

NIDA

**NATIONAL INSTITUTE ON
DRUG ABUSE**

**National Drug Abuse Treatment
Clinical Trials Network**

Gender Differences in Response to a 12-Step Engagement Intervention: Results of a National Drug Abuse Treatment Clinical Trials Network Study

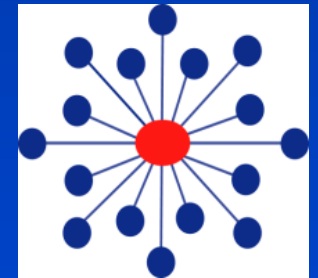
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Content is solely the responsibility of the authors and does not necessarily represent the official views of NIDA.

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Overall, 12 Step Attendance and Involvement Result in Better Outcomes

- ❖ AA / NA participation associated with ↑ abstinence, ↑ psychosocial functioning, & ↑ self-efficacy.
- ❖ 12-Step self-help groups reduce health care utilization & costs.
- ❖ Combined 12-Step & formal treatment → better outcomes than either alone.
- ❖ Active participation in 12-Step activities more helpful than merely attending.

Summary and Recommendations from William Miller on 12-Step Involvement

- ❖ 12-Step approaches cannot be ignored in understanding treatment outcomes.
- ❖ Treatment is the time to initiate 12-Step attendance. If 12-Step attendance is not initiated during the period of treatment, it is quite unlikely to happen.
- ❖ Without question, there are counseling procedures that significantly increase 12-Step attendance, at least during and often after treatment. **TSF therapy clearly did this in Project MATCH. Systematic encouragement [intensive referral procedures] can significantly increase attendance.**

Why Would Women and Men Respond Differently to 12-Step Interventions?

- ❖ Designed by (& for) men, 12-Step programs may not meet women's specific needs (Kaskutas, 1994).
- ❖ Living in a patriarchy, women might struggle with ideas of powerlessness and surrender (Rhodes & Johnson, 1994; Sered & Norton-Hawk, 2011).
- ❖ Women's experience of concept of powerlessness differs based on degree of dependence & recovery stage (Matheson & McCollum, 2008).
- ❖ Through women-only meetings & adapting AA/NA tenets and practices, women can use 12-Step programs in gender-specific ways (Sanders, 2006).

Do Women and Men Respond Differently to 12-Step Programs?

- ❖ No gender difference in outcomes related to AA attendance (Aharon, 2000; Ammon et al., 1999; DeLucchi & Kaskutas, 2010; Kelly et al., 2006; Schuckit et al., 1997).
- ❖ Women had better drinking outcomes in 12-Step than Relapse Prevention aftercare (Brown et al., 2002)
- ❖ 8-year follow-up - women more likely than men to participate in AA & women's drinking outcomes more related to AA attendance (Timko et al., 2002).
- ❖ Women's attendance at AA associated with ↓ alcohol dependence symptoms ↑ self-efficacy than men (Moos et al., 2006).
- ❖ Stronger relationships for women than men between 12-Step participation & abstinence from alcohol / other drugs across 9 years (Witbrodt et al., 2014).

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Women, Alcoholics Anonymous, and Related Mutual Aid Groups: Review and Recommendations for Research

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Our Study Questions

- ❖ In a multi-site trial that randomized stimulant (cocaine or methamphetamine) users to 12-Step Facilitation integrated into standard care (TAU) or to TAU alone:
 - ❖ Are there gender differences in substance use outcomes in response to assignment to either of the treatment arms?
 - ❖ Are there gender differences in attendance or involvement in 12-Step programs in response to either of the treatment arms?

