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STUDY PROTOCOL

Effects of alcohol consumption on emotion recognition

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Background Information

Alcohol is often consumed in social settings whilst in the company of others. Recent research has begun to examine the effects of acute alcohol consumption on the processing of socially relevant information such as facial expressions, as it may play a role in the changes in social interaction associated with alcohol consumption (e.g., increased aggression) (Attwood & Munafo, 2014; Hoaken, Giancola, & Pihl, 1998; White, 1997; Yudko, Blanchard, Henrie, & Blanchard, 1997). Recent research has indicated that acute alcohol consumption decreases sensitivity to recognising sad facial expressions (Craig, Attwood, Benton, Penton-Voak, & Munafo, 2009) and increases the likelihood of perceiving anger in ambiguous facial morphs (Attwood, Ataya, Benton, Penton-Voak, & Munafo, 2009). To date this research is limited, with studies only examining the effects of alcohol on a small number of emotions.

We recently explored the effect of acute alcohol consumption (0.4 g/kg) on emotional face processing using a task that presents all six primary emotional expressions (i.e., anger, sadness, happiness, surprise, disgust and fear). We found no difference between alcohol and placebo in accuracy of emotional identification, but there were greater false alarms for anger after alcohol compared to placebo (i.e., individuals were more likely to erroneously label a non-angry face as angry). In addition, alcohol consumption was associated with fewer false alarms for happiness compared to placebo. The current study will attempt to replicate these findings using the same six alternative forced-choice task (6AFC). In addition, this study will include a two alternative forced choice task (2AFC) presenting angry and happy facial morphs, to investigate whether there is a bias towards the identification of anger after acute alcohol consumption.

Study Objective and Hypotheses

To replicate preliminary work on the effects of acute alcohol consumption on emotional face processing.

H1: Acute alcohol consumption will result in more false alarms for anger compared to placebo.

H2: Acute alcohol consumption will result in fewer false alarms for happiness compared to placebo.

Study Design

This is a double-blind placebo-controlled study, which comprises one between-subjects factor of drink (0.4 g/kg alcohol, placebo). For the 6AFC task, there will be an additional within-subjects factor of emotion (happy, sad, angry, disgust, surprise, fear). The primary dependent variables will be accuracy and false alarms in the 6AFC task, and threshold in the 2AFC task. As 6AFC data are the primary outcome, the 6AFC task will be completed first for all participants. To investigate the subjective effects of alcohol, additional measures of intoxication and mood will be taken (see materials section) before and after drink consumption, and an additional factor of time (pre-inhalation, post-inhalation) will be included in the relevant analyses.

Study Site

School of Experimental Psychology, 12a Priory Rd, University of Bristol, United Kingdom.

Participants and Recruitment

Male and female weekly alcohol drinkers (n = 192; 50% male) will be recruited from the staff and students at the University of Bristol, and the general population. Participants will attend one session of approximately 60 minutes. Participants will be recruited by existing email lists and poster and flyer advertisements, and by word of mouth. They will be asked to contact the researcher for further details of the study if they are interested in taking part. Those who meet the study inclusion criteria will be sent the information sheet, and asked to contact the researcher again if they would like to sign up for the study or if they require further information. Participants will be required to not drink alcohol 24 hours prior to the study session. On completion of the study, participants will be reimbursed £5.

Inclusion criteria

- Aged between 18-40 years
- Weekly alcohol drinkers (between 5-35 and 10-50 units*/week if female and male respectively)
- English as first language or equivalent level of fluency

* One unit equals one 25ml single measure of spirit (ABV 40%), or a third of a pint of beer (ABV 5-6%) or half a standard (175ml) glass of red wine (ABV 12%).

