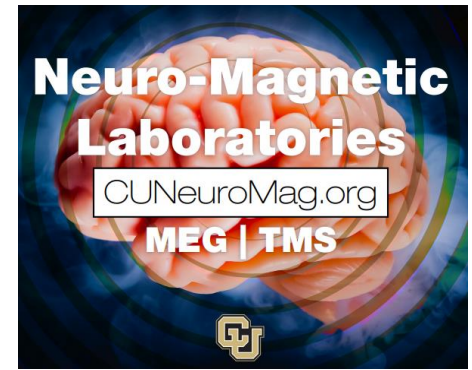




SCHOOL OF MEDICINE  
Department of Neurology

UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS



# State of the current research at the Colorado Movement Disorders Center

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RESEARCH DIRECTOR, CU NEUROMAGNETIC LABORATORIES

August 2<sup>nd</sup>, 2023

# Overview

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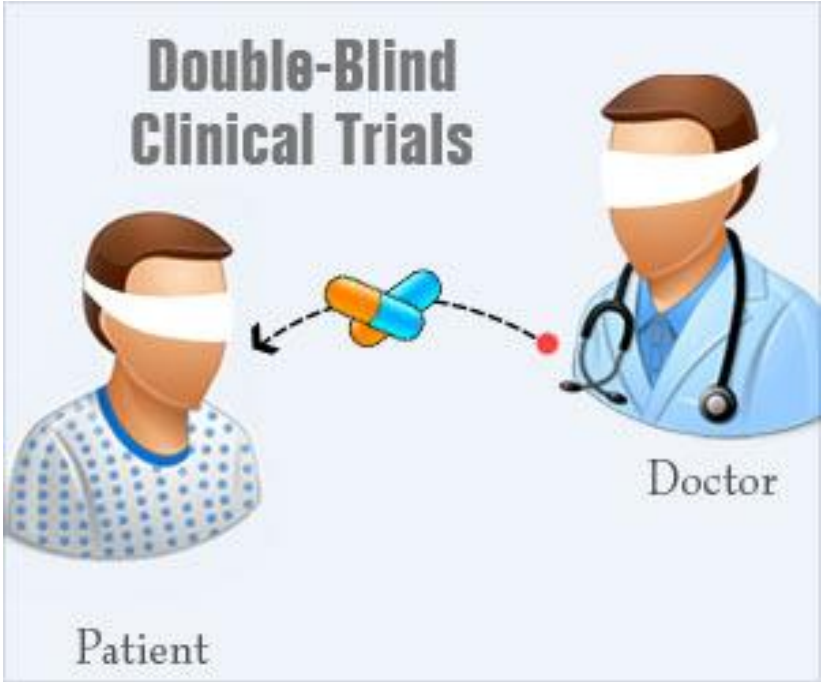
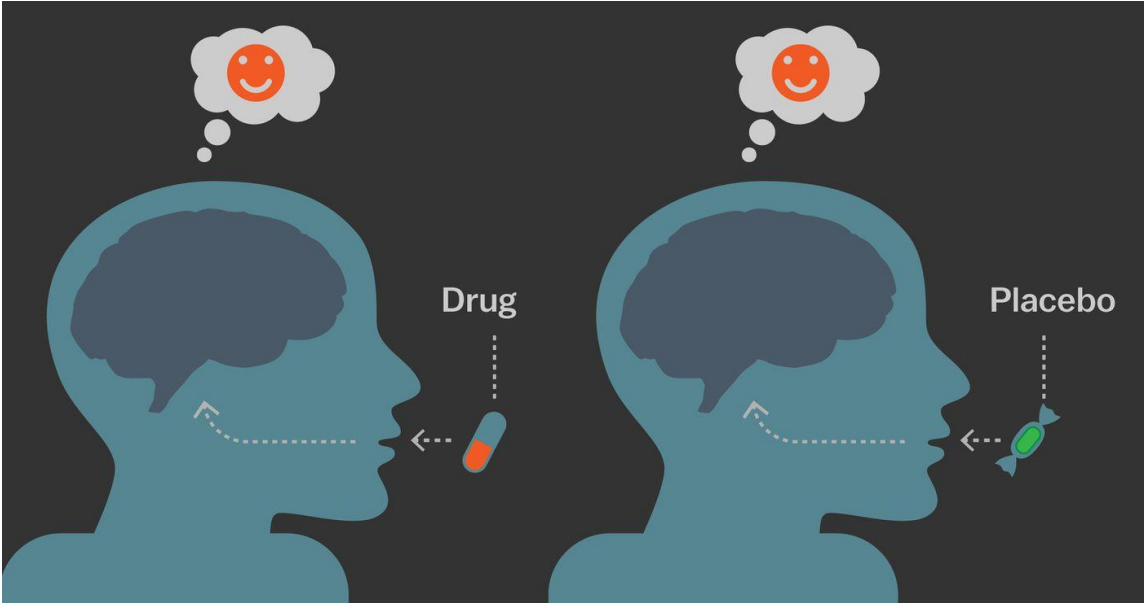
1. Definitions

