

The Women's Recovery Group Study

A Stage I trial of women-focused group therapy for substance use disorders vs. mixed gender group drug counseling

Shelly F. Greenfield, MD, MPH

Associate Professor of Psychiatry,
Harvard Medical School

Associate Clinical Director, Alcohol and Drug Abuse
Treatment Program, McLean Hospital

Acknowledgements

- National Institute on Drug Abuse
(R01 DA 015434)
- Co-investigators and Consultants: Kathleen Brady, MD, PhD, Dennis Daley, PhD Hadine Joffe, MD, Grace Hennessy, MD, Robert Gallop, PhD, Roger Weiss, MD
- Group Therapists: Monika Kolodziej PhD, Barbara Raymond, LICSW, Laura Ruegg, LICSW
- Research Staff: Amanda Cummings, BA, Laura Kuper, BA, Melissa Lincoln, BA, Kate McHugh, MA, Rebecca Popuch, BA, Elisa Trucco, BA

Scope of the Problem

In 2004:

- More than 7 million women had alcohol or drug dependence or abuse
- More than 15 million used illicit drugs and 7 million reported *past month* use
- More than 32 million smoked cigarettes and almost 28 million smoked in the past *month*

Women and Substance Abuse

Women with substance use disorders:

- Advance more rapidly from first use to regular use to first treatment episode
- Use smaller quantities of substances for fewer years
- Average more medical, psychiatric and social consequences
- Now initiate their use of substances at an earlier age and at approximately the same age as their male counterparts

Treatment Outcomes

- Given the vulnerability of women to adverse consequences of alcohol and drug abuse and dependence, what do we know about women's substance abuse treatment outcomes?
- What about outcomes for gender-specific or women-focused treatment?

Gender Differences in Treatment Outcomes

- Research studies over the past 20 years indicate that gender in itself *is not* a specific predictor of substance abuse treatment outcome (Greenfield et al, Substance abuse treatment entry, retention, and outcome in women: A review of the literature. Drug Alcohol Depend 2007; 86: 1-21)
- However, a number of known predictors of treatment outcomes may vary in prevalence, severity, or significance by gender (e.g., co-occurring disorders, trauma histories, employment, educational attainment, social support)
- Therefore, these predictors may have a different level of significance for men's and women's recovery

Gender-Specific Treatment

- What about women-only versus mixed-gender treatment?
- Do women have better outcomes in single-gender treatment?
- Are there specific subgroups of women with substance use disorders who have better outcomes in single-gender treatment?
- What is the role and rationale for this treatment?

Rationale for Gender-Specific Treatment

Individual Preferences: Certain men and women with substance use disorders may prefer single-gender vs. mixed-gender settings (e.g., women with trauma histories)

Effects of Gender on Group Process: Short-term groups may have enhanced cohesion by homogeneity; women cite preferences for women-only groups because of enhanced freedom to speak openly; gender composition can impact group process; decreased sex-role stereotyping, etc.

Gender-Specific Content: Certain topics may be of more interest to women (e.g., substance abuse and reproductive health, women's health, parenting and family relationships, etc.)

Women's vs. Mixed Gender Treatment

Women's experiences and perceptions:

- 34 women in 2 addiction treatment programs were interviewed about their experiences in therapy groups, both co-ed and women-only
- Women preferred women-only groups where they could talk about relationships, children and other intimates, free of sexualization and perceived harassment experienced in mixed-gender groups

(Kaufman et al., 1995)

Women's vs. Mixed Gender Treatment

Evidence-based research on effectiveness of women's treatment is limited:

- Women-only (WO) vs. Mixed Gender (MG) treatment programs
- Specific treatments for specific subgroups of women with substance use disorders (e.g., group therapy)

What Types of Women-Specific Groups or Treatments Are There?

Studies exist of women-only groups for:

- Parenting and pregnant women with SUDs (Mackie-Ramos, 1988; Reynolds, 1995; Stevens, 1995; Berkowitz, 1998; Luthar, 2000; Killeen, 2000)
- Women with co-occurring post-traumatic stress disorder and SUDs (Najavits, 1996; 1998; Hien et al., 2005)
- For patients with borderline personality disorder and drug dependence (Linehan et al., 1999)

New Research Study for Women's Recovery

- While there are a number of existing treatments for specific sub-groups of women with substance use disorders
- No current evidence regarding effectiveness of delivering generic substance abuse treatment in single-gender vs. mixed-gender group therapy format
- Group therapy is a mainstay of treatment in substance abuse treatment programs
- Need for a specific, manual-based group treatment designed for a heterogeneous group of women with substance use disorders in order to test hypotheses about women-only vs. mixed-gender group therapy

Women's Recovery Group Study

Overall Research Study Goals for Stage I Behavioral Therapy Development Trial:

- To develop a new manual-based group treatment for women with substance use disorders
- Two main Components
 - All women group composition
 - Content relevant to women in recovery
- Test this new group therapy vs. mixed-gender group treatment

