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TRENDS IN SUBSTANCE ABUSE TREATMENT, PART I

In this issue, which is the first part of a two-part exploration of the area of substance abuse treatment throughout the world, subject matter experts will examine the evolution of and trends in this ever-changing field. Substance abuse, as a health, economic, and societal concern, is a serious challenge on multiple levels. Substance abuse treatment, as a necessary outcome, is a complicated issue that is shrouded in controversy. However, there is no doubt that treatment is of vital importance to the individual and society in general. Therefore, this edition of the Journal will focus on the issues related to this topic, and on the various substance abuse treatment modalities and approaches used around the world.

The issue of medical marijuana use in patients enrolled in substance abuse treatment is examined in an article that looks at the prevalence of its use and how this use relates to treatment. The author reports on a study conducted in Colorado, a state where medical marijuana is legal

Also included in this issue, is an examination of the use of exercise as a treatment for the abuse of nicotine, alcohol, and other substances, suggesting that exercise may be a beneficial treatment for substance abuse.

There are two commentary pieces included in this issue. In the first, the author discusses how Communication Skills Training (CST) enhances substance abuse treatment programs. The San Patrignano therapeutic community in Italy, from the perspective of a drug-free approach to treatment, is the subject of the 2nd commentary piece.

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Edited by Eric A. Voth, MD, FACP and David A. Gross, MD, DFAPA, our intended readership includes clinicians, clinical researchers, policymakers, prevention specialists, and the interested public.



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Perceptions and Use of Medical Marijuana in an Urban Substance Treatment Program

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Abstract

Background: As of October 31, 2011, in the state of Colorado, 88,872 patients were registered with the state as eligible to receive medical marijuana. In Colorado, the use of marijuana in patients enrolled in substance abuse treatment is not well understood.

Methods: 141 participants in a substance treatment program completed an anonymous survey to evaluate use, and beliefs regarding medical marijuana. Using Fisher's Exact Tests, participants who reported having or planning to obtain a medical marijuana registration were compared to marijuana users without medical marijuana registrations with regard to frequency of marijuana use for non-medical reasons. Use of marijuana for non-medical reasons was reported by participants as use "to get high".

Results: 141 surveys were completed. 128 (91%) of respondents had a history of marijuana use. Of the 38 subjects who had or were planning on obtaining a medical marijuana registration, 3 (9%) indicated

they had used marijuana only for medical reasons, 28 (74%) had used marijuana both for medical reasons and for non-medical reasons, and 7 (18%) had used marijuana only for non-medical reasons. The frequency of marijuana use for non-medical reasons in the past year, and current use of marijuana for non-medical reasons, once a week or more in the last year, was significantly greater among subjects with a medical marijuana registration compared to subjects without a registration: 51% vs. 76% (p <0.048), 22% vs. 53% (p=0.014) respectively. Among other findings, only 33% believed marijuana use could cause addiction. 13% believed its use could cause psychosis, and a number of patients had no other treatment, other than marijuana, for the medical condition for which they were being treated.

Conclusions: The use of marijuana for non-medical reasons is more common among patients admitted to substance abuse treatment who are registered medical marijuana users, when compared to those who are not registered medical marijuana users. In our program, an urban substance abuse treatment center in Colorado, patient's perceptions of the potential risks of marijuana are inconsistent and generally not compatible with the known risks.

Introduction

The use of medical marijuana became legal in the state of Colorado in 2001. As of October 31, 2011, 88,872 patients were registered with the state as patients eligible to receive medical marijuana (Colorado Department of Public Health and the Environment, 2011). Despite this, there is little information regarding the characteristics of medical marijuana patients in substance treatment. We found one published study that evaluated the outcomes of 18 adult medical marijuana patients enrolled in substance treatment. Outcomes were measured by the California Outcomes Measurement System; results were available for only 8 outpatient treatment completers. Between medical marijuana and non-medical marijuana users, there were no statistically significant differences in substance abuse outcomes or social outcomes, such as: reduction in use of primary drug of choice, treatment completion rates, employment status at discharge, and criminal justice involvement in the last 30 days. Marijuana was listed as the primary or secondary drug for which treatment was being sought in the medical marijuana patients evaluated. The study was limited by its small sample size (Swartz 2010).

There is concern that medical marijuana may be used for non-medical reasons or result in marijuana dependence and addiction (American Society of Addiction Medicine, 2010). We found a study which showed that an overwhelming majority (87.9%) of 3038 applicants for a medical marijuana registration had tried marijuana before the age of 19, usually in a social setting (O'Connell and Bou-Matar, 2007). Based on the age and the setting, this indicates that first use of marijuana in these applicants was likely non-medical in nature: supporting the study's hypothesis that non-medical use of marijuana is common in patients seeking medical marijuana registration. This study also found that the use of illicit drugs in medical marijuana applicants was as high as 15.86% for male applicants having used heroin in the past, and 67.32 % of male applicants having used cocaine (O'Connell and Bou-Matar, 2007). This indicates that the population applying for medical marijuana registrations may have higher rates of substance abuse than the general population.

In Colorado, there is concern that recommendations by physicians for patients' use of marijuana for medical reasons, have not followed established principles of medical care (Nussbaum, Boyer, and Kondrad, 2011). There is no requirement that physicians evaluate patients for mental illness or addictive disorders, including marijuana dependence that could be adversely affected by the prescription of an addicting drug (Colorado Constitution 0-4-287 - ARTICLE XVIII). Physicians do not have to document the failure of other treatments before recommending marijuana (Colorado Constitution 0-4-287 - ARTICLE XVIII). Data generated by the Colorado Department of Public Health and Environment through January 31, 2011, showed that a small number of physicians recommend medical marijuana for the majority of registered patients. 15 physicians had recommended marijuana for 49% of patients with medical marijuana registrations (Nussbaum, Boyer, and Kondrad, 2011). This indicates that medical marijuana users may not be receiving adequate evaluation and treatment for the condition for which medical marijuana is being used (Nussbaum, Boyer, and Kondrad, 2011).

This study attempts to address several questions with regard to patients admitted to an urban substance abuse treatment center in Colorado. How do these patients perceive the use of medical marijuana? Among the patients who are registered medical marijuana users, what type of evaluation and treatment have they had for the underlying medical condition? Are patients who are registered medical marijuana users more likely to be currently using marijuana for non-medical reasons, when compared to patients with a history of marijuana use who are not registered medical marijuana users? The value to answering these questions is to improve substance abuse treatment for patients in states where medical marijuana is available. For instance, if patients with medical marijuana registrations are using marijuana for non-medical reasons, this may indicate the presence of a marijuana use disorder that should be addressed during the course of their substance abuse treatment. Further, if patients believe that medical marijuana can help treat addiction, its use may lead to negative treatment outcomes. Therefore, the study has the following aims:

- (1) To conduct a preliminary investigation into the prevalence of medical marijuana use in patients enrolled in substance abuse treatment.
- (2) To conduct a preliminary investigation into the nature of the evaluation and treatment that medical marijuana users have received for the medical condition for which they are using marijuana, and assess what conditions patients believe marijuana can help treat and what adverse effects marijuana may have.
- (3) To explore the hypothesis that patients with medical marijuana registrations or those planning on getting medical marijuana registrations were more likely to have a history of or to be presently using marijuana for non-medical reasons, when compared with patients without medical marijuana registrations.

Methods

Participants

Patients enrolled in outpatient substance treatment at an urban, safety-net hospital in Denver, Colorado, were asked if they would fill out a survey regarding medical marijuana use. They were required to meet the following criteria:

- 1) enrollment in the substance treatment program where the study took place, and
- 2) willingness to fill out the survey.

The exclusion criterion was an inability to read and complete the English-language survey.

Measures

The medical marijuana survey was a self-report, pen and paper questionnaire created for the study. Use of marijuana for non-medical reasons was assessed by asking patients whether or not they had used marijuana for medical reasons, or to get high. The survey included questions regarding participant's age, whether marijuana was used for medical reasons, to get high, or both, and the frequency of past and present marijuana use. The questionnaire included questions regarding whether or not participants had or were planning on obtaining a medical marijuana registration, the reasons for medical marijuana use, and the nature of evaluation and treatment received. Perceptions regarding the potential risks and benefits of marijuana were assessed. There were also questions about changes in use and availability of marijuana since medical marijuana became legal in the state. The exact instrument is available on request. The use of marijuana to get high once a week or greater was used to compare groups. This cutoff was chosen to be consistent with other instruments (Adamson and Sellman, 2003). Demographic information for patients who were admitted to the treatment program during the time period of the study was obtained by self report, as part of the standard admission process.

Procedures

Approval was obtained from the Colorado Multiple Institutional Review Board prior to beginning the study. Participants were asked by their counselors if they would like to participate in the study; they received a verbal explanation of the study and they gave verbal consent to be involved. There was no reimbursement for participants. All participants completed the questionnaire while they were enrolled in the treatment program. The survey was anonymous. It was returned by the participant in a sealed envelope. Subjects were informed that participation or non-participation would not affect their treatment.

Statistical Analysis

For aim 1 and 2, descriptive statistics were used to evaluate the participant's answers to survey questions. For aim 3, participants were separated into three groups: 1) those reporting having a medical marijuana registration, 2) those reporting having a medical marijuana registration and patients planning on obtaining a registration, and 3) those with a history of marijuana use but did not have and were not planning on obtaining a medical marijuana registration. Groups 1 and 2 were compared separately with group 3 with respect to the following variables: 1) having used marijuana to get high in the previous year, 2) having used marijuana once a week or more in the last year, and 3) having had a history of using marijuana once a week or more for any three month period in their life. In cases where the survey was not completely filled out, the study only included the available data. Fisher's Exact Tests were used to determine whether or not there was a significant difference between groups.

Results

Sample description

During the period of time the survey was handed out (6/1/10 to 12/31/10), 192 patients were admitted to treatment; 60% were male and 40% were female. Race was reported as follows: 58% Caucasian, 24% Hispanic, 14% black, 2% Native American, 1% Asian, and 1 % other. The primary drug of choice was reported as 55% alcohol, 20% heroin or other opioids, 10% cocaine, 8% methamphetamine, 7% marijuana, and 0.5% benzodiazepines. Of those admitted, 55% indicated having a secondary drug of choice; 15% of admissions described marijuana as the secondary drug of choice. Employment was reported as the following: 42% unemployed, 24% worked full time, 14% disabled, 13% worked part time, 3% students, 2% retired, and 2% other. Health status was reported as follows: 51% had a mental illness, 17% were HIV positive, and 3% were pregnant. Marital status was reported as the following: 62% single, 19% married, 18% separated/divorced, and 1% widowed. Referral sources were indicated as the following: 41% self-referred, 22% referred by criminal justice, 18% by another medical provider, 8% other substance treatment provider, 6% social/human services, 3% civil involuntary commitment, and 1% other.

141 surveys were completed. The average age of respondents was 37.4 years (SD=10.8, range 20-60). 128 (91%) of respondents had a lifetime history of marijuana use. Of those who indicated they used marijuana, 3 (2%) indicated they had used it for medical use only, 74 (58%) indicated they used it only for non-medical use, and 51 (40%) had used it for both medical use and non-medical use. The average age of first use of marijuana for non-medical use was 15.6 (SD=4.1, range 7-28); the average age for first experiencing the medical condition for which marijuana was used was 25.5 years (SD=8.9, range 12-51).

Survey responses

Table #1 reports participant responses to questions on whether or not they have or are planning on obtaining a medical marijuana registration: the safety of marijuana use in different groups, and questions regarding changes in use and availability of marijuana since medical marijuana became legal in the state.

Participants were asked if they felt marijuana was an effective treatment for a list of medical conditions. The percentage of participants answering yes were as follows: pain (60%), anxiety (57%), insomnia (50%), wasting due to HIV or cancer (48%), nausea (47%), depression (43%), glaucoma (35%), bipolar disorder (33%), other addictions (26%), ADHD (24%), multiple sclerosis (23%), psychosis (11%), other conditions (11%), and autism (6%).

