

HEALTHCARE INNOVATIONS CONFERENCE

New Technologies in Healthcare

Nov. 14, 2018 | Rochester Riverside Hotel

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Telehealth and Mobile Measures in Parkinson's Disease

11:15 am– 12:15 pm | Gleason



Jamie Adams, MD

*The University of Rochester
Medical Center*

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**To receive your credit hours, you must stay for the full conference.*

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Telehealth and Mobile Measures in Parkinson's Disease

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Department of Neurology
Center for Health & Technology
University of Rochester Medical Center



Outline

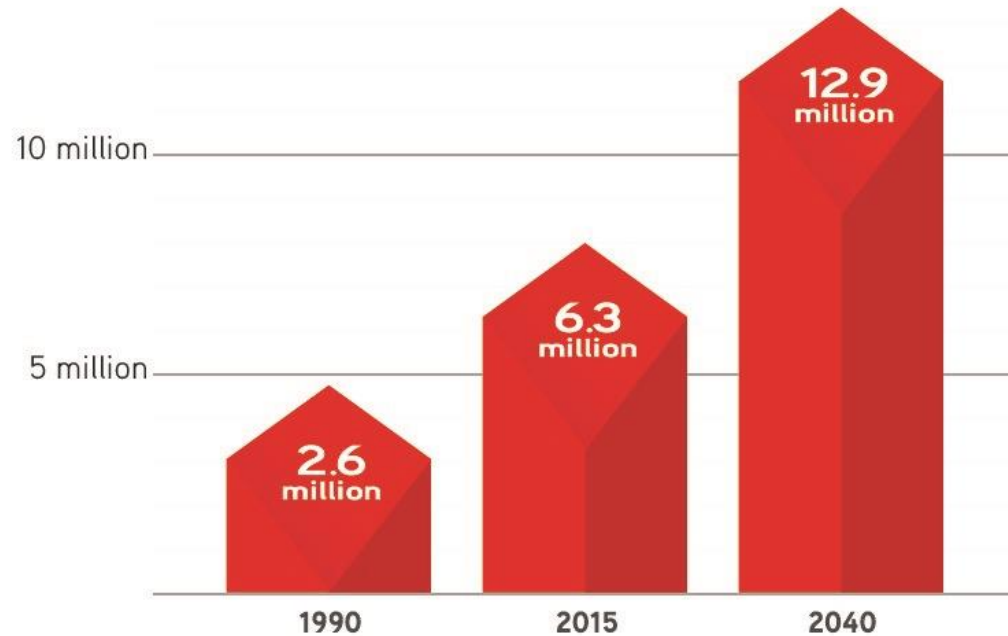
- Technology in Research Overview/Rationale
- Virtual Visits in Clinical Trials
- Mobile Measures
- Telehealth in Clinical Care

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The global burden of Parkinson disease is rising

Estimated and projected number of individuals with
PARKINSON DISEASE, 1990 – 2040



Source: Dorsey ER, Bloem BR, The Parkinson Pandemic: a call to action. *JAMA Neurology* 2017

Current clinical assessments are subjective, categorical, insensitive, and episodic

Assessment of motor function in Parkinson disease

3.4 FINGER TAPPING

Instructions to examiner: Each hand is tested separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to tap the index finger on the thumb 10 times as quickly AND as big as possible. Rate each side separately, evaluating speed, amplitude, hesitations, halts and decrementing amplitude.

- | | | | |
|--------------|--|--------------------------|---|
| 0: Normal: | No problems. | <input type="checkbox"/> | |
| 1: Slight: | Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the tapping movement; b) slight slowing; c) the amplitude decrements near the end of the 10 taps. | | R |
| 2: Mild: | Any of the following: a) 3 to 5 interruptions during tapping; b) mild slowing; c) the amplitude decrements midway in the 10-tap sequence. | <input type="checkbox"/> | |
| 3: Moderate: | Any of the following: a) more than 5 interruptions during tapping or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing; c) the amplitude decrements starting after the 1st tap. | | L |
| 4: Severe: | Cannot or can only barely perform the task because of slowing, interruptions or decrements. | | |

These rating scales lead to false and missed signals of efficacy

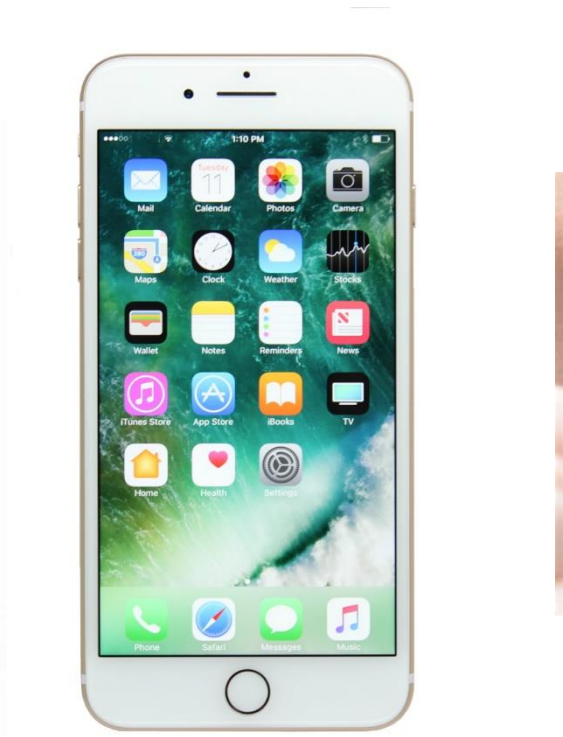
Recent phase 3 trials in neurodegenerative disorders that failed to replicate phase 2 findings							
Drug	Disease	Phase 2 Findings	Phase 3 Findings	N	Duration	Sponsor	Phase 3 Cost
<i>Creatine</i>	Parkinson disease	2.8 points improvement on total UPDRS over placebo	Failed, study terminated early due to futility	955	5 years	NIH	~\$25 million
<i>Coenzyme Q₁₀</i>	Parkinson disease	1.2-5.3 points improvement on total UPDRS over placebo	Failed, study terminated early due to futility	600	16 months	NIH	~\$14 million
<i>Idalopirdine</i>	Alzheimer disease	2.1 points improvement on ADAS-Cog over placebo	Failed, unchanged ADAS-Cog	2525	24 months	Lundbeck	~\$600 million
<i>Solanezumab</i>	Alzheimer disease	1.9 points improvement on ADAS-Cog over placebo for lowest dose	Failed, unchanged ADAS-Cog	2100	18 months	Eli Lilly	~\$600 million
<i>Gammagard</i>	Alzheimer disease	5.4 points improvement on ADAS-Cog over placebo	Failed, unchanged ADAS-Cog	390	18 months	Baxter	~\$30 million
<i>Coenzyme Q₁₀</i>	Huntington disease	0.34 point improvement on Total Functional Capacity over placebo	Failed, study terminated early due to futility	609	5 years	NIH	~\$22 million
<i>Pridopidine</i>	Huntington disease	1.0-1.2 point improvement on modified motor score over placebo in two trials	Failed, no significant improvement	400	6 months	Teva	~\$100 million

UPDRS = Unified Parkinson's Disease Rating Scale; ADAS-Cog = Alzheimer's Disease Assessment Scale – Cognitive subscale

Sources: Dorsey ER, Papapetropoulos S, Xiong M, Kieburtz K. *The First Frontier: Digital Biomarkers for Neurodegenerative Disorders*. Digit Biomark 2017

Atri A et al. Effect of Idalopirdine as adjunct to cholinesterase inhibitors on change in cognition in patients with Alzheimer disease: three randomized clinical trials. JAMA 2018

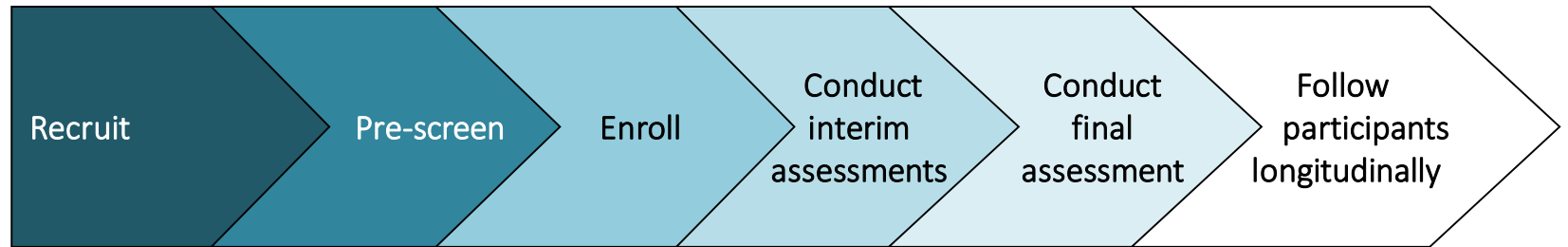
New tools can uncover new details about disease



