

Cover page

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Brown University Consent Form

Agreement to Participate in a Research Project

BEHAVIORAL ECONOMIC ANALYSIS OF DEMAND FOR MARIJUANA:

KEY INFORMATION:

You are invited to take part in a Brown University and Lifespan/Rhode Island Hospital research study. Your participation is voluntary.

- **PURPOSE:** The study is investigating the effects of marijuana on behavior. How much an individual might pay for marijuana may be related to how they react to it and how valuable they perceive marijuana to be.
- **PROCEDURES:** You will be asked to complete various questionnaires and interviews regarding your substance use, medical and psychiatric history and mood. You will be asked to refrain from all marijuana and tobacco smoking for 15 hours, alcohol for 24 hours, and caffeine for 4 hours prior to sessions. You will be asked to breathe into a tube to measure carbon monoxide levels in your lungs and also to measure blood alcohol concentration. You will be asked to complete a urine test for drug use and, if you are able to become pregnant, for possible pregnancy. At the baseline session, you will be asked to complete the questionnaires and also have a physical examination to ensure your safety in the study. For the following session, you will be asked to fill out more questionnaires and you will have the opportunity to purchase “hits” of marijuana to be smoked in the given duration of time. You will also be asked to complete a brief computerized eye-tracking task three times during the session.
- **TIME INVOLVED:** The study will take about 2 hours for the baseline session, and 4-5 hours for the experimental session.
- **COMPENSATION:** You may receive up to \$100 in Amazon gift cards for your participation in the study.
- **RISKS:** Some of the questionnaires pertain to sensitive information, which can make individuals uncomfortable. Therefore, you are free to refrain from answering any of the questions that make you uncomfortable. We also ask that you refrain from smoking for at least 15 hours prior to participation in the study, which may lead to uncomfortable symptoms associated with avoiding tobacco smoking. After smoking marijuana, your judgment may be impaired, so we ask that you stay for a few hours to avoid possible adverse events.
- **BENEFITS:** You will receive no direct benefit from this study. However, this research will help further our understanding of marijuana value and behavioral effects of marijuana use.

Principal Investigator

Elizabeth Aston, Ph.D., Center for Alcohol and Addiction Studies, Brown University School of Public Health, Box G-S121-5, Providence, RI 02903.

The Project.

The purpose of this Brown University research is to investigate the effects of marijuana on behavior. Demand for marijuana (how much an individual will pay for marijuana) may be related to how people react to marijuana and how valuable they perceive marijuana to be. In this study, we are interested in learning whether demand for marijuana is related to behavior and reaction to marijuana’s acute effects. The findings from this study may help increase our knowledge about marijuana’s effects.

What Will Be Done.

In order to confirm your eligibility for the study and complete today's session, you will be asked to complete several brief questionnaires and interviews about your substance use, medical and psychiatric history, and mood. You will be asked to breathe into a tube that will measure the amount of carbon monoxide in your lungs and this information will be used to confirm that you have avoided all smoking prior to today's session. If the test suggests you have smoked within the past 15 hours, you will not be able to complete the session and will be given one more opportunity to come in for a session without smoking. You will be asked to blow into a machine that will tell us whether you drank any alcohol before coming in. If there is alcohol in your breath, we will have to re-schedule the interview. You will also be asked to give a urine sample, which will be tested for recent drug use, and must be positive for marijuana. If you are a woman, the urine will also be tested for pregnancy. In the event of a positive urine test for illicit drugs other than marijuana, you may reschedule the session once. If you are found to be ineligible for the study based on the interview or a repeated positive urine drug test, you will be paid \$10 for your time and effort.

During today's session, you will complete paper-and-pencil questionnaires. If you are eligible to participate in the study based on the interview and a urine drug test, you will be asked to undergo a standard physical and a review of your medical history to determine if it is safe for you to be in the study. If it is determined that it would not be safe for you to be in the study, your participation will end. If we ask you to complete the physical exam, you will be paid \$30 in Amazon gift card at its completion (\$20 for completion of the baseline session and \$10 for completion of the physical exam). If you are eligible to participate in the study based on the physical exam, you will be asked to schedule one additional session. The next session should be completed from five days to three weeks from the previous session. If you are unable to complete them within this time frame, you will be withdrawn from the study.

For the next session, you will be asked to refrain from all smoking starting at least 15 hours before your sessions, avoid drinking alcohol for 24 hours and any caffeinated beverages for one hour prior to the sessions. Just as with the first session, you will be asked to breathe into a tube that will measure the amount of carbon monoxide in your lungs, and this information will be used to confirm that you have avoided smoking. If the test suggests you have smoked within the past 15 hours, you will not be able to complete the sessions and will be given one more opportunity to come in for these sessions without smoking. You will also be asked to blow into a machine that will tell us whether you drank any alcohol before coming in that day. If there is alcohol in your breath, you will not be eligible to continue. You will be asked to give another urine sample, which will be tested for recent drug use. If you are a woman, the urine will also be tested for pregnancy.

At the next session, you will be asked to fill out some brief questionnaires and a computerized eye tracking task. Then, you will be asked to smoke a marijuana cigarette. The cigarettes will be provided by the National Institute of Drug Abuse. During this session, you will have the opportunity to purchase "hits" of marijuana with a monetary tab we will provide to you. We will monitor your blood pressure and heart rate while you are smoking. Following the end of the marijuana administration portion of the session, you will be asked to complete the same computerized eye tracking task as you did prior to smoking. Afterwards, you will receive snacks and you will be asked to complete the eye tracking task again one hour later. For your safety, we ask that you remain in the laboratory for 3 hours after the end of the smoking portion of the study to allow for the effects of marijuana to dissipate. After 3 hours, you will be evaluated for signs of marijuana intoxication and you will complete a field sobriety test.