STAGE-12 Therapy Manual

NIDA-CTN-0031

Version 2.0

Stimulant Abuser Groups to Engage in 12-Step (STAGE-12)

January 2008

National Institute on Drug Abuse
Clinical Trial Network

STAGE-12

**Stimulant Abuser Groups to
Engage in 12-Step Programs**



*A Combined Group and Individual
Treatment Program*

**Version Number: 2.0
January 2008**

Stuart Baker, M.A.
Dennis C. Daley, PhD
Dennis M. Donovan, PhD
Anthony S. Floyd, PhD

- ❖ Based on and adapted from **Twelve Step Facilitation Therapy for Drug Abuse and Dependence**
- ❖ Adapted for use in group delivery format from Brown, et al. 2002
- ❖ Integrated with Intensive Referral procedures developed by Timko, et al., 2006, which actively attempts to get participants involved in 12-Step meetings
- ❖ Five group & 3 individual sessions over 8 weeks

Individual presents to one of 10
treatment programs
Screen for study eligibility
Informed consent
Baseline assessment
Randomized to condition

Treatment as
Usual (TAU)

STAGE-12
Integrated into TAU

During Intervention
Assessment

End of Intervention
Assessment

3-, 6-Month Post-Randomization
Follow-ups



Contents lists available at [SciVerse ScienceDirect](#)

Journal of Substance Abuse Treatment



Stimulant abuser groups to engage in 12-Step: A multisite trial in the National Institute on Drug Abuse Clinical Trials Network

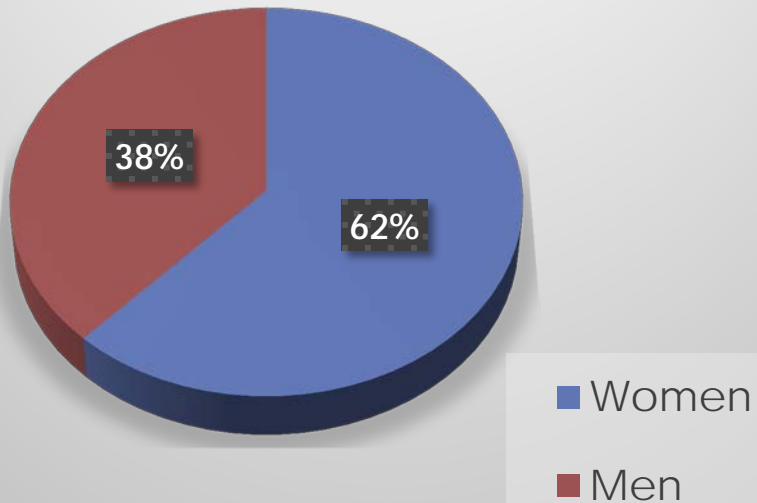
Dennis M. Donovan, Ph.D. ^{a,b,*}, Dennis C. Daley, Ph.D. ^c, Gregory S. Brigham, Ph.D. ^d, Candace C. Hodgkins, Ph.D. ^e, Harold I. Perl, Ph.D. ^f, Sharon B. Garrett, MPH ^a, Suzanne R. Doyle, Ph.D. ^a, Anthony S. Floyd, Ph.D. ^g, Patricia C. Knox, Ph.D. ^h, Christopher Botero, B.S. ⁱ, Thomas M. Kelly, Ph.D. ^{c,j}, Therese K. Killeen, Ph.D. ^k, Carole Hayes, M.A. ^l, Nicole Kau'iBaumhofer, M.A. ^m, Cindy Seamans, Ph.D. ⁿ, Lucy Zammarelli, M.A. ^o

Main Study Results Summary: STAGE-12 vs TAU

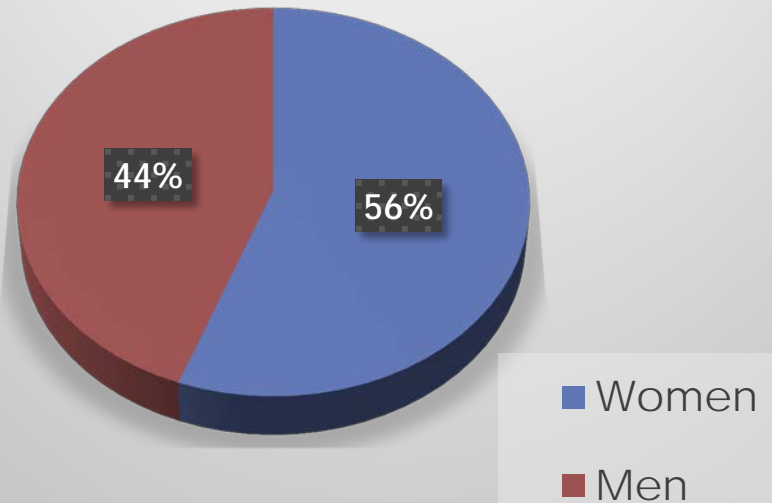
- ❖ STAGE-12 increases the probability of abstinence from stimulants during and in the last 30 days of the active treatment phase.
- ❖ If abstinence is not achieved during this period, rates of use are greater among STAGE-12 participants.
- ❖ STAGE-12 associated with significantly lower ASI Composite score at 3-month follow-up and greater change in this measure from baseline to 3-month follow-up
- ❖ STAGE-12 associated with greater number of
 - › days of 12-step self-help meeting attendance
 - › types of other 12-step activities engaged in
 - › maximum number of days of self-reported service activities at meetings at different periods during and following the active treatment phased

