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Gender-based Outcomes and Acceptability of a Computer-assisted Psychosocial Intervention for Substance Use Disorders

Aimee N. C. Campbell, PhD[a,b], **Edward V. Nunes, MD**[a], **Martina Pavlicova, PhD**[c], **Mary Hatch-Maillette, PhD**[d], **Mei-Chen Hu, PhD**[e], **Genie L. Bailey, MD**[f], **Dawn E. Sugarman, PhD**[g], **Gloria M. Miele, PhD**[a], **Traci Rieckmann, PhD**[h], **Kathy Shores-Wilson, PhD**[i], **Eva Turrigiano, MA**[a], and **Shelly F. Greenfield, MD**[g]

[a]Columbia University Department of Psychiatry New York State Psychiatric Institute, 1051 Riverside Drive, New York, NY 10032

[b]Mount Sinai St. Luke's Hospital Department of Psychiatry and Behavioral Health, 1111 Amsterdam Ave, New York, NY 10025

[c]Columbia University Mailman School of Public Health Department of Biostatistics, 722 West 168th Street, 6th Floor, New York, NY 10032

[d]University of Washington Department of Psychiatry and Behavioral Sciences and Alcohol and Drug Abuse Institute, 1107 NE 45th Street, Suite 120, Box 354805, Seattle, WA 98105

[e]Columbia University Medical Center, Department of Psychiatry, 630 West 168th Street, New York, NY 10032

[f]Stanley Street Treatment and Research Center and Brown University Alpert Medical School, 386 Stanley St, Fall River, MA 02720

[g]Harvard Medical School, Department of Psychiatry and McLean Hospital Division of Alcohol and Drug Abuse, 115 Mill Street, Belmont, MA 02478

[h]Oregon Health and Science University School of Medicine, 3181 S.W. Sam Jackson Park Rd., Portland, Oregon 97239

[i]University of Texas Southwestern Medical Center Department of Psychiatry, 5323 Harry Hines Blvd., Dallas, TX 75390

Abstract

Background—Digital technologies show promise for increasing treatment accessibility and improving quality of care, but little is known about gender differences. This secondary analysis uses data from a multi-site effectiveness trial of a computer-assisted behavioral intervention,

Corresponding Author: Aimee Campbell, PhD, New York State Psychiatric Institute, 1051 Riverside Drive, Box 120, Room 3572, New York, NY, 10032. (P) 212-740-3503, anc2002@columbia.edu.

conducted within NIDA's National Drug Abuse Clinical Trials Network, to explore gender differences in intervention acceptability and treatment outcomes.

Methods—Men (n=314) and women (n=192) were randomly assigned to 12-weeks of treatment-as-usual (TAU) or modified TAU + Therapeutic Education System (TES), whereby TES substituted for 2 hours of TAU per week. TES is comprised of 62 web-delivered, multimedia modules, covering skills for achieving and maintaining abstinence plus prize-based incentives contingent on abstinence and treatment adherence. Outcomes were: (1) abstinence from drugs and heavy drinking in the last 4 weeks of treatment, (2) retention, (3) social functioning, and (4) drug and alcohol craving. Acceptability was the mean score across five indicators (i.e., interesting, useful, novel, easy to understand, and satisfaction).

Results—Gender did not moderate the effect of treatment on any outcome. Women reported higher acceptability scores at week 4 (p=.02), but no gender differences were detected at weeks 8 or 12. Acceptability was positively associated with abstinence, but only among women (p=.01).

Conclusions—Findings suggest that men and women derive similar benefits from participating in a computer-assisted intervention, a promising outcome as technology-based treatments expand. Acceptability was associated with abstinence outcomes among women. Future research should explore characteristics of women who report less satisfaction with this modality of treatment and ways to improve overall acceptability.

Keywords

Internet-delivered treatment; computer-assisted treatment; substance use disorders; gender differences; acceptability

1. Introduction

Women with substance use disorders (SUD) are especially at risk for negative consequences associated with abuse, including symptom severity and number of psychiatric, social, and medical problems upon treatment entry, despite fewer years of use and smaller quantities used compared to men (Gentilello et al., 2000; Greenfield et al., 2007; Henskens et al., 2005; Hernandez-Avila et al., 2004; Randall et al., 1999). Women have unique and gender-specific barriers to seeking and engaging in SUD treatment (Greenfield et al., 2007). Programs that provide gender-specific and gender-responsive treatment and ancillary services may enhance women's treatment outcomes (Greenfield and Grella, 2009; Grella, 2008). Examining women's responses to substance abuse treatment program characteristics and clinical interventions can contribute to enhancing gender-responsive treatment and improving women's treatment outcomes.

