Addiction, Recovery and Technology: An Outcome Study: William B. Secor, Davila, Richard D. Froilan, and Wolskee, Patricia, 2017

Abstract

The research examined a technological device designed to enhance the treatment of addiction disorders and associated symptoms. The research examined client's self-reports on several physiological, psychological and emotional variables of fear, anger, and stress, depression, racing thoughts, physical pain, headaches, cravings and impulsive behavior. Each client was presented with a Likert type 10-point scale with 10 being the most severe and 1 being the least, which were to rate themselves both pre-session and post-session after device use. Each response was averaged over all sessions to determine if either a decrease or increase in their symptomatology was associated with each variable. Clients were also evaluated on their physiological readings of heart rate and other biofeedback readings. A statistical evaluation was performed to determine statistical significance. The research also examined client's, pre-sessions longitudinally to determine if there was a significant decrease in symptomatology chronologically through their 30 days, 60 or 90-day programs. The pre-test (pre-session) and post-test (post-session) scores were averaged for each client in each program based on any reduction or increase in their responses to the variables from their pre-session scores. In most of cases (over 90 percent), there was a statistically significant reduction between their higher pre-session scores, versus their post-session scores with a p (significance) level of at least 5 percent or less. Those clients and programs, which did not experience a reduction but an increase, were also indicated. It was suggested that some programs could to be contacted and advised of a more effective use of the device in their programs.

Introduction – Reasons for the Study

Importance of Scientifically Based Programs, Treatments and Devices

This research was conducted at a time when the United States and the world is experiencing an epidemic in opioid addiction, especially among the young. The use of these drugs could be the gateway to more serious drug use as it has been proven that the use of heroin can often result. Simultaneously, other research has demonstrated that the young (adolescents), are experiencing high rates of anxiety and depression. It is with these physiological, psychological and emotional symptoms that this research is focused.

When an addict enters a recovery program, important and extensive changes are made in their lives: their nutrition is improved, they are detoxed from deleterious substances, they receive

therapy of various kinds, they are removed from the environment and family and friends who knowingly and unknowingly reinforcing their addiction. In addition, research has shown that many addictions have a strong genetic component (they occur in families), and affect the brain's reward/pleasure centers including the dopamine producing process, involving the limbic system and the pre-frontal lobes of the brain (the cognitive system). As noted, the addicted person is also affected by environmental factors including family and friends, which can influence and reinforce addictive behaviors and attitudes. This research does not involve changes in genetic factors, but it does address the addicted persons many physiological, psychological and emotional symptoms such as fear, anger, anxiety, depression, stress, racing thoughts, body aches, headaches, cravings and poor impulse control, all components of the addict's behavior. Therefore, it is the physiological variables that this research was concerned (2016, Siobhan, Giordano, et. al.).

In a related, and important issue, the Federal Trade Commission recently announced a new Enforcement Policy Statement on Marketing Claims for Over-the-Counter (OTC) products such as homeopathic drugs. The policy statement examined how such drugs are marketed to consumers. The policy statement explained that the FTC will hold efficacy and safety claims for drug products to the same standard as other products making similar claims such as, companies must have competent and reliable scientific evidence for health-related claims, including claims that a product can treat specific conditions. The statement describes the type of scientific evidence that the Commission requires of companies making such claims for their products. The FTC stated that competent and reliable scientific evidence might not be deceptive if the advertisement or label where it appears effectively communicates that there is no scientific evidence that the product works; and the product's claims are based only on dubious citations or personal endorsements. It warns marketers not to undercut a disclosure with additional positive statements or consumer

endorsements reinforcing a product's efficacy, this can also include new devices such as the device examined in this research. This research and its hypotheses are restricted to the Biosound device and if it can access data regarding a client's psychological, emotional and physiological state. It uses a survey which has many years of use and validation.

Citations

Mitchell J. Katz, Office of Public Affairs, 202-326-2161
Michael Ostheimer, Bureau of Consumer Protection, 202-326-2699
Richard Cleland, Bureau of Consumer Protection, 202-326-3088

Coincidentally, in January (2017), the Joint Commission announced that it is revising its Care, Treatment, and Services (CTS) Standard CTS.03.01.09 to require that addiction treatment and behavioral health providers use Measurement-based Care. This announcement could mean changes for programs wishing to acquire or maintain Joint Commission accreditation. This new requirement is informed by research conducted by the Kennedy Forum, which supports the effectiveness of Measurement-based Care in improving patient outcomes. This relates directly to this research as care providers should implement a system of measurement-based care whereby validated symptom rating scales are completed by patients and reviewed by clinicians during treatment. Measurement-based care will help providers determine whether the treatment is working and facilitate treatment adjustments, consultations, or referrals for higher intensity services when patients are not improving as expected. Measurement-based practice means the ongoing and systematic use of symptom rating scales during treatment.

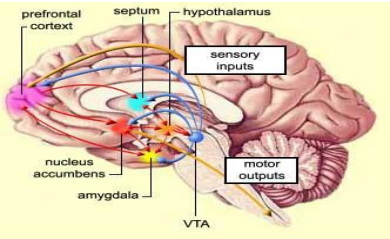
However, the terms "evidence-based practice" and "evidence-based practices" are ubiquitous and often misused. Evidence-based practices are therapies or programs that have been proven efficacious through research. Evidence-based Practice is the process of conducting research and

appraising findings to inform clinical decision making and is "the systematic search for, and appraisal of, best evidence to make clinical decisions that might require changes in current practice, while considering the individual needs of the patient." (Essential differences between research and evidence-based practice, Carnwell, Pos, Nurse Researcher (through 2013); Winter 2000; 8, 2; Nursing & Allied Health Database pg. 55.

Citations

Aronberg, David, Johnson, Alan, and Chapman, Justin, Presentation of the Palm Beach County Grand Jury, Fall Term, December 8, 2016.
The Joint Commission, 2017, Treatment, and Services (CTS) Standard CTS.03.01.09

Review of the Literature – Research which informs this Research



Relapse is the rule rather than the exception in addiction recovery, usually occurring within a few months after discharge from a recovery program. Because of recent scientific research in addictions indicating the genetic component, and the concept of addiction being a brain disorder, involving impaired cognition and the disruption of the dopamine system, the moral stigma is removed. Stressors, physiological, psychological and emotional factors are important components to the recovery process. (Sinha R. Stress and drug abuse. In: Steckler NHKT, Reul JMHM, editors. Handbook of Stress and the Brain. Part 2 Stress: Integrative and Clinical Aspects. Vol. 15. Elsevier; Amsterdam: 2005. pp. 333–356).

