Published in final edited form as:

J Anxiety Disord. 2013 March ; 27(2): 252–258. doi:10.1016/j.janxdis.2013.02.008.

Treating individuals with social anxiety disorder and at-risk drinking: Phasing in a brief alcohol intervention following paroxetine

Sarah W. Book^{a,*}, Suzanne E. Thomas^a, Joshua P. Smith^a, Patrick K. Randall^a, Matt G. Kushner^b, Gail A. Bernstein^b, Sheila M. Specker^b, Peter M. Miller^a, and Carrie L. Randall^a

^aCharleston Alcohol Research Center, Medical University of South Carolina, 67 President Street, Charleston, SC 29425, United States

^bUniversity of Minnesota, Department of Psychiatry, 2450 Riverside Avenue, Minneapolis, MN 55454, United States

Abstract

Paroxetine alone is not sufficient to decrease alcohol use in socially anxious alcoholics seeking anxiety treatment. We tested the hypothesis that adding a brief-alcohol-intervention (BI) to paroxetine would decrease alcohol use. All subjects ($N = 83$) had a diagnosis of social anxiety disorder, endorsed drinking to cope with anxiety, were NIAAA-defined at-risk drinkers, and were randomized to either paroxetine alone, or paroxetine plus BI. Both groups showed significant improvement in both social anxiety severity ($F(5,83) = 61.5$, $p < 0.0001$) and drinking to cope (e.g. $F(4,79) = 23$, $p < 0.0001$) and these two constructs correlated with each other ($B = 3.39$, $SE = 0.696$, $t(71) = 4.88$, $p < 0.001$). BI was not effective at decreasing alcohol use (e.g. no main effect of group, all p values > 0.3). Paroxetine decreased social anxiety severity in the face of heavy drinking and decreasing the anxiety was related to a concurrent decrease in coping related drinking. BI was not effective at decreasing drinking or drinking to cope.

Keywords

Social anxiety; Social phobia; At-risk drinking; Brief interventions; Drinking to cope

1. Introduction

Social anxiety disorder (SAD) has a well-documented relationship with problematic alcohol use. SAD often begins in early adolescence and predicts the development of an alcohol use disorder (AUD) in adulthood (Buckner, Timpano, Zvolensky, Sachs-Ericsson, & Schmidt, 2008). In fact, about 1 in 5 people who present for treatment for social anxiety disorder also have an AUD (Book & Randall, 2002). One explanation of this co-occurrence is that people with high social anxiety endorse drinking alcohol to cope with their anxiety (Buckner & Heimberg, 2010; Thomas, Randall, & Carrigan, 2003) and expect alcohol to be anxiolytic (Carrigan & Randall, 2003). Drinking to cope (DTC) in and of itself has been shown to be associated with alcohol related problems including the development of alcohol dependence (Buckner & Heimberg, 2010).

In a previous study, our research group previously showed that successfully reducing social anxiety through pharmacologic treatment with paroxetine does not translate into changes in drinking in individuals with co-occurring SAD and AUD who drink to cope (Book, Thomas, Randall, & Randall, 2008; Thomas, Randall, Book, & Randall, 2008). At that time, we conducted a double-blind, placebo-controlled trial of the efficacy of paroxetine in decreasing both anxiety and alcohol use in 42 social anxiety treatment seeking subjects over 16 weeks. Although the medication group experienced a robust amelioration of anxiety, comparable in magnitude to the effects of paroxetine in socially anxious subjects without an alcohol use disorder, there were no differences between the paroxetine and placebo group in traditional measures of alcohol use (i.e., quantity or frequency).

Although paroxetine did not change the overall amounts of alcohol consumed, it did decrease drinking specifically for the purpose of coping. Additionally, it uncoupled the relationship between anxiety and alcohol use. That is, in the group receiving paroxetine, there was no longer a significant positive relationship between quantity nor frequency of alcohol use and severity of social anxiety (Thomas et al., 2008). These data implied that although drinking did not automatically change, there may have been less reliance on alcohol for coping with social anxiety, and paroxetine-treated individuals might be receptive to targeted alcohol interventions once they no longer needed alcohol to cope.

These findings from our previous study were relevant in guiding the current randomized clinical trial, which examines whether the addition of an alcohol intervention (BI), delivered when social anxiety symptoms have been successfully reduced by paroxetine, results in reduced alcohol use in participants who engage in risky drinking as defined by NIAAA (National Institute on Alcohol Abuse and Alcoholism, 2009). We hypothesized that participants who received paroxetine and BI vs. paroxetine only would have lower quantity and frequency of drinking.