Women and Men Assigned to STAGE-12 and TAU

STAGE-12
N = 234



TAU
N = 237



Baseline Demographics by Treatment Arm and Gender

Characteristics	STAGE-12		TAU	
	Women (N=145)	Men (N=89)	Women (N=132)	Men (N=105)
Age				
Mean (Std.)	36.61 (9.97)	40.90 (9.62)	37.02 (9.11)	40.36 (9.48)
Ethnicity				
Hispanic or Latino	5%	9%	7%	6%
Race				
Caucasian	54%	34%	48%	53%
Black/African American	31%	48%	35%	35%
Marital Status				
Married	17%	13%	11%	10%
Widowed	1%	0%	6%	1%
Separated	12%	8%	11%	11%
Divorced	22%	28%	26%	19%
Never Married	49%	51%	46%	58%

Demographics (cont.)

Characteristics	STAGE-12		TAU	
	Women (N=145)	Men (N=89)	Women (N=132)	Men (N=105)
Education				
Mean (Std.)	12.08 (1.81)	12.48 (1.31)	12.03 (1.70)	12.12 (1.56)
Usual Employment				
Full Time	31%	43%	32%	44%
Part Time	22%	29%	23%	25%
Unemployed	47%	28%	45%	31%
Court Mandated				
Yes	19%	27%	16%	27%

Outcome Variables and Sources of Data

- ❖ Substance Use Calendar (SUC) (30-day intervals baseline - 180 days post-baseline)
 - › Stimulant Use Days
 - › Non-Stimulant Use Days
 - › 12-Step Meeting Attendance Days
- ❖ Addiction Severity Index (ASI) (baseline, 90- and 180-day follow-ups)
 - › Drug Composite Score
 - › Alcohol Composite Score
- ❖ Self-Help Activities Questionnaire (SHAQ) (30 day intervals - 180 days post-baseline)
 - › Maximum # Days Attending AA, NA, CA, CMA
 - › Days Speaking at Meetings
 - › Days Performing Duties at Meetings
 - › Number Other Types 12-Step Activities (0-6)
- ❖ Urine Drug Screens (UDS) (baseline, 30, 60, 90, 180 days)
 - › Presence of Stimulant Drug

Substance Use Outcomes

Zero-Inflated Negative Binomial Models – Stimulant and Non-Stimulant Use Days

Zero-inflated negative binomial random-effects model utilized allows for:

- ❖ Missing data across time
- ❖ Model-based predictions of the
 - probability of abstinence and
 - rate of stimulant substance use

within a 30-day window of assessment for all participants at each time point, based on maximum-likelihood estimation procedures.

- ❖ 3-way interaction of time-by-treatment-by-gender needed to assess gender moderation could not be obtained.
- ❖ Alternative: Gender differences were assessed within each treatment arm (STAGE-12 or TAU).

