A Psychotherapy Development Study for Internet Gaming

NCT03220581

Informed Consent Form

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IRB Review
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Informed Consent Form

Principal Investigator (PI): Kristyn Zajac, Ph.D.

PI Phone Number: 860-679-4556

Title of Research Study: A Psychotherapy development study for Internet gaming

Expected Duration of Subject's Participation: 24 weeks

IRB Number: 17-028-2

External Sponsor/Funding Entity: National Institutes of Health

Name of Research Participant: _____

Overview of the Research

You are being asked to provide consent to participate in a research study. Participation is voluntary. You can say yes or no. If you say yes now you can still change your mind later. Some key points to consider are summarized in this overview, but you should consider all the information in this document carefully before making your decision.

This research is being done to examine methods to reduce electronic game playing in young people.
This study lasts about 24 weeks. The study consists of either referral to services or attending 6 therapy sessions to help reduce gaming. There will also be 4 interviews over 24 weeks.
There are no serious risks of participating in this study. Some of the questions during the interviews may cause you discomfort. Risks are described in more detail later in this form. There may also be benefits from participation. You may receive an intervention that may help reduce your child's gaming.
A more detailed description of this research follows.

What Is The Purpose Of This Research Study?

The purpose of this study is to look at ways to help reduce electronic game playing problems in young people. The researchers will look at two different ways to help: 1) recommending standard support in the community or 2) a type of therapy for both you and your parent.

Why Am I Invited To Participate?

You are invited to participate because your parent reported your gaming is causing problems at home, school or a job. Your parent is aware that you are invited to participate in this study.

How Many Other People Do You Think Will Participate?

In total, we expect to have 60 parents and their children participate in this study.

Is Participation Voluntary?

Participation in this study is voluntary. Before deciding whether to participate in this research study, please read this consent form carefully. Please ask us any questions you have and talk with your parent about the study. You can choose not to participate. If you choose to participate in the study, you can change your mind later and stop participating.

If you decide not to participate or you withdraw from the study after starting, your decision will not affect your current or future medical care you receive at UConn Health. There will be no penalty. There will be no loss of benefits that you would get otherwise.

How Long Will My Participation In This Study Last?

You will be asked to meet with the research assistant 4 times over the next 24 weeks (about 6 months). Each interview will take about 1-2 hours. If you are randomly assigned to the therapy group, you and your parent will also meet weekly with the study therapist for up to 6 weeks. Each therapy session will be about 1 hour.

What Will I Be Asked to Do?

You will be interviewed today and 3 other times, in about 4, 8 and 24 weeks from today. At each of your interviews, we will ask you questions about your gaming and sleep habits. We will also ask you questions about school, a job if you have one, relationships with family and friends and any mental health, alcohol/drug use or legal problems.

You and your parent(s) will be randomly assigned (like the flip of a coin) to one of two treatment groups. If assigned to Group A, you and your parent(s) will be given information about addiction support in your local community such as the Department of Mental Health and Addiction Services and National Association for Mental Illness support groups. For any concerns about other mental health problems (e.g., for depression, attention deficit/hyperactivity disorder [ADHD], autism, substance use, conduct disorder, etc) you and your parent(s) will be referred for appropriate services as well. You will receive these referrals following the initial interview. If assigned to Group B, you and your parent(s) will be scheduled to complete 6 therapy sessions over the next 8 weeks. The study therapist will ask you to write down when you play games and for how long. The therapist will help you brainstorm other activities to do instead of gaming. The therapist will also help you and your parent to communicate better about gaming. At the end of the treatment, you will receive additional referrals following the procedure described for Group A.

The interviews and therapy may be audiorecorded (taped so the researchers can listen to what is said). Audiorecordings will be listened to only by research staff members. Research staff members listen to make sure interviews and therapy are being done correctly. If either you or your parent(s) decide not to have the sessions audiorecorded, you can still take part in the research study. Please make a choice by initialing one option below.

Initials: _____ **Yes**, I agree. My assessments and study treatment can be audiorecorded.

Initials: _____ **No**, I do not want my assessments and study treatment to be audiorecorded.

For the follow-up interviews, you may choose to complete some of the measures in advance of your in-person study visit. We can send you the surveys by e-mail (a link is provided to complete your questionnaires through a secure web-based data collection tool) or in paper format through the mail. If you choose to complete the surveys online or through the mail, you may not need to attend the in-person study visit at week 4 (you can complete the measures at home). You can still take part in the study if you do not want your surveys emailed or mailed to you (you can complete them at an in-person interview).

