CHAPTER I

INTRODUCTION

Problem Statement

Agitation after traumatic brain injury (TBI) is the most frequently observed behavioral problem and is a challenge to care providers. About one third of TBI patients exhibit agitation in the subacute stage of rehabilitation and during the posttraumatic amnesia (PTA) stage of recovery (Sandel & Mysiw, 1996; Weir, Doig, Fleming, Wiemers, & Zemljic, 2006). Agitation not only reduces the opportunity for patients to engage in rehabilitation but also becomes a major stressor for patients and their caregivers. Furthermore, a prolonged agitation period may reduce functional independence, induce a longer hospital stay, delay or prevent a return to work, and disturb family dynamics and community integration (Bogner, Corrigan, Fugate, Mysiw, & Clinchot, 2001; Brooke, Questad, Patterson, & Bashak, 1992; Citrome, 2002; Eslinger, 1995; Nott, Chapparo, & Baguley, 2006). Because there are many problems produced by agitation, dealing with agitation presents multiple challenges during rehabilitation after TBI.

Although the prevalence and severity of agitated behavior following TBI has long been known, there is surprisingly little known about its management. One possible reason for this dearth of knowledge is that because patients are excluded from rehabilitation due to their behavior, there is little chance to focus on agitation (Alderman, Knight, & Morgan, 1997). Among the current methods of intervention in many rehabilitation units, pharmacological intervention is the most likely to be used to manage agitation. Anticonvulsants, antidepressants, antipsychotics, beta-blockers, and neurostimulants are commonly used in agitated patients after TBI. Although pharmacological intervention can be beneficial, detrimental side effects can be more harmful than the untreated agitation symptoms. In addition, medication-induced drowsiness can interrupt patient participation in their therapies (Corrigan & Mysiw, 1988; Zafonte, 1997).

In addition to the pharmacological approach, physical restraints have been commonly used to control agitation. The use of physical restraints, such as bed rails, Posey vests, and 2-point and 4-point soft or hard restraints, often occurs during acute rehabilitation to protect agitated patients and caregivers. However, the use of physical restraints is related to minor injuries, such as sores and abrasions, increasing agitation, and more serious injuries, such as deep vein thrombosis and pulmonary embolism due to the immobilization of the patients (Evans & Strumpf, 1990; Hem, Steen, & Opjordsmoen, 2001; Laursen, Jensen, Bolwig, & Olsen, 2005).

Another intervention for agitation is the use of behavioral modification techniques, such as nonviolent crisis intervention, which focuses on how to identify the levels of escalation and includes hands-on training maneuvers for caregivers for their personal safety. However, this technique has limited utility for patients with cognitive or communicative impairments and also yields inconsistent results (Beaulieu et al., 2008; Geffen, Bishop, Connell, & Hopkins, 1994; Lombard & Zafonte, 2005).

Due to the limitations of the three interventions described above, the development of alternative interventions to control agitated behavior after TBI is required. In this study, preferred music, which combines a familiar environment and music therapy, was suggested as an alternative intervention. Preferred music refers to music selected according to an individual's preference.

Background to the Problem

TBI is the most common traumatic event involving the central nervous system and leads to significant morbidity and mortality (Schneier, Shields, Hostetler, Xiang, & Smith, 2006; Thurman & Guerrero, 1999; van der Naalt, van Zomeren, Sluiter, & Minderhoud, 2000). The general incidence of TBI is 200 per 100,000 people per year in developed countries and is 392 per 100,000 in the United States. TBI is the primary cause of death in people younger than 45 in the United States. Every year, 50,000 patients die from TBI in the United States (CDC, 1999; Langlois, et al., 2004). Innovations in medical technology for rehabilitation following TBI have increased the number of survivors, and the total rate of TBI-related hospitalization has decreased (Thurman & Guerrero, 1999). In spite of such technological innovations, the rate of TBI-related hospitalization for severe TBI in the United States has constantly increased up to 20 percent over time (Thurman & Guerrero, 1999).

As a result of TBI, patients suffer cognitive impairment and emotional instability, which result in agitation (Kim, 2002). After TBI, there is neurological damage, such as a break down of the blood-brain barrier and acute inflammation in the brain. This leads to cognitive impairment, such as memory deficits after temporal cortex damage and attention deficits and loss of executive function after frontal lobe damage. With these cognitive impairments, a person may have problems processing collected information and become confused, finally exhibiting agitated behavior. In addition, damage to the limbic system and the frontal lobe is associated with alterations in emotional function. Since the limbic system and the frontal lobe are controllers of fear and impulse, damage to these parts of the brain influence emotional control, resulting in agitation.

Agitated behaviors are characterized by the words "inappropriate" and "excessive". Inappropriate refers to mild and constant behaviors, such as repetitive, aimless, non-purposeful, unproductive, and goal-less movements, whereas excessive refers to more severe and violent behaviors, such as physical aggression or extreme behaviors in both verbal and motor activities (Brooke, Patterson, Questad, Cardenas, & Farrel-Roberts, 1992; van der Naalt et al., 2000). Approximately, 33-50% of TBI patients suffer agitation following recovery from the acute neurological condition of TBI (Kim, 2002; Sandel & Mysiw, 1996). Because the most frequently used treatments for agitation have limitations (the administration of pharmacological sedatives depresses cognitive functioning, and the use of physical restraints reduces voluntary movement), developing a new intervention to decrease agitation is imperative.

Among all the interventions, environmental intervention has been recommended as a known beneficial approach in decreasing agitation. Environmental stimulation, such as very loud noises and bright lights, can be the triggers for agitation. Simple environmental alterations, such as offering a private room and prohibiting TV watching, may be effective in reducing agitated behavior (Lombard & Zafonte, 2005). Another effective environmental alteration is providing a familiar environment, perhaps by bringing personal possessions from home to the hospital. Because people feel comfortable and safe in familiar environments, their agitated behaviors can decrease in this environment. This concept is consistent with the study by Willis and LaVigna (2003). According to the results of their study, cognitively impaired TBI patients were less agitated in a more familiar environment and were more agitated in a strange environment with new people (Willis & LaVigna, 2003). Therefore, examining the relationship between agitation after TBI and familiarity can provide a great opportunity to reduce agitation.

To investigate the effect of a familiar environment in this study, preferred music was selected among a multitude of familiar environmental factors because it is a more feasible and less costly intervention to manage agitation than other environmental factors. In addition, preferred music has a synergic effect on the reduction of agitated behaviors due to the combined effect of familiar environment and music therapy. The synergic effect on reducing agitation can occur by evoking positive memories and emotions in a familiar environment and inducing relaxation, which is created while listening to music. It was found that music can play a role in facilitating improvements in communication, promoting emergence from coma, increasing positive behaviors (smiling, nodding, and humming), and decreasing undesired behaviors after brain injury (Durham, 1994; Formisano et al., 2001; Glassman, 1991; Janelli & Kanski, 1997; Seibert, Fee, Basom, & Zimmerman, 2000). Furthermore, preferred music therapy has been successful in the management of agitated patients with dementia in many studies (Gerdner, 2000; Goodall & Etters, 2005; Park & Pringle Specht, 2009; Ragneskog, Asplund, Kihlgren, & Norberg, 2001; Sung, Chang, & Abbey, 2006). Therefore, exploring the relationship between preferred music and agitation after TBI can provide a foundation for further inquiry into the use of environmental interventions designed to decrease agitation after TBI.

This study potentially can provide confidence to health care providers that a modification of environmental stimulation, such as playing preferred music, can provide a valuable, non-invasive, and inexpensive method for decreasing agitation. Modification of stimulation by decreasing over-stimulation and providing a structured environment has been a commonly used intervention to reduce agitation in many rehabilitation units. In spite of the frequent use of this intervention, it has been performed with a lack of literature support. Therefore, this study provides the theoretical and empirical support to show that structured environmental stimulation (i.e., preferred music) is effective for decreasing agitation.

Theoretical and Conceptual Framework and Model

The theory of individualized music intervention for agitation (IMIA) is the theoretical basis of this study. This theory was developed because of a need to investigate alternative interventions for agitation (Gerdner, 1997). Although IMIA is focused on the cognitive impairment caused by Alzheimer's disease, the cognitive impairment after TBI and the cognitive impairment of Alzheimer's disease display similar patterns of memory, such as preserved implicit memory and explicit memory deficits. Thus, the theory of IMIA may be applicable to cognitive impairment after TBI. In addition, since this model hypothesizes that agitation results from a mismatch between a person's reduced cognitive abilities and environmental demands, it may be a good fit for this study, which focuses on an environmental intervention. The individualized music is based on an individual's personal preference, which is connected with past experience (Gerdner, 2000). The term "preferred music" is used instead of "individualized music" in this paper.

The theoretical elements of this model include cognitive impairment, lowered stress threshold, agitation, and preferred music (see Figure 1.1).

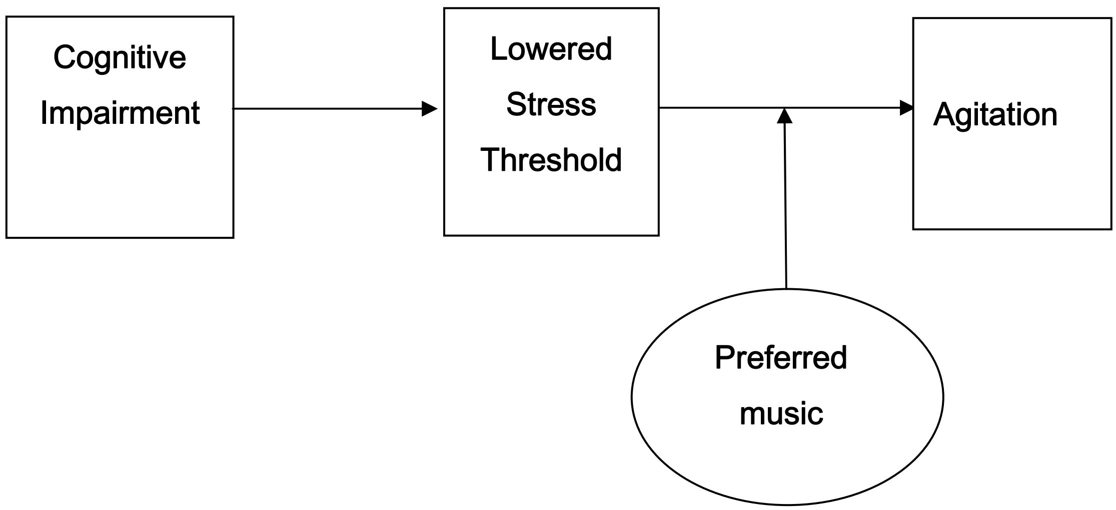


Figure 1.1. Model of preferred music and agitation after TBI.

Cognitive Impairment

Cognitive impairment is a key antecedent of agitation. Memory deficits, attention problems, loss of executive function and confusion and/or delirium are common after TBI (Davis, 2000; Lenzlinger, Morganti-Kossmann, Laurer, & McIntosh, 2001; Stuss et al., 1999). This decreased cognitive ability changes the patient's ability to recognize environmental stimuli. In the acute stage of recovery from TBI, most patients stay in an unfamiliar hospital or acute rehabilitation center. In general, people have a fear of the unknown and show cautious reactions in an unfamiliar environment (Kaplan & Kaplan, 1982). In the presence of cognitive impairment, an individual is overwhelmed by external stimuli, such as TV and large crowds. They are more likely to be fearful and insecure while staying in an unfamiliar environment. This reaction occurs because cognitively impaired patients need to expend more effort to process these stimuli but have a reduced ability to receive and process stimuli after TBI. Thus, patients are less able to cope with an unfamiliar environment than those without TBI and can be easily exhausted with these stimuli. Therefore, their stress threshold might progressively decline.

Lowered Stress Threshold

Persons with cognitive impairment have a lowered stress threshold because of their reduced cognitive ability to process and receive stimuli in unfamiliar environments. A decreased cognitive ability results in a decrease of the functional capacity to manage internal environmental stressors, such as pain and fatigue, and external ones, such as noise and light. When the environmental demands exceed a patient's lowered stress threshold, dysfunctional behaviors, such as agitation, emerge (Hall & Buckwalter, 1987). Modifying the environment to reduce environmental stressors is suggested for the intervention in agitation (Hall & Buckwalter, 1987; Richards & Beck, 2004).

Agitation

Agitation is defined as one or more repetitive, non-purposeful, and inappropriate verbal and/or motor behaviors. Often, external stimulation provokes agitated behavior. In addition, cognitive impairment and emotional instability lead to agitation. Interventions for agitated behaviors, including preferred music, are most effective before the peak level of agitation is reached (Hall & Buckwalter, 1987).

Preferred Music

Preferred music can be used to decrease agitation after TBI by eliciting pleasant memories and positive emotions. In general, music is a powerful tool for reminiscence, which can be associated with either pleasant or unpleasant memories (Bright, 1982). Preferred music can especially remind a person of pleasant memories because this music is related to personal preference and the person's life in the past. Fortunately, memory before brain injury is intact after TBI, whereas patients are commonly unable to recall new experiences after brain injury (Forrester, Encel, & Geffen, 1994; Moscovitch & McAndrews, 2002). Therefore, preferred music, which is associated with patients' memories of pleasing past experiences, might produce a soothing effect on agitation (Gerdner, 2000).

In addition, exposure to preferred music elicits positive emotions in healthy individuals as well as cognitively impaired individuals (Sarkamo et al., 2008). In general, people are more likely to try to escape from unfamiliar environments due to their unknown factors. On the other hand, familiarity allows people to predict the implications or the effects of stimuli easily and with little effort. Therefore, they seek familiar environments, which make them comfortable (Kaplan & Kaplan, 1982). Preferred music as a familiar environment induces positive emotional responses, including feelings of comfort, relaxation, and calmness, and is associated with a less confused and depressed mood (Sarkamo et al., 2008). These induced positive emotions produced by preferred music may relieve the greater cognitive burden, which is required to process unfamiliar environmental stimuli in cognitively impaired persons. In addition, they facilitate coping with stressors and unfamiliar environments (Fredirickson & Levenson, 1998; Fredrickson, 1998, 2001). Improved cognitive function and coping skills might decrease agitated behaviors. In conclusion, listening to music selected according to an individual's preference can elicit pleasant memories and positive emotions and, therefore, reduce agitated behavior.

This study proposed to fill the gap in knowledge related to the effect of preferred music on agitation after TBI by measuring the difference in agitated behaviors during preferred music intervention compared with before and after the music intervention and by comparing the reduction of agitated behaviors after the presentation of preferred music to the reduction after the presentation of classical "relaxation" music.

Research Questions and Hypotheses

The main purpose of this study was to evaluate the effects of preferred music on agitated patients after TBI compared to those of classical "relaxation" music. Additional purposes were to discover which components of agitation were effectively decreased after music intervention. Since this study could provide a valuable non-pharmacologic intervention for agitation in TBI patients, it could increase the opportunity for them to engage in rehabilitation, thereby shortening their recovery time. In addition, it could potentially reduce the burden on heath care providers and patients' families while caring for less agitated patients.

The research hypotheses were the following:

1. There is a significant decrease in the Agitated Behavior Scale (ABS) score during the presentation of preferred music compared to the ABS scores at baseline and post-intervention.
2. There is a significant decrease in the ABS score during the presentation of classical "relaxation" music compared to the ABS scores at baseline and post-intervention.
3. The effect of preferred music on reducing agitation after TBI is significantly greater than the effect of classical "relaxation" music.
4. Preferred music has significant effects on reducing the scores of each component

(physical, cognitive, behavioral, and verbal) of the ABS compared to the scores at baseline and post-intervention.

CHAPTER II

REVIEW OF LITERATURE

Traumatic Brain Injury

Definition, Causes, and Incidence of TBI

Traumatic brain injury (TBI) is defined as physical damage to living brain tissue caused by an external and mechanical force (Baker, 2001a; Melchers, Maluck, Suhr, Scholten, & Lehmkuhl, 1999). The primary injury is typically from blunt force (i.e., motor vehicle crashes or falls) or from a penetrating wound, (i.e., gunshot or knife wounds) (Roth & Farls, 2000). Traumatic brain injury does not include ischemic damage, such as damage from a stroke, or non-mechanical brain damage caused by brain tumors or seizures. Nearly half of TBI cases result from motor vehicle accidents. Other causes of TBI, in order of frequency, are falls, violence, firearm-related accidents, and sports-related activities (Duff & Wells, 1997; Krause & Sorenson, 1994).

The Centers for Disease Control and Prevention (CDC) reported in 2004 that 1.5 million Americans survive a TBI each year. By comparison, this amount is much greater than the number of survivors from breast cancer (175,000 individuals) and HIV/AIDS (44,000 individuals) each year in the United States (Brain Injury Association, 2002). More than 5.3 million people are currently living with long-term disabilities related to

TBI; approximately 90,000 are left with permanent disabilities (CDC, 1999; Langlois, et al., 2004), and 50,000 individuals die because of TBI every year (Langlois, Rutland-Brown, & Tomas, 2004).

Effect of TBI Analyzed by Age

The peak incidence of TBI occurs in young adulthood (Fields & Coffey, 1994). TBI is the major cause of death in the United States for young adults who are under 35 years of age (Frazee, 1986; Thurman & Guerrero, 1999). Males between the ages of 15 and 24 are at a much greater risk for death from TBI because they are more actively involved in driving a car and are involved in more car accidents, which is the most common cause of TBI (Michican Department of Community Health, 2004). Generally, most brain injuries in young adults are severe, and young adults more frequently show behavioral problems, such as hyperactivity and agitation, than do children (Geraldina et al., 2003; Wong, Dornan, Schentag, Ip, & Keating, 1993).

Children are also exposed to the risks of TBI. Approximately 30,000 children are hospitalized and 400,000 are treated in emergency rooms because of TBI in the United States annually (Centers for Disease Control and Prevention, 2003). Compared to adults suffering TBI, children may have a higher risk factor of poor neuropsychological outcomes, such as in intellectual and visuospatial function, after TBI (Verger et al., 2000). Since brain injuries in children occur in an immature brain, studies of children with TBI need to be approached differently from those of adults (W. M. Brooks et al., 2000).

Mortality after severe TBI rises constantly after age 65 (Jennett, 1982). TBI in elderly patients is more likely to involve cognitive complications, such as depression, apathy, and dementia (Ikonomovic et al., 2004; Levin, Benston, & Grossman, 1982). In addition, cognitive decline resulting from prior causes is accelerated by head injury (Luukinen, Viramo, Koski, Laippala, & Kivela, 1999). Head injury may increase the risk for other cognitive disorders, such as Alzheimer's disease, which may induce additional problems that need to be managed. For this reason, TBI research done on patients older than age 65 needs to take into account other cognitive disorders.

Adults 18 years and older were the target population for this study. Children and older adults who had a history of psychiatric disorders, including dementia, delirium, and Alzheimer's disease, were excluded due to possible confounding variables, such as developmental delay and other cognitive disorders mentioned above.

Effect of TBI Analyzed by Gender

A recent report from the CDC showed that death from TBI in males was 3.4 times more common than in females; specifically, males were 2.3 times more likely to have sustained injury by motor vehicle accident, 2.5 times more likely to have a TBI secondary to falls, and 6 times more likely to be injured via firearms (Adekoya et al., 2000). The majority of TBI research not only comes from male subjects, but studies have been lacking that analyze data according to gender.

