

Document Coversheet

Study Title: A Novel Drug Combination for Alcohol-Use Disorders: A Human Laboratory Study

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Office of Research Integrity
IRB, RDRC

Initial Review

Approval Ends:
5/23/2019

IRB Number:
44796

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FROM: Chairperson/Vice Chairperson
Medical Institutional Review Board (IRB)

SUBJECT: Approval of Protocol

DATE: 5/31/2018

The Medical Institutional Review Board approved minor revisions requested at the convened meeting on 5/24/2018 for your protocol entitled:

Behavioral Effects of Drugs: Inpatient (36) (Alcohol, Duloxetine, and Methylphenidate)

Approval is effective from 5/24/2018 until 5/23/2019 and extends to any consent/assent form, cover letter, and/or phone script. If applicable, the IRB approved consent/assent document(s) to be used when enrolling subjects can be found in the "All Attachments" menu item of your E-IRB application. [Note, subjects can only be enrolled using consent/assent forms which have a valid "IRB Approval" stamp unless special waiver has been obtained from the IRB.] Prior to the end of this period, you will be sent a Continuation Review Report Form which must be completed and submitted to the Office of Research Integrity so that the protocol can be reviewed and approved for the next period.

In implementing the research activities, you are responsible for complying with IRB decisions, conditions and requirements. The research procedures should be implemented as approved in the IRB protocol. It is the principal investigator's responsibility to ensure any changes planned for the research are submitted for review and approval by the IRB prior to implementation. Protocol changes made without prior IRB approval to eliminate apparent hazards to the subject(s) should be reported in writing immediately to the IRB. Furthermore, discontinuing a study or completion of a study is considered a change in the protocol's status and therefore the IRB should be promptly notified in writing.

For information describing investigator responsibilities after obtaining IRB approval, download and read the document "PI Guidance to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research" available in the online [Office of Research Integrity's IRB Survival Handbook](#). Additional information regarding IRB review, federal regulations, and institutional policies may be found through [ORI's web site](#). If you have questions, need additional information, or would like a paper copy of the above mentioned document, contact the Office of Research Integrity at 859-257-9428.

RESEARCH PROCEDURES

Participants that meet the inclusion criteria will participate as outpatients at the Laboratory of Human Behavioral Pharmacology (LHBP) of the University of Kentucky.

Thirty-two (≈ 11 women) non-treatment-seeking individuals with alcohol (ALC) use disorder (AUD) will complete the study. Participants, recruited from the community, will earn \$40/session and a \$40/session completion bonus if they finish the protocol. To maximize medication adherence, a contingency management approach will be used wherein participants will receive a monetary bonus each day that medications are administered per protocol as verified by Wisepill®. Payments will start at \$5 and increase by \$2 each consecutive day of dosing adherence.

The study protocol will use previously developed methods that have predictive validity for AUD treatment efficacy (Drobes et al., 2003; Hendershot et al., 2016; O’Malley et al., 2002). More specifically, the sensitivity of this clinical laboratory approach was established with a medication already known to be effective for AUD (i.e., naltrexone). After screening, participants will complete the protocol as outlined in Table 1. After completing the protocol, all participants will be offered referral to a treatment program per the NIAAA National Advisory Council guidelines (National Council on Alcohol, 1988; Sinha et al., 1999).

Day	Table 1: Experimental Procedures
0	Practice Session. ALC consumption designed to bring BAL to 0.03 g/dl. Subjective, physiological, and cognitive-behavioral measures collected (described in Table 2). Participants randomly assigned to a duloxetine (DUL) condition prior to completing this session.
1-6	DUL (0 or 60 mg/day) and methylphenidate (MTH; 0 mg/day) administered once daily (at 0900h) for 6 days.
7	Experimental Session. ALC consumption designed to bring BAL to 0.03 g/dl. Subjective, physiological, and cognitive-behavioral measures collected (described in Table 2). DUL-MTH maintenance continues.
8-13	DUL (0 or 60 mg/day) and MTH (20 mg/day) administered once daily (at 0900h) for 6 days.
14	Experimental Session. Details are the same as during Day 7. DUL-MTH maintenance continues.
15-20	DUL (0 or 60 mg/day) and MTH (40 mg/day) administered once daily (at 0900h) for 6 days.
21	Experimental Session. Details are the same as during Day 7. DUL-MTH maintenance continues.
22-27	DUL (0 or 60 mg/day) and MTH (60 mg/day) administered once daily (at 0900h) for 6 days.
28	Experimental Session. Details are the same as during Day 7. Participant receives taper medications to begin on the morning of Day 29.
29	Medical screening repeated. Follow-up visits scheduled.