Participants were asked if marijuana can cause any of the following adverse effects. The percentages of respondents answering yes were as follows: loss of motivation (48%), difficulty concentrating (44%), lung disease (43%), memory loss (42%), decreased performance at work or school (38%), weight gain (35%), addiction (33%), depression (30%), anxiety (29%), heart disease (22%), sexual problems (18%), psychosis (13%), trauma related to accidents (13%), bipolar disorder or mood swings (13%), infections (8%), loss of bone strength (7%), and other (1%).

Of the 17 subjects who had a medical marijuana registration, 2 (12%) indicated they had used marijuana only for medical use in their life, 14 (82%) had used marijuana both for medical use and non-medical use, and 1 (6%) subject had used marijuana only for non-medical use. Out of the 21

subjects planning on getting a medical marijuana registration, 1 (5%) had used only for medical use, 14 (67%) had used for both medical use and non-medical use, while 6 (28%) had used only for non-medical use.

Of the 16 subjects with a medical marijuana registration who used marijuana for medical reasons, 14 (88%) were diagnosed by a medical provider other than the physician recommending the medical marijuana registration; 13 (81%) had previous treatment, including non-marijuana prescription medication, over-the-counter medication, therapy, or surgery for the condition. Of the 15 respondents who planned on getting a medical marijuana registration and who used marijuana for medical reasons, 7 (47%) had the medical condition diagnosed by a medical provider, and 8 (53%) were treated for the medical condition with a non-marijuana treatment.

Table # 2 shows that non-medical use of marijuana was greater among subjects with a medical marijuana registration, when compared to subjects with a history of marijuana use who do not have and were not planning on obtaining a medical marijuana registration. The difference was statistically significant on two measures: any non-medical use of marijuana in the last year, and non-medical use of marijuana once a week or more in the last year. In the combined group of those with a medical marijuana registration and those planning on obtaining a registration, the non-medical use of marijuana was significantly greater on all variables when compared to subjects who do not have and are not planning on obtaining a medical marijuana registration.

Discussion

Summary of findings

The results support our hypothesis that patients with medical marijuana registrations or planning on getting medical marijuana registrations were more likely to use marijuana for non-medical reasons (to get high) than those without medical marijuana registrations. In our sample, use of marijuana was frequent for both medical reasons and non-medical use; use for medical reasons alone was an infrequent result. This indicates that even among patients who use marijuana for medical reasons, the majority are also using it for non-medical reasons. Although the presence of marijuana use disorders

among medical marijuana users was not directly measured in our study, there was a high prevalence of non-medical use of marijuana in these patients. This may indicate that marijuana use disorders are present in patients presenting to substance abuse treatment who state that they are using marijuana for medical reasons. Therefore, this should be evaluated as a part of treatment planning similarly to non-medical use prescription drugs, such as opiates or sedatives. A substantial number of respondents either thought marijuana was safe, or were unsure as to its safety for potentially vulnerable populations: pregnant women, children, and adolescents. A number of our subjects felt marijuana could help treat addiction, depression, bipolar disorder, and psychosis: even though there is evidence that marijuana use may potentially worsen these conditions (Hall and Degenhardt, 2009, Leweke and Koethe, 2008). This finding indicates that knowledge regarding the potential risks associated with marijuana use for these groups was limited in the study group.

Several patients with medical marijuana registration had never had treatment, other than marijuana, for their medical condition. This suggests the possibility that for some in this population, marijuana is being used prior to other more established treatments, and supports concerns that medical marijuana patients may not be receiving appropriate care for their medical problems.

Study limitations

Limitations of the study include its cross-sectional design, obtaining data from only a single site, relying on self-report, using a treatment sample, and not using a standardized measurement for risk factors for marijuana misuse. These limitations affect the generalizability of results to other settings and other treatment programs. Not using a standardized instrument may also affect the validity of the findings.

Implications

The study findings support further research to determine if medical marijuana is being used for non-medical reasons. Longitudinal studies should also be performed to evaluate substance treatment outcomes in these patients to determine the effect of marijuana use on treatment success. There should also be education of patients about the potential adverse effects of marijuana, to avoid misperceptions

regarding the risks and benefits of the drug. Further research should be done to determine if patients who use medical marijuana are receiving appropriate medical care for the conditions for which they are using marijuana.

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Table #1 Beliefs, behaviors, and intentions about medical marijuana (n=141)

	yes	no	unsure	no response
Do you have a medical marijuana registration?	17(12%)	114(81%)	0(0%)	10(7%)
Are you planning on getting a medical marijuana registration?	21(15%)	79(56%)	15(11%)	26(18%)
Do you believe marijuana is a safe drug for adults?	89(63%)	22(16%)	25(18%)	5(3%)
For children under the age of 13?	4(3%)	121(86%)	12(8%)	4(3%)
For adolescents ages 13-18?	20(14%)	84(60%)	32(22%)	5(4%)
For pregnant women?	15(11%)	98(69%)	23(16%)	5(4%)
Should marijuana be legal for recreational use?	73(52%)	40(28%)	24(17%)	4(3%)
Should marijuana be legal for medical use?	109(77%)	11(8%)	13(9%)	8(6%)
Has marijuana been more available on the street since medical use became legal?	32(23%)	41(29%)	64(45%)	4(3%)
Have you or people you know been using more marijuana?	49(35%)	57(40%)	30(21%)	5(4%)

Table #2 Comparison of medical and non-medical marijuana users

	Participants who had used marijuana in the past but do not have and are not planning on obtaining a medical marijuana registration N=69	Participants who have a medical marijuana registration N= 17	p-value	Participants who have a medical marijuana registration or are planning on obtaining a medical marijuana registration N= 38	p-value
Non-medical use of marijuana in the last year	35 (51%)	13 (76%)	0.0480	30 (79%)	0.0034
Non-medical use of marijuana once a week or more in the last year	15 (22%)	9 (53%)	0.0140	19(50%)	0.0029
Non-medical use of marijuana at least once a week for 3 month period in life	31(45%)	12(71%)	0.0512	25(66%)	0.0310
Non-medical use of marijuana in the last year and/or non-medical use of marijuana at least once a week for 3 month period in life	41(59%)	15(88%)	0.0211	32(84%)	0.0066

Note: Table #2 Compares the frequency of marijuana use on variables in the first column, between patients without a medical marijuana registration (column 2) and two groups 1) patients with a medical marijuana registration (columns 3 and 4) and 2) a combined group of patients who either have a medical marijuana registration or are planning on obtaining a registration (columns 5 and 6).

Biography:

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Conflict of Interest Statement:

I declare that I have no proprietary, financial, professional or other personal interest of any nature or

kind in any product, service and/or company that could be construed as influencing the position

presented in, or the review of, the manuscript entitled "Perceptions and Use of Medical Marijuana in

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Rationale for Using Exercise in the Treatment of Stimulant Use Disorders

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http://clinicaltrials.gov/ct2/show/NCT01141608?term=Stimulant+Reduction+Intervention+using+Dosed+

Exercise&rank=1

Abstract

Novel approaches to the treatment of stimulant abuse and dependence are needed. Clinical data

examining the use of exercise as a treatment for the abuse of nicotine, alcohol, and other substances

suggest that exercise may be a beneficial treatment for stimulant abuse. In addition, exercise has been

associated with improvements in many other health-related areas that may be adversely affected by

stimulant use or its treatment, such as sleep disturbance, cognitive function, mood, weight, quality of life,

and anhedonia. Neurobiological evidence provides plausible mechanisms by which exercise could

positively affect treatment outcomes in stimulant abuse. The National Institute on Drug Abuse (NIDA)

Clinical Trials Network (CTN) CTN-0037 Stimulant Reduction Intervention using Dosed Exercise

(STRIDE) study is a multisite randomized clinical trial that compares exercise to health education as

potential treatments for stimulant abuse or dependence. If effective, exercise may provide an additional

approach to the treatment of stimulant use disorders.

Key Words: stimulant abuse, stimulant dependence, exercise, health education, behavioral intervention

Introduction

Outcomes in the treatment of substance use disorders suggest a need for innovative modest treatments.

Stimulant use disorders are chronic, relapsing illnesses with few highly efficacious treatments (1). In

Treatment as Usual (TAU; i.e., the standard treatment one would receive at a substance use treatment

2

facility) for substance use disorders, typically only about 13% of participants achieve abstinence (1). Abstinence rates for treatments designed to augment TAU vary widely – ranging from 14%-60% (2, 3, 4, 5) – depending on the outcome variable and primary endpoint selected. Currently, the best treatments for cocaine and other stimulant abuse are behavioral treatments that combine cognitive behavioral therapy (CBT) with contingency management (1, 6). However, it is clear that new treatments are still needed for stimulant abuse and dependence.

Exercise is a promising new treatment option for stimulant abuse and dependence. There have been a number of studies of the effectiveness of exercise in improving outcomes with alcohol, other substance abuse, or tobacco, with the impact of exercise on smoking cessation receiving the most attention. There are also a number of studies of the impact of exercise on improving depressive symptom severity and other chronic diseases. As a whole, this literature suggests that exercise may have good potential to impact outcomes with substance use disorders. As a result, the STimulant Reduction Intervention using Dosed Exercise (CTN-0037; STRIDE) study was developed to assess the feasibility of the use of exercise as an augmentation to usual care in individuals with stimulant use disorders.

This review will examine the existing literature that provides the rationale for studying exercise as a treatment for stimulant use disorders. In addition, a brief description of the ongoing STRIDE CTN-0037 trial that resulted from the culmination of this information will be described.

Exercise as a Treatment for Substance Abuse

Exercise and Smoking Cessation

Randomized controlled trials examining exercise to improve outcomes in smoking cessation provide some of the most convincing support for investigating the use of exercise (most frequently, vigorous intensity exercise) to improve outcomes in stimulant abuse treatment. Several controlled trials found

vigorous high intensity exercise to improve outcomes in smoking cessation (7, 8, 9), although others did not find this effective (10, 11, 12). These older studies, however, had small samples and other methodological limitations.

Marcus et al. (9) evaluated a 12 week vigorous intensity high dose supervised exercise intervention (target of 60-85% of heart rate reserve, three supervised sessions per week at 30-40 minutes per session) added to a 12 week group cognitive behavioral smoking cessation program as compared with cognitive behavioral intervention plus attentional control (health and lifestyle sessions) in 281 women. Participants who exercised were significantly more likely than participants in the health education control group to achieve continuous abstinence at three time points: 1) after 12 weeks of treatment (19.4% vs 10.2%, p = 0.03), 2) three months following treatment (16.4% vs 8.2%, p = 0.03), and 3) one year following treatment (11.9% vs 5.4%, p = 0.05).

Marcus and colleagues (13) later completed a randomized controlled trial assessing exercise for a shorter duration of time and with more moderate intensity. The study examined an 8-week moderate intensity exercise program (target of 59-69% of maximum heart rate, one supervised session and 4 additional weekly sessions of at least 30 minute duration) added to an 8-week group cognitive behavioral smoking cessation program, compared to a cognitive behavioral program plus equal staff time, in 217 women. There were no differences in 7-day point prevalence abstinence (i.e., the number of participants abstinent 7 days after completing the program) between the groups at 8 weeks. The exercise group had better abstinence at 3-month follow-up, but not at 12-month follow-up, with no differences at any time point between the groups. In a post hoc analysis, among those with a higher level of exercise participation, however, the likelihood of smoking cessation was greater.

In a similar study of smoking cessation in 205 recovering alcoholics, moderate intensity exercise and behavioral counseling was superior to behavioral counseling and nicotine gum or usual treatment one week after participants quit smoking, but there were no differences at 6 or 12 month follow up (14). Interventions in this study were of variable lengths of time, however.

Exercise and Alcohol Use

In two small controlled trials evaluating the efficacy of exercise with alcohol use, exercise improved outcomes. In one study with 58 inpatients in alcohol rehabilitation, abstinence was better post treatment and at 3 and 18-month follow-ups (15), although subjects were not randomized to intervention and control groups, and control group sizes were very small. In a sample of college students who were drinking heavily, an exercise program reduced alcohol use compared with a control group, although sample sizes again were small (16).

