Motivational Enhancement Therapy for Pregnant Substance Users: Results from the NIDA CTN Trial

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Women and Substance Abuse Treatment
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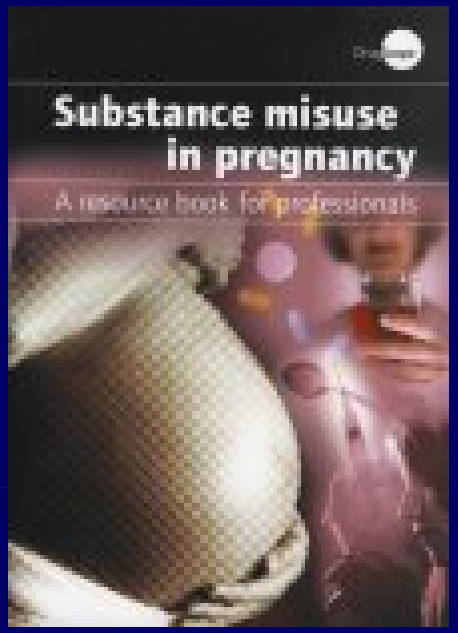
Scope Of The Problem

- During pregnancy, an estimated 4% of women use illicit substances, 4% binge drink and 18% smoke cigarettes



- The associated complications represent a leading preventable cause of mental and physical problems in children (SAMHSA, 2005)

- Substance abuse treatment is effective but retaining pregnant substance users can be difficult

Challenges Retaining Pregnant SU

- Pregnant substance users, compared to their non-using counterparts, have significantly more psychosocial needs, including greater needs for food, housing, medical care, transportation, education, mental health, and family and partner relationships (Jones et al., 2004)

- Pregnant substance users are frequently dealing with feelings of guilt and shame as well as fear of losing custody of their children (Finkelstein, 1994)

Retention Strategies

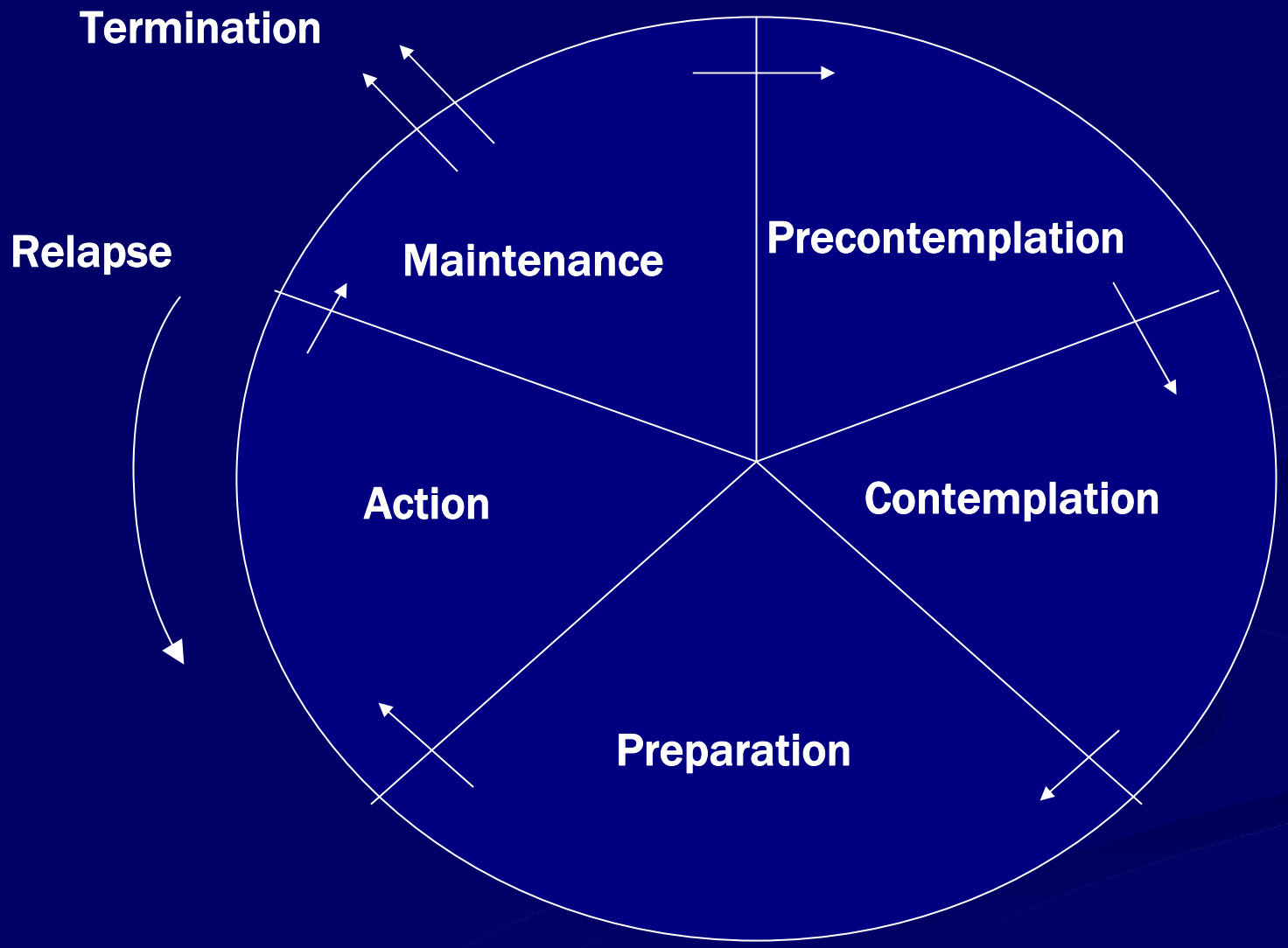
- Provide case management to help clients stabilize their lives
- Remove external barriers to attending treatment (e.g., provide transportation, child care services, etc.)
- Retention STILL a problem, how do we increase client motivation?

Motivational Enhancement Therapy

Motivational Enhancement Therapy (MET) seeks to support INTRINSIC motivation for change, which will lead the client to initiate, persist in, and comply with behavior change efforts.