Research Questions

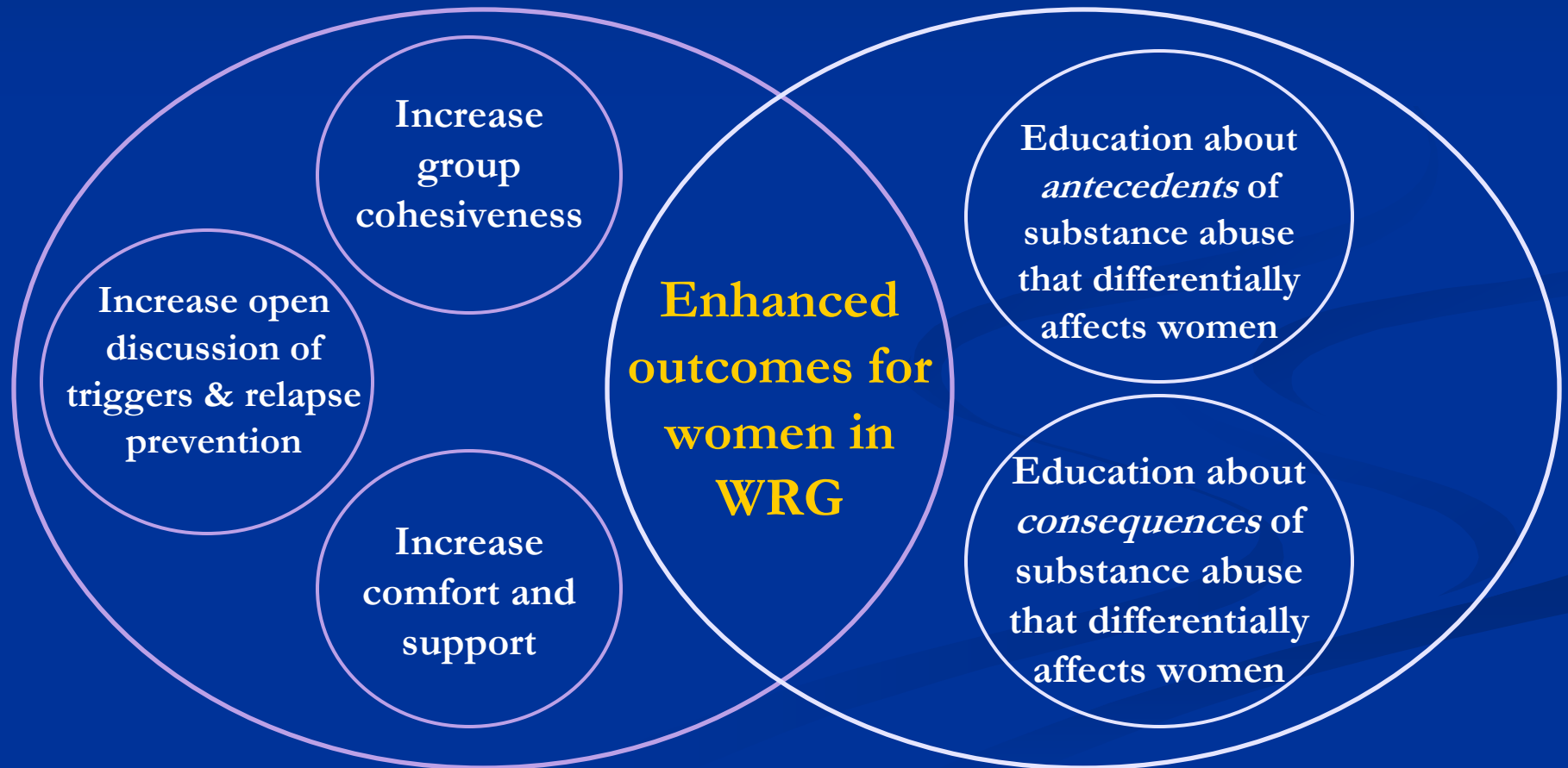
- Will the manual-based Women's Recovery Group (WRG) have patient acceptability and satisfaction?
- Are there any differences in *within-treatment* outcomes between women-focused WRG vs. an effective mixed-gender control group?
- Are there any differences in *6 month post-treatment* patient outcomes between single-gender WRG vs. mixed-gender control group?

(Greenfield et al, Drug and Alcohol Dependence, 2007)

Hypothesis Regarding Mechanism of Action

All women group composition

Women-focused group content



Women's Recovery Group Therapy Development

- Developed 12 session women-focused group therapy for women with substance use disorders: Women's Recovery Group (WRG)
- Includes 14 topics can be flexibly chosen to comprise the 12 sessions

WRG Therapy Development: Structure of Sessions

90 minute structured relapse prevention group therapy session:

- Brief check-in
- Review of skill practice and last week's topic
- Presentation of session topic
- Discussion by participants
- Review session's "take home message" and upcoming week's skill practice
- Check-out

Manual Development: Session Topics

1. The Effect of Drugs and Alcohol on Women's Health
2. What are the Obstacles to Seeking Treatment and Getting into Recovery
3. Managing Mood, Anxiety, and Eating Problems Without Using Substances
4. Violence and Abuse: Getting Help

Manual Development: Session Topics

5. Women and their Partners: The Effect on the Recovery Process
6. Women as Caretakers: Can you care of yourself while taking care of others ?
7. Women's Use of Substances Through the Life Cycle
8. Substance Use and Women's Reproductive Health

Manual Development: Session Topics

9. The Issue of Disclosure: To Tell or Not to Tell
10. How to Manage Triggers and High Risk Situations
11. Using Self-Help Groups to Help Yourself
12. Can I Have Fun and Not Use Drugs or Alcohol?
13. Coping with Stress
14. Achieving Balance in Your Life

Pre-Pilot Group Therapy Trial

- Two pre-pilot groups conducted sequentially by PI & another trained therapist (N=13)
- Minor revisions of manual based on therapist and subject evaluations and evaluation of consultant
- Next step to test in pilot phase the WRG versus a standard mixed-gender substance abuse group therapy control condition (e.g., Group Drug Counseling)

Control Condition: Group Drug Counseling (GDC)

