STATEMENT OF INFORMED CONSENT

TITLE OF STUDY: Online coping skills counseling for problem gambling and trauma
PRINCIPAL INVESTIGATOR: David M. Ledgerwood, Ph.D. of the University of Windsor (phone: 313-993-1380; fax: 313-993-1372; email: dledgerw@med.wayne.edu)
CO-INVESTIGATORS: Lisa M. Najavits, Ph.D. of Treatment Innovations (phone 617-299-1620; fax 617-701-1295; email: director@treatment-innovations.org); and Tracie O. Afifi, Ph.D. of the University of Manitoba (phone 204-272-3138; fax 204-789-3905; email tracie.afifi@umanitoba.ca)
CONTACT: If you have any questions or concerns about the research, please feel to contact any of the above.
SPONSOR: Manitoba Gambling Research Program

Introduction

You are invited to participate in a research study titled, *Online Coping skills counseling for problem gambling and trauma*, conducted by David M. Ledgerwood, Ph.D., Lisa M. Najavits, Ph.D., and Tracie O. Afifi, Ph.D. It is important that you read the following explanation of the proposed procedures.

This form describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. A member of the study staff can be available to help you read through the consent and discuss all the information via phone if you would like that (the phone number and hours of contact are at the end of this consent form). When you think you understand the study, you will then be asked if you agree to take part. You will have the option at the end of this form to select either the "agree" or "disagree" button. "Agree" means that you are choosing to participate in this research project; "disagree" means that you do not want to participate. You may show this electronic consent form to your family or trusted friends or your clinician or doctor before you sign it. You may want to discuss it with them to help you decide if you want to be part of the study. If you want to print out a copy of this form, you can do so by right-clicking and selecting "print".

Purpose

The goal of this study is to compare two different types of counseling-- Seeking Safety (SS) and Cognitive Behavioral Therapy for Problem Gambling (CBT-PG). We want to understand how helpful each type of counseling is for people who have problems related to trauma and gambling. We are recruiting up to 110 people. The two types of counseling will be delivered online, which is designed to make it easy for you to attend.

Dr. Najavits, a co-investigator on this study, is the developer of Seeking Safety and receives royalties from the publisher of the book by that title. Dr. Robert Ladouceur, a consultant on this study, is the developer of Cognitive Behavioral Therapy for Problem Gambling and receives royalties from publisher of the book by that title.

Procedures

If you decide to participate, you would first go through an assessment that will include both written meaures that you would fill in online regarding various aspects of your life and problems related to trauma and gambling. There will also be some questions that one of our team will ask you by telephone, at a time convenient for you. This first assessment is called "baseline". If you are eligible to participate based on this baseline assessment, you would then be assigned by chance to either the Seeking Safety treatment or the Cognitive Behavioral Therapy for Problem Gambling treatment. Whichever counseling type you are assigned to, you will be offered 12 weekly individual sessions of 1 hour, conducted by a trained, professional counselor. Sessions will be scheduled to be convenient for you and the counselor. We will give you instructions on how to log onto your computer or mobile device (tablet or smartphone) to attend the sessions. All sessions will be

audio-recorded so that we can understand how well the counselor is conducting the sessions; such recordings are not done to evaluate you in any way. These recordings will only be seen by members of the research team who are trained to evaluate the delivery of the counseling. If you choose to participate in this study, you will be allowed to receive any other medical care, counseling, self-help, or other services you choose to, including services you are already receiving or any new ones you choose to receive while in the study. During the 3 months that you are offered the 12 weekly individual counseling sessions (which we call the "active phase" of the study), you will be asked to complete a small assessment at 6 weeks, the halfway point. At the end of the active phase, which is at 3 months, you will be asked to complete a longer assessment that will repeat many of the measures you did at the baseline assessment. We will recontact you one year later to complete the same set of measures again, which is called the "one year followup assessment."

Voluntary nature of this study

Your participation in this study is voluntary. You can refusal to participate or to continue at any time. With regard to assessments, you can refuse to answer any questions that make you feel uncomfortable or you choose not to answer. With regard to the free online therapy sessions offered in this study, you can also stop those at any point. Your participation or withdrawal from this project or its treatment will not affect any of your existing or future medical care.

Potential risks, discomforts or inconveniences of the study

Foreseeable inconveniences/discomfort includes answering questions that may feel sensitive to some people. Such questions may occur as part of the assessments in the study and/or the online counseling sessions.

