School of Experimental Psychology
12a Priory Road
BRISTOL BS8 1TU
United Kingdom

Tel: +44 (0)117 331 0495
Email: a.eastwood@bristol.ac.uk
www.bristol.ac.uk

STUDY PROTOCOL

Effects of alcohol consumption on emotion recognition in high and low trait aggressive drinkers

Andy Eastwood, Ian S. Penton-Voak, Marcus Munafò & Angela Attwood

Background

Recent research indicates that acute alcohol consumption can alter the processing of emotional facial expressions. It has been suggested that this may be a mechanism underlying the changes in social interaction associated with alcohol consumption (e.g., increased aggression) (Attwood & Munafo, 2014). It is widely acknowledged that emotional expressions are a fundamental component of effective social interaction and social functioning (Kemper, 1978; Lewis, Haviland-Jones, & Barrett, 2008; Oatley & Johnson-Laird, 1996), and are capable of guiding behaviour (Eisenberg et al., 1989; Klinnert, 1983; Marsh, Kozak, & Ambady, 2007). Therefore, it is likely that alcohol-related changes in emotional processing will influence behaviour. For example, a tendency to perceive hostility in others will increase the likelihood of an aggressive response (Dodge, 2006). This in turn may be reciprocated, which validates the viewer's erroneous evaluation, and perpetuates a vicious of cycle of negative emotional evaluation and responding.

Increased bias towards perceiving angry faces (in ambiguous negative facial morphs) has been reported following acute alcohol consumption (Attwood, Ataya, Benton, Penton-Voak, & Munafo, 2009). This altered processing is likely to have a meaningful impact on behaviour, as a bias towards seeing anger will increase perceived provocation, which is a primary driver of aggression (Giancola et al., 2002). In addition, research has demonstrated a decreased sensitivity towards perceiving sadness following acute alcohol consumption (Craig, Attwood, Benton, Penton-Voak, & Munafo, 2009). This has further implications for alcohol-related aggression, as sadness is an indicator of submission (Hart, 2011), which may curtail aggression. More recent (currently unpublished) data from our group has found weak evidence supporting an anger bias after alcohol consumption, but effect sizes are small. The majority of this research has been conducted using unselected samples

(i.e., social drinkers). It is important to consider individual differences amongst alcohol consumers as only a small proportion of alcohol consumers reliably display alcohol-related aggression (Attwood & Munafo, 2014).

It is well established that higher levels of trait aggression are predictive of alcohol-related aggression after provocation (Bailey & Taylor, 1991; Eckhardt & Crane, 2008; Giancola, 2002; Giancola, Godlaski, & Parrott, 2005; Giancola et al., 2002; Giancola & Zeichner, 1995; Miller, Parrott, & Giancola, 2009; Moeller, Dougherty, Lane, Steinberg, & Cherek, 1998; Tremblay, Graham, & Wells, 2008). Furthermore, sober individuals high in self-reported aggression are more likely to misidentify anger in facial cues (Hall, 2006). Therefore, it is reasonable to speculate that alcohol may exacerbate these effects in high trait aggressive individuals, which in turn may contribute to the higher levels of alcohol-related aggression in these groups.

This study will investigate the effects of alcohol consumption on emotional face processing in social alcohol drinkers who are either high or low in trait aggression. Emotion recognition of six emotions (happy, sad, angry, disgust, surprise and fear) will be measured using a six-alternative forced choice (6AFC) task. In addition, two-alternative forced choice (2AFC) tasks presenting angry-happy and happy-sad emotional morphs will be used to test bias in the interpretation of ambiguous emotional expressions.

Study Objective and Hypotheses

To investigate the effects of acute alcohol consumption on emotional face processing in social alcohol drinkers who are either high or low in trait aggression.

H1. There will be lower emotional processing accuracy (i.e., total hit rate) following acute alcohol consumption compared to placebo (6AFC task).

H2. There will be an increase in anger perception (i.e., increased hit rate and false alarms towards angry emotions) following acute alcohol consumption compared to placebo (6AFC task).

H3. There will be a decrease in sadness perception (i.e., decreased hit rate and false alarms towards sad emotions) following acute alcohol consumption compared to placebo (6AFC task).

