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Recommendations and Guidelines Regarding the Preferred Research Protocol for Investigating the Impact of an Optimal Healing Environment on Patients with Substance Abuse

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ABSTRACT

The addictive disorders affect every aspect of a person's life, and thus the most effective interventions are those that address many or all of these issues. Although the initial evaluation and intake process for addiction assessment is lengthy, this process does give the practitioner an opportunity to provide what can be considered an optimal healing environment (OHE) in treating the addictive disorders. In addition to our traditional medical treatment modalities of pharmacotherapy and psychotherapy, many complementary and alternative treatment modalities address and provide additional support for the holistic approach to treatment and recovery. The important role of spirituality in obtaining and maintaining recovery and sobriety has been recognized for many years. Because one specific treatment is not effective for all people and for all of the addictive disorders, using a holistic approach and individualizing the treatment regimen is the recommended approach to disease intervention and establishing an OHE. There are instruments available for measuring the facility, the staff, and the patient in their contributions to providing an OHE for substance abuse treatment. This paper suggests study design considerations for investigating the impact of an OHE on the results of treatment and specific instruments designed for use in patients with addictive disorders.

INTRODUCTION

The addictive disorders are ubiquitous, and do not discriminate as to who is affected. They affect every aspect of a person's life, and they result in dramatic costs to society with respect to lost work productivity, social disorder, and increased health care utilization.[1,2] According to the 2002 National Survey on Drug Use and Health: National Findings, approximately 22 million Americans (9.2%) above the age of 12 are addicted to alcohol and other drugs. This survey also found that many addicted persons are not obtaining the help they need. An estimated 7.7 million persons, 3.3% of those over the age of 12, needed treatment for a drug problem, and 18.6 million persons, 7.9% of the population, needed treatment for a serious alcohol problem in 2002. Unfortunately, only 1.4 million persons received treatment for drug addiction, and 1.5 million received treatment for alcohol dependence.

The American Society for Addiction Medicine's *Principles of Addiction Medicine,* third edition, describes three major purposes of addiction rehabilitation: (1) to prevent a return to active substance use which would require detoxification or stabilization; (2) to assist in developing control over cravings and urges to use alcohol or other drugs; and (3) to assist in gaining or regaining improved personal health and social function. This improvement in personal health and social function is very important for maintaining sustained sobriety as well as for relapse prevention. With this perspective, the addiction field has moved to a more holistic approach to treatment over the past decade.

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TREATMENT IS EFFECTIVE

In the past 20 years, many of the traditional addiction treatment methods such as methadone maintenance, therapeutic communities, outpatient drug-free treatment, and inpatient treatment have been evaluated multiple times and have been shown to be effective.[3–7] This research has shown that the benefits of addiction treatment extend far beyond the reduction of substance use to include reduction in crime, increased employment, decreased health care utilization, reduction in the transmission of infectious diseases, and improved family and social functioning. The costs of addiction treatment provide a return to society between three- and sevenfold with respect to employment, health insurance, and to society within 3 years after treatment.[8]

A HOLISTIC APPROACH TO TREATMENT

The majority of people who begin addiction treatment have difficulties in many aspects of their lives, and thus often require attention and intervention in multiple arenas in addition to directly addressing their substance use. The severity of these other problems often has a direct impact on the patient's treatment outcome. McLellan et al.,[9] in 1994 showed that the best predictor of substance use after treatment was the severity of the patient's drug or alcohol problem at admission. Better social adjustment at follow-up was negatively predicted by more severe psychiatric, employment and family difficulties at admission, and positively predicted by more psychiatric, family, employment, and medical services provided during treatment.

A recent survey of 162 outpatient and 42 short-term inpatient/residential programs located throughout Minnesota examined whether a greater self-reported severity problem at intake was associated with a greater likelihood of receiving related ancillary treatment services. Life areas examined include medical, psychological, family/social, employment, financial and legal issues. Across treatment settings, those with higher problem severity were significantly more likely to receive ancillary services in areas of medical services, psychotropic medication, family/relationship counseling, financial services and legal services. For other areas, the positive association between problem severity and receipt of services was not always true. Thus, despite consistent relationships between service need and delivery, gaps remain with respect to programs' responsiveness to client needs.[10]

Interventions such as professional marital counseling, psychotherapy and medical care that target addiction-related problem areas can be applied in the usual care setting, and they increase the effectiveness of the chemical dependency treatment.[11] One study examined three different levels of care in an outpatient methadone maintenance treatment program: (1) methadone dispensation alone; (2) methadone plus standard counseling; and (3) methadone, counseling and onsite psychiatric care, medical care, employment counseling, and family therapy. The enhanced program with the additional services showed the greatest improvement in levels of continuous sobriety as well as in employment, alcohol and other drug use, criminal activity, and psychiatric status.[12]