2. Landscape of research in PD

3. Research projects going on at UCH

# Definitions

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## DISCOVERY & PRE-CLINICAL



## CLINICAL TRIAL

### PHASE I



### PHASE 2



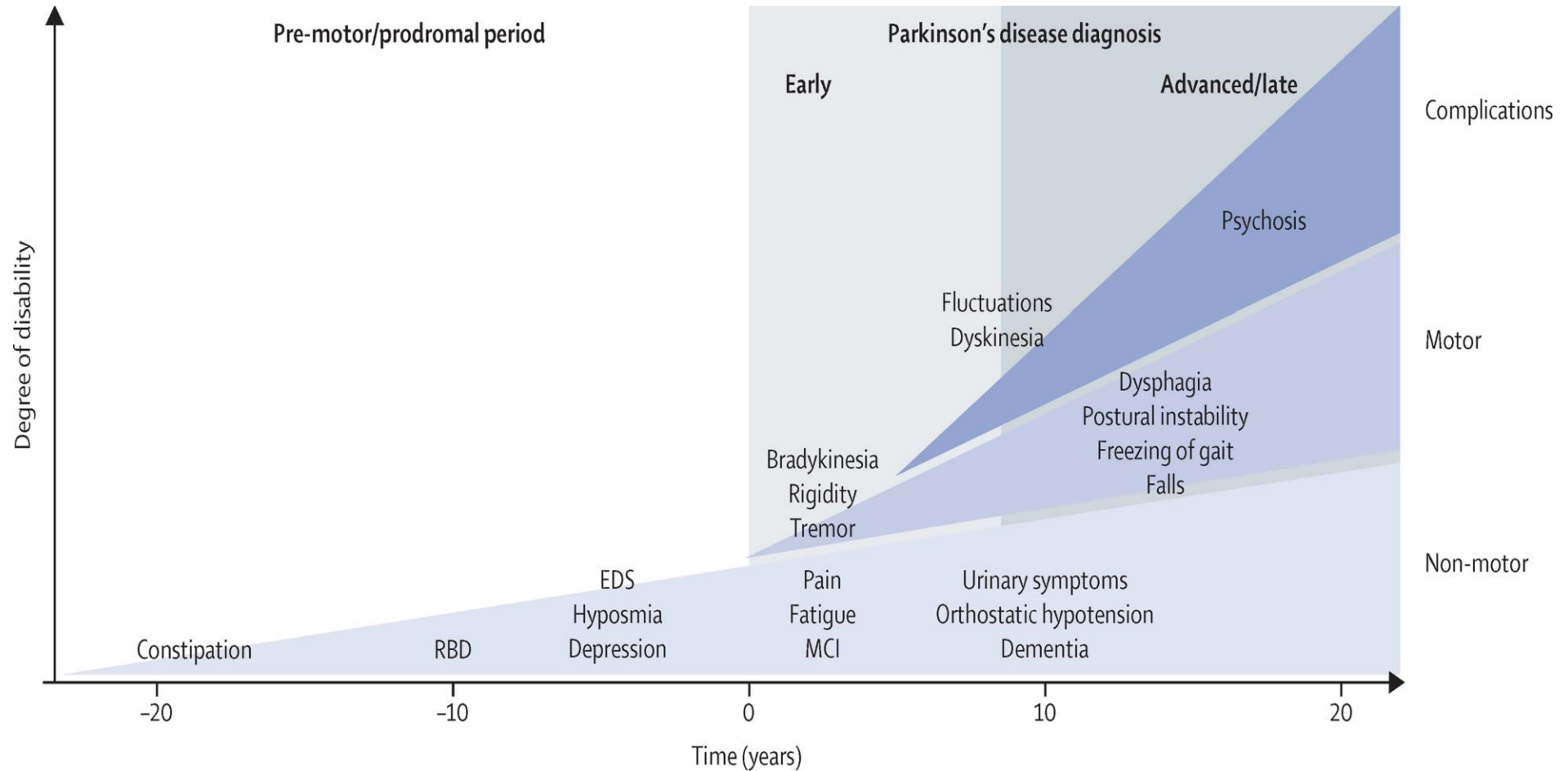
### PHASE 3



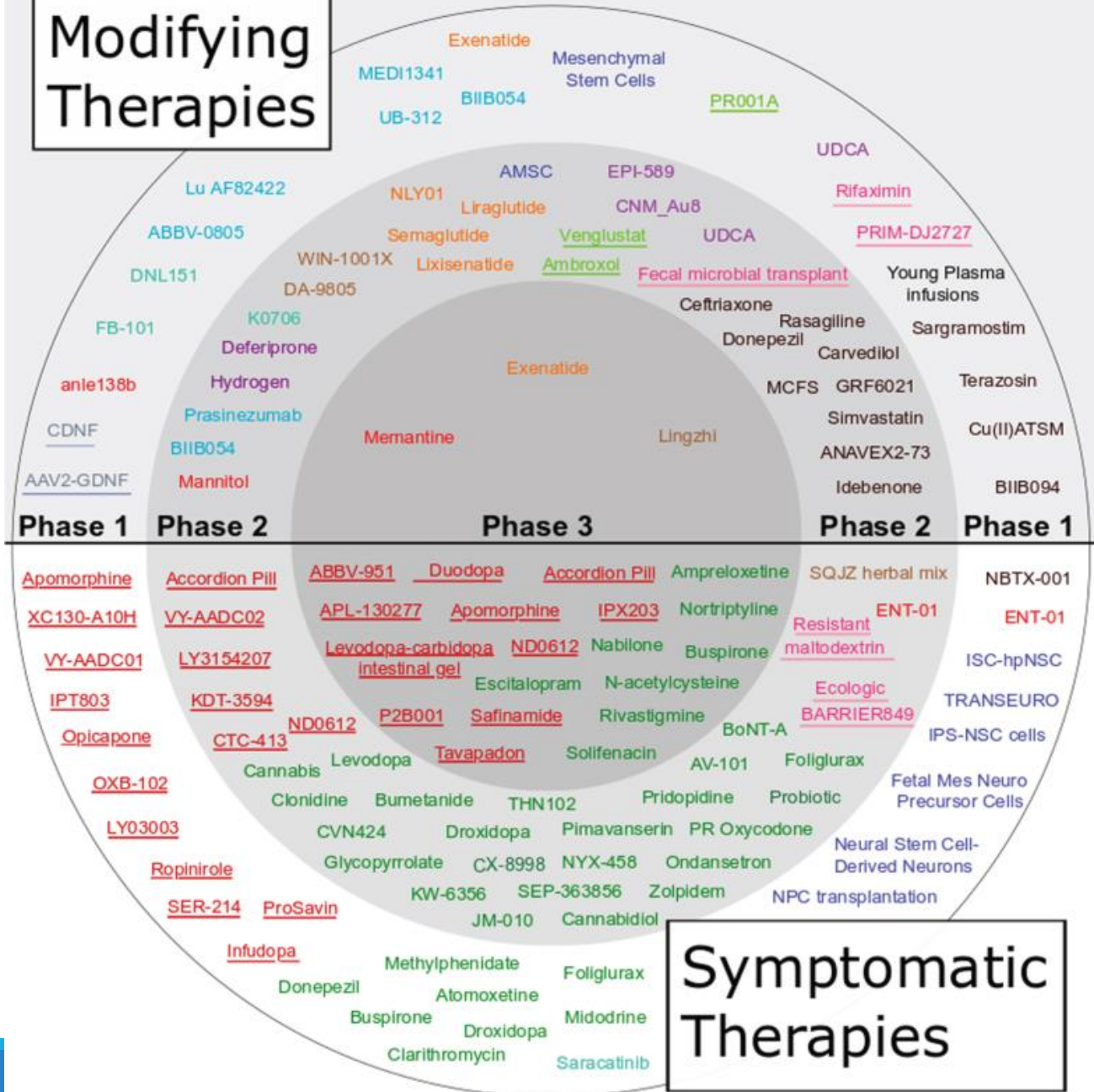
## FDA APPROVAL



# Disease Modification



# Disease Modifying Therapies



## Therapy Categories

- Targeting aSN
- Immunotherapy
- Microbiome/GIT
- DA symptomatic
- GBA
- Kinase inhib.
- Non-DA symp.
- Neurotrophic
- Botanicals
- Cell ther.
- Energy/mitoch.
- GLP-1 agonist
- Antioxidants
- Other

# Disease Modification Trials

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## Exenatide (anti-diabetic)

- Promising results in early trials
- Affects signaling in the brain
- Phase III trial in UK
- Phase II trial in Sweden, South Korea, USA (UCH)

## Ambroxol (cough syrup)

- AiM-PD: Phase II
- Improves lysosomal biochemistry
- Phase III trial starting soon (UK)

## BIIB122 (LRRK2 inhibitor)

- Phase III – efficacy & safety (400 people)
- LRRK2 mutation as a pathogenic genetic factor for PD
- Improve lysosomal function in CNS
- Ongoing at UCH

## PD01A (aSYN Vaccine)

- Jan 2020- announced intention for Phase II trial
- Sept 2020- presented encouraging results of Phase I study