Future trials will incorporate new tools that transform clinical trials

Characteristic	20th Century	21st Century
Study design	Randomized, double-blind, parallel-group, placebo-controlled trial	Randomized, double-blind, parallel-group, placebo-controlled trial using adaptive designs
Study population	All comers with a given disease	Individuals selected based on phenotypic and genetic results
Study recruitment	Clinical practices	Global clinical trial registries and social networks organized by
Trial visits	In person and audio calls	In person and audio and video calls
Data management	Paper and electronic forms	Electronic forms
Participant feedback	Limited, delayed	Almost universal, approximately real time
Outcome measures	Insensitive	Sensitive
	Episodic	Frequent or continuous
	Subjective	Objective
	Provider centered	Patient centered
	In clinic	Remote
	Unidimensional	Multidimensional

New model for clinical trials



Current



Future



Outline

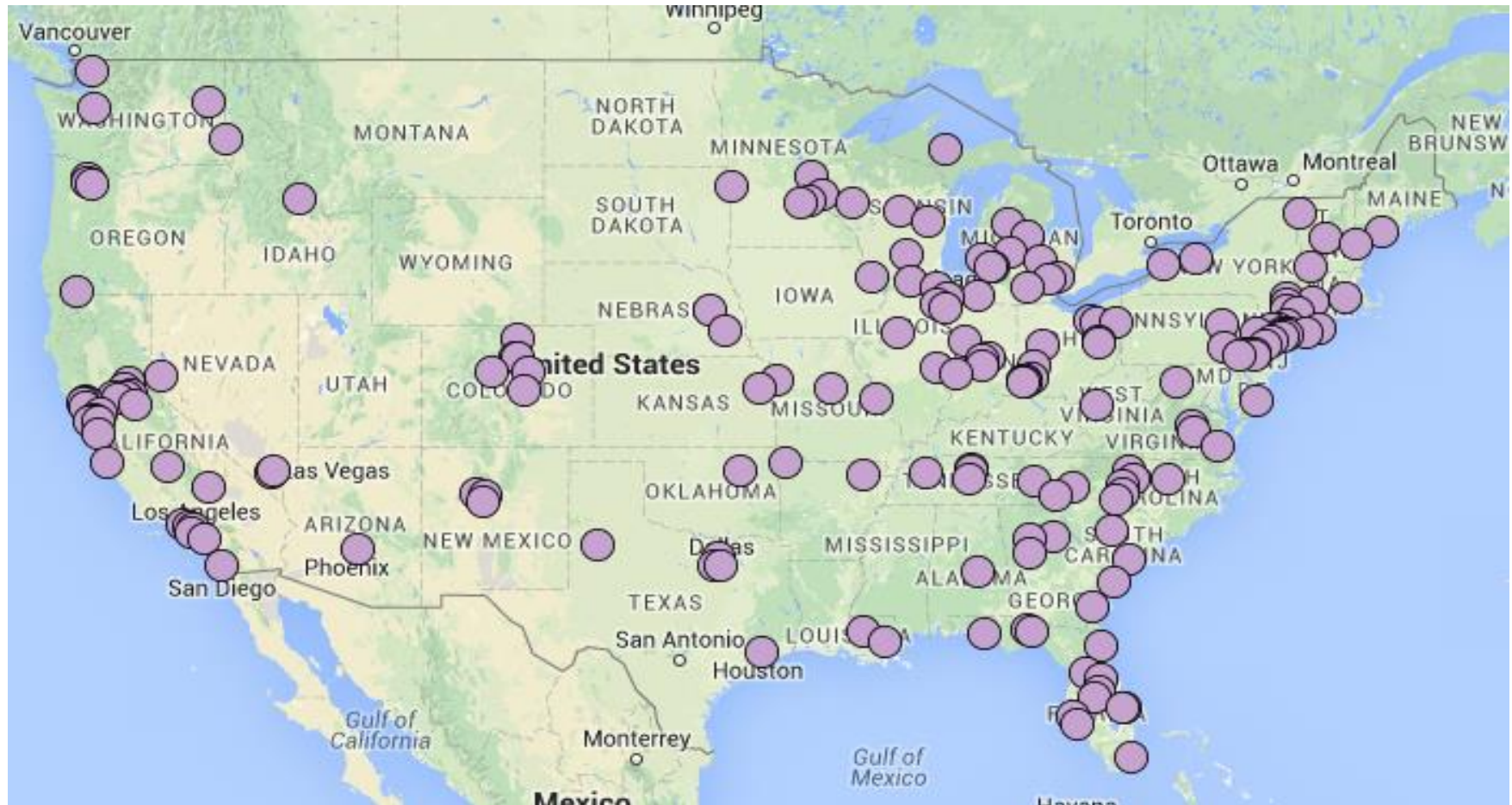
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- **Virtual Visits in Clinical Trials**
- Mobile Measures
- Telehealth in Clinical Care

Virtual studies offer many advantages over traditional site-based approaches

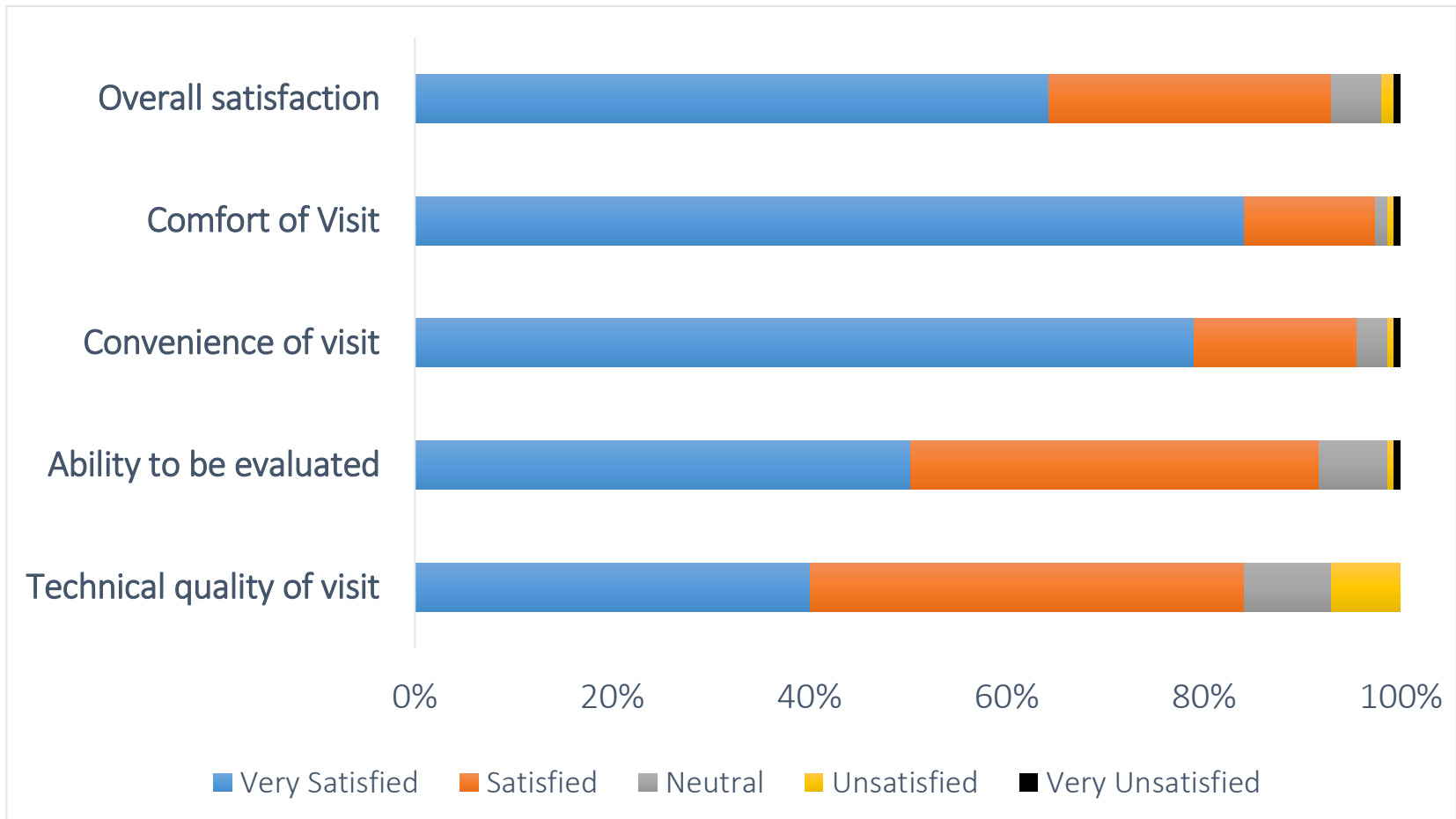
Comparison of the traditional and virtual research models		
Characteristic	Traditional Model	Virtual Model
Geographic Reach	Determined by site location	Determined by internet access
Sites	Many	One
Institutional Review Boards	Many	One
Time to initiate study	Long	Medium
Investigators	Many	Few
Time required for visits	Long	Short
Variance in assessments	High	Low
Burden on participants	High	Low
Cost	\$\$\$\$\$	\$\$

