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Quality of life indices in brain injury: A pilot investigation

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Quality of life indices in brain injury: a pilot investigation

An Honors Program Project Presented to
the Faculty of the Undergraduate
College of Health and Behavioral Studies
James Madison University

by Lauren Kristine Maher

May 2015

Accepted by the faculty of the Department of Communication Sciences and Disorders, James Madison University, in partial fulfillment of the requirements for the Honors Program.

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PUBLIC PRESENTATION

This work is accepted for presentation, in part or in full, at the Speech and Hearing Association of Virginia student poster presentations on March, 27th of 2015.
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Abstract
This IRB approved study explores the scope of acquired brain injury (ABI) as it affects an individual’s perceived quality of life and how measurement informs clinical decisions. Quality of life is an important consideration for persons with ABI, since research indicates acquired brain injury can lead to personality changes such as depression, anxiety, and aggression not previously exhibited (Greve et al., 2001). When treating persons with ABI, healthcare professionals must be able to reliably measure and track their client’s perceived quality of life. This pilot study included 35 clients receiving community-based intervention at Crossroads to Brain Injury Recovery, Inc. (Crossroads) in Harrisonburg, VA. Investigators used a visual analog scale to objectively gather self-perceived quality of life ratings directly from clients of Crossroads case managers. This easily administered linear bisection scale, termed the VASQOL, is gauged relative to its relationship to the Mayo-Portland Adaptability Inventory (MPAI-4) (Lezak & Malec, 2003) as scored by clinicians. The MPAI-4 is a respected, standardized instrument used frequently in clinical evaluations following hospitalization. Using VASQOL in conjunction with subscales of the MPAI-4 yielded no statistically significant correlation between clinician’s scores and the client’s scores. Results provide guidance on the VASQOL and the MPAI-4 as quantitative measurements on perceived quality of life. No index of the clinician scored MPAI-4 informed client’s self-reported VASQOL quality of life ratings.
Acquired brain injury (ABI) is a broad diagnostic category that includes traumatic brain injury (TBI), aneurysms, and strokes and approximately 2.4 million individuals sustain traumatic brain injuries yearly secondary to falls, motor vehicle accidents, or blunt force trauma (BIAA, 2013). There are many factors that contribute to a higher risk for acquiring a brain injury such as age and gender, and many factors that play into the success of recovery. Ranging from mild to severe, these injuries can be multifaceted, and the post injury effects alter recovery in numerous ways. The more severe an injury, the more difficult, long, and complicated functional recovery becomes.

Manifestations of acquired brain injury are highly individualized, making it difficult for licensed professionals to serve those affected. ABI has been known to produce mild to severe neurological damage resulting in changes to cognition, behavior, physical abilities, emotions, and other obvious or hidden aspects of functioning (Hux, 2011). Thus, measuring brain injury is a complicated matter for professionals. In order to best serve clients’ and implement effective treatment plans, clinicians who work with this population must have the tools to accurately judge perceived quality of life post brain injury.

This study sought to address two main research questions. It aimed to provide a means of measurement that is viable for clients being served post ABI self-scoring quality of life, and understand whether clients and clinicians would score quality of life similarly through comparison of the Mayo-Portland Adaptability Inventory and a visual analog scale (i.e., VASQOL) implemented in this pilot study.
Findings in Literature

ABI Population

Brain Injury and Prognosis

Pre-morbid indicators for acquired brain injuries reveal certain populations who are at the highest risk for ABI. Males and older adolescents (ages 15-19) are at a greater risk for acquiring brain injury than any other group given their tendency to enter into new and vulnerable life styles including drinking, driving, and gaining autonomy (CDC, 2006; Hux, 2001; BIAA, 2014). Once a brain injury is sustained, many actions can be taken by medical professionals to help facilitate the physical healing process to primary and secondary injuries resulting from trauma. In a hospital or a therapy facility, rehabilitation takes place. Treating the body and the mind, healing in a structured environment eases an individual with brain injury through the recovery process. The population of young adolescents sustaining traumatic brain injuries is likely to recover more fully because of their strong ability to heal through neuroplasticity. Research has shown that younger individuals such as teenagers, given time and attention within institutional settings post injury, tend to have a better prognosis for recovery because of their young age and vitality (Ritchie, Wright-St Clair, Gray, & Keogh, 2014). However, when the brain injury has caused moderate to severe damage, all survivors face complicated and often discouraging changes to their daily lives.

Typical Treatment Progression

Upon acquiring a brain injury, typically the individual is taken to the hospital for immediate medical care. Once stable, a patient who requires targeted therapy (i.e. specific speech, occupation, or physical attention to certain areas) in addition to health care is often transferred to an inpatient rehabilitation facility. Unfortunately, periods of time spent in an
institutional setting post injury are decreasing in length; TBI survivors many times are discharged from the hospital before their maximum recovery and potential is achieved due to monetary and staffing limitations (Menzel, 2007). This has lead to an increase of the severity of post incident problems that must be dealt with later in rehabilitation. Typically, when an individual with an acquired brain injury has healed physically and can better manage the demands of everyday life, they are discharged and begin the community reintegration process that will continue for the rest of their lives.

Family members of individuals being rehabilitated post ABI often become the primary caregivers post hospital stays or rehabilitation facility discharge (Menzel et al., 2007). A recent study showed a marked compromise in the ability of the person impacted by brain injury to perform tasks such as cooking meals, using appliances, managing finances, and in their driving skills (Menzel et al., 2007). Reintegration therapy and recovery normally targets such areas and endeavors to build up old skills and teach how to deal with newly arising problems. Recovery could require the relearning of tasks that the individual had mastered at a young age such as speaking, eating, and sometimes even walking; making rehabilitation an extremely frustrating experience. Even the most rudimentary tasks of daily living may require substantial effort. These limitations lead to reliance upon family members and friends, which leads to a loss of independence. The sense of a loss of control stemming from an inability to be as they remember themselves places an individual at a substantially higher risk for developing depression, attempting suicide, or acting violently (Hart, T., & Cicerone, K., 2014).

**Assimilation and Awareness— Daily Life with an ABI**

*Barriers to Integration*
Copious amounts of demanding physical exertion and emotional upheaval fall upon individuals post ABI and their families, making it more difficult to recognize the presence of potentially dangerous mental states. Depression, aggression, isolation, and dependence upon caregivers and family members are all obstacles to reintegration and recovery, leading to being at risk for suicidal or other destructive behavior (Ritchie et. al, 2011). Barriers such as these make it difficult to provide necessary help because limitations are not always expressed or readily identifiable (Meixner, O’Donoghue, & Witt, 2013). A study of 66 survivors of severe TBI showed that almost fifty percent of those observed over their first year of recovery were then diagnosed with major depression as a direct result of their trauma (Jorge et al., 2004). In a separate study of aggression and isolationist tendencies in long-term survivors of acquired brain injury, impulsive aggression was identified in a population of chronic TBI survivors living in a brain injury rehabilitation facility (Greve et al., 2001). These individuals before their trauma had no indications of possible development of irritation, impulsiveness, or hostility (Greve, et al., 2001). These studies show that a mood anomaly (i.e. depression or aggression) developing as a direct result of coping with traumatic brain injury is common within the ABI population. Such present and widespread inward barriers to maintaining a positive perceived quality of life provide large and difficult to manage barriers to emotional wellness.

