Investigating PTSD Clinical Trials: A Study of Patient Experience Patterns

An Informed Consent Form For Power Clinical Trial's Observational Clinical Study

Date: April 21, 2023

Understanding This PTSD Clinical Trial

We are conducting a clinical trial project and require participants to provide their consent to participate.

Participants have the right to withdraw from the study at any time. Our main objective is to identify the patterns in the experiences of PTSD patients who sign up for interventional clinical trials. The study involves completing questionnaires and follow-up calls to determine the reasons for enrollment, retention, or discontinuation from the clinical trials. As an observational study, there is minimal risk to participants and no clear medical benefit to participation.

However, the study's outcomes will enhance our knowledge of the factors that influence the enrollment rates of clinical trials for PTSD patients. We urge participants to read the consent form carefully, ask questions, and seek advice from their family, friends, trusted advisors, or medical professionals before deciding to participate. Participation is voluntary, and those who choose not to participate will not be denied any standard benefits, rights, or privileges.

Purpose of the Study

The purpose of this clinical trial is to investigate why certain demographics are underrepresented in PTSD clinical trials. We aim to identify the factors that affect a patient's decision to participate in the study, withdraw from it, or continue with it.

Additionally, we intend to recruit participants from a diverse range of demographic groups to determine if any observed results are statistically significant. Through this study, we hope to improve clinical trial participation and ultimately enhance the effectiveness of treatments for PTSD.

PTSD Clinical Trial Process

If you are currently undergoing therapy or treatment in an interventional trial for PTSD, you may be eligible to participate in our observational clinical research study. The study aims to collect data from participants who have previously taken part in, withdrawn from, or completed a clinical study, to identify the factors that influence patient enrollment, withdrawal, and clinical trial completion. The research team will recruit participants using electronic medical record systems and will collect data through questionnaires and phone or video chats every two weeks and every three months, respectively. The results of the study will be presented at conferences and published in scholarly journals to improve patient recruitment and retention in ongoing clinical studies.

Exploring Patient Decision-Making in PTSD Clinical Trials

Our observational study is centered on comprehending the various factors that influence patient decision-making regarding participation in clinical trials for PTSD. We are particularly keen to understand the reasons that led you to enroll in a clinical trial and the factors that impact your decision to continue or discontinue.

Your participation in this study is completely voluntary and will have no effect on your current treatment plan. We will conduct interviews to gather data, which will aid us in identifying the barriers and motivators that impact patient participation in clinical trials.

Your contribution will be immensely beneficial in developing more efficient strategies for improving patient recruitment and retention in clinical trials for PTSD. If you choose to participate, you may withdraw from the study at any time without any negative consequences. We appreciate and respect your participation in this research project.

Benefits and Risks For Participants

Patients with PTSD may derive benefits from participating in observational clinical trials since they can advance medical knowledge and potentially lead to improved treatment options in the future.

Throughout the study, patients may also receive access to expert care and supervision. While the observational study does not include experimental therapies such as drugs or surgery, it may not directly benefit the patient's medical condition.

Each individual should carefully consider the pros and cons before deciding whether to participate in a clinical trial based on their specific situation and goals. It is recommended that patients discuss their options with their doctor and the study team before making a decision.

Will My Personal Data Be Kept Safe

To the best of our ability, we will safeguard and maintain the confidentiality of any personal information about you that we acquire for this clinical research. However, as it could need to be shared by law, we cannot guarantee total privacy. No publications or presentations of the research findings will contain your name or any other information that may be used to locate you. Several organizations, including accrediting bodies, government and regulatory agencies, safety monitors, study sponsors, and authorized sponsor representatives, may have access to your medical information for research, quality control, and data analysis reasons.

An "Authorization Form" that details how and by whom your information may be used for research may be requested from you. Any information and/or study samples you provided may be distributed for future research without additional notice to other Power researchers, researchers from other academic institutions, or researchers from outside commercial businesses. Your private information will be deleted and kept private, nonetheless.

This Trial Compared to Other PTSD Clinical Trials

If you're interested in learning more about clinical trials, there are several online resources you can explore. By researching this topic, you can gain a better understanding of the importance of PTSD medical research and the impact it can have on the development of new treatments and therapies.

Clinicaltrials.gov is a great site if you need to find more PTSD studies. The National Institutes of Health (NIH) sponsors this website, which offers a thorough database of clinical studies from all around the world. To focus your search, you may choose from a number of search parameters, including location and condition. As an alternative, you may look for a list of PTSD clinical trials that are presently accepting new volunteers on Power's reference page.

More Reading Resources For Clinical Trial Diversity

In addition to these resources, there are many articles and publications available online that discuss the importance of diversity in clinical trials. By reading these materials, you can gain a deeper understanding of the current state of diversity in clinical trials and the steps being taken to address this issue.

Michos, Erin D., and Harriette GC Van Spall. "Increasing representation and diversity in cardiovascular clinical trial populations." *Nature Reviews Cardiology* 18, no. 8 (2021): 537-538.

Blumenthal, David, and Cara V. James. "A data infrastructure for clinical trial diversity." *New England Journal of Medicine* 386, no. 25 (2022): 2355-2356.

Declaration of Participant

I have read the material in the aforementioned paper in its entirety, and it has also been orally communicated to me. Any questions or uncertainties were answered to my satisfaction.

I am aware that my participation in this observational clinical study is entirely voluntary and that I can withdraw at any time without suffering any consequences. My signing on this document does not signify that I am waiving any of my legal rights.

I am aware that a copy of this informed consent form will be provided to me for my own keeping.

I am voluntarily and consciously declaring my desire to take part in the clinical trial described above by signing below.

_____

Printed Name of Participant

_____

Participant Signature

_____

Date

Statement of Researcher During the Informed Consent Discussion

The advantages, hazards, and procedures of this clinical study for ulcerative colitis have been thoroughly discussed with the participant, and I am convinced that the participant is aware of all of the information contained in this form.

I'm certain that the participant now has all the information they need to decide whether or not to take part in the experiment as a consequence of our talk. I am also certain that the participant fully comprehends the purpose of the study, the steps required, as well as any possible advantages and disadvantages.

_____

Printed Name of Researcher Conducting Informed Consent Discussion

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Signature

_____

Date