Wm Miller (1995)

Stages of Change (Prochaska & DiClemente)



Stages of Change (Prochaska & DiClemente)

- Precontemplation: Not yet thinking about making a change or are unable or unwilling to make a change

- Contemplation: Acknowledges that there is a problem and is contemplating making a change but remains ambivalent about changing

- Preparation: Committed to making a change but are still considering what to do

Stages of Change (Prochaska & DiClemente)

- Action: Working at change but are still early in the process

- Maintenance: Have reached some of their goals and are working to maintain the gains that they have made

Overview and Basic Principles of MET

- Client-centered therapy (Carl Rogers)

- Express Empathy: Gaining an understanding of the client and expressing that understanding in a non-threatening, respectful way is very important for building a therapeutic alliance.

- Develop Discrepancy: This process involves encouraging the client to focus attention on how her current behavior differs from her ideals and goals.

Overview and Basic Principles of MET

- Roll with Resistance:
  - Resistance is a normal part of ambivalence
  - Resistance indicates that the clinician needs to respond differently
  - Encourage new perspectives but do not impose them

- Support Self-Efficacy:
  - It is important for the client to believe that she can change

Motivational Interventions

- Brief motivational interventions have been found to increase treatment engagement and improve outcomes in alcohol and drug abusing populations

- Motivational Interviewing has been found to decrease self-reported intoxication in pregnant alcohol users (Handmaker et al., 1999)

- In compliant participants, a brief motivational intervention plus contingency management was associated with decreased substance use and increased birth weights (Jones et al., 2002)

National Drug Abuse Clinical Trials Network (CTN)

A research infrastructure of 16 RRTCs & 240 CTPs across 34 states, and Puerto Rico

NIDA Clinical Trials Network (CTN)

- CTN was created to bridge the gap between substance abuse researchers and treatment providers
- Evaluate previously tested treatments in “real world” settings, utilizing existing staff as the interventionists and the clinic patients as the participants
- Approximately 9,000 participants have been randomized across 31 clinical trials

MET For Pregnant SU (CTN-0013)

- Developed by a team of researchers and substance abuse treatment providers from community treatment programs (CTPs) with pregnant women programs

- Evaluate the efficacy of MET, compared to treatment as usual (TAU), in increasing treatment utilization and decreasing substance use in pregnant substance users

Participating Nodes and CTPs

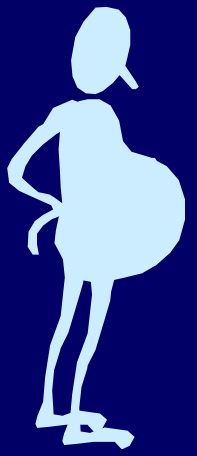
Node	Node PI	Protocol PI	CTP	Site PI	Location
Ohio Valley	Eugene Somoza	Diane Hague	JADAC	Diane Hague	Louisville, KY
		Leela Rau	Midtown	Dean Babcock	Indianapolis, IN
North Carolina	Bob Hubbard	Connie Renz	Horizons	Connie Renz	Chapel Hill, NC
Southwest	William Miller	Sarah Erickson	Milagro	Sylvia Price	Albuquerque, NM

Study Design

- Two hundred pregnant substance users randomly assigned to receive MET or TAU individual counseling
- Balanced for three dichotomous variables: pressure to attend treatment, self-report of drug and alcohol use, and need for methadone maintenance
- Active study phase was four weeks in duration. Follow up assessments were conducted at weeks 8 and 16

Study Eligibility

- Adult pregnant women, less than 33 weeks pregnant, entering outpatient substance abuse treatment



- Exclusion: significant suicidal/homicidal risk; being unlikely to complete the study due to plans to relocate or pending legal charges (other than those requiring treatment attendance) that might lead to incarceration

Outcome Measures

- Primary outcome measure: the percent of scheduled treatment hours attended based on clinic records

- Secondary outcome measures:
  - Number of treatment weeks attended
  - Number of weeks until treatment drop-out
  - Qualitative urine toxicology results (opiates, cocaine, methamphetamine, benzodiazepines, marijuana)
  - Self-report of alcohol/drug use
  - University of Rhode Island Change Assessment (URICA)

Study Treatments

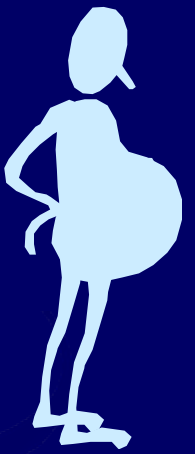
- TAU: the standard treatment provided by the CTP with the constraint that they were offered at least three individual sessions (including standard intake).

- MET: three individual sessions of manualized MET for pregnant substance users

- Participants enrolled in treatment activities at the clinic according to individual needs

MET for Pregnant Substance Users

- Adheres to MET principles
- Includes content for pregnant substance users:
  - Discussion of patient's feelings about her pregnancy
  - Information about how substance use impacts pregnancy outcomes
  - The degree to which patient is engaging in healthy pregnancy behaviors as part of the personal feedback report



