Effectiveness of an advanced form of transcranial electrical stimulation in cases of persistent anxiety, depression and insomnia

Nancy E. White, Ph.D.
The Enhancement Institute
Nexalin Advanced Therapy Houston
1900 St. James Place, Suite 800
Houston, Texas 77056
713-961-5243
www.enhancementinstitute.com
nancy@enhancementinstitute.com
Depression, anxiety and insomnia

• In an average year in the U.S.:
  – Some 40 million people suffer from anxiety
  – Another 20 million become clinically depressed

(The World Health Organization)

– The numbers continue to grow

– The number of Americans taking antidepressants has doubled in the last decade

Archives of General Psychiatry
Antidepressants

The number of Americans taking antidepressants has doubled in the last decade.

Archives of General Psychiatry
Side effects

- Antidepressants have a number of side effects up to and including death via suicide or uncontrolled behavior.
Four meta-analyses of antidepressant efficacy trials

• A recently published study involving four meta-analyses of antidepressant efficacy trials submitted to the FDA examines the current status of research on these medications’ effectiveness

• Authors suggest that antidepressants may be only marginally efficacious compared with placebos

Publication bias

- Authors document profound publication bias that apparently inflates efficacy figures.

- Authors’ conclusions argue for a reappraisal of the current recommended standard of care for depression and for the inclusion of proven alternative therapies in the treatment regimen.

Transcranial Electrical Stimulation (TES)

This TES, FDA-approved, device is non-invasive and is capable of normalizing neurochemistry by benignly stimulating the hypothalamus and associated brain structures with a specific waveform and a specific frequency that is patented.

No serious side effects
Hypothalamus

The levels of neuropeptides, neurotransmitters, and neuromodulators critical to maintaining normal mood and behavior appear to reregulate with this TES treatment.
Effects of normalizing the hypothalamus

Perceptions of an ongoing negative situation reach the hypothalamus, engage the hypothalamic-pituitary-adrenal (HPA) axis and hold the system in chronic state of fight/flight.

Chronic stress due to HPA dysregulation can be mediated as TES stimulation works to normalize hypothalamic activity.
Effects of normalizing the hypothalamus

Influence of TES on hypothalamic control of the HPA axis may account for many of the positive neurobehavioral and physiological effects arising from this treatment.
Balance and homeostasis

• We can hypothesize that, with the right maintenance program, normalization can be maintained for prolonged periods.

• At the completion of this therapy the hypothalamus has either adapted to a new level and stabilized or is in the process of stabilizing, resulting in the long lasting benefit.
Specifically designed Epicutaneous electrodes are applied on the forehead and behind each ear (mastoids);

Most patients sleep through the therapy;

Patients receive a two or three week treatment each consecutive weekday [weekends off] each session lasting 40 minutes.
Clinical practice results

Methods used to monitor the TES therapy

- **Qeeg** (pre-post) is used as an objective monitor of TES’s efficacy
- **3D Body Scan** (pre-post) is used as a second objective monitor of TES’s efficacy
- “0-10” **Scales and Clinical Assessment** are used as subjective measures of efficacy (daily)
Clinical practice results

**Qeeg** – Statistically significant improvements noted

- Changes appear to be unique to each patient
- Improvements are measured to be typically above 60% \([p<.0000]\) and in both directions
- Noted improvements coincide with the clinical improvements noted in the patients underlying conditions.
Clinical practice results

3D Body Scan – Clearly monitors the normalization of the brains neurochemistry (pre-post) TES therapy.

• Additionally, records changes in the conductivity and neuronal excitability
Clinical practice results

“0-10” Scales and Clinical Assessment—On a daily basis these measures are taken and result in the following average levels of improvement:

• **Traditional treatment results** might achieve 25% of patients having >30% improvement

• These **TES patients** had 100% with >30% improvement in their diagnosed condition.

