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Study protocol

Proposal title

Gender-related predictors of development of fluctuations and dyskinesia in Parkinson's disease: a 2-year observational longitudinal study

Short title

(max 50 characters)

Levodopa-related motor complications and Gender

Protocol's version and date should be included in this section

Protocol version n.1, 04/DEC/2016

Acronym title (max. 10 characters)

GEN-FLU-PD

Keywords (max 10 keywords)

Gender, levodopa, parkinson, motor fluctuations, non motor fluctuations, dyskinesia

Study Classification (IRG)

BDCN-Brain Disorders and Clinical Neuroscience

Study Classification (SS)

BDCN-CNN-0244 Parkinson's disease and other movement disorders

Institutional Address (Public Institution or No Profit Institution)

Center for Neurodegenerative Diseases (CEMAND), Department of Medicine, Surgery and Odontology "Scuola Medica Salernitana", Neuroscience Section, University of Salerno, Via Allende 1, 84081 Baronissi (SA)

Department/ Operative Unit Institutional Address (Optional)

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Abstract (max 4.000 characters)

This sections should include: Background, Objectives, Methods, Expected results

Parkinson's disease (PD) is a neurodegenerative disease characterized by motor as well as non motor symptoms. Dopaminergic treatment provide significant benefit during the early phases of the disease. However, as the disease progresses motor/non motor fluctuations (MNMF) as well as dyskinesias (DYS) complicate the course of the disease, being considered among the most important determinants of patients' disability as well as of PD-related costs for the National Health System. There are several gender differences in PD. Evidence regarding disease presentation would justify the definition of a more benign phenotype attributed to women compared to men. However, as the disease progresses women are more likely to develop MNMF as well as DYS, thus challenging the definition of a more benign female phenotype.

This is a 24-month, multicentric, observational, longitudinal, prospectical study involving 293 outpatients PD subjects starting levodopa, aimed at verifying if PD MNMF and DYS incidence and predictors (including clinical, metabolic, pharmacodynamic, pharmacogenetic and genetic assessments) differ by gender. Recruitment will last 6 months and will be performed in 15 Italian movement disorders centers. Based on previous evidence, we are expecting to find higher incidence of both MNMF and DYS among women.

Findings of our study may have several implications. On the clinical ground and in the near future, clinician may better identify PD patients at higher risk and consequently adopt a more conservative behavior (e.g., using lower LD dose and/or preferring to add an i-MAO/DA instead of increasing LD). In particular, by identifying predictive factors for motor complications in parkinsonian women, this study would provide guidance on a pharmacological approach tailored by gender. Notwithstanding the large amount of evidence of the recent years, therapeutic management of PD is still mostly based on clinician's experience. Deeply knowledge of clinical and biological predictors of MNMF and DYS would further improve the tailoring of antiparkinsonian medications based on patient's need. In turn, this may implicate longer time for PD patients to reach the complicated phase of the disease often requiring expensive and invasive complex treatments (i.e., infusional therapies and stereotactic surgery).

On a research ground and in the distant future, discovering DNA and RNA-based markers of development of MNMF and DYS may boost the development of novel therapies tailored for subjects at higher risk for LD-related complications

Furthermore, this study might give a boost to the starting of an Italian network of centers interested in PD-related gender medicine all over the national territory (including North, Centre, South and Islands).

Background -a (max 4.000 characters)

Please describe: an updated review of already available evidence in the relevant literature

Parkinson's disease (PD) is a neurodegenerative disease characterized by motor as well as non motor symptoms. Dopaminergic treatment provide significant benefit during the early phases of the disease. However, as the disease progresses motor/non motor fluctuations (MNMF) as well as dyskinesias (DYS) complicate the course of the disease. MNMF and DYS represent significant sources of disability for PD patients and their caregivers as well as major determinants of PD-related National Health System (NHS) costs, as they may be severe enough to require complex treatments (as infusional therapies or stereotactic surgery) [1]. Predictors of development of MNMF and DYS are only partially understood [2]. Indeed, disease duration as well as levodopa (LD) treatment duration and dosage represent major determinants of both MNMF and DYS, which are considered LD-related complications [2,3].

There are several gender differences in PD. As for epidemiology, men are more frequently affected than women (M:F ratio=1.5:1). At the disease onset, women are older and have more frequently tremor. Furthermore, women present better cognitive performances and are less likely to develop cognitive impairment and dementia. Taken together, these findings would justify the definition of a more benign PD phenotype attributed to women compared to men [4]. However, as the disease progresses women are more likely to develop MNMF as well as DYS, thus challenging the definition of a more benign phenotype in women [5,6]. Recent evidence delineated the features characterizing a subgroup of patients reporting a "brittle response" to LD, defined as the presence of highly disabling DYS after small doses (i.e., 100 mg or less per dose) [7]. Those extremely sensitive subjects are mainly women (58%) with lower body weight and body mass index (BMI) compared to patients without a "brittle response" [7].

Thus, women appear to be more sensitive to the development of LD-related complications. Notwithstanding, there is a dearth of prospective studies examining gender-related predictors of MNMF and DYS. Indeed, cross-sectional data show that several factors may contribute to the higher frequency of LD-related complications in PD women:

- LD pharmacokinetics studies show higher Area Under the Curve (AUC), peak-serum concentration (Cmax) and lower clearance in women justifying the greater levodopa bioavailability in female patients [8,9];
- there is an inverse correlation between LD AUC and T1/2 (half-life) and body weight, which is on average lower in women [10]
- evidence suggest that several genetic polymorphisms in dopaminergic and opioid receptors have a role in modulating PD MNMF and DYS risk and gender-related differences have been described (e.g., dopamine receptor D2 (DRD2) genetic polymorphisms have shown to be protective against the risk of developing levodopa-related complications in men but not in women) [11,12];
- evidence suggest the existence of gender discrepancies in the profound alteration in central control of energy metabolism observed in PD which determines continuous changes in body weight and composition and energy expenditure in relation to both disease progression and type of treatment [13].

However, other factors should be also considered. Underlying genetic background (i.e., mutations in genes associated with increased PD risk) is a well-known predictor of MNMF and DYS and should not be overlooked [14]. Furthermore, the change in the level of serum biomarkers as MicroRNAs (miRNAs) (i.e., small endogenous noncoding RNAs affecting gene expression very sensitive to LD) is far to be clear [15,16]

The scenario is complex and firm conclusions on gender-related discrepancies in MNMF and DYS predictors can not be drawn as the majority of data come from cross-sectional studies relative to patients already on LD [6,17].

Background -b (max 4.000 characters)

Please describe: the clinical question that will be the object of the study and what the study will add to the overall available evidence

Although women are known to be at higher risk for LD-related complications, there is a dearth of prospectical data examining predictors of development of MNMF and DYS in PD patients. The goal of the present study is to understand gender-related discrepancies in clinical and biological (including DNA and RNA-based markers) predictors of MNMF and DYS in a large cohort of PD patients since the LD start. Thi will be a 24-month observational, longitudinal, prospectical study following PD patients since LD start. Based on previous evidence, we estimated that a 2-year observation period will be enough to reach significant differences in the primary outcomes. Indeed, previous studies demonstrated that both motor fluctuations (detected by WOQ in 42% of patients with disease duration>2,5 years) and DYS (observed within 9 months since LD start in early PD patients, in different rates based on LD dosage: 30% in patients on 600 mg/die, 18% in patients on 300 mg/die; 16% in patients on 150 mg/die) appear early in the course of the disease [18,19]. Having biomarkers able in identifying patients at higher risk for MNMF and DYS would have different implications. On the clinical ground and in the near future, clinician may better identify PD patients at higher risk and consequently adopt a more conservative behavior (e.g., using lower LD dose and/or preferring to add an i-MAO/DA instead of increasing LD). In particular, by identifying predictive factors for motor complications in parkinsonian women, this study would provide guidance on a pharmacological approach tailored by gender. Notwithstanding the large amount of evidence of the recent years, therapeutic management of PD is still mostly based on clinician's experience. Deeply knowledge of clinical and biological predictors of MNMF and DYS would further improve the tailoring of antiparkinsonsonian medications based on patient's need. In turn, this may implicate longer time for PD patients to reach the complicated phase of the disease often requiring expensive and invasive complex treatments (i.e., infusional therapies and stereotactic surgery). On a research ground and in the distant future, discovering DNA and RNA-based markers of development of MNMF and DYS may boost the development of novel therapies tailored for subjects at higher risk for LD-related complications. Furthermore, this study might give a boost to the starting of an Italian network of centers interested in PD-related gender medicine all over the national territory (including North, Centre, South and Islands).

Background -c (max 4.000 characters)

Please describe: drug/drugs/ therapeutic regimen information

This is an observational, longitudinal study enrolling PD patients requiring LD administration upon clinician judgment. All enrolled patients, both men and women, will be treated with either Levodopa/Carbidopa (brand name: Sinemet) or Levodopa/Benserazide (brand name: Madopar) and/or Melevodopa/Carbidopa (brand name: Sirio).

LD is an oral, approved, on-label treatment for PD. As such, the costs for the drug will be on the NHS. Furthermore, being an observational study, we will not give indications on the dose as well as on the titration, which will be based on clinician judgment. Below, we describe some information on LD available in different formulations.

The optimum daily dosage of LD must be determined by careful titration in each patient. LD tablets are available in a 1:4 ratio of carbidopa/benserazide to LD (Sinemet and Madopar 25-100; Madopar 50-200; Sirio 25-100) as well as 1:10 ratio (Sinemet 25-250; Sirio 12,5-125). Tablets of the two ratios may be given separately or combined as needed to provide the optimum dosage.

Initiation of treatment: Dosage may be initiated with either Sinemet, Madopar or Sirio 25-100 with one tablet three or four times a day.

Dosage may be increased by one tablet every day or every other day until the targeted clinical benefit is reached.

Maintenance: Therapy should be individualized and adjusted according to the desired therapeutic response. When more LD is required, Sinemet 25-250 or Madopar 50-200 should be used. If necessary, the dosage may be increased by one-half or one tablet every day or every other day until the targeted clinical benefit is reached. The occurrence of involuntary movements may require dosage reduction.

Other common side effects include nausea and vomit and may require the transient co-administration of domperidone.

For further information cross-reference with drug information leaflets is suggested.

Rationale (max 4.000 characters)

Please describe: the possible impact on the Italian National Health Service (NHS) and/or on study population; the innovativeness of the study and the possible benefit/risk ratio.

This would be the first Italian study focused on gender differences in PD. Several reasons account for the paucity of data regarding parkinsonian women. The majority of PD patients are men and all the pharmacological studies include more men than women. Then, women are less keen than men in undertaking PD complex treatment for LD-related complications as stereotactic surgery. Notwithstanding, MNMF and DYS affect more frequently women. As a result, clinicians usually apply the evidence coming from studies including mainly men to women as well. As a matter of fact, recommendations for PD treatments take into account age at onset, disease duration but not gender. Deeply knowledge in the gender-related predictors of LD-related complications may provide clinician with helpful suggestions for LD management by gender in order to delay LD-related complications as much as possible. MNMF and DYS are highly disabling for patients and their caregiver and determine high costs for the NHS. Parkinson's disease has been added among the chronic disease target of the "National action plan for chronic disease" released on February, 2016. The ultimate goal of this plan is to improve the management of chronic patients to reduce costs for the NHS. Improving LD management during the early phase of PD would determine a delay of onset of LD-related complication which, in turn, would determine a reduction of patients disability and caregivers burden as well as NHS costs.

As for the innovativeness of the study, we aim at assessing the role of genetic and biological markers as predictors of development of MNMF and DYS. First, identifying reliable markers for LD-related complications would help identifying those subjects at higher risk. Furthermore, it would also support the discovery of new potential pharmacological treatments to be administered specifically to subjects carrying those markers. This would be the real tailoring of the antiparkinsonian treatment.

As for the benefit/risk ratio, this study has no specific risks. Being an observational study using an on-label treatment for PD, patients are not exposed to new, off-label treatment or the possibility of receiving placebo. On the other hand, enrolled subjects would benefit of a greater number of assessments possibly identifying unwanted side effects which can be properly addressed (e.g., impulse control disorders).

Objectives of the study (max 4.000 characters)

Please report the primary objectives and, if any, the secondary objectives of the study, the purpose of the trial and state the statistical hypothesis (e.g. superiority, equivalence or non-inferiority for the primary endpoint(s)).

The statistical hypothesis of this study is that PD MNMF and DYS incidence and predictors differ by gender. Such hypothesis will be tested through the following primary and secondary objectives.

The primary objectives of this study are:

- 1) describe gender differences in the development of MNMF during the 2-year observation period since the start of LD as evaluated by the 19-item Wearing-Off Questionnaire (WOQ-19)
- 2) describe gender differences in the development of DYS and motor fluctuations during the 2-year observation period since the start of LD as evaluated with the Movement Disorders Society-Unified Parkinson's disease rating scale-motor complications section (MDS-UPDRS-IV)

The secondary objectives are:

- 1) describe the gender-related differences in LD pharmacokinetics at visit 1, 2 and 3 as predictors of MNMF and DYS
- 2) describe the gender-related changes of metabolism at visit 1, 2 and 3, as evaluated with bioimpedanzometry and calorimetry, as predictors of MNMF and DYS
- 3) describe the gender-related changes in miRNAs at visit 1, 2 and 3 as predictors of MNMF and DYS
- 4) describe the role of gender-related dopamine and opioid receptors polymorphisms as well as the role of the genes responsible for typical forms of PD as predictors of development of MNMF and DYS
- 5) describe gender-related differences in behavioral complications from dopaminergic treatment (as assessed with the Parkinson's Disease Impulsive-Compulsive Disorders Questionnaire [QUIP]) and in progression of disease as assessed with motor (MDS-UPDRS-motor section [part III]) and non motor evaluations (MDS-UPDRS-non motor part [I], Hamilton Depression and Anxiety rating scale [HAM-D, HAM-A], Apathy scale [AS], Scales for Outcomes in Parkinson's disease - Autonomic [SCOPA-AUT], non motor symptoms severity scale [NMSS], Montreal Cognitive assessment battery [MoCA]) as well as in activities of daily living (as assessed with MDS-UPDRS-activities of daily living [part II] and Schwab&England activities of daily living [SEADL]) and quality of life (as assessed with the 39-item Parkinson's disease quality of life [PDQ-39]).

The secondary objectives 1,2,3 and 4 will be performed in a subgroup of at least 120 subjects.

Study design (max 4.000 characters)

Please describe the methodology applied according to questions on study proposal and implementation.

This is a 24-month longitudinal, prospective, observational study evaluating gender discrepancies in incidence and predictors of MNMF and DYS in a large cohort of PD patients started on LD. The project will last 36 months including 2 months for ethical approval and AIFA submission, 6-month screening period, 24-month observational period (including 3 visits, 1 before LD start and then 1- and 2-year after LD start), 4 months for data managing period (data lock, data cleaning, data analysis and production of the final report) and will involve 15 Italian movement disorders centers all over the country in accordance with Good Clinical Practice guidelines and the principles of the Declaration of Helsinki (see flowchart of the study and schedule of activities attached).

Study population (max 4.000 characters)

Please report: study population characteristics and the clinical setting (hospital, general practice, etc.) where the study will be conducted; enrolment procedure and accrual time. Please specify if special populations will be included in the study, also for those studies not related to this specific topic. Please specify withdrawal criteria and procedures.

Study population will include 293 idiopathic PD patients either drug-naïve or already on i-MAO and/or dopamine agonists and requiring LD. Subjects will be recruited consecutively during outpatient clinics in 15 Italian movement disorders centers. Enrollment will be run during routine clinics and will last 6 months. To increase enrollment, we will also consider announcements on the PD Italian associations webpages (www.accademialimpedismov.org), visited by thousands of Italian PD patients and caregivers. Being an observational study and enrolling consecutive outpatients, we are expecting to include 2/3 men and 1/3 women. Based on previous evidence (see paragraph on sample size estimate), this M:F ratio would be sufficient to reach the primary endpoints.

Although this project is presented for the gender medicine section, indeed it also includes fragile patients as elderly subjects affected by a neurodegenerative condition. Since the mean age for PD onset is 60 years old, we are estimating to include more than 50% of subjects with age above 65 years old (i.e., elderly). Participants with early termination due to all causes other than death will be asked to perform an early termination visit (with the same assessments as 1- or 2-year visit). Subjects with early termination for whom an in-hospital early termination visit will not be possible due to disease progression or other factors other than death, will be assessed by telephone using a structured interview. Early termination will be considered for subjects presenting serious adverse events, adverse events likely linked to the study drug.

Inclusion criteria (max 4.000 characters)

Subjects may be included in the study only if they meet all of the following criteria:

- 1) Clinical diagnosis of PD according to the United Kingdom Parkinson's disease Society Brain Bank criteria
- 2) Requiring LD administration based on clinician judgment AND drug-naïve for dopaminergic medications OR on monoaminoxidase inhibitors (i-MAO), as selegiline and rasagiline, AND/OR on one of the available dopamine agonists (DA), as pramipexole, ropirinoles and rotigotine
- 3) Aged 41 to 85 years at the time of screening
- 4) Judged by investigator to be able to comply with evaluations at baseline and throughout the study
- 5) Subjects able to provide written informed consent to participate in the study
- 6) Subjects reside outside a skilled nursing facility or dementia care facility at the time of screening, and admission to such a facility is not planned. Residence in an assisted living facility is allowed
- 7) Stable on other chronic medications for at least 30 days prior to screening.

Exclusion criteria (max 4.000 characters)

Subjects will be excluded from the study for any of the following reasons:

- 1) Any of the following: a. Abrupt onset of neurological symptoms associated with ictal events, b. Head trauma related to onset of neurological symptoms c. Cerebellar ataxia, d. Chorea/athetosis, e. Early, symptomatic autonomic dysfunction, e. Early postural instability and falls
- 2) Presence of other significant neurological or psychiatric disorders
- 3) Active suicidal ideation
- 4) Dementia as diagnosed according with DSM IV criteria
- 5) Concurrent treatment with memantine; acetylcholinesterase inhibitors; antipsychotic agents (other than quetiapine) or mood stabilizers (e.g., valproate, lithium)
- 6) History of deep brain stimulator surgery
- 7) Women who are pregnant or lactating and women of childbearing potential who are not using methods of birth control
- 8) History of a clinically significant medical condition that would interfere with the subject's ability to comply with study instructions, would place the subject at increased risk, or might confound the interpretation of the study results
- 9) Structural abnormality on available MRI that precludes diagnosis of PD, such as cortical infarct in brain region that might account for subject's symptoms
- 10) Known hypersensitivity to LD

Intervention (max 4.000 characters)

Please provide detailed information about treatments (or other type of intervention) for each group (treatment and control), including:

- Dose (and dose escalation) and the dosage form, packaging and labelling of the IMP;
- Duration of treatment (including number and duration of the cycles, if applicable) and the follow-up period for each IMP/trial treatment group/arm of the trial;
- Route of administration;
- Medication/treatment (including rescue medications) and not permitted before and/or during the trial;
- Procedure for monitoring subjects compliance;
- Description of the “stopping rules” or “discontinuation criteria” for individual subjects, part of trial, and entire trial;
- Accountability procedures for the IMP, including placebo and comparator if any.