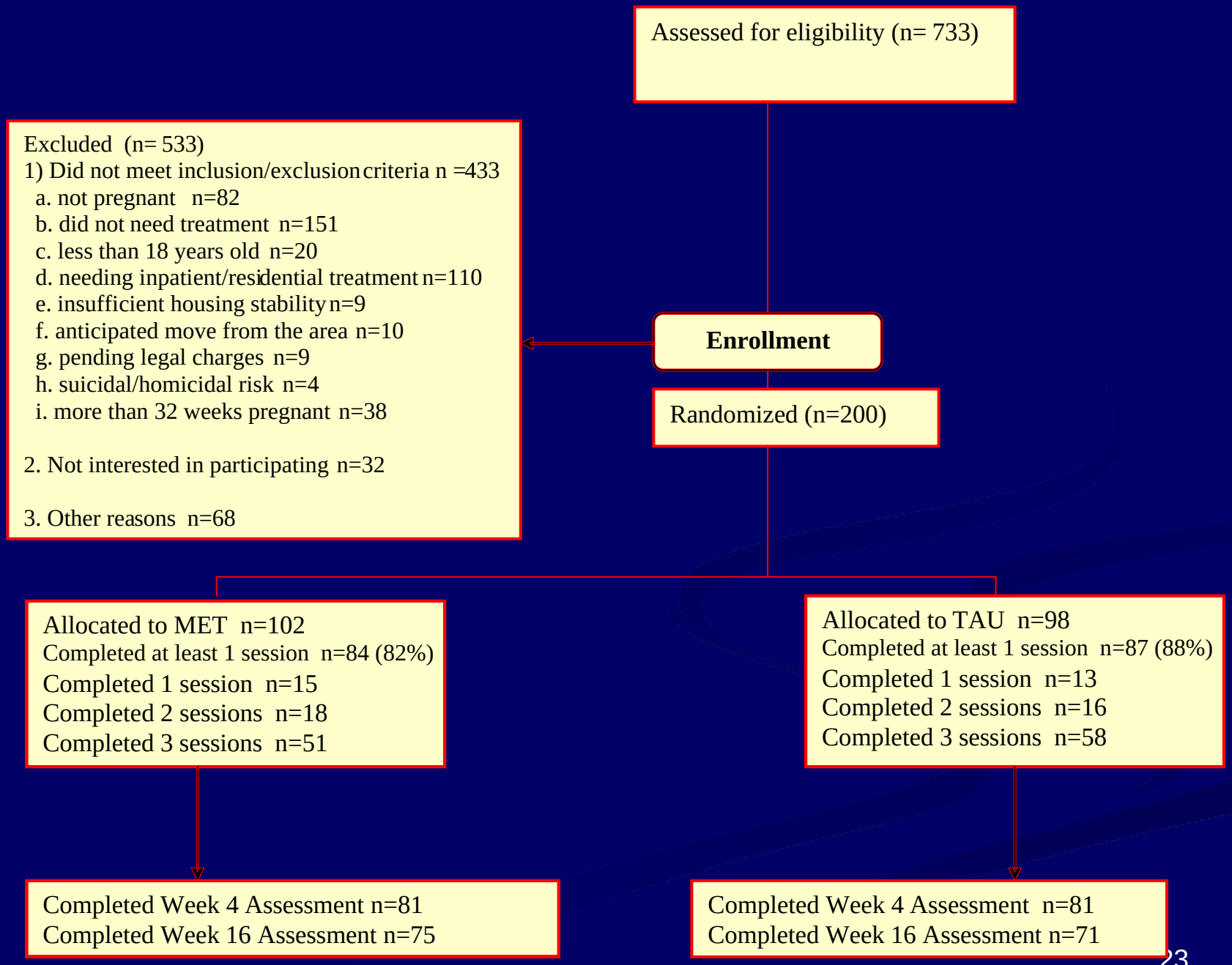
Training and Fidelity

- Three-day centralized training with MET expert followed by training cases
- On-going supervision and tape rating
- MET and TAU sessions rated by blind independent raters

Site Enrollment

- Target sample size per site was 50

- Due to recruitment problems at one site (n=10) other sites had to over-recruit:
  - Site A n=61
  - Site B n=74
  - Site C n=55
  - Site D n=10


Assessed for eligibility (n= 733)
Excluded (n= 533)
1) Did not meet inclusion/exclusion criteria n =433
a. not pregnant n=82
b. did not need treatment n=151
c. less than 18 years old n=20
d. needing inpatient/residential treatment n=110
e. insufficient housing stability n=9
f. anticipated move from the area n=10
g. pending legal charges n=9
h. suicidal/homicidal risk n=4
i. more than 32 weeks pregnant n=38
2. Not interested in participating n=32
3. Other reasons n=68
Enrollment
Randomized (n=200)
Allocated to MET n=102
Completed at least 1 session n=84 (82%)
Completed 1 session n=15
Completed 2 sessions n=18
Completed 3 sessions n=51
Allocated to TAU n=98
Completed at least 1 session n=87 (88%)
Completed 1 session n=13
Completed 2 sessions n=16
Completed 3 sessions n=58
Completed Week 4 Assessment n=81
Completed Week 16 Assessment n=75
Completed Week 4 Assessment n=81
Completed Week 16 Assessment n=71

Sample Characteristics

- On average, 26 years old (SD=5.4) and 20 weeks pregnant (SD=7.8)

- The majority were unmarried, were unemployed and, on average, had a high school education

Sample Characteristics

- Race/Ethnicity:
  - Caucasian 41.2%
  - African American 35.7%
  - American Indian/Alaskan 7.5%
  - Hispanic 21.6%
  - Asian 1%
  - Native Hawaiian/Pacif Isl 1%
  - Other 1%

- More Caucasians in the TAU (46.6%) compared to the MET (33.0%) group (X^2=3.85, df=1, p<.05).

Sample Characteristics

- Primary Drug of Choice:
  - Alcohol 10.5%
  - Cocaine 23.5%
  - Marijuana 31.0%
  - Opiates 13.0%
  - Methamphetamine 7.5%
  - Benzodiazepines 1.0%
  - Other 13.5%

- More MET had cocaine as a primary drug of choice (X^2=4.05, df=1, p<.05); more TAU participants had marijuana as a primary drug of choice (X^2=4.10, df=1, p<.05).

Sample Characteristics

- Randomization Balance Factors:
  - Days of use (past 28): 9.62 (11.24)
  - Need Methadone (%): 12.5%
  - Pressure to attend tx: 17.5%

- More participants with pressure to attend treatment were randomized to TAU than to MET with a trend towards statistical significance (X^2=3.26, df=1, p=.0710).

Validity Check: Treatment Discriminability

- Three blind raters rated tapes for adherence and skill for MET, General Counseling, and Anti-MET
- Raters evidenced good inter-rater reliability as evidenced by Intraclass Correlation Coefficients (range: .81 - .91)
- MET Sessions significantly higher on MET Scales and significantly lower on Anti-MET Scales ($p<.0001$ for all scales)

Statistical Approach

- A mix of Cox proportional hazards models, Generalized Estimating Equation models (GEE), and logistic regression was used depending on the distribution of the particular outcome measure.

