

# NET PD NEWSLETTER

This Newsletter is especially for NET PD LS-1 participants and their families.

**Volume 1 No. 1**

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## *NET PD...Exploring Options to Slow the Progression of Parkinson disease.....*

### **What is NET-PD?**

NET-PD actually stands for: **N**IH **E**xploratory **T**rials in **P**arkinson **D**isease. NET-PD is an ongoing process of federally supported clinical studies designed to test new treatments for Parkinson disease. Over the next few years, **NET-PD** study investigators hope to test several different drugs to learn if any of them can slow the progression of the disease.

### **Who is behind the NET-PD study?**

#### **Meet the researchers.....**

The NET-PD study was and continues to be developed and guided by a team of experts with experience in research, care and treatment of patients with Parkinson disease. The team is led by Principal Investigators who remain constant for the duration of the study. In the NET-PD study there are three Principal Investigators: Dr. Karl Kieburtz, a Neurologist, Dr. Tilley, a biostatistician and Dr. Babcock, also a Neurologist from the National Institute for Neurodegenerative Disorders and Stroke (NINDS), a division of the National Institutes of Health (NIH), the sponsor of the study. The team also consists of three Neurologists from the study centers, and a study Coordinator from a study center. Together these individuals make up what is known as a "Steering Committee." The Neurologists commit to a 3 year rotation of service to the committee and the Study Coordinator commits to 2 years of service. This rotation allows fresh ideas to be brought to the study team. The Steering Committee is responsible for the day to day activities of the study. Two team members will be highlighted in each newsletter on an ongoing basis.

The current NET PD LS-1 Steering Committee membership includes:

- Karl Kieburtz MD, MPH                      University of Rochester, Rochester, NY

- Barbara Tilley, PhD Medical College of South Carolina, Charleston, SC
- Debra Babcock, MD, PhD NINDS, NIH, Bethesda, MD
- Robert Hauser, MD, MPH University of South Florida, Tampa, FL
- Webster Ross, MD Pacific Health Research Inst. Honolulu, Hawaii
- Oksana Suchowersky, MD University of Calgary, Calgary, Alberta, Canada
- Sue Reichwein, CCRC Penn Neurological Institute, Philadelphia, PA

In this edition we would like to introduce you to Dr. Karl Kieburtz and Dr. Barbara Tilley, two very important people who worked hard to make the NET-PD LS-1 study happen. Dr. Kieburtz is the Principal Medical Investigator and Dr. Tilley is the Principal Biostatistician for the study.

**Karl Kieburtz, MD, MPH,** is Professor of Neurology and of Community and Preventive Medicine at the University of Rochester Medical Center in Rochester, New York. His primary clinical and research interests are in the treatment of neurodegenerative diseases affecting the basal ganglia, particularly Parkinson disease, Huntington disease, and HIV related neurologic disorders. He has been an active participant in the research activities of the Parkinson Study Group since 1989 and currently chairs the Executive Committee. He also directs the Clinical Trials Coordination Center at the University of Rochester and leads multi-center academic consortia, including the Huntington Study Group, and the NET-PD Investigators. His teaching responsibilities, publications and presentations have focused on experimental therapeutics and clinical research design strategies.



**Barbara C. Tilley, Ph.D.** is the Distinguished University Professor and Chair of the Department of Biostatistics, Bioinformatics, and Epidemiology at the Medical University of South Carolina (MUSC). Dr. Tilley received her Masters in Biomathematics at University of Washington, School of Public Health and her Ph.D. in biostatistics from University of Texas School of Public Health. Prior to coming to MUSC she was at Henry Ford Health System with an academic appointment at Case Western Reserve University. While there she led the Biostatistics Cores for several basic science program project grants in addition to leading Coordinating Centers for clinical trials in stroke (t-PA), rheumatoid arthritis (minocycline), and cancer prevention. She also had an active research program related to health disparities. She also chaired the department. She came to MUSC in 1999 as Department Chair. She has participated in multiple collaborative projects with investigators at MUSC and has continued her own research in clinical trials and health disparities. She currently leads the Statistical Coordination Center for NET-PD (SCC) and is Principal Investigator of the NET-PD Minority Recruitment Study. The SCC conducts the analyses of the data from NET-PD and assists in the design of new NET-PD studies.



