## STUDY TITLE:

Enhancing Rehabilitation Participation in Patients with SCI/D Using Motivational Interviewing

## PRINCIPAL INVESTIGATOR:

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## VERSION DATE:

12/12/2024

## RELATED STUDIES:

STU00204701- Training Therapists in Motivational Interviewing to Enhance Rehabilitation Participation for SCI

Check any **applicable** boxes in the table below – you will be asked for further detail on these topics later in the protocol form:

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|---|
| Indicate Vulnerable Populations to be enrolled:<br>☐ Children<br>☐ Cognitively Impaired Adults<br>☐ Pregnant Women (IF the research activities will affect the pregnancy or the fetus)<br>☐ Prisoners (or other detained/paroled individuals) |
| ☐ International Research (check this box if you will collect data from individuals located outside the United States) |
| ☒ Research involving external collaborators (some research activities will be carried out by individuals not employed by Northwestern or NU affiliates will carry out some research activities) |
| ☐ Research has U.S. Federal government funding via one or more direct awards or a sub-award (e.g., NIH, NSF, other federal agencies or departments) |

## 1.0 Purpose and rationale of the study:

### *1.1* Purpose

We plan to conduct a multi-site randomized controlled trial of motivational interviewing (MI) training for physical therapists (PTs) and occupational therapists (OTs) who treat people with SCI during inpatient rehabilitation. We will test whether patients treated by MI trained PTs and OTs demonstrate greater participation in therapy sessions and better functional, social, and educational/occupational outcomes relative to patients treated by therapists without MI training. This stage of research is appropriate because a Neilsen Foundation funded pilot study that we recently completed had promising results. Study results showed that SCI patients treated by MI trained PTs and OTs participated significantly more actively in therapy sessions compared to controls. However, the study had several limitations that need to be addressed to produce a more definitive and influential trial. First, the study was conducted at a single site and results may not generalize to other sites. Second, we did not examine whether MI training and improved participation resulted in patients having better clinically meaningful outcomes such as higher likelihood of discharge to home or superior functional, social, or educational/occupational outcomes. Third, therapists trained in MI achieved only minimal competency in MI skills. We hypothesize that if therapists received ongoing coaching to improve their MI

skills during the trial the positive impact on patient participation and other outcomes might be even more robust.

### *1.2* Project Aims:

1. To determine whether inpatients with SCI/D treated by PTs and OTs who receive MI training and coaching demonstrate greater therapy participation compared to those treated by therapists who do not receive MI training and coaching.
2. To determine whether inpatients with SCI/D treated by PTs and OTs who receive MI training and coaching demonstrate greater functional improvement at discharge from inpatient rehabilitation and greater community integration at 6 months after discharge compared to those treated by therapists who do not receive MI training and coaching.
3. To document an effect of training and coaching on MI skills and explore potential moderators and mediators of the effect of the intervention on therapy participation.

### *1.3* Background and rationale

Patient participation in physical and occupational therapy during inpatient spinal cord injury (SCI) rehabilitation is not always optimal. The cost of suboptimal participation is that patients with SCI experience significantly poorer outcomes in important functional domains such as whether the person discharges to home, their functional mobility at discharge from inpatient rehabilitation and at one-year, social integration, and whether they return to work or school one year after SCI. As such, the problem of suboptimal participation in inpatient therapies represents a critical gap in the field of SCI rehabilitation that merits increased attention. Therapy participation is a biopsychosocial phenomenon and strength of participation has downstream effects on physical, social, and occupational functioning. An intervention that improved therapy participation and then led to more people being discharged to home environments, returning to work or school, and having better functional and social integration outcomes could be quite beneficial based on the number of people affected and the importance of the results.

