IRB APPROVED
AS MODIFIED
Mar 15, 2022

Adolescent Age 18/Parent/Legal Guardian Consent Form

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
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STUDY-RELATED PHONE NUMBER(S): 508-834-7323 ext. 155
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Introductory Information and Purpose

This research study is funded by The Duke Endowment. It is being conducted by Outcome Referrals, Inc. (ORI), and Children's Hope Alliance (CHA).

We are conducting this research study because we are trying to learn more about the benefits and differences of traditional residential treatment and a treatment program that takes place in the home called the Child-Focused Assertiveness Community Treatment Team, or "Child ACTT," for short. You are/your child/ward is being asked to take part in this research because you/they are admitted to a treatment program in Psychiatric Residential Treatment Facility (PRTF) or Child ACTT. About 210 adolescent participants will be in this study, 105 in each group.

Description of Study/Procedures

You, your legal guardian/the child, and other raters (for example, clinical staff) will be asked to answer questions on a computer or mobile device about how you/the child has been feeling before treatment begins, every 30 days for up to six months during treatment, and then at three months after treatment ends. Study assessments will be administered to adolescent participants and other raters electronically through Outcome Referrals, Inc.'s secure data collection platform called WellnessCheck.net.

Comparing outcomes between the residential treatment program and administering the program to participants who are staying in their own homes is considered investigational.

Risks and Discomforts
We do not believe that anything bad will happen if you and your legal guardian/the child agree to let researchers look at your/their information. Some of the questions may cause sadness or pain.

You/the child may have challenges during treatment, but those are separate from what we are talking about on this page.

Additional risks associated with the community-based versus in-patient are included in the table below.

Expected Benefits
The information that you and others will provide on the assessments will be available to your/the child's treatment team to improve your/the child's care. This may be seen as a benefit, and may help everyone get on the same page. However, there is no guarantee that you/the child will receive any benefit from participating in this study. If you help/the child helps with this study, other kids or teenagers may get better treatment in the future.

We will tell you about any new information that may affect your/the child's health, welfare, or choice to stay in this research.

The table below shows the specific **Benefits and Risks** of each treatment program. There could be unexpected risks to you/the child from their participation in the study.

Treatment Program	Benefits	Risks
Child-Focused Assertive Community Treatment Team (Child ACTT	• Multi-disciplinary wrap-around service that includes psychiatry and health and wellness services • Case Management and coordination with other services • Access to licensed prescriber for medication management services • Individualized Behavioral Support Planning • Social, mental health, and biological factors that have impacted or are impacting each child and family are addressed. • Pre-scheduled daytime respite is available to be used strategically to assist in reaching treatment goals. • Enhanced child and family engagement through use of innovative technologies • CHA provides mobile devices to families to	• Sometimes symptoms get worse before they get "better." • If the client is not making progress or continuing to engage in serious risky behaviors, a recommendation may be made for a higher level of care, including residential placement. • Staff have a legal Duty to Warn others of stated or implied imminent threats of harm. Staff are also mandated reporters of suspected neglect and abuse

	access the CHA app. Families must agree to use the app to conduct short, daily check-ins, complete surveys and screening tools, communicate with the ACTT Team, and utilize educational resources.	and will report suspicions to the Department of Social Services. • Possible accidental injury during activities • Possible medication side-effects/adverse reactions
Psychiatric Residential Treatment Facility (PRTF)	• 24/7 staffed locked unit to ensure highest degree of safety and support to child • Access to Psychiatrist weekly for evaluation medication management services • Access to Pediatrician weekly for evaluation and medication management services • Registered Nurse on duty 24/7 for health and wellness needs • Weekly individual and group therapy. Family therapy as scheduled. • Comprehensive Clinical Assessments completed for all children, some children in the Diversion and Assessment Program will have additional assessments as indicated • Case Management and coordination with other services • Assistance with transition/discharge planning • Monthly Child and Family Team Meetings • School provided on-site • Therapeutic Leave and home visits when clinically indicated • Therapeutic recreation with other children and staff	• Possible accidental injury during recreation or due to negative interactions with peers • Possible medication side-effects/adverse reactions • Possible allergic reaction to meals served • Possible behavioral/emotional reaction to being in locked facility

Alternatives
You can choose not to participate in this research.

Payment for Participation
If you are/the child is in the treatment program for all 6 months, your family may receive up to a total of $500 for completing assessments during this study. You/the child will receive a) a gift card between $20 and $25 each time you/they complete a set of questionnaires corresponding to the research study timeline during treatment and b) a $50 gift card for completion of the questionnaires about you/the child from the researchers 3 months after you/the child leaves the treatment program. That means that if the child is in the treatment program for all six months and you/the child completes the final questionnaire three months later, you/the child would receive a total of $175. In addition, your legal guardian/you can receive up to $325 for completing the questionnaires. 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
TOTAL									$500

Payment will be provided to you by Children's Hope Alliance within 3 weeks of after you submit your completed assessments.

Confidentiality
The information we collect about you/the child from you, your legal guardian/the child, and other raters, will not be provided to anyone except the clinical team. Your/The child's information will be kept safely locked up/password protected. In addition, we will request permission for your/their health plan to confidentially share your/their diagnosis and billing information with the researchers for this study.

What happens to the information collected for this research?
Your/the child's private information and medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration
- The Institutional Review Board (IRB) that reviewed this research
- Health and Human Services

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

Questions
If you have any questions, concerns, or complaints about the study, or if you feel the research has hurt you/your child in any way, contact the research staff. 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.

If you have any questions, concerns or complaints about the study or questions about your/the child's rights as a research participant, you may contact the WCG IRB at (855) 818-2289.

Voluntary Participation/Withdrawal
You can freely say "yes" or "no" to this request for your permission to participate/allow the child to participate in this research study. Saying "no" will not cause anything bad to happen. You/Your child will continue with PRTF or ACTT treatment as usual. If you and the child/your legal guardian say "yes" and then later want to say "no" to letting researchers look at the child's information, nothing bad will happen. You or the child/legal guardian can withdraw from the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

AGREEMENT FOR THIS CHILD TO PARTICIPATE (Legal Guardian)
By clicking the box next to "I agree" below, you affirm that:

(1) you are the legal guardian of an adolescent who is admitted to either PRTF treatment or Child ACTT,

(2) the purpose and nature of this research have been sufficiently explained to you, your questions have been answered, and you have read and understood this consent form,

(3) you provide your permission, as legal guardian, for the child to participate in the study,

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

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

- All children are required to assent.
- If assent is obtained, have the child sign the assent form.

__ I agree for the child to participate in the study.

__ I do not agree for the child to participate in the study.

Type Legal Guardian's Name _____

Type Child's Name _____

_____ _____
Signature of child subject's parent, or individual authorized under st Date
or local law to consent to the child subject's general medical care

STUDY PAYMENT PREFERENCE (Legal Guardian)

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: _____

AGREEMENT TO PARTICIPATE (Adolescent, Age 18)
By clicking the box next to "I agree" below, you are saying that:

(1) you are an adolescent who is admitted to either PRTF treatment or Child ACTT,

(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.

Type Your Name: _____

Signature (Adolescent): _____

__ I have explained the study to the study participant and their legal guardian/ parent.

_____ _____
Signature of person obtaining consent Date

STUDY PAYMENT PREFERENCE (Adolescent, Age 18)

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: _____