INFORMED CONSENT FORM

ClinicalTrials.gov **NCT07590154**

Unsupervised Deep Representation Learning for Clinical Stratification in Substance Use Disorders

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Cross-sectional Functional Stratification Based on Psychometric Profiling and Machine Learning in Patients With Substance Use Disorders (SUD)

SISAP-TUS

Document Type:	**Informed Consent Form**
Protocol ID:	**SISAP-TUS-EFTP-ML-2024**
ClinicalTrials.gov:	**NCT07590154**
Document Version:	**1.0**
Document Date:	**14 March 2024**
Ethics Approval No.:	**UTT-CEI-2024_007-ML**
Ethics Approval Date:	**14 March 2024**

Sponsor-Investigator

Lauro Gutiérrez Castro
Under The Tree Therapeutic Community

Supporting Information for ClinicalTrials.gov

Document Control

Purpose of this document.
This document provides information about the SISAP-TUS research study and records the informed consent of an individual who agrees to participate. Participation in the study is voluntary. The participant should read this document carefully, ask any questions they may have, and take sufficient time to decide whether to participate.

Field	Value
Official Title	Unsupervised Deep Representation Learning for Clinical Stratification in Substance Use Disorders
ClinicalTrials.gov Identifier	NCT07590154
Protocol ID	SISAP-TUS-EFTP-ML-2024
Acronym	SISAP-TUS
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Document Version	1.0
Document Date	14 March 2024
Sponsor-Investigator	Lauro Gutiérrez Castro
Study Institution	Under The Tree Therapeutic Community
Ethics Committee	Under The Tree Ethics Committee
Ethics Approval Number	UTT-CEI-2024_007-ML
Ethics Approval Date	14 March 2024

1 Invitation to Participate

You are being invited to participate in a research study involving adults receiving residential treatment for a substance use disorder.

Before deciding whether to participate, you should understand why the study is being conducted, what participation involves, the possible risks and benefits, how your information will be protected, and your rights as a research participant.

Participation is voluntary. You may choose not to participate, and you may ask questions before making your decision.

2 Purpose of the Study

The purpose of this study is to examine patterns among clinical and psychological characteristics of people receiving residential treatment for substance use disorders.

The study uses standardized questionnaires and clinical information to develop a research model called an **autoencoder**. The model is designed to identify patterns in the information collected and represent those patterns in a smaller number of dimensions.

The study also explores whether patients can be characterized according to similarities in this research-based representation.

The model is being developed for research purposes. It is not being used to replace a clinical diagnosis or to make automated treatment decisions.

3 Why Have I Been Asked to Participate?

You are being invited because you are an adult receiving treatment at the participating residential treatment center and may meet the study's eligibility criteria.

The study includes adults aged 18 years or older who have a substance use disorder diagnosed according to DSM-5 criteria.

4 What Will Happen If I Participate?

Participation involves a single assessment session.

During the session:

1. A psychiatrist or clinical psychologist will confirm the diagnosis and assess eligibility for the study.
2. You will receive information about the study and, if you agree to participate, you will sign this informed consent form before the research procedures begin.
3. You will complete a battery of six standardized psychometric questionnaires. These questionnaires assess areas such as impulsivity, anger expression, behavioral activation and avoidance, borderline symptoms, anxiety, and perceived environmental reward.
4. Demographic and clinical information relevant to the study may also be recorded.
5. Your information will be assigned a study identifier for research purposes. Your name will not be included in the analytical dataset.

There are no additional study visits or experimental treatments associated with this research protocol.

5 How Much Time Will Participation Take?

The study involves one assessment session. The study does not require additional longitudinal visits or follow-up assessments associated with the machine learning model.

6 What Are the Possible Risks or Discomforts?

The questionnaires ask about experiences that may include substance use, emotions, anger, anxiety, impulsivity, borderline symptoms, and other psychological experiences.

Some questions may cause:

- mild emotional discomfort;
- temporary uneasiness;
- tiredness or fatigue; or
- discomfort when recalling personal experiences.

There are no invasive physical procedures, medications, devices, or experimental treatments involved in this study.

There is also a potential risk associated with the confidentiality of clinical and psychological information. The research team will use procedures designed to limit access to identifiable information and will use a study identifier for the analytical data.

7 What Happens If I Experience Discomfort?

You may tell the research or clinical staff if you feel uncomfortable, tired, or distressed while completing the questionnaires.

You may take a break or stop the assessment according to the study procedures. Psychological support is available from personnel at the treatment center when clinically appropriate.

Stopping participation in the research will not affect your ordinary clinical treatment at the center.

8 Are There Any Benefits to Me?

You should not expect a direct personal benefit from participating in this research.

The information obtained may contribute to scientific knowledge about clinical and psychological characteristics associated with substance use disorders. In the future, such knowledge may contribute to research on ways of improving patient characterization and treatment personalization.

These potential future benefits are not guaranteed.

9 Are There Alternatives to Participation?

The alternative to participating in this research is simply not to participate.

