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# Evaluating Neuromodulation Technologies in Early Recovery

**This study is not yet open for participant recruitment.** (see Contacts and Locations)

*Verified December 2014* by *Behavioral Health of the Palm Beaches*

**Sponsor:**
Behavioral Health of the Palm Beaches

**Information provided by (Responsible Party):**
Behavioral Health of the Palm Beaches

**ClinicalTrials.gov Identifier:**
NCT01993277

First received: November 16, 2013
Last updated: December 16, 2014
Last verified: December 2014
History of Changes



## Purpose

The study is an open-label comparative effectiveness clinical trial evaluating the impact of three neuromodulation treatment devices to improve the mental health and sobriety status of recovering substance abuse patients. We intend to enroll 200 patients to give us a sufficient number of subjects for the planned comparisons. Following informed consent and baseline assessment, patients will be randomly assigned to receive either 1) 15 40-minute sessions of Nexalin Brain Stimulator, a cranial electrical stimulation (CES) device, once-per-day within a 3-week time-frame; 2) 30 20-minute sessions of the Fischer Wallace Stimulator, another CES device, twice-per-day within a 3-week time-frame; 3) 15 40-minute sessions of the DAVID Delight, an audio-visual stimulation device (AVS), once-per-day within a 3-week time-frame; OR 4) the control-group condition of 15 40-minute relaxation therapy sessions once-per-day within a 3-week time-frame. All subjects will then be reassessed at the end of the 3 weeks of treatment and again 1, 3, and 6 months later. In addition to the assigned treatments, all patients will also receive the standard array of services that are provided by Behavioral Health of the Palm Beaches (BHOPB) including as clinically appropriate, psychiatric medication management and Eye Movement Desensitization Response (**EMDR**) therapy. Patients diagnosed with Post Traumatic Stress Disorder (PTSD) are assessed to determine their suitability for **EMDR** and if suitable, will receive 2 or more **EMDR** sessions. Patients without PTSD do not receive **EMDR** therapy.

| Condition | Intervention |
|---|---|
| Depression<br>Anxiety<br>Insomnia | Device: Nexalin Brain Stimulator<br>Device: Fischer Wallace Stimulator<br>Device: David Delight Stimulator<br>Behavioral: Relaxation Therapy |

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Comparator Trial Evaluating Three Neuromodulation Technologies' Effectiveness in Early Recovery From Substance Abuse Disorders as Compared to Relaxation Therapy

**Resource links provided by NLM:**

MedlinePlus related topics: Anxiety

U.S. FDA Resources

**Further study details as provided by Behavioral Health of the Palm Beaches:**

Primary Outcome Measures:

- The Quick Inventory of Depressive Symptoms—Self-Report (QIDS-SR) [ Time Frame: Change in baseline depressive symtpoms, after 3 weeks of treatment, and 1, 3, and 6 months followup ] [ Designated as safety issue: No ]
- State-Trait Anxiety Inventory (STAI) [ Time Frame: Change in baseline anxiety symtpoms, after 3 weeks of treatment, and 1, 3, and 6 months followup ] [ Designated as safety issue: No ]

- Pittsburgh Sleep Scale (PSS) [ Time Frame: Change in baseline insomnia symtpoms, after 3 weeks of treatment, and 1, 3, and 6 months followup ] [ Designated as safety issue: No ]
- 16-item Quality of Life Enjoyment and Satisfaction Questionnaire (QLES) [ Time Frame: Change in baseline quality of life, after 3 weeks of treatment, and 1, 3, and 6 months followup ] [ Designated as safety issue: No ]

Secondary Outcome Measures:

- Brief Substance Craving Scale (BSCS) [ Time Frame: Change in baseline craving intensity after the 5th, 10th, and 15th treatment sessions ] [ Designated as safety issue: No ]

Estimated Enrollment: 200
Study Start Date: December 2013
Estimated Study Completion Date: October 2015
Estimated Primary Completion Date: June 2015 (Final data collection date for primary outcome measure)

| Arms | Assigned Interventions |
|---|---|
| Active Comparator: Fischer Wallace Stimulator<br>30 20-minute sessions of the Fischer Wallace Stimulator administered twice-per-day within a 3-week time-frame; | Device: Fischer Wallace Stimulator |
| Active Comparator: Nexalin Brain Stimulator<br>15 40-minute sessions of Nexalin Brain Stimulator adminsitered once-per-day within a 3-week time-frame | Device: Nexalin Brain Stimulator |
| Active Comparator: DAVID Delight Stimulator<br>15 40-minute sessions of the DAVID Delight administered once-per-day within a 3-week time-frame | Device: David Delight Stimulator |
| Active Comparator: Relaxation Therapy<br>15 40-minute relaxation therapy sessions once-per-day within a 3-week time-frame | Behavioral: Relaxation Therapy |

## Eligibility

Ages Eligible for Study: 18 Years to 75 Years (Adult, Senior)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

**Criteria**

Inclusion Criteria:

Adults between the ages of 18 and 75 in early recovery from a substance abuse disorder.

Exclusion Criteria:

The exclusion criteria are patients diagnosed with 1) an uncontrolled seizure disorder, 2) a psychotic disorder with currently active features (e.g., paranoia), 3) a dissociative identity disorder, 4) a manic episode within the past month, 5) patients with a pace-maker or implanted vagal nerve stimulator, patients prescribed Subocone, Subutext, &/or any psychostimulant medication (e.g., Alderol, Concerta, Focalin, Metadate, Vyvance, etc.) since these medications interfere with the ability of these neuromodulation devices' ability to have the intended effect on patients, and 7) pregnant woman.

## Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01993277

**Contacts**

Contact: Kate Reynolds, MSW 561-465-1263 kreynolds@bhpalmbeach.com

**Locations**

**United States, Florida**

Behavioral Health of the Palm Beaches **Not yet recruiting**
North Palm Beach, Florida, United States, 33408
Contact: Kate Reynolds 561-465-1263 kreynolds@bhpalmbeach.com
Sub-Investigator: Alan Stevens, MSW

**Sponsors and Collaborators**

Behavioral Health of the Palm Beaches

**Investigators**

| | | |
|---|---|---|
| Principal Investigator: | Tammy Malloy, LCSW | Behavioral Health of the Palm Beaches |
| Principal Investigator: | Jodi Star, M.D. | Behavioral Health of the Palm Beaches |
| Principal Investigator: | Kate Reynolds, MSW | Behavioral Health of the Palm Beaches |

## More Information

| | |
|---|---|
| Responsible Party: | Behavioral Health of the Palm Beaches |
| ClinicalTrials.gov Identifier: | NCT01993277 History of Changes |
| Other Study ID Numbers: | 0001 |
| Study First Received: | November 16, 2013 |
| Last Updated: | December 16, 2014 |
| Health Authority: | United States: Institutional Review Board |

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