Personalized Parkinson Project - data quality enhancing strategies

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Background

Data quality of longitudinal observational patient cohorts should be indisputable since these data are increasingly used to model disease expression, search for novel biomarkers, and understand disease progression. However, incompleteness of data is a common problem in longitudinal studies, affecting the data quality. As the primary objective of the ongoing Personalized Parkinson Project is to make the data available for researchers worldwide, high standards for quality assurance were implemented.

Objective

To demonstrate the data quality enhancing and patient engagement strategies used in the Personalized Parkinson Project.

Methods

The Personalized Parkinson Project (PPP) is a single-center cohort study that started in 2017. It is enrolling 650 persons who are diagnosed with Parkinson's disease for ≤5 years, and following them for two years. The protocol includes various tests for deep phenotyping during annual in-clinic visits (Figure 1) and continuous monitoring at home (up to 23 hours a day, seven days a week) with the multi-sensor Verily Study Watch.

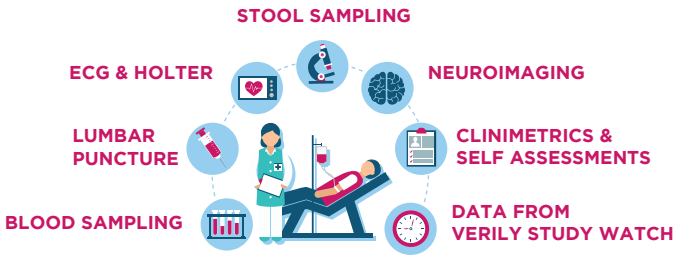

Figure 1: Overview of all the tests that are performed during the annual in-clinic visits.

Data quality enhancing strategies

- Single center study, dedicated team of eight assessors, and standard operating procedures to reduce unwarranted variability.
- Stratified inclusion to guarantee a representative sample.
- Innovative data storage and sharing infrastructure that supports privacy of the study participants.

Patient engagement strategies

- Patient participation in protocol design
- Optional invasive tests
- Overnight stay to reduce the burden of traveling
- Personal assessor throughout study
- Dedicated help desk
- Pro-active support
- Online education with expert vlogs
- Monthly newsletters to inform about progress
- Annual participant event

Results

Currently 498 Parkinson patients are enrolled. Their characteristics are presented in Table 1.

Completeness of data

- 93% of participants fulfilled predefined stratification model.
- At baseline, at least 87.7% of all assessments were performed according to protocol, which increased to 93.3% at one year of follow-up. At two years of follow-up, at least 80.0% of all assessments were performed according to protocol (Table 2).
- The median wear time of the Verily Study Watch was 22.1 hours/day (Figure 2).

After almost 3 years in the study, only eight patients (1.6%) dropped out.

Table 1. Baseline characteristics PPP cohort (N = 498)

		Total	Men (n=298)	Women (n=200)
Demographics				
Age (years)	**Mean (SD)**	61.7 (8.9)	62.0 (8.6)	61.3 (9.0)
Gender	**Count (%)**	498	298 (59.8)	200 (40.2)
Disease at onset				
Time since diagnosis (years)	**Mean (SD)**	2.7 (1.5)	2.8 (1.5)	2.6 (1.4)
Motor functioning in OFF state				
MDS-UPDRS part III	**Mean (SD)**	33.3 (12.9)	35.5 (12.8)	30.0 (12.2)
Hoehn & Yahr	**Count (%)**			
0 *(asymptomatic)*		0 (0)	0 (0)	0 (0)
1 *(unilateral)*		46 (9.3)	26 (8.7)	20 (10.1)
2 *(bilateral)*		388 (78.1)	240 (80.5)	148 (74.4)
3 *(physical independent)*		57 (11.4)	27 (9.1)	30 (15.1)
4 *(can still walk without help)*		6 (1.2)	5 (1.7)	1 (0.5)
5 *(wheel chair or bed)*		0 (0)	0 (0)	0 (0)
Cognition				
MoCa	**Mean (SD)**	26.8 (2.5)	26.4 (2.6)	27.4 (2.1)
≤ 26	**Count (%)**	174 (35)	122 (40.9)	52 (26.1)
				Status July 8, 2020

Table 2. Compliance to protocol within the PPP cohort at baseline and at one and two years of follow-up*

Patients		**Baseline (n = 497)**	**1 year follow-up (n = 253)**	**2 year follow-up (n = 45)**
MRI	N (%)	468 (97.7)	n/a	36 (80.0)
Stool samples	N (%)	472 (94.8)	236 (93.3)	42 (93.3)
Blood samples	N (%)	484 (97.4)	248 (98.0)	45 (100)
LP (optional test)	N (%)	257 (87.7)	n/a	16 (100)
ECG	N (%)	497 (100)	252 (99.6)	44 (97.8)
Grip strength	N (%)	496 (99.6)	253 (100)	45 (100)
Self-reported questionnaires	N (%)	479 - 485 (95.0 - 96.2)	244 - 246 (95.7 - 96.5)	43 - 44 (95.6 - 97.8)
Caregivers		**Baseline (n = 368)**	**1 year follow-up (n = 228)**	**2 year follow-up (n = 39)**
Self-reported questionnaire	N (%)	346 (94.0)	214 (93.9)	38 (97.4)
				Status July 7, 2020

*For more details on the protocol: Bloem BR, et al.. The Personalized Parkinson Project: examining disease progression through broad biomarkers in early Parkinson's disease. BMC Neurol. 2019 Jul 17;19(1):160.

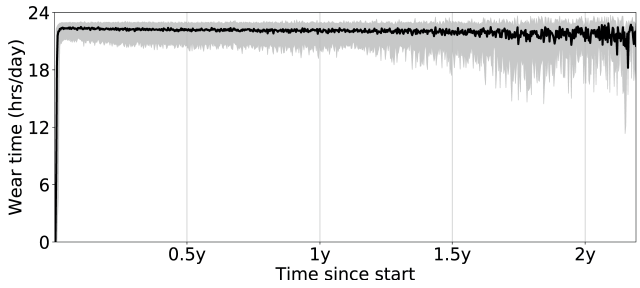

Figure 2: Hours of device wear time during follow-up (201,115 cumulative days). The black line indicates the median wear time per day with gray shading indicating the 75% confidence interval (median = 22.1h, mean = 19.6h). Increased variance over time reflects the fact that not all participants have been followed for 2 years at this time.

Conclusion

- Dedicated patient engagement efforts enhance the quality of the PPP data.
- Participatory research models should be an integral part of longitudinal cohort studies.

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verily
ParkinsonNet
Radboud University
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