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Does Prior NSSI Moderate the Relationship between Alcohol Intoxication, Pain, and Deliberate Self-Harm?

Matthew A. Timmins

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By

Matthew A. Timmins

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By

Matthew A. Timmins

Approved:

_____

Mitchell E. Berman, Ph.D.
(Major Professor)

_____

Michael R. Nadorff, Ph.D.
(Committee Member)

_____

Kevin J. Armstrong, Ph.D.
(Committee Member)

_____

Rick Travis, Ph.D.
Dean
College of Arts and Sciences

Name: Matthew A. Timmins

Date of Degree: December 1, 2017

Institution: Mississippi State University

Major Field: Psychology

Major Professor: Mitchell E. Berman, Ph.D.

Title of Study: Does prior NSSI moderate the relationship between alcohol intoxication, pain, and deliberate self-harm?

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Candidate for Degree of Master of Science

Experimental studies suggest alcohol facilitates deliberate self-harm (DSH). One explanation might be that alcohol increases pain tolerance (PT), which may then lead to DSH. This study aimed to examine whether PT mediated the relationship between alcohol and DSH. Further, alcohol is neither necessary nor sufficient to self-harm. Given past non-suicidal self-injury (NSSI) is a good predictor of future DSH, NSSI may moderate these relationships. This study also aimed to examine if mediation was conditional upon past NSSI. Participants (106 men and 104 women) reported on past NSSI and received a drink sufficient to produce target blood-alcohol content (BAC = .000%, .050%, .075%, or .100%). Participants completed a behavioral measure of DSH. Results revealed that the association between BAC and DSH was mediated through PT. Additionally, past NSSI moderated the path between PT and DSH but did not affect the path between BAC and PT. Clinical implications and limitations are discussed.

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CHAPTER I

INTRODUCTION

Terminology

For the purposes of this paper, *deliberate self-harm* (DSH) refers to any intentional behavior for which its primary goal is to cause injury to oneself ranging from non-lethal self-harm to death by suicide (Muehlenkamp, Claes, Havertape, & Plener, 2012). *Non-suicidal self-injury* (NSSI) is a specific subset of DSH in which causing death is not the primary motivation, regardless of the lethality of the behavior (e.g., cutting, burning, scratching, hitting). In contrast, *suicide* refers to DSH accompanied by the intention of causing death. Similarly, a *suicide attempt* is a non-fatal self-harm behavior with evidence that one intended to die (Crosby, Ortega, & Melanson, 2011).

General Introduction

The Centers for Disease Control (CDC) reported that there were 469,096 cases of DSH, which may include non-fatal suicide attempts, during 2014 in the United States as documented by hospitals and urgent care facilities (Centers for Disease Control and Prevention, n.d.). Similarly, there were 450,774 US emergency room visits and hospitalizations due to non-fatal DHS in 2010, resulting in a loss of $10.4 trillion in medical expenses and work lost. There were 38,364 deaths by suicide in the US during, meaning that there were 12 acts of non-fatal DSH requiring medical attention for every death by suicide in the same year. However, it should be noted that these cases of DSH

were only those brought to the attention of medical professionals. Thus, these data do not include cases of DSH not resulting in medical attention or death. Also, the data collected by the CDC do not differentiate between NSSI and non-fatal DSH with the intent to die. Unlike DSH data collected by the CDC, rates of NSSI in the US population is often based on population sampling during research studies.

Based on data collected from a 2008 random-digit dialing US sample (adults 18 years and older), lifetime prevalence of NSSI was approximately 6% with 0.9% engaging in NSSI within the past year (Klonsky, 2011). These data suggest that approximately 13.8 million US adults would have endorsed a lifetime history of NSSI with over 2 million US adults engaging in NSSI within the past year (based on 2008 population estimates by the United States Census Bureau: US Census Bureau, 2016). Younger participants (age 18 to 30) and those who were unmarried were more likely to endorse NSSI, with age 16 as the mean age of onset. No differences in gender or ethnicity—Caucasian versus non-Caucasian—emerged for lifetime prevalence of NSSI. Similarly, an international meta-analysis comparing and contrasting prevalence rates of NSSI and DSH in adolescents found that 18% endorsed a history of NSSI and 16% endorsed a history of DSH (Muehlenkamp et al., 2012).

Although individuals do not intend to die when engaging in NSSI and rarely use fatal methods, there are a variety of consequences related specifically to NSSI. For example, one study that followed emerging adults from age 16 to age 21 found that reporting engaging in NSSI at age 16 was associated with greater likelihood to endorse symptoms of depression, anxiety, and/or substance use at age 18 (Mars et al., 2014). These associations remained even after controlling for gender, socioeconomic status, and

depressive symptoms at age 16. Further, NSSI at age 16 was associated with more than a 4-fold increase in the likelihood of DSH within the past year at age 21. In sum, the number of NSSI cases in the United States treated by medical professionals is not trivial and likely underestimates actual rates of DSH, which appears to be relatively common in the general population.

The relationship between past and future DSH, both fatal and non-fatal, has been supported in multiple studies. In a meta-analysis of 117 studies examining the likelihood of engaging in DSH after receiving medical attention for DSH, 16% engaged in non-fatal DSH after one and/or two years (Carroll, Metcalfe, & Gunnell, 2014). Additionally, 22% engaged in non-fatal DSH within 5 years of receiving medical attention. For fatal DSH behaviors, approximately 1.6% of individuals died within 1 year of receiving medical attention, 2.1% died within 2 years, 3.9% died within 5 years, and 4.2% died within 10 years. These data suggest that previous DSH not only has a negative impact on future mental health, but also may be a "gateway" behavior (p. 491) for future suicidal behaviors (Whitlock et al., 2013). In the following sections, I briefly outline the current literature on the potential risk factors for DSH pertinent to this study: Alcohol use, pain tolerance (PT), and prior NSSI.

Alcohol and Deliberate Self-Harm

Repeated alcohol use has been associated with increased DSH in a cross-national sample of adolescents, whether or not participants endorsed intoxication during acts of DSH (Rossow et al., 2007). Similarly, higher levels of prior NSSI were associated with more problematic drinking behaviors within a non-clinical sample of college students (Hasking, Momeni, Swannell, & Chia, 2008). The results of these studies suggest that

drinking behaviors may be associated with DSH; however, the studies relied on data collected through self-report measures and did not include experimental manipulations, which prevents causal inferences to be drawn from the results. A few laboratory studies examining the relationship between alcohol and DSH, discussed below, may be used to help determine causal inferences.

Results from three prior experimental studies support the notion that alcohol intoxication facilitates DSH under controlled laboratory conditions (Berman et al., 2017; Berman et al., 2009; McCloskey & Berman, 2003). In two of the studies, ($N = 40$) male participants were given a drink containing sufficient levels of alcohol to produce on average an expire breath blood alcohol concentration of 0.100 or drink that contained no alcohol (either a placebo or veridical no-alcohol drink) before completing a behavioral analog measure of DSH known as the Self-Aggression Paradigm (SAP: Berman et al., 2009; McCloskey & Berman, 2003). The SAP consists of a competitive reaction-time task against a fictitious opponent during which participants can self-administer a noxious stimulus at a self-selected level of intensity.