Exercise and Other Substance Use

While randomized controlled trials in patients abusing substances other than tobacco or alcohol are not yet available, some studies report benefits such as increased abstinence and reduced substance use that are associated with the use of exercise. Exercise resulted in higher abstinence at follow-up for patients receiving substance abuse treatment (15). In two trials with adolescent substance abusers (17, 18), exercise increased abstinence and less substance use was reported. Furthermore, in a post hoc analysis of data from 187 participants in two randomized trials evaluating contingency management in the treatment of substance abuse disorders (19, 20), participants that reported exercise-related activities had an increased length of abstinence (21).

A recent pilot study (22) showed that cannabis use and cravings were significantly reduced following 10 sessions of moderate aerobic activity over a 2-week period. Follow-up evaluations indicated that cannabis use returned to pre-exercise levels after the 2-week program was completed; however, these preliminary data offer further support for exercise in substance using individuals. In another recent pilot study of moderate-intensity aerobic exercise added to treatment for 16 individuals with substance

dependence, participants had significantly more days with no drug or alcohol use (i.e., abstinence) at the end of treatment compared to the beginning of treatment, and 66.7% of the sample had been continuously abstinent at the end of a 12-week intervention (23).

Exercise and Drug Withdrawal

In a review of 12 studies evaluating the effect of one session of exercise versus a passive control condition on smoking cravings, withdrawal symptoms, or smoking, nine out of ten studies evaluating cravings showed reduction in cravings during and after exercise (24). Eight out of nine reported decreased withdrawal symptoms such as stress, anxiety, tension, poor concentration, irritability and restlessness during and following exercise, although exercise interventions were of variable intensity (24). These studies, however, measured abstinence within periods of only minutes or hours following exercise. Other studies have examined outcomes over a longer period of time and noted reductions in stress, anxiety, irritability and restlessness at several points during the first few weeks of abstinence during exercise based smoking cessation intervention (25, 26).

Ussher et al. (27) evaluated the impact of brief moderate versus light intensity exercise on alcohol urges and mood, but found effects on urges only during the intervention itself with no improvements post intervention. However, the authors suggest some possibilities for the lack of post-intervention effects, including the fact that much of the sample had a concomitant psychiatric disorder, and the possibility that exercise may have a different effect on withdrawal from central nervous system (CNS) stimulants such as tobacco as compared with CNS sedatives such as alcohol.

Exercise as a Treatment for Major Depressive Disorder

The investigation of exercise as a treatment for depression further supports the use of exercise as a treatment for stimulant use disorders. Observational studies and clinical trials suggest beneficial effects of exercise on depression and anxiety (28). The results of several randomized controlled trials evaluating the

use of exercise as a monotherapy (29, 30), augmentation (31, 32) or combination (33, 34, 35) in the treatment of depression suggest that exercise is efficacious in improving the symptoms of depression. However, recent meta-analyses caution that many trials have methodological limitations, and few methodologically sound trials have been conducted, the results of which provide more modest support for the use of exercise in depression (36, 37). Despite these cautions, much of this literature provides additional support for the feasibility of exercise trials for stimulant users.

As a precursor to a randomized controlled trial entitled, TReatment with Exercise Augmentation for Depression (TREAD) (38, 39), Trivedi et al. (40) conducted a pilot study in 17 subjects with MDD who received a therapeutic dose of antidepressant medication for at least 6 weeks, and had some benefit, but residual symptoms remained (HRSD score of greater than or equal to 14). Participants received 12 weeks of 16 KKW (kcal/kg/week) of aerobic exercise in supervised and home based sessions. There was a nearly 6-point reduction on the Hamilton Rating Scale for Depression (HRSD) in the intent to treat group and more than a 10-point improvement in the 8 completers, despite a mean of about 4 months of antidepressant treatment prior to study entry. Improvements in quality of life were also observed. This pilot study also assisted with developing a home-based exercise program, and suggested that beginning with supervised exercise but tapering to home-based exercise is generalizable to routine clinical care and essential for participants to be likely to incorporate exercise into their ongoing routines.

The TREAD study (38, 39) evaluated improvement in depressive symptoms as well as functioning and quality of life in 126 subjects with MDD. Participants had received 2-6 months of selective serotonin reuptake inhibitor (SSRI) treatment, at least 6 weeks at an adequate dose, but still had residual depressive symptoms as reflected by an HRSD score of greater than or equal to 14. Subjects received 24 weeks of either a higher-dose (16 KKW) or lower-dose (4 KKW) of exercise, avoiding the pitfalls of the other trials such as group exercise, un-blinded outcome evaluation, and lack of rigorous standardized diagnosis of MDD (38). The first 12 weeks included individualized aerobic exercise prescription, self monitoring tools

and an interactive website to maximize adherence, and a combination of supervised and home based sessions – 3 supervised sessions in week 1, two in week 2 and one per week in weeks 3-12 to maximize scheduling flexibility and minimize burden. The second 12 weeks included home-based exercise only. Both doses were associated with significant reductions in depressive symptom severity over 12 weeks, with adjusted remission rates of 28.3% and 15.5% for the 16 KKW and 4 KKW groups, respectively, which showed a trend toward significance (p<0.06) (39). These studies provide support for the use of exercise in psychiatric conditions and also helped to address design considerations applicable for future trials in this area.

Additional Beneficial Effects of Exercise

Stimulant use is detrimental to a number of important health outcomes, including sleep (41, 42) and cognitive function (43). Exercise has been shown to improve both sleep quality in many (44, 45, 46, 47, 48) although not all studies (49). Several studies have also shown improvements in cognitive function associated with exercise (50, 51, 52, 53, 54, 55). Similarly, exercise has been shown to improve quality of life in those with depression and other chronic medical illnesses (40, 48, 56, 57, 58, 59), although it only improved quality of life in the physical domain in one small study (60). Furthermore, weight gain is a common concern following cessation of abused substances that may increase risk of substance use relapse (61, 62, 63), and regular exercise has the potential to prevent or reduce post cessation weight gain. These positive health benefits associated with exercise indicate that it may therefore be important not only in directly impacting stimulant use, but also in improving these outcomes.

Possible Mechanisms of Action of Exercise

Exercise may improve outcomes through any of several possible mechanisms. Exercise is likely to impact the underlying biology of addicted persons, as well as act as a behavioral treatment intervention. The mechanisms by which exercise may exert an effect on use of alcohol or substances are unknown. Possible

mechanisms are described by Read et al. (64), Brown et al. (65), Ussher et al. (27) and Meeusen et al. (66).

Meeusen (66) notes that exercise results in changes in synthesis and metabolism of central dopaminergic, noradrenergic, and serotonergic systems, all of which are implicated in addiction. For example, activation of the serotonergic system from cardiovascular exercise may be a mechanism by which exercise impacts alcohol urges (67, 68) since reduced serotonin levels are found with alcohol dependence (69). Exercise may also achieve effects via the endogenous opioid system and dopaminergic reinforcement mechanisms (70, 71, 72) similar to the effects induced by alcohol and drug use (73, 74). Unlike alcohol and drug use, however, physical activity is associated with increases in dopamine receptor densities in the reward pathways of the animal brain that persist for days after physical activity ends (75, 76, 77), which may be particularly salient for the treatment of stimulant abuse.

Another possible advantage of exercise as an intervention for stimulant use disorders is the evidence of improved hippocampal function seen with exercise. There is clear evidence in animal studies that exercise increases brain derived neurotrophic factor (BDNF) levels and has been shown to induce molecular changes in the hippocampus. The most recent evidence suggests that molecular changes in the hippocampus may directly impact upon several factors associated with contextual learning. Specifically, Greenwood et al. (78) have demonstrated improvements in hippocampal-dependent contextual learning and memory in rats. Similar results have been found for exercise-induced hippocampal neurogenesis and improvement in spatial memory in rats and mice (79, 80, 81). Therefore, exercise augmentation may provide specific benefits for participants with a history of substance abuse since this disorder has been associated with memory impairments that would be influenced by hippocampal function (43).

Reduction in sugar cravings and increased blood glucose levels also could assist with alcohol urges (82). Additionally, exercise may decrease reactivity to stress (83) and decrease the use of alcohol (or

substances) as a way of coping with stress (84). Improving self-efficacy (85, 86) may be another mechanism for improving outcomes.

It has also been suggested that exercise may be a distraction (87), allowing attention to be diverted from urges to drink (27) or a lifestyle change that can substitute for use of substances such as alcohol (88, 89).

Finally, the effect of exercise on related health outcomes may mediate its efficacy on substance use. There is evidence that exercise improves anxiety, depression and self-concept in those also abusing alcohol (90, 91, 92, 93), which may then mediate improved outcomes. Exercise has been shown to reduce depression and anxiety during alcohol treatment (94, 95, 96) and with smoking cessation (97, 98). Reduction in depression symptoms in alcohol dependent participants receiving cognitive behavioral therapy mediated improved outcomes in drinking, suggesting that exercise may improve drinking outcomes via reductions in depression and anxiety (99).

Feasibility of Exercise with Stimulant Using Individuals

Existing studies utilizing exercise interventions have shown that good adherence to the interventions can be achieved in a variety of populations. Adherence, or attendance at exercise sessions, did not appear to differ meaningfully in the two studies of vigorous and moderate intensity exercise by Marcus and colleagues with an attendance at exercise sessions of 67.3% for vigorous intensity exercise (three sessions per week) (9) and 70.5% for moderate intensity exercise (one supervised session per week). Attendance was similar in the vigorous intensity trial even though the weekly attendance requirement was three times as high. Adherence rates have been similarly good in studies of exercise in depression, with rates of 71% for the public health dose of 17.5 KKW and 72% for the 7 KKW dose in the DOSE study (30) and 99.4% for the 4 KKW dose and 63.8% for the 16 KKW dose in the TREAD study (39). Studies in other health-related conditions provide further support that good adherence rates to exercise can be achieved. The DREW study with postmenopausal women (100, 101) had adherence rates of 94.6% for the exercise dose

of 4 KKW, 89% for the dose of 8 KKW, and 93% for the dose of 12 KKW. LIFE, which was a 12 month study in mobility impaired participants 70-89 years of age, achieved a retention rate of 94% at 12 months; and the exercise group had adherence rates of 71% and 61% at 6 and 12 months respectively (102). These studies suggest that exercise interventions may be successfully implemented with stimulant using individuals.

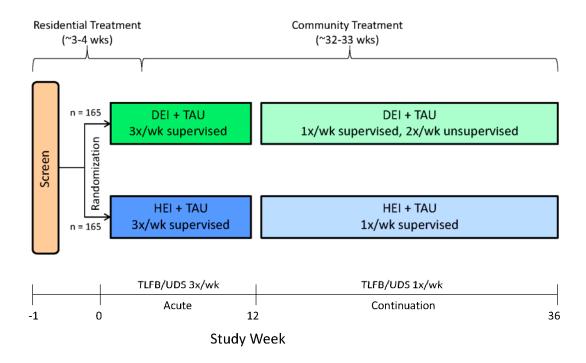
Developing a Trial to Examine Exercise in Stimulant Users: The CTN-0037 STRIDE Study

The converging evidence suggesting that exercise may positively impact stimulant use disorders led to the development of the CTN-0037 Stimulant Reduction Intervention using Dosed Exercise (STRIDE) study. This work is supported by the National Institute on Drug Abuse through the Clinical Trials Network for the Texas Node [3U10DA020024-06S1], Madhukar H. Trivedi, M.D., Principal Investigator; and the Stimulant Reduction Intervention using Dosed Exercise (STRIDE) study [2U10DA020024-06], Madhukar H. Trivedi, M.D., Lead Investigator. STRIDE is a multisite randomized, controlled trial aimed at comparing the augmentation of treatment as usual with either an exercise or health education intervention in a stimulant abusing population. Information on the selection of the primary outcome for the trial, the selection of study sites, and details of the protocol are provided elsewhere (103, 104, 105). A brief description of the trial is provided below.

The STRIDE study is designed as a two-group, randomized controlled trial and includes individuals diagnosed with stimulant abuse or dependence (cocaine, methamphetamine, amphetamine or other stimulant, except caffeine or nicotine) who begin substance use treatment in a residential setting. A schematic of the study flow is shown in Figure 1, as described in Trivedi et al. (105). Participants who provide informed consent and meet all inclusion criteria are randomized to one of two treatment arms:

DEI (Dosed Exercise Intervention Augmentation): Usual Care Augmented with Vigorous Intensity High Dose Exercise

HEI (Health Education Intervention Augmentation): Usual Care Augmented with Health Education.