COMPLEMENTARY AND ALTERNATIVE MODALITIES AND THE ADDICTIVE DISORDERS

Although there have been many significant advances regarding the physiologic, neurochemical, and pharmacologic bases of addiction, many physicians and researchers no longer are looking for one "magic bullet." Rather, they are successfully using a combination of therapies, including complementary and alternative medicine (CAM) modalities, to treat the addictive disorders.[13,14]

The 12-step program of recovery, a spiritual and not religious program, is a mainstay in many treatment facilities. The success of the 12-step programs has prompted incorporation of spirituality into the field of addiction medicine. Thus, there has been movement from the bio-psycho-social model into the bio-psycho-social-spiritual model of evaluation and treatment. The Joint Commission on Accreditation of Hospitals has recognized the central role that spirituality plays in the addictive diseases and in their recovery, and since the early 1990s has mandated that each intake assessment for chemical dependency include a spiritual assessment.

With the exception only of spirituality in the form of the 12-step programs, acupuncture treatments are the most widely used CAM treatment for substance abuse.[14] Acupuncture has been successfully used in the treatment of alcohol abuse with resulting increased program retention and decreased use of alcohol and fewer admissions for detoxification.[15,16] More recent studies on acupuncture for alcohol abuse have not shown any statistical benefit. However, the average length of time in treatment decreased from 28 days in previous acupuncture studies to 10 days at the time of study completion. This raises the issue of inadequate dose of acupuncture treatment received as reason for lack of benefit, rather than inefficacy of acupuncture.[17] Although clinical use of acupuncture for the treatment of cocaine abuse has expanded, the research has shown no positive outcomes. This raises the question of whether we have discovered the appropriate methodology to research this issue.[18,19]

Meditation has a long history of successful use in addiction treatment. Benson was one of the first researchers to find meditation beneficial for alcohol use.[20] Subsequently, there has been an abundance of literature on various forms of meditation and mindfulness and the addictive disorders.[21–26] Meditation consistently has been shown to be beneficial in reducing stress and for increasing a sense of well-being and contentment. These are feelings that counter drug

craving, and they help to support abstinence. Mindfulness meditation taught in the form of mindfulness-based stress reduction (MBSR) has been shown to be effective with a high rate of acceptance by patients in many disorders such as pain, psoriasis, cardiac disease, organ transplant and breast carcinoma.

Yoga has been used for treating the addictive disorders for many years, both in the United States and in India.[21,27,28] Yoga traditions incorporate meditation practice with the physical postures or *asana,* specific breathing practices or *pranayama,* and various lifestyle alterations including dietary and behavioral modification. Substance use creates a mind–body dissociation that the physical practice of the yoga *asanas* helps to reverse. Hatha yoga was shown to be as effective as group dynamic psychotherapy in preventing relapse for patients in an inner city methadone maintenance clinic.[29]

The recent popularity of yoga in the general public has helped facilitate acceptance of yoga as an intervention. Rigorously designed studies need to be completed regarding the efficacy of yoga in treating the addictive disorders. It may be difficult to determine exactly which component of a yoga intervention provides a specific benefit, because there are multiple different interventions possible in using a yoga practice. The yogic lifestyle includes a mostly vegetarian diet, exercise, meditation, and peaceful living and interactions with fellow human beings. Even in the MBSR work, the intervention consists of a combination of mindfulness meditation, yoga *asana,* and the body scan.

There should be a role for various CAM modalities in the optimal healing environment (OHE) setting as adjunct to the traditional interventions. CAM modalities often address an underlying spiritual component contributing to addictive disorders, and they also help facilitate increased resiliency and self-efficacy for the patients. These qualities help in relapse prevention.

STUDY DESIGN

Studying the impact of OHE in substance abuse may require various study designs. The depth and breadth of an OHE context, coupled with the universal effect addiction has on the person's life, precludes studying all aspects of both OHE content and addiction in one analysis set. Yet, it is important to collect data on all of these aspects to completely evaluate the success of implementation of on OHE, and to assess the full impact of the OHE on addiction.

The addictive diseases affect every segment of the population, and thus the clientele are wide and varied in their characteristics. A treatment that is specifically appropriate for an inner-city population may not be as beneficial in a rural area. Many of the treatment centers are very specialized in their patient population, and would not be directly comparable with each other. In addition, there are many varieties of treatment facilities ranging from inpatient programs to halfway houses. Each environment is unique and cannot necessarily be combined.

