriers. Using an existing structured-exercise program that is widely available in the United States, feasible for stroke survivors, and supported by qualified licensed professionals has the potential to impact the health and mobility of a large number of stroke survivors.
CHAPTER 3
INTEGRATING SURVIVORS OF STROKE INTO CARDIAC REHABILITATION IMPROVES CARDIOVASCULAR ENDURANCE AND FUNCTIONAL STRENGTH: A MIXED METHODS PILOT EFFECTIVENESS STUDY

Introduction

Physical inactivity is a major health concern for the majority of the seven million survivors of stroke in the United States (U.S.) with increased risk for additional stroke and cardiovascular disease. Exercise can mitigate these risks, but survivors of stroke are not exercising; 58% fail to meet stroke guidelines for physical activity (PA) and 82% do not meet guidelines for the general population. While many survivors of stroke receive physical therapy during recovery, time barriers and functional focus limit impact on aerobic exercise and endurance. As a result, survivors of stroke remain deconditioned after traditional rehabilitation, when they transition from one-on-one care with a physical therapist (PT) to self-directed individual activity. The lack of appropriate community group exercise programs impedes continuation of supervised activity. Without guidance or knowledge on appropriate activity, most survivors of stroke do not continue to exercise or engage in PA post-rehabilitation.

Structured exercise programs offer an opportunity to break the cycle of inactivity and reduce the risk for developing or worsening cardiovascular and comorbid
Cardiac Rehabilitation (CR) is a structured exercise and behavior modification program for people with cardiovascular diagnoses such as myocardial infarction. CR programs are prevalent in health care systems across the U.S. Participation in CR has been shown to increase functional exercise capacity, lower risk of hospital readmissions, and improve health related quality of life for traditional participants with cardiovascular disease. Previous studies of cardiovascular training in survivors of stroke have demonstrated that they can safely perform aerobic programs and achieve health benefits. Variation in dosage, staffing, and mode of activity impact the external validity of these studies; therefore, more knowledge is required to determine if benefits translate into existing CR programs. Programs in Canada suggest the potential for integration of survivors of stroke into existing CR programs, however, the dosage and insurance climate differs from U.S. programs. Effectiveness in existing CR programs for survivors of stroke that follow Medicare guidelines and have different staffing models has not been investigated. The purpose of this study was to determine if CR after rehabilitation improves the health and physical activity habits of survivors of stroke. Evaluation of these programs is supported by the American Heart Association and the American Stroke Association.

The primary aim was to investigate the impact of an existing CR program for survivors of stroke through pilot effectiveness measures for physical function (cardiovascular endurance, functional strength, walking speed), and for other health impacts (quality of life, balance confidence, depression, fatigue, exercise habits). A secondary aim was to evaluate participant perception of program impact on physical function, health, and future exercise plans.
Methods

The study was conducted at Novant Health’s Charlotte, North Carolina cardiac rehabilitation facility. A mixed methods design combined a single group, pre-post design, with a pragmatic qualitative inquiry of participant perception.

The project was approved by Novant Health Presbyterian Healthcare Institutional Review Board (IRB) and acknowledged by the University of South Carolina (USC) IRB. The study is a registered clinical trial through the United States National Library of Medicine (ClinicalTrials.gov ID: NCT03706105). Participation was voluntary and individuals were able to opt-out at any time. The program was free for study participants, with program costs ($237 per participant) covered by study grant funding. Participants completed informed consent and an authorization for use and disclosure of protected health information for research purposes. The study protected privacy through strict confidentiality (de-identification of results) and project material security (following IRB guidelines and utilizing RedCap (Research Electronic Data Capture) software hosted at USC).82

Potential participants were recruited from a variety of health system (stroke team nurses, physical therapists, physicians) and community sources (stroke support groups, word of mouth, outside rehabilitation providers) and were screened for eligibility.

The following inclusion criteria were applied: (1) diagnosed with stroke at least 3 months prior; (2) completed physical and occupational therapy rehabilitation, if applicable; (3) cleared by treating medical provider (physician or nurse practitioner) to participate; (4) demonstrated ability to walk at least 40 meters with or without an
assistive device; (5) demonstrated ability to transfer from sit to stand without assistance; and (6) demonstrated ability to follow instructions and to communicate exertion, pain, and distress. Potential participants were excluded from the study for any of the following: (1) presence of an acute medical problem rendering exercise unsafe; (2) complaints of significant pain that prevented standing or interfered with movement; or (3) history of an additional, non-stroke, neurologic condition.

Once eligibility was determined, the PI (a physical therapist) screened participants for safety and completed a battery of outcome measures. Participants completed a demographic intake form. (Appendix A) Table 3.1 presents the screening (a one-time mobility assessment) and outcome measures (repeated pre-program, post-program and six-months post-program). All physical outcome measures, the Stroke Impact Scale (SIS), the Activities Specific Balance Confidence (ABC) Scale, the Fatigue Severity Scale (FSS), and the Short Self-Efficacy and Outcome Expectation for Exercise (SSEE, SOEE) Questionnaire have been validated in survivors of stroke.\textsuperscript{46,83-87} The Patient Health Questionnaire 9 (PHQ-9) was selected due to current use for traditional CR participants.

Endurance (Primary Physical Outcome Measure-6MWT): The six-minute walk test (6MWT) is a measure of cardiovascular endurance and community walking capacity, and a standard measure of many CR programs including Novant CR. It is used in CR as an outcome measure and indicator of initial fitness. Participants were instructed to walk as far as possible in six minutes around an indoor track (220 feet). They could stop and rest as needed, but timing continued. Once six minutes passed, the distance walked was
Table 3.1: Screening and Outcome Measures

<table>
<thead>
<tr>
<th>Mobility Screening Measures (Pre-program, not repeated)</th>
<th>Outcome Measures (Repeate Program, Post-Program, Six-Month Follow-Up)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Upper and lower extremity range of motion</td>
<td><strong>Physical Measures:</strong></td>
</tr>
<tr>
<td>2. Upper and lower extremity strength</td>
<td>1. Six-Minute Walk Test (endurance)</td>
</tr>
<tr>
<td>3. Ability for hands to grasp and release</td>
<td>2. Five-Times Sit to Stand (strength)</td>
</tr>
<tr>
<td>4. Balance (standing feet together, single leg stance)</td>
<td>3. 10-meter walk test (walking speed)</td>
</tr>
<tr>
<td>5. Alterations in gait (e.g. inability to clear the paretic leg from floor, inability to negotiate around obstacles, use of assistive devices)</td>
<td>4. Maximum Metabolic Equivalent (fitness)(^a)</td>
</tr>
</tbody>
</table>

**Patient Reported Measures:**
1. Activities-Specific Balance Confidence Scale (balance perception)
2. Fatigue Severity Scale (fatigue)
3. Stroke Impact Scale (impact of stroke deficits)
4. Patient Health Questionnaire-9 (depression)
5. Short Self-Efficacy and Outcomes for Exercise Scales (exercise confidence and outcome beliefs)

\(^a\) Maximum Metabolic Equivalents were calculated at the beginning, middle and end of the program for each participant and were not measured at pre-program, post-program and six-month follow-up.
recorded. Heart rate (HR) was recorded using a pulse oximeter and Rating of Perceived Exertion (RPE) reported before the test began and immediately upon completion.

