

BASTYR UNIVERSITY

Complementary & Alternative Medicine Care in Parkinson's Disease

A prospective natural history study of diet & lifestyle factors associated with health.

"Positive Deviance is based on the observation that in every community there are certain individuals or groups (the positive deviants), whose uncommon but successful behaviors or strategies enable them to find better solutions to a problem than their peers. These individuals or groups have access to exactly the same resources and face the same challenges and obstacles as their peers.

The PD approach is a strength-based, problem-solving approach for behavior and social change. The approach enables the community to discover existing solutions to complex problems within the community."

http://www.positivedeviance.org/about_pd/index.html

28 Feb 2013

To Whom It May Concern:

Parkinson's disease (PD) is often said to be an incurable, progressive, and degenerative disease. It is our hypothesis that some of you do not, or will not, have a progressive disease.

We are seeking the positive deviants.

In this study, we are going to monitor your health and disease status, and describe the dietary and lifestyle factors associated with the positive deviants.

Among individuals with PD who are doing really well, what are they doing?

We invite you to participate regardless of your health status. The more people participate, the more we learn.

In order to participate in this study, you will need to:

- Have online access, an email address, and basic computer literacy.
- Fill out a questionnaire & return it every 6 months for 5 years. (~ 60-90 minutes)

Please direct any questions you may have about this survey or results of this study to Dr. Mischley at 425-602-3306. Any questions about your rights as a research subject should be directed to Lizbeth A. Adams at the Bastyr University Office of Research Integrity. Your time and efforts are appreciated.

Sincerely,



Laurie K Mischley, ND
Bastyr University Research Institute
Clinical Research Assistant Professor



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BASTYR UNIVERSITY RESEARCH INSTITUTE CONSENT FORM

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

Laurie Mischley, ND	Principal Investigator	Bastyr University Research Institute Clinical Research Assistant Professor	425-602-3417
Susan Eliza	Study Coordinator	Bastyr University Research Institute Research Coordinator	425-602-3306

Researchers' 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 consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form 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 form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We suggest you keep a copy of this form for your records.

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

After signing this consent form, you will be asked to fill out a Registration Form that will link your personal information with your answers for the duration of the study. We will keep this Registration Form separate, in an effort to protect your privacy.

We will ask you to give us permission to retrieve records and laboratory reports about your health from your other providers. You may participate without signing a release of records, or may choose

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to ask your provider to send a copy of your records and labs to the study. Not signing this release of records may result in some of your data becoming unavailable for analysis.

All surveys will be completed online. Each survey is made up of three components: a questionnaire about health and wellbeing (completed in REDCap) and two questionnaires about dietary intake (completed on ASA24.gov). Each component of the survey is administered separately, and you will be given all 3 components within a one week timespan. We will contact you every time a new component of the survey is ready. Each survey component will take approximately 45 minutes to complete, for a total time commitment of 1.5-2 hours per survey. We will ask you to complete the survey every six months for five years.

This study is not designed to provide care. You are encouraged to consult with any providers you wish. You may choose to receive care at Bastyr University, but this is not a requirement of study participation.

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 upon completion of the manuscript for quality control and 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. Only study staff trained in human subjects ethics and who have signed the Bastyr research subject confidentiality agreement form will be permitted to access confidential medical charts. Trained personnel may include licensed health care providers, clinic administrators, preceptors, and work-study students.

RISKS, STRESS, AND DISCOMFORT

Filling out questionnaires about your health and health care can sometimes be stressful. 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 this study is 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.

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PI: Laurie Mischley, ND

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 that you have suffered a research related injury, call the study number above immediately.

Confidentiality

The records of this study will be kept private. In any publications or presentations, we will not include any information that will make it possible to identify you as a subject. Your consent to participate in this study includes consent for the investigator and his/her assistants to review all your medical records as may be necessary for the purpose of the study. The investigator and his/her assistants will consider your records confidential to the extent permitted by law. We will label the information about you with a number, not your name. If study data is transmitted via the internet - only participant number will be used. We will keep your name; address, telephone number, and other information that might identify you separate from your laboratory reports and study data. The record that links the number with your name will be kept only by the researchers and will be destroyed within five years after the manuscript for the study has been written. Your records and results will not identify you in any publication. Bastyr University and the National Center for Complementary and Alternative Medicine (NCCAM) may review the data in this study and may also review your records 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.

If you decide to participate in this study, some private health information about you will be stored in a computer database at Bastyr University. This information will include your name and medical record number, your date of birth, your diagnosis, your race/ethnicity and information about your participation in this study. The purpose of storing this information is to assist in creating reports about research and in making sure that research studies are being done correctly. There are no plans to erase information from the database. It will be stored indefinitely in a secure virtual database.

Protected Health Information (PHI)

Your PHI created or received for the purposes of this study is protected under the federal regulation known as HIPAA. Refer to the attached HIPAA authorization for details concerning the use of this information.

Contacts and Questions

If you have questions about this study, please call Bastyr Neurology at 425-602-3306. 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, 14500 Juanita Dr. N.E. Kenmore WA 98028. Dr. Adam's phone number is (425) 602-3416.

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PI: Laurie Mischley, ND

Participant's statement:

"The study above has been explained to me. I voluntarily consent to participate in this activity. I have had an opportunity to ask questions. I understand that future questions I may have about the research or about my rights as a participant will be answered by one of the investigators listed above."

_____ Printed Name of Participant _____ Signature of Participant _____ Date

_____ Initials of Principal Investigator after review of signature _____ Date

Request for permission to contact you for future research:

"I give the research staff permission to contact me about future research studies at Bastyr University. I have had an opportunity to ask questions. I understand that future questions I may have about the research will be answered by one of the investigators listed above."

_____ Printed Name of Participant _____ Signature of Participant

_____ Date

Copies to: Participant, Investigator for Study Record

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