1.1. Computer-assisted Treatment

Computer-assisted technology for the prevention and treatment of SUD has increased over the past decade. Research has established empirical support for computer-assisted interventions for the prevention of SUD (Fang et al., 2010; Hester et al., 2012; Ondersma et al., 2005; Ondersma et al., 2014; Schinke & Schwinn, 2005; Schwartz et al., 2014). Although treatment research is more limited, several randomized studies provide support for the effectiveness of computer-assisted technology in the treatment of SUD (Bickel et al.,

2008; Budney et al., 2011; Carroll et al., 2008; Carroll et al., 2014; Chaple et al., 2013; Kay-Lambkin et al., 2011; Marsch et al., 2014; Rooke et al., 2013). Despite the increase in computer-assisted technologies research for substance use prevention and treatment, few studies have examined gender differences in these interventions. Moreover, previous literature on gender differences in computer-assisted technologies has been in *prevention* of SUD, rather than in the treatment of these disorders.

1.2. Gender and Computer-assisted Drug and Alcohol Interventions

Previous research demonstrates that women access traditional substance abuse treatment less often than men (Greenfield et al., 2007), but participate in technology-based services more frequently. A meta-analysis of online alcohol treatment services revealed women utilized various treatment tools at a greater rate than men and commonly cited 24-hour access and privacy as reasons for engagement (White et al., 2010). Similarly, female treatment-seekers were more likely than men to engage in electronic-based, supplemental treatments (VanDeMark et al., 2010). Technology-based interventions developed specifically for women also show promise, but with some mixed findings. Ondersma and colleagues studied screening and brief intervention platforms targeting substance abuse and smoking in pregnant and postpartum women using motivational enhancement and motivational interviewing. Results showed high acceptability and improved motivation to reduce substance use (Ondersma et al., 2005; Pollick et al., 2013), as well as actual substance use reduction (Ondersma et al., 2012; Ondersma et al., 2007). However, in a randomized controlled trial of a web-based alcohol treatment program among 44 rural women, no significant difference was detected between web-based and standard care groups at 3 month follow-up (Finfgeld-Connett and Madsen, 2008).

There are few studies that have explored potential gender differences for technology-based interventions, and this is especially true for technology-based *treatment* of SUD. Several studies have found that brief, computer-assisted interventions did not produce differential outcomes for women (Chiauzzi, 2005; Steiner, 2005). However, a recent meta-analysis among college students with hazardous alcohol use found that gender moderated the effect on quantity of alcohol consumed for computer-assisted interventions compared to no intervention controls; that is, computer-assisted interventions were less successful at reducing alcohol use when there was a higher proportion of women in the sample (Carey et al., 2012). Overall, women and men had comparable outcomes with similar face-to-face interventions. This is of potential concern, given that the vast majority of computer-assisted interventions are brief, grounded in assessment and personalized feedback, and primarily target alcohol. The authors of the meta-analysis concluded that future research should consider gender-based acceptability of computer-assisted interventions.

1.3. Study Purpose

Here we report one of the first analyses exploring the role of gender in a large scale effectiveness trial of a computer-assisted treatment for SUD. The study recruited from 10 diverse geographic community-based outpatient sites, representative of the primary mode of outpatient treatment for SUD in the U.S. The primary outcome analysis, previously published (Campbell et al., 2014), showed the computer-delivered intervention (comprised

of web-based psychosocial modules and contingency management), when added to treatment-as-usual, was superior to the treatment-as-usual control condition on the primary outcomes of abstinence and treatment retention. The purpose of this paper is to explore gender differences in treatment outcome and acceptability of the computer-assisted intervention. Specifically, the paper addresses the following the questions: (1) Does gender moderate the association between treatment and abstinence or retention? (2) Does gender moderate the association between treatment and other relevant outcomes such as social functioning and drug craving? (3) Do men and women differ in their acceptability of the computer-assisted treatment? and (4) Does gender moderate the association between acceptability and abstinence or retention among those in the computer-assisted intervention?

2. Methods

2.1. Recruitment Sites

Participants (N=507) were from 10 community-based, outpatient substance abuse treatment programs affiliated with the National Drug Abuse Treatment Clinical Trials Network and enrolled between June 2010 and August 2011. Outpatient addiction treatment programs were selected for geographic and patient diversity, and also varied in programming, consistent with the goals of an effectiveness trial to promote external validity. Each program was asked to enroll approximately 50 participants (range=38-60). Additional details of program selection, design, and methods have been previously published (Campbell et al., 2012).

2.2. Participants

Eligible participants were: (1) 18 or older, (2) using illicit substances in the 30 days prior to study entry (or 60 days if the patient was exiting a controlled environment), (3) within 30 days of entering the treatment episode, (4) planning to remain in the area and treatment program for ≥ 3 months, and (5) proficient in English. Participants were excluded if they were: (1) prescribed opioid replacement therapy (e.g., buprenorphine, methadone), or (2) unable to provide informed consent. The study was approved by the Institutional Review Boards of the New York State Psychiatric Institute and all participating clinical sites. After a complete description of the study to each patient, written informed consent was obtained. The study was registered on clinicaltrials.gov under the identifier NCT01104805.