Effect of TBI Analyzed by Race

TBI studies have reported that there is a higher incidence of TBI for African American compared with non-African Americans, particularly in young males. In the United States between 1992 and 1994, the annual incidence of TBI was 582 per 100,000 for African Americans, 429 for Caucasians, and 333 for other racial groups (Jager et al., 2000).

Outcomes after TBI

Every year, more than $9 billion dollars is spent on acute care and rehabilitation programs for TBI patients (National Institutes of Health (NIH) Consensus Statement, 1998). The societal cost of care for the survivors of TBI is estimated to be $48.3 billion per year (Thurman & Guerrero, 1999), while the emotional costs generated from TBI are immeasurable. In addition, TBI negatively alters the relationship between family members and TBI patients. For example, 45% of patients experienced divorce or separation from their partners during the 5- to 8-year period following a brain injury (Wood & Yurdakul, 1997).

Other negative aspects following TBI are psychosocial dysfunction, including cognitive, behavioral, and emotional disturbance. The cognitive impairment expected after TBI includes short-term and long-term memory loss, trouble paying attention, slowed ability to process information, and impairment of orientation and judgment. Therefore, TBI patients show poorer performance in attention and executive functioning (Trail-Making Test A and Trail-Making Test B, respectively) (Machamer, Temkin, & Dikmen, 2003). Dysfunction of cognitive control after severe brain injury inhibits appropriate responses to external stimuli, and cognitively impaired TBI patients commonly exhibit behavioral disturbances (Levine, Katz, Dade, & Black, 2002). Emotional disturbances, such as increased anxiety, impulsiveness, irritability, and depression, are frequently described by caregivers of TBI patients (Jorge, et al., 2004; Rapoport, et al., 2003; Rapoport, et al., 2005). Behavioral problems exhibited by individuals with TBI vary. Some individuals may have difficulty with outbursts, while others are socially inappropriate or noncompliant. Some individuals seem to experience no behavioral problems, whereas others exhibit a wide range of such problems. Restlessness and agitation are commonly found in the phases of recovery (Thomsen, 1984; Max, Robertson, & Lansing, 2001; Tateno, Jorge, & Robinson, 2003). These cognitive, emotional, and behavioral changes have been shown to negatively affect rehabilitation outcomes (Schootman & Fuortes, 1999). More than 25% of TBI patients have severe or multiple behavioral or emotional disturbances that significantly interfered with daily life (Jacobs, 1988). Reduction of these behavioral disturbances is one of the main focuses in rehabilitation after TBI.

Agitation after TBI

Prevalence of Agitation after TBI

Agitation, identified as one of the major behavioral disturbances after severe TBI, is common in the subacute stage of rehabilitation. The prevalence of agitation after TBI has been studied from 1978 to 2006 and is reported in Table 2.1.

As illustrated in Table 2.1, 11% to 96% of TBI patients experience agitation during the acute stage of recovery and 31% to 70% during the chronic stage. The onset of research varies from 24 hours after emerging from a coma (acute) to seven years after injury (chronic) (Oddy, Coughlan, Tyerman, & Jenkins, 1985). Many authors have suggested that the major period for the onset of agitation is from 24 hours to a week after emerging from a coma in the subacute stage of recovery (Bogner et al., 2001; Brooke, Questad et al., 1992; Galski, Palasz, Bruno, & Walker, 1994; Levin & Grossman, 1978; Rao, 1985; Silver & Yudofsky, 1994; van der Naalt et al., 2000). Brooke et al. (1992) studied the onset of agitation in detail for four weeks. Of the 11 subjects, 8 expressed their initial agitated behavior in the first week of recovery, and then the episodes of

Table 2.1.

Literature Review of Agitation Prevalence

Studies (Authors)	Years	Severity [a]	Sample (N [b])	Agitation	Follow-up [c]
Levin & Grossman	1978	All	62	35%	Acute
Rao et al.	1985	Severe	26	96%	Acute
Brooke et al.	1992	Severe	100	11%	Acute
Galski et al.	1994	All	28	39%	Acute
Van Der Naalt et al.	2000	Mild-moderate	67	19% (restlessness 40%, inappropriate behavior 35%)	Acute
Kadyan et al.	2004	Severe	158	41%	Acute
Nott et al.	2006	All	80	86.3%	Acute
McKinlay et al.	1981	Severe	55	67%	Chronic: 1year
Rao et al.	1985	Severe	26	64%	Chronic: Rehabilitatio n
Oddy et al.	1985	Severe	44	31%	Chronic: 7 years
Brooks et al.	1986	Severe	42	64%	Chronic: 5 years
Dikmen et al.	1986	Mild	20	40%	Chronic: 1 month/ 1 year
Bogner et al.	2001	All	340	36%	Chronic
Tateno et al.	2003	Severe	89	33.7%	Chronic: 6 months
Nott et al.	2006	All	80	70%	Chronic: 6 and 24 months

Note.
[a] Severity: All = severe + moderate + mild brain injury
[b] N: Number of samples
[c] Follow-up =Acute: acute stage of rehabilitation (from 24 hours to a week after emerging from a coma); Chronic: chronic stage of rehabilitation (from 6 months to several years after TBI)

agitation suddenly decreased, i.e., only once a week from the second to the fourth week. The persistence of agitation is related to a patient's level of consciousness (Galski et al., 1994). The rate of agitated behavior can be decreased following improved cognitive function in the recovery from a brain injury. Low cognitive function in rehabilitation shows a higher occurrence of agitation (Bogner et al., 2001).

Agitation is frequently found during recovery from severe brain injury (Angelino, Miglioretti, & Zotti, 2002). Severely brain-injured patients have been shown to have a higher percentage of agitation (30%) than mildly brain-injured patients (19%) (Angelino et al., 2002). Bogner and colleagues (2001) reported a similar result. Among all agitated patients, 64% were reported to have severe brain injuries and only 22% had mild brain injuries. In addition, since severe brain injured patients have poor arousal or awareness after coma and have impaired cognition, agitation occurs often in severely brain-injured patients.

Agitation is often the first symptom exhibited at the posttraumatic amnesia (PTA) phase during subacute rehabilitation. Once a TBI patient stabilizes from medical emergency, the patient may be admitted to a facility that offers a subacute rehabilitation program. In subacute rehabilitation, patients experience PTA. PTA is one the stages of recovery from TBI and immediately follows the period of coma (Mysiw, Corrigan, Carpenter, & Chock, 1990). In the PTA period, patients experience poor orientation, reduced ability to concentrate, irritability to the environment and poor ability to recall new experiences (Corrigan, Mysiw, Gribble, & Chock, 1992; Forrester et al., 1994). Poor orientation, concentration, and memory of environments and irritability lead to agitation.

Based on the prevalence of agitation, it is recommended to collect data in acute rehabilitation units because the majority of patients exhibit agitation during the subacute stage of rehabilitation. The target population of agitation research is severely brain-injured patients.

Problems Resulting from Agitated Behavior after TBI

The combative and assaultive characteristics of agitation can make caregivers feel a sense of threat while caring for the patient. In a five-year outcome study of head injuries, Brooks, Campsie, and Syminton (1986) found that 54 percent of caregivers reported that they had experienced threats and violence while caring for agitated patients after TBI. Sometimes, agitated behavior can involve physical aggression, and it can cause caregivers real harm or injury (Jackson, Clare, & Mannix, 2002).

In addition to threatening safety, agitation can be a burden and cause major stress to family and caregivers providing care to TBI patients (Silver & Yudofsky, 1994). A study of 79 TBI patients' families revealed that primary caregivers experienced high levels of psychological distress, such as anxiety, depression, fatigue, anger, and mood-disturbance (Perlesz, Kinsella, & Crowe, 2000). Eighty-three percent of siblings experienced a high level of psychological distress while taking care of TBI patients with behavior disturbances (Orsillo, McCaffrey, & Fisher, 1993).

Finally, agitated behaviors may preclude patients participating in therapies and decreasing the opportunity to engage in rehabilitation (Lequerica et al., 2007). Because of a patient's combative and threatening behaviors, health care providers may be very likely to suspend therapies to keep away from a dangerous situation. Furthermore, patients can be excluded from their therapy due to uncooperative behaviors. Therefore, the recovery process of agitated patients is slower, and additional visits for rehabilitation may be required (Lequerica et al., 2007). Bogner and colleagues (2001) found that a longer presence of agitation in rehabilitation patients increases the length of their hospital stay. This extended length of hospital stay and additional visits for rehabilitation results in financial burdens on a patient's family and caregivers (Teichner, Golden, & Giannaris, 1999).

In summary, threatened safety and distress for family members who take care of a TBI patient make them hesitate to interact with the patient. As a result, the patient is estranged from their family, and the relationship between the patient and their family may be disturbed. Furthermore, agitation can be disruptive to participation in rehabilitation, social contact, and returning to social groups and to the workplace because it changes the personality of TBI patients to aggressive and combative (Brooke, Questad et al., 1992; Brooks & McKinlay, 1983; Eslinger, 1995; McKinlay, Brooks, Bond, Martinage, & Marshall, 1981). Therefore, agitation produces multiple challenges in rehabilitation after TBI. Reducing agitation is a big concern for caregivers and health care providers who care for TBI patients.

Definition of Agitation

Agitation after TBI is currently a poorly defined phenomenon. This is because agitation has the potential to be difficult to differentiate from other cognitive disorders and/or behavior problems, such as aggression, restlessness, and akathisia, and because agitation after brain damage is complicatedly connected with physiological, neurological, and psychiatric components (Angelino et al., 2002; Bogner et al., 2001; Day, 1999; Fugate et al., 1997; Kim, 2002; Mysiw & Sandel, 1997; Sandel & Mysiw, 1996). A clear consensus on a definition of agitation would facilitate communication among health care providers and unify outcome measurements or inclusion criteria among researchers (Fugate et al., 1997). Therefore, a clear and consistent definition is needed and would allow for comparison across studies (Sandel & Mysiw, 1996).

Historical Uses of Agitation

Agitation is a broad term that includes various behaviors, such as restlessness, aggression, and akathisia (Roper, Shapira, & Chang, 1991). Agitation is found in a number of different clinical conditions, such as schizophrenia, dementia, brain injury, and ICU patients. Since this paper focuses on agitation after TBI in the acute stage of rehabilitation, historical uses of agitation concentrate on finding common attributes of agitation after TBI.

The English word "agitation" originated from the same French word of "agitation." Agitation in French means "the rough movement of the sea." The "agite" describes a rough, choppy sea (Collin & Ledesert, 1982). In 1866, Johnson defined agitation as the state of being moved in the water after storms. Given this, the word agitation focused on motion, especially rough motion.

Many behavioral characteristics are used to define agitation. Historically, agitation after TBI was described for the first time by Levin and associates in 1978. According to the authors, agitation is a behavior characterized by combativeness, thrashing of the arms, and truncal rocking; screaming; and signs of sympathetic activation. Agitated behaviors range from more mild behaviors, normally inhibited motions, including nail-biting, foot-tapping, hand wringing, the inability to sit still, or pacing, to more severe behaviors, such as hiding, hoarding behaviors, and violent outbursts, including physical aggression, biting, spitting, screaming, self-harm, and sexually inappropriate comments or actions (Cohen-Mansfield, Marx, & Rosenthal, 1989; Fugate et al., 1997). There are additional agitated behavioral features in the hospital setting. For example, typical agitated behaviors in health care facilities include dislodging intravenous tubes and catheters and attempts to get out of bed (Denny-Brown, 1945). The definition of agitation by Mysiw, Jackson, and Corrigan for TBI patients (1988) included specific behaviors, such as restlessness, derogatory or threatening demands, verbal abusiveness, sexually inappropriate comments or actions, or threats or attempts at physical violence. These definitions of agitation are focused on a description of the patient's behaviors.

Based on these definitions of agitation, agitated behaviors are characterized by using the words "inappropriate" and "excess" (Brooke, Patterson et al., 1992; van der Naalt et al., 2000). First, Cohen-Mansfield et al. (1989) and Lindenmayer (2000) characterized agitation as "inappropriate behavior." They stated that when a verbal or motor activity is inappropriate, this behavior is considered agitation. Next, excesses or extreme behaviors were also used as an attribute in defining agitation (J.A. Bogner & Corrigan, 1995; J. A. Bogner et al., 2001; Sandel & Mysiw, 1996). Sandel and Mysiw (1996) defined agitation as excesses of behaviors, including some combinations of aggression, akathisia, disinhibition, and/or emotional lability. Bogner and Corrigan (1995) defined agitation as an excess of one or more behaviors, and they explained that "excessiveness refers to the degree to which the behavior interferes with functional activities and the extent to which the behavior can be inhibited" (p. 294-5). If the behavior is extreme beyond ordinary or appropriate boundaries or is exhibited at an uncommon frequency according to social standards, this behavior is considered agitated behavior (Cohen-Mansfield et al., 1989).

Defining Attributes of Agitation

Behaviors including restlessness, aggression, disinhibition, and akathisia play an important role as attributes of agitation after TBI. These are highly related to agitation and are useful for explaining the uniqueness of agitation. Bogner and Corrigan (1995) pointed out one reason for using these behavioral characteristics in defining agitation; they state that there is no one type of behavior that exactly defines it, just that some component behaviors may be more dominant at certain times.

Restlessness. Restlessness appears a key behavior of agitation across many studies (Mysiw et al., 1988). Bogner et al. (2001) and Lindenmayer (2000) included restlessness in examples of extreme and/or inappropriate behaviors in the definition of agitation. In a survey study of a brain injury special interest group by Fugate et al. (1997), the authors indicated that restlessness is a highly related component to agitation according to physiatrists (physicians who work in physical medicine and rehabilitation). On the other hand, some authors tried to distinguish restlessness from agitation. Reyes, Bhattachayya, and Heller (1981) distinguished agitation from restlessness based on a patient's ability to inhibit his or her movement. The authors indicated that restlessness is an activity in which the patient can inhibit movement, whereas agitated patients cannot inhibit their movement (Reyes, Bhattacharyya, & Heller, 1981). However, in the case of brain-injured patients, it is not easy to determine if a patient has the ability to inhibit his or her movement. Therefore, Reyes and colleague's distinction may not be applicable to agitated patients after TBI.

Another way used to distinguish agitation from restlessness is by comparing the severity of behavior (Brooke, Questad et al., 1992; van der Naalt et al., 2000). If the behavior is severe enough to interrupt patient care and to require restraints, it is considered agitation, whereas if it is not severe enough for these measures, the behavior can be considered as restlessness. In an actual rehabilitation unit for TBI, the repeated restlessness behaviors can interrupt a patient's care and require the use of restraints in certain situations, such as nighttime. Therefore, a boundary between restlessness and agitation may not be clearly distinguished. Furthermore, it is the best way that restlessness can be included in one of the characteristics of agitation.

Aggression. The terms aggression and agitation are similar and are used interchangeably (Whittington, 2002). Fugate et al. (1997) mentioned that aggressive characteristics (physical aggression, verbal aggression, or explosive anger) are linked to agitation. Sandle and Mysiw (1996) indicated that descriptions of aggression encompass elements of agitation and are similar to behaviors observed in posttraumatic agitation. In addition, Littrell and Littrell (1998) explained the relationship between agitation and aggression according to their severity. They stated that aggression can be more threatening and serious than agitation. Over time and without intervention, agitation can possibly transition to be a more serious behavioral problem, such as aggression (Littrell & Littrell, 1998). Therefore, agitation includes aggression, which represents a severe and extreme form of agitation.

Disinhibition. Disinhibition is one of the essential components of agitation after TBI (Fugate et al., 1997). Disinhibition is the psychological term used to describe a lack of restraint. When behaviors that are normally suppressed before the brain injury cannot be inhibited after the brain injury (Fugate et al., 1997), these behaviors are described as disinhibition. Disinhibited behaviors are related to cognitive impairment. After brain injury, cognitive impairment can cause patients to lose their ability to inhibit their behaviors. Therefore, disinhibition can be used as one of the components for defining agitation. Sandel and Mysiw (1996) included disinhibition as one of the excessive behaviors in agitation.

Akathisia. The word "akathisia" originated from the Greek word "kathisis," which means sitting. Akathisia is defined as the inability to remain seated with a compulsion to move about (Sandel & Mysiw, 1996). The sensation of muscle quivering is a cause of motor restlessness in akathisia (Campbell, 1996). Akathisia has been reported after TBI, and the characteristics of akathisia are similar to those of agitation, including inner tension and motor restlessness (Sandel & Mysiw, 1996; J. T. Stewart, 1989). However, while akathisia is important in defining agitation, it is not sufficient. This is because akathisia is defined as motor restlessness without cognitive impairment, which is important in agitation after TBI.

In summary, typical features of agitated behavior after TBI include behaviors which (a) are repetitive and usually do not involve planning (non-purposeful), (b) are inappropriate or excessive, and c) involve restlessness, aggression, disinhibition, and akathisia (Yudofsky, Silver, & Hales, 1990).

Antecedents of Agitation after TBI

Cognitive impairment. After TBI, patients experience cognitive impairment, such as deficits of memory, attention, and executive function, and this cognitive impairment leads to confusion. In a confused state, TBI patients can exhibit agitation.

Cognitive impairments result from neurological damage in the brain. Neurological damage after TBI includes breakdown of the blood-brain barrier (BBB), infiltration of peripheral blood cells, activation of resident immunocompetent cells, and the intrathecal release of numerous immune mediators, such as interleukins and chemotactic factors. In addition, neurological damage initiates acute inflammatory responses in the brain, which may lead to neurological dysfunction; neurological dysfunction contributes to cognitive impairment (Lenzlinger et al., 2001). Following neurological damage, TBI patients pass through a period of cognitive impairment.

In particular, after severe brain injury, a patient commonly endures severe cognitive impairment (Matser, Kessels, Jordan, Lezak, & Troost, 1998). Severe brain injury may result in decreased frontal cortical cerebral blood flow and injury of an interconnection between the frontal cortex and the subcortical nuclei in the striatum, globus pallidus, substantia nigra, and/or the thalamus. Because this interconnection is related to arousal and cognitive function, recovery of the injured interconnection after TBI improves a patient's decreased arousal and impaired cognitive function (Kaufer, Cummings, & Christine, 1998). When TBI patients experience reduced arousal and cognitive function, their behavior is commonly agitated because cognitively impaired patients cannot easily interact appropriately with environmental stimulation. Therefore, a patient may naturally experience a period of agitation until his/her cognitive function is improved enough to interact with environments appropriately. Agitation is regarded as a natural stage of recovery from cognitive impairment after TBI (Corrigan & Mysiw, 1988).

Memory deficits. Memory deficits are one of the common cognitive impairments after brain injury (Ellenberg, Levin, & Saydjari, 1996). Contusions of the temporal cortex after TBI are related to memory deficits. In particular, damage to the hippocampal system in the temporal lobe is highly associated with a loss of recent memory (anterograde amnesia) (Corkin, Amaral, Gonzalez, Johnson, & Hyman, 1997; Davis, 2000). In the study of the magnetic resonance images (MRI) of severe TBI patients, the size of the hippocampus was reduced after TBI (Serra-Grabulosa et al., 2005). This hippocampal atrophy results in memory dysfunction because a function of hippocampus in encoding or storing information is involved. In particular, recall and recognition were impaired in patients with a damaged hippocampus (Manns, Hopkins, Reed, Kitchener, & Squire, 2003). Therefore, when patients have hippocampal damage, they may not recall their health care providers, and they may feel estranged from these persons, which may increase agitation. In addition, when a TBI patients' recognition memory is diminished, they have a hard time understanding their surrounding environment. They may think that this environment is not familiar, although they have been exposed to this environment before, and, thus, they may express agitation.

