12-MONTH TECHNICAL PROGRESS REPORT
SOUTH CAROLINA SPINAL CORD INJURY RESEARCH FUND
RFP 2014 – **I**

SCSCIRF # RFP 2014 – I 01

Name of Principal Investigator: Jennifer Trilk, Ph.D.

Title of Project: Community-based Virtual Reality Group Exercise Training in Persons with Spinal Cord Injury

Technical Progress Report: Twelve (12) Month Report (Added to the 6-month report as requested)

Progress to Date of: December 1, 2015

The overarching goal of the study is to determine whether differences exist in cardiometabolic health, psychosocial health and quality of life in persons with spinal cord injuries who lead active lifestyles vs those who are sedentary, as well as to determine whether 8 weeks of community-based virtual reality group hand cycling exercise training can improve cardiometabolic health, psychosocial health and quality of life in sedentary persons with SCI, and finally, whether these effects are maintained three months post-intervention.

The SCI Research team is comprised of Dr. Trilk, the lead investigator, Dr. Kopera, the co-investigator, **4 medical students** (a 4th student has requested to join and is now part of the team), the Human Performance Lab (HPL) manager as the Research Coordinator, an ACSM-certified Exercise Specialist to co-conduct data collection, two Greenville Health System staff members for recruitment and logistics, and Jim Cunningham, head coach of Team Roger C Peace and owner of the intervention site, Greenville Cycling and Multisport (GCM). We are currently working on Aim 2 of the study.

Overview of Progress to Date

The specific aims of the study have not changed from the original aims presented to SCSCIRF.

Specific Aim 2: To examine the effects of a community-based, 8-week VR group hand cycle exercise training program in sedentary persons with SCI on cardiometabolic health, psychosocial health and QOL, and whether these effects are maintained 3 months post-intervention.

Status: In Progress

A. Project Development

6-month: The research team has been meeting every Monday for six months to update and discuss pertinent and important topics to ensure the quality and efficacy of the study. Many of the meetings have focused around purchases needed, logistics of the study, and how the 'flow' of testing and intervention would work in detail. Many items were purchased in order to carry out the pretesting of Aim 2 with as few barriers as possible. The first item purchased was a wheelchair-accessible ramp for the intervention site. The ramp was necessary because GCM, the intervention site, was previously only accessible via stairs. The ramp remedied that problem and meets the 'code' guidelines for the facility. Items purchased to carry out the VO_2 max tests included two hand cycles, hand grips for participants with C-spine injuries, a wheelchair scale, an air bike tire pump, and Computrainer software for the exercise intervention. A Cholestech LDX machine was purchased to gather the participants' lipid profile, which measures current cardiovascular risk. Lastly, a flat fee was paid for each participant's iDXA body composition scan with GHS Ambulatory Radiology.

The logistics of the study can be broken down into the consenting process, the physicians screening, the pretests, and the intervention. It was/is the responsibility of the medical students to do the outreach and get SCI participants telephone screened, consented, and scheduled for the physician's screening.

12-month: The research team continues to meet on Mondays. The meetings now focus on the continued testing and training of the participants, process evaluation of the procedures ("how can we continuously improve procedures and streamline process?") as well as collecting the findings and testimonials

of success we are witnessing for the participants who are undergoing training. The wait-list participants in Waves 1 and 2 have now completed their training as well and have been post-tested. We also have completed Wave 3 training of participants in the VR Group. Wave 3 participants in the Wait-List Group will undergo training in January 2016. We plan to break for the holiday season and resume recruitment and testing/training again in January 2016.