2.3. Design

Following a baseline assessment, participants were randomized to 12 weeks of either: (1) treatment-as-usual; or (2) treatment-as-usual + the Therapeutic Education System (TES), whereby TES was a substitute for approximately 2 hours of usual care (i.e., clinician-delivered groups). Randomization was stratified by: treatment site; patient's primary substance of abuse (dichotomized as stimulant vs. non-stimulant); and whether or not the patient was abstinent at point of baseline assessment and study entry based on urine drug and breath alcohol tests. All participants were asked to provide self-reported substance use and urine drug and breath alcohol screens twice per week during the treatment phase; additional assessments were collected at weeks 4, 8, and 12.

2.4. Computer-assisted Intervention

The Therapeutic Education System (TES; Bickel et al., 2008) includes Contingency Management and 62 web-delivered, interactive, multimedia modules, grounded in the Community Reinforcement Approach (Budney and Higgins, 1998). An initial training module teaches participants how to use the computer-based program, followed by modules on cognitive behavioral relapse prevention skills, psychosocial functioning, and HIV and other sexually transmitted infection prevention and treatment information. Video clips show actors modeling the skills being taught and short quizzes at the end of each module assess patient's grasp of material and maximize individual mastery of the skills being taught. The Contingency Management component, also managed within the TES program, is a prize-based incentive system (Petry et al., 2005; Stitzer et al., 2010). Participants earn draws for submitting negative urine/breath alcohol screens and for completing TES modules (up to 4 per week). Draws are redeemed from a virtual “fish bowl” and yield congratulatory vouchers with messages (e.g., “good job”) or prizes of mostly modest value (usually around $1, occasionally around $20, rarely $80-$100). Participants randomized to the TES condition completed a mean of 36.6 (*SD*=18.1) modules and earned a mean of 118 (*SD*=90) voucher draws resulting in $277 (*SD*=226) worth of prizes.

2.5. Measures

Substance Use and Treatment Retention—Abstinence from drugs and alcohol was evaluated twice weekly during the 12-week treatment phase. Participant abstinence was based on: 1) a negative urine test for 10 drugs: cocaine, opioids, amphetamines, cannabinoids (THC), methamphetamines, benzodiazepines, oxycodone, methadone, barbiturates, and MDMA; and 2) self-reported abstinence from drugs and alcohol based on the Timeline Follow Back method (Sobell et al., 1992). A patient was abstinent if the urine screen and self-report were negative (for drugs and alcohol) and not abstinent otherwise. Abstinence data was considered missing if the urine screen was missing or if the urine screen was negative and the self-report was missing. The outcome was a binary measure of abstinence (yes or no) during the last 4 weeks of treatment (i.e., weeks 9-12). Abstinence in the last four weeks of treatment was the pre-specified primary outcome in the study protocol since this is a time when the treatment effect was expected (Campbell et al., 2012) and shown (Campbell et al., 2014) to be constant. Retention was evaluated as a binary outcome (retained in treatment to week 12 versus dropped out before week 12). Retention data was collected from treatment program records and based on last face-to-face contact prior to discharge.

Acceptability—Acceptability was comprised of both utility and satisfaction with the TES intervention using data collected across five indicators (1-10 point scales) at weeks 4, 8, and 12. Participants were asked in general (i.e., not for a specific timeframe) how useful (not at all to very), how much new information (none to a great deal), how easy to understand (very easy to very difficult; reverse coded), how interesting (not at all to very), and how satisfied (not at all to very) they were with the TES intervention (web-delivered modules and computer-assisted contingency management). Higher scores indicated a more positive perception, or greater acceptability, of the intervention. The internal consistency of the five acceptability indicators was adequate (α=0.84). Similar indicators were used in a previous

pilot study of TES with adolescents (Marsch et al., 2011). Acceptability of treatment-as-usual services was assessed separately, but not included for the purposes of this analysis.

Demographic and Clinical Characteristics—Sex, age, race/ethnicity, education, marital status, employment, and abstinence were assessed at baseline. Abstinence at baseline/study entry was defined as negative results on both the urine drug and breath alcohol screens. Social functioning was measured using the 54-item Social Adjustment Scale Self-report (Weissman, 1999) which assesses instrumental and expressive role performance over the prior two weeks. It is comprised of questions covering six social roles (work [paid worker, student, or homemaker], social and leisure activities, extended family relationships, marital relationship, role as a parent, and role within the family unit), relevant to both genders, and provides an overall indicator of social functioning (e.g., performance of expected tasks, interpersonal relationship quality, and satisfaction) (Weissman et al., 2001). Lower mean scores equate to better functioning (range=0-4). Drug and alcohol craving was assessed by asking participants on how many days in the last seven they experienced an urge, desire or craving for drugs or alcohol and coded categorically: 0 days (did not experience any craving; n=219), 1-3 days (n=128), and 4-7 days (n=100). Social adjustment and craving were both measured at week 12. Craving and social functioning are variables previously cited as important prognostic indicators for women in addiction treatment (Greenfield et al., 2010; Tiffany et al., 2012).

