

INFORMED CONSENT AND TEEN ASSENT

Mindfulness Mobile App to Reduce Adolescent Substance Use
(The Qlarity Study)

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Informed Consent for Participation in Qlarity Study

Study Title: Qlarity Study

Principal Investigator: Dana Smith, Ph.D.

Sponsor: National Institute for Drug Abuse (NIDA R44 DA043288-02)

SUMMARY

We are inviting your teen to take part in a research study. Your teen does not have to be in the study if s/he does not want to be. You and your teen can also decide to be in the study now and change your mind later.

This study is about helping teens reduce stress and make healthy decisions about behavior and avoiding substance use.

If your teen takes part in this study, we will ask her/him to answer survey questions about stress and behavior three times over three months and complete confidential urinalyses (UAs).

Some of the teens will be asked to use an app on their phones daily for a month. This app is designed to help teens develop stress management skills and reduce substance use. This study is testing the app to see how helpful it is for teens.

We plan to make the results of this study public but we will not include your name or other identifying information, and none of your information can be linked to you in any way.

We would like you to ask us questions if there is anything about the study that you do not understand. You can call (541) 484-2123 and ask to speak with someone from the Qlarity Study or email us at qlarity@influentSin.com.

You can also contact the Office for the Protection of Human Subjects with any concerns that you have about your rights or welfare as a study participant. This office can be reached at (541) 484-2123 or by email at kathryn@ori.org.

There are more details about the study in the following pages. On the last page, you can indicate if you give consent for your teen's participation.

Informed Consent for Participation in the Qlarity Study

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STUDY DETAILS

WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

Your teen is invited to participate in a research study about helping teens reduce stress and make healthy decisions about behavior and avoiding substance use. This study is being conducted by Dana K. Smith, PhD of Influents Innovations in Eugene, Oregon and is funded by the National Institute for Drug Abuse (NIDA R44 DA043288-02). We want everyone in the study to understand its focus. Please read this form and ask any questions you may have before agreeing to participate in the study.

This project will compare two different types of programs to see if one works better than the other. Everyone who takes part in the project will be randomly put into one of two groups. One group will receive services from the Department of Youth Services and use an app that is designed to help teens reduce stress and make healthy decisions about behavior and avoiding substance use. The other group will receive services as usual from the Department of Youth Services and not use the app. If you and your teen agree to take part, you should understand that s/he will be selected randomly, as by a coin toss, for one of the two groups.

WHAT WILL YOUR TEEN BE ASKED TO DO IN THIS RESEARCH STUDY?

If you and your teen decide to participate, your teen will be asked to complete 3 surveys for the Qlarity Study. For the first survey, your teen will complete an interview and some questionnaires about behavior, emotions, and use of alcohol and drugs. This visit can be done during a visit to Influents Innovations, located within Oregon Research Institute, or at home, using a video platform like Zoom to work remotely with an interviewer. The first visit will take about an hour and will include collecting a urine sample. The urine will be checked for the presence of drugs. The results will never be shared with anyone, including you, your teen, or anyone else. The urine samples will not be distributed or used for future research studies; samples will be destroyed after testing.

Half of the teens will be asked to use the Qlarity app. This is determined randomly, as by a coin toss. If your teen is using the app, this first visit will also include installing the app, receiving directions on its use, and completion of the first activity. The app has 12 activities, each with a teaching and a practice component. We ask the teens to complete the other 11 activities on 11 different days within the month following the first survey. The practice components can be repeated as often as desired. Study staff may check in with your teen by phone, text or email about use of the app during this month.

We will ask all teens to attempt to reduce their use of tobacco, alcohol, and other drugs in the month following the first survey. After 1 month, teens will be asked to complete the second survey. After another 2 months, teens will do the third and final survey. These surveys ask the same questions about behavior, emotions and substance use, and will take 30 to 45 minutes to complete. Teens who used the app will also be asked for their opinions about various features. These surveys may be done at home using a survey link sent via email or text or may be done during a visit to Influents Innovations. Urine samples may be collected at the times of these surveys.

