Acceptance and Commitment Therapy for Problematic Chemsex: a Pilot Study

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IP: Francisco Montesinos, Ph.D.

Informed Consent Form

INFORMATION SHEET FOR PARTICIPANTS AND INFORMED CONSENT

Study Title	Acceptance and Commitment Therapy for Problematic Chemsex: a Pilot Study
Study code	2023-324
Promoter	Universidad Europea de Madrid
Principal investigator	Francisco Montesinos, Ph.D.
Collaborating investigator	Rubén Rico
Faculty	Facultad de Ciencias Biomédicas y de la Salud. Universidad Europea de Madrid

Introduction.

We are reaching out to you to inform you about a research study in which you are invited to participate. The study is aimed at Spanish-speaking adults who engage in chemsex and wish to improve control over their sexual and substance use impulses.

The study has been approved by a Research Ethics Committee at the University Hospital of Getafe and by the Spanish Agency of Medicines and Medical Devices, in accordance with current legislation, Royal Decree 1090/2015 of December 4, and European Regulation 536/2014 of April 16, which regulate clinical trials with drugs.

Our intention is for you to receive accurate and sufficient information so that you can decide whether or not to participate in this study. To do this, please read this information sheet carefully, and we will clarify any doubts that may arise. If you have any questions, you can contact Dr. Francisco Montesinos, at the Department of Psychology of the Universidad Europea, by phone at 912115108 or by email at francisco.montesinos@universidadeuropea.es, or Rubén Rico, by email at ruben.proyecto.chemact@gmail.com. Additionally, you may consult with anyone else you deem appropriate.

This study involves the Universidad Europea de Madrid, the association Apoyo Positivo, and the University of Almería, with an estimated total of 5 participants across all centers.

Voluntary Participation.

We invite you to participate in the study because you are a person who engages in chemsex. You should know that your participation in this study is voluntary, and you may choose NOT to participate. If you decide to participate, you can change your decision and withdraw consent at any time, without any inconvenience to you. Likewise, if you are being invited to participate in a healthcare center or in the Apoyo Positivo association, deciding not to participate will not alter your relationship with your doctor or psychologist nor will it cause any harm to your healthcare.

Study Objective.

The objective is to evaluate the effectiveness of a psychological flexibility program aimed at helping individuals who are dissatisfied with their sexuality, specifically those who want to improve control over their sexual and substance use impulses. The results obtained will help us create effective intervention protocols, allowing individuals who are dissatisfied to improve their sexual health and emotional well-being.

Study Description.

The study targets Spanish-speaking adults who have used psychoactive substances or drugs to facilitate, maintain, and/or enhance their sexual relationships in the past year (chemsex) and who have resided in Spain during the last year.

This is the second phase of a larger research project to study and address psychosocial variables related to chemsex. You may have participated in the first phase of this study by completing some questionnaires about psychological aspects of chemsex, and after leaving your contact information upon completing the form, we may have contacted you to invite you to this second intervention phase.

In the initial contact, the researcher will conduct an initial assessment interview with questions and questionnaires. If you do not meet the proposed inclusion criteria, you cannot participate in this study. If you meet the inclusion criteria, you will receive an online group psychological intervention led by a specialized general healthcare psychologist.

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 manage your sexual impulses, substance cravings, and other emotions more effectively. The therapy will include training in various skills to manage difficult emotions that have been shown to be useful in previous studies for supporting individuals with difficulties in controlling their sexual impulses. It will also include personal work to clarify what is most important to you in life and to learn how to behave more consistently with what matters to you on a day-to-day basis. The intervention will be delivered over eight sessions (one session per week over two months), which will be recorded to improve the intervention and extract data from it; these recordings will be kept private and will only be available to the researchers. Additionally, to assess the intervention's effect, you will need to complete some questionnaires related to your psychological and sexual health at three different times: at the beginning of your participation, at the end of the psychological therapy, and three months later. In addition, at the beginning of each session, we will ask you for some data related to your sexual practices during the previous week.

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

Study Activities.

The total duration of your participation in the study will be approximately 21 weeks (5 months and one week).

The treatment phase will last 2 months and one week and will include the initial assessment and the assessment after treatment. The treatment phase will also include attending 8 sessions of group psychological treatment on a weekly basis. Each participant will need to complete questionnaires before starting the first intervention session and at the end of the eighth session. Additionally, the initial assessment will include a one-hour online individual interview. Throughout the intervention, you will need to collect weekly data on your sexual practices and social and leisure activities and send them to the therapist before the start of each session. The approximate duration of the online assessment questionnaire is about 20 minutes. The estimated duration of each intervention session will be 120 minutes. The start of the intervention after signing this informed consent may be delayed due to the need to form intervention groups.

The follow-up phase will last 3 months. After these 3 months following the intervention, you will be asked to complete the evaluation questionnaires again.

1st week	2nd week	3rd week	4th week	5th week	6th week	7th week	8th week	9th week	21st week
· Initial interview · Informed consent signing · 1st evaluation (scales administration)	1st treatment session	2nd treatment session	3rd treatment session	4th treatment session	5th treatment session	6th treatment session	7th treatment session	8th treatment session 2nd evaluation (scales administration)	Follow up: 3rd evaluation (scales administration)

Risks and Discomforts Arising from Your Participation in the Study.

