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Emotion Regulation Enhancement of Cognitive Behavior Therapy for College Student Problem Drinkers: A Pilot Randomized Controlled Trial

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Abstract

This pilot randomized clinical trial tested an emotion regulation enhancement to Cognitive Behavior Therapy (CBT) with 29 college student problem drinkers with histories of complex trauma and current clinically significant traumatic stress symptoms. Participants received eight face-to-face sessions of manualized internet-supported CBT for problem drinking with or without trauma-focused emotion regulation skills (Trauma Affect Regulation: Guide for Education and Therapy, TARGET). Both interventions were associated with sustained (at one-month follow-up) reductions in self-reported drinking frequency, drinking related impairment, and heavy drinking in the past week, as well as post-traumatic stress disorder (PTSD) and complex PTSD symptoms, and improvement in self-reported emotion regulation. The enhanced intervention was associated with significantly greater sustained reductions in complex PTSD symptoms and resulted in medium/large effect size reductions in days of alcohol use (versus small effects by CBT). Emotion regulation enhancement of CBT for college student problem drinkers with interpersonal trauma histories warrants further investigation.

Keywords

alcohol use; college students; PTSD; cognitive behavior therapy; emotion regulation

College attendance is associated with increased drinking and heavier episodic drinking (White, Anderson, Ray, & Mun, 2016), and increased negative consequences (including suicidality) of alcohol use related to depression (Kenney, Abar, O'Brien, Clark, & LaBrie, 2016). College attendance often involves separation from parent and family supports that are protective against peer influences which can lead to alcohol use and intentions to use, binge drinking, and negative alcohol-related consequences among late adolescents (Martinez, Ayers, Kulis, & Brown, 2015; Schwinn & Schinke, 2014). Moderate to heavy alcohol use has been found to be particularly persistent among adolescents transitioning into adulthood (Lee, Winters, & Wall, 2010). Similarly, drinking has been shown to increase among males upon entering college (Labrie, Lamb, & Pedersen, 2008), and to remain consistent across

semesters and predict hazardous drinking and alcohol dependence in students' senior year (Fairlie, Maggs, & Lanza, 2016). Most college students mature out of heavy episodic drinking (Greenbaum, Del Boca, Darkes, Wang, & Goldman, 2005), but maladaptive drinking places many college students at risk for subsequent abuse and dependence (Fairlie et al., 2016). College students are promising candidates for substance abuse treatment, however, with a recent study demonstrating that they are more likely than non-students to complete treatment (56% vs. 42%) and to do so in a relatively brief time period (i.e., less than four months) (Sahker, Acion, & Arndt, 2015).

Research on Interventions for College Student Problem Drinkers

Cognitive behavior therapy (CBT) interventions for problem alcohol use by college students have been shown to be efficacious in reducing alcohol use and associated psychosocial and educational problems and increasing the use of protective behavior strategies (Carey, Scott-Sheldon, Elliott, Garey, & Carey, 2012; Pearson, 2013; Reid & Carey, 2015). Web-based interventions provide an efficient approach to enabling large numbers of college students to access CBT for problem drinking, and have been shown to be efficacious with little or no bias introduced by having students complete pre-tests prior to the intervention (Fazzino, Rose, & Helzer, 2016). However, although brief CBT with motivational enhancement is associated with short-term reductions in college student problem drinking and associated negative consequences, there is substantial variability in its short- (Huh et al., 2015) and long-term effectiveness (Huh et al., 2015; Mun et al., 2015; Samson & Tanner-Smith, 2015). Brief CBT for college students with or at risk for substance use problems also has not demonstrated incremental efficacy compared to providing information about harm-reduction (N. C. Clarke, Field, & Rose, 2015) or motivational enhancement (La, Cail, Pedersen, & Migliuri, 2010).

