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What Should We Do When Participants Report Dangerous Drinking? The Impact of Personalized Letters Versus General Pamphlets as a Function of Sex and Controlled Orientation

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Abstract

Research in which participants report potentially dangerous health-related behaviors raises ethical and professional questions about what to do with that information. Policies and laws regarding reportable behaviors vary across states and Institutional Review Boards (IRB). In alcohol research, IRBs often require researchers to respond to participants who report dangerous drinking practices. Researchers have little guidance regarding how best to respond in such cases. Personalized feedback or general nonpersonalized information may prove differentially effective as a function of gender and/or level of self-determination. This study evaluated response strategies for reducing peak blood alcohol concentration (BAC) among participants reporting dangerous BACs ($\geq .35\%$) in the context of a two-year longitudinal intervention trial with 818 heavy drinking college students. After each assessment, participants who reported drinking to estimated BACs at or greater than $.35\%$ were sent either a personalized letter expressing concern and indicating their reported BAC or a nonpersonalized pamphlet that included general information about alcohol and other substances, referral information, and a BAC handout. Hierarchical linear modeling results revealed that both strategies were associated with reduced peak BAC when controlling for previous BAC. The personalized letter was more effective for women and for students who tend to regulate their behavior based on others' expectations and contingencies in the environment. This research provides some guidance for researchers considering appropriate responses to participants who report dangerous health behavior in the context of a research trial.

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Keywords

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Excessive alcohol consumption by college students has been associated with increased mortality rates due to alcohol poisoning, high blood alcohol concentrations (BACs), accidents, and assaults (Hingson, Zha, & Weitzman, 2009). As a reference point, in the United States, a BAC of .08% or higher is the most common legal criterion for driving under the influence of alcohol among adults older than 21 years of age. Despite deleterious risks, excessive drinking appears to occur frequently within the college population, as a large national study suggests 44% of college students engaged in heavy episodic drinking (defined as four drinks or more drinks per occasion for women and five drinks or more drinks per occasion for men) at least once in the previous 2 weeks (Wechsler et al., 2002). More recent data estimates heavy drinking rates (defined as five or more drinks in a row) over the past 2 weeks to differ by sex, with 49% of college males and 34% of women engaging in this behavior (Johnston, O'Malley, Bachman, & Schulenberg, 2009). In this latter study, 25% of college men and 6% of college women reported consuming 10 or more drinks during at least one occasion in the past 2 weeks.

As more research is conducted with college student drinkers, one question that frequently emerges is how best to manage safety for those students who report drinking at high levels during research assessments. Human Subjects Review Boards at many institutions require some form of a data and safety monitoring plan, which provides protection to research participants in clinical trials to ensure benefits outweigh the risks of the research (e.g., National Institutes of Health, 1998). The absence of evaluations or even detailed descriptions of procedures used to address risks in many alcohol studies provides little guidance in determining best practices for protecting research participants (Koocher, 1991). For research assessing alcohol use over time, it is likely that researchers will discover participants reporting high levels of intoxication, which raise serious concerns for participants' safety and well being. For example, recent studies on 21st-birthday drinking reported 35% of women and 49% of men exceeded BACs of 0.25% (Rutledge, Park, & Sher, 2008), whereas Neighbors and colleagues (Neighbors, Spieker, Oster-Aaland, Lewis, & Bergstrom, 2005) found estimated BACs exceeding .25% for 23% of participants during their birthday celebrations. Alcohol levels above a .30% are associated with risk of alcohol poisoning, and BACs above a .40% are associated with risk of coma or death. As reported BACs reach these levels, researchers have an ethical responsibility to intervene with research participants who are placing themselves at risk. Understanding the best way to intervene clinically with those who report high-peak BACs in research surveys has great importance in establishing best research practices.

Although for primary care practitioners, best practice guidelines suggest that once they identify an individual who is an "at-risk drinker," a referral for a more thorough assessment and possible treatment should be recommended (National Institute on Alcohol Abuse and Alcoholism, 1995), those guidelines appear to be rarely followed. In fact, D'Amico, Paddock, Burnam, and Kung (2005) reported that from a sample of adults who drank

heavily, only 2% received a referral and recommendation for pursuing treatment services from their primary care physicians. This occurred in spite of the fact that practitioners screened and identified their patients as “at risk.” Similar observations have been made by other researchers evaluating healthcare providers’ practices regarding screening and following up with adolescent tobacco users (Friend & Colby, 2006; Koontz et al., 2004). Although this literature represents an important first step in examining how to intervene with “at-risk” drinkers, more research is needed to explore ways to potentially reduce high BACs during longitudinal research studies.