- The statistical models included treatment group baseline differences:
  - Primary drug of choice: Cocaine and Marijuana
  - Pressure to attend treatment
  - Minority status

Statistical Approach

- The study was powered to detect treatment differences when the data were pooled across sites but an evaluation of treatment by site effects were included as exploratory analyses

- All analyses were conducted for the ITT sample and the evaluable sample, comprised of the 171 (85%) participants who received at least one MET or TAU session.

Treatment Utilization

- Percent of Scheduled Treatment Hours Attended:
  - No Treatment or Site x Treatment interaction effects, both groups attended 62% of scheduled treatment on average

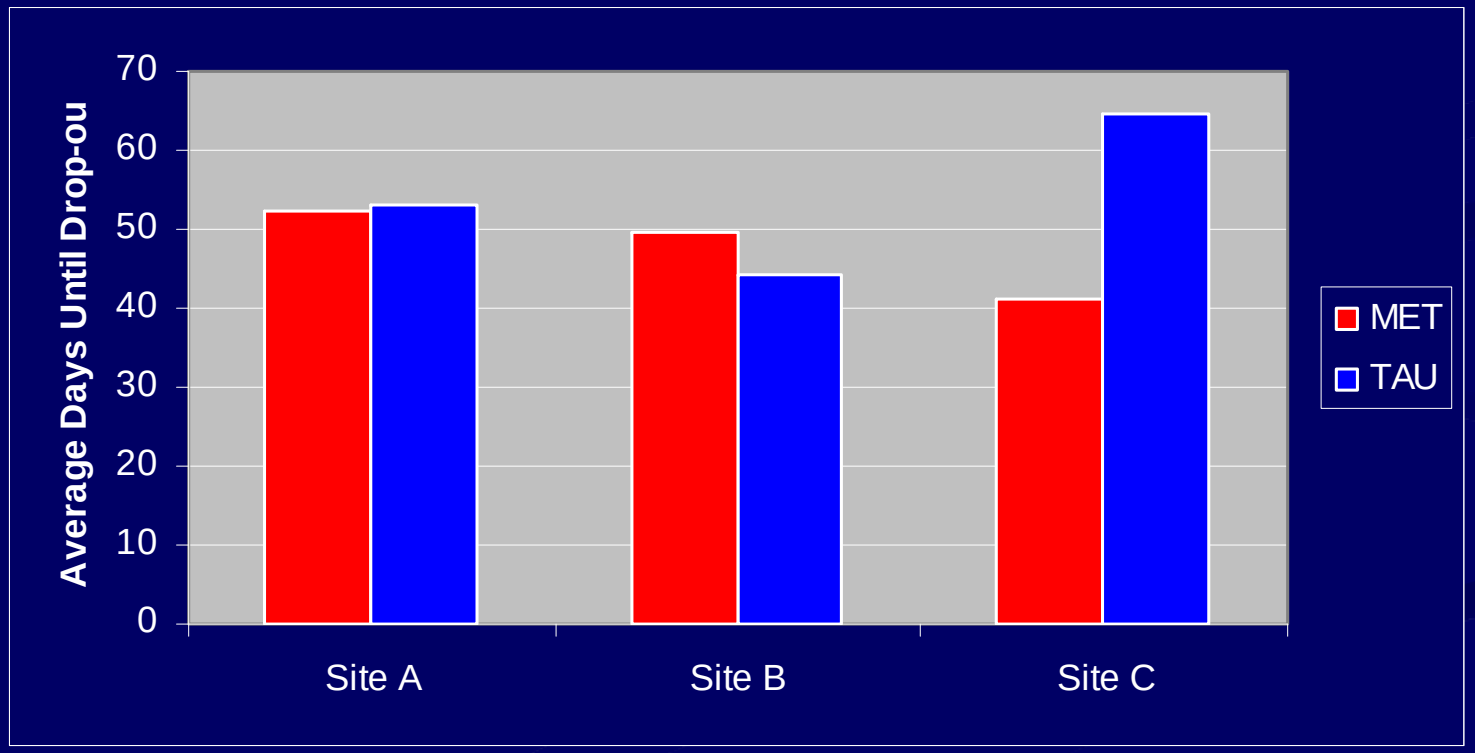
- Number of Treatment Weeks Attended:
  - No Treatment or Site x Treatment interaction effects

Treatment Utilization: Treatment Weeks Attended

	TAU		MET	
	n	X(SD)	n	X (SD)
First Month	98	2.7 (1.3)	102	2.4 (1.3)
Three Month Follow-up	75	6.0 (3.6)	75	5.0 (3.7)