One possible impediment to successful outcomes with CBT for substance use problems is the propensity of youth and young adults who are at risk or have substance use problems to be emotionally dysregulated (Stephanou et al., 2016). Transitional age youth with interpersonal trauma histories (e.g., childhood abuse) often experience problems with emotion regulation (Handley, Rogosch, Guild, & Cicchetti, 2015). Early adolescents who report high levels of affective self-regulation problems (Griffin, Lowe, Acevedo, & Botvin, 2015) or social or generalized anxiety (Tomlinson, Cummins, & Brown, 2013) are at risk for initiating alcohol use and developing alcohol use problems that persist into young adulthood (Lee et al., 2010). Adolescents at risk for substance use disorders have been found to exhibit amygdala hyperactivation and emotion processing difficulties (Thatcher, Pajtek, Tarter, Long, & Clark, 2014) that are consistent with the documented effects of exposure to complex interpersonal trauma (D'Andrea, Ford, Stolbach, Spinazzola, & van der Kolk, 2012).

The Potential Role of Complex Trauma in College Student Problem Drinking

Although college students are generally a healthy and often socioeconomically advantaged young adult population, they often (i.e., >75%) have complex trauma histories (Ford, Stockton, Kaltman, & Green, 2006; Kaltman, Krupnick, Stockton, Hooper, & Green, 2005;

Lauterbach & Vrana, 2001). Studies with adult community and clinical populations consistently suggest a link between exposure to abuse and other forms of interpersonal violence in childhood, and posttraumatic stress disorder (PTSD) with alcohol use problems (Brady & Back, 2012), and similar findings have been reported with college students (Ford et al., 2006; Kaltman et al., 2005; Lauterbach & Vrana, 2001). College students who have experienced abuse or other interpersonal violence earlier in life are at risk for not only PTSD but also for complex trauma symptoms related to affect dysregulation (Ford et al., 2006; Kaltman et al., 2005) that have been associated with increased risk of problem drinking and decreased use of protective behavior strategies among college students (Bogg, Lasecki, & Vo, 2016; N. Clarke et al., 2016; Langberg, Dvorsky, Kipperman, Molitor, & Eddy, 2015; Linden-Carmichael, Braitman, & Henson, 2015). As proposed in the 11th Edition of the International Classification of Diseases, there is evidence that adolescents with trauma histories may experience complex trauma symptoms involving disturbances of self-organization often co-occur with, but are distinct from, the symptoms of PTSD (Sachser, Keller, & Goldbeck, 2017).

CBT designed to simultaneously reduce PTSD symptoms and problem drinking has been found to be effective with chronically substance abusing adults (Frisman, Ford, Lin, Mallon, & Chang, 2008; Mills et al., 2012; Najavits & Hien, 2013), but has not been evaluated with college student problem alcohol users who have complex trauma histories. College student problem drinkers with elevated levels of PTSD symptoms have been found to be comparable to those with low levels of PTSD symptoms in their ability to benefit from brief motivational and CBT interventions, but only when delivered by a counselor rather than as a purely internet-based program (Monahan et al., 2013). This is consistent with the finding that the development of a working alliance through personal contact with a counselor who was perceived as warm and accepting predicted minority adolescents' completion of a brief motivational substance abuse intervention (Cordaro, Tubman, Wagner, & Morris, 2012). Combining internet-based plus in-person intervention provides a way to capitalize upon the strengths of each delivery format. It also is possible that enhancements of internet-only intervention that facilitate a therapeutic relationship (e.g., person-to-person virtual contacts) or enhancements of in-person interventions that provide highly structured skill-development algorithms, might increase retention and both substance misuse and trauma symptom outcomes with college student problem drinkers.

The Current Pilot Study

This pilot study therefore was designed as an exploratory randomized clinical trial of an in-person manualized emotion regulation enhancement of internet-supported CBT for moderate drinking with college student problem drinkers with interpersonal trauma histories. Although augmentation of substance abstinence-focused CBT has not always been successful (Carroll et al., 2012; Godley et al., 2014), an enhanced CBT was tested because adjunctive interventions that specifically target putative mechanisms of problem drinking have shown promise with brief motivational interventions for college student heavy drinkers (Murphy et al., 2012).