- Ascending doses trial ended prematurely in 2022

## Memantine (for dementia)

- Ongoing Phase III Trial
- No effect on working memory

## Prasinezumab (monoclonal aSYN Ab)

- PASADENA Phase II trial: results not significant; new extension trial is promising
- PADOVA phase II trial, started May 2021 (early stage PD)

# Clinical Research at the University of Colorado Movement Disorders Center

<https://www.cumovement.org/>

## University of Colorado Movement Disorders Center

The screenshot shows the website's navigation menu with options: Home, About Us, Movement Disorders, Community, Upcoming Events, Research, Fellowship Training, For Researchers, and a Donate button. The main content area features a 'Home' heading, three image-based buttons for 'Meet Our Team', 'Make An Appointment', and 'Read Our Blog', and a large welcome message: 'Welcome to the University of Colorado Movement Disorders Center'. On the right side of the page, there is a logo for the Movement Disorders Center and a Facebook follow button.

[neuroresearch@cuanschutz.edu](mailto:neuroresearch@cuanschutz.edu)

(303) 724-4644

## MOVEMENT DISORDERS RESEARCH

### Actively Enrolling Studies

If you think you may be eligible for one of these studies or if you would like more information, please fill out our [webform](#) or contact us at [NeuroResearch@CUAnschutz.edu](mailto:NeuroResearch@CUAnschutz.edu) or 303-724-4644.

Ataxia	+
Dystonia	+
Essential Tremor	+
Healthy Volunteers	+
Huntington's Disease (HD)	+
Multiple System Atrophy-Parkinsonian subtype (MSA-P)	+
Parkinson's Disease (PD)	+

### Get Connected

[Visit our Neurology Research Catalog!](#)

[Join our Neurology Recruitment Database!](#)



# CBD study – closed (Dr. Leehey)

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“A Study of Tolerability and Efficacy of Cannabidiol on Motor Symptoms in Parkinson's Disease”

Quadruple masking (Participant, Care Provider, Investigator, Outcomes Assessor), placebo-controlled trial, phase II, 74 participants

Goals:

- Characterize safety, efficacy, tolerability of treatment with 3 weeks of Cannabidiol

Results (adjusted for age and education):

- CBD group (n = 29) performed worse than the placebo group (n = 29) on Animal Verbal Fluency.
- Adverse cognitive events were reported at least twice as often by the CBD than the placebo group.
- Published in May 2023

# Clinical studies - biomarkers

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- PPMI (Progression Markers Initiative) sponsored by the Michael J Fox Foundation

PPMI 1.0: Observational international multi-center study to identify clinical, imaging, genetic and biologic markers of Parkinson disease progression.