For observational studies, the specific characteristics of the investigated exposure/treatment should be described.

This is a 24-week observational, longitudinal study enrolling PD patients requiring LD administration. Since the objective of the study is describe gender-related differences in incidence and predictors of MNMF and DYS the head to head comparisons will be between men and women and there will be no control group treated with placebo.

Being an observational study, there will be no standard maintaining or escalation dose. Every enrolled patient will follow the LD regimen based on clinician judgment and suggestions. LD is an oral, on-label treatment for PD and related costs will be on the NHS.

This study will last 24 months and will include 3 in-clinic evaluations (1 before LD start and then 1- and 2-year after LD start).

No rescue medication is needed. Dopaminergic treatment (including i-MAO and DA) may be modified according to clinician judgment and data will be recorded in the CRF.

Being an observational study involving an on-label treatment dispensed by the NHS with no fixed maintaining and escalation dose, there will be no accountability procedures for LD. However, in order to monitoring subjects compliance the Morisky Medical Adherence scale 8-items will be administered at 1- and 2-year visit [20].

Discontinuation criteria will include: death, SAEs, AEs likely related to the study drug in the opinion of the investigator, withdrawal of the consent form.

LD specific characteristics have been described in paragraph Background c. For further information cross-reference with drug information leaflets is suggested.

Outcomes (max 4.000 characters)

Please report: the primary and secondary outcome measures; the procedure for the ascertainment of the outcomes (with particular emphasis on the relation between subjective/objective evaluation of endpoints and blinding), justifications to support the validity of any surrogate or composite endpoints, if applicable (a brief comment on the clinical relevance of the aforementioned endpoints should be also included).

Primary outcome measures will include the WOQ-19, which is a self-administered questionnaire consisting of 9 items assessing fluctuations of motor symptoms (tremor, weakness, problems in speech, balance, slowness, reduced dexterity, general stiffness, muscle cramps and difficulty in getting out of the chair) and 10 items assessing non motor symptoms (including anxiety, fluctuating mood, sweating, pain, aching, feeling of hot and cold, cloudy mind, numbness, abdominal discomfort, panic attacks) (range:0-19). For each item patients are asked if the symptom is present and if improves after the following dose of antiparkinsonian treatment. A cut-off ≥ 2 has been previously established to disclose a diagnosis of wearing off (i.e., MNMF). As for DYS evaluation, the MDS-UPDRS-IV will be used, which assesses the presence/absence, severity and functional impact of DYS as well as of motor fluctuations (range: 0-24).

Being an observational study, there is no blinding to treatment for neither the clinicians or the patients. However, both the WOQ-19 and the MDS-UPDRS have been previously used in several unblinded studies involving PD patients and proven to efficaciously describe PD clinical condition. Furthermore, the WOQ-19 is a self-administered questionnaire, thus mainly based on patient's evaluation and not influenced by clinician judgment, while MDS-UPDRS-IV is mainly based on clinician judgment during patient interview. Thus, we will also have the opportunity to compare patients versus clinician perspective on motor fluctuations.

Secondary outcome measures will include:

1) laboratory data relative to LD pharmacokinetics (AUC, Cmax and t1/2 analysed using a validated analytical method as liquid chromatography tandem mass spectrometry) and mirRNA (quantified using mircury LNA assay (Exiqon) and expression fold changes will be calculated by the $2^{-\Delta\Delta CT}$ method) before and after starting LD (1- and 2-year follow up)

2) a genetic panel screening for polymorphisms in dopaminergic (DRD) and opioid receptors (OPRK1), ADOA2A, SV2C-SNPs as well as mutations in genes accounting for typical forms of PD (i.e., parkin, PINK1, DJ1, GBA, LRRK2) will be performed by using Taq-man SNP genotyping assays according to the protocol for the TaqMan allelic discrimination Real-Time PCR System (Applied Biosystems, CA, USA).

3) Body composition and Energy Expenditure evaluated with bioimpedanzometry and calorimetry before and after starting LD (1- and 2-year follow up)

4) the other sections of the MDS UPDRS (part I for non motor symptoms [range:0-52], part II for activities of daily living [range:0-52], part III for motor examination [range:0-136]; the SEADL evaluating the functional state (score range, 0-100); MoCA score evaluating cognition (range:0-30); the NMSS evaluating non motor symptoms (range: 0-360); quality of life evaluated with the 39-item Parkinson's disease questionnaire on the quality of life; the QUIP with 4 primary questions (one for each impulse control disorder) each scored with 5-point Likert scale (range 0-4); the AES evaluating apathy and consisting of 18 items; all items are scored on 4-point Likert scale with the following descriptors: not at all true, slightly true, somewhat true, very true (range: 18-72); the Hospital Anxiety Depression Scale (HADS) assessing the severity of anxiety and depressive symptoms; the SCOPA-AUT consisting of 23 items in six domains evaluating autonomic disturbances (range: 0-69).

Secondary outcome 1-3 will be assessed in a subgroup of at least 120 patients.

Methods -a (max 4.000 characters)

A description of the measures taken to minimize/avoid bias, including (but not limited to):

Randomization. Please report methods used to generate the random allocation sequence. Central randomization should be preferred; other randomization procedures should be adequately motivated. (Include a description of maintenance of trial treatment randomisation codes and procedures for breaking the code).

Blinding (masking). Please describe whether or not, the personnel involved in administering interventions and assessing outcomes is aware of group assignment and if not, how the success of masking is assessed.

Being an observational study, there is no blinding to treatment for neither the clinician or the patients. However, the clinician involved in scale administration will be blinded to LD dosage. Furthermore, both the WOQ-19 and the MDS-UPDRS have been previously used in several unblinded studies involving PD patients and proven to efficaciously describe PD clinical condition. Furthermore, the WOQ-19 is a self-administered questionnaire, thus mainly based on patient's evaluation and not influenced by clinician judgment, while MDS-UPDRS-IV is mainly based on clinician judgment during patient interview. Thus, we will also have the opportunity to compare patients versus clinician perspective on motor fluctuations. Finally, the majority of the scales used for secondary clinical outcomes are self-administered as the WOQ-19.

As for the other secondary outcomes, technicians involved in pharmacokinetics, genetics and mirRNAs evaluations will be blinded to LD dosage and patients gender. As for bioimpedanzometry and calorimetric evaluations, clinicians involved in these assessments will be blinded to LD dosage.

Methods -b (max 4.000 characters)

Information retrieval. Please report: data that will be gathered; the forms/tools used for the retrieval of information and their validity and reliability; the measures/indicators used; the potential sources of biases in the retrieval of information regarding study subjects and interventions/treatments; duration and frequency of follow up; expected estimate of subjects lost to follow up and possible implications for the findings of the study; potential confounding factors, and methods for taking into account their effect are of particular importance for observational studies. When the use of an electronic clinical reporting form (e-CRF) is envisaged, only validated systems that address traceability are acceptable (for instance, excel spreadsheets do not represent an adequate system for recording data). Please include in this section the identification of source data definition.

The scales included in the case report form (CRF) are attached. The CRF will be provided as printed version to each site in a number of 1 for each potential enrolled subject. Investigator will collect information on the printed CRF, then information will be transferred to the electronic CRF. Source documents will be kept at site for CRO inspection and will be identified with serial numbers preceded by a unique code different for each site involved. Being an observational study both clinician and patient will know the LD dosage. However, the clinician administering the scales will be unaware of patient's LD dosage to prevent biases derived from knowledge of treatment with higher dose.

Schedule of activities, including frequency of follow up is attached. Each subject will perform 3 hospital-based visits (lasting 4/5 hours) over the 24-month observation period.

According to previous studies, drop outs and lost to follow up should account for 10% of the sample size. This percentage has already been considered in the computation of the sample size (see next paragraph).

Methods -c (max 4.000 characters)

Sample size estimates. Please report the estimate of sample size and how it is determined. The information requested to calculate sample size includes the power, the level of significance, the underlying event rate in the population under investigation and the size of the treatment effect. Adjustment for other factors affecting the sample size calculation (e.g. expected compliance rates), should also be reported. For studies of equivalence – non inferiority the maximum acceptable difference should be stated.

Statistical analysis. Please report the main statistical analyses that will be carried out. Definition of the populations for main analysis, error probabilities, brief description of the statistical techniques, methods for additional analyses, such as subgroup analyses (if planned). Researchers should consider that the main statistical analyses that will be used in presenting the final findings (e.g., final reports, publications) need to be coherent with the content of this section. Explanation of each interim analysis (if planned) and predefined stopping rules should also be clearly stated.

Based on previous preliminary data available for the primary outcome (WOQ-19) [6] and considering a level of significance =0.05 and a power=80%, the estimate sample size is 266 according to Fleiss formula [21]. However, the final sample size required for this study include 10% of drop outs and is 293.

As for the statistical analysis, after checking the normal distribution of the variables by using both graphical and statistical methods, comparisons will be performed either by t-test or Mann-Whitney for continuous variables and Chi-square or Fisher exact test for categorical data, as appropriate. Accordingly, descriptive analyses will be shown in mean and standard deviation (SD), or median and interquartile range (IQR). Only fully completed scales will be considered for the statistical analysis.

The association between gender and outcomes will be explored by using multivariable logistic regression models for binary outcomes and multivariable ordered logistic regression models for ordinal outcomes. All models will be adjusted for significant covariates as age at onset, LD dosage, concomitant dopaminergic medications. Further covariates will be identified by means of exploratory analysis comparing disease features between genders. Results will be considered statistically significant if $p \leq 0.05$.

Methods -d (max 4.000 characters)

Organizational characteristics. Please describe: the participating centres, the specialties and experience needed for conducting the study. In case of multicentre studies, please specify:

- the institutions/units in charge of coordinating the study, assigning treatment, monitoring the procedures;
- the presence of steering committees and/or data monitoring committees (when applicable);
- the presence and the organization of centralized laboratories (when applicable).

Feasibility. Please describe: previous experience of the principal investigator; previous experience of the institution(s) that will coordinate the study; available technology that may be relevant for the study.

The following movement disorders centres will be involved:

Coordinating centre: Center for Neurodegenerative diseases (CEMAND), Department of Medicine, Surgery and Odontology "Scuola Medica Salernitana", University of Salerno, Principal Investigator: prof. Maria Teresa Pellecchia, collaborator: dr. Marina Picillo

1) Parkinson's disease center, University "Federico II" of Naples, Principal Investigator: prof. Giuseppe De Michele, collaborator: dr. Anna De Rosa

2) Department of Neurology General Hospital AOB "S. Michele", Cagliari, Principal Investigator: dr. Giovanni Cossu

3) Movement Disorders Centre, Hermitage-Capodimonte, Naples, Principal Investigator: dr. Marianna Amboni

4) IRCCS- Istituto di Scienze neurologiche and DIBINEM- Alma Mater Studiorum – Università di Bologna Principal Investigator: prof. Cesa Lorella Scaglione

5) IRCCS San Raffaele Pisana, Rome, Principal Investigator: prof. Fabrizio Stocchi

6) Dipartimento G.F. Ingrassia, sezione di Neuroscienze - University of Catania, Principal Investigator: prof. Alessandra Nicoletti

7) ISTITUTO NEUROLOGICO C. BESTA - MILANO, Unità di Neurologia, Principal Investigator: dr. Paola Soliveri

8) Neurology Unit, Azienda Ospedaliera di Rilievo Nazionale "S.G. Moscati, Principal Investigator: dr. Giulio Cicarelli

9) Fatebenefratelli e Oftalmico Hospital– Milan –Italy, Principal Investigator: dr. Vincenza Fetoni

10) Foundation I.R.C.C.S. "Ca' Granda" Ospedale Maggiore Policlinico, Milan, Principal Investigator: dr. Alessio Barnaba Di Fonzo

11) Department of Neurology and Clinical Neurophysiology, INSPE, San Raffaele Hospital Scientific Institute Milan, Principal Investigator: dr. Maria Antonietta Volontè

12) Casa di Cura Privata Villa Margherita- Neurology Service, Arcugnano (Vicenza), Principal Investigator: dr. Manuela Pilleri

13) Casa di Cura "Fondazione Gaetano e Piera Borghi", Brebbia (Varese), Principal Investigator: dr. Giulio Riboldazzi

14) Dipartimento di Sanità Pubblica, Medicina Clinica e Molecolare, Unità di Neurologia, University of Cagliari, Principal Investigator: dr. Paolo Solla

As for the laboratory testing, genetic analysis will be performed at the Molecular Neurogenetics Unit - "Center for advanced diagnostics and research on Neurological Mitochondrial Disorders of Infancy and Childhood" Department of Experimental Research and Diagnostics, Fondazione IRCCS Istituto Neurologico Carlo Besta, Milan, Principal Investigator: dr. Barbara Garavaglia; LD pharmacokinetics analysis will be performed at the Operative Unit of Clinical Pharmacology and Pharmacogenetics at University Hospital "San Giovanni di Dio e Ruggi d'Aragona" of the University of Salerno, Principal Investigator: dr. Valeria Conti

Monitoring of procedures will be assigned to a contract research organization (CRO).

The Principal Investigator of the study prof. Maria Teresa Pellecchia (coordinating centre) has been involved as Co-principal Investigator in several clinical trials involving movement disorders patients. Since she joined the Centre for Neurodegenerative Diseases at the University of Salerno in 2012 she performed as co-principal Investigator about 10 clinical observational and interventional trials for patients with Parkinson's disease and Multiple System Atrophy (a rare atypical parkinsonism). Thus, the personnel working at the Centre is well-trained in performing both phase 2 and phase 3 clinical trials and includes a study coordinator, two nurses and 4 neurologists experienced in clinical trials. Prof. Pellecchia's center is the only Italian site involved in the Parkinson's Progression Markers Initiative (PPMI), the international study founded by The Michael J. Fox Foundation for Parkinson's disease.

Furthermore, all the other Italian Principal Investigator involved and their collaborators have experience in clinical trials for movement disorders and neurodegenerative patients (CV attached).

Methods -e (max 4.000 characters)

Timing. Please report: the duration of the study (patient enrolment; treatment duration, follow up, etc.); predefined check points for the evaluation of work in progress; when the final report will be provided. Please estimate here the overall study duration from the First Patient First Visit (FPFV).

Good clinical practices. Experimental studies are required to be conducted in accordance with Good clinical practices (GCP). Please discuss what are the specific hazards of the study (e.g., risks for the patients, complexity of the study design, validity of the information retrieval, etc.), the procedures of risk minimisation (e.g., training activities, review of eligibility prior to randomization, data verification, drug reconciliation, etc.), the characteristics and frequency of monitoring activities and the institution(s) that will be in charge of this task.

Ethical aspects. Please describe: the potential risks for study subjects, either related to physical/psychological domains or to a possible excessive interference with the subject privacy, and the procedures that will be followed to prevent these potential risks. As mentioned above, it is not necessary to include the documentation required by the Italian ethics committees.

Insurance. Please include a comment about the application of the law about the study insurance agreement (DM 14 marzo 2009).

This will be a 24-month longitudinal, prospective observational study evaluating gender-related incidence and predictors of MNMF and DYS. The whole project will last 36 months including 2 months for regulatory approval (AIFA and ethical committee), 6-month screening period, 24-month observational period and 4 months for data cleaning, data analysis and final report. The study will involve 14 Italian movement disorders centers in accordance with Good Clinical Practice guidelines and the principles of the Declaration of Helsinki (see flowchart of the study attached). Duration estimation of the study from the First Patient First Visit (performed at the 3rd month after the AIFA and ethical committee approvals) is 30 months (Last Patient Last Visit). The last 4 months will be dedicated to the data managing and writing of the final report.

Each enrolled subject will participate in 3 in-hospital study visits over approximately 24 months.

The principal investigator, as well as all the Investigator involved in the participating centers, has already performed proper training for Good Clinical Practice compliance.

All personnel involved in the study will perform a teleconference training session on the study procedures before starting the enrollment to ensure uniformity in data collection.

Study medication compliance will be assessed with the Morinsky Medical Adherence scale 8-item.

Privacy issues will be managed according to Good Clinical Practice requirements. Each enrolled subject will be identified with a unique code in both the print and eCRF. As for the date of birth only the year will be available.

Being an observational study, insurance is not needed according to the Italian law (DM 14 March 2009).

References (max 4.000 characters or max 20/25 references)

Please report only the references that are strictly relevant to the study proposal. References should include authors (when there are more than 6 authors, report the first 3 authors only title, book or journal, year, volume number and page numbers. For books, the publisher should also be reported.

