

PARTICIPANT INFORMATION DOCUMENT (PHASE 1)

Title of the research study: Dissemination, acceptability and implementation study of two transdiagnostic psychological interventions based on emotional regulation for the treatment of alcohol addiction: Dialectical Behavioral Therapy and Unified Protocol

Principal Investigator: María Vicenta Navarro Haro
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Telephone:

Centre: Department of Psychology and Sociology of the University of Zaragoza and Instituto de Investigación Sanitaria de Aragón.

1. Introduction:

We are writing to request your participation in the first phase of the research project that we are carrying out from the University of Zaragoza and the Health Research Institute of Aragon, in collaboration with the Addiction Care Services of the Community of Aragon, Catalonia and the Community of Valencia and with funding from the National Plan on Drugs (Ministry of Health). This project has been approved by the Ethics Committee, but before making a decision it is necessary to:

- Read this entire document
- Understand the information contained in the document
- You have at your disposal an email address to ask all the questions you consider necessary.
- Make a thoughtful decision
- Accept the informed consent, if you finally wish to participate.

2. Why are you being asked to participate?

Your collaboration is requested as a professional working in addiction treatment to participate in this study, which aims to disseminate and implement two transdiagnostic interventions, Dialectical Behavioral Therapy for Substance Use Disorder (DBT-SUD) and the Unified Protocol (UP), to treat people with alcohol addiction. In this first phase, professionals will be randomized to receive one training (DBT or UP) and then the other. The trainings will be given by two expert trainers, in an online format and will last 20 hours each. In addition, they will be asked to answer a series of online questionnaires using the Qualtrics ® application before and after the training. The results of this study will provide information on the factors related to the therapist and their work environment when training in DBT-SUD and UP for patients with alcohol addiction, as well as the acceptability and intention to use these interventions in their work context.

A sample size of 160 professionals working in addiction treatment centers in the Valencian, Catalonia and Aragon regions are expected to participate in the study.

3. What is the purpose of this study?

The main objectives of this study are:

- To explore practitioners' attitudes and perceived efficacy of transdiagnostic treatments before and after DBT-SUD and UP training to treat alcohol addiction.
- To assess the acceptability and intention to use interventions after DBT-SUD and UP training to treat alcohol addiction.

- To explore participants' experiences and opinions about the training received and how to adapt it to their work context.

4. What do I have to do if I decide to participate?

-Attend both training sessions (DBT and UP). Each training lasts 20 hours and consists of a 3-session workshop (6-7 hours each session). The DBT and UP workshops total duration are 40 hours of training. They will be conducted online (via Zoom) with more professionals from the same sector.

-Answer a series of questionnaires through the Qualtrics ® online platform before and after the DBT training and before and after the UP training.

In addition, if you are interested, you will also be able to take part in a focus group with a reduced number of professionals in which the experiences and opinions of the participants about the training received will be evaluated, which will be carried out in online format and recorded via Zoom. In order to analyze the results of their experiences and opinions, the data of the recording will be stored by the research team at the Faculty of Human and Social Sciences of the University of Zaragoza. The recording will be deleted when the content of the recording has been transcribed. The transcribed content will be deleted no later than 12/31/2026, when the data analysis is expected to be completely finished.

5. How long does it take to answer the surveys?

The approximate duration is 20 minutes per survey before and after the training of each intervention.

6. What risks or inconvenience does it pose?

Answering the questions in this survey may be personal or may cause stress or discomfort. The researchers will take care to protect confidentiality. If you begin to experience any side effects, you may stop responding at any time.

7. Will I get any benefit from my participation?

As this is a research study oriented to generate knowledge, it is not likely that you will obtain any benefit for your participation, although you will contribute to scientific advancement and social benefit. You will not receive any financial compensation for your participation.

8. How will my personal data be treated?

The online survey platform Qualtrics ® complies with the RGPD (General Data Protection Regulation), has an ISO 27001 security certificate and allows the correction, modification and deletion of personal data permanently from its servers. In the following link: you can find more information about Qualtrics ® privacy policy: <https://www.qualtrics.com/uk/platform/gdpr/>

The Zoom platform also has a privacy and data protection policy: <https://explore.zoom.us/es/gdpr/>

Basic information about data protection:

Data controller: University of Zaragoza

Internal data controller: María Vicenta Navarro Haro

Purpose: Your personal data will be processed exclusively for the research work referred to in this document.

Legitimation: The processing of data for this study is legitimated by your consent to participate.