## What does LS-1 stand for?

LS-1 stands for **L**ong -term **S**tudy -**1**. The study is a **long** study as it will follow **P**eople **w**ith **P**arkinson (PWP) disease for a minimum of 5 years!! This study is also considered **large** because we hope to enroll 1,720 people with Parkinson disease into the study! The purpose of the study is to determine if the study drug, creatine, can slow the progression of Parkinson disease over time.



## Why are we using creatine?

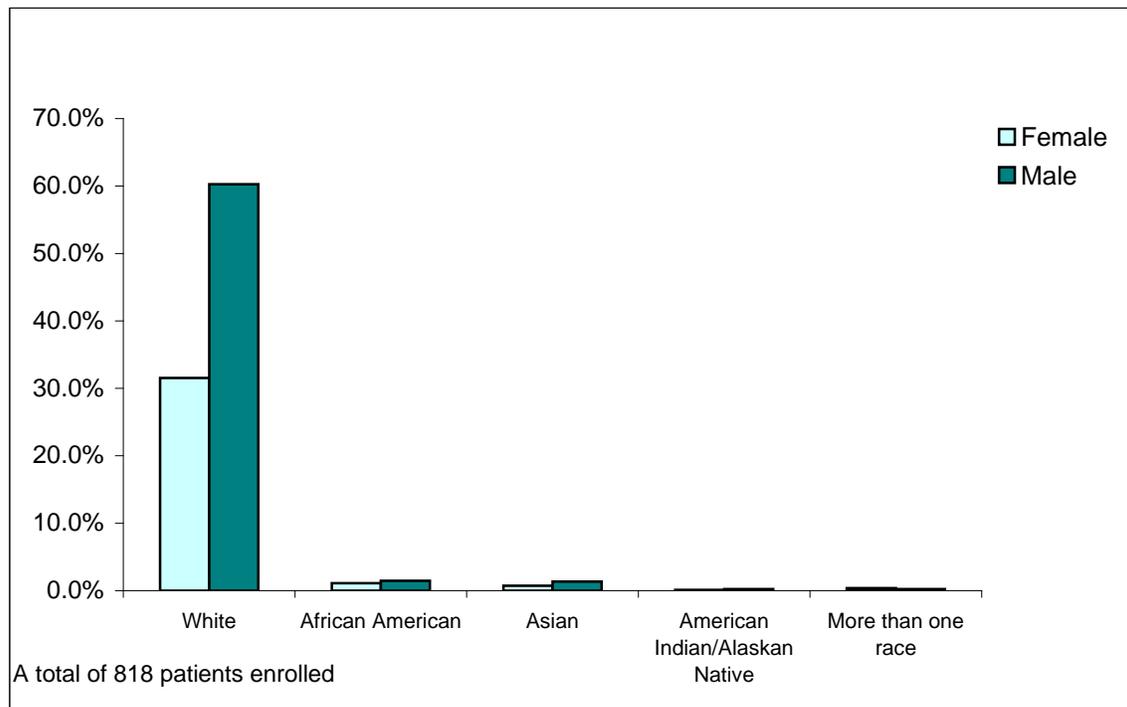
One theory as to what causes PD is something call “mitochondrial dysfunction” and “oxidative stress” ....you are probably saying mito who??? oxidative who??? about now! Translated to English...the mitochondria are the powerhouse of the cells of our body and oxidative stress is a process which damages the cells of our body. In PD it is thought that the powerhouses (mitochondria) are not working properly and the cells are undergoing stress leading to the symptoms of PD (slowness, stiffness, tremor and balance problems). Creatine has shown to help support the mitochondria and stabilize them. Creatine has been tested in a smaller study and felt to be safe and to show promise at slowing progression of Parkinson disease.\* The next step in determining if creatine actually works is to re-test creatine using larger numbers of people with Parkinson disease.

