Official Title: Evaluation of Bioness Integrated Therapy System (BITS) Touch Screen Technology to Improve Field Awareness

Clinical Trial Number: NCT04930822

Study Closeout: June 27, 2025

STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

**Methods**

Research design: Unblinded randomized control trial

Patient Population/Enrollment Criteria: Individuals enrolled in this study must meet the following criteria:

1. Individuals enrolled in this study must meet the following criteria:
    ii. Adults, 18 years or older who are able to provide consent or have Power of Attorney (POA) able to consent.
    iii. Must have an acute or subacute (diagnosed within the last 3 months) neurological diagnosis with a visual field deficit as verified by occupational therapist via confrontation testing.
    iv. Admitted into Gaylord Hospital, a long term acute care hospital
    v. Demonstrate the ability to follow 1 step directions
    vi. Demonstrate sufficient upper extremity strength (as deemed appropriate by occupational therapist) to utilize BITS touch screen technology
    vii. Ability to tolerate at least 30 minutes of intervention at a seated wheelchair level.

1. Exclusion Criteria:

    1. Severe cognitive impairments: Unable to follow one step directions, inability to communicate pain, or to stop intervention if needed
    2. Quadriparesis
    3. Previous significant visual impairment impacting visual fields or resulting in legal blindness in past medical history
    4. Re-admitted to Acute Care and do not return within 1 week
    5. Currently on a ventilator for respiratory support
    6. Unstable vital signs or deemed inappropriate to participate in therapy per RN/MD
    7. Uncontrolled or new (within 24 hours) arrhythmias.
    8. Unresolved or new (within 24 hours) deep vein thrombosis.
    9. Concurrent severe neurological pathology/disease or stroke within 72 hours.
    10. Any reason the physician may deem as harmful to the participant to enroll or continue in the study.

A total of at least 30 adult Participants meeting these criteria will be included. This will include 15 participants in “A” Group and 15 participants in “B” Group. There will be no upper age limitation.

Equipment and Intervention: Used for this study was the Bioness Integrated Therapy System (BITS©) (Valencia, CA) with 55-inch display. [1] As participants were consented and enrolled, they were alternately assigned to either the control group or the experimental group using the BITS. Over three-weeks, both groups received six, 20 minute long, vision-specific treatment sessions. The control group completed conventional table-top and pen and paper exercises, while the experimental group completed gamified, technology-assisted versions of similar exercises. Outside of these sessions, participants completed a standard rehabilitation regimen consisting of

three hours of daily comprehensive therapy (i.e., physical, occupational, speech, etc.) as prescribed by their treating physician.

Subject Assignment: Participants will be screened through an electronic report extracted from the electronic medical record. This will include all patients admitted under the stroke and traumatic brain injury (TBI) programs who have documentation supporting visual field impairments in the initial occupational therapy evaluation. Once they have been screened and all inclusion/exclusion criteria have been reviewed, patients will be consented to participate in the study and randomly assigned to "A" and "B" group in alternating fashion. If a participant exits the study before completion, their spot in the intervention will be replaced by a new participant.

Study Timeline: The enrollment period commences after the IRB has approved the study and the study initiation visit has been conducted. The enrollment and data collection periods are expected to last 12 months to obtain 30 participants. The goal is to have participants participate in scheduled occupational therapy sessions lasting a minimum of 20 but no more than 30 minutes for a total of six sessions focusing on vision therapy vs BITS training.

Outcome Measures and Data Collection: The primary outcome measures included the Bells Test, conducted by an occupational therapy practitioner involved in the study, and Kinetic Visual Field testing, conducted by a licensed neuro-optometrist. [2] Bells and Kinetic Visual Field Testing were completed at baseline and again following the six study sessions.

The Bells Test is a cancellation test that allows for assessment of spatial neglect. It consists of a field of 35 Bell icons embedded among 280 distractors. It is scored on a scale of 0 to 35 Bells correctly identified, with greater scores indicating lesser spatial neglect. In this study, participants were presented with a pen and paper copy of the Bells test. Realization and total time as well as total number of omissions and total number of identified distractors were also recorded.

Kinetic Visual Field Testing was conducted manually using a Kinetic Field Analyzer. Each eye was independently assessed and scored. The total field of view (FOV) of each eye was measured in degrees from the 8 primary meridians: Superior, Superior Temporal, Temporal, Inferior Temporal, Inferior, Inferior Nasal, Nasal, and Superior Nasal. For each region or each eye, the measured FOV is compared to normative values to calculate a percentage of Norm. Using reference data collected by investigator JP in their independent practice, the Visual Field Index (VFI), which represents the total amount of field loss as a percentage (100% being normal visual field and 0% being perimetrically blind) was calculated using the standard formula:

$$VFI = ([\text{Observed FOV} / \text{Reference FOV}]*100\%)$$

The VFI of the individual meridians were then averaged to get the Mean VFI. Mean Defect, which is the weighted average of the total deviation values in the visual test, was also calculated using the formula:

$$\text{Mean Defect} = (1/m)*\Sigma(\text{Reference} - \text{Observed})$$

where m = number of meridians assessed, which was 8. The more negative the Mean Defect, the greater the injury.

**Statistical Analysis**

Data Analysis: Data was analyzed using GraphPad Prism version 10.3.1 (GraphPad Software, San Diego, CA). A complete case analysis approach was used. Descriptive statistics and 95% confidence intervals were used to describe population characteristics. All data sets were analyzed for normality to evaluate if there were violations in the equal variances assumptions between groups. Nonparametric testing was used as necessary following the results of testing. Age data demonstrated normal distribution with comparable variance and was analyzed using an unpaired t-test. Length of stay (LOS) data demonstrated non-normal distribution and was analyzed using Mann-Whitney-U Rank sum test. Demographic characteristics were analyzed using Chi-Square ($\chi^2$). To assess for within and between group differences, a two-way repeated measures analysis of variance (ANOVA) with post-hoc uncorrected Fisher's least significant difference (LSD) multiple comparison test was completed. Statistical significance was set at an alpha level of 0.05 for all statistical tests.

References:


1. BITS - Bioness [Internet]. [cited 2025 Nov 13]. Available from: https://bionessmedical.com/bits/
2. Bells Test – Strokengine [Internet]. [cited 2025 Nov 13]. Available from: https://strokengine.ca/en/assessments/bells-test/