

Study Title: Parents and Teens Together (PATT): A Dyadic Digital Intervention to Prevent Substance Use Disorders

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Approved by the University of Vermont Institutional Review Board on February 22nd 2024

University of Vermont Consent to Participate in Research

Title of Research Project: Parents and Teens Together (PATT): Developing A Digital Intervention to Prevent Risky Health Behaviors

Lead Investigator: Amy Hughes Lansing, Ph.D.

Sites Where Research is Being Conducted: University of Vermont

Sponsors: University of Vermont, Department of Psychological Science

Throughout this document "you" refers to "you or your child".

Introduction

You are being invited to take part in this research study because you are a young teenager (12-14 years old) with a parent who wants to learn how to work with their teen to prevent risky health behaviors. This study is being conducted by the University of Vermont.

Your participation in this research study is optional. We encourage you to ask questions and take the opportunity to discuss the study with anybody you think can help you make this decision.

Key Information to Help You Decide Whether or Not This Study Is Right for You

This research project will help us learn more about how to help **families develop skills that can prevent risky behaviors** like experimenting with substance use in young teens.

- All participation in this study will happen from home. There are no in-person visits.
- **In this study we will ask teens and their parent to:**
 - Participate in a 2-hour virtual family management skills training session with a health coach.
 - Complete an online survey before and after the session.
 - Practice family management skills (parental monitoring, problem-solving, and communication about substance use) at home for 1 week.
 - Use online daily diary to report about use of these skills for 1 week.
 - Complete a 1-hour virtual interview about experience. Share your thoughts about how app-based technology could be useful when practicing these skills in the future.
- Risks to you: While participating in this study, you might experience emotional discomfort when discussing sensitive topics (family challenges, risky behaviors, or substance use). You can stop at any time. Another potential risk may be an accidental

- Here's some background: We know that behavioral family therapy is highly effective in preventing teens from engaging in risky behaviors and preventing mental health disorders including substance use disorders, but it is often not accessible to families. Although web- and app-based resources are more widely available, they do not provide in-the-moment, individualized support.
- Goal: Ultimately, our goal is to design a new family therapy prevention program that is accessible, supportive, and personalized. We hope that this will effectively prevent teens from engaging in risky behaviors and developing substance use disorders.

The information above is only a brief summary of the study. If you are interested in learning more, it is important to read the following pages for additional detailed information about the study. If you decide to take part in the research, you will be asked to provide written consent at the end of this document.

Why is This Research Study Being Conducted?

The purpose of this study is to better understand how to support families in building family management skills to prevent risky behaviors and substance use disorders. Our findings will help us design a new digital family therapy model that is accessible and personalized.

What Is Involved in The Study?

Study participation will last 8 days and take about 5 hours of your time total.

If you agree to be in this study, you will be asked to,

1. Complete pre- and post-session online survey about your health and well-being and family management skills, such as how you and your parent interact and communicate. The surveys will take about 30-45 minutes to complete.
2. Participate in a 2-hour session led by a health coach who will teach you about family management skills.
 - a. The first 80 minutes will involve only the health coach and parent. Content will include skills for setting house rules around unsupervised time, parental monitoring to prevent risky behaviors, communication about risky behaviors such as substance use, and collaborative family problem-solving.
 - b. The next 20 minutes will involve only the health coach and teen. Content will include identifying teen goals and skills for family communication and problem-solving.
 - c. The last 20 minutes will include the health coach, parent, and teen. You will plan family management goals to practice daily for the next 7 days and discuss how to complete the daily diary.
3. Use online surveys to record the frequency and quality of your interactions, such as if you solved a problem together, or had a conflict, in a daily diary for 1 week. These daily surveys will take less than 10 minutes to complete.
4. Answer virtual interview questions about ways that app-based technology could support your skill building process and daily interactions. Audio from your interview will be recorded and transcribed. The interview transcript will be identified only by number and will not be linked to your name. The interview will take about 1 hour.
5. You will be asked if you are willing to be contacted in the future to complete a second interview and offer feedback on the initial design of the app.

All study procedures will take place virtually, so you will not need to travel anywhere.

All collected data will be de-identified and may be used for future research or be given to another investigator for future research without additional informed consent.

What Are the Risks and Discomforts Of The Study?

Your participation does not involve any physical risk to you beyond that of everyday life. You may find that briefly discussing topics such as family communication, risky behaviors, and substance use causes feelings of emotional discomfort. Your participation is completely voluntary. You may skip any question or procedure that you find uncomfortable, and our research staff are available to help support you in managing any distress that arises or identifying resources for future support. Sometimes learning to communicate can be a stressful process. If at any point during the study you'd like more support with navigating this, our principal investigator is a clinical psychologist and is available to speak with you further, or identify other family therapy resources for you. Any time information is collected about you, loss of confidentiality is a possible risk. However, we are taking steps to ensure that your confidentiality is protected (see section on confidentiality on p. 4).

