

Official Title: A Quasi-experimental Longitudinal Study of Adolescents' Well-being in Community-based Treatment Versus in a Psychiatric Residential Treatment Facility (PRTF)

NCT number: NCT06498427

Date: March 15, 2022

## **Assent Form for Participants Age 12 - 17**

**TITLE:** A Quasi-experimental Longitudinal Study of Adolescents' Well-being in Community-based Treatment versus in a Psychiatric Residential Treatment Facility (PRTF)

**PROTOCOL NO.:** 1308049  
IRB® Protocol #20211997

**STUDY-RELATED  
PHONE NUMBER(S):** 508-834-7323 ext. 155  
508 834-7323 ext. 140

### **What is a research study?**

We are doing a research study about different types of treatment for adolescents who are having some struggles in their life. A research study is a way to learn more about people.

### **What is this research study and why are you being asked to participate?**

We are inviting you to be in this study because you are starting a treatment program at a live-in treatment facility or at home. About 210 other youth participants will be in this study.

This study was already explained to your legal guardian and they said that we could ask you if you want to be in it. You can talk this over with them before you decide, but we would like you to be the main person making the decision.

To help make your decision, there are some things about this study you should know.

### **If you join the study, what will you be asked to do?**

You will be asked to answer online survey questions about how you are feeling every month. Your legal guardian and your clinician will be asked to answer these questions about how you are doing too.

You are also being asked to provide permission for the researchers to get your diagnosis and billing information from your health plan.

### **You're probably wondering: How will being in this study affect me?**

*Potential Benefits:* Not everyone who takes part in this study will benefit. A benefit means that something good happens to you. We think a benefit might be that the treatment team has information from you and others on the online surveys to improve your care. If you help with this study today, other kids or teenagers may get better treatment in the future.

Here are some benefits of getting treatment while you are living at home: your treatment services come to you, your family gets support, and 24-7 access to your treatment team via a mobile phone that is also used for asking you questions and providing educational information.

Here are some benefits of getting treatment while you are living at a facility with other kids who also need help: your treatment takes place in a 24/7 staffed locked unit for your safety and support, you have access to a nurse all of the time and appointments with other treatment staff weekly (psychiatrist, pediatrician, therapist), and you go to school at the facility.

**Potential Risks:** We do not believe that anything bad will happen if you agree to let researchers look at your information. You may have challenges during treatment but those are separate from answering questionnaires during the study.

Here are some of the risks of getting treatment while you are living at home: your symptoms may seem like they are getting worse before they get “better,” you could get hurt during activities, you could have side effects from the prescribed medication.

Here are some of the risks of getting treatment while you are living at a treatment center with other kids who also need help: you may feel uncomfortable being in a locked building, you could get hurt by other kids at the center, you could have side effects from the prescribed medication.

### What happens next?

If you want to be in the study, you can sign this form and we will send you the questions. You will receive gift cards for answering these questions: if you are in the treatment program for all six months and complete the final questionnaire three months later, you would receive a total of \$175. See details below:

	Baseline - at treatment start	After 1 month in treatment	After 2 months	After 3 months	After 4 months	After 5 months	After 6 months	3 months post- discharge from treatment	TOTAL
Adolescent	\$20	\$10	\$15	\$15	\$20	\$20	\$25	\$50	\$175
Legal Guardian	\$40	\$20	\$30	\$30	\$40	\$40	\$50	\$75	\$325
<b>TOTAL</b>									<b>\$500</b>

When we are finished with this study, we will write a report about what was learned. This report will not include your name or that you were in the study.

If you do not want to be in this research study, we will let your health plan know and they will tell you about your treatment options.

**What if you have any questions?**

- You can ask any questions that you may have about the study. If you have a question later that you didn't think of now, you can call me, Liza Baxter, M.S.W., at (508) 834-7323 ext. 155 or the Principal Investigator, Dr. Kimberlee Trudeau, at (508) 834-7323 ext. 140.
- You can also take more time to think about being in the study and also talk some more with your legal guardian about being in the study.
- If you have any concerns about your rights as a research participant, you may contact an IRB Research Participant Specialist at (855) 818-2289.

**Other information about the study:**

- If you decide to be in the study, complete the section below.
- You can change your mind and stop being part of this study at any time. All you have to do is tell us. It's okay.

**AGREEMENT TO PARTICIPATE (Adolescent)**

By clicking the box next to "I agree" below, you are saying that:

(1) You are an adolescent who is starting a treatment program at a live-in treatment facility or at home,

(2) the study has been described to you, your questions about the study have been answered, and you read and understood this assent form,

(3) you agree to participate in this research study,

(4) you agree to provide written permission for your health plan to share your diagnosis and billing information with the researchers for this study,

(5) you are not giving up any legal rights by signing this assent form.

☐ I agree to participate in this study.

Name of Participant: \_\_\_\_\_

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date:

\_\_\_\_\_  
Name of Person who obtained assent

\_\_\_\_\_  
Date:

\_\_\_\_\_  
Signature of Person who obtained assent

\_\_\_\_\_  
Date:

## STUDY PAYMENT PREFERENCE (Adolescent)

### 1. Gift Card Type

\_\_\_ Amazon

\_\_\_ Walmart

### 2. Delivery Method

\_\_\_ I prefer my payments via **electronic gift card**.

Email Address: \_\_\_\_\_

Retype Email Address: \_\_\_\_\_

\_\_\_ I prefer my payments via **mailed gift card**.

Name on Envelope: \_\_\_\_\_

### *Mailing Address*

Street Address: \_\_\_\_\_

Apartment #: \_\_\_\_\_

Town/City: \_\_\_\_\_

State: \_\_\_\_\_

Zip Code: \_\_\_\_\_