**Strength (Five Times Sit to Stand-FTSS):** Performance on the FTSS test is highly and positively correlated with measures of lower body strength.\(^{88,89}\) Participants started sitting in a chair with arms across the chest and were asked to stand up and sit back down five times as quickly as possible without using their upper extremities to assist. Participants practiced one sit to stand to determine if able to complete as defined. If participants required upper extremity assistance to complete the test, it was noted. One trial was completed.

**Walking Speed (10-meter walk test):** Walking speeds, both self-selected speed and fast speed, have been well studied in survivors of stroke.\(^{45,46,90}\) A straight, flat area was utilized with a 5-meter acceleration area, a 10-meter timed area, and a 5-meter deceleration area. Participants were instructed to walk at their normal everyday pace for the self-selected test, and to walk as quickly but safely as they could for the fast speed. Use of assistive devices was noted. Three trials were completed for each condition.

**Balance Perception (Activities-Specific Balance Confidence (ABC) Scale):** The ABC Scale is a self-report measure rating the individual’s confidence to perform 16 activities without becoming unsteady or losing balance (0% “no confidence” to 100% “completely confident”). The ABC scale is a valid and reliable measure of balance self-efficacy for survivors of stroke.\(^{87}\) A score less than 67% indicates an increased risk of falls.\(^{91}\) A score greater than 80% is unlikely to achieve improvements from PA programs.\(^{92}\)
Fatigue Perception (Fatigue Severity Scale-FSS): The FSS is a measure to quantify fatigue in survivors of stroke. Post-stroke fatigue is a common problem; up to 66% of survivors of stroke report fatigue impacting their life and is a commonly identified barrier for PA and exercise. The FSS is a 9-item self-report scale that assesses the degree of impact affecting daily activity. It is a 7-point rating scale from 1-strongly disagree to 7-strongly agree. Higher overall scores indicated more severe fatigue.

Perceived Impact of Stroke (Stroke Impact Scale-SIS): The SIS is a self-report measure covering eight domains of impact (mobility, participation, activities of daily living, hand function, strength, communication, emotion and memory/thinking). It is a valid and reliable measure in survivors of stroke.

Short Self-Efficacy and Outcome Expectation for Exercise (SSEE and SOEE): Two five-item questionnaires evaluated self-perception of exercise self-efficacy on a scale of 1 (not confident) to 5 (Very Confident). The SSEE items assess confidence to complete exercise behaviors such as exercising alone or through fatigue. The SOEE measures exercise outcome expectations on a scale of 1(low) to 5(high) for exercise outcomes such as improving mood and improving endurance. Both measures are valid and reliable in survivors of stroke.

Depression (Patient Health Questionnaire 9-PHQ9): The patient health questionnaire is a nine-question self-report screening measure of depression that is a valid in patients with stroke. It assesses depressive symptoms on a scale of 0 (not at all) to 3 (nearly every day) for a total score of 0-27 with categories of 0 (no depression), 1 to 9
(minimum to mild depression), 10 to 14 (moderate depression), and 15 to 27 (moderately severe to severe depression). This scale is utilized as a screening tool in the Novant CR program.

**Maximum Metabolic Equivalents (METs):** METs are a standard measure of exercise tolerance and functional capacity in CR programs.\(^{48}\) Maximum METs at the beginning of the program are estimated based on the initial 6MWT and are progressed weekly based on improving fitness to match a rating of perceived exertion of 14 (somewhat hard). For the outcome measure, each participant's initial, mid-program, and final maximum METs were recorded from program documentation.

Power analysis was conducted based on findings from a previous study with a similar population and exercise intervention.\(^{101}\) Calculations suggested twenty-two participants would provide 80% power to detect pre-post changes moderate in magnitude (effect size \(d = 0.56\)) in the 6MWT. As a result, enrolling 30 participants to allow for attrition rate equal to historical attrition rate of 36.7% for the health system.

The mobility screening measures, and the pre-program outcome measures were shared with the CR staff for initial intensity goals and to recommend modifications to the standard CR program in a plan of care.

Participants were integrated into the standard CR program. Aside from modifications provided by the participant evaluation and recording of pain each session, the intervention did not differ from the standardized program. The program began with analysis to determine baseline levels of exercise intensity in METs based on participant’s 6MWT results. Target HR was estimated from resting HR and 6MWT completion HR.
Target exercise rating of perceived exertion (RPE) levels were set from 11-14 (somewhat hard to hard) on a scale of 6-20. RPE levels were used if medication rendered HR an ineffective measure of exertion. Training session intensity and activity plans were individualized based on the standard CR plan of care and the study screening recommendations. Training sessions were three times a week for 12 weeks with a target of 31-50 minutes of moderate aerobic activity each in session. Additional optional activities included strengthening, stretching, and/or relaxation depending on the individual needs and goals of the participant. While components varied by session and individual, the general format was warm up, cardiovascular endurance activities (treadmill, recumbent step machine, recumbent bike, over ground walking), cooldown, and optional activities.

Progression in the program was determined by participant response, including HR and RPE. If RPE was consistently rated ≤ 11, effort was increased to reach a rate of 14. Regular monitoring was completed both pre- and post-session for blood pressure, HR, and as needed blood sugar and heart rhythms. Discontinuation of a session or the program was determined by standard health system protocols. Staff recorded session data and included pre- and post- HR and blood pressure, blood sugar measures (if performed), time in each aerobic activity performed, max HR and RPE in each aerobic activity performed, and any optional activities. Comment sections captured participant concerns, education provided by staff, and staff concerns.

At the end of the 12-week CR program, all participants were reassessed using the study outcome measures and an additional inquiry of participant’s post-program exercise
Completion of the program was defined as attending at least part of the program with final outcome measures available.\textsuperscript{54}

Six-months after the end of the CR program, participants who completed the program returned for one final outcome measure assessment. In addition to the standard outcome measures, the six-month follow-up included a self-report on current exercise frequency and activities.

**Outcome Measures Analysis:**

Participant demographic information and outcome measures were aggregated with means, medians and standard deviations calculated. The outcome measure data for the full sample of completers pre-post program (n=24) were analyzed using a paired t-test, or Wilcoxon Signed Rank Test (for those not normally distributed or ordinal variables), for each outcome measure. The alpha level was set at 0.01 due to multiple comparisons and the desire to minimize both type I and type II errors.\textsuperscript{102} Effect sizes (Cohen’s d) were generated with expectations of moderate effect size (0.2 – 0.5) consistent with the rehabilitation literature.\textsuperscript{103} Finally, for the subset of the sample where six-month follow-up data were available (n=18), a repeated measures ANOVA or a Friedman’s test was completed for those measures found to be statistically different in the pre-post program comparison. Bonferroni adjustments were made to the ANOVA and Friedman’s Tests.

