

Appendix

Overview of Project Match

Many of the strategies described in this manual are those used in Project MATCH,¹²³ an NIAAA-sponsored, multisite collaborative study evaluating patient-treatment matching in alcohol-dependent individuals. As described in detail elsewhere,¹²⁴ Project MATCH involved two independent but parallel matching studies, one with clients recruited from outpatient settings (N=954), the other with clients receiving aftercare treatment following inpatient treatment (N=774). Treatment was provided in 10 sites affiliated with 8 clinical research units (5 outpatient, 5 aftercare) to provide geographic as well as client heterogeneity.

Subjects

Inclusion and exclusion criteria were used to define a heterogeneous sample of alcohol patients who were treatable within the limits of weekly outpatient or aftercare therapy, and thus were comparatively broad. Inclusion criteria included:

- Current DSM-III-R diagnosis of alcohol abuse or dependence
- Alcohol as the principal drug of abuse
- Drinking during the 3 months prior to study entry
- Minimum age of 18
- Sixth grade reading level
- Absence of legal or probation/parole requirements that might interfere with participation in the protocol.

Exclusion criteria included:

- Current DSM-III-R diagnosis of sedative, stimulant, cocaine, or opiate dependence
- Intravenous drug use in the past 6 months
- Current danger to self or others
- No clear prospects for residential stability
- Inability to identify at least one locator for assistance in followup tracking

- Severe organic impairment or acute psychosis
- Planned involvement in a more intensive form of treatment for alcohol problems than that provided by MATCH.¹²³

Subjects were assessed at baseline and at 3-month intervals after randomization to treatment (i.e., 3, 6, 9, 12, and 15 months).

Forms

Subjects were screened to determine their need for medically supervised detoxification before entering treatment. Those who agreed to outpatient detoxification were required to read and sign a contract (see sample) that spelled out the details of the agreement. All subjects were required to read and sign consent forms (see sample) before participating in treatment.

Treatments

Subjects were randomly assigned to one of three manual-guided psychosocial treatment conditions: Twelve-Step Facilitation (TSF), Cognitive-Behavioral Coping Skills Training (CBT), or Motivational Enhancement Therapy (MET). Treatments were delivered in individual sessions over 12 weeks, with weekly sessions for CBT and TSF. MET consisted of four sessions, occurring during the first, second, sixth, and twelfth weeks.

Treatments were selected on the basis of their meeting several criteria,¹²⁴ including:

- Documentation of clinical effectiveness
- Potential for revealing matching effects
- Applicability to the existing treatment system
- Distinctiveness from comparison treatments
- Feasibility of implementation within the constraints of a clinical trial.

Cognitive Behavioral Therapy

CBT¹²⁵ is based on the principles of social learning theory and views drinking behavior as functionally related to major problems in the individual's life. It posits that addressing this broad spectrum of problems will prove more effective than focusing on drinking alone. Emphasis is placed on overcoming skill deficits and increasing the individual's ability to cope with high-risk situations that commonly precipitate relapse, including both interpersonal difficulties and intrapersonal discomfort, such as anger or depression. The program consists of 12 sessions with the goal of training the individual to use active behavioral or cognitive coping methods to deal with problems, rather than relying on alcohol as a maladaptive coping strategy. The skills also include

Sample outpatient detoxification contract

Patient's Name: _____

Physician: _____ Clinical Coordinator: _____

Nurse: _____

I have already agreed to participate in the _____ alcoholism treatment program. I understand that I am to be medically detoxified from alcohol on an outpatient basis. I am being treated with _____ for signs and symptoms of withdrawal. I understand that this medication may cause drowsiness and/or impair my ability to operate machinery or a motor vehicle. I also understand that it can be dangerous to drink alcohol while taking this medication.

Some of the following symptoms may occur during the withdrawal process:

- shakiness or trembling
- excessive sweating
- extreme nervousness
- restlessness

Other more serious symptoms of withdrawal are:

- recurrent vomiting
- diarrhea—more than three loose bowel movements in 24 hours
- persistent or severe headaches
- any change in: vision, hearing, skin sensations

If you begin to experience any of these symptoms, contact the Program Staff immediately. Dial xxx-xxxx and ask for (nurse). If she is unavailable, call Dr. (Project Coordinator), at yyy.yyyy. If it is after the hours of 8 a.m. to 5 p.m. Monday – Friday, a weekend, or neither of the other two contact people are available, please dial zzz-zzzz and ask the operator to page Dr. (name). If you feel that your medical symptoms need immediate attention, please go to the nearest Emergency Room.

I agree to identify another person _____, phone number _____

who will assist me in monitoring the prescribed medication. Alternatively, I agree to come in for daily appointments for evaluation of withdrawal and medication monitoring, if this is deemed medically necessary. I agree not to ingest any alcohol during detoxification period.