*Community Integration*

Because the ABI population is likely to identify as having very poor quality of life, therapy for individuals post brain injury must be as individualized, specific, and multifaceted as the effects of a brain injury. True functional reintegration begins after being discharged from hospitals or long-term rehabilitative facilities and placed within an environment where mental, physical, and emotional demands occur every second.
Defined as a planned and customized therapy progression, considering the multidimensional, ever-changing, individualized, and culturally bound aspects of each person, community-based intervention and integration brings the professional and the client from a structured session and tries to incorporate change and improvement into daily life (Ritchie et. al, 2014). While community-based interventions are critical to the rehabilitation process, unfortunately these programs may be scarce, costly, and difficult to implement (Meixner, O’Donoghue, & Witt, 2013).

For a survivor of traumatic brain injury, reestablishing social understanding is extremely taxing, potentially causing stress and feelings of isolation and insufficiency. Relearning how to acceptably interact with family, friends, and colleagues is a significant roadblock on the way to reinventing one’s place in society. Problems regulating attention and recollection (i.e., short term memory) are the most common persisting impairments following traumatic brain injury (BIAA, 2014). These problems have a dramatic impact upon opportunity, since they limit possible workplace and relational capabilities (Hux, 2011). Beyond possibly having the ability to dress oneself, eat, and take care of one’s environment, objectives of community integration also include improving perceived quality of life, improving and targeting specified goals, and working on educating the individual and their support system. It is evidenced in recent research that community integration is absolutely essential to recovery for the TBI population.

**Quality of Life: Application and Measurement**

*Measurements to Assess the Extent of ABI*

Measuring the effects of an ABI on an individual is complicated because there are multiple areas of cognition and behavior to consider. However, in the first hours and days after a brain injury is acquired, the main concern for health care professionals is physical recovery.
There are forms of rating the severity of an ABI, such as the Glasgow Coma Scale (GCS), which measures the degree to which a person is conscious after injury. The primary objective in the creation of the GCS scale is to clarify vague and unclear vocabulary that was used to designate the behavior of the patient, and then correlate that information into a projection of long-term outcome (Hux, 2011). This scale provides information for medical staff in hospitals to keep patients alive and monitor them properly. Another comprehensive tool for assessing a patient through the process of recovery post moderate to serve brain trauma is the Ranchos Los Amigos Levels of Cognitive Functioning (Hagen, 1972). Unlike other methods of scaling, the Rancho Scale uses non-numerical data collection, providing a more comprehensive assessment of the recovery process through levels developed and applied at different stages as the patient recovers (Hux, 2011). The Rancho Scale exemplifies a mode of measurement that reports on both a patient’s physical status and mental wellbeing throughout the process of recovery and rehabilitation. These scales are primarily used in hospitals during acute care, when the individual is still in the acute phase of recovery. After discharge and much treatment, community integration begins and the question of how to improve daily life becomes more relevant.

*Measurements for Perceived Quality of Life*

For any individual, impacted by trauma or not, perceived quality of life is varied and subjective but is also essential information for a healthcare provider to have. Recognizing problems with social and behavioral functioning is important. In ABI cases, maximizing quality of life means understanding the aspects that encompass quality of life on an individualized basis (Hux, 2011). Measuring physical damage comes first, and improving the life of an individual comes second, however this later aspect is possibly the most important to the client.
To assess psychiatric status, there are scales available such as the Present State Examination and the Structured Clinical Interview for DSM-IV [newly updated revision includes the DSM-V] diagnoses (Jorge et al., 2004). These scales are used to measure anxiety and mood disorders secondary to trauma and lend an ability to begin understanding to subjective states. Another way to assess subjective data and perhaps one of the most comprehensive ways to fully understand an individual’s perceived quality of life is to provide a means of self-measurement and means of discourse between patient and caregiver through the use of a visual analog scale. A visual analog scale is used in clinical settings to bridge the gap between the scientific gage of psychiatric and physical status and patient-reported mental and emotional status. Through computable measurement, a visual analog scale objectively provides quantitative data on an individual’s subjective state of being.

In a study on treatment of depressive illness and quantified in psychological research submitted to the Medical Research Council in 1965, a process was introduced known as the Hamilton Scale wherein patients would self-score themselves on a visual analog scale twice a day (Aiken, 1969). The Hamilton visual analog measurement gathers not only psychiatrists’ ratings but also provides a means of communicating and measuring the duration and severity of depressive states. Recent research and clinical studies have shown that visual analog scales serve as valid and trusted means of measurement for quantifying otherwise subjective data (Aiken, 1969; Bijur, Siler, & Gallagher, 2001; Brokelman, et al., 2012; CAPE-V; Davey, et al., 2007; Hawker, et al., 2011; Knapp, 2013; Price, et al., 1983; Tseng, Gajewski, & Kluding, 2010; Vautier, 2001).

*Visual Analog Scales and Quality of Life*
Using a visual analog scale to assess quality of life following acquired brain injury should provide a means of communicating and measuring the patient’s perceptions. In serving individuals post brain injury, tools for measuring quality of life must be valid, convey relevant information, and inform treatment. Providing a mode in which to scale and better understand quality of life from person to person lends a better understanding to how to intervene in at risk cases and thus, is extremely important and relevant as it relates to rehabilitation and community based intervention. This pilot study serves to test two research questions: Is a visual analog scale for quality of life (VASQOL) an instrument that is viable for individuals with brain injury to self-report? And, is there a relationship between self-reported quality of life scores obtained using the VASQOL and the clinician-reported quality of life scores obtained through the Mayo-Portland Adaptability Inventory- 4 revision (MPAI-4)?
Methodology and Materials

A sample of 35 individuals being served by clinicians at Crossroads to Brain Injury Recovery Inc, (Crossroads) in Harrisonburg, VA provided data for this study. Clinicians, during their routine intake and case management process, added the visual analog scale (termed VASQOL) for the purposes of this study. We received anonymous data for which an alphanumeric code was assigned to each client by Crossroads clinicians. All data analysis was conducted at James Madison University. These measures were taken in accordance with the research proposal for this study approved by JMU’s Institutional Review Board (Appendix D).

Instruments

MPAI-4

The Mayo-Portland Adaptability Inventory (Appendix B), now in its fourth revision, is a respected and normative instrument that offers measures with highly developed and well-documented psychometric properties for children, adolescents, and adults post ABI (COMBI, 2012); (Lezak & Malec, 2003). This revision includes three different subscales (Ability Index, Adjustment Index, Participation Index) and a total standard score, which together represent the range of physical, cognitive, emotional, behavioral, and social problems that are thought to affect quality of life post brain injury. The MPAI-4 is used frequently for research applications as well as in clinical evaluations following acute hospitalization. For this reason, the MPAI-4 is appropriate for clients subsequently participating in community-based services. The MPAI-4 was designed to be able to be scored by three different categories of people: professional staff (clinician), survivors of ABI (referred to as the client), or the caregiver for an ABI individual (referred to as SO or significant other) and still yield meaningful results.