- 1)Lang AE, Lees A (2002) Management of Parkinson's Disease: An Evidence-Based Review, *Mov Disord* 17;S1-166.
- 2) Sharma JC, Bachmann CG, Linzasoro G (2010) Classifying risk factors for dyskinesia in Parkinson's disease, *Park Relat Disord* 16:490-497.
- 3)Cilia R, Akpalu A, Sarfo FS, et al. The modern pre-levodopa era of Parkinson's disease: insights into motor complications from sub-Saharan Africa. *Brain*. 2014 Oct;137(Pt 10):2731-42.
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- 11)Cilia R, Asselta R, Benfante R, Opioid K receptor variant delays the onset of dyskinesia in Parkinson's disease. poster MDS meeting Berlin 2016.
- 12)Zappia M, Annesi G, Nicoletti G, et al (2005) Sex differences in clinical and genetic determinants of levodopa peak-dose dyskinesias in Parkinson disease: an exploratory study, *Arch Neurol* 62:601-605.
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- 16)Serafin A, Foco L, Zanigni S, et al. Overexpression of blood microRNAs 103a, 30b, and 29a in L-dopa-treated patients with PD. *Neurology*. 2015;84(7):645-53.
- 17)Colombo D, Abbruzzese G, Antonini A, et al (2015) The "Gender Factor" in Wearing-Off among Patients with Parkinson's Disease: A Post Hoc Analysis of DEEP Study, *Scientific World Journal* 787451.
- 18) Stocchi F, Antonini A, Barone P, et al. Early DEtection of wEaring off in Parkinson disease: the DEEP study. *Parkinsonism Relat Disord*. 2014;20(2):204-11.
- 19)Fahn S, Oakes D, Shoulson I, et al. Levodopa and the progression of Parkinson's disease. *N Engl J Med* 2004;351:2498–2508.
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- 21)Fleiss, *Metodi di Statistica per Tassi e Proporzioni*, formule 3.18 & 3.19

Budget

Expenses need to be in line with the complexity of the study, adequately justified and detailed. Personnel related expenses should refer to the total number of person-months. The cost for drugs included in the Italian national formulary (reimbursed by the NHS) should not be incorporated since already covered by the NHS. To prepare the budget, please refer to the guidelines annexed to the Appendix B

C1. Personnel

Degree	Tasks	Contract	Participating centres	Duration (in months)	% of full time equivalent	Salary (€)	Quantity	Total (€) (salary* quantity)
MD	4. Clinical follow up	2. Contratto a tempo det.	Coordinating Centre	36	100,0%	€ 148.000,00	1,00	€ 148.000,00
PhD	1. Coordination	5. Assegno di ricerca	Coordinating Centre	12	33,0%	€ 24.000,00	3,00	€ 72.000,00
MD, PhD	1. Coordination	1. Contratto a tempo indet.	Coordinating Centre	36	8,0%	€ 7.264,00	1,00	€ 7.264,00
MD	5. Other	1. Contratto a tempo indet.	Coordinating Centre	12	35,0%	€ 17.500,00	3,00	€ 52.500,00
PhD	2. Data analysis	1. Contratto a tempo indet.	Coordinating Centre	14	100,0%	€ 7.875,00	1,00	€ 7.875,00
PhD	4. Clinical follow up	1. Contratto a tempo indet.	Operative Unit 1	36	8,0%	€ 9.938,00	1,00	€ 9.938,00
MD	4. Clinical follow up	1. Contratto a tempo indet.	Operative Unit 1	36	8,0%	€ 5.295,00	1,00	€ 5.295,00
MD	4. Clinical follow up	1. Contratto a tempo indet.	Operative Unit 2	36	16,0%	€ 10.591,00	1,00	€ 10.591,00
MD	4. Clinical follow up	1. Contratto a tempo indet.	Operative Unit 3	36	16,0%	€ 10.591,00	1,00	€ 10.591,00

MD	4. Clinical follow up	1. Contratto a tempo indet.	Operative Unit 4	36	16,0%	€ 10.591,00	1,00	€ 10.591,00
MD	4. Clinical follow up	1. Contratto a tempo indet.	Operative Unit 5	36	8,0%	€ 9.938,00	1,00	€ 9.938,00
MD	4. Clinical follow up	1. Contratto a tempo indet.	Operative Unit 6	36	10,0%	€ 9.080,00	1,00	€ 9.080,00
MD	4. Clinical follow up	1. Contratto a tempo indet.	Operative Unit 7	36	16,0%	€ 10.591,00	1,00	€ 10.591,00
MD	4. Clinical follow up	1. Contratto a tempo indet.	Operative Unit 8	36	16,0%	€ 10.591,00	1,00	€ 10.591,00
MD	4. Clinical follow up	1. Contratto a tempo indet.	Operative Unit 9	36	16,0%	€ 10.591,00	1,00	€ 10.591,00
MD	4. Clinical follow up	1. Contratto a tempo indet.	Operative Unit 10	36	16,0%	€ 10.591,00	1,00	€ 10.591,00
MD	4. Clinical follow up	1. Contratto a tempo indet.	Operative Unit 1	36	16,0%	€ 10.591,00	1,00	€ 10.591,00
MD	4. Clinical follow up	1. Contratto a tempo indet.	Operative Unit 2	36	16,0%	€ 10.591,00	1,00	€ 10.591,00
MD	4. Clinical follow up	1. Contratto a tempo indet.	Operative Unit 3	36	16,0%	€ 10.591,00	1,00	€ 10.591,00
MD	4. Clinical follow up	1. Contratto a tempo indet.	Operative Unit 4	36	16,0%	€ 10.591,00	1,00	€ 10.591,000
PhD	5. Other	1. Contratto a tempo indet.	Operative Unit 5	36	8,0%	€ 7.200,00	1,00	€ 7.200,00

PhD	5. Other	1. Contratto a tempo indet.	Operative Unit 5	6	100,0%	€ 11.500,00	2,00	€ 23.000,00			
PhD				5. Other	1. Contratto a tempo indet.	Operative Unit 6	36	33,0%	€ 21.780,00	1,00	€ 21.780,00
								0,0%			€ 0,00
								0,0%			€ 0,00
								0,0%			€ 0,00
								0,0%			€ 0,00
								0,0%			€ 0,00
								0,0%			€ 0,00
								0,0%			€ 0,00
								0,0%			€ 0,00
		0,0%			€ 0,00						
Total (€)								€ 490.371,00			

C2. Supplies

Please specify the cost of the main categories of supplies for the entire project

Categories of Supplies	Brief description, if needed (max 200 chars.)	Total budget for the entire project and for all participating centres (€)
1. Hardware		
2. Software		
3 Device		
4. Stationery	Stationery	€ 1.500,00
5. Other (specify; e.g.: labs material)	Laboratory material for: 1)RNA purification kits, MicroRNAs assays, plastics=73.250; 2)genetic analysis: 4 panels=64.000; 3)pharmacokinetics=21.200 Calorimetry/Bioimpedenzometry=24.000	€ 182.450,00
6. Other costs for supplies	Questionnaires and local study files	€ 5.000,00
Total (€)		€ 188.950,00

C3. Services

Please specify the cost of the main categories of services for the entire project

Services	Brief Description, if needed (max 200 chars.)	Total budget for the entire project and for all participating centres (€)
1. Data collection (e.g.: e-CRF)	e-CRF	€ 35.000,00
2. Study Monitoring		
A. Number of Expected site visit per centre		2,00
B. Number of Clinical centres		13,00
C. Number of Total site visits (automatic A x B)		26,00
D. Average cost for site visit (*) (*) <u>Excluding personnel and/or travels already budgeted in table C1 and/or C5</u>		€ 500,00
E. Total cost (C x D)		€ 13.000,00
3. Other (specify, e.g.: Publication costs – Reprints)		
Total (€)		€ 48.000,00

C4. Drug costs

	Brief description, if needed (max 200 chars.)	Total budget for the entire project (€)
Costs for drug(s) (blinding and/or packaging and/or placebo) for not approved indications, <u>if not provided free of charge by a Company or paid by others</u>		€ 0,00
In case the <u>drug(s)(*)</u> will be <u>provided free of charge</u> , please specify the provider:	Provided by others, please specify Note (to specify) Levodopa in on-label treatment for PD, as such the cost will be on the National Health System	

C5. Meetings, conferences, workshops, travels

	Brief description, if needed (max 200 chars.)	Total budget for the entire project and for all participating centres (€)
1. Coordination meetings	A coordination meeting before the start of the study will be held as a web-based teleconference	€ 3.000,00
2. Participation in scientific conferences (in Italy or abroad)		
3. Organization of scientific conferences related to the study project		
4. Travels	Included in previous item costs (monitoring)	
5. Other (specify)	Delivery of samples for genetic miRNAs and pharmacokinetics testing	€ 25.000,00
Total (€)		€ 28.000,00

C6. Overall expected costs for each of the items indicated below and for each year of the project

Please specify the overall expected costs for each of the items indicated below and for each year of the project

Items	Expected costs for the 1° year (€)	Expected costs for the 2° year* (€)	Expected costs for the 3° year* (€)	Total (€)
Personnel	€ 170.717,00	€ 170.717,00	€ 170.717,00	€ 512.151,00
Supplies	€ 62.983,00	€ 62.983,00	€ 62.983,00	€ 188.949,00
Services	€ 16.000,00	€ 16.000,00	€ 16.000,00	€ 48.000,00
Travels/ Meetings/ Courses	€ 9.330,00	€ 9.330,00	€ 9.330,00	€ 27.990,00
Overhead (max 10% of total)	€ 12.835,00	€ 12.835,00	€ 12.835,00	€ 38.505,00
Sub-total (€)	€ 271.865,00	€ 271.865,00	€ 271.865,00	€ 815.595,00
Drugs cost	€ 0,00	€ 0,00	€ 0,00	€ 0,00
Total (€) (Sub-total + Drugs cost)				€ 815.595,00

* If applicable

C7. Distribution of costs between coordinating and participating centres

	Total Costs (€)	%
Coordinating centre	€ 492.153,00	60,0%
Transfer to other centres	€ 323.442,00	40,0%
Total (€)	€ 815.595,00	100%

C8. Budget Annotation (not mandatory)

Note1: In the coordinating centre budget are included the followings: CRO expenses (including data analysis, monitoring, teleconference-based coordination meeting, travel expenses, e-CRF) and lab materials for mirRNA and pharmacokinetics

Note 2: one of the strenght of the project is the inclusion of 15 Italian movement disorders centers (including the coordinator). However, in section C1 relative to personnel costs there was the possibility to add up to 10 participating unit. Thus, the remaining 4 have been added repeting the count from Unit 1 to 4. Then at the end of C1 section the unit in charge of the genetic testing has been named as Unit 5 and the unit in charge of pharmacokinetic analysis has been named as Unit 6 (both repetitions)

Institution agreement (max 4.000 characters)

The Principal Investigator should state his/her willingness to submit in the Observatory on Clinical Trials all the documentation required by law to AIFA, as the Competent Authority and to Ethics Committee within 60 days of signing the contract.

Moreover, the Principal investigator should state the acceptance to conduct the study, as well as the institution agreement for the use of the human and technological resources described in the study protocol. Principal Investigator declaration must be presented within the study protocol; the institutional agreement has to be available by the date of contract signature.

The principal investigator declares she will present all the documentation needed according to current norms to AIFA, Observatory on Clinical Trials as the Competent Authority, and Ethical Committee within 60 days of contract signature. The Principal investigator states she accepts to conduct the study, as well as the institution agrees for the use of the human and technological resources described in the study protocol. Furthermore, the principal investigator declares her institution accept to run the study rendering personnel and technology available. Institutional agreement will be available by the date of the signature of the contract.

List of the investigators in charge of the units dedicated to data analysis and to GCP monitoring of the study (max 4.000 characters)

Please report the investigators responsible for the units dedicated to data analysis and GCP monitoring of the study (when applicable) –please make sure to follow applicable monitoring requirements.

Data analysis and GCP monitoring will be performed by a contractualized CRO. All investigator involved will be asked to present an update GCP certificate before taking part into the study.

A teleconference coordination meeting will be held before starting the study where two involved participants from each centre will take part. Investigators will perform assessments training and will learn al the study procedures.

CRO will ensure 2 monitoring visits for each site.

Curriculum vitae

-Name: Maria Teresa PELLECCIA
-Birth date: 3/6/1970
-Birth place: Avellino
-Personal Address: Via Tuoro 69, 83100 Avellino
-Office Address: Department of Medicine, University of Salerno
-Phone: +39-3274003951 (mobile), 089/969121 (office)
-E-mail: mpelleccia@unisa.it

Professional Position:

Associate Professor in Neurology at Department of Medicine and Surgery, University of Salerno, Italy

EDUCATION:

1988-1994 Student at the School of Medicine of University of Naples, Federico II
July 1994 Medical degree with honours from the University of Naples, School of Medicine
1999 Board of Neurology with honours from the University of Naples, School of Medicine
2000-2001 PhD in Neurodegenerative Disorders at the Department of Neurological Sciences, University "Federico II", Naples
2001-2005 PhD Degree in Neurosciences at the University of Naples, Federico II, with a thesis entitled: "Arginine test in the differential diagnosis of Parkinson's disease and atypical parkinsonisms".

TRAINING & EMPLOYMENT:

1999-present Consultant at the Regional Centre for Parkinson's Disease and Movement Disorders (Chair: Professor Paolo Barone) at the Department of Neurological Sciences, University "Federico II", Naples
2006-2010 Fellow at the Department of Neurological Sciences, University of Naples, Federico II
2011-2012 Researcher at the Department of Neurological Sciences, University of Naples, Federico II
2012-2014 Researcher in Neurology at the Department of Medicine, University of Salerno
Assistant neurologist at Center for Neurodegenerative Diseases (CEMAND), University of Salerno
2014-present Associate Professor in Neurology at the Department of Medicine, University of Salerno.
Chief of the Unit of Experimental Neurology at the University Hospital of Salerno San Giovanni di Dio e Ruggi d'Aragona.

Scientific activity

Prof. Pellecchia is author of more than one hundred papers on international journals with peer-review.

Her research interests include: progression of movement disorders, with particular regard to Parkinson's disease and multiple system atrophy; neuroendocrinology of Parkinson's disease and atypical parkinsonisms; neuroimaging in the differential diagnosis of parkinsonian syndromes; clinical neuropharmacology of movement disorders; blood and imaging biomarkers in neurodegenerative diseases.

She contributed to clinical trials of several antiparkinsonian drugs. Her contributions in clinical research have been focused on both clinical and genetics of movement disorders, especially related to PD and parkinsonisms. She contributed to develop new tests for the differential diagnosis of parkinsonisms.

She is an active member of the EMSA-Study Group (European Multiple System Atrophy Study Group) that contributed to the clinical, genetic and neuroimaging characterization of MSA and performed double-blind randomized clinical trials in MSA patients.

Research support as Principal Investigator or Co-PI (last 3 years)

- **Insulin-like Growth Factor-1 and DAT Imaging as Biomarkers of Early Cognitive Impairment in Parkinson's Disease.** Cognition biomarkers, 2013; Michael J. Fox Foundation; Grant ID 8800
- **Seven Tesla MR imaging as preclinical biomarker in populations at risk for Parkinson disease.** Ricerca Finalizzata, Italian Ministry of Health 2013-2014
- **A serum miRNAs signature as potential biomarker for MSA.** The Multiple System Atrophy Coalition, 2016.

Miscellaneous

- 2006-2009 Board of the Italian Movement Disorder Society (DISMOV-SIN)
- 2008 Co-organiser of the XXXV Congress of the Italian League for Parkinson's Disease (LIMPE), Salerno, Italy
- 2014 Co-organiser of the III Congress of Accademia LIMPE-DISMOV, Salerno, Italy
- 2016 Scientific and organizing Committee of the 5th International Congress on Multiple System Atrophy, Salerno, Italy
- 2016- Board of Accademia Limpe-DISMOV

Peer reviewed publications

- 1: Criscuolo C, D'Amico A, Peluso S, Popolizio T, Pellecchia MT. Adult-onset puretic disorder after post-traumatic hypoxic lesions of the globus pallidus.

Parkinsonism Relat Disord. 2016 Nov 18. pii: S1353-8020(16)30438-2.

2: Moccia M, Erro R, Picillo M, Vitale C, Longo K, Amboni M, Pellecchia MT, Barone P. Caffeine consumption and the 4-year progression of de novo Parkinson's disease. *Parkinsonism Relat Disord.* 2016 Nov;32:116-119.

3: Sailer A, Scholz SW, Nalls MA, Schulte C, Federoff M, Price TR, Lees A, Ross OA, Dickson DW, Mok K, Mencacci NE, Schottlaender L, Chelban V, Ling H, O'Sullivan SS, Wood NW, Traynor BJ, Ferrucci L, Federoff HJ, Mhyre TR, Morris HR, Deuschl G, Quinn N, Widner H, Albanese A, Infante J, Bhatia KP, Poewe W, Oertel W, Höglinger GU, Wüllner U, Goldwurm S, Pellecchia MT, Ferreira J, Tolosa E, Bloem BR, Rascol O, Meissner WG, Hardy JA, Revesz T, Holton JL, Gasser T, Wenning GK, Singleton AB, Houlden H; European Multiple System Atrophy Study Group and the UK Multiple System Atrophy Study Group.. A genome-wide association study in multiple system atrophy. *Neurology.* 2016 Oct 11;87(15):1591-1598.

4: Erro R, Picillo M, Vitale C, Amboni M, Moccia M, Santangelo G, Pellecchia MT, Barone P. The non-motor side of the honeymoon period of Parkinson's disease and its relationship with quality of life: a 4-year longitudinal study. *Eur J Neurol.* 2016 Nov;23(11):1673-1679.

5: Pellecchia MT, Savastano R, Moccia M, Picillo M, Siano P, Erro R, Vallelunga A, Amboni M, Vitale C, Santangelo G, Barone P. Lower serum uric acid is associated with mild cognitive impairment in early Parkinson's disease: a 4-year follow-up study. *J Neural Transm (Vienna).* 2016 Dec;123(12):1399-1402.

6: Morgante F, Fasano A, Ginevrino M, Petrucci S, Ricciardi L, Bove F, Criscuolo C, Moccia M, De Rosa A, Sorbera C, Bentivoglio AR, Barone P, De Michele G, Pellecchia MT, Valente EM. Impulsive-compulsive behaviors in parkin-associated Parkinson disease. *Neurology.* 2016 Oct 4;87(14):1436-1441.

7: Barone P, Santangelo G, Amboni M, Pellecchia MT, Vitale C. Pisa syndrome in Parkinson's disease and parkinsonism: clinical features, pathophysiology, and treatment. *Lancet Neurol.* 2016 Sep;15(10):1063-74.

8: Santangelo G, Falco F, D'Iorio A, Cuoco S, Raimo S, Amboni M, Pellecchia MT, Longo K, Vitale C, Barone P. Anxiety in early Parkinson's disease: Validation of the Italian observer-rated version of the Parkinson Anxiety Scale (OR-PAS). *J Neurol Sci.* 2016 Aug 15;367:158-61.

9: Moccia M, Pellecchia MT, Spina E, Barone P, Vitale C. Bilirubin and Uric Acid: Two Different Anti-oxidants in Parkinson's Disease. *Cell Biochem Biophys.* 2016 Jun;74(2):91-2.

10: Erro R, Picillo M, Vitale C, Palladino R, Amboni M, Moccia M, Pellecchia MT, Barone P. Clinical clusters and dopaminergic dysfunction in de-novo Parkinson disease. *Parkinsonism Relat Disord.* 2016 Jul;28:137-40.

11: Picillo M, Palladino R, Moccia M, Erro R, Amboni M, Vitale C, Barone P, Pellecchia MT. Gender and non motor fluctuations in Parkinson's disease: A prospective study. *Parkinsonism Relat Disord.* 2016 Jun;27:89-92.

12: Picillo M, Santangelo G, Moccia M, Erro R, Amboni M, Prestipino E, Longo K, Vitale C, Spina E, Orefice G, Barone P, Pellecchia MT. Serum uric acid is associated with apathy in early, drug-naïve Parkinson's disease. *J Neural Transm (Vienna).* 2016 Apr;123(4):371-7.

13: De Rosa A, Pellegrino T, Pappatà S, Pellecchia MT, Peluso S, Saccà F, Barone P, Cuocolo A, De Michele G. Myocardial (123)I-metaiodobenzylguanidine scintigraphy in patients with homozygous and heterozygous parkin mutations. *J Nucl Cardiol.* 2015 Dec 1. [Epub ahead of print]

- 14: Moccia M, Erro R, Picillo M, Santangelo G, Spina E, Allocca R, Longo K, Amboni M, Palladino R, Assante R, Pappatà S, Pellecchia MT, Barone P, Vitale C. A Four-Year Longitudinal Study on Restless Legs Syndrome in Parkinson Disease. *Sleep*. 2016 Feb 1;39(2):405-12.
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Public Declaration of Interests /Confidentiality Undertaking /Consent to personal data processing for those collaborating with AIFA activities

The present document consists of four parts, Personal Data, Public Declaration of Interests, Confidentiality Undertaking and Consent to personal data processing. All parts must be duly filled, signed and dated.
Should the document be hand – filled, make sure that any information is readable. Also not applicable or not pertinent fields have to be crossed off in any case.

PERSONAL DATA

I, (Qualification) Professor (First Name) Maria Teresa (Surname) Pellicchia

Country : Italy

Company / Institution: Center for Neurodegenerative

Diseases, Department of Medicine, Surgery and

Odontology "Scuola Medica Salernitana", University of

Salerno

Business address: Via S. Allende 1, 84081 Baronissi (Sa)

e-mail address: mpellicchia@unisa.it

Aware of the contents of the Italian criminal legislation in the event of false declarations and forgery of documents according to art.76 of the Presidential Decree n. 445 of 28/12/2000, I declare, under my own responsibility that I read the last section of this document called "Definition and Instructions for Filling" and I have not other direct or indirect interests in the pharmaceutical industry in addition to those listed below.