DEI = Dosed Exercise Intervention Augmentation
HEI = Health Education Intervention Augmentation

TAU = Treatment as Usual

Participants receive 3 months of acute phase intervention followed by an additional 6 months of intervention with less frequent supervision. Both groups receive drug abuse treatment as usual (TAU; i.e., usual care), which begins while the participant is in a residential setting, typically followed by community treatment. The two treatment conditions are structured such that they are similar with respect to number of visits to allow for equivalent contact between groups. Participants randomized to the exercise condition begin with supervised exercise sessions 3 times per week during the 12-week acute phase of the study. Supervised sessions are conducted as one-on-one (i.e., individual) sessions, although other participants may be exercising at the same time. Supervised sessions are monitored closely through the use of heart rate monitors. Additional exercise sessions may be completed for those needing more than three sessions a week to achieve the target dose. Vigorous intensity high dose exercise is prescribed at a dose of 12

kcal/kg/week (KKW), with intensity ranging from 70-85% maximal heart rate. This dose is equivalent to ≥150 min of moderate exercise per week (i.e., approximately 30-50 min, 3-5 days per week). Participants randomized to the health education condition also begin with visits 3 times per week during the 12-week acute phase. The health education sessions are also conducted as one-on-one (i.e., individual) sessions, although other participants may be receiving health education at the same time. Health education sessions consist of information on health-related topics distributed via methods such as didactics, websites, audio and video materials, and written materials. During the 6-month continuation phase, the frequency of supervised intervention visits for both the exercise and health education groups reduces to one time per week.

This study aims to answer the following question: "Can exercise be used to improve the effectiveness of substance use treatment?" If exercise is found to improve outcomes for substance use disorders, the public health significance would be great. A novel component of treatment would be available for substance users that may not only aid in acute treatment, but may also aid in the long-term prevention of subsequent relapse. Furthermore, additional health benefits for substance users could be realized, including improved cardiovascular status, decreased risk of diabetes, cardiovascular disease, metabolic syndrome and certain cancers, and increased longevity.

Design Considerations

The STRIDE study includes some important design elements geared to enhance adherence to the interventions. A comprehensive behavioral intervention approach to facilitating and monitoring adherence to the study interventions has been developed (38, 105) to help retain participants in the interventions and optimize participant adherence. This multi-component behavioral adherence plan incorporates empirically-validated behavioral strategies to reinforce participation in the interventions and reduce salient participant- and disease-related barriers to intervention adoption and maintenance. These strategies include: 1) multidisciplinary psychoeducation about adherence and the use of behavioral reinforcers for

attendance/adherence to the intervention (e.g., water bottles, pen and notepad, gift cards); 2) written reference materials; 3) skills training (e.g., instruction in appropriate exercise form, intensity); 4) weekly exercise prescription (for participants randomized to exercise); 5) self-monitoring of adherence and performance (e.g., heart rate, RPE, tracking of HEI topics); 6) adherence feedback from study website and intervention facilitators; and 7) weekly intervention planning (individually-tailored plan).

Additionally, the study staff is encouraged to have an ongoing partnership with participants to develop and review a proactive plan to overcome any anticipated barriers that may arise and prohibit participants from completing the intervention. Site staff is trained to be aware of warning signs such as mood changes, decrease in motivation, change in living situation, medical problems and relapse, any of which may adversely impact adherence. Study staff discuss with each potential participant prior to randomization the study responsibilities and time commitment, and they proactively talk through any anticipated barriers or concerns. The site staff reviews participant specific barriers as a team on a weekly basis.

Conclusion

Exercise appears to be a promising intervention for individuals with stimulant use disorders. Evidence of clinical efficacy from studies of exercise in smoking cessation, alcohol abuse, depression, and other chronic disorders suggest that exercise may directly impact stimulant use, as well as mediate other important health related outcomes, such as withdrawal symptoms, mood, quality of life, sleep, and cognitive function. The STRIDE study was designed to examine exercise augmentation, compared to health education augmentation, of treatment as usual in stimulant abusing individuals. If exercise were to have an impact on acute and longer-term outcomes when added to usual substance abuse treatment, this would be of substantial public health importance. Exercise has limited side effects compared with medications, is not likely to interact with concurrent pharmacotherapy (40), is lower in cost (106), can be performed at home, can be continued indefinitely if effective in diverting relapse, and may be useful with

vulnerable populations such as pregnant women. Exercise may also improve overall health and functional status (40) and reduce the cost burden associated with substance use disorders.

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Competing Interests:

Madhukar H. Trivedi, M.D. is a consultant to or on speaker bureaus for Abbott Laboratories, Inc., Abdi Ibrahim, Akzo (Organon Pharmaceuticals Inc.), AstraZeneca, Bristol-Myers Squibb Company, Cephalon, Inc., Cyberonics Inc., Eli Lilly & Company, Evotec, Fabre Kramer Pharmaceuticals, Inc., Forest Pharmaceuticals, GlaxoSmithKline, Janssen Pharmaceutica Products, LP, Johnson & Johnson PRD, Meade Johnson, Medtronic, Neuronetics, Otsuka Pharmaceuticals, Parke-Davis Pharmaceuticals, Inc., Pfizer Inc., Sepracor, SHIRE Development, Solvay Pharmaceuticals, VantagePoint, and Wyeth-Ayerst Laboratories. He receives research support from the Agency for Healthcare Research and Quality (AHRQ), Corcept Therapeutics, Inc., Cyberonics, Inc., Merck, National Alliance for Research in Schizophrenia and Depression, National Institute of Mental Health, National Institute on Drug Abuse, Novartis, Pharmacia & Upjohn, Predix Pharmaceuticals (Epix), Solvay Pharmaceuticals, Inc., and Targacept.

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Kolette M. Ring, B.A. declares that there is no conflict of interest.

Bruce D. Grannemann, M.A. declares that there is no conflict of interest.

Timothy S. Church, M.D., Ph.D., M.P.H. declares that there is no conflict of interest.

Eugene Somoza, M.D., Ph.D. declares that there is no conflict of interest.

Steven N. Blair, P.E.D. receives royalties from Human Kinetics for Active Living Every Day.

Jose Szapocznik, Ph.D. declares that there is no conflict of interest.

Mark Stoutenberg, Ph.D. declares that there is no conflict of interest.

Chad Rethorst, Ph.D. declares that there is no conflict of interest.

Diane Warden, Ph.D., M.B.A. has owned stock in Bristol Myers Squibb and Pfizer, Inc. in the last 5 years and has received funding from the National Alliance for Research in Schizophrenia and Depression.

David W. Morris, Ph.D. declares that there is no conflict of interest.

Andrzej S. Kosinski, Ph.D. declares that there is no conflict of interest.

Tiffany Kyle, Ph.D. declares that there is no conflict of interest.

Bess Marcus, Ph.D. declares that there is no conflict of interest.

Becca Crowell, M.Ed., Ed.S. declares that there is no conflict of interest.

Neal Oden, Ph.D. declares that there is no conflict of interest.

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Author Biographies

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Kolette M. Ring, B.A. is a Clinical Data Specialist in the Department of Psychiatry at the University of Texas Southwestern Medical Center at Dallas. She is the Project Coordinator for the STimulant

Reduction using Dosed Exercise (STRIDE; CTN-0037) study. Her primary research interests include studying the effects of physical activity on mental health.

Diane Warden, Ph.D., M.B.A. is an Associate Professor of Psychiatry at the University of Texas Southwestern Medical Center at Dallas. She received her B.A. from the University of Pennsylvania, Ph.D. from Bryn Mawr College and M.B.A. from the University of Texas at Dallas. Her primary research interests include treatment outcomes in depression, and substance abuse and dependence, and co-morbid medical and psychiatric disorders. Dr. Warden was senior project director for the largest multi-site clinical trial ever conducted in psychiatry, the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) trial. She has 28 years experience in research and health care management, holding senior leadership roles in behavioral healthcare organizations for nearly 20 years.

Mr. Grannemann is a faculty associate in the Department of Psychiatry at the University of Texas Southwestern Medical Center at Dallas. He earned a Masters of Clinical Psychology from the University of Arkansas and additional training in Psychometrics and Social Psychology at the University of Texas at Arlington. He has worked at UT Southwestern for over 20 years on the evaluation of clinical treatments for depression. He has also been part of the team of researchers developing and testing the use of exercise as an augmentation treatment for both depression and substance abuse.

Tim Church, M.D., M.P.H., Ph.D. is a Professor, the John S. McIlhenny Endowed Chair and is the director of the Laboratory of Preventive Medicine at the Pennington Biomedical Research Center in Baton Rouge, Louisiana. Dr. Church earned his Medical Degree and PhD (structural and cellular biology) from Tulane University School of Medicine in New Orleans. He completed a residency in preventive medicine at Tulane during which time he obtained a Masters in Public Health. He is a PI, Co-I, or investigator on a number of NIH grants, most of which address issues related to exercise and health including exercise and the treatment of diabetes, exercise and cancer survivorship, and exercise and

maintenance of function in the elderly. He is an author on more than 100 peer-reviewed publications, and has received several awards for his research.

Dr. Gene Somoza is a psychiatrist with a Ph.D. in physics and a strong interest in developing mathematical models in medicine and psychiatry. He has 26 publications in this area. He also has a reasonable amount of research experience in basic science attained mainly during his three years as a Research Associate at the School of Medicine of the Universidad Autonoma de Madrid. His mentors there were Drs. Rodriguez Delgado and Francis DeFeudis. This resulted in 19 publications. Recently, his focus has been on substance abuse treatment research (approximately 50 published articles in this area), which has included being a PI in approximately 25 clinical trials and an investigator in 15 others. This work was done as Director (and Founder) of the Cincinnati Addiction Research Center (CinARC) for the past 16 years. This Center is closely associated with the Cincinnati VA Medical Center and the University of Cincinnati Department of Psychiatry and Behavioral Neuroscience. The funding for this research has come from NIDA (90%), the VA Cooperative Studies Program (5%), and Pharmaceutical Companies (5%), with a total funding of \$M60 over this period. Currently (for the past 12 years) he has been Director of the Ohio Valley Node of NIDA's Clinical Trials Network (CTN) composed of his research center (CinARC) together with 30 Community Treatment Programs within a 15-state region in the Midwest. Approximately 160 individuals are currently working on conducting his clinical trials. He also has 28 years of clinical experience in psychiatry (with a strong focus on addictions) mainly at the Cincinnati VAMC. He started this as the Director of the Psychiatric Evaluation Center where he directly evaluated, or made final decisions on, approximately 20,000 patients over a seven year period, and supervised a registered nurse, a master's level social worker, and numerous psychiatric residents. He also worked at the University of Cincinnati Psychiatric Emergency Services (PES) for 12 years. Afterwards he became Director of the substance abuse programs at the Cincinnati VAMC where he supervised a staff of approximately 35 individuals (MDs, psychologists, RNs, social workers, psychiatric residents, and fellows). Over the past year he has been spending a great deal of time on the dissemination of medication-assisted treatment (MAT) for opiate dependent individuals. This has involved training primary care physicians on using suboxone, working with single-state agency directors (SSADs) to fund MAT in their states, giving seminars at large SSAD-sponsored meetings for substance abuse treatment providers, attempting to make naloxone injections available to addicted individuals and their families in order to reduce the prevalence of opioid overdose deaths, and serving on Ohio governor's committees dealing with the interaction between opioid treatment and the criminal-justice system.