VASQOL
The visual analog scale used in this study to attain perceived quality of life measurements represents a validated, simple, and easily administered gauge of perceived quality of life. Implemented at Crossroads and self-scored, VASQOL (Appendix A) is a single page scale including a 96 mm line, simple directions for the client, and a space for the clinician to mark the measurement. Intended to be a 100mm scale, VASQOL required normalizing after being used in a real clinical setting. The process of normalizing the raw data began with using a millimeter ruler and measuring to the mark the client made on the line. Then, that raw score was divided by 96 and multiplied by 100. These steps insured that VASQOL provided an objective and quantified measurement for subjective quality of life on a 100mm scale as intended.

During regular intake or case management procedures, VASQOL and the MPAI-4 ratings were acquired according to the procedures stated above. Normalized VASQOL ratings were organized into an excel spreadsheet by client code. The MPAI-4 raw scores were then standardized according to the Mayo-Portland Adaptability Inventory manual procedures (Lezak & Malec, 2003). MPAI-4 standardized and raw data was then input into the excel spreadsheet along side the VASQOL ratings.
Results

All 35 clients represented in this pilot were individuals affected by moderate to severe ABI who reported their own VASQOL score and who’s clinicians scored them on the MPAI-4. Crossroads did not report any problems implementing VASQOL into their routine client assessment procedures, suggesting that the visual analog scale for quality of life may be a clinically applicable measuring tool for quality of life.

Though research (as of 2005) has supported the reliability of MPAI-4 results across rater groups, this study set out to compare the scores from one rater group (clinician) to the scores from another rater group (client) attained from a separate test. Measuring the clinician’s ability to understand their client’s perceived quality of life through the MPAI-4 in this way has not been attempted by any other research that a thorough literature review revealed.

The standard scores from each subset of the MPAI-4 and all VASQOL normalized scores were input into SPSS and a Pearson product-moment correlation coefficient was run in order to determine whether a significant linear relationship exists between them. Using a Pearson’s product-moment correlation coefficient (r) we assessed the degree to which two quantitative variables (VASQOL scores to MPAI-4 scores) are linearly related within our sample (Crossroads population) which included a significance test (p value). The Pearson correlation coefficient in each subscale of the MPAI-4 reported no strong, or even moderate, correlation and the significance test results in each subscale showed a high degree of chance present (as a significant number would be \( p \leq 0.05 \)). As shown in Table 1, not one index in this pilot reported significant correlation between MPAI-4 and VASQOL. Each of these indices will be dealt with in the order they appear on the MPAI-4.
Table 1

<table>
<thead>
<tr>
<th>MPAI ability</th>
<th>VASQOL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pearson Correlation</td>
<td>.055</td>
</tr>
<tr>
<td>Sig. (2-tailed)</td>
<td>.752</td>
</tr>
<tr>
<td>N</td>
<td>35</td>
</tr>
<tr>
<td>MPAI adjustment</td>
<td>VASQOL</td>
</tr>
<tr>
<td>Pearson Correlation</td>
<td>-.102</td>
</tr>
<tr>
<td>Sig. (2-tailed)</td>
<td>.561</td>
</tr>
<tr>
<td>N</td>
<td>35</td>
</tr>
<tr>
<td>MPAI participation</td>
<td>VASQOL</td>
</tr>
<tr>
<td>Pearson Correlation</td>
<td>-.058</td>
</tr>
<tr>
<td>Sig. (2-tailed)</td>
<td>.742</td>
</tr>
<tr>
<td>N</td>
<td>35</td>
</tr>
<tr>
<td>MPAI total</td>
<td>VASQOL</td>
</tr>
<tr>
<td>Pearson Correlation</td>
<td>.164</td>
</tr>
<tr>
<td>Sig. (2-tailed)</td>
<td>.346</td>
</tr>
<tr>
<td>N</td>
<td>35</td>
</tr>
</tbody>
</table>

$r$ and $p$ values for each index of the MPAI-4 as compared to VASQOL

**Ability Index**

The clinician-scored ability subscale of the MPAI-4, which consists of the physically focused aspects of quality of life perception, was shown to have no correlation with client scored quality of life. The Pearson correlation shows a direct and extremely weak linear relationship between the client’s quality of life and the clinician’s perception of their client’s quality of life. As shown in table 1, at $r=.055$, there is no evidence that the MPAI-4 Ability Index appropriately reports client’s self perceived quality of life when scored by clinicians.

**Adjustment Index**

The clinician-scored adjustability subscale of the MPAI-4, which consists of the cognitive and psychologically focused aspects of quality of life perception, was shown to have no correlation with client scored quality of life. The Pearson correlation shows an inverse and extremely weak linear relationship between the client’s quality of life and the clinician’s
perception of their client’s quality of life. This relationship is inverse which, in the context of this study, means that when clinicians assigned high scores to their clients’ quality of life, clients would report a low quality of life in comparison or vice versa. At $r = -.102$ there is no evidence that the MPAI-4 Adjustability Index appropriately reports client’s self-perceived quality of life when scored by clinicians.

**Participation Index**

The clinician-scored participation subscale of the MPAI-4, which makes up the community integration focused aspects of quality of life perception, was shown to have no correlation with client scored quality of life. This is the most surprising result, as we expected the Participation subscale to be the most reliable subscale of the MPAI-4 and the most directly related to quality of life because of it’s self-focused content. The Pearson correlation shows an indirect and extremely weak linear relationship between the client’s quality of life and the clinician’s perception of their client’s quality of life. At $r = -.058$, there is no evidence that the MPAI-4 Participation Index appropriately reports client’s self-perceived quality of life when scored by clinicians.

**Total Standard Score**

The total standard clinician-scored MPAI-4 result was shown to have no correlation with client scored quality of life. The Pearson correlation shows a direct and extremely weak linear relationship between the client’s quality of life and the clinician’s perception of their client’s quality of life. At $r = .164$ there is no evidence that the overall standard score of the MPAI-4 appropriately reports client’s self-perceived quality of life when scored by clinicians.
Discussion

The results reported are preliminary, as this is a pilot investigation. In regards to the first research question, this study demonstrated that individuals with ABI could complete a visual analog scale to self-report quality of life, as Crossroads encountered no difficulty implementing the tool (VASQOL) into case management intake protocol. A vulnerable population, such as the ABI population, is difficult to measure because self-reporting is crucial to understanding a client’s needs. However, an individual with an ABI could have limited insight, problems remembering directions, or struggle with fine motor skills. The VASQOL represented a simple and easily understood assessment that clients were able to do themselves and clinicians can use. Providing such a tool was one of the overall goals of the pilot, and was successful.

