

LETTER TO THE EDITOR

Development and Effectiveness of a Placebo Beverage Similar in Sensory Properties to an Alcoholic Beverage

Dear Editor,

Studies employing a balanced placebo design to examine the effects of alcohol consumption, often report that the non-alcoholic placebo beverage used was credible as an alcoholic drink. In the majority of cases, subjective ratings of beverage sensory properties are used as validation for successful manipulation of the beverage. However, few studies report on participants' certainty of perception when reporting the success of the placebo manipulation. This letter presents findings from a study examining the effectiveness of a non-alcoholic beverage developed to have similar sensory properties to an alcoholic beverage. It aims to discuss the findings with reference to participants' certainty of perception. These findings may assist researchers using placebo beverages in future studies, providing some level of confidence in the beverage manipulation used.

It is well established that alcohol consumption influences human behaviour and can cause impairment in cognitive function (Fillmore, 2007). However, evidence suggests that the behavioural and cognitive responses to alcohol may be mediated by the expectancy of alcohol consumption (Burian et al., 2003; Finnigan et al., 1995; Hammersley et al., 1998; Williams et al., 1981). The expectancy of receiving alcohol is dependent on factors that influence perception and can occur as the beverage is being consumed or some time thereafter. Initially, individuals' expectations of alcohol consumption are influenced by their awareness of the beverage constituents and the sensory properties detected on consumption. In a research

environment, awareness can be controlled by manipulating information provided to study participants. However, the sensory properties of the beverage are determined by the individual during consumption. Physiological effects are often delayed and are difficult to control. Generally, they are detectable when the dose of alcohol received elicits blood alcohol concentrations (BACs) of 0.08% or higher (Hammersley et al., 1992) and these effects usually confirm the initial expectancy of receiving alcohol.

Studies often employ a balanced placebo design (Hull and Bond, 1986), where a low- or non-alcoholic beverage serves as a control treatment, allowing for the effects of an alcohol intervention to be compared against a control. In order for the placebo arm of the intervention to be valid, it is important that participants are unable to detect the placebo beverage as a non-alcoholic drink, or at least have a high degree of uncertainty in their perception. Preparation of a non-alcoholic placebo beverage that imitates an alcoholic drink is challenging because of the distinct sensory attributes that are often associated with alcoholic drinks. Alcoholic beverages are often detected by subtle taste and olfactory cues, as well as other factors such as the mouthfeel of the beverage (Ross and Weller, 2008) and interoceptive intoxication cues that appear after ingestion (Williams et al., 1981).

In an effort to disguise placebo beverages, several studies have employed methods such as participants sucking on an anaesthetic throat lozenge prior to drink administration (Tiplady et al., 2004), mixing the drink with Tabasco sauce (Weissenborn and Duka, 2003) or peppermint flavouring (Tiplady et al., 2004), and preparing the placebo drink with a small amount of undiluted alcohol floated on the top, smeared around the rim of the glass, and/or sprayed as a mist over the drink (Ross and Weller, 2008). Typically, studies also have a significant time lapse between the repeated trials where tastings occur, reducing participants'

ability to compare the different drinks. Validation of the placebo beverage occurs by asking participants to rate the alcoholic content of the beverages they receive within the study. This is normally done by assessing the subjective effects reported by participants (Finnigan et al., 1995), comparing the beverage with standard alcoholic drinks (Fillmore et al., 1998), or simply asking participants if they thought they had received an alcoholic drink (Hammersley et al., 1998). These checks often reveal that the manipulation was successful and a credible placebo beverage was provided. However, participants tend to report placebo beverages as having considerably lower alcohol content compared to the active dose conditions (Testa et al., 2006). Few studies actually report on participants' certainty of their perception.