National studies can be conducted from single sites

Map of participants in a virtual research study



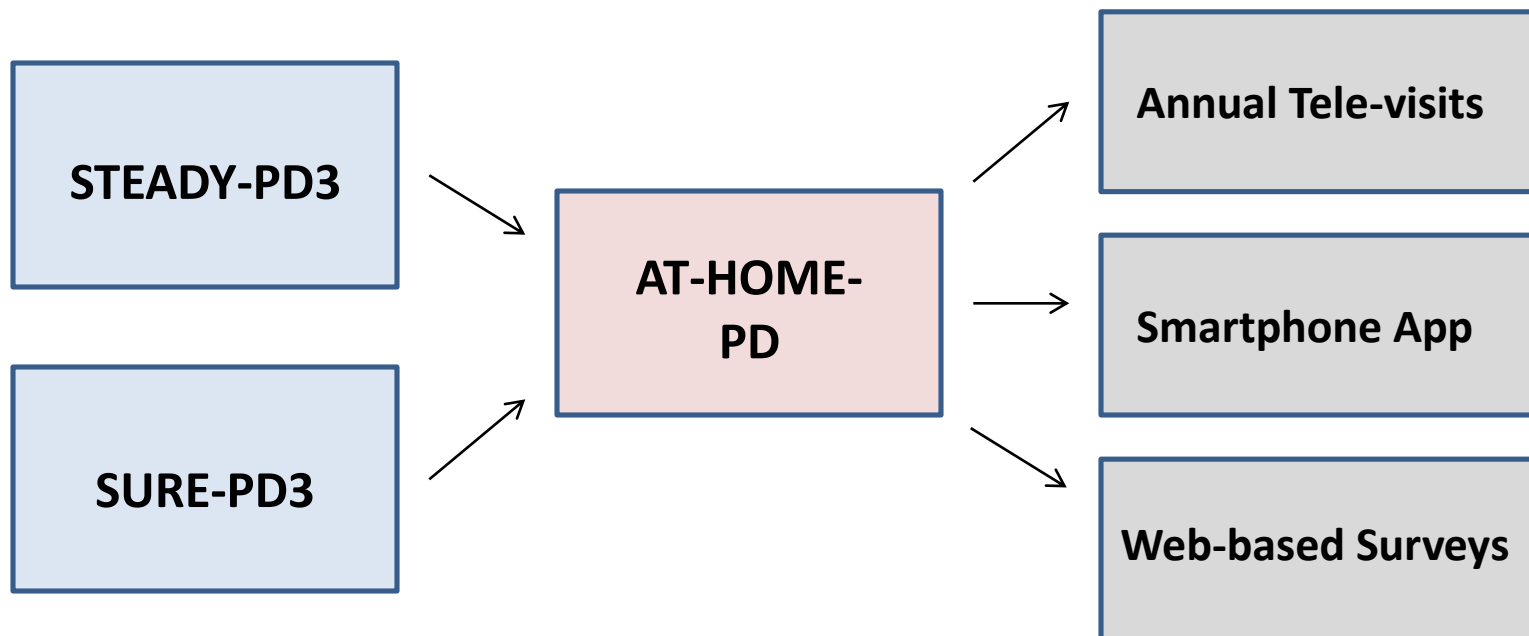
Research participants like virtual visits



Over 80% of participants said they would be more willing and able to participate in future research studies if could do so remotely

Virtual visits are being used for longitudinal follow-up of large clinical trials (AT-HOME PD)

Objective: To leverage modern technology to develop, pilot and implement a 100% virtual model for long-term follow up of clinical trial cohorts utilizing telemedicine and smartphone platforms for quantitative monitoring of clinician- and patient-reported outcomes.

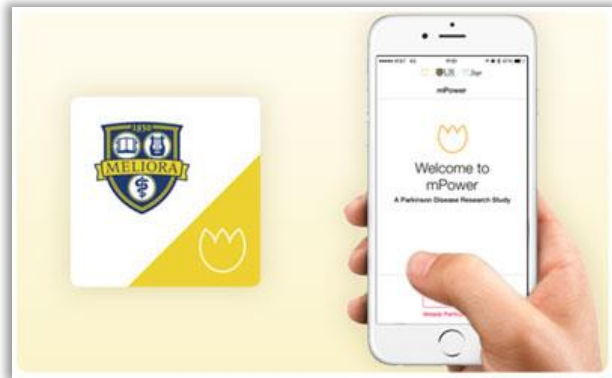


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Mobile technologies can enable more objective, sensitive, and frequent measures of PD

Objective



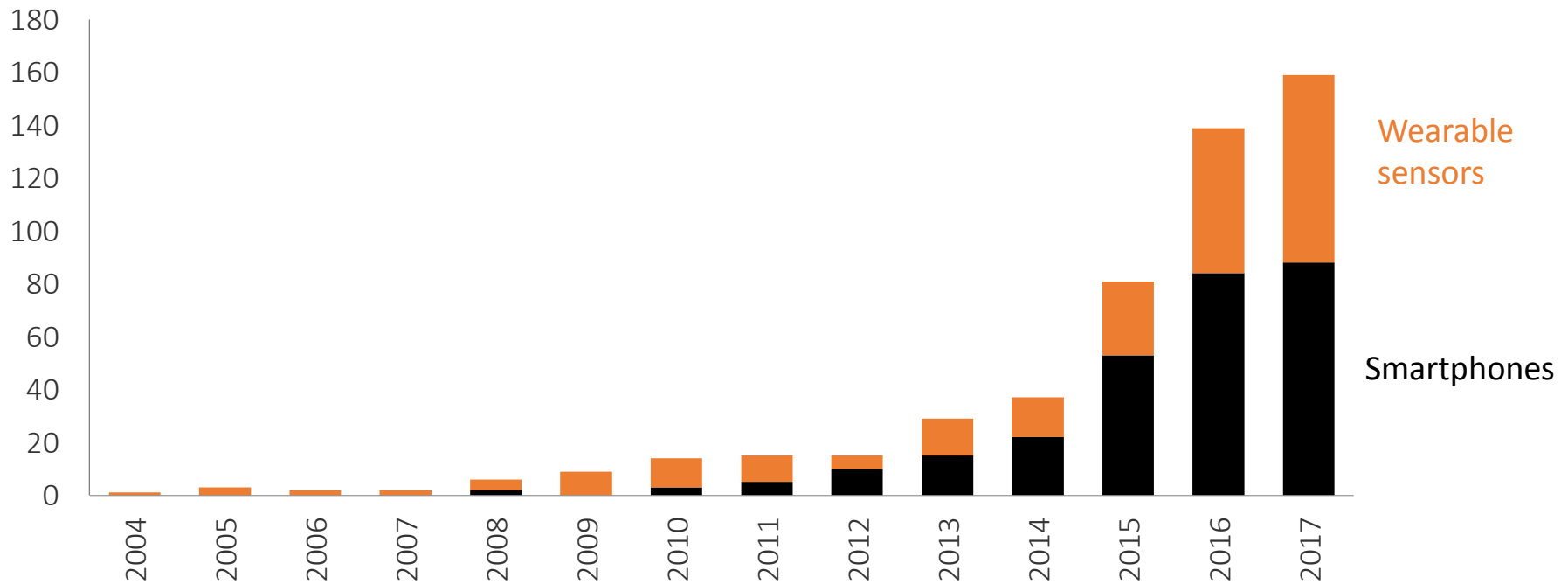
Sensitive



Frequent



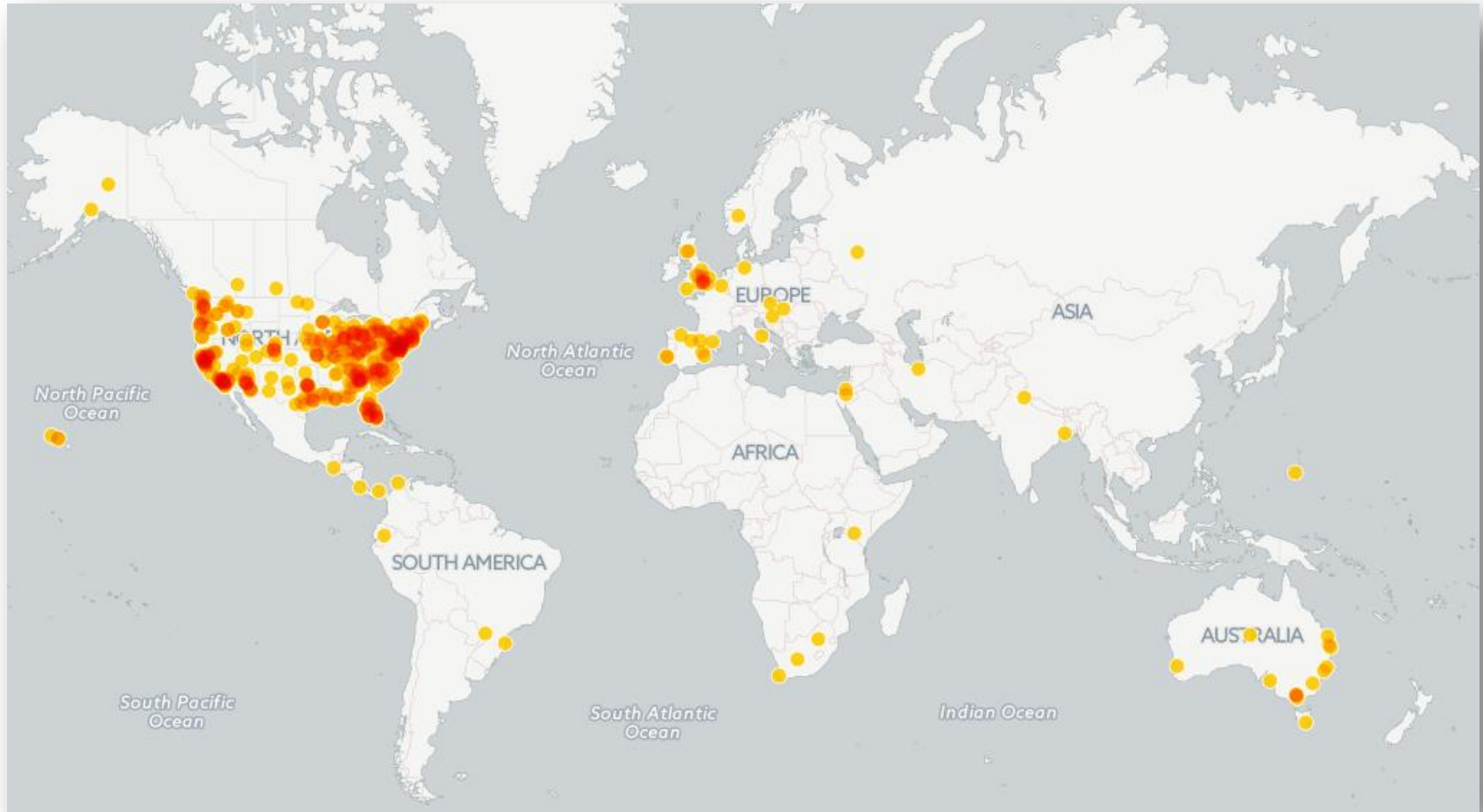
Smartphone and wearable sensor studies in neurology, 1992-2017



