HUMAN PSYCHOPHARMACOLOGY
Hum. Psychopharmacol Clin Exp 2016; **31**: 200–205
Published online 6 April 2016 in Wiley Online Library
(wileyonlinelibrary.com) **DOI**: 10.1002/hup.2529

The effects of alcohol mixed with energy drink (AMED) on subjective intoxication and alertness: results from a double-blind placebo-controlled clinical trial

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Objective The purpose of this double blind placebo controlled study was to examine if specific effects on subjective intoxication and alertness–sleepiness ratings could be demonstrated after consuming alcohol mixed with energy drink (AMED) when compared to consuming alcohol only (AO).
Methods 56 healthy volunteers rated their subjective intoxication on a scale ranging from 0 (sober) to 10 (highly intoxicated) at baseline, breath alcohol concentration (BAC) of 0%, and at BAC 0.08%, 0.05%, and 0.02%. Alertness–sleepiness was assessed with the Karolinska sleepiness scale. Scores of the AMED and AO condition, at each BAC level, were compared.
Results Subjective intoxication for AMED and AO did not differ significantly from each other at any BAC level, except for BAC 0.02%. A significant increase in sleepiness scores was found in the AO condition, whereas scores remained stable in the AMED condition. Sleepiness scores at BAC0.08% and 0.05% were significantly lower after AMED when compared to AO. However, the observed differences between AMED and AO were small and have no clinical relevance.
Conclusion Mixing alcohol with energy drink had no overall masking effect on subjective intoxication caused by alcohol, nor had a relevant effect on subjective alertness-sleepiness ratings. Copyright © 2016 John Wiley & Sons, Ltd.

KEY WORDS—energy drink; alcohol; AMED; masking; intoxication; sleepiness

INTRODUCTION

Energy drinks are non-alcoholic beverages which often contain ingredients, such as caffeine, taurine, and B-vitamins. Important reasons for consuming energy drinks, other than people liking the taste, are the effects of caffeine on reducing sleepiness and improving alertness and concentration (Verster *et al*., 2014).

The stimulant effects of caffeinated beverages (without alcohol) have been demonstrated consistently, and corresponding claims are recognized by the European Food Safety Authority (EFSA) (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011). Both coffee and energy drink have shown to decrease levels of sleepiness, and the resulting increased alertness may subsequently result in improved performance on cognitive and psychomotor functioning. Hence, it has been shown that caffeinated beverages improve driving performance (Mets *et al*., 2011; Mets *et al*., 2012) and their consumption has been associated with a significant reduction in traffic accident risk (Sharwood *et al*., 2013).

The stimulant effects of caffeine have also been demonstrated when caffeinated beverages are mixed with alcohol, although not consistently. In this context, it has been suggested that the stimulant effects of caffeine counteract the sedative effects of alcohol, and as a result of this so-called "masking-effect" alcohol mixed with energy drink (AMED) consumers would not be able to judge their level of intoxication accurately, i.e., AMED consumers may feel less intoxicated than they actually are. If the suggested masking effect exists, the consequences would be of great concern. For example, AMED consumers falsely perceiving themselves as more sober could be more likely to consider risk-taking behaviors such as driving a car.

A recent meta-analysis however showed that across a range of caffeine concentrations and BAC levels a masking effect could not be demonstrated (Benson *et al*., 2014). In line, the 2015 EFSA scientific opinion

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Received 6 May 2015
Accepted 7 February 2016

on the safety of caffeine concluded that alcohol consumption up to 0.65 g/kg bw (leading to a BAC of about 0.08%) combined with caffeine up to 200 mg is unlikely to mask the subjective perception of alcohol intoxication (EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2015).

To verify this, the current study aims to directly compare subjective intoxication and alertness-sleepiness levels after consuming AMED (alcohol to achieve a peak BAC of 0.08% plus 1 can of 250 ml energy drink containing 80 mg caffeine) or alcohol only (AO; alcohol to achieve a peak BAC of 0.08% plus 250 ml placebo energy drink) at different BAC levels. The BAC levels under investigation were chosen as they represent the most common legal limits for driving a car, i.e., BAC 0.08% (e.g., USA and UK), BAC 0.05% (e.g., The Netherlands), and BAC 0.02% (e.g., novice drivers in The Netherlands). Based on the results of previous research (Benson *et al*., 2014) it is hypothesized that despite possible stimulant effects of caffeine, combining alcohol with energy drink will not affect the judgment of subjective intoxication.

