Efficacy of a Group Intervention Grounded in Acceptance and Commitment Therapy (ACT) to Address Problem Gambling in Youth: A Randomized Clinical Trial

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Participant Information Sheet and Informed Consent

Study Title

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Promoter

Universidad Europea de Madrid

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Introduction

You are being invited to participate in a research study aimed at Spanish-speaking adults who engage in gambling activities (e.g., sports betting, poker, blackjack, slot machines, roulette) and wish to change this behavior and improve their psychological well-being.

This study has been approved by the Research Ethics Committee of the Hospital Universitario de Getafe and the Spanish Agency of Medicines and Medical Devices, in accordance with current legislation (Royal Decree 1090/2015 and European Regulation 536/2014).

Please read this information carefully. If you have any questions, you may contact:

Dr. Francisco Montesinos: francisco.montesinos@universidadeuropea.es

Dr. David Lobato: david.lobato@universidadeuropea.es

Mr. Rubén Pérez: ruben.perez@universidadeuropea.es

Voluntary Participation

Your participation is entirely voluntary. You may choose not to participate or withdraw at any time without any consequences or impact on future services.

Study Objective

To evaluate the efficacy of a brief online group psychological program based on psychological flexibility, aimed at helping individuals dissatisfied with their gambling behavior to manage it more effectively and improve their psychological well-being.

Study Description

The study is aimed at Spanish-speaking adults who regularly gamble and wish to change this behavior.

This study consists of the following phases:

First, the researcher will conduct an initial assessment interview with you, including questions and questionnaires. The objective of this contact is to verify whether you meet the proposed inclusion criteria. If you do not meet these criteria, you will not be able to participate in this study. If you do meet the inclusion criteria, you will receive an online group psychological intervention led by a specialized general health psychologist.

For the psychological intervention, there are two treatment groups: "immediate intervention" and "waiting list." The immediate intervention group will receive the psychological intervention shortly. The "waiting list" group will receive it after two months. Group assignment will be randomized following the instructions of a computer program. The psychological intervention is based on Acceptance and Commitment Therapy (ACT), a third-generation, evidence-based behavioral therapy that will provide you with tools to more effectively manage your emotions and thoughts, as well as your desire and urge to gamble. The therapy will include training in various skills, which have been shown to be useful in previous studies, for managing difficult emotions related to difficulties controlling gambling behavior. It will also include personal work to clarify what is most important to you in life and to learn to behave on a daily basis more consistently with what matters. The intervention will be administered over eight sessions (one session per week over two months).

To assess the intervention's effect, you will be required to complete several questionnaires related to your general health, psychological variables, and gambling behavior at different times: at the beginning of your participation, after the last session of psychological therapy, and three and six months after the intervention ends. Likewise, at the beginning of each session, we will ask you for some information related to your game practice and your emotional state during the previous week.

If the follow-up assessment determines that you may require additional psychological intervention, you will be offered the possibility of being referred to a specialized service.

Study Activities Timeline

The total duration of your participation in the study will be approximately 33 weeks.

Treatment phase (9 weeks). The treatment phase includes the individual assessment and attendance at eight weekly group psychological treatment sessions. Throughout the intervention, you will be required to collect weekly data on your gambling habits and emotional states and send it to the therapist before the start of each session.

The online assessment questionnaire will take approximately 30 minutes to complete. The estimated duration of each intervention session will be 90 minutes. The start of the intervention after signing this informed consent form may be delayed due to the need to form the intervention groups.

If you have been assigned to the "waiting list" group, you will have to wait two months to receive the intervention.

Risks and Discomforts

There are no anticipated risks. The intervention is evidence-based and has shown benefits in reducing gambling behavior and improving emotional well-being. All activities are conducted online.

Participant Responsibilities

- Complete all questionnaires honestly and privately
- Submit weekly data on gambling behavior and emotional state
- Attend all sessions in a private setting
- Maintain confidentiality and respect for other participants
- Notify the therapist of any emotional difficulties or absences
- Avoid starting other psychological treatments without prior consultation

Potential Benefits

Participating in this project can offer several benefits. First, the proposed intervention is designed to address gambling-related problems, promoting the development of skills that can improve quality of life and emotional well-being. Furthermore, as this approach is based on Acceptance and Commitment Therapy (ACT), participants will have the opportunity to work on identifying their personal values and taking actions that align with them.

Although direct benefits are not guaranteed for all participants, being part of this study also contributes to the advancement of scientific research, helping to develop more effective treatments for pathological gambling. Your participation can be an opportunity to reflect on your relationship with gambling and explore new tools for managing associated difficulties.