Because the study participants are seeking treatment for their anxiety, the alcohol intervention (BI) would need to have applicability in a mental health setting and be appropriate for individuals who are not motivated to change their drinking behaviors and do not view their alcohol use as a problem. To be adaptable for regular mental health practice, the alcohol intervention would need to be brief (without extended assessment, scoring, and feedback booklets) and unthreatening for a psychiatrist without experience in treating hazardous drinking in his/her practice. Additionally, it would have to be amenable to seamless integration into the treatment of a psychiatric disorder like social anxiety disorder in the sense that it could tie together for the study participant the relationship between drinking and relief from social anxiety with the risks involved in continued use of alcohol at risky levels.

Brief interventions meet all these criteria. They are effective (Moyer, Finney, Swearingen, & Vergun, 2002) and are recommended for individuals who are heavy drinkers with mild or moderate problems associated with alcohol. The brief intervention chosen for this study, *Helping Patients Who Drink Too Much- A Clinician's Guide* (National Institute on Alcohol Abuse and Alcoholism, 2007) is recommended for use in mental health settings and is used to link the severity of the social anxiety disorder being treated with the effect of continued drinking.

2. Methods

2.1. Participants

Participants were recruited from two metropolitan areas (Charleston SC and Minneapolis MN) through advertisements in the local media. Individuals interested in treatment for social

anxiety were invited to call study personnel for a confidential telephone screening interview. Alcohol treatment was not mentioned in the advertisement. The screening interview included questions from the Mini-SPIN (Connor, Davidson, Sutherland, & Weisler, 1999) to screen for probable social anxiety disorder and questions about alcohol use with the Alcohol Use Disorders Identification Test (AUDIT) (Saunders, Aasland, Babor, de la Fuente, & Grant, 1993). Individuals were required to meet preliminary screening criteria for probable social anxiety, report using alcohol to cope, and have AUDIT total scores that reflected moderate alcohol problems (between 4 and 15 for women and 8 and 15 for men). Prior to assessment and after the nature of the study procedures were explained, all individuals signed an Institutional Review Board-approved informed consent document, in compliance with the Code of Ethics of the World Medical Association (Declaration of Helsinki). All in-person interviews were conducted by clinically trained research personnel and by a study physician who had participated in inter-rater reliability training to ensure consistency across and within sites. Assessments used to confirm eligibility and to provide outcome data are described below.

2.2. Assessments

2.2.1. Social anxiety severity—Social anxiety disorder (and diagnosis of other Axis I disorders) was confirmed through structured clinical interview (MINI-SCID) by the participant's study physician (SWB, GAB, or SMS) (Sheehan et al., 1998). In addition, the Liebowitz Social Anxiety Scale (LSAS) and the Clinical Global Impression (CGI) were used to assess social anxiety severity. The LSAS (Heimberg et al., 1999) is a psychometrically validated standardized questionnaire used in research studies to quantify social anxiety severity. It can be either research-administered or self-rated, both of which have proven psychometric support (Baker, Heinrichs, Kim, & Hofmann, 2002; Oakman, Van Ameringen, Mancini, & Farvolden, 2003). The self-rating format was used in the present study. LSAS total scores range from 0 to 144. If individuals fear most social situations, the specifier "generalized" is used and is considered to be the more severe form of the disorder. Using area under a receiver operating characteristics (ROC) curve analysis, Mennin et al. (2002) determined an optimal LSAS cutoff value of 60 to predict generalized social anxiety disorder (Mennin et al., 2002). Participants had to score at least 60 on the LSAS to qualify for study eligibility. Because of the specific sample assessed (i.e., individuals who use alcohol to cope with social anxiety) the LSAS instructions were modified to instruct participants to rate each situation as if alcohol was not available to cope with the situation as described previously by our group (Randall et al., 2001). The Clinical Global Impression (CGI) is a clinician-delivered instrument utilized in pharmaceutical trials (Guy, 1976) and is an independent but corroborative assessment for social anxiety when used together with the LSAS. It has acceptable psychometric properties (Zaider, Heimberg, Fresco, Schneier, & Liebowitz, 2003) and measures comparable effect sizes to other commonly used measures when assessing clinical change in trials of social anxiety disorder (Hedges, Brown, & Shwalb, 2009). The LSAS was used to confirm eligibility, and both the LSAS and CGI were used as outcome measures.

2.2.2. Quantity and frequency of drinking—The Timeline Followback (TLFB) was used to assess quantity and frequency alcohol use during the study. The TLFB (Sobell & Sobell, 1992) is a calendar-based instrument used to assess alcohol use over a specific time period in the immediate past. In the present study, participants were asked about alcohol use during the 30 days prior to study participation, and then about alcohol use in the interim period between study visits. The primary alcohol use variables of interest were drinks per drinking day (DDD), drinks per week (DPW), percent days abstinent (PDA), and percent heavy drinking days (PHD), defined by the proportion of days in the assessment period that a woman consumed 4 or more standard drinks and a man consumed 5 or more standard

drinks. The TLFB was used to determine study eligibility and to assess change in alcohol use over time.