Following successful completion of the sobriety test, you will be permitted to leave. You may not drive yourself or operate any other form of transportation (e.g., a bike, scooter, skateboard, etc.) but you may use other forms of transportation to get home (e.g., designated driver, taxi, bus, walk, etc.).

Today's session will last about two hours and the next session will last 4-5 hours. In Amazon gift cards, you will earn \$20 for completing the baseline session, \$10 for completing the physical exam, and \$50 for completing the smoking session, plus the amount that you can earn during the experimental session (up to \$20). The total possible payment you may earn for participating in this study will be \$100 in Amazon gift card, and the minimum you will earn for completing both days is \$80. To ensure valid data, it is important that you complete all of the study-related activities according to the specified procedures.

You are free to stop the study at any point during the session. If you choose to stop participating before the second session is complete, you will receive a partial payment of \$10 for that session.

Benefits.

You will receive no direct benefit from the research procedures. However, data obtained from this research may further our understanding regarding marijuana value and behavioral effects of marijuana use.

Potential Risks and Protections Against Risk.

Some of the questions ask about personal matters, including thoughts and feelings which may be private, and about behaviors including drug use. For example, questions like, "How many hours are you high or under the influence of cannabis on a typical day?" will be asked. These questions may make you uncomfortable. Therefore, you are free not to answer any questions you do not wish to answer. In addition, you will be asked to avoid all smoking for a period of at least 15 hours. Avoiding tobacco smoking can cause some uncomfortable symptoms such as irritability, anxiety, difficulty concentrating, and craving for cigarettes. You will have the option to smoke a tobacco cigarette in the beginning of each of the study sessions after your carbon monoxide levels are tested upon arrival. You will be asked to smoke marijuana, which may contain tar and other cannabinoids and result in carbon monoxide increases, and is also classified as a controlled substance. Carbon monoxide exposure will be equivalent to one marijuana cigarette and may exceed that of a tobacco cigarette. After smoking marijuana, your judgment may be impaired for a few hours, which is why you will need to stay with us during that time. A possible adverse effect of active marijuana is an acute anxiety reaction. We will monitor your reactions to marijuana at all times during the smoking session. If you experience any anxiety, you will be immediately evaluated by the study's Principal Investigator, Dr. Elizabeth Aston. Dr. Jane Metrik, a study Co-Investigator, is a licensed clinical psychologist and will be readily available in case of any psychological adverse reaction to the drug. Another possible adverse event is short-term dry mouth, which should be mild. If you need water, we will provide it for you. Another possible adverse effect of active marijuana is a short-term increase in heart rate. We will monitor your heart rate, blood pressure, and your reactions to marijuana at all times during the experimental session. If you experience any heart rate increases that are more severe or longer-lasting than you have experienced previously with marijuana, or if you are experiencing chest tightening or chest pain, please let us know and we will ensure that the appropriate emergency medical treatment is provided. You are also free to stop smoking at any point during the smoking session.

Due to potential adverse effects of alcohol or marijuana on a fetus, it is important for female participants to use a reliable means of contraception if engaging in sexual intercourse with a man during the course of this study. If you are capable of becoming pregnant and want to participate in this study, you must agree to complete a pregnancy test that we will provide and to use a medically accepted means of birth control. Let us know if you change your mind and decide to become pregnant during the study. You must not nurse a baby while participating in this study.

The computerized eye tracking task is noninvasive. This task involves watching a brief video move around the perimeter of an LCD monitor positioned in front of you while a camera records your eye positions. As such, it is very unlikely to cause any discomfort. Further, the risk of breach of confidentiality associated with this technology is very low.

Confidentiality.

All data and other information related to you will be kept confidential. Given the sensitive nature of this research, we will implement multiple procedures to protect your identity. We will not put your name on any data forms; only this consent form and telephone/email contact form will have your identifying information on them. Your consent form and telephone/email contact information will be stored in a locked location separate from all the questionnaires and data. Your telephone/email contact form will be shredded after you complete the study unless you indicate that you are willing to be contacted for future research studies. All assessment data will be coded with an identification number rather than using your name and will be stored in locked file cabinets and password-protected computer files available to the investigators and our research team only. The cross-index of your name and participation ID number will be kept in a separate locked location. The cross-index will be destroyed after your study completion. The computer forms we use for the questionnaires will facilitate confidentiality by separating questions from answers.

Brown University and Lifespan/Rhode Island Hospital staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.

This research study is a clinical trial. A description of this clinical trial will be available on <https://www.clinicaltrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information. The Certificate of

Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse or intent to hurt self or others.

Right to Quit the Research at Any Time.

Participation in this study is strictly voluntary. If you decide to participate, you will be free to withdraw from the research program at any time and it will not affect your relationship with Brown University or Lifespan/Rhode Island Hospital. If you choose not to participate in this research, but would like information on marijuana treatment programs, we will provide you with a list of potential resources.

Who to Call.

Please ask any questions you may have now. If at any time you have further questions about this project or your rights as a participant, please feel free to ask the Principal Investigator, Dr. Elizabeth Aston, at (401) 863-6668. Please call Dr. Aston and study staff at (401) 863- 6668 if any potentially adverse events occur in between study visits. If you have any questions about your rights as a participant, you may also contact the Brown University Human Research Protection Program at (401) 863-3050.

Consent to Participate.

(Check Yes or No, and sign your initials)

I agree to be re-contacted for future studies: ☐ Yes ☐ No _____(initials)

Your signature below means that you have read the information on this form, asked any questions you have about the project, and agree to participate in this study as indicated above. You will be given a copy of this form to keep.

I agree to participate in this project.

Signature of participant

Date

Signature of witness (Research Staff)

Date

Copies to:

Participant; Investigator's files

(Version 9, date 10/8/2020)