Motivational interviewing is an evidence-based counseling style found to be effective in fostering positive health behavior change, including adherence to treatment in 119 randomized controlled trials and multiple meta-analyses.(Lundahl, 2010) MI counseling consists of five major skills: open-ended questions, affirmations, reflective listening, summarization and providing information and advice with permission. There is no theoretical framework for MI, but it is most closely associated with Self-Determination Theory (Deci & Ryan). Self-determination theory focuses on supporting intrinsic motivation, self-regulation and mental health in social contexts and posits that intrinsic motivation and self-regulation require competence, relatedness and autonomy.

In our pilot study, "Training Therapists in Motivational Interviewing to Enhance Rehabilitation Participation for SCI" (STU00204701), we recruited 62 inpatients with SCI/D to participate in the project. Patient participation in therapy was scored by therapists, the patients themselves, and a blinded project coordinator (researcher). In general, patients with SCI/D improved their therapy participation from Week 1 to Week 4. Multi-level modeling analysis revealed that patients treated by MI trained therapists scored significantly higher on the Pittsburgh Rehabilitation Participation Scale (PRPS) (M=4.26, SD=0.91) compared to controls (M=3.79, SD=1.15) after controlling for sex, age, and trauma type. The effect size was medium according to Cohen's d at 0.56. Patients in the MI intervention group had a flatter slope of PRPS improvement than patients in the control group across time. Patient-rated and therapist-rated PRPS scores had similar trends as researcher-rated PRPS despite less significant difference. Therapist-rated PRPS showed significant group difference between groups (MI intervention group had higher scores), but no difference was noted across Week 1 to Week 4. We aim to build on these initial outcomes by providing additional MI coaching to the trained therapists and recruiting a larger sample.

This is a multi-site project with two sites, Shirley Ryan AbilityLab and Baylor Scott White, each of which will follow the same protocol under review of their local IRBs. This protocol only covers research activities at SRAlab requiring Northwestern IRB approval. Any data shared between researchers at SRAlab and Baylor for analysis and/or quality assurance will be deidentified.

## 2.0 Enrollment Criteria:

*2.1* **Occupational and Physical Therapist** participants will be recruited from the inpatient spinal cord injury units at Shirley Ryan Ability Lab. They will be recruited at staff meetings and through email communication by the research team through coordination with allied health managers. During the staff meeting, the verbal therapist recruitment script will be read. An informational flyer will also be available. Recruitment emails will be sent out to the therapist listserv and followed up with each therapist individually.

**Therapist inclusion criteria:**

- Inpatient therapist specializing in spinal cord injury patients for at least 3 months;
- Practicing on one of the two designated SCI inpatient units at SRAlab (Floor 21 or 22);
- Willing to audio record conversations during regularly-scheduled rehabilitation therapy sessions with patients;

- Willing and able to participate in 16 hours of MI training; and
- Willing to receive feedback on MI skills.

**Therapist exclusion criteria:**

- Inability to speak and understand English
- Inpatient therapist specializing in spinal cord injury patients for less than 3 months; and
- Unwilling or unable to follow the study protocol

*2.2* **Patients with SCI** will be recruited using participating therapists' caseloads and randomly selecting participants to be approached about participating in the study. When approached, patients will be read the patient recruitment script.

**Patient Inclusion Criteria:**

- Adults (18+)
- Presence of a traumatic or non-traumatic spinal cord injury
- Inpatient in the spinal cord injury unit of SRAlab
- Has a physical or occupational therapist who is a participant in the study

**Patient Exclusion Criteria:**

- Inability to speak and understand English
- Cognitive deficits
- Unwilling to allow for therapy sessions to be recorded

# 3.0 Sample Size:

### *3.1* Local sample size

We expect to enroll 90 participants at SRAlab: 6 occupational or physical therapists plus 84 of their patients with SCI (of which n = 18 patients will only be enrolled as audio-only test participants).

