Implementing Evidence-Based Principles and Treatment Interventions: Challenges & Perils

TOTAL

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Why Use Evidence-Based Principles and Practices ?

- To go beyond our preferences and biases
- To improve the effectiveness of what we do: what works best, for whom
- Because funders will increasingly insist on optimum utilization of inadequate resources

Evidence Based Principles & Practices vs Evidence Based Treatment Interventions

- Principles and practices are derived from different types of research.
- Rigor often trumps relevance in determining what type of research is valued.
- Policy makers must be educated on these issues.

Important Distinctions

- Evidence-based **principles** and practices guide system development
  - Example: care that is appropriately comprehensive and continuous over time will produce better outcomes
- Evidence-based **treatment interventions** are important elements in the overall picture. They are not a substitute for overall adequate care.

Evidence-Based Principles

- Retention improves outcomes; we need to engage people, not discharge them prematurely.
- Addicts/alcoholics are a heterogeneous population, not a particular personality type.
- Addiction behaves like other chronic disorders
- Problem-service matching strategies improve outcomes. (Other matching strategies disappointing.)
- Harm reduction approaches yield benefits in terms of public health and safety.
- Pts in methadone maintenance show a higher reduction in morbidity and mortality and improvement in psychosocial indicators than heroin users outside treatment or not on MAT.

Policies and Practices **Not** Supported by Research

- Requiring abstinence as a condition of access to substance abuse or mental health treatment
- Denying access to AOD treatment programs for people on prescribed medications
- Arbitrary prohibitions against the use of certain prescribed medications
- Discharging clients for alcohol/drug use

Evidence-Based Practices: Key Issues in the Debate

Efficacy Studies

Specific psychosocial interventions are usually investigated in random assignment studies using manualized treatments in carefully controlled trials. Samples and settings are homogeneous and treatment is standardized. Specific procedures assure fidelity to the model.

Are RCT's Over-rated?

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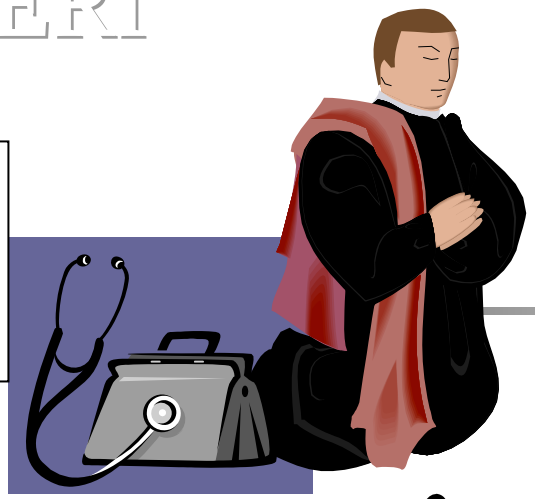


RCT

Mark Willenbring MD
(ASAM 2006)

Issues with RCT's

- Is the research question an appropriate question?
  - Example: CBT A compared with CBT B, vs CBT A compared with TAU
- Are the treatment effects modest or robust?
- What is the cost to achieve and maintain the intervention? Are the results worth it?

What Methodology Fits the Research Question?

Extending the Evidence Hierarchy:

- RCT designs have limitations and are not always best for investigating key aspects of behavior change process:
  - What influences people to seek and engage in treatment?
  - How do these self-selection processes and contextual influences contribute to the change process?

(Tucker & Roth, Addiction, 2006)

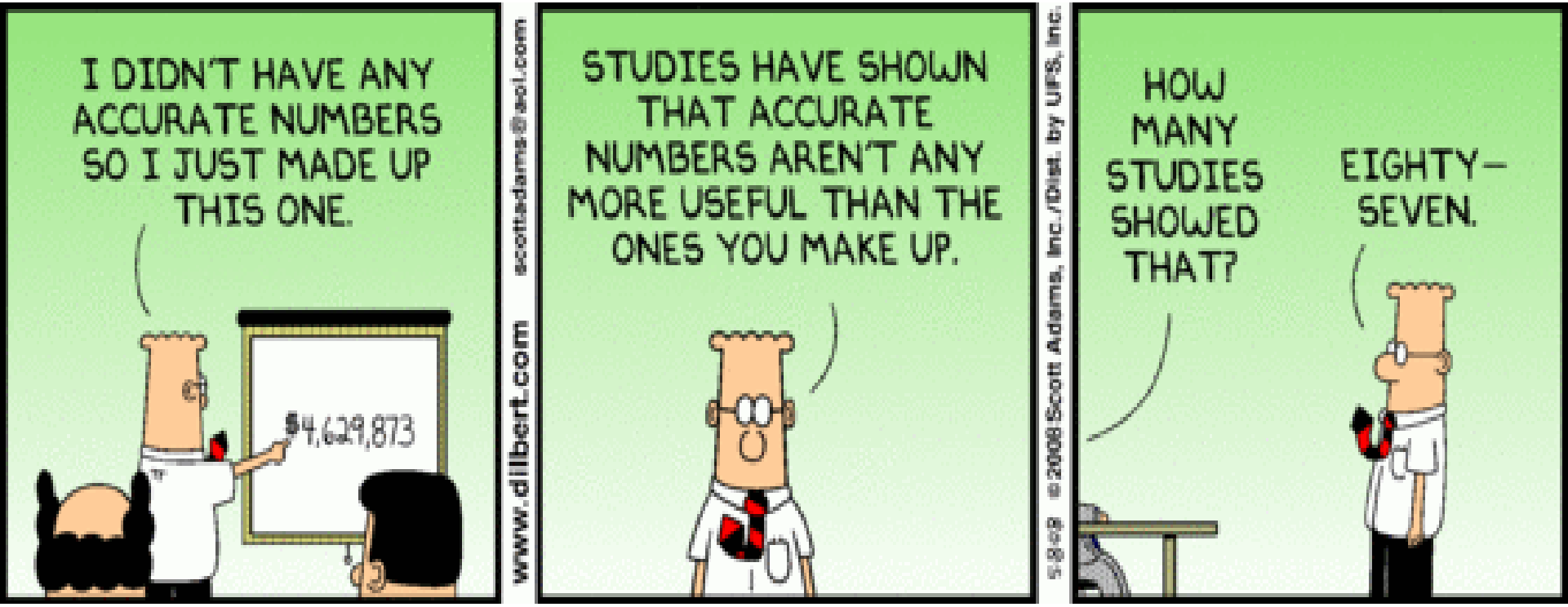
Evidentiary Pluralism, cont.

- RCT's commonly use restricted, unrepresentative samples
- Alternative methods: multivariate, longitudinal, and observational studies
- Investigate pathways and mechanisms of change, with or without treatment
- Public health perspective: a modestly efficacious treatment that is adopted and diffused easily can have much greater impact at the population level

(Tucker & Roth, Addiction, 2006)

Adaptive Designs: An Emerging Paradigm

- Individualize treatment using decision rules that recommend when and for whom tx should change
- Utilize a sequence of treatments, randomizing S's based on clinical response
- Starts with consensus-based clinical guidelines and fine tunes the sequence
- Example: The STAR-D study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www.dilbert.com scottadams@aol.com
STUDIES HAVE SHOWN THAT ACCURATE NUMBERS AREN'T ANY MORE USEFUL THAN THE ONES YOU MAKE UP.
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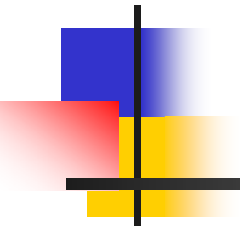
HOW MANY STUDIES SHOWED THAT?
EIGHTY-SEVEN.

What About the Therapeutic Alliance?