Other clinical laboratory studies have shown that alcohol-dependent people are more sensitive to relapse-provoking cues/stimuli compared with control subjects. This is because they often return to the same environments which they left prior to treatment. Alcohol-dependent subjects also are heavier drinkers and often experience an insidious return to excessive levels of alcohol consumption once a "slip" occurs after abstinence. Numerous rodent and primate models have been employed to examine the influence of dependence on relapse and have demonstrated increased alcohol responding and/or drinking in dependent compared with nondependent mice. The enhanced alcohol consumption in dependent animals during withdrawal produced blood and brain alcohol levels that nearly reached levels attained during the initial chronic alcohol exposure, which had produced the dependent state. Consistent with the findings of clinical studies, animals with a history of alcohol dependence exhibited exaggerated sensitivity to alcohol-related cues and various stressors that lead to enhanced alcohol-seeking behavior. These effects were observed long after the animals had experienced chronic alcohol exposure. Experience with repeated cycles of chronic alcohol exposure and withdrawal not only led to an exacerbation of the physiological symptoms of withdrawal, but also, to enhanced susceptibility to relapse. A growing body of evidence indicates that alcohol dependence and withdrawal experiences significantly contribute to enhanced relapse vulnerability and favor sustained elevated levels of alcohol drinking once a "slip" occurs. Thus, a repeated cycle is perpetuated.

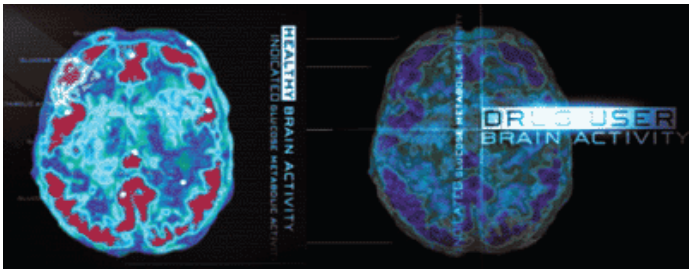
Citations

Meisch 1983; Meisch and Stewart 1994). Becker and Lopez 2004; Chu et al. 2007; Dhaher et al. 2008; Finn et al. 2007; Lopez and Becker 2005) and rats (O'Dell et al. 2004; Rimondini et al. 2003; Roberts et al. 2000; Sommer et al. 2008; Valdez et al. 2002). Lopez and Becker 2005; Rimondini et al. 2003; Valdez et al. 2002. Griffin et al. 2008; Roberts et al. 2000. Gehlert et al. 2007; Liu and Weiss 2002b; Sommer et al. 2008.

Additional, extensive research has also shown that addiction is a brain disease. The APA (American Psychological Association), states: “An ever-increasing body of scientific evidence suggests that the transition from voluntary user to addict occurs through a combination of processes, including a series of brain changes or neuro-adaptations that result from repeated drug exposure. Because changes in brain structure and function are fundamental to the development and expression of addiction, it qualifies as a brain disease, a brain disease expressed as compulsive behavior. It is the quintessential bio-behavioral disorder.”

Just saying no does not work. They are in a different brain state. Addiction is a complex bio-behavioral disorder whose development and expression depend heavily on social context; addiction treatment inevitably has many different components. The symptoms of this brain disease go beyond simply using a lot of drugs. Addiction has diverse medical, behavioral and social consequences that affect one's ability to function in virtually every life domain.

Understanding the bio-behavioral nature of addiction also helps in thinking about strategies to deal with addicted criminal offenders. Untreated addicted offenders have high post-incarceration rates of recidivism both to drug use and criminality. Untreated, the illness takes over as soon as they are released back into the community. Numerous studies have shown that treating addicted offenders while they are under criminal justice control dramatically reduces later criminality and drug use.



The National Institute on Drug Abuse (NIDA), believes that increased understanding of the basics of addiction will empower people to make informed choices in their own lives, adopt science-based policies and programs that reduce drug abuse and addiction in their communities, and support scientific research that improves the Nation's well-being."

Genetics

Anywhere from 40 to 60 percent (NIH and SAMSHA) of addiction is half genetics and half psychological in terms of susceptibility. Addiction is a 50 percent genetic predisposition and 50 percent poor coping skills. This has been confirmed by numerous studies. One study looked at 861 identical twin pairs and 653 fraternal (non-identical) twin pairs. When one identical twin was addicted to alcohol, the other twin had a high probability of being addicted. But when one non-identical twin was addicted to alcohol, the other twin did not necessarily have an addiction problem. Based on the differences between the identical and non-identical twins, the study showed 50-60% of addiction is due to genetic factors. Those numbers have been confirmed by other studies**.** The children of addicts are eight times more likely to develop an addiction. Another study looked at 231 people who were diagnosed with drug or alcohol addiction, and compared them to 61 people who did not have an addiction. Furthermore, it looked at the first-degree relatives (parents, siblings, or children) of those people. It discovered that if a parent has a drug or alcohol addiction, the child had an eight times greater chance of developing an addiction.

Dopamine

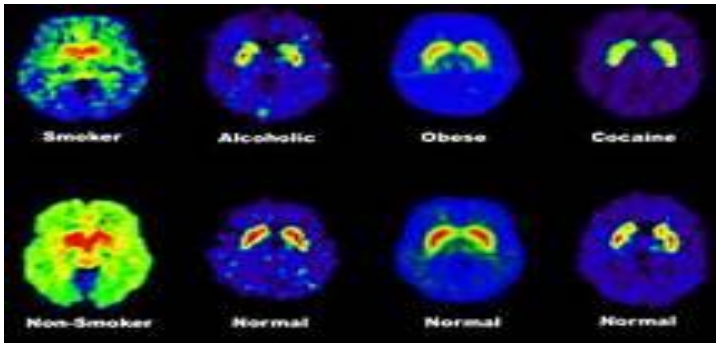
Dopamine is a neurotransmitter in the brain that plays vital roles in a variety of different behaviors. The major behaviors dopamine affects are cognition, pleasure, and motivation. The centers and circuits in the brain which are affected by additions. are the nucleus accumbens (the reward center in the brain associated with endorphins and euphoria), the amygdala and hippocampus in the limbic system, (memory and emotion), and the frontal area (the higher reasoning area of the brain). With addiction (alcohol, heroin, cocaine, gambling etc.), the brain is "high jacked" and these centers are taken over and controlled by the drug or addicting substance or behavior; and not the reasoning center in the frontal lobes. Although the addicted individual might want to stop their drug use and addictive behaviors, they cannot do so because their brain is no longer under the control of the "thinking areas". For the addicted person, only abstinence can restore the addicted brain to normal functioning.

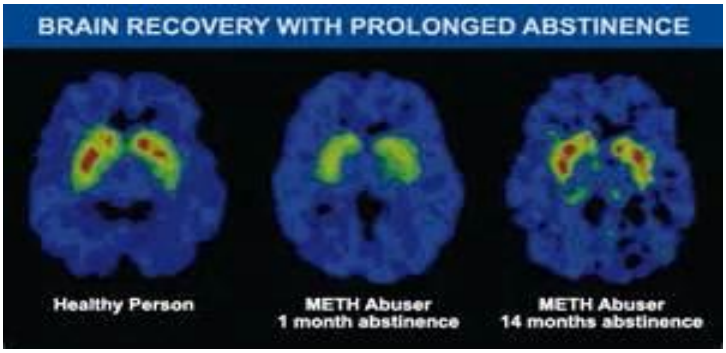
Brain images of the normal brain compared with the addicted brain show that the frontal and prefrontal areas are adversely affected, wherein the addicted brain shows less activity in this area. This area is important for thought, decision making, organization and other essential functions. With addictions, changes take place at the cellular level. This includes changes in the release of various neurotransmitters at the synapse, especially dopamine. Because of addiction, the synapse and its functioning experiences hyper-excitation, tolerance and hypo-excitation depending on the stages in their addiction.