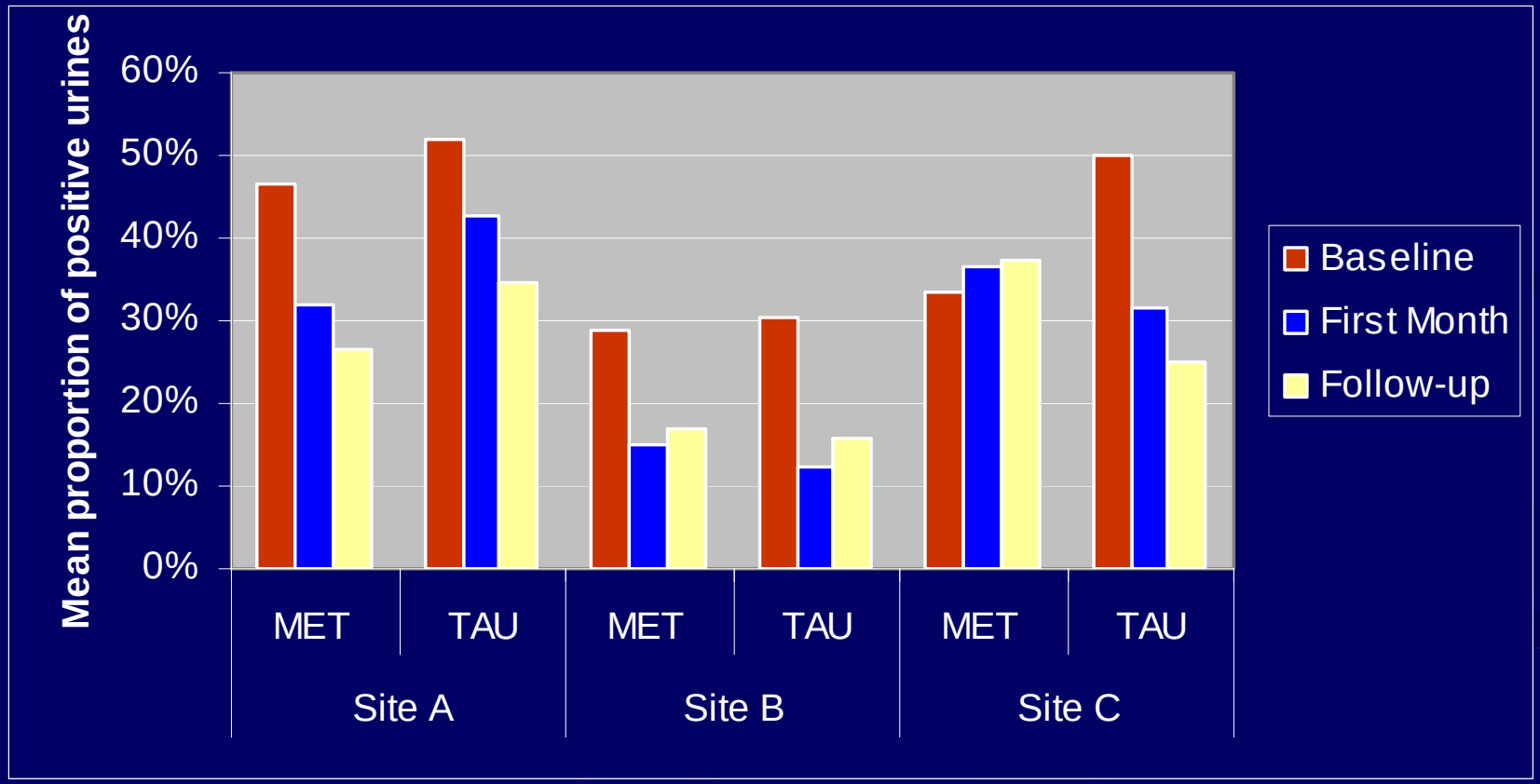
Number Days until Drop-Out While Pregnant

- No Treatment effect; a significant Site x Treatment interaction, reflecting earlier drop out in MET, compared to TAU, at Site C.



