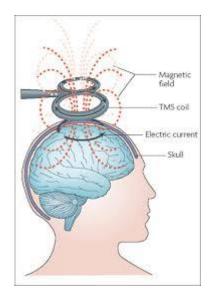


Introduction to Magnetic Stimulation VCAT+TMS

The Visual Attention Concentration Technology Plus Transcranial Magnetic Stimulation (VCAT+TMS) is making progress as a new noninvasive and non-electric induced method of regional brain's neural network stimulator to improve symptoms of co-occurring psychological/Psychiatric disorders such as depression, anxiety, Attention Deficit Hyper Activity Disorder (ADHD), and Substance and or Alcohol Addiction. The VCAT+TMS is identical to the active and FDA cleared Fisher Wallace Stimulator, FDA approved and or cleared TMS, Repeated TMS (rTMS), and the Transcranial Direct Current Stimulation (tDCS) devices, except VCAT+TMS does not induce an electrical current.

What is TMS?

There is a strong relationship between magnetic field and brain. A technology known as transcranial magnetic stimulation (TMS) can therapeutically alter activity in the brain by creating a magnetic field that produces a mild electrical current in the targeted brain region. Small amounts of electricity are naturally generated by neuronal connections, so any new electrical input can change these connections. According to the recent studies magnetic brain stimulation therapies can play a role in treating certain mental disorders. Brain stimulation therapies involve activating or inhibiting the brain directly with electricity, which could be induced by Magnetic Field (MF) applied to the head. While magnet therapy is less frequently used than medication and psychotherapies, they hold promise for treating certain mental disorders that do not respond to other treatments. Based on the principle of electromagnetic induction and magnetic field theories TMS modulates the brain's electrical environment using magnetic fields, which pass through the scalp and skull unimpeded. These fields are produced by passing rapidly alternating electrical currents through a coil with a ferromagnetic core (ie, an electromagnet in lieu of a permanent magnet). The magnetic field strength produced by TMS varies from 1.5 to 3 T and is comparable to an MRI device, except that it focuses on a limited area of the cortex using a circular, conical, or helmet-like coil design.

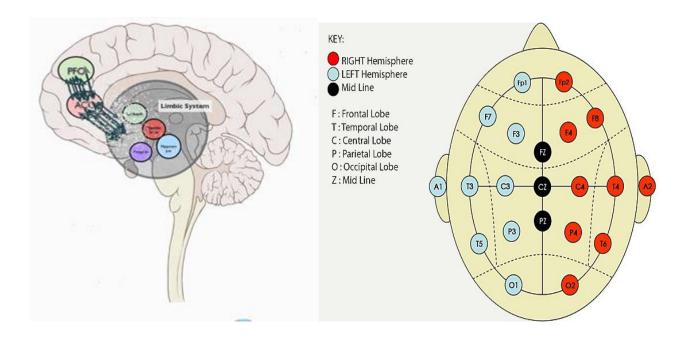


How VCAT+TMS work?

The TMS magnetic field stimulation is based on the laws of electromagnetic induction, where a current passing through a coil of wire generates a magnetic field perpendicular to the current direction in the coil. A rapid change of this magnetic field elicits in turn a transient electric field. This electric field affects the membrane potential of the nearby neurons, which may lead to depolarization and neuron discharging or interfere with the ongoing action potentials. Commercially available TMS stimulators offer the possibility to generate a peak of magnetic field up to 2.5 tesla with frequencies up to 30 Hz. A magnetic field of 1 to 1.5 tesla is required in order to be able to interact and depolarize neural networks of the targeted brain locations. The power of the stimulators and coils is measured in Tesla which is the International System of Units of <u>magnetic-field strength</u> or <u>magnetic-flux density</u>, commonly denoted as T, defined in 1960 in honor of the inventor of the Tesla Coil, Nikola Tesla. Modern devices develop 1.5 - 4 tesla (T) measured at the coil's surface with studies showing that cortical neurons are activated beneath the scalp to a depth of 1.5 - 2 cm).