Participants will be instructed to maintain their standard diet, ALC and cigarette intake throughout participation, with the exception that they will be asked to abstain from ALC for at least 12h prior to a session. All participants will provide urine and expired-breath samples prior to experimental sessions. The presence of drugs of abuse in the urine or positive BALs upon arrival for experimental sessions will result in rescheduling of the session. Repeated occurrences will result in study dismissal. Participants will not be allowed to smoke tobacco cigarettes during

experimental sessions, consistent with previous work (O’Malley et al., 2002).

Practice Session. This session will familiarize participants with the experimental procedures described below, prior to maintenance dosing, and to demonstrate equivalency between the DUL cohorts on their baseline and physiological responses to ALC.

Randomization to a DUL Cohort and Medication Maintenance. After screening and prior to completing the practice session, a participant will be randomized to a DUL dose condition with an urn randomization procedure to ensure balance across the DUL conditions along two variables: 1) severity of AUD (i.e., mild, moderate) and 2) sex (M/F).

Delayed-Release Capsules of DUL (0 or 60 mg/day) (Cymbalta®) and long-acting MTH (0, 20, 40, 60 mg/day) (Metadate CD®) will be prepared by over-encapsulating commercially available doses in a size 0 capsule. Capsules are then filled with lactose monohydrate powder, N.F. Placebo capsules will be identical, but contain only lactose. The dosing regimen of DUL and MTH were selected based upon clinical recommendations. DUL and MTH will be administered concurrently once daily (0900h).

Both DUL and MTH will be administered once a day using delayed-release (DUL) or long-acting (MTH) formulations. DUL produces peak blood levels approximately 6 h after dosing, but DUL levels in plasma remain relatively stable for at least 24 h after dosing. Participants randomized to 60 mg/day DUL will initially receive 30 mg/day for 2 days and the target dose (i.e., 60 mg/day) for 4 more days prior to completing the experimental session. This dosing regimen will allow participants to acclimate to a lower DUL dose before receiving the target dose. The long-acting formulation of MTH produces a biphasic profile with effects peaking 2 and 6 h after dosing. Levels of MTH decrease after the 6 h peak but are detectable for at least 24 h after dosing. This stable decrease for MTH, especially if given in the morning, will reduce any sleep disruptions associated with long-acting MTH administration while also ensuring clinically effective blood levels of MTH during participant waking hours. The MTH doses will be tested in ascending order because clinical guidelines recommend increases of 20 mg at weekly intervals to a maximum dose of 60 mg/day.

The duration of maintenance needed to reach steady-state plasma concentrations was calculated based on the pharmacokinetic profiles of delayed-release DUL and long-acting MTH, both of which follow first order kinetics. According to first-order kinetics, 4-7 half-lives is needed to attain steady state. The half-life of delayed-release DUL and long-acting MTH is approximately 12 and 5 hours, respectively. The maintenance period (i.e., 3-6 days) on each dose of DUL and MTH is sufficient to achieve steady state prior to completing experimental session in which an ALC challenge is administered. Participants will be provided with additional maintenance medications in the event that they are unable to attend an experimental session due to unforeseen circumstances. Overall, the use of the proposed formulations of DUL and MTH will result in more stable concentrations of clinically effective doses.

Medication adherence will be assessed using two approaches. First, all study medications will be encapsulated with 100 mg riboflavin to assess adherence via fluorescence detection. Second, participants will administer study capsules using the Wisepill® digital monitoring system. This system uses mobile phone and Internet technologies to provide real-time medication management. When a participant takes a capsule at the scheduled time, an electronic medication event record is sent to the Wisepill® central management system. Failure to take the capsule at the scheduled time results in a reminder “text” message being sent to the participant and the researchers. This is a significant advancement in the ability to track medication adherence. In particular, when a dose is missed, a participant can be contacted within a time frame that maximizes the likelihood of maintaining steady-state medication levels, which should translate to increased sensitivity to medication effects. The Wisepill® digital monitoring system is currently

being used in other studies conducted in our facility. Maintenance medications (i.e., DUL-MTH combinations) will be self-administered by participants once daily at approximately 0900h for the duration of the trial. The use of once-daily dosing formulations of the constituent compounds will improve adherence when advanced to clinical trials or practice.