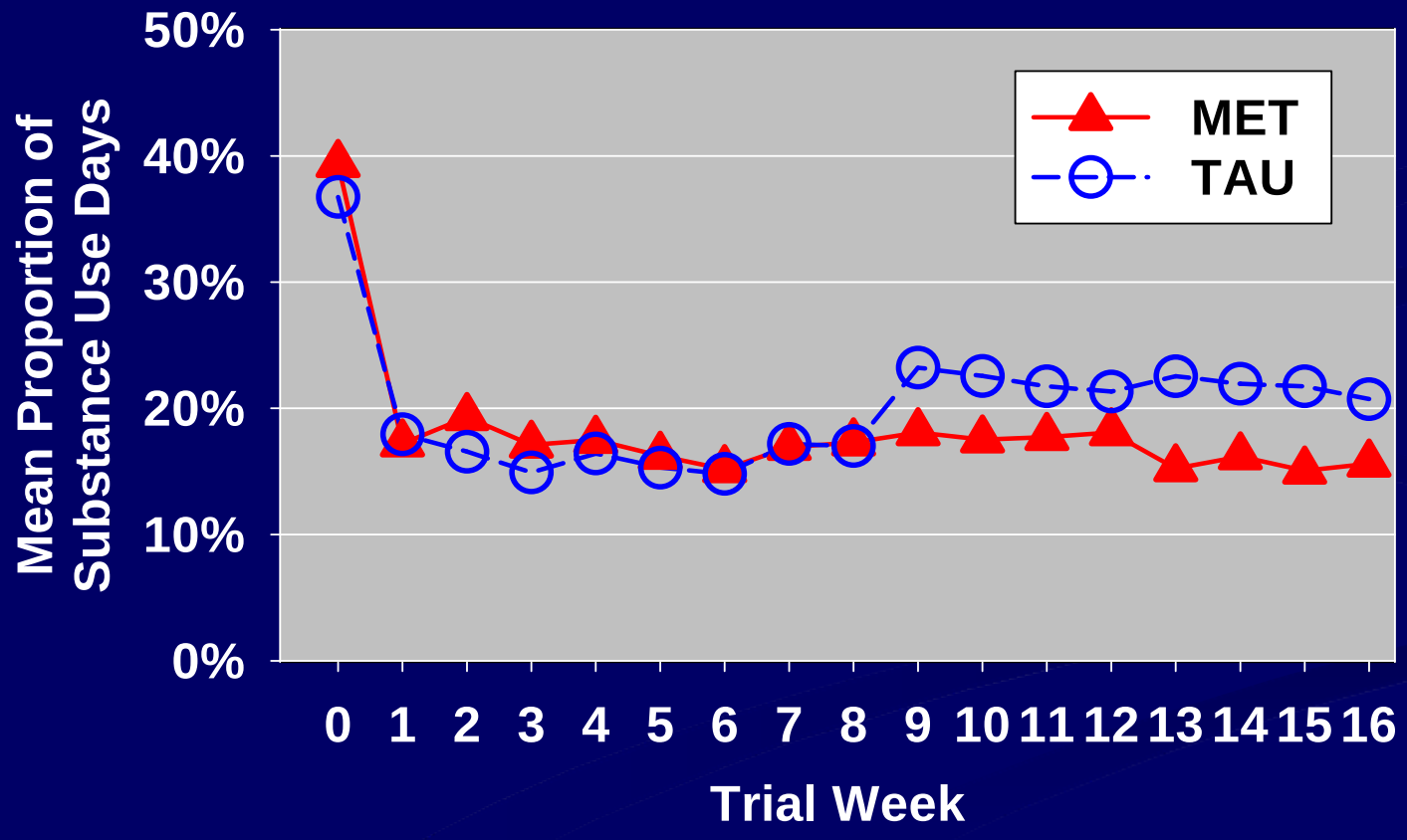
Urine Toxicology Results

- No Treatment effect; significant Treatment x Week x Site effect



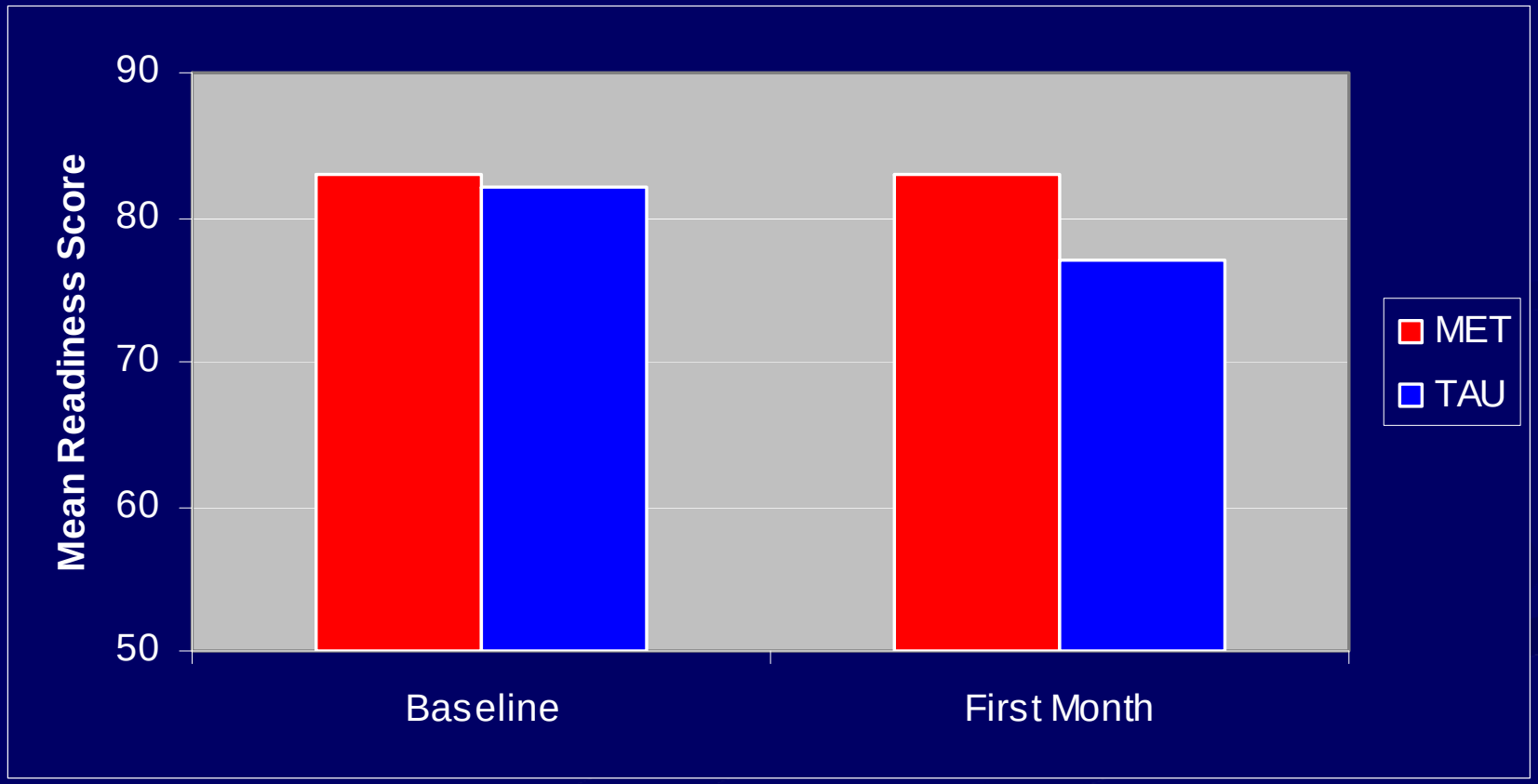
Self-reported Days of Alcohol/Drug Use

- No Treatment or Treatment x Site effects; significant Week effect during first treatment month (Z=-2.40, p<.05)