VCAT+TMS use the same magnetic field theory and principles as the TMS. The VCAT+TMS consists of a 3 U-shaped (headband like) pieces of adjustable headsets which are embraced of a flat coil of copper wire in a closed circuit with attached of 4 polymeric coated neodymium magnets (2x1" and 2x1/2" 13500 to 15000 gauss) on each headset to generate a constant magnetic field of approximate of 1.5 tesla with a penetration up to 6 inches (2.36 cm) to depolarize and interact with neuron discharges at a cellular level reinforcing an expansion of reginal neural activities in prefrontal cortex, parietal cortex, and limbic system. These areas are the main areas affected by ADHD, addiction, mood and emotional disorders such as depression and anxiety. According the 10/20 international system the VCAT+TMS frontal part covers Fp1, Fp2, F7, F3, F2, F4, and F8; The central and parietal parts cover T3, C3, C2, C4, T4, T5, P3, P2, P4, and T6. It is assumed that this 10/20 international based locations on VCAT+TMS would strengthen the neural

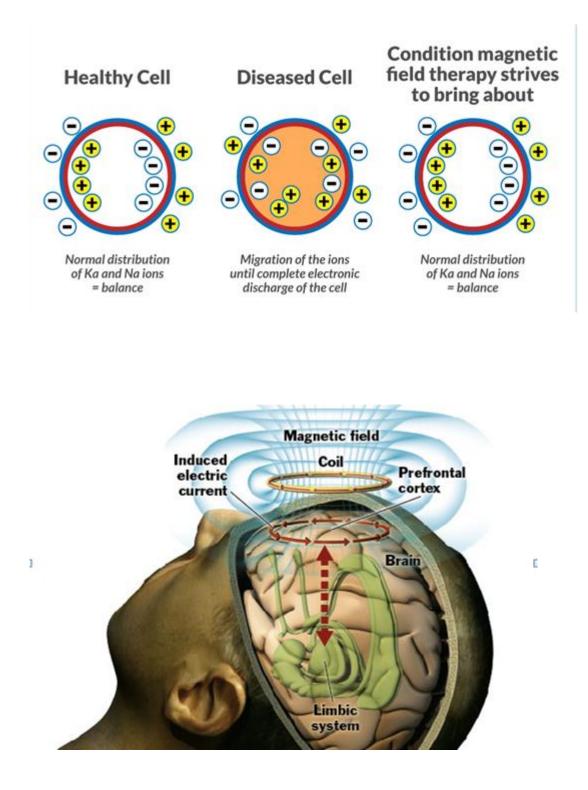
activities and neurotransmitters discharges generated in limbic system areas. The limbic system supports a variety of functions including emotion, behavior, motivation, and long-term memory.



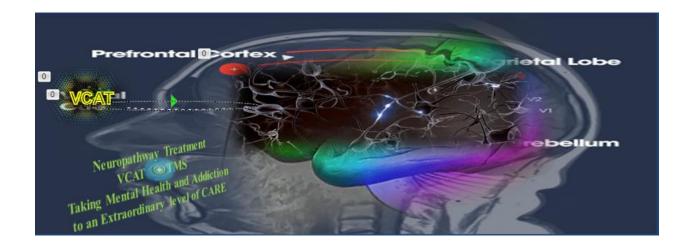
VCAT+TMS as an effective TMS Device

Transcranial magnetic stimulation, known as TMS, may be safe, effective, and noninvasive magnetic field stimulation for localized brains' neural network activation that has shown improvement in verity of psychological/psychiatric symptoms such as depression and anxiety as well as enhancement in cognitive functioning such as memory for individuals who are not responsive to medications and or psychotherapy. TMS creates a magnetic field to induce a small electric current in a specific part of the brain; the current comes from the magnetic field created by an electromagnetic coil that delivers pulses through the head. VCAT Neural Transcranial Magnetic Stimulator (VCAT+TMS) is a noninvasive and non-electric induced TMS device which is assumed to increase localized and regional neural activities, improving blood flow, and stimulating the brain to produce and balance neurotransmitters such as dopamine and serotonin in adults with ADHD and or substance and alcohol abuse. The VCAT+TMS main difference to common TMS and

other neuro stimulator devises is that VCAT+TMS is a non-electric induced neural stimulator. VCAT+TMS is wearable and portable which could also be used safely at home and or in a clinical setting, while patients remain awake and alert throughout the treatment. Furthermore, it is cost effective and affordable with no side effect.