- Studies outside substance abuse show this accounts for a greater % of the variance than specific techniques
- Different “specific” therapies yield similar outcomes, but there is wide variability across sites and therapists
- More therapist education/experience does not improve efficacy

(Adapted from W.R. Miller, Oct 06)



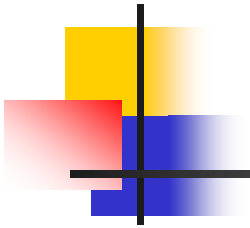
IMPLEMENTATION ISSUES

Barrier: Resource Allocation

99% = Investment in Intervention Research to develop solutions ($95 billion/yr)

1% = Investment in Implementation Research to make effective use of those solutions (Up from ¼% in 1977) ($1.8 Trillion/yr on service)

Dean Fixsen, 2006



Can we assume that interventions with documented efficacy will be effective in the community if we only implement them correctly?

Rethinking the Efficacy-to-Effectiveness Transition

- Assumption that effectiveness research naturally flows from efficacy research is faulty.
- The tight controls of efficacy studies limit their generalizability.
- Focus more on intervention reach, adoption, implementation, and maintenance.
- Published studies should include more info on external validity.

(Glasgow et al, AJPH, 2003)

Important Questions to Ask

What are the characteristics of interventions that can:

1. Reach large numbers of people, especially those who can most benefit
2. Be broadly adopted by different settings
3. Be consistently implemented by different staff with moderate training and expertise
4. Produce replicable and long lasting effects (with minimal negative impact) at reasonable costs.

(Glasgow et al, AJPH, 2003)

Considerations

- What is to be gained?
- Does the organizational culture support adoption?
- Is training available?
- Is clinical supervision available?

Ineffective Implementation Strategies

"...experimental studies indicate that dissemination of information does not result in positive implementation outcomes (changes in practitioner behavior) or intervention outcomes (benefits to consumers)"

(Fixsen et al, 2005)

Opinion Leaders: A Key to Knowledge Adoption

- Identified by peers as respected for their knowledge in a particular area
- Trained in the use of an evidence-based curriculum
- They then train their peers and supervise the application of the curriculum
- Changes in counselor behaviors and attitudes are measured to determine the effectiveness of the implementation process

(Rugs D, Hills HA, Peters R, 2004 at www.seekingsafety.org)

Key Ingredients

- Presenting information; instructions
- Demonstrations (live or taped)
- Practice key skills; behavior rehearsal
- Feedback on Practice
- Other reinforcing strategies; peer and organizational support

(Fixsen et al, 2005)

Coaching

Training and coaching are a continuous set of operations designed to produce changes

- Newly-learned behavior is crude compared to performance by a master practitioner
- Such behavior is fragile and needs to be supported in the face of reactions of others
- Such behavior is incomplete and will need to be shaped to be most functional in the service setting.

(Fixsen et al, 2005)

Degrees of Implementation: Paper

Policies and procedures are in place

- Makes it an official part of the structure
- Can match formally adopted programs and operational routines
- More prevalent when outside groups are monitoring compliance
- Paperwork alone is not enough

(Dean Fixsen, 2005)

Degrees of Implementation: Process

Putting new operating procedures in place:

- Conducting workshops
- Providing supervision
- Change information reporting forms
- New innovation-related language is adopted
- Is this functionally related to new practices or merely lip service?

(Dean Fixsen, 2005)

Degrees of Implementation: Performance

Putting procedures and processes in place that are used with good effects for consumers.

- How to measure?
- Who will pay for the effort to measure?

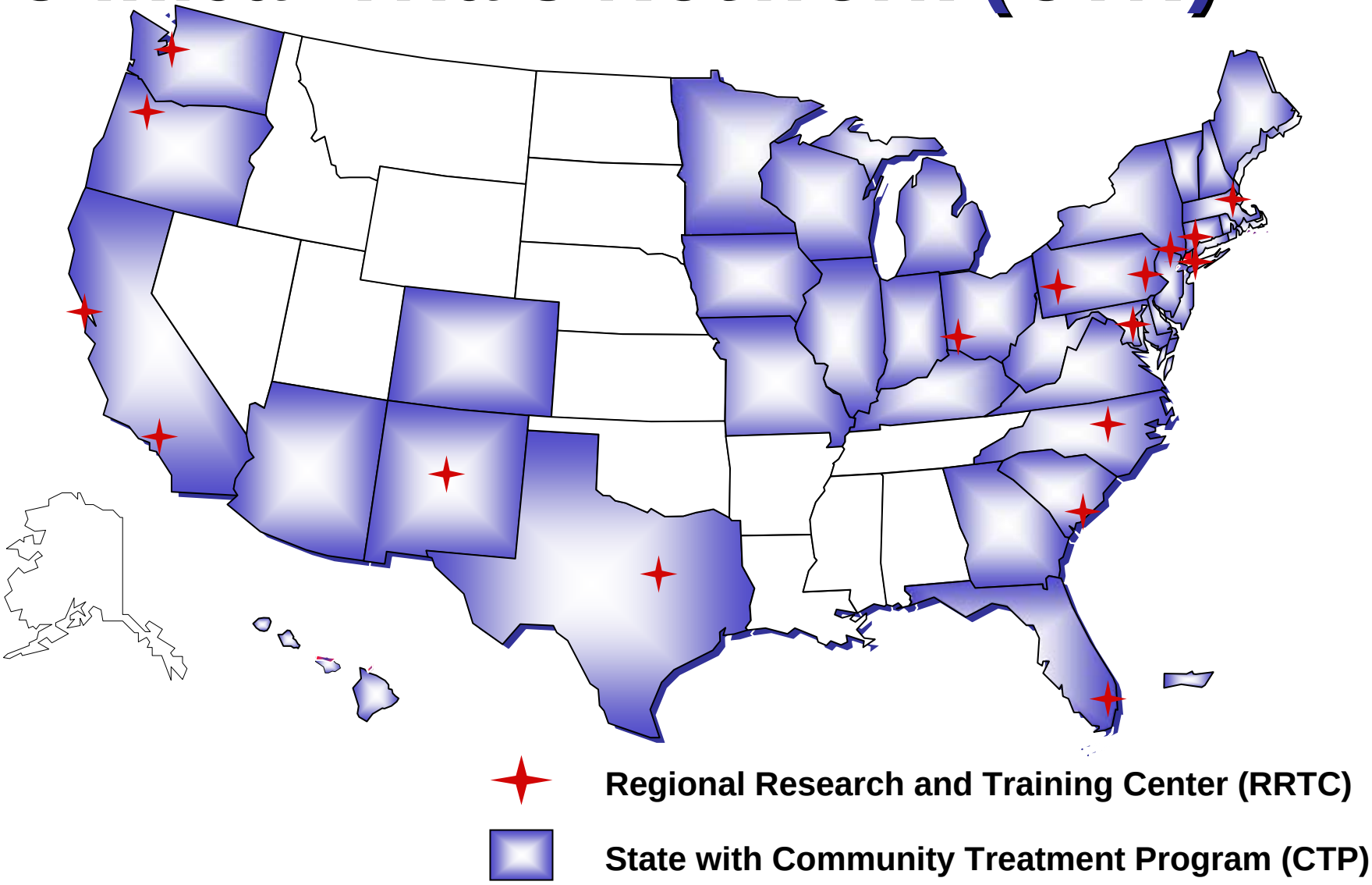
(Dean Fixsen, 2005)

DISSEMINATION MECHANISMS

NIDA's Clinical Trials Network

- Mission: to improve the quality of drug abuse treatment using science as the vehicle
- 17 regional centers; over 100 treatment programs throughout the US
- Conduct multi-site trials to determine effectiveness in broad range of settings and populations
- Ensure transfer of research results

National Drug Abuse Treatment Clinical Trials Network (CTN)



CTN: Influence on Disseminating EBT's

- # trials completed
- # trials in process
- # published papers
- # papers accepted for publication
- Availability of manuals and other materials

Addiction Technology Transfer Centers (CSAT)

The ATTC Network focuses on six areas of emphasis for improving addiction treatment:

- Enhancing cultural appropriateness
- Developing and disseminating tools
- Building a better workforce
- Advancing knowledge adoption
- Ongoing assessment and improvement
- Forging partnerships

(www.nattc.org)

Addiction Technology Transfer Centers (ATTC's)

What is NREPP?