The aim of this study was to develop an alcoholic and non-alcoholic (placebo) beverage that could not be distinguished from one another by taste or other sensory properties. Participants' perceptions of the placebo beverage will allow for an evaluation on the appropriateness of its use in other studies that require a placebo intervention. Thirty-four volunteers (7 male and 27 female, mean age \pm SD = 24.7 \pm 6.2 y) from Griffith University, Gold Coast campus agreed to participate in this study. Personal alcohol drinking habits were not collected prior to participation in this study. However, no participant reported complete abstinence from alcohol. All participants were fully informed of the procedures of the study before giving their verbal consent. The investigation was part of a larger study investigating the effects of dehydration, alcohol consumption and cognitive function, which was approved by the Human Research Ethics committee of Griffith University (PBH/01/10/HREC).

Each participant completed 5 trials, each separated by at least 1 day. On each day, participants' were presented with a sample of liquid (~30ml) that was either an alcohol containing beverage or placebo. Participants were randomly assigned to beverages for each

trial, so that half of the participants would receive an alcohol containing drink and half would receive a placebo drink for each trial. This design allows evaluation of drink order and its effect on participants' responses. The beverages were prepared outside of the participant's view and presented in white plastic cups labelled only with the participants' initials. Participants' consumed the beverage in an isolated room and on administration of the beverage were asked to first smell and then taste the drink by sipping the entire volume slowly. No time restraint was given for this process. At the same time, an experimental tasting questionnaire containing 6 rating scales and the following instructions were provided:

“You will be presented with a sample of liquid that either contains or does not contain alcohol, and asked to rate specific components of the beverage and your perception of the alcoholic concentration of the drink with certainty. Please taste the beverage and complete the following rating scales”.

The questionnaire consisted of four sensory attribute statements (Ross and Weller, 2008). Participants were asked to rate the beverage for acceptability, alcohol aroma intensity, alcohol flavour intensity and alcohol burn/mouth-feel on an 11-point Likert scale (0 = dislike extremely, no alcohol; 10 = like extremely, extremely strong alcohol). Participants then rated their perceived alcohol concentration of the beverage (no alcohol, low alcohol, moderate alcohol, high alcohol) and their certainty of perception rating (not at all certain, somewhat certain, very certain, absolutely certain) using a 4-point Likert scale (Ross and Weller, 2008).

The alcoholic drink was formulated using vodka (Smirnoff[®], 37% v/v ethanol) made up with equal parts of diet ginger beer cordial (Bundaberg Brewed Drinks Pty Ltd[®]) and diet ginger beer soft drink (Bundaberg Brewed Drinks Pty Ltd[®]), and one tenth the volume of diet lime

cordial (Bickfords[®], Australia). A large volume was made initially that contained 500ml vodka, 500ml ginger beer cordial, 500ml of ginger beer soft drink and 50ml of lime cordial, resulting in a beverage with an alcohol concentration of ~12% v/v, which was stored in the refrigerator until required, and decanted into ~30ml volumes for trial tastings. The placebo beverage was identical to the alcoholic drink however water was substituted for the vodka component. In addition, a single spray of vodka mist was applied over the placebo beverage and on the rim of the plastic drink containers during the individual trial tastings to provide olfactory cues similar to that of the alcohol containing beverage. A pilot test prior to this study confirmed that the vodka mist did not influence the alcohol content of the placebo beverage.

All statistical procedures were performed using SPSS for Windows, Version 19.0 (SPSS Inc., Chicago, IL). Chi-square analysis was generated to compare the frequency distribution of ratings for the perceived alcohol concentration of the beverage and certainty of perception. Both scales were collapsed into 3 categories and analysis was conducted between groups (alcohol and placebo) for individual trials. Independent samples t-tests were conducted to reveal differences between the groups for each of the sensory attribute variables. Comparisons between trials for each group were conducted using one-way analysis of variance (ANOVA). Post-hoc analysis (LSD) was performed where significant main effects were present. All data are reported as mean±standard deviation unless otherwise specified. Statistical significance was accepted at $p < 0.05$.