In individuals with co-occurring psychological/Psychiatric disorders such as depression, Anxiety, ADHD, and or Substance and or Alcohol Addiction, an imbalance develops in the neural circuits that link the prefrontal and parietal cortex with the limbic system. A current of magnetic field coming from a magnetic coil above the head and the targeted areas of the brain seems to restore a normal balance.



Use of VCAT+TMS

The VCAT+TMS can be used at home for relieving symptoms of anxiety, depression, and cravings for alcohol and or substances. Used daily for 20 minutes and or as needed, the headset can be placed comfortably over the forehead (frontal lobe) and center over the top of the head (parietal lobe) ten minutes for each location. VCAT+TMS stimulate the brain to produce and balance dopamine, serotonin, and other neurotransmitters required for healthy mood and mental clarity. In the four weeks research conducted by Dr. Nader Siahdohoni with a six months follow up participants showed significant symptom reduction within the first two weeks of VCAT+TMS daily use and continued stabilizing emotionally, mentally, and cognitively.

TMS Research and Studies

References:

 O'Reardon, J. P., H. B. Solvason, et al. (2007). "Efficacy and Safety of Transcranial Magnetic Stimulation in the Acute Treatment of Major Depression: A Multisite Randomized Controlled Trial." Biol Psychiatry 62(11): 1208-1216.

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3. Demitrack MA, Thase ME. Clinical significance of transcranial magnetic stimulation (TMS) in the treatment of pharmacoresistant depression: synthesis of recent data. Psychopharm Bull. 2009, 42(2): 5-38.

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VCAT+TMS Study

The Visual Attention Concentration Technology Plus Transcranial Magnetic Stimulation (VCAT+TMS) is a non- invasive and non-electric induced Magnetic Neural Stimulator for enhancement of intertwined and co-occurring psychological/Psychiatric disorders such as depression, anxiety, ADHD, and or substance and or alcohol Addiction.

Abstract

Visual Concentration Attention Technology Plus Transcranial Magnetic Stimulation (Vcat+TMS) is making progress as a new noninvasive and non-electric induced method of regional brain stimulator to improve symptoms of co-occurring psychological/Psychiatric disorders such as depression, anxiety, Attention Deficit Hyper Activity Disorder (ADHD), and or Substance and or Alcohol Addiction. This multicenter clinical research of 4 weeks with a 6 months follow up results used a quantitative, open label randomized controlled study design in which subjects in the study participated voluntary in an in-home 5 days a week 20 minutes intervention of non- electric induced and non- invasive VCAT+TMS therapy. The paired of magnetic field principles of TMS with non-invasive neuropathway therapy (VCAT; Siahdohoni, 2011) has shown to significantly improve and or eliminate symptoms of ADHD, depression, anxiety, and the urge of using drugs and or alcohol in adults with a dual diagnosis of these co-occurring disorders with each other. The headset device (Vcat+TMS) was identical to the active and FDA cleared Fisher Wallace Stimulator, FDA approved and or cleared TMS, Repeated TMS (rTMS), and the Transcranial Direct Current Stimulation (tDCS) devices, except Vcat+TMS did not induce an external electrical current to the brain instate it empowered and expanded brain's naturally reinforced electromagnetic field stimulated by noninvasive VCAT and VCAT's systematic self-stimulatory (VCATSSS) methodology (Siahdohoni) to recuperate and balance the brain functioning system. The social change implications are the value of a nonpharmaceutical intervention for ADHD, depression, anxiety, and substance and alcohol addiction

particularly in terms of no drug side effects, reduced health care costs, and improved quality of life for those suffering from these co-occurring disorders, who are not responding to medications and or psychotherapy.