Research has also shown that addicts have psychological problems in social settings (dysphoria and temperament). Initially, alcohol and drug use over time, they overcome these feelings of being

uncomfortable. However, when the individual is no longer using an addictive substance, these feelings of inadequacy, being uncomfortable in social settings and in interpersonal relationships return.

Addiction can influence memories and become triggers. Memories provide incentives for action by registering the value of important experiences. Rewarding experiences trigger the release of the brain chemical dopamine, telling the brain "do it again." What makes permanent recovery difficult is drug-induced change that creates lasting memories linking the drug to a pleasurable reward. Research shows that addiction involves many of the same brain circuits that govern learning and memory. Repeatedly taking drugs can change the brain cells and make the memory of the pleasurable effects very strong. Even after a return to normal functioning, addicts may remain hypersensitive to the drug and the cues that predict its presence.





Cocaine is the most severe form of addiction. Cocaine chemically inhibits the natural dopamine cycle. Normally, after dopamine is released, it is recycled back into a dopamine transmitting

neuron. However, cocaine binds to the dopamine, and does not allow it to be recycled. Thus, there is a buildup of dopamine, and it floods certain neural areas. The flood ends after about 30 minutes, and the person is left yearning to feel as he or she once did. That is how the addiction begins. Progressively, a tolerance builds up since the person is constantly trying to repeat the feeling that he or she had the first time. However, the person cannot, because dopamine is also released when something pleasurable yet unexpected occurs. After the first time, the person expects the same effect, however, less dopamine is released, and the experience is less satisfying, resulting in the use of more cocaine and/or larger doses.

Several studies have been conducted which targeted neural response to rewards. The results were unanimous; when one performed an action repeatedly, and was given a reward randomly, dopamine levels rose. If the reward was given consistently, (i.e. every fourth time the action was performed), the dopamine levels remained constant. Finally, if no reward was given, dopamine levels dropped. These same random rewards can be seen in gambling. Because the outcome is based on chance, one does not know if he or she will win. If the person once wins, dopamine levels increase. However, unlike cocaine, gambling causes addiction in only 4% of participants. This is since cocaine's chemical input is much more influential on dopamine levels than gambling's behavioral input. Therefore, only people whose dopamine levels are low, become addicted to gambling.

Because most people who become addicted to gambling have low dopamine levels, that same research group had endured a traumatic experience, and dopamine levels can change due to environmental factors. The mind and brain can change in response to environmental factors. Another study observed that a gene related to dopamine is found twice as often in pathological gamblers than non-gamblers. This supports the observation that dopamine levels are genetic. Two

plausible observations can be made. Environmental factors can affect genes which in turn affect one's brain and mind. This is due to the observations in the studies showing a strong correlation between pathological gambling, traumatic experiences and genetic influence.

Everything happens for a reason and the increase of dopamine levels is because of risk and reward. The reward is the release of dopamine and the feeling of satisfaction. Gambling is an example of this because the gambler sometimes wins (schedules of reinforcement/periodic reinforcement). These feelings of satisfaction that dopamine exhibits are so strong that one can often lose one's ability to reason to achieve satisfaction. The unconscious takes over and begins to make certain decisions. The brain develops neural circuits that unconsciously assess reward. Because the dopamine plays an active role in these circuits, a person will act in what they think is in their best interest, when in fact the only interest it satisfies is the release of dopamine. This can be exemplified in gambling where one insists on gambling even though he or she knows that the odds are against them. Probability and reason no longer are the most crucial factors in decision making. The unconscious need for the release of dopamine becomes most important. This supports the observation that the unconscious plays a vital role in decision making.

Therefore, using brain scanning (fMRI), researchers have established that all addictions can be traced to dopamine-induced expectations and associated changes in the brain. The expectations involve cocaine, nicotine, alcohol, sex, tobacco, gambling and food. The most common and dangerous behaviors involve easily denied psychological/emotional addictions. Psychological addictions are particularly insidious because dopamine is triggered by emotions, memories, thoughts, self-deceptions. Psychologist Abraham Maslow categorized deficiency needs. The deficiency needs can be divided into physiological needs (air, water, salt, food, sex) and

psychological/emotional needs (safety, power, control, acceptance, approval, attention, esteem and status).

The more powerful the addictions, the greater the self-deception and denial; there is less free will, and it is more likely addicts will ignore and dismiss information that threatens to expose their addictions and prevents them from satisfying their cravings. Dopamine changes the functioning of the brain and the physiological experiences of fear, anger, and depression etc. To keep the dopamine flowing, the heroin addicts continue to shoot up, alcoholics drink and gamblers continue to gamble. Therefore, addiction treatment must address the physiological, emotional, and psychological needs associated with alcohol, drug, gambling and other addictions.

Citations

Harvard Medical School website, November 25, 2016
Siddiqui, Imran, Bryn Mawr College, website, November 26, 2016,
1) Dopamine
2) The Dopamine Connection
3) Cocaine Abuse and Addiction
4) Hijacking the Brain Circuits with a Nickel Slot Machine
5) Mental and Physical Status of Gamblers: Physiological Findings

Finally, a recent research study, which is like this research, (2016, Siobhan, Giordano, et. al.,) "Audio therapy significantly attenuates mood in residential patient addiction treatment due to putative activation of dopaminergic pathways in the meso-limbic reward circuitry of humans", from the Abstract). Siobhan et al employed a Likert type survey, fMRI and monitored variables such as stress, anger, cravings, by scoring the intensity of their symptoms prior to treatment and after treatment (using a 25-minute audio listening portion). This research has brought together the many variables that make up addiction, as a disease, the genetic and dopamine component, and the physiology of the addict in early recovery. The research confirmed that audio therapy significantly attenuated aberrant mood in residential addicted patients in the meso-limbic reward circuity of

humans (2016, Siobhan, Giordano, et. al.) states that such therapy is a "standard of care especially in a holistic addiction treatment program."

Research Design, An Outcome Study- Results

A caveat, science and research are conservative enterprises. Their results do not go beyond the bounds of the results of the phenomena they are studying, nor do they make unsubstantiated claims about the research results. Although the results can often indicate areas for future research, as this research does. Therefore, the results of this research make no claims about any changes to the client's genetics or the brain, which is impossible and ridiculous. However, the results of the research do indicate that both the device and the Likert type survey instrument used can access the clients subjective psychological and emotional state at the time of use (repeated use), and that the BioSound device can reduce many of the ten cognitive symptoms often associated with addiction and of those in recovery, including those which are physiological in nature as they are controlled by dopamine levels in the brain including the cognitive functioning of the brain, and the limbic system. As we have noted, there is extensive research in this area noting that changes in behavior, the cessation of alcohol and drug use, and addictive behavior and changes in environment and therapy can result in changes in dopamine levels and cognitive functioning, both psychological and emotional.

This research provided a multilevel analysis of a recovery device and process involving a client's symptomatology as it relates to persons in early addiction recovery. This research is informed by Outcomes Research which is a branch of public health research, which studies the end results (outcomes) of the structure and processes of the health care system on the health and well-being of patients and populations.