Visits with Qlarity staff at Influents Innovations will be audio-recorded so that we can check accuracy of the data and for safety and training purposes. The use of audio-recordings will be limited to research and training of project staff under the supervision of the project directors. Research staff may at any time copy, erase, or destroy these recordings. Your teen may review the recording and request that any or all of the information be destroyed. Your teen may also request that the recording be stopped at any time during the interview.

After completing each survey, teens will have a choice of an Amazon gift card or a check. Teens who complete all 3 surveys will receive \$110.

Activity	Description	How long	Received
First Assessment	Complete first survey and urinalysis (UA); may install app on phone	About 1 hour	\$25
Using the App	Complete all 12 activities on 12 different days Complete daily check-ins	About 5-10 minutes per day	
1 Month Assessment	Complete second survey and possible UA	About 30-45 minutes	\$35
3 Month Assessment	Complete final survey and possible UA	About 30-45 minutes	\$50
	TOTAL		\$110

WHAT OTHER TYPES OF INFORMATION WILL THE PROJECT COLLECT?

In addition to the information we collect through surveys and urine samples, staff will also collect information from juvenile and/or adult court records.

WHAT ARE THE RISKS AND WHAT IS DONE TO REDUCE THE RISKS?

We will be getting personal information from your teen. There is always the possibility that someone who is not authorized might see it. We take the following precautions to prevent any unauthorized person from having any access to the information your teen gives us:

- Any information your teen gives us will be kept strictly confidential. Parents will not have access to their teen’s information. We train all staff members to protect the privacy of participants and store all information in safe, locked areas. We will remove all names from all the information we get (except this consent form). ID numbers will be assigned to the information your teen gives us, and only authorized staff will have access to the locked electronic file that links teens’ names to their ID numbers.
- All information about your teen is stored in locked file cabinets or in password protected electronic files. Identifying information is stored separately from information collected during assessments, so your teen’s name is not associated with any of her/his answers.
- We will be asking your teen some personal questions about feelings and experiences. Your teen might feel a little embarrassed or uncomfortable because of the personal nature of some of the questions. Remember, your teen is free to decline any questions or activities.
- We will do all we can to protect your teen’s confidentiality. However, because your teen is a client of DYS, others in DYS might be able to figure out that your teen is in this study.

We have a “Certificate of Confidentiality” which is a legal assurance from the federal government, which will help us protect your privacy even if the records are subpoenaed. We will not give information to anyone unless you provide a signed release telling us to do so, or unless we have reason to suspect: 1) abuse, neglect, or endangerment of a child or elder; 2) or that anyone is in immediate danger of seriously hurting himself/herself or someone else. In these situations, we may have to make a report to the appropriate authorities.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov> . This website will not include information that can identify your teen. At most, the website will include a summary of the research results. At the very end of the project, we will post a study consent form to the same website. The consent form will not have names on it. You can search this website at any time.

STORAGE & FUTURE USE OF YOUR INFORMATION

We may keep information about your teen forever because we may combine or compare data from this study with data from studies we might do in the future. We would like your permission now to use your teen's personal information without having to ask again in the future. We will only use this information in other studies about ways to help teens and families. We will remove all names and information that identifies participants before we use it in a new study. We will not share responses or other personal information with people outside of the study team. There is still a chance that someone could figure out that the information is about your teen.

WHAT ARE THE BENEFITS OF THIS STUDY?

There are also some benefits to your teen for taking part in this research project. The researchers affiliated with Influents Innovations and Oregon Research Institute are well respected and well known in the U.S. and in other countries. The studies we do improve our knowledge about people's health and behavior. The information gained from this project might help us understand more about teens and the tools that help them feel confident and make choices that promote their success.

WHAT HAPPENS IF YOU ARE INJURED?

This study involves talking to an interviewer, answering questions using an iPad or other mobile device, and possibly using an app on a mobile phone. We do not anticipate any injury happening to participants as a result of being in this study.