H4. There will be a greater bias towards angry emotional expressions (i.e., greater threshold change in favour of anger) following acute alcohol consumption compared to placebo (happy-angry 2AFC task).

H5. There will also be a reduced bias towards sad emotional expressions (i.e. greater threshold change in favour of happy) following acute alcohol consumption compared to placebo (happy-sad 2AFC task).

Study Design

This is a placebo-controlled experimental study, which comprises one within-subjects factor of drink (0.4 g/kg alcohol, placebo) and one between-subjects factor of trait

anger (high, low). For the 6AFC task (see Measures and Materials), there will be an additional within-subjects factor of emotion (happy, sad, angry, disgust, surprise and fear). The primary dependent measures will be hit rate and false alarms (6AFC task) and threshold response (2AFC tasks). We will also take subjective measures of state aggression, mood and intoxication. For these outcomes, there will an additional within-subjects factor of time (pre-consumption, post-consumption).

Study Site

School of Experimental Psychology, 12a Priory Road, Bristol University, Bristol BS8 1TU.

Participants and Recruitment

Male and female social alcohol drinkers (n = 88; 50% male) will be recruited from the staff and students at the University of Bristol, and the general population. Participants will attend two sessions of approximately 75 minutes each. Participants will be recruited by existing email lists, 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 initial study inclusion criteria will be asked to complete a short online screening questionnaire. Participants that are eligible 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 from the general population will be reimbursed £20 or equivalent course credits (if eligible).

Inclusion criteria

- Good physical and psychiatric health (self-report)
- Drinks between 5 and 35 alcoholic units* per week if female or between 10 and 50 alcoholic units* per week if male
- Aged between 18 and 40 years
- Be high or low in trait aggression, defined by a score above 41 and below 32 on the Anger Expression Index subscale of the State-Trait Anger Expression Inventory–2 (STAXI-2), respectively.
- Speaks English as first language or equivalent level of fluency
- Able to attend two sessions, at least one week apart

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

Exclusion criteria

- Alcohol consumption less than 24 hours prior to the study sessions
- 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) (self-report)
- History of psychiatric disorder (including drug addiction) (self-report)

- Uncorrected visual impairment
- Uncorrected auditory impairment

Sample size determination

A sample size calculation based on previous findings from a study using a between-subjects design (Craig et al., 2009) indicates an effect size of d = 1.0 for the difference between alcohol and placebo on sadness recognition (M = 0.14, SD = 0.02; M = 0.12, SD = 0.02, respectively). These data indicate that we require a total sample size of 46 participants to achieve 90% power at an alpha level of 5%. As we are including a between-subjects factor, we plan to recruit sufficient numbers in each group to achieve this level of power to observe a main effect of alcohol. However, as this is likely to be an inflated effect size, we used a more conservative effect size estimate of d = 0.7. Based on this estimate, 88 participants would be required in each drink condition in a between-subjects design to achieve 90% power at an alpha level of 5%. However, as our alcohol/placebo condition will be within-subjects, we consider this a conservative estimate for our study, as we are using a within-subject design that will be lessit will be subject to less individual variation. We will recruit 44 participants per trait group (total n = 88). This would achieve 90% to detect an effect size of dz = 0.5 (alcohol vs. placebo) within each trait group. Interaction analyses will be exploratory.

Withdrawal of participants

Participants will be informed that they can withdraw from the study at any time. If participants withdraw from the study due to an adverse event or reaction, they will receive full reimbursement (£20 or equivalent course credits). For all other withdrawals (i.e., not related to an adverse event or reaction), participants will be reimbursed an amount commensurate with the time spent in the laboratory.

Randomisation

Session order (i.e., alcohol vs. placebo) will be counterbalanced with equal numbers of participants in each order group. Participant numbers will be allocated session orders in advance of the study using random number generator software (www.randomizer.org).

Measures and Materials

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, disgust, surprise and fear). These run along a linear continuum from a neutral (i.e., emotionally ambiguous) prototype to the full emotional intensity. On each trial, a single image from the 90

available is presented for 150ms (backward masked), and 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 (happy, sad, angry, disgust, surprise and fear). The descriptor array appears on-screen for 10,000 ms, or until the participant responds. Each image is presented twice, giving 180 trials in total.