One solution that research groups may use in these situations is to provide participants who report higher levels of drinking with personalized feedback regarding their level of risk based on their drinking. Personalized feedback is an empirically supported approach that has been utilized in a wide range of studies seeking to reduce risky behavior, including strong support for personalized feedback in reducing drinking among high-risk drinkers (Carey, Scott-Sheldon, Carey, & DeMartini, 2007; Larimer & Crouce, 2007; Walters & Neighbors, 2005). In addition, there is some evidence that personalized feedback sent to students through the mail can be as successful in helping to reduce drinking and alcohol-related consequences as feedback presented in person (Collins, Carey, & Sliwinski, 2002; Larimer et al., 2007; Murphy et al., 2004; White et al., 2006). Although mailed feedback appears to be efficacious in reducing drinking and consequences for college students, it is unclear how these approaches can be applied in the research arena to protect research participants from reaching dangerous BACs.

Another solution that can be used by researchers is to provide research participants with general information regarding alcohol and its effects, as well as offer some brief advice for controlling use. Among adults with alcohol-related problems, there is a consistent support for better outcomes of brief generic advice when compared to no-treatment control condition (Bien, Miller, & Tonigan 1993; Fleming, Barry, Manwell, Johnson, & London, 1997; Gentilello et al., 1999; Welte, Perry, Longabaugh, & Clifford, 1998; Wilk, Jensen, & Havighurst, 1997). Although brief advice provided by a physician appears to be helpful in reducing alcohol consumption for many individuals, Larimer and Crouce (2007) concluded that brief advice in the form of general education based interventions may not be efficacious for changing alcohol consumption among college drinkers. In addition, there is little evidence available evaluating brief generic information and advice in mailed mediums, especially in regards to contacting research participants who are drinking at dangerous levels.

Many factors warrant consideration in the selection of protocols for data and safety monitoring for high BACs in the context of research studies. The relative effectiveness of strategies should be a principal consideration. Relative cost and effort associated with each approach is also an important factor to consider. Generating personalized feedback for participants within large research studies could exhaust already tight resources at both the financial and personnel levels. Issues of confidentiality arise when researchers have to attach names and other contact information to data to develop personalized reports. A brief generic information sheet offering referral information and describing risks of drinking to high BACs would likely be less costly and reduce concerns related to confidentiality in

comparison to more personalized letters expressing concern. However, as with many important topics related to research, there is an important distinction to make between what is practical and what is efficacious. Before such decision can be made, it is important to evaluate approaches to determine which is more efficacious. Thus, we designed the present research to evaluate two approaches for attending to participants who report high BACs, comparing a generic nonpersonalized pamphlet with referral information and didactic information regarding BAC with a personalized letter expressing concern and providing information regarding the participant's peak drinking occasion in the past month. We tentatively expected the personalized letter to be more effective in reducing subsequent peak BAC in comparison to the nonpersonalized pamphlet with BAC information.

A second aim of the research was to evaluate sex and controlled orientation as moderators of the efficacy of each approach. First, as male and female individuals typically report differing levels of drinking and BACs, it seems important to consider potential sex differences between the two approaches. There is preliminary support in the literature for moderating effects of sex on personalized feedback (see Larimer & Cronce, 2007, for review). Specifically, Larimer and colleagues (2007) reported that female students benefited more from mailed personalized feedback than did male students. Similarly, Murphy et al. (2004) reported that female students achieved greater treatment gains than did male students as a result of personalized feedback. Moreover, Lewis and Neighbors (2007) prospectively investigated the efficacy of gender-specific and gender-neutral feedback for college drinkers concluded that women may benefit from gender-specific feedback and men from gender-neutral. Thus, there is some evidence to suggest that female participants may benefit more from personalized feedback. It is less clear whether men and women may differ with respect to their responses to more generic educational information.