PPMI 2.0: Larger sample size, focus on prodromal cohorts, and incorporation of new science targeting neuroinflammation, lysosomal dysfunction and protein aggregation.

People with PD and Healthy Controls needed!

- EEG: To better understand freezing of gait and cognitive decline
- Cytokines (PD and ET) – inflammatory proteins

# Clinical studies – Symptoms management

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- TOPAZ study: Zoledronic acid to treat **fractures**. Placebo-controlled RCT. Supported by the Parkinson's Foundation
- Bukwang/SHINE study: buspirone (anti-anxiety) + zolmitriptan (anti migraine headaches) - synergistically reduce L-DOPA-induced **dyskinesia** in a rodent Parkinson's disease model by increasing serotonin levels
- Jazz PD tremor: "A Study of Suvecaltamide in Adults With Moderate to Severe Residual **Tremor** in Parkinson's Disease" – Suvecaltamide: calcium channel blocker  
Double blind placebo-controlled RCT

# Clinical studies – Exercise

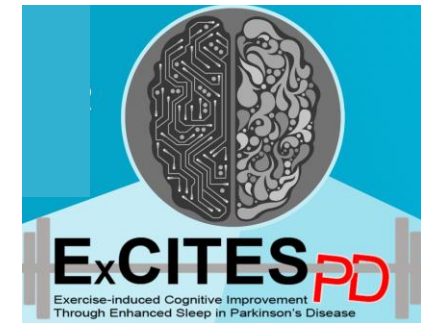
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- SPARX3: “Study in Parkinson Disease of Exercise Phase III Clinical Trial”

To learn about the effects of aerobic exercise in PD (early stage)  
Phase 3 multi-site, randomized, study of endurance treadmill exercise on changes in motor symptoms of PD at 12 months



- ExCITESPD: “Exercise-induced cognitive improvement through enhanced sleep in PD”



- NeuroPong: 12 weeks program of Table Tennis to improve balance and cognition



# Deep Brain Stimulation Surgery Studies

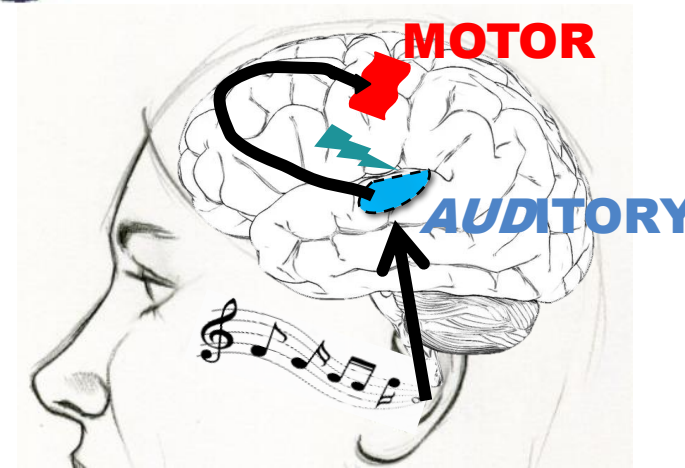
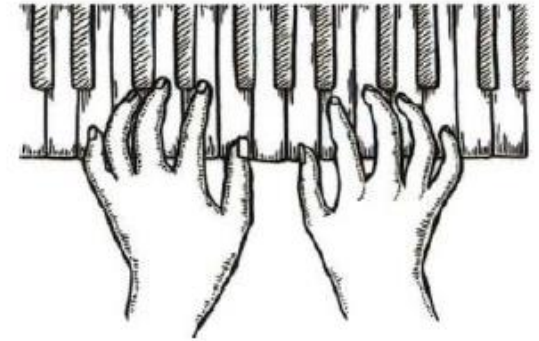
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- 1. DBS surgery is a proven therapy for PD that is underutilized for women. Better understand barriers women face when considering DBS.
- 2. Caregiver Expectations for DBS surgery and its relation to caregiver burden.
- 3. Use of Smartphone Applications in DBS Evaluation for Parkinson's Disease (Digibio)
- 4. Ceregate: DBS for freezing of gait (Gevia DBS system)