I understand that should my medical condition worsen, I will be asked to seek admission to an inpatient alcohol detoxification facility, where my medical status can be monitored more closely and appropriate treatment provided.

I have read and understand the above statements and I agree to abide by them.

Client's Signature _____ Date _____

Physician Signature _____ Date _____

**Sample informed consent form for participation
in treatment-matching outpatient study**

I, _____, agree to participate as a subject in a research project studying how different people benefit from two different types of outpatient treatment for problems associated with the use of alcohol. I understand that the study will involve treatment consisting of 26 weekly group sessions. Treatment will be based on one of the following approaches: (1) group therapy to foster insight into the way that I relate to other people or (2) group therapy based on learning new coping skills. Which type of treatment I receive will be decided by the investigators or on a random basis, but I understand that I will not be told which method of assignment is being used in my case.

I understand that if detoxification appears necessary I will receive a medical evaluation and may be detoxified on an outpatient basis prior to entry into the study; I will be responsible for the cost of medications for outpatient detoxification. If inpatient detoxification is recommended, the costs for that will be my responsibility. I understand that I will also be responsible for the cost of any medical care recommended by the Project's Medical Director or for the cost of more intensive treatment that would be recommended if my condition worsens in spite of the treatment I receive in this study.

As part of the research evaluation, I will be asked to give samples of my breath and blood for analysis at the beginning of the study. I will also be interviewed and asked to fill out questionnaires concerning many different aspects of my personal history and pattern of alcohol and drug use. This will require a few hours of my time, on two different occasions. In order to be assigned to treatment, I need to be sober during the evaluations.

Each week, before group therapy, I will be given a breath test and sometimes a brief questionnaire. At the end of the study I will be asked to fill out some more questionnaires and be interviewed again. This will take about two hours. Additional followup interviews will be conducted at 3, 6, 9 and 12 months after the end of my treatment. I will also be asked to give samples of blood and urine at some of the followup visits.

I have been told that I will receive compensation for the followup visits according to this schedule:

Interview at the end of treatment	\$50
Telephone interview 3 months later	\$20
Interview 6 months after treatment	\$50
Telephone interview 9 months after treatment	\$20
Interview 12 months after treatment	\$50

I hereby give my consent for the audiotaping of treatment sessions for the sole purpose of evaluating the treatment I receive.

I understand that a person identified by me (e.g., spouse, child, parent, or other relative or friend) will be asked about my well-being by a member of the evaluation staff. This individual will be called and asked about the presence or absence of any problems with alcohol and about my social adjustment. I understand that the purpose of these contacts will be to have an ongoing assessment of the effects of treatment in my case. I also agree to provide names of several people who will know my whereabouts over the next 18 months so that they may help the research staff to locate me if I change my address without notice. If no one knows my whereabouts, I agree that public information sources, such as motor vehicle records, telephone directories, Social Security Office information, or public access locator services, may be used to locate me. I am providing my Social Security number for later use in locating me, if necessary. I understand that this will be handled in a confidential manner, like all other information I provide.

Risks. We can foresee very few risks that might occur if you decide to participate in the study. The treatment you will receive will not differ much from what you would receive at this clinic if you decide not to participate in the study.

(continued)

Sample informed consent form (continued)

There is minimal risk associated with giving blood samples. Your blood will be drawn by trained technicians. It may hurt slightly or leave a black and blue mark from the needle stick. The amount of blood taken (2 vials) will be that usually required for regular medical laboratory tests.

We will make every effort to ensure your confidentiality. Your name will not appear in any publication or be released to anyone without your written consent. Information provided to the research staff will be kept strictly confidential and will not be shared with the person who provides the treatment to you. Also, the content of the interviews with you will not be revealed to your family, and the content of the interview with your family member or friend will not be revealed to you.

Benefits. Your participation in this study may benefit you in several ways, such as continued abstinence from alcohol and/or other improvements in your life. Another benefit is that the normal fees for the treatment program will be waived. Even if there are not specific benefits for you personally, this study might provide information that can be used to help other subjects in the future.

Subject Obligations. We would like you to tell us about any times you use any alcohol or other psychoactive drugs while in the study. We know that people are not perfect and that stopping alcohol use can be quite hard. In order to be helpful to you, we simply need to know about your alcohol use. The urine and breath tests enable us to be certain of our results. The only ways you might be dismissed from the study if you repeatedly do not show up, are repeatedly intoxicated at the treatment sessions or at the time of the interviews, and if you are untruthful about your alcohol use. Your obligation to the study is to do your best to stop using alcohol, to be honest about yourself and your problem, and to be available at the right times for tests and group therapy.

Other Information. One of your therapists or a therapist on call will be available by calling the Project Coordinator, (name), at (phone #), or the Principal Investigator, (name), at (phone #). You are encouraged to call at any time with questions or problems.

