A Comparison Study of Diagnostic Outcomes between the Music Therapy Assessment Tool for Awareness in Disorders of Consciousness (MATADOC) and the Coma Recovery Scale-Revised (CRS-R)

Caitlyn E. Bodine

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A COMPARISON STUDY OF DIAGNOSTIC OUTCOMES BETWEEN THE MUSIC THERAPY ASSESSMENT TOOL FOR AWARENESS IN DISORDERS OF CONSCIOUSNESS (MATADOC) AND THE COMA RECOVERY SCALE-REVISED (CRS-R)

by

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A Thesis submitted to the Graduate College in partial fulfillment of the requirements for the degree of Master of Music
School of Music
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Wendy Magee, Ph.D., MT-BC
The purpose of this study was to explore preliminary external validation of a standardized music therapy assessment tool used in the detection of awareness with the DOC patient population with an external reference standard. Eight subjects were administered both the MATADOC and the CRS-R within five days of one another, and results were compared on the levels of overall diagnosis, analogous domain subscales, and intra-assessment relationships between individual domains and overall diagnosis. Results indicated a very strong level of agreement for overall diagnosis ($r_s = .85, p < .01$), very strong relationships between the auditory and visual components of the two assessments ($r_s = .76, p < .05$, and $r_s = .81, p < .05$, respectively), and a strong, but non-significant relationship between arousal scores on the two assessments ($r_s = .68, p > .05$). The MATADOC demonstrated very strong relationships between each of the auditory, visual, arousal, and verbal command domains to the overall diagnostic outcome. The CRS-R showed a very strong relationship between the auditory domain and the overall diagnostic outcome, and a strong relationship between the communication domain and the overall diagnostic outcome. All of the findings have positive implications for the use of MATADOC as a diagnostic measure or a companion assessment in questionable or borderline cases. Limitations include a small sample and a single MATADOC assessor who both administered and scored the MATADOC sessions.
ACKNOWLEDGEMENTS

The diagnosing and care of patients with Disorders of Consciousness is fraught with tremendous complexity, and I would like to thank each of the patients, family members, and caregivers who agreed to participate in this research. Their determination and perseverance through incredibly challenging circumstances has been my inspiration.

Secondly, I would like to thank the members of my committee, Ed Roth, Brian Wilson, and Dr. Wendy Magee, for their support and valuable feedback along the way, and especially Ed Roth, for making himself available for countless ‘computation’ sessions and for providing a sounding board as I speculated on my findings.

This work would have been impossible without the cooperation of Spectrum Health Neurological Rehabilitation Hospital, and the hospital’s music therapist, Erin Wegener, who not only facilitated Spectrum’s approval of the research, but also administered and scored every single MATADOC session used in this project.

And finally, many thanks to my parents—Linda Bodine, for her cheerful enthusiasm and unconditional capacity to listen to every detail of my project and process, and John H. Bodine, who read through various drafts, let me wax poetic on subjects that only partially made sense to the uninitiated, listened to my frustrations when the process felt tedious, and never relented on the message ‘keep going, keep going, keep going.’

Caitlyn E. Bodine
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CHAPTER I
INTRODUCTION AND REVIEW OF LITERATURE

Introduction

Following brain injury (BI), a person’s awareness of self and of the environment is often impacted along a continuum, a condition which the medical community has termed disorders of consciousness (DOC) (Bernat, 2006). A person’s level of awareness at varying stages post injury can give significant insight into their prognosis for recovery. An unfavorable prognosis would likely result in denial or discontinuation of rehabilitative treatment and affect caregivers’ decision-making regarding future care planning, family support, and life sustaining measures. An accurate diagnosis of awareness, therefore, is vitally important in determining a person’s access to care and quality of life.

Historical Context

“Awareness of the self and the environment” was how William James defined consciousness in the 1890s (James, 1902). As far as James was concerned, consciousness was evidenced by reactions elicited by events in the internal or external realms. In the 1960s with the widespread use of the artificial respirator, awareness and arousal were distinguished from one another resulting in the term vegetative state (VS) in which one is awake, but remains without communication or behavioral signs of consciousness (Jennett & Plum, 1972). The term vegetative referred to preserved autonomous functioning of the nervous system (e.g., sleep-wake cycle, respiration, digestion, etc). The term persistent was added in cases where VS lasted for more than one month post injury. More than 20 years later, the Multi-Society Task Force was convened to clarify and further define VS (Multi-Society Task Force on PVS, 1994). The report emphasized the presence of sleep-
wake cycles in this state, as well as the inability to experience the environment despite being in a wakeful state. This report also proposed the term permanent be added in cases where the state was considered irreversible (unfortunately both resulting in the acronym PVS).

In the mid 1990s, not long after the Multi-Society Task Force Report on PVS was released, a second workgroup was formed of representatives in the fields of neurology, neurosurgery, neuropsychology, physical medicine and rehabilitation, nursing, allied health, and bioethics. This workgroup was called upon to resolve discrepancies between the diagnostic and prognostic recommendations offered by the Task Force and the position statement published a year later by the American Congress of Rehabilitation Medicine (ACRM) (American Congress of Rehabilitation Medicine, 1995). The Aspen Neurobehavioral Workgroup reconciled the diagnostic and prognostic guidelines for VS, and then shifted its focus to delineating a diagnostic category for those cases in which minimal behavioral signs of consciousness were present. Operational criteria for the Minimally Conscious State (MCS) (initially called the Minimally Responsive State) were published in 2002 by the American Academy of Neurology (Giacino et al., 2002). Although terminology continues to be discussed, as many clinicians have expressed discomfort with the term vegetative, the currently accepted terminology for the stages of DOC includes coma, VS, MCS (sometimes further classified into MCS – and MCS+), and Emerging from MCS.

*Diagnostic Categories Elaborated*
Although the term coma is often used as an umbrella term for anyone in DOC, a coma state is actually indicative of a complete failure of the systems for arousal. A person in coma does not display spontaneous eye opening, nor can he be awakened by vigorous sensory stimulation (Giacino et al., 2002). Although coma is considered a category within DOC, this paper does not include coma in its investigation.

As mentioned previously, a person in VS has preserved autonomic function (i.e., respiration, digestion, sleep-wake cycles, thermoregulation, etc), but an absence of any behaviors indicating environmental or self-awareness, interpersonal interaction, or sustained purposeful responses to sensory stimulation (Hirschberg & Giacino, 2011). Behaviors that are observed are unable to be replicated or sustained and are deemed to be non-purposeful and involuntary (Multi-Society Task Force on PVS, 1994).

MCS is defined as a state where consciousness is severely altered—where a person can demonstrate minimal but clear behavioral evidence of awareness of the self or environment (Giacino et al., 2002). A person in MCS can demonstrate cognitively mediated behaviors that are reproducible or able to be sustained long enough to distinguish them from reflexive behaviors, but not consistently (Giacino et al., 2002). Repeated or extended assessments may be necessary to determine whether simple responses that are observed infrequently occur in response to a specific event or randomly. Intelligible verbalizations, simple command following, gestural or verbal yes/no responses, and behaviors triggered by environmental stimuli which cannot be attributed to reflexive activity are all indicative of MCS (Giacino et al., 2002).
When functional communication or use of objects is established, however, a person is considered to be Emerging from MCS. Whereas purposeful behavioral responses may be inconsistent in MCS, *consistent* demonstration is required for a diagnosis of Emerging to be given (Giacino et al., 2002).

While each of these categories is mutually exclusive within DOC, a patient will often progress through these levels during rehabilitation as the brain heals. Rate of recovery and whether or not a patient pauses at any stage varies from case to case, based on the nature and extent of the injury. While some people eventually emerge from DOC and recover fully, many remain at some point along the DOC continuum for the rest of their lives (Bruno, Vanhaudenhuyse, Thibaut, Moonen & Laureys, 2011).

Unfortunately, determining a person’s location on that continuum can be extremely challenging due to the many complicating factors often present with severe BI that limit a person’s ability to respond to stimulation. Many people who have sustained a severe BI present with significant motor impairments, communication deficits, and extreme variability in arousal and alertness. None of which are necessarily related to whether or not a person is aware of his or her surroundings (Bruno et al., 2011; Giacino et al., 2009). Neuroimaging technology is beginning to reveal important insights regarding neural activation patterns for people diagnosed in the various categories of DOC, however the neural correlates for consciousness have yet to be mapped out. Thus, without a concrete diagnostic test to determine awareness, medical personnel must rely on behavioral assessments for the time being (Giacino et al., 2009).

*Neurobehavioral Assessments*
Several validated behavioral assessments are currently in use in hospitals and rehabilitation facilities worldwide. Common domains examined across standard behavioral assessments of consciousness include visual responsiveness, auditory responsiveness, arousal, functional communication, and motor responsiveness. The ACRM recently conducted a systematic and thorough review comparing behavioral assessment scales for DOC and provided evidence-based recommendations for the clinical use of these scales based on content validity, reliability, diagnostic validity, and the scale’s ability to predict functional outcomes (Seel et al., 2010). Diagnostic validity is currently considered ‘unproven’ for all scales because there is yet no absolute method of determining whether an outcome is ‘correct.’ Therefore, assessments were rated on ‘criterion validity,’ or the degree to which an assessment corresponds to a reference standard developed for a particular diagnosis. While the criterion validity for the Coma Recovery Scale-Revised (CRS-R) is unproven, it received the highest overall score with an ‘excellent’ rating for both content validity and test-retest reliability, and a ‘good’ rating for internal consistency and inter-rater reliability. Based on its performance across categories, the CRS-R was the recommended scale for diagnosis in DOC with only minor reservations (Seel et al., 2010).

The CRS-R consists of 23 hierarchically arranged items and tasks comprising six subscales addressing auditory, visual, motor, oromotor, communication, and arousal functioning. Within each domain, the hierarchy spans responses associated with brain stem, cortical, and subcortical processes, thus the lowest responses represent reflex activity and the highest responses represent cognitively mediated behaviors (Giacino, Kalmar, & Whyte, 2004; Giacino et al., 2009).
**Misdiagnosis within DOC**

Although the CRS-R has been endorsed by the ACRM, all behavioral assessments have limitations based on biases contributed by the examiner, the environment, and the patient (Giacino et al., 2009; Gill-Thwaites, 2006). Given the difficulty inherent in determining purpose or lack thereof behind behaviors which may be slight, hard to detect, or infrequently occurring, subtle signs of consciousness may be missed. Without specific neural correlates of consciousness established to either confirm or dispel behavioral diagnoses by way of neuroimaging, misdiagnosis of patients unable to speak or follow commands is alarmingly high.