The SAP provides the opportunity to prospectively examine self-aggressive behaviors that are believed to mirror DSH in a controlled laboratory setting (a more thorough description of the SAP is provided later in this paper). When no experimental manipulations other than alcohol consumption were included in the procedures, intoxicated participants were more likely to selected at least one extreme shock in a given block than those who received a placebo drink (McCloskey & Berman, 2003) or veridical drink (Berman et al., 2009). In contrast, when male participants' objective self-awareness was experimentally increased by allowing participants to view themselves in a

mirror during the SAP, intoxicated men in the increased self-awareness condition did not engage in significantly more DSH behaviors than controls (Berman et al., 2009). Given the self-awareness did not appear to influence the behavior of participants in the control drink condition, this study demonstrated that alcohol's effects can be attenuated by increasing awareness of one's actions, which may in turn increase awareness of social views of DSH. However, the above two studies are limited in that intoxication was dichotomous (either intoxicated or control) and only men participated in these studies. Without the inclusion of women or multiple levels of intoxication, the above results are limited to the differences in the presence or absence of alcohol in men.

In a third study, participants ($N = 210$; 106 men and 104 women) were given drinks with varying amounts of alcohol or a placebo (Berman et al., 2017). The amount of alcohol drinks consumed to reach a target blood-alcohol content (BAC) (target BAC's: .000% [placebo], .050% ["low dose"], .075% ["medium dose"], and .100% ["high dose"]) was based on an equation utilizing participants' weight and gender (see Watson, Watson, & Batt, 1981). The results of this third experiment revealed an alcohol dose-dependent association with DSH behaviors such that the higher the BAC of the participant during the experiment the more likely the participant was to engage in DSH. Of note, BAC influenced the behavior of both men and women; however, men's likelihood to engage in DSH based on BAC increased at a greater rate.

How might the results of the above experiments be integrated into a model of DSH? Specifically, what is the mechanism underlying the relationship between alcohol intoxication and DSH? To this end, I briefly outline the current research on alcohol and pain, as well as the role of pain in DSH behaviors. Specifically, pain perception might

serve as a mediator to explain part of the relationship between intoxication and DSH. I first focus on the effects of acute alcohol intoxication on the perception of pain. Next, I review how pain is associated with self-harm behaviors across the spectrum of lethality I also review the association between history of DSH and pain tolerance. At the end of this literature review, I describe the SAP in greater detail and the current study.

Alcohol and Pain

The relationship between alcohol and pain has been examined in several different ways. In laboratory rats, high doses of alcohol appeared to block the detection of painful stimuli, suggesting that alcohol has antinocicetive analgesic effects in pre-clinical species (Campbell, Taylor, & Tizabi, 2006). In humans, researchers have found that alcohol ingestion affects pain tolerance (PT) such that participants without a family history of alcohol abuse tolerated greater intensities of electric shock with greater levels of alcohol intoxication as measured by expired breath BAC; however, the same relationship was not present for participants with a family history of alcohol abuse (Perrino et al., 2008). In a recent meta-analysis of studies examining alcohol and pain in healthy participants, researchers found alcohol influenced the detection of painful stimuli and ratings of pain intensity (Thompson, Oram, Correll, Tsermentseli, & Stubbs, in press). Specifically, studies utilizing laboratory measures of pain (k = 13) found small effects of alcohol decreasing sensitivity to painful stimuli (Hedge's g = .35). Similarly, studies including self-reports of experienced pain intensity (k = 9) found a moderate effect of alcohol such that pain ratings decreased after consuming alcohol (Hedge's g = .64). In sum, alcohol intoxication is associated with greater ability and willingness to endure pain.

When examining alcohol and DSH, it is reasonable to posit that acute alcohol intoxication may increase one's ability to endure pain when one has consumed the dosage of alcohol sufficient to produce analgesia. In the following sections, I briefly review the current literature on the association between NSSI and pain, as well as the results from the Self-Aggression Paradigm based research.

NSSI and Pain

It is possible to view prior non-lethal DSH as a potential way to enhance one's capability to engage in NSSI. Specifically, the relationship between past NSSI and pain may influence the likelihood of engaging in future NSSI. In a previous analysis, previous NSSI did not influence the direct relationship between alcohol intoxication and outcomes on a laboratory analog measure of DSH (Berman et al., 2017). However, when examining a potential mediating role of PT between intoxication and DSH, there are two possible paths that prior NSSI may influence the current analysis. First, prior NSSI might moderate the relationship between intoxication and PT such that intoxication increases PT at a greater rate for those who report previous NSSI. Second, prior NSSI may moderate the relationship between PT and the laboratory analog measure of DSH such that past NSSI acts as a gateway for PT to influence DSH (i.e., PT will influence DSH for those who report prior NSSI but will have little to no effect for those who do not endorse prior NSSI).

The notion that previous NSSI influences one's ability to engage in DSH through habituation to pain has frequently been explored by examining the number of self-reported NSSI incidents and/or number of suicide attempts, and self-report (e.g., Ammerman, Burke, Alloy, & McCloskey, 2015) or laboratory measures of pain such as

cold pressor tasks (e.g., Franklin, Hessel, & Prinstein, 2011; Hamza et al., 2014) and algometer pressure tasks (e.g., Hooley et al., 2010; McCoy, Fremouw, & McNeil, 2010). Laboratory objective measures of pain (i.e., cold pressor and algometer pressure tasks) suggest that participants who reported a history of NSSI had increased pain thresholds and endured painful stimuli longer compared to participants who did not report a history of NSSI (Hamza et al., 2014; Hooley et al., 2010). The differences in objective pain between self-harming participants and controls appeared to be even greater for those who engaged in NSSI for longer periods of their lives (Hooley et al., 2010) and those who engaged in NSSI to self-punish (Hamza et al., 2014).

On the other hand, when examining the relationship between self-reported NSSI factors, including frequency and subjective experiences of pain, and reported suicide attempts, a study found that participants who endorsed more frequent NSSI behaviors also indicated that they experienced elevated subjective pain during NSSI behaviors (Ammerman et al., 2015). Further, the relationship between NSSI frequency and suicide attempts was moderated by subjective pain experiences such that participants who experienced more pain and engaged in NSSI more frequently were most likely to have reported a lifetime history of at least one suicide attempt. Based on these data, it could be that those who engage in NSSI have a greater willingness to endure pain rather than increasing PT with repetition. Instead, prior NSSI may act as a gateway to more severe forms of DSH.

Overall, the current literature suggests that previous NSSI may influence PT and/or the likelihood of engaging in future DSH. Although previous NSSI did not moderate the relationship between intoxication and DSH in a previous analysis (Berman

et al., 2017), endorsing a history of NSSI may influence indirect pathways between intoxication and DSH. Thus, previous NSSI was explored as a moderator for both indirect pathways in the current analysis (described later in this paper). In the following section, I describe the laboratory behavioral analog measure for DSH used in the present study.