Table 1. Public Declaration of Interests ¹

Interests in pharmaceutical industry	NO	Current	From 0 to 3 previous years	Over 3 previous years
DIRECT INTERESTS:				
1.1 Employment with a company: pharmaceutical company in an executive role	☒	☐	☐	☐ mandatory
1.2 Employment with a company: in a lead role in the development of a medicinal product	☒	☐	☐	☐ mandatory
1.3 Employment with a company: other activities	☒	☐	☐	☐ optional
2. Consultancy for a company	☒	☐	☐	☐ optional
3. Strategic advisory role for a company	☒	☐	☐	☐ optional
4. Financial interests	☒	☐	☐	☐ optional
5. Ownership of a patent	☒	☐	☐	☐ optional
INDIRECT INTERESTS:				
6. Principal investigator	☒	☐	☐	☐ optional
7. Investigator	☐	☒	☒	☐ optional
8. Grant or other funding	☐	☒	☒	☐ optional
9. Family members interests	☒	☐	☐	☐ optional

¹ Marking any grey box above (declared interests), you should provide further information in the following pages concerning the Company and the products. Should the form be filled in the grey part concerning the existence of any interests without providing further related information in the following pages, it shall be returned for completing it.

The Experts who have a collaboration with the AIFA must declare the interests of first-line members of the family of the expert (i.e. a spouse or a partner, children and parents)

Signature: Marco Irene Pellecchia Date: 4 December 2016

Table 2. DETAILS OF PUBLIC DECLARATION OF INTERESTS

(Fill this part if you have filled any grey box in table n. 1, otherwise cross off the following boxes anyway)

	Period of activity	Company or Institution	Products List all products for which you are responsible	Therapeutic Indication
1. Employment with a company				
	Period of activity	Company or Institution	Products List all products for which you have acted as consultant for developing them	Therapeutic Indication:
2. Consultancy for a company				
	Period of activity	Company or Institution	Area of activity/ Product	Therapeutic Indication:
3. Strategic advisory role for a company				
	Period of activity	Company or Institution	Type of financial interests	
4. Financial interests				
	Period of activity	Company or Institution	Area of activity/ Product	Therapeutic Indication:
5. Ownership of a patent				

Signature: Marco Irene Pellecchia Date: 4 December 2016

Table 2. DETAILS OF PUBLIC DECLARATION OF INTERESTS

(Fill this part if you have filled any grey box in table n. 1, otherwise cross off the following boxes anyway)

	Period of activity	Company or Institution	Area of activity/ Product	Therapeutic Indication:
6. Principal Investigator				
	Period of activity	Company or Institution	Area of activity/ Product	Therapeutic Indication:
7. Investigator		Biotie Astra Zeneca	Tozadenant Myeloperoxidase inhibitor	Parkinson's disease Multiple system atrophy
	Period of activity	Company or Institution	Type of Interest	
8. Grant or other funding	2013-2014	MJFox Foundation	Grant: Cognition biomarkers in PD	
	Current	MSA Coalition	Grant: miRNAs in MSA and PD	
	Current	Ricerca Finalizzata, Italian Ministry of Health 2013-2014	Research support as Coinvestigator: Seven Tesla MR imaging as preclinical biomarker in populations at risk for Parkinson disease	
	Period of activity	Company or Institution	Type of Interest	
Family Interests				

Signature: Anna Teresa Pellecchia Date: 4 December 2016

In addition to the aforementioned interests, I, the undersigned, aware of the contents of the Italian criminal legislation in the event of false declarations and forgery of documents according to art.76 of the Presidential Decree n. 445 of 28/12/2000 and aware of sanctions provided for art. 15 of Regulation on the conflicts of Interests of AIFA, declare that I DO NOT HOLD any other interest or to know any fact that should be brought to attention of AIFA or of public.

Should any of such interests or facts exist, please specify below:

Should any change to what declared above occur, I will forthwith report it to AIFA, filling a new declaration of interests.

Signature: Rosanna Pellecchia

Date: 4 December 2016

Section reserved to AIFA

The conflicts of interest are classified into 3 categories:

- a) Direct interests: Direct interests are assigned the highest risk level (level 3);
- b) Indirect interests: Indirect interests are assigned an intermediate risk level (level 2);
- c) No interest declared: the lowest risk level is assigned in case of no interest (level 1).

Risk level assigned by evaluator:

- ☐ Level 3
- ☐ Level 2
- ☐ Level 1

NOTES or COMMENTS

The evaluator

Name Last name (block letters) _____

Signature _____

Date _____

Confidentiality Undertaking

Considering the following definitions:

"AIFA activity": any meeting (including preliminary and follow-up meetings, talks or any other related activity) of Board Of Directors, Technical Scientific Commission and its sub-committees, of any groups of experts or any similar meeting working as a group of experts on scientific evaluations or on the development of guidelines.

"Confidential information": all the information, facts, data and any other matter I know, directly or indirectly, as a consequence of my activities with AIFA.

"Confidential documents": all drafts, preliminary information, documents as well as any other information to which I should have access, directly or indirectly as a consequence of my activities with AIFA, including documents, registrations and/or notes that I should write or register.

Should I attend any meeting and/or activity with AIFA, I commit myself:

1. To treat all confidential information and documentation in a strictly confidential way.
2. Not to disclose (or authorize any person to disclose) in any way to third parties² any confidential information or documentation.
3. Not to use (or authorize any person to use) any confidential information or documentation except for what is strictly related to my activities with AIFA.
4. To delete or destroy any confidential documents when no longer needed.
5. Not to disclose, unless expressly authorized, any document or any information to my knowledge related to my activities with AIFA.

Compliance with the aforementioned obligations shall not terminate with the end of the work relationship with AIFA. Such obligations shall not apply to documents and information that the undersigned may demonstrate to have known before the signing of this form, or that should be publicly disclosed for any reason not related to the breach of confidential information by the undersigned.

I declare that the information herewith provided are, for what I know, accurate and reliable and I agree that such information be kept and published on the AIFA web site, should AIFA consider such disclosure appropriate.

Signature: Nere Tere Pelledda Date: 4 December 2016

CONSENT to personal data treatment

I declare, under my own responsibility, that I have read the privacy Statement set out by par. 13, D. Lgs. N. 196/2003 (Italian Privacy Codice), available on AIFA website, section "Competitions", AIFA Consultants and Experts' List, on the following link:

http://www.agenziafarmaco.gov.it/sites/default/files/Mod350_03Rev.1_Informativa_privacy_consenso_trattamento_dati.pdf

and that I have found it complete.

I also declare to be aware that my name could not be inserted into AIFA Consultants' Database and I could not participate into any AIFA activity in case I refuse to sign this declaration.

Signature: Nere Tere Pelledda Date: 4 December 2016

² The Definition of "Third party" doesn't include the employees of Competent National Authorities who have signed confidentiality agreements or are subject to confidentiality obligations as a consequence of national legislations or duty of secrecy.

The following movement disorders centres will be involved:

Coordinating centre: Center for Neurodegenerative diseases (CEMAND), Department of Medicine, Surgery and Odontology "Scuola Medica Salernitana", University of Salerno,

Principal Investigator: prof. Maria Teresa Pellecchia, collaborator: dr. Marina Picillo, PD

patients followed in the last 2 years: 1500; estimated subjects to be enrolled in the study: 40

1) Parkinson's disease center, University "Federico II" of Naples, Principal Investigator: prof. Giuseppe De Michele, collaborator: dr. Anna De Rosa, PD patients followed in the last 2 years: 1000; estimated subjects to be enrolled in the study: 30

2) Department of Neurology General Hospital AOB "S. Michele", Cagliari, Principal Investigator: dr. Giovanni Cossu, PD patients followed in the last 2 years: 300; estimated subjects to be enrolled in the study: 25

3) Movement Disorders Centre, Hermitage-Capodimonte, Naples, Principal Investigator: dr. Marianna Amboni, PD patients followed in the last 2 years: 200; estimated subjects to be enrolled in the study: 20

4) IRCCS- Istituto di Scienze neurologiche and DIBINEM- Alma Mater Studiorum – Università di Bologna Principal Investigator: prof. Cesa Lorella Scaglione, PD patients followed in the last 2 years: 800; estimated subjects to be enrolled in the study: 25

5) IRCCS San Raffaele Pisana, Rome, Principal Investigator: prof. Fabrizio Stocchi, PD patients followed in the last 2 years: 1500; estimated subjects to be enrolled in the study: 30

6) Dipartimento G.F. Ingrassia, sezione di Neuroscienze - University of Catania, Principal Investigator: prof. Alessandra Nicoletti, PD patients followed in the last 2 years: 1000; estimated subjects to be enrolled in the study: 25

7) ISTITUTO NEUROLOGICO C. BESTA - MILANO, Unità di Neurologia, Principal Investigator: dr. Paola Soliveri, PD patients followed in the last 2 years: 1700; estimated subjects to be enrolled in the study: 25

8) Neurology Unit, Azienda Ospedaliera di Rilievo Nazionale "S.G. Moscati, Principal Investigator: dr. Giulio Cicarelli, PD patients followed in the last 2 years: 200; estimated subjects to be enrolled in the study: 20

9) Fatebenefratelli e Oftalmico Hospital– Milan –Italy, Principal Investigator: dr. Vincenza Fetoni, PD patients followed in the last 2 years: 400; estimated subjects to be enrolled in the study: 20

10) Foundation I.R.C.C.S. "Ca' Granda" Ospedale Maggiore Policlinico, Milan, Principal Investigator: dr. Alessio Barnaba Di Fonzo, PD patients followed in the last 2 years: 400; estimated subjects to be enrolled in the study: 20

11) Department of Neurology and Clinical Neurophysiology, INSPE, San Raffaele Hospital Scientific Institute Milan, Principal Investigator: dr. Maria Antonietta Volontè, PD patients followed in the last 2 years: 1000; estimated subjects to be enrolled in the study: 20

12) Casa di Cura Privata Villa Margherita- Neurology Service, Arcugnano (Vicenza), Principal Investigator: dr. Manuela Pilleri, PD patients followed in the last 2 years: 600; estimated subjects to be enrolled in the study: 20

13) Casa di Cura "Fondazione Gaetano e Piera Borghi", Brebbia (Varese), Principal Investigator: dr. Giulio Riboldazzi, PD patients followed in the last 2 years: 200; estimated subjects to be enrolled in the study: 20

14) Dipartimento di Sanita' Pubblica, Medicina Clinica e Molecolare, Unità di Neurologia, University of Cagliari, Principal Investigator: dr. Paolo Solla, PD patients followed in the last 2 years: 200; estimated subjects to be enrolled in the study: 20

As for the laboratory testing, genetic analysis will be performed at the Molecular Neurogenetics Unit - "Center for advanced diagnostics and research on Neurological Mitochondrial Disorders of Infancy and Childhood" Department of Experimental Research and Diagnostics, Fondazione IRCCS Istituto Neurologico Carlo Besta, Milan, Principal Investigator: dr. Barbara Garavaglia; LD pharmacokinetics analysis will be performed at the Operative Unit of Clinical Pharmacology and Pharmacogenetics at University Hospital "San Giovanni di Dio e Ruggi d'Aragona" of the University of Salerno, Principal Investigator: dr. Valeria Conti

Curriculum vitae

-Name: Maria Teresa PELLECCIA
-Birth date: 3/6/1970
-Birth place: Avellino
-Personal Address: Via Tuoro 69, 83100 Avellino
-Office Address: Department of Medicine, University of Salerno
-Phone: +39-3274003951 (mobile), 089/969121 (office)
-E-mail: mpelleccia@unisa.it

Professional Position:

Associate Professor in Neurology at Department of Medicine and Surgery, University of Salerno, Italy

EDUCATION:

1988-1994 Student at the School of Medicine of University of Naples, Federico II
July 1994 Medical degree with honours from the University of Naples, School of Medicine
1999 Board of Neurology with honours from the University of Naples, School of Medicine
2000-2001 PhD in Neurodegenerative Disorders at the Department of Neurological Sciences, University "Federico II", Naples
2001-2005 PhD Degree in Neurosciences at the University of Naples, Federico II, with a thesis entitled: "Arginine test in the differential diagnosis of Parkinson's disease and atypical parkinsonisms".

TRAINING & EMPLOYMENT:

1999-present Consultant at the Regional Centre for Parkinson's Disease and Movement Disorders (Chair: Professor Paolo Barone) at the Department of Neurological Sciences, University "Federico II", Naples
2006-2010 Fellow at the Department of Neurological Sciences, University of Naples, Federico II
2011-2012 Researcher at the Department of Neurological Sciences, University of Naples, Federico II
2012-2014 Researcher in Neurology at the Department of Medicine, University of Salerno
Assistant neurologist at Center for Neurodegenerative Diseases (CEMAND), University of Salerno
2014-present Associate Professor in Neurology at the Department of Medicine, University of Salerno.
Chief of the Unit of Experimental Neurology at the University Hospital of Salerno San Giovanni di Dio e Ruggi d'Aragona.

Scientific activity

Prof. Pellecchia is author of more than one hundred papers on international journals with peer-review.

Her research interests include: progression of movement disorders, with particular regard to Parkinson's disease and multiple system atrophy; neuroendocrinology of Parkinson's disease and atypical parkinsonisms; neuroimaging in the differential diagnosis of parkinsonian syndromes; clinical neuropharmacology of movement disorders; blood and imaging biomarkers in neurodegenerative diseases.

She contributed to clinical trials of several antiparkinsonian drugs. Her contributions in clinical research have been focused on both clinical and genetics of movement disorders, especially related to PD and parkinsonisms. She contributed to develop new tests for the differential diagnosis of parkinsonisms.

She is an active member of the EMSA-Study Group (European Multiple System Atrophy Study Group) that contributed to the clinical, genetic and neuroimaging characterization of MSA and performed double-blind randomized clinical trials in MSA patients.

Research support as Principal Investigator or Co-PI (last 3 years)

- **Insulin-like Growth Factor-1 and DAT Imaging as Biomarkers of Early Cognitive Impairment in Parkinson's Disease.** Cognition biomarkers, 2013; Michael J. Fox Foundation; Grant ID 8800
- **Seven Tesla MR imaging as preclinical biomarker in populations at risk for Parkinson disease.** Ricerca Finalizzata, Italian Ministry of Health 2013-2014
- **A serum miRNAs signature as potential biomarker for MSA.** The Multiple System Atrophy Coalition, 2016.

Miscellaneous

- 2006-2009 Board of the Italian Movement Disorder Society (DISMOV-SIN)
- 2008 Co-organiser of the XXXV Congress of the Italian League for Parkinson's Disease (LIMPE), Salerno, Italy
- 2014 Co-organiser of the III Congress of Accademia LIMPE-DISMOV, Salerno, Italy
- 2016 Scientific and organizing Committee of the 5th International Congress on Multiple System Atrophy, Salerno, Italy
- 2016- Board of Accademia Limpe-DISMOV

Peer reviewed publications

- 1: Criscuolo C, D'Amico A, Peluso S, Popolizio T, Pellecchia MT. Adult-onset puretic disorder after post-traumatic hypoxic lesions of the globus pallidus.

Parkinsonism Relat Disord. 2016 Nov 18. pii: S1353-8020(16)30438-2.

2: Moccia M, Erro R, Picillo M, Vitale C, Longo K, Amboni M, Pellecchia MT, Barone P. Caffeine consumption and the 4-year progression of de novo Parkinson's disease. *Parkinsonism Relat Disord.* 2016 Nov;32:116-119.

3: Sailer A, Scholz SW, Nalls MA, Schulte C, Federoff M, Price TR, Lees A, Ross OA, Dickson DW, Mok K, Mencacci NE, Schottlaender L, Chelban V, Ling H, O'Sullivan SS, Wood NW, Traynor BJ, Ferrucci L, Federoff HJ, Mhyre TR, Morris HR, Deuschl G, Quinn N, Widner H, Albanese A, Infante J, Bhatia KP, Poewe W, Oertel W, Höglinger GU, Wüllner U, Goldwurm S, Pellecchia MT, Ferreira J, Tolosa E, Bloem BR, Rascol O, Meissner WG, Hardy JA, Revesz T, Holton JL, Gasser T, Wenning GK, Singleton AB, Houlden H; European Multiple System Atrophy Study Group and the UK Multiple System Atrophy Study Group.. A genome-wide association study in multiple system atrophy. *Neurology.* 2016 Oct 11;87(15):1591-1598.

4: Erro R, Picillo M, Vitale C, Amboni M, Moccia M, Santangelo G, Pellecchia MT, Barone P. The non-motor side of the honeymoon period of Parkinson's disease and its relationship with quality of life: a 4-year longitudinal study. *Eur J Neurol.* 2016 Nov;23(11):1673-1679.

5: Pellecchia MT, Savastano R, Moccia M, Picillo M, Siano P, Erro R, Vallelunga A, Amboni M, Vitale C, Santangelo G, Barone P. Lower serum uric acid is associated with mild cognitive impairment in early Parkinson's disease: a 4-year follow-up study. *J Neural Transm (Vienna).* 2016 Dec;123(12):1399-1402.

6: Morgante F, Fasano A, Ginevrino M, Petrucci S, Ricciardi L, Bove F, Crisculo C, Moccia M, De Rosa A, Sorbera C, Bentivoglio AR, Barone P, De Michele G, Pellecchia MT, Valente EM. Impulsive-compulsive behaviors in parkin-associated Parkinson disease. *Neurology.* 2016 Oct 4;87(14):1436-1441.

7: Barone P, Santangelo G, Amboni M, Pellecchia MT, Vitale C. Pisa syndrome in Parkinson's disease and parkinsonism: clinical features, pathophysiology, and treatment. *Lancet Neurol.* 2016 Sep;15(10):1063-74.

8: Santangelo G, Falco F, D'Iorio A, Cuoco S, Raimo S, Amboni M, Pellecchia MT, Longo K, Vitale C, Barone P. Anxiety in early Parkinson's disease: Validation of the Italian observer-rated version of the Parkinson Anxiety Scale (OR-PAS). *J Neurol Sci.* 2016 Aug 15;367:158-61.

9: Moccia M, Pellecchia MT, Spina E, Barone P, Vitale C. Bilirubin and Uric Acid: Two Different Anti-oxidants in Parkinson's Disease. *Cell Biochem Biophys.* 2016 Jun;74(2):91-2.