Previous studies have shown that of patients diagnosed as VS, roughly 40% did in fact have some awareness of their environment (Andrews, Murphey, Munday, & Littlewood, 1996; Childs, Mercer & Childs, 1993). Despite the clarification of the operant criteria for MCS in 2002, a study by Schnakers et al. (2009) found that of patients believed to be in VS, 41% were misdiagnosed. In cases where the diagnosis was unclear, 89% were found to be in MCS, not in VS, and an additional 10% of those diagnosed with MCS had actually emerged from this state.

Due to the fallibility of neurobehavioral assessments and the current lack of diagnostic validity for DOC, it is recommended that several assessments be administered and a wide range of eliciting stimuli be presented across several sensory modalities (Giacino et al., 2002). If more than one assessment deliver the same diagnosis, diagnostic accuracy is more likely. However, differing outcomes may indicate a need for further testing. It is in the best interest of patients, considering all the complicating
factors mentioned previously, to give the best chance for optimal performance, particularly in cases where the outcome is questionable.

As far as sensory modalities are concerned, research suggests that the auditory sense is the most frequently intact following BI (Gill-Thwaites, 1997; Gill-Thwaites & Munday, 2004). During the development of a neurobehavioral assessment that tests responsiveness across all the sensory modalities, 66.7% of the 27 patients who showed awareness demonstrated responsiveness in only the auditory modality. An additional 25% were responsive in both the auditory and visual modalities (Gill-Thwaites & Munday, 2004). Interestingly, other research has indicated that impairments in the visual domain may be a major cause of misdiagnosis in DOC. Of the 43% of VS patients misdiagnosed in their study, Andrews et al. (1996) found that 65% of these were blind or severely visually impaired. Thus the auditory domain would appear to be an appropriate one to expand upon when attempting to detect awareness in DOC, particularly in cases where CRS-R outcomes are borderline or questionable.

**Auditory Processing in DOC**

Auditory evoked potentials at the level of the brainstem were normal for subjects in VS and MCS, as well as healthy controls in a study comparing auditory processing between these populations (Boly et al., 2004). However, higher order associative areas of the brain (specifically Brodmann area 22) were active only in control and MCS subjects. This suggests that while the brains of all subjects showed activation in response to auditory stimuli (Brodmann 41 and 42), only those in MCS and controls showed activation in areas associated with interpretation of sound stimuli, selective auditory
attention, and the analysis of the temporal acoustic features of speech. While this study did find differences in activation patterns, the differences were not determined to be significant. One reason offered was the lack of emotional salience of the stimulation presented, given the clinical experience that patients in MCS are often more responsive to stimuli with high emotional content (Boly et al., 2004).

The auditory portion of the CRS-R allows for two kinds of auditory stimuli to be presented: verbal commands (which rely on intact language processing skills and the ability to translate comprehension (if it exists) into action), and a handclap, voice or other sudden noise presented outside of the field of vision on both sides of the head, alternately. In the case of the handclap or sudden noise, the assessor is looking for a startle response at the lower level of function or localization to the voice or sound with either eye or head movement (Giacino & Kalmar, 2004). If patients are indeed more likely to respond to stimuli with emotional salience as suggested by Boly et al., (2004), a stimulus somewhere between a verbal command and a handclap may be indicated.

Music as a stimulus capitalizes on preserved auditory function and eliminates the need for intact language processing capacity. The emotion-triggering quality of music, particularly a selection known to be meaningful to the patient, could increase arousal, thereby allowing a patient brief access to higher-level responses (Sloboda, 1991). Following this logic, the Music Therapy Assessment Tool for Awareness in Disorders of Consciousness (MATADOC) was developed to complement other standardized coma recovery scales, providing higher sensitivity for diagnosis related to auditory stimulation (Magee, 2005; Magee, 2007; O’Kelly & Magee, 2013; Magee, Siegert, Daveson, Lenton-Smith & Taylor, 2013).
The MATADOC consists of 14 items for assessment including the behavioral domains typically addressed in DOC: visual, auditory, command following, arousal, and motor responsiveness. Auditory responsiveness, in particular, is evaluated across the entire assessment noting any behaviors that occur contingently to the presence or absence of an auditory stimulus. The principle subscale culminates in a diagnosis of VS, MCS, or Emerging and has fared well under rigorous testing for internal consistency, test-retest reliability, and inter-rater reliability (Magee et al., 2013).

When compared to the Sensory Modality Assessment and Rehabilitation Technique (SMART), the MATADOC was found to have higher sensitivity in the auditory and visual domains (O’Kelly & Magee, 2013). Given the MATADOC’s strength within the auditory domain, and the somewhat limited range of auditory stimuli and behavioral responses sought in the auditory function scale of the CRS-R, the MATADOC could be a desirable companion assessment to the CRS-R to either confirm a diagnosis or highlight a need for further testing.

This pilot study was the first comparing the MATADOC and the CRS-R and, while not a true replication, used the study conducted by O’Kelly & Magee (2013) comparing the MATADOC and the SMART as a reference for design and analysis. The purpose of this study is to explore preliminary external validation of the diagnostic capacity of a standardized music therapy assessment tool used in the detection of awareness with the DOC patient population with an external reference standard. Although the MATADOC includes separate sections useful for treatment planning and clinical care, this study will only address the principal subscale used for diagnosis.
Research Questions

1. What is the level of agreement of diagnosis between the MATADOC and CRS-R?

2. Are there significant differences in scores between each comparative domain (auditory, visual, motor, arousal, and communication) of the MATADOC and CRS-R?

3. What contrasting sensitivities exist between the two tools? (Within each assessment, how well does each domain correspond to the diagnostic outcome?)
CHAPTER II

METHOD

Participants

Participants were recruited from a convenience sample on the Brain Injury unit of Spectrum Health Neurological Rehabilitation Hospital in Grand Rapids, Michigan (n = 8). Participants were considered for inclusion if they:

- Were between 16 and 70 years of age
- Were medically stable
- Had a DOC diagnosis with level unconfirmed (i.e. VS, MCS, Emerging)

Because participants themselves were not able to give informed consent, permission was obtained from family members and/or legal guardians. Participants were excluded from the study if they:

- Became medically unstable at any point during the study
- Had a known pre-morbid hearing impairment
- Had a previous diagnosis of musicogenic epilepsy

Instruments

Two assessments were utilized for this study, the CRS-R and the MATADOC.

CRS-R

The CRS-R includes six items for assessment—auditory function, visual function, motor function, oromotor/verbal function, communication, and arousal, all further divided into specific behavioral responses ranging from no response to those associated
with purposeful, cognitively-mediated behaviors. If a patient demonstrates responses that indicate it is appropriate to administer, the CRS-R also has a supplementary item called the Assessment of Contingent Behavior to note behaviors that occur and the stimuli that appear to elicit them. This portion is not included in the scoring for diagnosis, but could be used to document behaviors that might warrant a re-evaluation, or to inform assessors of behaviors that could be targeted when giving verbal commands during the assessment.

A complete CRS-R is conducted in one session. For each domain an assessor will present specific stimuli or tasks, and if the desired response is achieved, will present the next task in the hierarchy until the highest level response is determined. A total score will range from 0 (lowest) to 23 (highest). Categorical diagnosis (VS, MCS, or Emerging) is not determined based on a specific numerical score, but rather the presence of certain indicated behaviors within each domain. Certain response levels within each item denote a behavior indicative of MCS, and a demonstration of any one of these behaviors would result in an overall diagnosis of MCS. If none of the behaviors designating MCS is displayed in any domain, a diagnosis of VS would be given (Giacino & Kalmar, 2006). In order to be considered Emerging, a patient must demonstrate the highest level response within either the motor function or communication scale. Not every behavioral assessment has the capability of scoring behaviors considered to be Emerging, and thus including Emerging as a possible diagnostic outcome is another strength of the CRS-R. The CRS-R is currently considered to be the strongest assessment that can do this, and while not yet demonstrated through research, the fact that the MATADOC can also deliver an outcome of Emerging could be a potential strength for it as well (Seel et al, 2010).
MATADOC

As mentioned previously, the MATADOC includes 14 items for assessment including the behavioral domains typically addressed in DOC: auditory, visual, motor, communication, and arousal. Three subscales within the MATADOC each have a specific purpose. Items 1-5 make up the Principal Subscale: Essential Categories, examining essential behaviors and culminating in a diagnosis of VS, MCS, or Emerging. Clinical intervention is informed by the musical parameters subscale in items 6-7, and finally items 8-14 contain clinical items helpful for goal setting and clinical care (Magee, 2007).

In order to account for variability in awareness and arousal, a complete MATADOC consists of four sessions, lasting approximately 12-25 minutes each, over the span of eight to ten days. Each session includes at least 3 min of observation immediately prior to and following the active interventions for the assessor to note any behaviors occurring (frequency and/or duration) in the absence of stimulation (Magee, 2007).

Administration of the MATADOC consists of four basic interventions which can be expanded based on the patient’s tolerance and level of functioning. The opening intervention is a simple song presented live with voice and an instrument of the clinician’s choice, entrained to the subject’s breathing, containing the words “hello” and the subject’s name. During the opening song, the clinician varies the timbre (guitar and voice), dynamics, and location of the stimulus in order to observe any changes in
behavior that coincide with changes in the stimulus. A visual response task follows in which a musical instrument or image (i.e. photo of an instrument, musician, or album cover, etc) is presented in the subject’s field of vision to the left and the right of the patient in turn. A verbal command is given to “look at the ___,” and the object is moved into all four quadrants of the participant’s visual field to assess the subject’s ability to pursue and track a visual stimulus.