Pregnancy Warning

Participation poses no risk in the event of pregnancy.

Alternative Treatments

If you do not wish to participate in the study, you may seek therapeutic assistance at the Comprehensive Drug Addiction Care Centers (CAID) of the Community of Madrid, the Addiction Care Centers of the Madrid City Council, or from the following associations: the Association for the Prevention and Assistance of Gambling Addiction (APEAP) or the Association of Rehabilitating Gamblers and Their Families of Madrid (AJER). If you live in another city or Autonomous Community, you may seek therapeutic assistance at other similar centers or associations in your city or Autonomous Community. The study researcher will provide you with further information upon request.

Insurance

The study promoter has an insurance policy in accordance with Royal Decree 1090/2015 to cover any harm related to participation.

Insurance

The study sponsor has an insurance policy that complies with current legislation (Royal Decree 1090/2015) and will provide you with compensation and indemnity in the event of any health problems or injuries that may occur in connection with your participation in the study, provided they are not a consequence of the disease being studied or the progression of your disease due to ineffective treatment.

If you require more information regarding this section, please consult the principal investigator of the study at your center.

Data Protection

The sponsor undertakes to comply with Organic Law 3/2018, of December 5, on the Protection of Personal Data and the Guarantee of Digital Rights. The data collected for the study will be identified by a code, so that it does not include information that could identify you. Therefore, your identity will not be revealed to anyone except in cases of medical emergency or legal requirement. The processing, communication, and transfer of the personal data of all participants will comply with the provisions of this law. Access to your personally identifiable information will be restricted to the study's principal investigator and collaborators, health authorities (Spanish Agency for Medicines and Medical Devices, foreign health authorities), the Research Ethics Committee, and personnel authorized by the sponsor (study monitors, auditors), when necessary to verify the study data and procedures, but always maintaining their confidentiality in accordance with current legislation.

The data will be collected in a research file under the responsibility of the institution and will be processed within the framework of your participation in this study. At the end of the questionnaire, if you wish to receive psychological support to improve your gambling control, you will be able to access a new form via a link separate from the current one, where you can leave your contact information. The sponsor will take the appropriate measures to guarantee the protection of your privacy and will not allow your data to be cross-referenced with other databases that could allow your identification. In accordance with data protection legislation, you may exercise your rights to erasure, objection, data

portability, restriction of access, and rectification of data, for which you must contact the principal investigator of the study. If you decide to withdraw your consent to participate in this study, no new data will be added to the database, but data already collected will be used. The encrypted data may be transmitted to third parties and other countries, but under no circumstances will it contain information that can directly identify you, such as your first and last name, initials, address, social security number, etc. If this transfer is made, it will be for the same purposes as the study described or for use in scientific publications, but confidentiality will always be maintained in accordance with current legislation.

Expenses and Financial Compensation

The sponsor of the study is responsible for managing its funding. You will not have to pay for the specific tests or psychological treatment. Since your participation in the study will be online, you will not need to travel, so your participation will not incur any additional costs.

Other relevant information

This clinical trial will be registered at https://www.clinicaltrials.gov/, where a description of the trial will be available.

Any new information regarding the psychological therapy used in the study that may affect your willingness to participate, which is discovered during your participation, will be communicated to you by your therapist as soon as possible.

By signing the attached consent form, you agree to comply with the study procedures explained to you.

If you withdraw from the study and stop attending therapy sessions or completing the evaluation questionnaires without withdrawing your consent, your therapist will contact you for follow-up.

What treatment will I receive when the clinical trial ends?

When your participation in the study ends (8 group intervention sessions), it will no longer be possible to provide you with further psychological intervention sessions. Therefore, neither the researcher nor the sponsor undertakes any commitment to continue this treatment outside of this study. However, they will be able to inform you of available resources for initiating a new treatment.

Contact for questions

If you have any questions or need more information during your participation, please contact the researchers, Francisco Montesinos, francisco.montesinos@universidadeuropea.es , David Lobato david.lobato@universidadeuropea.es or Rubén Pérez ruben.perez@universidadeuropea.es

Informed Consent Form

I, _____

☐Have read the information sheet

☐Have had the opportunity to ask questions

☐Have received sufficient information

☐Have spoken with _____

☐Understand that participation is voluntary

☐Understand I can withdraw at any time without explanation or impact on my care

I freely consent to participate in this study.

Participant Signature

Date: ____ / ____ / _____