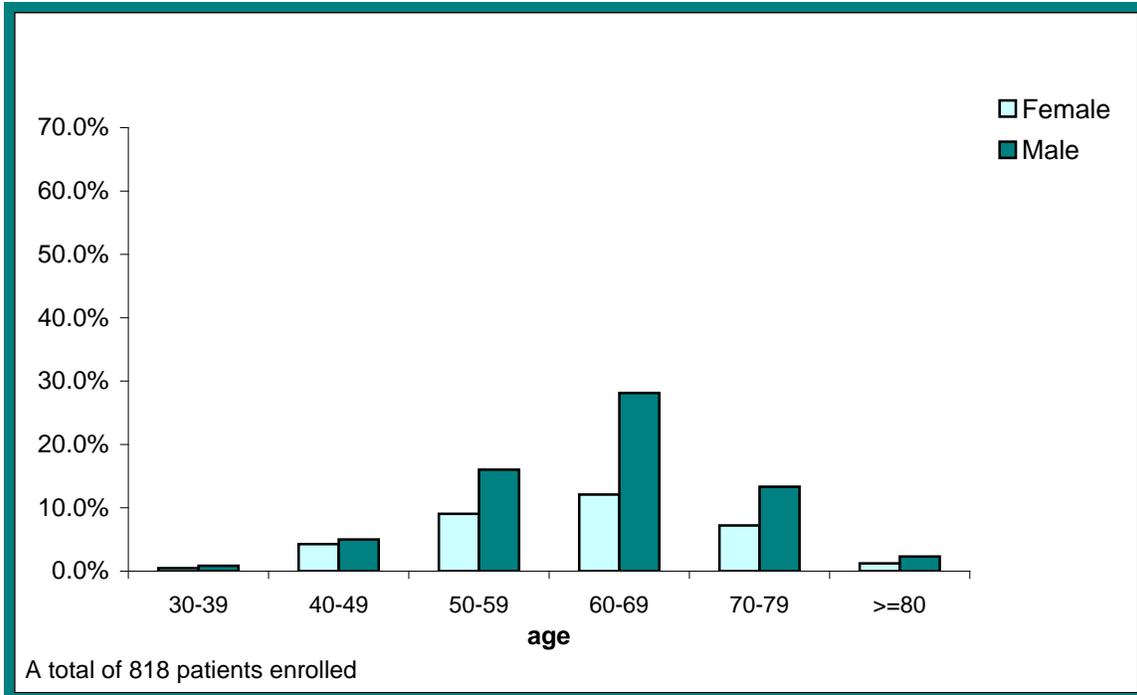
\* You can see the study results in the journal, *Neurology* 2006; 66:664-671. The name of the article is A Randomized, Double Blind, Futility Clinical Trial of Creatine and Minocycline in Early Parkinson Disease.

## Where are we today?

The LS-1 study began enrolling Parkinson disease patients in March of 2007. To date 818 patients have been enrolled!! We are well on our way and we thank each and every one of you for your efforts!