The recruitment breakdown and timeline is as follows:

- Recruitment phase 1: 6 occupational or physical therapists
- Recruitment phase 2: 12 patients with SCI, 2 patients per therapist, will be recruited as audio-only test participants to assess baseline motivational interviewing skills prior to therapist randomization and training.
- Recruitment phase 3: Half (n = 3) of the therapists at each site will be trained in MI, so we will recruit 6 additional patients (2 per MI-trained therapist) as audio-only test participants to assess MI competency during the initial MI training phase.
- Recruitment phase 4: We will recruit 60-66 patients with SCI—10-11 patients per enrolled therapist—for the experimental phase, which includes audio recording of therapy sessions plus two additional questionnaires.

### *3.2* Total sample size

Across sites, we expect to enroll 180 participants: 12 OT/PT's (6 per site) and 168 patients with SCI (84 per site).

### *3.3* Sample size justification

We anticipate a sufficient number of patients; full time therapists are budgeted to work with six patients daily while half time therapists are budgeted to work with three patients daily.

The effect size obtained from the pilot study was 0.56 (Cohen's *d*). Based on the G*Power 3.1.9.6 program we would need to study 104 patients (52 per group) to adequately power the study assuming an alpha level of .05, power = .80, two-tailed test, and 1:1 allocation. We anticipate 20% attrition rate leading to a total of 126 patient participants.

## 4.0 Recruitment and Screening Methods:

### *4.1* Recruitment and screening of therapists

The research team at SRAlab will recruit 6 rehabilitation therapists—ideally 3 physical therapists and 3 occupational therapists—working on the designated inpatient SCI units (floor 21 and 22). Therapists will be approached on the therapy floor during breaks in their workday using the therapist recruitment script and therapist recruitment flyer. The research team will notify and work with the allied health managers on each floor as needed to coordinate recruitment efforts with therapist schedules.

The research assistant will screen interested therapists based on the inclusion criteria: (1) inpatient spinal cord injury rehabilitation therapist working on floors 21 or 22 for at least 3 months, (2) willing and able to participate in 16 hours of MI training, and (3) willing to record audio of therapy sessions with enrolled patients.

Therapists who meet eligibility criteria will proceed with informed consent if still interested after screening questions. The research assistant will obtain written informed consent either on paper or REDCap e-signature. The therapist will be given a copy of the consent form, and they will be encouraged to read through the consent form and ask questions prior to enrolling.

### *4.2* Authorization form for audio-only test patients

As described in the sample size breakdown, 18 patients with SCI will be audio recorded to (1) assess baseline motivational interviewing skills (n = 12, 2 patients per therapist) and (2) assess post-training motivational interviewing skills (n = 6, 2 patients per MI-trained therapist). This activity does not qualify as human

subjects research because the patient identities will not be documented by the research team or associated with the recordings, and no survey data will be obtained. The audio will only be used to assess MI skills of the therapist participants. The recordings will be destroyed once the pre-experimental phase of the study is completed. Please see "SRAlabAudioConsentForm" in lieu of full informed consent document.

### *4.3* Recruitment and screening of inpatients with SCI

A convenience sample of patients with SCI will be recruited based on new admissions to inpatient rehabilitation and the participation of their rehabilitation therapist in the study. The research team will approach patients assigned to one of the enrolled therapists at the time of their admission to an SRAlab inpatient SCI unit (on floor 21 or 22).

A research assistant will screen patients newly admitted to the 21 or 22 floor for presence of a traumatic or non-traumatic SCI via admission records in Cerner. Patients must be 18 years or older at time of admission and must speak English without a translator. Potential participants must also agree to having audio recordings of their therapy sessions.

The research team will communicate with the enrolled therapist to schedule a time before, during, or after rehabilitation sessions to recruit and screen patients. We will approach eligible patients using the recruitment script and flyer after assessing initial eligibility through medical records.

Interested patients will review the informed consent document with a member of the research team.

During the consent process, patients must agree to audio recordings of their therapy sessions—they will be informed that the audio recordings focus on the therapist and not the patient, but both sides of the conversation are needed to provide context to the therapist's verbiage. We will instruct therapists to avoid using patients' full names when recording therapy sessions. Audio recordings will be uploaded to Shirley Ryan AbilityLab OneDrive with limited permissions to maintain privacy of therapists and patients.