2.6. Data Analysis

Demographic and clinical characteristics were described using means, standard deviations, and frequencies for the entire sample (N=506; 1 case missing gender); chi-square and t-tests were used to test differences between men and women.

To explore gender as a moderator of outcomes (i.e., abstinence during the last four weeks of treatment, retention, craving, and social adjustment) in Questions 1 and 2, the following variables were analyzed using generalized linear mixed effect models (with Proc GLIMMIX in SAS): treatment, gender, abstinence at study entry, age, and baseline scores corresponding to the outcomes of social adjustment and craving. Site and subject were treated as random effects. Interactions were tested (between treatment, gender, and abstinence at study entry) and included in the final model if significant. Time was included in the model testing abstinence (n=468); 38 cases were removed that were missing all four weeks of data. The correlation between the repeated measurements within subject was modeled using the first-order auto regressive structure, and logit link function for the dichotomous outcome variable. The models for social adjustment (normal distribution with identity link function) and craving (ordinal outcome with cumulative logit link function) each included n=447 cases; 59 cases were missing both variables at week 12. Missing data was assumed missing at random.

Generalized linear mixed effect models were fit to explore the association between gender and acceptability at weeks 4, 8, and 12 (Question 3) and acceptability at week 8 and the outcomes of abstinence and retention at week 12 (Question 4) among participants randomized to the TES treatment arm (n=255). The model exploring acceptability over time

included gender, age, abstinence at study entry, and time; interactions (gender and time; gender and abstinence at study entry) were tested and included if significant (25, 46, and 62 cases were missing at weeks 4, 8, and 12, respectively). Models exploring abstinence and retention included acceptability (week 8), gender, age, and abstinence at study entry; the interaction of gender, acceptability and abstinence at study entry was tested and included if significant. These two models were also tested excluding 3 (1 female, 2 males) acceptability outliers (based on the metric of greater than or equal to 3 standard deviations from the mean). Outcomes did not change; thus, we kept all cases in the analysis reported.

SAS version 9.3 was utilized for all analyses.

3. Results

3.1. Sample Characteristics

Among those screened for the study (N=1,781), there was no difference in the percentage of women who were ineligible (n=850; 35.4% women), those who were eligible but did not enroll (n=424; 39.9% women), and those included in the enrolled sample (n=507; 37.9% women) (Campbell et al., 2013). Thus, women, once screened, were just as likely to be eligible and decide to enroll in the study.

Table 1 displays the demographic and clinical characteristics of the total sample and TES sample only, by gender. Men and women did not differ on most characteristics; however, women were more likely to be unemployed (70.8% vs 51.6%; $X^2(1)=18.22$, p<.01) and have higher (worse) social adjustment scores (2.30 vs. 2.11; t=4.23, p<.01). These differences were also seen in the TES sample. The mean age of the sample was 34.9 years (*SD*=10.9) and most were White (52.8%) or Black/African American (22.1%). The majority of participants had a high school education (61.3%). Reported primary substance of abuse was marijuana (22.5%); opioids (21.3%); alcohol (20.6%); cocaine (20.0%); stimulants (13.6%); and other substances, including benzodiazepines and PCP (2%). Both men and women reported about 3 days of drug and alcohol craving in the week prior to study entry. Among the TES sample, men completed an average of 38.3 TES modules (SD=16.6, median=44.5, interquartile range=28, 49) and women completed an average of 36.5 TES modules (SD=19.04, median=41, interquartile range=22, 49).

3.2. Gender as a Moderator of Treatment Outcomes

Gender was explored as a moderator of four outcomes; Table 2 displays the models for each (A-D). For the abstinence outcome, no significant 3-way or 2-way interactions between treatment, gender, and abstinence at study entry were detected. Gender did not moderate the treatment effect on the outcome of abstinence in the last four weeks of treatment (i.e., no significant treatment by gender interaction, p=.64). There was also no significant main effect of gender (p=.71). The interaction of treatment by abstinence at study entry, although not reaching p<.05 level of significance, was similar to the primary outcome paper (F(1, 2443)=3.29, p=.07): the TES treatment effect among non-abstinent participants at study entry was significant (Adjusted Odds Ratio [AOR]=4.15, 95% CI=1.64, 10.49, p<.01); there was no significant difference between TES and treatment-as-usual among abstinent participants (AOR=1.31, 95% CI=0.57, 3.01, p=.52).

The model for retention at the end of treatment (Table 2, Model B) showed no significant 3-way or 2-way interactions; gender did not moderate the treatment effect (i.e., no significant treatment by gender interaction, p=.36). Men had greater odds of retention compared to women, although this did not reach significance (AOR=1.41, 95% CI=0.96, 2.07, p=0.08); observed retention rates were 47.1% for men and 38.5% for women at week 12. Participants in TES treatment had greater odds of retention compared to treatment-as-usual, but this also did not reach significance (AOR=1.37, 95% CI=0.95, 1.96, p=.09). Those abstinent at study entry demonstrated significantly greater odds of retention (AOR=1.66, 95% CI=1.14, 2.41, p<.01). Age was not significant (p=.16).