Introduction

The VCAT+TMS is a non- invasive and non-electric induced Magnetic Neural Stimulator (headset) developed and researched by Dr. Nader Siahdohoni (Siahdohoni, 2018). VCAT+TMS as a reginal neural network stimulator along with VCAT self- stimulatory brain exercising system (Siahdohoni, 2011) has shown enhancement in treating co-occurring psychological/Psychiatric disorders such as depression, anxiety, and ADHD with substance and or alcohol addiction. VCAT as a neuropathway therapy stimulates the brain through visual field to increase brain's naturally occurring neural networks' magnetic field deep at the cellular level while VCAT+TMS headset with its therapeutic magnetic supremacy synchronized and empowers VCAT driven cellular magnetic field to enhance neural activity, improving blood flow, and guiding the brain to discharge and balance neurotransmitters in areas of the brain controlling executive functioning and emotions.

Device/VCAT+TMS

VCAT+TMS headset- none electric and none invasive Transcranial Magnetic Stimulator Key Variables

Substance abuse and Addiction, ADHD, Anxiety and Depression

Objective

The purpose of this study was to examine the efficacy of VCAT+TMS for the treatment of intertwined and co-occurring psychological/Psychiatric disorders such as depression, Anxiety, and ADHD with Substance and or Alcohol Addiction.

Design

The proposed study is a quantitative open label within-subject pre- and posttest study design. This design will allow for gathering information of fundamental processes that are basis of clinical treatments as well as determination of the relationship between two factors, like the short and long term effectiveness of a noninvasive and nonelectric magnetic field induced by VCAT+TMS in improving of co-occurring symptoms of depression, anxiety, and ADHD with drug and alcohol abuse and whether addressing these symptoms would help adult population with drug and alcohol addiction continue to stay sober and eliminate such addictive behavior. This type of design will allow collecting and analyzing of numerical data in exploring relationship and/or interaction between variables for a comparison between and within different treatment groups as well as assessing changes in symptoms over time. The VCAT+TMS device was identical to the active and FDA approved TMS devices, except it did not conduct an electrical current.

Primary Effectiveness Endpoint

The primary effectiveness endpoint was the change from baseline in the post-treatment mean scores for VCAT+TMS (treatment group) week4 and week2 (pre/posttests, Table 2a) compared to the mean scores

of Healthy Control Group (HCG/Hpre/posttest) according to Goldberg Depression Scale (GDS) for depression, Hamilton Anxiety Scale (HAS) for anxiety, Wender Utah ADHD Rating Scale (WURS) for ADD/H, Michigan Alcohol Screening Test (MAST) for alcohol use, and the Drug Abuse Screening Test (DAST) for drug and substance use.

Secondary Outcome Measures

The secondary outcome measure was the change from last post-treatment mean scores of week4 compared to the six months follow up mean scores of week28 according to Goldberg Depression Scale (GDS) for depression, Hamilton Anxiety Scale (HAS) for anxiety, Wender Utah ADHD Rating Scale (WURS) for ADD/H, Michigan Alcohol Screening Test (MAST) for alcohol use, and the Drug Abuse Screening Test (DAST) for drug and substance use.

Inclusion Criteria

The control group was consisted with n=36 randomized healthy subjects (Healthy Control Group/HCG) with no current and or previous symptoms of ADHD, depression, anxiety and or dual diagnosis of psychiatric/psychological disorders with any kind of substance and or alcohol addiction. Participants in this group must not being on any psychiatric medication and or participated in any kind of psychological, psychiatric, TMS and or magnetic therapy of any kind. The VCAT+TMS group was enclosed with n=44 randomized voluntaries outpatients from our multicenter who were dual diagnosed of depression and anxiety with ADHD, substance and alcohol addiction (40% were primarily alcohol abusers, while the other 60% were single or polydrug abusers with the average number of drugs abused ranging from prescription drugs to

street drugs, including heroin, amphetamines, and cocaine). Participant's pool was consisted of mixed race with 47.5% Caucasians and 35% female. Diagnosis was verified using the Structured Clinical Interview (SCID-P) (First et al., 1995) based on the Diagnostic and Statistical Manual (DSM-IV-TR) (American Psychiatric Association, 1994, 2000). To be eligible to participate in the study's VCAT+TMS group, participants had to be carrying a dual diagnosis of depression, anxiety, ADHD, and substance and or alcohol abuse at the time of their recruitment.