Steven N. Blair is a Professor in the Departments of Exercise Science and Epidemiology/Biostatistics at the Arnold School of Public Health at the University of South Carolina. Dr. Blair is a Fellow in the American College of Epidemiology, Society for Behavioral Medicine, American College of Sports Medicine, American Heart Association, and American Academy of Kinesiology and Physical Education; and was elected to membership in the American Epidemiological Society. He was the first president of the National Coalition for Promoting Physical Activity, and is a past-president of the American College of Sports Medicine and the American Academy of Kinesiology and Physical Education. Dr. Blair is the recipient of three honorary doctoral degrees--Doctor Honoris Causa degree from the Free University of Brussels, Belgium; Doctor of Health Science degree from Lander University, U.S.; and Doctor of Science Honoris Causa, University of Bristol, UK. He has received awards from many professional associations, including the Honor Award from the American College of Sports Medicine and the Robert Levy Lecture and Population Science Research Awards from the American Heart Association. He also was granted a MERIT Award from the National Institutes of Health, and is one of the few individuals outside the U.S. Public Health Service to be awarded the Surgeon General's Medallion. He has delivered lectures to medical, scientific, and lay groups in 49 states and 49 countries. His research focuses on the associations between lifestyle and health, with a specific emphasis on exercise, physical fitness, body composition, and chronic disease. He has published over 550 papers and chapters in the scientific literature, and is one of the most highly cited exercise scientists, with over 27,000 citations to his work. He also was the Senior Scientific Editor for the U.S. Surgeon General's Report on Physical Activity and Health.

José Szapocznik, Ph.D., is Professor and Chair, Department of Epidemiology and Public Health, Director of the Center for Family Studies, Director of the Clinical Translational Science Institute and of the Florida Node Alliance of the National Drug Abuse Treatment Clinical Trials Network, all at the University of Miami Miller School of Medicine. He is also Professor of Psychology, Educational and Psychological Studies and Architecture, all at the University of Miami. Dr. Szapocznik has served on the faculty of the UM Miller School of Medicine for over 35 years and has long distinguished himself as a pioneer in the field of substance abuse, specifically in the national effort to prevent and treat adolescent drug abuse and other behavior problems among minority youth using family based approaches. Szapocznik's Brief Strategic Family Therapy has received national and international recognition for its success as a familybased intervention, including listing in the National Registry of Effective Prevention Programs. Dr. Szapocznik has authored 250+ scholarly publications. His manual on Brief Strategic Family Therapy for Adolescent Drug Abuse is the only adolescent treatment manual published as part of the National Institute on Drug Abuse's Treatment Manual Series. Dr. Szapocznik also leads a major interdisciplinary program of research on the relationship between the built environment, behavior and health. This work has focused on aspects of the built environment that affect school-age Hispanic children's behavioral adjustment, the psychological and physical adjustment of Hispanic elders, and most recently the risks to weight gain and disease inherent in immigration. The latter includes studies of the pathophysiology of weight gain and the mechanisms through which gain in adiposity bring about progress in metabolic syndrome indicators. This highly interdisciplinary program of research, funded by the Robert Wood Johnson Foundation, the National Institute of Mental Health, the National Institute of Environmental Health Sciences and the National Institute of Diabetes, Digestive and Kidney Diseases, includes architects, behavioral scientists, endocrinologists, epidemiologists, exercise physiologists, geneticists, nutritionists, psychologists, psychiatrists and statistical methodologists. Dr. Szapocznik has a distinguished record of service to the National Institutes of Health and has served on the national advisory councils for the National Institute on Mental Health, the National Institute on Drug Abuse and the

National Center on Minority Health and Health Disparities. He was also the first-ever behavioral scientist appointed to the NIH-wide AIDS Program Advisory Committee (now the NIH Office of AIDS). Dr. Szapocznik has also served as Principal or Co-Principal Investigator on over \$100 million in NIH-funded grants and contracts.

Mark Stoutenberg, Ph.D. is a Research Assistant Professor in the Department of Epidemiology & Public Health at the University of Miami. He received his B.A. in History from Columbia University, an M.S. (2004) and Ph.D. (2008) from the School of Education at the University of Miami and an MSPH from the Department of Epidemiology & Public Health at the University of Miami in 2011. His primary research interests include investigating novel approaches for using exercise interventions to improve health outcomes and designing community-based lifestyle modification programs as a means of primary chronic disease prevention. In 2009, Dr. Stoutenberg was a recipient of a NIDA CTN Fellow award and has since transitioned into a role in the STRIDE Study as the National Exercise Specialist and a local Node Coordinator. Dr. Stoutenberg is also actively involved in integrating physical activity into a patient-centered care program for cancer patients at the University of Miami Sylvester Comprehensive Cancer Center.

Chad D. Rethorst, Ph.D. is an Assistant Professor in the Department of Psychiatry at the University of Texas Southwestern Medical Center at Dallas. He obtained a Ph.D. in Kinesiology from Arizona State University and a masters degree in Counseling and Sport Psychology from Boston University. Prior to joining the faculty at UTSW, he completed a T32 fellowship in the Department of Psychiatry at the University of Rochester Medical Center. His research focuses on the effects of physical activity on mental health, specifically conducting intervention research examining the efficacy of exercise as a treatment for depressive and substance abuse disorders.

Robrina Walker, Ph.D. is an Assistant Professor of Psychiatry at the University of Texas Southwestern Medical Center in Dallas, TX and the Scientific Director of the Texas Node of NIDA's Clinical Trials Network. Dr. Walker obtained her Ph.D. in Clinical Psychology from Virginia Tech and completed post-doctoral training in addiction treatment at the Dallas Veterans Affairs Hospital. She has worked on 10 NIDA-funded, one NIAAA-funded, and two Veterans Affairs-funded studies, with the majority being randomized clinical trials evaluating behavioral or medication treatments for adolescent and adult substance use disorders. Dr. Walker's primary research interests are in behavioral treatments for addictive behaviors.

David W. Morris, Ph.D. is an assistant professor of psychiatry at the University of Texas Southwestern Medical Center in Dallas (UTSW). He was the outcomes manager for the STAR*D and CO-MED trials, as such was responsible for all aspects of data collection including rater training and certification. Dr. Morris also trained and certified all raters for the NIMH funded REVAMP study and B-SNIP study, and is currently performing this duty for the EMBARC study and the CTN 0037 trial. He has specific expertise in the development and implementation of clinical assessment procedures, and training and certification of clinical raters, having performed in this capacity for many of the largest federally funded multi-center psychiatric treatment trials to date. Dr. Morris received his Ph.D in clinical psychology from the University of Tulsa, and completed an NIMH research fellowship at UTSW Medical Center prior to joining the UTSW faculty.

Andrzej S. Kosinski, Ph.D. is an Associate Professor in the Department of Biostatistics and Bioinformatics at the Duke University. He received his B.S. from the AGH University of Science and Technology, Krakow, Poland; M.Sc. in Applied Statistics from University of Oxford, England; and a Ph.D. in Biostatistics from the University of Washington. He research interests include design of clinical trials, statistical methods for evaluation of diagnostic tests, and measures of agreement. He has received

research grants from the American Heart Association and participated in research supported by the National Institutes of Health and industry.

Tiffany Kyle, Ph.D., is Director of Research at The Center for Drug-Free Living in Orlando, Florida, a Volunteer Professor in the Department of Epidemiology and Public Health at the University of Miami, and a Research Professor in the Department of Psychology at the University of Central Florida. She earned a Ph.D. in Clinical Psychology from the University of Central Florida and has more than ten years of experience conducting research on the treatment of substance use disorders within community settings.

Bess Marcus, Ph.D., is Professor and Chair of the Department of Family and Preventive Medicine at the University of California, San Diego. Dr. Marcus is a clinical health psychologist who has spent the last 25 years conducting research on physical activity behavior and has published over 175 papers and book chapters as well as four books on this topic. She has developed a series of assessment instruments to measure psychosocial mediators of physical activity behavior and has also developed low-cost interventions to promote physical activity behavior in community, workplace, and primary care settings. Dr. Marcus has participated in numerous national and international committees and review groups including the American Heart Association, American College of Sports Medicine, Centers for Disease Control and Prevention, and National Institutes of Health. She has served on panels that have created recommendations regarding the quantity and intensity of physical activity necessary for health benefits. She was a contributing author to the Surgeon General's Report on Physical Activity and Health and is on the executive committee for the development of a National Strategic Plan for Physical Activity. Dr. Marcus serves or has served on the Editorial Board of the Journal of Physical Activity and Health, Journal of Behavioral Medicine, Psychology, Sport and Exercise, Journal of Lifestyle Medicine, Research and Sport, and Journal of Mental Health and Physical Activity. Dr. Marcus serves on the national advisory panel for the Centers for Disease Control and Prevention course on Physical Activity and Public Health. Dr. Marcus has also conducted a series of NIH-funded studies on the efficacy of physical activity

to enhance smoking cessation and minimize weight gain in women smokers. Dr. Marcus is currently Principal Investigator or Co-investigator on 10 National Institutes of Health grants on physical activity behavior including trials of primary and secondary prevention in adults. These studies involve interdisciplinary teams that include experts in cardiology, primary care, public health, epidemiology, costeffectiveness, and women's health. Dr. Marcus is currently involved in several studies examining different channels (print, phone, email, Internet) for promoting physical activity in order to determine both efficacy and cost-efficacy. These studies are conducted with a variety of populations including healthy adults, pregnant women, adults with substance use or abuse issues, patients in primary care practices, Spanish-speaking Latina women, and Spanish-speaking Latino men. Dr. Marcus has two ongoing RO1 grants to promote physical activity behavior in Latina women. In one study being conducted in the Northeast she is using a print-based approach to increase physical activity in Spanishspeaking Latinas. In the other study being conducted in San Diego she is using an Internet-based approach to increase physical activity in Spanish-speaking Latinas. These studies build on the print and technology-based physical activity studies she has been conducting with men and women for the past 25 years. Dr. Marcus has had continuous NIH funding for this line of work for the past 18 years. Dr. Marcus actively mentors graduate students, interns, post-doctoral fellows and members of the faculty and teaches courses on physical activity and obesity.

Becca Crowell, M.Ed., Ed.S is the executive director of Nexus Recovery Center, a women's drug treatment center in Dallas, Texas. She has a B.A., M.Ed. and Ed.S from the University of Florida and is a licensed professional counselor (LPC) and a Licensed Chemical Dependency Counselor (LCDC). Nexus participates in community-based drug treatment research in cooperation with the University of Texas Southwestern Medical School through the NIDA funded Clinical Trials Network. Ms. Crowell has coauthored several articles about these research activities and has presented on gender specific treatment and treatment of pregnant women.

Dr. Oden joined The EMMES Corporation in 1993 as a biostatistician. He has more than 10 years experience in the statistics of vision research. Currently, Dr. Oden works on variety of projects, including serving as a senior statistician at the Data and Statistics Center for the NIDA Clinical Trials Network. In this role, Dr. Oden has been involved in designing and supporting 3 clinical trials, and has performed methodological work on combining results of time-line-follow-back and urine drug screens to measure abstinence outcomes. Dr. Oden has also supported as a senior statistician The Standard Care vs. Corticosteroid for Retinal Vein Occlusion (SCORE) study, sponsored by NIH. SCORE is a multi-center clinical trial assessing the efficacy and safety of standard care versus triamcinolone acetonide injection(s) for the treatment of macular edema associated with central retinal vein occlusion (CRVO) and branch retinal vein occlusion (BRVO). Dr. Oden developed a Bayesian method to predict enrollment in multicenter clinical trials and performed statistical research on closed testing for controlling family wide error for trials with more than 2 arms. Previously, he was the Principal Investigator and Director of the Coordinating Center for the Supplemental Therapeutic Oxygen for Prethreshold Retinopathy of Prematurity Study Project (STOP-ROP), sponsored by the National Eye Institute. In this role, he directed day-to-day activities at the Coordinating Center, interacts with clinical and other staff, both internally and externally, negotiates with outside vendors, and has direct responsibility for staff, funding, and budgetary issues. He was active in presentations at major study meetings, and publication of study-related informational materials, and maintains good rapport with key study personnel and support staff. He was integrally involved in, and has considerable expertise in, the planning and implementation of data analyses, and the technical aspects of the databases and information systems.