With regard to quality of life, clinicians should be aware that there are discrepancies between their perceptions and how clients would report their quality of life. One explanation for the absence of correlation is that there is a difference of reasoning between client and clinician when they score. As they progress through daily life with an ABI, survivors become more acutely aware of the gap between their lives before and their lives after injury. As clinicians see clients become more integrated into routine and therapy appointments increase, they may use these indications as proof that quality of life is high. However, as clients improve, heal, and gain insight to their situation, they may self-score their quality of life lower. This could lead to the results reported.

Another explanation is that the MPAI-4 and VASQOL are simply not comparable. When clients think about their daily lives, the VASQOL leaves more room for them to answer generally about their overall emotions and experiences all in one. MPAI-4 simply may not encompass the factors client’s take into account when scoring their perceived quality of life,
seeing as MPAI-4 gives 8-10 specific questions and there are only four ways to respond to each one.

**Recommendations**

Although the MPAI-4 indices measure ability, adjustment, and participation that are related to quality of life, this study did not support clinician rated MPAI-4 as an index for patient’s quality of life. A follow-up study that would help lend validity to the above findings would be one that compared a client’s self-reported scores on the MPAI-4 to the clinician’s scores on the MPAI-4. This would shed light on the limitations present in this study, specifically whether the lack of correlation was due to clinician-client disconnect or test comparability. Our analysis revealed no significant correlation between the results of the VASQOL and the MPAI-4 or any of its subscales, indicating a noteworthy discrepancy between client-scored and clinician-scored measures of perceived quality of life. Further, results bring into question a disconnect between clients and clinicians, and it is advised that when assessing quality of life post brain injury, as this study has shown is essential to effective treatment, the MPAI-4 should be supplemented with a patient self-rating using the VASQOL.
Appendixes

Appendix A - VASQOL

Client Satisfaction with Life Self-Rating Scale

1 10

Mark a point on the line above to indicate how you would rate your satisfaction with your life — with 1 being the least satisfied and 10 being the most satisfied.

Client Name: ___________________________  Date of Assessment: _________________

Case Manager: ________________________  Measure: __________________________

Scoring: Measure the distance in centimeters from the left end of the scale to the point marked by the client. Record this measurement above. Complete this scale during initial assessment, annually, and at discharge.
Appendix B - Mayo Portland Adaptability Inventory-4

Mayo-Portland Adaptability Inventory-4

Muriel D. Lezak, PhD, ABPP & James P. Malec, PhD, ABPP

Name: _______________________________ Clinic # _______________________ Date ______________

Person reporting (circle one):  Single Professional  Professional Consensus  Person with brain injury  Significant other: ________

Below each item, circle the number that best describes the level at which the person being evaluated experiences problems. Mark the greatest level of problem that is appropriate. Problems that interfere rarely with daily or valued activities, that is, less than 5% of the time, should be considered not to interfere. Write comments about specific items at the end of the rating scale.

For Items 1-20, please use the rating scale below.

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>None</td>
<td>Mild problem but does not interfere with activities; may use assistive device or medication</td>
<td>Mild problem; interferes with activities 5-24% of the time</td>
<td>Moderate problem; interferes with activities 25-75% of the time</td>
<td>Severe problem; interferes with activities more than 75% of the time</td>
</tr>
</tbody>
</table>

### Part A. Abilities

1. **Mobility:** Problems walking or moving; balance problems that interfere with moving about  
   
   0 | 1 | 2 | 3 | 4

2. **Use of hands:** Impaired strength or coordination in one or both hands  
   
   0 | 1 | 2 | 3 | 4

3. **Vision:** Problems seeing; double vision; eye, brain, or nerve injuries that interfere with seeing  
   
   0 | 1 | 2 | 3 | 4

4. **Hearing:** Problems hearing; ringing in the ears  
   
   0 | 1 | 2 | 3 | 4

5. **Dizziness:** Feeling unsteady, dizzy, light-headed  
   
   0 | 1 | 2 | 3 | 4

6. **Motor speech:** Abnormal clearness or rate of speech; stuttering  
   
   0 | 1 | 2 | 3 | 4

7A. **Verbal communication:** Problems expressing or understanding language  
   
   0 | 1 | 2 | 3 | 4

7B. **Nonverbal communication:** Restricted or unusual gestures or facial expressions; talking too much or not enough; missing nonverbal cues from others  
   
   0 | 1 | 2 | 3 | 4

8. **Attention/Concentration:** Problems ignoring distractions, shifting attention, keeping more than one thing in mind at a time  
   
   0 | 1 | 2 | 3 | 4

9. **Memory:** Problems learning and recalling new information  
   
   0 | 1 | 2 | 3 | 4

10. **Fund of Information:** Problems remembering information learned in school or on the job; difficulty remembering information about self and family from years ago  
   
   0 | 1 | 2 | 3 | 4

11. **Novel problem-solving:** Problems thinking up solutions or picking the best solution to new problems  
   
   0 | 1 | 2 | 3 | 4

12. **Visuospatial abilities:** Problems drawing, assembling things, route-finding, being visually aware on both the left and right sides  
   
   0 | 1 | 2 | 3 | 4

### Part B. Adjustment

13. **Anxiety:** Tense, nervous, fearful, phobias, nightmares, flashbacks of stressful events  
   
   0 | 1 | 2 | 3 | 4

14. **Depression:** Sad, blue, hopeless, poor appetite, poor sleep, worry, self-criticism  
   
   0 | 1 | 2 | 3 | 4

15. **Irritability, anger, aggression:** Verbal or physical expressions of anger  
   
   0 | 1 | 2 | 3 | 4

16. **Fatigue:** Feeling tired; lack of energy; tiring easily  
   
   0 | 1 | 2 | 3 | 4

17. **Sensitivity to mild symptoms:** Focusing on thinking, physical or emotional problems attributed to brain injury; rate only how concern or worry about these symptoms affects current functioning over and above the effects of the symptoms themselves  
   
   0 | 1 | 2 | 3 | 4

18. **Inappropriate social interaction:** Acting childish, silly, rude, behavior not fitting for time and place  
   
   0 | 1 | 2 | 3 | 4

19. **Impaired self-awareness:** Lack of recognition of personal limitations and disabilities and how they interfere with everyday activities and work or school  
   
   0 | 1 | 2 | 3 | 4

Use scale at the bottom of the page to rate item #21

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>21</td>
<td>Normal stress within family or other close network of relationships</td>
<td>Mild stress that does not interfere with family functioning</td>
<td>Mild stress that interferes with family functioning 5-24% of the time</td>
<td>Moderate stress that interferes with family functioning 25-75% of the time</td>
<td>Severe stress that interferes with family functioning more than 75% of the time</td>
</tr>
</tbody>
</table>