What Are the Possible Discomforts Of Participating In This Study?

a) You may not like the study activities. If you are unhappy with the study activities, you may stop participating in this study.

b) You may feel uncomfortable with some of the questions we ask. We will keep the interviews as brief as possible. You may choose to skip a question or take a break.

c) You may argue with your parent about your gaming. Part of what you may learn in treatment is how to communicate better with your parent.

d) If you are assigned to Group B, your parents will be asked to increase their monitoring of your gaming. Though unlikely, this may lead to discovery of other undesirable behaviors that you may be keeping private from your parents, including illegal behaviors. If you parents uncover information that suggests that you or someone else is in danger and your or your parents report this information to the research team, we may need to break confidentiality to report this to state officials and to keep you safe. Your parents may also uncover information that does not require reporting on our part but that is distressing to you and/or your parents. In this case, your study therapist can assist you, either using strategies in the study treatment or by helping you to find additional resources in the

community. This risk is similar to the risks related to participating in family therapy for gaming problems in general.

What Are the Benefits Of Participating In This Study?

You may or may not benefit from this study. You may receive a treatment that may help reduce your gaming. You may also help us learn how to better help other people with gaming problems.

Will I Be Compensated For Participating In This Study?

You will receive $30 in the form of a gift card of your choice for completing the interviews today and in about 4 weeks, and $50 in gift cards in about 8 and 24 weeks after study treatment begins for a total of $160, with each card provided to you at the conclusion of each interview. Your parents will also have the opportunity to earn up to $160 in gift cards for completing the assessments.

What Alternative Procedures or Treatments Are Available To Me?

You can choose not to participate in this study. There are other programs available to help you (for example, private therapists or the Connecticut Department of Mental Health and Addiction Services).

How Will My Personal Information Be Protected?

We will protect the confidentiality of the information you give us for the study as best as we can, but we cannot guarantee 100% protection. We will do the following things to protect your information. The study staff will keep all your information locked in a secure location. Your information will be labeled with a code. The code will be a letter code identifying the study, followed by a 2-digit number that indicates the number of people that have been enrolled in the study. A master key document that links your name and code will be locked in separate location from your study information. This consent form will be stored in a secured location apart from your study information. We will not store your name, address or phone number on our computers. Any computer with your study information will be password protected to prevent people other than study staff from seeing it. Any laptop computers that will be used will be encrypted. Any study information that is shared with others will be coded to help protect your identity. When the study is over, we hope to publish an article or make a presentation showing the results of the study. We will present the information in a way that will not identify you. Additionally, the information from this study may be used for future research studies or distributed to another investigator for future research studies without additional informed consent, all identifiers will be removed from any identifiable private information.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

You should know that the National Institutes of Health, the Department of Health and Human Services, and UConn Health's Institutional Review Board and the Human Subjects Protection Office may inspect study records. They may inspect records to ensure that the study is being done correctly. Also, if we learn of child, elder, or spousal abuse or of communicable diseases, we have to report it to State officials.

A description of this trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.
You may not be provided with individual or overall results of the study.

What If I Decide To Stop Participating In The Study?
If you decide to stop taking part in the study, your relationship with UConn Health will not be affected. If you decide to stop, please call the research team at 860-679-4556. Or, send a written notice to Dr. Kristyn Zajac, 263 Farmington Avenue, Farmington, CT 06030-3944.

Can Someone Else Make Me Stop Participating In This Study?
The researchers may stop your study participation. They would do so only if they feel it is in your best interest. If this happens, it will not affect current or future care at UConn Health.

What if I Have Questions?
The Principal Investigator, Dr. Kristyn Zajac, is willing to answer any questions you have about the study. You are encouraged to ask questions before deciding whether to take part. You are also encouraged to ask questions during your study participation. If you have questions, complaints or concerns about the research, you should call the Principal Investigator at 860-679-4556.

If you have questions about your rights as a research participant, you may contact a coordinator at the Institutional Review Board at 860-679-1019, 860-679-4851, or 860-679-4849. You may also call a coordinator at the Institutional Review Board if you want to talk to someone who is not a member of the research team in order to pass along any suggestions, complaints, concerns or compliments about your involvement in the research, or to ask general questions or get information about participation in clinical research studies. Please do not call the IRB number for medical related issues or to schedule or cancel an appointment.

Consent To Participation:
By signing this form you acknowledge that you have read, or have had read to you, this informed consent document, have talked with research staff about this study, have been given the chance to ask questions and have them satisfactorily answered, and voluntarily consent to take part in this study as described in this form.

By signing this form the person obtaining consent/assent is confirming that the above information has been explained to the participant (and/or parent or guardian) and that a copy of this document, signed and dated by both the person giving consent and the person obtaining consent, along with a copy of the Research Participant Feedback Form, will be provided to the participant and/or parent or guardian.

_____	_____	_____
Participant's Printed Name	Participant's Signature	Date
_____	_____	_____
Printed Name of Parent/Guardian if participant is under age 18	Parent/Guardian's Signature if participant is under age 18	Date
_____	_____	_____
Name of Investigator or Person Obtaining Consent	Signature of Investigator or Person Obtaining Consent	Date