Attention deficits. The frontal lobe, as a common brain-injured area, is related to attention deficits and loss of executive function because the frontal lobe is associated with directing and maintaining attention and correcting, initiating, monitoring, and adapting behavior (judgment and self-regulation). Damage to the frontal lobe may interrupt the generation of additional attention needed to interact with a new environment. After TBI, patients cannot adequately focus their attention or sustain concentration (Davis, 2000; Stuss et al., 1999). As a result of attention deficit, TBI patients have difficulty following conversations and maintaining thought (Arciniegas et al., 1999).

Attention deficits are associated with agitation. Corrigan, Mysiw, Gribble, and Chick (1992) studied the relationship between agitation and attention. According to the authors, attention deficits were highly correlated with increased agitation. Furthermore, they concluded that an improvement in cognition (attention) is needed to decrease agitation (Corrigan et al., 1992). This result was consistent with the study of agitated patients with dementia (Whall, Black, Yankou, & Groh, 1994). In this research, agitated and aggressive behaviors of dementia patients were increased with attention deficits. Therefore, an attention deficit might be an antecedent of agitation.

Loss of executive function. Executive function is commonly impaired after a TBI. Impaired executive function is highly associated with damage to connecting structures or networks to the frontal cortex (Fluharty & Glassman, 2001). Impaired executive functions interrupt planning, organization, decision making processes, and appropriate judgment (Brooks, Fos, Greve, & Hammond, 1999). Therefore, TBI patients with a loss of these executive functions have difficulty in properly responding to and interacting with the environment and in handling situations that occur around them. This inappropriate response to the environment can be exhibited as agitated behavior after TBI.

Confusion or delirium. Cognitive impairment after TBI, including deficits in memory, attention, and executive function, causes a TBI patient's confusion. The confused period during acute rehabilitation is called posttraumatic amnesia (PTA). In the PTA period, patients have a diminished ability to form new memory (anterograde amnesia) and decreased capabilities of attention. This cognitive impairment results in disorientation to person, place, and time and confusion (Mysiw et al., 1990). Sandel and Mysiw (1996) suggested that as a result of the disorientation and confusion, a patient becomes agitated. For example, a TBI patient may wrongly perceive that he or she is at home with the family due to disorientation to person and place. Because TBI patients have anterograde amnesia (loss of recent memory), recently introduced people or places will always be recognized as new information. Therefore, nursing staff and other health care providers (i.e., physical therapists, social workers, and physicians) may be mistaken for intruders in his/her home. Consequently, this patient may show agitated behavior, climbing over the bedrail and getting out of bed (Gleason, 2003).

The Rancho Los Amigos (RLA) scale is the measurement to assess the level of recovery of brain injury patients. This scale is divided into eight stages according to the cognitive status and describes the various behavioral and cognitive statuses after a brain injury. The confused state is clearly described in RLA level IV: “confused and agitated state” (Hagen, Markmus, & Durham, 1979). At this level, a patient is alert and responds to simple commands but shows a confused state and agitated behavior. This particular feature of patients in RLA IV is caused by short-term memory problems, attention deficits, and a decreased ability to process information (Hagen et al., 1979). Although RLA level IV does not indicate a relationship between confusion and agitation, it does indicate that they occur together and that this confusion results from cognitive impairment.

Delirium is the term used in research for agitation after TBI when the confused state is described. Delirium, as a disturbance of consciousness, is used to refer to agitated and confused states (Taylor & Lewis, 1993). Delirium results from many etiologies, such as medications, metabolic alterations, and brain injury. Delirium resulting from traumatic brain injury is a focus of this paper. According to the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV), agitation after brain injury results from a cognitive disorder, such as delirium. However, delirium itself does not include behavioral features but only includes cognitive features. Thus, the course of onset in delirium is acute only, agitation, which could be acute or chronic and cognitive or behavioral, should be differentiated from delirium. Sandel and Mysiw (1996) suggested that agitation is defined as a subtype of delirium in their definition of agitation (Sandel & Mysiw, 1996; Taylor & Lewis, 1993). A confused state or delirium is an important feature of agitation (McCullagh & Feinstein, 2005).

Alteration of emotion. Emotion can strongly influence the motivation of one's behavior. For example, if a person gets angry, this can become the motivation leading to aggressive behavior. Likewise, agitation can be motivated from an unsafe feeling and/or uncontrolled impulsiveness (Bloom, Nelson, & Lsaerson, 2000).

In the case of TBI patients, their injuries related to emotional function can alter emotional responses (e.g., irritability, quickness to anger, disinhibition, or emotional lability) and can produce difficulty in controlling their impulses and having a sense of security. According to research, nurses taking care of patients with acquired brain injury identified that frustration in patients is the most common feeling before agitation. Patients also were reported to be distressed, anxious, scared, angry, and desperate prior to becoming agitated (Pryor, 2005). These losses of emotional control are influenced by brain damage. The limbic system (e.g., amygdala and hippocampus) and frontal lobe, which are commonly injured brain areas, are associated with emotional function. In the limbic system, the amygdala enhances the activity to respond to fearful stimuli and identifies threat (Dolan, 2002). Damage to the amygdala produced deficits in identifying threat and fear, which involve agitated behavior (Bechara et al., 1995). In addition, the amygdala functions to mediate impulses from the prefrontal cortex and the hypothalamus (Bloom, Nelson, & Lsaerson, 2000; Halgren, 1992). Therefore, when a patient has an injury to the amygdala, violent behavior and agitated/aggressive behavior are increased due to uncontrolled impulsiveness after the injury (Tonkonogy, 1991).

Next, the frontal lobe damage results in a lack of control over emotionally changed behavior (Patrick & Hebda, 1997; Sanchez-Navarro, Martinez-Selva, & Roman, 2005; Silver & Yudofsky, 1994). The frontal lobes regulate attention, provide continuity and coherence of behavior, and adjust behavior. Losses of these cognitive functions result in emotional lability, and deficits result in inhibitory control (Demark & Gemeinhardt, 2002; Patrick & Hebda, 1997). In clinical research, patients who suffered orbitofrontal area damage showed emotional disturbances, such as a lack of impulse control, irritability, hyperkinesis (Mattson & Levin, 1990), and mood changes (anxiety and depression) (Grafman, Vance, Weingartner, Salazar, & Amin, 1986; Phillips, Drevets, Rauch, & Lane, 2003).

In conclusion, agitation, as a result of a lack of impulse control and/or emotional lability, is generated from injury of the limbic system and is caused from a failure of inhibition control in the frontal lobe. A brain injured region in the frontal lobe and limbic system leads to alterations of emotion. As a result, a brain-injured patient may be highly impulsive and may more easily feel insecurity or fear (anxiety) in interaction with the environment than people without brain injuries. Therefore, alterations of emotion after TBI result in disturbed behaviors and agitation.

Stimulation. An important antecedent of agitation is external stimulation; noxious stimuli in environments, pain, and frustration exist before the agitation begins (Eckhardt & Deffenbacher, 1995). External stimulation, such as pain or frustration, were described in the Agitation Behavior Scale (ABS) as antecedents of agitated behaviors (Corrigan, 1989). Regular structured activities, including hygiene programs, meal times, and toileting, are directly observed before agitation during rehabilitation. Therefore, these activities can be another external stimulation and contribute to agitated behaviors. In particular, physical activities, such as bathing and toileting, causes a patient to be agitated because these activities pressure a patient to initiate movement (Algase et al., 1996). In addition, the direct contact to a patient's body or entering a patient's private space during these activities may make a patient feel insecure by invasion from a stranger, and, as a result, the patient may express more agitation. Therefore, the agitated behavior occurs as a response to external stimuli.

Consequences of Agitation after TBI

Interruption of treatment and threat of safety. The consequences of agitation can include interrupting treatment (Burke, Wesolowski, & Lane, 1988). These outcomes of agitation are illustrated in the results of studies of agitation after TBI (Brooke, Patterson et al., 1992; Mysiw, Jackson, & Corrigan, 1988; Page, 1992; Prigatano, 1987). Prigatano (1987) indicated that uncontrolled agitation might lead to rehabilitation failure. Page et al. (1992) stated that agitation subsequent to TBI hampered the rehabilitation process and delayed recovery. In the review article by Day (1999) and Brooke et al. (1992), the authors summarized the consequences of agitation as disruptions of nursing care or therapy in their definition of agitation. Bogner et al. (2001) studied the role of agitation in the prediction of outcomes after TBI. In their longitudinal study of 340 patients with brain injury, the presence of agitation was associated with a lengthier rehabilitation stay ($P < 0.001$). Furthermore, it decreased functional dependence at discharge, and patients with agitation were less likely to be discharged to a private residence ($P < 0.001$ for both).

Posttraumatic agitation disrupts rehabilitation; furthermore, it disturbs the achievement of functional goals (Sandel & Mysiw, 1996). Therefore, one of the common results of agitation after TBI is that agitation interrupts rehabilitation therapy and nursing care.

In addition, when agitation involves physically aggressive behavior, it can threaten the safety of patients and caregivers. In the unsafe situation involving threats and violence, the opportunity to engage in rehabilitation will be decreased as well. The attributes, antecedents, and consequences of agitation are summarized in Figure 2.1.

A Proposed Definition of Agitation after TBI

The need for a consistent definition for agitation after TBI has been acknowledged as a critical issue by many researchers who have proposed definitions. The ideal definition of agitation after TBI includes cognitive, emotional, and behavioral features. However, many authors have struggled to include cognitive and emotional features in their definitions because they are very hard to describe. Consequently, only behavioral characteristics, which are objectively observed, are used to define agitation. Nevertheless, in this study, the definition includes cognitive and emotional features as antecedents to agitation and behavioral ones as attributes of it. The following is proposed as the theoretical definition of agitation exclusively using behavioral features.

The defining characteristics of behaviors that contribute to agitation include the following: (a) repetitive and purposeless, (b) extreme (excess) and inappropriate, (c) verbal (i.e., screaming and making strange noises) and excessive motor behavior, and (d) restlessness, aggression, disinhibition, and/or akathisia. The antecedents of agitation are stimulation and confusion resulting from emotional alterations and cognitive impairment, including deficits of memory, attention, and executive function. Interruption of attributes,

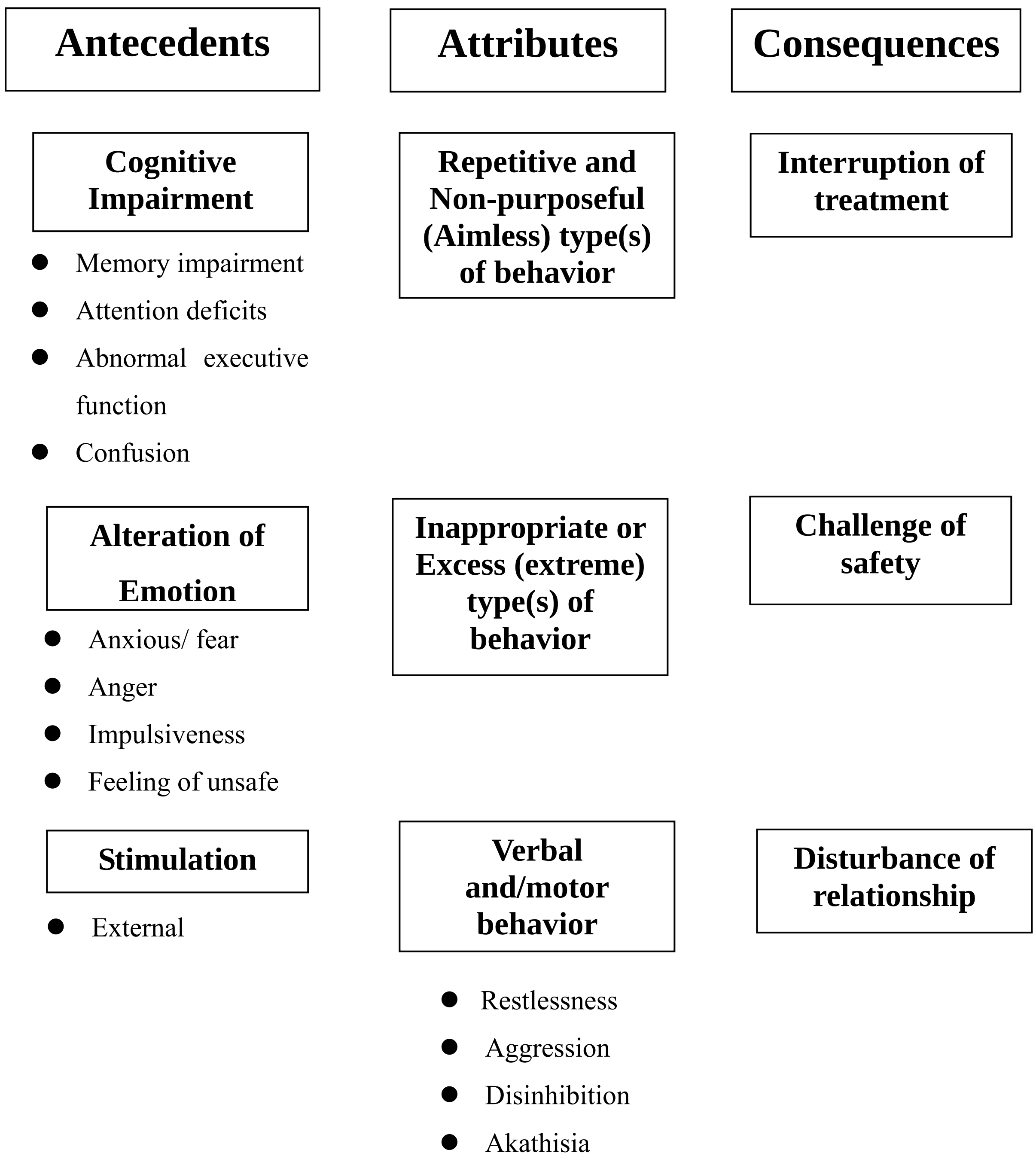


Figure 2.1. Antecedents, attributes, and consequences of agitation after TBI.

rehabilitation and therapy (care) is the consequence of agitation. Based on these antecedents, and consequences, a simple definition, but one that includes the essential parts to theoretically define agitation, is proposed as follows.

Agitation after TBI includes one or more repetitive, non-purposeful, and inappropriate verbal and motor behaviors, which may be provoked by external or internal stimulation, and occur during the confused state (PTA) which results from cognitive impairment and/or emotional instability after TBI. Agitation, furthermore, interrupts a patient's care, therapy, and/or safety. The behavior consists of some combination of restlessness, aggression, disinhibition, and akathisia.

Treatment for Agitation after TBI

Treatment for agitation after TBI is "a multi-disciplinary process that begins with a comprehensive assessment to determine various factors contributing to the problematic behaviors" (Kim, 2002, p. 301). Up to the present, pharmacological treatment, such as using sedative medication, behavioral therapy, and physical restraints are the most dominant methods to control agitation. However, pharmacological treatment can produce other problems, such as drug side effects and drug-drug interactions. Behavioral therapy does not have firm evidence of efficacy. Physical restraints are also discouraged for agitated patients because they might aggravate agitation and cause other injuries (Brooke, Patterson et al., 1992; Zafonte, 1997). For these reasons, the development of a safe and efficient intervention is required.

A recommended safe and efficient management for agitation is environmental management. In many clinical settings, physicians forbid patients to watch television and limit the number of visitors during the acute stage of rehabilitation. The purpose of these limitations is to protect patients from over-stimulation, which can produce agitation (Plylar, 1989; Wolf, Gleckman, Cifu, & Ginsburg, 1996; Yuen & Benzing, 1996). Therefore, offering a quiet, organized, and structured environment is emphasized to decrease agitation in rehabilitation units.

In addition to environmental control, bringing familiar pictures and possessions to TBI patients and the presence of family and familiar staff are encouraged as the therapeutic strategy for agitated patients. The reason is that familiar persons and objects elicit memories associated with positive emotions (affect). The positive emotions encourage individuals to engage in their environment and aid in recovery from negative emotions (Gerdner, 1997). In addition, in a familiar environment, people can predict their situation, use less effort, and more quickly extend their cognitive capacity to interact with their environment. As a result, a patient can focus on important stimuli without being disturbed by other complicated and confusing distractions (Gerdner, 2000), and they feel more comfortable (Kaplan & Kaplan, 1982) and show less agitated behavior.

In summary, there are several safe and efficient treatments for agitation after TBI: controlling environmental stimulation and providing familiar environmental factors. In particular, a familiar environment may be beneficial in managing agitation by reducing stimulation, decreasing the mismatch between stimuli and interpretation, and increasing emotional support, such as the feeling of safety. Therefore, the goal for the treatment of agitation will be minimizing unfamiliar or unexpected situations and promoting familiarity with the environment (Baker, 2001a).

Familiarity and TBI

First of all, in order for familiarity to be used as an intervention for agitation after

TBI, it is necessary to find out if patients can recognize the familiar environment even after brain injuries. In spite of the heterogeneity in brain injuries, most TBI patients suffering amnesia have exhibited intact familiarity but have displayed deficits of recollection (Moscovitch & McAndrews, 2002; Squire & Knowlton, 2000; Yonelinas, Kroll, Dobbins, Lazzara, & Knight, 1998). To identify whether the circumstance that one is currently experiencing was part of past experience, the person uses recognition memory. According to dual-process theory, recognition decisions are based on two processes: familiarity and recollection. When people have a feeling of familiarity to a specific item and/or incidence, although they cannot retrieve the source of that feeling, it is called familiar-based recognition. Recollection-based recognition occurs when people are able to identify the specific detail associated with the prior presentation of an item and/or incidence (Cleary, 2008).

Recognition is governed by different regions of the brain. Two subregions of the temporal lobe, the hippocampus and the perirhinal cortex, are associated with recognition memory. Familiarity is based on the perirhinal cortex, while the hippocampal region is the most critical for recollection. The hippocampal region and the perirhinal cortex are independent. In functional magnetic resonance imaging (fMRI) testing, the perirhinal cortex exhibit greater activation with familiarity, whereas a greater activation during recollection was exhibited by the hippocampus (Davachi, Mitchell, & Wagner, 2003). Another neuroimaging study found that detecting stimuli with familiarity depends on the perirhinal cortex while recollection is hippocampal dependent (Aggleton & Brown, 1999; Holdstock et al., 2002; Manns et al., 2003).

Two different thalamic-temporal connections make different contributions to recognition memory; the perirhinal cortex is connected with the medial dorsal thalamic nucleus, whereas the hippocampus is connected with the anterior thalamic nuclei. The perirhinal-medial dorsal thalamic system is related to familiarity, whereas the hippocampal-anterior thalamic system is related to recollection.