Recipients: No data will be transferred to third parties unless legally obliged to do so.

Rights: You may exercise your rights of access, rectification, deletion and portability of your data, limitation and opposition to its processing, in accordance with the provisions of the General Data Protection Regulation (RGPD 2016/679) to the principal investigator of the project, and may obtain information about it by sending an email to the address mvnavarro@unizar.es, or by

sending an email to the Data Protection Delegate of the University of Zaragoza (dpd@unizar.es). If your request is not answered, you can complain to the Spanish Data Protection Agency (<https://www.aepd.es>).

You may consult additional information on data protection at the University of Zaragoza at the following address: <https://protecciondatos.unizar.es/>.

The processing of your personal data will be carried out using techniques to maintain your anonymity through the use of random codes, so that your personal identity is completely hidden during the research process. Based on the results of the research work, scientific communications may be prepared for presentation at congresses or scientific journals, but they will always be made with grouped data and nothing that could identify you will ever be disclosed.

9. Will I be informed of the results of the study?

You have the right to know the results of this study. You also have the right not to know the results of this study if you wish to do so. If you do wish to know the results, please contact the principal investigator of the study.

10. Can I change my mind?

Your participation is completely voluntary. If you decide not to participate, you will not be penalized. You can decide not to participate or to withdraw from the study at any time without having to give explanations. You only need to tell the principal investigator of the study your intention. However, in the case of focus groups, since it is a group recording, it is not possible to request its destruction by an individual participant. The recording will be deleted once its content has been transcribed. The transcribed content will be deleted when it is analyzed by 12/31/2026 at the latest.

11. What happens if I have any questions during my participation?

On the first page of this document, you will find the name, telephone number and e-mail address of the investigator responsible for the study. You can contact her in case you have any questions about your participation.

Thank you very much for your attention, if you finally wish to participate, we kindly ask you to sign the attached consent form.

PARTICIPANT INFORMED CONSENT

Title of the research study: Dissemination, acceptability and implementation study of two transdiagnostic psychological interventions based on emotional regulation for the treatment of alcohol addiction: Dialectical Behavioral Therapy and Unified Protocol

I, (Participant name and surname)

-I have read the study's information sheet.

-I have read the privacy policy of the Qualtrics® platform: <https://www.qualtrics.com/uk/platform/gdpr/> and the Zoom platform: <https://explore.zoom.us/es/gdpr/> and the University of Zaragoza: <https://protecciondatos.unizar.es/politica-de-privacidad>

- I have been able to ask questions about the study and have received sufficient information about the study.

- I understand that my participation is voluntary and that my data cannot be associated with an identified or identifiable person because it has been replaced by a code.

- I am of legal age (I am at least 18 years old).

- I understand that I can withdraw from the study:

1. Whenever I want

2. Without having to give explanations

I want to be informed about the results of the study: yes no (check all that apply)

I agree that the pseudonymized data derived from this study may be used in the future in projects of the research line ___ Dissemination, acceptability and implementation of two transdiagnostic psychological interventions based on emotional regulation for the treatment of alcohol addiction: Dialectical Behavioral Therapy and Unified Protocol. _____ (identify line), whose responsible is María Vicenta Navarro Haro _____ (identify the responsible researcher) provided that they have obtained the favorable opinion of a Research Ethics Committee and have requested the appropriate permissions: YES NO (check as appropriate).

By clicking the button below, you agree that:

<input type="checkbox"/>	I confirm that I am of legal age and I freely give my consent to participate in the study, I give my consent for the access and use of my data as stipulated in the information sheet, and I accept that, in the case of participating in the focus groups, my participation through Zoom will be recorded. Likewise, I accept the privacy policy of the Qualtrics platform, the Zoom platform and the University of Zaragoza.
<input type="checkbox"/>	I am NOT of legal age or I do NOT freely consent to participate in the study.

PARTICIPANT INFORMATION DOCUMENT (PHASE 2)

Title of the research study: Dissemination, acceptability and implementation study of two transdiagnostic psychological interventions based on emotional regulation for the treatment of alcohol addiction: Dialectical Behavioral Therapy and Unified Protocol

Principal Investigator: María Vicenta Navarro Haro
978618101

mail: mvnavarro@unizar.es

Telephone: +34

Center: Department of Psychology and Sociology of the University of Zaragoza and Instituto de Investigación Sanitaria de Aragón.