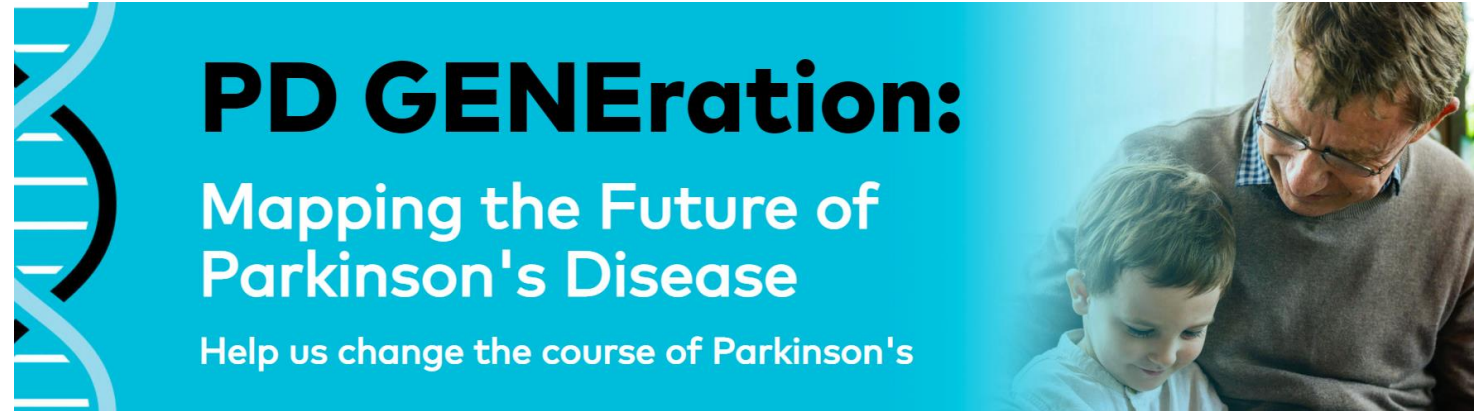
# Neurologic Music Therapy for Enhancing Fine Motor Control in PD

- Current treatments have limited effects on fine motor function
- Neurologic Music Therapy has proven benefits on gait
- We propose a patient-tailored music-based therapy to:
  - Restore brain motor function independently of PD pathology
  - Improve fine motor skills
  - Increase quality of life



# Genetic testing in people with Parkinson's disease.

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## Goals:

- To better understand the genetic architecture of Parkinson's disease.
- This may lead to improved understanding of dysfunctional cellular processes which lead to PD.
- By contributing genetic information, people with PD have the opportunity to contribute to scientific research and improve understanding of PD and potentially identify new and/or better treatment options.

# Other Clinical studies

## 1. DRIVE-PD: Diversifying Research through Inclusivity and Engagement

**Do you have Parkinson's disease?**

DRIVE-PD: DIVERSIFYING RESEARCH THROUGH INCLUSIVITY AND ENGAGEMENT IN PARKINSON'S DISEASE

We are looking for people with Parkinson's disease to tell us about their experience. This information may help other people with Parkinson's disease.

If you participate in this study you will be compensated \$25 for your time.

You may be able to join if you:

- 1 If you identify as Hispanic or Latino and have Parkinson's disease
- 2 If you are over 18 years old and have no memory problems

CALL OR EMAIL FOR MORE INFORMATION ABOUT THE **DRIVE-PD STUDY** AT:  
(303) 724-2842  
CAMILA.DAVILA@CUANSCHUTZ.EDU

**¿Tiene la enfermedad de Parkinson?**

DRIVE-PD: DIVERSIFICANDO LA INVESTIGACION DE LA ENFERMEDAD DE PARKINSON A TRAVES DE LA INCLUSION Y COMPROMISO

Buscamos personas con Parkinson para que nos cuenten sobre sus experiencias. Esta información podría ayudar a otras personas con Parkinson.