The adjunctive emotion regulation intervention integrated into CBT for moderate drinking in the current study was Trauma Affect Regulation: Guide for Education and Therapy (TARGET) (Ford, 2015). TARGET teaches cognitive (Black & Mullan, 2015) and also behavioral skills for mindful awareness and adaptive modulation of stress reactions that accompany and exacerbate post-traumatic intrusive re-experiencing or other intense negative emotion states. TARGET uses a single sequential skill set that de-mystifies and de-stigmatizes posttraumatic stress reactions and provides an efficient and easy-to-learn method for gaining control of stress-related impulsivity, cravings, habitual risky behavior, dysphoria, anxiety, and anger. TARGET has been shown to be efficacious in reducing PTSD-related beliefs and sustaining sobriety self-efficacy with adults in substance abuse treatment, and in reducing PTSD and comorbid symptom (including substance misuse) severity and enhancing emotion regulation and the use of protective behavior strategies with low income women in the community and in prison, girls involved in delinquency, and male military combat veterans (Ford, 2015). TARGET also has shown promising results in quasi-experimental field trial studies with primarily male samples of juvenile justice-involved youth and young adults for whom emotion and impulse regulation were often impaired (Ford & Hawke, 2012; Marrow, Knudsen, Olafson, & Bucher, 2012). The current study therefore compared the drinking and emotion regulation outcomes of CBT with or without enhancement by TARGET, with college student who both were current problem drinkers and had histories of childhood trauma.

The efficacy of CBT for co-occurring substance abuse and mental health problems has been shown to be proportionate to the “dose” of sessions attended (Hides, Samet, & Lubman, 2010). Contingency management (CM) has been shown to increase attendance in a behavioral activation intervention and engagement in physical exercise with sedentary hazardous drinking college students (Weinstock, Capizzi, Weber, Pescatello, & Petry, 2014). Therefore, the current study included a CM component to maximize attendance.

While this was an exploratory pilot study, the central hypothesis was that TARGET affect regulation component would enhance CBT with college student problem drinkers with histories of complex trauma (defined as two or more types of traumatic experiences, including at least one type of interpersonal trauma). Specifically, TARGET + CBT was hypothesized to produce greater benefits immediately following treatment and at a one-month follow-up than CBT alone in: (1) reductions in the frequency of alcohol use, related impairment, and heavy drinking, (2) and improvement in emotion regulation, and reductions in PTSD and complex PTSD symptoms.

METHODS

Participants

Participants were 29 college students (ages 18-22; $M[SD] = 20.1[1.1]$) who responded between February 2010 and April 2011 to public announcements offering therapy for alcohol and stress problems at no cost based on a research protocol approved by the University [blinded] Institutional Review Board. Inclusion criteria included: current alcohol abuse or lifetime alcohol dependence or intensive treatment, confirmed by independent research interview; past complex trauma history, and current self-reported traumatic stress

symptoms. Exclusion criteria included: imminent danger of suicide or inpatient psychiatric or addiction treatment in the past month. Eligible applicants were randomized CBT ($N=16$) or CBT+TARGET ($N=13$). Participants' were 52% female ($N=15$), and were from ethnoracial backgrounds that included 27% African American, Hispanic, or Native American or mixed race, 52% White not Hispanic, and 21% Asian American. The experimental conditions did not differ on age, gender, or race ($p > .50$).

All participants endorsed past exposure to at least two types of potentially traumatic stressors ($M[SD]=4.07[1.73]$ of nine possible types of traumatic exposure), including traumatic death or separation from significant others (62%, $N=18$), severe accidents or illness (62%, $N=18$), traumatic emotional abuse (45%, $N=13$), witnessing life-threatening community violence (41%, $N=12$), physical violence or abuse (35%, $N=10$), sexual trauma (24%, $N=7$), intimate partner violence (24%, $N=7$), witnessing family violence (17%, $N=5$), and other potentially life-threatening traumatic stressors (24%, $N=7$). Exposure to the potentially traumatic stressors occurred at varying ages ranging from as early as two-years old and as recently as within the past year. Participants assigned to the two experimental conditions did not differ in their cumulative number of types of past traumatic exposures ($M[SD]=4.06[1.48]$ versus $4.08[2.06]$, $t(27)=0.02$, $p=.98$) nor in their severity of self-reported PTSD symptoms ($M[SD]=36.69[9.36]$ versus $38.69[11.34]$, $t(27)=0.52$, $p=.61$). While they also did not differ in the severity of self-reported complex PTSD symptoms, this difference approached statistical significance ($M[SD]=16.79[6.76]$ versus $21.46[9.07]$, $t(27)=1.50$, $p=.12$).