When analyzing the outcome of social adjustment (lower scores indicate better adjustment, normally distributed), there were no significant 3-way or 2-way interactions between treatment, gender, and baseline abstinence at study entry and no main effect of treatment (p=.61). (Table 2, Model C). There was a significant main effect of gender (b=-0.12, 95% CI=-0.20, -0.04, p<.01) with men reporting better social adjustment scores than women at week 12 (observed average scores M=1.95, *SD*=0.42 for men versus M=2.15, *SD*=0.54 for women) controlling for baseline levels of social adjustment. Abstinence at study entry (p=.67) and age (p=.06) were not significantly associated with social adjustment scores.

For the outcome days of craving in the last week of treatment (three categories: none, low 1-3 days, high 4-7 days), there was no significant 3-way interaction between treatment, gender and abstinence at study entry. Gender did not moderate the treatment effect (i.e., the interaction between gender and treatment was not significant, p=.87), nor was there a significant main effect of gender (p=.41) (Table 2, Model D). The only significant 2-way interaction was between treatment and abstinence at study entry (t=-2.65, p<.01). Among those not abstinent at study entry, TES was associated with fewer days of craving at the end of treatment (AOR=0.48, 95% CI=0.28, 0.82, p<.01). Among those abstinent at study entry, there was no significant effect of TES compared to treatment-as-usual (p=.30) in craving. Age was also not significant in the model (p=.69).

3.3. Association between Gender and Acceptability of TES Intervention

Acceptability of the TES intervention was operationalized as the combined mean score (range=1-10) of five indicators: interesting, useful, new/novel information, easy to understand, and satisfaction. Gender, abstinence at study entry, age, and time were tested as predictors of acceptability over time (weeks 4, 8, and 12). The interactions between gender and time (F(2, 395)=6.13, p<.01) and gender and abstinence at study entry (F(1, 395)=4.40, p=.04) were both significant. Women reported significantly higher acceptability scores at week 4 compared to men (t=2.37, p=.02); there were no differences in acceptability scores between men and women at week 8 (t=-0.27, p=.79) or week 12 (t=1.48, p=.14). Among women, those who were not abstinent at study entry had significantly lower acceptability scores than those who were abstinent at study entry (t=-2.31, p=.02). Among participants who were abstinent at study entry, women reported significantly higher acceptability scores compared to men (t=2.55, p=.01). Age was also significantly associated with acceptability over time; older participants reported on average higher acceptability scores (t=2.51, p=.01).

3.4. TES Acceptability and Abstinence and Retention Outcomes

Perceived acceptability of the TES intervention at week 8, gender, abstinence at study entry, and age, were tested as predictors of abstinence and retention; gender, abstinence at study entry, and acceptability interactions were explored (see Table 3 Models A and B). The 3-way interaction of gender, abstinence at study entry, and acceptability was not significant (p=.77). For abstinence (Model A), there was only one significant 2-way interaction between gender and acceptability. The odds of being abstinent were greater among women with higher acceptability than the odds of abstinence among women with lower acceptability (AOR=2.08, 95% CI=1.20, 3.62, p=.01). This was not the case for men (AOR=0.87, 95% CI=0.59, 1.26, p=.45). Figure 1 shows the observed proportion abstinent during the final 4 weeks of treatment by gender and low, median, and high levels of acceptability at week 8 (median=8.6). The observed proportion abstinent at the final half-week of treatment (week 12b) was 85.7%, 47.8%, and 31.6% among female participants who had a high, median, and low level of acceptability respectively. Among men, proportion abstinent was 48.8%, 58.8%, and 65% for those with a high, median, and low level of acceptability respectively. Additional results in Model A demonstrate that participants who were abstinent at study entry were more likely to be abstinent in the final four weeks of treatment (p<.01). Age was not significantly associated with abstinence in the final four weeks (p=.87).

The three-way interaction of gender, abstinence at study entry, and acceptability was not significant in the model examining retention at week 12 (p=.63), nor were any 2-way interactions significant. There were no significant associations between the retention outcome and acceptability (p=.69), gender (p=.13), age (p=.89), or abstinence at study entry (p=.18) (Table 3, Model B).

4. Discussion

This study presents some of the first information on gender differences in acceptability and outcome of computer-assisted *treatment* for SUD. Findings show that gender did not moderate treatment outcomes of abstinence, retention, social adjustment or craving, and men and women derived similar benefits from participating in a computer-assisted intervention. Further, women and men both reported high acceptability of the intervention, with women reporting slightly higher acceptability on average, compared to men, early in the treatment phase. Adherence to TES was also high (76-80% of recommended modules completed), likely enhanced by the contingency management component of the intervention. These are promising outcomes as more computer-assisted treatments are being developed, tested and implemented for SUD. TES, in particular, was designed to be gender balanced, representing males and females in case vignettes, screen shots and videos. As such, its effectiveness and acceptability is generally equivalent in this large sample of men and women in outpatient treatment.