Si usted participa en este estudio, sería compensado/a \$25 por su tiempo.

Usted podría participar si:

- 1 Usted se identifica como hispano o Latino y tiene la enfermedad de Parkinson
- 2 Tiene más de 18 años de edad y no sufre de problemas de memoria

PARA MAS INFORMACION SOBRE EL ESTUDIO **DRIVE-PD**, POR FAVOR LLAME AL (303) 724-4644  
O MANDE UN CORREO ELECTRONICO A CAMILA.DAVILA@CUANSCHUTZ.EDU

## 2. Rock PD diary (Blue Rock Therapeutics)

## 3. Glove study:



## 4. REM sleep disorder (sleep monitoring + actigraphy)



# Misconceptions about research

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I want to do this study because I don't want to wait for the years that it takes to get FDA approval – when this drug will help me now.

I don't want to do this study because I might get a sugar pill.

I don't want to be a guinea pig.

# Why to participate in Research?

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All of your current treatments came through clinical trials.

However only 2-3% of those affect with a disease participate.

90% of clinical trials do not finish on time

- This means delays in advances, more expensive research, more expensive treatments

A unique gift to the PD community.



Parkinson's Disease

Hope Through Research

National Institute of Neurological Disorders and Stroke  
National Institutes of Health

# Where to participate?

Clinicaltrials.gov

## Find a study (all fields optional)

### Status ⓘ

Recruiting and not yet recruiting studies

All studies

### Condition or disease ⓘ (For example: breast cancer)

Parkinson Disease

X

### Other terms ⓘ (For example: NCT number, drug name, investigator name)

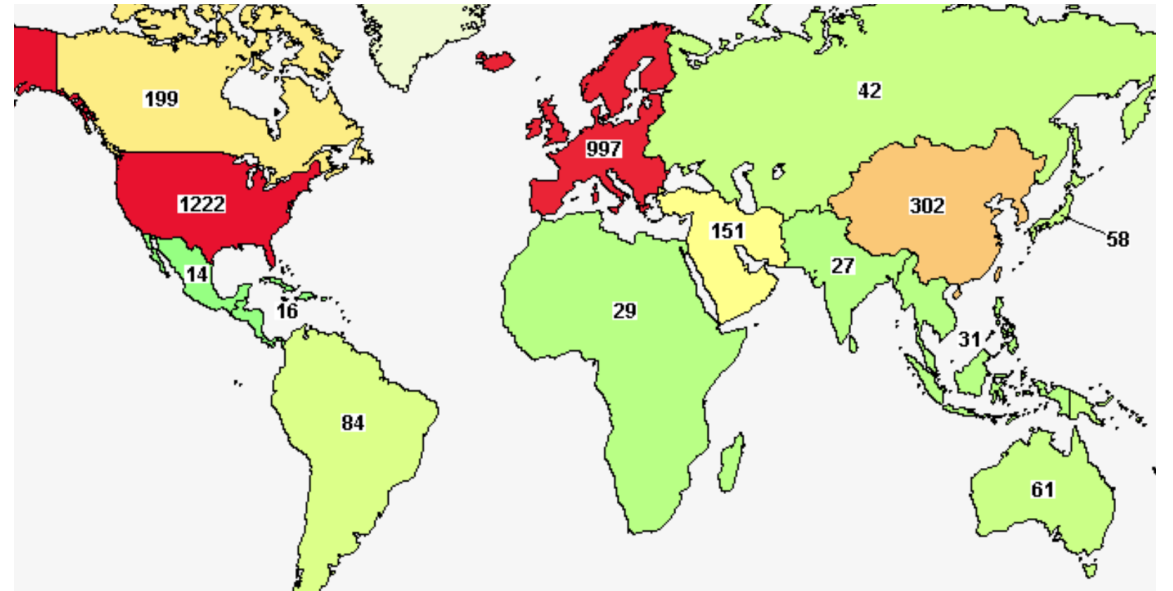
X

### Country ⓘ

▼ X

[Search](#)