Your participation in the study will not entail any risks. The psychological intervention will be based on previous research where Acceptance and Commitment Therapy has been applied to individuals struggling with sexual impulse control, resulting in reductions in anxiety and depression, as well as in the intensity of sexual addiction. Since both the assessment and intervention will be conducted online, you will not have to travel as a result of the study.

The participant's responsibilities will be:

- Answering all questions on the form as honestly as possible and in a private location before starting, at the end of the intervention, and in the three-month follow-up.
- Providing the therapist with weekly data on your sexual practices and social and leisure activities as requested.
- Setting aside time and a private location to attend the individual evaluation interview and all group intervention sessions online.
- Maintaining absolute confidentiality and utmost respect for other participants in the group therapy sessions.
- In case of justified inability to attend any intervention sessions, notifying the therapist before the session begins.
- Reporting any emotional difficulties experienced during therapy and not initiating any other psychological or psychiatric therapy without consulting the study therapist first.
- Committing to practicing exercises, tasks, and experiments outside of sessions during treatment.

Potential Benefits.

Your participation in the study may have some benefits for you, as it may lead to reflection or increased awareness about your practices, emotions, and health. It is also possible that your participation in the group intervention may contribute to reducing your levels of anxiety and depression and allow you to have greater control over your sexual and substance use impulses, as well as a decrease in the risk of sexually transmitted infections for you and your potential partners. However, it is also possible that some participants may not experience any health benefits from participating in this study.

Pregnancy Warning.

In the case of pregnancy, participation in the study does not pose any risks.

Alternative Treatments.

If you choose not to participate in the study, you may seek therapeutic assistance at the Apoyo Positivo association, the Comprehensive Drug Addiction Care Centers (CAID) of the Community of Madrid, the Addiction Care Centers of the City of Madrid, or, if you reside in another city or Autonomous Community, at other similar centers or associations in your city or Autonomous Community. The study investigator will provide you with more information if desired.

Insurance.

Apoyo Positivo has an insurance policy that complies with current legislation (Royal Decree 1090/2015) and will provide compensation and indemnification in case of harm to your health or injuries that may occur in relation to your participation in the study, provided that they are not a consequence of the disease being studied or the natural course of your disease as a result of treatment inefficiency.

If you would like more information on this section, please consult the principal investigator of the study at your center.

We inform you that your participation in this clinical trial may modify the general and specific conditions (coverage) of your insurance policies (life, health, accident, etc.). Therefore, we recommend that you contact your insurer to determine if participation in this study will affect your current insurance policy.

Protection of Personal Data.

The promoter is committed to complying with Organic Law 15/1999 of December 13 on the Protection of Personal Data and the Royal Decree that develops it (RD 1720/2007). The data collected for the study will be identified by a code, so it will not include information that can identify you, and only your study therapist will be able to relate this data to you and your medical history. Therefore, your identity will not be disclosed to anyone except in cases of medical emergency or legal requirement. The treatment, communication, and transfer of personal data of all participants will comply with the provisions of this law. Access to your identified personal information will be restricted to the study therapist, the Research Ethics Committee, and authorized personnel by the promoter (study monitors, auditors) when necessary to verify the data and procedures of the study, but always maintaining confidentiality according to 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.

In accordance with data protection legislation, you can exercise your rights of access, rectification, opposition, and cancellation of data by contacting your study therapist. If you decide to withdraw consent to participate in this study, no new data will be added to the database, but the data already collected will be used. Encoded data may be transmitted to third parties and other countries, but in no case will it contain information that can directly identify you, such as name and surname, initials, address, social security number, etc. In the event of such transfer, it will be for the same purposes of the study described or for use in scientific publications, but always maintaining confidentiality according to current legislation.

Expenses and Compensation.

The study promoter is responsible for managing its financing. For the conduct of the study, the promoter has signed a contract with the center where it will be carried out. You will not have to pay for specific study tests or for receiving 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 expenses.

What Treatment Will I Receive When the Clinical Trial Ends?

When your participation in the study ends (8 sessions of group intervention), it will not be possible to continue providing you with additional psychological intervention sessions. Therefore, neither the researcher nor the promoter are committed to maintaining such treatment outside of this study. However, they may inform you of available resources to initiate a new treatment.

Contact in Case of Doubts.

If you have any doubts or need more information during your participation, please contact the principal investigator Dr. Francisco Montesinos, at the Department of Psychology of the European University, by phone at 912115108 or by email at francisco.montesinos@universidadeuropea.es, or Mr. Rubén Rico, at the email address ruben.proyecto.chemact@gmail.com.

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I, (participant's name and surname)

☐ I have read the information sheet provided to me about the study.

☐ I have been able to ask questions about the study.

☐ I have received sufficient information about the study.

☐ I have spoken with the researcher.

☐ I understand that my participation is voluntary.

☐ I consent to the recording of sessions solely for the purpose of improving the intervention and extracting data from it.

☐ I understand that I can withdraw from the study:

- Whenever I want.
- Without having to give explanations.
- Without this affecting my medical care.

☐ I will receive a signed and dated copy of this informed consent document.

☐ I freely give my consent to participate in the study.

Participant's signature

Date: ___/___/_____

Investigator's signature

Date: ___/___/_____

(Name, ID, signature, and date in handwriting by the participant)