In the auditory response task, a verbal command is given to “turn toward the sound,” and four trials of a musical stimulus (i.e. hand bell tone, plucked guitar string, etc) are presented on both the subject’s left and right sides just outside of the field of vision. The MATADOC specifies that there should be two distinct musical stimuli, representing two distinct timbres or pitch registers, presented during the auditory portion of the assessment. While the onset should be sudden in order to ascertain whether there might be an auditory startle response, care should be taken to assure sounds are presented at a comfortable volume. The final standard intervention consists of a presentation of familiar/preferred music, determined based on interviews with friends and family of the patient, with documentation of any behavioral changes during the music stimulus. The presentation of familiar music was presented live by the music therapist assessor, except in cases where recorded music was necessary for authenticity (i.e. a patient of Mexican origin who prefers mariachi music). Depending on the patient’s response and tolerance, an assessor may choose to present additional tasks to assess command following, choice making, and social interaction or to increase the complexity of one or more of the basic interventions to examine these areas (Magee, 2013a).
Certain behaviors within each categorical hierarchy are indicative of MCS on the MATADOC, however unlike the CRS-R, the presence of one of these does not automatically translate into a diagnosis of MCS. Rather, the MATADOC scoring system converts the overall response across categories into a numeric score for each of four sessions, which then corresponds with a diagnosis (0 – 3 = VS; 4 – 7 = MCS; 8 and above = Emerging) (Magee, 2013b). From there, an overall diagnosis is assigned based on frequency of outcomes of all four sessions, and additionally arousal scores in cases where there is an equal division of two different diagnoses.

Procedure

MATADOC

Four MATADOC sessions were scheduled over a ten-day period for each participant in the study. Session times were chosen in accordance with the rest of the participants’ rehabilitation program, and thus time of day varied based on meals, rest periods, and therapy sessions. Each session began and ended with three minutes of observation of the participant at rest, designed to give the clinician an opportunity to note any behaviors that occurred in the absence of stimulation, and followed a clearly defined protocol including primarily live music, but also recorded music where necessary for authenticity (i.e. a patient of Mexican origin that has a preference for mariachi music). Sessions also included both unfamiliar music, improvised at a tempo that was matched to the participant’s breathing rate and response level, and familiar music known to be meaningful based on an intake interview completed with family members. Sessions lasted no more than 25 minutes depending on the participants’ response and level of fatigue, and each was video recorded for later analysis and scoring.
The MATADOC sessions were administered and scored by the hosting hospital’s on-staff music therapist, who underwent a 1.5-day training facilitated by the author of the MATADOC. Additional one-on-one coaching post-training was then provided in order to reach a level of ‘competency.’ The assessor had six years of experience working with the DOC patient population. Due to hospital policies, students who were not affiliated with the hospital in some way (i.e. residency, internship, etc) were not allowed to have contact with patients or protected health information. Thus, once the MATADOC sessions were administered and scored by the music therapist clinician, de-identified data was sent to the student researcher for analysis.

**CRS-R**

CRS-R scores were audited when a CRS-R had been conducted for clinical purposes within five days of the initial MATADOC session for each participant. If no CRS-R score was available within five days prior to the initial MATADOC session, a trained member of the Spectrum Health therapy team administered and scored the CRS-R for use in this study. CRS-R assessors’ experience working with the DOC population ranged from three – 15 years. Corresponding de-identified CRS-R scores were sent to the student researcher for analysis by the on-site music therapist clinician.
CHAPTER III

RESULTS

The purpose of this study was to explore preliminary external validation of a standardized music therapy assessment tool used in the detection of awareness with the DOC patient population with an external reference standard by (a) examining the level of agreement of diagnostic outcomes between the MATADOC and CRS-R, (b) exploring differences between comparable domains between the two tools, and (c) comparing sensitivities between the two assessments (if present) relative to the domains addressed. Research questions were as follows:

1. What is the level of agreement of diagnosis between the MATADOC and CRS-R?
2. Are there significant differences in scores between each comparative domain (auditory, visual, motor, arousal, and communication) of the MATADOC and CRS-R?
3. What contrasting sensitivities exist between the two tools? (Within each assessment, how well does each domain correspond to the diagnostic outcome?)

Demographics

Eight participants were included in this study. Demographic data including gender, age, etiologies, and length of time since injury is shown in Table 1.

Research Question #1

What is the level of agreement of diagnosis between the MATADOC and CRS-R?
The categorical diagnostic outcome (VS, MCS, or Emerging) between the CRS-R and the MATADOC were in agreement for five out of the eight subjects. In order to make statistical comparisons, Z scores were calculated between the CRS-R and the MATADOC raw numeric scores, as the scalar range differed between the two (0-23 for CRS-R and 0-17 for the MATADOC). In the case of the MATADOC, as there were four sessions with numeric data that factored into the categorical diagnosis, determining a basis for comparison with the CRS-R’s one set of raw numeric data required the researcher to condense the MATADOC numeric scores into one set of data. The student researcher chose to use the numeric data from the MATADOC administration that was closest in date to the corresponding CRS-R administration in effort to best minimize any differences in awareness due to progressive recovery or deterioration. However, a decision to use the mean score of all four MATADOC sessions could have also been appropriate and may have yielded slightly different results. This will be discussed further in the Discussion section.

Table 1

<table>
<thead>
<tr>
<th>Subject</th>
<th>Gender</th>
<th>Age</th>
<th>Etiology</th>
<th>Months since injury</th>
<th>Days between CRS-R and selected MATADOC session</th>
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</tbody>
</table>

*Note. TBI = traumatic brain injury*

*aBecause the MATADOC administration spanned 8-10 days, days between the assessments was calculated from the CRS-R and the MATADOC session closest in date to the CRS-R*
Statistical analysis utilizing z scores for the CRS-R numeric outcome and the raw numeric score for the selected MATADOC session (of the four), revealed a very strong positive correlation between the two tests, $r_s = .85$, $p < .01$. Categorical outcomes as well as overall numeric raw scores (pre-conversion in the case of the MATADOC) are shown for both assessments in Table 2. Tables 3 and 4 contain complete scores (domains and outcomes) for the CRS-R and the MATADOC, respectively.

Table 2

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Note. MATADOC numeric ratings were taken from the MATADOC session delivered closest in date to the CRS-R. CRS-R scores are out of a possible 23. MATADOC scores are out of a possible 17.

Table 3

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TOTAL / OUTCOME

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Note. Arousal scores could not be converted into ranked scores because the CRS-R did not assign diagnostic markers to any of the behavioral levels within the domain.

*Converted scores were used for correlation tests in this study, but are not a part of the CRS-R scoring process.

Table 4

**MATADOC Raw Ratings and Converted Scores**

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Table 4 - continued

<table>
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<tr>
<th>Participant 8</th>
<th>Visual</th>
<th>Auditory</th>
<th>Awareness of Mus Stim</th>
<th>Verbal Commands</th>
<th>Arousal</th>
<th>Total</th>
<th>Outcome</th>
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<tr>
<td></td>
<td>1</td>
<td>2</td>
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<td>4</td>
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<td>14</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>8</td>
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</tbody>
</table>

Note. 'Converted Scores,' are ranked according to 0 = VS, 1 = MCS, 2 = Emerging. Sum totals of converted scores correspond to 0-3 = VS, 4-7 = MCS, 8+ = Emerging.

Research Question #2

Are there significant differences in scores between each comparative domain (auditory, visual, motor, arousal, and communication) of the MATADOC and CRS-R?

The degree of relationship between comparable behavioral response domains (auditory, visual, and arousal) on both tools was also examined using the Spearman test for correlation (Table 5). The auditory and visual domains were compared after calculating z scores (given the scalar differences between the CRS-R and MATADOC), however as the scalar range for arousal was consistent between the two tools, z scores were not needed in that domain. To maximize the potential for accurate comparison of the status of patient awareness between the two assessments irrespective of recovery or deterioration over time, again, the single MATADOC session closest in date to the administration of the CRS-R was used (a rationale for choosing this method of analysis will be explained further in the discussion section).
Scores in the auditory domain between the two assessments demonstrated a strong positive relationship, $r_s = .76, p < .05$. Scores in the visual domain were found to be very strongly positively correlated, $r_s = .81, p < .05$. The scores for arousal demonstrated a strong positive relationship, but not at a level determined to be statistically significant, $r_s = .68, p > .05$.

Research Question #3

*What contrasting sensitivities exist between the two tools? (Within each assessment, how well does each domain correspond to the diagnostic outcome?)*

In order to determine the degree of relationship between each individual domain and the total diagnostic outcome for the MATADOC, a mean score was calculated for each domain from all four MATADOC sessions for each participant (a rationale for this method is included in the discussion section). The three diagnostic categories (VS, MCS, Emerging) were assigned a numeric rank in agreement with the values assigned to each domain in the conversion process of scoring the MATADOC (e.g. VS = 0; MCS = 1; Emerging = 2) (See Table 4, ‘Converted Scores’). The Spearman correlation coefficient was then calculated between the mean score of each domain (a value between 0 and 2) and the rank value assigned to the diagnostic outcome.

<table>
<thead>
<tr>
<th></th>
<th>$r_s$</th>
<th>significance</th>
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</thead>
<tbody>
<tr>
<td>Auditory</td>
<td>.76</td>
<td>$p &lt; .05$</td>
</tr>
<tr>
<td>Visual</td>
<td>.81</td>
<td>$p &lt; .05$</td>
</tr>
<tr>
<td>Arousal</td>
<td>.68</td>
<td>$p &gt; .05$</td>
</tr>
</tbody>
</table>
Likewise for the CRS-R, raw scores within each domain were first converted to a numeric rank (e.g. VS = 0; MCS = 1; Emerging = 2) based on whether the behavior was classified as triggering an overall diagnosis of MCS or Emerging. If neither of these was indicated for a particular response level, the rank assigned was 0 (See Table 3, ‘Converted (Ranked) Scores’). Once the raw domain scores had been converted, the overall diagnosis for each participant was similarly codified, and a Spearman correlation coefficient was calculated for each domain with the diagnostic outcome. Spearman correlation coefficients for each domain on each assessment are shown in Table 6, and how these individual domain relationships compare to their overall diagnostic counterpart are illustrated in Figure 1.