Risks of the study

Participation in this study may involve some risks or discomforts. These include:

1. It can be uncomfortable to provide your feedback and opinions to a member of our study team whom you have not met before. However, you can skip any questions that make you uncomfortable. The assessments we will conduct are widely used and rarely if ever have negative impact.
2. Loss of confidentiality is possible. A number of steps will be taken to minimize risk related to loss of confidentiality. To minimize that risk, we will use only a confidential participant identification number to identify you and will keep all study records and information that we collect on password-protected computer systems accessible only to our research team. We will retain strict control over all of the information that we collect from all participants, including the video recordings of counseling sessions, the surveys you complete, and information from counseling sessions. We will make sure that only study staff has access to information about you. Also, the video recordings will only record your face and shoulders using the webcam.
3. If you report any major distress or upset while participating in any aspect of this study, this will trigger us to contact your study counselor and/or your emergency contact people that you designate at the beginning of the study, or if a very serious situation, local police or emergency workers so that they can help provide assistance to you. Also if at any point you feel that you are experiencing any emergency or worsening of your emotional state, you should reach out immediately to your study counselor, the study staff, your physician or other healthcare professional (e.g., a counselor outside of our study), or, depending on the nature of the issue, a local hospital emergency room or 911 emergency services.

Expected benefits of the study

You may or may not benefit from participation in this study. The counseling provided in this study is designed to help people and thus may provide some benefit, but it is not guaranteed. You may also benefit from knowing that you are contributing to a scientific effort that may help others in the future. Some of the assessments we conduct may also be of benefit in helping you to become more aware of yourself.

Confidentiality
If you agree to join this study, the study team will ask you for some personal health information needed for the study. Personal health information is any information that could be used to identify you and, for participants in this study, includes your name, address, date of birth, and information on your mental health diagnoses.

All of the information that is collected for the study (including the assessments you complete and the video recordings of counseling sessions) will be kept on a password-protected computer indefinitely. All will be digital and will be coded using only your study identification number (no names or other identifying information); and will be stored on the study's password-protected computer at Treatment Innovations, the location of the co-investigator Dr. Najavits, and also at the University of Windsor, the location of the study principal investigator Dr. Ledgerwood. No information collected on this study will be destroyed.

Your name will not be publicly disclosed at any time and you will not be identifiable in any publications or presentation that may arise from this research.

If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission. None of your research records and the information you provide in any way will be used for any purpose other than that which is described in this consent form, with the exception of "later data analysis". "Later data analysis" refers to scientific efforts we may choose to do in the future to explore additional scientific questions that may be addressed by the data collected on this study.

While all efforts will be made to protect your privacy, you should understand that there are ethical and legal limits to confidentiality, and that there are some circumstances under which information that may identify you may be released. In particular, this may occur if you indicate or the research staff has reason to believe that you express a clear and credible threat or intention to do serious harm to yourself or to some other identifiable person. Under the law and our professional ethics codes, our study team would have an obligation to take all reasonable steps to protect both you and the intended victim. This usually involves notifying the other person but may involve notifying the police or others who could intervene to prevent harm from being done. In all cases, only the minimal necessary information would be released. A similar situation would exist if, during the research, you indicate that a child or elder in your care is being abused and/or neglected. There is a mandatory reporting law whereby the research staff would be required by law to report admitted or suspected child or elder abuse and/or neglect to a regional department of social services. Finally, if a court of law chose to subpoena (request) the records from this study, we would be required to release them; however, this is an extremely unlikely event.

The study team places a high value on the privacy of its research participants and the confidentiality of the data collected in all of its research projects. In order to strictly protect your confidentiality, all of your records will be kept in password-protected electronic files, under a code number rather than your name; the records will be strictly maintained according to current legal requirements. All electronic information, including video recordings, will be stored using a code number and coded initials rather than your name. Nothing shared will be traceable to you as an individual. Only authorized personnel will have access to your study records.

Costs
There are no costs for participating in this study. All of the counseling you receive and all assessments and contacts with our study team will be free of charge.

Payment
There are three major assessments, each expected to take about 1.5 hour: at baseline, end of treatment, and one year follow up. There will also be a minor assessment at 6 weeks, half way through the counseling, which is expected to take about a half hour. You will be provided $40 for each of the 3 major assessments and $25 for the minor assessment. You will be paid for the first three assessments (baseline, minor assessment, and end of treatment) *after* you complete the end of treatment assessment, which would total $105 at that point. After you complete the 1 year followup, you would receive an additional $40. All payments will be sent via email as an amazon.com giftcard to an email address that you provide to us for this purpose. If you miss an assessment or do not complete it, you would not be paid for it but you will be paid for any that you do complete.