Exclusion criteria

- Alcohol consumption less than 24 hours prior to the study
- Weight less than 50 kg if female or 60 kg if male
- Strong familial history of alcoholism defined as one or more immediate relative (parent, sibling) or more than one other relative (e.g., cousin, grandparent)
- History of psychiatric disorder (including drug addiction)
- Uncorrected visual impairment
- Uncorrected auditory impairment
- Potential, in the opinion of the investigator, to be non-compliant with the study or unable to give informed consent

Sample size determination

Sample size was determined from an effect size obtained in the previous study investigating the effects of acute alcohol consumption on emotional processing. This study indicated an effect size of $d = 0.41$ for the comparison between alcohol ($M = 4.8$, $SD = 4.2$) and placebo ($M = 3.2$, $SD = 3.6$) on angry false alarms. Based on these data, we require a sample size of 190 in order to achieve 80% power at an alpha level of 5%. In order to maintain equal numbers of male and female participants in drink groups we will recruit 192 participants.

Randomisation

Participants will be randomly assigned to the alcohol or placebo group. Equal numbers of participants per group will be maintained and groups will be stratified by sex. In advance of the study, an experimental collaborator will prepare a numeric randomisation code using random number assignment software.

Measures

Computerised tasks: The images used in both tasks are composite (i.e., prototypical) images created from photographs of 12 young male adults photographed under controlled conditions. Each trial in both tasks begins with a centrally-displayed fixation cross. A 350 × 457 pixel face stimulus is then presented for 150 ms, followed by a noise mask for 250 ms in order to prevent after-image effects. Tasks are run using E-Prime 2.0 Pro software, on a standard computer with a QWERTY keyboard.

In the six alternative forced choice task (6AFC), six 15-image morph sequences have been created, one for each emotion (happy, sad, angry, disgusted, fearful, surprised). These run along a linear continuum from a neutral (i.e., emotionally ambiguous) prototype to the full emotional intensity. On each trial, participants are required to identify the emotion represented in the face as quickly and as accurately as possible, by using the mouse to click on the most appropriate descriptor from an array of descriptors displayed on-screen (fearful, angry, happy, sad, disgusted and surprised). The descriptor array appears on-screen for 10,000 ms, or until the participant responds. Each image is presented once, giving 90 trials in total.

In the two alternative forced choice task (2AFC), one 15-image morph sequence has been created, which runs from one full emotional exemplar to another (i.e., unambiguously happy to unambiguously angry). The full exemplar images are used as endpoints to create a linear morph sequence of emotionally ambiguous images that change incrementally from happy to angry. On each trial, participants are required to identify whether the emotion in the face is happiness or anger, by pressing designated keys on the keyboard. Each image is presented three times, giving 45 trials in total.

Questionnaires: The questionnaire measures will include the Alcohol Urges Questionnaire (AUQ) (Bohn, Krahn, & Staehler, 1995), Positive and Negative Affect Schedule (PANAS) (Watson, Clark, & Tellegen, 1988), Biphasic Alcohol Effects Scale (BAES) (Martin, Earleywine, Musty, Perrine, & Swift, 1993) and Alcohol Use Disorders Identification Test (AUDIT) (Saunders, 1993).

Procedures

Participant screening and baseline assessments: On arrival, participants will be given the opportunity to read the information sheet again, and will provide written informed consent. The researcher will run through a short screening procedure to verify eligibility. Participants will be weighed and then complete questionnaire measures (AUDIT, PANAS, BAES, AUQ).

Participants will then be randomised to receive either an alcoholic or non-alcoholic drink. The alcoholic drink will be 0.4 g/kg alcohol (vodka) with one part vodka and three parts tonic water. The placebo beverage will comprise an equal volume of tonic water. All drinks will be flavoured with lime cordial and chilled prior to serving and the rim of the glass will be sprayed with an alcohol mist. Drinks will be made by a research collaborator and therefore administered double blind. This collaborator will also produce an unblinding envelope that will be passed to the researcher with the drink, which will enable the researcher to inform the participant of their drink allocation at the end of the session. Participants will be given 10 minutes to consume all of their drink and a further 10 minutes to sit quietly to allow for absorption. After drink consumption, participants will complete the two computer tasks (see below) and then questionnaire-based measures of mood (PANAS), intoxication (BAES), and alcohol urges (AUQ). Finally, participants will be asked to give another breath alcohol reading before being debriefed and reimbursed.