Table 6
CRS-R and MATADOC Domain Relationships with Diagnostic Outcomes

<table>
<thead>
<tr>
<th>Domain</th>
<th>CRS-R</th>
<th>MATADOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auditory</td>
<td>.80*</td>
<td>.94*</td>
</tr>
<tr>
<td>Visual</td>
<td>.69</td>
<td>.93*</td>
</tr>
<tr>
<td>Motor</td>
<td>.27</td>
<td></td>
</tr>
<tr>
<td>Oromotor/Verbal</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Communication</td>
<td>.72*</td>
<td></td>
</tr>
<tr>
<td>Arousal</td>
<td>N/A</td>
<td>.82*</td>
</tr>
<tr>
<td>Awareness Musical Stimuli</td>
<td></td>
<td>.54</td>
</tr>
<tr>
<td>Verbal Commands</td>
<td></td>
<td>.82*</td>
</tr>
</tbody>
</table>

*Note. Once the Oromotor/Verbal scores were ranked, all participants had the same score, therefore the Spearman test for correlation did not yield any output. The behavioral levels in the CRS-R Arousal domain were not linked to a categorical diagnosis, therefore a correlation test could not be performed.

*p < .05
Figure 1. Comparative relationships between individual domains and the diagnostic outcome of each assessment. Oromotor/Verbal scores could not be correlated because all participants had the same score once the levels were ranked. The CRS-R Arousal correlation test could not be performed because behavioral response levels in this domain had no variation in the indicating diagnostic outcome.
CHAPTER IV

DISCUSSION

The purpose of this study was to explore preliminary external validation of a standardized music therapy assessment tool used in the detection of awareness with the DOC patient population with an external reference standard by (a) examining the level of agreement of diagnostic outcomes between the MATADOC and CRS-R, (b) exploring differences between comparable domains between the two tools, and (c) comparing sensitivities between the two assessments (if present) relative to the domains addressed. 

Research questions were as follows:

1. What is the level of agreement of diagnosis between the MATADOC and CRS-R?

2. Are there significant differences in scores between each comparative domain (auditory, visual, motor, arousal, and communication) of the MATADOC and CRS-R?

3. What contrasting sensitivities exist between the two tools? (Within each assessment, how well does each domain correspond to the diagnostic outcome?)

Research Question #1

What is the level of agreement of diagnosis between the MATADOC and CRS-R?

As shown in Table 2, the overall diagnostic outcomes between the CRS-R and the MATADOC were closely related. While the categorical diagnoses (VS, MCS, or Emerging) were divergent in three of eight cases, perhaps suggesting a weak relationship between the two tests, a more detailed comparison of the numeric data associated with
the overall score revealed that, categorical nomenclature aside, the relationship of the actual numeric scores was very strong ($r_s = .85, p < .01$). Because true validity cannot currently be determined for any behavioral assessment of awareness given the lack of knowledge of the neural make-up of consciousness, the best measure of accuracy to date is external validation against a recommended reference standard. The CRS-R received the strongest ratings in the systematic review of neuro-behavioral assessments, thus it is an appropriate standard for comparison among newer or less thoroughly vetted assessments (Seel et al., 2010). Although the small sample size obtained for this study requires caution when drawing conclusions, the strong positive correlation between the outcomes of the MATADOC and the CRS-R suggests that the MATADOC could be an appropriate assessment for the DOC population, yielding a diagnosis that has external validity with the current reference standard (CRS-R).

It is interesting to note that in all three cases where the MATADOC and CRS-R categorical outcome differed (Participants 6, 7, and 8), the MATADOC rating was the higher of the two (i.e. MCS vs VS, etc). While this could be purely due to chance, other possible reasons include MATADOC rater bias, higher sensitivity of the MATADOC, or in fact, less sensitivity of the MATADOC.

Because only one clinician scored the MATADOC sessions—the same, in fact, who administered the sessions, there is potential for subjectivity to be present in the MATADOC scores (i.e. a clinician who tends to give the benefit of the doubt versus one who requires responses to be clearly discernible, etc).
As we will discuss in more detail later, the CRS-R response levels tended to be much more highly specific and defined than those of the MATADOC. If the MATADOC was able to incorporate and count more kinds of behavioral responses as indicative of awareness due to fewer restrictions on what kinds of response behaviors could be accepted, this could have resulted in both higher overall scores on the MATADOC and also an assessment with higher sensitivity. This would only be true, however, if the responses were, in fact, evidence of a patient’s awareness perhaps not captured in the highly defined acceptable responses of the CRS-R. However, if the highly defined acceptable response parameters of the CRS-R function to keep the clinician from attributing non-purposeful or limbic behaviors to evidence of awareness, then the higher MATADOC scores could be suggestive of a greater likelihood for false positives.

Whether chance or rater bias played a role in this case could be further examined with both a larger sample and the involvement of more than one MATADOC administrator and rater. A study comparing more than two assessments, while still not able to determine true validity, could provide more information in cases where the MATADOC and the CRS-R differed. If the other assessments examined tended to be more closely related to one or the other, then more insight into sensitivity could be suggested. In any case, the strength of relationship determined by analysis of the numeric scores in this case, mitigates the need to isolate a cause.

It should be noted, however, that while the numeric scores gave a means of more detailed comparison than simply a categorical one, deriving the numeric scores for comparison required some decision-making on the part of the researcher, as mentioned
previously. The MATADOC takes place over four sessions each with separate raw ratings, all converted into ranked domain scores and then summed to give four total scores, then converted again into the categorical diagnosis where 0-3 = VS, 4-7 = MCS, and 8+ = Emerging. From these four categorical diagnoses, the clinician assigns one overall diagnosis based on frequency, and additionally, arousal scores in cases where there is an equal division of two different diagnoses across the four sessions. As this one overall diagnosis is derived from the four outcomes, there is no one numeric overall score associated with it. Therefore, comparing the outcomes of these two assessments required the MATADOC scores to be condensed somehow into one set of numeric values. The two best options for condensing the MATADOC data seemed to be either a) taking a mean score for each domain and total outcome across all four sessions, or b) using the actual data of only one of the four MATADOC sessions, the most logical of which would be the session administered closest in date to the CRS-R in order to minimize potential differences in patient awareness due to recovery or deterioration over time.

While using the mean scores may have better reflected the MATADOC method and its intention to document the patient’s highest level of function over time, selecting a single MATADOC session seemed to be a more accurate ‘apples-to-apples’ comparison between the two assessments. The two resultant points for comparison were then both actual results collected during respective evaluations (rather than one actual and one consolidated result), and in terms of the repeated measures design, as closely related as possible with regard to arousal level, effects of any medications, and the general recovery status. Also since the MATADOC scoring and conversion process specifically does not take a mean score across the four sessions when determining the one overall diagnosis,
the researcher felt that selecting a single MATADOC session for the inter-assessment comparisons conformed to better research practice. This meant, however, that 75% of the data collected during the MATADOC sessions was ultimately not included in the inter-assessment analyses, which surely could have impacted the results reported here. This will be further discussed later.

Considering that 75% of the MATADOC data collected was not included in the analysis comparing overall level of agreement between the two assessments, it is of note that the two evaluations still ended up with a very strong positive correlation of overall diagnosis ($r_s = .85, p < .01$). This could lead to questions of why the other three MATADOC sessions are necessary if the results of one session are so closely related to those of the CRS-R. In general, the four MATADOC scores for each participant tended to be fairly closely related to one another, but there were a few cases (see Table 4, Participants 2 and 3) where at least one session score was very different from the rest. Likely using a mean score across sessions for those two patients in particular would have yielded different results due to the variability in their scores. Questions could be raised as to why the patient was able to score much higher on one day than another, and which of the two days is an accurate representation of his or her level of awareness. If arousal, or simply a ‘good’ day versus a ‘bad’ day could be implicated, then it would be in the patients’ best interest to use a model like the MATADOC which could capture performance over time.

It would be interesting in future research, particularly with a larger sample, to compare the correlation chosen for this study (single MATADOC session) with one that uses a mean of all four MATADOC scores, and to speculate further on the benefits or
drawbacks of measuring performance over time. Multiple administrations may be especially helpful in discerning strengths, challenges, preferences, and motivators for treatment planning purposes, but evaluating the MATADOC’s usefulness as a treatment planning tool was beyond the scope of this study.

Research Question #2

Are there significant differences in scores between each comparative domain (auditory, visual, motor, arousal, and communication) of the MATADOC and CRS-R?

Analysis between comparable domains of the MATADOC and CRS-R (Table 3), determined how closely related a particular subject’s scores were in a common domain across both assessments. The only three domains the two assessments shared were auditory, visual, and arousal, thus only these were included in the analysis. All three domains had strong positive relationships, but only the auditory and visual domains reached a level of statistical significance. The strength of the relationship of these scores, as an item by item comparison, reinforces the previous suggestion of the MATADOC’s validity against the CRS-R as an external reference standard.

Arousal

Arousal was the one domain of the three compared in which the strength of the relationship did not reach statistical significance. Although still a moderately strong relationship ($r_s = .68$), it was the weakest of the three. Arousal was a tricky domain to compare between the two assessments and also to examine with regard to its role within either assessment (discussed later) because of its bimodal nature. For both assessments,
arousal was evaluated and the patient’s performance in this domain influenced a
diagnosis, but it also was a kind of pre-requisite for overall effectiveness of either test
across the remaining domains.

The assessments also defined and approached arousal somewhat differently. The
CRS-R documents arousal across the entire evaluation if the arousal is spontaneous, but if
not, there is a defined, graduated protocol of stimulation to elicit arousal. The highest
score, attention, is given if the patient fails to respond to no more than three verbal
prompts in the entire session. The next lower level, eye opening without stimulation, is
given if the patient’s eyes remain open for the duration of the assessment without the
need for tactile pressure. If the patient’s eyes remain closed, as alluded to above, the
assessor is instructed to apply tactile pressure, most often at the nailbed, to observe
whether the patient’s eyes open in response. And finally, a score of 0 is given if the
patient is unarousable.

