Title: Proximal Effects of Alcohol on Same-Sex Intimate Partner Violence
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Research Protocol and Statistical Analyses

Title: Proximal Effects of Alcohol on Same-Sex Intimate Partner Violence
Principal Investigator: Dr. Dominic J. Parrott
Georgia State University
Department of Psychology
Sponsor: National Institute of Alcohol Abuse and Alcoholism

Project Summary and Project Goals

Partner violence among sexual and gender minoritized (SGM) individuals' intimate relationships occurs at rates comparable, if not higher, than in cisgender, heterosexual couples. Research indicates that this health disparity is due to the stress associated with individuals' sexual and gender minoritized (SGM) identities. In addition, research suggests that stress resulting from the COVID pandemic (i.e., COVID stress) may further exacerbate this health disparity. The purpose of this study is to test a dyadic, interactional framework to identify mechanisms of intimate partner violence (IPV) perpetration in sexual and gender minoritized couples. Specifically, the proposed project will determine (1) the temporal effect of sexual minority stress, gender minority stress, and COVID stress on IPV perpetration, (2) whether proximal alcohol use alters the threshold at which these stressors contribute to IPV perpetration, (3) the temporal sequence by which these stressors, proximal alcohol use, and other factors facilitate IPV perpetration, (4) how these interactive and mediational effects are altered by the patterning of individual- and couple-level risk and resilience factors for IPV perpetration, and (5) evaluate a brief, low-resource intervention to mitigate the effects of these stressors.

The primary outcomes will be self-reported IPV perpetration and alcohol use and the secondary outcomes will be sexual minority stress, gender minority stress, and COVID stress. Our overarching goals are to (1) develop an etiological model of IPV perpetration upon which intervention development may be based, and (2) provide data on the efficacy of a culturally-sensitive, low burden, and easy to disseminate intervention to mitigate these effects critical during a pandemic when access to care is limited

Rationale and Background Information

Intimate partner violence (IPV) within SGM intimate relationships is a critical but vastly understudied public health problem. Reviews indicate that IPV occurs at rates comparable, if not higher, than in heterosexual couples (Edwards, Sylaska, & Neal, 2015; Messinger, 2014). However, with one exception (Lewis, Mason, Winstead, & Kelley, 2016), an etiological framework for IPV perpetration in SGM relationships has not yet been advanced. Thus, unlike research with heterosexual couples, this literature is in desperate need of methodologically rigorous research that can lead to the development of culturally-sensitive interventions that will reduce IPV and its associated negative health consequences in SGM communities.

In addition, research indicates that stress and its concomitant negative mental health and physical health outcomes are direct results of pandemic episodes (Quinn et al., 2011). Stress related to COVID-19 is no exception (Holmes et al., 2020; Pfefferbaum & North, 2020;

Rajkumar, 2020). We argue that this stress – which we term COVID-19 stress – is temporally and proximally related to increases in alcohol use and IPV perpetration in SGM couples. This focus on SGM couples is purposeful. Because the COVID-19 pandemic poses greater economic, social, and personal challenges for SGM communities (Salerno, 2020), they must cope with both COVID-19 stress *and* well-established minority stressors (Meyer, 2003). Thus, they are more likely to engage in maladaptive coping behaviors, including alcohol use and IPV, relative to cisgender, heterosexual people.

In response, the scientific premise of the proposed project is to prioritize three perspectives highlighted by the Institute of Medicine report on LGBT Health (2011) – minority stress, social-ecology, and intersectionality – while simultaneously addressing critical methodological weaknesses, including (1) exclusive use of cross-sectional methods that cannot identify temporal relations among risk factors for IPV perpetration, (2) a paucity of studies that examine alcohol use as a risk factor for IPV perpetration, and no studies that examine the proximal effects of alcohol use on IPV perpetration, in SGM couples, (4) failure to assess the multiple, intersecting identities of respondents' and their partners, and (5) lack of brief, easy-to-disseminate interventions which bolster one's real-time capacity to inhibit a stress-induced proclivity toward alcohol use and IPV perpetration.

Methods

Sample and eligibility criteria. The study plans to conduct a randomized controlled trial of 240 couples, which will be comprised of 120 couples in which both partners identify as cisgender and a sexual minority and 120 couples in which at least one partner identifies as a gender minority, meaning one's gender identity is non-congruent with the sex they were assigned at birth.