In addition to independence between the hippocampus and the perirhinal cortex, the hippocampus is one of the vulnerable areas after TBI. In a study of 109 TBI patients, they had significant bilateral hippocampal atrophy after injuries (Ariza et al., 2006). Experimental studies in animals demonstrated neuronal loss in the hippocampus after induced TBI (Hicks, Smith, Lowenstein, Saint Marie, & McIntosh, 1993; Kotapka et al., 1991). Neuropathological studies in children (Kotapka, Graham, Adams, Doyle, & Gennarelli, 1993) and adults (Kotapka, Graham, Adams, & Gennarelli, 1994) revealed that a high prevalence of hippocampal damage is present after fatal head injury. Moreover, in vivo magnetic resonance imaging (MRI) studies revealed clear hippocampal reductions in TBI patients in children (Serra-Grabulosa et al., 2005) and in adults (Hopkins, Tate, & Bigler, 2005; Tate & Bigler, 2000; Tomaiuolo et al., 2004). Since hippocampal damage was a common consequence of TBI, the recollection based-recognition memory was deficient, while the familiar-based recognition was intact.

In summary, although familiarity and recollection come from recognition, they may be functionally independent. Because of this independence between the hippocampus and the perirhinal cortex, amnesic patients after damage to the temporal lobe (mostly hippocampus damage) can preserve the function of familiarity. Therefore, the intervention with familiar environments can be applicable to the management of agitation after TBI.

Application of Preferred Music in Agitation

Providing familiar environments to agitated patients after TBI is an important intervention to reduce the need for pharmacological or physical restraints. Use of familiar music is one such approach. Familiar music can be a more practical and feasible intervention to study agitated behaviors after TBI than other interventions using other kinds of environmental stimulation, such as familiar people and objects.

To generate strong positive emotion from familiar music, familiar music should be concretized with sub-categories. The familiar music can be either preferred or not preferred music. Familiar and preferred music indicates that the music is familiar and, at the same time, the favorite of an individual. Familiar but not preferred music is the music which is familiar but that the individual does not prefer over other forms of music. The former can generate positive feelings, but the latter cannot. Therefore, preferred music is the focus in this research because positive feelings play an important role in the reduction of agitation. Preferred music consists of two components: music and preference. In the next section, how music therapy is effective as an intervention to manage agitation and how music can have more power when an individual's preference is added will be addressed.

Therapeutic use of Music

Music therapy is defined as the "controlled use of music and its influence on the human being to aid in physiological, psychological, emotional integration of individual during treatment of an illness or disability" (Munro & Mount, 1978, p. 1029). Music therapy has been actively studied as an alternative intervention in many research fields. Advantages from music therapy are that music can induce relaxation and modify environmental stimuli by masking noises and preventing over stimulation.

The effect of music therapy as a clinical intervention is widely used to relieve pain and to improve negative mood (Magee & Davidson, 2002; Mitchell, MacDonald, & Brodie, 2006; Siedliecki & Good, 2006). Music therapy has the effect of decreasing pain for patients with leg fracture (Kwon, Kim, & Park, 2006), for patients recovering from cardiac surgery (Sendelbach, Halm, Doran, Miller, & Gaillard, 2006), and for patients in hospice and palliative care (Hilliard, 2005). A pilot study by Magee and Davidson (2002) reported that music therapy significantly promoted a positive mood change. Anxiety and hostility, in particular, were reduced after music therapy in the neuro-rehabilitation population, including TBI patients. This research suggests that music therapy is important when taking care of patients who suffer severe and complex neuro-disability and show a negative mood status, such as agitation.

General "relaxation" music has been used for agitated patients with dementia as a non-pharmacological treatment. Hicks-Moore (2005) studied the effect of relaxing music at mealtime on agitated patients with dementia. Thirty agitated nursing home residents received music therapy during weeks 2 and 4. In weeks 1 and 3, no music was played, and then the number of agitated behaviors was compared. In the results, agitated patients showed a greatly reduced amount of agitated behavior during the time when relaxing music was being played (Hicks-Moore, 2005). These studies showed that relaxing music therapy is effective to decrease agitation.

Listening to music can provoke emotional responses, such as relaxation and excitement (L. Stewart, von Kriegstein, Warren, & Griffiths, 2006). Studies using positron emission tomography (PET) and functional magnetic resonance image (fMRI) found that the right posterior temporal lobe and insula, which are related to emotional responses to music, are activated during listening to music (Blood & Zatorre, 2001; Koelsch, Fritz, Cramon, Muller, & Friederici, 2006; L. Stewart et al., 2006). In general, loud and fast music is associated with high energy and excitement, while slow and quiet music is associated with calmness and relaxation (Hanser, 1990; Sloboda, 2003; Sloboda & Juslin, 2001). Therefore, music might be selected to arouse emotional response according to the circumstances. In most studies, music selection for a reduction of agitation is relaxation music, such as slow and quiet music, because it is believed that calmness and relaxation help to decrease agitation. However, people can experience different emotional reactions to the same relaxation music because an individual's personal memory reminds him/her about particular past events involving strong emotions when listing to music (Sloboda, 2003). If the past events are not related to positive emotion, relaxation is not expected when listening to the music. In particular, because TBI patients have cognitive impairment, relaxation music can be additional stimuli that can generate agitated behavior. Therefore, the music itself is not enough to produce positive emotions. To evoke positive emotion, the music should be selected from preferred music that can generate positive personal memory.

Preferred Music and Agitation

There have been studies focusing the positive effects of preferred music on managing an individual's behavior and experiences. Janelli and Kanski (1997) studied the effect of preferred music on 30 hospitalized patients in restraints. They found that the number of positive behaviors (smiling, nodding, and humming) increased significantly while they listened to preferred music (Janelli & Kanski, 1997). The authors interpreted these positive behaviors as possibly resulting from positive feelings, which were elicited while they were listening. Mitchell et al. (2005) studied the effect of preferred music on pain and found that listening to preferred music significantly provided a greater tolerance to negative painful experiences than being exposed to humor. This is because preferred music elicits positive emotions, which enable people to control their perception of negative experiences (Mitchell et al., 2006). Furthermore, these positive feelings may be effective in controlling agitation.

Listening to preferred music has the potential to decrease agitation. In the theory of individualized music intervention for agitation (IMIA), Gerdner (1997) suggested that the selection of music is critical in the advanced management of agitated patients. Gerdner explained that to elicit positive memories, the music must be individualized. In addition, to maximize the effect of music therapy, the researcher recommended that music should reflect the person's life and personal preferences. To verify the theory of IMIA, Gerdner (2000) examined the effects of individualized music and classical "relaxation" music on agitated patients with dementia. She found that agitation was significantly reduced during and following individualized music therapy compared to therapy using classical "relaxation" music (Gerdner, 2000).

Ragneskog and colleagues (2001) showed similar results. When they analyzed video-recorded sessions of four agitated patients with dementia receiving music therapy, all patients reacted to the music in some way. Two of the four patients showed reduced agitation after listening to individualized music, while the others were marginally influenced by it. Interestingly, the two patients whose agitated behaviors decreased while listening to individualized music became agitated several times after the music stopped.

This recurrence of agitation with the discontinuation of individualized music strongly supported the theory of the effectiveness of individualized music on agitation. Again, the results showed that the effect of classical music was less than that of individualized music. The authors concluded that individualized music is effective in soothing agitation in people who suffer severe cognitive impairment with dementia (Ragneskog et al., 2001). In this study, the same conclusion has been applied to agitated patients after TBI, most of who suffer similar types of memory impairment as that of dementia patients. Both types of patients have impairment in explicit memory but conserved implicit memory. In addition, Corrigan et al. (1996) found that there was no significant difference in the behavioral components of agitation between TBI patients and patients with Alzheimer's disease because agitation is the same phenomenon across affected populations (Corrigan, Bogner, & Tabloski, 1996). Therefore, the results of intervention with preferred music, which was significantly effective in the reduction of agitation in patients with Alzheimer's disease, can be applicable to decreasing agitation after TBI.

Few studies have been done on the relationship between agitation after TBI and preferred music. Formisano and colleagues (2001) examined the effect of general music therapy on the agitated behavior of severe brain-injured patients. Thirty-four severe brain-injured patients showed a significant reduction of undesired behaviors, such as psychomotor agitation with active music therapy. Active music therapy included singing and playing different musical instruments. Although the music in this study did not include preferred music, the authors showed that music has an impact on agitation after severe brain injury (Formisano et al., 2001).

The case study by Seibert and colleagues (2000) confirmed the effect of preferred music therapy on cognitive recovery after TBI. A 20-year-old professional female oboist with severe brain injury listened to tapes of her past performances and her favorite music and, as a result, experienced less anxiety and became calmer. The author indicated that the lowering of anxiety and calming effect produced by preferred music allowed the patient to be more relaxed and focused on her tasks in therapy (Seibert et al., 2000). This study showed the value of preferred music as a vital tool in a TBI patient's cognitive recovery, which is essential in the reduction of agitation.

Baker (2001) conducted a research study on the effect of preferred music on the agitation of post-traumatic amnesia patients. Twenty-two patients were exposed to three situations: live music, taped music, and no music. The pieces of music were selected from each patient's favorite songs, a list of which was provided by the patient's family members. After experiencing two instances of each type of situation over six consecutive days, patients' agitation during preferred music therapy was significantly reduced compared with the agitation observed when there was no music therapy ($p < 0.0001$) (Baker, 2001a). The author explained the reasons for the effects of preferred music on agitation in several ways. She stated that preferred music enhances patients' orientation to their surroundings. Patients having better orientation exhibit less agitation because they are able to understand the unfamiliar environment and the actions of unfamiliar persons. In addition, the music provides a structural framework for the appropriate expression of agitation by the releasing of agitated energy in acceptable ways (Baker, 2001b).

The previously mentioned studies about preferred music and agitation verified that preferred music is effective in the reduction of agitation. There are additional studies concerning the rationale for this effect. First, the effect of music on agitation can be explained by using physiological factors. Listening to music can decrease person's cortisol level, which is one of the indicators of the presence of stress (Fukui & Toyoshima, 2008; Nilsson, 2009). This decreased cortisol level may influence the reduction of anxiety and the promotion of relaxation. Furthermore, reduced anxiety and increased relaxation can positively influence the reduction of agitation. In addition, Campbell (1997) examined the physiological effects of music therapy. The researcher found that music slows down brain waves, reduces tension, and increases endorphin levels. These physiological changes can alleviate agitation after TBI.

The second rationale for the effects of preferred music can be associated with cognitive factors. Listening to preferred music enhances one's ability to pay attention in new and unfamiliar environments. Therefore, under the influence of preferred music, patients might have a greater ability to understand and interact with their environment effectively. In addition, since preferred music therapy elicits positive memories associated with positive feelings, these memories and feelings might positively work to decrease the occurrence of agitated behaviors after TBI (Ragneskog et al., 2001).

In spite of the seriousness of the results of agitation in TBI survivors, few studies have been conducted on samples of these patients. Therefore, further investigation should be focused on this population. Consequently, the focus of the current study was on agitation after TBI and the effects of preferred music on agitation as an alternative intervention in these cases.

CHAPTER III

METHODS

This study identified the effects of preferred music and classical “relaxation” music on decreasing the agitation of severe TBI survivors during the subacute stage of recovery. In addition, the effects of “preferred” music therapy and of classical “relaxation” music were compared to each other. This chapter covers the study design, sample selection protocols and characteristics, evaluation of instruments, data collection procedures, and data analysis method.

Design

This study was a crossover design within subjects using a non-probability and purposive sampling method. Agitation was quantified with the Agitated Behavior Scale (ABS) by Corrigan (1989). Based on the previous studies on agitation after TBI, the subacute stage of recovery was selected to be the best time for a post-TBI agitation study.

The study consisted of two interventions and a control under the crossover design: preferred music, classical “relaxation” music, and no music (control). Patients had their own control group because randomizing people with TBI into cross-matched groups is difficult (Sohlberg & Mateer, 1989). Since each patient received both music interventions (preferred music and classical “relaxation” music) during the data collection period, there could have been possible cumulative effects of the first intervention on the second. To examine this possibility, patients were divided into two groups by the computer's random number generator (see Table 3.1). In the first group (Group A), patients were assigned to receive classical "relaxation" music on day 1 and then "preferred" music intervention on day 3. In the second group (Group B), patients received preferred music on day 1, and then classical "relaxation" music on day 3. The number of patients in both the preferred music and the classical music groups was the same.

Table 3.1.

Randomization of Group Assignment with 14 Patients

Subject	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Group	A	A	A	B	B	B	B	A	A	B	A	B	B	A

Note.
A: Classical "relaxation" music first
B: Preferred music first

Sample

The sample consisted of 14 patients admitted to the brain injury rehabilitation unit at the University of Pittsburgh Medical Center (UPMC) between July 2008 and September 2009. The sample was primarily composed of males because it has been shown that males are afflicted with head injuries more than females (male: female ratio, 3–4: 1) (Bell, & Sandell, 1998). However, females were not excluded when they were available, provided their families consented, because previous work has shown that the incidence of agitation after TBI is not dependent on gender (Kadyan et al., 2004). In this study, 11 out of 14 subjects were male, while 3 subjects were female. The ratio of male to female subjects was 5:1.

Power Analysis

The computer program Power Analysis and Sample Size (PASS) was used to calculate the sample size. According to the PASS, the total number of subjects was calculated to be 14. The proposed sample size of 14 had 80 percent power to detect an effect size of 2.6 using a two-tailed hypothesis with a significance level α of 0.05. A clinically significant mean difference of the ABS (mean difference (δ)) was estimated with 3.0 units and a standard deviation (σ) of 2.6 units based on a previous study by Baker (2001), which explored the effect of live and taped favorite music on agitation during PTA. Because the design (i.e., a crossover design within subjects) and concept of Baker's study were congruent with the proposed study, these results were used to estimate sample size.

Inclusion Criteria

Subjects eligible for the study had to satisfy the following inclusion criteria:

(a) Adults aged 18 years and older because immature developmental processes, such as learning skills, could influence the recovery from TBI in children/ adolescents,

(b) Patients admitted to an acute rehabilitation unit (a subacute stage of rehabilitation (Bogner et al, 2001; Van der Naalt et al., 2000)),

(c) Patients with a severe traumatic brain injury (Glasgow Coma Scale ≤ 8 at acute hospital admission, see Appendix A),

(d) Patients who exhibited a primary state of agitated behavior (history of the Agitated Behavior Score >20, see Appendix A),

(e) Patients with cognitive impairment (moderate or severe cognitive impairment indicated by a cognitive functioning examination and/or the Brief Neuropsychological

Cognitive Examination (BNCE) see Appendix A).

Co-investigators (physicians in the brain injury rehabilitation unit) identified potential subjects based on their medical records upon admission to the rehabilitation unit.

Exclusion Criteria

The five exclusion criteria were as follows:

(a) Known pre-morbid risk factors, including a history of psychiatric disorder, such as dementia, delirium, and Alzheimer's disease,

(b) Known withdrawal signs related to substance abuse,

(c) Obvious signs of uncontrolled pain or infection,

(d) No available relatives or friends who could provide information regarding the subjects' favorite music,

(e) A plan to discharge before the data collection was completed.

The patients were assessed for meeting the exclusion criteria by reviewing their medical records and by questioning staff members who were taking care of them.

Recruitment and Informed Consent

The research was approved by the health institutional review board (IRB) at both of the University of Michigan and at the University of Pittsburgh. After the research was approved by the IRBs, the recruitment of patients was started at the brain injury rehabilitation unit at the UPMC Southside and UPMC Mercy. Drs. Camiolo-Reddy and Shen, who were the attending physicians at the UPMC rehabilitation department, identified patients who met the study criteria during their daily inpatient rounds by reviewing the subjects' medical records.

Once eligible patients were identified, one of the attending physicians and a resident made initial contact with potential patients' family members to briefly explain the study. Because the patients were unable to give informed consent after brain injury, their family members had the responsibility of signing the consent form on their behalf (see Appendix B). When the family members were interested in participation in the study, the primary investigator and/or the physician obtained the signed consent. They informed the family members about the purposes of the study and potential risks and benefits. The family members were encouraged to ask questions. After answering any questions or concerns about the study, the family members signed the informed consent form and the Health Insurance Portability and Accountability Act (HIPAA) consent form.

Training a Research Assistant (RA)

The primary researcher hired an independent research assistant (RA) to prevent a possible bias in the rating of the ABS and to increase confidence in the data. Since the primary researcher knew the purpose of study, she might consciously or unconsciously give extra attention to the preferred music intervention group compared to the classical "relaxation" music intervention group. Therefore, a hired RA who was uninformed about the study purposes neutrally rated the ABS scores. In addition, the primary researcher could be confident in data trend by comparing the data trends between the primary researcher and the research assistant. In other words, ascending and descending data trends of the primary researcher and the RA were compared. When the trends of the data were similar, the primary researcher had confidence in the RA's data. Since the RA was absent several times during the data collection due to health problems, the RA's data could not be used for data analysis.

Sample Characteristics

Demographic data were collected from medical record reviews to obtain the age, gender, race, admitting GCS, neurocognitive evaluation record, substance use history, head injury information, such as date of injury, and additional health history information of patients. Before obtaining demographic data, the researcher received permission from the family members for the hospital to release the patient's medical records. Demographic information that could not be found from the medical records was obtained by asking questions of the subject's family members.

The average age of the subjects was 34.64 years (SD=13.66, range 19-61). Of the 14 patients, 12 were under age 45, and 7 subjects were between age 20 and 29; 11 out of 14 patients were males, and 3 patients were females. The characteristics of the study sample were similar to the statistical characteristics of TBI patients. Thirteen subjects were Caucasian, and one subject was Asian Indian (non-Caucasian).

Measures

Measures of Cognition

Glasgow Coma Scale (GCS). The GCS administered upon admission to the hospital was used for inclusion criteria purposes as a screen of the severity of brain injury. The GCS is based on the numerical values assigned to an individual's eye opening (4 points), verbal responses (5 points), and motor responses (6 points). Each response score is calculated separately, and then all scores are totaled. A total score of less than or equal to eight indicates severe brain injury. The advantages of GCS are that it is time efficient, easy to calculate, and requires very little user training (Iacono & Lyons, 2005).

Inter-rater reliability of the GCS is moderate (Pearson's r = 0.66) (Gill, Reiley, & Green, 2004) to good (Pearson's r=0.95) (Heard & Bebarta, 2004; Juarez & Lyons, 1995;

Segatore & Way, 1992), and Cronbach's alpha is reported to be 0.83 (Mayer et al., 2003). The GCS was moderately correlated with the 60-second test (Spearman *rho* = 0.72, $p < 0.01$) in construct validity.

Brief Neuropsychological Cognitive Examination (BNCE). The BNCE was used in this study to objectively measure cognitive functioning after TBI because this was the main evaluation form used to examine a TBI patient's cognitive functioning in the brain injury unit at the UPMC. It was administered by the neuropsychologist when a new TBI patient was admitted. The BNCE was developed to evaluate cognitive functioning, including memory, gnosis, praxis, language, orientation, attention, and executive functioning (Ball, Pastore, Sollman, Burright, & Donovick, 2009; Levin, O'Donnell, & Grossman, 1979). The advantage of this screening instrument is that the BNCE can assess the cognitive functioning in less than 30 minutes. It is divided into two parts: part I and part II. Part I was created to assess a patient's ability to use basic information, such as naming parts of the body and the patient's orientation to place and time. Part II was created to assess other cognitive functioning abilities, such as attention, verbal reasoning, and working memory. Each part contains five subtests that are designed to assess the information-processing abilities necessary for daily cognitive functioning. The total score was calculated to identify the overall severity of cognitive impairment and the level of cognitive functioning. It is interpreted as normal, mild, moderate, and severe cognitive impairment. A score between 28 and 30 is considered normal, between 22 and 27 is mild impairment, between 10 and 21 is moderate impairment, and between 0 and 9 is severe impairment.