Citations

INAHTA (International Network of Agencies for Health Technology Assessment) (Jun 1, 2015). "HTA Glossary.net". INAHTA.
Luce, BR, et al. (2010). ". EBM, HTA, and CER: clearing the confusion". Milbank Q. 88 (2): 256–76. doi:10.1111/j.1468-0009.2010.00598x. PMID 20579285.
European network for Health Technology Assessment) http://www.eunethta.eu/about-us/faq
Battista, RN: The scientific basis of health services. BMJ Publishing Group, 1996.Menon D.; Marshall, D (1996). "The internationalization of heath technology assessment". IJTAHC. 12 (1): 45–51. PMID 8690561.
INAHTA (International Network of Agencies for Health Technology Assessment). (Oct 8, 2013). "HTA glossary.". HTAi.

The Test Instrument

A Likert psychometric scale, which is the most widely used approach to scaling responses in survey research, (or more accurately the Likert-type scale) is often used interchangeably with rating scales. A10 item scale was used covering 10 variables, with a range of 1 to 10, with 10 being the most severe and 0 least severe. This scale and other like it such as the Beck et. al., Scales for Anxiety, Depression, Stress, etc., are well known, and extensively used scale, especially helpful when used with Cognitive Behavioral therapies (CBT).

Each of the variables was tested for each client, comparing their pre-session and post-session scores. The population was identified as to gender, age, number of sessions and length of each session. The research population came from a variety of treatment programs in various cities and states. Data was accessed by the researchers through the BioSound website using a confidential code allowing the researchers to access the pre-session and post-session data. Confidentiality was strictly maintained as no client or their program was identified and only client and program identification numbers were used. Additional information was gathered such as averages of time on the device, average age (differences in age), average number of sessions and a comparison of the results of the various treatment programs.

Of importance was the client's progress chronologically. It was suggested that a client might initially enter their program with high readings on the variables, but demonstrate a significant reduction in symptomatology. Those indicating an initial high reading, should decrease as they progressed in their treatment program. Therefore, those clients who experienced the BioSound therapy for a minimum of five sessions or more and were specifically examined to determine a reduction

The Device

The BioSound Therapy System includes a Vibrational Healing Bed and includes:

1) Heartmath Practitioner's Desktop Program preloaded with 2 pulse sensors.
2. BioSound Outcome Data Analyzer Program.
3. Five inspirational videos. For example, Creation Calls video and Christian Track program.
4. Software preloaded on a laptop with Proprietary BioSound Therapy Program:

Guided Imagery and Affirmations: 4 Sessions -140 minutes
Music & Massage Therapy: 4 Sessions -140 minutes
Detox Assistant: 2 Sessions - 90 minutes
Chakra Alignment: 1 Session - 60 minutes
Solfeggio Meditations: 3 Sessions -120 Minutes
Drum Therapy: 1 Session - 30 Minutes

The Research Population

The terms “addiction” and “addict” require some examination. Although an individual might have once been a “user” that is not synonymous with being an addict. Research has shown that many veterans, although addicted to drugs and alcohol while overseas in active service, after being detoxed, many did not return to their drug or alcohol use. Many users refuse to be associated with AA or a 12 Step Program, as they refuse to identify as an addict or an alcoholic (there are over 250 secular AA and 12 Step Programs), For this research, addiction is regarded as a spectrum disorder with many causes and magnifications along a continuum. Categories and labels have disadvantages and can often be misleading and destructive. This research focused solely on the device, and its ability to reduce physiological symptomatology. It did not address the type of addiction, or the individual addict per-se. Therefore, this research involved only those clients who were identified as addicts (including users of alcohol, heroin, cocaine, tobacco, compulsive gambling), and were in acute phase detoxification programs.

The research population came from many different geographical locations including Florida, Alabama, Georgia, Illinois, and Massachusetts. They were from many different cities, and were associated with a wide variety of treatment programs using a variety of treatment methods and philosophical and recovery orientations. Treatment methodologies ranged from detoxification only, to inpatient detoxification programs, the use of non-addicting treatment drugs such as Benzodiazepines, Zoloft, Clonidine, Naltrexone (Vivitrol). Acamprosate (Campral). Disulfiram (Antabuse), Methadone. Buprenorphine (Suboxone) and Naltrexone in 30, 60 and 90-day programs, some with aftercare, some using a 12-step program (both AA and non-AA), recovery coaching and family mentor personnel. However, prescribing these drugs and their monitoring

must be carefully assessed, Selection criteria for inclusion of clients and their data and treatment programs used in this research was:

1) Clients must have at least Five sessions or more on the BioSound device, because as a minimal, five sessions could represent four to five weeks (a month) on the device.

2) They must have used the device for a minimum of one half hour or more for each session because this allows clients to experience many of the techniques the device provides. These were multiple sessions by the same client over days, weeks and in some cases months.

The rationale for these requirements includes the recognition that the use of the device for one or two sessions would not provide sufficient experience and data or an adequate time-period for an accurate reflection of the effectiveness for the device. As noted, multiple sessions chronologically across time for five or more sessions could possibly indicate a possible reduction in symptomatology during their time at their treatment center. Such a rationale could indicate both the effectiveness of the device itself and the possible effectiveness of their treatments in their respective programs comparing 30, 60 and 90-day programs. The data was exported to MS Excel and then imported to Kwikstat (www.texasoft.com) a statistical software program for Statistical Data Analysis. The research data was obtained from the 31 treatment programs (See Addendum One). Each respondent's score between the pre-session and the post-session were averaged. Each variable was statistically analyzed as was each variable as a group (age, gender, and as a program). These results were placed into categories of gender, age, number of sessions and length of time using the device.

Finally, the latest meta-analyses have shown that it is necessary for at least eight hundred (800) patients to be accessed to determine the effectiveness of any psychotherapeutic techniques. This research accessed approximately 800 clients.

Citation

Are all psychotherapies equally effective in the treatment of adult depression? Pim Cuijpers (VU University, Netherlands), Ellen Driessen (VU University, Netherlands), Holly Swartz (Pittsburgh, USA), Andrea Cipriani (Oxford, UK), Michael Ostacher (Stanford, USA). The panel discussed Prof Cuijpers' paper which analyzed more than 100 comparative outcome trials, directly comparing two or more psychotherapies for adult depression. The paper examined whether these comparative trials had sufficient statistical power to detect clinically relevant differences between therapies (http://ebmh.bmj.com/content/19/2/39.f).

Some Important Definitions

Because addictions affect the brain, they can sometimes produce psychotic like symptoms of which mania and hypomania are examples. These are rapid thought patterns, sometimes marked by manic episodes and impulsive behavior, however, not the actual hearing of voices. What are the client's racing thoughts, what are they associated with, are they triggers, what is the client's physiological reaction to the thoughts, and what behavior results?

Cravings vary among clients; craving for food, alcohol, a specific drug, inappropriate sexual behavior (sexual abuse), at an inappropriate time and place, or with an inappropriate person.

Impulsivity is often observed in the behavior of addiction, in which their behavior is often unpredictable, erratic and inappropriate in time and place.

The Null-Hypothesis

The use of the BioSound Device and the results of the Likert Type Survey indicates no statistically significant valid indication that it can access and reduce the psychological, emotional and

physiological symptomatology indicated by the ten symptoms accesses, often associated with early addiction recovery.