Procedure

Initial screening was done with the Youth Adult Alcohol Problem Severity Test (Hurlbut & Sher, 1992), a 27-item questionnaire designed to detect alcohol problems among college students by assessing drinking consequences along with frequency of occurrence during the last year and past month. Eligibility required either probable alcohol abuse (>2 items #1-18 endorsed for past month) or probable lifetime alcohol dependence or past treatment (>5 items endorsed lifetime, or #22, 25, 26, or 27 endorsed). Eligibility also required confirmation at a subsequent baseline assessment by the Traumatic Events Screening Instrument for Adults (TESI-A) (Ford & Smith, 2008) of a complex trauma history (defined as >2 types of traumas, including at least one type of interpersonal trauma). Inter-rater agreement by the baseline interviewer and independent review by an assessor who had no other role in the study confirmed 100% agreement on complex trauma categorization. Eligibility also required clinically significant complex traumatic stress symptoms as confirmed by a score >10 on the Stress Reactions Checklist (SRC) (Ford, Hawke, Alessi, Ledgerwood, & Petry, 2007) (see below for description of the SRC).

Measures

Primary Outcomes: Alcohol Use and Abuse.—The *Global Assessment of Individual Need* Short Screener alcohol use sub-scales (GAIN-SS) assessed self-reported frequency of alcohol use (days of drinking in the past 30-days) and of impairment due to alcohol use (days impaired in the past 30-days), and heavy drinking in the past week, and alcohol abuse. The GAIN-SS substance use scales have been validated with youth and adults (Dennis,

Chan, & Funk, 2006). Inter-rater agreement by an interviewer blinded to participant randomization and an independent review of a random sample of audiotaped GAIN-SS interviews at each assessment timepoint by an assessor who had no other role in the study was 100% on the three GAIN scores.

Secondary Outcomes: Emotion regulation was assessed with the *Negative Mood Regulation Scale*, a 30-item measure that reliably (Cronbach's $\alpha = .91$ in current sample) and validly assesses expectancies for managing negative mood states (Catanzaro & Mearns, 1990; Catanzaro, Wasch, Kirsch, & Mearns, 2000). The *Stress Reactions Checklist for Disorders of Extreme Stress* (SRC) is a reliable ($\alpha = .79$ in current sample) and validated 17-item self-report measure of past 30-day severity of complex traumatic stress symptoms (Ford et al., 2007). The *PTSD Checklist* is a reliable ($\alpha = .86$ in current sample) and validated 17-item self-report measure of past 30-day severity of *DSM-IV* PTSD symptoms (Elhai, Gray, Docherty, Kashdan, & Kose, 2007).

Therapy Expectancy and Working Alliance.—Expectancy of Therapeutic Outcome (ETO)(Resick, Nishith, Weaver, Astin, & Feuer, 2002) is a 6-item scale with 9-point ratings for credibility, confidence in outcome, and willingness to recommend therapy. The Brief Working Alliance Inventory (BWAII) (Neale & Rosenheck, 1995) is a 7-item questionnaire assessing perceived importance of therapy and the therapist's ability to understand and help.

Therapists and Therapy Interventions—Two post-MA clinical psychology Ph.D. graduate students (one female, one male) who had conducted CBT at the university student counseling center received 10 hours of training by the first author to conduct both therapies and were randomly assigned to participants in order to prevent artifact due to nesting therapists within therapy conditions. Each therapist conducted at least 5 cases with each therapy modality (range = 5-9). Both therapists completed the entire on-line CBT website course, with the website developer answering all substantive and procedural questions, prior to their first study case. The first author provided 16 hours of intensive review of the TARGET curriculum and worksheets, first demonstrating and then coaching the therapists in rehearsing a manualized script for each session's key concepts and emotion regulation skills.

