The Cannabis Youth Treatment (CYT) study is a multi-site randomized field experiment examining five outpatient treatment protocols for adolescents who abuse or are dependent on marijuana. The purpose of the CYT project is twofold: (a) to test the relative clinical effectiveness and cost-effectiveness of five promising interventions targeted at reducing/eliminating marijuana use and associated problems in adolescents; and (b) to provide validated models of these interventions to the treatment field. The description of the CYT project's structure includes a detailed list of study questions addressed by the study and an overview of the five experimental treatment interventions. The presentation includes discussions of the project's inclusion/exclusion criteria for the target population, research design, data sources, timeline for project and current status. The presentation concludes with an outline of the project's immediate next steps. (Contains 35 references.) (GCP)
Treatment of Adolescent Marijuana Abuse: A Randomized Clinical Trial
Presentation 1: Structure of the Cannabis Youth Treatment Study

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Presented at the 107th Annual Convention of the American Psychological Association at Boston, Massachusetts, August 1999
8:00 a.m. to 9:50 a.m., Saturday, August 21
This paper provides an overview of the Cannabis Youth Treatment Project. The study aims to a) test the relative and cost-effectiveness' of five promising treatment interventions and b) provide validated models of these interventions to the treatment field. More specific hypotheses address clinical and cost-effectiveness issues.

The target population is adolescents ages 12 to 18 years with cannabis use disorders of abuse or dependence as defined by the American Psychiatric Association (1994) who are appropriate for treatment in outpatient settings.

The overall design includes five treatment interventions and four treatment sites. In each site, approximately 150 adolescents are randomly assigned to one of three treatment conditions.

Participants complete a comprehensive biopsychosocial battery at intake. Supplemental scales measure aspects of personality, coping, parenting, and the peer group. A subset of these assessments is repeated at three, six, and nine months post-randomization. Urine screens are used to detect recent cannabis and cocaine use. A "research collateral" -- most often a parent -- completes a parallel set of questions about the participant’s behaviors at intake, three, and six months post-randomization. The Drug Abuse Treatment Cost Analysis Program is used to evaluate the costs and cost-effectiveness' of the interventions.
Introduction and Purpose

The Cannabis Youth Treatment (CYT) study (Dennis, Babor, Diamond, Donaldson, S.Godley, Tims, et al., 1998) is a multi-site randomized field experiment examining five outpatient treatment protocols for adolescents who abuse or are dependent on marijuana. Organized as a cooperative agreement, the study is funded by the Substance Abuse and Mental Health Services Administration (SAMHSA) and its Center for Substance Abuse Treatment (CSAT) under the Department of Health and Human Services (DHHS). CYT is one of the largest adolescent substance abuse treatment experiments ever undertaken and a key component of U.S. Secretary Donna Shalala’s “Youth Initiative” to address rising rates of marijuana use among adolescents in the United States. The three-year study (10/97-9/00) is being conducted in collaboration with Chestnut Health Systems (CHS) in Bloomington and Madison County (MC), IL; the Alcohol Research Center (ARC) of the University of Connecticut in Farmington, CT; Operation PAR in St. Petersburg, FL; the Child Guidance Center (CGC) in Philadelphia, PA; and the University of Miami in Miami, FL. Four treatment sites are located at ARC, PAR, CHS-MC, and CGC, while the coordinating center is housed at CHS in Bloomington, IL. Staff of the University of Miami serve in a consulting role.

The purpose of the CYT project is twofold: (a) to test the relative clinical effectiveness and cost-effectiveness of five promising interventions targeted at reducing/eliminating marijuana use and associated problems in adolescents; and (b) to provide validated models of these interventions to the treatment field.

Background Research

After declining through the 1980s, use of tobacco, alcohol, and marijuana among adolescents rose again into the 1990s. In 1997, marijuana use among 10th and 12th graders peaked at levels not seen for at least a decade in terms of lifetime (42-50%), annual (35-38%), past month (20-24%), and daily use (4-6%). Among 8th graders, peak use occurred in 1996 (lifetime-23%, annual-18%, past month-11%, and daily-2%). Within the past two years, marijuana use among adolescents appears to have begun to decline, although still remains at disturbingly high levels (Johnston, O'Malley, & Bachman, 1998). Marijuana is the primary substance of abuse among adolescents entering treatment (OAS, 1997) and the leading substance mentioned in adolescent emergency admissions and autopsy reports (OAS, 1995a). It is also believed to be one of the major contributing factors to the leading causes of violence and death among adolescents: motor vehicle crashes (30%), homicide (20%), suicide (13%), and other unintentional injuries (10%) (CDC, 1997; McKeown et al., 1997; OAS, 1997).