Your decision will not change the treatment or services you are otherwise eligible to receive at the treatment center.

10 Is Participation Voluntary?

Yes. Participation is completely voluntary.

You may refuse to participate or withdraw your consent at any time, without penalty and without losing the clinical care or services to which you are otherwise entitled.

If you decide to withdraw, no new research information will be collected from you after withdrawal, except where retention or use of information is required by applicable law, regulatory requirements, or the conditions of the consent already provided.

11 How Will My Information Be Protected?

Your privacy will be protected as required by applicable ethical and legal requirements.

Your name and direct personal identifiers will not be included in the analytical dataset. Research information will be associated with a study identifier.

The clinical registry maintained by the treatment center may contain information that directly identifies you. Access to such identifying information will be restricted to authorized personnel with appropriate responsibilities.

Research results will be reported in aggregate or de-identified form. Individual participants will not be identified in scientific publications or presentations.

12 How Will My Research Data Be Used?

The information collected during the study may be used for the research objectives described in this consent form, including statistical analysis, machine learning analysis, scientific publication, and methodological research related to the study.

De-identified or appropriately de-identified research data may be shared with qualified researchers for scientifically justified secondary analyses, subject to applicable ethical, legal, confidentiality, and data-governance requirements.

Individual-level data will not be publicly released in a form that directly identifies you.

13 Will the Machine Learning Model Make Decisions About My Treatment?

No.

The machine learning model is being used exclusively for research purposes. Its outputs will not be used to make automated clinical decisions about your treatment, to determine whether you receive a specific intervention, or to replace the judgment of your treating clinicians.

14 Who May Review My Research Information?

Authorized members of the research team and, when applicable, persons responsible for ethical, scientific, regulatory, or institutional oversight may review study records as permitted by applicable law and institutional procedures.

Such access is subject to confidentiality and privacy protections.

15 Will I Have Any Additional Costs?

There are no expected additional costs to you as a result of participating in the research procedures.

Your routine residential treatment is separate from this research study.

16 Will I Be Paid for Participating?

Participant compensation: [TO BE COMPLETED ACCORDING TO THE ETHICS-APPROVED CONSENT FORM.]

If there is no payment or compensation, state explicitly:

No payment or financial compensation will be provided for participation in this study.

17 What If I Am Injured or Harmed Because of the Research?

The study does not involve invasive procedures, medications, devices, or experimental treatment, and no physical research-related injury is expected.

If you experience a problem that you believe is related to the research procedures, you should notify the study or clinical personnel promptly so that the situation can be evaluated and appropriate care can be provided.

Any applicable arrangements concerning medical treatment or compensation for research-related harm must follow the requirements established by the approved study documents and applicable Mexican law.

18 Will I Be Told About New Information?

If important new information becomes available during the research that could reasonably affect your decision to continue participating, the research team will provide that information in accordance with applicable ethical requirements.

19 Who Can I Contact If I Have Questions?

If you have questions about the study, your participation, or your rights as a research participant, please contact:

Principal Investigator:
Lauro Gutiérrez Castro
Institution:
Under The Tree Therapeutic Community
Telephone: [TO BE COMPLETED]
Email: [TO BE COMPLETED]
Institutional contact for participant questions or complaints: [TO BE COMPLETED]

20 Ethics Review

This study was reviewed by the institutional ethics committee identified below.

Ethics Committee: Under The Tree Ethics Committee
Approval Number: UTT-CEI-2024_007-ML
Approval Date: 14 March 2024

21 Statement of Consent

By signing below, I confirm that:

- I have read this informed consent document, or it has been read and explained to me.
- I have had the opportunity to ask questions about the study and have received satisfactory answers to my questions.
- I understand the purpose of the study and what participation involves.
- I understand the possible risks, discomforts, and expected benefits described in this document.
- I understand that participation is voluntary.
- I understand that I may refuse to participate or withdraw my consent without penalty or loss of the clinical care to which I am otherwise entitled.
- I understand how my research information will be collected, protected, analyzed, and potentially shared in de-identified form.
- I understand that the machine learning model is being used for research purposes and will not be used to make automated decisions about my treatment.
- I have been given sufficient time to decide whether to participate.
- I voluntarily agree to participate in the study.

22 Participant Identification

Participant field	Information
Participant name	_____
Study participant identifier	_____
Date of birth or age, if required by the approved form	_____
Date of consent	_____

23 Signatures

I confirm that I have read and understood the information provided in this informed consent form and voluntarily agree to participate in the study.

Participant

Printed name: _____ **Date:** _____

Signature: _____ **Time:** _____

Person Obtaining Consent

Printed name: _____ **Date:** _____

Signature: _____ **Time:** _____

Witness 1

Printed name: _____ **Relationship to participant:** _____

Signature: _____ **Date:** _____

Witness 2

Printed name: _____ **Relationship to participant:** _____

Signature: _____ **Date:** _____

24 Copy for the Participant

A signed copy of this informed consent form should be provided to the participant in accordance with the approved consent procedure and applicable institutional requirements.