Table 1. Timings of procedures of testing session

Time (minutes post arrival)	Task
0	Informed consent and screening
15	Questionnaire measures (4)
20	Drink administration
40	Task 1 – Emotional 6AFC
50	Task 2 – Emotional 2AFC
55	Questionnaire measures (3)
60	Debrief and depart

Statistical Plan

Analysis of the questionnaire scores will be conducted using mixed model ANOVAs with alcohol consumption (alcohol vs. placebo) as a between-subjects factors and time as a within subjects factor (before alcohol consumption, after alcohol consumption). Emotional task data from both tasks will also be analysed using ANOVAs with alcohol consumption as a between-subjects factor. The 6AFC task will have an additional within-subjects factor of emotion.

Ethical Considerations and Informed Consent

Ethics approval has been obtained from the Faculty of Science Research Ethics Committee at the University of Bristol. The study will be conducted according to the revised Declaration of Helsinki (2013) and good clinical practice guidelines. The investigator will explain the nature, purpose and risks of the study to the participant. The participant will receive the information sheet in advance of the study session. There will be no time restriction on how long participants take to respond, with the exception that participants who respond after all study places have been filled will not be offered a place on the study. Therefore, participants will be given sufficient time to read the information and consider any implications, and to raise any questions with the investigators prior to making a decision to participate. On arrival at the study session participants will be given the opportunity to read the information sheet again and ask the investigator any questions. Written consent will then be obtained. Participants will be informed that they are free to withdraw at any time.

Data Management

All aspects of the Data Protection Act will be adhered to. Consent forms will be retained by the School of Experimental Psychology. In the event that a participant revokes authorisation to collect or use personal health information, the investigator retains the ability to use all information collected prior to the revocation of participant authorisation.

Anonymised study data

The case report forms and data will be anonymised by a unique numeric identifier and stored in a locked office. All data requested on the CRF will be recorded. All missing data will be explained. If any entry errors are made, a single straight line will be drawn through the incorrect entry and the correct data entered above it; to correct such an error. All such changes will be initialled and dated. Once data from CRFs have been inputted into a data spreadsheet they will undergo a reliability check (20% check by independent researcher). After the data have been positively assessed, the CRFs will be destroyed in the School's confidential waste facility.

Original computer data files will be backed up immediately on a secured University of Bristol network drive. At the end of the electronic study data (including finalised data sheet) will be transferred to a designated University of Bristol Research Data Storage Facility. Study data will be kept for 5 years post study closure. At the appropriate time the data sheet will be locked and made open using the University of Bristol Data Repository.

Screening documents and participant contact details

Screening documents and participant names and contact details will be stored separately in a study master folder and kept confidential. These will be kept in the study master folder for one year post study completion, after which these documents will be destroyed. Failed screening documents will be shredded immediately using School's confidential waste facility.

Revoked data

If a participant decides that they do not want their data used after their participation they have the right to request that the data are withdrawn. They can request this up to one year post study completion or until the data are made open (whichever comes first). At this time links between participant identity and anonymised data set will be destroyed.

Safety

Half of the participants will be administered alcohol during the session. The dose will be 0.4 g/kg of body weight up to 90 kg. Participants weighing more than 90 kg will receive a dose based on 90 kg. This dosing will administer drinks ranging between around 2.5 to 4.5 units of alcohol (for weight ranges between 50-90 kg). We expect that at this dose, participants will feel some effects of alcohol but we do not expect high levels of intoxication. However, to ensure the safety of our participants, they will know in advance of the study that they may receive this dose of alcohol, and therefore will be able to make any necessary arrangements. They will also be unblinded at the end of the test session as to whether they received alcohol or not and the risks of alcohol will be reiterated. They will be advised that should stay behind until they feel the effects of alcohol have worn off and they shouldn't drive, operate heavy machinery or do anything that would be considered unsafe after drinking alcohol for the rest of the day. Participants who have received alcohol will be asked to read and sign a post-study safety form to confirm that they understand these risks. We have standard operating procedures in place for adverse effects of alcohol (i.e., nausea, intoxication) and have facilities for people to stay behind until they feel ready to leave. We will also offer a taxi home to all participants that have received alcohol.