- National Registry of Effective Programs and Practices
  - formerly the National Registry of Effective Prevention Programs
  - Part of science-to-service initiative
- Began in 1998 within SAMHSA's CSAP as a voluntary system for identifying & promoting interventions that are:
  - Well implemented
  - Thoroughly evaluated
  - Produce consistent positive and replicable results
  - Able to assist in dissemination and training efforts

NREPP www.nrepp.samhsa.gov

- Identify effective, evidence-based programs and practices – including successful coalition efforts
- Receive – or be linked with - “implementation assistance” to implement a model program/practice
- Seek – or be linked with - “development assistance” to build a program or practice evidence-base

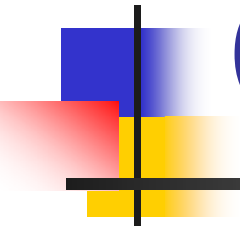
Evolution of NREPP

- NREPP was expanded to include treatment (c. 2002)
- Well-respected, evidence-based treatment providers did not pass muster
- Federal Register notice inviting public comment on plans for expansion and use (August 26, 2005)
- Changes announced, based on public comments (March 14, 2006)
- Federal Register on SAMHSA's priorities for 2007 (June 30, 2006)

Minimum Review Requirements (June 30, 2006)

- The intervention demonstrates one or more positive changes (outcomes) in mental health and/or substance use behavior among individuals, communities or populations.
- Intervention results have been published in a peer-reviewed publication or documented in a comprehensive evaluation report
- Documentation (e.g., manuals, process guides, tools, training materials) of the intervention and its proper implementation is available to the public to facilitate dissemination

(Federal Register/Vol 71, No. 126/Friday, June 30, 2006/Notices)



Challenges & Perils

Policy and Funding

- Policy makers misinterpreting research findings; drawing inappropriate conclusions
  - Example: buprenorphine (“transfer methadone pts to BPN and taper them off”)
  - Example: Feillin NEJM study 2006
- Funders adopting a “pick from this list” approach
- Achieving fidelity takes labor intensive supervision, and many states don’t fund supervision.

$1,000 Reward

Most doctors, dentists, pharmacists, medical equipment suppliers and other providers of Medi-Cal goods or services are committed to giving the finest care. Unfortunately, a few place profit before their patients. Help us protect California's most vulnerable people - its children, poor, elderly and disabled.

If you can answer yes to any of the following...

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Attorney General's Bureau of Medi-Cal Fraud & Elder Abuse Hotline:
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You may file a complaint online at:
www.stopmedicalfraud.ca.gov

BMFEA
Bureau of Medi-Cal Fraud & Elder Abuse
State of California Department of Justice

PUB-110

Marketing

- Impostors
  - Distinguishing evidence from marketing
  - Presenting multiple anecdotes with no comparison or control groups as “proof”

Research to Practice Issues

- Inadequate effectiveness studies
- Huge gaps in the research literature (s.g., group interventions, therapist variables)?
- High training fees for “proven” practices
- Fidelity vs cultural competence: What is the tradeoff between fidelity and the need to adapt interventions for specific populations? How can we make cultural adaptations and maintain the treatment effects?

Infrastructure Development

- The existing infrastructure cannot handle the expectation for data collection
- Funders want data but do not want to pay the costs
- Data collected by funders is often not used to improve services
- Workforce crisis is a huge problem and an opportunity. Must supply resources for training.

Stay Focused on Basic Principles

Maintain commitment to the principle of individualizing treatment

When an evidence-based treatment doesn't work for an individual, some staff members conclude that the problem is that the treatment isn't being implemented correctly, rather than examining the possibility that it does not fit the needs of the client.

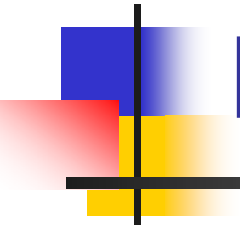
Example from Dual Dx listserve: dualdx.treatment.org

CONCERNS

- Journals
  - Bias
  - Unqualified or careless reviewers
- Cochrane Report
  - Seen as gold standard, but only addresses certain types of studies
  - Capable of carelessness

Is There Another Way?

- Fund programs to develop the infrastructure to examine how well they are doing with whom
- Draw on EBT's to improve in areas where there are problems
- Clarify realistic performance standards



Download Slides from:

www.ebcrp.org

Evidence-Based Practice: Psychosocial Interventions

Maxine Stitzer, Ph.D.

Johns Hopkins Univ SOM

NIDA Blending Conference

June 3, 2008

Cincinnati, Ohio

Talk Outline

- What is an evidence-based practice?
- What practices are evidence-based?
- Why should these be used?
- How to decide which one(s) to use?

What Is An Evidence-Based Practice?

- Developed by researchers
- Subjected to controlled evaluation
- Shown efficacious in 2 or more trials

Compared to Usual Care Practices

- Therapy specified in a detailed manual
- Therapists trained to proficiency
- Therapists monitored for adherence
  - presence of specified and absence of non-specified elements
- Clients meet inclusion and exclusion criteria
  - may be less complicated cases
- Intensive data collected on outcomes

Efficacy research shows that practices **can** work under ideal conditions

What Psychosocial Therapies are Evidence-based?

- Motivational Interviewing (MI/MET)
- Contingency Management (CM)
- Cognitive-behavioral therapy (CBT)

MI/MET: What Is It

- Style of therapist-client interaction
- Utilizes basic counseling skills for rapport
  - Reflective listening, open-ended questions, affirmation, summary statements
- Provide feedback and develop discrepancies between actual and ideal lifestyle
- Motivate “change talk” and hopefully, actual behavior change

MI/MET: Evidence For Efficacy

- Improved compliance in medical patients
- Reduced drinking in alcoholics
- Drug users contacted in a medical setting