1. Introduction:

We are writing to you to request your participation in the second phase of the research project that we are carrying out from the University of Zaragoza and the Health Research Institute of Aragon, in collaboration with the Addiction Care Services of the Community of Aragon, Catalonia and the Community of Valencia and with funding from the National Plan on Drugs (Ministry of Health). This project has been approved by the Ethics Committee, but before making a decision it is necessary to:

- Read this entire document
- Understand the information contained in the document
- An e-mail address is available for you to ask any questions you may have.
- Make a thoughtful decision
- Accept the informed consent, if you finally wish to participate.

2. Why are you being asked to participate?

Your collaboration is requested to be part of the second phase of this study aimed at psychologists who have received the training of the transdiagnostic treatments. In this study, the process of implementing one or both transdiagnostic interventions (Dialectical Behavior Therapy for Substance Use Disorder, DBT-SUD and the Unified Protocol, UP) in which you have been previously trained will be evaluated.

You will be asked to implement the interventions in your workplace for 3 months (12 group sessions, one per week) to treat users with alcohol addiction. For this purpose, you will receive weekly group supervision by the research team, with the objective of resolving possible problems and doubts raised regarding the implementation of the interventions. In addition, you will be asked to complete a series of questionnaires through the Qualtrics ® platform before and after the implementation, which will allow obtaining results on the implementation process of DBT and UP with people with alcohol addiction in routine clinical practice. The study is expected to involve about 50 professionals working in addiction treatment centers in the Valencian, Catalonia and Aragon regions.

3. What is the purpose of this study?

The objectives of this study are:

- To assess the implementation outcomes (adoption, reach, appropriateness, feasibility, fidelity, sustainability) of DBT and UP in clinical practice by practitioners who choose to implement the interventions after training.
- To determine the number and type of barriers and facilitators during the process of implementation of DBT and UP in clinical practice by the professionals who decide to implement the interventions after the training.

-To explore the predictor variables of a successful implementation taking into account the previous characteristics of the professionals and the organization.

4. What do I have to do if I decide to participate?

-Apply one or both interventions (DBT-SUD, UP) at their workplace for 3 months (12 sessions, one per week) in group format with users with alcohol addiction and attend, as necessary, supervisions with expert trainers.

-Answer a series of questionnaires through the online platform Qualtrics ® before and after the implementation process of the intervention with DBT-SUD and/or UP in your workplace.

In addition, if you are interested, you can also take part in a focus group with a small number of people in which the experiences and opinions of the participants on the process of implementation of the interventions will be evaluated, which will be conducted online and recorded via Zoom. In order to analyze the results of their experiences and opinions, the data from the recording will be stored by the research team at the Faculty of Human and Social Sciences of the University of Zaragoza. The recording will be deleted when the content of the recording has been transcribed. The transcribed content will be deleted no later than 12/31/2026, when the data analysis is expected to be completely finished.

5. How long does it take to answer the questionnaires?

The approximate duration is 20 minutes per survey before and after the implementation of each intervention.

6. What risks or inconvenience does it pose?

Answering the questions in this survey may be personal or may cause stress or discomfort. The researchers will take care to protect confidentiality. If you begin to experience any side effects, you may stop responding at any time.

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Rights: You may exercise your rights of access, rectification, deletion and portability of your data, limitation and opposition to its processing, in accordance with the provisions of the General Data Protection Regulation (RGPD 2016/679) to the principal investigator of the project, and may obtain information about it by sending an email to the address mvnavarro@unizar.es, or by sending an email to the Data Protection Delegate of the University of Zaragoza (dpd@unizar.es).

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INFORMED CONSENT

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- I understand that my participation is voluntary and that my data cannot be associated with an identified or identifiable person because it has been replaced by a code.

- I am of legal age (I am at least 18 years old).

- I understand that I can withdraw from the study:

1. whenever I want
2. Without having to give explanations

I want to be informed about the results of the study: yes no (check all that apply)

I agree that the pseudonymized data derived from this study may be used in the future in projects of the research line ____ Dissemination, acceptability and implementation of two transdiagnostic psychological interventions based on emotional regulation for the treatment of alcohol addiction: Dialectical Behavioral Therapy and Unified Protocol. _____ (identify line), whose responsible is María Vicenta Navarro Haro _____ (identify the responsible researcher) provided that they have obtained the favorable opinion of a Research Ethics Committee and have requested the appropriate permissions: YES NO (check as appropriate).

By clicking the button below, you agree that:

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<input type="checkbox"/>	I am NOT of legal age or I do NOT freely consent to participate in the study.