BROWN UNIVERSITY
ASSENT FOR RESEARCH PARTICIPATION

Supporting Adolescent Alcohol Treatment with Computer-Based ('Path180') Skills Training

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Key Information: You are invited to take part in a Brown University research study. Your participation is voluntary. This form describes the study, and a member of the study team will explain it to you and answer any questions.

- PURPOSE: This study will test whether an alcohol education and skills training program called 'Path180' helps teenagers, who are already getting counseling for mental health, alcohol, or other drug use, reduce their drinking.
- PROCEDURES: During study visits and while using an app on a smartphone in your daily life, you will be asked personal questions (e.g., questions about alcohol & drug use, mental health, etc.). You may also be asked to use Path180.
- TIME INVOLVED: The study takes about 8 weeks to complete, and then you will be asked to complete two follow-up visits 3 and 6 months later. In total, participation will take 15 hours of your time plus possibly using Path180.
- COMPENSATION: If you complete the study, you will receive up to $470 for your time.
- RISKS: Possible risks or discomforts include answering personal questions, possible loss of confidentiality, and undue pressure.
- BENEFITS: Path180 may help some participants cut back or stop drinking. In addition, we may learn something that will someday help other teenagers who are trying cut back or quit their alcohol use. But we cannot and do not guarantee or promise that you or anyone else will receive any benefits from this study.
- ALTERNATIVES TO PARTICIPATION: We do not offer other research options. The alternative is not to participate. You can continue to get counseling, treatment or clinical care for mental health or alcohol problems without being in this study or choose not to get any treatment.

1 Why am I being invited to take part in a research study?

We invite you to take part in Brown University research study because you are a teenager getting help, like counseling or therapy, for your mental health or substance use.

2 What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.
- If you have any questions about which entities fall under the above hospital or academic systems, please ask the study team.

3 Why is this research being done?

The purpose of this study is to find out whether an alcohol education and skills training program called 'Path180' helps teenagers, who are already getting counseling for mental health, alcohol, or other drug use, reduce their drinking. We also hope to learn just how Path180 might work to help teenagers. We will enroll about 112 teenagers.

Path180 is a 7-part computer-based program created specifically for teenagers. By educating teenagers about alcohol, boosting their motivation to change, and teaching coping skills, Path180 is designed to help youth cut back or stop drinking alcohol. Each module is brief (~15 to 20 minutes) and includes exercises to help teenagers learn new skills and apply them in their daily lives.

4 How long will the research last and what will I need to do?

We expect that you will be in this research study for eight weeks plus two visits at three and six months.

You will be asked to complete twelve study visits over six months and use an app on your phone every day for 56 days.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

5 Is there any way being in this study could be bad for me?

There are risks, discomforts, and inconveniences associated with any research study. Our study team will do our best to make sure you are comfortable during the study. The main risks for this study are minimal and unlikely.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

6 Will being in this study help me in any way?

We do not know if you will be helped by being in this study. If you are assigned to the Path180

group, it may help you cut back or stop drinking alcohol. In addition, we may learn something that will someday help other teenagers who are trying cut back or quit their alcohol or other drug use. But we cannot and do not guarantee or promise that you or anyone else will receive any benefits from this study.

7 What happens if I do not want to be in this research?

Participation in this study is entirely voluntary. You do not have to be in this study if you do not want to participate. Even if you decide to enroll in this study, you can change your mind and stop at any time by contacting the study team.

If you decide to stop your participation in this study, it is important to tell the study team so that we can pay you for any study activities you completed and if applicable, get the study electronic device from you. Stopping participation in this study will not affect your benefits or medical care to which you are entitled or your current or future relationship with Brown University, Dr. Miranda or other researchers, or any health care service providers.

If you choose not to be in this study, we do not offer any other research study. Your other choices may include getting standard clinical care for mental health or substance use, either through your current treatment/counseling provider or another treatment/counseling provider, without being in this study or not getting any treatment/counseling.

8 Detailed Information:

The following is more detailed information about this study in addition to the information listed above.

8.1 Who can I talk to?

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may contact them at irb@brown.edu or (401) 863-3050 if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

8.2 How many people will be studied?

We expect about 112 people to be in this research study.