CONTROLLED ORIENTATION

Second, personality factors may contribute to the efficacy of these approaches. Previous research has shown that individual differences in self-determination (Deci & Ryan, 1985b, 2002) are associated with drinking and other risk behavior among college students (Knee & Neighbors, 2002; Neighbors, Larimer, Geisner, & Knee, 2004; Neighbors, Lewis, Fossos, & Grossbard, 2007; Neighbors, Walker, & Larimer, 2003). Individuals who have a stronger tendency to be motivated by extrinsic factors (e.g., rewards, deadlines, expectancies) have been identified as being higher in controlled orientation and are more susceptible to normative influences on drinking (Knee & Neighbors, 2002; Neighbors, Lewis, Bergstrom, & Larimer, 2006; Neighbors et al., 2003).

More generally, individuals higher in controlled orientation tend to be more rigid, controlling, hostile, and defensive (Deci & Ryan, 1985a, 1985b; Goldstein & Iso-Ahola, 2008; Hodgins & Knee, 2002; Neighbors, Vietor, & Knee, 2002; Weinstein & Hodgins, 2009). Two dimensions of controlled orientation, directiveness and defensiveness, present competing hypotheses with respect to how individuals might vary in their reaction to personalized feedback versus a more generic approach. On one hand, individuals who are more controlled orientation tend to be more defensive in response to potentially ego-threatening information (Hodgins & Knee, 2002; Weinstein & Hodgins, 2009). Previous

research suggests that health information which indicates risk can be perceived defensively and subsequently discounted or ignored (Kunda, 1987; Liberman & Chaiken, 1992; Sherman, Nelson, & Steele, 2000). On the other hand, however, individuals higher in controlled orientation tend to be more directive and may be more amenable to clear structure and directives from outside sources (Neighbors, Walker, Roffman, Mbilinyi, & Edleson, 2008). Thus, because controlled orientation is associated with defensiveness, we might expect more controlled individuals to discount or ignore personalized and potentially threatening feedback and be more open to generic information. Conversely, personalized feedback might be particularly effective among more controlled individuals because it is perceived as pointed, direct, and personally relevant.

METHOD

Participants

Participants included 818 (57.6% female) college students. The ethnic/racial composition of the sample was 65.28% Caucasian, 24.21% Asian/Pacific Islander, 4.16% Hispanic/Latino, 1.47% Black/African American, 0.49% Native American/American Indian, and 4.40% other. This research was conducted in the context of a larger, longitudinal social-norms-based intervention trial, which is described in greater detail elsewhere (Neighbors et al., 2010). In 2005, 4,103 entering freshman were invited to complete a brief online screening questionnaire for a longitudinal prevention trial. Roughly half of the invited students ($N = 2,095$; 51.06%) completed the screening questionnaire, and 898 of these (42.86%) met screening criteria of having consumed at least five/four drinks on one or more occasion in the previous month for men/women. Of the 898 eligible participants, 818 (91.09%) were successfully recruited to baseline. Retention rates were 92.30%, 86.55%, 83.86%, and 81.30% at 6-month, 12-month, 18-month, and 24-month follow-ups, respectively.

Procedure

Participants were carefully monitored at each assessment point for consumption of potentially lethal amounts of alcohol, defined in this study as an estimated BAC of .35% or greater. Those reporting consumption of this potentially lethal level were randomly assigned to one of two conditions. They were immediately sent either a personalized letter expressing concern and indicating their reported BAC or a nonpersonalized pamphlet that included general information about alcohol and other substance, referral information, and a BAC handout.

The personalized letter provided information regarding the participant's peak drinking occasion in the past month. It included the number of drinks and number of hours they consumed those drinks as well as their calculated BAC for that drinking occasion. It said,

You mentioned that you had consumed XX drinks in XX hours which, given your reported weight, puts you at a blood alcohol content of XX. Reaching this blood alcohol level can be dangerous. Often people do not realize that they are drinking at levels that can place them at risk, and I wanted to bring your attention to this issue.

The letter also included an invitation to talk with the participant, a phone number for the participant to call, and assurance of confidentiality regarding the issue.

