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

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14. ABSTRACT This multi-centered study (6 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. The coordinating site and six participating sites are respectively, the University of Florida and the Ohio State University, Frazier Rehabilitation Institute, Kessler Rehabilitation Institute, TIRR at Memorial Hermann, Shepherd Center, and Magee Rehabilitation Hospital. Enrollment and data collection continue at all approved sites with 100% of the outpatient population completed and 97% of the in-patient population completed both initial and discharge NRS evaluations. Web-site construction is under development through streaming web services and video production is underway) to provide an introduction to the NRS via video and an instructional guide. The NRS has been presented at the APTA Combined Sections and American Spinal Injury Asso. Meetings.					
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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.
 - **COMPLETED, YEAR 3. Annual renewals completed for six sites. Tampa VA site was unable to achieve IRB approval in a timely manner in order to participate. (UF project coordinator orchestrated obtaining approvals).**

Milestone #1 Human Use Approvals –

- 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
- **In addition, the Tampa VA never received IRB approval and therefore, their subcontract was closed. YEAR 3**

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 3. All sites competent and actively conducting evaluations. UF project coordinator provided oversight and maintained records documenting recruitment rates and success.**

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

- COMPLETED, YEAR 2, database for VA site. 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)

- **COMPLETED, YEAR 3** identified and secured new video production company
- **COMPLETED, YEAR 3** all video collection of people with SCI
- NEARING COMPLETION, YEAR 3, postproduction of video for web dissemination
- ONGOING, YEAR 3 & 4, website development underway by OSU.

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

- **COMPLETED, YEARS 2 & 3, at approved IRB sites (6 NRN sites)**

2b. Collect NRS evaluation data at initial and discharge (out-patients)

- **COMPLETED, YEARS 2 & 3, at approved IRB sites (6 NRN sites)**

2c. Recruit subjects from Tampa VA & inpatient rehabilitation clinics (at NRN clinical sites)

- UNDERWAY and ON-GOING, YEARS 2 & 3, at 6 NRN sites
- **NOT COMPLETED YEAR 3 for Tampa VA due to lack of IRB approval.**

2d. Collect Phase evaluation data at initial and discharge (in-patients)

- UNDERWAY and ON-GOING, YEARS 2 & 3 at 6 NRN sites
- **NOT COMPLETED YEAR 3 for Tampa VA due to lack of IRB approval.**

2e. Data extractions requested from database, quality checks conducted.

- **COMPLETED, YEAR 3, data collection for the outpatient population.**
- UNDERWAY and ON-GOING, YEARS 2 & 3, data collection for the inpatient population.

Milestone #4. Produce Interim Report: Recruitment and Enrollment

- COMPLETED, YEAR 1, 2, and 3, INTERIM REPORTs

2f. Analyze phase data from 1) in-patient and 2) out-patient rehabilitation programs

- **COMPLETED, YEAR 3, 100% out-patient data collection** (progressed from 72% complete in year 2).
- NEARING COMPLETION, YEAR 3 & NCE YEAR 4 (6 mos requested), 97% of in-patient data collected as of 10-11-13 which progressed from 19% in Year 2.

2g. Write manuscripts

- UNDERWAY and ON-GOING, YEARS 2 & 3 & NCE YEAR 4 (6 mos requested), Manuscript in progress for Outpatient responsiveness led by University of Florida and OSU.
- **COMPLETED, YEAR 3, 100% quality control checks and data cleaning and preliminary analysis, data preparation for manuscript for out-patient data.**
- UNDERWAY, YEAR 3 & NCE YEAR 4 (6 mos requested), quality control checks and data cleaning and preliminary analysis, data preparation for manuscript for in-patient data.
- **NCE YEAR 4 (6 mos requested), complete and submit manuscripts (1 manuscript preparation and submission led by Tester – UF and Basso – OSU; and 1 manuscript preparation and submission led by Velozo – UF/MUSC).**

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

- COMPLETED, YEAR 2, 2nd Year Progress Report.
- COMPLETED Year 2 No Cost extension requested and approved
- No manuscripts submitted and no publications to date.
- COMPLETED, YEAR 2, Quad Chart completed and submitted.
- **COMPLETED, YEAR 3, Interim Report submitted (Basso OSU)**
- **COMPLETED, YEAR 3, Request for NCE submitted by OSU (Basso).**
- **COMPLETED, YEAR 3, Abstracts submitted and accepted to CSM, ASIA, and Military Healthcare (Behrman – UoL, Basso – OSU, and Velozo – UF/MUSC)**

Note abstract submitted to ACRM, not accepted

Milestone #6 Dissemination plan completed.