8.3 What happens if I say yes, I want to be in this research?

If you decide to be in this study, here's what will happen:

- You will complete a screening visit(s) (~1 hour) to see if this study is right for you. This visit will take place in a private location, either at our Brown University offices or remotely via Zoom. You will be asked about any alcohol or drug use that day. If you report drinking or drug use for that day, we will reschedule the visit. You will

complete an interview and survey forms that ask personal and sensitive questions about your alcohol and other drug use, mental health, and any counseling or therapy you receive. You may refuse to answer or skip any questions or parts of the study you don't want to complete or stop the study at any time. More than one visit may be scheduled to complete the screening process, if that works best for you.

- If you're eligible after the screening, this study takes about 14 hours and involves 11 study visits over 9 months.
- Some visits may be done by phone or Zoom video conference You may be asked to sign in or download an app to use Brown University's Zoom platform, depending on your device, and you will need internet connection. You will be asked to provide your current location (i.e., street address) at the start of all remote visits in case you report you've been thinking about harming yourself or someone else. This information will be destroyed immediately after the visit.
- In the first 8 weeks, you will be asked to:
    - Complete a study-start visit (~1 hour) that involves answering questions about your alcohol and other drug use, mental and physical health, relationships, and any counseling or therapy or other treatment you receive.
    - Complete 8 weekly check-in visits (~30 minutes each). At each visit, you will answer questions about your alcohol and other drug use, mental and physical health, relationships, and any counseling or therapy or other treatment you receive. The final check-in visit will occur at the very end of or shortly after the 8-week period.
    - Answer a brief set of questions on a smartphone app about 4 times per day as you go about your daily life. Each set of questions takes about 2 minutes to answer. You will answer questions when: (a) you wake up each morning, (b) the app prompts you (~4 times per day), and (c) you drink alcohol or use cannabis, if any. You'll record *where* you are, *what* you're doing, *who* you're with, and *how* you're feeling. You'll also report how much alcohol you drank or other substances you used, if any. You should ignore the app when you're driving or in other situations where it would be unsafe to use a handheld device. Please note that no one on the study team is monitoring your answers to these smartphone questions at any particular time. And so, other than during visits done remotely using Zoom, no member of the study team will know about your location, activities, mood, etc. in real time during the study.
    - Complete Path180 and practice the skills it teaches for about 7 hours over 8 weeks (less than 1 hour per week), *if you're assigned to the Path180 group*.

      This study has two different groups of participants. One group will use Path180; the other group will not. We use a method of chance to see which group you will be in. It's like flipping a coin or rolling dice. About half (i.e., 56) of the participants will be in the Path180 group; the other half will not. Neither you nor the study team can decide to which group you will be assigned.

If you're in the Path180 group, you will get a unique link to access the program on a secure website. You will also get a packet of worksheets so you can follow along with the program. You can use Path180 at our offices, the clinic, at home, and in other locations. It works on most devices connected to the internet (e.g., computers, tables, smartphones). Accessing Path180 through Wi-Fi is free. But accessing it through a device with a data plan outside Wi-Fi may result in charges that you would be responsible to pay.

Whenever possible, participants will complete a Path180 module at the weekly check-in visits. Additionally, we will remind participants through text messages to use Path180 throughout the 8-week skills training period.

- If you don't have an electronic device, you can borrow one from us. It should be used for this study only. You can pick it up at Brown University, we can deliver it to you at the clinic, or we can mail it to your home. When you're done with it, you can return it to our offices, the clinic, or through the mail using a pre-paid return envelope.
- You will complete 3 and 6-month follow-up visits (~30 minutes each). Each visit involves answering questions about your alcohol and other drug use, mental and physical health, relationships, and any counseling or therapy or other treatment you receive.
- At each study visit, we will update your contact information to help us keep in touch with you during the study. We will also ask you to provide us with contact information for family and friends who may know the best way to reach you in case we have trouble contacting you. If we need to contact those individuals, the study team will not reveal any information about the study or your treatment.

Timetable of Study Assessments

	Screening Visit	Study Start Visit	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Follow-up Visits
Interviews & survey forms	•	•	•	•	•	•	•	•	•	•	•
Path180 program			•	•	•	•	•	•	•	•	
Smartphone questions			•	•	•	•	•	•	•	•	

NOTE: Some study visits may be done by phone or Zoom video conference. Only participants assigned to the Path180 group will complete the Path180 program.

8.4 What happens if I say yes, but I change my mind later?

Participation in this study is entirely voluntary. You do not have to be in this study if you do not want to participate. Even if you decide to enroll in this study, you can change your mind and stop at any time by contacting the study team.