Research-Related Injury
As mentioned above, the assessments we will conduct are widely used and rarely if ever have negative impact. Nevertheless, every effort will be made to prevent any adverse reactions from occurring in the study. If you should experience any adverse reactions or injuries directly resulting from this research, we will do everything we can to manage the situation, in a timely manner, with the best possible care. If, during your assessment you have an adverse reaction (for example, becoming so upset that you are not safe), a trained counselor from our study team will intervene to protect your safety. This may include: communicating with other study staff, contacting your physician or counselor outside of the study, talking with you to help you decide on the best plan of action, and/or contacting local emergency services to check in on you and possibly to arrange transport to a local emergency room for evaluation. Please be aware, however, that there are no plans to provide medical care or financial compensation for any research-related or non-research-related medical injuries or adverse reactions.

In summary, if you become ill, injured or harmed during or as a result of taking part in this study, you will be referred to care. However, you will be responsible for the cost of this care unless it is part of the counseling and contact provided to you by your study counselor and/or our study team. Signing this consent form does not waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

Alternatives to participating in this study
If you choose not to participate in this study, you would simply not engage in the assessments and counseling that are part of this study. Your choice of whether or not to participate in this study will not alter any treatment you are receiving anywhere else, and will remain confidential (we will not communicate your decision to anyone outside of our study team).

New Findings
You will be told of any significant new findings that come to light during the course of this study and that may relate to your wanting to stay in the study.

Right to refuse or withdraw
For all assessments and counseling sessions, you can refuse to answer any questions that make you feel uncomfortable or that you choose not to answer. Your participation in all aspects of this study is voluntary and you may decide to withdraw your consent and discontinue participation in this project at any time. However, once you provide any study data or participate in any recorded counseling sessions, you will not have the option to withdraw these. Also, if you withdraw from the assessments, you will not be able to continue the counseling.

Possible removal from the study

Your participation in this study can be ended by the study team for any of the following reasons (even if you want to remain in the study):

1. If you are unable to keep your scheduled appointment(s) to participate;
2. If the investigator decides that you should no longer be in the study;
3. If you represent a clear threat to study staff or others;
4. If the study is cancelled by the sponsor or the University of Windor.
5. If new information shows that the study is no longer in your best interest;
6. If you do not complete the required study assessments;
7. If we are unable to reach you.

Who to contact in case of emergency

If you experience an adverse reaction or a research-related injury during the course of the study, you should immediately contact the study Principal Investigator, Dr. David Ledgerwood at 313-993-1380 at any time, including after hours. You can also call the Co-Investigator Dr. Najavits at 617-299-1620 at any time, including after hours. You can also seek immediate care from a resource that is available 24/7 such as an emergency room, doctor on call, or other service. You can also seek care from your physician or any other health professionals you choose throughout the course of the study.

Feedback about results of this study

A summary of the results of this research will be available at the following web location: www.treatment-innovations.org (section Library) after the study is complete and results are published, such as in a professional journal. It is anticipated that such results will be available in the fall of 2017 or thereafter.

Who to contact if you have questions about the study

Should you have any questions about the research in general you may contact Dr. David Ledgerwood at 313-993-1380 or by email at dledgerw@med.wayne.edu; or Dr. Lisa Najavits at 617-299-1620 or by email at director@treatment-innovations.org.

If you have questions about your rights as a research subject or other concerns about the research you can contact the Research Ethics Coordinator, University of Windsor, Windsor, Ontario, N9B 3P4; by phone at (519) 253-3000 ext. 3948 or by email: ethics@uwindsor.ca

VOLUNTEER'S STATEMENT

I have been given a chance to ask questions about this research study titled *Online coping skills counseling for problem gambling and trauma*. These questions have been answered to my satisfaction. I may contact Dr. Ledgerwood or Dr. Najavits if I have any more questions about taking part in this study.

I understand that my participation in this research project is voluntary. I know that I may quit the study at any time without harming my future medical care and/or my employment or losing any benefits to which I might be entitled. I also understand that the investigators in charge of this study may decide at any time that I should no longer participate in this study.

This study has received clearance from the University of Windsor.

By signing this form, I have not waived any of my legal rights.

I have read and understand the above information. I agree to participate in this study. I have been given a copy of this form.

_____
Name of Participant

_____ _____
Signature of Participant (or name typed out if submitted electronically) Date

At some future point after the study, we may want to contact you to see if you might be interested in a later follow-up study. Please type your initials here if you are willing for us to contact you after your involvement in the study_____, or type your initials here _____if you are not willing to have us contact you after your involvement in the study.

These are the terms under which I will conduct research.

_____ _____
Signature of Investigator (or name typed out if submitted electronically) Date