An Observational Study Investigating the Experience of Patients Undergoing Active Insomnia Clinical Trials

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

Date: July 28, 2023

Introduction

Your valued participation is requested in a non-interventional research study centered around insomnia. We assure you that your involvement in this study is entirely voluntary, and you have the autonomy to withdraw your consent whenever you see fit.

The reason you are being approached for this research study is because you are currently partaking in an active clinical trial dedicated to insomnia.

If you choose to accept our invitation and participate in this study, we will require you to sign the consent form provided. By signing this form, you acknowledge that the study's details have been effectively communicated to you, all your queries have been satisfactorily answered, and you willingly grant your permission to partake. It is crucial to understand that your regular medical care from your doctor will remain unaffected throughout the study.

Purpose

The primary purpose of this study is to amass valuable data on the potential effectiveness of new investigational tests in predicting suitable medications for specific patient groups. It is crucial to emphasize that, at present, these tests are being employed solely for research purposes.

Within the framework of this study, we aim to closely observe and comprehend the various factors that come into play during your insomnia clinical trial enrollment process. Our goal is to gain insights into how these factors might impact your ability to participate in the trial and successfully complete it.

Rest assured, the information gathered will be treated with utmost confidentiality, ensuring that the results are non-personally identifiable. The data will be analyzed to uncover trends related to the experiences of insomnia patients, with a particular focus on aspects that often contribute to unsatisfactory enrollment rates or low completion rates.

Since this study is purely observational, there will be no changes to your treatment regimen should you decide to take part in it.

This document serves as written evidence of all discussions you have had with our site staff or recruitment coordinators and can also serve as a point of reference for you as a participant in this clinical study.

Study Activities

Your commitment to this study will involve participating in bi-weekly surveys, with each survey expected to last approximately 30 minutes. Additionally, there will be quarterly check-in calls at various points during the clinical trial process.

To take part in this observational study, it is essential that you are currently enrolled in an interventional clinical trial. It is important to note that your treatment and the methodology prescribed by your primary care doctor will remain unchanged if you choose to be a part of this study.

Throughout the trial, our staff will be available to address any concerns or questions you may have, so please do not hesitate to reach out to them.

Before enrolling in this clinical study, it is imperative that you discuss your intention with your care team and obtain their approval.

Participant Responsibilities

Participation in this study does not require any obligatory visits or treatments. Instead, during your regular appointments, the study doctor or staff will input relevant health and medical information into the study database.

Throughout your involvement in the study, it is essential to communicate any changes in your health or well-being to the study doctor or staff.

If you decide to discontinue your participation in the study at any time, please inform the study doctor or staff accordingly. In the event that they encounter difficulties reaching you despite repeated attempts during the study, they may contact a person listed on the disclosure form at the study center to obtain updated contact information or to be informed about any changes in your health.

Potential Benefits

As a participant in this study, it is essential to understand that there will be no direct benefits to you. Nonetheless, the data collected from this study could hold significant relevance for researchers, facilitating comparisons with other observational studies that delve into patients' experiences in similar clinical trials.

Potential Risks

It is imperative to acknowledge the risk associated with the potential exposure of your protected health information, which could lead to your identification. To protect your identity and the associated data and samples collected, we have implemented a secure coding system using letters and numbers. The coded data may be retained for an extended period of time. For more details on the duration for which your coded samples might be stored for research purposes, please consult the study doctor or study staff.

Additionally, it is essential to understand that your genetic test results may be accessible to your insurance company, other healthcare providers, and various other entities. The Genetic Information Nondiscrimination Act (GINA) serves as a protective measure against certain forms of genetic discrimination. According to this federal law, health insurance companies, group health plans, and most employers are prohibited from discriminating against you based on your genetic information. Nevertheless, it is crucial to note that GINA does not offer protection against discrimination from companies that provide life insurance, disability insurance, or long-term care insurance.

Comparing This Trial to Other Insomnia Clinical Trials

Distinguished by its unique observational approach, this study differentiates itself from conventional insomnia trials. While interventional clinical trials concentrate on specific treatments, this study centers on meticulous observation and comprehensive data collection.

As a participant in this observational clinical trial, you can rest assured that there will be no alterations to your current treatment plan, and no treatment recommendations will be provided. The primary goal is to gather an abundance of data and insights concerning insomnia and its significant impact on patients' lives. By joining this study, you have the opportunity to contribute significantly to the existing body of knowledge and potentially influence future advancements in insomnia care.

For those interested in exploring other research options, clinicaltrials.gov serves as a valuable resource to discover ongoing insomnia studies. Furthermore, Power's online page offers a dedicated section exclusively focused on insomnia clinical trials, presenting a wealth of information for individuals eager to explore available opportunities.

More Resources on Diversity in Research Trials

If you are eager to delve deeper into the dynamics of participation rates in clinical trials, a plethora of enriching experiences awaits through the following recommended sources. These references offer an abundance of information and comprehensive studies solely dedicated to exploring and understanding the factors that significantly influence individuals' decisions to participate in clinical research:

Sharma, Ashwarya, and Latha Palaniappan. "Improving diversity in medical research." Nature Reviews Disease Primers 7, no. 1 (2021): 74.

Woodcock, Janet, Richardae Araojo, Twyla Thompson, and Gary A. Puckrein. "Integrating research into community practice—toward increased diversity in clinical trials." New England Journal of Medicine 385, no. 15 (2021): 1351-1353.

Alternatives to This Study

Please be aware that this study does not offer treatment for your insomnia condition. You have the option of choosing not to participate in this study as an alternative. Rest assured, your decision to be part of this study will have no impact on the care provided by your regular doctor. Similarly, should you decide to discontinue your participation, it will not affect the treatment approach your regular doctor has for managing your insomnia.

New Information

Rest assured that your study doctor or study staff will keep you informed if any new information arises during the course of this study that may impact your decision to continue participating.

Contacts

Feel free to reach out with any questions about the study at any point during the research. Should you have any inquiries, concerns, or complaints about the study, please contact the study doctor or study staff using the phone number listed on page 1 of this form. In case you experience any injuries or illnesses during the study that you believe may be related to your participation, please promptly get in touch with our study researcher.

Consent to Participate

This form has been thoroughly reviewed by me, and I have had the opportunity to engage in discussions with my study doctor or the study staff, who have been forthcoming in addressing all my inquiries about this study. With full understanding and without coercion, I willingly provide my consent to participate in this study.

Additionally, I hereby grant permission for the use and sharing of my records in relation to this study, as outlined above. It is important to note that signing this form does not diminish any of my legal rights as a research participant. I will be furnished with a signed copy of this consent form for my personal records.

_____

Printed Name of Participant

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Participant Signature

_____

Date

I have provided the participant with a thorough and detailed explanation of this study, covering its objectives, procedures (if any), potential risks, benefits, and the voluntary nature of their involvement. The individual was encouraged to seek clarification by asking questions, and all inquiries were promptly addressed. Additionally, a signed copy of this form has been given to the participant for their records.

_____

Printed Name of Person Taking Consent

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Signature of Person Taking Consent

_____

Date