The nonpersonalized pamphlet, "Finding Out What You Need to Know About Alcohol and Other Drugs," was the same pamphlet that is annually distributed through the Office of the Vice President for Student Affairs and provides educational information on alcohol and other drugs. The BAC handout listed estimated BACs as a function of weight and number of drinks for women and men with instructions for factoring time (i.e., "Subtract .015 for every hour of drinking or subtract .01 for every 40 minutes of drinking"). The BAC handout also included two examples of how to calculate BAC, a standard drink chart, and information about alcohol poisoning. Participants in this condition were not told what their peak BAC was, nor were they told that they were receiving the pamphlet because they reported a high BAC.

Across the trial, 262 participants reported drinking at estimated BACs of .35% or higher at least once. Of these 157 did so only once, 61 did so twice, 27 did so three times, 12 did so four times, and five did so at all five assessments. Assignment to condition was random for the first violation. A second violation resulted in assignment to the condition other than the one they were in following the first offence. For a third offence, condition was again based on random assignment. A fourth offence resulted in assignment to the condition other than the one they were in following the third offence. Finally, condition after a fifth incident of meeting or exceeding a BAC of .35% was again based on random assignment. Thus, if a participant met or exceeded a BAC of .35% at baseline, 12-month, and 18-month follow-up, their condition at baseline was based on random assignment. If at baseline they were randomly assigned to receive the pamphlet, the next time they met or exceed .35% they were assigned to the personalized letter condition. At 18-month follow-up, their condition would have again been based on random assignment.

At baseline, 134 participants reported drinking to BAC estimates of .35% or greater. Of these, based on random assignment, 69 were mailed a personalized letter and 65 were mailed the non-personalized pamphlet with BAC handout. At 6-month follow-up, 85 participants met or exceed an estimated BAC of .35%, of whom 45 were assigned to receive the letter and 40 the pamphlet. At 12, 18, and 24 months, 74, 71, and 69 participants met or exceeded a BAC of .35%, respectively. At 12, 18, and 24 months, 42, 39, and 35 were assigned to the letter condition, and 32, 32, and 34 were assigned to the pamphlet condition, respectfully.

Measures

Participants completed a brief baseline questionnaire assessing demographic information such as age, gender, ethnicity, and weight (used for BAC calculation). At each assessment point, participants completed an Alcohol Frequency–Quantity Questionnaire (Dimeff, Baer, Kivlahan, & Marlatt, 1999), which included an assessment of peak drinking. Participants were asked, "Think of the occasion you drank the most this past month. How much did you drink?" Response options included all integers from 0 to 24 drinks, with the highest response option being "25 + drinks." Participants were also asked "How many HOURS did you spend drinking on that occasion?" Response options included all hour ranges from 0–1

to 9–10, with the highest option being “10 + hours.” Peak BAC level was estimated using the formula from the National Highway Traffic Safety Administration (1994). Estimates based on gender using weight and a gender constant, number of drinks, and number of hours spent drinking were used: $BAC \% = [Number\ of\ Drinks \times [2.24146232 / (Weight \times 0.58\ for\ men\ or\ 0.49\ for\ women)]] - [0.017 \times Hours]$. The BAC obtained for each particular day of the week was reviewed to determine which day had the highest BAC level. This indicated the peak BAC in the past month.

Controlled orientation—During the baseline assessment, participants completed the 17-item subscale of the General Causality Orientations Scale (Deci & Ryan, 1985a). The items yield a score on three different orientations from self-determination theory (Deci & Ryan, 1985a, 1985b, 2002)—autonomy, controlled, and impersonal. Only the controlled orientation score was used in analyses, as this was the construct of theoretical interest to this study. The scale contains 17 scenarios followed by three items regarding how one would react to each scenario, from 1 (*very unlikely*) to 7 (*very likely*). Each subscale contains one question for each of the 17 scenarios. For example, one scenario describes finding out that you did poorly on a test, followed by three items containing autonomous, controlled, and impersonal reactions. The General Causality Orientations Scale has been used in multiple studies within the social psychology literature (e.g., Hodgins, Koestner, & Duncan, 1996) and specifically pertaining to alcohol use within the college population (e.g., Neighbors et al., 2006; Neighbors et al., 2003). Internal reliability in the current sample for the controlled orientation subscale was acceptable ($\alpha = .74$).