2.2.3. At-risk drinker status—The NIAAA Guidelines (National Institute on Alcohol Abuse and Alcoholism, 2007) were used to indicate at-risk drinker status in participants (a dichotomous construct). This measure was used to determine study eligibility. To be classified as an at-risk drinker according to these guidelines, an individual must drink more than 3 (women) or 4 (men) standard drinks per drinking day or more than 7 (women) or 14 (men) standard drinks per week.

2.2.4. Drinking to cope—We used two measures to determine drinking to cope behaviors: a modification of the TLFB and the drinking to cope rating scale used in our previous studies (Thomas, Carrigan, & Randall, 2005; Thomas et al., 2008), now called the Social Anxiety Drinking Scale (SADS).

When the TLFB was administered, participants were asked for every drinking day whether (s)he consumed at least one drink for the purpose of relieving social anxiety. If so, that day was considered a “drinking to cope day” and used as a variable in outcome analyses. In addition, research personnel asked subjects to indicate for each day whether they had the opportunity to participate in a social situation, and, if so, whether they avoided the situation or participated. These data were recorded on the TLFB calendar and used to compute “percent DTC”: the percent of the social opportunity days participated that were also drinking to cope days.

Participants also completed a drinking to cope questionnaire used in our previous studies (Thomas et al., 2005, 2008) that has recently been reported to have good psychometric properties as a measure of drinking to cope with social anxiety and has been named the Social Anxiety Drinking Scale (SADS) (Smith, Book, Thomas, & Randall, 2012). For the current clinical trial, the SADS collected information about the participant’s self-reported use of alcohol to feel more comfortable prior to and during social situations, including what percentage of the time participants reported that they drank before engaging in a social situation (SADS-B) (0 = none of the time; 5 = half of the time; 10 = all of the time) and during a social situation (same response options) (SADS-D). The SADS-B and SADS-D were used to determine eligibility and examined as outcome measures.

2.3. Eligibility

Eligibility was determined at the end of the in-person interview. Inclusion criteria were as follows: (1) age 18–65; (2) diagnosis of social anxiety disorder via MINI SCID (3) LSAS score ≥ 60 ; (4) “at-risk” drinker per NIAAA Clinicians guidelines and (5) endorsement on SADS-B or SADS-D of drinking to cope at least 40% of the time before or during social situations, a cut-off determined a priori based on previous work by our group (Thomas et al., 2003). Individuals were excluded if they met criteria for bipolar disorder, schizophrenia, substance abuse or dependence other than alcohol or nicotine, or endorsed suicidality. Participants were also excluded if they reported unsuccessful trials of paroxetine or were unwilling to take paroxetine.

2.4. Anxiety treatment

All participants were initiated at a dose of 10 mg per day of paroxetine following confirmation of eligibility; participants received weekly medication supply at each visit for the first 4 weeks of the trial. The dose was titrated as tolerated; typical titration included increasing the dose to 20 mg at the second visit, 40 mg at the third visit, and 60 mg at the fourth visit. Participants with side effects to paroxetine could have their dose decreased.

Participants who did not want to increase the dose were not required to do so. After 4 weekly visits, participants were scheduled for visits at 4-week intervals, starting at week 6 (6, 10, 14, 18, and 22). All visits included medication management, in which the study physician evaluated the participant's anxiety severity and improvement with the CGI and assessed medication adverse effects with a checklist.

2.5. Randomization to brief alcohol intervention

Participants who were receiving at least 20 mg per day of paroxetine at week 6 qualified for randomization and continuation in the study regardless of their level of social anxiety. We selected to initiate the brief intervention at week 6 (for the intervention group) based on results from our prior study in a similar patient population that showed that 6 weeks of paroxetine treatment resulted in robust reductions in social anxiety severity (Book et al., 2008). Fig. 1 shows study flow chart and sample size at each phase of the protocol. Participants were randomized to either continue receiving paroxetine with no alcohol intervention, similar to our previous trial (Book et al., 2008), or to receive paroxetine plus the brief alcohol intervention (BI) as described in the NIAAA Clinician's Guide "Helping Patients Who Drink Too Much: A Clinician's Guide" (National Institute on Alcohol Abuse & Alcoholism, 2007). This intervention is designed for primary care and mental health clinicians. The research staff who collected drinking and other research data at weekly visits were blind to study assignment. Random assignment to study arm was conducted using a computerized urn randomization program to ensure equal representation between the BI and control group of potentially confounding variables (Stout, Wirtz, Carbonari, & Del Boca, 1994). Urn randomization variables were gender (M/F), alcohol dependence diagnosis (yes/no), and baseline LSAS score ($<$ or ≥ 80). A separate urn was created for each site (Charleston and Minneapolis).