The Self-Aggression Paradigm

The SAP is a laboratory task in which participants are given the chance to willingly engage in an analog behavior for DSH. Participants are told that they will be competing in a reaction-time task against a fictitious opponent (actually a computer program). During the task, participants are given the opportunity to self-administer a noxious stimulus, an electric shock, at a self-selected intensity during losing trials. The stimulus intensity is entirely determined by the participant, who may select from a "0" (no shock), "1" to "10" (intensity based on the participant's pain threshold as determined by a threshold task prior to beginning the reaction-time trials), or "20" (described as twice the participant's pain threshold but in reality, it equivalent to his/her pain threshold). As the participants are told that the "20" shock will be "very painful," the conscious decision to select "20" is analogous to DSH. By introducing manipulations prior to beginning the reaction-time task (e.g., ingestion of varying amounts of alcohol), researchers may prospectively observe the effect of the manipulation on DSH, allowing causal inferences to be drawn based on the resulting data.

Support for the validity of the SAP has arisen from positive relationships with self-report measures of suicidal ideation, suicidal behaviors, and prior NSSI behaviors (Berman, Jones, & McCloskey, 2005; Berman & Walley, 2003; McCloskey, Look, Chen,

Pajoumand, & Berman, 2012). Similarly, positive relationships have been found between data from the SAP and variables suggested to be risk factors for DSH via non-experimental studies, such as acute alcohol intoxication (McCloskey & Berman, 2003), use of a benzodiazepine (Berman et al., 2005), previous depressive episode(s) (McCloskey, Gollan, & Berman, 2008), and modeling effects (Berman & Walley, 2003; Sloan, Berman, Zeigler-Hill, & Bullock, 2009; Sloan, Berman, Zeigler-Hill, Greer, & Mae, 2006). Further, divergent validity for the SAP has been demonstrated by no relationships emerging between the SAP and anxiety, performance on reaction-time tasks, competitiveness during reaction-time tasks, or social desirability (Berman & Walley, 2003). Based on the parallels between the SAP and non-laboratory measures of self-harm, as well as the lack of a relationship between SAP results and variables specific to this task and to psychological studies as a whole (e.g., performance on reaction-time tasks, social desirability), data from a previous study utilizing the SAP was used for the current study.

Current Study

In this study, I examined the relationships between BAC during the SAP, pain thresholds, prior non-lethal self-aggressive behaviors, and DSH as observed employing the SAP. These data are archival data collected under a NIAAA award. By using an experimental paradigm, results of the study may be used to draw causal inferences about the relationships between BAC, pain, and DSH. The lack of laboratory measures of self-harm in the current literature has made it difficult to determine mechanisms by which alcohol may influence self-harm behaviors (see Anestis, Joiner, Hanson, & Gutierrez, 2014). The first aim of the analysis was to determine if participants' measured pain

threshold mediates the relationship between participants' BAC during the SAP task and DSH reported in Berman et al. (2017). The second aim of the analysis was to determine if self-reported history of DSH behaviors interacts with the relationship between BAC and pain tolerance and/or interacts with the relationship between pain tolerance and the SAP measure of DSH.

Predictions

Based on the presented literature, there were three hypotheses for the re-analysis. Prediction 1 (P1) was that PT measured during the SAP would mediate the relationship between participants' BAC during the task and the behavioral measure of DSH (see Figure 1 in Appendix A). Prediction 2 (P2) was that reported NSSI behaviors prior to the SAP will moderate the relationship between BAC and PT such that those who report a history of NSSI would have higher PT when intoxicated compared to participants who did not report a history of NSSI when intoxicated (see Figure 2 in Appendix A). Prediction 3 (P3) was that reported NSSI prior to the SAP would moderate the relationship between PT and behaviorally measured DSH such that participants who have a high PT and report a history of NSSI would engage in more DSH during the SAP than participants with a high PT who do not report past NSSI (see Figure 3 in Appendix A). For the analyses, PT was operationalized as the objective PT measured by the pain threshold task in the SAP.

Planned Analyses

For the purposes of this study, DSH was measured by the total number of "20" shocks selected throughout the task. To test the predictions described above, three separate models were analyzed (see Figures 1, 2, and 3 in Appendix A). All analyses

were conducted using PROCESS (Hayes, 2013) for IBM Statistical Package for Social Sciences, Version 24.

To test P1, a mediational analysis was conducted to examine the direct effects of BAC during the SAP on DSH and the indirect effects of BAC to PT to DSH. To test P2, a conditional process analysis on the mediation model from P1 such that a self-reported history of NSSI behaviors was used to moderate the relationship between alcohol intoxication and PT. To test P3, a separate conditional process analysis on the mediation model from H1 such that self-reported history of NSSI was used to moderate the relationship between PT and DSH.

CHAPTER II

METHOD

Participants

Participants consisted of 210 (106 men and 104 women), ages 21 to 54 (M_{age} = 26), from Southeastern region of US (65.2 % Caucasian, 24.8% African American, 3.8% Hispanic, 6.2 % Other) recruited from the community as part of a larger study (see Berman et al., 2017). All participants endorsed drinking alcohol at some time in their lives prior to the original study and were considered "healthy social drinkers" based on scoring ≤ 8 on the Alcohol Use Disorders Identification Test (AUDIT: Saunders, Aasland, Babor, De la Fuente, & Grant, 1993) or scoring ≤ 3 on the Short Michigan Alcoholism Screening Test (SMASS) if scoring a 7 or 8 on the AUDIT. Participants were excluded from the original study if they met any of the following conditions: previously participated in an alcohol- or shock-related study in the original lab; current prescription for a medication contraindicated with alcohol; current mood, psychotic, or other severe psychological problem requiring treatment; suicide attempt within 6 months prior to the study; pregnancy or nursing; positive urine toxicological screening or expired-breath BAC > .000% on the day of the study; significant medical condition (e.g., kidney or liver problems); or the inability to refrain from the use of medications for one week leading up to the study.

Materials and Procedures

History of NSSI Behaviors

Before engaging in the laboratory experiment and manipulations, participants completed the Deliberate Self-Harm Inventory (DSHI: Gratz, 2001). The DHSI is a 17-item self-report measure which is used to collect data about an individual's NSSI behaviors. Each item asks the individual if he/she has ever engaged in a specific behavior (*"Yes"* or *"No"*). If the individual responds *"Yes"* to the specific behavior, he/she is then asked the following questions: 1) *How old were you when you first did this*, 2) *How many times have you done this*, 3) *When was the last time you did this*, 4) *How many years have you been doing this (If you are no longer doing this, how many years did you do this before you stopped)*, 5) *Has this behavior ever resulted in hospitalization or injury severe enough to require medical treatment*. Although this does not provide a frequency of the behavior, higher scores reflect multiple methods of NSSI. This implies that those who endorsed more than one item must have engaged in NSSI at multiple times. Good to adequate internal consistency (α = .82) was reported in the original validation study (Gratz, 2001), German psychiatric inpatients (α = .82; Fliege et al., 2006), US undergraduate students (α = .72 current and α = .90 lifetime; Wester, Ivers, Villalba, Trepal, & Henson, 2016), and US and Canadian community samples (Turner et al., 2015). The DSHI also demonstrated good internal consistency within a larger sample of 219 participants which overlapped to include participants in the current study (α = .81). A copy of the DSHI is provided in Appendix B.