**Feasibility Measures and Analysis:**

Feasibility was measured separately from participant outcomes and is presented in Chapter 2. To establish fidelity of the program for context of the results, aggregate means
and standard deviations for total number of sessions, session time and minimum and maximum RPE are repeated in this chapter.

**Qualitative Methods and Analysis:**

A pragmatic qualitative approach evaluated participant perspectives on program outcomes, and future exercise plans.\textsuperscript{104,105} Interview questions were developed based on study aims and framed by the World Health Organization’s International Classification of Function and Social Cognitive Theory.\textsuperscript{106,107} The interview guide is in Appendix B.

Participants who began the program and met qualitative eligibility requirements were invited to voluntarily participate. Participants who had previously participated in CR or had verbal communication limitations were ineligible for the qualitative portion. Those who qualified and agreed to participate completed informed consent and received a $20 gift card as an incentive. Semi-structured interviews were conducted in a private room at the time of post-program outcome measures collection. Interviews were audio recorded, and transcribed verbatim. Questions were piloted in the first two interviews and revised slightly. The number of participant interviews were determined by voluntary participation of those eligible in order to achieve saturation of themes.\textsuperscript{108} Field notes and addition of quantitative data added rigor.\textsuperscript{52} Lastly, rich data were assured through the qualitative interviews and comparisons to quantitative data.\textsuperscript{52}

The researchers completed inductive thematic analysis using NVivo software (version 12, QSR International).\textsuperscript{53} and loaded de-identified transcripts and observation notes into NVivo. One researcher coded all interviews to phrases or sentences directly from the transcripts and structured observations. Results were reviewed in committee.
with a second researcher. Both researchers then independently performed inductive categorizing of the open coding and reviewed the results as a team. A final codebook was agreed upon, including thematic categories, and subcategories. (Appendix E) Each researcher updated independent coding to reflect the codebook. Data conflicting with primary themes were identified as part of the codebook to present alternative viewpoints. Results were compared, and any discrepancies resolved together. Final coding was reviewed with a third researcher and naming conventions and minor alterations were made.

Results

The study recruited participants through health system providers, community stroke support groups and word of mouth. Of the 29 participants starting the program, 24 completed the study and had post-program outcome measures available. (Figure 3.1) Eighteen of the 24 completers returned for six-month follow-up assessments. (Figure 3.1) Eleven completers participated in the qualitative interviews. Program participant demographics are presented in Table 3.2. The average number of sessions per completer was 25.25 (SD 5.82) with a range of 12-36 sessions. Participants averaged 38.93 (SD 5.64) exercise minutes per session and met RPE targets of 11 (light) to 14 (somewhat hard) with minimum RPE median of 11.00 (IQR 0.625) and maximum RPE median of 13 (IQR 1.00) across all sessions. More details are provided in Chapter 2.

The 6MWT and FWS had normal distributions (Shapiro-Wilk p > 0.05) while the remaining measures were non-normal (Shapiro-Wilk p <0.05). For the 6MWT and FWS, paired t-tests were performed pre-program to post-program (n=24) and a repeated measures ANOVA for pre-program, post-program and 6-month follow-up (n=18). The
Figure 3.1: Study Flowchart

- 29 Started Program
- 24 Completed Program
- 18 Completed Six-Month Follow Up
- 5 Dropped Out
- 6 Lost to Follow Up
## Table 3.2: Demographics of Program Participants

<table>
<thead>
<tr>
<th>Gender, % (number)</th>
<th>Age, mean (SD)</th>
<th>Race / Ethnicity, % (number)</th>
<th>Type of Stroke, % (number)</th>
<th>Time Since Stroke, mean (SD)</th>
<th>Initial 6MWT Distance Category, % (number)</th>
<th>Initial SSWS, mean (SD)</th>
<th>Pre-Program Exercise Level, % (number)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completers (n=24)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>79% (19) Male</td>
<td>62.2 (12.4)</td>
<td>71% (17) White</td>
<td>65% (15) Ischemic</td>
<td>29.7 (29.9) Months</td>
<td>83.3% (20)  ≥ 288m</td>
<td>1.17 (0.21)</td>
<td>12.5% (3) None</td>
</tr>
<tr>
<td>21% (5) Female</td>
<td></td>
<td>25% (6) African American</td>
<td>12.5% (3) Hemorrhagic</td>
<td></td>
<td>16.7% (4) &lt; 288m</td>
<td></td>
<td>12.5% (3) &lt; 1 x week</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4% (1) Asian</td>
<td>25% (6) Unknown</td>
<td></td>
<td></td>
<td></td>
<td>37.5% (9) 1-3 x week</td>
</tr>
</tbody>
</table>

| Non-Completers(n=5) | |                             |                           |                            |                                        |                        |                                        |
| 60% (3) Male       | 68.4 (15.0)    | 60% (3) White               | 40% (2) Ischemic          | 37.0 (41.8) Months             | 40% (2)  ≥ 288m        | 0.67 (0.28)                          | 40% (2) None                         |
| 40% (2) Female     |                | 40% (2) African American    | 40% (2) Hemorrhagic       |                            | 40% (2) < 288m          |                        | 0% (0)  <1 x week                      |
|                    |                | 20% (1) Unknown             | 20% (1) no 6MWT           |                            |                                        |                        | 60% (3) 1-3 x week                    |

Abbreviation: SD, standard deviation; 6MWT, six-minute walk test; SSWS, self-selected walking speed; m/s, meters per second; m, meters;
a six-minute walk test ≥ 288m indicates community ambulator status.45
remaining measures were compared using the Wilcoxon Sign Rank Test for pre-program to post-program comparisons (n=24) and Friedman’s Test for pre-program, post-program and 6-month follow-up comparisons (n=18). Results of pre to post-program comparisons are presented in Table 3.3 and for pre-program, post-program and 6-month post-program comparisons in Figure 3.2. Outcomes and qualitative themes are presented for (1) endurance, (2) other physical outcomes and general health, (3) emotional health, (4) energy and fatigue, and (5) exercise self-efficacy, exercise outcomes expectations and post-program exercise.

Cardiovascular Endurance:

The 6MWT, the SIS-mobility subscale and maximum METs measured cardiovascular endurance. The 6MWT, the primary outcome measure for aerobic and walking capacity, improved by 61.92 m (95% CI 33.99 – 89.84 m) pre-post program with a large effect size (0.94), which is greater than the minimal detectable change of 34 m for survivors of stroke. 46,109 (Table 3.3) Comparisons including the six-month follow-up results (Figure 3.2a) demonstrate a maintenance of gains.