MI intervention for drug users (N = 778) contacted at a medical clinic visit

Bernstein et al., Drug & Alc Depend, 2005

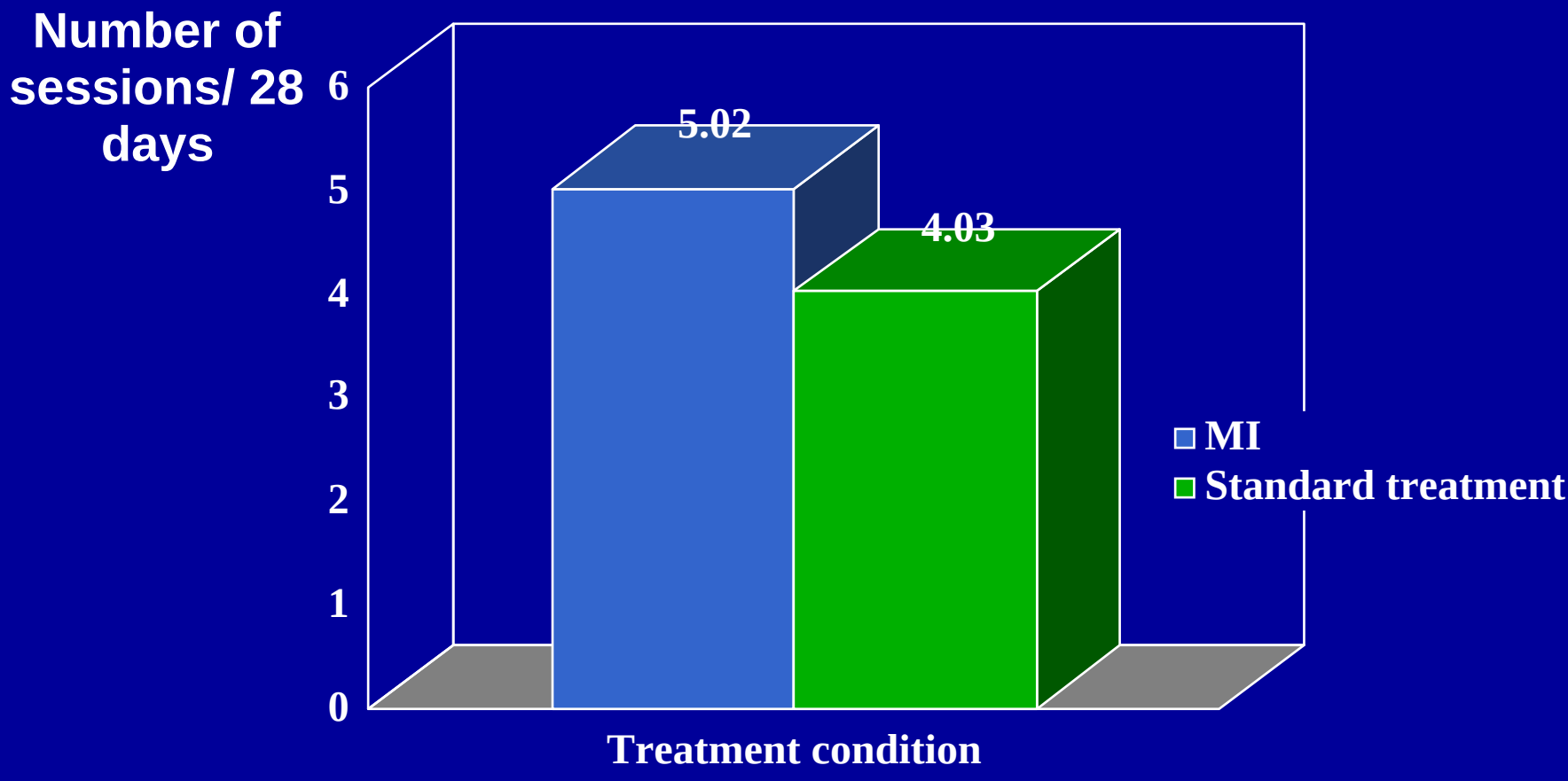
MI in Drug Treatment Settings

- **Evidence mixed**
  - **Some studies find benefits**
  - **Others find no benefits**

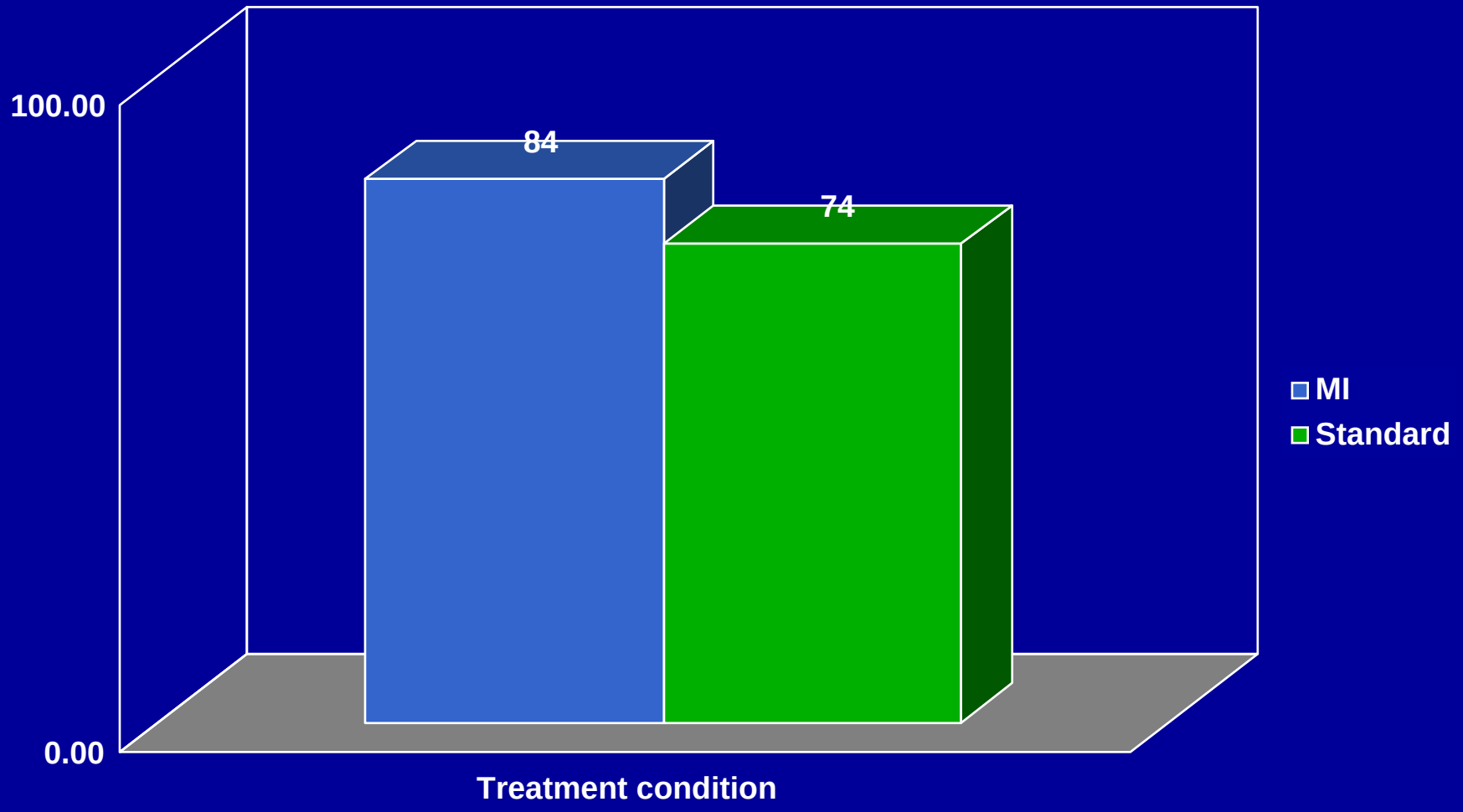
CTN MI Effectiveness Study Methods

- 418 patients randomized at 5 sites
- 375 were exposed to protocol
- Counselors trained in MI conducted intake session as a MI “sandwich”
  - Client-centered discussion with reflection, open-ended questions, etc before & after intake questionnaires