Inclusion criteria require that participants are either (a) healthy cisgender men and women aged 21 and older with a sexual minority identity who are in an intimate relationship with a cisgender, sexual minority partner with the same sex assigned at birth, or (b) healthy gender minority people (e.g., trans men, trans women, and/or gender non-binary, non-conforming, or queer) aged 21 and older who are in an intimate relationship with a cisgender, sexual minority partner or a gender minority partner. Gender minority participants will not be excluded based on their sexual orientation. In addition, all participants must:

- Report heavy episodic drinking (i.e., 4-5 drinks in a single drinking episode) at last three days in the past year or report consuming an average of 2 or more standard alcohol drinks per occasion an average of twice per month or more for the past year.
- Report being in their current relationship for at least one month
- Report at least 2 days of face-to-face contact each week with their partner
- Report relatively comparable responses as their partner regarding their relationship (e.g., how long they have been together, how many days per week they see each other in person, and how they met).

Exclusion criteria include not speaking English fluently, females assigned a birth who endorse being pregnant or are trying to get pregnant, participants who are seeking treatment or in

recovery for an alcohol or substance use disorder, and endorsement of severe IPV (e.g., IPV that caused them to fear for their life, caused serious injury requiring medical attention, and/or resulted in them seeking shelter or other services for partner violence).

Recruitment. This project will use a multi-pronged recruitment approach which includes: (1) a heavy emphasis on the use of different social media platforms (e.g., Facebook, Instagram); (2) referrals from our community-based partners; (3) outreach activities at public events and venues frequented by SGM individuals such as bars, LGBT festivals, and LGBT events (e.g., PRIDE); (4) posting of flyers in strategic community sites friendly to LGBT populations; (5) targeted newspaper and print ads, and (6) respondent driven sampling procedures that elicit peer referrals from enrolled participants.

Study Design and Procedures. Informed consent will be obtained prior to the baseline assessment. The baseline assessment will be conducted online and include measures of (1) economic, social, and personal impacts of COVID-19, (2) sexual minority stress and gender minority stress, and (3) pre-intervention levels of emotion regulation and distress tolerance, and individual- and couple-level factors that align with empirically-based risk and resilience factors for IPV. After both partners complete the baseline assessment, they will participate together in an online informational session which provides an overview of the daily diary procedures.

After completing the informational session, participants will be enrolled into a measurement burst daily diary design comprised of four 14-day bursts of daily surveys with three 14-day intervals that do not include daily surveys. There are three intervention conditions: (A) no intervention; (B) attention-control text messaging; or (C) CBT text messaging intervention (for more information on intervention conditions, see below). Between bursts 1 and 2 (Interval 1), all participants will be assigned to condition A (no intervention) such that all will complete the first two bursts (28 days) before receiving an intervention. Between bursts 2 and 3 (Interval 2) and bursts 3 and 4 (Interval 3), couples will be randomized to one of the following eight patterns of conditions: AA, AB, AC, BA, BB, BC, CA, or CB. There is no "CC" condition because the CBT intervention is not intended to be given in multiple two-week intervals.

Condition A: No intervention. Participants do not receive any messages during the interval period.

Condition B: Attention control. Over a 14 day period, participants will receive two text messages per day (one at 8 a.m. and one at 4 p.m.). They will receive hourly reminders for four hours or until the message is read. Participants receive the same messages in the same order. All texts will be supportive messages which express empathy and unconditional positive regard and provide support for dealing with stressors. These messages will be nondirective and will not include any CBT skill suggestions.

Condition C: CBT Messaging Intervention. Over a 14 day period, participants will receive two text messages per day (one at 8 a.m. and one at 4 p.m.). They will receive hourly reminders for four hours or until the message is read. Participants receive the same messages in the same order, with content equally distributed across the four content areas (i.e., psychoeducation regarding effects of stress, distress tolerance, emotion regulation, alcohol reduction).

On the morning after the informational session, participants will begin the first daily survey burst. For each burst, participants will complete daily reports of (1) alcohol use, (2) sexual minority, gender minority, and COVID-19 stress (note: gender minority and COVID-19 stress are added for this proposal), and (3) IPV perpetration. All daily surveys will be completed using the LifeData app.

Retention Plan. To maximize our retention rate, we will utilize an secure database to organize all activities involving assessment and retention. We also have systems in place (e.g., through LifeData) that can be used to send text messages and e-mail reminders about pending follow-up assessments. We will efficiently maintain our sample and implement multiple strategies, including: (1) maintaining cell phone, address, email and other records; (2) providing change-of-contact (email, cell phone, address) "postcards" for participants to send electronically; (3) sending email "meeting" invites; (4) providing adequate compensation for completing daily diary assessments (i.e., $14 for completing each day of the 14-day burst via the LifeData App, bonuses for completing higher percentages of daily surveys; and (5) monitoring participant progress and contacting them if they miss daily surveys to remind them of bonuses and problem solve potential barriers. Participants can easily track the number of prompts that have completed on the LifeData ap. Our current laboratory personnel comprised of full time research assistants and doctoral students will be responsible for conducting all retention-related activities.