B. Recruitment

6-month: For the first wave of the study, participants were recruited from the Greenville SCI support group that meets every month at Roger C Peace (RCP) Rehabilitation Hospital. The medical students presented the study to the group and distributed flyers to interested individuals. These individuals called the research number listed on the flyer to participate in the phone screening to determine initial eligibility for the study. If they were initially eligible, they were then scheduled for a physician's screening by Dr. Kopera in the occupational therapy (OT) gym at RCP to determine final eligibility. Flyers were also given to RCP OTs to distribute to their appropriate patients. Jenny Hall, a physical therapist at RCP, identified possible participants from previous patients. She mailed out study flyers with the researchers contact information. Dr. Robbins-Cantillion (RCP Physical Medicine and Rehabilitation physician) was given study flyers to distribute to her patients. The SC Spinal Cord Injury Association outreach coordinator was provided recruitment materials to distribute to individuals within her community. Recruitment is still underway and the research team members have scheduled a presentation at the Spartanburg SCI support group for May.

Of the 12 participants who participated in the first wave of telephone screening, 9 were eligible for the secondary physicians screening by Dr. Kopera. Eight of these participants passed the physicians screening and were consented to participate in the study where they were then scheduled for pretesting in the HPL.

12-month: Recruitment procedures have continued as stated above. Recruitment went well and as anticipated for the number of eligible individuals available in the Greenville County and Roger C Peace Rehab Hospital. We have successfully recruited, testing, trained and completed the study for 3 Waves of the study; e.g. for a total in 8 participants in the VR Group and 4 participants in the Wait-List Group.

C. Data Collection

6-month: The pretesting took place over April 6 – April 14. Four-hour blocks of time were scheduled for each participant to allow ample time for each participant to complete all the pretest requirements. Average testing is approximately 3.5 hours. On the day of a test, the participant was met by a SCI research team member at GHS Ambulatory Radiology where they were weighed and had an iDXA scan. After their scan, a research team member escorted the participant to Roger C Peace Rehabilitation Hospital and into the HPL. At the HPL the following tests were performed: a resting, supine 12-lead EKG, an echocardiogram, a lipid profile, lactate threshold, and VO_2 max test using the handcycle as the exercise mode. They were also given two quality of life surveys, the Exercise Motivations Inventory-2 (EMI-2) and Rand SF36V survey for non-ambulatory participants. All 8 participants completed their baseline HPL testing with no adverse events.

12-month: 8 participants have now completed pre-testing, 8-weeks of training, and post-testing procedures as stated. We have been able to improve average testing time from 3.5 hours to 3.0 hours. We are witnessing improvements in all outcome metrics, and testimonials are giving us a qualitative representation of the success of the study (testimonials are attached in Appendix A). All participants completed the study with no adverse events.

D. Intervention

6-month: After all tests were complete, the participants were randomized into the intervention or control group. Four participants were selected into the intervention group and 4 into the control. (*Note: this research team has decided for ethical purposes to have a "waitlist" group instead of a control group. The waitlist group will complete the 8 weeks of normal daily living without intervention, perform their post-testing, and then be offered to participate in 8 weeks of VR hand cycling at GCM.)* The first wave of participants in the intervention group represents a diverse population. Their ages range from 29-68 years, with one female and three males. Of these four individuals, three are Caucasian and one is African American, and all have varying levels of injury, body mass index's, and VO_2 max base levels. Their personalities are just as diverse, all of

which will enhance the external validity of the study. The intervention is currently taking place at GCM, located in Greenville and is being led by Jim Cunningham.

The first day of the community-based, group VR exercise intervention was April 20 and was a success. Mr. Cunningham had a brief planning session with the participants before the exercise session to determine any needs related to either their injury or the exercise. There was full attendance and each participant was able to hand cycle for about 30 minutes at a beginners pace with rest intervals. Starting April 20 and continuing for 8 weeks, the intervention will take place on Monday and Wednesday from 3:30-4:30. Each participant has transportation to and from the site and at the site each person has a designated handcycle fit to their specifications they will use each week. Water, fans, and towels are provided and treatment delivery is controlled and monitored by research staff to ensure that each participant exercise safely. For each session, participants have a 10-minute warm up period at 45% VO2 max followed by a 20-50 minute main exercise (progressing in duration each week) at a moderate-to-vigorous, fluctuating work intensity consistent with a Computrainer class session. The increasing target intensities are as follows: 50-65% VO_2 max in the first two weeks, 60-75% in the second two weeks, and 60-90% VO2 max in the last four weeks of training. A 5-minute cool down period completes each session. After the 8-week training session has ended, we will repeat the pretest operations in order to carry out our post-test.