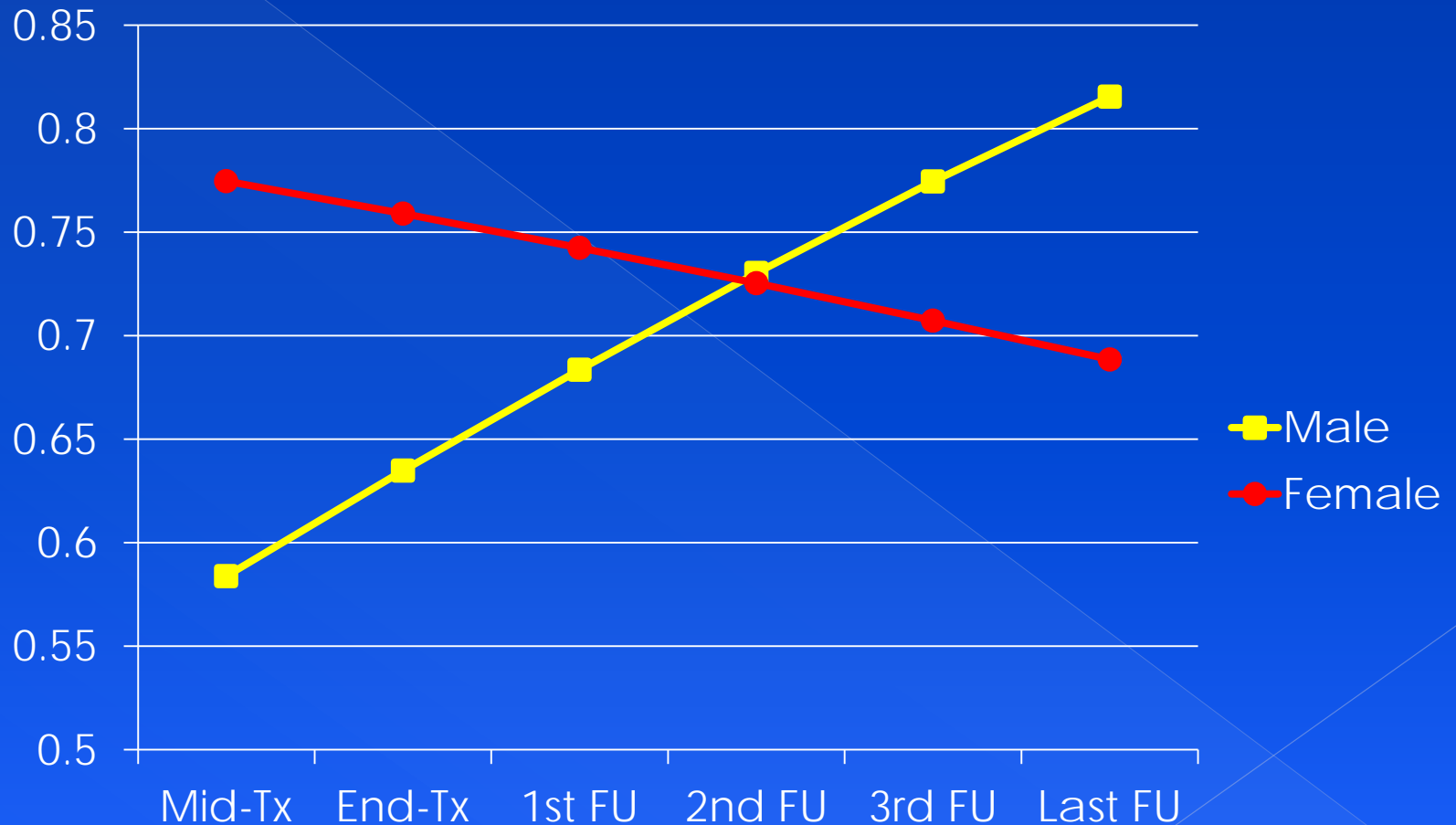
Interpretation of Zero-Inflated Negative Binomial Models

- ❖ The logistic portion (abstinence) and the negative binomial (or count) portion are typically interpreted and described separately
- ❖ Generally presented and interpreted in terms of odds ratios (logistic) and incidence rate ratios (negative binomial) with corresponding 95% confidence limits to assess statistical significance.

