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Study Protocol and Statistical Analyses for

Group-based Intervention for Alcohol, Drugs and Aggression Among Club Patrons AA022331

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I Background information

Our prior research indicated that most (91.6%) of club patrons arrive in groups (Miller, et al., 2015). Considerable evidence indicates that peers can influence drinking and drug use (Dumas et al., 2014; O'Grady et al., 2011; Phua, 2011). The peer group can engage in preventive or protective behaviors for group members (Boekeloo &Griffin, 2009; Boekeloo et al., 2009) and prior research indicates a willingness for club patrons to look out for each other when in the club environment (Byrnes et al., 2016).

I II. Purpose of Study

Our primary purpose was to engage groups of young adults who are planning an evening of partying at nightclubs and to determine whether the social group that arrived together would protect each other from harms related to drinking and drug use and partying. The intervention was designed to provide skills to identify early signs of alcohol/drug related problems as well as threats to personal safety from aggression. The intervention provided skills for individuals to intervene with each other to avoid unwanted outcomes like overuse of alcohol/drugs, experiences of aggression (physical/sexual). The primary outcome was to increase these protective actions within the group. Secondary outcomes included decreasing actual alcohol/drug use and experiences of aggression.

III. Study Design

a. Description of intervention

Nightlife Safety Plans (NSP) was designed to be a brief, group-based intervention, delivered to nightclub patrons as they entered the club. NSP was designed to encourage group members to look out for each while partying at the club. The underlying premise was to use social influences in positive, nonjudgmental ways to encourage more protective behaviors within the group. Four major objectives were addressed in this brief intervention: 1) to assess the level and type of risks related to over use of alcohol/drugs, aggression (physical or sexual) and safety within the group; 2) to develop an ability to recognize early indicators of problems that were likely to escalate; 3) to deliver practical, simple actions within the group that would lower the likelihood of negative outcomes when group members detected risks; 4) to encourage a group consensus to initiate safety actions within the group. A risk algorithm based upon survey questions at entrance and calculated in real time, predicted group risk levels for overuse of alcohol/drugs, aggression (physical or sexual), and unsafe exit (driving impaired). Computer tablets were programmed to show the specific level of risk that their group was in danger of experiencing that night based upon the algorithms. Examples of early indicators of risk behaviors likely to lead to unwanted outcomes were provided to aid early detection of problems. Finally, actions that could be taken to de-escalate the situation were demonstrated.

The intervention was conveyed in visual pictures drawn by a graphic artist to convey the message with minimal reading required. Finally, each group was asked to discuss and form a consensus to the types of strategies that they were willing to implement if an early indicator was observed that might lead to an unwanted outcome for the group. There was total of 15 pages of interactive content programmed on the tablet and on average groups spent 5.5 minutes reviewing the content (SD=1 minute, 4 seconds).

b. Description of the Control Condition

The control condition consisted of information about fire safety at nightclubs. Examples of fires that had occurred in nightclubs were provided. Patrons were encouraged to identify exit locations in the club and to agree, a priori, meeting locations outside the club should they become separated in an emergency. A discussion after reviewing the fire safety materials was part of the control condition to mirror the group discussion of the experimental condition.

c. Selection and Exclusion of Subjects & Randomization procedures

There are two levels of randomization in this study. First, participants were randomly approached on the sidewalk. Social groups arriving at the club together were randomly approached using the portal recruitment methodology (Johnson et al., 2012; Miller et al., 2009, 2013b). The first person to cross an imaginary line on the sidewalk in front of the club was approached to recruit this person and their social group. Nightclubs with at least 200 patrons on a typical weekend night were contacted to seek permission to establish a data collection site outside the club. Clubs held different types of events on different nights, attracting different patrons, depending upon the event being featured. A total of 41 events across 7 nightclubs in the San Francisco area were selected for the data collection from June 2016 through October 2017. These events occurred on Friday and Saturday evenings when the attendance was the greatest. Patrons who were attending the club that evening and were arriving with at least one other person who agreed to participate were considered eligible. Anyone working that evening at the club was not eligible. A total of 352 groups, representing 959 patrons were included in the study. The study was able to recruit 25% of the groups that were stopped and given a description of the study and data collection procedures which included breath tests for estimates of blood alcohol levels and oral fluid samples for detecting drug use and surveys at entrance and exit. Retention for the sample was 88% at exit. Recruitment and data collection occurred outdoors with a data collection site adjacent to the entrance to the club. Participants provided informed consent, and all study procedures were approved by the Pacific Institute for Research Evaluation's Institutional Review Board.

d. Survey and Randomization Procedures

Once patrons agreed to participate in the study, each participant was given a unique number on a wrist band that allowed matching of individuals within a group and entrance/exit data. No names were collected to provide anonymity.