[Advanced Search](#)



# Where to participate?



University of Colorado  
Movement Disorders Center  
[www.ucdenvermovement.org](http://www.ucdenvermovement.org)



researchmatch



[WWW.PARKINSON.ORG](http://WWW.PARKINSON.ORG)  
NATIONAL PARKINSON  
FOUNDATION

Learn about Parkinson's clinical trials



[WWW.PDTRIALS.ORG](http://WWW.PDTRIALS.ORG)

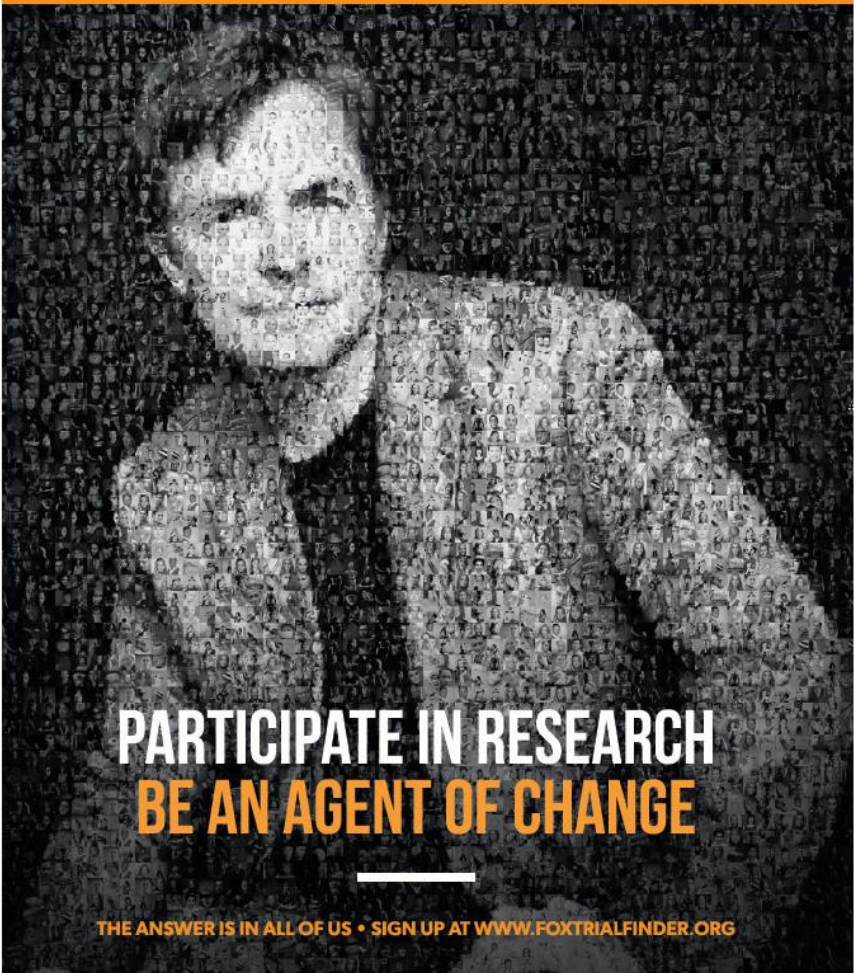


Parkinson Association  
of the Rockies



**ClinicalTrials.gov**  
A service of the U.S. National Institutes of Health

**FOX TRIAL FINDER**  
THE MICHAEL J. FOX FOUNDATION FOR PARKINSON'S RESEARCH



**PARTICIPATE IN RESEARCH  
BE AN AGENT OF CHANGE**

THE ANSWER IS IN ALL OF US • SIGN UP AT [WWW.FOXTRIALFINDER.ORG](http://WWW.FOXTRIALFINDER.ORG)

# Thank you!

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Questions?

Interested in research?

- Talk with your doctor
- Contact [neuroresearch@cuanschultz.edu](mailto:neuroresearch@cuanschultz.edu) or 303-724-4644