Programs also have different orientation toward abstinence. These range from harm reduction models, to complete abstinence where pharmacotherapies such as methadone are forbidden, to models of maintenance pharmacotherapy. Some maintenance programs have a dose cap, while others are flexible and do not have a maximum methadone dose. Different levels of service are also seen between different maintenance and treatment facilities. Some maintenance clinics solely dispense medication, others have counseling available and others are full-service programs. Each type of program will have a unique approach to the management of addiction, and varying rates of success. Studies on various subsets of OHE implementation could result in different outcome measures according to the audience segmentation. For example, administrators may be more interested in hidden barriers to implementing OHE, and medical directors may be interested in decreased use of narcotic analgesics from CAM pain modalities.

BASIC ELEMENTS FOR AN OHE

We suggest the following as the ideal basic elements of an OHE in substance abuse treatment. To have these elements in place and operational at the study onset would facilitate complete assessment of the OHE environment. Variables that are important for OHE assessing include:

- An awareness of the importance of a healing environment in patient care by at least one high-ranking administrator/supervisor
- An awareness of the importance of a healing environment on patient care by the clinic staff, including the receptionist
- Willingness to facilitate change in current behavior
- Respectful manner of treating patients/clients
- Physical sense of safety while present in the facility
- Cleanliness of facility
- Areas for privacy available for counseling and consultations
- Access to medical care
- Access to dental care
- Access to onsite psychiatric care
- Access to vocational counseling
- Medication dispensation for medications additional to those for the addictive diseases
- Support groups onsite
- Continuity of care between counselor and patient/client
- Thorough intake process to establish baseline needs assessment for obtaining/maintaining recovery
- Ongoing counselor access if needed
- Methods of following patients' progress sequentially through an extended period of time

- Continuity and communication between medical director and primary physician
- Communication between medical director and consultants
- Adequate interpreter services
- Ability of the system to be flexible in accommodating treatment assessments and requirements for patients with varied needs.

VARIABLES IN THE PATIENT'S LIFE

All of the following elements of the patient's life need to be addressed in the OHE setting. A thorough intake process, using validated and verified instruments, will facilitate obtaining information in all of these areas.

- Family: level of support, proximity to patient
- Friends: number of close contacts, number of close contacts who are sober
- Community: supportive of sobriety, level of engagement of person into the various communities, level of commitment to the community as a member
- Religious affiliation: any formal association, how often services attended
- Level of spirituality: how the person obtains support and strength, reestablish personal values, living in concert with their values, meaning of life/ life's purpose concept, any specific spiritual practice
- Employment history/capabilities: past employment, current employment, Social Security status, disability
- Legal status: incarcerations, probation
- Lifestyle: exercise, diet, smoking, mind–body interventions
- Mental/emotional condition: presence of axis l and axis ll disorders, thought content
- Medical needs assessment: chronic disease conditions, routine preventive medicine assessment, dental health assessment.

SPECIFIC INSTRUMENTS RECOMMENDED

Instruments that measure patient satisfaction include the Press-Ganey questionnaire. Instruments for measuring an institution's readiness for change (organizational readiness for change [ORC]) include the Texas Christian University ORC questionnaire, which was developed, validated, and verified specifically for use in addiction clinics and treatment centers. Texas Christian University has formulated different questionnaires which measure organizational readiness for change/survey of organizational functioning, survey of program training needs, services tracking records, survey of program clients and a program identification/description questionnaire.

Other specific instruments recommended include:

- Addiction Severity Index (ASI)
- Structured Clinical Interview for *DSM-IV* (SCID)
- South Oakes Gambling Screen
- Michigan Alcohol Screening Test (MAST)
- Attention Deficit Disorder (ADD) Rating form
- Short Form (SF)-36
- Hamilton Depression Rating Scale-17
- Beck Depression Inventory
- Texas Christian University (TCU) Survey of Organizational Functioning
- TCU/CESI Pretreatment Survey of Clients
- TCU Survey of Program Training Needs
- TCU Services Tracking Record
- TCU Program Identification and Descriptor

RECOMMENDATIONS FOR PRIMARY DESCRIPTOR AND OUTCOME VARIABLES

The quantity and quality of OHE attributes present in the setting should serve as a marker for the support of the individual in their healing process. They should be able to separate out the inpatient/outpatient/clinic settings, separate out different levels of care (full service, medication only) and separate out different concepts regarding the orientation toward abstinence. Among the outcome variables are these categories:

1. **Physical environment level**

- Size of space
- Temperature
- Cleanliness
- Level of perceived safety by staff and patients in the setting
- Handicapped accessible
- Clarity of signs
- Sound and noise decibel level
- Art and architecture.