Cognitive Functioning Log. A cognitive functioning log was included in the initial neurocognitive evaluation and recorded by the neuropsychologist in the brain injury rehabilitation unit at the UPMC. It consists of eight subgroups: orientation, expressive language, attention, comprehension problems, visuospatial problems, problem solving/judgment problems, memory problems, and executive functioning problems. The physician used this record to identify eligible patients who had cognitive impairment. When the result of a patient's cognitive functioning log was greater than or equal to moderate, the patient was considered cognitively impaired, which was one of the inclusion criteria of this study.

Measures of Agitation

Agitated Behavior Scale (ABS). Agitation was measured by the widely used Agitated Behavior Scale (ABS) (Corrigan, 1989). The scale consists of 14 observable items. Each item is rated by a level of severity ranging from one to four. A score of one indicates that the behavior is not present; two indicates that the behavior is present to a slight degree but does not interfere with adaptive functioning; three indicates that the behavior interferes with functioning (to a moderate degree) but is redirectable; and four indicates that the behavior is so severe that it cannot be redirected (extreme degree) (J. A. Bogner, Corrigan, Stange, & Rabold, 1999). With a score three or four, redirection should be attempted. Therefore, the researcher gave subjects redirection (extra cueing) when necessary during the data collection. A score of greater than or equal to 21 indicates that a patient is agitated. A maximum score of 56 suggests that all 14 types of agitated aspects are found to an extreme degree. The ABS scale is divided into no (< 21), mild (21–28), moderate (29–35), and severe (≥ 36) agitation (Zun & Downey, 2008).

According to Baker (2001), the ABS scores were classified by four different components of agitation: physical, cognitive, behavioral, and verbal.

(a) Physical: These ABS components (Appendix A, items 6, 7, 8, 9, 10) measure the severity of unnecessary physical movements indicative of agitation. These include pulling at restraints or tubes, rocking, rubbing and self-stimulating behavior, wandering and pacing, restlessness and excessive movements, and repetitive behavior.

(b) Cognitive: These ABS components (Appendix A, items 1, 2) measure the levels of cognition that reflect agitation. These comprise impulsivity, impatience, intolerance, and poor concentration and attention.

(c) Behavioral: These ABS components (Appendix A, items 3, 4, 5, 12, 13, 14) measure the levels of abnormal behavior. Behavioral signs of agitation comprise sudden changes in mood, incidences of threats of violence, unpredictable anger, uncooperative behavior, easily initiated or excessive crying/laughing, and incidences of self-abuse.

(d) Verbal: This ABS component of agitation (Appendix A, item 11) measures the incidence or severity of rapid, loud or excessive talking.

A positive score indicates that agitation decreased.

The ABS has high inter-rater reliability (r = 0.92) and high internal consistency (Cronbach's alpha = 0.92) in the neuro-rehabilitation population. In a study focusing on the reliability of the ABS within the long-term-care facility population (Bogner et al., 1999), the correlation coefficient of 0.87 and Cronbach's alpha of 0.81 suggest that the ABS is a reliable instrument for measuring agitation in patients with TBI. Two studies explored the content validity of items in the ABS and stated that (a) the ABS predicts changes in cognitive status (Corrigan & Mysiw, 1988) and (b) the ABS is able to differentiate between confusion and inattention (Corrigan et al., 1992). Construct validity has been demonstrated with a factor analysis (Corrigan & Bogner, 1994). This analysis found that agitation, as measured by the ABS, is best represented by a single construct with three underlying factors: aggression, disinhibition, and lability. The concurrent validity of the ABS was shown by correlation of the ABS with the Braintree Agitation Scale. The correlation between these scales ranged from 0.42 to 0.71, which indicates good construct validity (Corrigan, 1989).

Measures of Preferred Music and Classical "Relaxation" Music

Information about preferred music was provided by each patient's family members rather than by the patient because of the patient's severe degree of cognitive impairment. Each patient's family was asked to make a list of the patient's favorite songs and to bring his/her music collection. When they were unsure of specific songs, then music artists and/or kinds of music were collected instead. In cases where the family members could not prepare favorite songs from the patient's own music collection, the researcher recorded the CD of favorite songs based on the songs listed by the family members and the availability of music and popularity when they did not know specific songs (Baker, 2001a). When the family members did not know the patient's preferred music, the researcher consulted the patient's close friends about the patient's favorite songs. A CD of favorite songs was made to be played for one hour.

In this study, *Meditation-Classical Relaxation vol.3* was used for the classical "relaxation" music and was purchased from a record store. The album is an anthology of classical music by a variety of composers (i.e., Grieg, Beethoven, and Schubert). This music was judged by the team of music therapists to be soothing in effect and sedative in quality. This was the only classical music to be played for all subjects. No preferred music selection overlapped the classical "relaxation" music.

Procedures

This study was implemented over a period of three days. Data were collected for three hours each day. Day 1 was the first intervention day. The researcher selected 3 hours between 3 pm and 9 pm to avoid any conflict with a patient's therapy schedule. Also, it was predicted that patients might show more agitation at this time because they are generally more tired after therapies. Between 3 pm and 9 pm, all patients received structured nursing care according to their routine schedules and had dinner or tube feeding. Many TBI patients (68.4%) exhibit agitation during the structured nursing care (Alderman et al., 1997). The structured nursing care included checking vital signs, administering medication, helping with toileting, running feeding tubes, feeding the patients dinner, changing dressings, partial bathing, and so on. The nurses and/or nurse's aids performed these tasks as part of the patients' routine care. Each patient received all necessary medical treatments and regular medications during the data collection. In addition, a patient sitter, who was hired by the hospital and assigned according to unit policy, stayed with each patient at the bedside during data collection because the physician ordered one-to-one supervision for safety. However, family members were discouraged from visiting as much as possible when the study was in progress because interactions with family members could be a confounding variable.

The total time of observation was three hours per day, during which the ABS score was obtained every hour. The baseline agitation data were collected for the first hour of observation. At the end of the hour, the ABS score was calculated. Then, music was played for next hour according to the assigned music selection: classical "relaxation" music or preferred music. After one hour of music, the second ABS score was calculated. During the last hour of observation, no music was played. At the end of that hour, the final ABS score was obtained (see Figure 3.1).

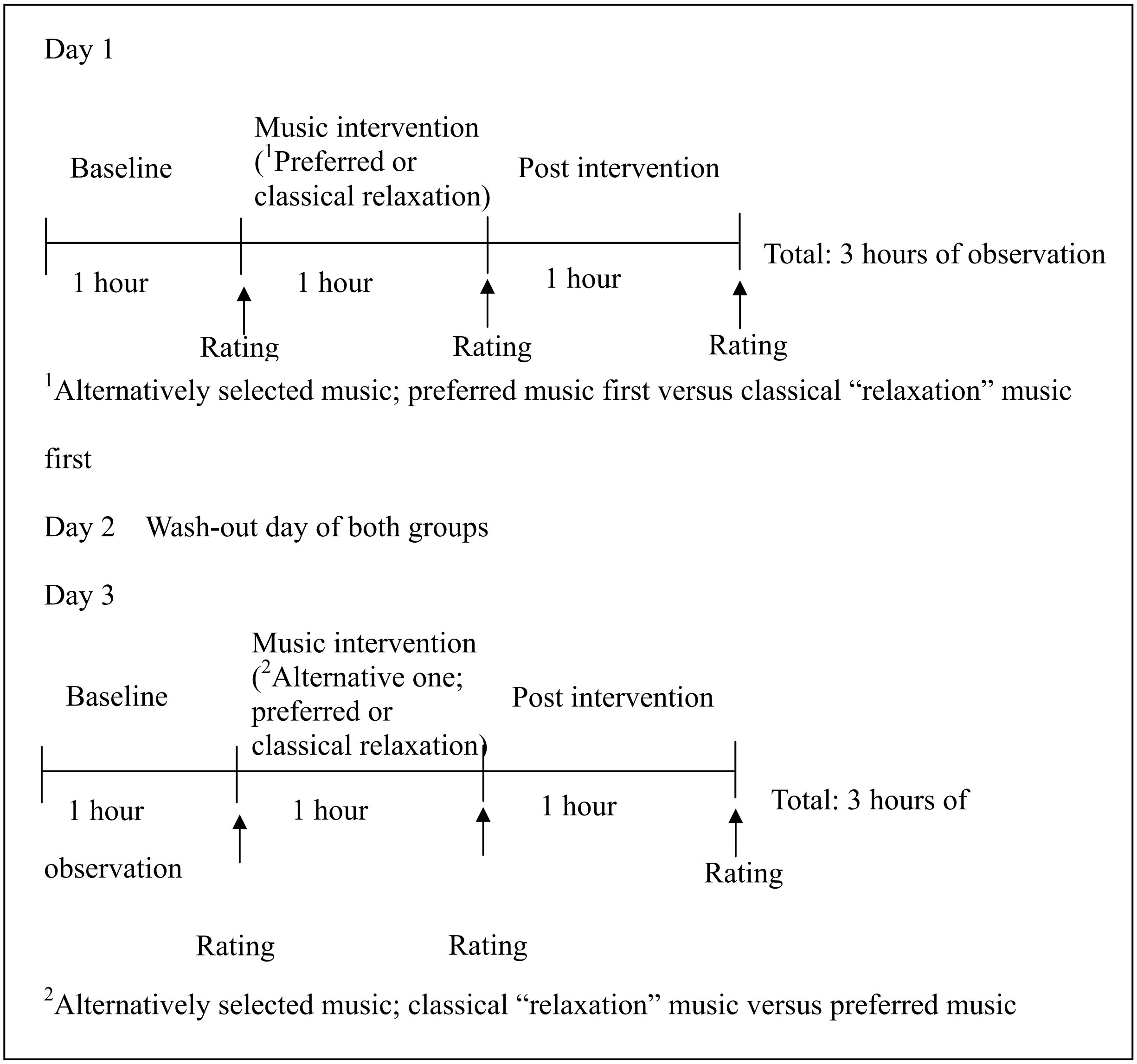


Figure 3.1. Time frame of music intervention

When the ABS score was greater than three (moderate degree), the patient was redirected. During the time of redirection, to lead the subject to appropriate behavior, the researcher talked to the patient to calm him/her down and verbally gave external cues, such as telling the person to tone down his/her loud voice or to stop pulling on a tube.

The duration of data collection was selected to be one hour in consideration of the patients' brain injuries and the time required to rate the ABS score. Aldridge et al. (1990) advised that the duration of music therapy sessions with people with head injuries should match the patients' short attention spans. More than one hour would be too long for a brain-injured patient to pay attention to music. On the other hand, the investigator's clinical experience and Corrigan's study (1989) indicated that an observation period of more than 30 minutes is required to complete the 14 items of the ABS and for the ABS to be reliable and valid. Therefore, the duration of intervention was selected to be one hour for this study. This was sufficient time to administer the ABS but not too long an observation time to work with brain-injured people.

On day 2, all patients went through the washout period to reduce the possible cumulative effects of the music intervention. On that day, patients were not involved in any research procedure.

On day 3, the procedure was the same as on day one except for the order of the music. Patients received preferred music on day 3 if they had received classical "relaxation" music on day 1. Patients, who had received preferred music on day 1, received classical "relaxation" music on day 3. The data were collected at the same time as on day 1.

Anecdotal notes were recorded by the researcher to acquire more information about the patients' agitated behaviors. All patients' behavioral patterns and any responses to stimuli that the patient exhibited were recorded during the observation. These notes provided qualitative data that extended beyond the ABS measurement. They provided a more holistic view of the patients' responses and evaluated the clinical significance of the preferred music intervention in addition to the statistical significance (Gerdner, 2000).

A majority of the data (10 patients) was collected only in the patients' rooms in the brain injury rehabilitation unit at the UPMC. However, when the rest of the patients were wandering around the unit, data were also collected in the hallway and/or the day room, which is the place for therapy and recreation.

There are types of patient rooms in the brain injury rehabilitation unit at the UPMC: private and semi-private rooms. The private rooms provided the quiet necessary for hearing the music clearly and the privacy necessary for preventing interruptions during the research. Since patients in the semi-private rooms shared their room with another patient, the researcher selected a quiet time, such as when the patients were alone in their rooms, to prevent extra noise and the interruption of privacy. There were no changes of the patients' room type between day 1 and day 3, so that the locations of all experimental procedures were consistent. A "study in progress" sign was posted on the doors of the patients' rooms for notification purposes.

The researcher attempted to limit factors that could stimulate patients. Whenever possible, all kinds of noise other than the music, such as TV or radio, were reduced. All patients who understood simple commands were asked to sit and listen to the music. In addition, all verbal interactions were kept to a minimum, except for redirection or external cueing used by the researcher to rate the ABS. This helped to avoid over-stimulation and to prevent verbalizations from becoming a confounding variable. However, when the patients initiated conversations, the researcher responded because ignoring the subjects could have further confused or agitated them.

The music was played with an audiocassette player, which could play both CDs and cassette tapes prepared by the researcher. When a patient's family brought the patient's own music player, such as an MP3 player, it was used for data collection. No headsets or earphones were used because they could be removed during listening. Music was played at a low volume as recommended by Aldridge et al. (1990).

Before data collection, the researcher ascertained whether a patient had taken non-regular (as needed), short-acting sedative medication. When a patient was given any non-regular, short-acting sedative medication before the scheduled time of data collection, the researcher did not collect data on that day because short-acting sedative medication could have changed the results of the study.

Data collection was discontinued whenever patients or healthcare providers wanted to stop the music. In one circumstance, a patient requested that the music be stopped in the middle of the music intervention to take a break. Music playing was stopped at that point, and the study resumed the next day.

Data Analysis

Data were analyzed using the Statistical Package for the Social Sciences (SPSS), version 17.0. First, the independence of the two groups according to the order of music selection was analyzed using a Fisher's exact test for the categorical variables and an independent sample t-test for the continuous variables. After that, a 3 (time) x 2 (music) x 2 (group) mixed model ANOVA was used to examine the differences in mean ABS scores according to the order of music selection over time. A repeated measures ANOVA with Least Square Difference (LSD) comparison post-hoc analysis was used to check the significance of changes and differences in the mean ABS scores over time (before, during, and after intervention) during the two music interventions (classical “relaxation” music and preferred music) (Hypotheses 1 and 2). An independent t-test was used to assess the carry-over effect and compare the effects of preferred music to those of classical “relaxation” music (Hypothesis 3). Finally, a repeated measure ANOVA with LSD was used to determine the specific effect of preferred music intervention on decreasing the mean scores of the four components (physical, cognitive, behavioral, and verbal) of the ABS (Hypothesis 4).

CHAPTER IV

RESULTS

Clinical Characteristics

The results of this study are based on data from 14 severely brain injured patients in the brain injury rehabilitation unit at the University of Pittsburgh Medical Center located in western Pennsylvania. Data were analyzed using the Statistical Package for the Social Sciences (SPSS), version 17.0.

The average time from the date of accident to the time of data collection was 40 days (SD= 23.15, range 15- 105). Half of the patients were assessed within 30 days after injury, while the other half was assessed between 40 and 105 days post-injury. The majority (n=10) of patients suffered TBI resulting from motor vehicle accidents (MVA), especially motorcycle accidents (n= 5). Falls (n=2), assaults (n=1), and unknown reasons (n=1) were causes of TBI after MVA. As shown in Table 4.1, the most common diagnoses were subarachnoid hemorrhage (SAH) and skull fractures. Subdural hemorrhage (SDH) was the next common diagnosis. Intraventricular hemorrhage (IVH), epidural hemorrhage (EDH), hematoma, and contusion followed. The right side of the brain (n=10) was injured three times more often than the left side (n=3).

The average GCS score at admission was 5.16 (SD=1.34), representing severe brain injury (less than 8). The GCS scores of Subjects 1 and 4 were not available because the transferred medical records from other hospitals did not contain the scores. The majority of patients (n=12) exhibited severe cognitive impairment on either the BNCE or cognitive functioning log. The average ABS score, used to identify the eligibility of the patients for the study, was 28.57 (SD=7.93 range 21- 46), indicating that the patients were agitated (greater than 21). Nine out of 14 patients showed mild (ABS score from 22 to 28) agitation, one of them showed moderate agitation (ABS score from 29 to 35), and four of them showed severe agitation (ABS score from 36 to 56) (see Table 4.1).

Table 4.1.

Clinical Characteristics of Each Patient in Group A (Classical "Relaxation" Music on Day 1)

Subject	Diagnosis	GCS	BNCE or Cognitive functioning log	ABS
Subject 1	Right EDH, SAH	NA	Severe	25
Subject 2	Right temporal EDH, right temporal bone fracture	7	Severe	24
Subject 3	Right SDH, right temporal bone fracture, Right temporal SAH	7	Severe	24
Subject 8	Right SAH, SDH, IVH	5	Moderate	38
Subject 9	Right occipitoparietal hematoma	5	Severe	38
Subject 11	Left anteriotemporal SAH	7	Severe	22
Subject 14	Right temporal, frontoparental SAH, SDH, right temporal lobe fracture	3	Severe	46

Table 4.2.

Clinical Characteristics of Each Patient of Group B (Preferred Music on Day 1)

Subject	Diagnosis	GCS	BNCE or Cognitive functioning log	ABS
Subject 4	Right temporal SDH, SAH	NA	Severe	28
Subject 5	Right facial-orbit fracture	3	Severe	31
Subject 6	Right retrobular hematoma	5	Severe	21
Subject 7	Left frontal, temporal, parietal fractures	5	Severe	36
Subject 10	Skull base fracture	5	Severe	26
Subject 12	Left temporal frontal contusion, SDH, IVH	5	Moderate to severe	21
Subject 13	Right frontal and temporal SDH, SAH, skull fracture	5	Severe	22

Note. GCS = Glasgow Coma Scale
BNCE = Brief Neuropsychological Cognitive Examination
ABS = Agitated Behavior Scale
EDH = Epidural hemorrhage
SAH = Subarachnoid hemorrhage
SDH = Subdural hemorrhage
IVH = Intraventricular hemorrhage

The list of preferred music of all the patients is shown in Table 4.3. The types of favorite music of all patients varied from old pop songs to heavy metal. Most of the favorite music was classified as rock (n=3), country (n=3), and pop music of a different generation (n=7). In only two cases, favorite music recordings were retrieved from the patients' own music collection. Favorite music for the rest of the 12 patients was prepared by the researcher according to the list of favorite songs made by the family members. The family members of 11 patients provided information about the types (genres) of preferred music or the preferred artists because they did not know the patients' favorite songs.

Table 4.3.