The MATADOC, on the other hand, records arousal across the entire evaluation,
using gentle prompts to elicit or maintain arousal as necessary throughout, rather than
following a specific protocol. The MATADOC defines arousal as the patient having eyes
open or demonstrating active physical movement such as nodding his or her head within
interactions or hand movements to scratch, etc. A lack of arousal was defined as eyes
closed, no body movements, and heavier than normal breathing. Instructions are given
for the assessor to attempt to keep the patient aroused throughout the session by speaking
and using gentle physical prompts, but rather than functioning as a specific intervention,
this scale is designed to score the patient’s arousal by documenting for what portion of
the session the patient was alert, if at all. The MATADOC notes that low arousal will
likely affect all areas of test performance, and recommends considering rescheduling the evaluation in cases where arousal is low. It is interesting to note that in the two cases with notable variability across the four session scores, the high overall score occurred in conjunction with a high arousal score (participant 2, session 3 and participant 3, session 4) (See Table 4). The role of arousal in influencing the diagnostic outcome in both tests will be discussed more thoroughly later.

Table 7
Raw Arousal Scores

<table>
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<tr>
<th>Subject</th>
<th>MATADOC Arousal Mean&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Single Session MATADOC Arousal&lt;sup&gt;b&lt;/sup&gt;</th>
<th>CRS-R Arousal</th>
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<tbody>
<tr>
<td>1</td>
<td>1.25</td>
<td>2</td>
<td>0</td>
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<td>1.75</td>
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<td>2</td>
<td>2</td>
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<tr>
<td>4</td>
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<td>0</td>
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<tr>
<td>6</td>
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<td>8</td>
<td>3</td>
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<td>2</td>
</tr>
<tr>
<td>Mean</td>
<td>2.094</td>
<td>2.125</td>
<td>1.25</td>
</tr>
</tbody>
</table>

<sup>a</sup> MATADOC mean is derived from all four sessions administered for each patient. <sup>b</sup> Single session refers to the same selected MATADOC session used in the analysis for the inter-assessment comparisons.

While there is variability in the parameters defining this domain between assessments, as mentioned previously, it seems logical to the researcher that the noxious stimulus of the CRS-R would be more effective, at least for momentary arousal, than the gentle physical or verbal prompts described in the MATADOC. Interestingly, however, raw arousal scores on the MATADOC tended to be higher in general than arousal scores on the CRS-R (see Table 7). Again, while the descriptors accompanying the numeric score under the arousal domain were different between the two assessments, the numeric
scale used (0-3) was the same. This could suggest that music, as an emotionally salient stimulus interspersed throughout the assessment, is more effective at capturing and sustaining the patient’s attention throughout the evaluation. However, as mentioned previously, the small sample, the single MATADOC administrator, and the fact that the relationship proved statistically insignificant, compel the researcher to approach these insights with curiosity rather than authority. In future research, a rater, or perhaps a team of raters, trained to score both the MATADOC and CRS-R may be able to further explore comparisons between patient arousal during the two different assessments.

**Visual**

The visual domains of the MATADOC and CRS-R were the most strongly correlated of all three domains tested \((r_s = .81)\). This was somewhat surprising to the researcher given the different kinds of stimuli presented in each, and the different levels of complexity of presentation and allowable response therein.

The CRS-R protocol calls for a graduated approach of different stimuli and carefully defined acceptable responses as the Visual Function Scale progresses from least to most functional. It begins with the administrator passing a finger within 1 inch of the patient’s eye (which could be manually opened if necessary), taking care not to touch the lashes or create a breeze, to which the eyelid must flutter or blink in two of four trials (visual startle). The next level, fixation, involves a brightly colored or illuminated object presented 6 to 8 inches from the patient’s face and then moved quickly into the right, left, upper, and lower visual fields, to which the eyes must change from their initial fixation point and refixate on a new target for at least two seconds in at least two of four trials.
The next level, visual pursuit, uses a hand mirror positioned 4 to 6 inches in front of the face, a verbal encouragement to look at the mirror, and then slowly moving the mirror 45 degrees to the right and left of the vertical midline, and above and below the horizontal midline. The patient’s eyes must follow the mirror for 45 degrees without losing fixation in at least two trials in any direction.

The next level, object localization: reaching, consists of placing a relevant object within the field of vision, approximately 8 inches to the left or right of the resting position of the limb pre-identified as having the greatest range of motion, then instructing the patient to touch the object without providing any tactile cues. The patient must move the relevant limb in the correct direction within ten seconds of the command in three of four trials, although contact with the object is not required. The final level, object recognition, consists of the administrator commanding at least one object-related (discerning between two objects with either limb or eye movement) and one non-object related movement that the patient has been observed to demonstrate, but with low spontaneous frequency. The patient must respond discernibly and accurately within ten seconds on all four trials of both commands in order to score at this level. This task is actually the same task as the highest level of function on the Auditory subscale, consistent movement to command. Therefore if a patient scored at the highest level of function on the auditory scale (4), they would automatically score at the highest level of visual function (5) and vice versa.

The visual component of the MATADOC calls for the administrator to present a visual stimulus such as an instrument (without sound) or a picture of a musician in the patient’s field of vision and slowly move it into the upper, lower, left and right visual
fields. The patient’s response is considered inconsistent if instances of tracking or localization occur less than 75% of the opportunities given, whereas a consistent response requires a rate of 75% or greater. The highest level of response indicates that the patient can focus alternately at two different stimuli presented simultaneously, given a command to look at one or the other. While the aforementioned is the specific intervention designed to assess the visual component of the MATADOC, the manual encourages the administrator to reflect on the session as a whole and the patient’s response to any stimuli presented only in the visual mode (i.e. the assessor’s movements around the room, etc).

Although the two assessments approached the visual portion of the evaluation differently, the patient’s scores on both were closely related ($r_s = .81, p < .05$). This demonstrates how reliably the patient’s performance on the visual component of one of the assessments could predict his or her performance on the visual component of the other. The suggested stimuli in the CRS-R (mirror, illuminated object, etc) seemed to the researcher to be more broadly appealing in the base levels of awareness than the visual stimuli suggested in the MATADOC (instrument without sound, picture of a musician, etc), and yet, the two domains yielded a very strong positive relationship. Perhaps the indication in the MATADOC for the assessor to note visual responsiveness across the session as a whole (assessor’s movements through the room, etc) balanced out the difference in visual stimuli between the two. Or perhaps the suggested visual stimuli in the MATADOC hold more salience than expected given their association with music.

In at least one study (Andrews et al, 1996), impairments in the visual domain were implicated in a majority of cases where patients in MCS were incorrectly diagnosed as VS. While the meta-analysis by Seel et al (2010) did not detail performance in
individual domains, the CRS-R did receive a rating of ‘excellent’ for content validity. Therefore the fact that the MATADOC visual domain scores were strongly aligned with the CRS-R, bodes well for the MATADOC which has not received the same level of scrutiny as other evaluations to date.

**Auditory**

The protocol for presentation of stimuli in the auditory modality was much more similar between the two assessments than in the visual component. The CRS-R auditory function protocol begins with the administrator presenting a loud noise directly above the patient’s head, outside of the field of vision while watching for an immediate blink or eyelid flutter (visual startle) for at least two of four trials. The next level, localization to sound, involves an auditory stimulus (voice, noise, etc) presented outside of the field of vision on one side of the patient’s head for a duration of five seconds, then repeated on the other side for a total of four trials. The patient must orient the head and/or eyes toward the location of the sound on both trials in at least one direction in order to score at this level. The task for the final two levels, reproducible movement to command and consistent movement to command, is the same as the task for the highest level of function in the visual domain. Just as in the visual function intervention, the administrator must give at least one object-related and one non-object related movement command that the patient has been observed to demonstrate, but with low spontaneous frequency. To score in the ‘reproducible’ level, the patient must demonstrate three clearly discernible responses of four trials to any one of the object or non-object related commands. The ‘consistent’ level requires discernible and accurate responses within ten seconds of the stimulus to all four trials of both object and non-object related commands.
The MATADOC intervention designed to assess auditory responsiveness involves presenting two different musical sounds (i.e., one in a low pitch register and one in a high pitch register) on alternate sides of the patient’s head outside of the field of vision. As in the intervention testing visual responsiveness, the patient’s response is recorded as ‘inconsistent’ if the patient has demonstrated the ability to localize to an auditory stimulus by moving the head or turning toward it less than 75% of the opportunities presented within the session. The response is ‘consistent’ if the patient localizes to the stimulus 75% or more of the opportunities given. Administrators are to allow 20 seconds between stimulus presentations in the event that patients have delays due to cognitive impairments. The highest score in the auditory domain is given when the responses indicate that the patient can focus alternatively on more than one auditory stimulus presented in sequence.

Comparing the auditory domain performances on both the CRS-R and the MATADOC yielded a strong positive relationship ($r_s = .76; p < .05$) indicating that the patient’s performance on the auditory function scale of one assessment could predict with a reasonable degree of accuracy the performance on the auditory portion of the other. As previously discussed, the auditory sense has been reported to be the most frequently intact following brain injury (Gill-Thwaites, 1997; Gill-Thwaites & Munday, 2004). Given the reliance of the MATADOC on the auditory sense, and the emotional salience and complexity of music as an auditory stimulus, one might expect the auditory scores on the MATADOC to more heavily influence the overall diagnosis than the auditory scores of the CRS-R.
Upon closer inspection, however, the presentation of musical sounds outside of the field of vision in the MATADOC does not appear markedly different from the presentation of a non-categorized sound outside of the field of vision in the CRS-R. A tone chime could be said to be more pleasing than a handclap or a voice, but otherwise the complexity and salience of a simple tone appears to be about the same as a non-categorized sound.

The CRS-R also includes tasks associated with command-following under the auditory function scale, which might lead to an assumption that of the two, the CRS-R could be better able to capture more sophisticated information on auditory responsiveness than the MATADOC. However, the reliance on verbal commands to elicit responses within the auditory domain could, in fact, be a limitation of the CRS-R in cases where language processing skills are impaired or English is not the primary language, as previously mentioned. It should be noted that verbal command-following is assessed in the MATADOC as well, but under a separate domain than auditory function.