Blood-Alcohol Content

During the study, participants were assigned to one of four alcohol doses: placebo (.000% BAC), "low" (.050% BAC), "medium" (.075% BAC), or "high" (.100% BAC). All participants not in the placebo condition were given a mixture of orange juice and 190-proof (95% ethanol) grain alcohol in two cups. The juice was added to the mixture to achieve a 5-to-1 ratio of juice to alcohol. The amount of the alcoholic drink for each participant was based on an equation that included weight and gender to achieve a target BAC (Watson et al., 1981). For the placebo condition, participants were given an amount of orange juice equal in volume to those in the medium dose condition with alcohol rubbed around the rim of the cups and a few drops of alcohol floating on the top of the drink. All participants were told that the drink could contain alcohol but did not receive any further information about the drink.

Participants were given varying amounts of time to consume the drink based on dose condition: 15 (low), 22.5 (medium), or 30 (high) minutes. Participants in the placebo condition were given the same amount of time as the medium condition to finish the drink. After finishing the drink, a 20-minute waiting period elapsed to allow participants to reach the target BAC of their assigned condition. After the wait period, BAC was measured using an expired-breath sample obtained with an Alco-Sensor IV (Intoximeters, Inc., St. Louis, MO) hand-held breathalyzer. BAC data were collected at three points during the original study. Of interest to the current study, BAC was obtained before and after completion of the SAP task.

Objective Pain Tolerance

After completing the BAC manipulations, each participant completed the SAP, including a *pain threshold procedure*. The pain threshold procedure began by attaching fingertip electrodes on the middle and index fingers on the participant's non-dominant hand, followed by a series of shocks that increased in intensity in 100-microampere intervals. During this, the participant indicated the intensity at which he/she sensed the shock and the intensity at which the shock became "painful" to the participant. Once the participant indicated that the shock had become painful, the threshold procedure ended. For the purposes of the current study, objective pain tolerance will be defined as the microampere level at which the participant indicated the shock had become painful. It should be noted that the pain threshold task, as well as the SAP, has a maximum microampere level to avoid harm to the participants; thus, some participants may not have indicated that the shock was painful. In such cases, the pain threshold was recorded as the maximum microampere level. This is a limitation to the current study as some individuals may have a generally high pain tolerance. Although it is predicted that a higher objective pain tolerance will be associated with greater measures of NSSI, it is reasonable to assume that those who have a higher objective pain tolerance will be more willing to select higher shock selections during the SAP task – which may still be considered supportive of this prediction. A copy of the instructions for the threshold procedure given during the original study is included in Appendix C.

Behavioral Measure of DSH

Once the pain threshold of the participant was obtained, participants completed the Self-Aggression Paradigm (SAP: Berman et al., 2009; Berman & Walley, 2003;

McCloskey & Berman, 2003). As described above, the SAP is a behavioral analog measure used to prospectively observe DSH under controlled laboratory conditions. The intensity of the shock provided at each self-selected level was based upon a percentage of each participant's individual pain threshold with "10" being equivalent to the participant's PT. Participants were instructed that "20" was equivalent to "twice the pain threshold;" however, "20" was actually equivalent to the participant's PT. As the "20" shock was explicitly described to be painful, the conscious selection of a "20" is considered indicative of an intentional act of self-harm. For the current study, DSH was measured by the number of "20" shocks selected throughout the SAP task. A copy of the procedures and instructions for the SAP task given during the original study is included in Appendix C.

CHAPTER III

RESULTS

The average BAC during the SAP task ranged from .00 to .15 (M = .11, SD = .08). Participants' PT ranged from 0.32 milliamperes to 2.5 milliamperes (M = 1.59, SD = 0.79). Participants' shock selections ranged from 0 to 20 (M = 2.86, SD = 5.80). DSHI scores ranged from 0 to 10 (M = 0.47, SD = 1.38). Missing data for DSHI of seven participants were replaced using the mean DSHI scores of the available data. As the number of missing data was less than 5% of the DSHI scores, using mean replacement will not place undue influence on the analyses. Due to the positive skew of DSHI (*kurtosis* = 19.50) and total 20's selected (*kurtosis* = 2.68), logarithmic transformations were conducted for these items prior to mediational analysis and the conditional process analyses. A correlation table of the participants' age, gender, average BAC, pain tolerance, transformed DSHI scores, and transformed total 20's selected is provided. Participant gender was positively correlated with pain tolerance (r = .21, p < .01) and total 20's (r = .34, p < .001). BAC was positively correlated with pain tolerance (r = .22, p < .01) and total 20's (r = .25, p < .001). Total 20's was correlated with PT (r = .35, p < .001) and DSHI (r = .19, p < .01). See Table D1 in Appendix D for all variables.

Mediation Analysis (Prediction 1)

A mediation analysis examining the direct and indirect effects of BAC on total 20's through PT was conducted. In this model, an increase in BAC predicted an increase

in PT ($a = 4.48$, $p < .01$). In turn, increased PT predicted increased total 20's ($b = 0.18$, $p < .001$). A bias-corrected bootstrap confidence interval for the indirect effect ($ab = .39$) based on 5,000 bootstrap samples did not include zero (CI [0.30, 1.51]). Examination of the Sobel test ($p < .01$) indicates that the mediation model is significant, supporting P1. As P1 was supported by PT mediating the relationship between BAC and total 20's, further analyses were conducted to test P2 and P3. See Table D2 in Appendix D for the full model.

Conditional Process Analyses

DSHI Moderating Path *a* (Prediction 2)

A conditional process analysis was conducted to determine if the relationship between BAC and PT was conditional upon past NSSI. Both BAC ($c' = 2.09$, $p < .005$) and PT ($b = 0.18$, $p < .001$) remained significant predictors of total 20's selected. However, no main ($p = .32$) or interaction ($p = .23$) effects of DSHI on PT were found. Further, examination of the index of the moderated mediation of path *a* revealed that the confidence interval included 0 (CI [-1.19, 4.07]), indicating that the relationship between BAC and PT was not conditional upon past NSSI; thus, the results did not support P2. See Table D3 in Appendix D for the full model.

DSHI Moderating Path *b* (Prediction 3)

A conditional process analysis was conducted to determine if the relationship between PT and total 20's was conditional upon past NSSI. Both BAC ($c' = 1.90$, $p < .01$) and PT ($b = 0.17$, $p < .001$) remained significant predictors of total 20's. Significant main ($d = 0.27$, $p < .01$) and interaction ($bd = 0.38$, $p < .01$) effects were found for DHSI such that the effect of PT on total 20's increased as DSHI scores increased. Using the

normal theory approach for examining the moderated mediation (CI [0.40, 3.60]), the model was significant and supports P3. See Table D4 in Appendix D for the full model.

It should be noted that an analysis of DSHI as a simultaneous moderator for path *a* and path *b* was conducted; however, results are not presented here because they were similar to the previous results.

CHAPTER IV

DISCUSSION

General Discussion

The results of the mediation analysis support Prediction 1 in that the relationship between participants' average BAC during the SAP task and the total number of level "20" shocks self-selected was mediated by pain tolerance (i.e., milliamperes at which participant indicated the shock would be painful). In other words, it is possible that the analgesic effects of alcohol account for a significant portion of the relationship between acute alcohol intoxication and DSH. A caveat to this interpretation should be mentioned: as PT was measured after but not measured prior to alcohol consumption, the degree of alcohol's influence on individual PT cannot be determined explicitly from these data. However, it can be inferred from previous animal research that alcohol may have induced analgesic effects by blocking participants' pain detection (Campbell et al., 2006). Further, alcohol was associated with increases in PT and pain sensitivity recent meta-analysis that included within-subjects and between subjects designs (Thompson et al., in press). Based on the existing literature, it is reasonable to assume that PT measured in the current study was influenced by alcohol consumption.