In addition, a happy-angry and a happy-sad two-alternative forced choice task (2AFC) will also be run. For each of these tasks, a 15-image morph sequence has been created, which runs from one full emotional exemplar to another (i.e., unambiguously happy to unambiguously angry / unambiguously happy to unambiguously sad). 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 in one task version and happy to sad in the other. On each trial of the happy-angry 2AFC task, a frame from this morph continuum is presented for 150 ms (backward masked), and participants are required to identify whether the emotion in the face is happiness or anger, by pressing designated keys on the keyboard. On each trial of the happy-sad 2AFC task, a frame from this morph continuum is presented for 150 ms (backward masked), and participants are required to identify whether the emotion in the face is happiness or sadness. Each image is presented three times, giving 45 trials in total for each 2AFC task.

Questionnaires: Trait aggression will be measured using the anger expression index subscale (AXi) of the State-Trait Anger Expression Inventory (STAXI-2) (Spielberger, 1999). This is a widely-used measure of aggression that has been validated on a variety of normal and clinical samples (Forgays, Forgays, & Spielberger, 1997). Normative data for the STAXI-2 scale are based on samples of normal adults (n=1,644) ranging from 16-63 years old; these data shows a mean score of 32.9 (SD = 13.4) for the AXi subscale. High and low trait groups will be defined by a score above the 60th percentile and below the 40th percentile on this subscale, respectively.

Other questionnaire measures will include the State Anger Subscale (S-Ang) of the STAXI-2 (Spielberger, 1999), 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, Aasland, Babor, Delafuente, & Grant, 1993).

Procedure

Prior to testing, participants will complete the STAXI-2 online. Only individuals that meet the high/low trait anger inclusion criteria will be invited to participate. On arrival at the first session, participants will be given the opportunity to read the information sheet again and ask questions, before providing written informed consent. The researcher will conduct a short screening procedure to verify eligibility, which includes taking measures of weight and breath alcohol concentration (BrAC) (only participants with a BrAC of zero will be enrolled). Study documentation from failed screenings will be destroyed using the School's confidential waste facility. If eligible, participants will complete questionnaire measures (AUDIT, PANAS, BAES, S-Ang).

Participants will attend two sessions (order counterbalanced): at one session they will consume an alcoholic drink and at the other they will consume a matched placebo drink (see Drug Administration section for more details). Testing sessions will be held at least one week apart. 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 6AFC and 2AFC tasks. They will then complete questionnaire measures (PANAS, BAES, S-Ang), and a BrAC reading. Before leaving the session, participants will be required to read and sign a safety card, be offered the opportunity to stay behind until they feel any effects of alcohol have worn off and be offered a taxi home. At the end of session two, participants will be debriefed and reimbursed.

Table 1: Testing procedure timeline

Time (min)	**Activity/Task**
0	Informed consent and screening (session one only)
10	Questionnaire measures (AUDIT, PANAS, BAES, S-Ang)
20	Drink administration
30	Alcohol absorption period
40	Computerised tasks
65	Questionnaire measures (PANAS, BAES, S-Ang), BrAC reading
75	Debrief and reimbursement (session two only).

Drug Administration

The alcoholic drink will be 0.4 g/kg alcohol (vodka) with one part vodka and three parts tonic water. The placebo drink will comprise the same volume of tonic. Drinks will be flavoured with lime cordial and chilled prior to serving. The rim of the glass will be sprayed with a vodka mist. Drinks will be served double blind and will be made at the start of each session by a research collaborator.

Statistical Plan

Computerised Tasks: Total hits and thresholds will be assessed for outliers using boxplots. Participant data will be removed if scores are 1.5 times greater than the interquartile range. Data will also be assessed for Normality using skewness and kurtosis statistics. Where Mauchly's Test of Sphericity is $p < .05$, Greenhouse-Geisser corrected statistics will be reported.