Marijuana and alcohol use are highly intertwined, according to data from the National Household Survey on Drug Abuse (OAS, 1995b). While 60 percent of adolescents aged 12-17 were not actively using in the past year, 24 percent were using alcohol, 15 percent were using both alcohol and marijuana, and 1 percent were using marijuana only. Moreover, 2 out of 3 weekly adolescent users were using both alcohol and marijuana (McGeary, Dennis, French, & Titus, 1999).

High rates of marijuana use among adolescents are related to many other problems. A recent investigation (Dennis & White, in press; McGeary, Dennis, French, & Titus, 1999) found that, relative to adolescents who do not use, weekly marijuana and alcohol users were four times more likely to report symptoms related to conduct or attention deficit disorders (57% vs. 13%), to have dropped out of school (25% vs. 6%), been in a fight (47% vs. 11%), or been engaged in illegal activity (69% vs. 17%). Weekly users were over eight times more likely to have stolen from a store (41% vs. 4%), stolen from someone else (33% vs. 4%), or to have damaged property (31% vs. 3%).
During the past year they were, consequently, also much more likely to have been to an emergency room (33% vs. 17%), been arrested (23% vs. 1%), or to have been on probation (16% vs. 1%).

Long-term implications of early marijuana use are coming to light. Analyses of the incidence data from the 1995 National Household Survey on Drug Abuse (NHSDA) (Dennis & McGeary, 1999; Dennis, McGeary, French, & Hamilton, 1999) reveal that the odds of lifetime users having one or more symptoms of marijuana dependence as an adult are six times higher for those who first used under the age of 15 than for those starting over the age of 18 (24% vs. 4% reporting 1+ symptoms of dependence as an adult).

Despite the rise in substance use, range of related problems, and potential for long-term consequences, fewer than 10% of adolescents with past-year symptoms of dependence have ever received treatment (McGeary, Dennis, French & Titus, 1999). Of those who do, over two thirds are treated in outpatient settings (OAS, 1997). While information is still emerging about adolescent treatment effectiveness, there is considerable tension between efforts to develop short-term, cost-effective treatments and findings that 50 percent or more of adolescents relapse to marijuana or alcohol use within the first 3 months after discharge (Brown & Vik, 1994; Brown, Vik, & Creamer, 1989; Catalano, Hawkins, Wells, Miller, & Brewer, 1991; Kennedy & Minami, 1993). There are, however, several promising options for improving treatment effectiveness by focusing on motivational enhancement, relapse prevention, problem solving, coping strategies, case management, family support, family therapy, and working with the adolescent’s concerned others to change their environments (Azrin, Donohue, Besalel, Kogan, & Acierino, 1994; Brown, Myers, Mott, & Vik, 1994; Graham, Annis, Bret, & Venesoen, 1996; Kadden, Cooney, Getter, & Litt, 1989; Liddle et al., 1995).

Study Questions

The target population is adolescents with cannabis use disorders of abuse or dependence as defined by the American Psychiatric Association (1994) who are appropriate for treatment in outpatient settings. The initial questions addressed by the cooperative agreement are:

1) What are promising models of outpatient treatment for adolescents with cannabis use disorders?
2) What are the characteristics and co-occurring problems of participants presenting for treatment?
3) What do we know about the costs and/or cost constraints on adolescent treatment?

Following completion of treatment of all participants, the cooperative agreement hopes to answer the following additional questions:

4) What level of behavioral change and/or family involvement occurred during treatment?
5) What services do participants actually receive and to what extent did they receive the services specified in the manual?
6) Do the treatment models differ in terms of their effectiveness during and after treatment in terms of marijuana use, alcohol use, behavior/cognitive problems, school problems and illegal activity?
7) What were the average accounting and economic costs of providing each treatment model to the participant?
8) Relative to the briefer and less expensive intervention used across sites, do the more intensive/expensive interventions tested in each site vary in terms of their cost-effectiveness in terms of days of marijuana use, alcohol use, behavior/cognitive problems, school problems and illegal activity?
9) Do the clinical effectiveness, cost and/or cost-effectiveness appear to vary for specific subpopulations (e.g., by gender, substance use severity, level of criminal justice system involvement, comorbid mental health issues, environmental problems).
Treatment Interventions