CBT sessions were provided by the therapists in eight twice-weekly 50-minute outpatient sessions, to equate for therapist contact. Weekly review of samples of session audiotapes was done the first author individually with each therapist, first independently and then together with each therapist, for every case. Formal fidelity and competence monitoring was done by the first author based on review of all sessions for each therapist's first two cases in each modality, and then with a random sample of 33% of sessions in each case thereafter. Fidelity was achieved on 100% of all items in all sessions in both therapies, with no instances observed of use of TARGET terminology or procedures in any CBT-only session. Both therapists rated the credibility of each treatment for this population as very high before and after the first two cases.

In order to maximize attendance and completion of homework, all counseling sessions included a Contingency Management (CM) component to: \$5 for session attendance and \$5 for completing on-line homework in each of the 8 counseling/education sessions. In

addition, a prize of either \$30 (29/35 participants were assigned to receive this prize = .83 likelihood), \$50 (3/35=.085 likelihood), or \$100 (3/35= .085 likelihood) was awarded to participants for attending all 8 sessions and the post-therapy study assessment interview.

CBT for problem alcohol use was provided using modules from a sequential multimedia internet-based curriculum (www.moderatedrinking.com) that participants reviewed together with the counselor initially and then used independently to complete between-session homework. CBT sessions were manualized (see Table 1) using a standard protocol that has shown evidence of efficacy (Campbell, Hester, Lenberg, & Delaney, 2016) and that is consistent with prior studies of CBT for college problem drinking (Carey et al., 2012; Reid & Carey, 2015). The TARGET (Ford, 2015) emotion regulation skills enhancement was a 20-minute module in each session that teaches a sequential skill set designed to complement CBT skills for moderate drinking by enhancing awareness of and modulation of stress reactivity: (a) focusing attention on core values; (b) recognizing triggers for stress reactions, (c) distinguishing stress related (reactive) versus value-driven (adaptive) emotions, beliefs, goals, and behavioral choices, and (d) enhancing others' lives as well as one's own (see Table 1). Therapy activities in each session were the same in both conditions with the exception that the CBT+TARGET condition included 20 fewer minutes allocated to CBT in order to provide time for the TARGET activities.

RESULTS

Expectancy of Therapeutic Outcome and Therapeutic Working Alliance

Participant expectations of therapeutic outcomes were consistently high at both baseline and the conclusion of the intervention in both CBT (M/SD = 38.18[12.46]) and 47.23[5.08]), and CBT+TARGET (M/SD = 41.10[7.81] and 45.19[8.39])—with the majority of item ratings either “6=between somewhat and a lot” or “7=a lot” on the 9-point scale for degree of agreement that the treatment would be or was beneficial. Participant perceptions of their working alliance with the counselor also were consistently high in both conditions after the first and last session, with most ratings either “3=agree” or “4=strongly agree” that a collaborative, trustworthy and helpful alliance had been established by the counselor: CBT (M/SD = 23.24 [3.76] and 25.23[2.45]); CBT+TARGET (M/SD = 23.18[3.00] and 22.17 [4.69]). There were no treatment ($F[1,27] = 0.36 - 0.81 - \text{and } 0.09-3.92, p > .05$), therapist ($F[1,27] = 0.88-1.06 \text{ and } 0.41 - 0.78, p > .30$), or therapist by treatment ($F[1,27] = 1.04 - 1.61 \text{ and } 0.00 - 0.38, p > .20$), differences in outcome expectancies or working alliance, respectively, either early or at the end of therapy.

Participant Attendance

Most participants (59%) attended all eight sessions; 21% attended seven sessions, and 7% attended 5 or 6 sessions. Two CBT (13%) and two CBT+TARGET (16%) participants attended fewer than half of the sessions (see Figure 1). Number of sessions attended by CBT (M/SD = 6.4[3.0]) and CBT+TARGET (M/SD = 7.0[1.5]) participants were equivalent ($t[27] = 0.67, p = .51$). All CBT+TARGET participants completed the post-test assessment, as did 81% of the CBT participants (Figure 1). There was a good deal of attrition at the 1-

month follow-up assessment, with 61% of CBT+TARGET participants and only 38% of CBT participants still in attendance.

