



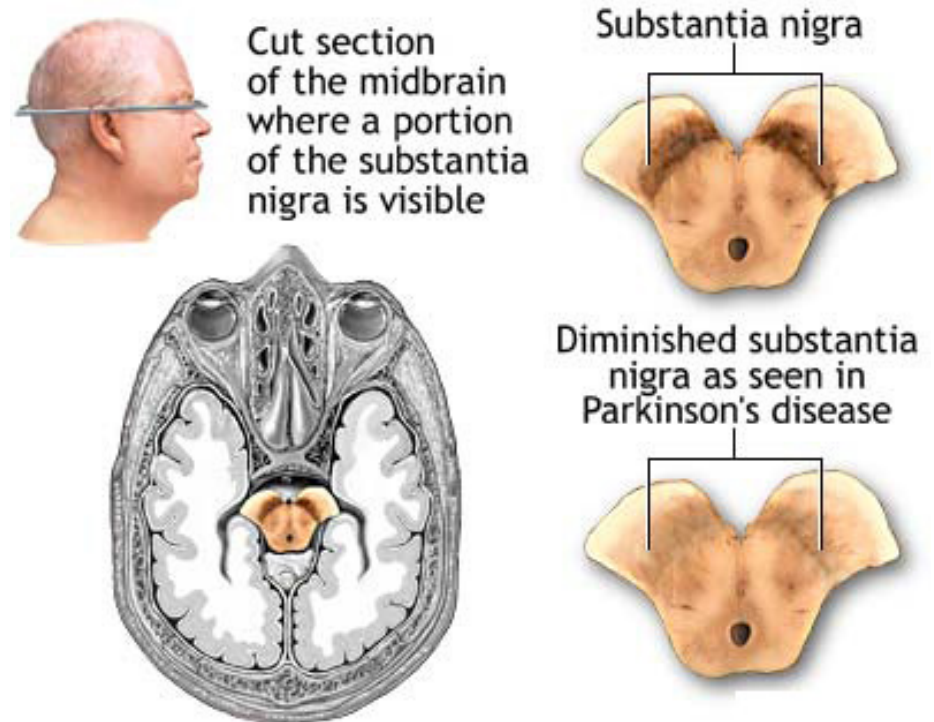
Advancing the Understanding and Treatment of Parkinson's disease through Clinical Trial Participation

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Parkinson's Disease

- History
 - Dr. James Parkinson (1817)
- Diagnostic Criteria
 - Bradykinesia and at least one of the following:
 - Muscular rigidity
 - 4 – 6 Hz rest tremor
 - Postural Instability
- Prevalence
 - ~ 1.5M in US
 - ~70,000 new cases each year (Hampton, JAMA 2005)
 - The prevalence of parkinsonian symptoms has been estimated to be over 25% in individuals over the age of 65



Therapies

- **Pharmacological**

- L-DOPA
- DA agonists
- MAO inhibitor
- Glutamate antagonists

- **Surgical**

- Pallidotomy
- Deep Brain Stimulation
 - STN
 - GPi

- **Focus on symptoms**

- **Needed: *Neuroprotection***

- *A neuroprotective therapy is the single most important unmet medical need in Parkinson's disease (Olanow et al., 2008)*

Why Participate in Research???

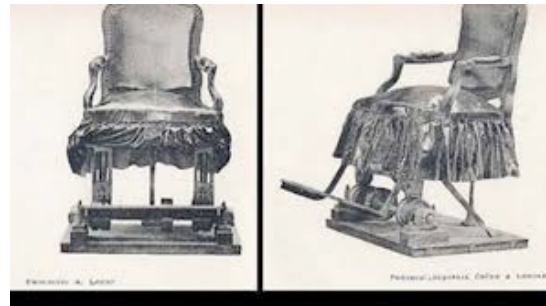


Evolution of Parkinson's disease Research

PD was first described by James Parkinson in "An Essay on the Shaking Palsy"

