Title: The Benchmark Clinic: An Interdisciplinary Comprehensive Care Model for People with Parkinson Disease

PI: Kyle Mitchell, M.D.

Version Date: 09/16/2020

Pro00105281

NCT04555720

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
ADULT
The Benchmark Clinic: An Interdisciplinary Comprehensive Care Model for People with Parkinson Disease

CONCISE SUMMARY

The purpose of this study is to determine if an interdisciplinary clinic can help people with Parkinson's disease care for themselves, improve their ability to follow recommended treatments, and have fewer problems like falls or visits to the emergency room.

You will be randomly assigned (like the flip of a coin) to receive either interdisciplinary care or standard care.

This study involves 3 clinic visits and you will be in the study for between 6 months and 1 year. The study will end for you upon completion of Visit 3.

If you are interested in learning more about this study, please continue reading below.

You are being asked to take part in this research study because you have Parkinson's Disease. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, Dr. Kyle Mitchell or Dr. Sneha Mantri will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to determine if an interdisciplinary clinic can help people with Parkinson's disease care for themselves, improve their ability to follow recommended treatments, and have fewer problems like falls or visits to the emergency room. Our interdisciplinary clinic is a group of medical professionals which includes a doctor, a physical therapist, an occupational therapist, a speech therapist, a pharmacist, social workers, and a physician's assistant. Normally, people with Parkinson's disease will

see a doctor, and that doctor will decide which referrals to skilled therapists they need at Duke or close to home (standard care). This interdisciplinary clinic is different, because it includes visits with all of the skilled therapies recommended in Parkinson's disease in the same day. The group of medical professionals then meets to decide the best treatment recommendations as a team. We are studying if an interdisciplinary clinic can be more helpful for people with Parkinson's than standard care.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 200 people will take part in this study at Duke.

WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to sign and date this consent form. You will have the following tests and procedures to make sure that you are eligible:

- Physical exam and medical history

You will be randomly assigned (like the flip of a coin) to receive either interdisciplinary care or standard care. You have a 1 in 2 chance of being assigned to interdisciplinary care.

The study involves 3 visits.

Visit 1: your doctor will perform a physical exam to evaluate the symptoms of your Parkinson's disease (like tremors, stiffness, and walking problems). You will then complete surveys about how you see your Parkinson's treatment and how your Parkinson's affects you and your care partner. This visit will take about 30 minutes.

Visit 2 is the interdisciplinary clinic day. It will occur about 3-6 months after visit 1. If you were assigned the interdisciplinary group, you will see social work, physical therapy, occupational therapy, speech therapy, pharmacy, and a physician's assistant in a scheduled rotation for about 45 minutes each. After these evaluations, the team meets with your doctor for a discussion of your treatment. After this meeting, your doctor will meet with you to discuss your treatment plan and make recommendations. This visit lasts from around 8AM-1:30 PM with a built in 45 minutes for lunch from 12:15-1PM. If you were assigned to the standard care group, you will not have this visit but may have normally scheduled visits with your neurologist

Visit 3 occurs 3-6 months later. It is the same as visit 1 with the same surveys and doctor evaluation.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
ADULT
The Benchmark Clinic: An Interdisciplinary Comprehensive Care Model for People with Parkinson Disease

If you were assigned to standard care but you would like to participate in our interdisciplinary care clinic after the study is over, we will schedule you in this clinic. This interdisciplinary clinic will not be part of this study.

Participation in this study is voluntary. Refusal to participate will involve no penalty or loss of benefits.

You can withdraw from the study at any time. You just need to notify your doctor or the study team.

If you do not sign this consent form, you will continue to receive care, but not as a part of this study.

HOW LONG WILL I BE IN THIS STUDY?

You will be in the study between 6 months and 1 year. The study will end for you upon completion of Visit 3.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?

There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may be direct medical benefit to you. Comprehensive interdisciplinary care may help with your engagement with your Parkinson's treatment, prevent falls, help with swallowing safety, improve voice volume, and improve your ability to care for yourself. We hope that in the future the information learned from this study will benefit other people with your condition.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?

Instead of being in this study, you have the following alternative:
You can participate in our already established interdisciplinary clinic as part of your clinical care.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
ADULT
The Benchmark Clinic: An Interdisciplinary Comprehensive Care Model for People with Parkinson Disease

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include the Duke University Health System Institutional Review Board and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

The study results will be retained in your research record forever. Any research information in your medical record will also be kept indefinitely.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?

You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. Kyle Mitchell or Dr. Sneha Mantri**.** At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
ADULT
The Benchmark Clinic: An Interdisciplinary Comprehensive Care Model for People with Parkinson Disease

We will monitor your DUHS patient care charges to make sure that costs are directed appropriately. If you have any questions or concerns about appropriate billing, contact your study team coordinator so that he/she can help find a resolution.

Taking part in this study may cost you and/or your insurance company more than the cost of getting regular medical treatment in the form of copays for each skilled therapy visit. This would only be more than regular medical treatment if you would not already be seeing these therapists as part of your regular medical care.

WHAT ABOUT COMPENSATION?

You will be compensated $100 via Duke Clincard when you complete the final study visit.

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Kyle Mitchell or Dr. Sneha Mantri at 919-668-2879 during regular business hours and on weekends and holidays by calling 919-684-8111 and asking that Dr. Mantri or Mitchell be paged.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Kyle Mitchell or Dr. Sneha Mantri in writing and let him/her know that you are withdrawing from the study. The mailing address for both physicians is 932 Morreene Road, DUMC Box 3333, Durham, NC 27705.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
ADULT
The Benchmark Clinic: An Interdisciplinary Comprehensive Care Model for People with Parkinson Disease

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. Regulatory agencies may stop this study at any time without your consent. We do not anticipate any specific reasons or scenarios that would cause this. If this occurs, you will be notified and your study doctor will discuss other options with you.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them.

The use of your data may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Kyle Mitchell or Dr. Sneha Mantri at 919-668-2879 during regular business hours and on weekends and holidays by calling 919-684-8111 and asking that Dr. Mantri or Mitchell be paged.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____
Printed Name of Subject

_____ _____ _____
Signature of Subject Date Time

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
ADULT
The Benchmark Clinic: An Interdisciplinary Comprehensive Care Model for People with Parkinson Disease

_____	_____	_____
Signature of Person Obtaining Consent	Date	Time