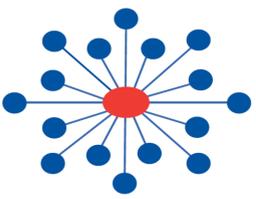


Gender-based Outcomes and Acceptability of a Web-delivered Psychosocial Intervention for Substance Use Disorders

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BACKGROUND AND RESEARCH QUESTIONS

Digital technologies show great promise for increasing treatment accessibility and improving quality of care, but little is known about gender differences.

Here we report one of the first studies exploring outcomes by gender in a large scale effectiveness trial of a computer-assisted treatment for substance use disorders conducted in the National Drug Abuse Treatment Clinical Trials Network (CTN). Research questions are: (1) Does gender moderate the association between treatment and outcomes; (2) Do men and women differ in their perceived acceptability; and (3) Is acceptability associated with outcomes.

METHODS

Sample

Men (n=314) and women (n=192) (1 participant chose not to answer and were excluded from analysis) from 10 outpatient substance abuse treatment programs were: 1) ≥18, 2) within the first 30 days of treatment episode, 3) using illicit drugs ≥ 1 day in past 30, 4) not currently prescribed opioid replacement medication, and 5) proficient in English.

Procedures

Patients were referred to research staff, provided a brief description of the study, and completed an eligibility screen (after verbal consent). Eligible clients completed full study informed consent and a baseline assessment. Participants were randomized to receive 12 weeks of (1) treatment-as-usual (TAU), or (2) modified TAU + Therapeutic Education System (TES),¹ whereby TES replaced about 2 hours of standard treatment per week.²

Measures

Abstinence: in the last 4 weeks of treatment, evaluated twice weekly: 1) a negative urine test for 10 substances; and 2) self-reported abstinence from drugs/heavy drinking using the Timeline Follow Back method.³

Retention: proportion retained in TAU at week 12

Social Functioning: mean score (wk 12) from the Social Adjustment Scale⁴ comprised of six social role areas (work, social and leisure, family relationship, marital relationship, parental role, and role within the family unit). Lower mean scores=higher levels of functioning .

Craving: days in the past 7 (week 12) experiencing urge, desire or craving for drugs or alcohol (0 days, 1-3 days, 4-7 days).

Acceptability: five indicators of utility and satisfaction (0-10 scale) (1) how useful (not at all to very), (2) how much new information (none to a great deal), (3) how easy to understand (very easy to very difficult; reverse coded), (4) how interesting (not at all to very), and (5) how satisfied (not at all to very); higher scores=more positive perception/greater acceptability (internal consistency of .84).

Data Analysis

Generalized linear mixed (GLM) effect models with appropriate link functions:

- Fit to explore gender as a moderator (i.e., gender by treatment interaction) on four outcomes (abstinence, retention, social functioning, craving); models included treatment, gender, baseline abstinence (i.e., biological measure at study entry), age, baseline scores of social adjustment and craving, and interactions (treatment, gender, baseline abstinence).
- Fit to explore association between acceptability (week 12) and abstinence and retention; models included gender, age, baseline abstinence, acceptability and gender x acceptability interaction.

Interactions were included only if significant ($p < .10$); missing data was treated as missing at random

Therapeutic Education System (TES)¹

- 62 interactive, multimedia modules based on the Community Reinforcement Approach;⁵ includes relapse prevention skills, psychosocial functioning, and HIV/HCV/STI information. Short quizzes assess grasp of material and maximize individual mastery.
- Plus contingency management:^{6,7} draws earned for abstinence and module completion and redeemed from a virtual "fish bowl" for vouchers with messages or intermittent prizes.
- TES Participants completed $M=36.6$ ($SD=18.1$) modules; earned $M=118$ ($SD=90$) voucher draws for $M=\$277$ ($SD=226$) in prizes.



Figure 1. TES Screen Shot

RESULTS

Participant Characteristics (N=506)

- Age** $M=34.9$ years ($SD=10.9$)
- Race/Ethnicity** White (52.8%), Black/African American (22.1%), Multi-racial/Other (14.2%), Hispanic/Latino (10.9%)
- Education** <HS (23.3%), HS/GED (61.3%), >HS (15.4%)
- Primary Substance** Cannabis (22.5%), Opioids (21.3%), Alcohol (20.6%), Cocaine (20.0%), Stimulants (13.6%), Other (2%)
- Men and women differed on two characteristics: women were more likely to be unemployed (70.8% vs 51.6%; $p < .01$) and have higher (worse) social adjustment scores (2.30 vs. 2.11; $p < .01$).

Gender as a Moderator of Treatment

- Gender was not a moderator of treatment for any of the four outcomes (i.e., no significant gender x treatment interactions)

Table 1. Generalized linear mixed effect final models, as a function of treatment arm, gender, baseline abstinence, age, and time (model A only)