METHODS

The objective of this double-blind, randomized, placebo-controlled, cross-over trial was to examine if combining alcohol with energy drink has an impact on subjective intoxication when compared to consuming alcohol only. The study was conducted at the Division of Pharmacology at Utrecht University between May and October 2013. The study protocol was reviewed and approved by the Medical Ethics Committee Twente, and written informed consent was obtained from all participants.

Subjects

$N = 72$ healthy volunteers were recruited by advertisement at Utrecht University. Students, male or female, were included if they were 18–35 years old, non-smokers, had a BMI between 18 and 25, consumed caffeine (e.g., coffee, energy drinks) and alcohol by self-report, and were familiar with achieving a BAC of 0.10% (seven to eight alcoholic drinks on one occasion). Subjects were excluded in case of current drug use (as shown by a positive urine drug screen on amphetamines, MDMA, barbiturates, cannabinoids, benzodiazepines, cocaine, and opiates), using psychoactive medication (by self-report), a positive breath alcohol test, self-reported intake of caffeine over 400 mg/day, self-reported irregular sleep pattern (e.g., shift worker), or a positive test on the urine pregnancy test (women only). Participants were withdrawn from the study if they reported an intake of psychoactive medication, drug use, intake of alcohol from 24 h before the test day, intake of caffeine-containing beverages during the test day, smoking during the test days, poor sleep quality as indicated by a score of 6 or higher on the Groningen Sleep Quality Scale, or food intake within 2 h before the start of the test day.

Treatments and administration

A standardized amount of alcohol was titrated to reach a peak BAC just above 0.08%. To achieve this BAC, the amount of alcohol was adjusted for gender and body weight according to the formula by Mathews and Miller (1979). Treatments were alcohol mixed with 250-ml energy drink (AMED) or alcohol mixed with 250-ml placebo energy drink (i.e., alcohol only, AO). Red Bull® Energy Drink and placebo-Red Bull were provided by Red Bull GmbH. Red Bull® Energy Drink (250 ml) contains 27-g sugar (sucrose and glucose), 1-g taurine, 80-mg caffeine, inositol, and B vitamins (niacin, pantothenic acid, vitamin B6, and vitamin B12). The placebo drink was Red Bull® Energy Drink without taurine, caffeine, inositol, and vitamin B complex. Treatments were blinded by having the same taste and color. Treatment identification was further masked by drinking the beverages from blinded cups.

Procedures

Subjects were screened and trained (approximately 2 h), followed by two test days. Test days were scheduled in the early evening (starting between 3 pm and 4 pm) to coincidence with normal drinking hours and had a duration of approximately 5 h, depending on individual alcohol metabolism rates. Each test day, up to six subjects were examined simultaneously. Test days were separated by a washout period of at least 5 days.

After arrival at the Institute discontinuation criteria were checked. At the start of the test day, subjects completed the 14-item Groningen Sleep Quality Scale (GSQS) (Mulder-Hajonides van der Meulen *et al*., 1980). GSQS scores range from 0 to 14. In general, if sleep is unrestricted and undisturbed, subjects score 0 to 2 points. Scores above 6 indicate disturbed sleep. In that case the test day was postponed.

After conducting baseline assessments, subjects received treatment (AMED or AO), which had to be consumed within 15 min. Treatment on test days was randomized and included alcohol-Red Bull and alcohol-placebo, according to a double-blind crossover design. Breath alcohol measurements were conducted

DOI: 10.1002/hup

using Alcometer breath analysers. Measurements were conducted before consumption of the beverage (BAC = 0%, baseline measurement, Time 1), and every 5 to 10 min thereafter to establish BAC 0.08% (Time 2), BAC 0.05% (Time 3), and BAC 0.02% (Time 4). After completion of the tests at BAC 0.05%, subjects received a currant bun and a glass of water. After the last test session (BAC 0.02%) subjects could leave the Institute when they felt sober and BAC was below BAC 0.01%.

Assessments of subjective intoxication and sleepiness

At each BAC level (0%, 0.08%, 0.05%, and 0.02%) subjective intoxication and sleepiness were measured. Subjective intoxication was measured using a visual analog scale ranging from 0 (sober) to 10 (highly intoxicated), with increments of 0.5 point. Subjects had to mark an "X" on the line from 0 to 10. The subjective intoxication score was the increase from 0, measured with 1 decimal. The Karolinska sleepiness scale (KSS) was completed to determine the level of subjective sleepiness of the subjects. In contrast to the original KSS, subjects rated their current subjective sleepiness, not sleepiness during the last 5 min. Subjects had to choose one of nine statements about their current state of sleepiness ranging from 1 (extremely alert) to 9 (extremely sleepy, fighting sleep) (Åkerstedt and Gillberg, 1990).