For participants randomized to BI, the study physician concluded the medication management visits at weeks 6, 10, 14, and 18 with a discussion about the participant's alcohol use. The study physician asked the participant to estimate how many drinks s/he consumed on a typical drinking day and in a typical week. The physician then related drinking practices to social anxiety severity. The discussion with the participant was standardized and non-confrontational. The topic was introduced as follows: "The NIH has guidelines for healthy levels of drinking. People who drink more than these guidelines are at higher risk for developing alcohol problems, including worsening of anxiety. The paroxetine may be helping your anxiety now, but if you can keep your alcohol use within these limits, your social anxiety may improve even more or stay lower even when and if you want to stop taking the medication." If the participant reported drinking at levels higher than the recommended levels (which was a requirement for entry into the study), the physician added "Are you interested in trying to cut back on your alcohol use?" If the participant agreed (89%), the physician helped him/her set a goal of drinks per drinking day and total drinks per week for the period until the next appointment. The physician informed the participant that they would review his/her progress when they met again for the medication management visit in 4 weeks and new goals would be set. At the end of the first BI session (week 6), the participant was given an educational pamphlet, "Rethinking Drinking" (National Institute on Alcohol Abuse & Alcoholism, 2009), and s/he was encouraged to use the included alcohol diary cards to keep track of daily and weekly alcohol use. Participants who expressed no interest in reducing their drinking ($n = 5$) were supported non-judgmentally; they were still given the "Rethinking Drinking" pamphlet to take home, but no goals were set to reduce drinking. The total time required for the BI added 10 min to the doctor's visit. For participants randomized to the control condition, none of the medication management visits included discussion of alcohol use.

2.6. Quality control

To reduce variability across physicians and across research assistants and between sites, all study personnel attended an intensive 2-day training session that systematically reviewed the study rationale, methods for screening and determination of participant eligibility, database organization and maintenance, delivery of study assessments, and delivery of the BI. For the purpose of training physicians, participant-actors were used to allow demonstration and practice of all assessments and delivery of the BI. This included role-play exercises and discussions related to potential challenges. During the course of the study, every visit with the study physician was audiotaped, beginning at week 6. These tapes were reviewed by an independent evaluator (PMM) to be sure that the BI was adhered to at each visit, and that alcohol was not mentioned for the control condition. The evaluator also conducted regular telephone supervision with the physicians as a group. The physicians used this telephone time to confer with each other to ensure consistency.

2.7. Outcomes assessment

Participants completed study-related visits at baseline, weeks 1–4, week 6, 10, 14, 18, and 22. After 22 weeks of paroxetine treatment, participants were given the option of being tapered off the medication or referred to their primary care provider to continue the medication. Participants returned for follow-up visits at weeks 34 and 46. Follow-up data will be reported separately. Participants were financially remunerated at baseline (\$10), week 10 (\$50), week 14 (\$50), and week 22 (\$50).

At each research visit, participants reported quantity and frequency of drinking and completed assessments of social anxiety severity and drinking to cope. These instruments were administered by research personnel who were blind to treatment assignment and were not involved in clinical management of subjects. These assessments were not shared with the physician. Although the physician also discussed alcohol use behaviors with the subjects randomized to BI, this information was not used in the data analysis, nor was it shared with research staff. In this way, clinical and research ratings were collected independently to minimize any unintentional bias.

2.8. Data analytic plan

Comparisons of demographics between treatment groups were performed with simple ANOVA and Chi-Square as appropriate. Analyses were conducted both to confirm that paroxetine was associated with reduced social anxiety (a necessary outcome for the integrity of the study) and to test the primary hypotheses. The primary drinking variables (drinks per week and drinks per drinking day) were cumulated across 4 periods: weeks 1–6 (all subjects on paroxetine prior to randomization to BI vs control condition), then weeks 7–12, 13–18, and 19–22. This was done to provide a sufficient smoothing for the TLFB variables while allowing reasonable assessment over time if, as was our a priori expectation, the BI effect increased with time during the trial. Other repeated measure variables are also reported at the 4 time periods described above.

To evaluate the relationship between change in anxiety severity and change in drinking to cope over time, a scatter plot was created to depict the percent of time drinking to cope during a social engagement (SADS-D) at 10 weeks as compared to the slope of LSAS decline over the first 6 weeks. The scatter plot is corrected for drinking to cope at baseline, i.e., the partial regression.

Continuous outcomes (e.g. LSAS and drinking variables) were tested as a mixed model (SAS 9.0 PROC MIXED) with an unstructured variance/covariance matrix and ordinal or binary variables were tested with generalized estimation equation procedure (SAS 9.2

PROC GENMOD). Baseline drinking values were entered as covariates for the basic analysis of drinking variables.

3. Results

3.1. Demographic and baseline data

Of 1676 potential participants who went through an initial telephone screening process, 160 qualified, 123 received paroxetine at baseline and 83 were randomized at week 6. Progress of recruitment and randomization is summarized in Fig. 1.