Interview was conducted by Dr. Nader Siahdohoni, a licensed clinical psychologist

Exclusion Criteria

Patients were excluded from the study if they had a history of schizophrenia, schizoaffective disorder, other (non-mood disorder) psychosis, depression secondary to a medical condition, psychotic features in this or previous episodes, amnestic disorder, dementia, delirium, mental retardation, an active suicidal plan, or history of suicide attempt within the past 12 months, as determined by the Columbia Suicide Severity Rating Scale (CSSRS) (Posner et al., 2011). Additional exclusion criteria were significant current history of autoimmune or endocrine disorder affecting the brain, unstable cardiac disease, uncontrolled hypertension, sleep apnea, history of skull fracture, cochlear and or metallic implants, seizures, epilepsy, pregnancy, or having a pacemaker.

Device application and Protocol Summary

VCAT+TMS devices were assigned to randomized participants after the 8 hours VCAT-orientation. Subjects had 4 weeks of 5 days a week (a total of 20 in home treatments for 20 minutes each). Outcome measures were done at the end of week 2, 4 and week28 (six months follow up).

Study Blinding

An open-label study in which both the researchers and participants know which treatment is being administered.

Outcome Measures

Prior to start the research participants in both groups were assess for depression with Goldberg Depression Scale (GDS), anxiety with Hamilton Anxiety Scale (HAS), ADHD with Wender Utah ADHD Rating Scale (WURS), Alcohol abuse with Michigan Alcohol Screening Test (MAST), and the Drug Abuse Screening Test (DAST) for a pretest baseline. The established reliability and validity for each assessment tool includes in the following literature:

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- Maier, W., Buller, R., Philipp, M.. & Heuser, I. (1988). The Hamilton Anxiety Scale: Reliability, Validity and Sensitivity to Change in Anxiety and Depressive Disorders. 14(1) J Affect Disord 61-68.
- Selzer, M.L. (1971). The Michigan Alcoholism Screening Test (MAST): The quest for a new diagnostic instrument. American Journal of Psychiatry, 127, 1653-1658.
- Ward, M. F., Wender, P. H., & Reimherr, F. W. (1993). The Wender Utah Rating Scale: An aid in the retrospective diagnosis of childhood Attention Deficit Hyperactivity Disorder. Am J Psychiatry; 150: 885-890.

Pre-Specified Criteria for Success

Pre-specified criteria for success was set at \geq 50% improvement for anxiety, \geq 50% improvement for

depression, and \geq 50% improvement for ADHD, and \geq 50% improvement in sobriety for using drug and or

alcohol throughout the clinical trial.

Power Analysis and Sample Size

A power analysis was done and indicated that for two groups at least 80 subjects were needed for a sample t

test analysis, an effect size of d=0.50 and p=0.05.

Results

Subjects

Of the 88 subjects who enrolled in the study, 80 subjects completed the study. There were 44 subjects in the active VCAT+TMS group, 36 subjects in the HCG (Healthy Controlled group).

Baseline Measurements: Group Equivalence

There was no statistically significant difference at baseline between active VCAT+TMS and HCG on subject characteristics of age and gender (Table1). However, there was a significant difference at the pre baseline tests of anxiety, depression, ADHD, and drug and alcohol use.

Data Analysis

Subjects completed mid-point testing at the end of week2 and endpoint testing at the week4. The six months follow up was conducted at the week28. Data were analyzed using in depended sample t test. Cohen's d was used to determine effect sizes (Cohen, 1998).

The review of the participants' mean scores for VCAT+TMS week4 and week2 (pre/posttests, Table 2a) compared to the mean scores of HCG (Hpre/posttest) indicate a significant improvement in depression (M =11.35, SD=6.28), Anxiety (M=10.46, SD=6.89), ADD/H (M=42.65, SD=9.78), Alcohol (M=1.18, SD=0.63) and substance use (M=5.91, SD= 2.91) at the end of week4 of VCAT+TMS Therapy.

