Understanding the Patient Perspective: An Observational Study on Experiences of OCD Clinical Trial Patients

This is an informed consent form for OCD patients joining Power Clinical Trial's observational medical trial.

Date: May 19, 2023

OCD Clinical Trial Overview

OCD stands for Obsessive-Compulsive Disorder. It is a mental health disorder characterized by recurring and distressing thoughts, known as obsessions, and repetitive behaviors or mental acts, known as compulsions. People with OCD often experience intrusive thoughts, images, or urges that cause significant anxiety or distress. To alleviate this distress, they engage in repetitive behaviors or mental rituals as a way to temporarily reduce their anxiety.

By participating in this observational clinical trial, patients living with OCD have the opportunity to contribute their personal experiences and perspectives, which can play a crucial role in informing the development of new treatments and support programs. The insights gained from this trial can significantly advance our understanding of OCD and ultimately lead to improved outcomes for patients.

The primary goal of this study is to gain valuable insight into the factors that may contribute to lower participation or completion rates among OCD patients in clinical trials. To achieve this, we extend an invitation to you to take part in an observational clinical trial. Through this trial, we aim to identify any recurring patterns in the patient experience that could potentially impact these rates. We want to emphasize that any information you provide during the trial will be treated with the utmost confidentiality and meticulously analyzed.

It is essential to understand that this trial is strictly observational and will not involve any modifications to your current treatment plan. Your participation in this trial does not entail receiving any form of treatment. Throughout the trial process, you can refer to this document for comprehensive information regarding the recruitment process and the dedicated staff involved in the trial.

Informed Consent and Study Specifics

Your participation in this study is completely voluntary, granting you the freedom to discontinue your involvement whenever you desire. This practice is standard in medical research studies. Importantly, it should be noted that your treatment plan will remain unaffected if you choose to take part. This study is purely observational, which means that your diagnosis, medications, and care will continue as they are if you are presently undergoing treatment. The study team is explicitly prohibited from interfering with your treatment or monitoring your care status.

Clarification and Support Channels

During the course of the study, it is vital that you feel confident and have a clear understanding of the study's details. If you encounter any uncertainties or require additional explanations, please don't hesitate to seek clarification. The study team is readily available to address any questions or concerns you may have regarding instructions, explanations, or any aspect of the study. Your comprehension and peace of mind are highly valued and prioritized by the study team.

Aims of the Study

Clinical trials have historically focused on specific demographic groups, resulting in a limited understanding of the factors that hinder the involvement of OCD patients in these trials.

This research study aims to collect comprehensive information from participants to identify consistent factors that prevent individuals from enrolling or completing clinical trials. Through meticulous examination of the collected data from various demographic perspectives, patterns that impact the experiences of future OCD patients can be identified. Your active participation in this study can provide invaluable insights that have

the potential to improve the participation and completion rates of OCD patients in clinical trials.

Understanding Interventional and Observational Studies

In order to take part in this study, it is necessary to be enrolled in an interventional clinical trial. It is essential to note that participating in this observational clinical study will not have any impact on your existing OCD care regimen if you are already involved in a different clinical trial. Should you have any concerns or inquiries about your interventional clinical trial, we encourage you to reach out to your care team for additional information and clarification.

Study Requirements and Check-up Calls

As a participant in this observational clinical study, you will be asked to complete bi-weekly surveys, with an estimated completion time of approximately 30 minutes. Additionally, there will be quarterly check-up calls scheduled specifically for your interventional clinical trial, which are separate from this observational research. It is important to ensure that you schedule and attend these calls as required to actively participate in both components of the study.

Assessing Potential Risks

Engaging in a medical study involves considering potential risks. However, in this observational clinical trial, the risks are minimal. The possibility of altering care regimens, which could result in adverse effects for participants, is not applicable to this study as it is solely observational. Your treatment will remain unchanged throughout the trial. Another potential risk is the breach of confidentiality due to regular video conferences and online reporting. To mitigate this risk, we employ encryption and password protection to secure all electronic data.

Determining Potential Benefits

Participating in this study also offers potential benefits. The outcomes of this trial will provide valuable insights into the factors that can impact the participation and

completion rates of diverse OCD patients in clinical studies. This knowledge will be instrumental in enhancing future clinical trials that aim to include individuals with OCD. By actively participating in this study, you can contribute to a deeper understanding of the factors that may affect the participation of diverse patient populations in these trials.

This Study Compared To Other OCD Clinical Trials

This study, unlike many others for OCD patients, is totally observational. This indicates that there is no predetermined course of therapy that participants must adhere to. It is important to note that the study's team may lack in-depth expertise of past OCD research. However, there are tools available to assist you. A comprehensive list of studies on OCD may be found at ClinicalTrials.gov. You may also look at Power's reference page for a list of OCD clinical trials that are actively seeking volunteers.

Exploring Diversity in Clinical Trials: Recommended Reads

Despite the limited research on the representation of diverse populations in clinical trials, there are several studies that offer valuable insights. We have compiled a list of recommended readings that you may find interesting:

1. Adashi, Eli Y., and I. Glenn Cohen. "The FDA initiative to assure racial and ethnic diversity in clinical trials." *The Journal of the American Board of Family Medicine* 36, no. 2 (2023): 366-368.

2. Polo, Antonio J., Bridget A. Makol, Ashley S. Castro, Nicole Colón-Quintana, Amanda E. Wagstaff, and Sisi Guo. "Diversity in randomized clinical trials of depression: A 36-year review." *Clinical Psychology Review* 67 (2019): 22-35.

Stringent Measures for Confidentiality

Preserving the privacy and confidentiality of your personal information is a paramount concern in this clinical study. To ensure the utmost protection, we have implemented rigorous measures. Your records will be assigned a unique code or number, guaranteeing anonymity throughout the study. All identifying materials will be securely stored in a locked file cabinet under the close supervision of the researcher. We highly value your privacy and will not disclose any personal information without your explicit

consent, except when required by law, such as in situations involving abuse or suicide risk.

Voluntary Acknowledgment of Participation

By providing my signature below, I acknowledge that I have been fully informed about the nature and purpose of this study. I understand that my involvement is entirely voluntary, and I have the freedom to withdraw from the study at any point without experiencing any adverse consequences. The reassurance that my decision to withdraw will not impact my current or future medical care is greatly appreciated. I request a copy of this consent form for my personal records.

_____

Printed Name of Participant

_____

Signature

_____

Date

Confirmation of Participant Understanding

In my role as the clinical trial personnel responsible for discussing the consent form with the participant, I am pleased to confirm that the participant has exhibited a comprehensive understanding of the risks, benefits, and procedures involved in this clinical research. Through open and informative discussions, all queries and uncertainties have been addressed, ensuring that the participant has a clear grasp of the study's implications and protocols.

_____

Printed Name of Person Getting Consent

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Signature of Person Getting Consent

_____

Date