RESULTS

Descriptive Statistics

Average peak BAC at baseline was .20% ($SD = .10\%$), which did not vary considerably over time (the range over the 5 assessment points was .16%–.20%). The number of participants receiving a personalized letter was 69, 45, 42, 39, and 35 at baseline, 6 months, 12 months, 18 months, and 24 months, respectively. Similarly, the number of persons receiving a general pamphlet was 65, 40, 32, 32, and 32, over the course of the trial. Of the 3,476 person-assessments, 195 of these followed the receipt of a personalized letter and 169 followed receipt of a general pamphlet. At baseline, women had slightly higher peak BACs ($M = .21\%$, $SD = .10\%$) than men ($M = .19\%$, $SD = .10\%$), $t(816) = 3.16$, $p < .01$. No sex differences in peak BAC were observed at any other time point. Controlled orientation, which was assessed only at baseline, was not significantly associated with peak BAC at any assessment point. Finally, controlled orientation was somewhat higher among men ($M = 4.24$, $SD = .67$) than women ($M = 4.11$, $SD = .66$), $t(816) = 2.73$, $p < .01$.

Analysis Strategy

The data were analyzed using random coefficient models also known as hierarchical linear models or multilevel models (Raudenbush & Bryk, 2002; Singer & Willett, 2003). Analyses were conducted using HLM 6 (Raudenbush, Bryk, & Congdon, 2004) where random effects were included to represent within person variability in intercepts across the 5 assessment points. We were interested in examining the impact of receiving a personalized letter or an

impersonal pamphlet on subsequent peak BAC ($PBAC_{t+1}$), controlling for the Peak BAC that determined whether they received any BAC information ($PBAC_t$) where t represents a time vector from t1–t4 (corresponding to 0, 6-, 12-, and 18-month assessments). Thus $t+1$ represents the time point after receiving or not receiving BAC materials from t2–t5 (corresponding to 6-, 12-, 18-, and 24-month assessments). $PBAC_t$ determined whether individuals received any BAC information and was thus included as a covariate. We were also interested in evaluating the relationship between controlled orientation (assessed at baseline and considered time invariant) and changes in BAC, as well as whether the impact of a personalized letter or impersonal pamphlet varied as a function of controlled orientation and sex. Finally we were interested in determining whether the impact of a personalized letter or impersonal pamphlet varied as a function of $PBAC_t$ and whether this in turn was moderated by controlled orientation. Analyses were conducted hierarchically with $PBAC_t$, $Letter_t$, and $Pamphlet_t$ and controlled orientation entered at Step 1. Letter and pamphlet were dummy coded such that the reference group represented those who received neither.

Random effects were specified for the intercept and $PBAC_t$. Models were represented by the following equations:

$$\text{Step 1 level 1: } PBAC_{t+1} = \pi_0 + \pi_1(\text{time}) + \pi_2(PBAC) + \pi_3(\text{Letter}) + \pi_4(\text{Pamphlet}) + e$$

$$\text{Step 1 level 2 : } \pi_0 = \beta_{00} + \beta_{01}(\text{Sex}) + \beta_{02}(\text{Controlled Orientation}) + r_0; \pi_1 = \beta_{10}; \pi_2 = \beta_{20} + r_2; \pi_3 = \beta_{30}; \pi_4 = \beta_{40}.$$

$$\text{Step 2 level 1: } PBAC_{t+1} = \pi_0 + \pi_1(\text{time}) + \pi_2(PBAC) + \pi_3(\text{Letter}) + \pi_4(\text{Pamphlet}) + e$$

$$\text{Step 2 level 2 : } \pi_0 = \beta_{00} + \beta_{01}(\text{Sex}) + \beta_{02}(\text{Controlled Orientation}) + \beta_{03}(\text{Sex X Controlled Orientation}) + r_0; \pi_1 = \beta_{10}; \pi_2 = \beta_{20} + r_2; \pi_3 = \beta_{30} + \beta_{31}(\text{Sex}) + \beta_{32}(\text{Controlled Orientation}); \pi_4 = \beta_{40} + \beta_{41}(\text{Sex}) + \beta_{42}(\text{Controlled Orientation}).$$