DO YOU HAVE A RIGHT TO WITHDRAW FROM THE PROJECT?

Participation is entirely voluntary and the decision whether or not to participate will involve no penalty or loss of benefits that your teen might otherwise receive. If you and your teen decide to participate, s/he can stop participating any time without penalty. Teens receive checks or gift cards for each part of the study that is completed.

If you or your teen have questions about the research at any time, or if you or your teen have a visual or other impairment and require this material in another format, please call (project staff member's name and telephone/address.) If you have questions about your rights as a research subject and/or research-related injury, call the Office for the Protection of Human Subjects, Oregon Research Institute, (541) 484-2123. ORI's TDD number is 800-735-2900. You will be given a copy of this form to keep.

WHAT DOES MY SIGNATURE ON THIS CONSENT FORM MEAN?

Your signature below indicates that you:

- have read and understand the information provided above
- willingly agree to allow your teen to participate
- understand that you may withdraw your consent and stop your teen's participation at any time without penalty
- that you have received/will receive a copy of this consent form.

I have the legal authority to give consent for my teen to take part in this program because I am the biological or adoptive parent or legal guardian and I have sole or joint legal custody of my teen.

Teen's Full Name

___/___/___
Teen's Birthday

Parent/Guardian Signature

Parent/Guardian Name (Please Print)

___/___/___
Date

Parent/Guardian Phone Number

Parent/Guardian Email

Qlarity Study

Teen Assent

The purpose of this study is to help teens reduce stress and make healthy decisions about behavior and avoiding substance use.

All teens in this study are asked to:

- Do an initial interview that takes about an hour. We will ask you some questions, and you'll read and answer some questions, about your behavior, emotions, stress management, and substance use. We'll also ask you to do a UA (urinalysis), which means that you provide a urine sample and we check it for the presence of drugs. We do not tell the results of the UA to you, your parents, or anyone else.
- Do two more interviews and UAs, 1 month after your first interview and again 3 months after the first interview. The questions will be very similar to those in the first interview, asking about your behavior, stress management, and substance use.
- Read and answer the questions about behavior, emotions and substance use completely and honestly.
- Reduce your use of substances in the month following your first interview. By substances, we mean alcohol, pot, vapes, and any other drugs.

Teens in this study will be asked to try different methods of reducing stress and substance use. Some teens will be asked to use an app daily for about a month. If you are asked to use the app:

- There are 12 activities (each containing a training and practice exercise) to complete
- We will help you install the app and complete the first activity at your first interview
- Please use the practice exercises as often as you like
- Share your thoughts and feedback about the app as part of the next survey
- We may contact you to see how you are doing with the app

All the answers that you provide, including the results of the UA, are confidential. We use a code number instead of your name to identify your answers. Your name is not on the UA and the results are not shared with parents, teachers, or DYS. None of your information is shared with anyone. The only exceptions to this are the following:

- If you ask that we share your information and you provide a signed release for us to do so
- If we learn about abuse, neglect, or endangerment of a child or elder
- If we learn that anyone is in danger of hurting her/himself or someone else

Your participation is voluntary. No one is requiring you to participate in this study and you can decline to answer questions or discontinue the study at any time without penalty.

The interviews are audio-recorded so that we can check for accuracy of the data and for safety and training purposes.

After completing each survey, you will receive a check or Amazon gift card. Teens who complete all 3 surveys will receive \$110.

Activity	Description	How long	Received
First Assessment	Meet to complete first survey and UA; may install app on phone	About 1 hour	\$25
Using the App	Complete all 12 activities on 12 different days Complete daily practices	About 5-10 minutes per day	
1 Month Assessment	Complete second survey	About 30-45 minutes	\$35
3 Month Assessment	Complete final survey and UA	About 30-45 minutes	\$50
	TOTAL		\$110

I understand the research project as described above and I agree to participate.

Signature Name (Please Print) Date __ / __ / __

Phone Number Email __ / __ / __ Birthday

Facebook name Which do you prefer? Check Amazon gift card