Treatment Outcomes

Scores for each continuous outcome measure's assessments (baseline, post-treatment, and 1-month follow-up) were analyzed using SPSS Version 23 General Linear Model analyses of variance to control for baseline between-group differences, on an intent-to-treat basis using the last observation carried forward. Effect size estimates were calculated using Cohen's (1980) d for change from baseline to post-treatment and follow-up for each condition. The dichotomous past week heavy drinking variable was analyzed by cross-tabulation, with relative risk calculated for CBT+TARGET at post-treatment and follow-up (vs. CBT-only as the reference category).

Across both treatments, there was evidence of statistically significant reduction in days of alcohol use in the past month ($F[2,26] = 5.61, p = .006$; see Table 2). Days of impairment due to alcohol use were reduced at post-treatment and follow-up only for the CBT +TARGET group, but the base rate was very low (approximately one and one quarter days in the past month) and the change for both groups was not statistically significant ($F[2,26] = 0.59, p = .56$). Tests of treatment by time interactions revealed no statistically significant differences in change between the treatment conditions for days of alcohol use ($F[2,26] = 0.59, p = .56$) or days of impairment due to alcohol use ($F[2,26] = 0.28, p = .75$). These findings were unchanged when analyses were conducted with baseline complex PTSD symptom severity included as a covariate.

Heavy drinking in the past week was reported by almost all (88%) CBT and all (100%) CBT + TARGET participants at baseline. This was reduced to approximately 50% of participants in both conditions at post-therapy and follow-up, with no significant difference between conditions on this variable at any study time point (Table 2).

Emotion regulation capacities increased ($F[2,26] = 3.86, p = .03$), and PTSD symptoms ($F[2,26] = 5.07, p = .01$) and complex PTSD symptoms ($F[2, 26] = 5.91, p = .007$) were reduced, at post-test and follow-up across both treatments. However, tests of treatment by time interactions revealed no statistically significant differences associated with treatment condition in change in emotion regulation, ($F[2,26] = 0.29, p = .75$), PTSD symptoms ($F[2,26] = 0.15, p = .86$), or complex PTSD symptoms ($F[2,26] = 2.80, p = .08$) symptoms. These findings were unchanged when analyses were conducted with baseline complex PTSD symptom severity included as a covariate.

Because the treatment by time interaction for complex PTSD symptoms approached statistical significance, change from baseline to follow-up was examined in order to determine if there was a difference between treatments in sustained reductions in these symptoms. This treatment by time interaction effect was statistically significant, indicating that the CBT+ TARGET (Effect Size $d = 0.90$) was associated with a greater degree of sustained improvement in complex PTSD symptoms from baseline to follow-up than the CBT cohort ($d = 0.13$) ($F[1,27] = 5.53, p = .02$).

Despite the general absence of treatment by time effects in the repeated measures ANOVAs, an exploratory examination of effect size estimates for change in each treatment condition revealed potential differences that warrant further study (Table 2). Medium ($> .40$) effect sizes were found in both treatment conditions for improvement in PTSD symptoms at post-test and at follow-up. For the CBT+TARGET cohort only, a large ($> .80$) effect was found for improvement at follow-up in complex PTSD symptoms, as well as a medium effect for improvement at post-therapy. In the CBT+TARGET cohort only, a medium effect also was found at both post-therapy and follow -up for reduction in the number of days of alcohol use in the past month for reduction in guilt, and for improvement in emotion regulation (Table 2).

DISCUSSION

Results suggest that a brief (8-sessions in a 4-week period) modular CBT intervention combining internet and face-to-face counseling (Carey et al., 2012) with homework can reduce not only problem drinking but also traumatic stress symptoms and deficits in emotion regulation that are associated with heightened risk of chronic alcohol use problems among college students (Avant, Davis, & Cranston, 2011; Cheng & Mallinckrodt, 2015; McDevitt-Murphy, Murphy, Monahan, Flood, & Weathers, 2010; Tripp, McDevitt-Murphy, Avery, & Bracken, 2015). CBT with or without TARGET was associated with positive expectancies and a perceived therapeutic working alliance (Moyers, Houck, Rice, Longabaugh, & Miller, 2016) that may have contributed to the 50% reduction in the proportion of students engaging in heavy drinking in the past week by CBT with or without TARGET, and all of these gains maintained at a one-month follow-up.