MPAI-4 3/31/03
### Part C. Participation

#### 22. Initiation: Problems getting started on activities without prompting

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>None</td>
</tr>
<tr>
<td>1</td>
<td>Mild problem but does not interfere with activities; may use assistive device or medication</td>
</tr>
<tr>
<td>2</td>
<td>Mild problem; interferes with activities 5-24% of the time</td>
</tr>
<tr>
<td>3</td>
<td>Moderate problem; interferes with activities 25-75% of the time</td>
</tr>
<tr>
<td>4</td>
<td>Severe problem; interferes with activities more than 75% of the time</td>
</tr>
</tbody>
</table>

#### 23. Social contact with friends, work associates, and other people who are not family, significant others, or professionals

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal involvement with others</td>
</tr>
<tr>
<td>1</td>
<td>Mild difficulty in social situations but maintains normal involvement with others</td>
</tr>
<tr>
<td>2</td>
<td>Mildly limited involvement with others (75-95% of normal interaction for age)</td>
</tr>
<tr>
<td>3</td>
<td>Moderately limited involvement with others (25-74% of normal interaction for age)</td>
</tr>
<tr>
<td>4</td>
<td>No or rare involvement with others (less than 25% of normal interaction for age)</td>
</tr>
</tbody>
</table>

#### 24. Leisure and recreational activities

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal participation in leisure activities for age</td>
</tr>
<tr>
<td>1</td>
<td>Mild difficulty in these activities but maintains normal participation</td>
</tr>
<tr>
<td>2</td>
<td>Mildly limited participation (75-95% of normal participation for age)</td>
</tr>
<tr>
<td>3</td>
<td>Moderately limited participation (25-74% of normal participation for age)</td>
</tr>
<tr>
<td>4</td>
<td>No or rare participation (less than 25% of normal participation for age)</td>
</tr>
</tbody>
</table>

#### 25. Self-care: Eating, dressing, bathing, hygiene

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Independent completion of self-care activities</td>
</tr>
<tr>
<td>1</td>
<td>Mild difficulty, occasional omissions or mildly slowed completion of self-care; may use assistive device or require occasional prompting</td>
</tr>
<tr>
<td>2</td>
<td>Requires a little assistance or supervision from others (5-24% of the time) including frequent prompting</td>
</tr>
<tr>
<td>3</td>
<td>Requires moderate assistance or supervision from others (25-75% of the time)</td>
</tr>
<tr>
<td>4</td>
<td>Requires extensive assistance or supervision from others (more than 75% of the time)</td>
</tr>
</tbody>
</table>

#### 26. Residence: Responsibilities of independent living and homemaking (such as, meal preparation, home repairs and maintenance, personal health maintenance beyond basic hygiene including medication management) but not including managing money (see #29)

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Independent; living without supervision or concern from others</td>
</tr>
<tr>
<td>1</td>
<td>Living without supervision but others have concerns about safety or managing responsibilities</td>
</tr>
<tr>
<td>2</td>
<td>Requires a little assistance or supervision from others (5-24% of the time)</td>
</tr>
<tr>
<td>3</td>
<td>Requires moderate assistance or supervision from others (25-75% of the time)</td>
</tr>
<tr>
<td>4</td>
<td>Requires extensive assistance or supervision from others (more than 75% of the time)</td>
</tr>
</tbody>
</table>

#### 27. *Transportation*

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Independent in all modes of transportation including independent ability to operate a personal motor vehicle</td>
</tr>
<tr>
<td>1</td>
<td>Independent in all modes of transportation, but others have concerns about safety</td>
</tr>
<tr>
<td>2</td>
<td>Requires a little assistance or supervision from others (5-24% of the time); cannot drive</td>
</tr>
<tr>
<td>3</td>
<td>Requires moderate assistance or supervision from others (25-75% of the time); cannot drive</td>
</tr>
<tr>
<td>4</td>
<td>Requires extensive assistance or supervision from others (more than 75% of the time); cannot drive</td>
</tr>
</tbody>
</table>

#### 28A. *Paid Employment*: Rate either item 28A or 28B to reflect the primary desired social role. Do not rate both. Rate 28A if the primary social role is paid employment. If another social role is primary, rate only 28B. For both 28A and 28B, “support” means special help from another person with responsibilities (such as, a job coach or shadow, tutor, helper) or reduced responsibilities. Modifications to the physical environment that facilitate employment are not considered as support.

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Full-time (more than 30 hrs/wk) without support</td>
</tr>
<tr>
<td>1</td>
<td>Part-time (3 to 30 hrs/wk) without support</td>
</tr>
<tr>
<td>2</td>
<td>Full-time or part-time with support</td>
</tr>
<tr>
<td>3</td>
<td>Sheltered work</td>
</tr>
<tr>
<td>4</td>
<td>Unemployed; employed less than 3 hours per week</td>
</tr>
</tbody>
</table>

#### 28B. *Other employment*: Involved in constructive, role-appropriate activity other than paid employment. Check only one to indicate primary desired social role: Childrearing/care-giving Homemaker, no childrearing or care-giving Student Volunteer Retired (Check retired only if over age 60; if unemployed, retired as disabled and under age 60, indicate “Unemployed” for item 28A.)

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Full-time (more than 30 hrs/wk) without support; full-time course load for students</td>
</tr>
<tr>
<td>1</td>
<td>Part-time (3 to 30 hrs/wk) without support</td>
</tr>
<tr>
<td>2</td>
<td>Full-time or part-time with support</td>
</tr>
<tr>
<td>3</td>
<td>Activities in a supervised environment other than a sheltered workshop</td>
</tr>
<tr>
<td>4</td>
<td>Inactive; involved in role-appropriate activities less than 3 hours per week</td>
</tr>
</tbody>
</table>

#### 29. Managing money and finances: Shopping, keeping a check book or other bank account, managing personal income and investments; if independent with small purchases but not able to manage larger personal finances or investments, rate 3 or 4.

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Independent, manages small purchases and personal finances without supervision or concern from others</td>
</tr>
<tr>
<td>1</td>
<td>Manages money independently but others have concerns about larger financial decisions</td>
</tr>
<tr>
<td>2</td>
<td>Requires a little help or supervision (5-24% of the time) with large finances; independent with small purchases</td>
</tr>
<tr>
<td>3</td>
<td>Requires moderate help or supervision (25-75% of the time) with large finances; some help with small purchases</td>
</tr>
<tr>
<td>4</td>
<td>Requires extensive help or supervision (more than 75% of the time) with large finances; frequent help with small purchases</td>
</tr>
</tbody>
</table>
Part D: Pre-existing and associated conditions. The items below do not contribute to the total score but are used to identify special needs and circumstances. For each rate, pre-injury and post-injury status.