The SIS-Mobility subscale had a statistically significant median improvement after the program of 6.94%, which is greater than the clinically important difference of 4.5%.110 (Table 3.4) However, comparisons including the six-month follow-up did not find a statistically different change over time (p=0.057).

Maximum METs progressed with a median difference of 3.6 from the beginning of the program to the end of the program. (Table 3.4) Individual progressions are presented in Figure 3.3.
Table 3.3: Results Pre-Program to Post-Program: Paired T-Test Outcome Measures

<table>
<thead>
<tr>
<th>Test</th>
<th>N</th>
<th>Mean (SD) Pre</th>
<th>Mean (SD) Post</th>
<th>Mean (SD) Change</th>
<th>95% CI of Mean Change</th>
<th>t</th>
<th>df</th>
<th>Significance (p)</th>
<th>Effect Size (d)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6MWT (m) a</td>
<td>24</td>
<td>397.80 (119.23)</td>
<td>459.71 (118.46)</td>
<td>↑ 61.92 (66.13) b</td>
<td>33.99 – 89.84</td>
<td>4.587</td>
<td>23</td>
<td>&lt;0.001 c</td>
<td>0.94</td>
</tr>
<tr>
<td>FWS (m/s) d</td>
<td>23</td>
<td>1.50 (0.42)</td>
<td>1.59 (0.50)</td>
<td>↑ 0.09 (0.18)</td>
<td>0.02 – 0.17</td>
<td>3.167</td>
<td>22</td>
<td>0.019</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviation: 6MWT, Six Minute Walk Test; m, meters; FWS, Fast Walking Speed; m/s, meters per second.

a Higher distance indicates an improvement in score.

b Greater than the minimal detectable change for stroke of 31m. 46

c Shaded areas indicate statistically significant changes.

d Higher number indicates a faster walking speed.
### Table 3.4: Results Pre-Program to Post-Program: Wilcoxon Signed Rank Test Outcome Measures

<table>
<thead>
<tr>
<th>Test</th>
<th>N</th>
<th>Median (IQR) Pre</th>
<th>Median (IQR) Post</th>
<th>Median (IQR) Change</th>
<th>Z</th>
<th>Sig. (p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FTSS (s)</td>
<td>23</td>
<td>14.42 (11.14)</td>
<td>12.2 (6.47)</td>
<td>↓ 2.85 (4.03)</td>
<td>-3.528</td>
<td>&lt; 0.001c</td>
</tr>
<tr>
<td>SSWS (m/s)</td>
<td>23</td>
<td>1.16 (0.34)</td>
<td>1.18 (0.38)</td>
<td>↑ 0.02 (0.16)</td>
<td>1.095</td>
<td>0.274</td>
</tr>
<tr>
<td>ABC Score (% Confidence)</td>
<td>24</td>
<td>73.44 (35.28)</td>
<td>86.38 (21.48)</td>
<td>↑ 1.78 (14.61)</td>
<td>1.686</td>
<td>0.092</td>
</tr>
<tr>
<td>FSS (1-low to 7-high)</td>
<td>24</td>
<td>3.28 (2.42)</td>
<td>3.17 (5.78)</td>
<td>↓ 0.11 (1.50)</td>
<td>-0.426</td>
<td>0.670</td>
</tr>
<tr>
<td>SIS-Physical (0-100%)</td>
<td>24</td>
<td>62.50 (37.50)</td>
<td>75.00 (37.50)</td>
<td>- 0.00 (18.75)</td>
<td>1.350</td>
<td>0.177</td>
</tr>
<tr>
<td>SIS-Memory (0-100%)</td>
<td>24</td>
<td>78.57 (37.50)</td>
<td>82.14 (27.68)</td>
<td>- 0.00 (16.96)</td>
<td>2.076</td>
<td>0.038</td>
</tr>
<tr>
<td>SIS-Mood (0-100%)</td>
<td>24</td>
<td>77.78 (29.17)</td>
<td>86.11 (20.14)</td>
<td>↑ 4.17 (13.19)</td>
<td>1.869</td>
<td>0.062</td>
</tr>
<tr>
<td>SIS-Communication (0-100%)</td>
<td>24</td>
<td>87.50 (50.00)</td>
<td>83.93 (31.25)</td>
<td>- 0.00 (13.39)</td>
<td>1.623</td>
<td>0.105</td>
</tr>
<tr>
<td>SIS-ADLs (0-100%)</td>
<td>24</td>
<td>90.00 (31.25)</td>
<td>90.00 (16.90)</td>
<td>↑ 2.50 (9.38)</td>
<td>2.425</td>
<td>0.013</td>
</tr>
<tr>
<td>SIS-Mobility (0-100%)</td>
<td>24</td>
<td>72.22 (31.25)</td>
<td>77.78 (29.17)</td>
<td>↑ 6.94 (11.11)</td>
<td>2.665</td>
<td>0.008c</td>
</tr>
<tr>
<td>SIS-Hand (0-100%)</td>
<td>24</td>
<td>85.00 (43.75)</td>
<td>92.50 (40.00)</td>
<td>- 0.00 (10.00)</td>
<td>1.002</td>
<td>0.316</td>
</tr>
<tr>
<td>SIS-Participation (0-100%)</td>
<td>24</td>
<td>70.31 (53.91)</td>
<td>76.56 (39.06)</td>
<td>↑ 3.13 (21.09)</td>
<td>1.976</td>
<td>0.048</td>
</tr>
<tr>
<td>SIS-Recovery (0-100%)</td>
<td>24</td>
<td>80.00 (15.00)</td>
<td>82.50 (15.00)</td>
<td>↑ 5.00 (10.00)</td>
<td>1.715</td>
<td>0.086</td>
</tr>
<tr>
<td>SSEE (1-low to 5-high)</td>
<td>22</td>
<td>4.20 (1.19)</td>
<td>4.50 (0.69)</td>
<td>↑ 0.25 (1.06)</td>
<td>2.023</td>
<td>0.043</td>
</tr>
<tr>
<td>SOEE (1- low to 5- high)</td>
<td>22</td>
<td>4.00 (0.60)</td>
<td>4.20 (1.60)</td>
<td>↑ 0.20 (0.65)</td>
<td>2.397</td>
<td>0.017</td>
</tr>
<tr>
<td>MET Max (1-low to 12 high)</td>
<td>24</td>
<td>2.95 (0.88)</td>
<td>6.00 (3.00)</td>
<td>↑ 3.6 (2.35)</td>
<td>&lt;0.001c</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviation: IQR, interquartile range; Sig, significance; FTSS, Five-Times Sit to Stand; s, seconds; SSWS, Self-Selected Walking Speed; m/s, meters per second; ABC-Activities Specific Balance Confidence; FSS, Fatigue Severity Scale PHQ-9, Patient Health Questionnaire-9 (depression); SIS, Stroke Impact Scale; ADLs, Activities of Daily Living; SSEE, Short Self-Efficacy for Exercise; SOEE, Short Outcomes Expectations for Exercise; MET Max, Metabolic Equivalents Maximum.