What Are the Benefits of Participating In The Study?

Brief education about family management skills is helpful to some families in preventing risky behaviors. Because the single session with a health coach is a new approach for the delivery of these skills, we cannot guarantee that there will be a direct benefit to you as a participant. However, you may benefit from completing the family management skills training session. We also hope that in the future, teens and their parents will benefit from the new intervention that will be developed using findings from this research study.

What Other Options Are There?

Another option is to decide to access online resources for family management skills training and risky behavior prevention from the list provided by the research team and not to participate in this study.

Are There Any Costs?

No costs are associated with participation in this study other than your time. You will need access to the internet to participate.

What Is the Compensation?

Because we recognize that participation will take your time and energy, each parent and teen participant will receive \$75 for the initial session, \$35 for completing at least 5 out of the 7 daily diaries, and another \$50 for the interview. Maximum earnings are \$160. All compensation will be given in the form of preloaded Visa gift cards.

You will be required to provide your name and address each time you receive a payment. You will also be asked to provide your social security number if the amount of the payment is \$100 or if the total payments from UVM are equal to or greater than \$600 in a calendar year. If you are not a US Citizen or Permanent Resident Alien you will be required to complete additional paperwork including your immigration status for payment. This information will be strictly confidential and will be strictly confidential and will be used for tax withholding and reporting



Can You Withdraw or Be Withdrawn From This Study?

You may discontinue your participation in this study at any time. If you decide to discontinue your participation, any data collected will only be used in the study with your permission. Data can be withdrawn at your request. The researcher may discontinue your participation in this study at any time at which point you would be compensated for your participation and asked if you would like your data withdrawn from the study. We do not anticipate withdrawing you from the study but reserve the right to do so under rare circumstances. For example, while conflict between teens and parents is normal, if you were experiencing extreme levels of conflict that would prohibit you from participating in this study together, we would instead direct you to resources for accessing other family services.

What About Confidentiality?

All information collected about you will be kept confidential to the fullest extent possible by law. On all research data retained by the researchers, you will be identified by number only. Any personally identifying materials, like consent forms and contact information, will be stored separately from your data. All data will be electronically stored, protected by passwords known only to the research staff on encrypted servers. All responses and data are kept strictly confidential. We will not share teen's answers with parent(s) unless there is a concern about safety. The only time we would give others information about you is if we were worried about your safety or the safety of others.

When the research is completed, our research team may save the survey data and transcripts from the audio recordings from this study for use in future research done by myself or others. The same measures described above will be taken to protect confidentiality of this study data. We will destroy the audio recordings at the end of this study. No video recordings will be made.

If results of this study are published or presented, individual names and other personally identifiable information will not be used. Finally, we inform you that the project's research records may be reviewed by departments at the University of Vermont that are responsible for regulatory research and oversight.

The sponsor(s) or their appointed designees as well as the Institutional Review Board and regulatory authorities will be granted direct access to your original research records for verification of research procedures and/or data.

If your record is used or disseminated for government purposes, it will be done under conditions that will protect your privacy to the fullest extent possible consistent with laws relating to public disclosure of information and the law-enforcement responsibilities of the agency.

Audio recordings of your interviews will also be stored in a secure server that only research team members can access and will not include your name. They will be destroyed at the end of the study. Transcripts of the audio records will be retained that contain only number IDs.

Any communications through email and social media are not considered private or secure. Though we are taking precautions to protect your privacy, you should be aware that information sent electronically through these methods could be read by a third party.

If you have questions or concerns about the use and disclosure of your health information, you should ask a member of the study team at insert phone number or the Chief Privacy Officer at The University of Vermont at (802) 656-2003.

We will keep your study data as confidential as possible, with the exception of certain information that we must report for legal or ethical reasons, such as child abuse, elder abuse, or intent to harm yourself or others.

Clinical Trials Registration

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.

Contact Information

You may contact Dr. Hughes-Lansing, the Investigator in charge of this study, at 802-656-2670 for more information about this study. If you have any questions about your rights as a participant in a research project or for more information on how to proceed should you believe that you have been harmed as a result of your participation in this study, you should contact the Director of the Research Protections Office at the University of Vermont at 802-656-5040.

Statement of Consent

You have been given and have read or have had read to you a summary of this research study. Should you have any further questions about the research, you may contact the person conducting the study at the address and telephone number given below. Your participation is voluntary and you may refuse to participate or withdraw at any time without penalty or prejudice.

You agree to participate in this study, and you understand that you will receive a copy of this form.

Minor Providing Assent

Date

Name of Minor Providing Assent Printed

Signature of Parent/Guardian

Date

Name of Parent/Guardian and Participant Name Printed

Signature of Principal Investigator or Designee

Date

Name of Principal Investigator or Designee Printed

Name of Principal Investigator: Amy Hughes-Lansing, Ph.D.

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