Prediction 2 was not supported by the results from the first condition process analysis which examined the potential conditional effects of past NSSI (e.g., DSHI scores) on path *a* (BAC → PT) of the above mediation analysis. In this case, DSHI did not moderate path *a* and therefore did not significantly influence the relationship between

BAC and PT. Interestingly, DSHI also did not demonstrate a main effect on PT in this model, suggesting that previous NSSI behaviors did not influence PT. There are a few potential reasons as to why DSHI did not demonstrate main or interaction effects. First, as BAC remained significant, it is possible that the analgesic effects of acute intoxication are vastly more influential than past NSSI, and therefore alcohol eliminated the influence of historical NSSI. However, the actual influence of alcohol cannot be determined from these data as PT was not measured prior to alcohol consumption. Another explanation may be that frequency of NSSI rather than number of methods used is more influential to increasing PT, which would may be considered consistent with the concept of *capability* found in theories of suicide (i.e., Interpersonal Theory of Suicide: IPTS; Van Orden et al., 2010; Three-Stage Theory: 3ST; Klonsky & May, 2015). Although the number of methods used—how the DSHI was used in the current study—can be indicative of frequency, the current study cannot compare participants who have regularly engaged in NSSI for a long period of time to those who have engaged in isolated NSSI. Similarly, the recency of NSSI, which also was not measured in the current study, may alter PT. In any case, the results of the current study add to the inconsistency found in the current literature. A recent meta-analysis found that studies examining NSSI factors and behavioral laboratory measures of pain show mixed results such that some, but not all, studies have found significant associations (Kirtley, O'Carroll, & O'Connor, 2016).

Unlike the second model, the third model, where DSHI moderated path *b* (PT → total 20's), provided support for Prediction 3 and found both significant main and interaction effects for DSHI. Specifically, the effects of PT on the total 20's selected increased as DHSI scores increased. Thus, participants with high PT who also endorsed

multiple forms and instances of prior NSSI were most likely to engage in DSH during the task. Taken together with the other models, it appears that the relationship between BAC and DSH was mediated by participants' PT. Further, the relationship between PT and observed DSH was conditional upon a reported history of NSSI while the relationship between BAC and PT was independent of a reported history of NSSI.

The clinical implications of these results suggest both past behavior and immediate situational factors should be taken into account when determining risk of DSH. Notably, mental health professionals should take into account past behavior, reported pain perception, and alcohol sensitivity when assessing for risk. Clients who report the ability to endure more pain than their peers and past DSH are at much greater risk than those who report greater endurance alone. Further care should be taken with clients who also report having a heightened sensitivity to alcohol (i.e., need fewer drinks to perceive the effects of intoxication). Expanding on this, professionals should caution clients with a history of DSH about using any substance that has analgesic effects. Although alcohol was the only substance examined in the current study, the relationship was mediated by PT, which suggests that any substance that creates an acute increase in PT may also increase situational risk of DSH.

Strengths and Limitations

One strength of the analyses is that the study from which these data were collected utilized a relatively large sample size, which allows for BAC to be treated as a dimensional variable to increase power. The sample also includes both men and women, which opens the possibility to use gender as a moderating variable in an exploratory

analysis to determine if gender plays a significant role in a behavioral measure DSH while intoxicated.

The analyses also have several limitations. The use of archival data does not allow for direct manipulation of variables for the purposes of this analysis and relied on a self-selection convenience sample. This sample, while large for a prospective study using acute alcohol intoxication, may be underpowered; however, bootstrap samples were utilized to mitigate the limits of power. Further, PT was measured using a threshold procedure with a limitation on shock intensity, which reduced potential harm to participants but may not have allowed for all participants to reach their actual pain threshold. Related, PT was measured with a single instance and did not allow for within-participant variations. Finally, while the SAP allows for a prospective behavioral measure of DSH, the DSHI is a self-report measure about participants' past NSSI and is susceptible to reporting biases.

Future Research Directions

Building upon the current study, future research should attempt to directly examine the influence of alcohol on pain. For example, future experiments might include a baseline measure of PT (i.e., completing the threshold procedure prior to alcohol consumption) and use the difference in PT before and after alcohol consumption as a mediating variable to determine how much of the PT observed during the task is accounted for by intoxication. If results of such studies find that there is significant mediation while the direct effect remains significant, other potential influences of alcohol (e.g., decreased impulse control) may be examined for additional mediating effects.

Future research may also examine the influence of specific NSSI factors (e.g., frequency, recency, method) within these models. The various ways in which NSSI and pain perception have been measured may have added to the mixed results in the literature, including this study (e.g., Kirtley et al., 2016). Larger studies comparing the effects of specific factors of NSSI on individual laboratory measures of pain should be conducted to help explain the current literature (e.g., examining all NSSI factors on electrical shock and cold pressor rather than some NSSI factors on electrical shock and other factors on cold pressor). By utilizing universal measures, researchers may find that different factors of NSSI may have varying effects on forms of pain perception.

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APPENDIX A

PREDICTED MODELS

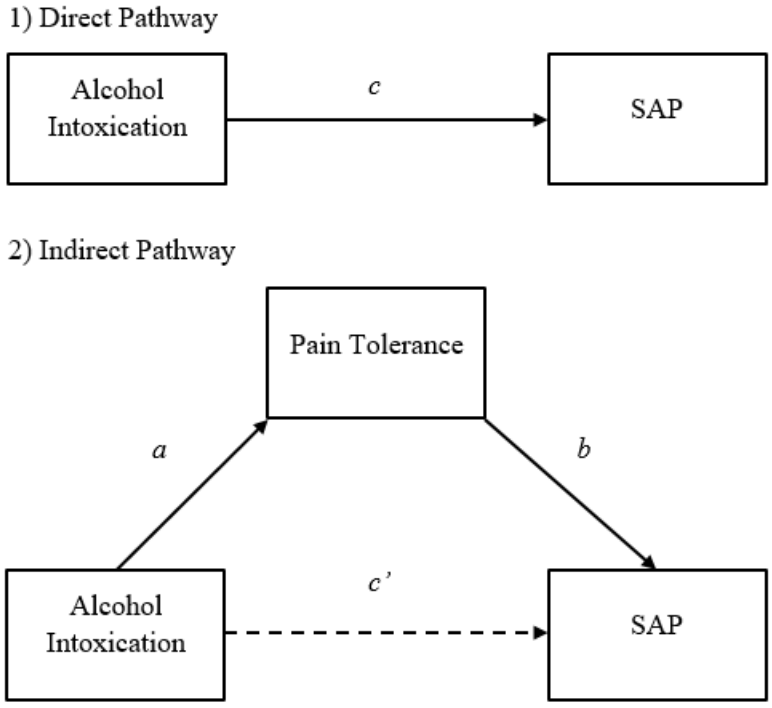

Figure A1. Direct and indirect pathways from BAC to deliberate self-harm through pain tolerance for prediction 1

