

BASTYR UNIVERSITY

BASTYR UNIVERSITY RESEARCH INSTITUTE Participant Information Sheet

COMPLEMENTARY AND ALTERNATIVE MEDICINE CARE IN PARKINSON'S DISEASE (CAM CARE IN PD)

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Researcher's Statement

We are inviting you to be in a research study to monitor the outcomes of individuals who have been diagnosed with Parkinson's disease (PD). The purpose of this sheet is to give you the information you will need to help you decide whether to be in the study or not. Please read this sheet carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this sheet that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not.

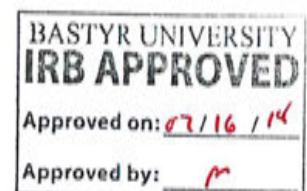
PURPOSES AND BENEFITS

We are trying to identify factors associated with improved quality of life and fewer PD symptoms. We are attempting to identify practices, beliefs, and therapies used by individuals who report excellent quality of life, few PD symptoms, and reduced rates of progression. If you agree to participate, we will ask you to fill out questionnaires about your experience with PD and your health in general along with your food intake every six months for five years. You do not need to answer questions you do not feel comfortable answering. You will not directly benefit from the study, but information gathered during the course of this study may help us begin to assess the longer-term effects of complementary and integrative care on health, disease progression and quality of life in PD patients.

PROCEDURES

You will be asked to complete online surveys every six months for five years. The time requirement is about an hour to an hour and a half every six months.

At each six month time point we will send you an email with the link to the CAM Care in PD survey, a questionnaire about health and wellbeing (completed in REDCap). After you have completed this survey we will send you a link to the second survey, about dietary intake (completed on ASA24.gov). Because there is a designated window of time during which surveys must be completed, you may receive a gentle reminder from us if time is running out.



This study is not designed to provide care. You are encouraged to consult with any providers you wish.

To protect your privacy, your information will be assigned a confidential study code. The link between the number and your name will be kept in a secured location, separate from the study information. This link will be kept for up to five years after completion of the manuscript, December 2022, for quality control. The identifying link will then be destroyed. The de-identified data will be kept indefinitely. We will strive to protect your privacy at all times and your identifying information will not be used to contact you for other purposes or provided to anyone else. If we publish the results of this study, we will not use your name or provide information that would allow you to be identified.

RISKS, STRESS, AND DISCOMFORT

Filling out questionnaires about your health and health care can sometimes be stressful. In the event you need to talk with someone about feelings generated while completing the survey, you are encouraged to contact your primary care provider, neurologist, or your local crisis line. Participants in the U.S. may call 1-800-273-TALK (8255). Though there is some small chance that your personal information might not remain confidential, all efforts will be made by research staff to preserve your confidentiality at all times.

OTHER INFORMATION

Voluntary Nature of the Study

Participation in this study is voluntary. You may refuse to answer or leave unanswered any questions in the study questionnaires. Your decision whether or not to participate in this study will not affect your current or future relations with the University or researchers. If you decide to participate, you are free to withdraw at any time without affecting those relationships. An alternative to participating in this study is to not to participate in the study, as this is the only prospective study of its kind that we are aware of.

Study Costs/Compensation

There is no cost and no payment to you for participating in this study. You will be responsible for any costs related to your clinical care which is not covered by your health care insurance.

Research Related Injury

It is unlikely that completing these surveys will result in a research related injury. Should an injury occur, care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think you have suffered a research related injury, call the study number above immediately.

Confidentiality

The records of this study will be kept private. Only research staff who have signed research confidentiality agreements have access to information collected in this study. In any publications or presentations, we will not include any information that will make it possible to identify you as a subject. Bastyr University and the National Center for Complementary and Alternative Medicine (NCCAM) may review the data in this study for audit purposes for up to 15 years. Every effort will be made to respect your privacy. Confidentiality is not absolute, as no system is without limitations.

Study Results

Study results will be available approximately January 2021. Please visit www.bastyr.edu to learn about study results.

Contacts and Questions

If you have questions about this study, please contact Dr. Mischley at: neuroresearch@bastyr.edu. If you have any questions about your rights as a research subject, you may contact Lizbeth Adams, Ph.D., Director of the Bastyr University Office of Research Integrity, Dr. Adam's phone number is: 425-602-3416.

