Dissertation Title

John Doe

John Doe University

A Clinical Research Project presented to the faculty of John Doe University in partial fulfillment of the requirements for the degree of Doctor of Psychology in Clinical Psychology.

July, 2013

Abstract

VIVITROL® is the only first once a month extended-release injectable medication for treating alcohol dependence. It was approved by F.D.A in april of 2006. VIVITROL® targets psychosocial and physical drivers of chronic, unhealthy drinking and is effectively adjuncts to the treatment of alcohol dependence. However, adherence to substance-abuse medication is the major concern, because the high rates of nonadherence limits the benefits that could be realized from this type of medication-assisted treatment. My study was an adjunct to larger study, with UCLA Integrated Substance Abuse Programs; and the Substance Abuse Prevention and Control office (SAPC) Tarzana Treatment Centers Inc. been asked by UCLA and SAPC to investigate if VIVITROL® can be used to help to improve the treatments offered of Los Angeles County programs. The larger study, with UCLA and SAPC aims to tracking clients who have accept VIVITROL® treatment, in an effort to identify: ways it could be used more frequently for clinical practice. A goal of this specific added on study was to identify characteristics of the patients who more likely to denied VIVITROL® treatment, in order to identify the themes and the barriers to their treatment that also might inform future recommendations on how addressing these barriers.

Table of Contents

Abstract .... **ii**

Table of Contents .... **iii**

Chapter 1: Introduction **5**

Background of the Problem **5**

Statement of the Problem .... Error! Bookmark not defined.

Chapter 2: Literature Review .... Error! Bookmark not defined.

Urge to Drink .... Error! Bookmark not defined.

Personality Traits and Alcohol .... Error! Bookmark not defined.

Alcohol Dependence and Psychosocial Interventions . Error! Bookmark not defined.

VIVITROL® and Psychosocial Interventions .... Error! Bookmark not defined.

Chapter 3: Methods .... Error! Bookmark not defined.

Participants .... Error! Bookmark not defined.

Procedure .... Error! Bookmark not defined.

Measures .... Error! Bookmark not defined.

Chapter 4: Results .... Error! Bookmark not defined.

Hypothesis Testing .... Error! Bookmark not defined.

Post Hoc Analysis Results **6**

Chapter 5: Discussion .... Error! Bookmark not defined.

Clinical Implications .... Error! Bookmark not defined.

Limitations .... Error! Bookmark not defined.

Future Recommendations .... Error! Bookmark not defined.

References **9**

Appendix: Informed Consent Form .... Error! Bookmark not defined.

Chapter 1: Introduction

Alcohol dependence is known as neurobiological disease and the third leading cause of depression and of death in the United States (Krishnan-Sarin, O'Malley, & Krystal, 2008). According to the Substance Abuse & Mental Health Services Administration (2006), about 19 million adults (7.7%) in the United States abused or dependent on alcohol in just 2005 alone. Only 1.6 million people reports receiving treatment for alcohol dependence, and even fewer receive medication-assisted treatment (Substance Abuse and Mental Health Services Administration, 2006). Interest of alcohol treatment continues to growing, which is due to alcohol-dependence persisting as a chronic medical disease which most typically entails frequently relapses and bad adherence to treatment. In order to, address the major problems associating with relapse and poor adhreence, research is increasing surrounding use of pharmacotherapy or medication-assisted treatment in alcohol dependence (Swift 2007).

<u>Background of the Problem</u>

The primary interventions to be for addressing alcohol dependence are mainly psychosocial, or also known as non-medication-assisted treatments. These include: substance abuse counseling; spiritually based approaches, like as Alcoholics Anonymous (Cutler & Fishbain, 2005; Williams, 2005); and more recently, motivational interviewing (Lundahl & Burke, 2009). Unfortunately, a big number of patient fail to complete psychosocial treatment that is because of thier relapse or poor adherence (Swift, 1999), and evidences suggests psychosocial interventions used by alone aren't effective to everyone (Kenna, McGeary, Swift 2004).

Post Hoc Analysis Results

Since the hypothesises were not supported, post hoc analyses were run involving Pearson correlations among all variables for determine whether if there were any significant relationship. When post hoc analysis was conducted, some significant relationships were observed for all 3 hypotheses.