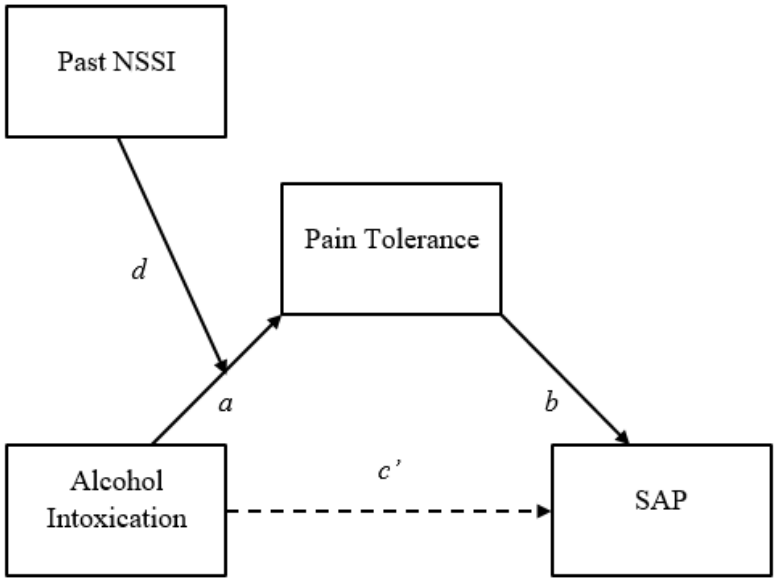

Figure A2. Conditional effects of NSSI on the relationship between BAC and pain tolerance for Prediction 2

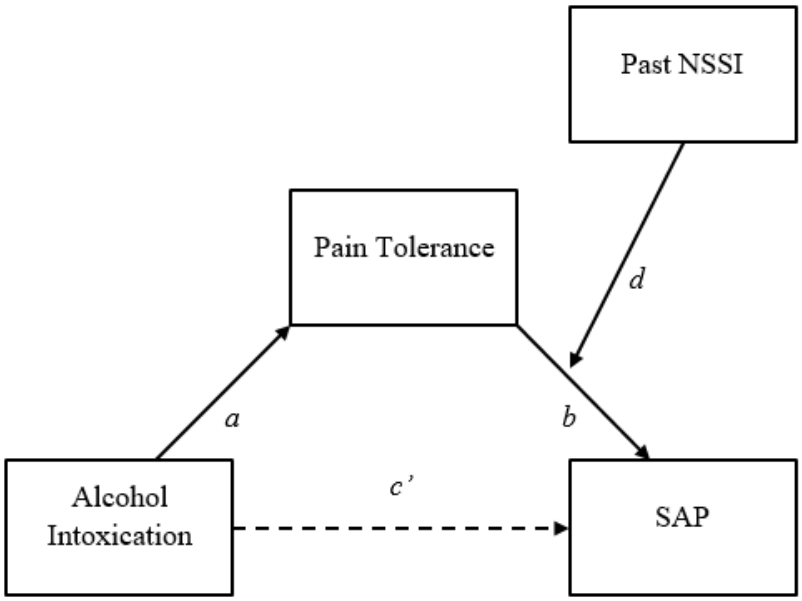

Figure A3. Conditional effects of NSSI on the relationship between pain tolerance and deliberate self-harm for prediction 3

APPENDIX B

DELIBERATE SELF-HARM INVENTORY

Deliberate Self-Harm Inventory

This questionnaire asks about a number of different things that people sometimes do to hurt themselves. Please be sure to read each question carefully and respond honestly. Often, people who do these kinds of things to themselves keep it a secret, for a variety of reasons. However, honest responses to these questions will provide us with greater understanding and knowledge about these behaviors and the best way to help people. Please answer yes to a question only if you did the behavior intentionally, or on purpose, to hurt yourself. Do not respond yes if you did something accidentally (e.g., you tripped and banged you head on accident). Also, please be assured that your responses are completely confidential.

1. Have you ever intentionally (i.e., on purpose) cut your wrist, arms, or other area(s) of your body (without intending to kill yourself)? (circle one):

1. Yes 2. No

If yes,

How old were you when you first did this? _____

How many times have you done this? _____

When was the last time you did this? _____

How many years have you been doing this? (If you are no longer doing this, how many years did you do this before you stopped?) _____

Has this behavior ever resulted in hospitalization or injury severe enough to require medical treatment? _____

Have you ever intentionally (i.e., on purpose)

2. Burned yourself with a cigarette?

3. Burned yourself with a lighter or a match?

4. Carved words into your skin?

5. Carved pictures, designs, or other marks into your skin?

6. Severely scratched yourself, to the extent that scarring or bleeding occurred?

7. Bit yourself, to the extent that you broke the skin?

8. Rubbed sandpaper on your body?

9. Dripped acid onto your skin?

10. Used bleach, comet, or oven cleaner to scrub your skin?

11. Stuck sharp objects such as needles, pins, staples, etc. into your skin, not including tattoos, ear piercing, needles used for drug use, or body piercing?

12. Rubbed glass into your skin?

13. Broken your own bones?

14. Banged your head against something, to the extent that you caused a bruise to appear?

15. Punched yourself, to the extent that you caused a bruise to appear?

16. Prevented wounds from healing?

17. Done anything else to hurt yourself that was not asked about in this questionnaire? If yes, what did you do to hurt yourself? _____

APPENDIX C

INSTRUCTIONS AND PROCEDURES FROM THE ORIGINAL STUDY

Threshold Procedure

THRESHOLD TASK AND INSTRUCTIONS

Chose the male or female folder (depending on the gender of the subject)

Say:

Okay Subject A and B.

"First, I will give you a series of shocks, increasing the intensity with each one. When the shock is first presented, it will be below your threshold and you will not feel it. As the intensity increases, first, you will become aware of it; second, it will feel like a tingling sensation; third, it will feel like a vibration; and finally, the shock will reach an intensity that is definitely painful. I want you to tell me two things: one, report when you first feel the shock, and two, report when you don't want anymore, that is, when it is definitely painful. Okay Subject A, let's start with you. Tell me when you first feel the shock."

Pause threshold WAV file. Determine lower threshold and prepare for upper threshold determination.

Restart WAV file.

"Okay Subject A, now I want you to tell me when the shock becomes definitely painful. By painful I mean that it is so unpleasant that you really couldn't take anymore. Don't say it is painful unless it really is."

Pause WAV file.

Determine upper threshold.

Restart WAV file. immediately

"Okay Subject A, we'll stop there. (Pause 4 seconds). Subject B, your turn. Tell me when you first feel the shock."

10 second delay-voice (male or female) says:

"Okay, yeh, I think I feel it."

5 second delay

"Okay Subject B, same with you-now I want you to tell me when the shock becomes definitely painful. By painful I mean that it is so unpleasant that you really couldn't take anymore. Don't say it is painful unless it really is."

Pause WAV file for the number of seconds to reach the Upper Threshold for subject A. Start WAV file. 5 second delay.

"Whoah!, That's pretty intense! No more."

4 second pause "Okay, we'll stop there B." 5 second pause.