## 5.0 Research Locations:

This protocol describes research activities that will take place at Shirley Ryan AbilityLab under review of the Northwestern IRB. Therapy sessions will be held and recorded in the usual SCI rehabilitation units on the 21 or 22 floor. Research documents will be saved on the secure SRAlab network using SRAlab-approved devices. The research team will use REDCap to collect survey data and otherwise store participant information in password-protected files on the SRAlab server.

An identical protocol will be conducted at Baylor Scott White in Texas which will be reviewed under their local IRB. Any information that the SRAlab research team must share with the Baylor research team will be stripped of direct patient identifiers, such as full name and address.

## 6.0 Multi-Site or Collaborative Research:

### *6.1* Primary research sites

This study is funded by the Craig H Neilsen Foundation (non-federal) and involves two primary research sites, SRAlab (Chicago, IL) and Baylor Scott White (Dallas, TX).

The Principal Investigator at SRAlab is Dr. Linda Ehrlich-Jones, PhD, RN, Associate Director of the Center for Rehabilitation Outcomes Research. The Co-Investiagor at Baylor Research Institute is Simon Driver, PhD, Research Center Director.

Each site will administer an identical protocol under the review of their local IRB.

### *6.2* Motivational Interviewing Consultant

Dr. Charles Bombardier is a clinical psychologist and Professor in the Department of Rehabilitation Medicine at the University of Washington. Dr. Bombardier is a co-Investigator on this study, serving as an expert on motivational interviewing (MI).

He is a member of the international Motivational Interviewing Network of Trainers (MINT). He collaborated with Dr. Ehrlich-Jones on the pilot study that set the stage for this trial. As a Co-Investigator, he will assist with training and coaching of the PTs and OTs to use motivational interviewing techniques in their work with inpatients with SCI. He will also assist with interpretation of study results, co-authoring publications and presentations, and contributing to other dissemination efforts.

The University of Washington is not a research site, and Dr. Bombardier will not be involved in the recruitment or data collection activities taking place at SRAlab and Baylor. He will assist the Principal Investiagor in motivational interviewer training, initial assessment of therapist MI competency, and analysis, interpretation, and dissemination of findings. These activities will take place through secure, remote technology platforms hosted by the primary research sites, SRAlab and Baylor.

## 7.0 International Research (where data collection will occur outside the United States and U.S. territories, including online activities)

N/A

## 8.0 Procedures Involved:

Please check the boxes for all applicable data collection procedures you plan to use:

☐One-on-one interviews

☐Focus Groups

☒Questionnaires/surveys

☒Secondary Data Analysis (medical record data, educational records, government or private sector datasets, etc.)

☐Ethnographic observation

☐Physiological measurements (e.g., EEG, EKG, MRI)

☐Biospecimen collection (saliva samples, blood draws, hair samples, etc.)

☒Mobile applications/data collection devices (e.g., Fitbits, actigraphs, etc.)

☐Behavioral decision making tasks (e.g., puzzles, interactive games, etc.)

☐Physical activities such as walking and other forms of exercise

☐Other procedures (briefly list types of procedures here if not covered by the check-boxes above): _____

*8.1* **Baseline data collection and randomization of therapists**:

- Once the research team enrolls 6 physical therapists or occupational therapists, demographic information will be collected by the research assistant via REDCap survey (see 'DemographicSurvey' under 'supporting documents'). The therapist participant may fill out the demographic survey via REDCap themselves if they prefer – the research assistant will review the answers and follow up with participants in-person to clarify as needed..
- All therapists will audio record two therapy sessions with SCI/D patients wearing a digital recorder on their name badge lanyard or on their clothing. This will provide a baseline level of MI skills. Audio-only test patients will sign an authorization to have their therapy session recorded (see "EditedSRAlabAudioConsentForm"). We will not obtain full informed consent from the audio-only patients because their identities will not be recorded and they will not participate in the patient questionnaires described below. The test audio recordings obtained in steps 8.1 and 8.2 will be destroyed after therapists' motivational interviewing skills are assessed.
- After all baseline recordings are complete, the data manager will perform a central computer-generated randomization and then transmit treatment allocation to Dr. Ehrlich-Jones, the MI trainer, via secure email. Dr. Ehrlich-Jones will then contact enrolled PTs and OTs at each site to set up training as indicated. Randomization will be stratified based on therapist type (PT vs.