Interaction Odds Ratios and Incidence Rate Ratios within **STAGE-12** Arm (n = 204): Days of Stimulant Substance Use within 30-day Window of Assessment

	Logistic (Abstinence)		Negative Binomial (Count)	
	Odds Ratio	95% CI for Odds Ratio	Rate Ratio	95% CI for Rate Ratio
Mid-Treatment	7.14	1.56, 32.74	1.65	0.85, 3.21
End-of-Treatment	3.77	1.05, 13.50	1.53	0.85, 2.78
First Follow-up	1.99	0.64, 6.14	1.42	0.81, 2.49
Second Follow-up	1.05	0.34, 3.20	1.32	0.75, 2.33
Third Follow-up	0.55	0.16, 1.92	1.23	0.66, 2.27
Last Follow-up	0.29	0.07, 1.28	1.14	0.57, 2.28

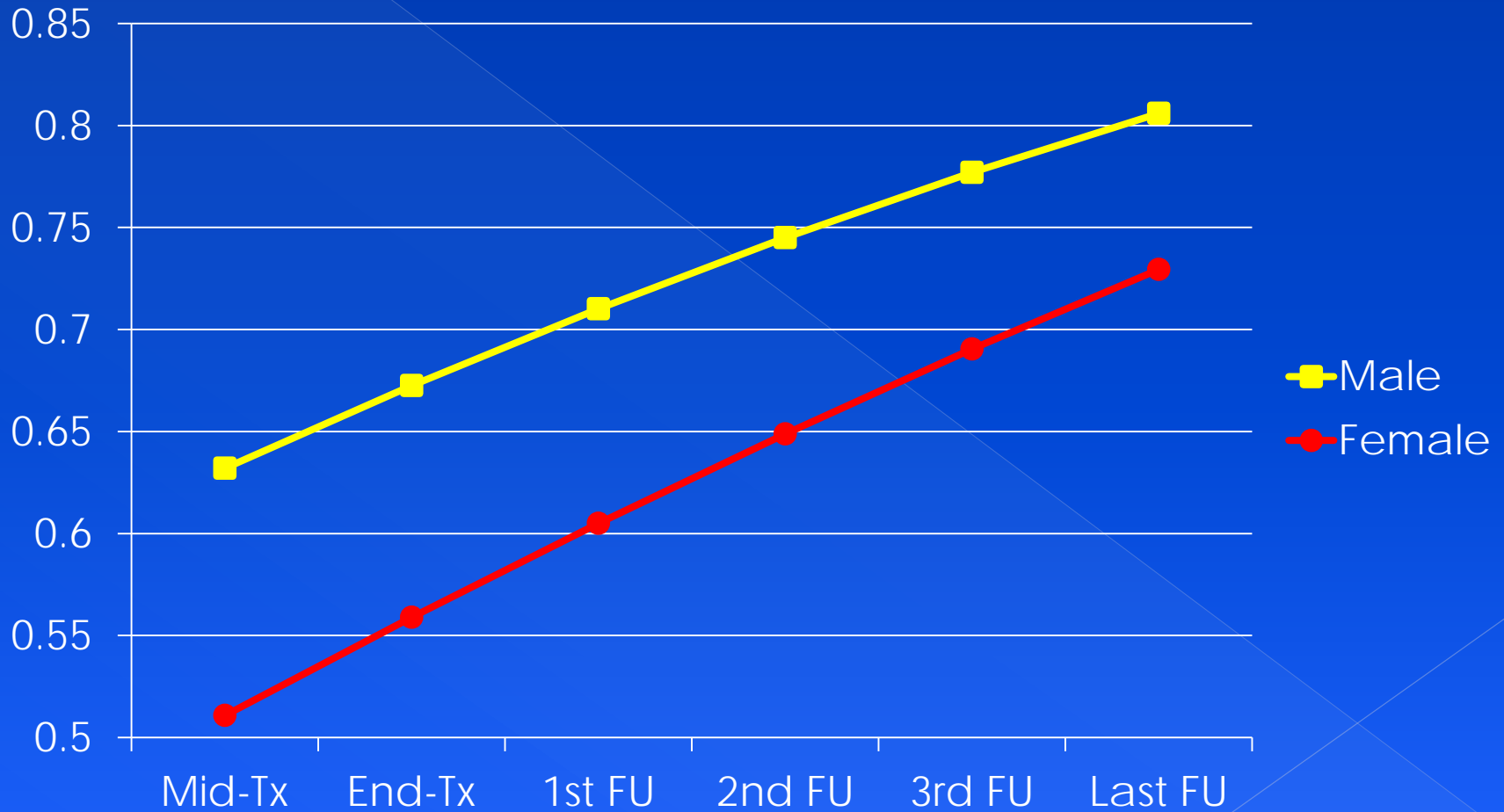
Model-based Average Predicted Probability of Abstinence from Stimulant Use: Gender within STAGE-12