There were no significant baseline differences between the group randomized to BI ($n = 44$) and the group randomized to the control condition ($n = 39$) on gender (about 55% male), race (about 75% Caucasian), or age (early 1930s), nor did groups differ on baseline social anxiety severity and alcohol use severity. Social anxiety disorder was relatively severe with a mean LSAS of 93, and many participants (43%) received a CGI severity rating by the study physician of at least “markedly ill.” Mean ($\pm$ SD) age of onset of social anxiety was 13 ($\pm$ 5.7). As an inclusion criterion, all participants endorsed using alcohol to cope with their social anxiety, and all participants drank at levels considered “at-risk” (National Institute on Alcohol Abuse and Alcoholism, 2007). For men, the mean ($\pm$ SD) number of drinks per drinking day was 6.3 ($\pm$ 2.7) and drinks per week was 19.0 ($\pm$ 12.4). Baseline mean ($\pm$ SD) drinks per drinking day for women was 4.2 ($\pm$ 1.6) and drinks per week was 11.8 ($\pm$ 10.5). The mean age of onset of at-risk drinking was 23.9 ($\pm$ 8.4). These and other baseline characteristics are detailed in Table 1.

3.2. Treatment adherence

In general, participants adhered to the intervention and attended the treatment sessions. Those randomized to BI were more likely to attend all sessions as compared to those randomized to control (91% vs 72%) (Fisher’s exact test $p = 0.043$). A majority of the participants in the BI group ($n = 39$, 89%) agreed to set a “drinks per week” and/or “drinks per drinking day” goal in the context of the intervention. Of the 83 randomized subjects, final visit data were collected on all but 12 (3 BI, 9 control), for an 86% research data completion rate.

3.3. Social anxiety and drinking to cope outcomes

Social anxiety severity decreased significantly over time during the course of the study. As shown in Fig. 2, LSAS total scores decreased over time, with the most significant reduction occurring, as expected, in the first 6 weeks of treatment. The overall analysis revealed a significant effect of time on LSAS scores ($F(5,83) = 61.5$, $p < 0.0001$). Similarly, CGI-Severity for social anxiety also improved significantly over time ($F(9,83) = 29$, $p < 0.0001$). Neither of these measures showed a time $\times$ treatment group effect (all F values < 1.7 , all p values > 10).

In addition to reporting decreases in social anxiety severity over time, participants also reported a significant decrease in drinking to cope (DTC) with anxiety. Specifically, participants reported less percent time DTC before social situations over time ($F(4,79) = 14$, $p = 0.0001$) and less percent time DTC during social situations ($F(4,79) = 23$, $p < 0.0001$) as measured by SADS-B and SADS-D, respectively. However, there were no group $\times$ time differences on these measures (SADS-B: $F < 1$, $p = 0.43$; SADS-D: $F < 1$, $p = 0.63$). Similarly, Fig. 3 shows the significant decrease over time without a treatment $\times$ time effect of the percent DTC as measured on the TLFB (and described in Section 2).

There was a strong relationship between the improvement in LSAS total scores and the improvement in DTC ($B = 3.39$, $SE = 0.696$, $t(71) = 4.88$, $p < 0.001$). Fig. 4 shows a partial regression plot of SADS-D scores (percent of time drinking during a social engagement corrected for baseline) on improvement in LSAS (slope of baseline to week 6 from the piecewise regression). LSAS improvement accounted for 65% of the reduction in SADS-D scores.

3.4. Drinking outcomes

Contrary to our hypothesis, quantity and frequency of drinking did not differ between the two groups, nor did drinking decrease over the course of time. Drinks per week and drinks per drinking day outcomes are shown in Fig. 5. The mixed model analysis revealed no systematic differences between the two groups in the trajectories of either of these drinking variables. Analyses reported all use baseline values of the dependent variable as a covariate. There were no overall group mean differences on either measure (i.e., no main effect of group, all p values $>.3$), no change over time (i.e., no main effect of time, all p values >0.45), nor any interaction of group with time (all p values >0.7) for either of the drinking variables. All possible covariates in Table 1 were examined and none altered these main findings.

4. Discussion

The present study tested the hypothesis that adding a phased brief alcohol intervention (BI) sequentially after social anxiety has been effectively treated with paroxetine would result in reduced risky alcohol use (quantity and frequency) and reduced reliance on alcohol as a coping strategy (drinking to cope measures). The results of this trial did not support this hypothesis.

As expected and consistent with our previous findings (Book et al., 2008), social anxiety severity was effectively decreased, with the most dramatic change occurring within the first 6 weeks of the trial. Validated measures of social anxiety severity showed this effect, including the self-rated Liebowitz Social Anxiety Scale (LSAS) and the clinician-rated Clinical Global Impression Scale (CGI). In the present study, the total LSAS score decreased by an average of 45% at week 6, comparable to the 35% decrease seen in the paroxetine-treated group at week 6 in our previous study. Similarly, the CGI ratings showed that at week 6 in the present study 94% of participants were rated by physician as improved, comparable to 83% of paroxetine-treated participants in the prior trial.