\( ^a \) ↑ indicates improvement, ↓ indicates decline, and - indicates no change.

\( ^b \) Change is greater than the 1.14s minimal detectable change for survivors of stroke.\(^{111}\)

\( ^c \) Shaded areas indicate statistically significant changes \(<0.01\)

\( ^d \) SIS-ADLs change score distribution was not symmetrical, so a Sign test was completed instead of Wilcoxon-Signed Rank Test.

\( ^e \) Change is greater than the clinically important difference rate of 4.5%.\(^{110}\)
(a) Improvements over time in mean six-minute walk test distance (p=0.001); **p=0.002, *p=0.013. Error bars are standard deviation.

(b) Improvements over time in the five-times sit to stand test time in pairwise comparisons (p<0.001); **p<0.001. Faster time indicates a better score. Boxplots show median, interquartile range, minimum and maximum. One participant used one upper extremity for support to rise to standing during testing.

**Figure 3.2:** Changes Over Time (a) Six-Minute Walk Test, (b) Five Times Sit to Stand Test
Figure 3.3: Individual Participant Maximum Metabolic Equivalents Progression from Program Beginning, to Program Mid-point, to Program End. Abbreviation: METs, Metabolic Equivalents.
Qualitative results revealed many participants believe the program impacted their endurance, with themes for improved stamina, improved stair climbing, and needing less rest breaks during activity. For some, improved endurance impacted their physical activity tolerance, and they were able to do more of what they enjoy.

Participant 11: “I think that, because of improving my stamina and my endurance, that has um, helped me in other things. So, um it, it’s allowed me to do a little bit more dancing, and a little bit and, and not have to constantly be resting as much. So, I, like I said, my stamina is a little bit better. I can do a little bit more things so.”

Participant 15: “Um, yes it's...think...just walking and uh, uh just general um physical activities and I think...I don't wanna over say it, it but ah I have to think that, ah, it's improved my every day, ah, activity tolerance.”

Other Physical Outcomes and General Health:

Physical health measures included walking, stability and balance, strength, and general health impacts. Walking speed was measured at both self-selected and fast speeds, neither of which resulted in statistically significant changes. The ABC Scale measured balance which did not change in a statistically significant manner. The proportion of participants in the highest fall risk category (ABC Scale <67%) was 33.3% (n=8) pre-program, and 20.8% (n=5) post-program. A few participants noticed balance improvements, with qualitative themes noting the ability to walk without use of a cane or
the need to look at the ground, improved reaction times, and better confidence in balance. The FTSS test measured strength which improved by a median of 2.85 (IQR 4.03) seconds (Table 3.4) and gains remained at six-month follow-up. The SIS-Physical subscale measured self-perception of strength which did not have statistically significant changes. Several participants noted improvements in their walking in the qualitative outcomes, with a walking improvement theme, often related to improved stability, balance and strength.

Participant 18: “My reflexes are getting quicker. I can, I can look both ways quicker on the crosswalk, and I can run across the street and I can read the car coming at me quicker.”

General health outcomes included the remaining Stroke Impact Scale subscales (SIS-ADLs, SIS-Hand, SIS-Communication, SIS-Memory, SIS-Participation and SIS-Recovery (overall self-rated stroke recovery)); all without statistically significant changes. A few participants noted other health changes not covered above; themes included weight loss/improved physical appearance, positive medication changes, and improved awareness of importance of health.

Participant 3 “I think positive though not dramatic and um but I have been thinking about my health and how to live the best life that I can and I think this program has encouraged this thinking on my part.”
Interviewer: “Okay, and what are you thinking you need to do to live the best life? Like are you thinking about changes you need to make?”

Participant 3: “Well I got a referral for speech therapy and I am doing that now, and I am not sure that would have occurred to me before. And um I think the eating has been better.”

**Emotional Health:**

The study used several measures of Emotional health: the PHQ-9, which is a general depression screening (not stroke specific) used by the CR program, the SIS-Mood subscale and an analysis of qualitative interviews. The SIS-Mood subscale did not have statistically significant changes pre-post program. Twenty-three participants had initial PHQ-9 depression screen scores at pre-program: 11.5% (n=2) in the moderately severe-depression categories, 17.4% (n=4) in moderate depression category, 69.6% (n=16) in the minimum-mild depression category and 4.3% (n=1) in the no-depression category. These depression category proportions remained mostly unchanged at post-program where 24 participant scores were available with 11.5% (n=2) in the moderately severe-severe depression categories, 11.5% (n=2) in moderate depression category, 70.8% (n=17) in the minimum-mild depression category and 12.5% (n=3) in the no-depression category. While a few participants noted no changes to mood or outlook as a result of the program, many participants noted improvements. Qualitative themes related to emotional health included reduced depression, contributions to a positive attitude, and
improved self-perception. Participants noted a new or renewed sense of enthusiasm for exercise or for engaging in activities and feeling more confident about their abilities.

Participant 12: “Overall experience was, it was, it was kind of life changing. Kind of life saving. Um, definitely haven't been nearly as depressed as I was before I came in here. Not at all. Um, and that doesn't just have to do with [life change]. It was, it was night and day difference. After about two weeks of being in here, it was night and day difference. From being really dark and, and in a really bad way. Um, really depressed, and, and trying to almost, uh, not really sure what to do with it, and I kind of starting, getting faith again, hope, feeling good, wanting to take care of myself, and, and just being happy.”

Energy and Fatigue:

The FSS measured participant fatigue pre- and post-program and did not change. Participant comments about fatigue were mixed, with a few noting no changes in their fatigue levels and some noticing improvements, either in a reduction in severity or a reduction in episodes.

Participant 11: “just the activity I think has improved my um, my fatigue levels. Um, I do crash but it’s, I used to crash like hit my stroke wall um almost every day, if not 4
or 5 times a day, uh 4 to 5 times a week. Um, now I’m, I might hit it once a week or once every two weeks.”

Exercise Self Efficacy, Exercise Outcome Expectations and Post-Program Exercise:

The SSEE Scale assessed the participant’s confidence in being able to exercise under several conditions, while the SOEE rated the participant’s beliefs in the enjoyment and health benefits of exercise. Participants had high initial scores for both the SSEE (median 4.20 out of 5) and the SOEE (median 4 out of 5) indicating their confidence to exercise was high and that they anticipated benefits from exercise. Changes post-program were not statistically significant.

All completers in the qualitative responses had plans for post-program continued exercise. Plans included continuing at CR through the self-pay maintenance program, participating in group-based exercise classes, joining a gym and performing aerobic and strength activities, doing exercise at home, and working with a personal trainer.

