SERVIZIO SANITARIO REGIONALE
EMILIA-ROMAGNA
Azienda Unità Sanitaria Locale di Parma

UNIVERSITÀ
DI PARMA

Integrated Care Department of Mental Health and Addiction Services
University-Affiliated Hospital Psychiatric Services Unit

Obsessive-Compulsive Disorder: Formal and Content Modalities, Factors Involved in Loss of Insight, Role of Trauma, and Correlations with Schizophrenia Spectrum Disorders

Promoter: AUSL of Parma – Integrated Care Department for Mental Health and Pathological Addictions, at the Hospital Psychiatric Services, under University Management.

Principal Investigator: Prof. Matteo Tonna, M.D., PhD. Associate Professor of Psychiatry, University of Parma, Hospital Psychiatric Services with University Management, AUSL Parma.

INFORMATION SHEET

Dear Sir/Madam,

You have been asked to participate in this study promoted by the Integrated Care Department for Mental Health and Pathological Addictions, Hospital Psychiatric Services with University Management.

The study titled **"Obsessive-Compulsive Disorder: Formal and Content Modalities, Factors Involved in Loss of Insight, Role of Trauma, and Correlations with Schizophrenia Spectrum Disorders"** is observational in

nature, meaning that it does not involve any additional instrumental or laboratory investigations beyond those already performed in clinical practice.

The aim is to analyze the formal characteristics of ritualized behavior in patients with OCD and correlate them with clinical manifestations, severity of the disorder, assessment of factors involved in loss of insight, and psychotic vulnerability. The study also aims to assess how patients with OCS (obsessive-compulsive symptoms) respond to multisensory stimuli (auditory, tactile, and audio-tactile) to determine whether there are correlations between their audiotactile integration capabilities and psychopathological variables, with particular attention to trauma, as well as the structure of the ritual.

You are free to decide whether or not to participate in this study; you may also discuss it with your family doctor or others. If anything is unclear, feel free to ask any questions to the doctor who proposed the study. Their contact information is provided at the end of this document.

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If you choose to participate, the doctor will ask you to sign a form confirming that you have read and understood all aspects of the study and that you wish to participate. You will receive a copy of the signed form.

What will happen if I decide to participate?

The study consists of three parts. First, you will be given some questionnaires to complete. Then, a clinical interview will be conducted to discuss your responses.

You will also be asked to provide a video recording of a ritualized behavior, which will be analyzed using specialized software.

Following this, a task involving multisensory integration will be administered.

What will happen if I decide not to participate?

If you decide not to participate in the study, there will be no consequences regarding the quality of the care or treatment you receive.

Can I withdraw from the study at any time?

You are free to withdraw from the study at any time, without any consequences.

What are the benefits?

There are no direct benefits to you from participating in this observational study. However, your participation will help to improve our understanding of Obsessive-Compulsive Disorder.

What are the risks?

There are no specific risks associated with participation in this study. No experimental drugs will be used. You will be promptly informed if new information becomes available that might affect your willingness to continue participating.

Will my data remain anonymous?

All information related to your participation in this study will be handled with strict confidentiality in accordance with Good Clinical Practice (Legislative Decree 211/2003), the European Data Protection Regulation no. 679/2016 (GDPR), and current Italian privacy laws.

Personal data, including sensitive information, will be coded in such a way that it cannot be traced back to you. Only the study doctor will be able to link the code to your identity.

The specialist following you in the study, authorized monitoring personnel, and regulatory authorities may access your personal data, subject to the restrictions of the Data Protection Authority guidelines (Resolution no. 52 dated 24/07/2008 and subsequent amendments). All study personnel are obligated to maintain confidentiality.

Insurance Coverage

As this is an observational study involving only the collection and analysis of data, no insurance coverage is required.

How will the results be used?

All data will be collected by the physician. No one, except authorized personnel, will be able to identify you.

The results of this study may be disclosed and/or published in scientific journals. Your identity will never be revealed.

Who can I contact for more information?

For any questions or further information, please contact the study's responsible specialist, Prof. Matteo Tonna, or the doctor who proposed your participation.

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At the end of the study, you may request to review the results obtained thanks to your contribution.

This study and its related documentation have been approved by the Ethics Committee of the Emilia Nord Area.