Dementia Clinical Trials: A Study on the Clinical Trial Participation of Dementia Patients

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

Date: April 28, 2023

Background

You have been invited to participate in a non-interventional research study on a voluntary basis, and you reserve the right to revoke your consent at any moment.

The study is focused on dementia, and its objective is to observe and comprehend the different aspects of the dementia interventional study enrollment process that may impact your ability to participate and complete the clinical trial successfully.

By agreeing to participate, you will be required to sign this consent form, indicating that you have been thoroughly informed of the study's details and that you authorize your participation. Please be advised that your participation in this study will not affect your regular medical care from your physician.

Purpose of the Study

You are being requested to participate in a research study, and it is important to understand the purpose of this study and its requirements before making your decision. Please carefully review the information provided below and feel free to ask the researcher for any additional information or clarifications.

This research aims to collect comprehensive data on the clinical trial experience of dementia patients. Its goal is to identify the factors that limit patients' ability to join or complete a trial successfully. Clinical trial participation often favors specific demographic

groups, and limited research exists on the impact of trial attributes on participation. Therefore, this study aims to analyze data from various demographic groups and identify any recurring trends that could provide valuable insights for future dementia patients.

Dementia Clinical Trial Process

To participate in this study, you will need to complete bi-weekly questionnaires that will take roughly 30 minutes to finish. Additionally, there will be quarterly check-in calls during the clinical trial procedure. Please note that to be eligible to participate, you must be a current participant in an interventional clinical study. Your primary care doctor's recommended treatment and methods will not be altered if you decide to join this observational research. If you have any concerns or questions during the trial, please contact our team for clarification. Please speak with your care team if you are interested in participating in this clinical research.

This Study Compared to Other Dementia Clinical Trials

Unlike most other dementia trials, this is an observational study that does not involve any changes to your current treatment regimen. Other trials are interventional clinical trials where patients are assigned a specific treatment plan that may differ from their current care.

If you are interested in exploring other trials, you can search for ongoing dementia studies on clinicaltrials.gov. You can also visit Power's online page, which provides a list of available dementia clinical trials that are actively recruiting participants.

You can also read more research on participation rates in clinical trials to learn about potential factors that may impact participation. Here are some research papers you might be interested to read:

Chang, Susan M., Fred G. Barker, Meic H. Schmidt, Andrew E. Sloan, Rachel Kasper, Leslie Phillips, Karen Shih, Subramanian Hariharan, Mitchel S. Berger, and Glioma Outcomes Investigators. "Clinical trial participation among patients enrolled in the Glioma Outcomes Project." *Cancer* 94, no. 10 (2002): 2681-2687.

Caldwell, Patrina HY, Sharon B. Murphy, Phyllis N. Butow, and Jonathan C. Craig. "Clinical trials in children." *The Lancet* 364, no. 9436 (2004): 803-811.

Study Benefits and Risks

Participating in this study will not offer you any direct benefits, but we hope that it will assist individuals with dementia in the future.

This is an observational clinical study, and therefore, there will be no changes made to your current treatment regimen. There is no risk associated with treatment change. You will be reporting online and participating in video calls with other dementia patients throughout the duration of the trial.

However, there is a risk that your protected health information may be accessed, and your identity could be revealed. We will use a code of letters and numbers to protect your identity and the associated data and samples that are collected. The coded data may be kept for many years, and you can speak with the study doctor or study staff to learn how long your coded samples will be retained for research purposes.

Protection of Confidentiality

Your privacy is important to us, and your responses to the survey will be treated with the utmost confidentiality. To maintain this confidentiality, the researcher will assign code names or numbers to participants and use these codes in all research notes and documents.

The researcher will also store any identifying participant information, such as notes, interview transcriptions, and other materials, in a secure, locked file cabinet.

However, if the researcher is required by law to report certain incidents, such as incidents of abuse or suicide risk, participant data may be disclosed.

Voluntary Participation

Your decision to participate in this study is entirely up to you, and you are under no obligation to do so. If you do decide to take part, you will be asked to sign a consent form, but you can withdraw from the study at any time, without giving a reason. Your

relationship with the researcher will not be impacted if you choose to withdraw, and any data collected before your withdrawal will be returned to you or destroyed.

Consent

The provided information has been carefully reviewed and understood, and any questions have been asked prior to signing this consent form. I fully understand that I am free to withdraw from the study at any time, without the need to provide a reason and without any financial impact. I understand that I will receive a copy of this consent form, and my participation in this study is completely voluntary.

_____
Printed Name of Participant

_____
Signature

_____
Date

Statement of Person Getting Consent

I have had a comprehensive discussion with the participant regarding the information provided in this document.

I attest that the participant has comprehended the advantages, hazards, and measures involved in this clinical trial for dementia.

_____
Printed Name

_____
Signature

_____
Date