The MATADOC session is actually full of music and/or sound stimuli throughout the evaluation in every intervention except the visual domain, thus the patient has many opportunities to respond to auditory stimuli beyond just the tones on either side of the head as described in the auditory intervention. And as in the other domains already discussed, the administration manual instructs the clinician to consider all of the patient’s responses to auditory stimuli across the session, (i.e. a delayed head turn toward a voice or music, or a purposeful sigh when a musical stimulus is removed, etc) not just those that occur during the intervention specific to auditory function.
An additional domain is also included in the diagnostic subscale of the MATADOC called “awareness of musical stimuli.” While not categorized as either auditory or visual function, this domain requires the assessor to indicate whether the patient’s behaviors throughout the session appeared contingent to or related to the musical stimuli (reminiscent of the Supplementary Item for the CRS-R). Types of responses that could be scored as related to musical stimuli include localizing to sound or movement, opening or closing the eyes when the music stops, and looking toward the assessor at the conclusion of the music. Also possible are interactive responses such as the patient playing an instrument (i.e. a drum) or vocalizing, and changing tempo or dynamic level in response to the assessor’s music, or playing or vocalizing within pauses given in the music for them to play. Two of the four specifically detailed interventions of the MATADOC are particularly suited for the assessor to note responses in this domain. One is the opening “hello song” in which the assessor first entrains a tempo to the patient’s breathing on a guitar, then gradually begins to improvize a vocal hum, phrased to accompany the patient’s breathing. Once established, the hum evolves into non-language vocables (i.e., la, dee, etc), and then to sung phrases accompanied on the guitar that simply repeat “hello” and the patient’s name.

A study which explored brain activation patterns of patients with DOC in response to their own first name found a P300 potential evoked in response to the subject’s own name, embedded in a list of other common names, for all of the MCS patients tested and for three of five VS patients (Perrin et al, 2006). Saying a patient’s name, then, especially combined with music, could have potential to increase arousal and elicit some kind of behavioral response. The MATADOC does not specify what the
behavior needs to be in order to be counted in this domain, but the scoring is based on whether the behavior appeared to occur contingently to the music stimulus presented rather than at random.

The other musical intervention related to the ‘awareness of musical stimuli’ domain involves the presentation of a preferred piece of music, identified by friends or family members as being a favorite or having some emotional significance. The piece of music is played live by the music therapist assessor where possible, or a recording is played where necessary for authenticity purposes (i.e. a patient of Mexican origin who prefers mariachi music). Again, as mentioned above, the MATADOC does not specify what behavioral responses can be counted, but rather asks the clinician to observe and rate to what degree the behaviors appear related to the music.

Obviously some level of auditory function is necessary in order to demonstrate responsiveness in the ‘awareness of musical stimuli’ domain, however, it is also curious to ponder whether music could evoke contingent behavioral changes that are not necessarily indicative of awareness. The work of Paltsev & Elner (1967) and Rossignol and Jones (1976) has long since explained the ability of sounds to arouse motor neurons along the reticulo-spinal tract even below the level of cognition, therefore could it be possible that patients move in response to music, but not necessarily purposefully? The MATADOC manual specifically states that reflexive behaviors such as these do not constitute an active response indicating an awareness of stimuli, thus the assessor must take particular care when scoring responses in this category. Interestingly, this domain had the lowest correlation with the overall MATADOC diagnosis ($r_s = .54$, $p > .05$) and
the result was the only one of the five that did not achieve the level of statistical significance. This will be discussed in greater detail in the next section.

Overall, while patient performances on comparable domains were closely related, it is clear from closer inspection that measuring responsiveness in only one modality is difficult—thus the overlap and bleed among various domains (i.e., audio, visual, command following, arousal, etc). The MATADOC could be said to be a more holistic tool given its design to assess awareness over four separate sessions rather than one, and the encouragement to consider responsiveness across the session, recording the highest level of function observed, versus the CRS-R’s relatively rigid and clearly defined acceptable responses. However, the graded approach of the CRS-R and the cross-over between multiple domains also allow some built-in flexibility for the CRS-R administrator that may not be apparent at first glance.

Research Question #3

*What contrasting sensitivities exist between the two tools? (Within each assessment, how well does each domain correspond to the diagnostic outcome?)*

Contrasting sensitivities were difficult to analyze since the only two comparable domains in this case were the auditory and visual subscales. As noted previously, the CRS-R arousal to diagnosis correlation could not be calculated because none of the behavioral levels within the arousal domain of the CRS-R were ranked as corresponding with VS, MCS, or Emerging. While interesting to note the relationship between other domain subscales and the overall diagnosis, they don’t determine contrasting sensitivities simply because they were not analogous, and therefore, could not be compared between
these two particular assessments. Examining how well each domain corresponded to the overall diagnostic outcome, on the other hand, lead to some interesting insights. Running a correlation test, again, required using only two data sets for each assessment—one being the overall diagnosis (in this case the rank equivalent of the categorical diagnosis), and the other being the particular domain score. Therefore, as before, the MATADOC data from four sessions had to be somehow condensed to one set of data. In this case, unlike previously, the researcher chose to take a mean across all four sessions rather than choosing any one single session. The resultant data point from the domain score mean was then more closely related to the overall diagnosis (also derived from all four sessions). On the whole, the individual domains were more closely related to the overall diagnosis within the MATADOC than they were within the CRS-R, and possible reasons for this will be discussed.

**Auditory**

While the auditory domain’s relationship to the overall diagnosis was very strong and reached statistical significance within both assessments, the relationship within the MATADOC for this domain was particularly notable ($r_s = .94, p < .05$). As previously discussed, the MATADOC assessment is saturated with auditory stimulation, and thus, potential opportunities to observe the patient’s response were ample throughout the evaluation.

While not as extreme as in the MATADOC, the relationship between the auditory domain and the overall diagnosis within the CRS-R ($r_s = .80, p < .05$) was actually the strongest of all the domains analyzed within the CRS-R. This is not terribly surprising
considering that projections from the auditory processing region of the brain into the spinal cord are direct rather than routed circuitously through the frontal cortex as other sensory processes are. Audition is the fastest sensory process, therefore patients with damaged brains could potentially respond better in that domain than others, thus the responses would be more closely related to an overall diagnosis of awareness (Koelsch & Siebel, 2005; Paltsev & Elner, 1967; Rossignol & Jones, 1976). This also further supports the suggestion that the auditory sense is the most frequently intact following BI (Gill-Thwaites, 1997; Gill-Thwaites & Munday, 2004).

But why would the auditory to diagnosis relationship in the MATADOC surpass the analogous CRS-R relationship by such a margin? It should be restated that the highest two levels of the CRS-R auditory function scale (those associated with a diagnosis of MCS) actually relate to the patient’s response to object related and non-object related commands, whereas the MATADOC has a separate domain to assess the response to verbal commands. Perhaps the inclusion of verbal commands in the auditory domain of the CRS-R weakened the relationship between this subscale and the overall diagnosis. Interestingly, the relationship of the verbal commands domain of the MATADOC to the overall diagnosis ($r_s = .82, p < .05$) was nearly identical to the CRS-R auditory subscale, leading to a suggestion that the two evaluations could be relatively equal in terms of measuring patient responsiveness to command following.

**Visual**

A strong positive correlation for the auditory domain of the MATADOC was expected given the MATADOC’s reliance on the auditory domain, the rich variety of
auditory stimuli presented, the potential emotional salience of the eliciting stimuli, and the ample opportunity for the assessor to observe auditory responsiveness throughout the assessment. Less expected, however, was that the visual domain’s relationship to the overall diagnosis for the MATADOC would be equally as strong as the auditory scale, and also statistically significant ($r_s = .93, p < .05$). These results seem particularly surprising when compared with the corresponding correlation of the visual domain to the overall diagnosis within the CRS-R ($r_s = .69, p > .05$). Granted, the relationship obtained for the visual domain of the CRS-R could still be considered strong, but the fact that this relationship was neither determined to be statistically significant causes it to recede further from the strength of the findings of the analogous correlation in the MATADOC.

Reasons why these two relationships differ to the degree they do are unclear, particularly since the relationship between the patient’s performance on the visual subscales of both assessments were closely related, as were the overall diagnostic outcomes. Although here, again, the highest two levels of behavioral response within the visual domain (those associated with a diagnosis of MCS) involve verbal commands, thus perhaps the MATADOC scores show a stronger relationship to the overall diagnosis simply because command following has been teased out more effectively (though not completely) and put in its own subscale, leaving the auditory and visual responses to be more purely associated with their respective domains. Although difficult to determine based on the sample size limitations already mentioned, this could certainly be a strength of the MATADOC in cases where language processing skills may be impaired.

Arousal
In line with previous assertions that arousal seems key to performance across domains, the arousal domain on the MATADOC demonstrated a very strong relationship to overall diagnosis ($r_s = .82, p < .05$), although not quite the same strength as either the auditory or the visual domains. Unfortunately, as mentioned before, the corresponding correlation for arousal could not be calculated for the CRS-R because the behavioral levels identified in the subscale were not ranked as indicating a particular diagnosis, therefore they could not be correlated with the categorical diagnoses the same way the other subscales were.

That said, given that arousal scores on the CRS-R tended to be lower in general than those of the MATADOC (see Table 7), this could be a possible reason why the CRS-R domains, in general, were not as closely related to the overall diagnosis as those of the MATADOC. If a more alert and highly aroused state allowed a patient to demonstrate his or her highest level of function, than the potential for the musical stimuli presented throughout the MATADOC to boost the patient’s arousal throughout the assessment should allow their response across domains to be more closely aligned with the actual state of awareness. However, care must be taken in suggesting this, knowing that the given diagnosis may or may not be accurate based on the lack of true validity associated with any measure of awareness.

It is also possible that the multiple sessions of the MATADOC and the variability therein actually strengthened the relationships between the individual domains and the overall diagnosis. With more opportunities to capture an accurate representation of a patient’s level of function in any one domain, one would expect the balance of all four
sessions to be more strongly aligned with the resulting overall diagnosis than performance of a single moment in time.

It would be interesting in future research to further examine the influence of arousal on performance in other domains by running correlation tests on arousal versus the other individual domains within either test to see to what degree they are related. Based on the previous research and some superficial review of the raw scores in this study, a strong relationship between arousal and most other domains would be expected.