Computer tablets were handed to each participant to complete the entrance survey. Oral fluid samples for drug analyses and breath tests for determining blood alcohol level were collected during this time by trained research staff. Groups were randomly assigned to either experimental or control after the data for the entire group was collected at baseline. At this point, the research assistant was made aware of the random assignment to either experimental or control condition for the group. Randomization was determined by a randoms number table that determine whether the first group was experimental or control. Given that multiple groups were recruited simultaneously, the supervisor was tracking the assignments of condition and alerting the research assistants as to this assignment. The experimental condition consisted of the Nightlife Safety Plans (NSP) intervention described above. The control condition was given the Fire safety information described above. Given that both the experimental and control group conditions focused on safety in the club, we did not disclose to the participants which safety intervention was under investigation in this study. Once the group finished, they were given an incentive ($15) and reminded that we would complete a survey when they exited the club with an additional incentive ($25) offered. As patrons exited the club, they were surveyed again, using the same procedures established at entrance.

e. Measures

Primary Outcomes:

Number of Protective actions to keep the Group Safe: For each individual, five types of actions were assessed related to identifying a potential problem (observing overuse, physical, or sexual aggression) for a friend: There were 5 possible actions to keep their group members safe that were assessed at exit from club (checked in with friends to assess safety during evening, monitored group members alcohol consumption, encouraged pacing drinking, discouraged drug use, encouraged steps to sober up).

Protective action reported for physical aggression incident: Among those who experienced physical aggression, the prevalence of a group member taking action(s) to intervene was reported.

Protective action reported for sexual aggression incident: Among those who experienced sexual aggression, the prevalence of a group member taking action(s) to intervene was reported.

Secondary outcomes

Legally intoxicated: Breathalyzer readings were recorded and all participants who were at a reading of .08 % alcohol or higher, were considered to be legally intoxicated.

Prevalence of recreational drug use: Oral fluid samples were sent to an outside laboratory for analyses. Substances were assayed into the following seven categories (1) tetrahydrocannabinol (THC); (2) cocaine-including benzoylecgonine, cocaethylene, norcocaine; (3) amphetamine/3,4-methylenedioxy-methamphetamine(MDMA), including methamphetamine, methylenedioxyamphetamine (MDA), and methylenedioxyethylamphetamine(MDEA); (4) opiates/analgesics, including morphine, codeine, oxymorphone,6 a.m., hydrocodone, hydromorphone, and oxycodone; (5). methadone; (6). phencyclidine (PCP); and (7). ketamine. Any drug use was considered positive for drug use.

Leaving club with Friends arrived with: At exit, participants were asked if they were leaving the club with the same group of friends with whom they arrived.

Other Pre-Specified outcomes

Experienced sexual aggression: While at the club, the respondent was asked if someone touching them sexually in a way that they did not want to be touched or did something else sexual to the respondent that they did not want them to do

Experienced physical aggression: While at the club, respondent was asked if someone intentionally pushed, shoved, or punched

Experienced sexual harassment: While at the club, respondent was asked if sexually came on to them after indicating no interest

f. Sample characteristics

The average age of participants was 28 years and 43% were female. A fifth of the sample identified as Hispanic or Latino and racial characteristics were as follows: 44% white, 21% Asian, 18% unknown or not reported, 8% Black, 7% more than one race, 2% Native Hawaiian or other Pacific Islander, 1% American Indian or Alaska Native.

g. Analyses

Number of Protective actions to keep the Group Safe: These items were summed to create an index of protective actions for each individual. Then an average score was created within the group based upon the scores of each group member divided by the number of individuals in the group. This provided an overall indicator of how safe the group was because of the collective action of the members.

Protective action reported for physical aggression incident: Among those who experienced physical aggression, the percent who reported some protective action by a member of their group was reported.

Protective action reported for sexual aggression incident: Among those who experienced sexual aggression, the percent who reported some protective action by a member of their group was reported.

Legally intoxicated: Percent who were legally intoxicated (BAC.08% or higher). Breath samples provided an estimate of the blood alcohol concentration (BAC) and the MarkV Alcovisor (PAS Systems International, Fredericksburg VA) was used to obtain the breath samples. The estimate of the BAC is presented as measured by this device. Given the short window of time (average of 1 hour 54 minutes, SD=1 hour, 3 minutes) that persons were in the club, only exit BAC is used to reflect drinking and this represents a cumulative total for the evening. Level of intoxication reported which reflects the legal standard of BAC= 0.08% or higher.