Further, adding TARGET was associated with medium-to-large effect size reductions in days of drinking, and a greater reduction of complex PTSD symptoms at follow-up than CBT alone. The findings suggest that college student problem drinkers with complex trauma histories may benefit from learning about the role of traumatic stress in drinking and practical skills for regulating trauma-related emotional distress, when receiving CBT for problem drinking (Tripp et al., 2015). Complex PTSD symptoms are associated with adolescent substance abuse severity (Simmons & Suarez, 2016) and with poorer substance abuse treatment outcomes (Ford et al., 2007). Study findings indicate that treatment for adolescents and young adults with these co-occurring problems may be most effective in reducing both substance use and complex PTSD symptoms if both are addressed simultaneously (Stappenbeck et al., 2015).

Combining therapeutic interventions has potential downsides e.g., dilution of the active ingredients in the separate components, and over-complication and cognitive overload for recipients (Foa et al., 2005; Hides et al., 2010). However, modular tailoring of interventions to individual risks and needs can reduce both mental health problems such as PTSD (Weisz et al., 2012) and alcohol use problems (Moyers et al., 2016). Although the study did not compare a combined in-person plus internet-based intervention with separate in-person or internet-based delivery formats, the results suggest that combining these two formats did not dilute the efficacy of the overall intervention but instead resulted in positive outcomes for both substance abuse-focused CBT and for the integrated CBT+TARGET modality.

Limitations

Methodological limitations make study findings preliminary and in need of replication. The small sample size resulted in limited statistical power to detect significant differences, particularly between the interventions when there were medium to large effect sizes for change in CBT+TARGET and small or null effect sizes in CBT-only. Inferences based on effect size estimates in pilot studies must be made with great caution due to potential sample-specific results that may not withstand tests of replication and that may be inflated by small *N* cell sizes (Leon, Davis, & Kraemer, 2011). Although therapist effects were partially accounted for by having two therapists (one male, one female) conduct both interventions, a larger cohort of therapists would be needed to detect or rule out therapist effects entirely. Despite preliminary evidence of sustained benefits over a one-month follow-up, a longer follow-up period extending over academic years and post-graduation is needed in order to determine if the results of the interventions are sustained. The presumed mechanism of TARGET enhancement of CBT, emotion regulation, was measured only by self-report, and improved in both conditions; multi-source multi-measure assessments of emotion regulation are needed in future research. The apparent benefit of the CBT intervention, with or without TARGET enhancement, was not directly tested with the inclusion of a non-CBT control condition.

Participants, despite acknowledging problem drinking, complex trauma histories, and clinically significant levels of complex PTSD symptoms, were relatively high functioning and reported few days of impairment weekly due to drinking. Replication with more impaired college problem drinkers is needed. Reliance entirely on self-report measures would be improved in future studies by the use of collateral reports, biological assays, and more ecologically valid and proximate measures such as device-validated time-sampled self-reporting *in situ*. Although using CM to incentivize attendance provided a strong test of intervention efficacy with a typically full “dose” of treatment, replication without attendance incentives would be more ecologically valid.

Conclusions

In sum, combined face-to-face and internet-based CBT showed promise in reducing college students’ problem drinking and PTSD symptoms, and the addition of modules on trauma-focused emotion regulation skills potentially enhanced the intervention’s impact on complex post-traumatic symptoms and daily drinking. Further research is needed to test the effectiveness of this combined approach to co-occurring alcohol use and complex traumatic stress problems with college students. Whether the inclusion of a trauma memory processing component as well as TARGET’s present-centered approach further enhances outcomes also warrants investigation (Mills et al., 2012). In the interim, the brief and readily replicable CBT+TARGET intervention could be clinically tested on a case-by-case basis in college and university counseling clinics.

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Figure 1.
CONSORT flow chart.

Table 1.