Statistical Analysis

Mean post-session treatment scores were calculated and compared with pre-session scores for each of the 10 symptoms using the 10 item Likert Survey of clients in many programs. Two statistical analyses were run, the Wilcoxson Nonparametric Signed Rank Test (alternative to the paired t test) with repeated measurements calculated for each of the 10 symptom scores obtained from the BioSound Device. The results were significant for the 10 symptoms. An ANOVA of Paired T Test of Repeated Measures was also run resulting in the number of repeated measures, number of symptoms read, (10), means and standard deviations for the repeated measures. Repeated measures VALUE 1 (pretest) and VALUE 2 (posttest).

Sign Test Results were the number of positive signs = 10, the number of samples with differences > 0 = 10, binomial distribution results: p = .002 (Two-tailed), binomial distribution results: p = .001 (One-tailed). Sum of the positive ranks = 55, sum of the negative ranks = 0, number of samples = 10. Using the normal approximation, z = -2.8031 p = .0051 (two-tailed). (Mean = 27.5 s.d = 9.811). 1) VALUE1: mean = 3.52, s.d. = 0.5731, 2) VALUE2: mean = 1.74, s.d. = 0.18379, Mean Difference = 1.78, s.d. (difference) = 0.41042, 95% C.I. about Mean Difference is (1.48604, 2.07397), Calculated t = 13.71487 with 9 D.F. p = < 0.001 (two-sided).

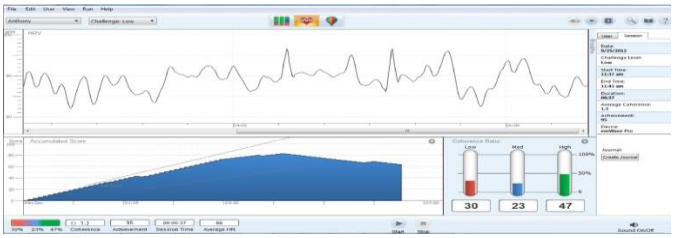
All results remained significant after applying a Bonferroni correction test for multiple comparisons required for $p<.005$ to obtain a significant level of $p<.05$. Examination of the changes in means (the decrease in symptomatology) showed a range of 44 to 57 percent decrease in symptomatology (see Chart: “Changes in Percentages”), and demonstrated a significant decrease from the pre-session treatment scores to the post-session treatment scores. At the end of treatment most clients registered a statistically significant improvement. The Null hypothesis (N_0) was therefore rejected.

Descriptive Statistics Results

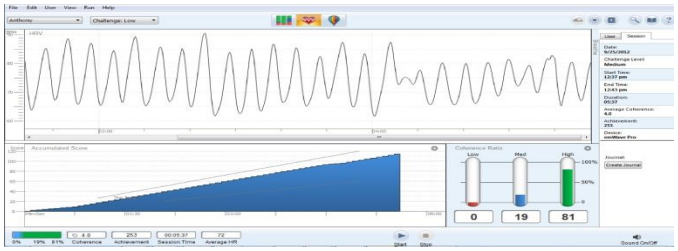
Total N = Approximately 800 client sessions (Although over 3,000 client responses were examined, not all clients were used for analysis, because they did not meet the strict criteria).
Total programs: 31 (10 usable based on our criteria)
Criteria; A least 5 sessions per client and a minimal of ½ hour on the device.
Age Range: 12-60
Range of Responses to Variables (fear, depression etc.): 1-10 (with 10 being the most severe. 1 the least)
Gender: Female to Male Ratio: A preponderance of males 75 percent to 25
Average Age (All Clients): 30s
Average Time on Device: (at least ½ hour on the device):
Average Number of Sessions (5): Some programs had 20 or more, one program had the most number of clients and sessions.

Physiological Readings

Many of the programs in this research also conducted physiological readings of their clients. These included biofeedback of heart rate (HRV), variability, and pulse. A representable sample of those readings are as follows:



Pre-Session-Feedback



Post-Session Feedback

This research study presented robust evidence that the BioSound Device could significantly reduce severe physiological, psychological and emotional symptoms associated with addiction recovery, across all variables from stress to headaches. These research findings are consistent with preliminary research which was published in two professional journals ("The Counselor", 2016 and Treatment and Recovery: Industry Insider Sept/Oct. 2015). The present research demonstrated the plasticity of the mind/brain and its ability to assess and be influenced by the therapy provided by the Biosound Device, including binaural beats, music, guided imagery, and meditation. Our findings are also consistent with those results found by the 2016 research by Siobhan & Giordano, et. al., noted previously.

Discussion

Interpretation of Scores

Although the person in recovery might have had a successful detoxification in a 28 day, 30 days, 45 days, 60-day or 90-day treatment program, most still returned to the environments they left, still experiencing many of the same physiological and psychological effects of their addiction.

Their significant others often are still relating to those in recovery as they perceived him or her during their addiction phase (usually associated with shame, labeling and stigmas), and not as the recoveries are presently coping with their addiction. For this reason, those in early recovery are especially prone to relapse (White, et al.). Family members of those in recovery will be researched at a different time. The research examined the BioSound device from both a macro and micro levels, from an individual level to the use of the device by many clients in many different programs. Much could be learned by examining an individual client's responses and responses from the different programs.

A Note About the Programs Used in this Research

Our research demonstrated the success of the device, in which there was considerable improvement. The success of the device is also related to how it is utilized and integrated into a holistic, multimodal treatment environment and how it can be used as a diagnostic tool, as an aid to treatment This was obvious from the analysis of the raw data and the pre-session and post-session scores. No programs per-se were evaluated.

Recommendations

The researchers suggested that a treatment program could benefit greatly by integrating the BioSound program more effectively into their total addiction recovery program. Research has shown that effective addiction recovery services embrace a continuity of care, a holistic, multimodal approach in which physiological variables (fear, anger, depression etc.) are significant as they can often trigger a relapse, and impede progress. Our data and their analysis revealed that the device can effectively reduce these variables from severe to a lower level of experience. These readouts can be consulted by the program professionals as they indicate some important variables relating to a client's individual recovery on a day by day, week by week, or month by month basis. Some clients initially indicated very high readings in anxiety, depression, fear, and anger and then demonstrated a significant decrease. These physiological and psychological variables are important in addressing the person in recovery's personalized program, as the BioSound biotherapy device can also function as a diagnostic and assessment tool. The device could be used early in the morning (pre-session, followed at the end of the day by the post-session). This would give an indication of the possible successfulness of their activities and therapies during that day. The client's date and time on the device could indicate which option they have chosen to use it,

either in one session with the posttest immediately following the pre-session, or the pre-session early in the day, and the post-session at the end of the day. Finally, it should also be noted that although most clients indicated a significant reduction in symptomatology, they also show an intermittent increase in symptomatology. This is normal for many clients in early recovery as they often have good and bad days. This information could be used in the treatment process.

Acknowledgements

The researcher would like to thank the following individuals and programs for their cooperation during the conduction of this research: Dr. Richard D. Davila, Ph.D., Recovery All and Recovery 4 All, Tampa, Florida. Dr. Michael Galer, Mr. Richard Gallant and Mr. Christopher Gallant, BioSound Inc. and Alan C Elliott, Texas Soft, 1739 Green Tree Lane, Duncanville, Texas 75137-3600, Statistical Software.