Participant 19: “So my, my goal is to work three to five days in the gym, hopefully get into a routine that at a certain time I'm there and I'll start to see people that work at the same time and maybe be friends and have a workout buddy. And if I can find a workout buddy, then I'm done, definitely, there as often as the poor company, he'll be there. ‘Cause I've done that once before and that is great motivation for me.”
At six-month follow-up, 83.3% (15/18) of participants reported engaging in exercise at least once a week, 44.4% (8/18) with a frequency of one to three times a week, and 38.9% (7/18) with a frequency of greater than three times a week. Reported activities included walking (50%), gym-strengthening (22.2%), gym-aerobic (50%), home-aerobic (33.3%), home-strengthening (11.1%), group exercise (22.2%), and other (22.2%) which included swimming, yardwork, horseback riding, and running.

**Discussion**

Survivors of stroke integrated into CR demonstrated improvements in cardiovascular endurance as measured through the 6MWT, maximum METs, the SIS-mobility subscale and an analysis of qualitative responses. The 6MWT test improvements suggest better community walking status and real world walking capability. The importance of this increase in capacity is especially important to survivors of stroke who have mobility impairments which result in a higher energy cost for walking. The 6MWT improvements were maintained at six-month follow-up supporting maintenance of gains after CR. Maximum METs had a median increase of 3.6 METs pre-post program. These changes are important measures of overall health. A meta-analysis by Kodama et al. found that in healthy individuals, for each one MET increase in exercise capacity, all-cause mortality was reduced by 13% and incidence of coronary heart disease and cardiovascular disease was reduced by 15%. Similar results have been found for traditional CR participants. The SIS-mobility scale measures participant perception of home and community mobility capabilities, and improvement pre-program to post-program supports the link between capacity and participation. These results were not maintained at six-month follow-up, however. Participation is influenced by a variety of
factors outside of capacity, including social support and community factors. The addition of social support during the CR program may have impacted the SIS-Mobility results which did not continue in the follow-up period. Collectively, improvements in cardiovascular endurance support the integration of survivors of stroke into U.S. based CR programs.

Cardiovascular endurance improvements were achieved regardless of whether participants were already exercising regularly (at least once a week) before the program. Regular exercisers included 75% (18/24) of the completers in this study. Improvements, despite current activity levels, suggest that applying the correct dosage and progressing intensity through the program are important factors in increasing aerobic capacity. The CR program’s dosage, initial intensity based on 6MWT performance, and progressing effort based on response is supported by the current physical therapy clinical practice guidelines for survivors of stroke. Recommendations also include appropriate staffing and oversight to insure safety and correct intensity.

Strength, measured by the FTSS test as a functional strength measure, improved pre- to post-program and was maintained at six-month follow-up. In addition to strength, the FTSS has speed and control components. For survivors of stroke, taking longer to complete the FTSS test correlates with lower bilateral knee flexor strength and increased risk of falls. For geriatric populations, which often include survivors of stroke, a slower time is predictive of less independence in activities of daily living within three years.
While the change in walking speed was not statistically significant, average and median walking speeds were initially high, introducing potential ceiling effects. The average initial fast walking speed was 1.50 m/s, and the median initial self-selected walking speed was 1.16 m/s, both greater than the suggested cutoff for unlimited community ambulators of 0.93 m/s. While walking improvements were noted in the qualitative portion, there were few notations about walking speed and more comments on walking endurance and stability or confidence in walking.

Emotional health was measured by the general screening measure for depression, the PHQ-9, the SIS-Mood subscale, and an analysis of qualitative responses. While neither the PHQ-9 or the SIS-mood subscale changed, the initial scores indicated low initial depression with median six out of 27 on PHQ-9 and higher initial mood with medians of 77.78% on the SIS-Mood subscale. Exercise can impact depression. A meta-analysis by Eng et al. found that exercise reduces depressive symptoms after at least four weeks of exercise but that reduction is not maintained after the program completes. One participant noted that the program had an important impact on his depression and attributed the change to a combination of the activity, socialization and acceptance. Related to emotional health were the qualitative themes of renewed confidence and sense of self. Higher self-esteem is known to positively impact self-perception of identity after stroke. A qualitative study by Erikson found that finding a positive new self-identity after stroke was tied to engaging with others through meaningful activities which a program like CR can provide.

Self-efficacy for exercise and outcome expectation for exercise scores were high at pre-program suggesting good to excellent confidence in exercise abilities (SSEE,
median 4.2) and belief in benefits of exercise (SOEE, median 4.0). With a maximum score of 5 on both the SSEE and the SOEE, achieving significant changes was difficult due to a ceiling effect. The high initial scores in this sample may be related to the importance of having self-efficacy and positive outcome expectations to commit to structured exercise programs. All of the completers had concrete plans for continued exercise at the completion of the program. At six-months, the majority were still active, suggesting that 12 weeks is long enough to build habits for maintained activity. However, improved exercise habit results require more investigation, as this sample had a high proportion of participants with high self-efficacy for exercise and some exercise experience prior to the program, both key drivers of on-going physical activity in survivors of stroke.

Study limitations include the use of a single group pilot design at a single CR program, and lack of diversity among participants. While a diverse sample of mobility impairments, gender, age and racial/ethnic diversity was desired, most participants were Caucasian men with few mobility limitations. Future studies can expand to multiple health system sites and utilize a randomized control trial design with recruiting plans imbedded with specific participant characteristics.

Conclusion

CR for survivors of stroke had a positive impact on cardiovascular endurance and functional strength. CR also influenced participant’s perception of their home and community mobility, their walking capability, and their emotional health. Improvements in maximum metabolic equivalents correspond to reduced risk for mortality and cardiovascular disease. Endurance and strength improvements were maintained at six-
month follow-up, and most participants continued to exercise in the follow-up period. Findings support the use of CR programs for survivors of stroke after rehabilitation to improve endurance, health status and quality of life. Further investigations can confirm findings and explore integrating survivors of stroke as a standard of care.
CHAPTER 4

CARDIAC REHABILITATION IS FEASIBLE AND EFFECTIVE FOR SURVIVORS OF STROKE

Cardiac Rehabilitation (CR) using Medicare guidelines for dosage and components is a feasible, safe, effective and enjoyable exercise opportunity for survivors of stroke. Results support integrating survivors of stroke into existing programs. CR was the right intensity, provided the attention of motivating, qualified staff and had the accountability of a regularly scheduled program but with the extra benefit of session time flexibility. Recruitment and uptake were barriers to implementation of CR for survivors of stroke. These barriers may be mitigated by strategies to increase survivors’ self-efficacy for exercise, to make referral easier for clinical providers and to reduce participant level barriers to participation.