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- 93: Pellecchia MT, Pivonello R, Salvatore E, Faggiano A, Barone P, De Michele G, Lombardi G, Colao A, Filla A. Growth hormone response to arginine test distinguishes multiple system atrophy from Parkinson's disease and idiopathic late-onset cerebellar ataxia. *Clin Endocrinol (Oxf).* 2005 Apr;62(4):428-33.
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- 100: Pellecchia MT, Ambrosio G, Salvatore E, Vitale C, De Michele G, Barone P. Possible gluten sensitivity in multiple system atrophy. *Neurology.* 2002 Oct 8;59(7):1114-5.
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- 102: Cicarelli G, Pellecchia MT, De Michele G, Pizzolato G, Barone P. Paradoxical response to apomorphine in a case of atypical parkinsonism. *Mov Disord.* 2002 May;17(3):604-6.
- 103: Perretti A, Pellecchia MT, Lanzillo B, Campanella G, Santoro L. Excitatory and inhibitory mechanisms in Wilson's disease: investigation with magnetic motor cortex stimulation. *J Neurol Sci.* 2001 Nov 15;192(1-2):35-40.
- 104: Pellecchia MT, Salvatore E, Pivonello R, Faggiano A, Barone P, De Michele G, Colao AM, Filla A. Stimulation of growth hormone release in multiple system atrophy, Parkinson's disease and idiopathic cerebellar ataxia. *Neurol Sci.* 2001 Feb;22(1):79-80.

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106: Barbieri F, Pellecchia MT, Esposito E, Di Stasio E, Castaldo I, Santorelli F, Perretti A, Santoro L, De Michele G. Adult-onset familial laryngeal abductor paralysis, cerebellar ataxia, and pure motor neuropathy. *Neurology*. 2001 May 22;56(10):1412-4.

107: Pellecchia MT, Scala R, Perretti A, De Michele G, Santoro L, Filla A, Ciacci C, Barone P. Cerebellar ataxia associated with subclinical celiac disease responding to gluten-free diet. *Neurology*. 1999 Oct 22;53(7):1606-8.

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109: Pellecchia MT, Cuomo T, Striano S, Filla A, Barone P. Paroxysmal dystonia in Behçet's disease. *Mov Disord*. 1999 Jan;14(1):177-9.

110: Pellecchia MT, Scala R, Filla A, De Michele G, Ciacci C, Barone P. Idiopathic cerebellar ataxia associated with celiac disease: lack of distinctive neurological features. *J Neurol Neurosurg Psychiatry*. 1999 Jan;66(1):32-5.

111: Vallone D, Pellecchia MT, Morelli M, Verde P, DiChiara G, Barone P. Behavioural sensitization in 6-hydroxydopamine-lesioned rats is related to compositional changes of the AP-1 transcription factor: evidence for induction of FosB- and JunD-related proteins. *Brain Res Mol Brain Res*. 1997 Dec 15;52(2):307-17.

Curriculum Vitae

Marina Picillo, MD



A. Date Curriculum Vitae is Prepared: 2016 October 21

B. Biographical Information

Date of birth	December, 23rd 1982
Country of birth	Italy
Citizenship	Italian
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1. EDUCATION

Degrees

2001 - 2007	MD, Final Grade: 110/110 Cum Laude, Università Federico II, Naples, Italy
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Postgraduate, Research and Specialty Training

2014 - to date	PhD in "Translational Medicine: biomarkers of degenerative diseases" at the University of Salerno, Italy - tutor: prof. M.T. Pellecchia
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2014 - 2015	Clinical Fellowship in Movement Disorders - Deep Brain Stimulation Program at the Movement Disorders Centre of the Toronto Western Hospital, Toronto, Ontario, Canada – tutor: dr. Alfonso Fasano
2009 - 2014	Residency in Neurology, Final Grade: 50/50 Cum Laude, Neuroscience Department, University Federico II, Naples, Italy
2006	Fellowship in Neurology, Medical Students' International Program, Hospital Sao Joao, Porto, Portugal

Qualifications, Certifications and Licenses

2008 - present	Medical License, College of Physicians and Surgeons of Naples, Italy, 32260
2014 Aug - 2015 June	Medical License, College of Physicians and Surgeons of Ontario, 104723

2. EMPLOYMENT

Current Appointments

2015	Research Consultant for the project <i>Relationship between IGF-1 and cognition in early Parkinson's disease</i> , Cognition biomarker grant by the MJFF- Centre for Neurodegenerative Diseases (CEMAND), Department of Medicine and Surgery, University of Salerno
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Previous Appointments

2008	Research Consultant, Department of Neuroscience, Movement Disorders Centre, University Federico II, Naples, Italy
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3. GRANTS, HONOURS AND CAREER AWARDS

INTERNATIONAL	GRANT
2014-2015	Rapid response Innovation Award from the Michael J Fox Foundation for the project "Segmental progression of cardinal motor symptoms in Parkinson's disease".
NATIONAL	AWARDS
2012	Best Poster Award , "IGF-1 and progression of motor symptoms in early, drug-naive parkinsonian patients" Congresso Limpe, Pisa, Italy. (Distinction)
2009	Best Poster Award , "Neuropsychiatric disturbances in parkinsonian patients with Freezing of gait" Congresso Limpe, Genova, Italy. (Distinction)

4. PROFESSIONAL AFFILIATIONS AND ACTIVITIES

Professional Associations

American Academy of Neurology (AAN)
International Parkinson and Movement Disorders Society
Italian Society of Neurology (SIN)
Accademia italiana per lo studio della malattia di Parkinson e i disordini del movimento (LIMPE-DISMOV)

Peer Review Activities

MANUSCRIPT REVIEWS

Reviewer

2014 - present

Parkinsonism and related disorders
BioMed Research International
Case Reports in Neurological Medicine
Canadian Journal of Neurological Sciences
Neuroscience and Biobehavioral reviews
International Journal of Brain disorders and Treatment
Future Neurology
Experimental Gerontology
Journal of Medical Internet Research
Journal of the Neurological Sciences
Sleep Medicine
Movement disorders
Clinical neurology neurosurgery

C. Publications

1. PEER-REVIEWED PUBLICATIONS

Journal Articles

1. Erro R, **Picillo M**, Vitale C, Amboni M, Moccia M, Santangelo G, Pellecchia MT, Barone P. The non-motor side of the honeymoon period of Parkinson's disease and its relationship with quality of life: a 4-year longitudinal study. Eur J Neurol. 2016 Nov;23(11):1673-1679. **Coauthor or Collaborator**
2. Pellecchia MT, Savastano R, Moccia M, **Picillo M**, Siano P, Erro R, Vallelunga A, Amboni M, Vitale C, Santangelo G, Barone P. Lower serum uric acid is associated with mild cognitive impairment in early Parkinson's disease: a 4-year follow-up study. J Neural Transm (Vienna). 2016 Sep 28. [Epub ahead of print] **Coauthor or Collaborator**

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3. Fasano A, Appel-Cresswell S, Jog M, Zurowski M, Duff-Canning S, Cohn **M**, **Picillo M**, Honey CR, Panisset M, Munhoz RP. Medical Management of Parkinson's Disease after Initiation of Deep Brain Stimulation. Can J Neurol Sci. 2016 Sep;43(5):626-34. **Coauthor or Collaborator**
4. Moccia M, Erro R, **Picillo M**, Vitale C, Longo K, Amboni M, Pellecchia MT, Barone P. Caffeine consumption and the 4-year progression of de novo Parkinson's disease. Parkinsonism Relat Disord. 2016 Aug 4. pii: S1353-8020(16)30289-9. **Coauthor or Collaborator**
5. Moccia M, Tedeschi E, Uggla L, Erro R, **Picillo M**, Caranci F, Barone P, Brunetti A. White matter changes and the development of motor phenotypes in de novo Parkinson's Disease. J Neurol Sci. 2016 Aug 15;367:215-9. **Coauthor or Collaborator**
6. Zibetti M, Moro E, Krishna V, Sammartino F, **Picillo M**, Munhoz RP, Lozano AM, Fasano A. Low-frequency Subthalamic Stimulation in Parkinson's Disease: Long-term Outcome and Predictors. Brain Stimul. 2016 Sep-Oct;9(5):774-9. **Coauthor or Collaborator**
7. Erro R, **Picillo M**, Vitale C, Palladino R, Amboni M, Moccia M, Pellecchia MT, Barone P. Clinical clusters and dopaminergic dysfunction in de-novo Parkinson disease. Parkinsonism Relat Disord. 2016 Jul;28:137-40. **Coauthor or Collaborator**
8. Munhoz RP, **Picillo M**, Fox SH, Bruno V, Panisset M, Honey CR, Fasano A. Eligibility Criteria for Deep Brain Stimulation in Parkinson's Disease, Tremor, and Dystonia. Can J Neurol Sci. 2016 Jul;43(4):462-71. **Coauthor or Collaborator**
9. **Picillo M**, Palladino R, Moccia M, Erro R, Amboni M, Vitale C, Barone P, Pellecchia MT. Gender and non motor fluctuations in Parkinson's disease: A prospective study. Parkinsonism Relat Disord. 2016 Jun;27:89-92. **Principal Author**
10. Honey CR, Hamani C, Kalia SK, Sankar T, **Picillo M**, Munhoz RP, Fasano A, Panisset M. Deep Brain Stimulation Target Selection for Parkinson's Disease. Can J Neurol Sci. 2016 Mar 15:1-6. **Coauthor or Collaborator**
11. **Picillo M**, Lozano AM, Kou N, Puppi Munhoz R, Fasano A. Programming Deep Brain Stimulation for Parkinson's Disease: The Toronto Western Hospital Algorithms. Brain Stimul. 2016 May-Jun;9(3):425-37. Review. **Principal Author**
12. **Picillo M**, Lozano AM, Kou N, Munhoz RP, Fasano A. Programming Deep Brain Stimulation for Tremor and Dystonia: The Toronto Western Hospital Algorithms. Brain Stimul. 2016 May-Jun;9(3):438-52. Review. **Principal Author**
13. **Picillo M**, Santangelo G, Moccia M, Erro R, Amboni M, Prestipino E, Longo K, Vitale C, Spina E, Orefice G, Barone P, Pellecchia MT. Serum uric acid is associated with apathy in early, drug-naïve Parkinson's disease. J Neural Transm (Vienna). 2016 Apr;123(4):371-7. **Principal Author**
14. Moccia M, Erro R, **Picillo M**, Santangelo G, Spina E, Allocca R, Longo K, Amboni M, Palladino R, Assante R, Pappatà S, Pellecchia MT, Barone P, Vitale C. A Four-Year Longitudinal Study on Restless Legs Syndrome in

- Parkinson Disease. Sleep. 2015 Nov 6. pii: sp-00132-15. [Epub ahead of print] **Coauthor or Collaborator**
15. Moccia M, Mollenhauer B, Erro R, **Picillo M**, Palladino R, Barone P. Non-Motor Correlates of Smoking Habits in de Novo Parkinson's Disease. J Parkinsons Dis. 2015 Oct 19;5(4):913-24. **Coauthor or Collaborator**
 16. **Picillo M**, Fasano A. Recent advances in Essential Tremor: Surgical treatment. Parkinsonism Relat Disord. 2016 Jan;22 Suppl 1:S171-5. **Principal Author**
 17. Santangelo G, Vitale C, **Picillo M**, Moccia M, Cuoco S, Longo K, Pezzella D, di Grazia A, Erro R, Pellecchia MT, Amboni M, Trojano L, Barone P. Mild Cognitive Impairment in newly diagnosed Parkinson's disease: A longitudinal prospective study. Parkinsonism Relat Disord. 2015 In press **Coauthor or Collaborator**.
 18. **Picillo M**, Dubbioso R, Iodice R, Iavarone A, Pisciotta C, Spina E, Santoro L, Barone P, Amboni M, Manganelli F. Short-latency afferent inhibition in patients with Parkinson's disease and freezing of gait. J Neural Transm. 2015 In press **Principal Author**.
 19. **Picillo M**, Kou N, Barone P, Fasano A. Recruitment strategies and patient selection in clinical trials for Parkinson's disease: Going viral and keeping science and ethics at the highest standards. Parkinsonism Relat Disord. 2015 In press **Principal Author**.
 20. **Picillo M**, Moro E, Edwards M, Di Lazzaro V, Lozano AM, Fasano A. Subdural Continuous Theta Burst Stimulation of the Motor Cortex in Essential Tremor. Brain Stimul. 2015;8(4):840-842. **Principal Author**.
 21. Santangelo G, Vitale C, **Picillo M**, Cuoco S, Moccia M, Pezzella D, Erro R, Longo K, Vicidomini C, Pellecchia MT, Amboni M, Brunetti A, Salvatore M, Barone P, Pappatà S. Apathy and striatal dopamine transporter levels in de-novo, untreated Parkinson's disease patients. Parkinsonism Relat Disord. 2015;21(5):489-93. **Coauthor or Collaborator**.
 22. Moccia M, **Picillo M**, Erro R, Longo K, Amboni M, Santangelo G, Palladino R, Allocca R, Caporale O, Triassi M, Pellecchia MT, Barone P, Vitale C. Increased bilirubin levels in de novo Parkinson's disease. Eur J Neurol. 2015;22(6):954-9. **Coauthor or Collaborator**.
 23. Moccia M, **Picillo M**, Erro R, Allocca R, Barone P, Vitale C. Diagnosis and treatment of restless legs syndrome in progressive supranuclear palsy. J Neurol Sci. 2015;350(1-2):103-4. **Coauthor or Collaborator**.
 24. Erro R, **Picillo M**, Amboni M, Moccia M, Vitale C, Longo K, Pellecchia MT, Santangelo G, Martinez-Martin P, Chaudhuri KR, Barone P. Nonmotor predictors for levodopa requirement in de novo patients with Parkinson's disease. Mov Disord. 2015;30(3):373-8. **Coauthor or Collaborator**.
 25. Pellecchia MT, **Picillo M**, Santangelo G, Longo K, Moccia M, Erro R, Amboni M, Vitale C, Vicidomini C, Salvatore M, Barone P, Pappatà S. Cognitive performances and DAT imaging in early Parkinson's disease with mild cognitive impairment: a preliminary study. Acta Neurol Scand. 2015;131(5):275-81. **Coauthor or Collaborator**.

26. Moccia M, Erro R, **Picillo M**, Vassallo E, Vitale C, Longo K, Amboni M, Santangelo G, Palladino R, Nardone A, Triassi M, Barone P, Pellecchia MT. Quitting smoking: an early non-motor feature of Parkinson's disease? *Parkinsonism Relat Disord*. 2015 Mar;21(3):216-20. **Coauthor or Collaborator**.
27. Amboni M, Tessitore A, Esposito F, Santangelo G, **Picillo M**, Vitale C, Giordano A, Erro R, de Micco R, Corbo D, Tedeschi G, Barone P. Resting-state functional connectivity associated with mild cognitive impairment in Parkinson's disease. *J Neurol*. 2015;262(2):425-34. **Coauthor or Collaborator**.
28. Moccia M, Pappatà S, Erro R, **Picillo M**, Vitale C, Amboni M, Longo K, Palladino R, Barone P, Pellecchia MT. Uric acid relates to dopamine transporter availability in Parkinson's disease. *Acta Neurol Scand*. 2015 Feb;131(2):127-31. **Coauthor or Collaborator**.
29. Santangelo G, Barone P, Cuoco S, Raimo S, Pezzella D, **Picillo M**, Erro R, Moccia M, Pellecchia MT, Amboni M, Santangelo F, Grossi D, Trojano L, Vitale C. Apathy in untreated, de novo patients with Parkinson's disease: validation study of Apathy Evaluation Scale. *J Neurol*. 2014;261(12):2319-28. **Coauthor or Collaborator**.
30. Moccia M, Pappatà S, **Picillo M**, Erro R, Coda AR, Longo K, Vitale C, Amboni M, Brunetti A, Capo G, Salvatore M, Barone P, Pellecchia MT. Dopamine transporter availability in motor subtypes of de novo drug-naïve Parkinson's disease. *J Neurol*. 2014;261(11):2112-8. **Coauthor or Collaborator**.
31. Moccia M, **Picillo M**, Erro R, Vitale C, Longo K, Amboni M, Santangelo G, Palladino R, Capo G, Orefice G, Barone P, Pellecchia MT. Presence and progression of non-motor symptoms in relation to uric acid in de novo Parkinson's disease. *Eur J Neurol*. 2015;22(1):93-8. **Coauthor or Collaborator**.
32. Sharma M, Wenning G, Krüger R; European Multiple-System Atrophy Study Group (EMSA-SG). Mutant COQ2 in multiple-system atrophy. *N Engl J Med*. 2014 Jul 3;371(1):80-1. **Coauthor or Collaborator**.
33. Santangelo G, Vitale C, Trojano L, **Picillo M**, Moccia M, Pisano G, Pezzella D, Cuoco S, Erro R, Longo K, Pellecchia MT, Amboni M, De Rosa A, De Michele G, Barone P. Relationship between apathy and cognitive dysfunctions in de novo untreated Parkinson's disease: a prospective longitudinal study. *Eur J Neurol*. 2015;22(2):253-60. **Coauthor or Collaborator**.
34. **Picillo M**, Erro R, Amboni M, Longo K, Vitale C, Moccia M, Pierro A, Scannapieco S, Santangelo G, Spina E, Orefice G, Barone P, Pellecchia MT. Gender differences in non-motor symptoms in early Parkinson's disease: a 2-years follow-up study on previously untreated patients. *Parkinsonism Relat Disord*. 2014;20(8):850-4. **Principal Author**.
35. Olgiati S, De Rosa A, Quadri M, Criscuolo C, Breedveld GJ, **Picillo M**, Pappatà S, Quarantelli M, Barone P, De Michele G, Bonifati V. PARK20 caused by SYNJ1 homozygous Arg258Gln mutation in a new Italian family. *Neurogenetics*. 2014;15(3):183-8. **Coauthor or Collaborator**.
36. Erro R, Santangelo G, Barone P, **Picillo M**, Amboni M, Longo K, Giordano F, Moccia M, Allocca R, Pellecchia MT, Vitale C. Do subjective memory complaints herald the onset of mild cognitive impairment in Parkinson disease? *J Geriatr Psychiatry Neurol*. 2014;27(4):276-81. **Coauthor or Collaborator**.