Additional References

1) Arkowitz, Hal, Scott, O. and Lilienfeld, Scientific American: August 1, 2012
2) Blacksnakes, A., Ladouceur, R., & Shaffer, H.J. (2004). A science-based framework for responsible gambling: the Reno model. Journal of Gambling Studies, 20, 301-317.
3) Blum, K., Nichole, EP, Sheridan PJ, Montgomery A, Ritchie, T. et al. (1990) Alethic association of human dopamine D2 receptor gene in alcoholism. JAMA 263: 2055-2060.
4) Davila, Richard, D. http://www.rec, overy4all.com/bio-for-dr-davila.html
5) Davila, Richard, D. Davila, Richard, and Michael Galer (2014, Addiction Professional), Guided 12-Step Type Recovery for Gamblers by Enhancing, Supporting and Encouraging Fellowship and Recovery Coach Principles.
6) _____ Adding education to the model, July 26, 2013 Michael Mendel Galer, MEd, DBA, MSW, ACSW, PhD
7) Drugs, Brains, and Behavior: The Science of Addiction, How Science Has Revolutionized the Understanding of Drug Addiction, https://www.drugabuse.gov/publications/drugs-brains-behavior-science-addiction/preface
8) Enoch, M. A., & Goldman, D., The genetics of alcoholism and alcohol abuse. Current Psychiatry Rep, 2001. 3(2): p. 144-51.

9) Effects of drug addiction: physical and psychological, https://www.healthyplace.com/addictions/drug-addiction/effects-of-drug-addiction-physical-and-psychological/
10) Evid. Based Mental Health: doi:10.1136/eb-2016-102341
11) Genes and addiction, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2715956/
12) Genes matter in addiction, http://www.apa.org/monitor/2008/06/genes-addict.aspx
13) Goldstein, A. 91980), Thrills in response to music and other stimuli Physiol Psychol 8: 126-128.
14) Han, DH, Yoon, SJ, Sung YH, Lee YS, Kee BS, et al. (2008) A preliminary study: novelty seeking, frontal executive function, and dopamine receptor (D2) Tag: a gene polymorphism in patients with methamphetamine dependence. Compr Psychiatry 49: 387-392.
15) Hou QF, Li SB (2009) Potential association of DRD2 and DAT1 genetic variation with heroin dependence. Neurosci Lett: 464 127-130.
16) Lindberg DA (2005) Integrative review of research related to meditation, spirituality and the elderly. Geriatr Nurs 26: 372-377.
17) Menon, V. Levitin DJ (205) The rewards of music listening response and physiological connectivity of the mesolimbic system. Neuroimage 28. 175-184.
18) Merikangas, K. R., Stolar, M., Stevens, D. E., Goulet, J., et al., Familial transmission of substance use disorders. Arch Gen Psychiatry, 1998. 55(11): p. 973-9.
19) Morgenstern, J. Kahler, C.W., Frey, R.M. and Labouvie, E. (1996), Modeling therapeutic response to 12 Step treatments; Optimal responders, non-responders, partial responders. Journal of Substance Abuse, 8 (1), 45-59.
20) Physical versus psychological addiction, https://www.rehabs.com/just-the-facts-psychological-vs-physical-addiction/
21) Physical and psychological addiction, http://alcoholrehab.com/addiction-articles/physical-and-psychological-addiction/
22) Physiological Effects of Alcohol, Drugs, and Tobacco on Women https://www.ncbi.nlm.nih.gov/books/NBK83244/
23) Prescott, C. A., & Kindle, K. S., Genetic and environmental contributions to alcohol abuse and dependence in a population-based sample of male twins. *Am J Psychiatry*, 1999. 156(1): p. 34-40.
24) Sinha R. Stress and drug abuse. In: Steckler NHKT, Reul JMHM, editors. Handbook of Stress and the Brain. Part 2 Stress: Integrative and Clinical Aspects. Vol. 15. Elsevier; Amsterdam: 2005. pp. 333–356.
25) Siobhan, Morse, John Giordano, Kenneth Perrier, B. Williams Downs, Roger L. Waite, Margaret Madigan, John Bailey, Eric Braverman, Ulma Damle, Jennifer Knopf, Thomas Simpactico, Monty D. Moeiler, Debmalya, Barth, and Kenneth Blum. Audio therapy significantly attenuates aberrant mood in residential patient addiction treatment: Putative activation of dopaminergic pathways in the meso-limbic reward circuitry of humans. Journal of Addiction and Residential Therapy, 2017, S3:001.
26) The science of addiction: Genetics and the Brain, http://learn.genetics.utah.edu/content/addiction/

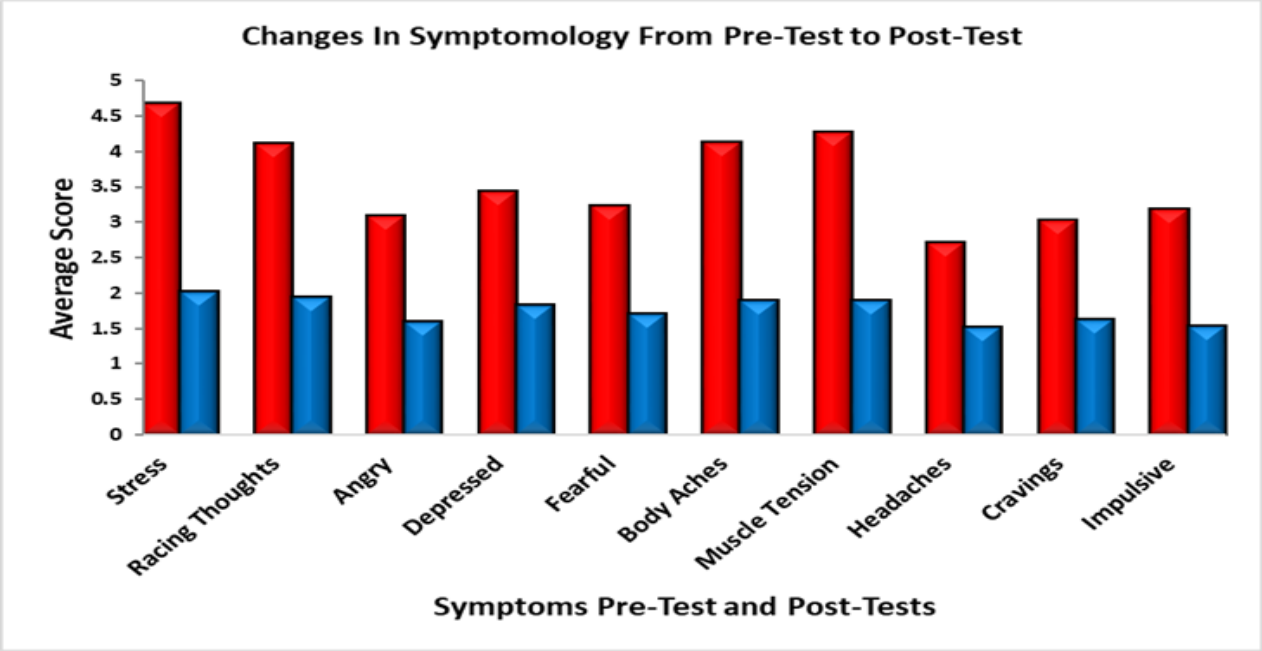
27) Understanding Addiction: How addiction hijacks the brain, https://www.helpguide.org/harvard/how-addiction-hijacks-the-brain.htm
28) Washington, Kris, Essential differences between research and evidence-based practice, Carnwell, Pos, Nurse Researcher (through 2013); Winter 2000; 8, 2; Nursing & Allied Health Database pg. 55
29) White, W. (2004b) Recovery coaching. A lost function of addiction counseling? Counselor, 5(6), 20-22
30) White, Sponsor, recovery coach, addiction counselor, The importance of role clarity and role integrity. Philadelphia, PA: Department of Behavioral Health.
31) White, W. (2009). Peer-based Addiction Recovery Support: History, Theory, Practice, and Scientific Evaluation. Chicago, IL: Great Lakes Addiction Technology Transfer Center and Philadelphia Department of Behavioral Health and Mental Retardation Services.
32) White, W. (2006). Sponsor, Recovery Coach, Addiction Counselor: The Importance of Role Clarity and Role Integrity. (Monograph) Philadelphia, PA: Philadelphia Department of Behavioral Health. Blaszcynski & Nower, (2002).
33) www.YouTube.com, BioSound posting