In addition to the expected significant decrease in social anxiety severity, participants in this trial also reported the expected significant decreases in drinking to cope (DTC) with social anxiety. The present study included two different measures of DTC: the TLFB and the SADS. The TLFB captured the proportion of social engagement days in which the participant endorsed using alcohol to cope (see Section 2). In our previous study we also used the TLFB to measure DTC however we only asked participants whether or not a drinking day was a DTC day. We realized we lost salient information by not inquiring about the number of days that the individual participated in social situations where s/he typically would have consumed alcohol to relieve social distress (Thomas et al., 2008). Having learned from that process, in the present study we modified this methodology to evaluate whether participants continued to use alcohol as a coping mechanism when socializing. Results of the current trial indicate that when participants engage in social situations they are less likely to drink to cope.

On the second DTC measure, the Social Anxiety Drinking Scale (SADS), participants were asked to consider the degree to which they rely on alcohol in social situations. Baseline

inclusion criteria required drinking to cope with social anxiety at least 40% of the time during or before a social situation. During the course of the study, self-reported reliance on alcohol to participate in social situations was significantly reduced. This, together with the TLFB outcome, suggests that participants not only subjectively believed they did not need alcohol in stressful situations, but that they also actually relied on alcohol less when socializing. In other words, both subjectively and behaviorally, participants became less reliant on alcohol to cope with anxiety.

Over the course of the study not only did social anxiety severity significantly decrease over time, and DTC was similarly reduced, results also indicate the decrease in anxiety was associated with decreases in DTC. While the design of the study does not permit determination of causality, this makes sense intuitively. This is the first report to our knowledge that suggests the possibility that decreasing anxiety in and of itself may result in decreases in coping-related drinking.

Interestingly, while these outcomes were related, neither were associated with decreases in quantity and frequency of drinking. This finding replicates results from our previous study (Thomas et al., 2008). The current study additionally indicates that the addition of a BI had no effect on decreasing alcohol quantity, frequency or any measure of drinking to cope. BI was chosen because it is recommended by NIAAA in both primary care and mental health settings. The timing of presenting the intervention when we did was also empirically based. However, despite these considerations, the intervention did not improve drinking or reduce the practice of drinking to cope. The reasons for these negative results are speculative. It is notable that BI is not universally effective among at-risk drinkers. A recent review by Kaner and colleagues evaluating the comparative effectiveness of BI for different subpopulations reports that the cut-off for “excessive” alcohol use had been decreasing from 1987 to 2006 and that BI may be less effective at the lower levels of alcohol use (Kaner et al., 2009). Our population had relatively low levels of alcohol use. Additionally, Kaner and colleagues report that studies of BI usually include mostly men and that BI may be less effective in women. Although we do not have a large enough sample size to compare efficacy of the intervention by gender, our results may have been impacted by the higher percentage of women (nearly 50%) than generally seen in BI trials.

There are limitations of this study that should be recognized. First, the baseline drinking quantity and frequency values, though meeting criteria for “at-risk” levels-an important classification that has been shown to predict poor health outcomes- may nonetheless have been too low to effectively measure change over time (floor effect). Second, 33% of participants started on paroxetine at baseline did not make it to randomization at week 6, resulting in a potentially biased sample. While this is a higher drop out rate than our previous study, other clinical trials involving participants with social anxiety disorder have been mired with substantial numbers of participants leaving treatment early (Eskildsen, Hougaard, & Rosenberg, 2010; Hofmann & Suvak, 2006; Turner, Beidel, Wolff, Spaulding, & Jacob, 1996). Related, although we have had good success with paroxetine in ameliorating social anxiety disorder severity, this medication has been reported to have a higher discontinuation rate as compared to other serotonin reuptake inhibitors (Mullins, Shaya, Meng, Wang, & Harrison, 2005).

Two of our measures of drinking-to-cope, the SADS-B and SADS-D, have been used extensively by our group. In addition, while the TLFB is widely used for assessing quantity and frequency of drinking, we are the first to use it to capture data specifically related to the construct of drinking to cope and reliance of drinking as a coping strategy for dealing with social situations. We view this as an innovative approach to capturing clinically relevant outcomes, but because it is novel, it is not yet widely utilized as an outcome.

In summary, treating social anxiety disorder for individuals at-risk for developing alcohol problems by phasing in a brief alcohol intervention after anxiety is treated with paroxetine was not effective at decreasing alcohol quantity and frequency or drinking to cope. Social anxiety severity was significantly reduced as was drinking to cope (as a function of time).

Acknowledgments

The authors are also very grateful to Ms. Elizabeth McGuan, Ms. Emily Hartwell, Mr. Eric Maurer, Ms. Kay Fernandes, Mr. Robert Peiffer, and Ms. Nancy White for their invaluable assistance and support. This study was funded by NIAAA through grant numbers P50AA010761, R01AA013379, and K02AA017886.