Within the MATADOC, the domain for the awareness of musical stimuli stands out in relationship to the other figures reported as both a weaker relationship (although technically still a moderate one), and a failure to achieve statistical significance \( r_s = .54, \ p > .05 \). Given the open-ended behavioral response allowed in this domain (target behaviors not specified, but rather whether or not they appear related to musical stimuli), a weaker relationship is somewhat expected. Perhaps the information gathered under this domain adds strength to the auditory and visual responsiveness, but has less weight in actually determining a diagnosis.

The ‘awareness of musical stimuli’ domain appears to be a kind of catch-all category, open-ended enough to be able to record behaviors despite the variety of complicating factors and impairments that are often comorbid with brain injury, and consistent with the MATADOC’s intention to give the patient the best possible chance for response. It would be interesting in future research to examine how the overall diagnosis would be affected if this domain was not included in the scoring, given its only moderate relationship with the diagnosis and the nonsignificant \( p \) value determined in this
study ($r_s = .54, p > .05$). The function of this domain would then be similar to the supplementary item (Assessment of Contingent Behavior) of the CRS-R—useful for indicating when a re-evaluation is warranted, or informing the assessor’s choice of targeted verbal and motor commands based on behaviors the patient appears capable of demonstrating.

The motor domain of the CRS-R demonstrated the weakest relationship with the overall diagnosis of all those tested ($r_s = .27, p > .05$). In most cases in this particular study, that meant that even where patients received a high overall score or a diagnosis of either MCS or Emerging, their motor behaviors were ranked as indicative of VS. This seems to support previous research detailing the presence of comorbid deficits commonly occurring with severe BI that limit responsiveness and present challenges in determining awareness (Bruno et al., 2011; Giacino et al., 2009).

It seems noteworthy to also point out that the verbal commands given in both the auditory and visual subscale tasks are, at least in part, movement related (i.e. “touch the comb,” “kick the ball,” etc). If a patient has severe motor limitations, they may be unable to complete the higher levels of either the auditory or visual tasks even if their awareness is more acute, thus perhaps lowering their scores in these two domains as well. The CRS-R does give several options for types of commands an assessor can give including eye movement, limb movement, or oral movement/vocalization based on the patient’s physical capacity, but it is possible that any of these could be problematic in cases of serious motor impairment.
CHAPTER V
CONCLUSION

The lack of a criterion standard measure of diagnostic validity is problematic for comparing any behavioral assessments of DOC because when discrepancies arise, it is difficult to determine the cause (Seel et al, 2010). That said, to the extent that the CRS-R was rated and recommended by the ACRM, the MATADOC appears to hold up well in this preliminary study of external validation.

Because the behavioral performance of a patient can vary widely even within a day, a factor in an accurate interpretation of behavior is most likely duration and frequency of evaluation. It is likely for this reason, although more cumbersome to administer and score, that the MATADOC is designed to capture performance over four separate sessions and score the highest level of function within each. For comparison purposes, however, the analyses for two of the three research questions in this study used the performance scores of only the single MATADOC session administered closest in date to the CRS-R evaluation, thus perhaps diminishing some of the strength of the MATADOC to capture a more accurate picture of the patient’s status and performance across time. Despite the adjustments, both the overall diagnostic scores and the domain to domain comparisons between the two evaluations demonstrated generally strong relationships.

True comparisons between domains were difficult to sort out because of the challenges apparent in eliciting and isolating patient behaviors within discreet domains. There was overlap to some degree in nearly all of the domains examined, thus it is
difficult to discern in which domains there may be particular challenges or strengths. That said, the purpose of any behavioral assessment of awareness is to give the patient the best possible chance to demonstrate consciousness in any way they are able, but also to distinguish between those behaviors that are purposeful and those attributed to reflexive or limbic activity. Clearly, this is no easy feat.

In order to improve accuracy in diagnosis where diagnostic validity is absent, it is recommended that multiple different behavioral assessments be utilized, using a broad range of eliciting stimuli to encourage varied responses, particularly in borderline or questionable cases (Giacino et al., 2002). It was beyond the scope of this study to identify true borderline cases, but the performance of the MATADOC in this preliminary external validation study suggests that it could be an appropriate assessment to confirm or refute a questionable diagnosis. The MATADOC also has two other sections designed to inform treatment planning, clinical intervention and ongoing care which were not analyzed in this study.

Limitations

Limitations previously mentioned, besides the manipulations to the MATADOC data during analysis, include the small sample size obtained for this pilot study and the lack of multiple assessors and scorers for the MATADOC. While in general, by happenstance, the assessors of the respective assessments were blind to the results of the other assessment, this was not a variable that was controlled for in the course of the study. Also, the participants in this study included both patients in the sub-acute stage who had spent very little time in this particular rehabilitation hospital, and those whose
stay had lasted for many months, even multiple years in some cases. The assessors were, therefore, more familiar with some patients than others, and it is possible that familiarity with a patient may have influenced the assessor’s perception of the patient’s capacity.

Suggestions for Future Research

In future studies it would be interesting to understand more fully the effect of arousal on all the various domains across each assessment, and to elaborate on the brief speculation here that perhaps the music stimuli in the MATADOC could elicit higher arousal levels which could improve performance throughout.

A larger study or one involving more than two assessments could add much more depth to both the question of sensitivities and external validation, and adding another rater for the MATADOC would allow an inter-rater reliability coefficient to be obtained and decrease the chance of rater bias or error. As mentioned previously, the researcher chose logical methods of condensing the MATADOC data for comparison purposes against the CRS-R, but it is possible that other ways of condensing the data would have given different or even perhaps more appropriate results. It would be interesting to explore how this alternate way of comparing the data would impact the results, and even to compare the two different analysis approaches to one another.

The purpose of this study was to explore preliminary external validation of a standardized music therapy assessment tool used in the detection of awareness with the DOC patient population with an external reference standard by (a) examining the level of agreement of diagnostic outcomes between the MATADOC and CRS-R, (b) exploring differences between comparable domains between the two tools, and (c) comparing
sensitivities between the two assessments (if present) relative to the domains addressed. In general, the MATADOC performed well overall against the CRS-R as a reference standard in this preliminary external validation pilot study. While the author could draw insights and make suggestions from the initial data collected and interpreted, a subsequent study addressing some of the limitations and further questions documented above could bring much more depth and clarity on the contribution of the MATADOC in detecting awareness for patients with DOC, not only as a diagnostic assessment but also as a tool for treatment planning and clinical intervention.
REFERENCES


APPENDIX A

SH HSIRB Approved Informed Consent Form

Permission to Take Part in a Human Research Study &
HIPAA Authorization for Release of Health Information for
Research Purposes

Title of research study: A comparison study of diagnostic outcomes between the Music
Therapy Assessment Tool for Awareness in Disorders of Consciousness (MATADOC) and
the JFK Coma Recovery Scale-Revised (CRS-R)

Sponsor: Spectrum Health Continuing Care Centers & Western Michigan University

Investigator: Erin Wegener, MM, MT-BC (principal investigator; Music Therapist at Spectrum
Health Rehab and Nursing Center); Caitlyn Bodine, MT-BC (student investigator)

"You" refers to the subject.
"We" refers to Spectrum Health and Western Michigan University.

We invite you to take part in a research study because you have a Disorder of
Consciousness (DOC) with an undetermined level of awareness.

What you should know about a research study?
- Someone will explain this research study to you.
- You volunteer to be in a research study.
- Whether or not you take part is up to you.
- You can choose not to take part in the research study.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- Feel free to ask all the questions you want before you decide.

Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you talk to the
investigator (Erin Wegener) or members of the research team at 616-486-7007 or
Erin.Wegener@spectrumhealth.org

This research has been reviewed and approved by the Spectrum Health Institutional Review
Board. You may talk to them at (616) 486-2031 or irb@spectrumhealth.org for any of the
following:

MATADOC & CRS-R Comparison Study
Version Date 06/26/14, Vs. 3

Page 1 of 8

SH IRB Approved on: 06/30/2014
Do Not Use After: 06/29/2015
Your questions, concerns, or complaints are not being answered by the investigator or research team.
- You cannot reach the investigator or research team.
- You want to talk to someone besides the investigator or research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

**Why are we doing this research?**
After a brain injury, it can be difficult to determine at what level a person is responding to their environment. This research is designed to detect a person's level of awareness and how they are responding to their environment. This research will compare a typical assessment used by physical therapists (CRS-R) to a music therapy assessment (MATADOC) in order to compare the two, and provide additional information about a person's responses after severe brain injury.

Research has also indicated that a person's sense of hearing is the most frequently intact following a severe brain injury. The Music Therapy Assessment Tool for Detecting Awareness in Disorders of Consciousness (MATADOC) uses different kinds of musical sounds to see what, if any, behaviors occur in response to the music presented. This study aims to compare responses, scores, and diagnoses of the MATADOC with the responses, scores, and diagnoses of the standard assessment used with this population in rehab settings, the Coma Recovery Scale – Revised (CRS-R) in order to understand the rate of agreement between the two assessments, and to explore what factors may be at play in cases where the results are different.

**How long will I be in the research?**
A complete CRS-R assessment, administered by a Physical Therapist, occurs in one session lasting up to 30 minutes. A complete MATADOC assessment, administered by the Music Therapist, occurs over 4 sessions lasting 12-25 minutes each over an 8-10 day period. In order to be compared, the two assessments must be administered within 5 days of each other. Therefore, each participant's total time commitment will be no more than 130 minutes over 8-15 days.

**How many people will be studied?**
We expect 6 people will be included in this research study.

**What happens if I say yes, I want to be in this research?**
Both of these assessments are currently administered to appropriate patients on the Brain Injury unit of Spectrum Health Rehab & Nursing Center- Kalamazoo Ave. and NeuroRehab-Residential Services in Grand Rapids, Michigan as part of the standard plan of care, therefore those who are selected to participate in this study are agreeing to allow the data collected from these two assessments to be further analyzed and reported on by the Student.
Investigator. Information related to demographics and nature of injury will also be collected from participants’ medical charts.

