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Development and testing of two lifestyle interventions for persons with chronic mild-to-moderate traumatic brain injury: Acceptability and feasibility

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ABSTRACT

This clinical methods discursive highlights the development, piloting, and evaluation of two group interventions designed for persons who experienced chronic traumatic brain injury (TBI). Intervention science for this population is limited and lacking in rigor. Our innovative approach to customize existing interventions and develop parallel delivery methods guided by Allostatic Load theory is presented and preliminary results described. Overall, parallel group interventions delivered by trained leaders with mental health expertise were acceptable and feasible for persons who reported being depressed, stressed, and symptomatic. They reported being satisfied with the overall programs and mostly satisfied with the individual classes. Attendance was over the anticipated 70% expected rate and changes in daily living habits were reported by participants. These two group interventions show promise in helping persons to self manage their chronic stress and symptomatology.

1. Introduction

Worldwide, an estimated 10 million people (Institute of Medicine, 2011) experience traumatic brain injury (TBI). It results from a force impacting the brain and is an "alteration in brain function or other evidence of brain pathology, caused by an external force"(Menon, Schwab, Wright, & Maas, 2010). Motor vehicle crashes (17.3%), blunt impact (16.5%), falls (35.2%), assaults (10%) or blasts (Centers for Disease Control [CDC], 2015) are major causes.

TBI is costly and affects those of all ages. The majority are aged 18–25 or over 75 years. Every year, nearly 1.7 million emergency department visits occur and about 25% of these visits require hospitalization for TBI (CDC, 2015). Furthermore, the annual sum of direct and indirect costs associated with TBI hospitalizations and rehabilitation are estimated to exceed $76 billion (CDC, 2015). These costs are incurred within various healthcare transitions involving acute hospitalization, rehabilitation, and outpatient therapies.

Not everyone experiences complete recovery after TBI. Currently, TBI is considered a disease with lifelong consequences and reduced mortality (Bay & Chartier, 2014; Bazarian, Cernak, Noble-Haeusslein, Potolicchio, & Temkin, 2009). Thus, interventions are likely needed to disrupt the intricate pathogenesis and chronic difficulties that result in a myriad of healthcare encounters. Currently, the CDC recommends comprehensive rehabilitation linked to public health interventions (CDC, 2015). We believe such interventions should focus on lifestyle interventions aimed at stress reduction and symptom management.

Efforts to deliver interventions linked to lifestyle interventions after TBI have been limited. Mindfulness-based group interventions for persons with TBI have focused on outcomes of attention (McMillan, Robertson, Brock, & Chorlton, 2002), quality of life (Bedard et al., 2003), self-efficacy (Azulay, Smart, Mott, & Cicerone, 2012) and depression (Bedard et al., 2013). To our knowledge, these studies are without active comparison groups or focus on stress or symptom management outcomes, both foci in the mindfulness research literature. However, this research did suggest that mindfulness could improve self-efficacy and depression, rather than cognition. Wellness interventions have been suggested to be important, but are without specific trials. Here, we intend to describe the two tailored lifestyle interventions, their methods of delivery, and participants' levels of satisfaction for persons with chronic TBI.

2. Description of two lifestyle interventions and their theoretical bases

Two group therapy interventions were developed and included: Positive focused mindfulness group therapy (PFM-GT) and healthy-living after TBI group therapy (HLA-GT). Both interventions fall within

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the definition of complex interventions as defined by the Medical Research Council (Moore et al., 2015). They include multiple components that must be mastered in combination and are impacted by the expertise of the interventionist and the culture of the setting in which they are delivered (Mohler, Bartoszek, & Meyer, 2013). Researcher organizations such as Consort and the British Medical Research Council have recognized that non-pharmaceutical bio-behavioral interventions require a specific process of evaluation in order to promote reproducibility and successful phase III long term interventional study (Mohler, Kopke, & Meyer, 2015). In keeping with the steps outlined in their framework, we will describe the underlying theoretical basis of the interventions, their pre-clinical phase development leading to the pilot study, and satisfaction findings and comments from our participants.

Both interventions were tailored for persons who were within 3–24 months from the injury event or in the chronic phase of recovery. In this phase, residual symptoms may be present and include challenges in mood (depression), cognition (deficits in planning, memory or attention), sleep, or behavior (irritable, isolative or critical of others). (Bay & Chartier, 2014) Chronic stress, present before, during, and after the event of TBI (Bay, Kirsch, & Gillespie, 2004; Griesbach, Hovda, Tio, & Taylor, 2011) is reported to mediate the relationship between TBI symptoms and psychological functioning (Bay, Sikorskii, & Gao, 2009). Additionally, hormones and chemicals involved in stress regulation are noted to be dysregulated after TBI. These findings are aligned with Allostatic Load (AL) Stress theory.