Despite the lack of a moderation effect of gender, acceptability of the intervention differed based on abstinence status at study entry among women; women who were negative for drugs/alcohol at study entry reported higher TES acceptability. Further, women who reported higher TES acceptability had greater odds of being abstinent in the last four weeks of treatment. This was not the case for men, in that acceptability was not associated with

abstinence outcomes. It is unclear what is driving the lower acceptability of the computer-assisted treatment among women who are not abstinent at study entry and who likely have a poorer prognosis for success. Future research might include such a component (e.g., qualitative interviews) to better understand differences in acceptability among women.

One speculation, based on the difference in acceptability by abstinence status and the association between acceptability and abstinence, is that women in the poorer prognosis group might feel the need for more personal treatment contact. Previous studies show women with SUD may experience unique vulnerabilities (e.g., more severe SUD, childhood trauma, intimate partner violence, and fewer socioeconomic opportunities) that influence treatment trajectories (Greenfield et al., 2007) which in turn may increase the need or desirability for interpersonal treatment modalities. Women with fewer vulnerabilities or challenges (i.e., those who have achieved some degree of abstinence at study entry) may be better able to navigate non-face-to-face treatment modalities, such as TES. In this case, and in line with prior research suggesting that addiction treatment that focuses on the distinctive needs of women can increase effectiveness (e.g., Cummings et al., 2010; Greenfield et al., 2007; Greenfield et al., 2013; Tross et al., 2008), some gender-specific tailoring of TES may improve acceptability among women.

Prior work recommends craving and psychosocial functioning as salient and relevant domains to be assessed beyond standard substance use outcomes (Tiffany et al., 2012). These domains of functioning may be critical to women based on their association with successful treatment outcomes (Greenfield et al., 2010). The current study found no differences in drug and alcohol craving by gender, although among those not abstinent at study entry, TES was associated with fewer craving days. TES includes specific relapse prevention content (e.g., identifying triggers, avoiding people, places, and things that may encourage use) that could be helpful in managing craving and may be particularly useful to active users. Though beyond the scope of this paper, additional analyses should explore craving as a mediator of the treatment effect on outcomes.

Treatment was not associated with social functioning and no moderator effect of gender was detected. Increasing role performance and interpersonal functioning may require more time or require sustained abstinence. Modifications to the TES intervention may also be needed to enhance social functioning, including greater monitoring of goals and progress by clinicians. Men reported better social adjustment at study entry and at the end of treatment. This further supports the idea that women may experience greater challenges related to role performance, including roles as parents and as paid workers (e.g., women are more likely to be unemployed). Men may have fewer primary role responsibilities, have greater access to social support (e.g., less stigmatization due to SUD), or be able to address interpersonal issues more quickly or directly (e.g., men may be less involved in parental roles or experience fewer challenges obtaining employment).

4.1. Limitations

The following limitations should be noted. First, this was a secondary analysis (albeit one that was pre-specified), and the study was not powered to detect treatment by gender interactions. There were no significant gender by treatment interactions detected for any of

the four outcomes; however, we cannot rule out the possibility of significance in a larger sample size. A second limitation is that questions assessing acceptability did not differentiate between Community Reinforcement Approach content and computer-assisted delivery in general. Still, high overall acceptability is promising. Third, the study examined TES as a package (i.e., Community Reinforcement Approach and contingency management); thus, it is not possible to determine the interaction (with gender) or acceptability of each individual component. Finally, the sample, self-identified as men and women, does not provide a more comprehensive assessment of gender identity.

4.2. Conclusions

This study is an important starting point for illuminating ways in which men and women may or may not differ on outcomes and in acceptability of computer-assisted treatment for SUD. In this large multi-site effectiveness trial, interactions between gender and treatment were not detected. These data suggest that there is not a large gender by treatment interaction. Women did demonstrate slightly greater perceived acceptability compared to men, although a subgroup of women actively using substances at study entry found the intervention less acceptable, and women with lower acceptability demonstrated less end of treatment abstinence. Studies powered to detect gender differences are needed to optimize interventions like TES to ensure future computer-assisted treatments serve men and women equally well.

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Highlights

- Data is drawn from a national, multi-site trial of a computer-assisted behavioral intervention.
- Intervention includes multimedia modules and contingency management for achieving and maintaining abstinence.
- Differences in intervention acceptability and treatment outcomes as a function of gender are explored.
- Men and women derive similar benefits from the computer-assisted intervention.
- Greater acceptability of the intervention was associated with abstinence among women.