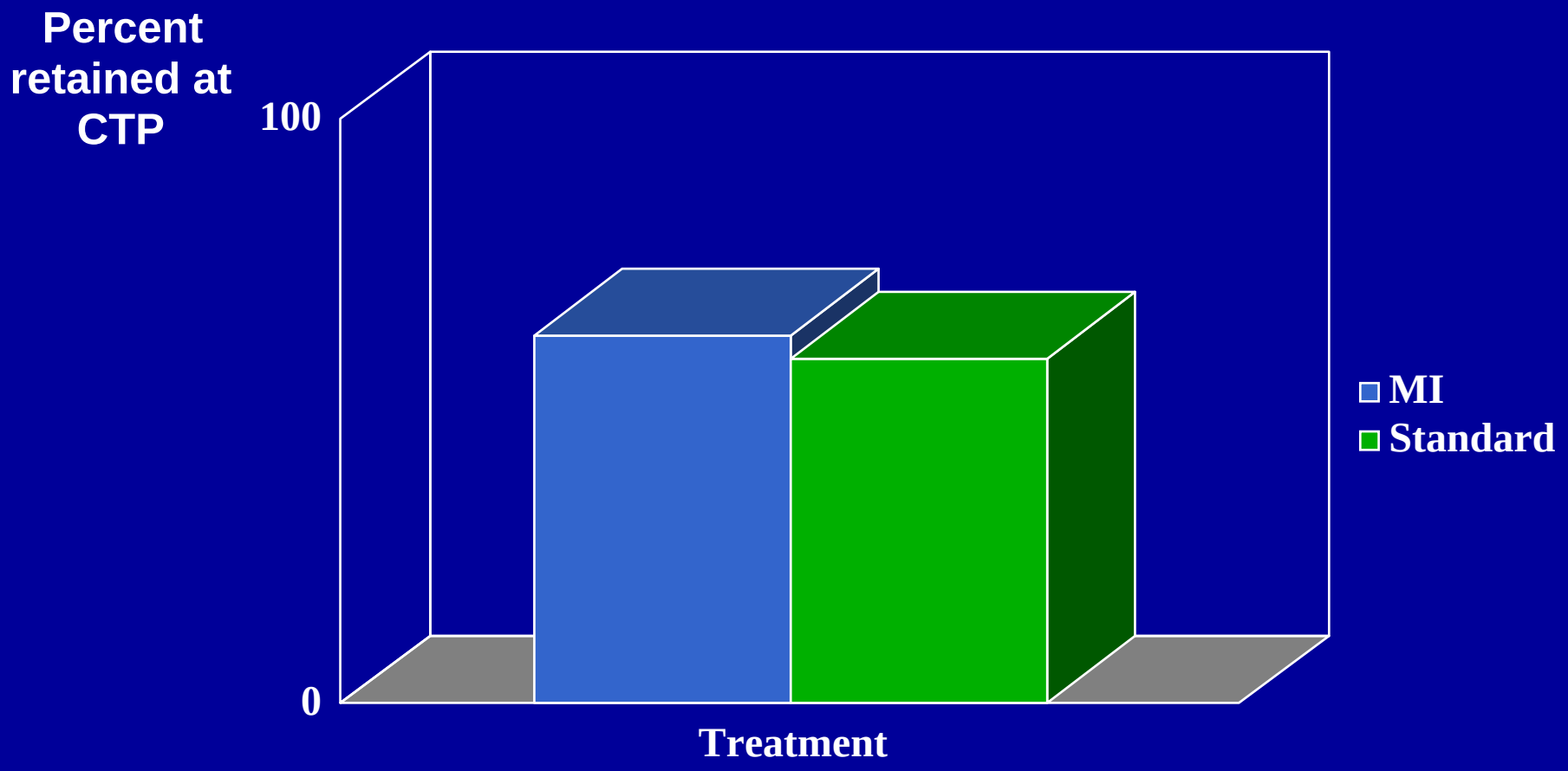
Patients assigned to MI completed more sessions in month 1 than those in standard treatment



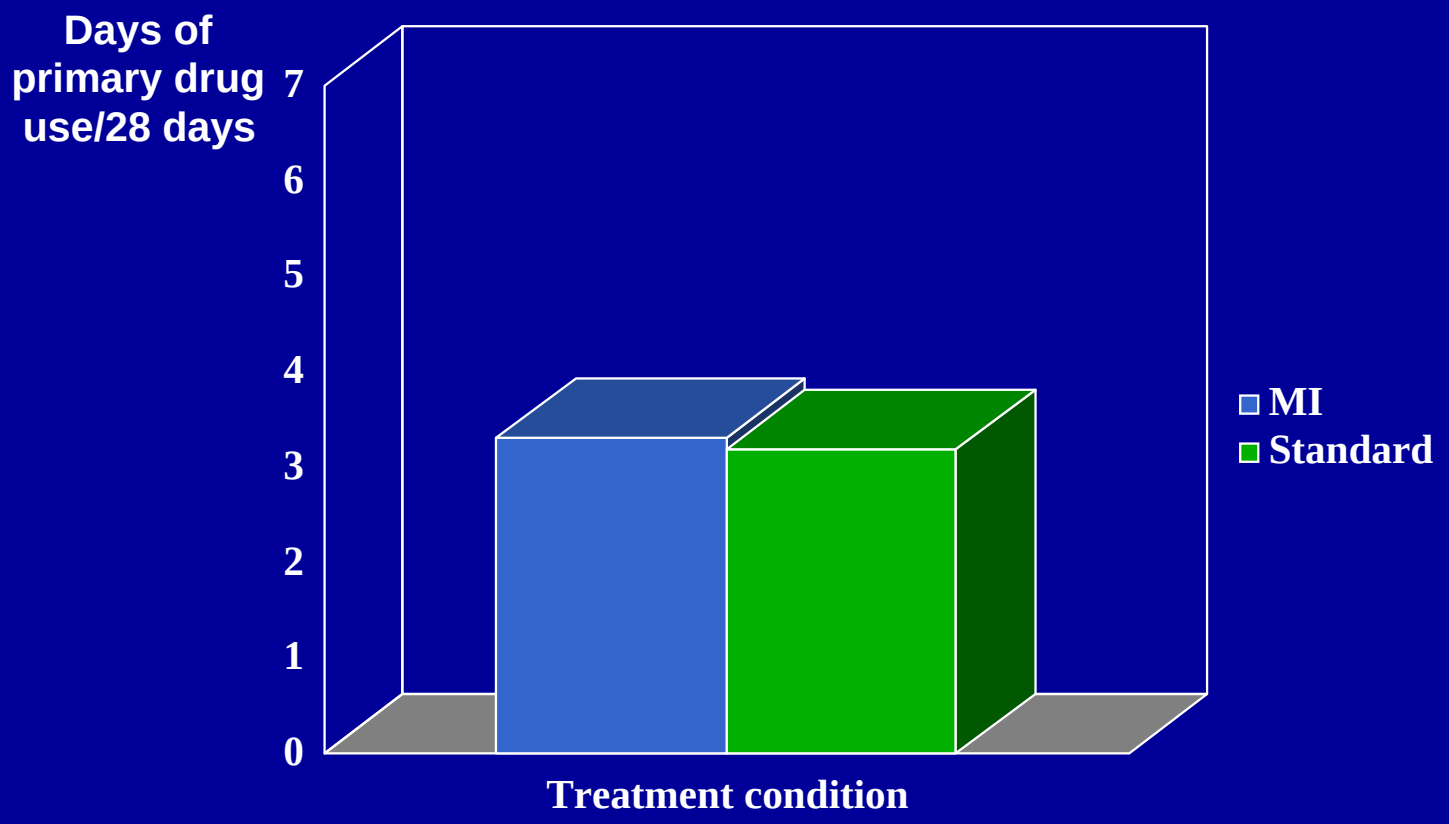
More MI patients were retained at 1-month