Informed Consent. Participants who are eligible to participate in the study, and choose to do so, will be asked to complete a web-based baseline questionnaire battery, an in-person or on-line informational session, and a daily diary study. A waiver of documentation of consent is required.

Informed consent will be obtained separately for the web-based questionnaire battery and for the informational session and daily diary surveys. The consent form for the questionnaire battery will be displayed online and participants will be asked to check a box to indicate that they wish to proceed with the survey. An online version of the consent form for the online informational session and daily diary surveys will be sent to participants via a weblink prior to the online informational session. The consent form will ask participants to check a box to indicate that they wish to proceed with the online informational session and subsequent daily diary surveys.

Safety Considerations

The three potential risks associated with this research, and our procedures for mitigating those risks, are enumerated below.

1. One potential risk associated with all research that is not anonymous is breach of confidentiality, which could cause negative social or legal consequences. Given the longitudinal nature of this project, this is an important risk to consider. We believe that the risk is very low, given that data are collected electronically and stored securely and separately from identifying data. In addition, all participants will be informed that the study includes receiving text messages via the LifeData platform. Thus, there are potential risks to confidentiality associated with receiving text-messages that may appear on their phone screen.

In addition, we will use personal identification numbers, access codes, and passwords on surveys administered via Qualtrics and the LifeData app. Only the PI and select members of the research team will have access to these dadta. Qualtrics web-survey platform and the LifeData app employ a high level of data encryption. All data and recruitment materials will be stored on the PI's password-protected desktop located in his locked office at GSU.

2. A second potential risk is that participants' relationships may be adversely affected by participation. There is little evidence that participation in relationship-based research is harmful, rather, most couples find it beneficial (Bradbury, 1994; Laurenceau & Bolger, 2005). Nevertheless, as an important way of minimizing the risk of harm from participation, participation is limited to community volunteers who complete an extensive screening process and are provided with detailed information on what participation entails. We believe that individuals who are concerned that the study might be unpleasant or exacerbate conflict are very unlikely to choose to participate. However, we will exclude from participation any couples who indicate very severe, clinical levels of violence.

   While excluding the most seriously violent couples will greatly reduce the risk of serious violence occurring during the course of the study, it will not eliminate this risk. Thus, we will remain vigilant to the occurrence of any negative effects of participation or of any serious violence. There will be regular contact with participants throughout the course of the study. At each contact, research personnel will ask whether there are any difficulties or negative consequences associated with participation, and any issues with privacy or independence of responses. All participants will be provided with a list of community resources in the orientation packet that they receive at their first appointment and may be referred to additional resources if warranted. These resources will include services catering to the needs of sexual minorities.

3. A third potential risk is that participants will feel uncomfortable answering questions. Participants will be reminded that they have the right to refuse to answer any question in the baseline or daily assessments or to discontinue participation at any time. All instruments are programmed to allow participants to skip any question but still complete the survey. The consent documents will provide participants with contact information on mental health services. The research team will be prepared to provide resources for participants should they request a referral.

Data Management and Statistical Analysis

Data Management. All data collected during the baseline survey phase will be initially stored on Qualtrics' secure servers. Qualtrics complies with the privacy standards imposed on health care records by the Health Insurance Portability and Accountability Act (HIPAA). Participant data will be stored on GSU secure computing systems that are accessible only by authorized personnel through the use of unique system IDs and passwords. After downloading the data, all data will be deleted from Qualtrics.

Microsoft Teams will be used for video conferencing for on-line informational sessions. Microsoft Teams is compatible with the Health Insurance Portability and Accountability Act (HIPAA). These sessions will not be recorded.

All data collected during the daily diary survey phase will be initially stored on LifeData's secure servers. LifeData complies with the privacy standards imposed on health care records by the Health Insurance Portability and Accountability Act (HIPAA). Participant data will be stored on GSU secure computing systems that are accessible only by authorized personnel through the use of unique system IDs and passwords. After downloading the data, all data will be deleted from LifeData.

All PCs that will store data for this project are in locked rooms when users are not present. The department, as well as University Key Control, maintains a list of individuals with authorized access. All PCs and servers are password-protected. Only individuals with a correct password can gain access to individual PCs and departmental servers. User accounts are created and maintained by the department Technical Support team. To protect individual computers from unauthorized intrusion, computer users do not have administrative privileges on workstations and servers, and therefore are unable to install unauthorized applications and services or modify critical system files that could create vulnerabilities. Only the departmental Technical Support team members have administrative rights to PCs and servers. In addition, firewalls protect each individual computer and server from intrusion. Further, Georgia State University has additional firewalls and other security devices to protect the network infrastructure from outside the campus. Auditing and password security policies are enabled on computers and servers to track login attempts and restrict unauthorized access.