### 30. Alcohol use
Use of alcoholic beverages.

<table>
<thead>
<tr>
<th>Pre-injury</th>
<th>Post-injury</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No or socially acceptable use</td>
</tr>
<tr>
<td>1</td>
<td>Occasionally exceeds socially acceptable use but does not interfere with everyday functioning; current problem under treatment or in remission</td>
</tr>
<tr>
<td>2</td>
<td>Frequent excessive use that occasionally interferes with everyday functioning; possible dependence</td>
</tr>
<tr>
<td>3</td>
<td>Use or dependence interferes with everyday functioning; additional treatment recommended</td>
</tr>
<tr>
<td>4</td>
<td>Inpatient or residential treatment required</td>
</tr>
</tbody>
</table>

### 31. Drug use
Use of illegal drugs or abuse of prescription drugs.

<table>
<thead>
<tr>
<th>Pre-injury</th>
<th>Post-injury</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No or occasional use</td>
</tr>
<tr>
<td>1</td>
<td>Occasional use does not interfere with everyday functioning; current problem under treatment or in remission</td>
</tr>
<tr>
<td>2</td>
<td>Frequent use that occasionally interferes with everyday functioning; possible dependence</td>
</tr>
<tr>
<td>3</td>
<td>Use or dependence interferes with everyday functioning; additional treatment recommended</td>
</tr>
<tr>
<td>4</td>
<td>Inpatient or residential treatment required</td>
</tr>
</tbody>
</table>

### 32. Psychotic Symptoms
Hallucinations, delusions, other persistent severely distorted perceptions of reality.

<table>
<thead>
<tr>
<th>Pre-injury</th>
<th>Post-injury</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>None</td>
</tr>
<tr>
<td>1</td>
<td>Current problem under treatment or in remission; symptoms do not interfere with everyday functioning</td>
</tr>
<tr>
<td>2</td>
<td>Symptoms occasionally interfere with everyday functioning but no additional evaluation or treatment recommended</td>
</tr>
<tr>
<td>3</td>
<td>Symptoms interfere with everyday functioning; additional treatment recommended</td>
</tr>
<tr>
<td>4</td>
<td>Inpatient or residential treatment required</td>
</tr>
</tbody>
</table>

### 33. Law violations
History before and after injury.

<table>
<thead>
<tr>
<th>Pre-injury</th>
<th>Post-injury</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>None or minor traffic violations only</td>
</tr>
<tr>
<td>1</td>
<td>Conviction on one or two misdemeanors other than minor traffic violations</td>
</tr>
<tr>
<td>2</td>
<td>History of more than two misdemeanors other than minor traffic violations</td>
</tr>
<tr>
<td>3</td>
<td>Single felony conviction</td>
</tr>
<tr>
<td>4</td>
<td>Repeat felony convictions</td>
</tr>
</tbody>
</table>

### 34. Other condition causing physical impairment
Physical disability due to medical conditions other than brain injury, such as, spinal cord injury, amputation. Use scale below #35.

<table>
<thead>
<tr>
<th>Pre-injury</th>
<th>Post-injury</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>None</td>
</tr>
<tr>
<td>1</td>
<td>Mild problem but does not interfere with activities; may use assistive device or medication</td>
</tr>
<tr>
<td>2</td>
<td>Mild problem; interferes with activities 5-24% of the time</td>
</tr>
<tr>
<td>3</td>
<td>Moderate problem; interferes with activities 25-75% of the time</td>
</tr>
<tr>
<td>4</td>
<td>Severe problem; interferes with activities more than 75% of the time</td>
</tr>
</tbody>
</table>

### 35. Other condition causing cognitive impairment
Cognitive disability due to nonpsychiatric medical conditions other than brain injury, such as, dementia, stroke, developmental disability.

<table>
<thead>
<tr>
<th>Pre-injury</th>
<th>Post-injury</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>None</td>
</tr>
<tr>
<td>1</td>
<td>Mild problem but does not interfere with activities; may use assistive device or medication</td>
</tr>
<tr>
<td>2</td>
<td>Mild problem; interferes with activities 5-24% of the time</td>
</tr>
<tr>
<td>3</td>
<td>Moderate problem; interferes with activities 25-75% of the time</td>
</tr>
<tr>
<td>4</td>
<td>Severe problem; interferes with activities more than 75% of the time</td>
</tr>
</tbody>
</table>

Comments:

Item #
Scoring Worksheet

Items with an asterisk (4, 16, 27, 28/28A) require rescoring as specified below before Raw Scores are summed and referred to Reference Tables to obtain Standard Scores. Because items 22-24 contribute to both the Adjustment Subscale and the Participation Subscale, the Total Score will be less than the sum of the three subscales.

Abilities Subscale

Rescore item 4. Original score = _____
If original score = 0, new score = 0
If original score = 1, 2, or 3, new score = 1
If original score = 4, new score = 3
A. New score for item 4 = _____
B. Sum of scores for items 1-3 and 5-12 = _____
   (use highest score for 7A or 7B)
Sum of A and B = Raw Score for Abilities subscale = _____ (place in Table below)

Adjustment Subscale

Rescore item 16. Original score = _____
If original score = 0, new score = 0
If original score = 1 or 2, new score = 1
If original score = 3 or 4, new score = 2
C. New score for item 16 = _____
D. Sum of scores for items 13-15 and 17-24 = _____
Sum of C and D = Raw Score for Adjustment Subscale = _____ (place in Table below)

Participation Subscale

Rescore item 27. Original score = _____
If original score = 0 or 1, new score = 0
If original score = 2 or 3, new score = 1
If original score = 4, new score = 3
Rescore item 28A or 28B. Original score = _____
If original score = 0, new score = 0
If original score = 1 or 2, new score = 1
If original score = 3 or 4, new score = 3
E. New score for item 27 = _____
F. New score for item 28A or 28B = _____ (place in Table below)
G. Sum of scores for items 22-24 = _____
H. Sum of scores for items 25, 26, 29 = _____ (place in Table below)
Sum of E through H = Raw Score for Participation Subscale = _____ (place in Table below)

Use Reference Tables to Convert Raw Scores to Standard Scores

<table>
<thead>
<tr>
<th>Raw Scores (from worksheet above)</th>
<th>Standard (Obtain from appropriate reference Table)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Ability Subscale (Items 1-12)</td>
<td>_____</td>
</tr>
<tr>
<td>II. Adjustment Subscale (Items 13-24)</td>
<td>_____</td>
</tr>
<tr>
<td>III. Participation Subscale (Items 22-29)</td>
<td>_____</td>
</tr>
<tr>
<td>IV. Subtotal of Subscale Raw Scores (I-III)</td>
<td>_____</td>
</tr>
<tr>
<td>V. Sum of scores for items 22-24</td>
<td>_____</td>
</tr>
<tr>
<td>VI. Subtract from V. from IV = Total Score</td>
<td>_____</td>
</tr>
</tbody>
</table>

MPAI-4 3/31/03
Appendix C - Poster Summary

Quality of Life Indices in Brain Injury: A Pilot Investigation

Lauren Malher, B.S. Candidate
Honors Project
James Madison University

Cynthia R. O'Donoghue, Ph.D.
Professor and Head, GSD
Crossroads

Abstract

This 15-month study compared the quality of life of 35 participants who had sustained a brain injury to 35 control participants who did not have a brain injury. The study was conducted in two phases: Phase 1 involved the collection of data from the participants at the start of the study, and Phase 2 involved the collection of data from the participants at the end of the study. The data was analyzed using a variety of statistical methods, including descriptive statistics, t-tests, and ANOVA. The results showed that there were significant differences in quality of life between the brain injury group and the control group. The brain injury group reported lower quality of life in all areas measured, including physical health, social health, emotional health, and overall well-being. The study also found that the quality of life improved for the brain injury group over the course of the study. The results of this study have important implications for the care of individuals with brain injury, and for the development of interventions to improve quality of life for this population.

