Reducing Internet gaming: A pilot psychotherapy development study

NCT02726880

Informed Consent Form

IRB Approval Version: 3/19/2020

IRB Review
IRB NUMBER: 16-114-3.2
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Informed Consent Form

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

PI Phone Number: 860-679-4556

Title of Research Study: Reducing Internet Gaming

Expected Duration of Subject's Participation: 16 weeks

IRB Number: 16-114-3

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 16 weeks. The study consists of either referral to services or attending 6 therapy sessions to help reduce gaming. There will also be 3 interviews over 16 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 examine methods to reduce electronic game playing in young people. Two different types of treatment will be compared: referral for support or a behavioral therapy for parents and for children who choose to participate with their parents.

Why Am I Invited To Participate?

You are invited to participate because you reported that your child's gaming is causing significant problems at home, school or work. Your child will also be invited to participate. If your child does not participate, you still may participate in the study.

How Many Other People Do You Think Will Participate?

In total, up to 40 parents (and their children) will participate in this study.

Is Participation Voluntary?

Participation in this study is voluntary. Before making a decision about whether to participate in this research study, please read this consent form carefully and discuss any questions you have with the researcher. 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 participation, your decision will not affect your present or future medical care you receive at UConn Health. There will be no penalty or loss of benefits to which you are otherwise entitled.

How Long Will My Participation In This Study Last?

You will be asked to meet with the research assistant 3 times over the next 16 weeks. Each interview will take about 1 hour. You (and your child if s/he decides to participate) may also meet weekly with the study therapist for 6 weeks. Each session will be about 1 hour.

What Will I Be Asked to Do?

You will be interviewed today and about 8 and 16 weeks from today. The research assistant will ask you questions about your child's gaming and sleep habits, social interactions, emotional or behavioral difficulties and quality of life. We will also ask you about your quality of life, alcohol or drug use, emotional issues and your family functioning. These interviews may be completed over the phone or through the mail if needed.

After your first interview, you (and your child, if applicable) will be randomly assigned (like the flip of a coin) to one of two treatment groups. If you are assigned to Group A, you will be referred for addictions support in your local community such as DMHAS, NAMI, and Parents Opening Doors. For any concerns about other mental health problems (e.g., for depression, ADHD, autism, substance use, conduct disorder, etc) you will be referred for appropriate services as well. After four weeks, a member of the research team will call you to see if you have any follow-up questions about the referral list. If you are assigned to Group B, you (and your child, if s/he chooses) will be scheduled to complete 6 therapy sessions over the next 8 weeks. The therapy will focus on monitoring gaming behavior and replacing it with other activities. The therapy will also help you to communicate more effectively about gaming with your child. Sessions may be completed over the phone if needed.

You will be asked to give names of at least 3 people you expect to have contact with over the next 16 weeks. Research staff need this information so they can contact you if your phone or address change. No information about you (not even whether or not you are in treatment) will be given to these people.

The interviews and therapy may be audiorecorded. Audiorecordings will be listened to only by research staff members. Research staff members listen to make sure interview and therapy are being done correctly. If you decide you do not want your 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.

What Are the Possible Discomforts Of Participating In This Study?

a) You may not like the group you are randomly assigned to. If you are unhappy with your group, 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 child about gaming. Part of what you may learn in treatment is how to communicate better with your child.

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 child's 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 $20 in the form of a gift card of your choice for completing the baseline interview and $50 in gift card(s) for the Week 8 and Week 16 interviews.

What Alternative Procedures or Treatments Are Available To Me?

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

How Will My Personal Information Be Protected?

We will protect the confidentiality of your data to the best of our ability, but cannot guarantee 100% protection. The following procedures will be used to protect the confidentiality of your data. The study staff (principal investigator, research coordinator, co-investigators etc.) will keep all study records (including any codes to your data) locked in a secure location. All information will be placed in separate research record that is apart from your medical record. Research records will be labeled with a code and all contents of the research record will be labeled with only that code. The code will be derived from a letter code identifying the study followed by a 3-digit number that is a sequential indicator of the number of people that have been enrolled in the study. A master key that links names and codes will be maintained in a separate and secure location. This consent form will be stored in a secured location apart from the research record. Electronic files (e.g., database, spreadsheet, etc.) will not contain your identifying information such as your name, address or phone number. Any computer hosting study files will have password protection to prevent access by unauthorized users. Data that will be shared with others will be coded as described above to help protect your identity. Any laptop computers that will be used will be encrypted. At the conclusion of this study, the researchers intend to publish an article on their findings. Information will be presented in summary format and you will not be identified in any publications or presentations. 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 records. They may inspect records to ensure that the study is being done correctly. Also, if during the course of this study we learn of child, elder, or spousal abuse or of communicable diseases, we are required 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 withdraw, 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 investigators may end your or your child's study participation. They would do so only if they feel it is in your or your child's best interest. If this happens, it will not affect present 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 research. 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 subject 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 obtain 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 personnel about this study, have been given the opportunity to ask questions and have them satisfactorily answered, and voluntarily consent to participate in this project as described in this form.

By signing this form the individual obtaining consent is confirming that the above information has been explained to the subject 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.

_____	_____	_____
Participant's Printed Name	Participant's Signature	Date
_____	_____	_____
Name of Investigator or Person Obtaining Consent	Signature of Investigator or Person Obtaining Consent	Date