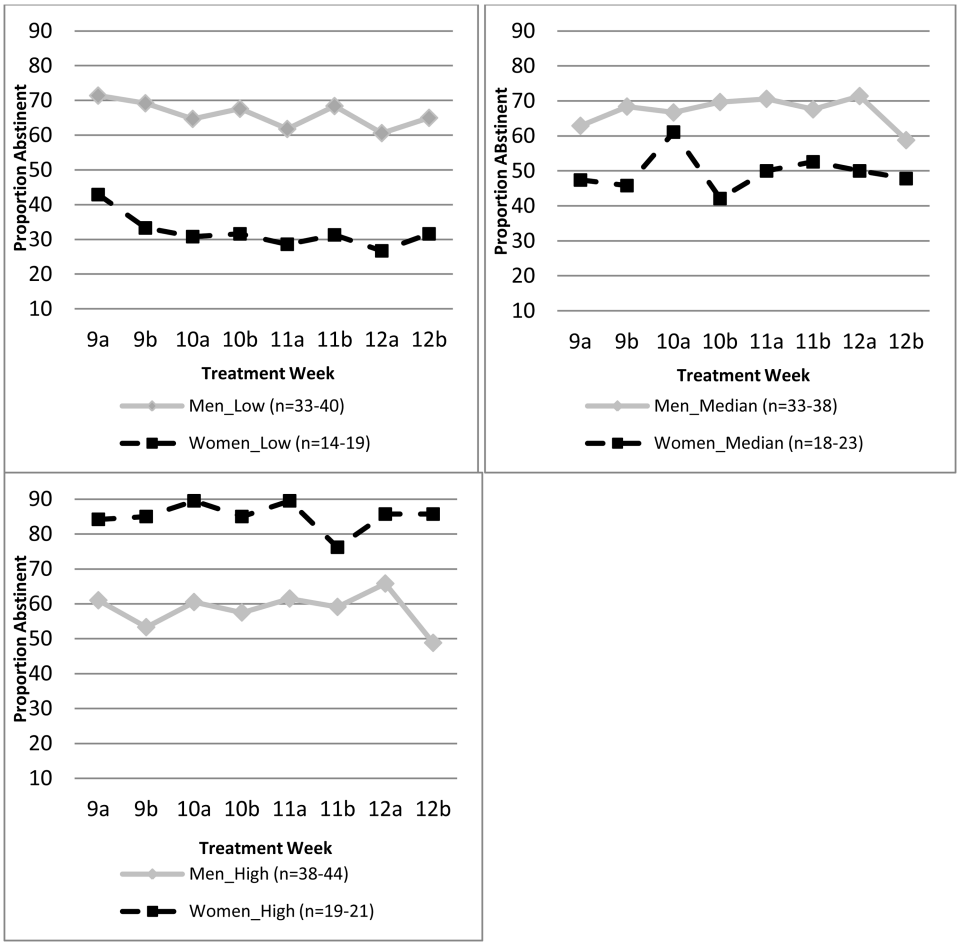

Figure 1.

1a – 1c Observed proportion of the Therapeutic Education System (TES) treatment arm sample abstinent from drugs and alcohol during the final four weeks (weeks 9-12) of the 12-week treatment phase (y-axis) as a function of gender (male vs. female) and low (≤7.8; Figure 1a), median (7.9-9.3; Figure 1b), and high (≥9.4; Figure 1c) levels of TES acceptability at week 8 (0-10 point scale). Time (x-axis) is presented in half-weeks (9a-12b) to reflect the twice weekly urine drug screen results. Sample size ranges correspond to available data at each half-week (9a-12b).

Table 1

Baseline characteristics of the total sample, and as a function of gender (males vs females) and the Therapeutic Education System (TES) treatment arm sample as a function of gender (males vs females)