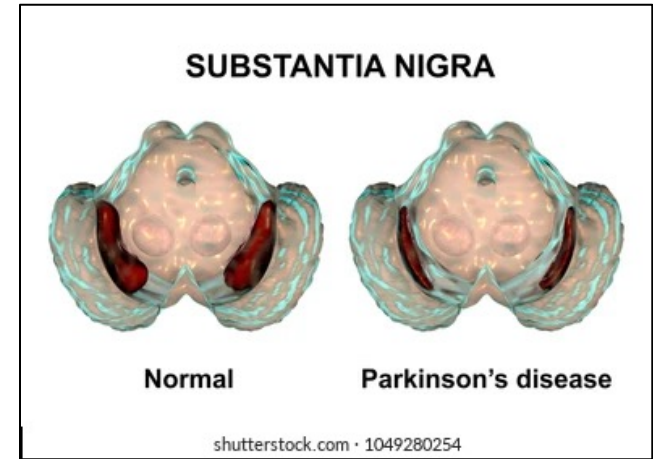
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Charcot used a "jiggling chair" and "jiggling hat" as treatments, adamant that PD was not a disease of muscle weakness



Evolution of Parkinson's disease Research

Substantia nigra was first associated with PD



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Hoehn and Yahr published a PD staging system that is still used clinically today

Evolution of Parkinson's disease Research

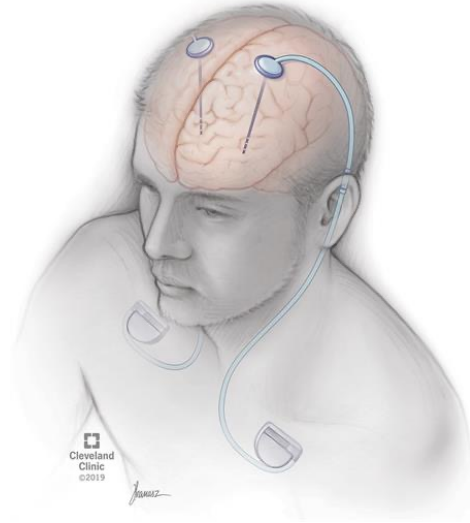
First large-scale results of treatment with Levodopa published (includes information about the trials, with the first effective treatment in 1961)

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Discovery that MPTP induces PD in “accidental” incidences

Evolution of Parkinson's disease Research



Deep brain stimulation surgery found to be effective treatment for PD

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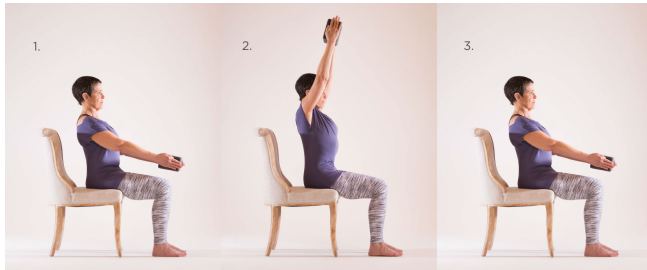
Genetics research are able to identify several specific genes associated with PD

Evolution of Parkinson's disease Research

American Parkinson's Disease Association: Aerobic exercise recommendations include walking or gardening



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“Insufficient evidence to support or refute the value of exercise.”
(Goodwin et al., 2008)
American Academy of Neurology recommends chair-based exercise; move slowly; utilize soup cans to increase intensity

Meanwhile, somewhere in Iowa...

Dr. Alberts observed a PD patient's symptom improvement after a day of tandem cycling at a high rate of revolutions per minute

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RAGBRAI (Register's Annual Great Bicycle Ride Across Iowa)