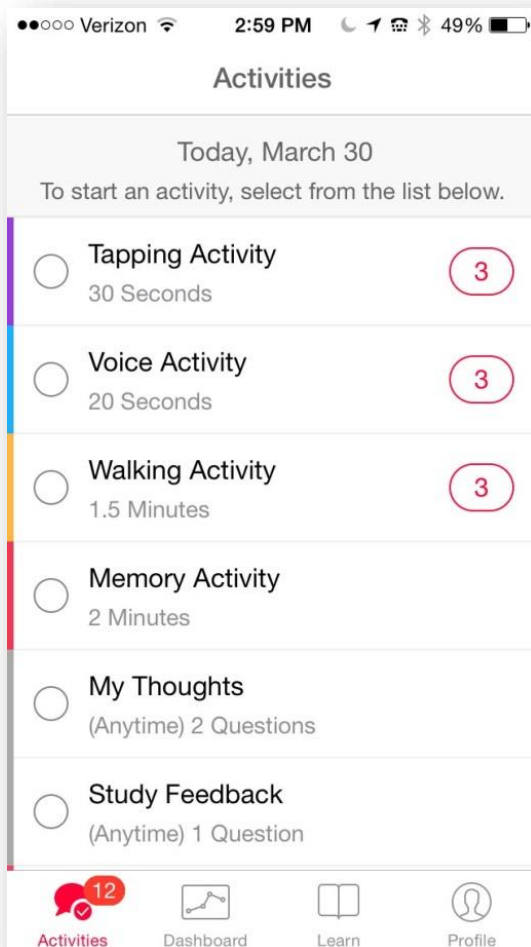
Source: PubMed searches of smartphone and wearable sensor studies for neurology and associated conditions on 12/31/2017

New tools enable research to be conducted at unprecedented scale and scope

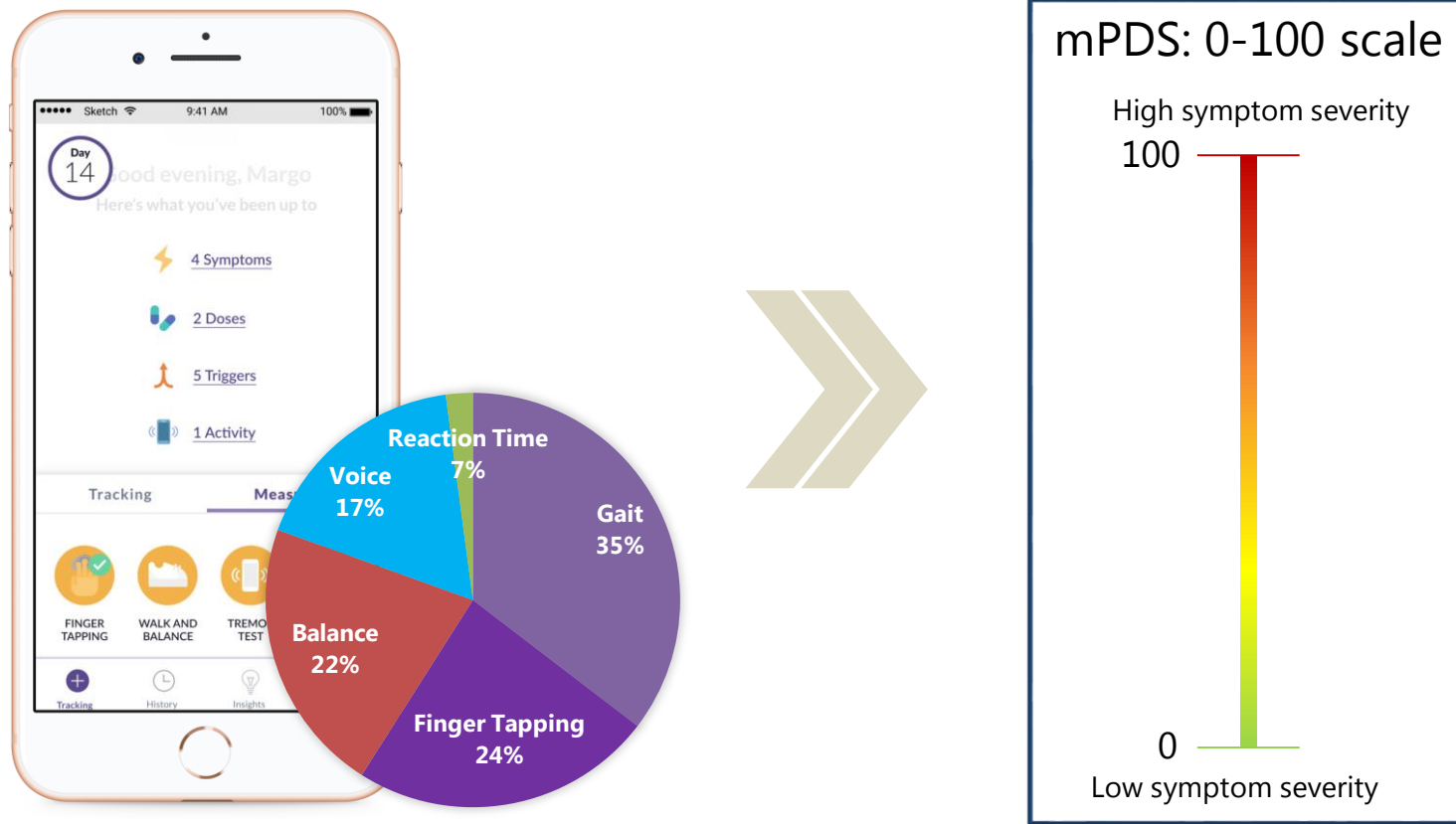
Geographical representation of study participants (N~1000 participants)



Smartphone research apps contain surveys, structured tests, and passive monitoring



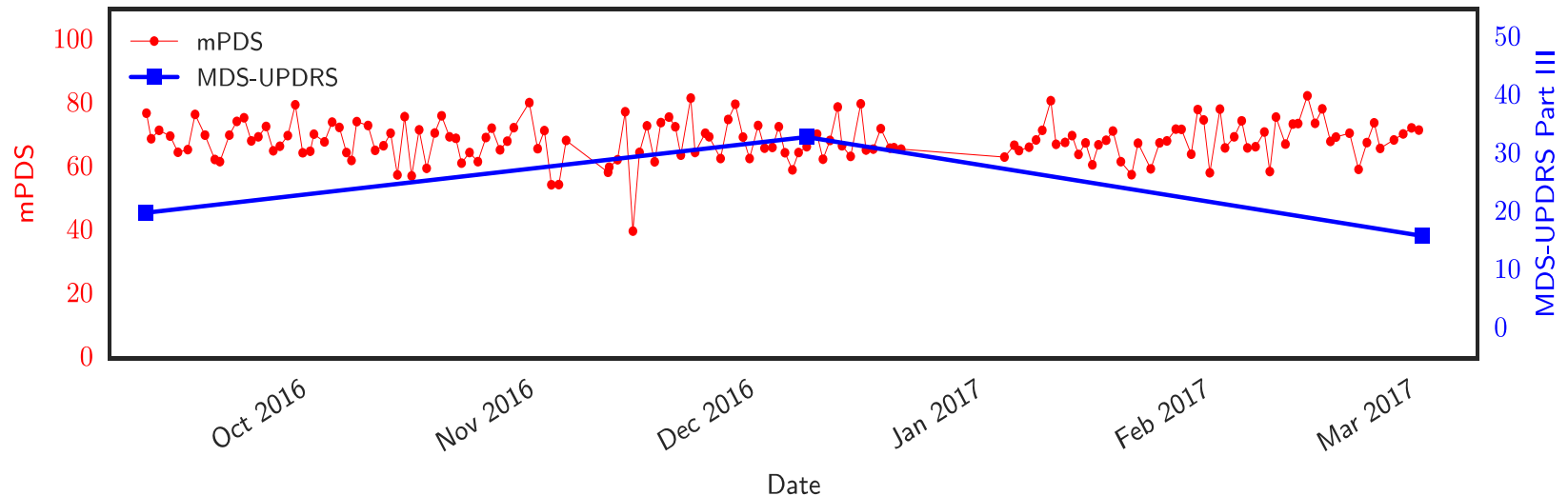
A mobile Parkinson disease score has been developed using a smartphone application