OT). The allocation sequence will be concealed from any study staff involved in enrollment of participants or data collection via a restricted access database program.

- Half of the therapists will be assigned to the experimental Motivational Interviewing group, and the other half will be assigned to the control group.

***8.2*** **Train therapists in Motivational Interviewing**

- MI training will follow the standard, evidence-based training model recommended within the MI expert community of 16 hours of training.(Miller, Yahne et al, 2004 Journal of consulting and clinical psychology, 72: 1050-1062.) Dr. Ehrlich-Jones is an experienced trainer and a member of the international MI Network of Trainers (MINT). Dr. Bombardier (co-I, University of Washington) is also an experienced trainer and member of the MINT will assist her with the training. The training will take place virtually via Zoom in eight 2-hour time blocks either weekly or bi-weekly dependent on the therapists' work schedule. Training times will take place outside of patient treatment times.
- After all training is complete, each therapist in the MI training and coaching group will provide Dr. Ehrlich-Jones with two audio recordings so that she can assess the therapists for MI competency using the MITI 4.2.1. Based on prior research training of rehabilitation professionals as well as published research, basic competency in MI can be attained with this amount of training and coaching. (Miller, Yahne, et al., 2004).
- We will ask the therapists who are trained in MI not to share any of the training with the untrained therapists over the course of the study. We will provide free MI training to the untrained therapists once the treatment phase of the study is complete.
- Therapist participants in the MI group will receive $200 as compensation for participation in training. Those in the control group will be offered the MI training and $200 compensation at the end of the study. All payment will be administered via ClinCard.

*8.3* **Recruit participants – Inpatients with SCI**

- Once the MI trained PTs and OTs achieve basic MI competency, the experimental phase of the study will begin. The research assistants at both sites will approach a convenience sample of eligible inpatients that the PTs and OTs in the study are treating, for participation in the study. The research assistants will recruit and consent 10-11 inpatients for each of the therapists who were trained in MI as well as for each of the therapists who were not trained in MI for a total of 126 inpatients.

- The research assistants will ask the therapists when they feel comfortable to add another patient participant to their research caseload so as not to overburden the therapist with the research tasks. The patients will be kept blinded to whether their therapist has been trained in MI or not.

*8.4* **Data collection**

- Patient participants will be asked demographic questions following informed consent, and the research assistant will enter answers via REDCap (see 'DemographicSurvey' under 'supporting documents). The research assistant will abstract available variables about patient demographics and SCI injury characteristics, such as diagnosis and injury level, from the medical record. The patient participant may fill out the demographic survey via REDCap themselves if they prefer – the research assistant will review the answers, confirm with medical records if available, and follow up with participants in-person to clarify as needed.
- A research assistant will complete the Pittsburgh Rehabilitation Participation Scale (PRPS) for each patient participant during one randomly selected therapy session each week throughout the 4 weeks the participant is enrolled in the study. These PRPS scores will be recorded through REDCap, averaged, and analyzed.
- A research assistant will extract demographic data for each patient from the electronic medical record as well as minutes of therapy for each day from the electronic medical record for each patient participant. Demographic data extracted from the medical records will include: age, sex, injury level and severity, traumatic vs non-traumatic, injury etiology, years of education, and marital status, at the start of participation.
- All therapists will audio record therapy sessions with their patients as many times a week as possible (at least 3 sessions). They will download the recordings to a secure site so that a weekly session can be randomly chosen to send for **Motivational Interviewing Treatment Integrity (MITI)** coding. The MITI provides a global rating on five concepts of motivational interviewing: evocation, collaboration, autonomy/support, direction, and empathy. The ratings are on a 5-point Likert scale from 1 (low) to 5 (high). An average rating of 3.5 in the five concepts is considered beginning proficiency. In addition, frequency counts of MI behaviors that are open-ended questions, simple and complex reflections and MI adherent behaviors are tallied. Summary scores of reflection to question ratio, percent open questions, percent complex reflections and percent MI adherent behavior are computed.