Interaction Odds Ratios and Incidence Rate Ratios **within TAU Arm (n = 217):** Days of Stimulant Substance Use within 30-day Window of Assessment

	Logistic (Abstinence)		Negative Binomial (Count)	
	Odds Ratio	95% CI for Odds Ratio	Rate Ratio	95% CI for Rate Ratio
Mid-Treatment	0.45	0.11, 1.89	1.19	0.63, 2.25
End-of-Treatment	0.47	0.14, 1.60	1.20	0.67, 2.13
First Follow-up	0.50	0.17, 1.44	1.20	0.70, 2.08
Second Follow-up	0.52	0.19, 1.45	1.21	0.70, 2.10
Third Follow-up	0.55	0.18, 1.64	1.22	0.68, 2.20
Last Follow-up	0.57	0.16, 2.04	1.23	0.64, 2.38

Model-based Average Predicted Probability of Abstinence from Stimulant Use: Gender within TAU



Other Substance Use Findings

- ❖ No significant gender effects in abstinence or rate of use of **non-stimulant drug use**.
- ❖ For ASI Drug composite score, only in **STAGE-12**, at the last 180-day follow-up, women had higher odds (OR = 2.4904. $p = 0.0074$) than men of a non-zero Drug composite.
- ❖ No Alcohol composite gender findings.
- ❖ No gender differences in odds of having a stimulant-positive UDS.

12-Step-Related Outcomes

Women Less Active than Men in 12-Step Programs

- ❖ Negative binomial random effects regression models.
- ❖ Meeting attendance: women attended 12-Step meetings at a lower rate than men during post-treatment follow-up periods in both TAU and STAGE-12.
- ❖ Speaking at meetings: In STAGE-12, at the last follow-up, women reported speaking at meetings at half the rate of men (Rate Ratio = 0.50). Not significant at other time points. No gender main effects
- ❖ Performing duties: No within-treatment-arm gender effects or main effects of gender.
- ❖ Other 12-Step Duties: In STAGE-12, at the last follow-up, women reported a lower rate of doing other types of self-help activities (RR = 0.78).

Summary and Conclusions

- ❖ Preponderance of literature indicates 12-Step involvement no less helpful for women than for men.
- ❖ Some research suggests women benefit more than men from 12-Step involvement.
- ❖ Current study consistent with both of these assertions. We found no indication that women fared worse in STAGE-12, and some evidence they had greater during-treatment abstinence in STAGE-12 than men.

Summary and Conclusions (cont.)

- ❖ In both treatment arms, women attended outside 12-Step meetings less than men. Consistent with some prior studies (e.g., Orwat et al., 2011) and not others (e.g., Witbrodt & Delucchi, 2011).
- ❖ By 6 months, women in STAGE-12 showed less active involvement in 12-Step meetings than men. This might account for the reversal over time in men's and women's abstinence.
- ❖ Conclusions limited by inability to test 3-way interaction. Study *n* insufficient given data distributions to fully test gender moderation.

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- ❖ Center for Psychiatric & Chemical Dependency Services, Pittsburgh, PA;
- ❖ ChangePoint, Inc. Portland, OR;
- ❖ Dorchester Alcohol & Drug Commission, Summerville, SC;
- ❖ Evergreen Manor, Everett, WA;
- ❖ Gateway Community Services, Jacksonville, FL;
- ❖ HinaMauka, Kaneohe, HI;
- ❖ Maryhaven, Columbus, OH;
- ❖ Nexus Recovery Center, Dallas, TX;
- ❖ Recovery Centers of King County, Seattle, WA; and
- ❖ Willamette Family Treatment Services, Eugene, OR