Edward V. Nunes, M.D. is a Professor of Clinical Psychiatry in the Department of Psychiatry at Columbia University College of Physicians and Surgeons, a research psychiatrist at the New York State Psychiatric Institute (NYSPI), and Co-Chairman of the NYSPI Institutional Review Board. Following study at Dartmouth College (earned A.B. in Psychology and Chemistry in 1977) and University of Connecticut School of Medicine (earned M.D. in 1981), Dr. Nunes completed an internship in internal

medicine at St. Elizabeth Hospital in Boston (1982) and a psychiatry residency (1982-1985) and a research fellowship in clinical psychopharmacology (1985-1987) at the New York State Psychiatric Institute. During his fellowship training, he developed an interest in treatment of addictions and co-occurring psychiatric disorders and clinical trials design and analysis, which became the foci of his research career. Dr. Nunes has been principal investigator or collaborator on numerous NIH-funded R01s and, since 2000, has served as principal investigator of a node in the National Institute on Drug Abuse (NIDA) Clinical Trials Network (now in its third funding period), which has led three multi-site clinical trials. He has authored over 175 book chapters and articles and edited a recently published volume on diagnosis and treatment of co-occurring psychiatric and substance use disorders. He has received consecutive career development awards from the National Institute on Drug Abuse (K20, two K02s, and K24) and serves as a research mentor to numerous junior faculty members and fellows at the NYSPI.

Madhukar H. Trivedi, M.D. is currently a Professor and Chief of the Division of Mood Disorders in the Department of Psychiatry at the University of Texas Southwestern Medical Center at Dallas. He holds the Betty Jo Hay Distinguished Chair in Mental Health. Dr. Trivedi is an established efficacy and effectiveness researcher in the treatment of depression. Dr. Trivedi has focused his research on pharmacological, psychosocial, and other nonpharmacological treatments for depression. Dr. Trivedi has been a principal investigator in multiple clinical trials funded through NIMH and the Texas Department of Mental Health. He is the Principal Investigator of the NIDA-funded "Stimulant Reduction Intervention using Dosed Exercise (STRIDE)" study that tests the effectiveness of adding exercise to treatment as usual in improving drug treatment outcomes. Dr. Trivedi is also Principal Investigator of the Texas Node of the NIDA-funded Clinical Trials Network. Additionally, he was the Principal Investigator of three NIMH grants entitled "CBASP Augmentation for Treatment of Chronic Depression (REVAMP)," "TReatment with Exercise Augmentation for Depression (TREAD)," and "Computerized Decision Support System for Depression (CDSS-D)." He was the Principal Investigator of the Depression Trials Network "Combining Medications to Enhance Depression Outcomes (CO-MED)" trial, which focused on

the use of specific antidepressant combinations to increase remission rates by treating a broader spectrum of depressed patients and by capitalizing on additive pharmacological effects. He was also the Co-Principal Investigator of the NIMH-funded project entitled "Sequenced Treatment Alternatives to Relieve Depression (STAR*D)." Most recently, Dr. Trivedi has been selected to Lead the team conducting the EMBARC project. This project is at the core of the NIMH's initiative to identify a biosignature for depression. This work will focus on neuroimaging, EEG, clinical and behavioral phenotypes and other blood-based biological markers. His ongoing work as the Lead PI of the EMBARC study provides an extensive background for his contribution to the Neurobiological Markers employed in the study. Note this grant is designed to be a linchpin in the development of a biosignature for depression and is unique in its design to evaluate biomarkers from across full spectrum possible biological markers. As the lead site, he will be able to provide new clinical research opportunities to work at cutting edge of translational research in depression. Dr. Trivedi has received numerous awards including the Gerald L. Klerman award from the National Depressive and Manic-Depressive Association Scientific Advisory Board-NDMDA and the Psychiatric Excellence Award from the Texas Society of Psychiatric Physicians-TSPP. Dr. Trivedi has mentored multiple psychopharmacology postdoctoral fellows and research track residents over the past many years in Mood and Anxiety Disorders and is the Principal Investigator of an NIMHfunded Postdoctoral T32 training program. He is or has been a member of several institutional review groups of the NIMH. Dr. Trivedi has published over 380 articles and chapters related to the Diagnosis and Treatment of Mood Disorders.



Awareness into Action: How Communication Skills Training Enhances Traditional Substance Abuse Treatment Programs

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Leslie Tod, MA.

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Abstract:

Treating substance use disorders and co-existing mental health disorders requires sophistication and professional training. This client population can be difficult to treat and providers often have to do so within limited timeframes. These individuals face numerous challenges throughout their course of treatment and their recovery post treatment. This article will review the potential benefits of communication skills training (referred to as CST throughout the remainder of this text) as a value-added treatment component both during residential treatment and post-discharge. CST is the process through which an individual is taught how to appropriately use a range of behaviors in order to convey a message. CST seeks to develop both language and expression, so that one may communicate effectively with others. This article will identify the reasons as to why this client population would likely benefit from skill strengthening even more than, as a field, we might consider. The words coping skills, social skills, and communication skills will be interchangeably used throughout this article.

In addition, the authors will provide evidence and discussion related to the existing research on CST used with those who have been diagnosed and/or treated for substance use disorders. The benefits of CST in regards to increasing clients' treatment outcomes and incorporating these skills into their daily life, post treatment, will be identified and discussed. Practical difficulties in regard to incorporating CST will also be presented.

Keywords: communication skills training, substance abuse treatment, substance abuse, social skills, relapse prevention.

Communication is a fundamental element of our daily experiences, thereby creating the misconception that communication comes naturally and without impediment. For this reason, CST may be an area of skills training that may be overlooked when considering client needs in treatment. Basic social nature demands that we seek out communication with other people (2). However, not everyone possesses the ability to communicate effectively, and for individuals with substance use disorders, this particular skill may be especially challenging. The importance of developing and maintaining this skill set may be unnoticed and even considered unimportant as a necessary and key component of substance abuse treatment.

Effective communication coaching can enhance conventional treatment program regimens by providing clients the opportunity to work towards the objective of clear and productive communication. With substance abusers, both in residential and outpatient programs, CST can aid these individuals in areas that are directly tied to their daily experiences and offer insight into any deficits that may exist.

When a substance abuser enters treatment, immediate focus is typically and necessarily geared towards their physiological and psychological stabilization. Throughout the course of treatment, clients participate in therapeutic interventions both to continue stabilization efforts and to initiate their personal recovery process. Many treatment facilities have also begun to include non-traditional integrative interventions. There is growing evidence that both conventional and non-conventional therapies are legitimate treatment choices (3). The use of CST as a value-added treatment component is especially effective as a social component to the therapeutic design, by both increasing the client's ability to get the most out of social aspects of treatment and by enhancing skills that translate to their experiences outside of the context of treatment.

Communication Needs/Research Study Results

Communication is generally considered simply "something we all do". Therefore, the importance of good communication skills may be disregarded as something that may be improved upon but not as a clinically relevant or critical skill to develop. What we say, how we say it, and when it is said, can have a significant impact on how we relate, converse, and socialize with others. Behavioral communication, including the use of eye contact, body language and the ability to listen to others, is vital to an individual's ability to relate well to others. Skills that are not developed can interfere with central relationships and contribute to an individual's difficulty with managing conflict and maintaining or setting personal boundaries, resulting in unnecessary misunderstandings. All of these potential issues can be considered therapeutic challenges for a client and can create preventable frustration, social alienation, and feelings of helplessness.

When researching the topic of CST as it relates to the medical/treatment profession, the authors were able to identify numerous articles and research, however, few related to training skills for the consumer. The majority of scholarly articles reviewed tended to focus on the importance of how professionals communicate with their patients/clients as opposed to the actual importance of the substance abuse client/consumer enhancing their personal skill sets.

There are only a few studies that have focused on researching the effectiveness of CST when applied to consumers of substance use treatment. However, such identified studies are considered outdated and tend to focus on a specific subset of this particular population. Some studies have researched only individuals with a diagnosis of alcohol abuse or dependency and have not included those with secondary mental-health disorders or those struggling with polysubstance abuse/dependence. Despite the limited research available for review, the results are promising.

One study conducted by Rosenhow et al., and published in 2001, resulted in the following conclusions:

Communication skills training continues to show value for alcoholics in intensive treatment programs (1).

CST appears to yield good results especially during intensive treatment (1).

There is a need for more data to support whether programs and providers could or should expand services to include communications skills training and social skills training as fundamental components of their respective programs. A recent and yet to be published survey (11) shows results indicating the need to consider the importance of training and developing this particular skill set.

The survey assesses the need and usefulness of CST and focuses on three groups of people. Respondents include professionals in the field of addiction and mental health who are in a position to refer to treatment programs, consumers of treatment programs, and the families and support system of treatment center consumers. The following research results are an abbreviated version of the research.

When selecting a program, 65.4% of professionals surveyed indicated that communication skills training/coaching was important when selecting a program for a client.

In regards to identified challenges clients seem to encounter post treatment, professionals indicated observed difficulties in the following social/communication realms: General problem solving (40.8%), difficulty with family boundaries (51.%), ability to communicate personal needs and feelings (46.9%), getting along with others in general (40.8%), and setting boundaries (59.2%).

Family/social support respondents, many self-identified as being "extremely involved" in their loved ones treatment process, indicated that in regards to treatment programs which had offered skills training, only 18.9% reported participation in this program component.

58.3 % of this respondent pool indicated that their loved one seemed to have difficulty asking for help when needed. Issues with social anxiety (40.4 %) and social isolation (34.6%) were also identified as post-treatment issues for these individuals.

Consumers of treatment were also asked to participate in this research study. In regards to whether they were offered social skills training components in treatment, only 16.7 % of respondents indicated in the affirmative, while 20.8% had been offered communications skills training/coaching while in treatment.

Pertaining to communication and social skills issues, the following had been reported in terms of challenges faced: 45.8 % reported communication skills deficits, 41.7 % indicated social skills development and maintenance were lacking, 54.2 % reported difficulties with maintaining boundaries with self and others, and 50.0% had indicated that they struggled with issues related to conflict resolution.

Based on this research, there appears to be sufficient evidence that supports the benefit of skills training, both in residential treatment as well as post-discharge.

Substance Abusers and Skills Training

Beginning in residential and throughout the continuum of care, clients are encouraged to maintain their personal boundaries, respect those of others, increase their social support systems, establish healthy connections with others, and maintain healthy relationships.

Therefore, it is suggested that program professionals formally asses the need and properly introduce skills training as part of the client's treatment plan. People in treatment for substance addictions who have struggled with building healthy relationships may benefit from skills development in the area of interpersonal communication, given that it is so integral to recovery capital (4).

This particular client population may be especially prone to communication and interpersonal skill deficits. Many clients being treated for substance use disorders report their experience of communication being chaotic, abusive, and manipulative. Additionally, they may have been raised in an environment where the substance use of others hindered exposure to healthy communication styles.

This population is also exceptionally vulnerable to social isolation, repeated patterns of involvement in traumatic or abusive relationships, and ongoing difficulties with low self confidence and self esteem.

Healthy interpersonal relationships may feel foreign and unnatural to them. Intrinsic issues of mistrust may color their relationships with others. Additionally, ongoing use and abuse of substances can severely and negatively affect the relationships with family members as well as with friends, employers, and coworkers.

Individuals with secondary mental health disorders, in addition to their substance use disorders, may encounter even more struggles in the areas of communication, social functioning, and coping.

According to NAMI (National Association on Mental Illness) a consumer's social support is critical.

Their immediate environment has a direct impact on their choices and mood; therefore consumers need help strengthening positive relationships and jettisoning those that encourage negative behavior (7).

One particular subset of this clinical population that may especially benefit from CST is those individuals who have previously participated in more than one program, or otherwise considered "chronic relapsers". These individuals, because of their repetitive treatment experiences, tend to already know what they "need" but have little training putting new skills to the test outside of treatment.