The paired Samples Test (Table 2b) measures is used to analyze pair wise comparisons of the means for posttest week4 and posttest week2 on Pair1week4GDS, Pair2week4HAS, Pair3week4WURS, Pair4week4MAST, and Pair5week4DAST for the long term affect with four weeks of VCAT+TMS therapy. The analysis indicated the differences between means were significant for all dependent variables derived from the posttests of week 4 compared to all posttest of week 2 assessments. Furthermore, all the posttest scores were positively correlated with participants' level of perceived performance on the tests after using VCAT+TMS along with its VCAT self-stimulatory brain exercising.

Furthermore, the Paired Samples Test (Table2b) compares all five paired groups. It calculates the difference between each set of pairs, and analyzes that list of differences based on the assumption that the differences in the entire population follow a Gaussian distribution. If the significance value is less than .05 (alpha), there is a significant difference; and if the significance value is greater than. 05, there is no significant difference between the pairs. In addition, the measure of effect (Eta2 = t2/(t2 + DF)) will show what percentage of the variability in the DV (test scores) is actually due to the IV (VCAT+TMS device).

Pair1 was statistically significant, t(43) = 32.044, p < .05, with M = -11.44 and SD = -2.37, and Eta2 result (0.93) of 93%, Pair2 was statistically significant, t(43) = 32.044, p < .05, with M = -11.44 and SD = -2.37, and Eta2 result (0.96) of 96%, pair3 was statistically significant, t(43) = 31.372, p < .05, with M = -13.71 and SD = -0.29, and Eta2 result (0.96) of 96%, Pair4 was statistically significant, t(43) = 17.777, p < .05, with M = -0.321 and SD = -0.12, and Eta2 result (0.88) of 88%, and Pair5 was statistically significant, t(43) = 117.333, p < .05, with M = -1.76 and SD = -0.1, and Eta2 result (0.99) of 99%, which means that there is a significant difference between all the posttest week4 compared to the posttest week2 scores. These variabilities in the scores confirm all participants gained improvement due to the use of VCAT+TMS device along with VCAT self-stimulatory brain exercising with the effect of 93% for depression, anxiety 96%, ADD/H with 96%, alcohol and substance use with an effect in sobriety of 88% and 99%, which is a large effect.

Additional follow up Paired Samples Test (Table3a) compares all five paired groups at the end of week28. It calculates the difference between each set of pairs, and analyzes that list of differences based on the assumption that the differences in the entire population follow a Gaussian distribution. If the significance

value is less than .05 (alpha), there is a significant difference; and if the significance value is greater than. 05, there is no significant difference between the pairs.

The six months follow up assessments compared to the week four posttests (Table3b) verifies that participants continued to stay sober with improved of their co-occurring symptoms of depression (Pair1FinaltestGDS was statistically significant, t(43) = 13.407, p < .05, with M = -1.81 and SD = -0.9), Anxiety (Pair2FinaltestHAS was statistically significant, t(43) = 2.475, p < .05, with M = -0.25 and SD = -0.67), ADD/H (Pair3FinaltestWURS was statistically significant, t(43) = 12.074, p < .05, with M = -3.09 and SD = -1.7), Alcohol use (Pair4FinaltestMAST was statistically significant, t(43) = 5.666, p < .05, with M = -0.17 and SD = -0.03), and substance use (Pair5FinaltestDAST was statistically significant, t(43) = 21.627, p < .05, with M = -0.93 and SD = -0.29).

CONCLUSIONS

VCAT+TMS significantly improved the co-occurring symptoms of anxiety, depression, ADHD and substance use. Subjects reported to be able to stay sober after the follow up report with no adverse events during the study.