2. **Organizational atmosphere**

- Clarity of mission and goals
- Staff cohesiveness
- Staff autonomy
- Openness of communication
- Stress level
- Level of readiness for change
- Adequacy of office space
- Staffing to patient ratio
- Training resources
- Computer access.

3. Staff atmosphere

- Autonomy
- Stress
- Cohesion
- Adaptability
- Job satisfaction
- Sick time.

4. Patient/client level

- Psychologic scales: self-esteem, depression, anxiety, decision making, clinic attendance, Alcoholics Anonymous (AA)/other self-help group attendance, hostility, risk taking
- Social functioning: employment, family interaction/support, criminal behavior
- Treatment engagement: compliance with treatment plans, satisfaction with care, counseling rapport, participation in AA/other self-help groups, number of days abstinent, urine toxicology screens, amount of drugs used when not abstinent.

5. Amount of sequential change successfully instituted by the program toward OHE

- Overall program success
- Staff implementation success
- Patient perceived change toward OHE goals.

SUGGESTIONS FOR THE SUBJECT AND THE CONTROL GROUPS

Considering the abovementioned divergent populations in treatment facilities as well as the varied patient population and characteristics, directly comparing all programs will not yield externally valid results. To counter this divergent population, each center can serve as their own control. The outcome measurements will derive from taking a baseline assessment of the unit/physical plant, staff attitudes and behavior, and client/patient perspectives followed by serial replications of the instruments.

The inclusion/exclusion criteria can be separated into facility criteria and patient criteria.

Facility inclusion criteria include:

- Outpatient treatment facility that treats addictive disorders
- Inpatient treatment facility that treats addictive disorders
- Halfway house that treats addictive disorders
- Therapeutic community that treats addictive disorders
- Addiction clinics that treat addictive disorders.

Facility exclusion criteria include:

- A facility that does not wish to participate
- Correctional institutions
- Patient inclusion criteria:
- Resident of treatment facility participating in OHEstudy
- Clinic member of treatment facility participating in OHE study
- English language proficiency (because most instruments have not yet been validated in multiple foreign languages)
- Patient exclusion criteria:
- Acute or chronic psychosis
- End-stage hepatic or renal disease
- Patients who decline study participation.

STATISTICAL CONSIDERATIONS

The following statistical issues need to be addressed in designing the study:

- Missing data within the same subject on many variables, multiple values on one variable, or across all subjects on one variable
- The combination of qualitative data and quantitative data
- Longitudinal data such as the time to abstinence, the interaction between time to abstinence and the degree of abstinence requires special attention
- The use of repeated measurements
- Statistical methods to address ordinal data, nominal data and continuous data.

INVESTIGATOR TEAM

The investigator team would include the principal investigator (PI) and coinvestigators. Each treatment facility will require an investigator for implementing the OHE recommendations and for administering the instruments. During the implementation of the OHE interventions, it is essential to have support from the administration and the nursing and counseling supervisors to avoid resistance to change.

- Administrators: implementing procedure changes required, approving expenses associated with initiation/implementation of the OHE
- Physicians: open to the holistic approach to treatment and supportive of OHE implementations
- Nurses: overseeing effective implementation of OHE for in-patient and often outpatient treatment centers
- Counselors: direct contact with the person through the treatment process
- Allied health practitioners/CAM practitioners: administering modalities such as acupuncture, massage, energy therapies, meditation, body movement therapies would ideally be included in the OHE system
- Statisticians: study design and ongoing data analysis.

SUMMARY

The addictive disorders affect every aspect of a person's life, and thus the most effective interventions are those which address many or all of these issues. Although the intake process and initial evaluation of a person with addiction is very lengthy, this process does give the practitioner an opportunity to provide what we would now term an OHE in treating the addictive disorders. In addition to the traditional medical treatment modalities of pharmacotherapy and psychotherapy, many of the CAM modalities address and provide additional support for the holistic approach to treatment and recovery. Because there is not one specific treatment that is effective for all people and for all of the addictive disorders, using a holistic approach and individualizing the treatment regimen is the recommended approach to disease intervention. Designing a clinical research study for investigating the impact of an OHE on patients for substance abuse is a goal that can be achieved with current study design and outcome measuring instruments.

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