References

- Baker SL, Heinrichs N, Kim HJ, Hofmann SG. The liebowitz social anxiety scale as a self-report instrument: a preliminary psychometric analysis. *Behaviour Research & Therapy*. 2002; 40:701–715. [PubMed: 12051488]
- Book SW, Randall CL. Social anxiety and alcohol use disorders. *Alcohol Research and Health*. 2002; 26:130–135.
- Book SW, Thomas SE, Randall PK, Randall CL. Paroxetine reduces social anxiety in individuals with a co-occurring alcohol use disorder. *Journal of Anxiety Disorders*. 2008; 22:310–318. [PubMed: 17448631]
- Buckner JD, Heimberg RG. Drinking behaviors in social situations account for alcohol-related problems among socially anxious individuals. *Psychology of Addictive Behaviors*. 2010; 24:640–648. [PubMed: 21198225]
- Buckner JD, Timpano KR, Zvolensky MJ, Sachs-Ericsson N, Schmidt NB. Implications of comorbid alcohol dependence among individuals with social anxiety disorder. *Depression & Anxiety*. 2008; 25:1028–1037. [PubMed: 18781667]
- Carrigan MH, Randall CL. Self-medication in social phobia: a review of the alcohol literature. *Addictive Behaviors*. 2003; 28:269–284. [PubMed: 12573678]
- Connor KM, Davidson JR, Sutherland S, Weisler R. Social phobia: issues in assessment and management. *Epilepsia*. 1999; 40:S60–S65. S73–S74. [PubMed: 10530685]
- Eskildsen A, Hougaard E, Rosenberg NK. Pre-treatment patient variables as predictors of drop-out and treatment outcome in cognitive behavioural therapy for social phobia: a systematic review. *Nordic Journal of Psychiatry*. 2010; 64:94–105. [PubMed: 20055730]
- Guy, W. *Ecdeu assessment manual for psychopharmacology*. Washington, DC: DHEC; 1976. p. 218–222.
- Hedges DW, Brown BL, Shwalb DA. A direct comparison of effect sizes from the clinical global impression-improvement scale to effect sizes from other rating scales in controlled trials of adult social anxiety disorder. *Human Psychopharmacology*. 2009; 24:35–40. [PubMed: 18980264]
- Heimberg RG, Horner KJ, Juster HR, Safren SA, Brown EJ, Schneier FR, et al. Psychometric properties of the liebowitz social anxiety scale. *Psychological Medicine*. 1999; 29:199–212. [PubMed: 10077308]
- Hofmann SG, Suvak M. Treatment attrition during group therapy for social phobia. *Journal of Anxiety Disorders*. 2006; 20:961–972. [PubMed: 16621439]
- Kaner EF, Dickinson HO, Beyer F, Pienaar E, Schlesinger C, Campbell F, et al. The effectiveness of brief alcohol interventions in primary care settings: a systematic review. *Drug & Alcohol Review*. 2009; 28:301–323. [PubMed: 19489992]
- Mennin DS, Fresco DM, Heimberg RG, Schneier FR, Davies SO, Liebowitz MR. Screening for social anxiety disorder in the clinical setting: using the liebowitz social anxiety scale. *Journal of Anxiety Disorders*. 2002; 16:661–673. [PubMed: 12405524]
- Moyer A, Finney JW, Swearingen CE, Vergun P. Brief interventions for alcohol problems: a meta-analytic review of controlled investigations in treatment-seeking and non-treatment-seeking populations. *Addiction*. 2002; 97:279–292. [PubMed: 11964101]