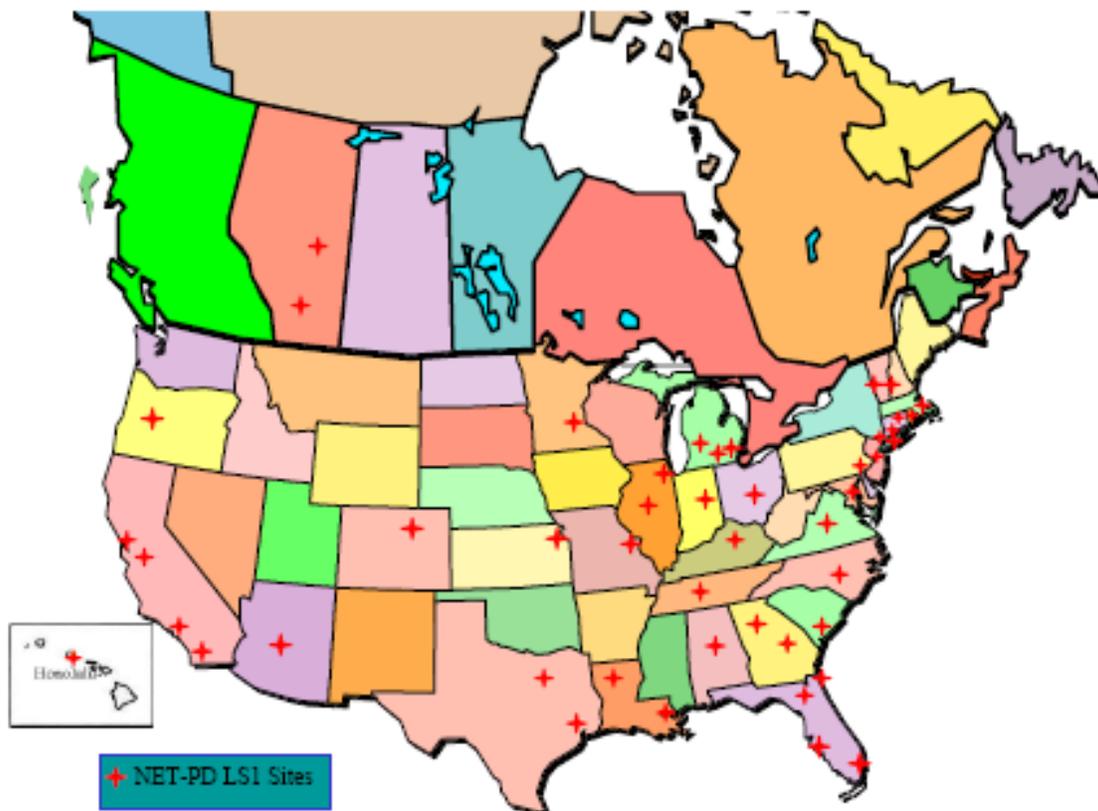
## Who are the people with Parkinson disease that are participating?





### Where are the NET PD sites?

The NET-PD LS-1 study is a multinational study with 50 centers within the United States and Canada enrolling patients with Parkinson disease.



Barrow Neurological Institute	Phoenix, AZ
Baylor College of Medicine	Houston, TX
Brigham & Women's Hospital	Boston, MA
Dartmouth Hitchcock Medical Center	Lebanon, NH
Emory University School of Medicine	Atlanta, GA
Indiana University School of Medicine	Indianapolis, IN
Johns Hopkins University	Baltimore, MD
Medical College of Georgia	Augusta, GA
Michigan State University	East Lansing, MI
North Shore-LIJ Health System	Manhasset, NY
Ochsner Clinic Foundation	New Orleans, LA
Pacific Health Research Institute	Honolulu, HI
SUNY Downstate Medical Center	Brooklyn, NY
The Parkinson's & Movement Disorder Institute	Fountain Valley, CA
Thomas Jefferson University	Philadelphia, PA
UMDNJ	New Brunswick, NJ
University Of Vermont	Burlington, VT
University of Alberta	Edmonton, Alberta, Canada
University of California San Francisco	San Francisco, CA
University of Florida	Gainesville, FL
University of Kentucky	Lexington, KY
University of Miami	Miami, FL
University of Pennsylvania	Philadelphia, PA

University of Southern California	Los Angeles, CA
University of Virginia	Charlottesville, VA
Vanderbilt University	Nashville, TN

### **Tip of the day:**

With Parkinson disease, as with living in general, it is important to get into a good routine which includes eating a healthy diet, making exercise part of your daily activities and be sure to keep your brain stimulated by interacting with people, reading and just having fun.