Overview of session topics for CBT and CBT+TARGET face-to-face counseling

<u>CBT for Alcohol Use Problems</u>	
Session 1: Introduction to CBT Website (http://www.moderatedrinking.com) + Increasing Motivation Activity #2 + Setting Goals + Doing a “30” (Reduced Drinking) + Keeping Track	
Session 2: Review/Revise Goals + Self-Monitoring Feedback + Rules for Drinking + Slowing Drinking + Tracking Urges	
Session 3: Review/Revise Goals + Self-Monitoring Feedback + Identify/Manage Triggers	
Session 4: Review/Revise Goals + Self-Monitoring Feedback + Measure Mood + Alternatives	
Session 5 & 6: Review/Revise Goals + Self-Monitoring Feedback + Problem Solving	
Session 7: Review/Revise Goals + Self-Monitoring Feedback + Lapses/Relapses + Abstaining	
Session 8: Review/Revise Goals + Self-Monitoring Feedback + Setting Long-term Goals	
<u>CBT+TARGET (adds the following components to each CBT session)</u>	
Session 1: Stress Reactions and the Brain’s Alarm, Memory, and Thinking Centers	
Session 2: The SOS Focusing Skill	
Session 3: Identify/Manage Alarm Triggers	
Session 4: Alarm versus Main (Focused) Emotions	
Session 5: Alarm versus Main (Focused) Thoughts and Goals	
Session 6: Alarm versus Main (Focused) Options	
Session 7: Making a Contribution by Using the FREEDOM Steps Consistently	
Session 8: Using the SOS to Keep Main Goals in Focus	

Table 2.

Baseline, post-therapy, and follow-up intent to treat sample last observation carried forward scores and effect size estimates

<u>Measure</u>	<u>Therapy</u>	<u>N</u>	<u>Baseline Scores</u>			<u>Post-test Scores</u>			<u>Follow-up Scores</u>		
			<u>Mean</u>	<u>SD</u>	<u>SE</u>	<u>Mean</u>	<u>SD</u>	<u>SE</u>	<u>Mean</u>	<u>SD</u>	<u>SE</u>
Days of Alcohol Use	CBT	16	9.06	4.65	1.32	7.50	5.69	1.31	7.25	6.23	1.41
	CBT+T	13	11.08	5.97	1.46	7.84	4.63	1.46	7.69	4.87	1.55
Days of Impairment	CBT	16	1.25	2.21	0.50	1.69	1.70	0.54	1.19	1.76	0.41
	CBT+T	13	1.38	1.66	0.55	1.23	1.79	0.60	0.85	1.46	0.45
Emotion Regulation	CBT	16	106.31	18.25	4.49	111.75	15.52	3.58	109.47	15.15	4.00
	CBT+T	13	100.68	17.54	4.98	107.87	12.69	4.00	107.60	16.62	4.39
Complex PTSD Sx	CBT	16	16.79	6.76	1.97	15.50	6.16	1.55	16.00	5.77	1.46
	CBT+T	13	21.46	9.07	2.18	15.77	6.21	1.72	14.54	5.91	1.62
PTSD Sx	CBT	16	36.69	8.36	2.57	32.75	5.88	1.92	31.88	6.26	2.26
	CBT+T	13	38.69	11.34	2.85	34.69	9.46	2.13	32.77	11.62	2.51
Heavy Drinking in Past Week		<u>N</u>	<u>Frequency</u>	<u>%</u>		<u>Frequency</u>	<u>%</u>	<u>RR</u>	<u>95% CI</u>	<u>Frequency</u>	<u>%</u>
	CBT	16	14	88		9	56	1.22	0.59-	8	50
	CBT+T	13	13	100		6	46		2.53	7	54
											1.87

Note: CBT=Cognitive Behavior Therapy for Problem Drinking; CBT+T = CBT augmented by Trauma Affect Regulation; Guide for Education and Therapy (TARGET); Days of Alcohol Use = number days of drinking in the past 30 days; Days of Impairment = number of days impaired by alcohol use in the past 30 days; Sx = symptoms; ES = Effect Size (Cohen's *d*) for change from baseline, medium-to-large and large effects (*d* > .60) noted in **bold font**; RR = relative risk comparing CBT versus CBT + TARGET; 95% CI = 95% Confidence Interval.