- Effective manual based group treatment delivered in the NIDA Collaborative Cocaine Treatment Study (Crits-Christoph et al., 1999); adapted for other substances of abuse (Weiss et al, 2007)
- Developed to closely resemble group drug counseling as delivered in treatment programs
- Conducted in a mixed-gender group composition
- 12 weekly sessions
- One 90 minute session each week focusing on a specific topic

Pilot Randomized Control Trial

- Conducted Pilot RCT of WRG versus GDC (mixed-gender Group Drug Counseling)
- Pilot RCT conducted in 2 rounds, WRG (N=16) vs. GDC (N=7 women, 10 men)
- To minimize therapist effects, two women therapists trained in WRG & GDC
 - Switched to control for therapist effects

Hypothesis Regarding Outcomes of Pilot RCT of WRG vs. GDC

- Pilot RCT of WRG vs. GDC:

Women enrolled in WRG will have better post treatment outcomes than women enrolled in mixed gender control group (Group Drug Counseling or GDC):

- Compared with Baseline:

- Fewer days of any substance use
- Fewer drinking days
- Fewer drinks/drinking day
- Greater improvement in the Addiction Severity Index (ASI)

Inclusion and Exclusion Criteria

Inclusion:

- Age 18 or older and signed informed consent
- Diagnosis of any Substance Dependence according to DSM-IV (in addition to nicotine dependence)

Exclusion:

- Medical or psychiatric condition that would prevent regular group attendance
- Co-occurring Axis I disorders according to the SCID for DSM-IV (First, 1996) (psychotic, bipolar, or post-traumatic stress disorders)
- Mandated to treatment
- Residential treatment or simultaneously participation in other substance abuse (SA) treatment programming (not including self-help groups, individual therapy, pharmacotherapy, other non SA groups) during study
- Required medical detoxification (these patients were eligible to enter the study after being detoxification)

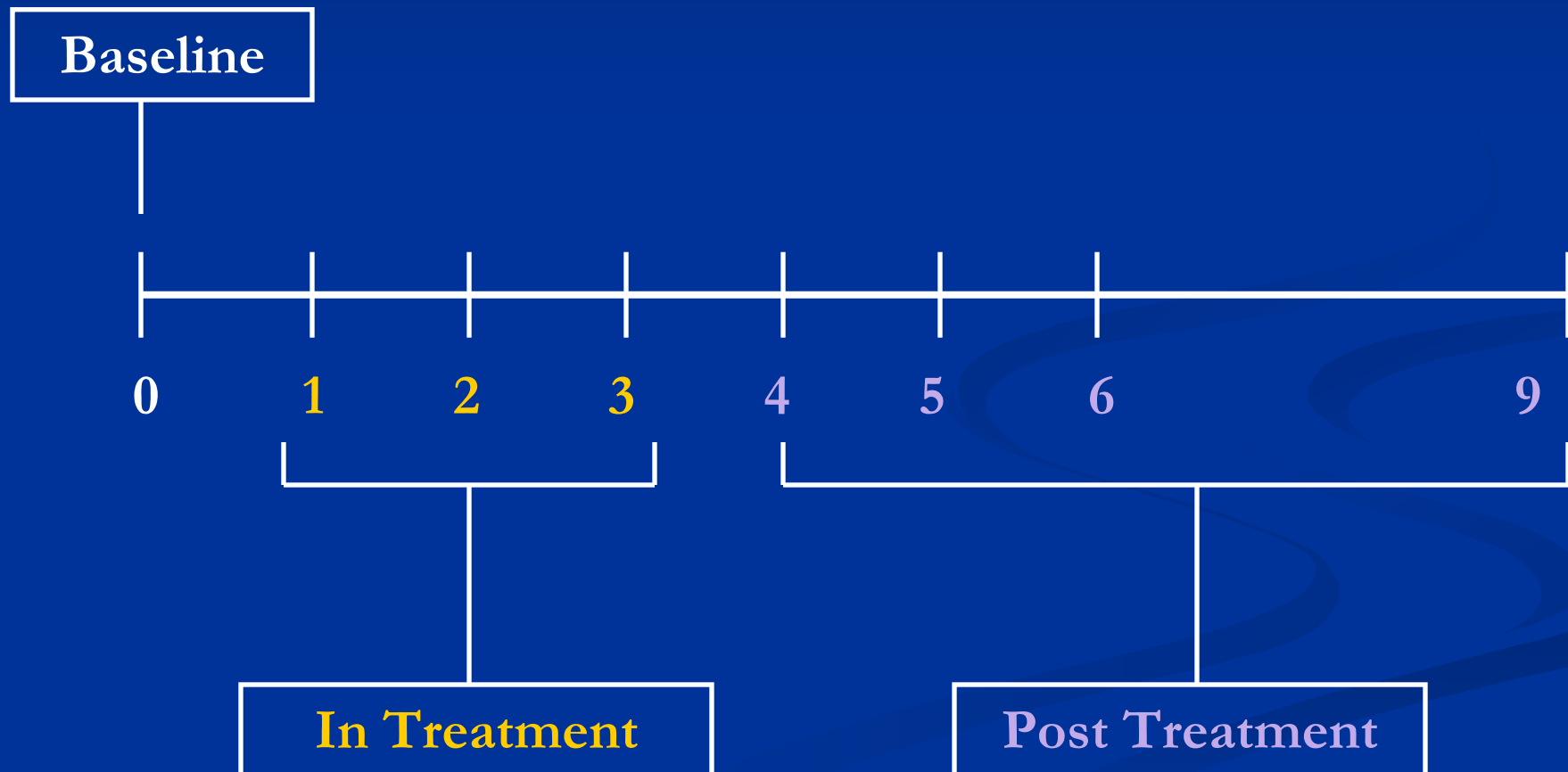
Recruitment

Patients were recruited from the following:

- McLean Hospital
- Advertisements in the community
- Participants were asked to participate in a study examining “investigational group therapy treatments”

Schedule of Assessments

MONTHLY ASSESSMENTS



Outcome Measures

- **Monthly Assessment of Substance Use Outcomes:**
 - Time Line Follow-Back (TLFB) reduction from baseline:
 - Days of Any Substance Use
 - Drinking Days
 - Drinks/Drinking Day
 - Addiction Severity Index (ASI) reduction in ASI Alcohol Composite Score from baseline
- **Assessment of Satisfaction (Pilot Study):**
 - Measured by Client Satisfaction Questionnaire (CSQ-8) plus 4 questions about helpfulness of therapist, group content, & group composition at weeks 3, 6, 9, & 12

Analytic Plan

- Analyses were conducted across 4 subsets of study participants
 - Pre-Pilot WRG women (N=13)
 - Pilot WRG women (N=16)
 - All WRG women (N=29)
 - All GDC women (N=7)
- All groups were compared with respect to demographic and clinical characteristics at baseline
- Outcome analyses were conducted by phase of treatment compared to baseline
 - In-Treatment Phase (months 1-3)
 - Post-Treatment Phase (months 4-9)

Statistical Methods

- Implemented mixed model analysis of variance (mixed effects ANOVA)
- Focuses on differences in averages between groups longitudinally
- Estimates means per group
- Accounts for within subject correlation
- Maximizes the power to conduct the analyses

Results: Demographics

- Predominantly white, well-educated (>90% had >12th grade), 41% married
 - Pilot WRG subjects were younger on average than Pilot GDC subjects (42 v. 58 y; $p < .001$)
 - All WRG subjects younger on average than pilot GDC subjects (45 v. 58 y; $p < .001$)
- *Outcome analyses control for age differences between groups

Results: Current and Lifetime Drug Use Disorder Diagnoses

- Predominantly alcohol dependent (86%)
- Other current substance dependence: cannabis (6.8%); cocaine (3.4%); other stimulants (3.4%)
- Lifetime other drug diagnoses:
 - **WRG:** Cannabis dependence/abuse (10%/10%)
cocaine dependence/abuse (10%/7%)
stimulant dependence (7%)
opioid abuse (3%)
sedative abuse (3%)
hallucinogen abuse (3%)
 - **GDC:** cannabis abuse (14%)

Results: Co-occurring Disorders

- Mood Disorders: Lifetime 75.9% Current 37.9%
- Anxiety Disorders Lifetime 44.8% Current 31%
- Axis II disorders 34.5%
- No statistical differences in prevalence of Axis I or Axis II disorders between WRG and GDC groups

Retention of Women Subjects in Trial and Follow-up

- Pre-pilot:

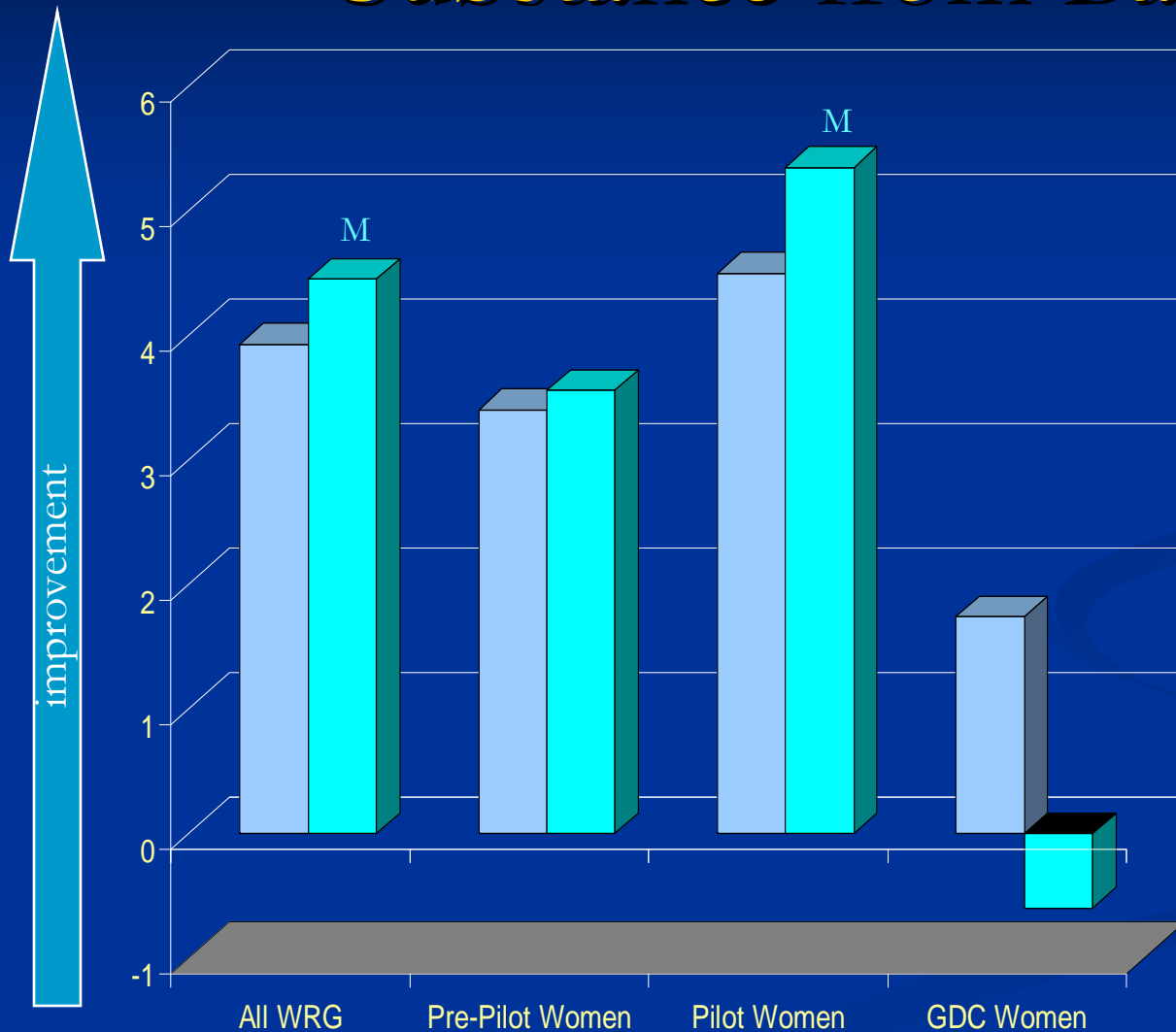
13/13 (100%) enrolled completed
treatment and follow-up