For 6AFC analysis, total hits will be analysed using a 2 drink (alcohol, placebo) × 2 aggression (high, low) mixed model ANOVA to test emotion processing accuracy following an acute dose of alcohol. Interactions will be explored in post-hoc analyses using t-tests. To investigate processing accuracy of angry and sad faces following and acute dose of alcohol, emotion specific false alarms and hit rates will also be analysed using 2 drink (alcohol, placebo) × 2 aggression (high, low) mixed ANOVAs; two for anger and two for sadness. The 2AFC data will be analysed using the same statistical model as the 6AFC total hit rate data to investigate whether there is an increased bias towards anger (happy-angry 2AFC) and a reduced bias towards sadness (happy-sad 2AFC) following an acute dose of alcohol. In addition, 6AFC hit rates will also be

analysed using an exploratory 2 drink (alcohol, placebo) × 2 aggression (high, low) x 6 emotion (happy, sad, angry, disgust, surprise, fear) mixed model ANOVA.

Questionnaire data will be analysed using 2 drink (alcohol, placebo) × 2 aggression (high, low) × 2 time (pre-consumption, post-consumption) mixed model ANOVAs. Interactions will be explored in post-hoc analyses using t-tests. Correlations between post-consumption state anger (S-Ang scores) and false alarms/hit rates (6AFC task) will be analysed using simple linear regression models.

Ethical Considerations and Informed Consent

Ethics approval has been obtained from the Faculty of Science Research Ethics Committee at the University of Bristol (approval code: 26011747361). The study will be conducted according to the revised Declaration of Helsinki (2013) and the 1996 ICH Guidelines for Good Clinical Practice E6(R1). 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, consider any implications, and 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 questions. Written consent will then be obtained. Participants will be informed that they are free to withdraw at any time.

Safety

Participants will be administered alcohol during one of the sessions. 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 (all participants will be weekly alcohol consumers). 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 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. Participants will be offered a local taxi at the end of the session.

Adverse Event Reporting

Adverse events or adverse reactions will be documented at the end of the relevant session using an adverse event report, and will be recorded in the CRFs. The adverse event reports will be anonymised by unique study identifier and stored in the master

file. Adverse events or adverse reactions will be followed up until resolved if possible. At the end of the study a safety report will be complied and sent to the Principal Investigator (PI) listing all adverse events and adverse reactions. All procedures related to adverse events will follow the University of Bristol adverse events policies and procedures.

Data Management

All aspects of the Data Protection Act will be adhered to. Consent forms will be retained by the School of Experimental Psychology for a period of 10 years post study completion. 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

Case report forms (CRFs) and electronic data will be anonymised by a unique numeric identifier. CRFs will be 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.

Original computer data files will be backed up on a secured University of Bristol network drive. At the end of the study, electronic study data (including finalised data sheet) will be transferred to a designated University of Bristol Research Data Storage Facility for long-term archiving. Study data will be kept for a minimum of 15 years. At the appropriate time the data sheet will be locked and made open using the University of Bristol Research Data Repository.

Screening documents and participant contact details

Screening documents, participant contact details and participant identifier logs will be stored separately in a study master folder and kept confidential. Following screening, ineligible participant records will be destroyed: online records deleted and hardcopy data shredded using School's confidential waste facility. Those who are eligible but do not enrol on the study sessions will have their records kept for the duration of the study as they may be contacted for participation until the sample target is met, after which these documents will be destroyed. Data obtained from eligible participants will be kept in the study master folder for one year after study completion or until data are made open (whichever comes first), after which these documents will be destroyed.

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 after study completion or until the data are made open (whichever comes first).

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 one of the 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.

Study Personnel

Andy Eastwood
School of Experimental Psychology
5 Priory Rd
Bristol BS8 1TU
Tel: +44 (0)117 331 0495
Fax: +44 (0)117 928 8588
Email: a.eastwood@bristol.ac.uk

Ian Penton-Voak
School of Experimental Psychology
12a Priory Rd
Bristol BS8 1TU
Tel: +44 (0)117 928 8667
Fax: +44 (0)117 928 8588
Email: i.s.penton-voak@bristol.ac.uk

Marcus Munafò
School of Experimental Psychology
12a Priory Rd
Bristol BS8 1TU
Tel: +44 (0)117 954 6841
Fax: +44 (0)117 928 8588
Email: marcus.munafo@bristol.ac.uk

Angela Attwood
School of Experimental Psychology
12a Priory Rd
Bristol BS8 1TU
Tel: +44 (0)117 331 7450
Fax: +44 (0)117 928 8588
Email: angela.attwood@bristol.ac.uk

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