Survivors can Integrate into Current CR Program Structure

There are several studies and programs outside the U.S. that support the use of CR for stroke survivors, but they either lack the same dosage or create an entirely new program just for survivors. While other research has examined modified CR in the U.S. and found it to be effective and feasible, these studies have not presented why programs separate from the standard CR programs are required or desired. Utilizing existing CR programs, which are widely available in the U.S., has potential implementation advantages over creating new programs. The current study demonstrates that stroke
survivors with a variety of mobility and other limitations can meet CR standards with prescribed intensities, and that they value the variety of activities available. CR staff (EPs and nurses) are qualified to monitor the cardiovascular system as was well demonstrated in the current study. PT touchpoints in the current study were at referral, at initial evaluation for program modification, and during the program for consultation. The current study results support the use of standard CR staff personnel with PT support needed only for referral, consultation, and staff training, much of which could be handled through referral specification, CR staff training, and email or phone consultations.

**Survivors Can Meet CR Intensity Demands**

CR improves cardiovascular endurance with progressive, moderate-intensity exercise adjusted to the individual, with staff providing motivation and expert monitoring. Survivors of stroke can meet the intensity demands which they perceived as appropriate. Dosing at three times a week for 12 weeks was acceptable to most participants. The findings of the current study support standard CR model dosing for stroke survivors. Previous research and evidence-based recommendations also support CR dosing for survivors. 55

**CR is a Safe Environment for Survivors to Exercise**

Safety, through monitoring and staff experience identifying and handling adverse cardiac events, was an important finding. CR staff was trained and experienced in identifying and swiftly addressing blood pressure, blood sugar and heart rhythm issues. Exercise was impacted where necessary, but simple interventions such as water or nutrition and retesting allowed participants to continue with their exercise routine.
Several of the issues efficiently identified and handled in the CR environment, including identifying atrial fibrillation episodes (both new and chronic) and abnormal blood pressure or blood sugar readings, would not have been monitored in a standard fitness facility. As a result, a CR facility promotes safety and helps address underlying medical issues that can affect exercise tolerance, safety and risk.\textsuperscript{115} The participants recognized the focus on safety and the staff’s ability to handle adverse occurrences as a major benefit of the program. Safe exercise for a population with cardiovascular co-morbidities like the current sample was a benefit of CR and supports use of CR as a transitional program for stroke survivors.

**Survivors Improve Cardiovascular Endurance and Strength**

Survivors of stroke made improvements in cardiovascular endurance, functional strength and perceived mobility regardless of prior exercise activity levels. Improvements in cardiovascular endurance and functional strength were maintained at the six-month follow-up suggesting the possibility of lasting changes. Pre- to post-program improvements in perceptions of home and community mobility corroborate the link between endurance and participation. These results were not maintained at six-month follow-up. The addition of social support during the CR program, which did not continue in the follow-up period, may have impacted these perceptions.\textsuperscript{74}

Improvements, despite a large portion of the sample regularly exercising before the program, suggest that applying the correct dosage and progressing intensity through the program are important factors in increasing cardiovascular endurance. All program completers had concrete plans for continued exercise at the completion of the program.
At six-months, the majority were still active, suggesting that 12 weeks is long enough to build habits for maintained activity.

**Positive Exercise Self-Efficacy Promotes CR Participation for Survivors**

Program participation facilitators included high exercise self-efficacy, belief that exercise is beneficial for health, flexible session times, making exercise a priority, and social support. These facilitators are consistent with the existing literature for traditional CR participants and the general exercise literature for survivors of stroke. Program completers knew exercise was important for their health, wished to avoid further strokes and health complications, and wanted to improve themselves. Self-efficacy for exercise and outcome expectation for exercise scales were high pre-program suggesting good to excellent confidence in exercise abilities and belief in benefits of exercise. The high initial scores in this sample may be related to the importance of having self-efficacy and positive outcome expectations to commit to structured exercise programs. Despite these beliefs, many felt like they did not have the proper tools to exercise well on their own or lacked the accountability piece that the CR program provided. Social support encouraged continued participation through shared experiences with other participants, encouragement and ongoing evaluation from staff, and relationships with other participants and staff.

**Survivor Recruitment and Uptake is a Challenge**

Participant recruitment was the largest barrier to the present study. It is a common problem in traditional CR, with a 2018 report noting a 60-85% referral rate for common cardiac diagnoses and of those referred, a 50% uptake. Referrals from the health system
providers in the current study were low, and uptake for those referred from the health system was also low. Survivors of stroke were interested, because they self-referred through support groups and community members. An easy electronic referral process and prompts in electronic medical records to consider referral to these programs would reduce process burden on healthcare providers. Readily available educational materials for patients and training of healthcare providers could also influence referral and uptake.\textsuperscript{56,57}

Community outreach and education through support groups, a successful recruitment tool in the present study, is another potential recruitment tool that allows for education directly to the stroke survivor outside of the stressful health care environment.\textsuperscript{60}

**CR Accommodates Many Exercise Barriers for Survivors**

Barriers to the program for study participants were related to other time obligations including work, transportation or distance to the site, and impairments related or unrelated to their stroke deficits. CR programs address several of these barriers through a variety of exercise activities that could be modified to accommodate mobility impairments, a staff qualified to address medical complications, and a flexible session schedule.

Educational interventions using evidence-based strategies may positively influence survivors of stroke without exercise self-efficacy, a key driver of participation. These types of interventions have been shown to influence both stroke survivors and traditional CR participants to exercise.\textsuperscript{59,62} Utilizing self-efficacy and outcome expectation for exercise measures, like the SSEE and the SOEE, may help identify survivors of stroke at risk for not starting or not finishing programs in order to tailor interventions. PTs have a unique opportunity for these education and previously
mentioned referral interactions, because they have touchpoints with almost all survivors of stroke.⁶³

**CR is Feasible, Effective, Acceptable and Safe for Survivors of Stroke**

CR is feasible for survivors of stroke who meet dosage and intensity goals, improve cardiovascular endurance and functional strength, and perceive the program as needed, regardless of their mobility limitations or previous exercise experience. Improvements in maximum metabolic equivalents correspond to reduced risk for mortality and cardiovascular disease. Endurance and strength improvements were maintained at six-month follow-up, and most participants continued to exercise in the follow-up period. Participants enjoy the camaraderie and positive environment and feel safe and supported by staff. Challenges to CR integration include managing referral and uptake of the program. Clinical providers need an easy way to refer and educate patients on the importance of exercise. Survivors need positive exercise beliefs and strategies to overcome scheduling, transportation and other barriers. Findings support the use of CR programs for survivors of stroke after rehabilitation to improve endurance, health status and quality of life. Further investigations can confirm findings and explore integrating survivors of stroke as a standard of care, potentially impacting the health and mobility of a large number of survivors of stroke in the U.S.
REFERENCES


71. Hansen TB, Berg SK, Sibilitz KL, et al. Availability of, referral to and participation in exercise-based cardiac rehabilitation after heart valve surgery:


88. Mong Y, Teo TW, Ng SS. 5-repetition sit-to-stand test in subjects with chronic stroke: reliability and validity. Archives of physical medicine and rehabilitation. 2010;91(3):407-413.


111. Kwong PW, Ng SS, Chung RC, Ng GY. Foot placement and arm position affect the five times sit-to-stand test time of individuals with chronic stroke. *BioMed research international.* 2014;2014.