- Pilot:

21/26 (81%) women randomized completed
treatment

23/26 (88%) women randomized completed
follow-up

Average Reduction of Days Using Any Substance from Baseline¹



M = med. effect size

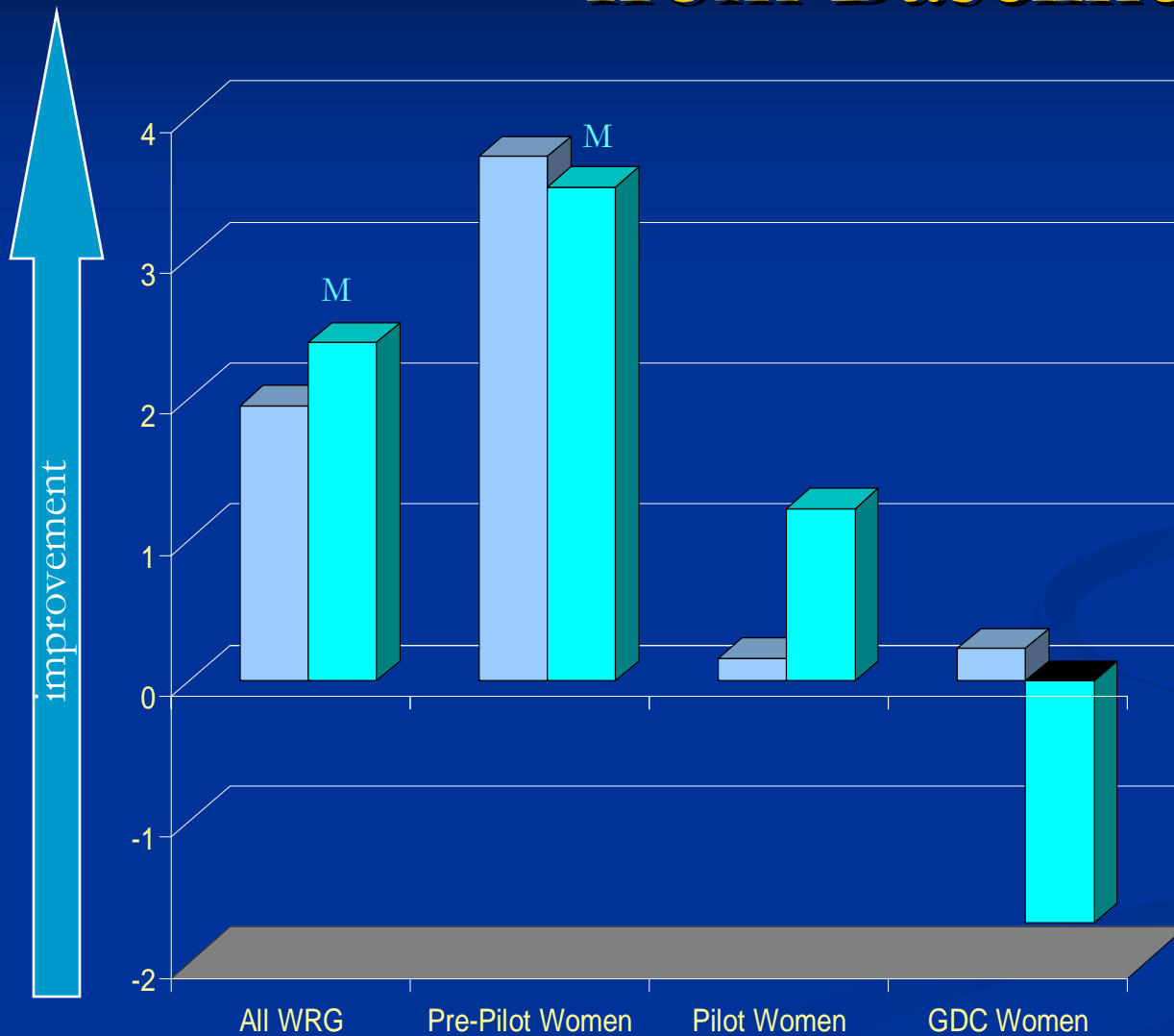
■ in tx

■ post tx

	Pr > t	Effect Size
GDC vs All WRG In Tx	0.527	0.23
GDC vs PPilot WRG In Tx	0.611	0.19
GDC vs Pilot WRG In Tx	0.449	0.28
PPilot WRG vs Pilot WRG In Tx	0.690	0.15
GDC vs All WRG Post Tx ^M	0.140	0.55
GDC vs PPilot WRG Post Tx	0.226	0.45
GDC vs Pilot WRG Post Tx ^M	0.112	0.59
PPilot WRG vs Pilot WRG Post Tx	0.509	0.25

