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

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## ARTICLE INFO

## 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.

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## 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

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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 unintimidating 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