The five experimental treatments are organized under two research arms, both comparing a strong five-session brief intervention with two more intensive interventions. In the “incremental arm,” each subsequent intervention builds upon the features of the previous intervention. Treatments in the incremental arm include: a brief five-session treatment (MCB5; Sampl & Kadden, 1998); a second intervention in which additional group sessions are added to the five-sessions (MC12; Webb, Scudder, & Kaminer, 1998); and a third intervention in which family sessions are added to the second intervention, thereby creating a longer-term group intervention with family support (FSN; Bunch, Hamilton, Tims, Angelovich, & McDougall, 1998). In the “alternative arm,” the same brief five-session intervention is compared with: a longer individualized approach for the second condition (ACRA; Meyers, Smith, S. Godley, M. Godley, & Karvinen, 1998); and an individualized family therapy approach for the third (MDFT; Liddle, 1998). While both of the latter involve more exposure/resources, they also involve different approaches. Further description of the five treatment interventions is presented in a companion paper for this symposium.

Inclusion/Exclusion Criteria

Our target population is adolescent cannabis users appropriate for outpatient treatment. To be included in the study a participant must meet all of the following criteria: a) be between the ages of 12 and 18 years old, b) meet criteria for current DSM-IV diagnosis of cannabis abuse or dependence, c) have used marijuana in the past 90 days (or 90 days prior to being in a controlled environment), and d) meet ASAM (1996) patient placement criteria for level I (outpatient) or level II (intensive outpatient, under state waiver where applicable).

For safety and logistical reasons, participants will be excluded if they meet any of the following criteria: a) have used alcohol 45 or more days of the 90 days prior to intake (or prior to being in a controlled environment where relevant), b) have used other drugs 13 or more of the 90 days prior to intake (or prior to being in a controlled environment where relevant), c) have an acute medical condition that requires immediate treatment or is likely to prohibit full participation in treatment and cannot be managed in this level of care, d) have an acute psychological condition that requires immediate treatment and/or is likely to prohibit full participation in treatment and cannot be managed in this level of care, e) appear to have insufficient mental capacity to understand the consent and/or participate in treatment, f) currently live outside of the program’s catchment area or expect to move out within the next 90 days, g) have a history of violent behavior, severe conduct disorder, predatory crime or criminal justice system involvement that is likely to prohibit full participation in treatment (e.g., pending incarceration), h) lack sufficient ability to use English to participate in treatment, i) have previously participated in this study, j) cannot understand the informed consent, and k) have a significant other (typically a parent) who cannot understand the collateral consent form.

Participants with all of the above inclusion criteria and none of the above exclusion criteria are considered “eligible” and invited to participate in the study. Participation is voluntary, so those who meet all criteria except willingness to participate will be considered to have “refused” and be part of pre-inclusion attrition. Only those who are eligible, agree to participate, have parental consent, and who complete all intake assessments are randomly assigned.

Research Design

Table 1 provides an overview of the research design using Cook & Campbell’s (1979) design notation. There are four treatment sites (ARC, PAR, CHS-MC, CGC). In each site, approximately 150 adolescents are systematically assigned based on a randomly ordered list to one of the three conditions. At ARC and PAR, they are assigned to the brief intervention (MCB5) or one of the two other individual/group combinations (MC12 or FSN). At the CHS-MC and CGC sites, adolescents are assigned to the brief MCB5 treatment or one of the two individual approaches (ACRA or
All conditions are replicated in two or more sites and are manual driven with expert work groups supporting them. The four sites are paired in order to counterbalance the academic clinics (ARC & CGC) with the two larger community-based treatment programs (PAR & CHS-MC). All participants are assessed at intake, 3, 6, and 9 months. The first half of the recruited sample also completes 12 month assessments. The three-month interview is approximately the primary point of discharge, so the six-, nine-, and twelve-month interviews occur approximately three, six, and nine months post-discharge, respectively.