Task Instructions (also presented before drink administration):

"The purpose of this task is to determine the effect of alcohol consumption and competition on the speed with which a finger can be pulled off a reaction time key. Two of you, situated in separate rooms, will be competing in this task. Both of you have the same apparatus in front of you and the same task to perform. Both of you also received the same amount of alcohol to drink at about the same time.

When you see on the computer screen an instruction to press the space key, you are to depress the space key and hold it down. When the release signal comes on the screen, you are to remove your finger from the space bar as fast as you can. Of course, you both will receive the release signal at the same time. The object of each trial is to get your finger off the space bar as fast as possible in order to beat your competitor. The person who does not get his (her) finger off in the shortest time, that is, the person with the slower reaction time, will select a shock to self-administer. If you win a trial, you will not have the opportunity to select a shock to self-administer. However, a signal will come on telling you that you beat the other person.

There are 12 different intensities of shock you can administer if you have the slower reaction time on a trial. After a losing trial you will see a message on the computer screen asking you to select a shock for yourself. When you see this signal, simply click the mouse on one of the 12 button boxes on the screen. The 1-button corresponds to the least intense shock. The 10-button corresponds to the shock level that you judged painful in the preliminary trials. The 9 shock is 95% of the 10 shock, 8 is 90%, 7 is 85% and so on down to the 1 shock. The 20-button corresponds to a severe shock, about twice the intensity of the shock you judged painful in the preliminary trials. This level of shock may cause minor tissue damage that will heal quickly. The 0-button corresponds to no shock. After you select a shock, you will receive a one second shock of that intensity, unless of course, you select a 0.

To summarize: You will press the space bar down and hold it down when signaled, until the 'release' light flashes. At this time, you are to remove your

finger as fast as possible. The slower person on that trial will select a shock to receive. The faster person will not be able to select a shock to receive.

SAP Task Procedure

I. Before the subject arrives:

Turn on Coulborne shock equipment from top box to bottom box.

Clean electrode plates gently with just a small amount of alcohol. Let dry.

Set shock to "Manual" and "Subject." Turn current to 0. Place electrodes on finger and have someone increase shock to ensure the equipment is working.

Set the dial back to "Program" (far counter-clockwise) and "Test."

Open the "NIAAA Study" folder

Open "Initialize Shock."

Hit #8, Equipment Test

Hit #5, Shocker Test

Hit CTRL-R

Move shock meter up by hitting + about 10 times. If this works, hit the esc key to exit.

MAKE SURE THE SAP MONITOR IN THE SUBJECT ROOM IS OFF BY MOVING SWITCH TO PC1-THE SWITCH SHOULD BE FLASHING!!

II. Greeting the subject:

When the subject arrives, greet them at the door and say in a low voice:

> "Other subjects are already here and working on paperwork. We need to speak softly. You'll stay in this room during the day—you'll be Subject A, okay?"

Lead subject to the Subject A room and have them sit on the couch or a chair away from the SAP keyboard. Complete all pre-SAP events in the Running Log.

Make sure that <u>every time</u> you interact with the real subject, you pretend to do the same with a second subject in another room. That is, open the door to another room in the lab (but not the control room), and say the same script as naturally as possible to the pretend second subject. Don't overdo it, or the deception may not be believed!

III. Preparation for the SAP Procedures:

Seat the subject in front of the SAP keyboard. Say,

> "The purpose of the next task is to see if alcohol consumption affects the speed with which people can pull a finger off a reaction time. You and the other person will compete in this task as soon as I get both of your ready. Are you right handed or left handed? Okay, I'm going to put the electrode on your non-dominant hand then."

Attach the finger tip electrodes firmly to the index and middle fingers. Say,

> "Okay, I want to rest your hand with the electrodes on the table palm up and try not to move. You'll use your other hand to do the reaction time task. Give me a few minutes to hook up the other subject and we'll get started. If you don't mind, I'll give the task instructions to both of you at the same time over the intercom."

Leave the room, and "repeat" for Subject B.

IV. Running the SAP-Thresholds:

Load SAP paradigm in using the win or lose file depending on randomization. Enter subject information including handedness. When ready to start the procedure, open the microphone and say:

> "Okay Subject A and B. I'm going to open the microphone so we can all hear each other. Okay? We're going to start by calculating discomfort thresholds for both of you. First, I will give you a series of shocks, increasing the intensity with each one. When the shock is first presented, it will be below your threshold and you will not feel it. As the intensity increases, first, you will become aware of it; second, it will feel like a tingling sensation; third, it will feel like a vibration; and finally, the shock will reach an intensity that is painful. I want you to tell me two things: one, report when you first feel the shock, and two, report when you don't want anymore, that is, when it is painful. Let's start the procedure with Subject A in the room closest to the door. Okay Subject A, tell me when you first feel the shock. All you have to say is 'I feel it.'"

Determine lower threshold and prepare for upper threshold determination.

> "Okay Subject A, now I want you to tell me when the shock becomes painful. By painful I mean that it is so unpleasant that you really couldn't take anymore. Don't say it is painful unless it really is. Just say 'That's enough' when it is painful"

Determine upper threshold. If subject seems to be stopping short of the threshold, continue to let the computer run for 1 or more trials and say (skip this step if a high threshold is reached that is clearly uncomfortable for the subject):

> "Subject A, is it okay if I try just a couple more to make sure that I have it right."

Stop immediately when subject shows some discomfort or declines further shock. Be sure to click to rectangular button that says something like "click before the subject starts pressing the space bar" after the upper threshold – this will record the thresholds.

> "Okay Subject A, we'll stop there. (Pause 4 seconds). Subject B, your turn. Tell me when you first feel the shock."

After a 5 second delay, or equate to approximate delay of responding for Subject A, play the WAV file of the voice (male or female to match Subject A) that says:

> "Okay, yeh, I think I feel it."

Pause (the "ll" symbol) WAV file immediately! After a 5 second delay say:

> "Okay Subject B, same with you-now I want you to tell me when the shock becomes definitely painful. By painful I mean that it is so unpleasant that you really couldn't take anymore. Don't say it is painful unless it really is."

Pause WAV file for the number of seconds minus 5 seconds to reach the Upper Threshold for subject A. Start WAV file (has a 5 second delay) that says:

> "Whoah!, That's pretty intense! No more."

After a 4 second pause, say

> "Okay, we'll stop there B."

V. Running the SAP (Task Instructions):

> "Okay Subject A and B. We'll do the task now. The purpose of this task is to determine the effect of alcohol consumption on the speed with which a finger can be pulled off a reaction time key—the space bar on the computer. Two of you, situated in separate rooms, will be competing against each other to see who has the fastest reaction time. Both of you have the same apparatus in front of you and the same task to perform. Both of you also received the same amount of alcohol to drink at about the same time.
>
> You will see the instructions "Wait, Get Ready, Hold Spacebar, and Release" on the computer screen. When the computer says to Hold Spacebar, you are to press and hold down the space bar. When the release signal comes on the screen, you are to remove your finger from the space bar as fast as you can. Of course, you both will receive the release signal at the same time. The object of each trial is to get your finger off the space bar as fast as possible in order to beat your competitor. The person who does not get (his/her) finger off in the shortest time, that is, the person with

the slower reaction time, will chose the level of shock (he/she) will receive. If you win a trial, you will not have the opportunity to select a shock. However, a signal will come on telling you that you beat the other person, and to wait while they select a shock.
If either of you lift your finger off the space bar before the release signal comes on, a message saying 'Subject released space bar too soon' will come on and the two of you will repeat the trial.