The dosing regimen described above will be reversed to taper DUL and MTH. During the first week after discharge participants in the 60 mg/day DUL cohort will be maintained on 30 mg/day DUL and 20 mg/day MTH and 20 mg/day DUL and 10 mg/day MTH during the second week following discharge. Participants in the 0 mg/day DUL cohort will be maintained on 0 mg/day DUL and 20 mg/day MTH in the first week and 0 mg/day DUL and 10 mg/day MTH during the second week following discharge. All participants will be scheduled for the final follow-up visit 1 week after discontinuing DUL and MTH (as described below).

All participants, whether or not they complete the study, will be scheduled for follow-up visits 1-, 2- and 3-weeks following discharge. Participants will complete the laboratory screening procedures used during screening for study participation (e.g., laboratory chemistry values). These laboratory tests, including liver function, used for study inclusion will be repeated the day following discharge (Day 29) on participants who finish or drop out. If elevated liver enzymes are detected, we will follow them until they return to normal and consult with our study physicians on a course of action. In addition, a questionnaire used on Research Electronic Data Capture (REDCap), a secure, web-based application designed to support efficient, secure and confidential data collection for clinical research. The REDCap questionnaire will be used to assess recent activities (e.g., sleep quality, past 24 h alcohol and drug use, ALC craving) and the emergence of adverse events. At each follow-up visits the Timeline Followback (TLFB) questionnaire, also administered electronically, will be used to assess the quantity of alcohol use during the past week. Participants will be paid \$50 for each follow-up visit.

Monitoring Adverse Events. Once daily during medication maintenance, participants will complete the REDCap questionnaire (the same questionnaire described above) to assess recent activities (e.g., sleep quality, past 24 h alcohol and drug use, ALC craving) and the emergence of adverse events during medication maintenance. Participants will be asked whether they have experienced any of the side effects listed in the informed consent document. If they endorse any side effects, they will be asked to rate the severity and whether they believe it was related to the study medication. They will also have the opportunity to report other side effects not included in the questionnaire. A staff member will verify that the questionnaire has been completed at the appropriate approximate time, and contact the study physician and PI if any significant side effects are noted. We are using similar procedures to monitor side effects in ongoing projects. During experimental sessions, adverse events will be monitored via observations by the medical and research staff, spontaneous report by the participants, regular measurement of cardiovascular indices and use of the UKU Side Effects Rating Scale and subjective effects questionnaires. Chronic users are more likely to tolerate acute intoxication and are less likely to be impaired under acute dose.

Apparatus. Participants will come to the LHBP on the day that each of the 5 sessions (i.e., 1 practice; 4 experimental) are completed. During these sessions, participants will not be permitted to leave the LHBP premises, nor will visitors be allowed. Upon arrival to the LHBP, the LHBP staff will also take the participant's car keys and will return them when the participant is released from the LHBP two hours after ALC consumption and upon provision of a BAL that is below 0.02 g/dl. Should the participant leave the LHBP prior to that time, the LHBP staff or participant will arrange alternate transportation (e.g., arrange a taxi). The car keys will be returned to participants after ensuring that alternate transportation for the participant has been confirmed (e.g., taxi driver has arrived at the LHBP premises).

Participants will be tested in individual rooms in order to eliminate the effects of social factors

on the behavioral and physiological effects of ALC. Participants will complete experimental tasks on a laptop computer. The computer records the data and relays them to the participant's respective file where they are stored. This computer system automates the collection of behavioral data, increasing the efficiency and accuracy of data collection and management.

On session days, participants will arrive at the LHPB at approximately 1400h. Urine toxicology, ADHD and depression ratings, expired breath samples for BAL determination will be obtained. A field sobriety test will be administered to confirm sobriety. Presence of riboflavin in the urine will be verified using a hand-held ultraviolet light detector. Participants whose urine does not fluoresce will not be permitted to proceed with the scheduled experimental session and any subsequent experimental sessions, and will be dropped from the study. Time of maintenance dosing will be confirmed by self-report and Wisepill® log. Following completion of the above-mentioned procedures, participants will be provided a standardized light snack. Participants will report their ALC consumption and craving in the natural environment during each 6-day maintenance block using the REDCap questionnaire. As outlined in **Table 2**, self-reported ALC craving, subjective effects questionnaires and inhibitory control tasks will be completed at 1500h (i.e., baseline).