¹Greenfield et al, Drug and Alcohol Dependence, 2007

Average Reduction of Drinking Days from Baseline¹



	Pr > t	Effect Size
GDC vs All WRG In Tx	0.495	0.25
GDC vs PPilot WRG In Tx	0.228	0.45
GDC vs Pilot WRG In Tx	0.873	0.06
PPilot WRG vs Pilot WRG In Tx ^M	0.070	0.68
GDC vs All WRG Post Tx ^M	0.094	0.62
GDC vs PPilot WRG Post Tx ^M	0.053	0.72
GDC vs Pilot WRG Post Tx	0.336	0.36
PP WRG vs Pilot WRG Post Tx	0.227	0.45

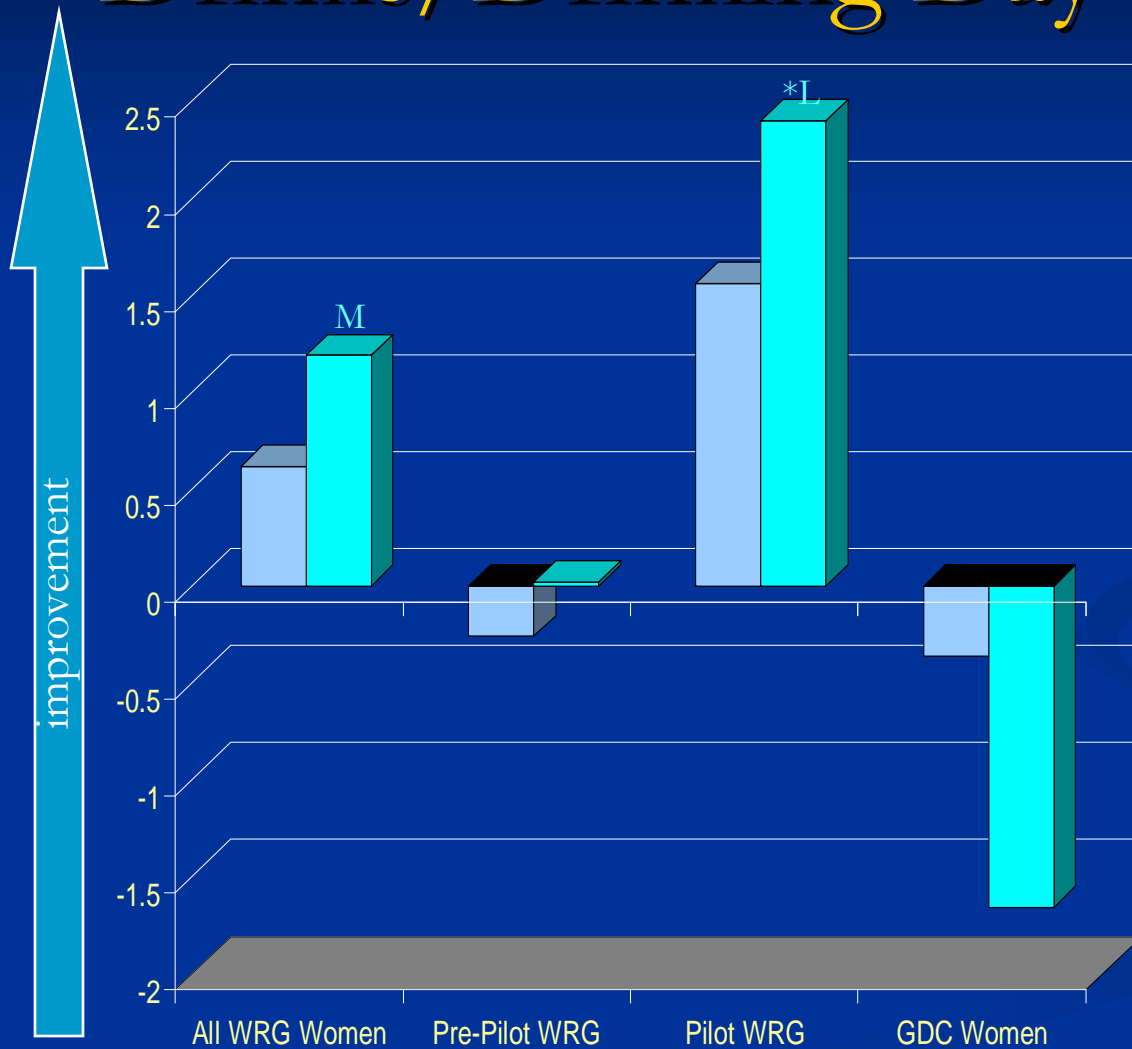
M = med. effect size

■ in tx

■ post tx

¹Greenfield et al, Drug and Alcohol Dependence, 2007

Average Reduction of Drinks/Drinking Day from Baseline¹



	Pr > t	Effect Size
GDC vs All WRG In Tx	0.596	0.20
GDC vs PPilot WRG In Tx	0.841	0.07
GDC vs Pilot WRG In Tx	0.277	0.40
PP WRG vs Pilot WRG In Tx	0.202	0.48
GDC vs All WRG Post Tx ^M	0.120	0.58
GDC vs PPilot WRG Post Tx	0.294	0.39
GDC vs Pilot WRG Post Tx ^{*L}	0.031	0.81
PP WRG vs Pilot WRG Post Tx ^M	0.090	0.63