Preferred Music Selections Used for Each Patient in Group A (Classical "Relaxation" Music on Day 1)

Subject	Type of Preferred Music (detail information; artists or songs)
Subject 1	Rock and roll
Subject 2	80's popular music
Subject 3	Old pop music
Subject 8	50's and 60's popular music
Subject 9	Country music (Tim McGraw, Kenny Chesney, Alabama)
Subject 11	70's popular music
Subject 14	Country music (Dierks Bentley, Shania Twain, Turbie, Kenny Chesney, Martina McBride, and Billy Currington)

Preferred Music Selections Used for Each Patient of Group B (Preferred Music on Day 1)

Subject	Type of Preferred Music (detail information; artists or songs)
Subject 4	Pop music (Chicago, Michael Jackson)
Subject 5	Old pop and rock (Lynyrd Skynyrd, Three doors down, Beatles)
Subject 6	Hindu religious music
Subject 7	Current pop music (Butterfly kisses, Forever young, Bittersweet, Angie, Piano man)
Subject 10	Rap music
Subject 12	Heavy metal (Slayer, Slipknot, Tool, Pantera, Ozzy Osbourne)
Subject 13	Rock, country music

Order of Music Selection

There was no significant difference in the ABS scores between patients who received preferred music first and patients who received classical relaxation music first. Independence between the two patient groups was first established because a crossover design was used. Because at least one cell in 2 by 3 table had an expected values less than five, a Fisher's Exact Test in Chi Square was used to compare the categorical data between these two patient groups: gender, race, injury type, and BNCE results. There were no significant associations between all categorical data ($p > .05$). Therefore, there were no associations in gender ($\chi^2 = .42$, df = 1, $p = .515$), race ($\chi^2 = 1.08$, df = 1, $p = .299$), injury type ($\chi^2 = 2$, df = 3, $p = .572$), or the BNCE results ($\chi^2 = 2.00$, df = 2, $p = .368$), depending on the order of played music; furthermore, this result verified the adequacy of randomization. Next, an independent sample t-test was used for the continuous variables: age, time from the accident, the ABS score, and the GCS score. The patients in the two groups did not differ significantly in the period from the accident (t = 1.15, df = 12, $p = .275$), the ABS score (t = .16, df = 12, $p = .269$), and the GCS score (t = 1.34, df = 10, $p = .209$). Even though significant differences emerged in age (t = 2.54, df = 12, $p = .026$), this difference might not be associated with agitated behavior because the agitated behavior was compared within subjects. Based on these results, it was inferred that the patients in the two groups were similar to each other in demographic and clinical profile.

A 3 (time) x 2 (music) x 2 (group) mixed model ANOVA was used to examine the main effect for groups, which were divided by the order of music (classical "relaxation" music first (Group A) vs. preferred music first (Group B)). There was no significant difference in ABS scores between the groups (F = .73, df = 1, *p* = .41). In other words, Group A (M = 24.48) was not different from Group B (M = 22.10) in the ABS scores. In addition, there were no significant differences between the two groups according to the types of music and over time (see Table 4.4). Therefore, patients who received their preferred music first were combined with patients who received classical relaxation music first for hypotheses testing.

Table 4.4.

Results of the Mixed Model ANOVA for Comparing Group A and Group B

	F	df	p-value
Time*music*group	.20	2	.16
Time*group	.73	2	.49
Music*group	.49	1	.50

Research Hypothesis 1

There are significant decreases in the ABS score during the presentation of preferred music compared to the ABS scores at baseline and post intervention.

A significant decrease in ABS scores was observed when preferred music was played. Means of the ABS scores (standard deviation) for agitated patients were 23.57 (5.95) at baseline, 20.21 (5.79) after the preferred music intervention, and 23.29 (7.36) post intervention. Figure 4.1 illustrates that the mean ABS score first decreased and then increased post intervention. A repeated measures ANOVA was used to analyze the differences in the ABS scores between the three times of measurement (before, during, and after intervention) with an alpha of 0.05. Mauchly's test indicated that the assumption of sphericity had not been violated ($\chi^2 = 4.04$, df = 2, $p = .13$). The differences in mean ABS scores at baseline, with preferred music intervention, and post intervention were statistically significant (F = 5.53, df = 2, $p = .01$). An LSD comparison post hoc analysis revealed that the mean ABS score during preferred music intervention was significantly different from the mean ABS score at baseline (mean difference = 4.07, $p = .02$) and from the mean ABS score at post intervention (mean difference = -3.43, $p = .03$). In other words, agitation was significantly decreased during the preferred music intervention (M = 20.29) compared to agitation before the intervention (baseline) (M = 24.36). The mean ABS score at post intervention (M = 23.71) was significantly greater than that during preferred music intervention. This result indicated that there was no continuing effect of preferred music intervention after stopping the music. These findings support the significant effect of preferred music intervention on reducing agitation after TBI. Hypothesis 1 was supported.

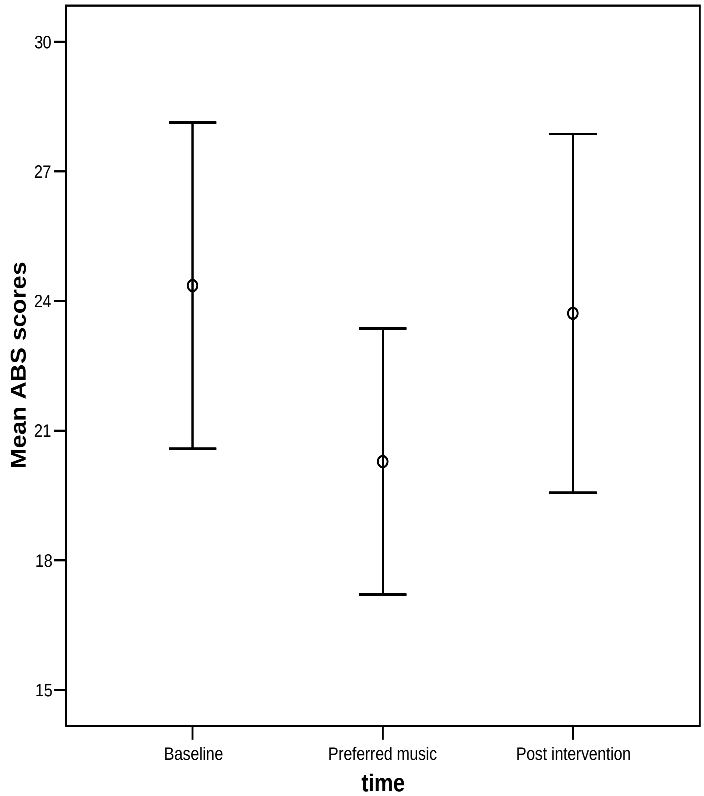


Figure 4.1. Mean ABS scores for preferred music (error bar = standard error of the mean)

This result of reduced ABS scores during preferred music intervention was supported by the anecdotal notes taken during the data collection. The researcher documented extraneous factors that might have affected the patients' behavior and responses to each music intervention during the data collection. During the presentation of preferred music, 8 out of 14 patients (Subjects 3, 4, 7, 9, 10, 11, 13, and 14) positively responded to the music intervention. They actively responded to the music by keeping time with the music by moving their hands, feet, and/or their head, and some patients sang along with their preferred songs. In addition, during listening to preferred music, 4 out of 14 patients fell asleep at the end of the music session (Subjects 2, 3, 8, and 11), implying a relaxation effect of the music.

Research Hypothesis 2

There are significant decreases in the ABS score during the presentation of classical "relaxation" music compared to the ABS scores at baseline and post intervention.

There was no significant effect of classical "relaxation" music on reducing ABS scores. Means of the ABS scores (standard deviation) for agitated patients were 23.5 (5.40) at baseline, 24.29 (6.68) during the classical "relaxation" music intervention, and 23.71 (6.31) post intervention. Figure 4.2 shows the mean ABS scores for classical "relaxation" music. A repeated measures ANOVA was performed to compare the mean ABS scores at three different times (baseline, during classical relaxation music intervention, and post intervention). Mauchly's test indicated that the assumption of sphericity had not been violated ($\chi^2 = .07$, df = 2, $p = .97$). No significant difference was found in the mean ABS scores between the three different times of measurement ($F = .28$, df = 2, $p = .76$). These findings support that the classical "relaxation" music intervention had no significant effects on reducing the agitation after TBI, and, therefore, Hypothesis 2 was rejected.

In the anecdotal notes, no patients showed responses to classical "relaxation" music, such as keeping time with the music. Even while the classical relaxation music was playing, Subjects 13 and 14 did not focus on the music and instead kept wandering around the unit. Only Subject 3 fell asleep at the end of listening to the classical "relaxation" music.

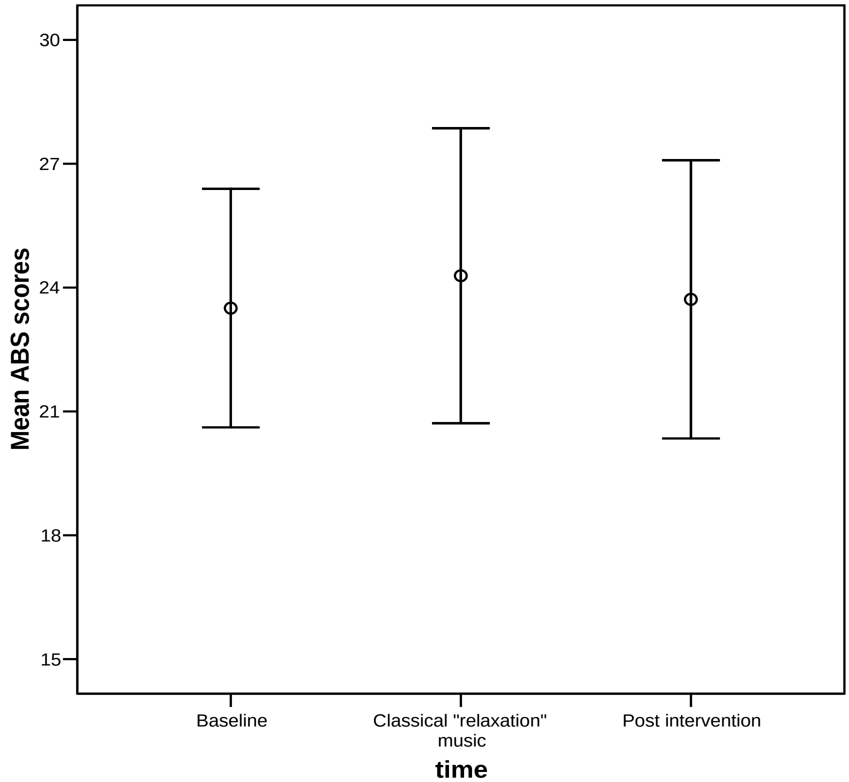


Figure 4.2. Mean ABS scores for classical “relaxation” music (error bar = standard error of the mean)

Research Hypothesis 3

The effect of preferred music on reducing agitation after TBI is significantly greater than the effect of classical “relaxation” music.

There was a significantly greater effect of the preferred music intervention on reducing agitation than that of the classical “relaxation” music. First of all, the carry-over effect was checked using a t-test of the total scores at baseline and during music intervention. In this study, a carry-over difference was not statistically significant (t = -1.427, df = 12, p = .18). This result indicated that the effect of one music intervention given in the first time period might not be present at the start of the following period when the second music intervention was presented.

An independent t-test was used to compare the effect of preferred music to that of classical "relaxation" music. A statistically significant interaction was found between preferred music intervention and classical "relaxation" music intervention ($t = -2.22$, $df = 12$, $P = .046$). The visual depiction in Figure 4.3 facilitates comprehension of this interaction. The trend of ABS scores of the preferred music intervention was significantly different from the trend of ABS scores of the classical "relaxation" music intervention over time. The mean difference in ABS scores during the preferred music intervention ($M = 1.43$) was greater than that during the classical music intervention ($M = -8.29$). Since higher mean differences of ABS score indicates that patients exhibited less agitation, preferred music posed a greater effect on reducing agitation than the classical "relaxation" music.

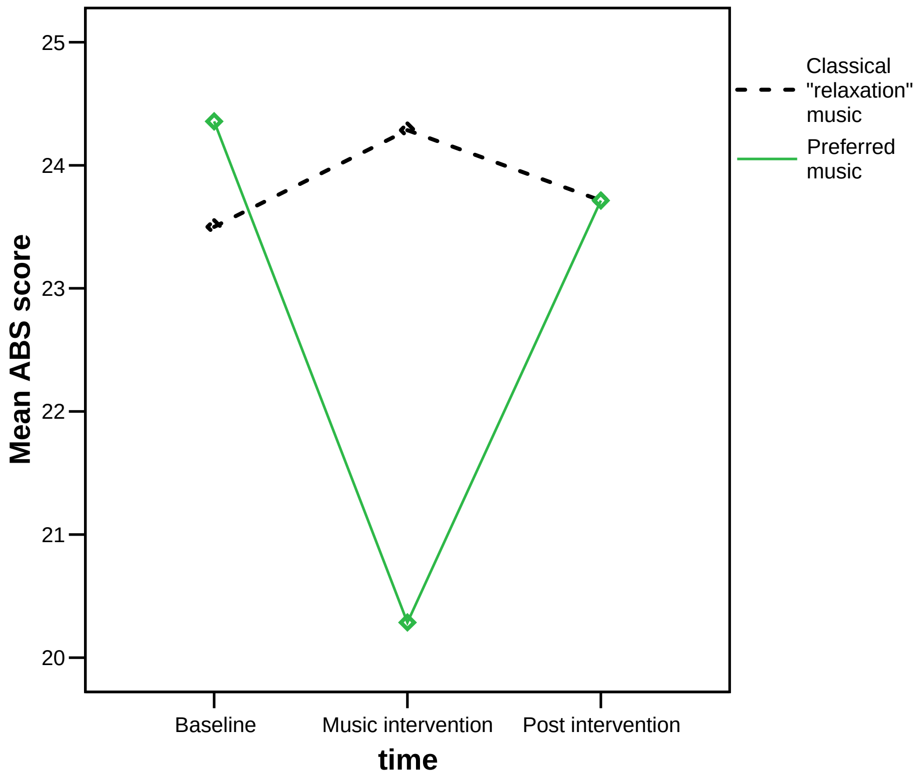


Figure 4.3. Changes in the mean of ABS scores for preferred music and for classical "relaxation" music

Research Hypothesis 4

Preferred music has significant effects on reducing the scores of each component (physical, cognitive, behavioral, and verbal) of the ABS compared to the scores at baseline and post intervention.

There were significant effects of preferred music on decreasing the scores of the cognitive and physical components among the four different categories of the ABS. A repeated measures ANOVA was used to discover differences in the scores of each component of the ABS over time. Significant differences in the scores of cognitive agitation (F = 5.78, df = 2, p = .008) and physical agitation (F = 6.34, df = 2, p = .006) were found among the four components of agitation. Follow-up comparisons using the LSD post hoc procedure were performed to test that the ABS score of each category during the preferred music intervention was different from either that at baseline or post intervention. In the cognitive component of agitation, the ABS score significantly decreased during the preferred music intervention compared to that of the baseline (mean difference = 1.07, p = .013) and increased post intervention (mean difference = -.79, p = .043) (see Table 4.5). During the preferred music intervention, the ABS score of the physical component of agitation significantly decreased compared to that at baseline (mean difference = 2.14, p = .006). However, compared to post intervention, the change was not significant (mean difference = -1.5, p = .052). These findings were consistently found in the mean ABS scores of cognitive and physical components of agitation over time. During the preferred music intervention, the mean ABS scores decreased in the cognitive component and in the physical component compared to the mean scores at baseline (see Table 4.6).

Table 4.5.

Repeated Measure ANOVA with LSD on All 4 Components of ABS (Preferred Music)

Component	F		df	p- value
Cognitive	5.78		2	.008*
	Baseline – music intervention	Mean difference 1.07		.013*
	Music intervention – post intervention	Mean difference -.79		.043*
Behavioral	1.12		2	.34
Physical	6.34		2	.006*
	Baseline – music intervention	Mean difference 2.14		.006*
	Music intervention – post intervention	Mean difference -1.5		.052
Verbal	1.56		2	.229

* p value < .05

Table 4.6.

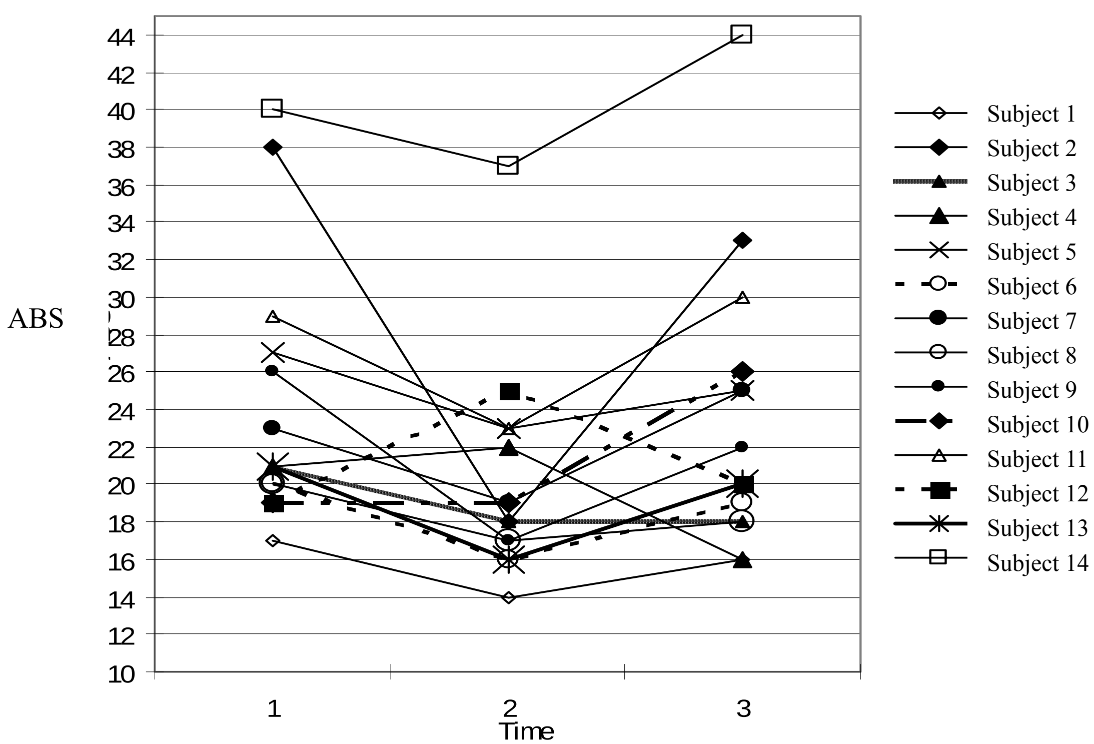
Mean ABS Scores of the Cognitive Component and Physical Component in the ABS During the Preferred Music Intervention

Component	Time	Mean	SD
Cognitive	Baseline	5.21	1.31
	Preferred music intervention	4.14	1.51
	Post intervention	4.93	1.49
Physical	Baseline	7.93	2.79
	Preferred music intervention	7.21	1.53
	Post intervention	8.07	2.7

Trend of Individual Data

Figure 4.4 and Figure 4.5 represent the trend of individual data with different types of music (preferred music vs. classical relaxation music). The effect of preferred music on each patient is depicted in Figure 4.4. The majority of patients (n = 11) exhibited a pattern in which ABS scores declined with the preferred music intervention and then increased post intervention. In particular, subject 2 showed the steepest reduction of the mean ABS scores while listening to preferred music among all 14 patients. Subject 2 exhibited extreme agitation on the preferred music intervention day (ABS score = 38). This participant tried to take off the restraints and to get out of a zipped Posey bed, which is a bed canopy system. However, when the preferred music was played, the participant appeared visually calmer, stopping trying to escape from the bed, actually began keeping time with the music by hand movements, and finally fell asleep.