Time	Table 2: Experimental Session Activities
1400-1500h	Arrival to LHPB. Urinalysis, BAL samples, field sobriety, vitals, and self-reported time of maintenance dosing. Participant provided a light standardized snack.
1500-1530h	Baseline measures (e.g., BAL samples; vitals; ALC craving; subjective effects questionnaires; ABBA; Hypothetical Delay Discounting; Purchase Tasks).
1545-1615h	ALC Sampling (i.e., single administration of ALC designed to raise BALs to 0.03 g/dl). BAL, ALC craving, and subjective effects determined at 10, 20, and 30 min. ABBA, Hypothetical Delay Discounting, and Purchase Tasks completed at 30 min.
1645h	BAL sample collected, ALC craving and subjective effects, vitals assessed.
1715h	BAL sample collected, ALC craving and subjective effects, vitals assessed.
1745h	BAL sample collected, ALC craving and subjective effects, vitals assessed.
1800h	BAL sample collected, vitals assessed, field sobriety test, and discharge from LHPB (receive maintenance medication in the Wisepill® device or taper doses if last experimental session, payment, and car keys).

ALC Dose. Participants will consume the ALC dose at approximately 1545h during experimental sessions to acquaint them with ALC effects. Participants will receive a single administration of 95% ALC mixed with non-alcoholic mixer (e.g., lemon lime soda, tonic water) (designed to raise BALs to 0.03 g/dl), to be consumed over 5 minutes. The measures of interest are described below in the following paragraphs.

ALC Craving. A single, reliable and valid instrument, the Penn Alcohol Craving Scale, will be used to measure craving during the experimental sessions described above and in the natural ecology during the medication maintenance phases.

Subjective-Effects Questionnaires. Five subjective-effects questionnaires that measure various aspects of mood and ALC effects will be used: 1) Subjective High Assessment Scale (SHAS); 2) a Drug-Effect Questionnaire (DEQ) modified for use with ALC; 3) Biphasic ALC Effects Scale; 4) Profile of Mood States (POMS); and 5) Snaith-Hamilton Pleasure Scale (SHAPS).

Inhibitory Control Measures. Inhibitory control measures include: 1) ABBA (see Appendix A) and 2) Hypothetical Delay Discounting (see Appendix B). These tasks are completed at baseline and after the sampling dose of ALC.

Commodity Purchase Tasks (Appendix C). Commodity purchase tasks will be used to assess economic demand for alcohol and soda (Amlung et al., 2015; Bruner and Johnson, 2014; Murphy and MacKillop, 2006; Strickland and Stoops, 2017). In these tasks, participants are asked to indicate the hypothetical number of items (e.g., one alcoholic drink) they would purchase at a range of monetary increments (e.g., \$0.00 [free] to \$15/drink). All choices are hypothetical and will not be purchased or administered. Data from the commodity purchase task will be analyzed using economic demand equations previously applied to purchase task data (e.g., Strickland et al., 2016). Primary outcomes of this task include elasticity of demand (α) and intensity of demand (Q_0).

ALC Use in the Natural Ecology. ALC use in the natural ecology will be assessed daily for each maintenance period using the REDCap and prior to each of the experimental sessions in order to construct of calendar of ALC use during maintenance. The TLFB questionnaire will be administered electronically and will be used during the practice session and at each of the three follow-up visits.

Safety and Tolerability Measures. Physiological measures (i.e., BAL measurements, heart rate and blood pressure) will be recorded upon arrival at the LHBP, before ALC administration and throughout the session at the intervals noted in Table 2 using digital monitors. ALC will not be administered if a participant's heart rate is ≥ 100 bpm, systolic pressure is ≥ 150 mmHg or diastolic pressure is ≥ 100 mmHg. A participant will be excluded from further participation if he/she exhibits hypersensitivity (i.e., heart rate > 130 bpm, systolic pressure > 180 mmHg, diastolic pressure > 120 mmHg) during maintenance on MTH and DUL and/or to the effects of ALC. The UKU Side Effects Rating Scale will be completed at the end of sessions (Lingjaerde et al., 1987).

Data Analysis

Data will be analyzed as raw scores. Statistical significance refers to $p \leq 0.05$.