To date, we have had one participant miss 2 days (Mon/Wed combination) due to a sinus infection; however, all other sessions have been attended by all participants.

12-month: Training continues to go very well with extremely positive feedback from the participants. Eight (8) participants have now completed training. On average, participants are missing one (1) training session. Protocol does not allow for participants to miss more than 2 training sessions (e.g. 85% of the total training intervention). We have not lost a participant to non-adherence (e.g. missing more than 2 sessions) to the training intervention.

E. Plans

6-month: We are continuing to screen participants for the next intervention wave that will begin in June. Our next recruitment is scheduled at the Spartanburg SCI support group for May 19th.

12-month: After the 2015 holidays, we plan to resume the recruitment process and will then screen participants for the wave that will begin in January 2016. Our next recruitment is scheduled for the next RCP SCI support group in January, as it will have been one year since the last recruitment, and we anticipate those who were under the 1-year eligibility will now be considered eligible to participate in the program.

Specific Aim 2 Special Note: Three of our sedentary hand cyclists who underwent training in our program have gone beyond the intervention study and chose to continue cycling on their own. These three also competed in a community/charity 5K event on their hand bikes (picture attached in Appendix A). One participant is now in training with Mr. Cunningham to start racing for sport.

Specific Aim 1: To compare differences in cardiometabolic health, psychosocial health and QOL between athletes and non-athletes with SCI.

12-month status: In Progress

A. Project Development

6-month: We chose to start with Aim 2 of the study in order to give the opportunity to community persons with SCI to start their exercise intervention in the late spring and also due to the logistics taking a substantial amount of time to develop. As Aim 1 is a cross-sectional analysis, we are scheduling the professional para-athletes with SCI throughout Phase 2 as they become available to participate in testing (most travel and compete throughout the United States).

12-month: Aim 1 of the study is now in progress.

B. Recruitment

6-month: Handcycle athletes with SCI are being recruited through word-of-mouth and email contact. We have identified 6 competing athletes who are scheduled and/or will/have participated in data collection.

12-month: Four (4) professional para-athletes have completed Aim 2 testing successfully. We have recruited four (4) more to complete testing in March 2016 when they arrive in Greenville for the Roger C Peace Paracycling Team Camp. The travel schedules of the pro-athletes makes recruitment for this population slower. The three (3) pro-athletes who completed the study had no adverse events.

C. Data Collection

6-month: One female hand-cycling athlete with SCI has completed data collection for Aim 1. She is a world champion para-cyclist and did very well in her testing with no adverse events.

12-month: Four (4) professional para-athletes have completed Aim 2 testing successfully with no adverse events. As anticipated, the professional para-athletes are scoring higher (raw data) in cardiorespiratory and metabolic fitness, as well as psychosocial functioning, then the non-athletes at baseline.

D. Intervention

N/A

E. Plans

6-month: We plan to test a minimum of 8 professional handcyclists for Aim 1 of the study over the next 6 months as they become available to participate.

12-month: We plan to test a minimum of four (4) more professional handcyclists for Aim 1 of the study over the next 6 months as they become available to participate.

Appendix A. Testimonials to Date

SCI_007: I really enjoyed this study for my health. I think it helped me improve in a lot of different ways. It also helped research our health. I will try to keep up with the riding on my own time. I would like to thank you so much for having me participate.

SCI_008: I was invited to participate in a research study on the effects of exercise on people suffering from a spinal cord injury. I went into the study unsure of what to expect. I was first tested in the RCP Human Performances lab to get a base line of my condition. Over the course of about eight weeks I then participated in hand cycle training classes twice a week for an hour a day. I could have taken it easy in the sessions but I wanted to push myself to see what I could get out of the study. The training sessions were hard but very enjoyable. I learned many things about conditioning and my personal health. At the conclusion of the training we were again tested in the lab. Over just eight weeks my performance improved just over 20%. The whole process was very profession and efficient. Every person I came into contact with was extremely nice as well. I can honestly say the people I came into contact with were the type of people I would invite over to my house for dinner which means I was very comfortable with everyone. If an opportunity arises in the future to work with this group again I would not hesitate to participate.