If you decide to stop your participation in this study, it is important to tell the study team so that we can pay you for any study activities you completed and if applicable, get the study electronic device from you. Stopping participation in this study will not affect your benefits or medical care to which you are entitled or your current or future relationship with Brown University, Dr. Miranda or other researchers, or any health care service providers.

8.5 Is there any way being in this study could be bad for me? (Detailed Risks)

There are risks, discomforts, and inconveniences associated with any research study. Our study team will do our best to make sure you are comfortable during the study. The main risks for this study are minimal, unlikely, and include:

- You might feel uncomfortable, embarrassed, or bored by some of the questions. You may refuse to answer or skip any questions or parts of the study you don't want to complete or stop your participation at any time. You may also request to schedule a time speak with Dr. Miranda, a board-certified licensed clinical psychologist, if you experience emotional distress regarding study assessments or procedures.
- You will be asked to answer personal and sensitive questions, such as questions about your alcohol and other drug use, mental and physical health, and any counseling or therapy you receive. There is a risk of loss of privacy or confidentiality of this information. We take this risk very seriously, and we will take steps to protect your personal information. To protect your privacy during study visits, we will make sure no one can overhear the conversation. We ask you to use headphones if possible and have others leave the room for visits conducted remotely by phone or video conference. Additionally, you will be able to choose a day and time for remote visits to help ensure privacy.

  Your name will never be recorded on any study assessments or data. All information that could identify you, such as your name, email address, phone number, etc., will be kept in a separate file from your research data. A study number unique to you will be used to identify all study assessments and research data. The link between your identity and the study number is confidential and will be kept separate from all study data. Only the principal investigator and members of the study team who have direct contact with you will have access to your identity.
  Research data is kept in file cabinets located in our locked offices at Brown University. These file cabinets are locked except when in use. Computer data files will be kept on secure servers at Brown University and saved with password protection.

  When we are finished doing this study, we will write reports about what we learned. These reports will not list your name. Your identifiable private information will be stripped of identifiers and may be used for future research.

  There is a possibility that someone outside the study will see the private text messages sent by the study team to you reminding you to: (a) attend upcoming study visits, (b) answer questions on the study smartphone app, and (c) if applicable, use the Path180 program. All text messages from the study team will be limited to simple general reminders; no message will include or request any personal or sensitive information. We encourage you to use a strong password or passcode on your smartphone to help reduce any privacy-related issues concerning study messages on your phone.

  There is a possibility that others may see you answer questions on the study smartphone app when you are in public places or with others. Similarly, it is possible others may see you using the Path180 program if you are assigned to the Path180 group. We encourage you to answer smartphone questions and, if applicable, use

Path180 in private. We also urge you not to read or respond to study text messages or answer smartphone questions while you are driving or in other situations where it is unsafe. You should wait until you are in a safe and private place before doing study-related activities on your phone.

As with any research study, there may be risks that are not yet known or expected. We will let you know if we learn of anything new about our study that might change your mind about participating. Please tell us about any concerns that come up while you're in this study.

- Sometimes people can feel pressured to participate in a research study. This pressure can happen if they are offered a lot of money or a reward for their participation. Such pressure is unlikely in this study because the payment is fair for the time and effort required, and it is like other studies in our local area. There will be no other rewards or payments. You will be paid using e-gift certificates to Amazon or ClinCard as you complete each part of the study, as described in the payment schedule (see Section 4). You will not receive cash or a large sum at the end of the study. Additionally, even if you stop participating for any reason, we will pay you for any parts of the study you complete.

8.6 What happens to the information collected for the research?

Any information we collect as part of this study that identifies you will remain confidential. Only a study number will be used to identify your private information; your name will not be matched with your private information. We will keep all information about you locked up and password protected. It will be disclosed only with your permission or as required by law.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

8.7 Will my data or samples be used for future research?

Identifiers will be removed from your identifiable private information, and after such removal the information could be used for future research studies by the study team without additional informed permission from you.

8.8 Can I be removed from the research without my OK?

The study team may stop you from taking part in this research study at any time if they believe it is in your best interest (e.g., continuing participation could be harmful to you), if you do not follow the study procedures or the instructions of the study team, or if the study is cancelled.