Demographics. Demographic data from each DUL cohort (0 or 60 mg/day) will be compared using unpaired t-tests. Should the cohorts differ on any demographic variables (e.g., subclinical levels of ADHD and depression), they will be used as covariates in subsequent statistical analyses. ADHD and depression will be re-determined during each of the experimental sessions allowing us to determine changes as a function of maintenance condition and whether these changes impact subjective, physiological, or cognitive-behavioral changes following ALC consumption.

Outcome Measures. ALC craving during the experimental session, physiological, and subjective responses (i.e., Subjective High Assessment Scale; Drug-Effect Questionnaire; Biphasic ALC Effects Scale; Profile of Mood States; and Snaith-Hamilton Pleasure Scale) following consumption of the ALC dose will be analyzed similarly as peak effect (i.e., maximum effect observed following the ALC sampling dose) and area-under-the-time-action curve (AUC; calculated for each participant using the trapezoidal method). These data will be analyzed with two-factor mixed-model ANOVA with DUL (between-subject variable; 0 or 60 mg/day) and MTH (within-subject variable; 0, 20, 40, 60 mg/day) as the factors. A significant attenuation (e.g., decreased ALC craving) will be inferred if the main effect of DUL or MTH, or the interaction of DUL and MTH attains statistical significance in the ANOVA. If the DUL-MTH interaction attains statistical significance, the mean square error term will be used to conduct Tukey's HSD *post-hoc* test to make appropriate pair-wise comparisons between means. Naturalistic ALC use and craving will be used to determine if the effects of the DUL-MTH combinations are additive, supra-

additive or infra-additive (i.e., isobolographic analysis). Naturalistic ALC use and craving (group mean and standard error) under a dose combination will be considered: 1) additive if it overlaps with the arithmetic sum of the effects observed under the DUL and MTH doses alone; 2) supra-additive if it is greater than the sum of the individual dose alone and without overlap; or 3) infra-additive if it is less than the sum of the effects of the individual doses alone and without overlap.

Data from the ABBA (i.e., proportion of inhibitory failures to no-go targets following ALC go cues, reaction time to go targets following go cues), Hypothetical Delay Discounting (k values), commodity purchase tasks (elasticity of demand [α] and intensity of demand [Q_0]) will be analyzed using mixed-model ANOVAs with the factors described above, but with time (pre- vs. post-alcohol-challenge). A significant improvement will be inferred if the main effect of DUL or MTH, the interaction of DUL and MTH, or the interaction of DUL, MTH and Time attains statistical significance in the ANOVA. If the DUL-MTH-Time interaction attains statistical significance, the mean square error term will be used to conduct Tukey's HSD *post-hoc* test to make appropriate pair-wise comparisons between means. Outcomes from the commodity purchase tasks will also be correlated with subjective effect and physiological data to explore the mechanisms by which MTH and DUL attenuate the effects of the ALC challenge.

Power and Sample Size Considerations. In light of the modifications as of June 2020 and given that a mixed-model design is still being used, we anticipate enrolling 16 participants in each DUL cohort (2 cohort, n = 32 participants) will provide sufficient statistical power to detect changes in naturalistic ALC use, ALC craving, and the behavioral, subjective, and physiological responses to an ALC challenge. The new total sample size is supported by the 'One in Ten Rule' (Harrell et al., 1984) wherein 10 participants are needed for each predictor. Within the context of this study (3 predictors: DUL cohorts, MTH dose, and time [e.g., pre- vs post-alcohol-challenge]). Participants that do not complete will be replaced in order to ensure adequate statistical power to detect the hypothesized effects.

APPENDIX A

Attentional Bias-Behavioral Activation Task

Instructions (read to the participant before task)

This is a reaction time task that I would like you to perform. While you are performing the task, please place your right index finger on the key that has the green sticker.

Presented on the screen will be squares that are green or blue in color. If the color GREEN appears on the screen, you are to press the green button as quickly as possible. If the color BLUE appears on the screen, then no response is required. Now, before the green or blue color appears, you will see a plus sign in the middle of the screen. It serves as a fixation point so that you know where to focus your attention on the computer screen. After the plus sign disappears, a picture will appear on the screen. The pictures are of various objects. Do not respond to any picture. They are just there to get you ready to respond to the target colors of GREEN and BLUE when they appear. Again, if the color GREEN appears, respond as quickly as possible by pressing the green key. If the color BLUE appears, then no response is required.

Any questions about that?