Charts 1a and 1b

Percent of Change: Data represents the mean of psychological, psychological and emotional symptoms comparing the pre-test (pre-sessions) with the post-test (post-session) scores. Each percent of change was calculated to its nearest tenth. There were no increases or no change. There was a change from an original 8 symptoms to 10 symptoms, with cravings and impulsive later added to some programs.

Symptom	Percent of Increase/Decrease in Symptomatology	Increase	Decrease
Stress		**0**	**57%**
Racing Thoughts		**0**	**53%**
Anger		**0**	**48%**
Depressed		**0**	**47%**
Fearful		**0**	**47%**
Body Aches		**0**	**54%**
Muscle Tension		**0**	**56%**
Headaches		**0**	**44%**
Cravings		**0**	**46%**
Impulsive		**0**	**52%**

1b



Red = Pre-test, Blue = Post-test

Chart Three

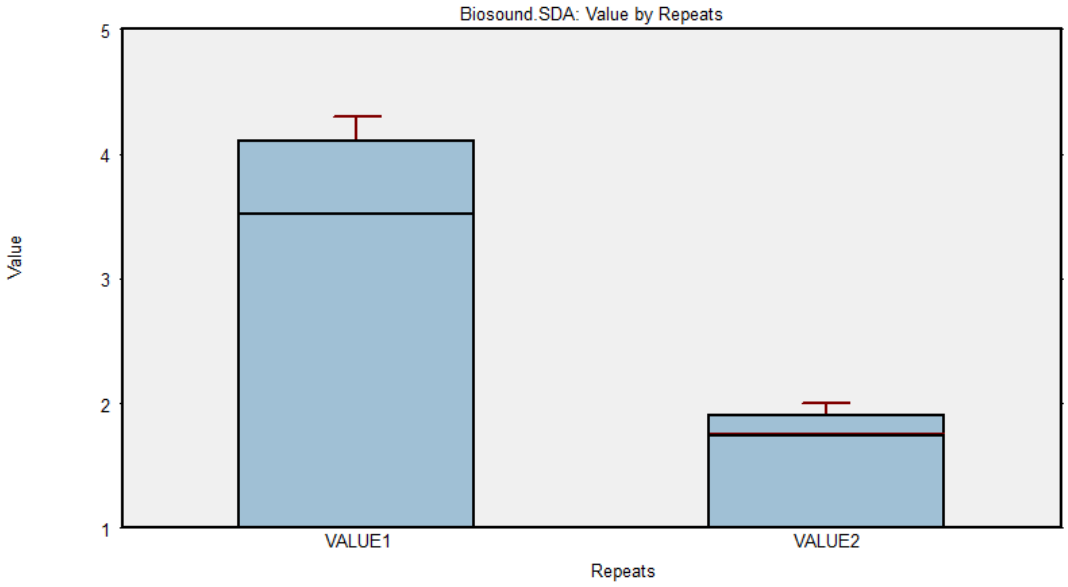


Chart Four

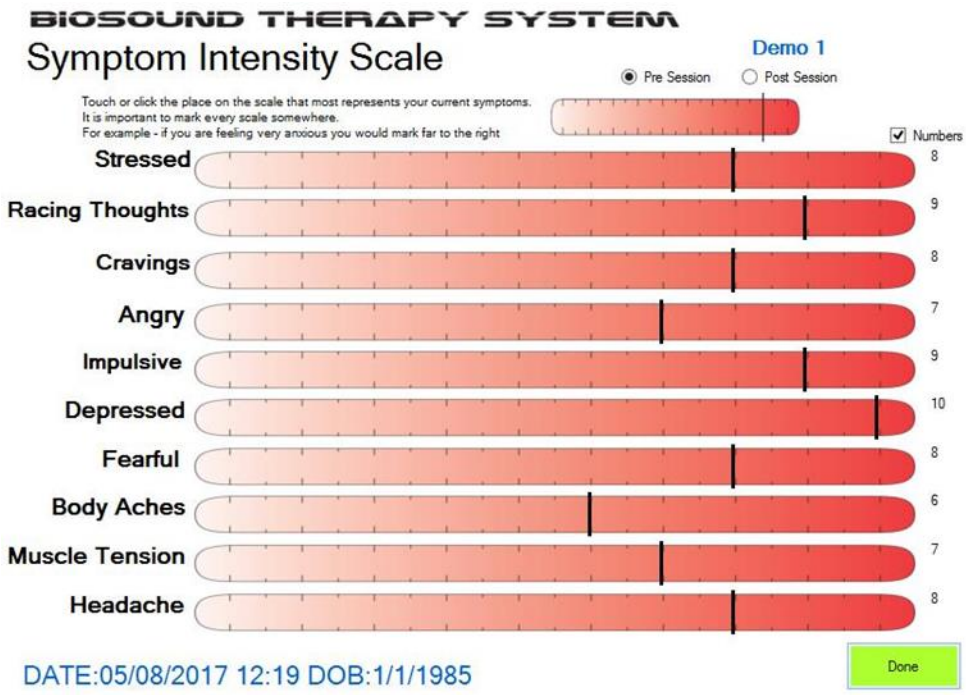
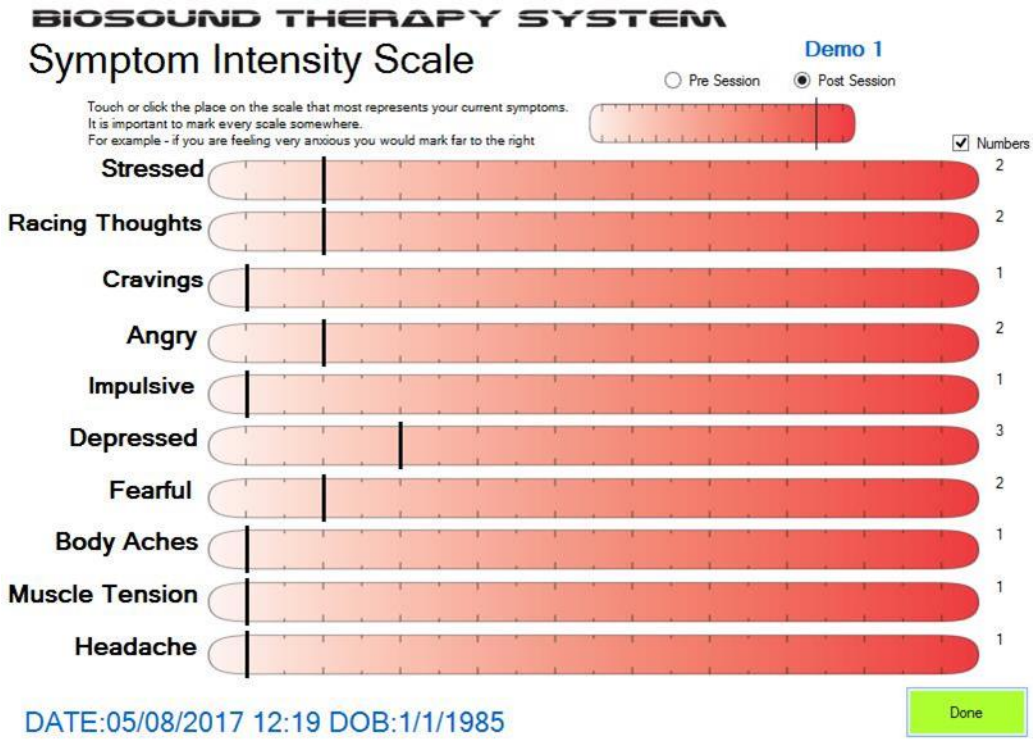