• These **TES patients** had 90% with >50% improvement in their diagnosed condition

<table>
<thead>
<tr>
<th>TES therapy</th>
<th>Anxiety</th>
<th>Depression</th>
<th>Insomnia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosed Average Improvement</td>
<td>77%</td>
<td>74%</td>
<td>84%</td>
</tr>
</tbody>
</table>
Houston; Clinical Trends for TES Therapy [27 patients]

Based on a “0 – 10” Scale used at the Institute
Patient #1

Objective: Using Qeeg to monitor TES’s effectiveness

Female – Age 50
Career – Medical Doctor

From ADD to peak performance

Treatment – 10 Sessions (40min. each)
BEFORE LinkEars (Eyes Closed) AFTER LinkEars
Patient #1 Outcome

The patient wanted to experience the treatment as she initially was ADD and a bit scattered. After the treatment her delta and theta reduced significantly (36% – 51%; \([p< .0000]\)) and her alpha (particularly high alpha) and beta (particularly low beta) increased significantly (78% - 87%; \([p<.0000]\)).

She is now much more functional as evidenced by her writing four training manuals without effort and now is proposing to enhance her medical practice. She reports being more organized and functional. She feels great and thinks the planet could benefit from having everyone do this treatment.
Patient #2

Objective: Using Qeeg & 3D Body Scan device to monitor TES’s effectiveness for severe depression, social anxiety and psychosis.

Male – Age 17
Diagnosed severe depression – social anxiety – psychosis

Career – Student

Symptoms: Patient was withdrawn, unable to communicate coherently, socially isolated, non responsive to traditional treatments, unable to attend school, and was hearing voices.

Treatment – 15 Sessions (40min. each)
Deymed EC (Eyes Closed)
3D Body Scan Device

Second form of Objective measure used to confirm the efficacy of the TES therapy
### BEFORE

- **Patient:** Petan
- **Age:** 17
- **Visit:** 6/5/2010 15:07, 1A1 max = 73, 1A1 min = 70

### After 15 Sessions

- **Patient:** Petan
- **Age:** 17
- **Visit:** 1/6/2010 10:39, 1A1 max = 79, 1A1 min = 72

#### Brain Analysis

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Under</th>
<th>Normal</th>
<th>Over</th>
<th>Values</th>
<th>Norms</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cerebral tissue state indicators</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right Frontal lobe conductivity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right Frontal lobe Tissue Oxygen pressure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left Frontal lobe conductivity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left Frontal lobe Tissue Oxygen pressure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right limbic system conductivity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right limbic system Oxygen pressure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left limbic system conductivity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left limbic system Oxygen pressure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neuronal excitability indicator</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Values:**
- Neuronal excitability: 2.000 - 5.000 ms

#### ANS Indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Values</th>
<th>Norms</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cerebral Neurotransmitters indicators</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimated cerebral Serotonin</td>
<td>8.0</td>
<td>7.0</td>
<td>U1</td>
</tr>
<tr>
<td>Estimated cerebral Dopamine</td>
<td>8.0</td>
<td>7.0</td>
<td>U1</td>
</tr>
<tr>
<td>Estimated cerebral Adrenaline / Noradrenaline</td>
<td>8.0</td>
<td>7.0</td>
<td>U1</td>
</tr>
<tr>
<td>Estimated acetylcholine</td>
<td>50</td>
<td>22-34</td>
<td>%</td>
</tr>
</tbody>
</table>
Patient #2 Outcome

The patient’s behavior improved over the first week of TES therapy (4 – 5 days), exhibiting normal behavior and capable of carrying on an effortless conversation with various staff members. There was no further social anxiety behavior a month after the therapy ended.

This success continued through the remainder of the therapy and now 4 months of follow up has confirmed that there are no repeat episodes of the psychotic behavior or voices. Measured improvements ranged from 54% - 67% \([p<.0000]\)

This patient has now entered college successfully.
Patient #3

Objective: Using the 3D Body Scan device to monitor TES’s effectiveness for severe depression and diagnosed bipolar.