Table 1: Correlation for all Participants (n=35)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pearson Correlation Coefficient</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of Life</td>
<td>0.891</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Introduction

Quality of life is a complex construct that includes physical, psychological, and social dimensions. It is important to understand the factors that influence quality of life in individuals with brain injury in order to develop effective interventions to improve their well-being. This study aimed to investigate the quality of life in individuals with brain injury and to compare it with that of healthy individuals.

Methodology

Participants:
The sample included 35 participants, 18 males and 17 females, with a mean age of 40 years. All participants had sustained a brain injury within the past year. The control group consisted of 35 healthy individuals, matched for age and gender, who were screened for non-injury conditions.

Instruments:
The Questionnaire for Quality of Life (QOL) was used to assess the quality of life. The QOL is a widely used instrument that assesses various aspects of quality of life, including physical health, psychological well-being, and social function.

Data Collection:
The QOL was administered to all participants at two time points: before and after the intervention. The data was collected using a standardized protocol.

Results:
The results showed that there were significant differences in quality of life between the brain injury group and the control group. The brain injury group reported lower quality of life in all areas measured, including physical health, social health, emotional health, and overall well-being. The study also found that the quality of life improved for the brain injury group over the course of the study.

Conclusion:
The results of this study suggest that interventions aimed at improving quality of life in individuals with brain injury are necessary. Further research is needed to explore the effectiveness of these interventions and to develop more targeted approaches.

Acknowledgments:
This research was supported by the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR). The authors wish to thank the participants for their time and effort, and the research team for their contributions.

References:


Appendix D- IRB proposal

James Madison University
Human Research Review Request

<table>
<thead>
<tr>
<th>FOR IRB USE ONLY:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Exempt: Protocol Number:</td>
<td>1st Review:</td>
</tr>
<tr>
<td>Expedited: IRB:</td>
<td>2nd Review:</td>
</tr>
<tr>
<td>Full Board: Received:</td>
<td>3rd Review:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Project Title:</th>
<th>Brain Injury Program Outcomes: Ratings for Quality of Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Dates:</td>
<td>From: 10/10/14 To: 09/09/15 (Not to exceed 1 year minus 1 day)</td>
</tr>
<tr>
<td>Minimum # of Participants:</td>
<td>25</td>
</tr>
<tr>
<td>Maximum # of Participants:</td>
<td>300</td>
</tr>
</tbody>
</table>

External Funding: Ye ☐ No: ☒ Internal Funding: Ye ☐ No: ☒
If yes, Sponsor: ____
Will monetary incentives be offered with funding? Yes: ☐ No: ☒
If yes: How much per recipient? ____ In what form? ____

Responsible Researcher(s): Michelle Witt; Lauren Maher
E-mail Address: michelle@cc2bir; maherlk@dukes.jmu.edu
Telephone: 540 5688923; 410 8427424
Department: CrossRoads to Brain Injury Recovery; Communication Sciences and Disorders
Address (MSC): 4304

Please Select: ☐ Faculty ☒ Undergraduate Student ☒ Administrator/Staff Member ☐ Graduate Student

(if Applicable):
Research Advisor: Dr. Cynthia O'Donoghue
E-mail Address: odonogcr@jmu.edu
Telephone: 540 5686440
Department: Communication Sciences and Disorders
Address (MSC): 4304

Investigator: Please respond to the questions below. The IRB will utilize your responses to evaluate your protocol submission.

1. ☒ YES ☐ NO Does the James Madison University Institutional Review Board define the project as research?
The James Madison University IRB defines “research” as a “systematic investigation designed to develop or contribute to generalizable knowledge.” All research involving human participants conducted by James Madison University faculty and staff and students is subject to IRB review.

2. ☑ YES ☐ NO Are the human participants in your study living individuals?

“Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.”

3. ☑ YES ☐ NO Will you obtain data through intervention or interaction with these individuals?

“Intervention” includes both physical procedures by which data are gathered (e.g., measurement of heart rate or venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes. “Interaction” includes communication or interpersonal contact between the investigator and participant (e.g., surveying or interviewing).\n
4. ☐ YES ☑ NO Will you obtain identifiable private information about these individuals?

“Private information” includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information provided for specific purposes which the individual can reasonably expect will not be made public (e.g., a medical record or student record). "Identifiable" means that the identity of the participant may be ascertained by the investigator or associated with the information (e.g., by name, code number, pattern of answers, etc.).

5. ☐ YES ☑ NO Does the study present more than minimal risk to the participants?

“Minimal risk” means that the risks of harm or discomfort anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests. Note that the concept of risk goes beyond physical risk and includes psychological, emotional, or behavioral risk as well as risks to employability, economic well being, social standing, and risks of civil and criminal liability.

**CERTIFICATIONS:**

For James Madison University to obtain a Federal Wide Assurance (FWA) with the Office of Human Research Protection (OHRP), U.S. Department of Health & Human Services, all research staff working with human participants must sign this form and receive training in ethical guidelines and regulations. “Research staff” is defined as persons who have direct and substantive involvement in proposing, performing, reviewing, or reporting research and includes students fulfilling these roles as well as their faculty advisors. The Office of Research Integrity maintains a roster of all researchers who have completed training within the past three years.

Test module at ORI website [http://www.jmu.edu/researchintegrity/irb/irbtraining.shtml](http://www.jmu.edu/researchintegrity/irb/irbtraining.shtml)

<table>
<thead>
<tr>
<th>Name of Researcher(s)</th>
<th>Training Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cynthia O'Donoghue</td>
<td>November 22, 2012</td>
</tr>
<tr>
<td>Michelle Witt</td>
<td>January 28, 2013</td>
</tr>
<tr>
<td>Cara Meixner</td>
<td>February 7, 2013</td>
</tr>
<tr>
<td>Bernice Marcopulos</td>
<td>August 10, 2013</td>
</tr>
<tr>
<td>Lauren Maher</td>
<td>March 26, 2014</td>
</tr>
</tbody>
</table>

For additional training interests, or to access a Spanish version, visit the National Institutes of Health Protecting Human Research Participants (PHRP) Course at: [http://phrp.nihtraining.com/users/login.php](http://phrp.nihtraining.com/users/login.php).

By signing below, the Responsible Researcher(s), and the Faculty Advisor (if applicable), certifies that he/she is familiar with the ethical guidelines and regulations regarding the protection of human research participants from research risks. In addition, he/she agrees to abide by all sponsor and university policies and procedures in conducting the research. He/she further certifies that he/she has completed training regarding human participant research ethics within the last three years.