37. Moccia M, **Picillo M**, Erro R, Vitale C, Longo K, Amboni M, Santangelo G, Spina E, De Rosa A, De Michele G, Santoro L, Barone P, Pellecchia MT. Is serum uric acid related to non-motor symptoms in de-novo Parkinson's disease patients? *Parkinsonism Relat Disord*. 2014;20(7):772-5. **Coauthor or Collaborator**.
38. Moccia M, **Picillo M**, Erro R, Vitale C, Amboni M, Palladino R, Cioffi DL, Barone P, Pellecchia MT. How does smoking affect olfaction in Parkinson's disease? *J Neurol Sci*. 2014;340(1-2):215-7. **Coauthor or Collaborator**.
39. **Picillo M**, Ranieri A, Orefice G, Bonifati V, Barone P. Clinical progression of SYNJ1-related early onset atypical parkinsonism: 3-year follow up of the original Italian family. *J Neurol*. 2014;261(4):823-4. **Principal Author**.
40. De Rosa A, De Michele G, Guacci A, Carbone R, Lieto M, Peluso S, **Picillo M**, Barone P, Salemi F, Laiso A, Saccà F, Tessitore A, Pellecchia MT, Bonifati V, Crisculo C. Genetic screening for the LRRK2 R1441C and G2019S mutations in Parkinsonian patients from Campania. *J Parkinsons Dis*. 2014;4(1):123-8. **Coauthor or Collaborator**.
41. **Picillo M**, Iavarone A, Pellecchia MT, Amboni M, Erro R, Moccia M, Vitale C, Longo K, Santangelo G, Spina E, Scannapieco S, Orefice G, Barone P. Validation of an Italian version of the 40-item University of Pennsylvania Smell Identification Test that is physician administered: our experience on one hundred and thirty-eight healthy subjects. *Clin Otolaryngol*. 2014;39(1):53-7. **Principal Author**.
42. Erro R, Lees AJ, Moccia M, **Picillo M**, Penco S, Mosca L, Vitale C, Barone P. Progressive parkinsonism, balance difficulties, and supranuclear gaze palsy. *JAMA Neurol*. 2014;71(1):104-7. **Coauthor or Collaborator**.
43. Stocchi F, Antonini A, Barone P, Tinazzi M, Zappia M, Onofri M, Ruggieri S, Morgante L, Bonuccelli U, Lopiano L, Pramstaller P, Albanese A, Attar M, Posocco V, Colombo D, Abbruzzese G; DEEP study group. Early DEtection of wEaring off in Parkinson disease: the DEEP study. *Parkinsonism Relat Disord*. 2014 Feb;20(2):204-11. **Coauthor or Collaborator**.
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45. **Picillo M**, Pellecchia MT, Vitale C, Barone P, Amboni M. Pallidal stimulation in atypical pantothenate kinase-associated neurodegeneration: six-year follow-up. *Mov Disord*. 2014 Feb;29(2):276-7. **Principal Author**.
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78. Amboni M, Cozzolino A, Longo K, **Picillo M**, Barone P. Freezing of gait and executive functions in patients with Parkinson's disease. *Mov Disord*. 2008 Feb 15;23(3):395-400. **Coauthor or Collaborator**.

Book Chapters

1. Barone P, Amboni M, Santangelo G, **Picillo M**, Erro R, Pappatà S, Brunetti A (2012). Le demenze. In: Barone - Brunetti - Cappabianca - Filla - Gangemi - Maiuri - Santoro-Spaziente. *Sistema nervoso* . p. 281-298, NAPOLI:Idelson-Gnocchi, ISBN/ISSN: 978-88-7947-553-2. **Coauthor or Collaborator**.
2. **Picillo M**, Puppi Munhoz R. Medical Management of Movement Disorders. In: *Controversies in Movement Disorders*. Edited by Ajay Niranjana, L. Dade Lunsford and Mark Richardson, Pittsburgh (PA). In press. **Principal Author**.
3. Walsh R, de Bie RMA, Fox SH. What do I do now? *Movement disorders – second edition*, Oxford University Press. **Coauthor or Collaborator**.

Editorials

1. **Picillo M**, Fasano A. How much does sex matter in Parkinson disease? *Neurology*. 2015;84(21):2102-4. **Principal Author**.

Commentaries

1. **Picillo M**, Barone P, Amboni M, Moccia M, Pellecchia MT. Comment on Szewczyk-Krolikowski et al.: the influence of age and gender on motor and non-motor features of early Parkinson's disease: initial findings from the Oxford Parkinson Disease Center (OPDC) discovery cohort. *Parkinsonism Relat Disord*. 2014;20(11):1319-20. **Principal Author**.
2. **Picillo M**, Barone P, Pellecchia MT, Santangelo G, Kano O, Ikeda K, Iwasaki Y. Evolution of mild cognitive impairment in Parkinson disease. *Neurology*. 2014;82(15):1384. **Principal Author**.
3. **Picillo M**, Barone P, Erro R, Spina E, Pellecchia MT. Comment on Numao et al.: Clinical correlates of serum insulin-like growth factor-1 in patients with Parkinson's disease, multiple system atrophy and progressive supranuclear palsy. *Parkinsonism Relat Disord*. 2014;20(6):680-1. **Principal Author**.

D. Presentations and Special Lectures

1. INTERNATIONAL

Invited Lectures and Presentations

2013 Sep 6 **Speaker**. Biomarkers for detection, diagnosis and prognosis of Parkinson's disease. International Conference for new therapies for Parkinson and Alzheimer. Pisa, Italy

2. NATIONAL

Invited Lectures and Presentations

2013 Sep 19 **Speaker**. Cognitive disturbances in Parkinson's disease. Update on parkinsonism and dementia: clinics, biomarkers and neuropathology. Verona, Italy

2016 May 06 **Speaker**. Gender differences in Parkinson's disease: epidemiology and clinics. Accademia Linpe-Dismov National Congress. Bari, Italy

2016 Jun 24 **Speaker**. Deep brain stimulation in Parkinson's disease. Management of advanced phase of Parkinson's disease. Campus Biomedico, Roma, Italy

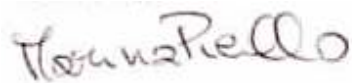
3. LOCAL

Invited Lectures and Presentations

2014 May 28 **Speaker**. New semeiology of Parkinson's disease. High impact neurological diseases: Epilepsy and Parkinson's disease. Solofra (Avellino), Italy

2015 Sep 12 **Speaker**. Experiences with Deep Brain Stimulation in Parkinson's disease. Convegno Regionale SIN SINC Campania, Napoli, Italy

2016 Jun 10 **Speaker**. Management of parkinsonian disorders. Università di Salerno, Italy



Napoli, 12 September 2016

SHORT CURRICULUM VITAE**Giuseppe De Michele**

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Professional Address:

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Current Position

2014-present Full Professor of Neurology, Department of Neurosciences and Reproductive and Odontostomatological Sciences, Federico II University of Naples.

Previous Positions

2001-2014 Associate Professor of Neurology, Department of Neurosciences and Reproductive and Odontostomatological Sciences, Federico II University of Naples.

1981-2001 Assistant Professor of Neurology at the Federico II University of Naples.

1980 Fellow at the Department of Neurobiology of the "Institut of Clinical Research of Montreal", Montreal, Canada (Prof. A. Barbeau).

1977-1979 Fellow at the at the Department of Neurology, Federico II University of Naples.

Education and Diplomas

2014 Accreditation for Full Professor of Neurology, Ministry of Research, Rome

2000 Accreditation for Associate Professor of Neurology, University of Siena

1986 Accreditation for Chief of Neurology Department, Ministry of Health, Rome

1979 Board certification in Neurology "cum laude" at the Federico II University of Naples

1975 Medical degree "cum laude" at the Federico II University of Naples

Clinical Activity

2015-present Responsible of the Movement Disorders Center at the Federico II University

2003-2015 Responsible of the Hereditary Diseases Unit at the Federico II University

1987-2003 Senior Assistant in Neurology at the Federico II University of Naples.

1980-1987 Assistant in Neurology at the Federico II University of Naples.

Teaching Activities

Professor of Neurology, Clinical Neurochemistry, Physiopathology of the Central Nervous System, Otoneurology, Statistics and Biometry, for postgraduate courses (Medicine, Odontoiatry,

Biotechnological Sciences), undergraduate courses, Specialization Schools, Doctoral School in Neurosciences at the Federico II University and in Biology and Doctoral School of Medical Biochemistry at the University of Bari.

Research and publications

Main fields of research are clinical and molecular aspects of Friedreich's ataxia, dominant ataxias, familial spastic paraplegias, Parkinson's disease, and Huntington's disease.

Two-hundred sixty-seven papers published mostly on international journals (total impact factor: 921; H-index: 45), 16 book chapters.

Scientific coordinator and responsible of research units in projects funded by Italian Ministry of University and European Community.

Coordinator of the Italian Group of the European Huntington's Disease Network.

Member of the Committee on Bioethics of the Federico II University.

Clinical trials (in the last three years)

A Phase 2, to Evaluating the Safety and Efficacy of Pridopidine Versus Placebo for Symptomatic Treatment in Patients With Huntington's Disease NCT02006472

A Clinical Study in Subjects With Huntington's Disease to Assess the Efficacy and Safety of Three Oral Doses of Laquinimod NCT02215616

A Study Evaluating if Pridopidine is Safe, Efficacious, and Tolerable in Patients With Huntington's Disease NCT02494778

Efficacy Study of Epoetin Alfa in Friedreich Ataxia (FRIEMAX) NCT01493973

Safety and Tolerability of Lithium in Spinocerebellar Ataxia 2 NCT00998634

I consent to the use of my personal data in accordance with the provisions of Legislative Decree 196/2003.

Selected papers

1. De Michele G., Filla A., Cavalcanti F., Di Maio L., Pianese L., Castaldo I., Calabrese O., Monticelli A., Varrone S., Campanella G., Leone M., Pandolfo M., Coccozza S. (1994) "Late onset Friedreich's disease: clinical features and mapping of mutation to the FRDA locus." J. Neurol. Neurosurg. Psychiat 57, 977-979.
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- Filla A, De Frutos R, Palau F, Patel PI, Di Donato S, Mandel JL, Coccozza S, Koenig M, Pandolfo M (1996) "Friedreich's ataxia: autosomal recessive disease caused by an intronic GAA triplet repeat expansion." *Science* 271, 1423-1427.
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 5. De Michele G., Perrone F., Filla A., Mirante E., Giordano M., De Placido S., Campanella G. (1996) Age of onset, sex and cardiomyopathy as predictors of disability and survival in Friedreich's disease. A retrospective study on 119 patients." *Neurology* 47, 1260-1264.
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 9. De Michele G, Cavalcanti F, Criscuolo C, Pianese L, Monticelli A, Filla A, Coccozza S (1998) Parental gender, age at birth and expansion length influence GAA repeat intergenerational instability in the X25 gene: pedigree study and analysis of sperm from patients with Friedreich's ataxia. *Hum. Mol. Genet.* 7, 1901-1906.
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 13. Criscuolo C, Banfi S, Orio M, Gasparini P, Monticelli A, Scarano V, Santorelli FM, Perretti A, Santoro L, De Michele G, Filla A. (2004) A novel mutation in SACS gene in a family from southern Italy. *Neurology* 62, 100-2.
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 15. Papa S, Petruzzella V, Scacco S, Sardanelli AM, Iuso A, Panelli D, Vitale R, Trentadue R, De Rasmo D, Capitanio N, Piccoli C, Papa F, Scivetti M, Bertini E, Rizza T, De Michele G. Pathogenetic mechanisms in hereditary dysfunctions of complex I of the respiratory chain in neurological diseases. (2009) *Biochim Biophys Acta* 1787, 502-17.
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 20. Fogel BL, Cho E, Wahnich A, Gao F, Becherel OJ, Wang X, Fike F, Chen L, Criscuolo C, De Michele G, Filla A, Collins A, Hahn AF, Gatti RA, Konopka G, Perlman S, Lavin MF, Geschwind DH, Coppola G. (2014) Mutation of senataxin alters disease-specific transcriptional networks in patients with ataxia with oculomotor apraxia type 2. *Hum Mol Genet* 23, 4758-69.
 21. De Michele G, Filla A. (2015) Movement disorders: Friedreich ataxia today—preparing for the final battle. *Nat Rev Neurol* 4, 188-90

22. Becherel OJ, Sun J, Yeo AJ, Nayler S, Fogel BL, Gao F, Coppola G, Criscuolo C, De Michele G, Wolvetang E, Lavin MF. (2015) A new model to study neurodegeneration in ataxia oculomotor apraxia type 2. *Hum Mol Genet* 24, 5759-74.
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Curriculum vitae

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ACADEMIC EDUCATION AND DEGREES

1998 MD (cum laude), University "Federico II", Naples

2000-2004: Resident

2004 Board certification in Neurology, University "Federico II", Naples

2008 PhD in Neurosciences, University "Federico II", Naples

PROFESSIONAL APPOINTMENTS

2008-2009: Staff Neurologist

San Remo Hospital, Italy

2010-present: Researcher

Department of Neurosciences and Reproductive and
Odontostomatologic Sciences, Federico II University, Naples, Italy

SHORT RESEARCH PROFILE

The research and clinical activity is focused on genetic and clinical features of neurodegenerative diseases, such as Parkinson's disease, ataxias, hereditary spastic paraparesis, Huntington's disease, dystonia and other movement disorders. Research on biomarkers and genetic factors in multiple sclerosis.

SKILLS

Expertise in screening of *LRRK2* gene mutations in large series of patients with familial and sporadic Parkinson's Disease.

Clinical management of advanced Parkinson's Disease (DBS, infusional therapies) atypical parkinsonism, and other movement disorders.

Management of new generation infusion and oral treatments in multiple sclerosis.

CLINICAL TRIAL

MATCH study: Aspirin and clopidogrel compared with clopidogrel alone after recent ischaemic stroke or transient ischaemic attack in high-risk patients

STRIDE-PD: Stalevo Reduction In Dyskinesia Evaluation in Parkinson's Disease

Scientific publications

Anna De Rosa

Pubblicazioni scientifiche

- 1) De Lucia N, Peluso S, **De Rosa A**, Salvatore E, De Michele G and Grossi D. Constructional Apraxia is related to Different Cognitive Defects across Dementia. J Alzheimers Dis Parkinsonism 2016, 6:4
- 2) Saccà F, Pane C, **De Rosa A**, Matarazzo M, Brescia Morra V. Lamivudine and fingolimod co-administration in two patients with multiple sclerosis and occult hepatitis B virus infection. Neurol Sci. 2016 Oct 3.
- 3) Morgante F, Fasano A, Ginevrino M, Petrucci S, Ricciardi L, Bove F, Criscuolo C, Moccia M, **De Rosa A**, Sorbera C, Bentivoglio AR, Barone P, De Michele G, Pellecchia MT, Valente EM. Impulsive-compulsive behaviors in parkin-associated Parkinson disease. Neurology. 2016;87(14):1436-1441
- 4) **A. De Rosa**, A. Tessitore, L. Bilo, S. Peluso, G. De Michele. Infusion treatments and deep brain stimulation in Parkinson's Disease: The role of nursing. Geriatric Nursing. 2016 Jul 18
- 5) Peluso S, De Michele G, Antenora A, **De Rosa A**, and Bilo L. The magnetic apraxia of Denny-Brown. Neurology. 2016. 9;87(6):644
- 6) Saccà F, Puorro G, Marsili A, Pane C, Russo CV, Lanzillo R, **de Rosa A**, Cittadini A, De Angelis G, Brescia Morra V. Mobitz type I and II atrioventricular blocks during fingolimod therapy. Neurol Sci. 2016;37(9):1557-9
- 7) Saccà F, Puorro G, Marsili A, Antenora A, Pane C, Casali C, Marcotulli C, Defazio G, Liuzzi D, Tatillo C, Cambriglia DM, Schiano di Cola G, Giuliani L, Guardasole V, Salzano A, Ruvo A, **De Rosa A**, Cittadini A, De Michele G, Filla A. Long-term effect of epoetin

- alfa on clinical and biochemical markers in friedreich ataxia. *Mov Disord.* 2016;31(5):734-41
- 8) Marsili A, Puorro G, Pane C, **de Rosa A**, Defazio G, Casali C, Cittadini A, de Michele G, Florio BE, Filla A, Sacca` F. Stability of erythropoietin repackaging in polypropylene syringes for clinical use. *Saudi Pharmaceutical Journal* (2016)
 - 9) **A. De Rosa**, T. Pellegrino, S. Pappatà, M. Lieto, V. Bonifati, V. Palma, A. Topa, L. Santoro, L. Bilo, A. Cuocolo, G. De Michele. Non-motor symptoms and cardiac innervation in SYNJ1-related parkinsonism. *Parkinsonism and Related Disorders Parkinsonism Relat Disord.* 2016 Feb;23:102-5
 - 10) Bilo L, Peluso S, Antenora A, **De Rosa A**, Esposito M, Barbato S, Pappatà S, De Michele G. Parkinsonism in adult-onset Rasmussens's encephalitis: a clinical picture presenting as corticobasal syndrome. *Int J Neurosci.* 2015;27:1-6
 - 11) **De Rosa A**, Pellegrino T, Pappatà S, Pellecchia MT, Peluso S, Saccà F, Barone P, Cuocolo A, De Michele G. Myocardial 123-metaiodobenzylguanidine scintigraphy in patients with homozygous and heterozygous parkin mutations. *J Nucl Cardiol.* 2015 Dec 1
 - 12) Picillo M, **De Rosa A**, Pellecchia MT, Criscuolo C, Amboni M, Erro R, Bonifati V, De Michele G, Barone P. Olfaction in Homozygous and Heterozygous SYNJ1 Arg258Gln Mutation Carriers. *Mov Disord clinical practice.* 2015.
 - 13) Moccia M, Lanzillo R, Palladino R, Chang KC, Costabile T, Russo C, **De Rosa A**, Carotenuto A, Saccà F, Maniscalco GT, Brescia Morra V. Cognitive impairment at diagnosis predicts 10-year multiple sclerosis progression. *Mult Scler.* 2015;22(5):659-67
 - 14) Moccia M, Lanzillo R, Palladino R, Maniscalco GT, **De Rosa A**, Russo C, Massarelli M, Carotenuto A, Postiglione E, Caporale O, Triassi M, Brescia Morra V. The Framingham cardiovascular risk score in multiple sclerosis. *Eur J Neurol.* 2015 Apr 27
 - 15) Santangelo G, Vitale C, Trojano L, Picillo M, Moccia M, Pisano G, Pezzella D, Cuoco S, Erro R, Longo K, Pellecchia MT, Amboni M, **De Rosa A**, De Michele G, Barone P. Relationship between apathy and cognitive dysfunctions in de novo untreated Parkinson's disease: a prospective longitudinal study *Eur J Neurol*, 2015;22(2):253-60.
 - 16) Peluso S, **De Rosa A**, Antenora A, Lieto M, Criscuolo C, Barbieri F, Pappatà S, De Michele G. Efficacy of dopamine agonist treatment in delayed-onset parkinsonism due to midbrain hemorrhage. *Parkinsonism Relat Disord.* 2015;21(2):156-8
 - 17) **De Rosa A**, Carducci C, Carducci C, Peluso S, Lieto M, Mazzella A, Saccà F, Brescia Morra V, Pappatà S, Leuzzi V, De Michele G. Screening for dopa-responsive dystonia in