## APPENDIX A

### STANDARD INTAKE FORM

<table>
<thead>
<tr>
<th>Name</th>
<th>First</th>
<th>Last</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Birth</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address</td>
<td></td>
<td></td>
</tr>
<tr>
<td>City/State/Zip</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contact Info</td>
<td>Phone</td>
<td>Email</td>
</tr>
<tr>
<td>Emergency Contact</td>
<td>Name</td>
<td>Phone</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Male
- Female
- Prefer not to answer

| Race |  |  |
|------|-----------------|

- American Indian or Alaska Native
- Asian
- Black or African American
- Hispanic or Latino/a or Spanish Origin
- Pacific Islander
- White
- Other:___________________
- Prefer not to answer

<table>
<thead>
<tr>
<th>Date of Last Stroke</th>
<th>Month:________ Year:________</th>
</tr>
</thead>
</table>

| Have you had more than one stroke? |  |  |
|-----------------------------------|-----------------|

- No
- Yes, specify number:____________

| Stroke Type? |  |  |
|-------------|-----------------|

- Ischemic(clot)
- Hemorrhagic(bleed)
- Unknown

| Did you have therapy (PT, OT, Speech) |  |  |
|--------------------------------------|-----------------|

- No
- Yes

Select all that apply:  
- In-hospital
- In-home
- In-clinic
**APPENDIX B**

**INTERVIEW GUIDE**

<table>
<thead>
<tr>
<th>Question</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tell me a little bit about your stroke experience?</td>
<td>Background / exercise experience / Context</td>
</tr>
<tr>
<td>If they had rehabilitation: What was your rehab experience? What was it like when you finished rehabilitation?</td>
<td></td>
</tr>
<tr>
<td>What information was provided about the program?</td>
<td>Process – Recruitment</td>
</tr>
<tr>
<td>What were the reason(s) you wanted to participate when you first heard about the program? What motivated you to come? What motivated you to continue to come?</td>
<td>Facilitators / Exercise &amp; Health Beliefs</td>
</tr>
<tr>
<td>Tell me about your experience getting started (Schedule, initial visit, beginning program)</td>
<td>Process – Research Process</td>
</tr>
<tr>
<td>What did you expect the program would be like? In what ways did it meet your expectations or not meet your expectations?</td>
<td>Process-Recruitment, Facilitators, Program Experience, Acceptability</td>
</tr>
<tr>
<td>What was your experience like in the program? What parts did you enjoy? What parts did you not enjoy?</td>
<td>Program Experience - Program Delivery, Acceptability</td>
</tr>
<tr>
<td>Tell me about an experience, if any, where you felt it was too easy or too hard? Tell me about an experience, if any, where you felt unsafe.</td>
<td>Program Experience - Program Delivery, Acceptability</td>
</tr>
<tr>
<td>Tell me about working with the Exercise Physiologist Robert. What was that like? In what ways was it similar to working with a therapist (PT, OT, SLP)? In what ways was it different than working with a therapist (PT, OT, SLP)? Was there anything he did in supervising you that you wish was done differently? Anything that stands out in your mind as helpful?</td>
<td>Program Experience - Program Relationships</td>
</tr>
<tr>
<td>What did you think of the gym atmosphere? What was it like exercising with the other participants (Stroke/cardiac)? what did you talk about? (i.e. Did you feel accepted and a part of the gym?)</td>
<td>Program Experience - Program Delivery, Program Experience - Program Relationships</td>
</tr>
<tr>
<td>Tell me about any instances that interrupted your participation during the 3 months?</td>
<td>Barriers/Facilitators</td>
</tr>
<tr>
<td>What factors helped to participate regularly? (transportation, family support, relationships, results)</td>
<td>Barriers/Facilitators</td>
</tr>
<tr>
<td>What things would you change about the program?</td>
<td>Program Experience - Modifications, Acceptability</td>
</tr>
<tr>
<td>What, if any, impacts did the program have on your health?</td>
<td>Program Outcomes and Impact-physical</td>
</tr>
<tr>
<td>How do you think the program has impacted your mobility, if at all?</td>
<td>Program Outcomes and Impact-physical</td>
</tr>
<tr>
<td>Question</td>
<td>Topic</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>--------------------------------------------</td>
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</tr>
<tr>
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</tr>
<tr>
<td>What did you expect the program would be like? In what ways did it meet your expectations or not meet your expectations?</td>
<td>Process – Recruitment, Facilitators, Program Experience, Acceptability</td>
</tr>
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</tr>
<tr>
<td>Tell me about an experience, if any, where you felt it was too easy or too hard? Tell me about an experience, if any, where you felt unsafe.</td>
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</tr>
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</tr>
<tr>
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</tr>
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<td>What, if any, impacts did the program have on your health?</td>
<td>Program Outcomes and Impact – Physical</td>
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<tr>
<td>How do you think the program has impacted your mobility, if at all?</td>
<td>Program Outcomes and Impact – Physical</td>
</tr>
</tbody>
</table>
APPENDIX C

STRUCTURED OBSERVATION FORM

Observation Checklist

DATE:

1. Participant Observed:

2. Activities Performed:

3. Interactions Observed: (Participant-EP, Participant-SS participant, Participant-Cardiac participant):

4. Barriers and Facilitators to Activities and Interactions:

5. Safety Factors (+/-):

6. Other Comments/Notes:
APPENDIX D

FEASIBILITY QUALITATIVE CODEBOOK

RECRUITMENT

1. How they found out about the program
2. Initial Interest-Motivation

BARRIERS AND FACILITATORS - -can be initial and ongoing.

1. Barriers
2. Facilitators

PROGRAM DELIVERY

1. Safety
2. Gym Environment (overall environment both physical and people and energy)
3. Process-Interaction with staff (general process, what they did with staff, what they think about staff, what they did or did not know about, expectations) * sometimes doubled in facilitators or barriers
4. Dosing (frequency, duration, intensity)
5. Socialization (with others besides staff)
6. Recommended modifications to program
7. Activity Preferences (likes, dislikes)
8. Other
9. Adherence (why they had to miss) *can also be doubled in barriers

OTHER – FEASIBILITY – anything that you felt was related to feasibility but did not have a place for above
OTHER – NOT RELATED TO FEASIBILITY - Put in here anything that doesn’t fit above, things like for the outcomes paper (outcomes, future exercise plans), details on stroke story, therapy received, exercise pre-stroke and pre-program, PT vs. CR
APPENDIX E

OUTCOMES QUALITATIVE CODEBOOK

1. Endurance
   a. Positive
   b. Null or Negative
2. Physical-Not Endurance and General Health
   a. Positive
   b. Null or Negative
3. Emotional Health
   a. Positive
   b. Null or Negative
4. Fatigue and Energy
   a. Positive
   b. Null or Negative
5. Post-Program Exercise Plans