As a real example, Mary P., who is considered a "chronic relapser" self-admits into a local day treatment program for those with co-occurring disorders. This woman had previously been in more than 12 formal treatment programs for issues including alcohol and depression. She is clinically savvy and seems to know what to say to her treatment providers as she continues her course of treatment. On the surface, Ms. P. appeared highly motivated, intelligent, and to be truly benefitting from the program. In groups, she shared freely, provided feedback to her peers, and was extremely attentive. She was able to communicate well and was articulate in her verbal correspondence. Staff and peers alike often complimented her in her progress and her participation. However, when one looked at her history, much of what she said and did merely reflected her ability to manipulate and avoid her true challenges- by saying what she felt others wanted to hear. Sadly, her real challenges, including maintaining boundaries, setting limits, socializing with others, and being able to manage and negotiate conflict, initially went unaddressed. Thus, she

continually experienced the same discharge and re-entry challenges without truly knowing why. Once she began to participate in both individual and group CST, the client's struggles with communication became clearer to her and those who worked with her. Initially, she had expressed feeling "insulted" that CST was being recommended as part of her course of treatment. She indicated that she was able to communicate well and there was no need for this training. However, as her work in CST continued, Ms. P. began to identify the skills she needed to develop post discharge. As her training progressed, she was able to notice positive changes regarding her familial relationships. Her self confidence in the area of socializing improved and, as a result, she reported feeling less isolated.

Incorporating CST into Treatment

There are several ways in which CST can be implemented and utilized during the course of treatment. Ideally, skills training would first occur in the residential setting as this would allow for ongoing monitoring, feedback, and flexible learning formats. CST can be easily built into mainstream treatment protocols, provided its importance to treatment outcome is recognized and understood.

Treatment plans for substance addicted clients often include strengthening interpersonal skills and increasing the ability to interface with others effectively. Since building supportive and healthy relationships requires effective communication skills, (4) providing education, support, and highlighting the benefit to communication skills building can be helpful to clients participating in treatment programs.

Treatment also tends to focus on the development of "self" and aims to improve self esteem, self efficacy, and self confidence. Understanding one's new "role" as a recovering individual and what that entails may be particularly confusing. These individuals may receive benefit from evaluating their new roles and responsibilities. Skills training in this particular realm could consist of assisting the client in identifying the variety of roles they assume and how to best interface with others in this new role. Emphasis would be on developing an understanding of how roles create conflict, must be negotiated, and require an

understanding of perceived responsibility. When a client begins to experience the benefits of CST, his or her confidence in their ability to communicate and problem solve may improve.

In treatment, CST training may be combined with other forms of therapeutic programming, such as individual and group therapy. The ability to incorporate CST in these modalities and the ability to continue strengthening these skills can serve as a stepping stone to improved social connections post treatment. Anticipation of specific challenges post treatment can be discussed in these modalities as well.

It is important to note that when a client is participating in a residential program, coaching may occur informally and via several treatment team members and disciplines. When a client traverses along the continuum of care and is expected and/or encouraged to apply the skills into their daily life, coaching experiences can be of significant use to the client. The person is generally participating less in therapeutic environments and is beginning to face challenges common to a newly recovering person. Upon discharge from residential or moving from one level of care to another, the intensity and frequency of their therapeutic exposure lessens. As a result of this re-entry, the client will begin to encounter a set of stressors common to their new experiences.

Social support is critical for the recovering individual, especially as they transition through the various stages of recovery. Skills training teaches alcoholics how to seek support and resolve conflict, when faced with emotional distress (8). Research shows that these skills play a role in recovery from addiction (4).

Therefore, it may be especially useful for outside treatment providers to provide CST. Navigating the challenges one may face post-discharge can be stressful. Ongoing assistance with skills training can better equip the individual to meet these challenges in a rehearsed and constructive manner.

Practical Limitations

While evidence points to the fundamental need to provide CST to clients, both in residential and outpatient programs, there are limits to the practical implementation of CST.

Many clients are only afforded the ability to participate in shorter term programs due to finances or other reasons. Limited time in treatment may complicate a program's ability to provide CST to their clients.

If clients lack insight into the nature of skill set deficits, they may perceive skills training as a criticism of their person and may be reluctant participants in CST. In this circumstance, the provider may want to present skills training as an avenue to better cope with stress. That is, "Being open and willing to discussing and resolving personal disagreements, misunderstandings, and areas of conflict that could otherwise lead to stress" (9).

Though skills training can be an important element of treatment, it does require ongoing learning and practice However, there are few programs that offer this treatment component. "Abstaining from substance use is a complex and multi-faceted challenge for those who suffer from addictions, and exposure to a few sessions of communication skills training is not enough to alter patterns of behavior that may have persisted over years" (4).

Outpatient skills training may be needed for those individuals who are unable to financially afford admission into a residential treatment program. Some substance dependent people are not able to afford any level of treatment and often are referred to 12-step meetings, which are free of charge.

12-Step programs, such as Alcoholics Anonymous and Narcotics Anonymous, require some degree of social participation. Meetings are conducted in a group format, and socialization with relationship building among attendees, is highly encouraged and touted as imperative to the continued recovery process. So critical is the social aspect of the various 12-steps programs that they are often referred to as "fellowships".

Recovering individuals have reported that they feel "at home" when they attend meetings and feel comfortable being with others with similar challenges. Other recovering individuals have opted out of regular attendance or participation and have cited the following reasons: feeling uncomfortable talking in

front of others, feeling socially awkward, and feeling uncertain about what is expected of them communication wise.

For this second group of individuals, their socialization anxieties may prevent them, or make it difficult for them, to participate in 12-step programs. As a result, they may not be afforded the same level of social support as their peers that do not exhibit these difficulties. Self-help group involvement then affects subsequent coping responses, life stressors and social resources. (10) It is surmised that if this group received CST as a therapeutic component, these concerns may have been addressed and possibly resolved.

Research suggests that CST can support ongoing recovery efforts and further research may be helpful to improving treatment outcomes for clients who seek treatment for substance use disorders.

Summary

Treatment programs that treat substance use disorders provide physiological, psychological, and social components. Clients of these programs are frequently provided with a wide range of therapeutic interventions to promote personal growth and ongoing recovery.

The use of CST as a value-added component, both in residential treatment as well as in outpatient, can be an integral part of a client's therapeutic and healing experience. Such training can serve as a tool that can be aligned with conventional therapeutic approaches to assist a client in the following ways: managing critical needs including establishing and maintaining boundaries, communicating more effectively in the various roles a person assumes in day to day life, negotiating conflict and improving conflict resolution skills, increasing social and relational skills, and promoting greater self confidence.

Clients who participate in treatment services require considerable degrees of social support. However, they must have the skill set to effectively gain support. Therefore, developing these skills, and enhancing relationships with family, friends, and professionals should be an important part of treatment (4).

However, CST is not a panacea for all ills. This intervention is not a cure all, but a way of putting awareness information into action.

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Conflict of Interest Statement:

We declare that we have no proprietary, financial, professional, or other personal interest of any nature or kind in any product, service, and/or company that could be construed as influencing the position presented in, or the review of, the manuscript entitled Awareness into Action: How Communication Skills Training Enhances Traditional Substance Abuse Treatment Programs; Except both authors provide services to ICM Associates, Inc.



A Drug Free Approach to Treatment – Cultural/Social Aspects and Follow-Up Studies: the case of 'San Patrignano' Therapeutic Community

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Abstract

The dispute between those who seek to accommodate drug misuse (whose opponents dismiss them as 'fatalists') and those who seek to enable a return to drug-free lifestyles (whose opponents dismiss them as 'dreamers') has long existed in many countries. This paper, originally presented by its author, verbally in Italian at a conference in Rimini, Italy, targets this dispute, and expands on it by looking at the related social, cultural, and sociological factors. As the author explains, drug addiction can be seen as a 'disease of the soul' – and in this setting, detoxification is the least of the problems. After discussing and characterising this change of paradigm, the author supports it by presenting research results based on the experiences of present and former residents of the San Patrignano Community, the facility on which this paper is based.

Introduction and Background

The research described in this paper is substantially based on experience within the San Patrignano Therapeutic Community, located in Rimini, on the Adriatic coast of Italy. San Patrignano Community houses and interacts with almost 1,500 residents at any one time, and since it's founding in 1978 has served more than 18,000 people, at no charge. The resident group is diverse, and includes families with children. Some residents are HIV positive. The community provides medical care through a sizeable hospital within the site. Residents receive training to prepare them for possible employment in diverse trades and professions.

The community philosophy is perhaps best summed up in the words of the founder, the late Vincenzo Muccioli, who said: "Among the problems that affect the drug addict, drug use is the least relevant. The core of the problem is not drugs, nor the abstinence crisis: it is the human being with his fears and the black holes that threaten to suck him in. That is why I do not like to say nor hear that ours is a community for drug addicts. Ours is a community for living, where you can restart after years spent as a social outcast. Ours, if we really need a definition, is a community against social marginalisation."

In favour of a cultural approach to drug addiction

In this paper, the author will focus on the issue of drug addiction in cultural terms rather than using the antiquated idea of a medical vs. social approach to drug addiction (in this context, this opposition between medical and social made sense 25 years ago when, for instance, it was important to legitimise and show the value of the work done by therapeutic communities).

Today, if one assumes that the pioneering stage of intervention can be considered as 'behind us', the clash is reduced between 'medical approach' and 'social approach'. But the clash still exists: it is primarily a cultural clash between the tendency to consider drug addiction as a lifestyle choice, and the tendency to approach drug addiction as a disease that highlights the drug-free condition.

In this sense, the cultural dimension cuts across the medical and the social approaches. A drug-free culture may influence physicians and other relevant workers' interventions; similarly, a culture that is bound to the idea of drug addiction as a lifestyle (often inspired by what is generally known as "harm reduction") may be a source of inspiration for social intervention, possibly implemented by professionals who are typically present in the social field (e.g. sociologists and social workers).

Given this general distinction, and since a clear stance should be expressed by everyone addressing these issues, the preference of this author is to adhere to the drug-free approach: the approach of "sobriety" to quote a favourite term of Alcoholics Anonymous. Against this background, some of the main implications of this approach will be considered within the space limitations of this paper.

Choosing a drug-free approach means that one considers drug addiction to be a non-chronic disease, despite being a recurring one. This implies that the objective is to abstain from substance use and to be able to live without drugs throughout time (i.e. living permanently without drugs).

The **first implication** of this choice can be characterised as follows: it is possible to stop taking drugs and drug addicts are not chronic patients. Obviously, this does not mean that relapses do not occur and that the way out of drug addiction is linear. On the contrary, relapses and interruptions are the rule: since these 'incidents' are ever present, this supports the suggestion that drug addiction is not a chronic disease. Unfortunately, as is too often the case, drug addicts are considered unrecoverable (i.e. terminally ill patients).

Clearly, in this type of scenario, the objective is not to improve the quality of life of those who continue to be drug addicts; rather, the objective is to find a way out of drug addiction. In radical terms, the drug-free approach combines the idea of quality of life with the idea of living permanently without drugs (In contrast, the harm reduction approach focuses only on the improvement in the quality of life of the addict, regardless of the drug-free condition and regardless of the impact on the rest of the community at large.

The **second implication** concerns the distinction between different types of drugs. If one opts for a *drug-free* approach, the distinction between soft and hard drugs becomes less significant. This is not to say that there are no differences between substances but, this aspect is irrelevant for those who choose an approach aiming at sobriety and who consider sobriety to possess value.

In this sense, the distinction between different types of drugs is only significant with a view to better targeting interventions, whose main objective should be to achieve a drug- free condition (for instance, in case of drug addicts who do not perceive themselves as such, it would be necessary to implement outreach strategies to act upon this very frequent situation today).

The **third implication relates to** the duration of treatment and its minimum prerequisites. Considering minimum prerequisites first, without going into detail about different modes of intervention, once the drug-free approach is adopted, the aim of the course of treatment should also include abstinence from

drug use and monitoring that abstinence should be maintained throughout treatment. From this perspective, even when alternative medications are employed (e.g. methadone), it is necessary to ensure that no drug be used together with methadone (in fact, this is something more than likely to occur, regardless of the norms in place, as can be testified by people working in this sector). In sum, treatment cannot be compatible with the use of illegal substances.

From this perspective, the course of treatment is of paramount importance, not only because it aims at living permanently without drugs once it has been completed, but also because the subject is in a drug-free condition for the entire duration of the treatment itself (in many therapeutic communities this means that even methadone-based treatment is excluded, with only few exceptions and for a short period of time).