	Total Sample (N=506 [a])	Males (n=314)	Females (n=192)	TES Sample (n=255)	
				Males (n=164)	Females (n=91)
Variable	n (%) or Mean (SD)				
Age (years)	34.87 (10.87)	35.20 (11.44)	34.32 (9.91)	36.16 (11.58)	34.56 (8.92)
Race/Ethnicity (%)					
White	267 (52.8)	161 (51.3)	106 (55.2)	75 (45.7)	51 (56.0)
Black/African	112 (22.1)	67 (21.3)	45 (23.4)	46 (28.1)	22 (24.2)
American	55 (10.9)	37 (11.8)	18 (9.4)	18 (11.0)	8 (8.8)
Hispanic/Latino	72 (14.2)	49 (15.6)	23 (12.0)	25 (15.2)	10 (11.0)
Multi-racial/Other					
Education (%)					
< High School	118 (23.3)	68 (21.7)	50 (26.0)	37 (22.6)	23 (25.3)
High School or GED	310 (61.3)	198 (63.1)	112 (58.3)	104 (63.4)	57 (62.6)
> High School	78 (15.4)	48 (15.3)	30 (15.6)	23 (14.0)	11 (12.1)
Single or Never Married (%)	307 (60.7)	197 (62.7)	110 (57.3)	99 (60.4)	49 (53.9)
Currently Unemployed (%) [b]	298 (58.9)	162 (51.6)	136 (70.8)	85 (51.8)	67 (73.6)
Primary Substance (%)					
Alcohol	104 (20.6)	65 (20.7)	39 (20.3)	40 (24.4)	18 (19.8)
Cocaine	101 (20.0)	54 (17.2)	47 (24.5)	31 (18.9)	22 (24.2)
Stimulants	69 (13.6)	46 (14.7)	23 (12.0)	24 (14.6)	9 (9.9)
Marijuana	114 (22.5)	70 (22.3)	44 (22.9)	35 (21.3)	19 (20.9)
Opiates	108 (21.3)	74 (23.6)	34 (17.7)	31 (18.9)	18 (19.8)
Other	10 (2.0)	5 (1.6)	5 (2.6)	3 (1.83)	5 (5.5)
Abstinent at Study Entry (%)	274 (54.2)	169 (53.8)	105 (54.7)	89 (54.3)	47 (51.7)
Social Adjustment Score [c]	2.18 (0.5)	2.11 (0.48)	2.30 (0.50)	2.11 (0.46)	2.29 (0.52)
Craving Last 7 Days (days)	3.24 (2.9)	3.16 (2.9)	3.37 (2.9)	3.25 (2.98)	3.44 (2.91)
Treatment Arm: TES (%)	255 (50.4)	164 (52.2)	91 (47.4)	n/a	n/a
TES Modules Completed (#)	n/a	n/a	n/a	38.26 (16.61)	36.48 (19.04)

[a] one case missing response to gender question;

[b] significant difference between males and females in the total sample ($X^2(1)=18.22$, $p<.01$) and TES sample ($X^2(1)=11.55$, $p<.01$);

[c] significant difference between males and females in the total sample ($t=4.23$, $p<.01$) and TES sample ($t=2.83$, $p<.01$)

Table 2

Generalized linear mixed effect final models of (A) abstinence in the last four weeks of treatment, (B) proportion of participants retained in treatment at week 12, (C) mean Social Adjustment Scale scores at week 12, and (D) number of alcohol and drug craving days at week 12 for the prior 7 days, as a function of treatment arm (Therapeutic Education System [TES] vs treatment-as-usual [TAU], gender (male vs female), abstinence at study entry, age, and time (model A only); 3-way and 2-way interactions were tested between treatment, abstinence at study entry, and gender and retained in the model if significant (p<.05).

	Estimate	SE	t-value
Model A: Abstinence in Final Four Weeks (n=468)			
Time	-0.008	0.021	-0.40
Treatment (TAU)	-0.270	0.424	-0.64
Gender (men)	0.160	0.338	0.47
Abstinence at Study Entry	-1.971	0.452	-4.36**
Age	0.019	0.015	1.28
Model B: Proportion Retained at Week 12 (n=506)			
Treatment (TAU)	-0.314	0.184	-1.71
Gender (men)	0.345	0.195	1.77
Abstinent at Study Entry	0.504	0.192	2.62**
Age	0.012	0.009	1.42
Model C: Social Adjustment Scale Total Score (n=447)			
Treatment (TAU)	0.020	0.039	0.52
Gender (men)	-0.117	0.041	-2.87**
Abstinent at Study Entry	-0.016	0.039	-0.42
Age	0.003	0.002	1.88
Baseline Social Adjustment	0.451	0.040	11.38**
Model D: Days of Craving (n=447)			
Treatment (TAU)	0.732	0.273	2.68**
Gender (men)	0.163	0.200	0.82
Abstinent at Study Entry	0.171	0.275	0.62
Age	-0.004	0.009	-0.40
Baseline Craving	0.252	0.035	7.14**
Treatment (TAU) × Abstinence at Study Entry	-1.004	0.378	-2.65**

* p<.05,

** p<.01

Table 3

Generalized linear mixed effect final models of (A) abstinence in the last four weeks of treatment and (B) proportion of participants retained in treatment at week 12, as a function of gender (male vs female), acceptability at Week 8 (mean), abstinence at study entry, age, and time (model A only) among participants randomized to the Therapeutic Education System (TES) treatment arm (n=255); 3-way and 2-way interactions between gender, abstinence at study entry, and acceptability were tested and retained in the model if significant (p<.05).

	Estimate	SE	t-value
Model A: Abstinence in Final Four Weeks (n=207)			
Time	-0.041	0.031	-1.33
Gender (men)	7.575	2.898	2.61**
Abstinent at Study Entry	1.301	0.475	2.74**
Age	0.004	0.021	0.17
Acceptability (wk 8)	0.732	0.282	2.59**
Gender (men) × Acceptability	-0.876	0.341	-2.57*
Model B: Proportion Retained at Week 12 (n=209)			
Gender (men)	0.464	0.307	1.51
Abstinent at Study Entry	0.400	0.297	1.35
Age	0.002	0.014	0.14
Acceptability (wk 8)	0.037	0.094	0.40

* p<.05,

** p<.01