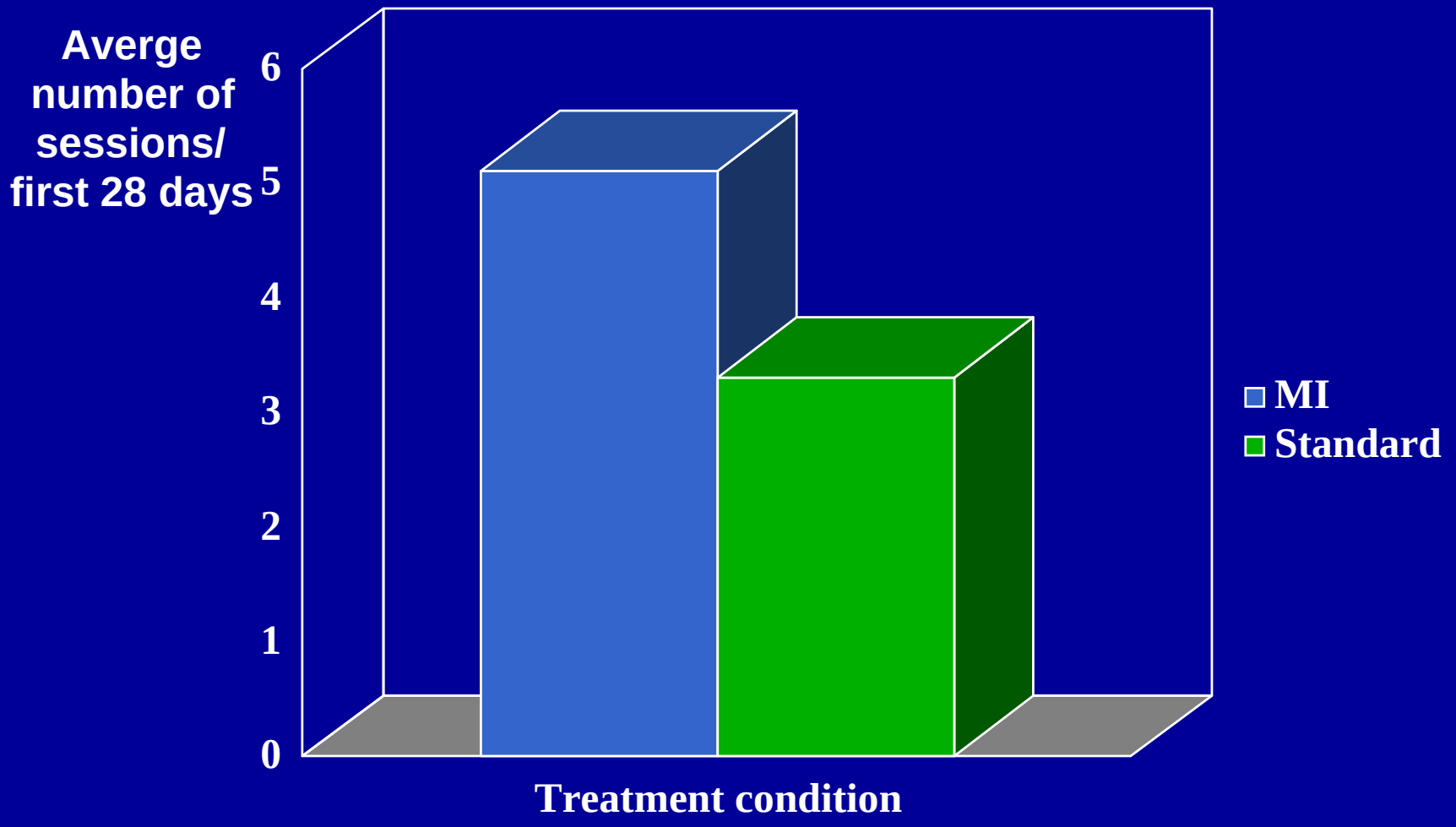
No differences in retention at the 84-day follow-up



No differences in drug use during first 28 days



Alcohol users (n=172) were the ones who benefited



MI Overview

- Excellent foundation for counseling skills
- Builds client internal motivation for change

- Evidence-based practice with good data supporting use with alcoholics
- Jury still out on effectiveness with drug users especially in treatment settings

CBT: What Is It

- Structured skills training lessons
  - Manage cravings
  - Avoid triggers
  - Drug refusal
  - Coping/problem solving
- Lectures, practice, homework
- Manualized
  - NIDA Therapy Manual for Drug Addiction #1

CBT Efficacy Evaluation

- Many studies have demonstrated efficacy
- Some show during treatment effects
- Some show benefits only after treatment ends (“sleeper” effects)

IOP Treatment: CBT vs 12-Step

QuickTime™ and a
TIFF (Uncompressed) decompressor
are needed to see this picture.

Maude Griffin et al., 1998

CBT vs Clinical Management: 1x per week

Carroll et al., 1994

CBT Overview

- Provides structured content for DA therapy
- Potential for building highly useful skills
  - Coping, problem solving, drug avoidance, etc
- Shown efficacious both during and after Tx
  - Provided clients can learn what is taught and put it into practice

Contingency Management Motivational Incentives: What Is It

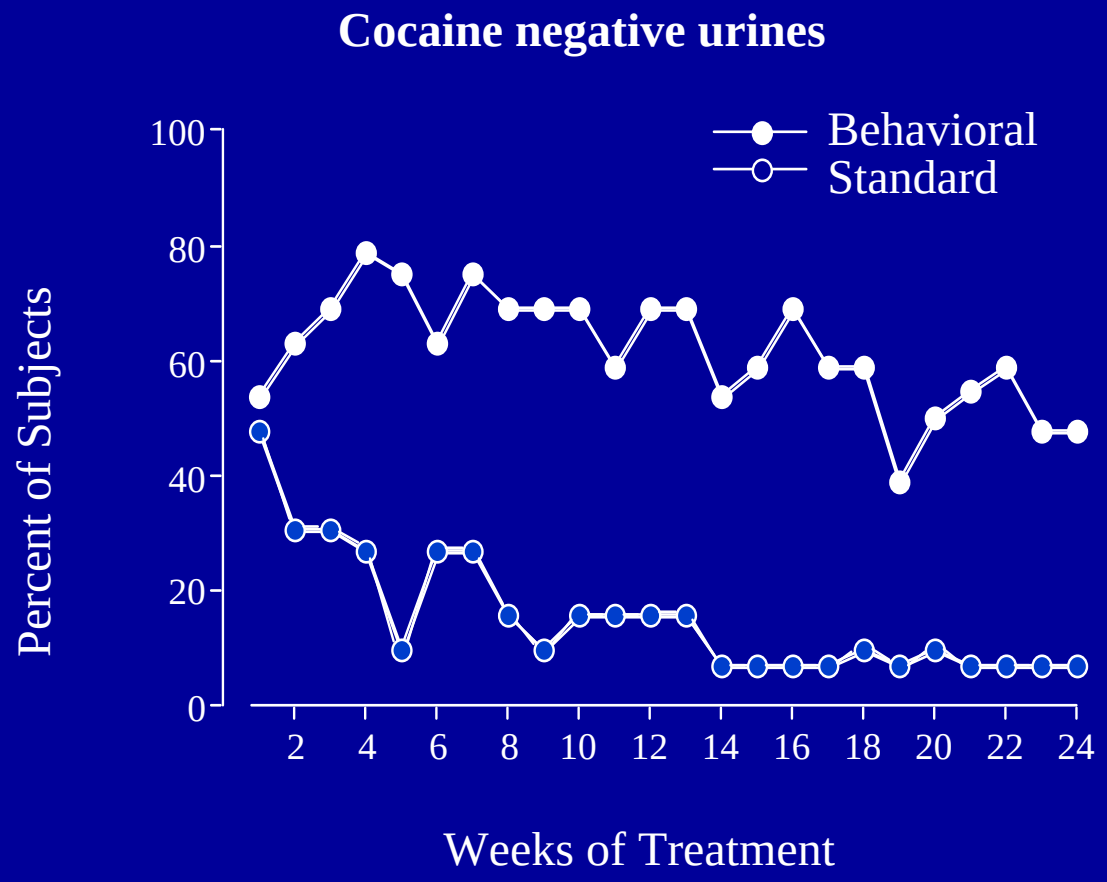
- Adds source of external motivation to counseling
- Provides tangible positive reinforcement for specified desired behavior
  - Behavior can be attendance, drug abstinence, goal achievement
  - Reinforcers can be cash-value vouchers or prizes

Voucher Reinforcement
for abstinence initiation and maintenance in cocaine abusers

- Principle of alternative reinforcement:
  - Making abstinence today a more attractive option
- Points earned for cocaine negative urine results
  - Escalating schedule of point earnings
  - Trade in points for goods
  - $1000 available over 3 months

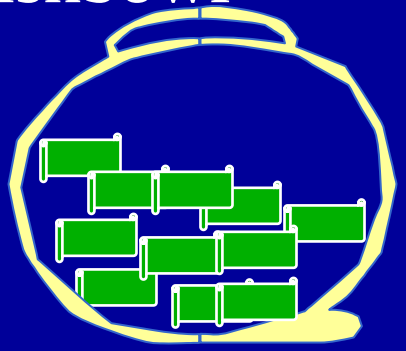
Voucher Incentives for Outpatient Drug-free Treatment of Cocaine Abusers