Statistical Analysis. All data analysis will be led by Dr. Masyn. Data analysis will be conducted using Stata and MPlus. Because this is the first daily report study to assess IPV among SGM couples, it is important to begin by describing the frequency and types of IPV events that are reported by SGM and drinking status. Measures of central tendency and dispersion will be used to summarize all primary outcomes (i.e., daily alcohol use and daily IPV perpetration) and secondary outcomes (i.e., daily sexual minority stressors, daily gender minority stressors, and daily COVID-19 stressors) for each of the eight intervention conditions (i.e., AA, AB, AC, BA, BB, BC, CA, and CB) corresponding to each of the four 14-day daily diary bursts.
In order to examine associations between the primary outcomes, we will utilize a multilevel generalized structural equation modeling approach, with burst days (Level 1) nested within individuals or dyads (Level 2). This flexible modeling framework will allow us to model both within-individual/dyad associations and between-individual/dyad variation in those associations. For example, we will use a multilevel logistic regression to estimate the within-individual/dyad association between daily alcohol use and IPV perpetration across burst days (Level 1) and test for intervention moderation of the effect of alcohol use on IPV perpetration (Level 2). We will evaluate Level 2 intervention effects using a controlled comparison of pre- to post-intervention bursts for those assigned to one of the four conditions exposed to the CBT text messaging. We can further extend this approach to model each partner's pathways from SGM and COVID-19 stressors to IPV via alcohol use. At Level 1, we can include repeated measures of alcohol use, SGM and COVID stress, and incidents of IPV perpetration. At Level 2, we can include within burst and across bursts data as well as IPV risk and resilience factors assessed at baseline. IPV

perpetration outcomes will be dichotomous at Level 1 (i.e., perpetration or not) and SGM stress, COVID-19 stress, alcohol use, and risk and resilience factors will be modeled using scale scores.

Sample Size. The primary outcomes will be self-reported IPV perpetration and alcohol use and the secondary outcomes will be sexual minority stress, gender minority stress, and COVID stress. Parameter estimates were informed by cross-sectional studies of IPV in SGM couples (Lewis et al., 2017; Mason et al., 2016) and previous daily-diary studies of heterosexual IPV and alcohol use that used an APIM framework (Testa & Derrick, 2014). In addition, there is not sufficient data to inform hypothesized daily effects involving effects of SGM stress, COVID stress, or our proposed Level 2 effects. Thus, we assumed small effects for all analyses of primary and secondary outcomes.

Quality Assurance

Data Safety and Monitoring Plan. The proposed study is considered to present minimal risk to participants, given that they will complete surveys. In accordance with the NIH recommendations as this is a NIH clinical trial we will have a Data Safety Monitoring Board (DSMB). The DSMB members will be chosen by Dr. Parrott. The members, who will all be voting members, will be chosen based upon their knowledge of clinical trial methodology, their experience with the topical area (i.e., alcohol use, intimate partner violence, sexual and gender minoritized communities), and absence of conflicts of interest. They will be appointed for the life of the project.

Monitoring of safety and data quality in the proposed study will be the responsibility of all personnel on the project, with primary responsibility and supervision by the Dr. Parrott. The Institutional Review Board at Georgia State University will approve the Statement of Informed Consent for the study and will provide additional oversight of data and safety issues. The study protocol will be approved prior to soliciting or consenting any participants. Moreover, the study will be reviewed on an annual basis by the GSU IRB committee with regard to recruitment and retention and annual reports will be made by the PI to Dr. Stuart regarding the progress of the proposed project, including any issues pertinent to recruitment, retention, confidentiality, and safety of human subjects. Any incidents that involve a breach of this plan or serious accident/injury will be reported to Dr. Stuart and the DSMB board, the IRB chair at Georgia State University, and the NIAAA Safety and Monitoring Board.

The PI will have weekly meetings with laboratory personnel that interact with research participants. All aspects of participant interaction and monitoring, including adverse events, will be discussed during these meetings. Research personnel will be trained to do the following if an adverse event occurs: (1) take any and all appropriate medical actions necessary that are detailed in the protocol for dealing with emergency medical situations, including calling 911 if needed; (2) immediately contact the PI to notify him of the occurrence; and (3) provide a detailed description of the event on a standardized "Unexpected Problems Checklist" in the subject's data record. Immediately after being notified about the adverse event, the PI will inform the IRB. The IRB will then advise the PI on how to report this event to all appropriate committees and agencies including NIH.

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