There are 12 different intensities of shock you can choose to select if you have the slower reaction time. When you see a message that says you lost and to choose shock, push a number from 1 through 20 or 0 on the top row of the keyboard. The 1-button corresponds to the least intense shock. The 10-button corresponds to the shock level that you judged painful in the preliminary trials. The 9 shock is 95% of the 10 shock, 8 is 90%, 7 is 85% and so on down to the 1 shock. The 20-button corresponds to a severe shock, about twice the intensity of the shock you judged painful in the preliminary trials. This level of shock may cause minor tissue damage that will heal quickly. The 0-button corresponds to no shock. After you select a shock, you will receive a one second shock of that intensity, unless of course, you select a 0.

We'll repeat this process for a number of trials. Neither of you will be informed about the shocks selected by the other person. All you'll know will be whether you won or lost a particular trial.

To summarize: You will press the space bar down and hold it down when signaled, until the 'release' signal flashes. At this time, you are to remove your finger as fast as possible. The slower person on that trial will select a shock to receive. The faster person will not be able to select a shock to receive.

Okay, I am going to turn on the computer monitors for both of you, and we'll start the task. Give me a 'thumbs up' if you can see your monitor"

Turn the monitor to PC2 and start the task.

VI. After the SAP is complete, <u>turn off the monitor</u> (to PC1) and say:

"Okay Subjects A and B, I'm going to bring in some more questionnaires to complete."

Bring in post task q set and make sure the subject has a pen. Leave electrode on while they complete this and you take the BAC. When complete, remove the electrode and make sure all questions on the form were completed. Continue running log.

VII. Clean up tasks:

Copy data from c:/aggression/data/ and place on the main computer—save the file as the subject number.initials. Print out data and place in subject binder.

APPENDIX D

CORRELATIONS AND REGRESSION TABLES

Table D1 *Correlations Between Age, Gender, Average BAC, Pain Tolerance, DSHI Scores, and Total 20's Selected*

Correlations

	1	2	3	4	5
Age					
Gender	-.002				
Average BAC	.115	-.03			
Pain Tolerance	-.002	.21*	.22*		
DSHI	-.09	.08	.07	.09	
Total 20's	-.05	.34**	.25**	.35**	.19*

Note: *$p < .01$, ** $p < .001$

Table D2 *Mediation Analysis for Prediction 1*

Mediation Analysis - Pain Tolerance Mediating the Relationship between Average BAC during SAP and Total 20's Selected

		Outcomes						
		Pain Tolerance				Total 20's		
		Coeff.	*SE*	*p*		Coeff.	*SE*	*p*
BAC	*a*	4.48	1.37	< .01	*c′*	2.09	0.73	< .005
Pain Tolerance		—	—	—	*b*	0.18	0.04	< .001
Constant	i_1	1.34	0.10	< .001	i_2	-0.13	0.05	< .05
		$R^2 = .05$, $MSE = .60$, $F(1, 208) = 10.57$, $p < .005$				$R^2 = .15$, $MSE = .18$. $F(2, 207) = 18.58$, $p < .001$		

Table D3 *Conditional Process Analysis for Prediction 2*

Conditional Process Analysis - DSHI Moderating the Relationship between BAC and Pain Tolerance in the Mediation Analysis

		Outcomes						
		Pain Tolerance				Total 20's		
		Coeff.	*SE*	*p*		Coeff.	*SE*	*p*
BAC	*a*	4.36	1.41	< .005	*c′*	2.09	0.73	< .005
Pain Tolerance		—	—	—	*b*	0.18	0.04	< .001
DSHI	*d*	0.26	0.26	.32		—	—	—
BAC × DSHI	*ad*	8.26	6.89	.23		—	—	—
Constant	i_1	1.59	0.05	< .001	i_2	-0.01	0.05	.85
		R^2= .06, *MSE* = .60, $F(3, 206) = 4.36$, $p < .01$				R^2= .15, *MSE* = .18, $F(2, 207) = 18.58$, $p < .001$		

Table D4 *Conditional Process Analysis for Prediction 3*

Conditional Process Analysis - DSHI Moderating the Relationship between Pain Tolerance and Total 20's Selected in the Mediation Analysis

		Outcomes						
		Pain Tolerance				Total 20's		
		Coeff.	*SE*	*p*		Coeff.	*SE*	*p*
BAC	*a*	4.47	1.37	< .005	*c′*	1.88	0.70	< .01
Pain Tolerance		—	—	—	*b*	0.17	0.04	< .001
DSHI		—	—	—	*d*	0.27	0.12	< .01
Pain Tolerance × DSHI		—	—	—	*bd*	0.38	0.14	< .01
Constant	i_1	-0.25	0.10	< .01	i_2	0.16	0.04	< .001
		R^2= .05, *MSE* = .60, $F(1, 208) = 10.57$, $p < .005$				R^2= .20, *MSE* = .17, $F(2, 207) = 11.74$, $p < .001$		

APPENDIX E

HUMAN RESEARCH PROTECTION PROGRAM APPROVAL LETTER

MISSISSIPPI STATE UNIVERSITY

Office of Research Compliance

Institutional Review Board for the Protection of Human Subjects in Research
P.O. Box 6223
53 Morgan Avenue
Mississippi State, MS 39762
P. 662.325.3294

www.orc.msstate.edu

NOTICE OF APPROVAL FOR HUMAN RESEARCH

DATE:	April 26, 2017
TO:	Matthew Timmins, BS, Psychology
FROM:	Jodi Roberts, HRPP Officer, MSU HRPP
PROTOCOL TITLE:	Alcohol Effects on Physiology and Behavior - II
PROTOCOL NUMBER:	IRB-17-067
	Approval Date: April 26, 2017 Expiration Date: April 21, 2021

This letter is your record of the Human Research Protection Program (HRPP) approval of this study as exempt.

On April 26, 2017, the Mississippi State University Human Research Protection Program approved this study as exempt from federal regulations pertaining to the protection of human research participants. The application qualified for exempt review under CFR 46.101(b)(4).

Exempt studies are subject to the ethical principles articulated in the Belmont Report, found at www.hhs.gov/ohrp/regulations-and-policy/belmont-report/#

If you propose to modify your study, you must receive approval from the HRPP prior to implementing any changes. The HRPP may review the exempt status at that time and request an amendment to your application as non-exempt research.

In order to protect the confidentiality of research participants, we encourage you to destroy private information which can be linked to the identities of individuals as soon as it is reasonable to do so.

The MSU IRB approval for this project will expire on April 21, 2021. If you expect your project to continue beyond this date, you must submit an application for renewal of this

HRPP approval. HRPP approval must be maintained for the entire term of your project. Please notify the HRPP when your study is complete. Upon notification, we will close our files pertaining to your study.

If you have any questions relating to the protection of human research participants, please contact the HRPP by phone at 325.3994 or email irb@research.msstate.edu.

We wish you success in carrying out your research project.

Jodi Roberts

Review Type: EXEMPT
IRB Number: IORG0000467