Higgins et al. Am. J. Psychiatry, 1993



Intermittent schedule/prize system

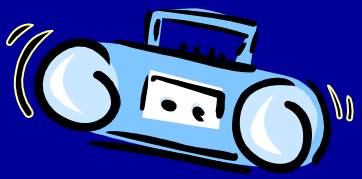
- Draws from a fishbowl



- Advantages: can be less expensive than vouchers; cost can be controlled by varying number and cost of prizes and percentage of winning chips

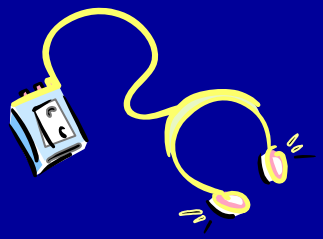
Half the slips are winners
Win frequency inversely related to cost

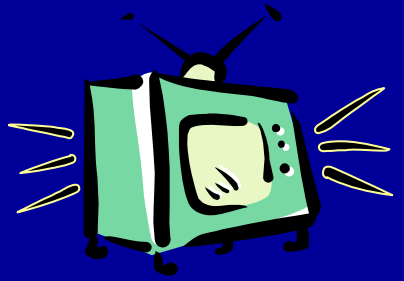
- largest chance of winning a small $1 prize



- moderate chance of winning a large $20 prize

- small chance of winning a jumbo $100 prize

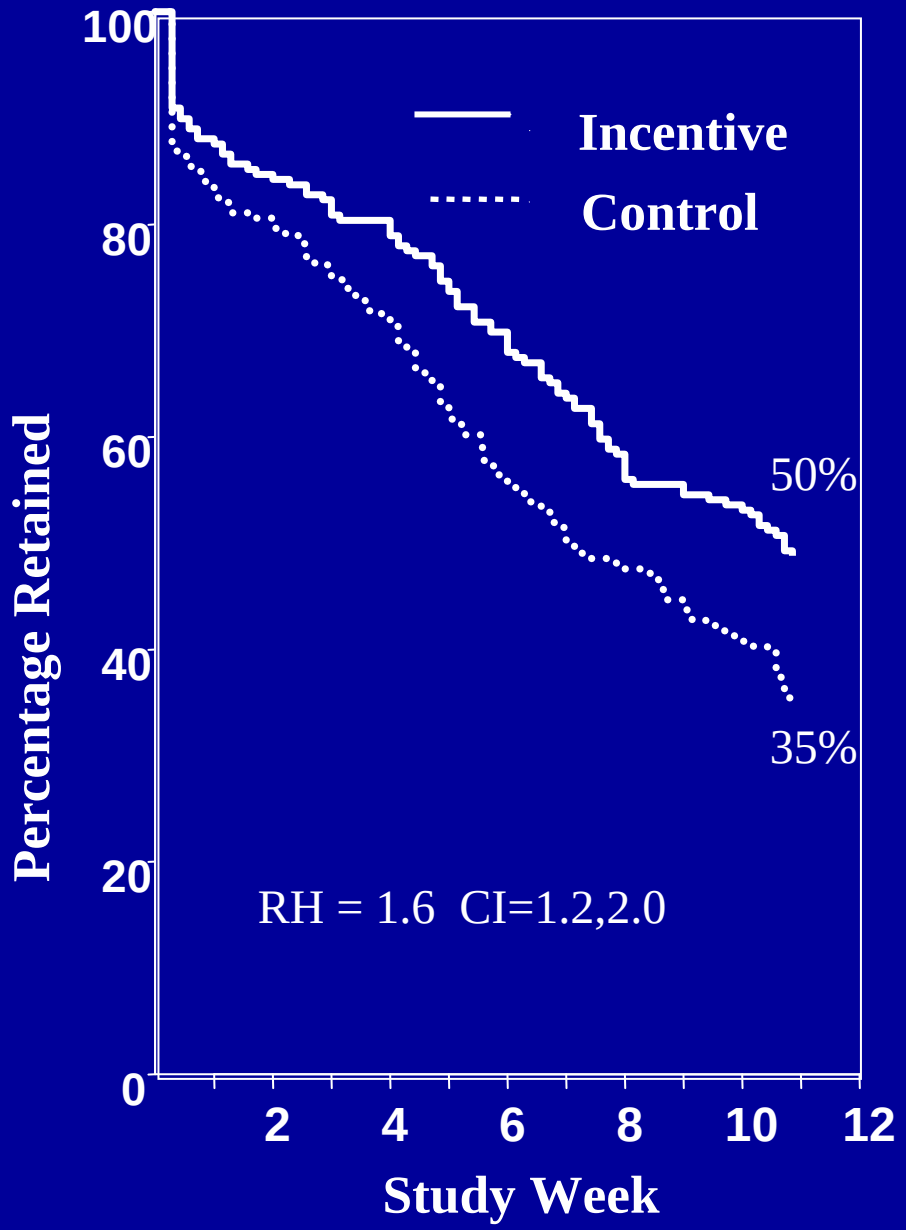




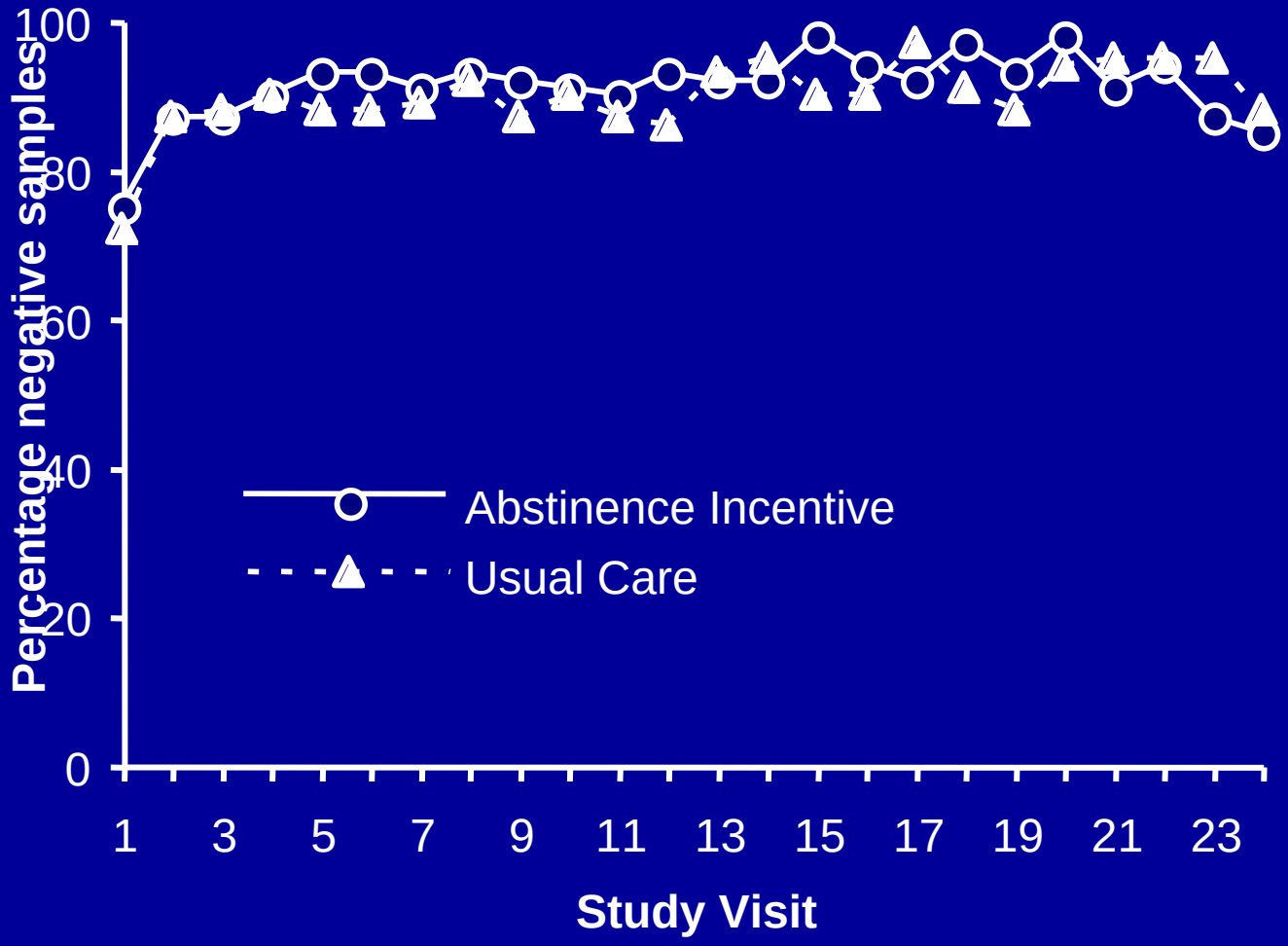
CTN MIEDAR Study

Participants could earn up to $400 in prizes on average during 12-week study if they tested negative for cocaine, methamphetamine alcohol, opiates, and marijuana

Incentives Improve Retention in Counseling Treatment



Percent of Submitted Samples Testing Stimulant and Alcohol Negative



Abstinence Incentives in Psychosocial Counseling Tx

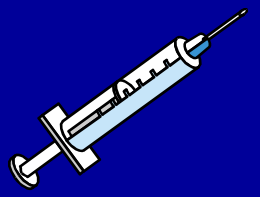
- Increased duration of drug-free treatment participation
- Good relapse prevention strategy
- Positive impact on long-term outcomes
  - Longer during-treatment abstinence translates into better long-term outcome

Generality of Abstinence Incentive Effects Across Abused Substances

Cocaine

Opioids

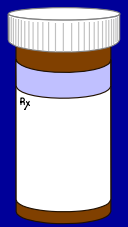
Methamphetamine

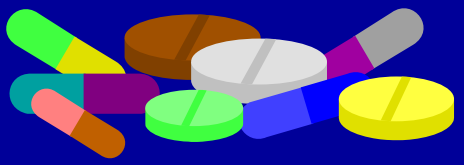


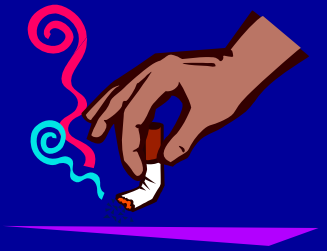