$$\text{Step 3 level 1 : } PBAC_{t+1} = \pi_0 + \pi_1(\text{time}) + \pi_2(PBAC) + \pi_3(\text{Letter}) + \pi_4(\text{Pamphlet}) + e$$

$$\text{Step 3 level 2 : } \pi_0 = \beta_{00} + \beta_{01}(\text{Sex}) + \beta_{02}(\text{Controlled Orientation}) + \beta_{03}(\text{Sex X Controlled Orientation}) + r_0; \pi_1 = \beta_{10}; \pi_2 = \beta_{20} + r_2; \pi_3 = \beta_{30} + \beta_{31}(\text{Sex}) + \beta_{32}(\text{Controlled Orientation}) + \beta_{33}(\text{Sex X Controlled Orientation}); \pi_4 = \beta_{40} + \beta_{41}(\text{Sex}) + \beta_{42}(\text{Controlled Orientation}) + \beta_{43}(\text{Sex X Controlled Orientation}).$$

Test of parameter estimates are presented in Table 1. Results at Step 1 revealed that previous peak BAC was, not surprisingly, strongly associated with current peak BAC. Relative to assessments, which did not follow receipt of either a letter or pamphlet, and controlling for previous peak BAC, participants reported lower peak BAC after receiving either a letter or pamphlet. Results at Step 2 revealed three significant interactions. Interactions were graphed using methods described in Cohen, Cohen, West, and Aiken (2003), where predicted values were based on parameter estimates. For interactions with controlled orientation, high and low values were specified as 1 *SD* above and below the mean respectively.

An interaction between sex and the letter condition revealed that a personalized letter was associated with reducing peak BAC among women but not men (see Figure 1). There was also an interaction between controlled orientation and the letter condition, indicating that a letter of concern reduced peak BAC among students higher in controlled orientation but not among students lower in controlled orientation (see Figure 2). Finally, there was an interaction between sex and controlled orientation, which was complementary to the interactions with the letter condition, revealing that among women, a higher controlled orientation was associated with a higher peak BAC, whereas, among men, having a higher controlled orientation was associated with lower peak BAC.

In subsequent analyses we changed the contrast coding to evaluate potential differences between the two conditions. These results revealed that there was not a significant overall difference between the personalized letter and the pamphlet in reducing BAC, $t(3302) = -0.59, p = .55$. Step 2 results of these analyses revealed an interaction of the contrast between letter and pamphlet, with controlled orientation indicating that the letter was significantly more effective in reducing peak BAC among those who were higher in controlled orientation relative to those who were lower in controlled orientation, $t(3297) = -3.45, p < .001$. Differences between letter and pamphlet did not vary by sex, $t(3297) = 1.05, p = .29$. However, the three way interaction of sex by contrast between letter and pamphlet by controlled orientation was significant and suggested that the interaction of the contrast between letter and pamphlet with controlled orientation was more evident among women than men, $t(3295) = -2.50, p = .01$. Moreover, controlling for previous peak BAC and relative to the pamphlet, the personalized letter resulted the lowest peak BACs when sent to women who were higher in controlled orientation.

DISCUSSION

In research studies, investigators must balance the needs of the project with the concept of beneficence, or ensuring that participants do not come to harm through research participation. The present study was designed to explore the effects of mailing either a personalized feedback letter or a general information pamphlet in response to high peak BACs among heavy drinking college students involved in a large research study with multiple assessment time points. Within-person effects were found for both the receipt of the letter or the pamphlet, such that after controlling for peak BAC at the previous assessment, participants who were sent either a personalized letter or a nonpersonalized pamphlet had lower estimated peak BACs in comparison to those who were not sent a letter or pamphlet. Thus, receiving information regarding risks of reaching high BACs from the research staff, whether personalized or not, appeared to contribute to reductions in peak BACs on the subsequent assessment. This effect was qualified by sex, such that reductions in peak BACs were stronger for women who received a personalized letter. In addition, only those higher in controlled orientation subsequently reduced their peak BAC after receiving the personalized letter. Complimenting these results was an interaction between sex and controlled orientation, such that women with higher controlled orientation reported higher peak BACs and men with lower controlled orientation reported higher BACs. This finding suggests that the letter may have worked better for those who were drinking at the highest levels to begin with. Subsequent analyses examining direct comparison between the

personalized letter and the nonpersonalized pamphlet revealed that although there were not differentially effective overall. However, the personalized letter was superior to the pamphlet among participants who were higher in controlled orientation, and this was particularly true for women.