Both assessments will encourage participants to visually track a moving object with their eyes, to move in response to commands, to turn toward a sound presented where the patient cannot see it, and the CRS-R also includes a component where slight pressure is applied to the patient’s nail bed to observe the patient’s reflex response. The MATADOC will use music and musical instruments to encourage these responses, and the CRS-R will use a variety of props and verbal commands.

All assessment sessions will occur privately, either in the patients’ rooms or in a private treatment room, and will be video recorded for later scoring and analysis. When various musical sounds, visual targets, verbal commands, etc. are presented an assessor will document any behaviors (movement, vocalization, alertness responses, i.e. change in rate of breathing, eye opening, etc.) that occur in response.

**What happens if I say no, I do not want to be in this research?**
You may decide not to take part in the research and it will not be held against you. A refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

**What happens if I say yes, but I change my mind later?**
You can agree to take part in the research now and stop at any time it will not be held against you.

Discontinuing participation will not result in penalty or loss of benefits to which you are otherwise entitled.

**Could being in this study be bad for me?**
This is a minimal risk study, therefore, the only risk to you is loss of confidentiality. To protect against this, we will only store information on password protected computer files. In addition, information such as your name and medical record number will be stored on a separate password protected file. All sounds presented within the MATADOC sessions will be presented at a comfortable volume, and participants will be excluded from the study if they become medically unstable at any point during the assessment period.

**Will I need to pay for any of the tests or procedures in the study?**
There are no costs associated with participation in this study.

**Will being in this study help me in any way?**
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include furthering the knowledge and access to this assessment to individuals with DOC, should the assessment be found useful. This will also help music
therapists and physical therapists to further understand the unique sensitivities of each tool, and provide best care to patients. Also, it is not guaranteed that every patient with DOC will be administered the MATADOC at SHCC. Patients in the study will ensure definite administration of this tool and will help to better identify and improve processes for administering it in the future.

What happens to the information you collect?
Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information for quality assurance and data analysis include:

- The Investigator and his/her research staff
- Spectrum Health staff or its agents
- The Spectrum Health Institutional Review Board (IRB) and staff
- Western Michigan University

Some of these organizations may be given direct access to your medical records for verification of the research procedures/data involved. By signing this document you are authorizing this access.

Federal law provides additional protections of your personal information. These are described in a later section.

Can I be removed from the research without my OK?
The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include becoming medically unstable at any point during the study, emerging from Disorders of Consciousness at any point during the study or if the person in charge decides that the research study is no longer in your best interest. The sponsor can also end the research study early.

What else do I need to know?

HIPAA Authorization for Release of Health Information for Research Purposes
The information we are asking to use and share is called Protected Health Information (PHI). It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission.

What will be done with my information?
Your health information will be collected and entered in a database along with the information from other people taking part in this study.
Why am I being asked to release it?
Your health information will be used to evaluate the MATADOC’s performance in detecting awareness in DOC.

What will be released?
To complete this research study, we will need to collect and release (disclose) information about you. This information may include:
- Existing medical records and medical history.
- New health information collected for purposes of this study.
- Full-face video recordings and any comparable images.

Who will use it or share it?
- The investigator and her research staff
- Spectrum Health staff or its agents
- The Spectrum Health Institutional Review Board (IRB) and its staff
- Western Michigan University

Once your protected health information has been disclosed it is possible that anyone who receives that information may re-disclose it. Because some of these individuals who receive your protected health information may not be required by law to keep your information confidential, we cannot guarantee that your information will not be released or made available to another party once it leaves Spectrum Health. Therefore, we share your information only if necessary and we use all reasonable efforts to request that those individuals who receive your information take steps to protect your privacy.

How long will my health information be used?
This authorization has no expiration date.

Can I stop my protected health information from being collected?
You can tell us to stop collecting health information that can be traced to you at any time. We will stop, except in very limited cases if needed to comply with law, protect your safety, or make sure the research was done properly. If you have any questions about this please ask.

If you want us to stop, you must tell us in writing. Write or email Erin Wegener (Erin.Wegener@spectrumhealth.org) or Spectrum Health Neuro Rehabilitation Services, 4130 Kalamazoo Ave SE, Grand Rapids, MI 49508

What happens if I do not want you to collect and release my information?
If you decide not to authorize release of your health information as part of this study, your decision will in no way affect your medical care or cause you to lose any benefits to which you are entitled. You cannot participate in this research study if you do not authorize the use or release of your PHI.
When will it be destroyed?
We do not know when your information will no longer be used. Therefore, the information will be kept for an indefinite length of time.
Signature Block for Adult Unable to Consent

Your signature below documents your permission for the participant named below to take part in this research and to the use and disclosure of this person's protected health information. You will receive a signed copy of this complete form.

Printed name of participant

Signature of legally authorized representative  Date

Printed name of legally authorized representative  Relationship to participant

Signature of person obtaining consent  Date

Printed name of person obtaining consent
Signature Block for Children

Your signature below documents your permission for the child named below to take part in this research and to the use and disclosure of this child’s protected health information. You will receive a signed copy of this complete form.

____________________________
Printed name of child

____________________________
Signature of parent or guardian

Date

☐ Parent
☐ Guardian (See note below)

Printed name of parent or guardian

Note on permission by guardians: An individual may provide permission for a child only if that individual can provide a written document indicating that he or she is legally authorized to consent to the child’s general medical care. Attach the documentation to the signed document.

____________________________
Signature of person obtaining consent

Date

____________________________
Printed name of person obtaining consent
APPENDIX B

SH HSIRB Approval Letter

July 1, 2014

Erin Wegener, Masters of Music
Spectrum Health Rehab & Nursing Center
4118 Kalamazoo Ave.
Grand Rapids, MI 49508

TYPE OF REVIEW: Initial, Non-Committee Review

IRB#: 2014-124 (please reference this number in all correspondence with the IRB)

PROTOCOL NAME: A comparison study of diagnostic outcomes between the Music Therapy Assessment Tool for Awareness in Disorders of Consciousness (MATADOC) and the JFK Coma Recovery Scale-Revised (CRS-R)

SPONSOR: Investigator

Dear Ms. Wegener:

The above referenced protocol and associated materials were reviewed and approved by the IRB via expedited review on June 30, 2014 under categories 4, 5, 6 and 7 as described in 45 CFR 46.110.

The approval period for this research is from June 30, 2014 to June 29, 2015.

The IRB reviewed the following documents related to the approval of the research proposal:

- Initial application signed 06/07/14
- Study protocol version 2 dated 6/23/14
- Informed consent form version 3 dated 6/26/14
- Data collection sheets:
  - Correlation tool for PI use only, not dated
  - Participant Demographics, revised, not dated
  - Pre-Observation, revised, not dated
  - Post-Observation, not dated
  - Score Record page 1, revised, not dated
  - Score Record page 2, not dated
  - Session Record page 1, revised, not dated
  - Session Record page 2, not dated
  - CRS-R Raw Scores, not dated
  - MATADOC Raw Ratings, not dated
  - MATADOC Converted Scores, not dated

The IRB made the following determinations:

1. RESEARCH INVOLVING CHILDREN: The inclusion of children has been approved per 45 CFR 46.404.
2. PARENTAL PERMISSION: The IRB determined that the permission of one parent is sufficient for the research to be conducted.

3. ASSENT: The IRB determined that assent is not required from any of the children because the capability of these children is so limited that they cannot reasonably be consulted.

4. RESEARCH INVOLVING PREGNANT WOMEN: The IRB approves the inclusion of pregnant women in this minimal risk research.

5. RESEARCH INVOLVING ADULTS UNABLE TO CONSENT: The IRB determined that the inclusion of cognitively impaired adults is approved. Assent is not required from these adults. Informed consent of the participant’s legally authorized representative is required in accordance with Spectrum Health policy.

Any changes made to the study following this approval, including informed consent changes, require submission in writing to the IRB and approval by the committee. Changes may not be implemented until approved by the IRB except when necessary to eliminate apparent immediate hazards to the subject. Approval of your research means you are responsible for complying with all applicable policies and procedures of the FDA, OHRP, HIPAA, Spectrum Health, and the Spectrum Health IRB. Also, please be advised that unanticipated problems involving risk to subjects or others must be promptly reported to the IRB. You may reference the Investigator Manual for guidance on expectations of the IRB after approval.

The IRB requires submission of the Continuing Review Progress Report or Study Completion Notification to the committee prior to the study expiration date. It is recommended you submit this xform 4-6 weeks prior to the expiration date to allow time for processing. Your study approval expires on June 23, 2015 at 11:59pm and cannot continue until re-approved by the Spectrum Health IRB. If your study has been completed, terminated, or if you do not wish to continue, please submit the Study Completion Notification before the expiration date.

If you have any questions please contact the Spectrum Health IRB office at 616-486-2031, email irbassist@spectrumhealth.org, or visit us on the web at www.spectrumhealth.org/HRPP.

Sincerely,

Jeffrey Jones MD
Chair, Spectrum Health IRB
APPENDIX C

WMU HSIRB Approval Letter

Western Michigan University

Date: July 3, 2014

To: Ed Roth, Principal Investigator
    Caitlyn Bodine, Student Investigator for dissertation

From: Amy Naugle, Ph.D., Chair

Re: HSIRB Project Number 14-07-06

This letter will serve as confirmation that your research project titled “A Comparison Study of Diagnostic Outcomes between Music Therapy Assessment Tool for Awareness in Disorders of Consciousness (MATADOC) and the JFK Coma Recovery Scale-Revised (CRS-R)” has been approved under the expedited category of review by the Human Subjects Institutional Review Board. The conditions and duration of this approval are specified in the Policies of Western Michigan University. You may now begin to implement the research as described in the application.

Please note: This research may only be conducted exactly in the form it was approved. You must seek specific board approval for any changes in this project (e.g., you must request a post approval change to enroll subjects beyond the number stated in your application under “Number of subjects you want to complete the study.”) Failure to obtain approval for changes will result in a protocol deviation. In addition, if there are any unanticipated adverse reactions or unanticipated events associated with the conduct of this research, you should immediately suspend the project and contact the Chair of the HSIRB for consultation.

Reapproval of the project is required if it extends beyond the termination date stated below.

The Board wishes you success in the pursuit of your research goals.

Approval Termination: July 2, 2015