M = med. effect size

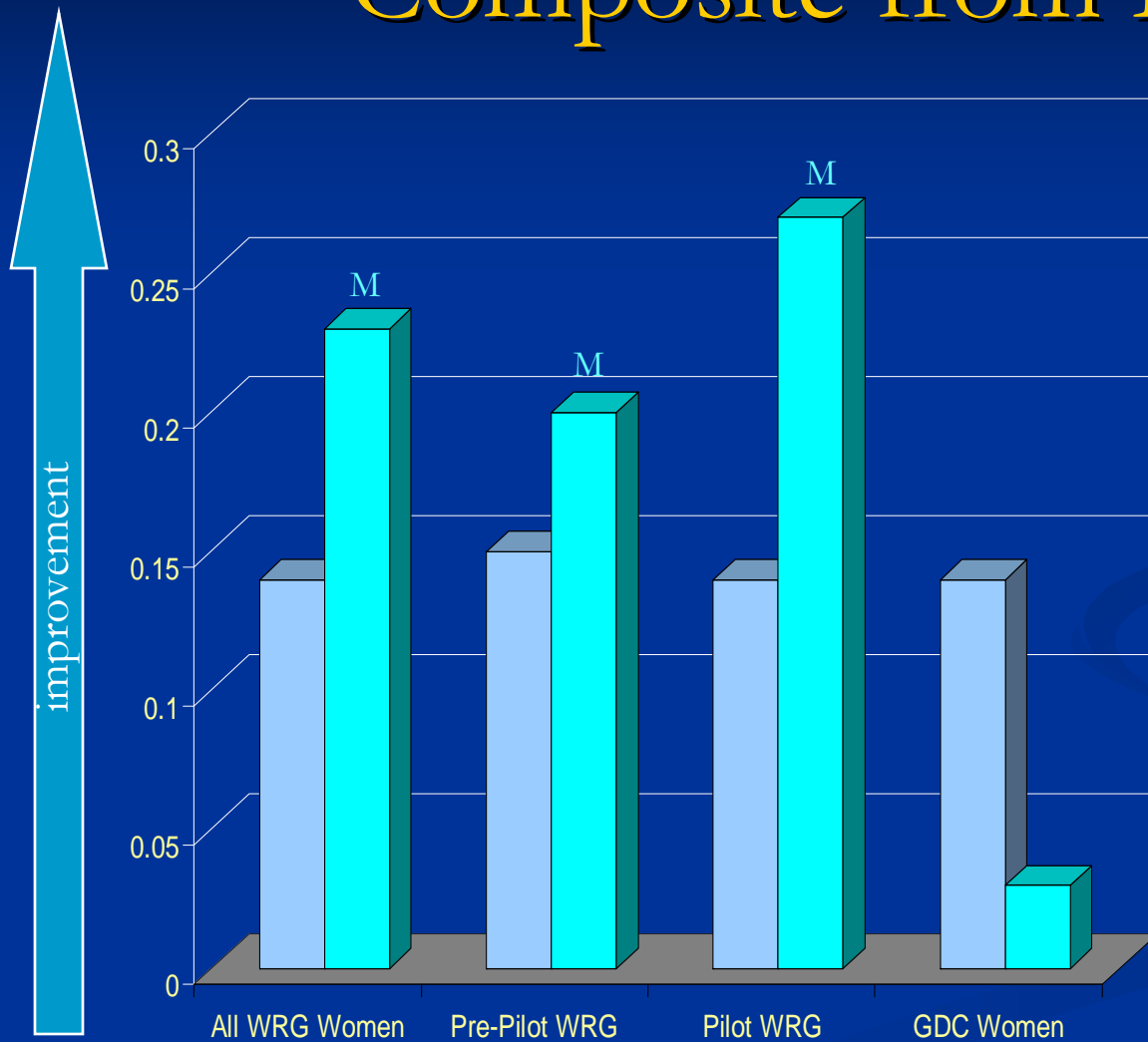
■ in tx

■ post tx

*L = p<.05, large effect size

¹Greenfield et al, Drug and Alcohol Dependence, 2007

Average Reduction of ASI Alcohol Composite from Baseline¹



	Pr > t	Effect Size
GDC vs All WRG In Tx	0.982	0.01
GDC vs PPilot WRG In Tx	0.954	0.02
GDC vs Pilot WRG In Tx	0.999	0.00
PPilot WRG vs Pilot WRG In Tx	0.938	0.03
GDC vs All WRG Post Tx ^M	0.063	0.69
GDC vs PPilot WRG Post Tx ^M	0.130	0.56
GDC vs Pilot WRG Post Tx ^M	0.051	0.73
PPilot WRG vs Pilot WRG Post Tx	0.442	0.29