Prevalence of recreational drug use: Any use of recreational drugs present in oral fluid tests based upon lab results. Laboratory analyses were conducted using the Quantisal collection device (Immunalysis Corporation, Pomona, CA) to assess the following drug categories: (a)Tetrahydrocannabinol (THC); (b) cocaine, including benzoylecogonine, coaethylene, and norcocaine; (c) amphetamine/e, 4 methylenedioxy-methamphetamine (MDMA), methamphetamine, methylenedioxy-amphetiamen (MDA), and methylenedioxyethylamphetamine (MDEA); (d) opiates/analgesics, including morphine, codeine, oxymorphone, 6-acetylmorphine, hydrocodone, hydropmophone, and oxycodone; (3) methadone; (f) phycyclidine (PCP), and (g) ketamine. Self-report of GHB was also assessed (no lab tests were available for this drug). The prevalence of any drug use at exit from the club was created.

Physical Aggression experienced: Participants were asked at the exit survey whether anyone had intentionally pushed, shoved, or punched you while at the club during the evening.

Sexual aggression experienced: Participants were asked at the exit survey whether anyone had touched you in a sexual way that you did not want or do something else sexual to you that you didn't want them to do.

Leaving club with friends arrived with: The prevalence of the safety action to leave the club with the same friends with whom they arrived.

Females comprised 45.3% of the sample. Ethnicity/race was as follows: 44.2% White, 21.5% Asian, 7.9% African American, 1.7% Pacific Islander, 1.3% Native American, 7.1%

multiracial, 6.8% other, and 9.5% unknown. Slightly more than a fifth (21.1%) were Hispanic. The average age was 27.99 years (SD=6.35). The average group size was 3.38 persons (SD1.43).

Descriptive analyses were conducted for the overall group and for the experimental and control groups. To account for the clustering within event and group, mixed-model regressions in SPSS were used to test simple effects of the intervention on continuous background variables. Parallel models were conducted for categorical background variables using Mplus Version 7 (Muthen & Muthen, 1998-2015).For key outcomes, multilevel models via mixed-model regressions in SPSS 21 were conducted to account for nesting by event and group. Analyses used an intent-to-treat approach to examine assignment to the intervention as a predictor, controlling for background variables, history of drinking/other drug use and risk level. Listwise deletion was used for missing cases.

IV. Assessment of Efficacy-Overview

Exposure to the intervention, NSP, significantly increased the number of safety actions taken within the group to protect others in their group from the unintended consequences from behaviors and experiences in the club that evening related to alcohol use and drug use (Byrnes, Miller, et al., 2019a). The study found that group cohesion related to fewer safety strategies being used and that group cohesion was unrelated to AOD use (Byrnes, Miller, et al., 2019b). This suggests that more risk taking behavior may occur when groups are familiar and comfortable with each other, possibly lowering their sense of risks. The relatively low rates of experiencing physical and sexual aggression impacted the power of the intervention to assess protective actions related to physical or sexual incidents that occurred in the evening. Although the main focus of the intervention was on taking actions to reduce harms, there was also an impact on a secondary outcome related to alcohol use. For participants exposed to NSP, there was a significantly lower BAC at exit. Prevalence of recreational drug use was not impacted by the intervention but prior research (Miller et al., 2013b) indicates that few club patrons (<6%) convert from no drug use at entry to drug use at exit, indicating that recreational drug use has already been initiated prior to coming to the club. The intervention did not significantly alter the rates of physical or sexual aggression while at the club. However, aggression experiences are less under the control of the participants as persons outside the group can be the offender in these incidents. Thus, the group can respond and de-escalate the impact of the aggression but may not be effective at keeping aggressive incidents from happening. Finally, participants exposed to the intervention were significantly more likely to leave as a group and “stick together.” Given that the intervention was focused on promoting looking after each other for the evening,

this was an important safety impact. There are anecdotal reports of individuals leaving the club with someone they just met or being assaulted while traveling home by themselves. However, data on the prevalence of this type of experience is not available from prior studies or this study.