This multivariate biological model of stress is based on the assumption that the brain regulates reciprocal and flexible stress systems (cardiovascular, immune, endocrine and metabolic systems) to achieve a state of allostasis (Juster, McEwen, & Lupien, 2010). Allostasis, the ability to maintain stability through change, can be threatened by chronic stress. Chronic stress contributes to inefficiencies or over activity of these flexible stress systems, termed allostatic load. Then, symptomatology or behavioral change can occur over time that is aligned with chronic disease development. Allostatic load has been hypothesized to contribute to the development of chronic diseases associated with TBI, including dementia, depression, vascular disease, and post-traumatic stress disorder (PTSD)(Bay & Chartier, 2014; McEwen, 2002). For purposes of this study, we suggest that allostatic load, operationalized as chronic stress, can be moderated by lifestyle interventions focused on stress management and lead to reductions in depressive and TBI symptoms and improvements in psychological functioning.

3. PFM-GT: the pre-clinical stage of development

Aligned with current findings on mindfulness therapies after TBI, our PFM-GT intervention was developed. This focused not only on controlling attention, but also developing or regaining a positive self-image while experiencing feelings of self-criticism and challenges in relationships and social situations. Therefore, the primary intervention focused on meditation and was based on components of the Mindfulness-based Stress Reduction program (MBSR) (Kabat-Zinn, 1982). It included positive mantra/affirmation development, compassionate meditation and developing positive body awareness. The Positive Focused Mindfulness Group Therapy (PFM-GT) class sessions were: 1) Introduction to bodily sensations and the concept of mindfulness, 2) Positive body awareness and gentle movement, 3) Single focused meditation using a self-created positive mantra, and 4) Self- compassionate meditation and focus on positive affirmations.

The PFM-GT provided the opportunity to practice and develop attentional focus through learning both exclusive and inclusive focused meditation while tailoring these skills to the needs of persons with TBI. Specifically, the PFM-GT avoided the more challenging aspects of MBSR by replacing the mindful experience of negative emotions with a focus on ambient sounds and providing body movement classes using three gentle QiGong movements that did not exacerbate problems with balance or vertigo. Further, positive self-created mantras, self-compassion meditation skills and the use of positive affirmations provided several opportunities to address negative self-concepts and teach self-soothing skills (Kabat-Zinn, 1982).

4. HLA-GT: pre-clinical stage of development

The HLA-GT, our control intervention, was a tailored self-care intervention for persons with TBI and adapted from the Health Enhancement Program (HEP) (Maccoon et al., 2011). The HEP program is a control intervention developed for those receiving MBSR therapies and emphasizes self-care and wellness. Classes were developed in nutrition, physical activity, functional movement and music therapy that paralleled classes in mindfulness. For our population, we tailored this control intervention according to AL Stress theory, general cognitive and functional abilities of the population, and the group format.

While the core elements of the HEP were upheld (structural equivalence, social support, common facilitators, trained teachers/trainers, flexibility in content delivery), we developed interactive content that emphasized brain health through stress management and lifestyle change. Our content focused on mood and stress management, armchair exercises and nutrition for everyday living, and sleep hygiene. Our group activities were based on principles of health education and included establishing weekly personal goals, healthy choices, and strategies to maintain the behavior changes. Our content was derived from government-sponsored websites.

5. Design and methods

This 8-week randomized control trial was designed to determine whether these newly developed interventions were feasible and acceptable for persons with chronic TBI who were participating in an out-patient rehabilitation program. Both complemented the physical, speech, vocational, and occupational therapies prescribed by the treating team.

The sample consisted of consenting adults aged 18–80 who were enrolled in two programs affiliated with large trauma health systems. Because it was anticipated that most participants would have some cognitive challenges, other trauma-related injuries, and depression, our interventionists possessed content expertise and experience in mental health. All interventionists were oriented to common problems and symptoms associated with TBI and trained to deliver consistent interpersonal messages while minimizing unnecessary social support and discussion about the TBI event and medical interventions. The same interventionist delivered the in-person and subsequent telephone class. We asked all participants to record their minutes of daily practice for 84 days along with their daily ratings of depression and stress on a log sheet. Program evaluation of persons' satisfaction with the program, individual classes, and overall barriers to practice were collected at the 12-week assessment.

Staff from two TBI outpatient rehabilitation programs affiliated with large trauma systems assisted with recruiting participants for this pilot study. Neuropsychologists affiliated with both programs provided the initial list of potential participants to ensure that participants met standard criteria for mild or moderate TBI. Providers at each site facilitated enrollment.

Recruitment occurred during 2012–2013. Institutional Review Board approval was obtained at both Midwest urban settings. Fidelity of intervention was insured with the use of an established manual for all classes as well as a non-biased observer for 50% of the classes, attendance logs, and recordings of the telephone classes. Classes occurred during the winter.

Data on main study variables were collected at baseline, immediately post intervention, and 12 weeks following the start of the program. These main outcomes included continuous data on depressive and TBI symptoms as measured with the Center for Epidemiological Studies-Depression (CES-D) scale, and the Rivermead Post-Concussion