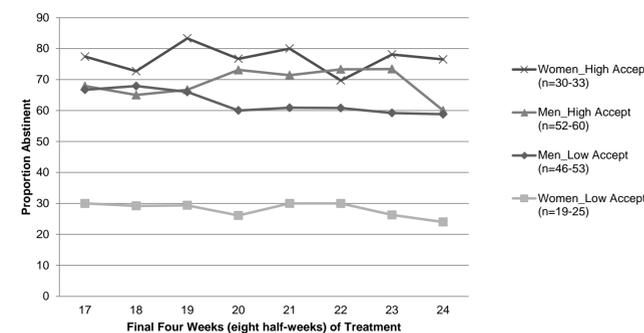
	t-value
Model A: Abstinence in Final Four Weeks (n=468)	
Time	-0.40
Treatment (TAU)	-0.64
Gender (men)	0.47
Abstinence at Study Entry	-4.36**
Age	1.28
Treatment (TAU) x Abstinence at Study Entry	-1.81†
Model B: Proportion Retained at Week 12 (n=506)	
Treatment (TAU)	-1.71†
Gender (men)	1.77†
Abstinent at Study Entry	2.62**
Age	1.42
Model C: Social Adjustment Scale Total Score (n=447)	
Treatment (TAU)	0.52
Gender (men)	-2.87**
Abstinent at Study Entry	-0.42
Age	1.88†
Baseline Social Adjustment	11.38**
Model D: Days of Craving (n=447)	
Treatment (TAU)	2.68**
Gender (men)	0.82
Abstinent at Study Entry	0.62
Age	-0.40
Baseline Craving	7.14**
Treatment (TAU) x Abstinence at Study Entry	-2.65**

† $p < .10$, * $p < .05$, ** $p < .01$

Acceptability and Outcomes

- Men and women did not differ in acceptability of TES
- Among women (but not men), acceptability (week 12) differed by baseline abstinence ($p=.02$):
 - Abstinent Women (n=34): $M=9.02$, $SD=1.32$
 - Not abstinent Women (n=31): $M=7.81$, $SD=1.80$
- Abstinence (Figure 2):** Gender x Acceptability interaction was significant; abstinence was greater among women with higher acceptability vs lower (AOR=2.68, 95%CI=1.61, 4.48, $p=.004$); this was not the case for men
- Retention:** No significant associations in the model

Figure 2. Observed proportion of the TES sample abstinent during the final four weeks of the 12-week treatment phase as a function of gender and median level of TES acceptability (≥ 8.4 is high and < 8.4 is low, 0-10 scale). Time (x-axis) is presented in half-weeks to reflect the twice weekly urine drug screen results.



DISCUSSION

- Gender did not significantly moderate treatment on outcomes of abstinence, retention, social adjustment or craving; TES, in particular, was designed to be gender balanced, and as such its effectiveness is generally equivalent in this large, diverse sample.
- However, among women, those negative for drugs/alcohol at study entry had higher TES acceptability at the end of treatment; women who reported higher acceptability had greater odds of abstinence. Women who continue to struggle in recovery appear to benefit less from TES; prior research suggests women with substance use disorders may experience unique vulnerabilities (e.g., partner violence) that influence treatment trajectories⁹ which may increase the need or desirability for interpersonal treatment modalities.
- Those in TES, regardless of gender, reported fewer days of craving; this is consistent with the primary outcome study of this intervention⁹ which found greater abstinence for those in TES. TES includes specific relapse prevention content that could be helpful in managing and reducing cravings to use alcohol and drugs.
- Limitations:** (1) although a pre-specified secondary analysis, the current study was not powered to detect treatment by gender interactions; (2) questions assessing acceptability did not differentiate between intervention content and computer delivery; and (3) participants self-identified as male or female, but information on gender identity was not collected.

CONCLUSION

Gender may be an important factor to consider when thinking about using technology-based interventions. Given the potential of these interventions to expand treatment access and improve outcomes, future research should endeavor to understand ways in which acceptability may differ among women and men and impede effectiveness.

REFERENCES

- Bickel, W.K., Marsch, L.A., Buchhalter, A., et al. (2008). Computerized behavior therapy for opioid dependent outpatients: A randomized, controlled trial. *Exp Clin Psychopharmacol.* 16, 132-143.
- Campbell, A.N.C., Nunes, E.V., Miele, G.M., et al. (2012). Design and methodological considerations of an effectiveness trial of a computer-assisted intervention: An example from the NIDA Clinical Trials Network. *Contemp Clin Trials.* 33(2), 386-395.
- Sobell, M., Sobel, L.L., Bogardis, J., et al. (1992). Problem drinkers' perceptions of whether treatment goals should be self-selected or therapist-selected. *Behav Ther.* 23, 43-52.
- Weissman MM. (1999). Social Adjustment Scale – Self Report. Multi Health Systems, North Tonawanda, NY.
- Budney, A.J., Higgins, S.T., 1998. Therapy manuals for drug addiction, a community reinforcement plus vouchers approach: treating cocaine addiction. National Institute on Drug Abuse, Rockville, MD.
- Petry, N.M., Peirce, J.M., Stitzer, M.L., et al. (2005). Effect of prize-based incentives on outcomes in stimulant abusers in outpatient psychosocial treatment programs: A National Drug Abuse Treatment Clinical Trials Network study. *Arch Gen Psychiat.* 62, 1148-1156.
- Stitzer, M.L., Petry, N.M., Peirce, J.M., 2010. Motivational incentives research in the National Drug Abuse Treatment Clinical Trials Network. *J Subst Abuse Treat.* 38(S1), S61-69.
- Greenfield, S.F., Brooks, A.J., Gordon, S.M., Green, C.A., Kropp, F., McHugh, R.K., Lincoln, M., Hien, D., Miele, G.M., 2007. Substance abuse treatment entry, retention, and outcome in women: A review of the literature. *Drug Alcohol Depend.* 86, 1-21.
- Campbell, A. N. C., Nunes, E. V., Matthews, A. G., et al. (2014). Internet-delivered treatment for substance abuse: A multi-site randomized controlled clinical trial. *Am J Psychiatry.* epub ahead of publication.

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