Alzheimer's Clinical Trials: An Assessment of Clinical Trial Experiences of Alzheimer's Disease Patients

This is an informed consent form arranged by Power Clinical Trial for Alzheimer's disease patients who are participating in an observational clinical trial.

Date: January 2, 2023

Alzheimer's Clinical Study Overview

This study is inviting you to participate in an observational clinical trial. The purpose of this trial is to learn more about what factors may lead to lower participation or completion rates among Alzheimer's disease patients during clinical trials. We want to see if there are any patterns in the patient experience that may contribute to these rates. The information collected during this trial will be kept anonymous and carefully analyzed.

It is important to note that this trial is purely observational, which means that your treatment will not be changed in any way. Participating in this trial is different from being a patient receiving treatment. This document will provide you with a summary of the recruitment process and information about the staff involved in the trial. You can use this as a reference if you need to review any previously discussed information as you go through the trial process.

Important Notes

Participating in this study is completely voluntary, which means you can decide to stop participating at any time. This is common in medical studies. It's important to note that if

you decide to join this study, your treatment will not be affected. Our study is observational, which means that if you are already receiving treatment, your diagnosis, prescriptions, and care will stay the same. The staff involved in this study will not be able to intervene in your treatment or monitor your care status.

It's also important to speak up if you don't understand something. If at any point during the study you have questions or are unclear about instructions or explanations, it's crucial that you let the team know. Don't be afraid to ask for clarification.

Why This Alzheimer’s Research is Being Conducted

In the past, clinical trials have sometimes only been available to certain demographic groups. However, there is a lack of research on what factors may impact the participation of Alzheimer's disease patients in these trials.

This study aims to gather a wide range of information from research study participants to determine what factors may be consistently preventing individuals from joining or completing the study. The information collected will be thoroughly analyzed from different demographic perspectives in order to identify patterns that may impact the experiences of future Alzheimer's disease patients. By participating in this research, you can help to provide valuable insights that may improve the participation and completion rates of Alzheimer's disease patients in clinical trials.

Possible Risks

There are certain risks associated with participating in any medical study. These risks include:

Consequences of changing treatment processes: There is always a chance that modifying care regimens could have an adverse effect on the participant. However, you can be assured that this will not happen in this clinical trial because it is purely observational. An observational study cannot change your treatment regimen or care process.

Breach of confidentiality: This clinical trial requires regular communication through video conferences and frequent online reporting with the individuals involved. There is always a risk of information leakage when using online platforms to process consent forms and other information.

We take steps to minimize the risk of exposing confidential data. We use encryption and password protection to secure electronic copies of documents, call logs, and other information obtained from conversations between patients and personnel. This information is stored and analyzed in a secure environment.

Benefits

The results of this observational clinical trial can provide insights into the factors that may impact the participation and completion rates of diverse Alzheimer's disease patients in clinical studies. The data collected will be valuable for future clinical trials that aim to enroll people with Alzheimer's disease. It may help researchers to better understand the factors that may affect the participation of diverse patient populations in these trials.

Comparison To Other Clinical Trials For Alzheimer's

Many studies for Alzheimer's disease patients are interventional, which means that the patients are required to receive a specific treatment regimen. This clinical study is different because it is an observational research study. We will not offer or require any treatment as part of this study.

The staff involved in this study may not have extensive knowledge about all Alzheimer's disease studies. If you want to learn more about these types of studies, you can search for Alzheimer's trials on ClinicalTrials.gov or find relevant Alzheimer's clinical trials on the Power website. These resources can provide you with more information about the various clinical trials available for people with Alzheimer's disease.

What You Need to Do as a Participant

To participate in this study, you must first be enrolled in an interventional clinical trial. It's important to note that your participation in this study will not affect your existing Alzheimer's disease care regimen under a different clinical trial. If you have any questions about your interventional clinical trial, please contact your care team for more information.

As a participant in this observational clinical study, you will be asked to complete bi-weekly surveys that will take approximately 30 minutes to complete. In addition, there will be quarterly check-up calls scheduled during the course of your interventional clinical trial outside of this observational research. Please be sure to schedule these calls as needed.

More Reads on Representation In Clinical Trials

There is limited research on diversity in clinical trials, but here are some studies you may be interested in looking at:

Ramos, Edward, Katie Baca-Motes, Jay A. Pandit, and Toluwalase A. Ajayi. "Improving participant representation in the era of digital clinical studies." *Trends in Molecular Medicine* (2022).

Hussain-Gambles, Mahvash, Karl Atkin, and Brenda Leese. "Why ethnic minority groups are under-represented in clinical trials: a review of the literature." *Health & social care in the community* 12, no. 5 (2004): 382-388.

Banzi, Rita, Paolo Camaioni, Mauro Tettamanti, Vittorio Bertele, and Ugo Lucca. "Older patients are still under-represented in clinical trials of Alzheimer's disease." *Alzheimer's research & therapy* 8, no. 1 (2016): 1-10.

Participant's Statement

I confirm that I have read this document and had it explained to me. All of my questions have been answered clearly and to my satisfaction.

I am not being forced to sign this form and understand that I can choose to withdraw from the clinical trial at any time because participation is voluntary. I am not giving up any legal rights by signing this form. I will also be given a copy of this consent form after signing it.

By signing below, I am indicating my willingness to participate in this observational clinical trial.

_____

Printed name of Participant

_____

Participant Signature

_____

Date

Statement of Clinical Trial Personnel

I have thoroughly discussed the contents of this consent form with the participant and believe that they fully understand the form, as well as the risks, benefits, and procedures involved in this clinical research. The participant has demonstrated their knowledge and understanding of the content of this consent form.

_____

Printed name of Person Conducting Informed Consent Discussion

_____

Person Conducting Informed Consent Discussion Signature

_____

Date