- A research assistant will administer the Spinal Cord Injury Functional Indedependence (SCI-FI) via interview within approximately one week of patient discharge from inpatient rehabilitation. A research assistant will administer the Participation Assessment with Recombined Tools-Objective (PART-O) to patient participants at 6 months post-discharge from inpatient rehabilitation. Scores will be recorded on a fillable PDF and then entered into REDCap.

*8.5* **Study Duration and Compensation**

- Enrolled therapists are expected to be in the study for the duration of the data collection window, approximately 1 year.
- Therapists will be compensated $200 via Clincard for participating in MI training and $5 for uploading each audio recording of their therapy session with enrolled patients. We expect therapist participants to upload 2 recordings per week per patient participant.
- Patient participants will receive $25 for completion of the SCI-FI measure and $25 for completion of the PART-O measure.
- All research payment will be administered via ClinCard

## 9.0 Research with Vulnerable Populations

We will not recruit children, prisoners, or adults with cognitive impairments.

This research does not involve any physical procedures outside of regular inpatient rehabilitation care, so activities are not expected to affect pregnancy. It is unlikely that pregnant women will be enrolled due to the low incidence of pregnant inpatients with SCI, but we will not exclude participants who are pregnant if they meet all other eligibility criteria.

The research assistant conducting initial screening via medical chart review will exclude participants with cognitive deficits noted in the admissions records. If the presence of cognitive deficits is unclear based on chart review, the research team will contact the patient's clinical team to ask if the person is able to provide informed consent without presence of a witness of proxy. The clinical team can also advise against approach if they determine that research participation is not in the patient's best interest.

## 10.0 Incomplete Disclosure or Deception:

*10.1* Randomization and blinding

Half of the therapists will be trained in motivational interviewing, and the other half will proceed with normal care. As such, therapist participants cannot be blinded to their group assignment. Therapists who are not assigned to the MI group will have the opportunity to complete the training after completion of the study intervention.

Group assignments will be randomized by the study investigator, but the rest of the research team participating in data collection will be blinded to MI assignments. The research assistants collecting data and observing therapy sessions will not be trained in MI to further prevent bias.

Patient participants will be blinded to their group assignment—the therapists will be instructed not to disclose whether they are using MI techniques during therapy sessions or not. Patient participants will be told the nature of the intervention during the informed consent process.

## 11.0 Consent Process:

*11.1* Written, informed consent will be obtained for all participants in the study, including therapist participants (n = 6 local) and SCI participants (n = 66 local).

*11.2* The informed consent process will take place at Shirely Ryan AbilityLab by IRB-approved team members.

*11.3* The research member obtaining consent will explain the study to potential participants in-person and provide a hard copy of the consent document for review. Participants will be encouraged to read the full consent document and ask any questions prior to signing. Two copies of the consent form will be created for each enrolled participant—the original copy will be stored in locked filing cabinets on the study team unit, and the second copy will be provided to the participant for their personal records. Consent may also be obtained online via REDCap if the participant prefers this process to a hard copy.

*11.4* Any potential patient participant may refuse to participate and this will not impact the care that they receive at SRAlab. Similarly, therapists' participation in this research study is entirely voluntary and unrelated to their responsibilities as an employee of SRAlab. They will be neither rewarded nor penalized for their activities related to the research study. Also, these activities should not impact their responsibility to perform their duties as an SRAlab-employed therapist. Participants can also withdraw at any time by verbally stating that they do not wish to participate anymore.