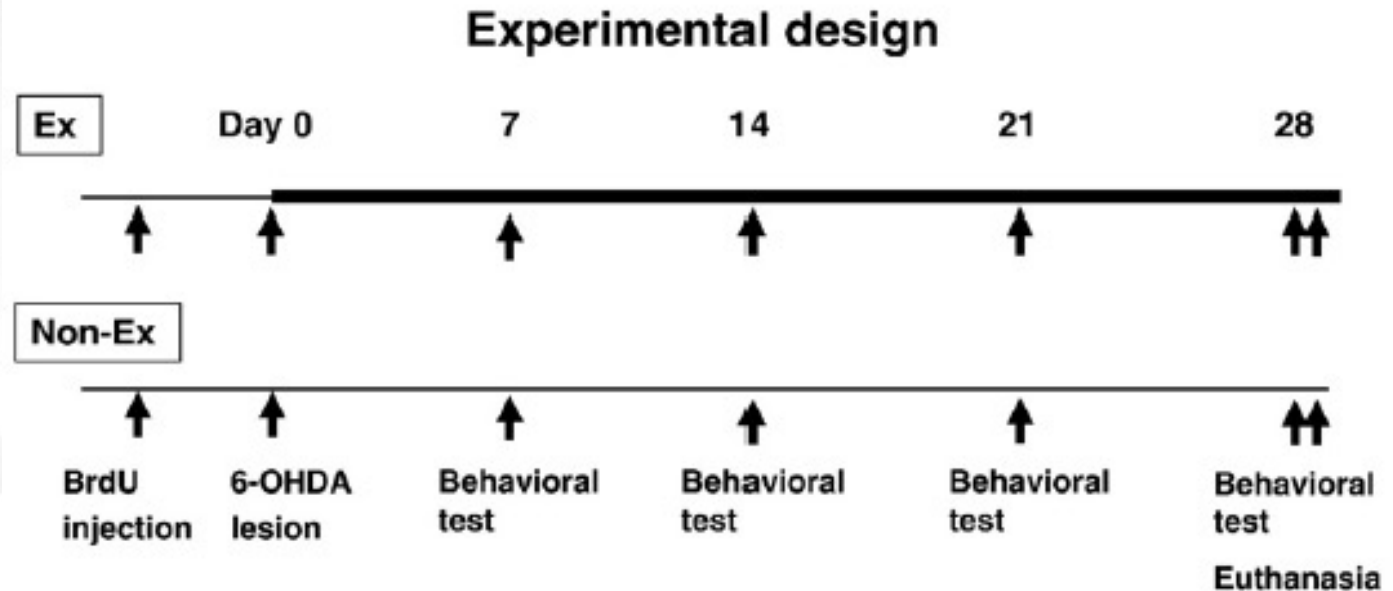


RAGBRAI Team Picture: 2003

What can animal models tell us about exercise and PD?



Forced-exercise and neuroprotection in rodent models of PD



Exercise —————
(30 minutes each day, consecutive
5 days/week for 4 weeks)



Evolution of a Research Study: Pilot Phase

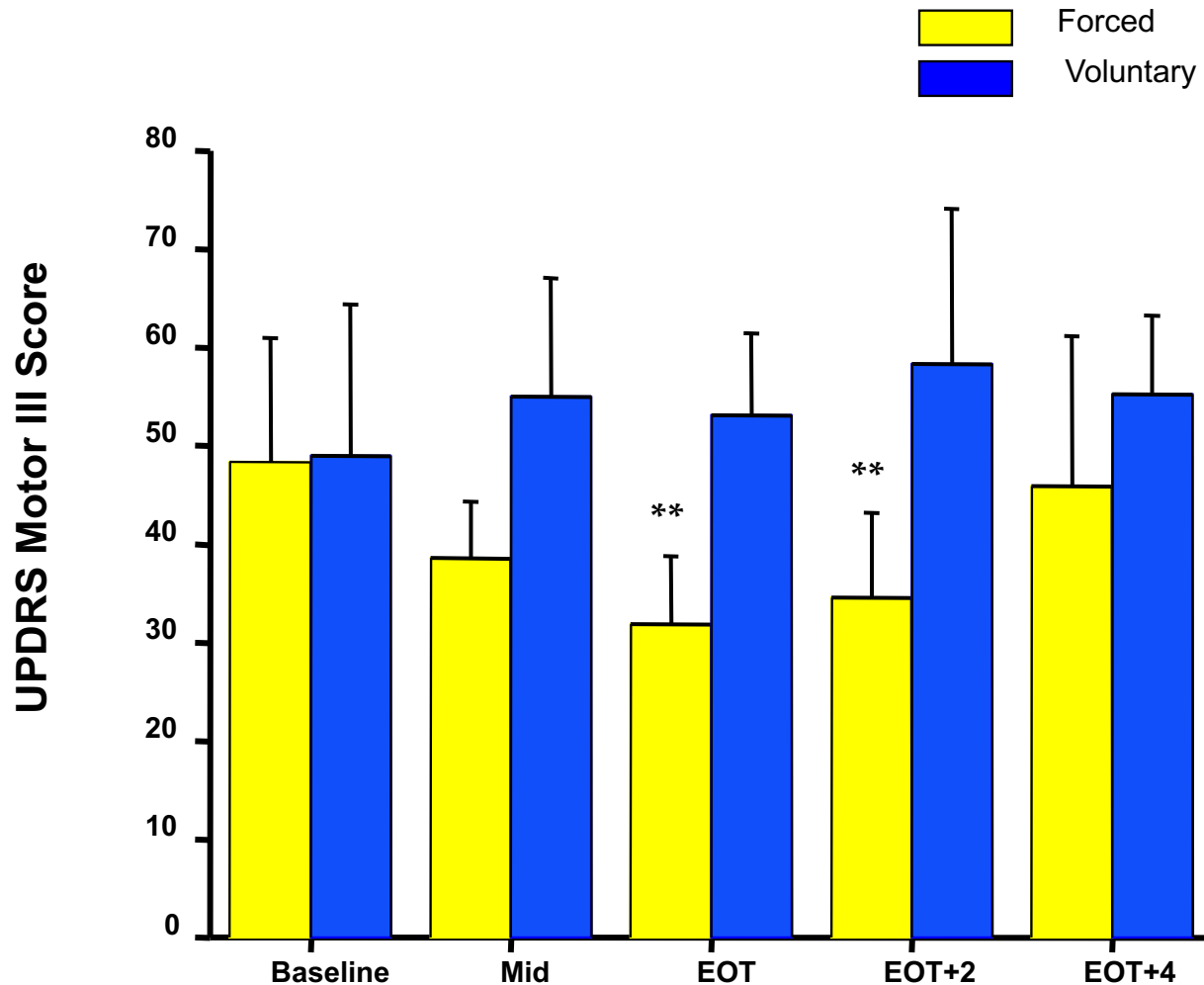
Conducted a Forced Exercise vs. Voluntary Exercise with 10 PD participants