Statistical analyses

Statistical analyses were conducted with the SPSS statistical program, version 23. For each parameter, mean and standard deviation (SD) were computed. A general linear model was used to compare scores of the AMED and AO condition for the KSS and subjective intoxication on each BAC level. As it is essential to have similar BACs to allow a meaningful comparison between the two treatment conditions, the BAC difference between the two conditions was used as covariate in the analyses. Differences were regarded statistically significant if $p < 0.05$.

RESULTS

$N = 72$ subjects were screened. Of them, one subject did not start the study and $N = 5$ others only completed test day 1 and then withdrew participation on their own decision. Three other subjects were excluded because of a positive urine drug test, and another two subjects were discontinued because of the use of non-permitted psychoactive medication. Finally, one subject withdrew because of sickness after test day 1.

A total of $N = 60$ subjects completed the study. Of these, $N = 4$ subjects were excluded from the analyses because they had a Groningen Sleep Quality Score > 6. Data from $N = 56$ subjects (28 males and 28 females) was included in the statistical analysis. Their mean (SD) age was 21.8 (2.6) years old. The GSQS scores did not differ between the test days (1.18 versus 1.25, $p = 0.796$).

$N = 10$ subjects did not reach the desired BAC of 0.08% and thus were not tested at this BAC level. This happened for one subject in both the AO and AMED condition, for six other subjects only in the AO condition, and for three other subjects only in the AMED condition All subjects were tested at BAC 0.05% and 0.02%. There were no significant differences in achieved BAC levels between the AO and AMED condition (see Table 1). Also, the time to reach the desired BAC levels (calculated from finishing treatment consumption) did not significantly differ between the AO and AMED condition.

Mean (SD) subjective intoxication scores are shown in Table 2 and Figure 1. Pairwise comparisons revealed no significant differences between AMED and AO for any BAC level, except for BAC 0.02% ($p = 0.047$). No significant gender differences were observed at any BAC level.

Mean (SD) sleepiness scores obtained at each BAC level are summarized in Table 3 and Figure 2. KSS scores did not significantly differ at baseline (BAC 0%). Sleepiness scores remained stable in the AMED condition. Relative to the AMED condition, a significant increase in sleepiness scores was seen in the AO condition at BAC 0.08% ($p = 0.001$) and BAC 0.05%

Table 1. Mean (SD) BAC and time points after consumption at which subjective intoxication and sleepiness were measured in the AMED and AO condition

		Objective BAC (%)			Time after alcohol consumption (min)		
BAC	*N*	AO	AMED	*p*-Value	AO	AMED	*p*-Value
0.08	46	0.075 (0.006)	0.075 (0.005)	0.795	63.5 (17.2)	62.5 (21.2)	0.797
0.05	56	0.050 (0.001)	0.050 (0.001)	0.728	139.7 (32.6)	136.0 (33.4)	0.472
0.02	56	0.020 (0.0)	0.020 (0.001)	0.872	256.3 (39.1)	251.4 (42.5)	0.433

AMED, alcohol mixed with energy drink; AO, alcohol only; BAC, breath alcohol concentration; *N*, number of subjects.

DOI: 10.1002/hup

Table 2. Mean (SD) subjective intoxication scores in the AMED and AO condition

BAC		AO	AMED		
(%)	*N*	Mean (SD)	Mean (SD)	*p*-Value[a]	Effect size[b]
0.00	56	0.06 (0.23)	0.09 (0.30)	0.082	0.052
0.08	46	4.81 (1.96)	4.46 (1.60)	0.142	0.048
0.05	56	2.66 (1.68)	2.56 (1.19)	0.591	0.005
0.02	56	0.93 (1.16)	0.61 (0.63)	0.047*	0.0071

AMED, alcohol mixed with energy drink; AO, alcohol only; BAC, breath alcohol concentration; *N*, number of subjects.
*Significant differences ($p < 0.05$). [a]*p*-Values are corrected for ΔBAC.
[b]Partial eta squared.

($p = 0.0001$). No significant gender differences were observed at any BAC level.

Finally, on each test day participants were asked to guess which treatment they received. This was guessed correct in 61.6% of cases, i.e., relative close to chance level (50%), suggesting adequate blinding.