## 12.0 Waiver of Participant Signature on Consent Form:

N/A

## 13.0 Waivers and Alterations of Consent Information:

N/A

## 14.0 Financial Compensation:

Patient participants for the randomized controlled trial will receive $25 for completion of the SCI-FI measure and $25 for completion of the PART-O measure. Therapists will be compensated $200 for participating in MI training and $5 for uploading each audio recording of their therapy session with enrolled patients. We expect therapist participants to upload 2 recordings per week per patient participant.
All research payment will be administered via ClinCard.

## 15.0 Audio/Video Recording/Photography

Therapy sessions will be audio recorded 2 times per week on mobile audio recording devices. The research team led by Dr. Ehrlich-Jones will provide the therapist participants with the devices after they are enrolled in the study. The recordings will be the length of the therapist's typical session, approximately one hour but up to two hours. The therapists will download the audio recordings to a secure file (Shirley Ryan AbilityLabMicrosoft Teams secure network). Then Dr. Ehrlich-Jones and Dr. Bombardier will listen to a sample of the audio recordings and rate the therapists' competency in MI using the Motivational Interviewing Treatment Integrity skill coding system during the baseline and MI competency phase.

Audio recordings will be stored separately from participant identifiers and will be labeled with Subject ID #'s rather than names. Audio recordings will be uploaded to Shirley Ryan AbilityLab OneDrive with limited permissions to maintain privacy of therapists and patients.

Participants will be informed of audio recordings during the informed consent process and throughout their study participation period. Audio recordings will be deleted after completion of the data analysis period.

During the randomized control trial phase, one random recording per week per patient participant will be shared with the Motivational Interviewing Treatment Integrity coding lab who will rate the motivational interviewing skills of the therapists by listening to 20 minutes of the recording and rating the session using the MITI 4.2.1 rating scale. These scores will be used to provide feedback to the therapists on their MI skills and to guide coaching sessions of the therapists for their MI skills. Coaching sessions of the therapists will take place individually approximately monthly or more often as needed based on the MITI scores.

## 16.0 Potential Benefits of this Research:

*16.1* Therapist participants will be trained in motivational interviewing, an evidence-based skill that requires at least 16 hours of training by a designated instructor. Therapists who are not randomly assigned to the MI group during the

study period will have the opportunity to be trained in MI after completion of the study period. CEU credits will be offered upon completion of the MI workshop.

*16.2* SCI patient participants may experience increased participation in physical/occupational therapy, improved treatment satisfaction, and improved therapy outcomes including self-care and mobility.

## 17.0 Potential Risks to Participants:

There is no physical risk associated with participation in this study, either as a therapist or patient participant.

It is possible that therapists may lose their recorders with audio still on the device that may have identifying information. Therapists will have a place to lock recorders when not in use and will be asked not to use patient's full name in recordings to prevent against a breach in confidentiality.

## 18.0 Provisions to Protect Participant Privacy and Data Confidentiality:

### *18.1* Participant Privacy

All recruitment, informed consent, assessments, and intervention sessions will take place in as private a setting as possible, away from public waiting areas. Therapists will be instructed not to use the patient participant's full name on audio recordings of therapy sessions. Participants will be assigned unique identifiers (i.e. subject ID #) that will be used for data collection and storage. Participant identities will be crosslinked on a password-protected Excel file on the secure SRAlab network. During both the initial assessment and all follow-up assessments, participants will have the option to skip any questions they do not wish to answer.

### *18.2* Confidentiality of data

All paper forms are kept in locked file cabinets. Digital data files, tracking logs, etc. are kept in encrypted, password-protected files on a server at the Shirley Ryan AbilityLab with access restricted to investigators and their staff through password-protected computers. Access to the Shirley Ryan AbilityLab's server using off-site computers requires a verification process, which involves a Duo Mobile logon utility and remote network approval. Survey data will be collected and stored on SRAlab's REDCap, which requires authenticated access that will be limited to members of the study team.

