Title: Pilot Study: The effects of Telehealth Mindfulness Meditation Program on Sleep Quality and Anxiety in Acquired Brain Injury Population
PI: Nabila Enam
Date: 11/11/24

Cover Page

Identifiers: NCT06717399

Title: *Pilot Study: The Effects of Telehealth Mindfulness Meditation Program on Sleep Quality and Anxiety in Acquired Brain Injury Population*

Study status: Completed

Study start: January 1, 2025

Primary completion: May 2, 2025

Study completion: May 7, 2025

Sponsor/Collaborators: Saint Joseph's University

Principle Investigator: Nabila Enam, Clinical Associate Professor

Affiliation: Saint Joseph's University

Human subject review: Board status: Approved

Approved number: 2233742-1

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Study Protocol

Study Description

Brief Summary: Individuals with acquired brain injury (ABI), 18 years or older with minimum to moderate cognitive deficits, participated in 8 virtual mindfulness meditation sessions over 4 to 5 weeks (minimum 2 sessions per week). Each session was 30 minutes long, consisting of 15 minutes for guided mindfulness meditation led by researchers, followed by a brief period of educational discussion. Before starting the mindfulness meditation session, baseline data were collected.

Detail Description: Sleep is regarded as the fifth pillar of health, essential for overall well-being. Individuals with acquired brain injuries (ABI) are more susceptible to poor sleep quality and high anxiety due to neurological impairment. Mindfulness meditation may improve sleep quality and decrease anxiety in the ABI population. Limited research exists on virtual mindfulness meditation involving sleep quality and anxiety in the ABI population. The researchers measured changes in sleep quality and anxiety after participants completed eight virtual mindfulness meditation sessions, using the Pittsburgh Sleep Quality Index (PSQI) and the PROMIS anxiety short form.

Conditions: Sleep
Keywords: Sleep, anxiety, Acquired brain injury, mindfulness meditation

Study design
Study type: Interventional
Primary purpose: Treatment
Interventional study model: Single Group Assignment
Number of arms: 1
Masking: None
Enrollment: 12

Arms	Assigned Interventions
Virtual mindfulness meditation	Virtual mindfulness meditation, subjects participated in 30 minutes of a virtual mindfulness meditation session, totaling eight sessions.

Eligibility

Minimum age: 18 years
Sex: All
Inclusion Criteria:
- Known diagnosis of acquired brain injury

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- Score 19 or below on the Short Orientation-Memory-Concentration Test of Cognitive Impairment (SOMC)
- 18 years or older
- Can speak and comprehend English
- Have access to an internet connection and an electronic device

Exclusion Criteria:

- Diagnosis of aphasia

Participant Flow:

- 12 participants enrolled in the study. 11 participants completed the intervention sessions and outcome measures.

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Statistical Analysis Plan

1. **Primary Outcome**
   Title: Pittsburg Sleep Quality Index (PSQI)

Description: The PSQI is 19-question self-reported assessment is made up of seven subcategories, 1) subjective sleep quality, 2) sleep latency, 3) sleep duration, 4) habitual sleep efficiency, 5) sleep disturbances, 6) use of sleeping medication, and 7) daytime dysfunction. Each component is scored from "0" is no difficulty and "3" is severe difficulty during the past month. The component scores are summed to produce a global PSQI score, which ranges from 0 (good sleep quality) to 21 (poor sleep quality). If individual scores higher than a 5 overall, it is an indication of poor sleep quality.

Outcome measure time frame: 10 minutes

2. **Secondary outcome measure**
   Title: PROMIS Anxiety Short Form

Description: The PROMIS Anxiety Short Form is an eight-question self-report measure to assess anxiety. Participants were asked to rate their responses to questions relating to feelings of anxiety in the past seven days. Participants rated their feelings using a 5-point Likert scale, with responses ranging from 1 to 5. Responses were scored as follows: 1 corresponds with "never", 2 with "rarely", 3 with "sometimes", 4 with "often", and 5 with "always. A higher score on the PROMIS Anxiety Short Form is an indication a greater severity of anxiety.

Outcome measure time frame: 10 minutes

3. **Other Pre-specified Outcome**
   Title: Patient Global Impression of Change (PGIC)
   Description: The PGIC is one question in a likert-scale format for the participants to provide feedback about how their overall status has changed from the beginning of the study to the completion of the program. The seven possible responses range from (1) very much improved to (7) very much worse. The lower the number, the greater the participant's satisfaction with their overall status.
   Outcome measure timeframe: Less than 1 minute

Microsoft Excel© statistical software package will be used to analyze data for the study. Descriptive and inferential statistics will be used to evaluate the quantitative data in the study. Pre-test and post-tests are provided in order to assess changes in anxiety and sleep quality since the implementation of mindfulness meditation sessions. In order to determine a statistical significance, a paired two-tailed t-test with an alpha level set at .05 will be used.