SCI_009: Dr. Trilk and The Human Performance Lab Team fabulous!!! The 8 week handcycling clinical trial was an opportunity that I honestly was a little hesitant in agreeing to participate. The idea of submitting myself to an extensive medical screen and a high level training program was very daunting, but the guidance, direction, and encouragement from Dr. Trilk and her staff empowered me to make one of the most beneficial decisions I have ever made. In hindsight, choosing to follow through with the clinical trial has given me more than expected. The encouragement to become more active in my own physical well-being was a major result of my participation and prompted me to continue training for my first marathon. This experience has introduced me to possibilities that I had no idea were available to me, and most importantly an additional platform to share my passion of encouraging others to live beyond their potential. Thank You Dr. Trilk and the Human Performance Lab staff!!!

SCI_006: I'm a para confined to a wheelchair since 1992, I was recently invited to participate in a study held at Rogers C P by Dr. Trilk and the Human Performance Lab. At first I didn't know what to expect being I am 46 yrs of age what study could I possibly be of help with , the study turned out to be 8 weeks of Handcycling. From the beginning we had a session of training just to test my endurance it was hard, from there the 8 weeks started and each week was different level of endurance which we did this twice a week for 8 weeks. Being I am 46 the experience I had was exhilarating, each week I could feel my endurance getting stronger and stronger and I had never done Handcycling before and to experience such was beneficial to my body. After each class I could tell I had a good work out . I enjoyed it so much I am now in the process of trying to obtain an Handcycle. Over those 8 weeks I lost fat in areas of my upper extreme that I didn't think it was possible to loose. I just want to thank Dr Trilk and her staff for allowing me to be a part of the study it was a great experience for me. If there ever comes another opportunity to be a part of that study I definitely would sign up . Thanks again for such an wonderful experience.

SCI_003: It was a privilege to be involved in the handcycling study. It was hard work, but I fell in love with handcycling during the process. Then I began to reap health benefits from the exercise, the type of exercise that is very difficult for a paraplegic to achieve in other ways. My upper body strength, respiration and cholesterol really improved. Socially I made new friends and now participate in the handcycle events offered by RCP. I plan to continue to handcycle as much and as often as possible. I really appreciate all the benefits this study has given me.

SCI_002: I was very excited and happy that I was chosen to participate in the Hand Cycling Research Program. My dream was to ride the Swamp Rabbit Trail but I knew I would need help with my cardio. When I went thru the pre-testing I was hoping to be accepted but thought some of the other candidate's probably stood a better chance than I did. On April 15th. I was informed that I had been chosen to participate . At first the hand cycling was very easy. After the third session I was struggling and starting to doubt myself . Jim and Jason from Greenville Cycling and Multi Sport were very encouraging and coached our group on the fundamentals of cycling. When we were struggling they would keep us encouraged and kept us updated on how much time we

had remaining. As the cycling times increased I was struggling and often discouraged because I often did not think I could complete the 8 weeks. In the middle of the program I began to realize some improvements that helped me stay focused and try harder to finish. I began to sleep better my appetite improved and my overall attitude improved. On June 23rd I was able to fulfill my dream of riding The Swamp Rabbit Trail. In 97 degree weather I rode 6 miles and rested a few minutes then rode another 4 miles. My overall health also improved. See below my end results.

Cardiorespiratory Fitness and heart health improved 2.5%
Metabolic Fitness improved ----------14%
Abdominal fat was 7.95 pounds decreased to 7.56
Total Cholesterol before 183 mg/dl after 181mg/dl
HDL Cholesterol before 15mg/dl after 34mg/dl
Total weight loss was 5 lbs.