The results in Table 1 illustrating the significant correlations between baseline Urge to Drink score, and Urge to Drink score in the second and 3rd months for Hypothesis 1. Baseline Urge to Drink score and Urge to Drink score in the 2nd month as significantly correlated at $r = .754$, $p < .01$. As the baseline, Urge to Drink score increased, so did Urge to Drink score in the second month. Baseline Urge to Drink Score and Urge to Drink Score in 3rd month were as well significant correlated at $r =.617$, $p < .05$. And also, the Urge to Drink score in the second month and Urge to Drink score in the third month were significantly correlated at $r = .942$, $p < .01$. As the Urge to Drink score increased in the second months, Urge to Drink increased in third month. Additionally, there was to be found significant correlations between negative affect and Urge to Drink scores in the second month ($r = .537$, $p < .05$) and in the third month ($r = .548$, $p < .05$).

Table 1: *Significant Correlations of Participants' UTD Baseline* *2nd month* *and 3rd Month Scores*

	Time2	Time3
Baseline	.754**	.617*
Pearson	.002	.019
Correlation	14	14

Sig. (2-tailed) N				
Negaffect	.537*	.548*		
Pearson	.048	.043		
Correlation	14	14		
Sig. (2-tailed)				
N				

Note. *Correlation is significant at the 0.05 level (2-tailed). ** Correlation is significant at the 0.01 level (2-tailed)

The results in Table 2 illustrate significant correlations found between the personality characteristics of the negative affect and acting out, negative affect and hostile control, and of the health problems and suicidal thinking for Hypothesis 2. Negative Affect and Acting Out personality characteristics were significantly correlated at $r = .675$, $p < .01$. As negative affect increased so did acting out personality traits. Negative Affect and Hostile Control also significantly correlated at $r = .573$, $p < .01$. As negative affect increased so did hostile control personality traits. Health problems and Suicidal thinking were also significantly correlated at $r = .599$, $p < .01$. As health problems went up so did suicidal thinking. See the Table 2.

Table 2

Significant Correlations of PAS scores

	Actingout	Hostile Control	Suicidal Thinking

Negaffect	Pearson Correlation	.675**	.573*	
	Sig. (2-tailed)	.008	.032	
	N	14	14	
Healthprob	Pearson Correlation			.599*
	Sig. (2-tailed)			.024
	N			14

Note. *Correlation is significant at the 0.05 level (2-tailed). ** Correlation is significant at the 0.01 level (2-tailed)

References

Alkermes. (2013). *VIVITROL* [Full Prescribing Information]. Waltham, MA: Author.

American Psychiatric Association. (2000). *Diagnostic and statistical manual of mental disorders* (4th ed., text rev.). Washington, DC: Author.

Anton, R. (2008). Understanding alcohol dependence, the brain, and VIVITROL®. New England Journal of Medicine*, 359*, 715-721.

Anton, R., Moak, D, Latham, P. (1996). The Obsessive Compulsive Drinking Scale: A new method of assessing outcome in alcoholism treatment studies. Archives of General Psychiatry, 5*3*(3), 225-231.

Anton, R., O'Malley, S., Ciraulo, D., Cisler, R., Couper, D., Donovan, D., . . . Zweben, A. (2006). Combined pharmacotherapies and behavioral interventions for alcohol dependence, the COMBINE study: A randomized controlled trial. *Journal of the American Medical Association,* 295 (17) , 2003-2017.

Armor, D., Polich, J. (1982. Measurement of alcohol consumption. In E.M. Pattison, & E. Kaufman (Eds.), *Encyclopedic handbook of alcoholism* (pp 72-80). New York, NY: Gardner Press.

Bottlender, M., and Soyka, M. (2005) Outpatient alcoholism treatment: Predictors of outcome after 3 years. Drug and Alcohol Dependence*, 80*(1), 83-89.

Cannon, D., Keefe, C., & Clark, L. (1997) Persistence predicts latency to relapse following inpatient treatment for alcohol dependence. *Addictive Behaviors, 22*, 535-543.