Although you must be getting counseling/therapy for your mental health or substance use to enroll in this study, your participation in this research study will not end if you decide to discontinue counseling/therapy at any time during the study. It is very important, however, that you understand that neither Path180 nor participation in this research study more broadly is intended to take the place of standard clinical care for alcohol or other drug use or any related mental health issues.

9 What else do I need to know?

This research is being funded by the National Institute of Health.

You will receive up to $470.00 for your participation. You will be paid for all parts of the study you complete even if you stop the study early for any reason. You will be paid $20 for the screening visit even if you are found to be ineligible.
Participants in the Path180 group will not be paid for using the Path180 program. The payment schedule is as follows:

Study Activity	Total Possible Compensation	
Screening visit	$20	
Study-start visit	$20	
8 weekly check-in visits	$160	$20 for each check-in visit
8-week smartphone period	$140	$2.50 per day for using the study app
3-month follow-up visit	$40	
6-month follow-up visit	$40	
Bonus	$50	For completing all visits
	Total = $470	

Payment for participating in this study will be made using e-gift certificates to Amazon or

ClinCard, a pre-paid Mastercard that works like a debit card. If you choose ClinCard, you will be given one card for the entire time of your participation and this card may be used to pay you in any future Brown University studies that use ClinCard. You will also get information about how to use this card and whom to call if you have any questions. Be sure to read this information, including the cardholder agreement from Greenphire.

Money will be added to your card based on the study's payment schedule (see above). You can use this card online or at any store that accepts Mastercard. Please read the FAQ information sheet from the study team for details about the ways you can use the card, some of which may involve fees that will reduce the amount of money on the card.

If you earn $600 or more from Brown University in a single calendar year (either in a one study or across multiple studies), Brown will request your social security number to correctly identify you in the payment system and issue you an IRS 1099 Form. You may also be asked to complete a Form W9. This may affect your taxes. Only payments for being in research studies will be used to decide if you should receive the IRS form. Money for study-related parking, food, and other expenses are not included in this IRS disclosure.

This card is administered by an outside company called Greenphire. Greenphire will be given your name, address, and date of birth. They will use this information only as part of the payment system, and it will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating. If your card is lost or stolen, please call the study team for a free replacement card. If you request a replacement card from Greenphire directly, you may be charged a fee.

You will install the free application on your phone via the Apple Store or Google Play store. The app is supported by both Android and IOS. Your Apple ID or Android account will not be required to install the app. Research staff will be available via Zoom to assist with installation and training. No identifiable information is collected by the app including GPS, cookies, or IP addresses. The app collects your answers to the self report questions and does not collect other data. The app is not an Apple research app and will not share data with Apple Health.

Signature Page

This form contains important information to help you decide if you want to join this study. If you have any questions that are not answered in this form, ask the principal investigator or another study team member.

Before you say yes or no to being in this study, we want to make sure you fully understand what this study is about and what you would be asked to do if you decide to enroll. Before signing this consent form, please answer the following six questions.

1. Can you tell me what this study is about?
2. What is something that you will be asked to do in the study?
3. Can you tell me one of the risks of the study?
4. Will this study help you?
5. Will the researchers ever tell someone you were in this study?
6. Do you have to be in this study?

Please answer YES or NO to the following questions.

		Circle Yes or No
1.	Is this document in a language you understand?	Yes No
2.	Do you understand the information in this form?	Yes No
3.	Have you been given enough time to ask questions and talk about the study?	Yes No
4.	Have all your questions been answered to your satisfaction?	Yes No
5.	Do you think you received enough information about the study?	Yes No
6.	Do you give your consent of your own free will and without being pressured by the principal investigator or other members of the study team?	Yes No
7.	Do you know that you can leave the study at any time without giving a reason and without affecting your health care?	Yes No
8.	Do you know that your records from this study may be reviewed by the study sponsor and by government authorities?	Yes No

You must also be able to answer "Yes" to questions 1 to 8 listed directly above.

Please check YES or NO and write your initials to let us know whether you agree to be recontacted to learn about future studies. Your answer to this question will not influence in any way your ability to participate in this study.

_____Yes _____No Initials _____

Your signature below shows that you have read and understood the information in this document. The study team has answered your questions to your satisfaction, and you agree to volunteer as a research participant for this study.

Your signature documents your permission to take part in this research.

_____

Signature of participant Date Time

_____

Printed name of participant

_____

Signature of person explaining consent Date Time

_____

Printed name of person explaining consent