- patients with scans without evidence of dopaminergic deficiency (SWEDD). *J Neurol.* 2014;261(11):2204-8
- 18) Provitera V, Nolano M, Caporaso G, Stancanelli A, Manganelli F, Iodice R, Selim MM, **De Rosa A**, Lanzillo B, Pellecchia MT, De Michele G, Santoro L. Postganglionic sudomotor denervation in patients with multiple system atrophy. *Neurology.* 2014 17;82(24):2223-9
- 19) Olgiati S, **De Rosa A**, Quadri M, Criscuolo C, Breedveld GJ, Picillo M, Pappatà S, Quarantelli M, Barone P, De Michele G, Bonifati V. PARK20 caused by SYNJ1 homozygous Arg258Gln mutation in a new Italian family. *Neurogenetics*, 2014;15(3):183-8
- 20) Moccia M, Picillo M, Erro R, Vitale C, Longo K, Amboni M, Santangelo G, Spina E, **De Rosa A**, De Michele G, Santoro L, Barone P, Pellecchia MT. Is serum uric acid related to non-motor symptoms in de-novo Parkinson's disease patients? *Parkinsonism Relat Disord.* 2014, 20(7):772-5.
- 21) **De Rosa A**, De Michele G, Guacci A, Carbone R, Lieto M, Silvio Peluso S, Picillo M, Barone P, Salemi F, Laiso A, Saccà F, Tessitore A, Pellecchia MT, Bonifati V, Criscuolo C. Genetic screening for the LRRK2 R1441C and G2019S mutations in parkinsonian patients from Campania. *Journal of Parkinson's Disease.* 2014, 4(1):123-8
- 22) Pellecchia MT, Santangelo G, Picillo M, Pivonello R, Longo K, Pivonello C, Vitale C, Amboni M, De Rosa A, Moccia M, Erro R, De Michele G, Santoro L, Colao A, Barone P. Insulin-like growth factor-1 predicts cognitive functions at 2-year follow-up in early, drug-naïve Parkinson's disease. *Eur J Neurol.* 2014;21(5):802-7.
- 23) Bilo L, Peluso S, Antenora A, **De Rosa A**, Auletta G, Pappatà S, De Michele G. Parkinsonism may be part of the symptom complex of DOOR syndrome. *Parkinsonism Relat Disord.* 2014, 20(4):463-5.
- 24) Picillo M, Amboni M, Erro R, Longo K, Vitale C, Moccia M, Pierro A, Santangelo G, **De Rosa A**, De Michele G, Santoro L, Orefice G, Barone P, Pellecchia MT. Gender differences in non-motor symptoms in early, drug naïve Parkinson's disease. *J Neurol.* 2013, 20(4):463-5
- 25) Erro R, Vitale C, Amboni M, Picillo M, Moccia M, Longo K, Santangelo G, **De Rosa A**, Allocca R, Giordano F, Orefice G, De Michele G, Santoro L, Pellecchia MT, Barone P. The heterogeneity of early Parkinson's disease: a cluster analysis on newly diagnosed untreated patients. *PLoS One.* 2013, 1;8(8): e70244
- 26) **A De Rosa**, Sabina Pappatà, Teresa Pellegrino, Maria Fulvia De Leva, Gennaro Maddaluno, S De Luca, R Carotenuto, M Petretta, A Filla, G De Michele, A Cuocolo. Reduced cardiac 123I-metaiodobenzylguanidine uptake in patients with spinocerebellar

- ataxia type 2. A comparative study with Parkinson's disease. *European journal of nuclear medicine and molecular imaging*. 2013, 40(12):1914-21
- 27) Ragno M, Berbellini A, Cacchiò G, Manca A, Di Marzio F, Pianese L, **De Rosa A**, Silvestri S, Scarcella M, De Michele G. Parkinsonism is a Late, Not Rare, Feature of CADASIL: A Study on Italian Patients Carrying the R1006C Mutation. *Stroke*. 2013;44:1147-9
- 28) **De Rosa A**, Guacci A, Peluso S, Del Gaudio L, Massarelli M, Barbato S, Criscuolo C, De Michele G. A case of restless leg syndrome in a family with LRRK2 gene mutation. *Intern Journ of Neurosci*. 2013 Apr;123(4):283-5.
- 29) Peluso S, Antenora A, **De Rosa A**, Roca A, Maddaluno G, Brescia Morra V, De Michele G. Antiphospholipid-related chorea. *Front Neurol*. 22;3:150.
- 30) Erro R, Picillo M, Vitale C, Amboni M, Moccia M, Longo K, Cozzolino A, Giordano F, **De Rosa A**, De Michele G, Pellecchia MT, Barone P. Non-motor symptoms in early Parkinson's disease: a 2-year follow-up study on previously untreated patients. *J Neurol Neurosurg Psychiatry*. 2013 Nov;260(11):2849-55
- 31) Pellecchia MT, Santangelo G, Picillo M, Pivonello R, Longo K, Pivonello C, Vitale C, Amboni M, **De Rosa A**, Moccia M, Erro R, De Michele G, Santoro L, Colao A, Barone P. Serum epidermal growth factor predicts cognitive functions in early, drug-naïve Parkinson's disease patients. *J Neurol*. 260(2):438-44
- 32) **De Rosa A**, Rossi F, Lieto M, Bruno R, De Renzo A, Palma V, Quarantelli M, De Michele G. Subacute combined degeneration of the spinal cord in a vegan. *Clin Neurol Neurosurg*. 2012;114(7)
- 33) Erro R, Santangelo G, Picillo M, Vitale C, Amboni M, Longo K, Costagliola A, Pellecchia MT, Allocca R, **De Rosa A**, De Michele G, Santoro L, Barone P. Link between non-motor symptoms and cognitive dysfunctions in de novo, drug-naïve PD patients. *J Neurol*. 2012;259(9):1808-13
- 34) **A. De Rosa**, C. Rinaldi, T. Tucci, S. Pappatà, F. Rossi, V. Brescia Morra, A. Faggiano, A. Colao, G. De Michele. Coexistence of primary hyperparathyroidism and Parkinson's disease in three patients: an incidental finding? *Parkinsonism and related disorders*. 17 (2011) 771–773
- 35) Criscuolo C, **De Rosa A**, Guacci A, Simons EJ, Breedveld GJ, Peluso S, Volpe G, Filla A, Oostra BA, Bonifati V, De Michele G. The LRRK2 R1441C mutation is more frequent than G2019S in Parkinson's disease patients from Southern Italy. *Mov Disord*. 2011, 1;26(9):1733-6

- 36) Perretti A, **De Rosa A**, Marcantonio L, Iodice V, Estraneo A, Manganelli F, Garavaglia B, Filla A, Santoro L, De Michele G. Neurophysiological evaluation of motor corticospinal pathways by TMS in idiopathic early-onset Parkinson's disease. *Clin Neurophysiol*. 2011;122(3):546-9.
- 37) Fonteyn EM, Schmitz-Hübsch T, Verstaappen CC, Baliko L, Bloem BR, Boesch S, Bunn L, Charles P, Dürr A, Filla A, Giunti P, Globas C, Klockgether T, Melegh B, Pandolfo M, **De Rosa A**, Schöls L, Timmann D, Munneke M, Kremer BP, van de Warrenburg BP. Falls in Spinocerebellar Ataxias: Results of the EuroSCA Fall Study. *Cerebellum*. 2010;9(2):232-9.
- 38) De Joanna G, **De Rosa A**, Salvatore E, Castaldo I, De Luca N, Izzo R, Manzo V, Filla A, De Michele G. Autonomic nervous system abnormalities in spinocerebellar ataxia type 2: a cardiovascular neurophysiologic study. *J Neurol Sci*. 2008, 15;275:60-3.
- 39) **De Rosa A**, Criscuolo C, Mancini P, De Martino M, Giordano IA, Pappatà S, Filla A, De Michele G. Genetic screening for LRRK2 gene G2019S mutation in Parkinson's disease patients from Southern Italy. *Parkinsonism Relat Disord*. 2009 Mar;15:242-4.
- 40) Bianchi S, Dotti MT, Perretti A, **De Rosa A**, Manganelli F, Federico A. Novel human pathological mutations. Gene symbol: NOTCH3. Disease: CADASIL. *Hum Genet*. 2007;122(5):558.
- 41) **De Rosa A**, Carducci C, Antonozzi I, Giovanniello T, Xhoxhi E, Criscuolo C, Menchise V, Striano S, Filla A, De Michele G. A novel mutation in GCH-1 gene in a case of dopa-responsive dystonia. *J Neurol*. 2007;254:1133-4.
- 42) Criscuolo C, Volpe G, **De Rosa A**, Varrone A, Marongiu R, Mancini P, Salvatore E, Dallapiccola B, Filla A, Valente EM, De Michele G. PINK1 homozygous W437X mutation in a patient with apparent dominant transmission of parkinsonism. *Mov Disord*. 2006;22:1265-7
- 43) Salvatore E, Varrone A, Sansone V, Nolano M, Bruni AC, **De Rosa A**, Santoro L, Pappatà S, Filla A, De Michele G. Characterization of nigrostriatal dysfunction in spinocerebellar ataxia 17. *Mov Disord*. 2006;21:872-5
- 44) **De Rosa A**, Volpe G, Marcantonio L, Santoro L, Brice A, Filla A, Perretti A, De Michele G. Neurophysiological evidence of corticospinal tract abnormality in patients with Parkin mutations. *J Neurol*. 2006;253:275-9.
- 45) **De Rosa A**, Striano P, Barbieri F, de Falco A, Rinaldi C, Tucci T, Striano S, Filla A, De Michele G. Suppression of myoclonus in SCA2 by piracetam. *Mov Disord*. 2006;21:116-8.
- 46) E. Marano, F. Briganti, F. Tortora, A. Elefante, **A. De Rosa**, F. Maiuri, A. Filla (2004) Neurosyphilis with complex partial status epilepticus and mesiotemporal MRI abnormalities

mimicking herpes simplex encephalitis. Journal of Neurology, Neurosurgery and Psychiatry, 2004; 75; 6:833

- 47) D'Amico A, Caranci F, Giugliano V, De Marco A, Briganti F, **De Rosa A**, Filla A, Cirillo S, Elefante R. A MS study on three cases of cerebrotendineous xanthomatosis Van Bogaert-Scherer-Epstein disease. Rivista di Neuroradiologia, 17(4); 561-567

GIOVANNI COSSU

CURRICULUM VITAE

PERSONAL DATA

- Date of birth: November 15 1967
- Place of birth: Cagliari (Italy)
- Residence: Via Scano 11, 09129 Cagliari (Italy)
- Nationality: Italian
- Address: Dept. of Neurology General Hospital AOB “S. Michele” - P.le Ricchi,1 (09134) Cagliari (Italy)
- Tel.: +39-70-539639
- Fax: +39-70-539639
- E-Mail: giovannicossu@aob.it

HIGHER EDUCATION

- 1990-1992: Doctoral Studies:*Neurobiology of CRF*. Supervisor: Prof. W. Fratta Dept. of Neuroscience “B.B.Brodie” University of Cagliari
- Jul 1993: Degree in Medicine (110/110 cum Laude) , University of Cagliari
- Doctoral thesis: “The role of CRF in the regulation of electrical activity in the brain” . Supervisor: Prof. F. Marrosu
- 1993-1997: Postgraduate education/specialisation/training: Neurology. (50/50), Institute of Neurology , University of Cagliari. Director: Prof. M. Giagheddu)
- Oct 1996- Jul 1997 and Sept 1998-Sept 1999: Fellowship: Neurology and Neurophysiology. (Tutors : J Valls-Solè E Tolosa – Dept of Neurology Mov Disord Unit – Hospital Clinic Barcelona Spain)
- Sept-Nov 2012: Honorary contractor Movement Disorders and DBS Unit -UCL Institute of Neurology National Hospital for Neurology and Neurosurgery Queen Square, London

LANGUAGES

Italian, Spanish, English

PROFESSIONAL EXPERIENCE/FIELD OF INTEREST

- 1999-present: Clinical Assistant at the Department of Neurology - Brotzu General Hospital Cagliari

- 2009-present: Head of Movement Disorders Center - Department of Neurology - Brotzu General Hospital Cagliari (coordinates activities of two doctors neurologists, one psychologist, one nurse practitioner).

The Centre activity is particularly dedicated to:

a) Advanced Therapies of M. Parkinson and Movement Disorders: since 2000 is practiced therapy with continuous infusion s.c. of Apomorphine; since 2004, in partnership with NCH, were performed 37 interventions of deep brain stimulation (DBS) for the treatment of patients with Parkinson's disease, drug resistant tremor, focal and generalized dystonia. Since 2006 is performed intraduodenal infusion therapy with levodopa / carbidopa (40 patients operated)

b) Treatment centre dedicated to: M. Parkinson and Tremor, Botulinum toxin (treatment of various forms of dystonia, spasticity, overactive gland) for a total of approximately 1200 active patients

- 2015-present Deputy Director at the Department of Neurology - Brotzu General Hospital Cagliari

CLINICAL RESEARCH EXPERIENCE

- 2009-2013 Principal investigator in: Prevalence of neuropathy in patients with parkinson disease on treatment with levodopa: A multicentric study.
- 2008-2010: Sub-investigator in "Ferrochelating treatment in patients affected by neurodegeneration with brain iron accumulation (nbia) clinicaltrials.gov identifier: NCT00907283"
- 2007-8: Sub-investigator in the "Priamo study: prevalence of non-motor disorders in parkinsonism"
- 2005-2006 Responsible for the study "Prevalence of Primary blepharospasm in Sardinia, Italy.". Funded (€ 15,000) by Merz Pharma Italy 01/09/2005 01/03/2006
- 2008-2009: PI of the study "Restless legs syndrome in multiple sclerosis" Funded (30,000 euro) from Boehringer Ingelheim Italy Spa
- 2013: Co investigator in the TRUST study SP854 (Rotigotine Transdermal Uer Surveillance Study)
- 2013: Scientific Advisory Mandate by Chiesi Farmaceutici SpA to "Update on the role of iron chelator in Neurological syndromes"

- 2013: Co investigator in Post Marketing Observational Study Protocol "P13-893 MONOTREAT"
- 2014: PI of the study "Levodopa-carbidopa intrajejunal gel in advanced Parkinson's disease with ON freezing of gait". Funded (€ 75,000) from Abbvie Inc USA
- 2010: Responsible as IP at the "Studio IRIS: Italian validation of the revised MDS-Unified Parkinson's Disease Rating Scale - The IRIS study" (ClinicalTrials.gov Identifier: NCT01092936) entrusted by the Foundation Onlus Neureca
- 2014: Assignment Consulting for the therapeutic management of patients with Neurodegeneration with Intracerebral Accumulation of Iron by the Ministry of Health Russian Federation - Federal State Institution RDKB - Pediatric Clinic Moscow 03.18.2014 18.03.2014
- 2016: Project leader. rehabilitation, atypical antipsychotics and Parkinson's disease: the benefits and risks associated Funded by Fondazione Banco di Sardegna (15000 euro)

SOCIETY MEMBERSHIPS:

- Italian Society of Neurology (SIN);
- Movement Disorders Society (MDS).
- Italian Movement Disorders Society (Accademia LIMPE)

SERVICE TO PROFESSIONAL PUBLICATIONS:

- *Ad hoc* reviewer:
- Neurology
- Movement Disorders
- Parkinsonism Related Disorders
- Neurol Sci
- J Neurol Transmission
- Parkinson's Disease

PUBBLICATIONS

CHAPTERS OF BOOKS

1. **Cossu G**, Valls-Solé J. Reflex responses of hemifacial muscles at the onset of regeneration after facial palsy in: Brainstem Reflexes and Functions. Editors: J Valls-Solé and E Tolosa p 258 (1998)
2. **Cossu G**. Malattia di Hallervorden-Spatz in La malattia di Parkinson ed i disturbi del movimento Seconda edizione. CIC Edizioni Internazionali. Editor: C Colosimo. pp. 233-243 (2005).
3. Pinna A, Wardas J, Domenici MR, **Cossu G**, Morelli M. Control of motor function by Adenosine A_{2A} Receptors. Blom Book. In press (2016)

PEER-REVIEWED ARTICLES

4. CMKE de Cuba, A Albanese, A Antonini, **G Cossu**, G Deuschl, R Eleopra, A Galati, CFE Hoffman, K Knudsen, ALandi, MR Lanotte, A Marcante, A Mosch, M Pilleri, MM Reich, V Ricchi, S Rinaldo, LM Romito, F Saba, HE. Sacristan, PR Schuurman, A Trezza, P van den Munckhof, J Volkmann, M Zibetti, MF Contarino. Idiopathic delayed-onset edema surrounding deep brain stimulation leads: insights from a case series and systematic literature review. Parkinsonism Relat Disord. 2016 (accepted)
5. Pau M, Corona F, Pili R, Casula C, Guicciardi M, **Cossu G**, Arca R, Murgia M. Quantitative assessment of gait parameters in people with Parkinson's Disease in laboratory and clinical setting: are the measures interchangeable? Parkinson's Disease 2016 (accepted)
6. **Cossu G**, Ceravolo R, Zibetti M, Arca R, Ricchi V, Paribello A, Murgia D, Merola A, Romagnolo A, Nicoletti V, Palermo G, Mereu A, Lopiano L, Melis M, Abbruzzese G, Bonuccelli U. Levodopa and neuropathy risk in patients with Parkinson disease: Effect of COMT inhibition. Parkinsonism Relat Disord. 2016 Apr 20. pii: S1353-8020(16)30120-1. doi: 10.1016/j.parkreldis.2016.04.016. [Epub ahead of print]
7. Arca R, Ricchi V, Murgia D, Melis M, Floris F, Mereu A, Contu P, Marrosu F, Melis M, **Cossu G**. Parkinsonism and dementia are negative prognostic factors for the outcome of subdural hematoma. Neurol Sci. 2016 Apr 27. [Epub ahead of print]
8. **Cossu G**, Melis M The peripheral nerve involvement in Parkinson Disease: A multifaceted phenomenon. Parkinsonism Relat Disord. 2016 Jan 30. pii: S1353-8020(16)30026-8. doi: 10.1016/j.parkreldis.2016.01.026
9. Sensi MC*, **Cossu G***, Mancini F, Modugno N, Pilleri M, Quatrone R et al. Italian survey on intraduodenal levodopa gel treatment in advanced Parkinson disease: State of the art 10 years after marketing. Parkinsonism Relat Disord 22:e97-e98 · January 2016 *equal contribution
10. Tinazzi M, Fasano A, Geroi C, Morgante F, Ceravolo R, Rossi S, Thomas A, Fabbrini G, Bentivoglio A, Tamma F, **Cossu G**, Modugno N, Zappia M, Volontè MA, Dallochio C, Abbruzzese G, Pacchetti C, Marconi R, Defazio G, Canesi M, Cannas A, Pisani A, Mirandola R, Barone P, Vitale C; Italian Pisa Syndrome Study Group. Pisa syndrome in Parkinson disease: An observational multicenter Italian study. Neurology. 2015 Nov 17;85(20):1769-79.