DISCUSSION

The current study did not demonstrate significant differences in subjective intoxication scores, except at the lowest BAC level (BAC 0.02%). However, the absolute subjective intoxication scores at BAC 0.02% in both conditions were both below 1, indicating that on a scale from 0 (sober) to 10 (highly intoxicated) subjects cannot be regarded as intoxicated at that time. Hence, the observed statistically significant difference at BAC 0.02% has no clinical relevance. Our findings are consistent with previous findings that mixing alcohol with energy drink has no relevant effect on the judgment of subjective intoxication (Benson *et al.*, 2014).

A statistically significant increase in sleepiness ratings was found after consuming AO at BAC 0.08% and BAC 0.05%, whereas sleepiness scores remained stable in the AMED condition. However, all scores ranged between the anchors "alert" and "not alert, nor sleepy", and the magnitude of the observed differences in alertness–sleepiness scores between the AMED and AO condition were small (generally less than <1 point on a 9-point KSS). Therefore, the observed differences on the KSS must not be regarded as having any clinical relevance (Åkerstedt, 2015, personal communication).

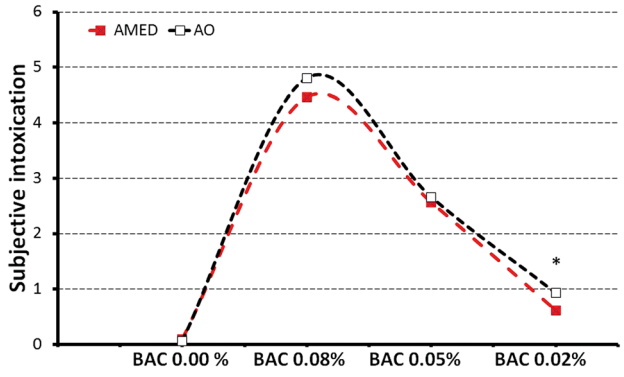

Figure 1. **Mean subjective intoxication scores after consuming AMED or AO.** Subjective intoxication was scored on a scale ranging from 0 (sober) to 10 (highly intoxicated). Statistically significant differences ($p < 0.05$) between AMED and AO are indicated by * Abbreviations: AMED = alcohol mixed with energy drink, AO = alcohol only, BAC = breath alcohol concentration.

Our findings on alertness–sleepiness are in line with previous studies examining the effects of alcohol plus caffeine or mixed with energy drink on stimulation, sedation, sleepiness, and alertness. Except for one study (Peacock *et al.*, 2013), it was consistently found that "stimulation" ratings after consuming alcohol plus caffeine were not significantly different from alcohol plus placebo (Fillmore, 2003; Marczinski and Fillmore, 2003; Attwood *et al.*, 2012; Marczinski *et al.*, 2011; Marczinski *et al.*, 2012; Marczinski *et al.*, 2013; McKetin and Coen, 2014, Heinz *et al.*, 2013, Benson and Scholey, 2014). Similarly, no significant effect of alcohol plus caffeine was found on "sedation" ratings (Benson and Scholey, 2014; Fillmore, 2003; Marczinski *et al.*, 2011; Marczinski *et al.*, 2012; Marczinski *et al.*, 2013, Marczinski and Fillmore, 2003; McKetin and Coen, 2014; Peacock *et al.*, 2013; Heinz *et al.*, 2013), and with only few exceptions (Drake *et al.*, 2003; Marczinski *et al.*, 2012; Smith, 2013), the vast majority of studies did not find significant effects of alcohol plus caffeine (versus alcohol only) on various subjective assessments related to sleepiness and alertness (Alford *et al.*, 2012; Attwood *et al.*, 2012; Ferreira *et al.*, 2006; Ulbrich *et al.*, 2013; Azcona *et al.*, 1995; Benson and Scholey, 2014; Liguori and Robinson, 2001; Peacock *et al.*, 2014; Marczinski *et al.*, 2011; Peacock *et al.*, 2013). In case significant differences were found (Drake *et al.*, 2003; Marczinski *et al.*, 2012; Smith, 2013), like in the current study the effects were small and had no clinical relevance. The existing data is thus in line with our findings.