The mobile Parkinson disease score reveals inter-day variation that the traditional assessments miss

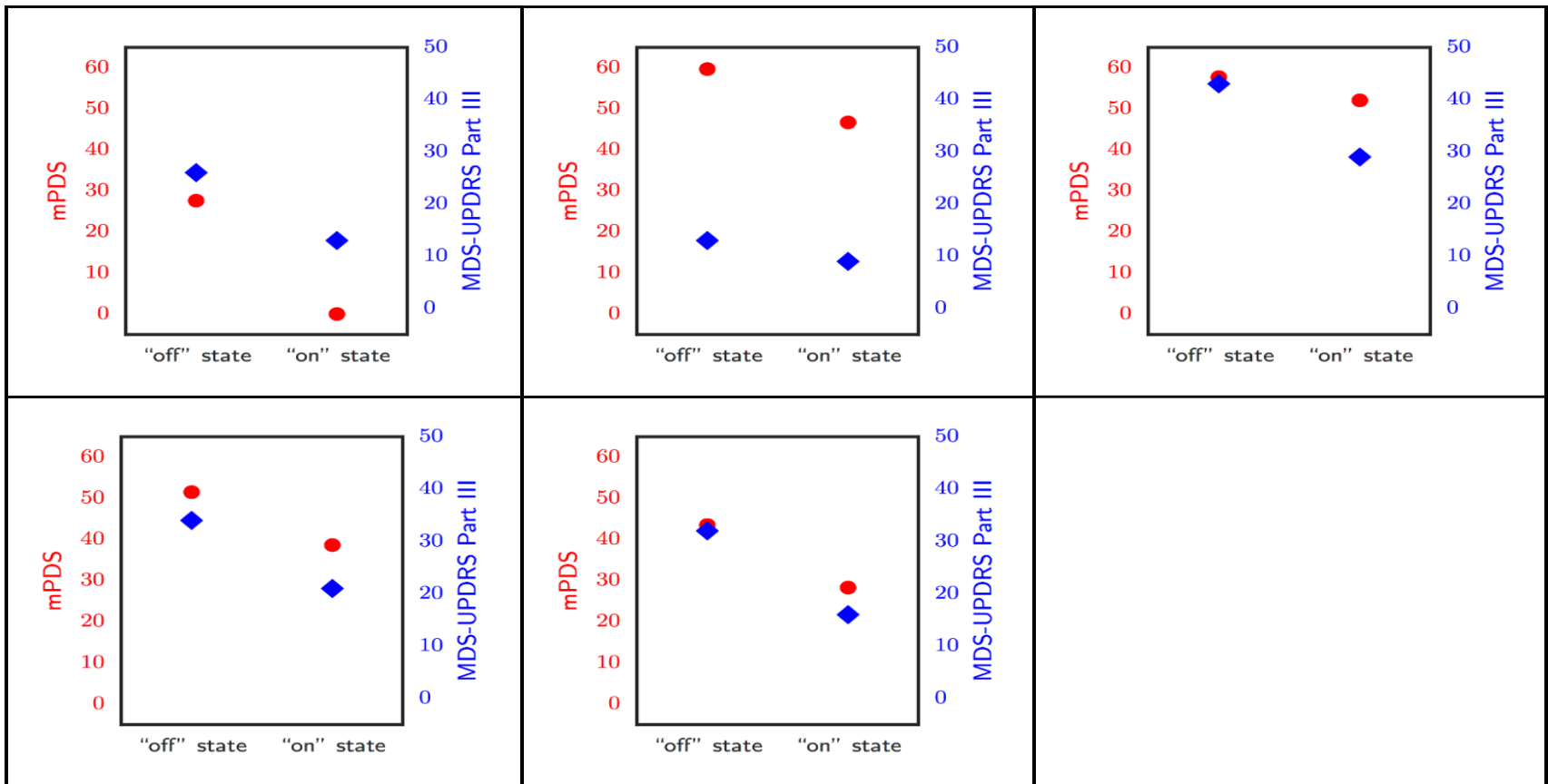
Individual with advanced Parkinson disease

Number of tests: 152



Smartphone apps can detect responses from medications

Comparison of change in mPDS and MDS UPDRS Part III between the OFF and ON medication states



Despite the many benefits of health applications, they still face challenges

Limitation	Description	Solution
Selection bias	Most health applications and research studies are only available on iPhone	<ul style="list-style-type: none">• Make health applications available on Android devices• 77% of Americans currently own smartphones
Retention	After initial interest in health applications interest and use wanes	<ul style="list-style-type: none">• Increase valuable feedback to participants<ul style="list-style-type: none">• Provide data relative to other participants• Predict course of disease• Increase engagement with healthcare team
Privacy	Study participants are concerned over the privacy of their health data	<ul style="list-style-type: none">• Disclose who has access to data• Give study participants ability to choose who gets their data and for what purpose
Validation	Health applications need to be validated and their efficacy determined	<ul style="list-style-type: none">• Validate health applications in in-person observational studies• Use in clinical trials for validation

Wearable Sensors



We evaluated wearable sensors for Parkinson disease and Huntington disease

MC10 BioStampRC

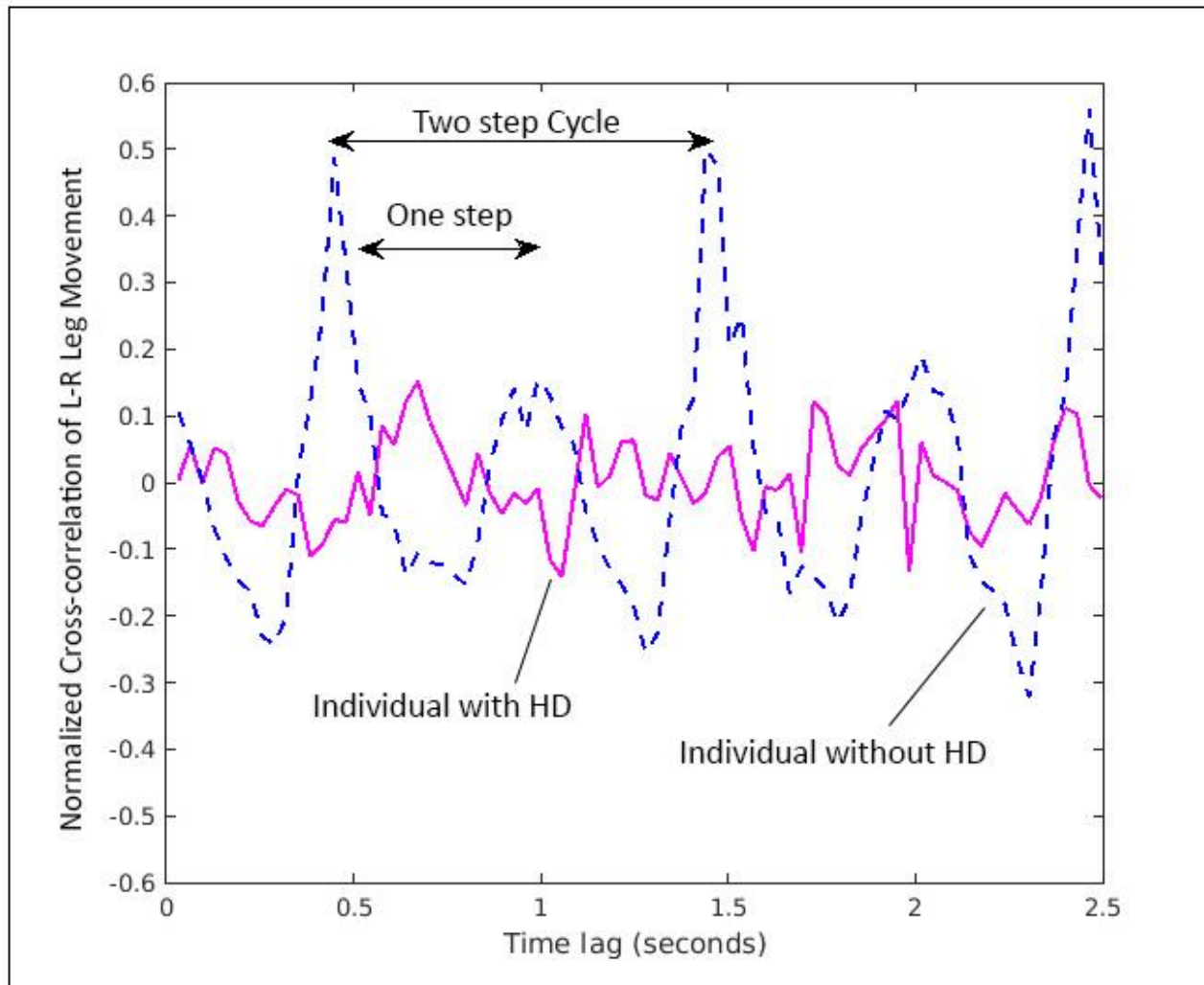


Sensor-MD Overview:

- We enrolled 56 participants
 - 16 with Parkinson disease
 - 15 with Huntington disease
 - 5 with prodromal HD
 - 20 without a movement disorder
- Participants wore 5 sensors on their chest and limbs

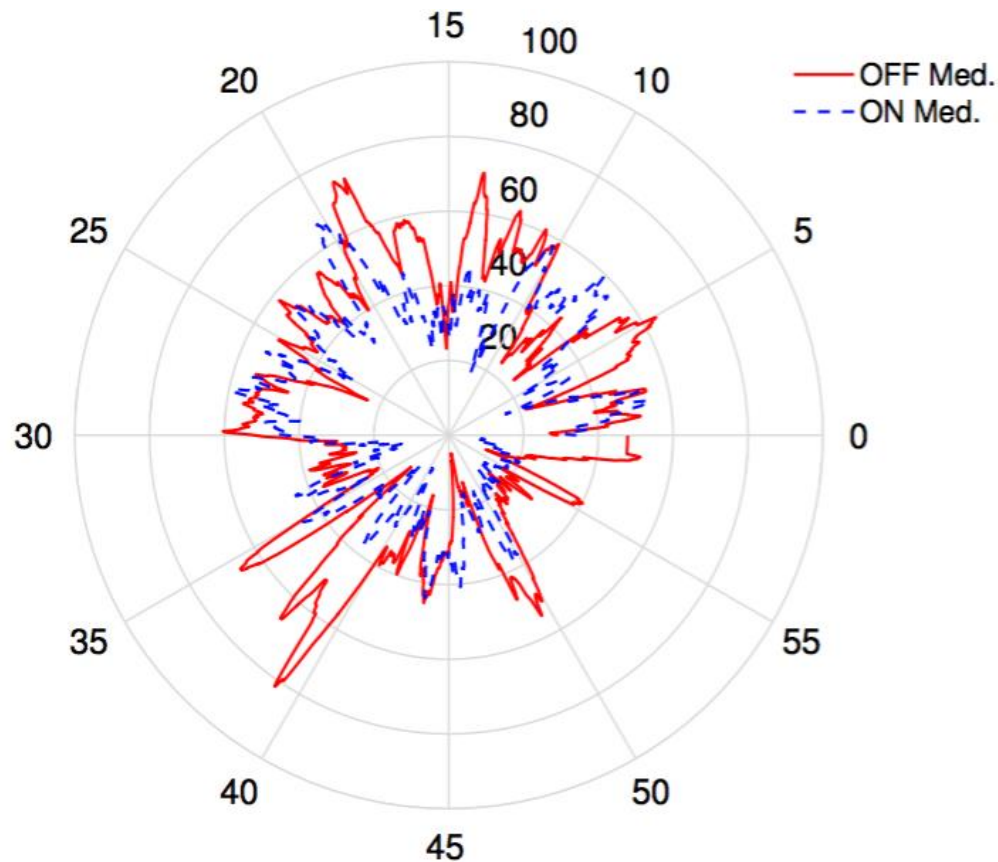
Sensors can distinguish between individuals with and without movement disorders

Comparison of gait between an individual with HD and a control



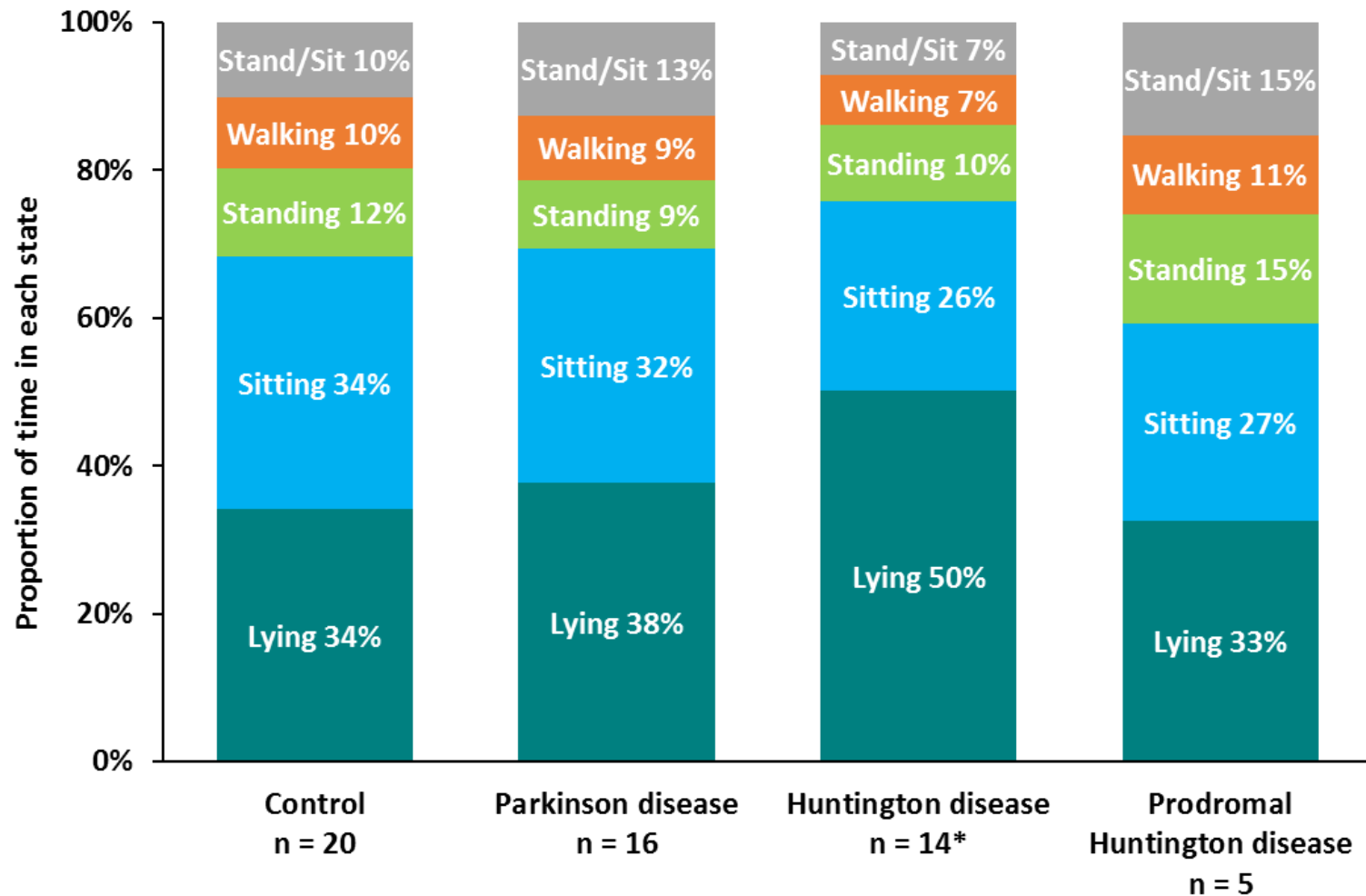
Not only can sensors track known motor symptoms over time...

Frequency and severity of tremor detected over one hour period



...but can also capture novel data objectively and continuously in clinic and at home

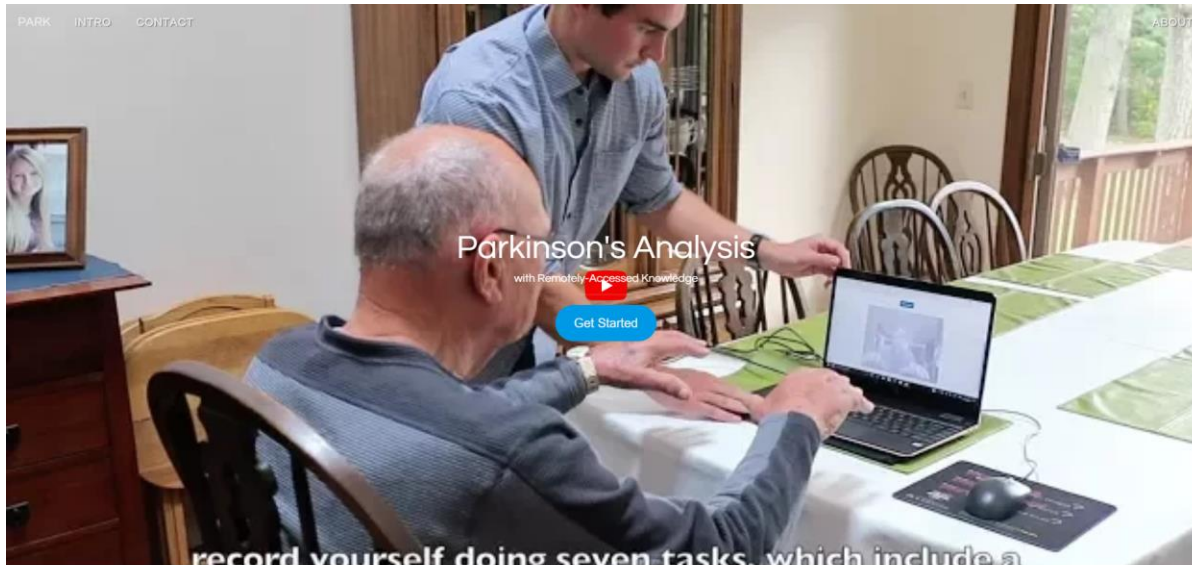
Proportion of day individuals spend lying down, sitting, standing, and walking



In collaboration with MIT, we are now using cellular waves to monitor gait and movement



Video analytics are another emerging tool for measuring disease



Requires only webcam, microphone and an internet connection.