No difference was observed in the proportion of perceived alcohol concentration ratings between the groups on trial 1 ($p > 0.05$). There was a significant difference between the groups on subsequent trials (trials 2-5), with more participants able to correctly identify the

beverages ($p < 0.05$). However, there was a degree of uncertainty in participants' perception of the alcoholic content of the beverages, with higher ratings (~62% on average) of 'not at all certain - somewhat certain' in many of the trials. No differences in certainty were found between the two groups in any of the trials ($p > 0.05$). Participants reported no difference in any of the sensory attributes between the alcohol containing drink and placebo beverage in trial 1 ($p > 0.05$). On all subsequent trials there was a significant difference between the two beverages with higher mean acceptability ratings reported for the placebo beverage, and higher mean alcohol flavour intensity and alcohol burn/mouth-feel ratings for the alcohol containing drink ($p < 0.05$). No difference was observed between the two beverages for alcohol aroma intensity in any of the trials ($p > 0.05$).

Results from this study show that a placebo beverage prepared in accordance with the procedures outlined in the methods has credibility in providing expectancy manipulation. The ginger beer ingredients used in the preparation of the beverages may have provided some sensory cues similar to an alcoholic drink, which is indicated by no difference in the ratings of alcohol flavour intensity and alcohol burn/mouth-feel between the two beverages in the first taste testing trial. Participants possessed a greater ability to identify the placebo beverage in subsequent trials, which suggests that the cues received from the first trial allowed comparison of the drinks and greater detection of differences between beverages. However, the degree of certainty did not change throughout, with most participants only 'somewhat certain' of their perception. This suggests that there may have been some degree of guessing by participants when selecting the perceived alcohol concentration rating of the beverage and provides some evidence for successful manipulation of the non-alcoholic drink.

Based on the alcohol aroma intensity alone, participants were not able to distinguish between the alcohol and placebo beverages throughout trials. The alcohol mist sprayed over the placebo was successful in providing olfactory cues that imitated the ethanol aroma in the alcohol containing drink. Whilst other cues such as the flavour and mouth-feel were rated different between the beverages, similar ratings of alcohol aroma intensity between the drinks suggest that the aroma of the beverage may have provided the cue to instigate a degree of uncertainty in participants' perception of alcohol concentration.

Several studies have employed methods where beverages are prepared in front of the participant (Burian et al., 2003; Finnigan et al., 1995). In these cases, commercial alcohol containers are filled with water and standard measures are used to prepare the placebo drink, allowing participants a visual perception of alcohol preparation when in fact they are receiving placebo. The preparation of placebo beverages allowing visual cues has been suggested to have the strongest association with placebo credibility (Rohsenow and Marlatt, 1981). Viewing the preparation of beverages did not occur in the present study. In addition, participants were told that they may receive either an alcoholic beverage or a placebo drink at each trial. An awareness of the placebo beverage may influence participants' expectancy of alcohol and result in an overestimated detection rate of the placebo. Slight procedural manipulations such as preparing the drinks in front of the participant and giving an expectancy of receiving only an alcoholic beverage may have induced different results, particularly in subjective ratings of perceived concentration and certainty of perception throughout the trials. These additional procedural factors are recommended for administration of the beverages in future studies.

In Summary, a placebo beverage prepared in accordance with the procedures outlined in the methods of this study has credibility in providing expectancy manipulation. However, additional factors such as visual cues through the preparation of beverages in front of participants may improve the credibility of deception and are recommended in the administration of a non-alcoholic beverage where a balanced placebo design study is required. The small sample size and unbalanced gender group used in this study was a limitation. Further research should investigate the credibility of non-alcoholic placebo beverages to ensure future studies use placebo beverages that have the best perception manipulation. Investigating the credibility of placebo beverages in different sample groups (habitual alcohol consumers vs. abstainers, older vs. younger population groups) may also assist with the improved development of beverages that can be used in studies requiring administration of a non-alcoholic placebo.

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