

AD _____

Award Number: W81XWH-10-1-0957

TITLE: Responsiveness of a Neuromuscular Recovery Scale for Spinal Cord Injury:
Inpatient and Outpatient Rehabilitation

PRINCIPAL INVESTIGATOR: Craig Velozo, Ph.D., Principal Investigator

CONTRACTING ORGANIZATION: University of Florida
Gainesville, FL 32610-0154

REPORT DATE: October 2012

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE 1 Oct 2012		2. REPORT TYPE Annual		3. DATES COVERED 30 Sep 2011 – 29 Sep 2012	
4. TITLE AND SUBTITLE Responsiveness of a Neuromuscular Recovery Scale for Spinal Cord Injury: Inpatient and Outpatient Rehabilitation				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81xwh-10-1-0957	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Craig Velozo, Ph.D., Principal Investigator E-Mail: cvelozo@phhp.ufl.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS University of Florida Gainesville, FL 32610-0154				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT This multi-centered study (7 performance sites) assesses the responsiveness of the Neuromuscular Recovery Scale (NRS) for people with spinal cord injury. The NRS evaluates true recovery of pre-injury movement, rather than compensatory progress, during inpatient and outpatient rehabilitation for spinal cord injury. At the time of this report, approvals have been received and are current for the coordinating site, the University of Florida and for six clinical performance sites, the Ohio State University, Frazier Rehabilitation Institute, Kessler Rehabilitation Institute, TIRR at Memorial Hermann, Shepherd Center, Magee Rehabilitation Hospital. One site has IRB proposal under review. Enrollment and data collection continue at all approved sites with 72% of the outpatient population completed and 19% of the in-patient population completed both initial and discharge NRS evaluations. Web-site construction is under development through streaming web services at Ohio State University (OSU) to provide an introduction to the NRS via video and an instructional guide					
15. SUBJECT TERMS Neuromuscular Recovery Scale (NRS), spinal cord injury, multicenter study					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	9	19b. TELEPHONE NUMBER (include area code)

Table of Contents

Introduction.....	4
Body.....	5
Key Research Accomplishments.....	8
Reportable Outcomes.....	9 None
Conclusions.....	9
References.....	9 None
Appendices.....	9 None

Introduction

The purpose of this study is to assess the responsiveness of the phase system (Neuromuscular Recovery Scale, NRS) in measuring recovery from SCI over time and across therapy settings. This scale uniquely detects return of normal function over time after SCI. Compensation for weakened or paralyzed muscles by stronger muscles, substitutions, or devices do not contribute to the score. Preliminary data indicate the current utility of the NRS to distinctly classify people with SCI based on performance of normal, pre-morbid movement function. Our intent is that the NRS will serve as a clinically-relevant SCI outcome measure for use in rehabilitation clinics, cohort studies, and randomized clinical trials.

Hypothesis

We hypothesize that individuals post-SCI undergoing physical rehabilitation will demonstrate significant change in Neuromuscular Recovery Scale scores from initial to discharge evaluations during the period of a) in-patient rehabilitation and usual care and b) outpatient rehabilitation (chronic SCI) receiving an intense, activity-based therapy.

Specific Aims

Aim 1: Assess the responsiveness of the Neuromuscular Recovery Scale for evaluating recovery from SCI over the period of 1) in-patient rehabilitation (sub-acute SCI) receiving usual care and 2) outpatient rehabilitation (chronic SCI) while receiving an intense, activity-based therapy.

A) Ninety-four patients, AIS A, B, C & D undergoing *usual* care rehabilitation in an inpatient setting during the sub-acute period post-SCI will be enrolled for completion of initial and discharge Phase System evaluations. We anticipate attrition will result in a study population of 72 subjects with initial and discharge evaluations.

B) Seventy-two NeuroRecovery Network (NRN) patients, chronic AIS A-D undergoing the standardized locomotor training program in an out-patient rehabilitation program will undergo initial and discharge evaluations. Only persons included in the NRN database having completed both initial and discharge evaluations will be included in our dataset.

Relevance

The results of this study will establish the ability of the NRS to detect rehabilitation-induced changes in recovery of function after acute or chronic SCI. By being able to classify initial functional deficits with the NRS, we will be able to better tailor interventions for each individual with SCI. By including VA and military personnel in the study, incorporation of the NRS in the care and treatment of soldiers or veterans with SCI will be immediate. Furthermore, web documents will support training of other military rehabilitation centers.