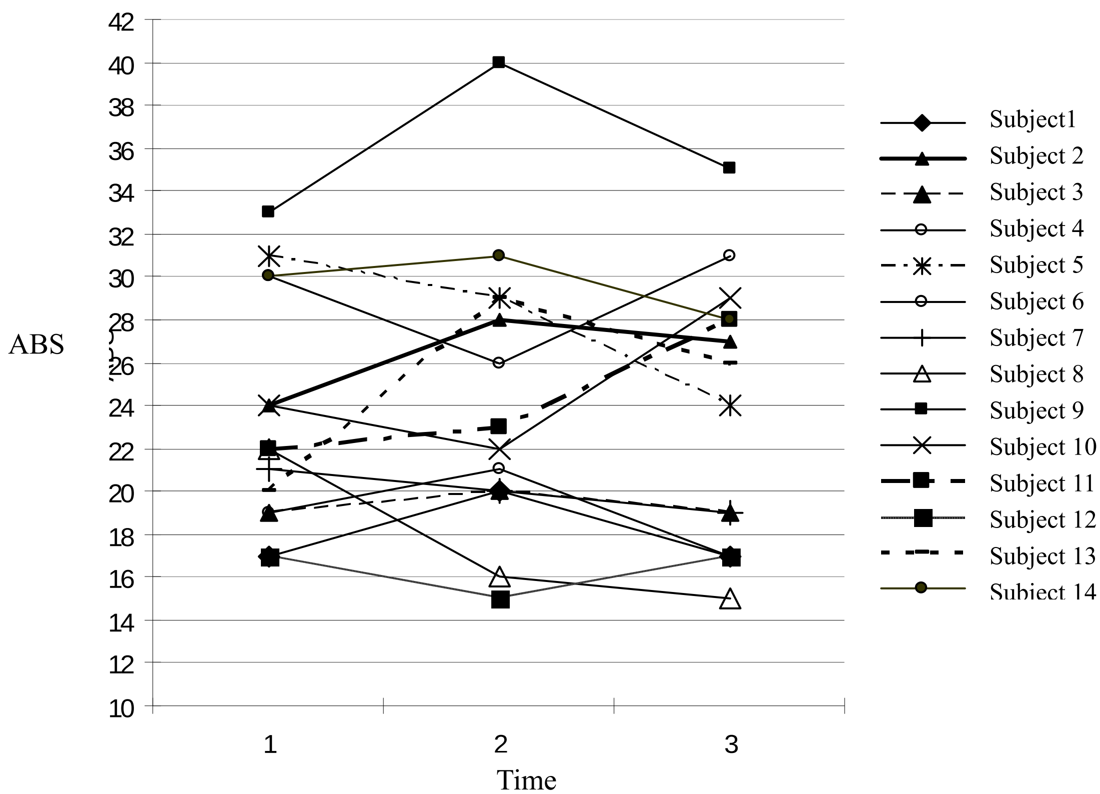
In contrast, three patients (Subjects 4, 10, and 12) exhibited increases in their ABS scores during the preferred music intervention. In the case of Subject 4, there was an unexpected visit by his girlfriend during the music intervention. Since the patient wanted her to stay with him during data collection, she stayed in his room for about 20 minutes. The patient's agitation level increased as a result, and her visit could have been conceived as an external stimulation. In addition to Subject 4, increased agitation was observed in Subjects 10 and 12. A possible explanation for this was associated with the stimulating nature of their preferred music. Subject 10 liked rap music, and Subject 14's preferred music was heavy metal. With these kinds of music, subjects showed more agitation.



Note. Time 1= baseline, Time 2= preferred music intervention, Time 3 = post intervention

Figure 4.4. Trend of individual data for preferred music

The trend of ABS scores of classical "relaxation" music intervention is graphed in Figure 4.5. The ABS scores increased in 8 out of 14 patients when classical "relaxation" music was played and then decreased one hour after the music was stopped. However, the rest of the patients (Subjects 4, 5, 7, 8, 10, 12) exhibited decreased ABS scores during classical "relaxation" music intervention. Subjects 4, 10 and 12 displayed decreased agitation during the presentation of the music and then increased agitation after the music stopped. In Subjects 5, 7 and 8, their ABS scores continuously decreased even during the post intervention period. In particular, Subject 5 showed that the amount of decreased agitation after the music stopped was greater than that during the music intervention.



Note. Time 1= baseline, Time 2= preferred music intervention, Time 3 = post intervention

Figure 4.5. Trend of individual data for classical "relaxation" music intervention

Table 4.7.

ABS Scores of All Patients

	Classical music			Preferred music		
Patient	1	2	3	1	2	3
1	17	20	15	17	14	16
2	24	28	27	38	18	33
3	19	20	19	21	18	18
4	30	26	31	21	22	16
5	31	29	24	27	23	25
6	19	21	17	20	16	19
7	21	20	19	23	19	15
8	22	16	15	20	17	18
9	33	40	35	26	17	22
10	24	22	29	19	19	26
11	22	23	28	29	23	30
12	22	15	17	19	25	20
13	22	29	26	21	16	20
14	30	31	28	40	37	44

Note.

1 = Baseline, 2 = Music intervention, 3 = Post intervention

Summary

In summary, the preferred music intervention was more effective in decreasing agitation after TBI than classical “relaxation” music. While listening to preferred music, the patients’ agitation levels decreased compared with the levels before and after intervention. In particular, both physical and cognitive agitation were remarkably decreased during the preferred music intervention, but the patients did not show any significant decrease in behavioral and verbal agitation. In contrast, there was no difference in agitation levels during the classical “relaxation” music intervention compared with those before and after intervention. The anecdotal report was consistent with these findings. Agitated patients exhibited positive responses while listening to the preferred music. In addition, there were different agitation trends between preferred music and classical "relaxation" music. Agitation decreased during the preferred music intervention and then increased post intervention, but the opposite occurred with the classical "relaxation" music intervention.

CHAPTER V

DISCUSSION

Preferred music as compared with classical "relaxation" music was examined to determine the effects of the reduction of agitation after TBI in this study. Previously, the preferred music intervention had not been tested with agitated TBI samples but was mainly focused on agitated patients with dementia. Agitated patients with dementia exhibited a significant reduction in agitation after preferred music intervention in several studies (Camberg et al., 1999; Gerdner, 2000; Goodall & Etters, 2005; Lindenmayer, 2000; Roper et al., 1991; Sung et al., 2006). In order to determine whether this benefit from the preferred music intervention is also applicable to agitated TBI patients, four hypotheses discussed in the previous chapters were tested in this study. The following sections illustrate the interpretation and discussion of the findings, relates these findings to the existing research and theory about the relationship between preferred music and agitation, and presents the limitations of the study.

Demographic Findings

The participants of this study were similar in gender, race, and age to those in the general population. The ratio of males to females was 5:1, which is similar to the gender ratio of all TBI patients as reported by Bell and Sandell (1998) (male: female ratio, 3–4:

1). Caucasian was the most common race represented in this study and is the dominant population of Pittsburgh, according to the American Community Survey Three-Year Estimate of 2005–2007. The majority of the sample was under age 45, and most subjects between 20 and 29 years of age. This corresponds to the peak incidence of TBI in the general population, which is early adulthood (Bruns & Hauser, 2003).

Findings of Clinical Characteristics

Clinical characteristics of the patients ranged broadly due to the variability of the patients' condition. First, the time elapsed between the date of the accident, and the time of data collection varied from 15 days to 105 days because this time gap depended upon how soon the patients were transferred from other hospitals or from other units at the UPMC after urgent medical care or operations. Second, the primary ABS score, used to identify potential subjects, ranged from 21 (mild agitation) to 46 (severe agitation), indicating that patients were in diverse stages of agitation, from mild to severe, when chosen for the study. In addition, there were differences between the primary ABS scores and the baseline ABS scores in some subjects resulting from the time gaps between the dates of obtaining the primary ABS scores and the baseline ABS scores. This difference did not have an effect on the results of this study.

Preferred Music Intervention

The results of this study clearly showed that the reduction in agitation in TBI patients occurred following the playing of preferred music. This finding is interpreted by the theory of individualized music intervention for agitation (IMIA) by Gerdner (1997). Gerdner proposed that preferred (individualized) music elicits pleasing memories and positive emotions because preferred music is integrated into a person's life and chosen according to personal preferences. The positive memories and emotions might influence a reduction in agitation. This concept is supported by the study using positron emission tomography (PET) to study the neural mechanism underlying pleasant emotional responses to music (Blood & Zatorre, 2001). The subjects reported pleasant emotional responses, such as chills (euphoric experience), during 77% of PET scans when their preferred music was played. In addition, there was decreased activity in the amygdala, which is known to be involved in fear and other negative emotions, and increased activity of the ventral striatum, which is associated with reward and pleasure. Therefore, during listening to preferred music, pleasure may be maximized not only by activation of the ventral striatum but also by simultaneously decreasing activity in the amygdala related to negative emotions. This elicitation of positive emotions will have a soothing effect on patients with agitation. In this study, there was evidence that patients exhibited positive emotions while they were listening to their preferred music. In the anecdotal records, patients sometimes exhibited their pleasure and positive feelings by keeping time with the music and singing their favorite songs.

In addition, the effect of preferred music can be explained with the lowered stress threshold model. According to this model, agitation might occur as a response to stressors produced when environmental demands exceed a lowered stress threshold (Hall & Buckwalter, 1987). Preferred music can increase this lowered stress threshold by altering the perception of stressors. Agitated patients may not perceive internal (fatigue) and external (noise) environmental stimulation as stressors while listening to preferred music, whereas these stimuli could be perceived as such without the music. This is because preferred music overrides confusing, unpleasant, and meaningless environmental stimuli and instead provides interpretable stimuli.

In contrast, patients showed a significant increase in agitation in the post intervention period, although they showed a significant reduction in agitation during the preferred music intervention. This finding might imply that the preferred music itself was effective in reducing the level of agitation, but the residual effect of the preferred music was not prolonged beyond one hour after the intervention was stopped. This result is in line with the previous study by Garland and colleagues (2007) and Ragneskog and colleagues (2001). During the preferred music intervention, physical agitation was decreased for the 15 minutes of the intervention, whereas the agitation level increased after the intervention was discontinued (Garland, Beer, Eppingstall, & O'Connor, 2007a). In the analysis of video-recorded sessions for agitated dementia patients, patients who decreased their agitated behaviors with individualized music became agitated several times when the music was stopped (Ragneskog et al., 2001). Another previous report (Ledger & Baker, 2007) of the long-term effects of music therapy supported this result. No significant reduction in agitation was found between the preferred music therapy group and the control group over a one-year period, although the music therapy participants exhibited a short-term reduction in agitation. The authors suggested that the preferred music intervention has only immediate effects on decreasing agitation without any accumulated effects. The possible explanation for the lack of a sustained effect is related to decision-making power. Since the time of music intervention (one hour) was determined by the research protocol, the music was stopped after one hour of presentation regardless of the patient’s desire. In other words, the authority to decide whether to play or stop the music was not delegated to the patients. For example, even if a patient wanted to keep on listening to the music after one hour of presentation, the music was stopped, and, as a result, the patient might have felt unhappy the music being stopped. This could have influenced the reemergence of agitation after the music was stopped. Therefore, it is recommended that future studies explore providing decision-making power on continuing or stopping the music to patients if possible.

Another suggestion to facilitate the sustained effect of music intervention on agitation after the music was stopped is adding familiar types of activities while the patients are listening to the preferred music. Since patients' procedural memory, which is memory for how to do familiar activities is not impaired after injury they are able to undertake familiar activities, such as brushing their teeth or combing their hair. These familiar activities might provide a synergetic effect on agitation with the preferred music intervention. Therefore, it may be expected that the effects of preferred music could be sustained more effectively after it is stopped.

Classical "Relaxation" Music Intervention

Classical "relaxation" music did not result in a statistically significant reduction in agitation compared to baseline ($p = .76$). In contrast to the preferred music intervention, during the classical music intervention, agitation slightly increased; this was followed by a decrease in agitation in the post intervention period. These results could indicate that the classical music had no calming influence on agitated patients and, in fact, evoked more agitation than was evident before the music intervention. One possible explanation could be that the classical music might not have captured the patients' attention and/or interest compared to the background noise heard in their rooms during the intervention (Gerdner, 2000). Therefore, environmental stimuli, such as background noise, might continuously bother TBI patients and induce them to be agitated. Another interpretation could be that the classical music did not generate any connections to patients' personal experiences, which might have produced positive memories and emotions (Garland, Beer, Eppingstall, & O'Connor, 2007b). For these reasons, the classical "relaxation" music was recognized as an additional stimulant to TBI patients, which increased agitation. Gardner (2000) emphasized that music must be individualized to elicit positive memories and emotions according to the theory of IMIA.

Although classical relaxation music intervention was not show to be able to statistically decrease agitation, 6 out of 14 patients exhibited somewhat decreased agitation. In particular, the agitation of Subjects 10 and 12 did not decrease during the preferred music intervention but decreased during the classical relaxation music intervention. This may be because their type of preferred music was very fast and stimulating (rap and heavy metal). Therefore, calm and slow music, such as the classical relaxation music, was more effective in decreasing their agitation. Although only a few patients responded to classical relaxation music, there still remains a potential for classical relaxation music to decrease agitation. It is recommended that future study on the effect of classical relaxation music be conducted with a larger sample than that used here.

Four Components of Agitation

To indicate which of the ABS items are most affected by the preferred music intervention, the items in the ABS were organized into four components: physical, cognitive, behavioral, and verbal agitation. Of the four components of agitation, only the cognitive and physical were affected, showing a significant decrease in agitation over time during the preferred music intervention.

The Effect of Music Intervention on Cognitive Agitation

During the preferred music intervention, there was significant improvement in the cognitive component in agitation, which consisted of items, such as attention span, impulsiveness, and tolerance for pain and frustration ($p = .008$). According to the theory of IMIA, cognitive impairment is one of the causes of agitation. Due to cognitive impairment, patients receive environmental stimuli as stressors, and their ability to cope with these stressors decreases. Since preferred music enhances the activation of cognitive functions and cognitive recovery by eliciting positive memories associated with positive emotions, music can reduce cognitive agitation (Gerdner, 2000). The effects of preferred music on cognitive function were supported by previous studies about neuroimaging and cognitive function tests.

First, using functional magnetic resonance imaging (fMRI), Soto and colleagues (2009) found that preferred music activated brain areas associated with emotion and cognition; the retrosplenial cortex is linked to emotional response, and the orbitofrontal cortex involves cognitive processing. In addition, preferred music activated subcortical dopamine systems in the ventral segmental area, the substantia nigra, and the caudate, which were associated with positive emotion (Ashby, Isen, & Turken, 1999).

Second, the effects of preferred music on cognitive recovery were confirmed by studies of improving cognitive function tests (Seibert et al., 2000; Soto et al., 2009; Van de Winckel, Feys, De Weerdt, & Dom, 2004). In the study of cognitively impaired stroke patients (Sarkamo et al., 2008), the favorite music listening group exhibited significant improvement in cognitive function, focused attention and verbal memory. In another study of cognitively impaired patients with dementia, patients demonstrated significantly higher scores on the cognitive function test, the Mini Mental State Examination (MMSE), while listening to music. The authors suggested that this improvement in cognition might be related to the increase in speed of processing information and the enhancement of arousal (Van de Winckel et al., 2004). In the study of the severe brain-injured professional oboist, she showed improvement in her ability to perform tasks of cognitive function during her therapy (Seibert et al., 2000). Preferred music intervention could be one of the most effective ways among the many possible ways of stimulating cognitive functions due to its feasibility.

The Effect of Music Intervention on Physical Agitation

There was a significant decrease in physical agitation (P p = .006). This indicated that the preferred music had a remarkable effect on decreasing inappropriate and excessive physical movements. During the preferred music intervention, agitated movements, described as inappropriate physical expressions of patient confusion and stress, were switched to acceptable alternative ways of releasing agitated energy. In this study, patients showed excessive and inappropriate physical movements, such as hitting the netted bed (Posey bed) and trying to take off their restraints (mostly mittens), before the presentation of the preferred music. However, when the preferred music was played, these inappropriate behaviors were decreased or replaced by appropriate ones, such as the tapping of feet or hands in time to the rhythm of the music. This change of movement illustrated that the preferred music facilitated the release of agitated energy and transformed inappropriate agitated behaviors to appropriate expressions of agitation (Baker, 2001). In addition, music has the physical benefit of reducing muscle tension and improving body movement (Campbell, 1997).

The effect of preferred music on physical agitation was previously reported in studies by Baker (2001) and Garland et al. (2007). Baker found that preferred music was effective in reducing physical agitation, as defined by relevant items in the ABS. Garland and colleagues found preferred music to be effective in decreasing physical agitation, which they defined as spitting, hitting, and pacing. Thus, it appears that preferred music can decrease inappropriate movements during an agitated state. The physical component can be more reliably and accurately measured than the cognitive component because the physical component can be visually observed and requires less subjective interpretation to identify it (Baker, 2001).

The Effect of Music Intervention on Behavioral Agitation

The behavioral component of agitation described as abnormal behavior was not reduced significantly while preferred music was played ($p = .34$). This finding corresponds to the results found by Janelli et al. (2004) and Van de Winckel et al. (2004). Preferred music intervention did not significantly decrease patients' negative behaviors or increase positive behaviors (Janelli, Kanski, & Wu, 2004). For patients with dementia, music could not significantly influence behavioral changes, which were evaluated with the Abbreviated Stockton Geriatric Rating Scale (Van de Winckel et al., 2004). One possible interpretation could be that it might take longer for music to have an effect on the behavioral component of agitation than the one hour of intervention that was offered. Since brain injury slows reaction time in general (Bashore, & Ridderinkhof, 2002), TBI patients might need more time to improve behavioral agitation. It is recommended that the period of observation or music intervention should be extended in future studies.

This study followed Baker's four-component classification of the ABS items. However, the classification of behavior and physical components was hardly distinguishable. Baker differentiated the physical and behavioral components of agitation with the characteristics, such as unnecessary movement and abnormal behavior. However, it is difficult to identify whether the behavior belonged to abnormal or unnecessary behavior. For example, the item "pulling at tubes" can be considered as either unnecessary movement or abnormal behavior. Therefore, this classification of ABS items needs to be reconsidered. It is suggested that all items that are observable and associated with physical movements are classified as a physical behavior (items 4, 6, 7, 8, 9, 10, 12, and 14). The rest of the items (items 3, 5, 13: sudden changes in mood, unpredictable anger, and easily initiated or excessive crying/laughing) are considered as a new components of agitation, "emotional agitation".

The Effect of Music Intervention on Verbal Agitation

There was no significant reduction in verbal agitation over time due to the preferred music intervention in this study ($p = .23$). The result is consistent with the previous observations on patients with dementia, for whom preferred music was not effective in decreasing verbal agitation, although the music was effective in reducing physical agitation (Garland et al., 2007b). However, there is a possible limitation on generalizing this research because the verbal component of agitation was defined by only one item in the ABS: the incidence or severity of rapid, loud or excessive talking. This criterion may not be sufficient to accurately describe verbal agitation. In this study, only 4 out of 14 patients responded to the verbal component in the ABS with an exhibition of agitation as defined above. Although the other 10 patients were not rated as verbally agitated by the suggested measure, it could be possible that they were, in fact, somewhat verbally agitated. Therefore, before generalizing the effect of music intervention on verbal agitation, it is recommended that future research be done using additional individualized criteria that indicate verbal agitation.