DOI: 10.1002/hup

Table 3. Mean (SD) Karolinska sleepiness scores in the AMED and AO condition

BAC		AO	AMED		
(%)	*N*	Mean (SD)	Mean (SD)	*p*-Value[a]	Effect size[b]
0.00	56	3.38 (1.30)	3.34 (1.31)	0.857	0.001
0.08	46	4.76 (1.47)	3.48 (1.24)	0.0001*	0.244
0.05	56	4.75 (1.59)	3.79 (1.51)	0.0001*	0.257
0.02	56	4.30 (1.22)	3.83 (1.41)	0.114	0.046

AMED, alcohol mixed with energy drink; AO, alcohol only; BAC, breath alcohol concentration; *N*, number of subjects.
*Significant differences ($p < 0.05$). [a]*p*-Values are corrected for ΔBAC.
[b]Partial eta squared.

Strengths of our study include the use of a color and taste matched placebo energy drink to facilitate adequate blinding, conducting measurements at different BAC levels, and the large sample size. Adequate blinding is essential and an issue of concern in energy drink research. As typical energy drink has a distinctive (after)taste, it is easily recognized by participants who are familiar with the drinks. It has shown to be extremely difficult to develop a suitable placebo beverage for energy drink research. In the current study, the placebo drinks were provided by the sponsor, ensuring that they had exactly the same taste, flavor, and color of the actual energy drink. This resulted in adequate blinding of the AO and AMED conditions. As we used a cross-over design, if caffeine withdrawal would have played a role, it would have so on both test days in a similar way. We therefore conclude that any effect on the study outcome is unlikely. Also, the fact that both the energy drink and the placebo drink contained sugar confirms that sugar does not play a role in the study outcome.

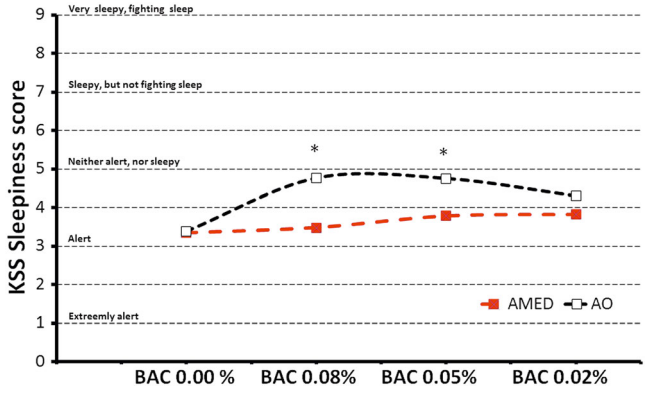

Figure 2. **Sleepiness–alertness scores after AMED and AO.** Sleepiness–alertness was measured on a scale ranging from extremely alert (1) to very sleepy, fighting sleep (9). Statistically significant differences ($p < 0.05$) between AMED and AO are indicated by * Abbreviations: AMED = alcohol mixed with energy drink, AO = alcohol only, BAC = breath alcohol concentration.

It may be viewed as a limitation that only one dosage of caffeine (80 mg) was examined in this study. Dutch data show however that the majority of AMED consumers (69.5%) drink 1 can (80-mg caffeine) of energy drink and 5.4 alcoholic drinks on a single drinking occasion (De Haan *et al.*, 2012), which was well reflected by the current treatment administration. As some studies from other parts of the world reported higher AMED consumption rates (e.g., Peacock *et al.*, 2012), the survey by De Haan *et al.* is currently being replicated in Australia and U.K. Other studies that investigated masking with higher caffeine levels also revealed no significant difference between subjective intoxication in AMED and AO conditions, both under controlled laboratory conditions (see Benson *et al.*, 2014 for a review) and on-premise (Verster *et al.*, 2015).

Taken together, the current data supports previous research that mixing alcohol with energy drink has no relevant effect on subjective intoxication and alertness–sleepiness ratings compared to alcohol only consumption.

ACKNOWLEDGEMENTS

The study was supported by Red Bull GmbH. Red Bull GmbH was not involved in the design and conduct of the study, collection, management, analysis, interpretation of the data, or preparation of the manuscript.

Joris Verster has received grants/research support from The Dutch Ministry of Infrastructure and the Environment, Janssen Research and Development, Nutricia, Takeda, and Red Bull, and has acted as a consultant for Canadian Beverage Association, Centraal Bureau Drogisterijbedrijven, Coleman Frost, Danone, Deenox, Eisai, Purdue Pharma, Red Bull, Sanofi-Aventis, Sepracor, Takeda, Transcept, and Trimbos Institute.

CONFLICT OF INTEREST

The authors have declared no conflict of interest.

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