Body

Year 1: As outlined in our SOW, we dedicated considerable time attaining human subject approval, setting up procedures and attaining electronic data transfer approval for the Tampa VA, training the James A Haley VA Medical Hospital (Tampa VA) physical therapists and enrolling subjects. As we are leveraging the standard clinical practice of the NeuroRecovery Network (NRN) in routinely evaluating out-patients with the NRS at initial evaluation and discharge, we additionally incorporated three upper extremity items consistent with the NRN. These items were added to the NRS in May, 2011 and should assist in better gauging responsiveness as now the legs, trunk, and arms are all encompassed in the assessment. The approved IRB includes all of these items.

Task 1. Prepare and standardize all sites (NRN and Tampa VA) for data collection (Months 0-10)

1a. Planning meetings held among partnering investigators, statistician, and Systemax Corp.

- **COMPLETED, YEAR 1**

1b. Planning meeting held for NRN sites and Tampa VA with a) site PI and b) site Supervisors; ongoing monthly meetings scheduled

- **COMPLETED, YEAR 1**

1c. Prepare and submit IRB materials to each institution. Revise, as requested by IRB for approval.

- **COMPLETED, YEAR 2 for the six NRN sites. Annual renewals completed for all six and the coordinating center at UF. The Tampa VA site's IRB is currently under review.**

Milestone #1 Human Use Approvals –Tampa VA IRB documents are under review.

- Since our last report, one of the 7 NRN centers left the network without completing IRB or enrolling any subjects. Six NRN centers remain. **YEAR 2**

1d. Tampa VA study staff visits NRN-OSU clinical site for Phase System/NRS training. On-site competency skills checklist completed and passed.

- **COMPLETED, YEAR 1**

1e. After practice with 3-5 patients, Tampa VA completes and passes competency skills checklist for conducting NRS at Tampa VA site via submission of Phase System/NRS evaluation recording.

- **COMPLETED, YEAR 2, refresher competency proposed during NCE**

1f. NRN sites and Tampa VA site establishes procedures for patient/subject referral and data collection with in-patient rehabilitation SCI program

- **COMPLETED, YEAR 2.**

Milestone #2 All sites readied for data collection with Phase System instrument and in-patient SCI population

1g. Establish and modify database

- **COMPLETED, YEAR 1**

1h. Tampa VA site added to 7 NRN sites as a research site for data entry to database

- **DATABASE COMPLETED FOR VA SITE, YEAR 2.** Current database system relies on use of SS#. This has hindered the use of the database for data entry and delivery from the Tampa VA site. Alternative routes have been discussed and put in place for VA data entry.

1i. Develop website for dissemination of instrument at introductory level including on-line video demonstrations. (preparation for dissemination – Year 2)

- **UNDERWAY**-video production and web site in development at OSU, **YEAR 2**

Milestone #3. Active database for all partnering institutions and clinical sites

- **COMPLETED, YEAR 2**

Task 2 Determine responsiveness of the Phase System (9-20 months)

2a. Identify subjects from NRN outpatient Locomotor Training programs

- **UNDERWAY and On-GOING (YEAR 2)** at approved IRB sites (6 NRN sites)

2b. Collect NRS evaluation data at initial and discharge

- **UNDERWAY and ON-GOING (YEAR 2)** at approved IRB sites (6 NRN sites)
2c. Recruit subjects from Tampa VA & inpatient rehabilitation clinics (at NRN clinical sites)
- **UNDERWAY and ON-GOING (YEAR 2)** at 6 NRN sites and **PENDING HUMAN SUBJECTS APPROVAL (Tampa VA site) (YEAR 2)**
2d. Collect Phase evaluation data at initial and discharge
- **UNDERWAY and ON-GOING (YEAR 2)** at 6 NRN sites and **PENDING HUMAN SUBJECTS APPROVAL (Tampa VA site) (YEAR 2)**
2e. Data extractions requested from database, quality checks conducted.
- **On-GOING (YEAR 2)**

Milestone #4. Produce Interim Report: Recruitment and Enrollment

- **COMPLETED INTERIM REPORT, YEAR 1**
2f. Analyze phase data from 1) in-patient and 2) out-patient rehabilitation programs
- **UNDERWAY (YEAR 2)**, 1) in-patient data, 19% of data collection completed, 2) out-patient data, 72% (n=52) of data collected and undergoing cleaning process for preliminary analysis, 28% yet to be collected (n=20, however n=39 currently enrolled and receiving treatment). We are awaiting their discharge for completion of data set.
2g. Write manuscripts
- **UNDERWAY (YEAR 2)**, Manuscript in progress for Introduction and Methods, and Data Preparation: quality control checks and cleaning for analysis

Milestone #5 Final Report, Publications (2) and abstracts submitted for national conferences. **YEAR 2**

- 2nd Year Progress Report – Completed.
- No cost extensions requested from PI and 2 Partnering PIs.
- No manuscripts submitted and no publications to date.
- Quad Chart completed and submitted.