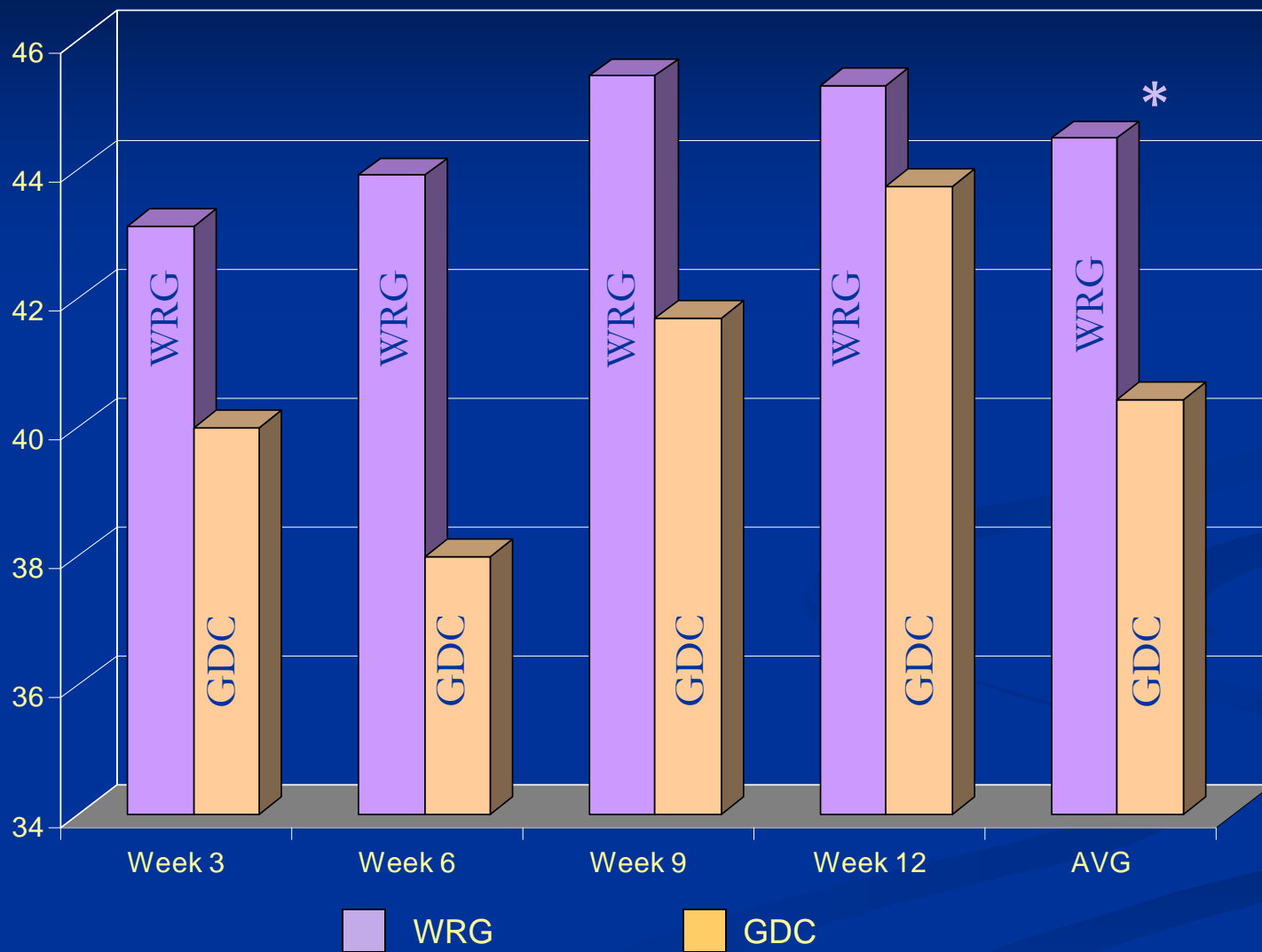
M = med. effect size

in tx

post tx

¹Greenfield et al, Drug and Alcohol Dependence, 2007

Pilot Client Satisfaction¹



WRG vs. GDC across assessments*

$p = 0.009$

effect size = 1.11

¹Greenfield et al, Drug and Alcohol Dependence, 2007

Limitations

- Stage I development trial
- Small numbers for comparison
- Small proportion with current drug dependence compared with alcohol dependence
- Demographically homogeneous

What might account for the difference between Groups?

Exploring Moderators of WRG:

- Psychiatric symptoms and disorders may negatively effect treatment outcome (Greenfield et al., 1998), especially in women (Haver & Gjestad, 2005)
 - Did women with greater psychiatric symptom severity at baseline have better outcomes in WRG than GDC?
- Greater baseline self-efficacy is related to better substance abuse treatment outcomes (Ilgen et al., 2005)
 - Did women with higher self-efficacy in WRG at baseline have better substance use outcomes at follow-up than women in GDC?

Summary

Six-month post-treatment reductions from baseline were greater for WRG subjects than mixed-gender GDC subjects in the change from baseline in:

- Mean days of substance use (medium effect size)
- Mean drinking days (medium effect size; trend to statistical significance)
- Mean drinks/drinking day (statistically significant in pilot WRG vs. GDC with large effect size)
- Improvement in ASI scores (medium effect size, trend to significance)

Satisfaction ratings for WRG exceeded GDC (large effect size, statistically significant)

Greenfield SF et al: The Women's Recovery Group Study: A Stage I Trial of Women-Focused Group Therapy for Substance Use Disorders versus Mixed-Gender Group Drug Counseling. *Drug Alcohol Depend.* 2007;90:39-47
(doi:10.1016/j.drugalcdep.2007). Greenfield et al, *Drug and Alcohol Dependence*, 2007)

Conclusions

- The Women's Recovery Group is a manual-based group therapy for women with substance use disorders
- WRG is feasible and acceptable with high satisfaction
- In a small pilot study, WRG produced reductions in substance use within treatment equivalent to GDC; however, sustained improvements in substance use in the 6-month post-treatment phase were greater in WRG compared with GDC

Future Research Directions

- If WRG is effective, what are the most effective “ingredients” of the treatment?
 - Single gender composition?
 - Women-focused content?
- Group process analysis
- Will we see similar results with a larger more heterogeneous sample of women?

The primary aim of our next study is to conduct at two sites a randomized controlled Stage II trial of WRG in a larger, more diverse sample of women than characterized that of our Stage I trial.