Alcohol

Marijuana

Nicotine (Tobacco smoking)

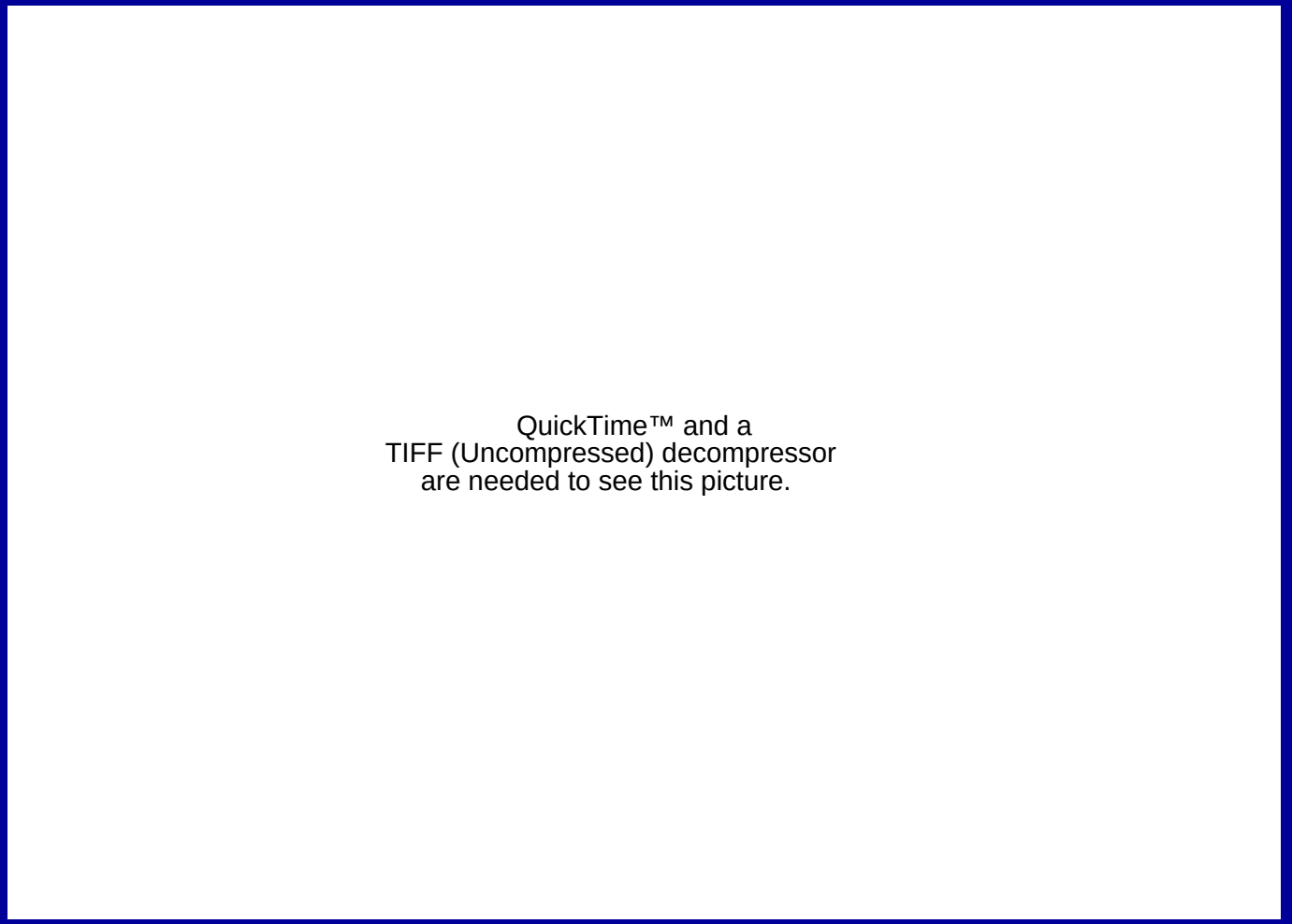






Combination of treatments may be best for long-term recovery

Adult marijuana users treated with voucher and CBT: 12-month outcomes



Budney et al., JCPP, 2006

Why Should Evidence-Based Practices Be Used?

- Enhance counseling skills and proficiency
- Engage in culture of CQI
- Better treatment outcomes
- Satisfy accreditation boards; federal and insurance payers

Which Evidence-Based Practices Should Be Used?

- Selected by needs of the clients?
- Selected by clinic's ability to implement?
- Selected by research effect sizes?
- All adopted in some logical sequence?

Sequential Adoption Plan

1) Motivational Interviewing
2) Contingency Management
3) Cognitive-Behavior Therapy

Addressing Client Needs

- Improve early engagement (MI/MET)
- Improve retention (CM)
- Stop on-going drug use (CM)
- Prevent relapse (CM/CBT)
- Build alternative non-drug reinforcers (CBT)

Evidence-Based Practices Summary

- EBP's are shown efficacious in clinical trials and effective in real world settings
- Adoption improves care quality and outcomes
- Three recommended are MI, CM and CBT
- Sequential adoption and combined use may be optimal strategy

Benefits of EBP Adoption

- Counselors will like it
  - New counseling skills (MI), structured content (CBT) and behavior change tools (CM)
- Clients will like it
  - Therapy may be more engaging and useful
- Funders will like it
  - Pathway to better outcomes