The Selection of Preferred Music

Since the preferred music used for the intervention in this study was chosen based only on the patients' preferences, the music selections varied widely in tempo, dynamics, pitch, and rhythm. The preferred music of most participants had a strong beat and fast rhythm, which was found in country, pop, and rock and roll music. In previous research, adverse effects of fast and rhythmical music on negative behaviors have generally been reported (North, Desborough, & Skarstein, 2005). However, this kind of music was not excluded for this research when it was preferred by the subjects because an individual could perceive the well-liked music differently from music that is not liked (Cullari & Semanchick, 1989). For example, Fucci and colleagues showed that individuals perceived rock music as less loud if they liked it (Fucci, et al, 1996). Therefore, it is argued that the patients of the study might perceive fast and rhythmical music more positively than others who do not like this kind of music.

While most of the patients showed decreased agitation levels while listening to their preferred music, despite its being fast and rhythmical, two patients (Subjects 10 and 12), whose favorite music was heavy metal and rap, showed increased agitation levels. Both kinds of music contain negative lyrics, are louder, and have a faster rhythm, tempo and a stronger beat than the preferred music of the other 10 subjects. As a result, these kinds of music may have been perceived as external stimulation that could have deteriorated their condition and increased their agitation. According to North and colleagues (2005), fast and dynamic rhythm and tempo plus a strong beat might over stimulate agitated subjects, and negative lyrics might promote negative thoughts and elevate psychosis. Rubin, West, and Mitchell (2001) found that those people who listened to heavy metal and rap exhibited more aggression than those who listened to other genres, and Hansen and Hansen (1991) found that they also exhibited antisocial behaviors and attitudes (Hansen & Hansen, 1991). Therefore, according to Baker's suggestion about music therapy (2006), it was concluded that selected preferred music should not be too stimulating (i.e., fast or rhythmically complex) and should contain positive lyrical content in future studies.

Limitations of the Current Study

Although this study demonstrated the significant effect of preferred music on reducing agitation levels, there are several limitations to the study that are mostly attributable to the difficulties in systemizing data collection, including the small sample size, difficulties in getting information about patients' preferred music, uncontrolled confounding variables, and data usage of the research assistant. First, the number of subjects (N=14) may not be sufficient to generalize the findings. However, with an average incidence of agitated patients of one per month in the one rehabilitation unit used for this study, it took more than 15 months to complete the data collection for 14 subjects. Therefore, to collect data for a larger sample, it is recommended that future studies include more than one rehabilitation unit. The inclusion criteria can be broadened for future studies. Brain injury type can be varied from TBI to acquired brain injury, including stroke, brain tumors, infection, poisoning, hypoxia, and ischemia. In addition, because the majority of the current sample consisted of Caucasians, this sample may not be representative for all TBI patients in the process of rehabilitation. Therefore, it is also recommended to include other racial groups so that the results are not affected by racial/ethnic background.

An additional limitation was associated with the difficulties in getting information about patients' preferred songs and in getting the songs from their own music collections. Since no patients were able to express their own musical preferences, their family members were interviewed to make a list of preferred music. Patients' family members, mostly their parents, did not in all cases have enough information about the patients' preferred music because patients in early adulthood often did not share their preferred music with them. In addition, some family members had difficulty accessing subjects' own music collections because most of the patients lived far from the hospital, or family members did not know where the music collections were kept. In this study, only two patients' family members provided specific preferred songs and their own music collection. For the rest of the subjects, the researcher searched for preferred songs in the list of preferred genres and artists and recorded them for data collection. Therefore, there is some variability in the degree of match between the patient's preferred music and the actual music played during the data collection. DeLoach (2003) reported that using a patients' preferred music genre or artist is as effective as using a patient's specific preferred song in decreasing anxiety levels. Although the effect of music intervention would vary depending on the degree of musical matches, the major conclusion of this study would not significantly change because the better matches would only increase the positive effect of preferred music observed in this study. In future studies, it would be suggested that selecting a preferred music based on preferred music genres or artists would be a reasonable second choice if the patients' actual pieces of music are not available. If information about preferred music genres or artists is available, preferred songs can be selected according to availability and popularity (Baker, 2001a).

Uncontrolled variables that contributed to the agitation levels could also be a limitation of this study. There were many outside factors that could not be controlled by the researcher and which affected the results of the study, although many attempts were made to do so. In this study, structured routine nursing care and stimulation from unexpected visitors were potential outside factors. Since it was impossible to avoid routine nursing care during data collection, it is recommended to consider more detailed information about the nursing care and its potential influence on agitation in future studies. Another variable was unexpected visitors. A patient's agitation level could be changed by an unexpected visitor during data collection (Subject 8). In other words, the individual's relationship with unexpected visitors could influence agitation negatively or positively. Therefore, preventing agitated subjects from having unexpected visitors during data collection is encouraged to enhance the reliability of the findings.

Finally, the data collected from the hired research assistant (RA) had a limitation in being used for data analysis. The RA was hired to prevent a possible bias in the rating of the ABS. However, the RA could not participate in some of the data collection due to her health problems. Since there were missing data in the data collection, it could not be used for data analysis. Although the data were not complete, it could be used to compare the trends of the data between the RA and the primary researcher. The trends of the data, ascending and descending, were compared, and the RA's anecdotal record was also referred in data analysis.

Conclusion

This study was designed to evaluate the effects of preferred music on agitation after TBI compared with the effects of classical “relaxation” music. In this study, preferred music was effective in decreasing agitation levels, whereas classical “relaxation” music was not. A possible explanation for this could be that preferred music elicits pleasant memories and positive emotions, whereas classical “relaxation” music does not elicit pleasant memories and positive emotions because it may not capture a patients’ interest. In addition, preferred music might help keep the balance between environmental demands and the stress threshold, which is lowered due to the cognitive impairment after TBI.

The findings of this study support the use of preferred music as an alternative approach to managing agitated patients after TBI. Up until now, music has been regarded as stimulation, and, thus, there was no confident evidence of an advantage to music therapy in reducing agitation. Therefore, the results of this study support the idea that music is not contraindicated and is an important intervention in the care of agitated patients.

In practical clinical settings, a key factor for the successful application of this intervention is the identification of music preference. Preferred music information should be as specific as possible, including titles of preferred songs (Gerdner, 2000). However, if not possible, then information about preferred music genres, albums, and artists is a useful option. Songs with positive lyrical content and music that is not overly stimulating should be selected to avoid negative responses, including increased agitation (Baker &

Kennelly, 2006). Since the effect of preferred music is not sustained after discontinuing the music intervention, it is recommended to provide preferred music in circumstances in which patients often exhibit agitation.

APPENDIX A

INSTRUMENTS

Glasgow Coma Scale

Developed by Graham Teasdale and Bryan J. Jennett

Patient Name:____

Rater Name: ____

Date: ____

Activity		**Score**
EYE OPENING		
None	1= Even to supra-orbital pressure	
To pain	2= Pain from sternum/limb/supra-orbital pressure	
To speech	3= Non-specific response, not necessarily to command	
Spontaneous	4= Eye open, not necessarily aware	
		_______
MOTOR RESPONSE		
None	1= To any pain; limbs remain flaccid	
Extension	2= Shoulder adducted and shoulder and forearm internally rotated	
Flexor response	3= Withdrawal response or assumption of hemiplegic posture	
Withdrawal	4= Arm withdraws to pain, shoulder abducts	

Localizes pain	5= Arm attempts to remove supra-orbital/chest pressure
Obeys commands	6= Follows simple commands

______

VERBAL RESPONSE

None	1= No verbalization of any type
Incomprehensible	2= Moans/groans, no speech
Inappropriate	3= Intelligible, no sustained sentences
Confused	4= Converses but confused, disoriented
Oriented	5= Converses and oriented

______

Total (3-15): ______

Agitated Behavior Scale

Developed by John D. Corrigan

Patient:____

Observation environment:____

Rater/Disc:____

Period of observation: From_____am/pm at Date___/___/___

To _____am/pm on Date___/___/___

At the end of the observation period, indicate whether the behavior described in each item was present and, if so, to what degree: slight, moderate or extreme. Use the following numerical values and criteria for your ratings.

1 = absent: the behavior is not present.

2 = present to a slight degree: the behavior is present but does not prevent the conduct of other contextually appropriate behavior. (The individual may redirect spontaneously, or the continuation of the agitated behavior does not disrupt appropriate behavior.)

3 = present to a moderate degree: the individual needs to be redirected from an agitated to an appropriate behavior, but benefits from such cueing.

4 = present to an extreme degree: the individual is not able to engage in appropriate behavior due to the interference of the agitated behavior, even when external cueing or redirection is provided.

DO NOT LEAVE BLANKS.

___ 1. Short attention span, easy distractibility, inability to concentrate.

___ 2. Impulsive, impatient, low tolerance for pain or frustration.

___ 3. Uncooperative, resistant to care, demanding.

___ 4. Violent and/or threatening violence toward people or property.

___ 5. Explosive and/or unpredictable anger.

___ 6. Rocking, rubbing, moaning or other self-stimulating behavior.

___ 7. Pulling at tubes, restraints, etc.

___ 8. Wandering from treatment areas.

___ 9. Restlessness, pacing, excessive movement.

___ 10. Repetitive behaviors, motor and/or verbal.

___ 11. Rapid, loud or excessive talking.

___ 12. Sudden changes of mood.

___ 13. Easily initiated or excessive crying and/or laughter.

___ 14. Self-abusiveness, physical and/or verbal.

___**Total Score**

Cognitive Functioning Log

1) Orientation x 4

_____Yes ____No

If no, indicate deficit(s): ____Person ____Place ____Situation ____Date

(Year/Month/Day of Week)

2) Expressive language

_____Fluent ____Nonfluent ____Intelligible ____Dysarthric

(Slight/Mild/Mod/Severe)

_____Hesitant _____Goal Directed _____Paraphasic Errors _____Low volume

Other ___________________

3) Attention/Concentration/Distractibility Problems _____________

4) Comprehension Problems _____________

5) Visuospatial/Visuoconstructive Problems _____________

6) Problem Solving/Reasoning/Judgment Problems _____________

7) Memory Problems _____________

8) Executive/ Frontal Lobe Functioning Problems _______________

9) Comments _____________

*** Limiting Factors

_____Fatigue _____Agitation ______Trach ____Uncooperative

______ Vision/Hearing Other ______________

Brief Neuropsychological Cognitive Examination (BNCE)

Developed by Joseph M. Tonkonogy

1) Impairment Range

N = None, Mi = Mild, Mod = Moderate, S = Severe (If applicable)

2) Part I: Orientation ______ Presidential Memory ______ Naming ______

Comprehension ______ Constructional Praxis ______

3) Part II: Shifting Set ______ Incomplete Pictures ______ Similarities ______

Attention ______ Working Memory __________

4) Total Score = ________, which is in the _________ impairment range

APPENDIX B

INFORMED CONSENT

THE UNIVERSITY OF MICHIGAN

LEGALLY AUTHORIZED REPRESENTATIVE CONSENT FOR THE RESEARCH

This form gives you important information about the study. It describes the purpose of this study and the risks and benefits of the study.

Please, take the time to read this information carefully. When you have finished, you should talk to the researcher and ask any questions you have. You may wish to talk with others about participating in this study. If you decide to let your family member or the person you are taking care of participate in the study, you will be asked to sign this form. *Before you sign this form, be sure you understand what the study is.*

STUDY TITLE: Effect of Preferred Music on Agitation after Traumatic Brain Injury

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1. PURPOSE OF THE STUDY

Agitation is a state of extreme activity. It is described as frequent, meaningless, and violent speech and/or behavior. More than 30 to 40 percent of brain-injured patients experience agitation. The patients themselves, as well as their caregivers, can be in danger because of the agitated behavior. This can interfere with getting proper treatment. Often, agitation is controlled by drugs and physical restraints. However, drugs often cause side effects, and physical restraints can cause other injuries.

Some studies show that the favorite music that patients loved before the brain injury may help to decrease their agitation. This music can help the patient relax and recall good memories. Therefore, we want to find out whether listening to the patients' favorite music can decrease their agitation. We will compare the effect of favorite and classical "relaxation" (not favorite) music.

2. STUDY PARTICIPANTS

1) Who can take part in this study?

Participants must be 18 years and older, and they should be the patients at the rehabilitation unit at the University of Pittsburgh Medical Center (UPMC)-South Side. Patients must be in stable medical condition after brain injury. A patient should have thinking problems after his/her severe brain injury. The patient may not know where he/she is, what day today is, and what he/she did several minutes ago. The patient must also show signs of agitated behaviors. These include screaming, pulling on tubes, the inability to sit still, loud talking, and sudden changes of mood. A patient will not be chosen if he/she already had any disorder resulting in agitation before the brain injury, such as Alzheimer's disease, Parkinson's disease, autism, and so on. The patient will also not be chosen if he/she shows withdrawal signs. These can be pain, nausea, sweating or depression. These signs appear when a drug is regularly used for a long time and is then suddenly taken away. If a patient's pain or fever on the days of data collection is severe enough to interfere with the process of the study, he/she will not be chosen. Patients should not have a plan to be discharged from the hospital before the study is finished.

2) How many people are expected to take part in this study?

We will choose a total of 14 participants.

3. STUDY PROCEDURES

1) What are the procedures of this study?

The legally authorized representative will be asked to provide the researcher with a list of the participant's favorite music. Once the patient's favorite music becomes available, the study will start at any time of week, including weekends. The study will be conducted for three days in a row. The data will be collected on day 1 and day 3 for three hours each day. Data collection will be performed anytime between 4:00 pm and 9:00 pm when a patient is in the room alone. The data collection will occur during the same 3-hour span on day 3 as it did on day 1. On day 2, no data will be collected because it is a resting day. All scheduled medications will be given during the study. Family visits are discouraged during the study.

On day 1 and day 3, the patient's agitated behavior will be observed without music for the first hour and the last hour. For the second hour, the patient will be listening to either his/her favorite music or classical "relaxation" music. If a patient listens to his/her favorite music on day 1, he/she will listen to the classical "relaxation" music on day 3. If a patient listens to the classical "relaxation" music on day 1, the patient will listen to his or her favorite music on day 3.

The study will be held in the patient's room. A private room is preferred due to better noise control. However, the patient can be in a semi-private room. In this case, the researcher will select a time when the patient is alone in the room. The "study in progress" sign will be posted on the door of the patient's room. Other kinds of noise, such as TV or radio, will be turned off during the study. If the patient takes any medication that makes them sleepy, the researcher will not collect data on that day.

2) What are conditions mean that the patient can be removed from participation without consent?

A patient's participation will be terminated if one of the following occurs:

1) If a patient has a plan to be discharged before the data collection is completed,
2) If a patient shows signs, like depression, anxiety, craving, or suicide attempt, during data collection due to substance abuse prior to the brain injury,
3) If a patient is sick enough not to continue the study (e.g., fever or severe pain)
4) If a patient's room type changes between day 1 and day 3, the patient will be removed from the study.

4. RISKS AND BENEFITS

1) What risks will the patient face to take part in the study? What will the researcher do to protect the patient against these risks?

There is a slight risk associated with participation in this study. The patient may become tired during listening to music. The music could increase stimulation. As a result of both cases, the patient may temporally show increased agitation. When he/she shows increased agitation, the researcher will talk to the patient to calm him/her down. The music will also be stopped at that point. The patient will be given a short break. If needed, nurses may help the patient to relax. The study will be continued if the patient becomes stable in less than 15 minutes. Otherwise, the study will start over the next day.

There is the potential risk of breaking of the patient's confidentiality, but we will do everything possible to protect the patients' confidentiality. Identifiers, such as the patient's name, social security number, and medical record number, will be removed from the research records, which will be labeled with a participant code. Information linking the code to identifiers will be kept in a locked cabinet.

2) How could a patient benefit if the participant takes part in this study? How could others benefit?

Participation in the study can potentially benefit patients, their families, and caregivers in many ways. The patient may experience a decrease in agitation during the study. This can be because of the calming and relaxing effect of using music. In addition, they may be remembering positive memories before the injury during listening to their favorite music. These can help decrease agitation and may reduce the stress of their caregivers.

It may help the patient better use rehabilitation and possibly shorten hospital stay. This can further help the patient's recovery. This study will help doctors and nurses in the treatment of agitation.

5. RIGHTS AND RESPONSIBILITIES

Participation in the study is completely voluntary. The patients can withdraw from the study at any time by notifying the researcher (Soohyun Park, whose information is listed in the "contact information" section). Patients or their legal representatives may choose not to participate or may withdraw at any time. In this case, there will be no penalties or disadvantages to the medical treatment that they receive. The patients will continue to receive appropriate medical care.

Refusal to participate or withdrawal from the study will not affect your current or future relationship with any University of Pittsburgh or UPMC. If a patient is withdrawn from the participation, his/her research records will be destroyed.

The patient's doctor is involved as an investigator in this research study. As both a doctor and research investigator, she is interested in both your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your doctor.

6. FINANCIAL RESPONSIBILITIES

There is no cost to the patient or the insurance company for participating in the study. In addition, the patient will not be paid for taking part in this study.

7. CONFIDENTIALITY

1) How will the researchers protect the patient's privacy?

Any information about a patient obtained from this research will be kept as confidential (private) as possible. All records related to patient involvement in this research study will be stored in a locked file cabinet. The patient's identity in these records will be indicated by a case number rather than by his/her name, and the information linking these case numbers with his/her identity will be kept separate from the research records. The patient will not be identified by name in any publication of the research results unless you sign a separate consent form giving your permission (release).

In unusual cases, the investigators may be required to release identifiable information related to participation in response to an order from a court of law. It is also possible that authorized representatives from the University of Pittsburgh Research Conduct and Compliance Office may review the identifiable research information for the purpose of monitoring the appropriate conduct of this study.

2) After the study is over, or a patient withdraws from the study, what will happen to his/her information?

If a patient withdraws from the study, or when the study is completed, the research record is stored in locked files and will be kept for a minimum of seven years per university policy.

8. AUTHORIZATION TO RELEASE A PATIENT'S HEALTH INFORMATION

By signing this form, you will allow the researchers to collect a patient's information, including a patient's medication list and therapy/treatment schedule on days of data collection for this study. Information about the patient may be obtained from any hospital record, doctor, and other health care provider involved in the patient's care.

9. CONTACT INFORMATION

If you have any concern about the study, please contact the researcher listed below.

Soohyun Park
Telephone:
E-mail: sp.umich@gmail.com

10. DOCUMENTATION OF THE CONSENT

One copy of this signed document (with signatures) will be kept in the locked file for our records. A second copy will be given to you for your records.

1) Voluntary Consent

I understand the information printed on this form. I have discussed this study, its risks, and potential benefits. My questions so far have been answered by the researcher. I understand that if I have more questions or concerns about the study, I may contact the researcher again. I understand that I will receive a copy of this form at the time I sign it and later, upon request.

Any questions I have about ______________'s (a participant's name) rights as a research subject will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668). My signature below means that I have agreed for my family member or the person you are taking care of to participate in this study.

Patient’s assent Date

Legal authorized representative’s consenting signature Date

Legal authorized representative’s name (print legal name) Relationship to participant

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