You are free to choose not to participate. If you do become a subject you are free to withdraw from this study at any time. If you decline to participate or if you withdraw, it will not adversely affect your relationship with this clinic or the doctors here; a list of alternative treatment providers is available upon request, and, if you wish, the staff will make recommendations to assist you in making your choice from among them.

Please feel free to ask about anything you don't understand. Please consider this research and the consent form carefully before you agree to participate. You may take as much time as necessary to think it over.

I, the undersigned, have understood the above explanation and give consent to my voluntary participation in this research project. I have received a copy of this consent form.

Date: _____ Location: _____

Social Security # _____

Signature of Subject: _____

Witnessed by: _____

Investigator/Person Obtaining Consent Signature: _____

a means of obtaining social support critical to the maintenance of sobriety.

Twelve-Step Facilitation

TSF¹²⁶ is grounded in the concept of alcoholism as a spiritual and medical disease. The content of this intervention is consistent with the 12 Steps of Alcoholics Anonymous (AA), with primary emphasis given to Steps 1 through 5. In addition to abstinence from alcohol, a major goal of the treatment is to foster the patient's commitment to participation in AA. During the course of the programs' 12 sessions, patients are actively encouraged to attend AA meetings and to maintain journals of their AA attendance and participation. Therapy sessions are highly structured, following a similar format for each week that includes symptoms inquiry, review and reinforcement for AA participation, introduction and explication of the week's theme, and setting goals for AA participation for the next week.

Motivational Enhancement Therapy

MET⁶¹ is based on principles of motivational psychology and is designed to produce rapid, internally motivated change. This treatment strategy does not attempt to guide and train the client, step by step, through recovery, but instead employs motivational strategies to mobilize the client's own resources. MET consists of four carefully planned and individualized treatment sessions. The first two sessions focus on structured feedback from the initial assessment, future plans, and motivation for change. The final two sessions at the midpoint and end of treatment provide opportunities for the therapist to reinforce progress, encourage reassessment, and provide an objective perspective on the process of change.

Therapist Training, Supervision, and Monitoring

Extensive efforts were made to provide Project MATCH treatments at a high and consistent level of integrity and quality through the use of a comparatively elaborate protocol for selecting and training therapists, as well as monitoring their implementation of study treatments throughout the protocol. For example, the following selection criteria were required of MATCH therapist candidates:

- Completion of a master's degree in counseling, psychology, social work or a closely related field, or certification as an alcoholism counselor
- At least 2 years of clinical experience after completion of degree or certification
- Submission of a taped clinical work sample to the Principal Investigator at each clinical research unit and to the Coordinating Center for review

- Commitment to and experience with the MATCH treatment that the therapist would be conducting
- Experience treating alcoholics or a closely related clinical population.

By setting uniform training and experience standards across conditions, while also seeking credible therapists representative of the usual practitioners of the study treatments, these selection criteria were intended to strike a balance between comparability of therapists across treatment conditions and generalizability of findings to the broader field of alcohol treatment.¹⁰⁵

Training and supervision of Project MATCH therapists was centralized at the Coordinating Center using methods developed in previous large-scale collaborative studies.¹²⁷ All therapists attended a training seminar that included:

- Background and rationale for Project MATCH
- Detailed review of the pertinent treatment manual
- Review of taped examples of treatment sessions
- Practice exercises
- Extensive discussion of unique issues related to treating clients in matching studies, particularly consideration of challenges related to treating a heterogeneous patient population while conforming to manual guidelines.

Each therapist was then assigned a minimum of two training cases, which were conducted following the MATCH protocol and supervised by Coordinating Center supervisors in weekly individual sessions, in addition to weekly group supervision that was provided at each of the research units.

After certification, therapist adherence and competence were monitored through several sources during the main phase of the study.

- First:
 - All sessions were videotaped and sent to the Coordinating Center, where one-third of each subject's sessions were reviewed by the Yale-based supervisors.
 - Telephone supervision was provided monthly by the Coordinating Center supervisors and supplemented with weekly onsite supervision at each Clinical Research Unit.

All monitored treatment sessions were rated for therapist skillfulness, adherence to manual guidelines, and delivery of manual-specified active ingredients unique to each approach. These ratings were sent monthly to the Project Coordinators at each site to alert local supervisors of therapist drift. Therapists whose performance deviated in quality or adherence to the manual were “redlined” by the Coordinating Center supervisors. Redlined therapists were not assigned new subjects and the frequency of their supervision was increased from monthly to weekly until the therapist’s performance returned to acceptable levels.

■ Second:

- Session tapes were evaluated for therapist adherence and competence by independent raters who were blind to treatment conditions using the MATCH Tape Rating Scale, which assesses therapist behavior of 5 types: CBT techniques, TSF techniques, MET techniques, therapy structure, and nonspecific techniques.
- Compliance was also monitored by a study-wide treatment-tracking system, which assessed sessions attended (treatment dose) and other aspects of compliance.