URICA Readiness Score

- Treatment effect (X^2=5.77, p<.05), no Site x Treatment effect



Minority Analyses

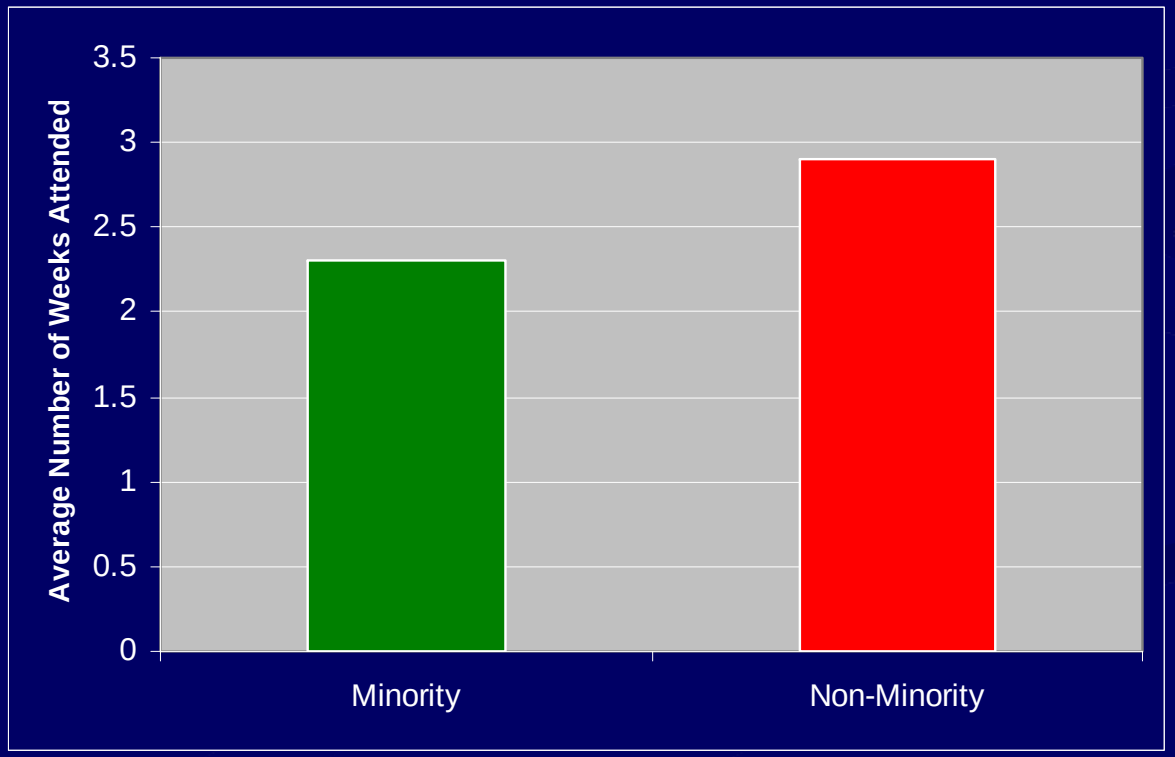
- NIH guidelines require analyses to determine whether treatment is differentially effective for individuals from a minority group.
- A meta-analysis revealed that the effect sizes of MI were larger in ethnic minorities (Hettema et al., 2005)
- Due to sample size, we evaluated minority vs. non-minority status; analyses included Minority and Minority x Treatment effects in the models

Minority Status and Receipt of Study Treatment

- Minority, compared to non-minority, participants were significantly less likely to receive at least one MET/TAU session ($X^2=10.4$, $p<.01$)

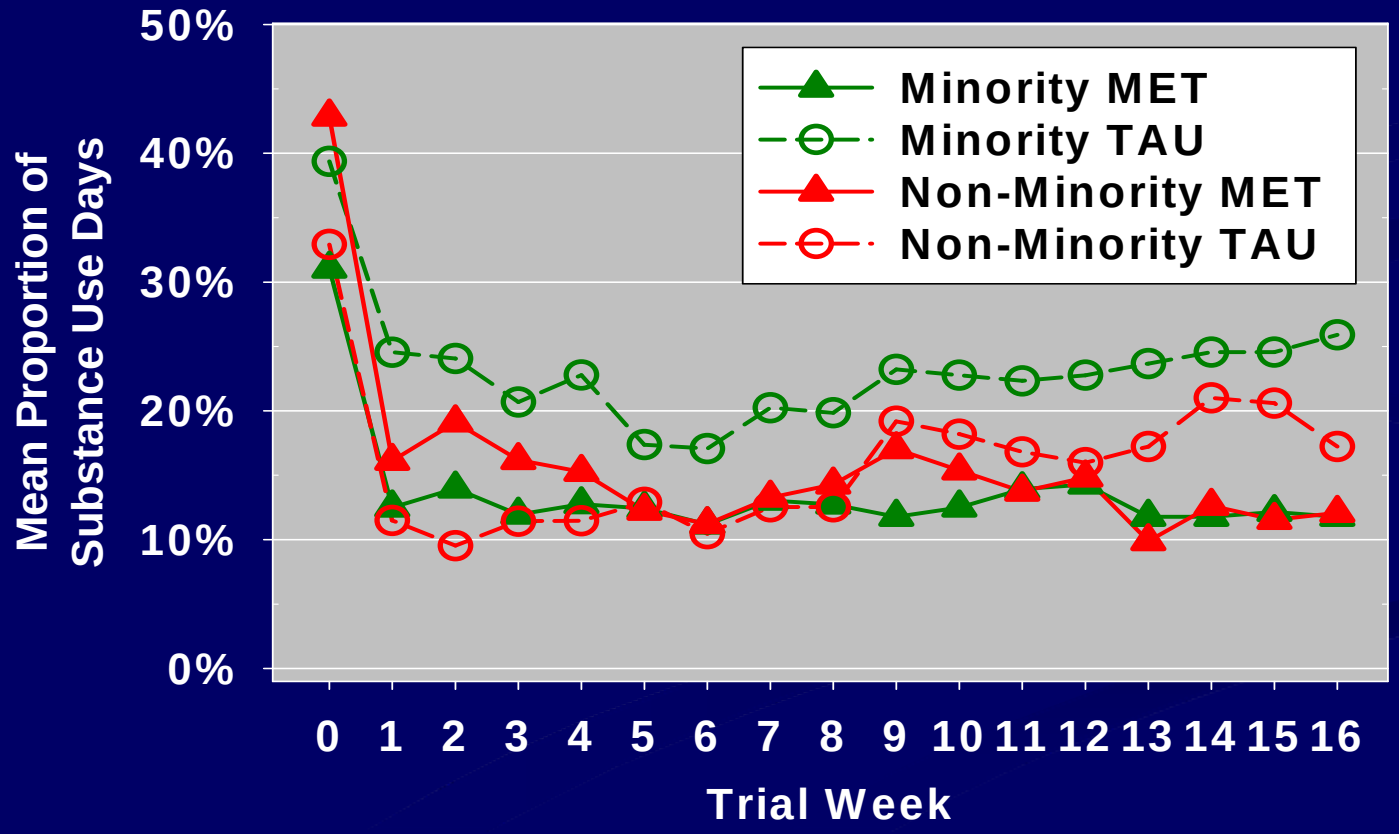
Treatment Utilization

- No Minority effects for percent of scheduled hours attended or days until drop-out.
- Significant Minority effect for treatment weeks attended during first month ($X^2=8.64$, $df=1$, $p<.01$)