To help you to respond quickly, the computer will display how fast you are pressing the key when the target appears. Once you respond to a green target, the screen will show you the amount of time it took for you to make that response, in milliseconds (the fewer milliseconds, the faster the response). So lower numbers are better. If you accidentally respond to a blue target, the screen will say 'Incorrect Response'.

Any questions about that?

So just to recap, if the color GREEN appears, press the green key as quickly as possible. You are always trying to respond in the shortest time – the fewest milliseconds. If the color BLUE appears, no response is required.

The time to complete this test is about 15 minutes that includes 4 breaks. Please pay attention to the task throughout the entire session and try not to become distracted. In the breaks, a beep will sound when there are 10 seconds left on the break so that you may get ready to start again. I will stay in the room with you for the beginning of the task to make sure that you have understood the instructions and that there are no problems, so please just ignore me and do not talk while performing the task. Once you are underway, I will leave. When the test is over, please open the door and have a seat so that I will know that you are done.

Any questions? Are you ready to begin? OK, I am going to start the task, so remember to respond as quickly as possible and do your best.

Appendix B

5-Trial Adjusting Delay Discounting Task (Table from Koffarnus and Bickel 2014)

The below table describes the outcomes for the 5-trial task. For each of the 5 choices (i.e., No.), the participant is asked if they would prefer the immediate or delayed reinforcer. The delay to the delayed choice is systematically increased or decreased based on previous trial choice (i.e., Delay Choice; increases if delay is chosen, decreases if immediate is chosen). The primary outcome is k as labeled in the table below.

Table 1

Parameters of the Possible Individual Choice Trials in the 5-Trial Adjusting Delay Task

Index	Delay choice	No.	ED ₅₀ (days) if last choice is:		k if last choice is:	
			Immediate	Delayed	Immediate	Delayed
1	1 hr	5	0.04167	0.05893	24.0	17.0
2	2 hr	4				
3	3 hr	5	0.1021	0.1444	9.79	6.93
4	4 hr	3				
5	6 hr	5	0.2041	0.3062	4.90	3.27
6	9 hr	4				
7	12 hr	5	0.4330	0.7071	2.31	1.41
8	1 day	2				
9	1.5 days	5	1.225	1.732	0.816	0.577
10	2 days	4				
11	3 days	5	2.450	3.464	0.408	0.289
12	4 days	3				
13	1 week	5	5.292	8.573	0.189	0.117
14	1.5 weeks	4				
15	2 weeks	5	12.12	17.15	0.0825	0.0583
16	3 weeks	1				
17	1 month	5	25.28	43.05	0.0396	0.0232
18	2 months	4				
19	3 months	5	74.56	105.4	0.0134	0.00949
20	4 months	3				
21	6 months	5	149.1	210.9	0.00671	0.004741
22	8 months	4				
23	1 year	5	298.2	516.5	0.00335	0.00194
24	2 years	2				
25	3 years	5	894.7	1265.	0.00112	0.000791
26	4 years	4				
27	5 years	5	1633.	2310.	0.000612	0.000433
28	8 years	3				
29	12 years	5	3579.	5368.	0.000279	0.000186
30	18 years	4				
31	25 years	5	7748.	9131.	0.000129	0.000110

Note. ED₅₀ = Effective Delay 50%.

Appendix C

Commodity Purchase Task

Example Instructions for Participants

This is a series of questions designed to assess choices for alcohol across changes in price. This information is entirely for research purposes. All questions about purchasing are completely hypothetical (pretend).

Imagine a TYPICAL DAY during which you drink alcohol. The following questions ask how much alcohol you would consume if it cost various amounts of money. The alcohol is your preferred brand and type (e.g., beer, wine, liquor). Assume that each drink is a standard drink (i.e., 12 oz. beer, 5 oz. wine, 1.5 oz. shot alone or in mixed drink). Assume that you have the same income that you have now and NO ACCESS to any alcohol products than those offered at these prices. In addition, assume that you would consume all the alcohol you purchase on that day; that is you cannot save or stockpile any for a later date.

Example Questions for Participants (for the Alcohol Purchase Task)

Price/Drink	# Drinks Purchased
Free	
\$0.02	
\$0.05	
\$0.13	
\$0.25	
\$0.50	
\$1.00	
\$2.00	
\$3.00	
\$4.00	
\$5.00	

\$6.00	
\$7.00	
\$8.00	
\$9.00	
\$10.00	
\$11.00	
\$12.00	
\$13.00	
\$14.00	
\$15.00	