- Mullins CD, Shaya FT, Meng F, Wang J, Harrison D. Persistence, switching, and discontinuation rates among patients receiving sertraline, paroxetine, and citalopram. *Pharmacotherapy: The Journal of Human Pharmacology & Drug Therapy*. 2005; 25:660–667.
- National Institute on Alcohol Abuse and Alcoholism. Helping patients who drink too much: A clinicians guide. Rockville, MD: US Department of Health and Human Services; 2007.
- National Institute on Alcohol Abuse and Alcoholism. Rethinking drinking: Alcohol and your health. Rockville, MD: US Department of Health and Human Services; 2009.
- Oakman J, Van Ameringen M, Mancini C, Farvolden P. A confirmatory factor analysis of a self-report version of the liebowitz social anxiety scale. *Journal of Clinical Psychology*. 2003; 59:149–161. [PubMed: 12508338]
- Randall CL, Johnson MR, Thevos AK, Sonne SC, Thomas SE, Willard SL, et al. Paroxetine for social anxiety and alcohol use in dual-diagnosed patients. *Depression and Anxiety*. 2001; 14:255–262. [PubMed: 11754136]
- Saunders JB, Aasland OG, Babor TF, de la Fuente JR, Grant M. Development of the alcohol use disorders identification test (audit): who collaborative project on early detection of persons with harmful alcohol consumption: II. *Addiction*. 1993; 88:791–804. [PubMed: 8329970]
- Sheehan DV, Lecrubier Y, Sheehan KH, Amorim P, Janavs J, Weiller E, et al. The mini-international neuropsychiatric interview (m.I.N.I.): the development and validation of a structured diagnostic psychiatric interview for dsm-iv and icd-10. *Journal of Clinical Psychiatry*. 1998; 59(Suppl. 20): 22–33. quiz 34–57. [PubMed: 9881538]
- Smith, JP.; Book, SW.; Thomas, SE.; Randall, CL. Psychometric characteristics and utility of the Social Anxiety Drinking Scale. Paper presented at the 35th Annual Research Society on Alcoholism Scientific Meeting; San Francisco, CA. 2012.
- Sobell, LC.; Sobell, MB. Timeline followback: a technique for assessing self-reported ethanol consumption. In: Allen, J.; Litten, RZ., editors. *Measuring alcohol consumption: psychological and biological methods*. Totowa, NJ: Humana Press; 1992. p. 41-72.
- Stout RL, Wirtz PW, Carbonari JP, Del Boca FK. Ensuring balanced distribution of prognostic factors in treatment outcome research. *Journal of Studies on Alcohol*. 1994; 12:70–75.
- Thomas SE, Carrigan MH, Randall CL. Predictors of frequency of drinking to cope in socially anxious men and women: a pilot study. *Journal of Dual Diagnosis*. 2005; 1:27–39.
- Thomas SE, Randall CL, Carrigan MH. Drinking to cope in socially anxious individuals: a controlled study. *Alcoholism: Clinical and Experimental Research*. 2003; 27:1937–1943.
- Thomas SE, Randall PK, Book SW, Randall CL. A complex relationship between co-occurring social anxiety and alcohol use disorders: what effect does treating social anxiety have on drinking? *Alcoholism: Clinical & Experimental Research*. 2008; 32:77–84.
- Turner SM, Beidel DC, Wolff PL, Spaulding S, Jacob RG. Clinical features affecting treatment outcome in social phobia. *Behaviour Research & Therapy*. 1996; 34:795–804. [PubMed: 8952122]
- Zaider TI, Heimberg RG, Fresco DM, Schneier FR, Liebowitz MR. Evaluation of the clinical global impression scale among individuals with social anxiety disorder. *Psychological Medicine*. 2003; 33:611–622. [PubMed: 12785463]

Fig. 1.
Flowchart of participants' progress through phases of the trial. BI, brief intervention.

Fig. 2. Social anxiety severity scores over time and by treatment group as measured by the LSAS. There is a significant decrease from baseline to week 6 for both groups. There is no effect of treatment group.

Fig. 3.

Drinking to cope over time and by treatment group as measured by the modified TLFB. This is a measure of the percent of days participants engaged in social situations (denominator) that were also days they endorsed drinking to cope (numerator). There is a significant decrease in both groups over time. There is no effect of treatment group.

Fig. 4.

Partial regression plot of DTC (as measured by SADS-D scores) on changes in social anxiety severity (as measured by the slope of LSAS scores from baseline to week 6). Social anxiety improvement accounted for 65% of the reduction in coping related drinking.

Fig. 5. Drinking outcomes by treatment group. There was no effect of time or treatment group in drinks per drinking day or drinks per week.

Table 1

Comparison of baseline characteristics of participants.

	BI group (n = 44)	Control group (n = 39)	p Value
Male (%)	52	59	0.35
Caucasian (%)	77	74	0.95
Age, mean (SD)	31 (10.6)	31 (10.4)	0.97
Never married (%)	68	72	0.75
College grad (%)	30	28	0.82
Working full-time (%)	27	36	0.80
Non-smokers (%)	57	72	0.09
Age of social phobia onset	14.3	12.3	0.12
Comorbid mood or anxiety disorder (%)	64	59	0.42
ADS score (scale 0–47), mean (SD)	8 (5.3)	9.3 (6.4)	0.30
LSAS score, mean (SD)	94.2 (18.9)	91.4 (13.9)	0.46
At least “markedly severe” (CGI-S) (%)	43	41	0.76
Drinks per week, mean (SD)			
Men	18.0 (8.6)	19.3 (14.9)	0.68
Women	12.5 (12.4)	9.8 (6.2)	0.44
Drinks per drinking day, mean (SD)			
Men	6.9 (2.4)	5.9 (2.9)	0.14
Women	4.3 (1.6)	3.9 (1.5)	0.46
Alcohol dependent (%)	34	51	0.11
Alcohol abuse (%)	16	15	0.95

All statistical comparisons by simple ANOVA or Chi square as appropriate.