BIOSOUND THERAPY SYSTEM
Symptom Intensity Scale
Demo 1
Pre Session
Post Session
Touch or click the place on the scale that most represents your current symptoms.
It is important to mark every scale somewhere.
For example - if you are feeling very anxious you would mark far to the right
Numbers
Stressed 8
Racing Thoughts 9
Cravings 8
Angry 7
Impulsive 9
Depressed 10
Fearful 8
Body Aches 6
Muscle Tension 7
Headache 8
DATE:05/08/2017 12:19 DOB:1/1/1985
Done

Chart Five


BIOSOUND THERAPY SYSTEM
Symptom Intensity Scale
Demo 1
Pre Session
Post Session
Touch or click the place on the scale that most represents your current symptoms.
It is important to mark every scale somewhere.
For example - if you are feeling very anxious you would mark far to the right
Numbers
Stressed 2
Racing Thoughts 2
Cravings 1
Angry 2
Impulsive 1
Depressed 3
Fearful 2
Body Aches 1
Muscle Tension 1
Headache 1
DATE:05/08/2017 12:19 DOB:1/1/1985
Done

Addendum Four

Repeated Measures Analysis Summary for BioSound, Statistical Data Analysis

Repeated measures are VALUE 1 and VALUE 2 (1 = Pretest,2 = Posttest), i.e.., pre-sessions, post-sessions respectively.
Wilcoxon's Signed Rank Test Results

Number of negative signs = 0
Number of positive signs = 10
Number of samples with differences > 0 = 10

Binomial distribution results: p = .002 (Two-tailed)
Binomial distribution results: p = .001 (One-tailed)

Sum of the positive ranks = 55.
Sum of the negative ranks = 0.
Number of samples = 10

Using the normal approximation = -2.8031 p = .0051 (two-tailed)
(Mean = 27.5 s.d. = 9.811)

ANOVA Repeated Measures Analysis Summary for BioSound Statistical Data Analysis: Number of repeated measures is 2, Number of symptoms read is 10

Means and standard deviations for 2 repeated measures:

1)VALUE 1: mean = 3.52 s.d. = 0.5731 (Value 1= pre-session)
2)VALUE 2: mean = 1.74 s.d. = 0.18379 Value 2 = post-session)

Mean Difference = 1.78 s.d. (difference) = 0.41042

95% C.I. about Mean Difference is (1.48604, 2.07397)
Calculated t = 13.71487 with 9 D.F. p = < 0.001 (two-sided)

Addendum Five

Research on Evidence Based Medication and Addiction Recovery Cited in this Research. This recent research is cited here because it examines similar phenomena as was the phenomena examined in this present research using some similar assessment tools.

Evidence-based medicine (EBM) is an approach to medical practice intended to optimize decision-making by emphasizing the use of evidence from well-designed and well-conducted research. Evidence Based Decision-Making is a process for making decisions about a program, practice, or policy that is grounded in the best available research evidence and informed by experiential evidence from the field and relevant contextual evidence.

Identifying and ranking implicit leadership strategies to promote evidence-based practice implementation in addiction health services. Aarons, Gregory A., Guerrero, Erick G., Padwa, Howard, Fenwick, Karissa1, Harris, Lesley M.

Abstract

Despite a solid research base supporting evidence-based practices (EBPs) for addiction treatment such as contingency management and medication-assisted treatment, these services are rarely implemented and delivered in community-based addiction treatment programs in the USA. As a result, many clients do not benefit from the most current and efficacious treatments, resulting in reduced quality of care and compromised treatment outcomes. Previous research indicates that addiction program leaders play a key role in supporting EBP adoption and use. The present study expanded on this previous work to identify strategies that addiction treatment program leaders report using to implement new practices. We relied on a staged and iterative mixed-methods approach to achieve the following four goals: (a) collect data using focus groups and semi-structured interviews and conduct analyses to identify implicit managerial strategies for implementation, (b) use surveys to quantitatively rank strategy effectiveness, (c) determine how strategies fit with existing theories of organizational management and change, and (d) use a consensus group to corroborate and expand on the results of the previous three stages. Each goal corresponded to a methodological phase, which included data collection and analytic approaches to identify and evaluate leadership interventions that facilitate EBP implementation in community-based addiction treatment programs. Results: Findings show that the top-ranked strategies involved the recruitment and selection of staff members receptive to change, offering support and requesting feedback during the implementation process, and offering in vivo and hands-on training. Most strategies corresponded to emergent implementation leadership approaches that also utilize principles of transformational and transactional leadership styles. Leadership behaviors represented orientations such as being proactive to respond to implementation needs, supportive to assist staff members during the uptake of new practices, knowledgeable to properly guide the implementation process, and perseverant to address ongoing barriers that are likely to stall implementation efforts. Conclusions: These findings emphasize how leadership approaches are leveraged to facilitate the implementation and delivery of EBPs in publicly funded addiction treatment programs. Findings have implications for the content and structure of leadership interventions needed in community-based addiction treatment programs and the development of leadership interventions in these and other service settings.

Reference: Implementation Science. 5/14/2016, Vol. 11, p1-13. 13p

of the copy. Users should refer to the original published version of the material for the full abstract. (Copyright applies to all Abstracts.)

Author Affiliations

1School of Social Work, University of Southern California, 655 West 34th Street, Los Angeles CA 90089, USA
2University of California, Los Angeles, Integrated Substance Abuse Programs, 11075 Santa Monica Boulevard, Suite 200, Los Angeles CA, 90025, USA
3Kent School of Social Work, University of Louisville, Louisville KY 40292, USA
4Department of Psychiatry, University of California, 9500 Gilman Dr. (0812), San Diego, La Jolla CA 92093-0812, USA