Electronic Consent Form

Remote data collection to objectively quantify the severity of Parkinson's disease.

[Click here to download the consent form.](#)

Please click the "Yes" button to enroll in the study. If you choose not to participate, there will be no penalty to you. A blank copy of this consent form can be downloaded from this attachment for your review prior to providing consent. Please keep this copy for your records.

- Being in this study is voluntary - [it is your choice](#).
- You can change your mind and [stop at any time](#).
- If you choose not to take part, your (routine medical care, employment status, educational status, etc.) will not be changed in any way.
- There are risks from participating and you should understand what these mean to you.

Do you agree to participate in this study?

You may revoke your consent at any time.

I agree

I disagree

[Click the tab to expand:](#)

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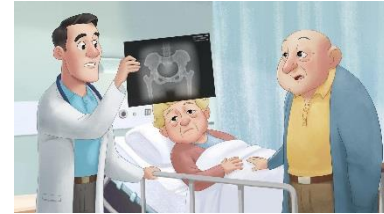
Access to PD care is limited and has adverse health and economic consequences

40% of individuals with PD do not see a neurologist



Those who do not see a neurologist are...

15% more likely to have a hip fracture



20% more likely to be placed in a skilled nursing facility



20% more likely to die

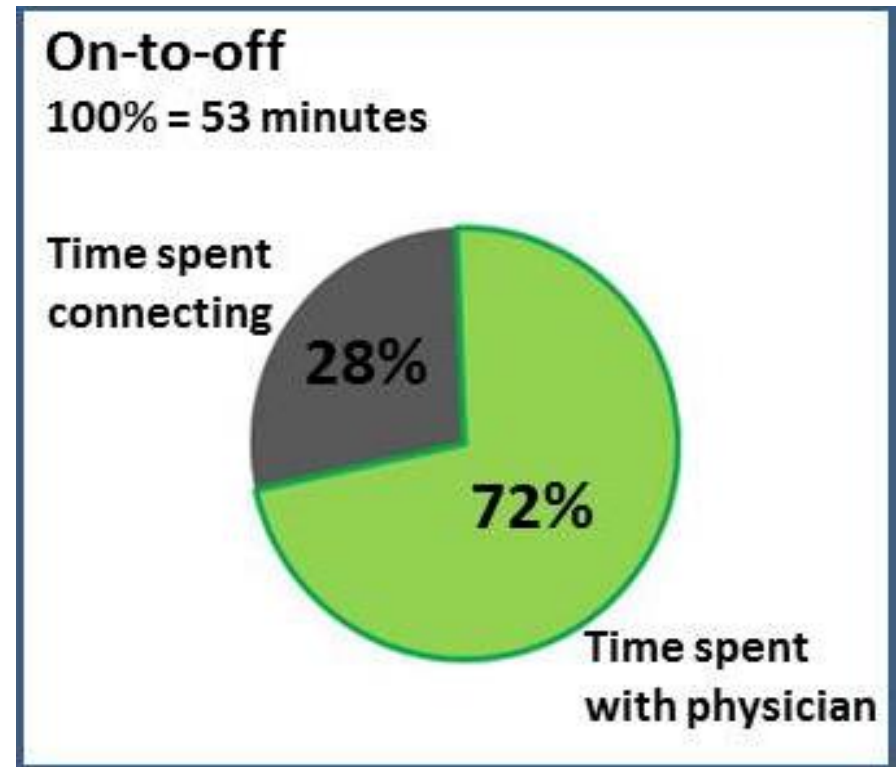
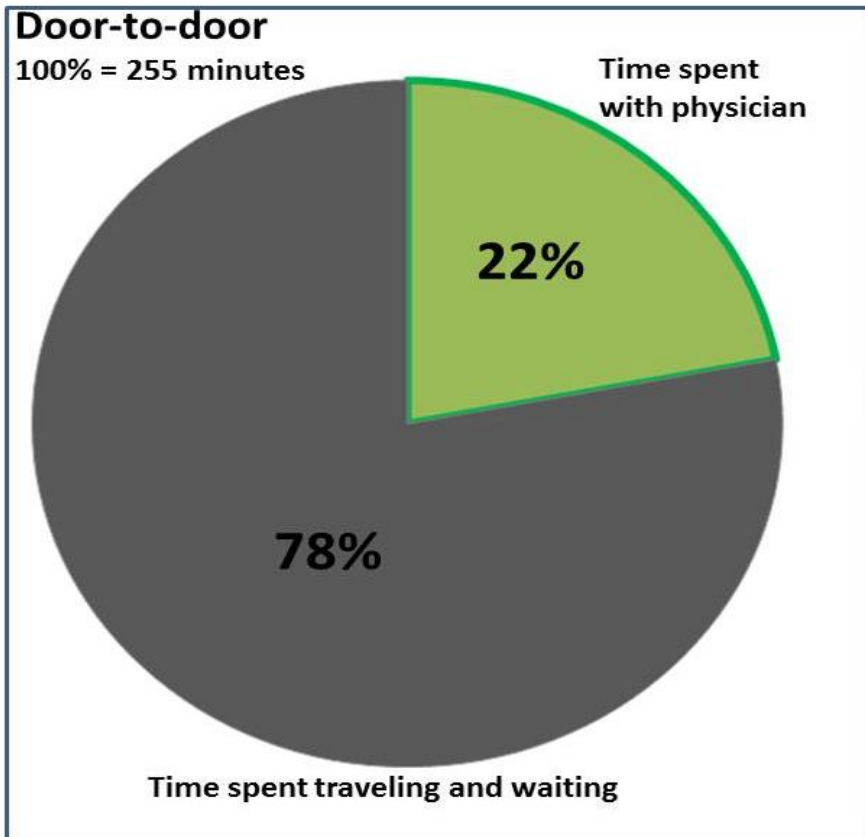


New models bring care to patients rather than patients to care

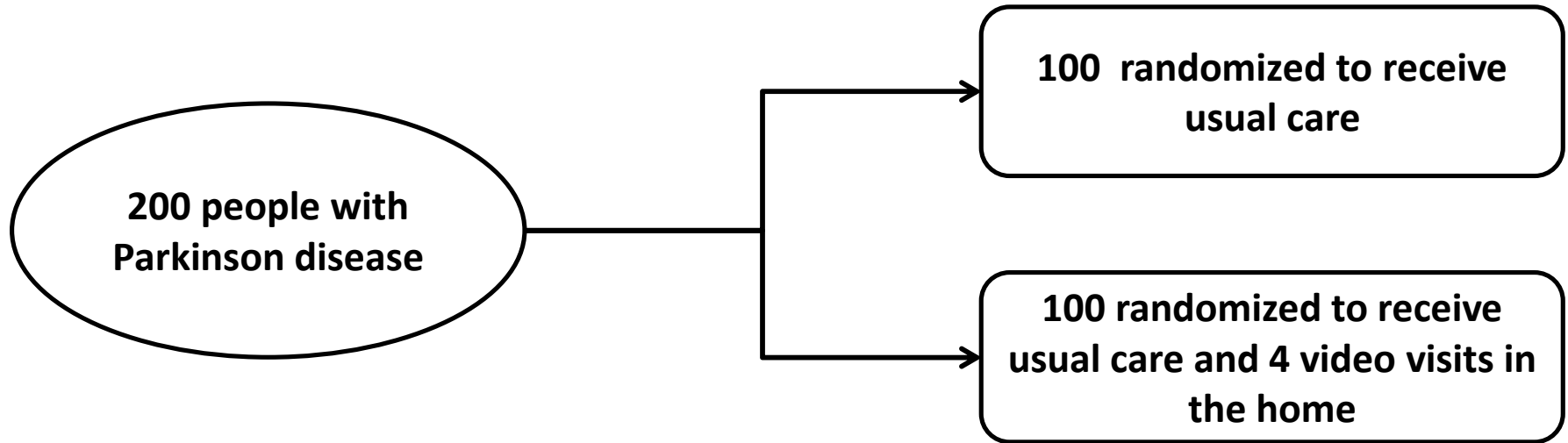


Virtual visits flip the care paradigm

Patient time spent on in-person versus telemedicine visits



Connect.Parkinson: a national randomized controlled trial of telemedicine in PD



Aims

1. To demonstrate the feasibility of using telemedicine to deliver specialty care into the homes of individuals with PD
2. To evaluate its effect on quality of life
3. To assess the impact on quality of care
4. To evaluate the value of the approach to decrease caregiver burden, save time, and reduce travel