Milestone #6 Dissemination plan completed.

3a. Finalize informative materials re: Phase instrument for distribution in publications and on-line. **UNDERWAY, ON-GOING, (YEAR 2)**

3b. Finalize web-based introductory program to Phase Instrument. **UNDERWAY, ON-GOING, (YEAR 2)**

3c. Distribute to VA Health Care System SCI facilities and NRN sites.

- Presented methods to NRN site at National Summit meeting of 6 sites, 2012. Research outcomes planned for presentation at National Summit, May, 2013 and presentation to all sites. **(ON-GOING, YEAR 2)**

- Work with Tampa VA re: distribution to VA SCI Centers. **(No Cost Extension)**

3d. Submit abstract for national SCI conferences and VA. **ON-GOING, YEAR 2**

- Abstract submitted re: Neuromuscular Recovery Scale (NRS) for presentation at American Spinal Injury Association Meeting, May 2013

- Abstract accepted for Combined Sections Meeting, APTA, Jan. 2013, only methods to be presented in context of introduction of NRS
- Invited lecture, Braintree Rehabilitation Conference, Nov. 2012, only methods to be presented in context of introduction of NRS as new outcome measure and potential utility

Key Research Accomplishments, YEAR 2

Data Collection

- **In-patient enrollment and data acquisition** is currently at 19% (n=13) of the targeted population of n=72 subjects with both initial and discharge evaluations.
- As indicated in the Interim Year 1 Report, a longer period for IRB approval, one site leaving the NRN, and the TAMPA VA IRB finally under review, has meant that an extension of grant time is required to complete the data collection.
- *Solution:* Each site is expected to increase enrollment to 2 evaluations per month. At this rate and with the six approved sites participating, the sites should achieve the target goal before June, 2013.
- **Out-patient enrollment and data collection** is currently at 72% (n=52). 28% (n=20) have yet to be completed. However, 39 enrollees have completed an initial NRS and when 20/39 are discharged with a second, completed NRS evaluation, the out-patient enrollment will be completed.
- *Solution:* A No Cost Extension request has been submitted by the PI, Craig Velozo (University of Florida) and Partnering PIs each, Michele Basso (Ohio State University), and Andrea Behrman (University of Louisville) for continued enrollment and grant funding through a 3rd year (2012-2013) to complete data collection, subsequent analysis, manuscript preparation and submission, and dissemination.

Data Analysis

- Quality control checking and data cleaning has begun with the out-patient dataset (n=52).
- As the additional n=20 is added, this dataset will be checked.
- Data cleaning of in-patient data will follow with the 19% collected and then every subsequent 20% through completion.
- Data analysis will begin and manuscript results section written.

Abstracts and Manuscripts

- **Two abstracts have been submitted:**
 - o APTA Combined Sections Meeting, 2013, accepted, responsiveness study methods only to be reported and the NRS instrument introduced
 - o American Spinal Injury Association, May, 2013, symposium proposal submitted and under review
 - o If military associated conference occurs in the next year, preference to submit and attend for distribution to associated military and VA sites.
- **Invited presentations:**
 - o Braintree Rehabilitation Conference, Nov. 2012, Boston, methods only to be reported and the NRS instrument introduced
 - o Brazilian NeuroPhysical Therapy Conference, Nov. 2012, methods only to be reported and the NRS instrument introduced

- o 4th International Congress of Neuronal Plasticity and Brain Restoration, Merida, Mexico, Oct 2012, methods only to be reported and NRS instrument introduced.
- **Responsiveness Manuscripts**
- o In-patient – Data cleaning underway, Introduction and Methods in preparation.
- o Out-patient – Data cleaning underway, Introduction and Methods in preparation.

Reportable Outcomes

None at this time

Conclusion

We have completed IRB approval and renewals for Year 2 and 3, with the exception of the Tampa VA. We have advanced subject enrollment in Year 2, however, we will require a no cost extension to complete the in-patient and out-patient enrollment. We have initiated preparation for the web site for dissemination, submitted 2 abstracts (one focuses on methods, one will include results) to national SCI and Physical Therapy conferences, and are including an introduction to the instrument and methods at three invited presentations (one national, two international). We will focus on reportable outcomes in Year 3, should no-cost extension be extended, including activation of the web site, submission of 2 manuscripts and dissemination of findings at national meetings.

References

None

Appendices

None