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Forced Exercise Participant: 2007

Only FE Improved Clinical Ratings



Phase I Randomized Clinical Trial

Utilized a research prototype to scale the feasibility of the intervention to a larger number of participants. Sixty person study with FE, VE, and a control group.

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Forced Exercise Participant: 2009

Phase II Randomized Clinical Trial

Further refined the prototype recumbent bicycle with a larger research group. A 100 person study was conducted with an FE, VE, and control group.

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Forced Exercise Participant: 2012

Phase II Multi-Site Randomized Clinical Trial

Semi-supervised intervention utilizing a Peloton cycling platform. 250 total participants at two demographically diverse sites.



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Informing other research and programming



Pedaling for Parkinson's sites across the country



Informing other research and programming



Pedaling for Parkinson's Class in Colorado- 2018

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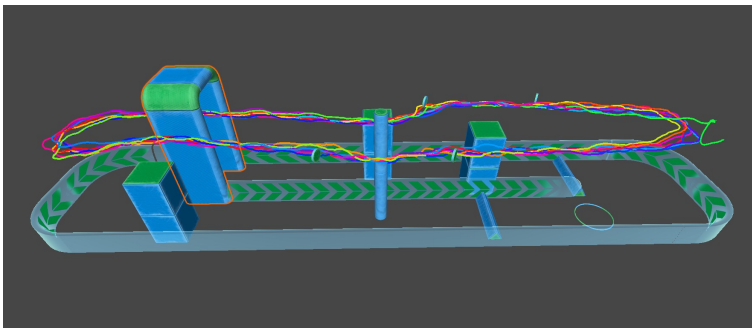
Observational study sponsored through the Davis Phinney Foundation examining the results of PFP classes at four different sites



Informing other research and programming

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Examining whether dual-task training can improve walking and balance in patients with PD utilizing augmented reality.



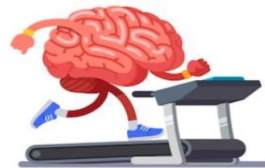
Augmented reality “obstacle course” utilized in the DART study, 2020



Informing other research and programming

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Examining treadmill exercise at different heart rate intensities for de novo PD participants.



Why Participate in Research?

- Keeps bloodletting and lobotomies from re-emerging as “viable” treatments
- Opportunity to be a part of significant medical advancements
- Additional support and monitoring from research staff
- If a study treatment works, participants could have a better outcome
- Potential to build camaraderie with other participants and research staff
- Chance to learn more about own health

What to Consider Before Participating in Research

- Understand the potential risks and benefits
- Consider discussing with trusted family and/or friends
- Understand study commitment – time, visits, etc.
- What will you be asked to do as a study participant?
- Do you have to pay for any part of the trial? Will insurance be billed for any part of the study?
- Is there any reimbursement for time and/or travel, including parking, meals, etc?
- What information will be collected and how might it be used/distributed?