Data Sources

Table 2 lists the measures collected at each time point. For the adolescent participant, a screening instrument and informed consent are completed prior to assignment to determine eligibility, willingness to participate, and to avoid unnecessary assessments. If the adolescent appears eligible, s/he completes an intake assessment consisting of: a) a Global Appraisal of Individual Needs (GAIN; Dennis, 1998), a comprehensive biopsychosocial assessment battery that measures functioning and service utilization; b) a Supplemental Assessment Form (SAF), a collection of short assessments that covers the adolescent’s reasons for quitting, family environment, friends, relapse coping, specific personality dimensions, temperament, and program evaluation at discharge; c) an EZ Screen Urine Test (Medtox Diagnostic, Inc.) using the NIDA recommended cut-offs for THC (50ng/ml) and Cocaine (150ng/100); d) a detailed follow-up locator form; and e) various releases. Once randomized and enrolled in an intervention, participants complete at least two urine screens during treatment as well as a measure of the working alliance with their therapist (WAI-P, based on Tracey & Kokotovic, 1989; see also Conners, Carroll, DiClemente, Longabaugh, & Donovan, 1997). At 3, 6, 9, and 12 months post-randomization, participants complete follow-up versions of the GAIN and SAF. Urine tests are repeated at 3 and 6 months. The 3 and 6 month interviews are designed to be in-person interviews, while the 9 and 12 month interviews can be completed over the phone. However, to minimize attrition, any interview that cannot be done in person is done by phone.

To further validate self-reported substance use and problems, the participant identifies a “research collateral”, an adult (guardian, parent, or other non-peer adult) who has lived with the participant during part or all of the past 90 days. Following consent, the research collateral completes an intake assessment consisting of: a) the Collateral Assessment Form (CAF), a parallel set of questions about the participant’s behaviors; b) the problem scales from the Child Behavior Checklist (CBCL) (Achenbach, 1991); c) a detailed follow-up locator form; and d) various releases. During treatment, collateral’s whose adolescents were enrolled in MDFT complete a measure of the working alliance with the therapist (WAI-C, based on Tracey & Kokotovic, 1989). At 3 and 6 months post-randomization, collaterals complete a follow-up version of the CAF.

Therapists and/or therapist supervisors also complete a number a treatment-related questionnaires: a) Service Contact Logs (SCL) completed by therapists to document every encounter in terms of content (e.g., procedures, session curriculum), duration, location, and engagement; b) a Therapist Skillfulness Scale (TSS) completed by clinical supervisors on sessions they observe; c) a measure of the working alliance between the therapist and participant (WAI-T) at least once during treatment, and between the therapist and collateral (WAI-TC, for MDFT only; based on Tracey & Kokotovic, 1989); and d) a Discharge Questionnaire - Therapist Version (DQT) that parallels the adolescent/collateral versions embedded in the SAF and CAF at the 3 month assessments, respectively.

To estimate the cost of each intervention, coordinating center staff from the University of Miami are working with the program directors and PIs at each site during year two of the project using the Drug Abuse Treatment Accounting Program (DATCAP; French, 1999; French, Dunlap, Zarkin, McGary & McLellan, 1997). This software measures both accounting costs and economic value.
with the latter taking into account the value of resources that are nominally free of charge or at substantial discount (e.g., from federal subsidies or institutional decisions). The DATCAP data will allow standardized estimates across the CYT sites and comparisons with several adult cost studies. The middle period of the study (i.e., year two) is used to estimate costs so as to avoid atypical start-up or wind-down costs.

All staff complete a Staff Background Form (SBF). Information collected will enable description of the training and experiences of the CYT staff. The form and its computerized version also allows for tracking of staff training and certification in the interventions and assessments. The SBF forms the backbone of the customized data entry system by allowing access only to those with valid project ID numbers and passwords as defined on the SBF.

**Timeline and Current Status**

The three-year study began October 1, 1997. Recruitment efforts across sites began in June, 1998 and 600 adolescents should be randomized by the end of 1999. Treatment will extend through February, 2000. Nine-month follow-up interviews on the entire sample are expected to last through August of 2000, while twelve-month follow-up interviews on the sample recruited through April of 1999 (the first 300 participants) are expected to last through April of 2000. Analyses will be conducted during the project on baseline needs, costs, outcomes, and cost-effectiveness. The final report is due in September, 2000.

As of July 26, 1999, 851 adolescents across all sites have been screened for inclusion in the project (78% males, 22% females). Of the 851 screened, 663 (78%) meet all inclusion criteria. The largest group failing to meet inclusion was 22% who were screened as “too severe for outpatient treatment” based on ASAM (1996) patient placement criteria. This is slightly higher than the national average percent in inpatient, which our collaborating providers attribute to a lack of available beds in the system, not a problem with our screening. Of those who meet inclusion criteria, 517 (61% of total screened and 78% of those meeting inclusion criteria) meet all inclusion criteria and fail none of the exclusion criteria. Almost all of the exclusions were based on information discovered during a detailed intake or from people other than the adolescent (e.g. participants reported higher level of use at the intake assessment, adolescent was sent to jail, parent and probation officer reported high levels of violence). Of the 522 adolescents ultimately deemed eligible, 432 (83%) agreed to participate and were randomly assigned to one of the five treatments. Reasons for refusing to participate were varied but most often the adolescent and/or a parent just weren’t interested or chronically no-showed for intake appointments, thereby never completing the pre-randomization assessment and consent procedures.