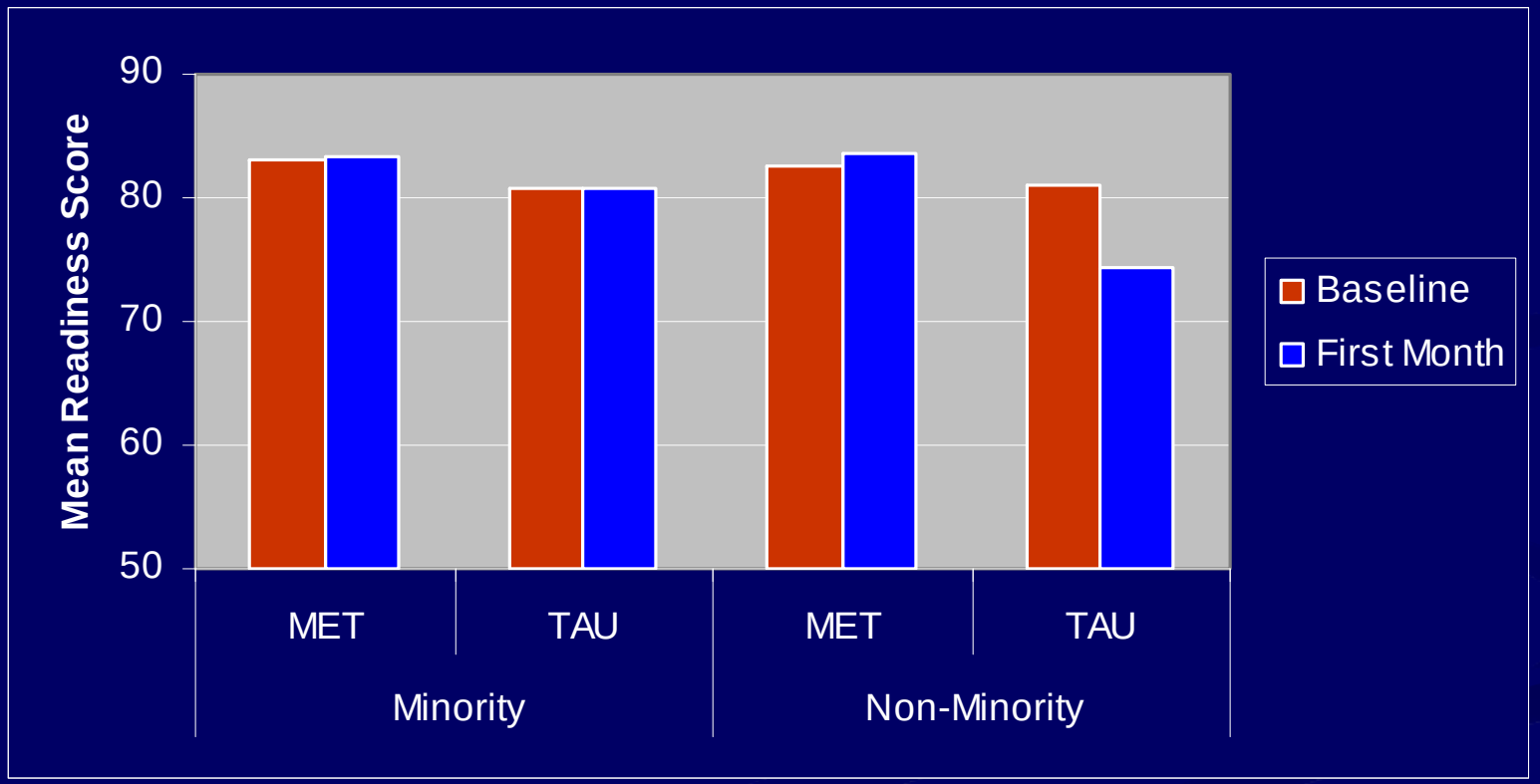
Alcohol/Drug Use

- No Minority effects for urine toxicology results
- Significant Minority x Treatment effect for self-report of alcohol/drug use (Z=2.24, p<.05)



URICA

- Significant Minority x Treatment effect for readiness to change (X2=5.99, df=1, p<.05).



Discussion

- MET was not more effective in increasing treatment utilization or decreasing substance use in the sample as a whole
- Consistent with Jones et al (2004) in which MI plus behavioral incentives had minimal effect in increasing treatment retention
- Inconsistent with Handmaker et al (1999) which found a significant effect of MI for reducing alcohol use in pregnant alcohol users

Discussion

- Growing literature suggests that the benefits of MET might be more inconsistently observed for primary drug, compared to primary alcohol, users
  - Only 21 participants (10.5% of sample) reported alcohol as the primary drug of choice
- Current control treatment much more intensive than the letter used in Handmaker et al. (1999)

Discussion

- TAU might have been an enhanced version of TAU:
  - One program modified its normal treatment to include 2 weekly individual counseling sessions that normally would not have been provided
  - Research assessments as well as the additional attention and follow-up provided by both clinic and study staff to all participants

Discussion

- Significant Site by Treatment interaction effects
  - Only 3 sites had sufficient sample size to be included in the analysis of site effects; the pattern of results makes it difficult to speculate about what site characteristics, if any, might have contributed to the results observed.
  - Site effects consistent with the results of the CTN MET study

Discussion

- Minority participants were less likely to receive an initial MET/TAU session and attended fewer treatment weeks during the first month
  - Suggests minority pregnant substance users might be particularly susceptible to being lost early in treatment
  - Consistent with findings that AA pts were more likely to drop out of a cocaine clinical trial and with a retrospective chart review that AA women were more likely to drop out of treatment

Discussion

- Minority participants in MET reported a greater decrease in substance use compared to TAU minority participants
  - Consistent with results of a meta-analysis of MI studies finding larger effect sizes in minority populations (Hettema et al., 2005)
  - If replicated, this finding might be of interest for culturally-based treatment approaches

Two Primary Conclusions

- MET for pregnant substance users was not more effective in increasing treatment utilization or decreasing substance use in the sample as a whole

- There might be particular subgroups or treatment programs for which MET might be more or less effective than TAU

Acknowledgments

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