Official Title: Glutamatergic Modulation of Impaired Inhibitory Control in

Skin Picking and Compulsive Behaviors: A Neural Mechanism

Investigation

NCT Number: NCT06956157

Document Date: April 27, 2021

Research Informed Consent Form

Study Protocol Version Number: 2

Informed Consent Form Version Number: 20210402 Ethics Committee Contact Information: 020-83525975

Research Project: A Study on the Role of Glutamate and Neural Mechanisms Underlying Inhibitory Control Deficits: Comparing Skin Picking Disorder and Obsessive-Compulsive Disorder

Introduction

We would like to invite you to participate in this magnetic resonance imaging (MRI) study of the brain. Before you agree to participate in this study, please read the following information carefully. To ensure you understand what participation in this study involves, please ask as many questions as you need. After carefully reading the details of this study and asking your questions, please sign this consent form if you agree to participate.

Research Background

Preliminary research suggests that Skin Picking Disorder (SPD) is an obsessive-compulsive related disorder. There may be close links in the neural mechanisms between SPD and Obsessive-Compulsive Disorder (OCD). SPD shares numerous biological and clinical phenomenological connections with OCD, yet there are also distinct differences. Exploring the neuroimaging differences in inhibitory control impairment between SPD and OCD, further clarifying the intrinsic connection between SPD inhibitory control impairment and the fronto-striatal neural network, and identifying shared and distinct neurocognitive metabolic and functional characteristics of SPD and OCD will provide new evidence for understanding the pathogenesis of SPD and deepen our understanding of the mechanistic relationship between SPD and OCD.

Research Purpose

This study uses multimodal imaging techniques (fMRS, fMRI, 3D) to elucidate the similarities and differences in the neural network basis of patients with SPD and OCD. The aims are: to investigate the functions of behavioral inhibition and cognitive inhibition in patients with SPD and OCD, and their differences; to construct brain network models of impaired inhibitory control in SPD and OCD; to explore the shared

and distinct cognitive neural mechanisms of SPD and OCD; and to provide a new theoretical basis for further revealing the onset, development, and prognosis of Skin Picking Disorder.

Research Procedures

If patients with SPD or OCD meet the eligibility criteria for this study, you will undergo approximately two hours of testing. This will include the collection of general demographic information, psychological function tests, and the first brain MRI scan. Participants may take breaks during the testing process.

After the first brain MRI scan, SPD patients will receive free oral N-acetylcysteine (NAC) treatment for 12 weeks, at a dosage of 1800mg–3000mg per day. We will regularly assess your treatment response, adverse reactions, and psychological function on a monthly basis.

We would like to invite SPD patients whose condition has improved after the treatment ends to undergo another session of approximately two hours of testing. This session will include symptom assessment, psychological function tests, and a second brain MRI scan.

Discomforts and Side Effects

Brain magnetic resonance imaging (MRI) is a very safe procedure. You only need to lie still on the examination table during the scan. The noise from the machine during operation might cause slight discomfort or fatigue, but it is not expected to cause any lasting harm or side effects.

The N-acetylcysteine (NAC) medication you may take is a promising investigational treatment for SPD patients, and previous studies suggest it is generally safe and potentially effective. Studies report that NAC is generally well-tolerated with minimal adverse reactions. Initial intake may cause mild nausea or runny nose, but these symptoms usually disappear naturally as your body adapts.

Potential Benefits

Participation in this study may lead to improvements in clinical symptoms and cognitive function for SPD patients. Additionally, both SPD and OCD patients will receive a series of psychological function tests and MRI scans free of charge. The findings of this study will contribute to a better understanding of the biochemical metabolic and functional changes in the brains of individuals with Skin Picking Disorder and Obsessive-Compulsive Disorder. This will advance our knowledge of the development of obsessive-compulsive related disorders and potentially benefit more people in the future.

Costs Associated with Participation

To compensate for any inconvenience caused by participating in this study, the study will cover the costs of the psychological assessments, brain MRI scans, and NAC medication provided during your participation.

Confidentiality

Personal information obtained during the study will be kept strictly confidential. Your name will not be published in any reports or literature without your explicit consent. Study data will be anonymized.

Voluntary Participation

Participation in this study is entirely voluntary. You may withdraw at any time without penalty or loss of benefits to which you are otherwise entitled, and without affecting the treatment you are currently receiving or may receive in the future.

The researcher may end your participation in the study if:

- 1. The researcher believes it is in your best interest.
- 2. You no longer meet the study requirements.

Informed Consent Form

Project Title: A Study on the Role of Glutamate and Neural Mechanisms Underlying Inhibitory Control Deficits: Comparing Skin Picking Disorder and Obsessive-Compulsive Disorder

Institution: Guangdong Mental Health Center

Principal Investigator: Zheng Huirong

Declaration of Consent

I have read and understood the information provided above.

I have carefully read the details regarding this study and have had the opportunity to ask questions. The researcher has fully explained the potential risks, side effects, and benefits to me. My questions about the study procedures, possible risks, adverse reactions, and the study medication have been answered to my satisfaction. Based on this information, I voluntarily agree to participate in this study.

Participant Signature:	
Contact Telephone:	
Date Signed:	
Researcher Signature:	
Researcher Signature: Contact Telephone:	_