Of the 432 adolescents randomized by 7/26/99 (82% males, 18% females), 33% have been assigned to MCB5, 14% to MC12, 16% to FSN, 18% to ACRA, and 19% to MDFT. Across the sites, of the adolescents assigned to a treatment thus far, approximately 72% have been discharged. Of the latter, approximately 72% successfully completed the core components of the intervention as specified in the research design (4 to 5 sessions of MCB5; 8 to 12 sessions of MC12; for the FSN treatment, 8 to 12 sessions of MC12 and collateral completion of 4 or more family nights and 3 or more home visits; 8 or more sessions of ACRA; and 8 or more sessions of MDFT).

Across the sites, follow-up rates are consistently strong. For the three-month assessment, the participant and collateral follow-up rates are each 99%, and 90% of participant urine samples were successfully obtained. For the six-month assessment, follow-up rates are 96% for participants and 98% for collaterals, while 84% of participant urine samples have been successfully obtained thus far. Longer-term follow-up has recently commenced. As of 7/26/99, 96% of the assessments due at nine-months and 100% of those due at twelve months have been completed. (There is no collateral assessment or urine collection at nine or twelve months).
Organization

The CYT cooperative agreement is collectively managed by a steering committee (SC) composed of the principal investigators (PIs), co-PIs, and clinical directors of the four treatment sites; the PI and senior staff of the coordinating center (CC); the project officer and an evaluation specialist from CSAT (both full collaborators); and one to three consultants. The four site PIs, coordinating center PI, and CSAT project officer are the voting members of this committee. The PI and the CSAT evaluation specialist also make up an executive committee (EC) that is expected to meet more frequently and have final responsibility for making the cooperative agreement work. The PI of the coordinating center serves as chair of the steering and executive committees under an appointment from the director of CSAT.

Each treatment site’s staff is organized under a PI who is responsible to the SC, CC, and CSAT project officer. The sites have as many co-PIs or other staff as they designate, but must each specify a person to serve in each of the following critical roles: a research coordinator to supervise the collection, editing, and data processing of all data for the study; a therapist coordinator to provide general clinical supervision to the local therapists in all conditions and to provide protocol monitoring to therapists who deliver the treatment condition led by the site; and a data processing coordinator (who may be one of the above or someone else) who is responsible for coordinating the transmission of data to the coordinating center and/or resolution of any data problems that are identified.

The coordinating center is organized under a PI who is responsible to the steering committee and CSAT project officer. There are three positions that work with the parallel site staff: a cross-site research coordinator, cross-site therapist coordinator, and cross-site data processing coordinator. In addition, there are two major subcontracts: a subcontract to the University of Connecticut to lead the development and monitoring of the common intervention (MCB5) across sites; and a subcontract to the University of Miami to lead the economic analyses. The coordinating center staff also includes in-house experts in design, follow-up, and analysis.

Next Steps

The project’s immediate next steps are to complete recruitment by the end of the year, complete treatment early in 2000, and complete follow-up by the summer of 2000. In addition, outcome analyses are expected to begin early next year.

The CYT cooperative agreement recently submitted a proposal for longer-term follow-up. If funded, the project will collect 12-month data on the second half of the sample (N=300) and conduct 18-, 24-, and 30-month follow-up interviews on all 600 participating adolescents (including urine and collateral assessments at 18 and 30 months). Further refinement of the treatment manuals will be made, and the impact of several co-occurring, moderating, and mediating factors on treatment outcomes are planned, including the roles of therapeutic alliance, gender differences, age differences, vulnerability to relapse, externalizing disorders, motivation, coping skills, family and peer group factors, and early treatment career and utilization patterns.
References


Table 1
Cannabis Youth Treatment Cooperative Agreement Research Design

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Table 2
Measures Collected at Assessment Waves

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<td>Service Contact Logs (SCL) - per session; two versions per treatment</td>
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Notes: IP = in-person, interviewer-administered; SR = self-report; PH = phone interview; * Two or more in-treatment urine tests are done in each condition.
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