This study emphasizes the importance of considering gender as a moderator of outcomes. Based on these results, personalized information appeared most important for women in reducing BAC. These results are consistent with some evidence suggesting that personalized feedback about drinking behavior may be more efficacious in reducing drinking for women than men (Larimer et al., 2007; Lewis & Neighbors, 2007; Murphy et al., 2004). Although we hypothesized that men would benefit more from the nonpersonalized pamphlet, these effects were not observed in the present sample. Thus, both women and men received some benefit from the pamphlets, and the effect of the pamphlet did not differ significantly between men and women.

In addition, we found that those higher in controlled orientation reduced drinking after receiving the personalized letter. Considering that higher controlled orientation suggests one is more motivated by external factors (e.g., how the researcher might perceive the person; normative influence), the personalized method may have influenced those high in controlled orientation to feel singled out by the researchers for being one of the only students to drink at such high levels or for being of special import. This idea is consistent with research indicating that those higher in controlled orientation may be more susceptible to normative influences on drinking (Knee & Neighbors, 2002; Neighbors et al., 2006; Neighbors et al., 2003). Moreover, Neighbors et al. (2006) found that personalized norms feedback was significantly more effective in reducing alcohol-related problems among heavy drinkers who were higher in controlled orientation. Although research suggests that those higher in controlled orientation may be more defensive, particularly in regards to information that may threaten one's ego (Hodgins & Knee, 2002; Weinstein & Hodgins, 2009), these findings suggest that other factors associated with controlled orientation may support the efficacy of a personalized letter relative to a nonpersonalized informational pamphlet. Although we did not directly evaluate perceptions of the participants, in addition to potentially suggesting a discrepancy from the norm, we would speculate that the relative directness and structure of the personalized letter may be particularly effective among more controlled individuals. In combination, the personalized letter might be most relevant in facilitating more controlled students to explore their choices regarding drinking behavior and subsequently consider reducing use.

These findings suggest that when considering all participants, a pamphlet seemed to have a similar moderate reduction in drinking effect to the personalized letter for all participants. Thus although it may be important to distribute personalized feedback letters to students (especially women), if researchers discover engagement in dangerous drinking behavior, it may be that sending a generic pamphlet of information can be a cost- and time-effective alternative if resources to create personalized letters are unavailable. It is also important to consider possible confidentiality issues in relation to the decision to send personalized information regarding drinking behavior versus a generic pamphlet, given the overall similar degree of efficacy across the two interventions. Although for women and for those who are

more controlled, personalized feedback did seem more affective, there are possible risks were someone to read the personalized feedback of a research participant. With generic feedback, these risks are substantially reduced. In research trials, an inadvertent breach of confidentiality of participant risk is not one to be taken lightly.

For college drinking studies, there are practical implications from these findings for managing participant risk in relation to high BACs that may help guide both researchers and Institutional Review Boards (IRBs). At minimum, the presents research is encouraging in suggesting that both of the approaches evaluated here were associated with some benefit. In those studies that recruit all female or predominantly female samples, these results suggest that there may be significant benefit for providing personalized BAC information for those participants who are drinking in high-risk ways, despite the added time and effort. This is only true, of course, in situations where this information does not breach participant confidentiality. However, for studies that are mixed gender or that are exclusively men, the benefit-to-cost ratio of personalized letters over nonpersonalized pamphlets may be diminished. One possibility, especially in studies using computer-based data collection, is the option to provide differential feedback based on factors such as gender and/or controlled orientation. Thus investigators could match the strategy for best responding to high BACs in college drinking research trials selected on individual characteristics rather than using a “one-size-fits-all” approach.