Audio recordings will be uploaded and kept on Shirley Ryan AbilityLab OneDrive, a secure online server. Audio will not be associated with direct participant identifiers and will be identified using Subject ID #'s. A random subset of audio

recordings will be assessed for MI quality throughout the study, and the audio files will be destroyed after completion of the study period.

The data will have restricted access, unless required by law, to only the study investigators, members of the investigators' staff, representatives of the sponsor, the Northwestern University Institutional Review Board, and representatives from relevant medical oversight committees, and these persons are required to maintain confidentiality regarding subjects' identities.

## 19.0 Data Monitoring Plan to Ensure the Safety of Participants:

This is a minimal risk clinical trial. There are no invasive interventions or sensitive questions involved in data collection that may result in physical or emotional harm to any participants.

## 20.0 Long-term Data and Specimen Storage and Sharing:

N/A

## 21.0 Qualifications of Research Team to Conduct the Research:

The Principal Investigator, Linda Ehrlich-Jones, PhD, RN, is a Clinical Research Scientist at Shirley Ryan AbilityLab's Center for Rehabilitation Outcomes Research and a Research Associate Professor in the Department of Physical Medicine and Rehabilitation at NU's Feinberg School of Medicine. She received her BSN from Rush University, her MSN from Loyola University of Chicago, and her PhD in Nursing Sciences at the University of Illinois at Chicago. Her research interests include development and implementation of behavioral interventions to improve the QOL of patients with chronic illnesses.

Dr. Ehrlich-Jones, with research staff in the Center for Rehabilitation Outcomes Research, previously led a pilot randomized controlled trial of MI training for PTs and OTs to improve patient participation during SCI rehabilitation. The study was a single site randomized controlled study in which seven therapists were randomized to a MI training condition and seven were randomized to a no training control condition. After PTs and OTs were trained, the study enrolled and followed 62 patients undergoing inpatient rehabilitation for SCI/D. The main outcome of the study was independently rated patient participation in therapy sessions using the PRPS. The results of the study were promising. Analyses revealed a significant group effect (patients treated by MI trained therapists scored significantly higher on the PRPS (M = 4.26, SD = 0.91) compared to controls (M = 3.79, SD = 1.15) after controlling for sex, age, and trauma type. The Cohen's d was 0.56, which is a medium effect. Analyses also showed a group x time effect based on adjusted and unadjusted models (adjusted odds ratio = 0.35, $p < .01$). MI training had a larger effect relative to controls during the first 1-2 weeks while

PRPS scores converged by week 4. There was a significant time effect with PRPS scores improving over time, particularly in the control group (adjusted odds ratio = 2.36, $p < .01$).

Motivational interviewing is an evidence-based approach to behavior change counseling demonstrated to be effective in multiple meta-analyses. Dr. Ehrlich-Jones is an expert in motivational interviewing and has used it successfully in previous physical activity and behavior change trials. Dr. Ehrlich-Jones is an experienced trainer and a member of the international MI Network of Trainers (MINT). Dr Bombardier, also an experienced trainer and member of the MINT, will assist her with the training. Fidelity to the treatment protocol will be assured through education, specific training in protocol related procedures and practicing and troubleshooting the procedures in role-plays with staff in the intervention group. During the trial, Dr. Ehrlich-Jones will assure fidelity through completion of session content and via review of audiotaped sessions for MI skill.

After all training is complete, each therapist in the MI training and coaching group will provide Dr. Ehrlich-Jones with two audio recordings so that she and Dr. Bombardier can assess the therapists for MI competency using the MITI 4.2.1. Based on prior research training of rehabilitation professionals as well as published research, basic competency in MI can be attained with this amount of training and coaching.

All research team members will complete CITI training, and receive training on the informed consent process, and data collection, as appropriate to their role in the study.