Interpretation of the findings need to take into consideration that NSP was designed to impact the participants for the single evening at a club. It is unknown whether providing this type of brief intervention in real world settings could facilitate a more widespread adoption of these basic strategies as part of club safety behaviors adopted by patrons. It is unknown how the single exposure to the intervention might impact subsequent trips to a nightclub. It is unknown whether a single individual exposed to the intervention might practice any of the skills in other social groups in future evenings at a nightclub. The study has limitations introduced by only being conducted in one geographic location but the results are made more robust by the diversity of race/ethnicities, genders, gender identities, and ages represented in this sample.

V. Assessment of Safety (Adverse events, ethics)

There were no serious adverse events or adverse events connected to the intervention.

VI. Citations in this summary

Boekeloo, B.,& Griffin, M. (2009). Collegiates' intention and confidence to

intervene into others' drinking. *American Journal of Health Behavior*, 33, 91–100. doi:10.5993/AJHB.33.1.9

Boekeloo, B. O., Novik, M. G., Bush, E. N.,& O'Grady, K. E. (2009). Impact of the "peers as family" dormitory wing-based intervention on college student alcohol use and its secondhand effects. *Journal of Drug Education*, 39, 339–359. doi:10.2190/DE.39.4.a

Byrnes, H. F., Miller, B.A., Bourdeau, B., Johnson, M. B., & Voas, R. B. (2016). Drinking group characteristics related to willingness to engage in protective behaviors with the group at nightclubs. *Psychology of Addictive Behaviors*, 30, 168–174. doi:10.1037/adb0000142

Byrnes, H.F., Miller, B.A., Bourdeau, B., Johnson, M.B., Buller, D.B., Berteletti, J. &Rogers, V.A. (2019a). Prevention of Alcohol and other drug overuse among nightclub patrons: A Randomized trial of a group-based mobile intervention at nightclubs. *Journal of Studies on Alcohol and Drugs,* 80(4); 423-430. doi: 10.15288/jsad.2019.80.423. PubMed ID: 31495379

Byrnes HF, Miller BA, Bourdeau B, Johnson MB. Impact of Group Cohesion Among Drinking Groups at Nightclubs on Risk From Alcohol and Other Drug Use. J Drug Issues. 2019b Oct;49(4):668-679. doi: 10.1177/0022042619859257. Epub 2019 Sep 8. PubMed ID: 34658404

Dumas, T. M., Wells, S., Flynn, A., Lange, J. E., &Graham, K. (2014). The influence of status on group drinking by young adults: A survey of natural drinking groups on their way to and from bars. *Alcoholism: Clinical and Experimental Research,*38, 1100-1107. doi:10.1111/acer.12314

Johnson, M. B.,Voas,R.B., & Miller,B.A.(2012). Driving decisions when leaving electronic music dance events: Driver, passenger, and group effects. *Traffic Injury Prevention*, 13, 577–584.doi:10.1080/1538958 8.2012.678954

Miller, B.A., Bourdeau, B., Johnson, M., &Voas, R. (2015).Experiencing aggression in clubs: Social group and individual level predictors. *Prevention Science*,16, 527–537. doi:10.1007/s11121-014-0494-y

Miller, B.A., Byrnes, H. F.,Branner, A., Johnson, M., & Voas, R.(2013a). Group influences on individuals' drinking and other drug use at clubs. *Journal of Studies on Alcohol and Drugs*, 74, 280–287. doi:10.15288/jsad.2013.74.280

Miller, B.A., Byrnes, H. F.,Branner, A.C., Voas, R., &Johnson, M. B. 2013b). Assessment of club patrons' alcohol and drug use: The use of biological markers. *American Journal of Preventive Medicine*,45, 637â€“643. doi:10.1016/j.amepre.2013.06.014

Miller, B.A., Furr-Holden, D., Johnson, M. B., Holder,H., Voas, R., & Keagy,C.(2009). Biological markers of drug use in the club setting. *Journal of Studies on Alcohol and Drugs*, 70, 261–268. doi:10.15288/jsad.2009.70.261

Muthén, L. K., & Muthén, B. O. (1998–2015). MPlus user'sguide (7th ed.).

Los Angeles, CA: Authors.

O'Grady, M.A., Cullum, J., Tennen, H., &Armeli, S. (2011). Daily relationship between event-specific drinking norms and alcohol use: A four-year longitudinal study. *Journal of Studies on Alcohol and Drugs*, 72, 633–641. doi:10.15288/jsad.2011.72.633

Phua, J. (2011). The influence of peer norms and popularity on smoking and drinking behavior among college fraternity members: A social network analysis. *Social Influence*,6,153-168. doi:10.1080/1553451 0.2011.584445
i.org/10.1177/0163278717742189