- 3a. UNDERWAY and ON-GOING, YEARS 2, 3 & YEAR 4 NCE (6 mos), Finalize informative materials re: Phase instrument for distribution in publications and on-line.
- 3b. UNDERWAY and ON-GOING, YEARS 2, 3 & YEAR 4 NCE (6 mos), Finalize web-based introductory program to Phase Instrument.
- 3c. Distribute to VA Health Care System SCI facilities and NRN sites.
 - COMPLETED, YEAR 2, Presented methods to NRN site at National Summit meeting of 6 sites, 2012.
 - COMPLETED, YEAR 3, Research outcomes presented at National Summit, May, 2013 and presentation to all sites.
- 3d. Submit abstract for national SCI conferences and VA.
 - **COMPLETED, YEAR 3, Abstract accepted for Combined Sections Meeting, APTA, Jan. 2013, only methods to be presented in context of introduction of NRS. (Velozo – UF, co-author; Behrman – UofL, co-author).**
 - **IN PROCESS, Year 3: Invited to present at Military Healthcare conference, Dec 9-12, 2013, San Diego. Request in process for travel expenses (Basso-OSU; Behrman- UofL, Velozo - MUSC), NCE – YEAR 4 (6 months).**

Key Research Accomplishments, YEAR 3

Data Collection

- In-patient enrollment and data acquisition is currently at 97% (n=69) of the targeted population of n=72 subjects with both initial and discharge evaluations. Two are currently enrolled and we anticipate a 3rd by 10-31-13 to be enrolled.
- Out-patient enrollment and data collection is currently at 100% (n=72) and completed.

Data Analysis

- Quality control checking and data cleaning has been completed with the out-patient dataset (n=72).
- Data cleaning and quality checks of in-patient data is underway.
- Data analysis completed (YEAR 3) and **manuscript in preparation with out-patient population (led by Tester – UF and Basso - OSU). Complete during NCE – Yr 4 (6 months), Request in process.**
- Data analysis initiated and manuscript in preparation with in-patient population. (YEAR 3) Complete during NCE – YEAR 4 (6 months), Request in process.

Abstracts and Manuscripts

- **Two abstracts presented:**
 - **APTA Combined Sections Meeting, 2013, responsiveness study methods only reported and the NRS instrument introduced (Basso, Behrman – UofL, Velozo – UF/MUSC, YEAR 3)**
 - Invited presentations:
 - **4th International Congress of Neuronal Plasticity and Brain Restoration, Merida, Mexico, Oct 2012, methods only reported and NRS instrument introduced. (Basso, OSU, YEAR 3)**
 - **Invited to present at Military Healthcare conference, Dec 9-12, 2013, San Diego. Request in process for travel expenses (Basso- OSU, Behrman UofL, Velozo – UF/MUSC), NCE – YEAR 4 (6 months).**
 - **Responsiveness Manuscripts**
 - Out-patient –Methods, Results, Discussion in preparation. NCE – YEAR 4 (6 months). **Manuscript preparation led by Tester (Proposed PI), UF, and Basso – OSU NCE – YEAR 4 (6 months).**
 - In-patient – Data cleaning underway, data analysis and manuscript in preparation.

Other

- A request for a change in PI has been submitted for DoD approval to replace Dr. Craig Velozo who moved away from UF to MUSC, with Dr. Nicole Tester (UF).
- Since Tampa VA was unable to obtain IRB approval, their subcontract with UF was terminated. A request for redistribution of these funds was made in a request for the NCE (Tester/Velozo, UF, YEAR 3).
- **A request for the NCE has been submitted to the DoD (Basso, OSU, YEAR 3).**

Reportable Outcomes

None at this time.

Conclusion

We have completed IRB approval and renewals for years 3-4, with the exception of the Tampa VA which has withdrawn from the study. We have completed enrollment for the out-patient population and are at 97% for the in-patient population. We have initiated preparation for the web site for dissemination and videography of the assessments, presented 2 abstracts to national SCI and Physical Therapy conferences, and included an introduction to the instrument and methods at three invited presentations (one national, two international). We have been invited to present at the Military Healthcare conference in December 2013. We are requesting a no-cost extension for Yr 4 (6 months) to finalize data analysis and submission of manuscripts (Tester, Behrman, Basso, Velozo), complete videos and website dissemination (Basso-OSU), complete data checks and cleaning (Behrman-UoL), finalize all reports and IRB close-outs (Tester-Velozo, UF-MUSC), complete payments to all sites for fee for service evaluations and IRB management and data entry (Tester, UF), and present at Military Healthcare conference in Dec. 2013 (Behrman- UoL, Basso-OSU, Velozo-MUSC). Please note that Dr. Velozo has left the University of Florida in August, 2012. Dr. Tester has agreed to be the PI for the coordinating center at UF to the completion of the project. This was discussed with Patricia Henry as a viable and appropriate solution. Dr. Tester has been instrumental in these last months in preparation for the NCE in collaboration with Dr. Velozo and in maintenance of all IRB records with Sarah Suter, Project Coordinator. The IRB has been approved with this temporary change of PI while under DoD review.

References

None

Appendices None