Currently this is an area where researchers and IRBs are often forced to make decisions about how to manage high BACs of research participants without much in the way of guidance from funding agencies, professional organizations, or the scientific literature. In the literature on college student drinking, researchers rarely report how they responded to participants reporting high BACs in either survey studies or randomized clinical trials, although this information is useful in understanding how investigators manage participant safety issues clinically. There are currently no widely accepted published guidelines or recommendations regarding best practices for how to manage this risk and how to best balance participant safety and participant confidentiality. Thus, individual investigators and IRBs have been left to develop their own responses without much in the way of guidance. This stands in stark contrast to other participant risk issues such as child abuse, suicidal ideation, or harm to others, where there are established best practices, ethical statutes, and resources for investigators. Our present report may be helpful to both researchers and IRBs in making decisions as to how to respond to individuals reporting dangerous levels of alcohol intoxication.

Limitations

Although the present findings are promising, there are a number of limitations to consider. Although reductions in peak BAC were statistically significant, the differences between the two interventions were not large. It is also important to note that many of the participants who exceeded an estimated BAC of .35% and who were sent a personalized letter or nonpersonalized pamphlet repeatedly reported high BACs. Of the 262 participants who exceed an estimated BAC of .35%, 40% did so at least twice and 17% did so three or more times. For these participants, it is unclear what would be the best response to reduce their

drinking levels. In addition, many of these participants had received a brief intervention as part of a randomized controlled trial (Neighbors et al., 2010) and who were continuing to drink at high levels. In some ways, this study can be thought of as an additional intervention for nonresponders. Our analytic strategy of simply controlling for the BAC at the previous assessment point is an additional limitation as it may obfuscate the effects of additional doses of the intervention. In addition, data were self-report and relied on retrospective accounts of behavior, though use of self-report measures is generally supported in confidential research contexts when measures with established reliability and validity are utilized (Babor, Steinberg, Anton, & Del Boca, 2000).

Conclusions

The current findings attempt to address a void in the existing literature regarding how to respond to participants who report dangerous levels of drinking. The findings demonstrate that brief personalized letters or nonpersonalized informational pamphlets may be effective for the majority of individuals in reducing high-risk drinking. In addition, for women and for those who are motivated more by extrinsic factors, personalized letters are more effective and may thus be worth the extra time and cost. However, we also found a therapeutic effect for a generic pamphlet with campus resources and information regarding drinking behavior, suggesting that when cost or confidentiality factors are of critical importance, this may be a good strategy for responding to these situations in research protocols. Future research is necessary to determine whether these findings are replicated in other populations, where drinking behavior may be harder to address, as well as whether there is added benefit for participants being able to choose whether they receive generic versus personalized information.

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FIGURE 1.
Peak blood alcohol concentration (BAC) (%) as a function of the interaction between sex and receiving a personalized letter of concern.

FIGURE 2. Peak blood alcohol concentration (BAC) (%) as a function of the interaction between controlled orientation and receiving a personalized letter of concern.

TABLE 1

Hierarchical Linear Modeling Results for Fixed Effects Evaluating PBAC as a Function of Time, Personalized Letter, General Pamphlet, Sex, and Controlled Orientation, Controlling for Previous PBAC

<i>Predictor</i>	<i>B</i>	<i>B SE</i>	<i>T</i>
Step 1			
Time	−0.001	0.001	−0.84
Previous PBAC	0.262	0.026	10.25***
Letter	−0.029	0.009	−3.25**
Pamphlet	−0.024	0.009	−2.67**
Sex	−0.001	0.005	−0.16
Controlled orientation	0.005	0.004	1.30
Step 2			
Sex × Letter	0.033	0.015	2.178*
Sex × Pamphlet	0.014	0.016	0.888
Controlled Orientation × Letter	−0.047	0.011	−4.238***
Controlled Orientation × Pamphlet	−0.002	0.012	−0.188
Sex × Controlled Orientation	−0.016	0.008	−2.082*
Step 3			
Sex × Letter × Controlled Orientation	−0.036	0.022	−1.614
Sex × Pamphlet × Controlled Orientation	0.032	0.025	1.285

Note. Step 1 $df = 782$ and 3,302 for Level 1 and Level 2 effects, respectively. Step 2 $df = 781$ and 3,297 for Level 1 and Level 2 effects, respectively. Step 3 $df = 781$ and 3,295 for Level 1 and Level 2 effects, respectively. PBAC = peak blood alcohol concentration.

*
 $p < .05$.

**
 $p < .01$.

 $p < .001$.