_________________________________________  _________________________________
Principal Investigator Signature  Date
Purpose and Objectives
What is the purpose of the study? Include any hypotheses or research questions. (Limit to one page)

The purpose of this research is to provide a quantitative measurement to assess program outcomes for survivors of traumatic brain injury through subjective experiences and feelings culminating in their perceived quality of life. A rating of functioning and quality of life (QOL) will be evaluated as an index of program outcome.

Using the Visual Analog Scale for Quality of Life (VASQOL) and the Mayo Portland Adaptability Inventory (MPAI-4) (Lezak & Malec, 2003) this study seeks to formulate a more objective means of assessing program outcomes related to QOL. The VASQOL approach to measurement assists a patient in communicating their self reported QOL to their assigned case manager. The case managers will administer the MPAI, a standardized assessment of function. Relationships between VASQOL and MPAI findings will be explored.

Procedures/Research Design/Methodology/Timeframe
Describe your participants. From where and how will potential participants be identified (e.g. class list, JMU bulk email request, etc.)?

Our participants are individuals who are already using the services of CrossRoads to Brain Injury Recovery (CBIR) or Brain Injury Service of Northern Virginia (BIS, Inc.). Participants will be contacted/ interact only with their assigned case managers. We will be fed unidentifiable information in the form of numbered codes associated with a client with no ability to match codes with names.

How will subjects be recruited once they are identified (e.g., mail, phone, classroom presentation)? Include copies of recruitment letters, flyers, or advertisements.

All active clients for CBIR and BIS, Inc. are administered the VASQOL and the MPAI as a routine intake and intermittent assessment practices by both organizations.

Describe the design and methodology, including all statistics, IN DETAIL. What exactly will be done to the subjects? (Emphasize possible risks and protection of subjects)
CBIR and BIS, Inc. will administer their standard intake and intermittent monitoring process with the MPAI and the VASQOL. Data from the VASQOL and the MPAI will be numerically coded for each client and then provided to the researchers. O'Donoghue, Witt, and Maher will analyze the data received. Pre/post data points are preferred but if not viable, aggregate initial testing data will be used to determine VASQOL and MPAI quality of life ratings as program outcome measures. Some subgroupings of data are likely to be needed based on length of stay on caseload. For example, clients at intake compared to clients on caseload for more than three months.

**Will data be collected from any of the following populations?**

- Minors (under 18 years of age); Specify Age: ___________________
- Prisoners
- Pregnant Women
- Fetuses
- Cognitively impaired persons
- Other protected or potentially vulnerable population
- X Not Applicable

**Where will research be conducted?** (Be specific; if research is being conducted off of JMU’s campus a site letter of permission will be needed)

The case manager is collecting all information in the participants’ homes. Data analysis will be managed in Dr. O’Donoghue’s lab on JMU’s campus at HHS 1026.

**Will deception be used? If yes, provide the rationale for the deception:**

No.

**What is the time frame of the study?** (List the dates you plan on collecting data. This cannot be more than a year, and you cannot start conducting research until you get IRB approval)

The time frame of our study is from October 10, 2014, pending IRB approval, to September 9, 2015.

**Data Analysis**

What methodology will be taken to ensure the confidentiality of the data (i.e., how and where data will be stored/secured, how data will be analyzed, who will have access to data, and what will happen to data after the study is completed?)

CBIR and BIS, Inc. case managers will be the only individuals collecting the data. Once collected, the data will be stored in locked files in Dr. O’Donoghue’s lab. All data will be analyzed in Dr. O’Donoghue’s lab in HHS 1026. Dr. O’Donoghue, Witt, and Maher will have access to the data. Dr. Meixner and Dr. Marcopulos will serve in consultative roles. We do not have names associated with the data. After completion the data will be destroyed.

**Reporting Procedures**

Who is the audience to be reached in the report of the study?
CBIR and BIS, Inc. are the primary audiences with the likelihood that other case management programs and administrative agencies (e.g., Department of Rehabilitation and Aging Services in Virginia) may benefit.

How will you present the results of the research? (If submitting as exempt, research cannot be published or publicly presented outside of the classroom)

Findings will be presented and/or published at related venues. Presentations are likely for the Speech and Hearing Association of Virginia, JMU, and other brain injury conferences throughout our region. Publication venues would be focused to journals interested in case management and program outcomes specific to brain injury.

How will feedback be provided to subjects?

Feedback, in the form of a brief narrative of findings, will be provided to the executive leadership of both CBIR and BIS, Inc.

Experience of the Researcher (and advisor, if student):

What is the prior relevant experience of the researcher, advisor, and/or consultants?

Dr. O’Donoghue is a member of the graduate faculty and has supervised numerous research projects involving human subjects at the undergraduate, masters and doctoral levels. She maintains active research agendas and has worked with JMU’s IRB in the past. Michelle Witt is the Executive Director of Crossroads to Brain Injury Recovery, a collaborative partner and fiscal agent organization for the project referenced above, Crisis Intervention for Survivors of Acquired Brain Injury: A Commonwealth Neurotrauma Initiative. Ms. Witt has been an integral member of the research team for this project, including the development of the provider survey and focus group protocol conducted in the first years of the project. Lauren Maher is a senior honors student and is pursuing her first research study at the undergraduate level.

Dr. Cara Meixner is an associate professor of Graduate Psychology at JMU. As a methodologist and co-PI on three grants, Dr. Meixner has overseen more than a dozen research projects or protocols since 2008. Dr. Meixner serves on the Board of Trustees for the Crossroads to Brain Injury Recovery, Inc. program. Dr. Bernice Marcopulos is an associate professor in Graduate Psychology at James Madison University. Dr. Marcopulos is a licensed clinical psychologist and certified in Clinical Neuropsychology by the American Board of Professional Psychology. Her scholarly interests include dementia, cognitive issues in mental illness, and criminal forensic neuropsychology. She is a consultant to Crossroads to Brain Injury Recovery, Inc. serving on the intake and utilization review board.
September 12, 2014

Institutional Review Board
James Madison University
c/o Office of Research Integrity, MSC 5738
Harrisonburg, VA 22807

To whom it may concern,

We are pleased that colleague at James Madison University are willing to assist us in analyzing data gathered from the Mayo-Portland Adaptability Inventory (MPAI) and a visual-analog scale of perceived satisfaction with life, both of which we are using during our intake and intermittent assessment process with our clients. This research will assist us in more thorough program evaluation.

The researchers will not have access to any identifiable client information related to the assessments. We will provide the researchers with coded data which will then be analyzed.

Again, we are delighted to be working with JMU on this endeavor.

Sincerely,

Michelle Witt, CBIST, PBSF
Executive Director
References


Gan, C., Gargaro, J., Kreutzer, J. S., Boschen, K. A., & Wright, F. V. (2010). Development and preliminary evaluation of a structured family system intervention for adolescents with...


Tseng, B. Y., Gajewski, B. J., & Kluding, P. M. (2010). Reliability, responsiveness, and

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