

# **Effectiveness of a Mindfulness Based Group Therapy (MBGT) using IREST in improving the quality of life in people who have had a brain injury: A Pilot Study**

## **Abstract:**

### **Introduction:**

Acquired brain injury (TBI) is a major health problem in industrialized countries that has reached epidemic proportions. There are numerous physical, neurological and psychiatric consequences of TBI that interfere with a person's day-to-day functioning. Many people with TBI often have to establish a 'new baseline' and re-learn many simple activities, including personal activities of daily living. Compared to non-disabled individuals, people with brain injury often report to poor quality of life and loss of identity. While physical, neurological and cognitive problems are often addressed in rehabilitation; little attention is paid to a person's sense of quality of life. It is well known that rehabilitation is a multi-factorial process integrating numerous factors such as person's sense of awareness of deficits, motivation to get better and emotional issues, all of which are important aspects of quality of life. Pharmacological interventions are important and can help with recovery but they often target certain specific syndromes. Therefore, a more holistic approach, including a combination of pharmacotherapy and psychotherapy is necessary. There is recent evidence that Integrative Restoration (iRest); a mindfulness based group therapy is efficacious in the treatment of many debilitating conditions such as persistent pain, anxiety and even chronic medical illnesses. The advantages of a mindfulness based group therapy in addition to other types of psychotherapy are that it is easy to learn, it is complete in 10 weeks, it can be done either in individual therapy or group therapy, the patient can continue it for life and learns lifelong skills that can be applied in future experiences, the patient tailors it to their own needs with very little intervention from the therapist. As far as it is known only one study by Beddard et al (2003) has assessed the efficacy of mindfulness based group therapy in improving the quality of life in people with TBI. The goal of this pilot study was to replicate the findings of the study by Beddard, et al., and use the data to design a larger funded study.

### **Overarching Goal & Specific Aims:**

Primary Objective: To determine the effectiveness of a mindfulness intervention in improving quality of life.

Hypothesis: Compared to participants who receive 'Usual standard of Care' those who receive Usual Care + mindfulness based group therapy (MBGT) will have improved quality of life as assessed by improved scores on SF36 (used by Beddard) ,and the Five Facet Mindfulness questionnaire

Secondary Objective: To determine effectiveness of this mindfulness intervention in decreasing symptoms of depression as assessed by the Zung depression scale. Hypothesis: Compared to participants who receive 'Usual Care' those who receive Usual Care + MBGT will have lower scores on the Zung depression scale.

Tertiary objective: To determine the effectiveness of mindfulness based group therapy in improving (a) Cognition as assessed by the Modified Mental state exam (b) Sleep as assessed by PSQI & Epworth (c) Behavior problems as assessed by NP (d) Subjective pain as assessed by patients' subjective description.

Hypothesis: Compared to participants who receive 'Usual Care' those who receive Usual Care + MBGT will have improved scores on tests of cognition, reduced behavior problems and reduced insomnia, and reduced pain

### **Methods:**

This is a Hopkins IRB approved study. A total of 17 subjects with acquired brain injury were enrolled in the study. Written informed consent was obtained for all subjects. All subjects were patients at Johns Hopkins Bayview Brain Injury (Neuropsychiatry clinic). All subjects had complete psychiatric evaluations and were

receiving psychiatric treatment by licensed/board certified psychiatrists and licensed mental health therapists. The treatment of each subject was defined by the diagnosis and individualized as in any other outpatient clinic.

The 17 subjects were randomized by pulling a number from hat to either continue usual standard of care or have additional MBGT. MBGT involved 10 weekly sessions.

All subjects received baseline evaluations to determine mood, cognitive and behavioral status. The same scales were administered at the end of 10 week period to subjects both in the MBGT+ Usual care group and the Usual care group.

### **Results:**

A total of 17 subjects were enrolled. Of these only 9 completed the study. Eight subjects dropped out for various reasons, the most common being difficulty coming to the clinic on a regular basis.

Sample Demographics: Of the 17 subjects 53% were females. The mean age was 50.1(sd 9.4) and mean education 13.5 years (SD1.6).

Demographics of Completers & Non-completers: On comparing the completers to non-completers, there was no statistically significant difference between the groups in age but the non-completers had fewer years of education (14.8 vs 12.2 p=0.04). There was a trend towards statistical significance (p=0.06) with more females compared to males completing the study ( 77.8 %vs 25 %) and completers having overall better medical health status compared to non-completers (80% vs 50%; p= 0.07).

Comparison of Experimental versus Control Group. There were no differences between the Experimental Group ( N=5) and the Control group (N=4) in age, gender, education or medical health status.

The 2 groups were compared at baseline and after the 10 week study on several scales.

On comparison of the 2 groups on the Five Facet Mindfulness Questionnaire (FFMQ) at baseline, the experimental group had higher scores on the 'Description' domain indicating that they were better able to describe feelings( 27.5 vs 18 p=0.001). There were no statistically significant difference between the 2 groups on the other domains of the FFMQ or on the overall score of the FFMQ.

On comparing the 2 groups post-treatment, the experimental group had higher overall scores on the FFMQ ( 132.5 vs 118.5 p=0.049) and higher scores on the non-judgmental domain (31.5 vs 17; p=0.01). The difference noticed on the 'Descriptive' domain persisted but was no longer statistically significant ( 24.7 vs 25.2 p=0.46)

There were no differences between the groups post-treatment on any of the domains on the SF-36 scale. Similarly there were no differences between the 2 groups on depressive symptoms as assessed by the Zung depression scale, behavior as assessed by the Neuropsychiatry Inventory, cognition as assessed by the Mini Mental State Exam, sleep as assessed by Medical Outcome Sleep scale and Pittsburgh Sleep Quality Index and Social functioning.

**Conclusion:** This was a small pilot study to determine the efficacy of efficacy of mindfulness based group therapy over and above standard care.

The major finding of the study is that the experimental group ( Mindfulness + standard treatment) compared to the Control group (Standard treatment) had higher overall scores on the FFMQ indicating increased mindfulness skills and higher scores on the non-judgmental domain indicating increased skills to assess situation and thoughts in a non-judgmental way. There were no differences between the 2 groups on other domains of mental health functioning such as mood, behavior, sleep, cognition or social functioning.

The 2 major limitations include small sample size and high attrition rate. Other limitations include the technical difficulties the researchers had in carrying out the study as it was non-funded. None of the researchers had

protected time to complete the study. The main study investigator (LO) administered all the tests (pre and post study) and the 10week mindfulness session. Another co-investigator (VR) helped maintain the database and completed the analyses. There were no other research team members – e.g. research assistant or coordinator to help with the different aspects of the study.

Despite these limitations and the small sample size there are signals that mindfulness based group therapy may help to increase awareness of inner experiences and approach them in a non-judgmental way.

The study demonstrates feasibility and the ability to provide mindfulness based group therapy in clinic settings. With more research support, it may have been possible to minimize attrition and complete the study on time.

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