Tables

Table 1Demographic Characteristics

Sex

		Male	Female	Total
Ethnicity	Caucasian	25	13	38
·	African American	19	11	30
	Hispanic	8	3	11
	Other	0	1	1
	Total	52	28	80

	Male	Fema	.le	Total	
HCG (Healthy Control Group)	26	10		36	
VCAT+TMS (TR/Investigative)		24	20		44
Total	50	30		80	

Table 2a

Independent Samples t test's scores on Objective Measures and Compares Mean scores for Dependent and Independent Variables Objective Week2 Week4

Objective	Week2	Week		
Participants	VCAT+TMS	Hpre/posttest	VCAT+TMS	Hpre/posttest
Measures	Mean/SD	Mean/SD	Mean/SD	Mean SD
PretestGDS	40.87/17.99	7.83/1.18	15.23/7.38	7.83/1.18
PosttestGDS	15.23/7.38	7.83/1.18	11.35/6.28	7.83/1.18
Pretest HAS	50.43/10.07	9.23/1.69	21.90/9.26	9.23/1.69
PosttestHAS	21.90/9.26	9.23/1.69	10.46/6.89	9.23/1.69
Pretest WURS	82.36/14.88	12.31/4.54	56.36/10.07	12.31/4.54
PosttestWURS	56362/10.07	12.31/4.54	42.65/9.78	12.31/4.54
Pretest MAST	3.78/1.09	1.06/0.41	1.50/0.75	1.06/0.41
PosttestMAST	1.50/0.75	1.06/0.41	1.18/0.63	1.06/0.41
PretestDast	22.80/7.27	0.88/0.38	7.67/3.01	0.88/0.38
PosttestDAST	7.67/3.01	0.88/0.38	5.91/2.91	0.88/0.38

Table 2b

Paired Samples Test measures for comparisons of the means (week4posttest-VCAT+TMS to week2posttest-VCAT+TMS) for long term affect Paired Differences

Measures	Mean(dif) SD(dif)	t	df	Sig. (2-tailed) 95% Confidence Interval
Pair1week4GDS	-3.88 -101	23.515	43	0.009 -3.239 to 4.520
Pair2week4HAS	-11.44 -2.37	32.044	43	0.0067.3355 to 15.523
Pair3week4WURS	-13.71 -0.29	31.372	43	0.001 -0.77 to 1.970
Pair4week4MAST	-0.321 - 0.12	17.777	43	0.033 -0.314 to 0.325
Pair5week4DAST	-1.76 -0.1	117.333	43	0.007 -1.733 to 1.786

Table 3a

Independent Samples t test's scores on Objective Measures and Compares Mean scores for Dependent and Independent Variables with follow up (Finaltest) scores after six months (week 28) compared to Week4 posttest scores

Objective	Week28		Week4			
Participants	VCAT+TMS	Hpre/posttest	VCAT+TMS	Hpre/posttest		
Measures	Mean/SD	Mean/SD	Mean/SD	Mean SD		
Pair1FinaltestGDS	9.54/5.38	7.83/1.18	11.35/6.28	7.83/1.18		
Pair2FinaltestHAS	10.21/6.22	9.23/1.69	10.46/6.89	9.23/1.69		
Pair3FinaltestWURS	39.09/8.08	12.31/4.54	42.65/9.78	12.31/4.54		
Pair4FinaltestMAST	1.01/0.60	1.06/0.41	1.18/0.63	1.06/0.41		
Pair5FinaltestDAST	4.98/2.62	0.88/0.38	5.91/2.91	0.88/0.38		

Table 3b

Paired Samples Test measures for comparisons of the means (week28 and week4) for continues improvement after six months follow up affect Paired Differences

Measures	Mean	SD	t	df	Sig. (2-tailed)	95% Confidence Interval
Pair1FialtestGDS	-1.81	-0.9	13.407	43	0.037	-1.565 to 2.054
Pair2FinaltestHAS	-0.25	-0.67	2.475	43	0.038	-0.224 to 0.275
Pair3FinaltestWURS	-3.09	-1.7	12.074	43	0.001	-2.299 to 3.881
Pair4FinaltestMAST	-0.17	- 0.03	5.666	43	0.035	-0.0219 to 0.023
Pair5FinaltestDAST	-0.93	-0.29	21.627	43	0.046	-0.889 to 0.969