Male – Age 19
Career – Student
Diagnosed: Depression, TBI, Bipolar

Symptoms:
- Couldn’t/wouldn’t talk
- Body out of physical balance
- Hearing voices
- Bipolar behavior

Treatment – 10 Sessions (40min. each)
3D Body Scan Results

BEFORE

AFTER 3\textsuperscript{rd} SESSION
AFTER 6TH SESSION

AFTER 10TH SESSION
3 MONTHS AFTER TREATMENT

<table>
<thead>
<tr>
<th>Indicators</th>
<th>Under</th>
<th>Normal</th>
<th>Over</th>
<th>Values</th>
<th>Norms</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cerebral tissue state indicators</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right Frontal lobe conductivity</td>
<td>9.09</td>
<td></td>
<td></td>
<td>4.27 - 14.04</td>
<td>10-6 S.m-1</td>
<td></td>
</tr>
<tr>
<td>Right Frontal lobe Tissue Oxygen pressure</td>
<td>32.0</td>
<td>22.0</td>
<td>44.0</td>
<td>mmHg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left Frontal lobe conductivity</td>
<td>9.52</td>
<td>22.0</td>
<td>44.0</td>
<td>mmHg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left Frontal lobe Tissue Oxygen pressure</td>
<td>47.0</td>
<td>44.0</td>
<td>46.0</td>
<td>mmHg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right limbic system conductivity</td>
<td>8.70</td>
<td>44.0</td>
<td>46.0</td>
<td>mmHg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right limbic system Tissue Oxygen pressure</td>
<td>23.0</td>
<td>22.0</td>
<td>44.0</td>
<td>mmHg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left limbic system conductivity</td>
<td>11.06</td>
<td>44.0</td>
<td>46.0</td>
<td>mmHg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left limbic system Tissue Oxygen pressure</td>
<td>44.0</td>
<td></td>
<td></td>
<td>22.0 - 44.0</td>
<td>mmHg</td>
<td></td>
</tr>
<tr>
<td>Neuronal excitability indicator</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neuronal excitability</td>
<td>3.500</td>
<td>2.000</td>
<td>5.000</td>
<td>ms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cerebral Neurotransmitters indicators</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimated cerebral Serotonin</td>
<td>8.0</td>
<td>7.0 - 9.0</td>
<td>UJ</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimated cerebral Dopamine</td>
<td>8.0</td>
<td>7.0 - 9.0</td>
<td>UJ</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimated cerebral Adrenaline / Noradrenaline</td>
<td>8.0</td>
<td>7.0 - 9.0</td>
<td>UJ</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimated acetylcholine</td>
<td>19</td>
<td>22 - 34</td>
<td></td>
<td>%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ANS indicators</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4 MONTH CHART
Neuronal Excitability

3 Months after treatment

Beginning of 2nd Week of Treatment
4 MONTH CHARTS

Neurochemistry

Conductivity

Beginning of 2\textsuperscript{nd} Week of Treatment

3 Months after treatment
Patient had a dramatic transformation in a short period of time [3 – 6 days] and has maintained the TES effectiveness for more than 5 months

- Conversant and literate in his thoughts & speech
- No bipolar episodes
- No more voices
- Able to jog again and partake in physical activities
- Pleasant to be
Patient #4
Objective: Using the Qeeg to monitor TES’s effectiveness for changes in brain patterns.

Male – Age 29
Diagnosed Severe Depression, insomnia & Substance Abuse (crack cocaine)

Career – Restaurant Business

Symptoms: Excess with everything, ADHD, self medicate with anything, years as an addict, family history of addicts, he described himself as “a mess”. Non-responsive to traditional treatments.

Treatment – 20 Sessions (40min. each) of TES
15 Sessions of Alpha – Theta work
DeymedEC

(Eyes Closed)

FFT Relative Power Percent Difference (%)

Warning: Absolute power must be consulted to interpret relative power.

FFT Relative Power Paired t-Test (P-Value)

Warning: Absolute power must be consulted to interpret relative power.
Patient #4 Outcome

The patient changed dramatically during the first week of therapy and overall on the order of reductions of 65% - 70% \([p<.0000]\) and increases on the order of 56% - 65% \([p<.0000]\). He also stated he lost the cravings for cocaine.

The most notable clinical changes were his energy, alertness, positive attitude, ability to interact with people, and he return to full time work in his family’s business. 4 months of follow up has resulted in consistent sobriety and excellent functioning.
Thank You