Alberts Lab Current Studies

- Study in Parkinson Disease of Exercise Phase 3 Clinical Trial
 - MacKenzie Dunlap: (216) 219-3949
- Validation of the Cleveland Clinic Virtual Reality Shopping Task
 - Morgan McGrath: (440) 476-9772

Center For Neurological Restoration (CNR) Observational/Registry Studies

- PD GENERation: Genetic Testing/Counseling Registry
- nQ: Touchscreen Project for Remote Management of Early PD
- ADROIT: Gathering Clinical Data on Abbott DBS Systems
- PPMI: Long-term Observational Study to Identify Markers and Characteristics of PD over time

CNR Interventional Studies:

- REASON: Spinal Injection for Early PD Subjects
- TEMPO 2: Tavapadon in Early PD
- SPARC: Subjects with Early PD
- BouNDless: Continuous Levodopa Infusion
- TEMPO 3: Tavapadon As Adjunctive Therapy for PD in Levodopa-Treated Adults with Motor Fluctuations
- Dipraglurant for Dyskinesia in Levodopa-Treated Subjects
- Monthly Infusion in Early Parkinson's Disease to Slow Progression
- ENGAGE-PD: Enhancing Gait Using Alternating-Frequency DBS
- Modulatory Effects of DBS on Cerebral Cortical Activity
- TAME PD: Physical Therapy, Atomoxetine, Methylphenidate to Enhance Gait and Balance

Is Exercise Medicine?

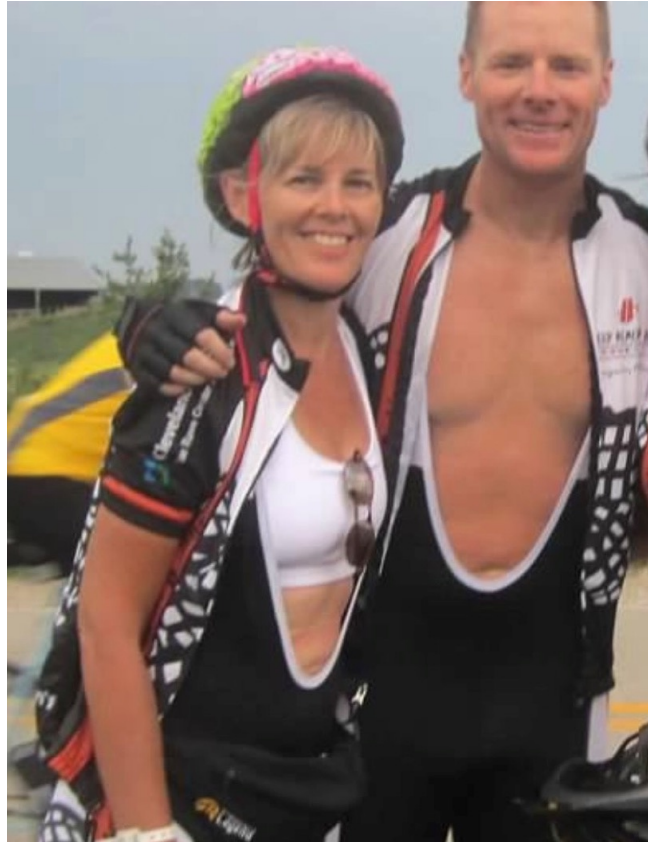
Yes



No



You probably know Karen, and maybe even Glenn....



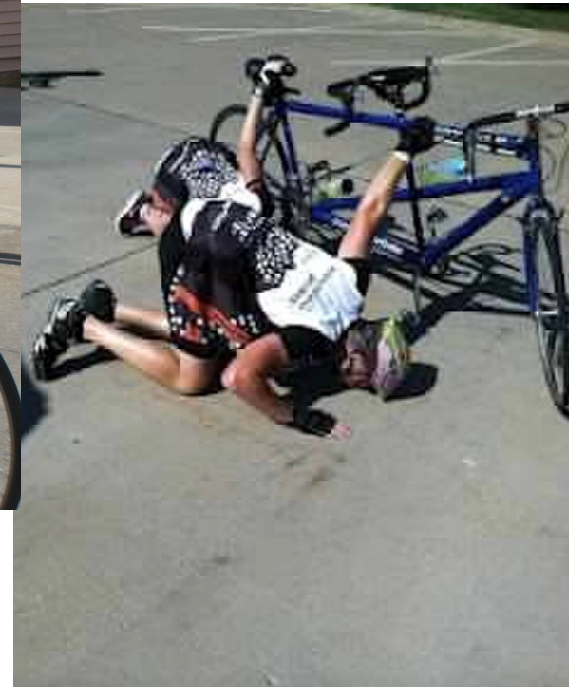
Have you met Big Blue?



2003



2009



2011