Quality Control and Quality Assurance

The investigators will be responsible for data quality. After approximately 10% of data collection has been completed, the study will undergo an in-house quality assessment. During this monitoring process all CRFs and study documents will be assessed as well as the investigators laboratory management and participant engagement, and corrected where necessary.

Insurance

This study will be sponsored by the University of Bristol. The University has Clinical Research Insurance to cover the liability of the University to research participants. In the event that something goes wrong and a participant is harmed during the research

study there are no special compensation arrangements. If a participant is harmed and this is due to someone's negligence then they may have grounds for a legal action for compensation against Bristol University or other parties to the research, but they may have to pay their own legal costs.

Publication Policy

The findings from this research study may be published in an appropriate scientific journal (and made available open access), and/or presented at an appropriate meeting. Study data will be collected and held by the study investigators. The data will be made available for sharing via a University of Bristol online data repository.

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References

Attwood, A. S., Ataya, A. F., Benton, C. P., Penton-Voak, I. S., & Munafo, M. R. (2009). Effects of alcohol consumption and alcohol expectancy on the categorisation

of perceptual cues of emotional expression. *Psychopharmacology (Berl), 204*(2), 327-334. doi: 10.1007/s00213-009-1463-1

Attwood, A. S., & Munafo, M. R. (2014). Effects of acute alcohol consumption and processing of emotion in faces: Implications for understanding alcohol-related aggression. *J Psychopharmacol, 28*(8), 719-732. doi: 10.1177/0269881114536476

Bohn, M. J., Krahn, D. D., & Staehler, B. A. (1995). Development and Initial Validation of a Measure of Drinking Urges in Abstinent Alcoholics. *Alcoholism-Clinical and Experimental Research, 19*(3), 600-606. doi: DOI 10.1111/j.1530-0277.1995.tb01554.x

Craig, L. C., Attwood, A. S., Benton, C. P., Penton-Voak, I. S., & Munafo, M. R. (2009). Effects of acute alcohol consumption and alcohol expectancy on processing of perceptual cues of emotional expression. *J Psychopharmacol, 23*(3), 258-265. doi: 0269881108092126 [pii]10.1177/0269881108092126

Hoaken, P. N., Giancola, P. R., & Pihl, R. O. (1998). Executive cognitive functions as mediators of alcohol-related aggression. *Alcohol Alcohol, 33*(1), 47-54.

Martin, C. S., Earleywine, M., Musty, R. E., Perrine, M. W., & Swift, R. M. (1993). Development and validation of the Biphasic Alcohol Effects Scale. *Alcohol Clin Exp Res, 17*(1), 140-146.

Saunders, J. B., O. G. Aasland, T. F. Babor and M. Grant (1993). Development of the alcohol use disorders identification test (AUDIT): WHO collaborative project on early detection of persons with harmful alcohol consumption-II *Addiction, 88*(6), 791-804.

Watson, D., Clark, L. A., & Tellegen, A. (1988). Development and validation of brief measures of positive and negative affect: the PANAS scales. *J Pers Soc Psychol, 54*(6), 1063-1070.

White, H. R. (1997). Longitudinal perspective on alcohol use and aggression during adolescence. *Recent Dev Alcohol, 13*, 81-103.

Yudko, E., Blanchard, D. C., Henrie, J. A., & Blanchard, R. J. (1997). Emerging themes in preclinical research on alcohol and aggression. *Recent Dev Alcohol, 13*, 123-138.