On the issue of treatment duration, in this author's view, drug addiction is a disease (suffering) of the soul (in practical terms, this means that physical detoxification is the least of the problems, and to achieve behavioural change, it is not enough to stay drug-free throughout time, unless it is associated with a certain "internal" dynamic). If drug addiction is considered a disease of the soul, the timing of treatments would be the same as what would be required for psychoanalysis. However, the author is not suggesting that people on drugs need to undergo psychoanalysis (indeed, a competent analyst would never accept to treat anyone on drugs); but it should be recognized that it takes years to quit drug addiction, insomuch as a short-term, analytically-oriented psychotherapy (i.e. not psychoanalysis proper) would normally last no less than three years. Thus, to better clarify the position, it is conceded that "it is true that there is a way out of drug addiction, but it is equally true that it is a long and hard way to go" and that in order to be fruitful, possibly it should be drug-free.

Finally, the **fourth implication** of a drug free approach necessarily regards follow-up. Indeed, choosing this type of approach means that the first aspect to be assessed is abstinence from substance use throughout time – only after this will reintegration and social behaviour be evaluated.

On the issue of assessment in general, and follow-up or outcome evaluation in particular, a key point worthy of further consideration is that results need to be evaluated starting with an assessment of the

drug-free condition, possibly by means of scientific trials, such as hair strand analysis, which makes it possible to trace back up to several months.

In the particular case of outcome evaluation, some fundamental integrations are essential, including programmes' retention factor or, even prior to that, enrolment selection criteria in individual therapeutic programmes.

These are a few of the implications involved in a drug-free approach. Building on extensive field experience (spanning nearly 30 years), the aim of this paper is to provoke more widespread appreciation of this paradigm, and to establish parameters, as a first step towards systematizing and evaluating the evidence (possibly scientific evidence) around the paradigm.

On a cautionary note, this shared knowledge should not be entangled in political or ideological confrontations and reductionism, which too often, especially in the Italian context, have characterised the debate over drug addictions.

The "Beyond the community" research project¹: methodological aspects and findings Phases of the study

The aim of this research project was to examine subjects who were residents in the 'San Patrignano' therapeutic community in Italy. Evaluations were carried out during their therapeutic program and in the following two to four years after the completion of the aforementioned program (*follow-up*). Three Universities were involved in the Project, namely Bologna, Pavia and Urbino.

The first phase of the study, conducted by the Department of Forensic Medicine and Public Health of the University of Pavia, included an evaluation of retention in treatment: specifically, the percentage of subjects who remained in treatment for a predetermined amount of time. Indeed, one of the main parameters that should be considered when carrying out a comparative evaluation of drug abuse treatment facilities is the capacity to keep patients in treatment for a reasonable length of time. To this end, the therapeutic community's archives, with data about residents from 1999, 2000, 2001, and part

of 2002, were examined to calculate the percentage of subjects who were still present in treatment after one, two, and three years. The percentage of those still in treatment after one year, which is the typical standard used in this type of study, was between 61% (1999) and 71% (2001). After two to three years, the percentage of subjects still in treatment was between 52-55%, and 45%, respectively.

The second phase of the research was a *follow-up* study of former community residents. The data set of cases under consideration included only subjects who had been treated at San Patrignano for drug addiction-related problems (the majority had problems related to heroin), were permanent residents of the community for at least 3 years, and who left the community in 2000, 2001, or 2002. Of these, 408 subjects were discharged from the community, whereas 103 subjects left the community without consent. The objective was to evaluate abstinence from drugs after two, three, and four years from the completion of the therapeutic program. Data collection took place between May and November 2004.

Results of hair strand analysis

The evaluation was carried out by means of hair strand analysis, which makes it possible to detect exposure to drugs back to one month per centimetre of hair analyzed.

A considerable difference was found between subjects who left the community with consent and those who left the community without consent, both in terms of participation and results. Of all the subjects who left San Patrignano with the community's consent, on average 61% took part in the study, with a peak of 70% among former residents who left in 2002 (2 year follow-up) and a minimum of 53% among those who left in 2001 (3 year follow-up).

The percentage of subjects involved in the study and who resulted negative for drug use at the time of the research was 78% two years after leaving the community, 62.3% after three years, and 70% after four years.

The percentage of subjects who took part in the study and who resulted negative, but who left the community without consent was considerably smaller (39%) than those who completed the program and left the community with consent.

In a group of 247 participants, hair strand analysis found a total of 50 positive samples for one or more illicit substances. Cocaine was the most frequently used substance (12% of analyzed samples), followed by cannabinoids (8.5%), methadone and opioids (7% and 6%, respectively) and ecstasy derivatives (1%).

Samples testing positive for more than one substance (i.e. opioids, methadone and cocaine, cocaine and cannabinoids) accounted for half of the positive samples (25 cases). The other half resulted positive for just one class of substances (44% were cannabinoids).

Sociological analysis: main results

Features of interviewees

The sociological part of the research involved 252 subjects, who were asked to fill out an interview-questionnaire. The interview-questionnaire consisted of fifty-seven questions, including three open questions. The questionnaires were administered in face-to-face interviews by interviewers experienced in the field of drug addiction, in locations that guaranteed full privacy and a neutral environment.

The interviewees included 200 men (79.4%) and 52 women (20.6%), averaging thirty-six years of age at the time of the interview, and twenty-nine when they entered the community for treatment. The age of the subjects ranged from a minimum of twenty to a maximum of fifty-five years at the time of the interview, and from a minimum of fourteen to a maximum of forty years at the time of entrance into the community.

As highlighted earlier, the prerequisite for taking part in this study was a minimum stay in the community of three consecutive years. In this respect, the group of relevant subjects was divided as follows: 101 subjects (40.1%) had spent between three and four years in the community; 107 subjects (42.5%) had spent four to five consecutive years, and 44 subjects (17.5%) had spent more than five years.

Even those who had spent at least three years in treatment did not necessarily leave "with consent" by the community's staff. In fact, 222 subjects (88.1%) left with consent, whereas 30 subjects (11.9%) left on their own, i.e. against the community staff's recommendations.

With respect to the addiction period of each subject, about 39% had been using illicit substances for more than ten years (97 cases). Of these, fifty one subjects (20%) had been drug addicts for more than sixteen years. About 23% declared that they had been drug addicts for a period of "up to five years".

As to the types of substances used, the majority of interviewees (95%) had used heroin, whereas 53% had used cocaine. It is worth pointing out that more than 12% of the subjects ticked the box "all" as an answer to what substances had been used. 36% had previously been in therapeutic programs in other communities. 17% went to San Patrignano under house arrest or under court order (of these, 59% had a sentence of more than two years).

After leaving the community

Upon leaving the community, 37% of subjects "found a job and were working in one workplace", 19% of subjects "were doing the same job in more than one workplace", 20% of subjects "changed their job once", and 24.5% of subjects "changed their job more than once". Within the reference group, the types of occupations were extremely diverse: 135 different answers were given to the question "what is your current occupation?" "Worker" was the most frequent answer – the only one selected more than ten times.

To the question of "place of origin", 63% of subjects answered that they were living in the same city where they used to live before entering the community, whereas 37% were living in a different city. Furthermore, 33% of subjects (84 cases) were living with their parents (this figure was almost 60% in the period immediately after leaving the community), 46% (115 cases) had a family of their own, and about 20% were living on their own. Among those who "have their own family" (i.e. a different family from their family of origin), 67% of these subjects formed their family after leaving the community, 25% already had their family when they entered the community, and the remaining 8% formed their

family while living in the San Patrignano Community. Of those who built their own family, 63% had at least one child (in 25 cases they had two and 9 couples had three children).

Considering the data presented above, a number of conclusions can be drawn.

- The range of professions (135), within the subject group, was very diverse. It is worth emphasising this result, in that it can be considered as evidence of the correlation between the professional training received within the community and the increasingly diverse skills that are necessary in the current job market. Indeed, it seems likely that the professional development gained within the community provided subjects with more flexibility, i.e. the ability to better adjust to the opportunities encountered in the job market and its specialised sectors.
- Among the 252 subjects who took part in the study, 97 stated that they had been drug addicts for over eleven years. Of these, 51 stated that they had been addicts for more than sixteen years. These 97 subjects would have been classified as chronic and incurable by most standards in Italy and abroad, using traditional approaches to drug addiction. Indeed, harm reduction and similar strategies are often considered the only option for those who have been addicts for ten years or more. This is why it is exceptional that about 60% of these ninety-seven people (with more than eleven years of experience as drug addicts, and some with as much as 20 years) are not only alive and well, but have also stopped taking drugs as a form of emotional anaesthesia, and as a means to relate with the outside world.
- Generally, these subjects would not have been considered viable candidates for starting a "drug-free" program, but could only hope for (at best) a "maintenance" program involving a substitutive therapy. Instead, the introduction of long-term drug addicts into a protected environment, where they were trusted and counted upon in their daily life and in the workplace, proved to be a system that offered tangible, undisputable and scientifically solid results.

When examining the relationships between the subjects and the San Patrignano community, or its associations (which are bound to the community and deal with drug addiction), we see some interesting correlations. A stay of at least thirty-six months contributed to building up of a close "bond" with the community. In the past, this "bond" would have been considered equivalent to a "dependence" on the community, thus ascribing a negative connotation to this feeling. However, in this situation, such a "dependence" on the community derived from a sense of belonging and gratitude towards a place (and people, obviously) by its ex-residents, not from an incapacity to develop autonomy. Sixty subjects did some sort of volunteer work in the fight against drug addiction after completing their program, and thirty-five subjects (about 14%) were continuing to do so at the time of the interview.

The 'relapses'

- In conducting a study based on toxicological analysis of biological samples (hair strands), 'relapses' can be defined as those cases where analysis returned a positive result (in our case there were fifty subjects). In this sense, it is of critical importance to focus on this group of subjects, who represent about 20% of the original sample.
- Among the fifty subjects who "relapsed", thirty-nine (or 17% of the total group numbering 222) had left the community "with consent" and eleven had left the community "without consent" (37% of the "relapsed" group). Among the 39 subjects "with consent", 10 cases resulted positive exclusively to "cannabinoids" (among those who had left the community without consent, only one subject was found positive exclusively to cannabinoids: in this group, relapses involved mostly other substances, such as cocaine, heroin and methadone).
- When dealing with figures and percentages, caution is advised. However, a sociological character profile can be constructed, even though a limited number of subjects were involved in this study.
- The group of relapsed individuals included forty-four men and six women. This might be indicative of a trend: women tended to "relapse" less (11.5% compared to 22% among male subjects). As could be expected, the length of time spent in the community had a substantial

effect on the subjects' probability to relapse. Indeed, the incidence of relapse was almost 28% among those who lived in the community from four to five years, whereas, it dropped to 11% for those who had lived there for more than five consecutive years.

- The sociological profile of this specific group can be further defined by using the information gathered with the interview-questionnaire about the life of subjects "after the community".
- Among those in this group, thirteen people sought help in other communities or at state-run facilities (called Ser.T) after leaving San Patrignano (eleven subjects approached Ser.T services and two subjects went to therapeutic communities. In particular, this group showed a greater level of instability in their jobs (the results showed an increase by 15% in the number of people who gave a positive response to the questionnaire item "changed job more than once").
- Two aspects deserving special attention regard what has been defined as "change of environment". The relapse rate was decidedly higher, more than 11% higher, among those who decided to return to live in the same city where they used to live before entering the community. The relapse rate was also higher among those who returned to live with their family of origin after leaving the community (eight percent higher than those who went to "live on their own", and twelve percent higher than those who "went to live with their own family"). Furthermore, as stated above, the relapse rate was greater among those who went to live with their parents than those who opted for living alone or with the family they created.

To summarize, the data shows that the relapse rate was greater for those who returned to their city of origin and those who returned to live with their parents. A "break" with the place of origin, therefore, appears to be a vital factor in the stabilization of the results that have been achieved during the subjects' therapeutic program. This evidence should be investigated further, steering clear, as always, of simplistic or unidimensional conclusions.

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Conflict of Interest Statement:

I have no financial interest or conflict in writing this paper. I have not been paid to write this paper.

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Marco Castrignanò was also member of the research teams that conducted the following studies.

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