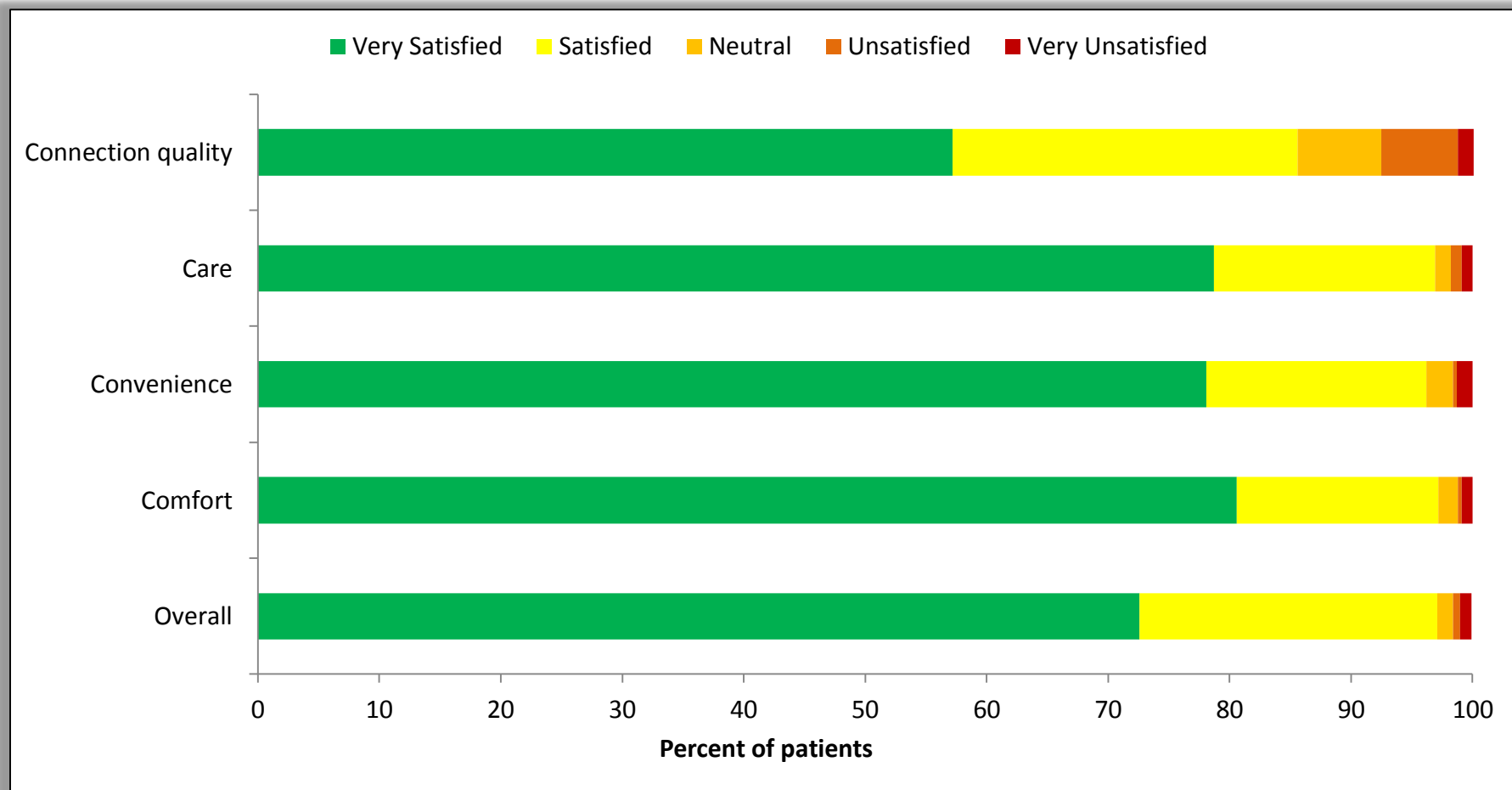
Connect.Parkinson was conducted nationally



In collaboration with:



Patients like virtual visits





Who: Any New Yorker with Parkinson disease

What: Multidisciplinary care including virtual visits with a Movement Disorders specialist

Where: New York state, especially the 9 counties surrounding Rochester

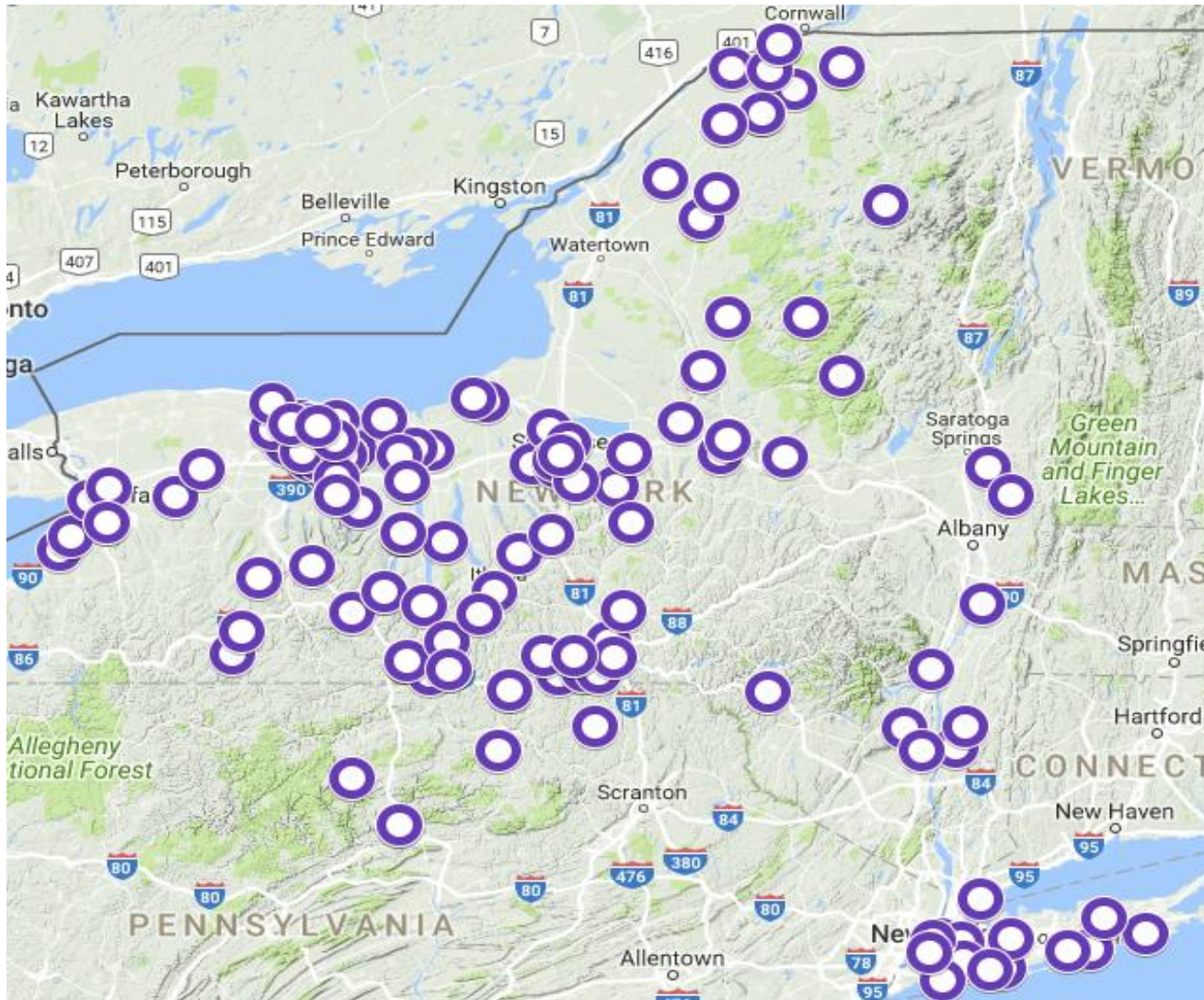
When: Now

Why: To provide comprehensive PD care to residents of New York state, especially the underserved

Supported by: Greater Rochester Health Foundation and the Edmond J. Safra Foundation

For more information: www.pdcny.org

We are reaching patients throughout New York state



Take-home points

- Technology is pushing the migration of care and research from the hospital/clinic to the home
- Telemedicine and mobile tools are poised for exponential growth and can improve research and clinical care for our patients

UR Named National Center of Excellence for Parkinson's Research

Wednesday, October 03, 2018

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The University of Rochester has been selected as a Morris K. Udall Center of Excellence in Parkinson's Disease Research by the National Institute of Neurological Disorders and Stroke (NINDS). The new \$9.2 million award brings together researchers from industry and multiple academic institutions to focus on the development of digital tools to enhance understanding of the disease, engage broad populations in research, and accelerate the development of new treatments for Parkinson's disease.