Participating in Schizophrenia Clinical Trials: Understanding the Journey of Patients

This is an informed consent form for schizophrenia patients joining Power Clinical Trial's observational clinical study.

Date: May 12, 2023

Schizophrenia Clinical Study Overview

Schizophrenia is a chronic and severe mental illness that affects a person's thinking, emotions, and behavior. The disorder is characterized by symptoms such as delusions, hallucinations, disorganized thinking, and abnormal behaviors. People with schizophrenia may also experience difficulties with social interactions, motivation, and emotional expression. There is no cure for it, but treatments such as medication and psychotherapy can help manage symptoms and improve overall quality of life.

An observational clinical trial is important for schizophrenia patients because it can provide valuable information on the natural history of the disorder and how it affects patients over time. Unlike interventional clinical trials, which test the effectiveness of specific treatments or interventions, observational trials simply observe and collect data on patient's experiences with the disorder.

We are conducting an observational clinical trial and would like to invite you to participate. The trial aims to gain a better understanding of why participation and completion rates among schizophrenia patients may be lower during clinical trials. We will be looking for patterns in the patient experience that may contribute to these rates. Please be assured that any information you provide during the trial will be kept anonymous and analyzed carefully.

It is essential to note that this trial is purely observational, and no changes will be made to your current treatment. Participation in the trial does not involve receiving any treatment. This document provides a summary of the recruitment process and

information about the staff involved in the trial, which you can refer to for any previously discussed information during the trial process.

Initial Notes

This research study is completely voluntary, meaning you have the freedom to withdraw from the study at any point if you decide to. It is common in medical research for participants to have this option. It is essential to note that participating in this study will not affect your ongoing treatment. This study is observational, which implies that if you are currently receiving treatment, your diagnosis, prescriptions, and care will remain the same. The study staff will not be allowed to interfere with your treatment or monitor your care status.

If at any point during the study, you have questions or are unsure about instructions or explanations, it is crucial to speak up and let the team know. It is vital not to hesitate in asking for clarification.

The Significance of Schizophrenia Research Conducted

Clinical trials have been available to specific demographic groups in the past. However, research on the factors that may influence schizophrenia patients' participation in these trials is limited.

This research aims to gather diverse information from study participants to identify factors that may consistently deter individuals from joining or completing the study. The collected data will be carefully analyzed from different demographic angles to identify patterns that may affect the experiences of future schizophrenia patients. By taking part in this research, you can provide valuable insights that may enhance schizophrenia patients' participation and completion rates in clinical trials.

Clinical Trial Process

If you are interested in participating in this study, you must first be enrolled in an interventional clinical trial. It's important to note that taking part in this observational clinical study will not have any impact on your current schizophrenia care regimen under a separate clinical trial. If you have any inquiries or concerns regarding your interventional clinical trial, please contact your care team for additional information.

As a participant in this observational clinical study, you will be requested to complete bi-weekly surveys that should take approximately 30 minutes to complete. Additionally, quarterly check-up calls will be scheduled throughout the duration of your interventional clinical trial, independent of this observational research. Please ensure that you arrange these calls as required.

Benefits and Risks of Participating in a Schizophrenia Observational Clinical Trial

This observational clinical trial comes with potential risks, such as the possibility of adverse effects due to modifying care regimens. However, participants can rest assured that this will not happen in this study as it is purely observational. Additionally, there is a risk of breach of confidentiality due to regular communication through video conferences and online reporting. However, we have taken steps to minimize this risk by securing electronic data with encryption and password protection.

Despite the potential risks, participating in this study also has potential benefits. The results of this trial will provide valuable insights into the factors that may impact the participation and completion rates of diverse schizophrenia patients in clinical studies. This information will be useful for future clinical trials that aim to enroll people with schizophrenia. By participating in this study, you can contribute to a better understanding of the factors that may affect the participation of diverse patient populations in these trials.

More Schizophrenia Disease Clinical Trials

Clinical trials for schizophrenia patients can be interventional or observational. This clinical trial is unique because it is an observational research study and does not involve any specific treatment regimen. If you are interested in learning more about other types of schizophrenia studies, you can explore ClinicalTrials.gov or the Power website for information on relevant schizophrenia clinical trials available for people with this condition.

Recommended Reading: Learning More About Diversity in Clinical Trials

While there is a lack of research on the representation of diverse populations in clinical trials, there are some studies that shed light on this important issue. To learn more, we recommend checking out the following readings:

Lindenfeld, JoAnn, Mona Fiuzat, and Christopher O'Connor. "Promoting diversity in clinical trial leadership: a call to action." *Heart Failure* 9, no. 5 (2021): 401-402.

Chen, Vivien, Shifa Akhtar, Caiwei Zheng, Vignesh Kumaresan, and Keyvan Nouri. "Assessment of changes in diversity in dermatology clinical trials between 2010-2015 and 2015-2020: a systematic review." *JAMA dermatology* (2022).

Safeguarding Your Confidentiality in the Clinical Study

We take the confidentiality of your information very seriously in this clinical study. We will use a code or number to identify you in the study records, and all identifying materials will be kept securely in a locked file cabinet under the supervision of the researcher. Your privacy is of the utmost importance to us, and we will not disclose any of your confidential information without your explicit consent, except when required by law, such as in cases of abuse or suicide risk.

Consent

By signing this document, I confirm that I have received sufficient information regarding the purpose, procedures, and risks associated with this study. I understand that my participation is entirely voluntary and that I am free to withdraw from the study at any time without any repercussions. I further acknowledge that I will receive a copy of this consent form for my records.

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Printed Name of Participant

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Signature

_____

Date

Personnel Affirmation of Participant Understanding

As the clinical trial personnel responsible for explaining the consent form to the participant, I affirm that they have fully understood the information presented. Through our discussions, the participant has demonstrated their knowledge and comprehension of the risks, benefits, and procedures associated with this clinical research.

_____

Printed Name of Person Getting Consent

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Signature of Person Getting Consent

_____

Date