

Official Title of Study: Alcohol PBS and Thinking about the Past

NCT Number: Not Assigned

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Planned Analysis

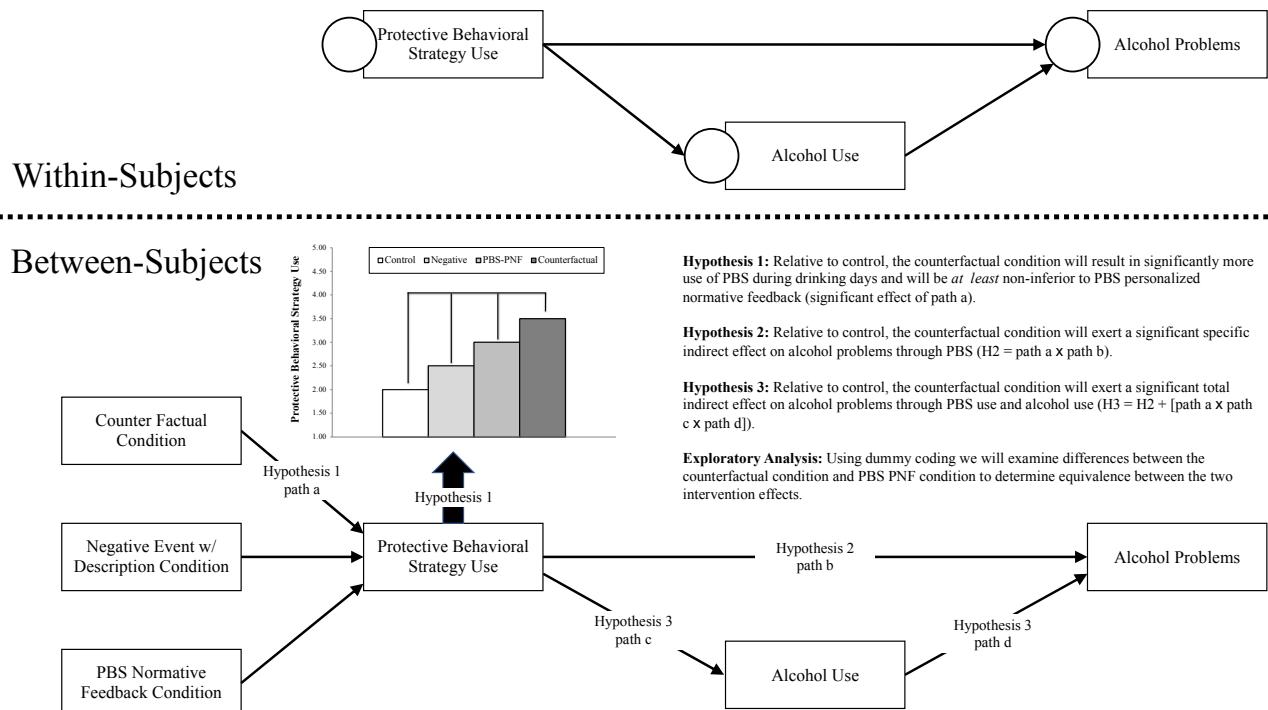
Statistical Design: The statistical design uses a multilevel structural equation model. The model will compare three conditions: Negative Event, Negative Event w/ a detailed description of the event, Negative Event w/ generated Counterfactuals to reduce future negative events, and Protective Behavioral Strategy Personalized Normative Feedback (PBS-PNF). Each condition will be used to predict protective behavioral strategies. Protective behavioral strategies will then predict alcohol and alcohol consequences. As the conditions are at the between-subject level, the hypotheses are specific to between subject effects, however, the data will be modeled at both the within- and between- subjects level (see Figure 1). In order to decompose variance across levels, all level 1 variables will be centered at the person level while all level 2 variables will be centered at the grandmean. Only weeks during which participants consume alcohol will be included in the analysis, as the intervention target (PBS) only occurs on drinking days.

Covariates: At level 1, we will control for week of study and number of drinking days. At level 2 we will control for biological sex at birth.

Hypothesis 1: Relative to control, the counterfactual condition will result in significantly more use of PBS during drinking days and will be *at least* non-inferior to PBS personalized normative feedback (significant effect of path a).

Hypothesis 2: Relative to control, the counterfactual condition will exert a significant specific indirect effect on alcohol problems through PBS (H2 = path a x path b).

Hypothesis 3: Relative to control, the counterfactual condition will exert a significant total indirect effect on alcohol problems through PBS use and alcohol use ($H3 = H2 + [\text{path a} \times \text{path c} \times \text{path d}]$).



Mplus Code:

usevar are CFcondition PBSPNFcondition NegEventcondition L1PBS L1Drinks
L2PBS L2Drinks Problems;

within are L1PBS L1Drinks;

between are CFcondition PBSPNFcondition NegEventcondition L2PBS L2Drinks;

cluster = ID;

analysis:

estimator = mlr;

PROCESSORS = 2;

type = twolevel;

model:

%within%

L1Drinks on L1PBS;

Problems on L1Drinks L1PBS;

[L1Drinks @0];

[L1PBS @0];

%between%

L2PBS on CFcondition(a);

L2PBS on PBSPNFcondition;

L2PBS on NegEventcondition;

L2Drinks on L2PBS(c);

Problems on L2PBS(b);

Problems on L2Drinks(d);

Model Constraint:

New(H1 H2 H3);

H1 = a;

H2 = a*b

H3 = H2+(c*d);

Exploratory Analysis: We will examine differences between the counterfactual condition and PBS PNF condition to determine equivalence between the two intervention effects. This approach will use a two one-sided equivalence test (TOST), to compare the two active treatments (Lakens, 2017). This allows for a comparison of a new treatment against the observed effects of an existing treatment (rather than against the traditional null hypothesis). In doing so, we will specify an “equivalence” margin of Cohen’s d -0.20 to 0.20 (a small effect in both directions). We will then calculate 95% confidence intervals of the effect size difference between the Counterfactual and PBS-PNF. A positive value indicates a stronger effect of Counterfactual relative to PBS PNF, while a negative value indicates a weaker effect. This approach allows for the statistical determination of whether the observed effect is equivalent to the standard treatment, superior to the standard treatment, or inferior to the standard treatment.