11. [Cossu G](#), [Ricchi V](#), [Pilleri M](#), [Mancini F](#), [Murgia D](#), [Ricchieri G](#), [Mereu A](#), [Melis M](#), [Antonini A](#). Levodopa-carbidopa intrajejunal gel in advanced Parkinson disease with "on" freezing of gait. *Neurol Sci*. 2015 Sep;36(9):1683-6
12. Barone P, Santangelo G, Morgante L, Onofri M, Meco G, Abbruzzese G, Bonuccelli U, [Cossu G](#), Pezzoli G, Stanzione P, Lopiano L, Antonini A, Tinazzi M A randomized clinical trial to evaluate the effects of rasagiline on depressive symptoms in non-demented Parkinson's disease patients. *Eur J Neurol*. 2015 May 12. doi: 10.1111/ene.12724. [Epub ahead of print]
13. Quadri M,* Yang X,* [Cossu G](#),* Olgiati S, Saddi VM, Breedveld GJ, Ouyang L, Hu J, Xu N, Graafland J, Ricchi V, Murgia D, Guedes LC, Mariani C, Marti MJ, Tarantino P, Asselta R, Valdeoriola F, Gagliardi M, Pezzoli G, Ezquerra M, Quattrone A, Ferreira J, Annesi G, Goldwurm S, Tolosa E, Oostra BA, Melis M, Wang J, Bonifati V. An exome study of Parkinson's disease in Sardinia, a Mediterranean genetic isolate. *Neurogenetics*. 2014 Oct 8. [Epub ahead of print *equal contribution]
14. Wong TH, Chiu WZ, Breedveld GJ, Li KW, Verkerk AJ, Hondius D, Hukema RK, Seelaar H, Frick P, Severijnen LA, Lammers GJ, Lebbink JH, van Duinen SG, Kamphorst W, Rozemuller AJ; Netherlands Brain Bank, Bakker EB; International Parkinsonism Genetics Network ([Cossu G](#)+ 37), Neumann M, Willemsen R, Bonifati V, Smit AB, van Swieten J. PRKAR1B mutation associated with a new neurodegenerative disorder with unique pathology. *Brain*. 2014 May;137(Pt 5):1361-73.
15. [Cossu G](#), Abbruzzese G, Matta G, Murgia D, Melis M, Ricchi V, Galanello R, Barella S, Origa R, Balocco M, Pelosin E, Marchese R, Ruffinengo U, Forni GL Efficacy and safety of deferiprone for the treatment of pantothenate kinase-associated neurodegeneration (PKAN) and neurodegeneration with brain iron accumulation (NBIA): results from a four years follow-up. *Parkinsonism Relat Disord*. 2014 Jun;20(6):651-4.
16. McNeill A, Wu RM, Tzen KY, Aguiar PC, Arbelo JM, Barone P, Bhatia K, Barsottini O, Bonifati V, Bostantjopoulou S, Bressan R, [Cossu G](#), Cortelli P, Felicio A, Ferraz HB, Herrera J, Houlden H, Hoexter M, Isla C, Lees A, Lorenzo-Betancor O, Mencacci NE, Pastor P, Pappata S, Pellecchia MT, Silveria-Moriyama L, Varrone A, Foltynie T, Schapira AH. Dopaminergic neuronal imaging in genetic Parkinson's disease: insights into pathogenesis. *PLoS One*. 2013 Jul 23;8(7):e69190. doi: 10.1371
17. Ceravolo R,* [Cossu G](#),* Bandettini di Poggio M, Santoro L, Barone P, Zibetti M, Frosini D, Nicoletti V, Manganello F, Iodice R, Picillo M, Merola A, Lopiano L, Paribello A, Manca D, Melis M, Marchese R, Borelli P, Mereu A, Contu P, Abbruzzese G,* Bonuccelli U*. Mov Disord. Neuropathy and levodopa in Parkinson's disease: Evidence from a multicenter study. *Movement Disorders* 2013 Jul 8. doi: 10.1002/mds.25585. [Epub ahead of print] *equal contribution

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*equal contribution
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Cagliari, 30.11.16

Dott. Giovanni Cossu

A handwritten signature in black ink, appearing to read 'G Cossu', with a stylized, cursive script.



PERSONAL INFORMATION

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WORK EXPERIENCE

01/10/2006–Present

Medical doctor

IDC Hermitage-Capodimonte
Via Cupa delle Tozzole, 2, 80131 Naples (Italy)
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-Neurology Department: Head physician assistant
-Outpatient clinic for Movement Disorders

01/02/2015–Present

Professor on contract of Psychodiagnostic

University Suor Orsola Benincasa, Naples (Italy)

2003–2011

Clinical Co-Investigator

Department of Neurological Sciences, University of Naples Federico II, Naples (Italy)

"A 12 month double blind- multicenter study to evaluate the long term safety, tolerability and efficacy of E 2007 in patients with Parkinson's disease with wearing off motor fluctuations and on period dyskinesias" (prot. EISAI E-2007 E044-205; NCT00368108; Agosto 2006-Gennaio 2008).

"A 12 month open label- multicenter extension study to evaluate the long term safety, tolerability and efficacy of E 2007 in patients with Parkinson's disease with wearing off motor fluctuations and on period dyskinesias" (prot. EISAI E-2007 E044-205; NCT00368108).

"Studio Clinico in doppio cieco, multicentrico internazionale, di fase III, per valutare la sicurezza di un trattamento a lungo termine con Rotigotina cerotto in soggetti affetti da malattia di Parkinson idiopatica in fase avanzata, non adeguatamente controllati con levodopa" (prot. SP515 – SCHWARZ – PHARMA; NCT00244387; Marzo 2004-Luglio 2005).

"Studio Clinico di Estensione in aperto, multicentrico internazionale, di fase III, per valutare la sicurezza di un trattamento a lungo termine con Rotigotina cerotto in soggetti affetti da malattia di Parkinson idiopatica in fase avanzata, non adeguatamente controllati con levodopa" (prot. SP516 – SCHWARZ – PHARMA; NCT00244387).

"A single-blinded assessment of the short-term effects of cabergoline vs. Carbidopa/levodopa on SPECT dopamine transporter density in out-patient subjects with Parkinson's disease" (Prot. AMAD001; NCT00129181; Agosto 2005-Agosto 2009).

"A double-blind, multicenter, multinational Phase III follow-up study to investigate the long-term safety and efficacy of Sarizotan HCl 1 mg b.i.d. in patients with Parkinson's disease suffering from treatment associated dyskinesia" (prot. EMR (prot. EMR 62225-019 MERCK; NCT00105521; Settembre 2004-Marzo2006).

"An open-label, multicenter, multinational Phase III follow-up study to investigate the long-term safety and efficacy of Sarizotan HCl 1 mg b.i.d. in patients with Parkinson's disease suffering from treatment associated dyskinesia" (prot. EMR 62 225-030 MERCK; NCT00105521).

"The Parkinson's Progression Markers Initiative" sponsorizzato da The Michel J Fox Foundation for Parkinson's disease. Principal Investigator Ken Marek, Institute of Neurodegenerative Disorders, New Haven, Connecticut, USA (NCT01141023; Giugno 2010-In corso).

"A randomised, double blind, placebo-controlled study to evaluate if rasagiline can improve depressive symptoms and cognitive function in non-demented, idiopathic Parkinson's disease patients. ACCORDO Study" (prot. 12962A; EudraCT No 2009-011144-19; NCT01055379; Marzo2010-Luglio2012).

"A double-blind, randomized, comparative study of Cabaser and Sinemet CR for the treatment of nocturnal disability in levodopa-treated Parkinson's disease patients" (prot A7231001/CABAS-0067-049; NCT00174239; Luglio 2004-Settembre 2005).

"Multicentre, randomized, double blind, double dummy, parallel group, controller vs-L-Dopa plus carbidopa (Sinemet) study to evaluate efficacy and safety of CHF 1512 effervescent tablets in parkinsonian patients with predictable motor fluctuations during the day" (prot 2804/004/02).

"A phase III, double-blind, placebo-controlled, randomized study comparing the efficacy, safety, and tolerability of Sumanitrol versus Placebo or Ropinirole as an adjuvant to Levodopa in patients with advanced Parkinson's disease" (prot 666E-CNS-0075-022; NCT00058838; Aprile 2003-Settembre 2004).

"A 24-week Prospective, Randomized, Multicenter, Double-blind, Placebo-controlled, Parallel-group Study of Efficacy, Tolerability, and Safety of 3-12 mg/day of Exelon (Rivastigmine) Capsules in Patients with Parkinson's Disease Dementia" (prot CENA713B2311).

"Pramipexolo nel trattamento dei sintomi depressive di pazienti con malattia di Parkinson idiopatica e in terapia con levodopa. Studio clinico randomizzato, a gruppi paralleli, in cieco per il valutatore, controllato vs sertralina" (prot CTN 528E-CNS-0072-0126).

PERSONAL SKILLS

Job-related skills

Research products:

Moccia M, Erro R, Picillo M, Santangelo G, Spina E, Allocca R, Longo K, AMBONI M., Palladino R, Assante R, Pappatà S, Pellecchia MT, Barone P, Vitale C (2016). A Four-Year Longitudinal Study on Restless Legs Syndrome in Parkinson Disease. SLEEP, ISSN: 0161-8105

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Spina Emanuele, Barone Paolo, Mosca Lucia Luciana, Forges Davanzati Rosanna, Lombardi Agnese, Longo Katia, Iavarone Alessandro, AMBONI M. (2016). Music Therapy for Motor and Nonmotor Symptoms of Parkinson's Disease: A Prospective, Randomized, Controlled, Single-Blinded Study. JOURNAL OF THE AMERICAN GERIATRICS SOCIETY; p. 10.1111/jgs.14295-10.1111/jgs., ISSN: 0002-8614, doi: 10.1111/jgs.14295

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(2015). Short-latency afferent inhibition in patients with Parkinson's disease and freezing of gait. JOURNAL OF NEURAL TRANSMISSION, vol. 122; p. 1533-1540, ISSN: 0300-9564, doi: 10.1007/s00702-015-1428-y

Erro Roberto, Picillo Marina, AMBONI M., Moccia Marcello, Vitale Carmine, Longo Katia, Pellecchia Maria Teresa, Santangelo Gabriella, Martinez-Martin Pablo, Chaudhuri K Ray, Barone Paolo (2015). Nonmotor predictors for levodopa requirement in de novo patients with Parkinson's disease. MOVEMENT DISORDERS, vol. 30; p. 373-8-378, ISSN: 0885-3185, doi: 10.1002/mds.26076

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Positions and Employment

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Neurophysiology

B. ongoing research

- observational study ENROLL HD
- observational study on pain in Huntington Disease and Dystonia
- observational study Registro Italiano Distonie

C. previous research

- 2008-2014 Registry HD
- 2012-2013 Validation of Italian version of MDS UPDRS
- 2005-2008 Priamo study

D. peer-reviewed publications (in chronological order).

- Martinelli P, De Mitri P, Macri S, Nassetti S and **Scaglione C**. Non-Hodgkin's lymphoma mimicking amyotrophic lateral sclerosis. Eur J Neurol 1996 ; 3: 479.
- Martinelli P, Macri S, **Scaglione C**, Stumpo M, Poppi M. Acute brachial plexus neuropathy as a presenting sign of peripheral nervous system involvement in paraproteinaemia. Acta Neurol Scand 1997; 95:319-320.
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Book Chapter

Co-editing, "Wiley-Blackwell", A John Wiley & Son, Ltd, Publication:

Parkinson's Disease: non-motor and non-dopaminergic features. Edited by: CW Olanow, F Stocchi, AE Lang. 2011

- Chapter 25: Bladder dysfunction in Parkinson's disease and other parkinsonism. Stocchi F, Torti M, Palleschi G, Carbone A. 274-283

Principles of Treatment in Parkinson's Disease. Edited by: Schapira, A., Olanow, C.W. Elsevier Inc. 2005

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Data	15/02/2003
Titolo della qualifica rilasciata	Post-graduate Diploma in Epidemiology
Nome e tipo d'organizzazione erogatrice dell'istruzione e formazione	London school of Hygiene and Tropical Medicine (DLSHTM)
Data	1/11/2002
Titolo della qualifica rilasciata	Degree of Master of Science (MSc) Epidemiology
Nome e tipo d'organizzazione erogatrice dell'istruzione e formazione	London school of Hygiene and Tropical Medicine (University of London, UK)
Data	18/12/1995
Titolo della qualifica rilasciata	Diploma di specialista in Neurologia
Nome e tipo d'organizzazione erogatrice dell'istruzione e formazione	Università di Catania
Data	1991
Titolo della qualifica rilasciata	Abilitazione all'esercizio della professione di Medico Chirurgo e conseguente iscrizione all'albo dei Medici Chirurghi ed Odontoiatri della Provincia di Catania
Data	1/07/1991
Titolo della qualifica rilasciata	Laurea in Medicina e Chirurgia
Nome e tipo d'organizzazione erogatrice dell'istruzione e formazione	Università degli Studi di Catania
Data	1984/1985
Titolo della qualifica rilasciata	Maturità Classica
Nome e tipo d'organizzazione erogatrice dell'istruzione e formazione	Liceo classico statale "Mario Cutelli di Catania

Capacità e competenze personali

Madrelingua	Italiano
Altra(e) lingua(e)	Inglese, spagnolo

Autovalutazione
Livello europeo (*)

Comprensione		Parlato		Scritto
Ascolto	Lettura	Interazione orale	Produzione orale	

Lingua Inglese**Lingua Spagnolo**

C1	Livello Avanzato	C1	Livello Avanzato	C1	Livello Avanzato	C1	Livello Avanzato	C1	Livello Avanzato
C1	Livello Avanzato	C1	Livello Avanzato	C1	Livello Avanzato	C1	Livello Avanzato	C1	Livello Avanzato

() Quadro comune europeo di riferimento per le lingue***Campi di Ricerca:**

L'attività di ricerca è stata prevalentemente rivolta al settore della Neuroepidemiologia, Neurologia Tropicale, Malattia di Parkinson e Sclerosi Multipla. La suddetta attività scientifica è comprovata da oltre 150 pubblicazioni, su riviste peer reviewed a diffusione Internazionale. H-index 27.

CURRICULUM VITAE

INFORMAZIONI PERSONALI

Nome	SOLIVERI PAOLA
Data di nascita	Milano, 02 maggio 1956
Qualifica	<i>Dirigente Medico</i>
Amministrazione	ISTITUTO NEUROLOGICO C. BESTA - MILANO
Incarico attuale	Dirigente Medico in Neurologia presso Fondazione IRCCS Istituto Neurologico C. Besta
Numero telefonico dell'ufficio	+39 02 23942368
Fax dell'ufficio	+39 02 23942539
E-mail istituzionale	soliveri@istituto-besta.it

TITOLI DI STUDIO E PROFESSIONALI ED ESPERIENZE LAVORATIVE

Titolo di studio	Laurea in Medicina e Chirurgia conseguita presso l'Università degli Studi di Milano il 7/4/1983											
Altri titoli di studio e professionali	- Specializzazione in Neurologia presso l'Università degli Studi di Pavia il 17/7/1987 - Dottorato di Ricerca in Neuroscienze presso l'Università degli Studi di Milano il 23/10/1995											
Esperienze professionali (incarichi ricoperti)	- Borsista/Contrattista di Ricerca presso Istituto Neurologico C. Besta, Milano con incarichi annuali (dal 1984 al 1989 e dal 1991 al 1992) - Clinical Research Fellow at The National Hospital for Neurology and Neurosurgery, London (dal 1989 al 1991) - Dirigente Medico in Neurologia presso Ospedale Niguarda Ca' Granda, Milano (dal 1992 al 1994) - Dirigente Medico in Neurologia presso Fondazione IRCCS Istituto Neurologico C. Besta (dal 1994 ad oggi)											
Capacità linguistiche	<table><tr><th>Lingua</th><th>Livello Parlato</th><th>Livello Scritto</th></tr><tr><td>Inglese</td><td>ECCELLENTE</td><td>ECCELLENTE</td></tr><tr><td>Francese</td><td>SCOLASTICO</td><td>SCOLASTICO</td></tr></table> <i>Livelli: Scolastico, Fluente, Eccellente, Madrelingua</i>			Lingua	Livello Parlato	Livello Scritto	Inglese	ECCELLENTE	ECCELLENTE	Francese	SCOLASTICO	SCOLASTICO
Lingua	Livello Parlato	Livello Scritto										
Inglese	ECCELLENTE	ECCELLENTE										
Francese	SCOLASTICO	SCOLASTICO										
Capacità nell'uso delle tecnologie	Microsoft Office PowerPoint											
Altro (partecipazione a convegni e seminari, pubblicazioni, collaborazioni a riviste, ecc. e ogni altra	<i>Ha pubblicato oltre 80 articoli su riviste internazionali di argomento neurologico con particolare riguardo ai disordini del movimento. Partecipa a congressi nazionali ed internazionali ed a corsi di aggiornamento in qualità di relatore.</i>											

CURRICULUM VITAE

**informazione che il
dirigente ritiene di dover
pubblicare)**

In ambito neurologico il campo di interesse e di competenza specifica è quello dei disturbi del movimento.

Milano 18 marzo 2016

Paola Soliveri

CURRICULUM VITAE

PERSONAL DETAILS

Name: Cicarelli, Giulio

Address: 14, Via Casicarillo, 83028, Serino, Italy

Telephone: 3487446874 (mobile)

e-mail: cicalio@libero.it

Nationality: italian

Date of Birth: 05-08-1966

WORK EXPERIENCE

2012-2016: Head of the Scientific Committee, ONLUS Foundation "A. Cirino" - Parkinson Project - Avellino, Italy

2005-2016: Professor on contract, Neuropsychology, bachelor degree course in Physical Therapy, University of Campania "Luigi Vanvitelli"

2000-2016: neurologist, permanent position, Neurology Unit, Azienda Ospedaliera di Rilievo Nazionale "S.G. Moscati", Avellino, Italy

1999: neurologist, temporary work, Neurology Unit, Azienda Ospedaliera di Rilievo Nazionale "S. Giovanni di Dio e Ruggi d'Aragona, Salerno, Italy

1998: neurologist, temporary work, Azienda Ospedaliera di Rilievo Nazionale "S.G. Moscati", Avellino, Italy

1997: psychiatrist, temporary work, Psychiatric Hospital

"Materdomini", Nocera Superiore, Salerno, Italy
1996: neurologist, temporary work, Psychiatric Hospital
"Leonardo Bianchi", Napoli, Italy
1991-1995: resident in Neurology, University of Naples
"Federico II"

EDUCATION

1995: Specialization in Neurology, University of Naples
"Federico II" (summa cum laude)
1991: Degree in Medicine, University of Naples
"Federico II" (summaa cum laude)
1984: High School Diploma, Secondary School focusing
on humanities "Umberto I", Napoli, Italy (with full marks)

MEMBERSHIP IN SCIENTIFIC SOCIETIES

Accademia LIMPE-DISMOV (Accademia Italiana per lo
Studio della Malattia di Parkinson e dei Disordini del
Movimento)
MDS (Movement Disorders Society)
ANIRCEF (Associazione Neurologica Italiana per la
Ricerca sulle Cefalee)

Mother tongue: Italian
Other languages: English

Author or co-author of 20 paper published on peer-
reviewed journals and 35 scientific communications in
national and international meetings (main topic:

Parkinson's Disease, Movement Disorders).

Speaker/teacher/discussant in more than 30 scientific meeting and courses (main topic: Parkinson's Disease)



Curriculum Vitae

PERSONAL
INFORMATION**Vincenza Fetoni**

📍 Via Verdi, Res. Ginestre, 452 Basiglio 20080 Milano - ITALY

✉ vincenza.fetoni @libero.it; vincenza.fetoni @asst-fbf-sacco.it

TAX CODE FTNVCN59P68F499D

Sex F | Date of birth 28/09/1959 | Nationality ITALIAN

WORK EXPERIENCE

March 2012 to present

Hospital physician at Neurologic Dept., **Fatebenefratelli e Oftalmico Hospital** – Milan – Italy, with highly professional assignment in the field of degenerative diseases of the CNS

May 2000 to February 2012

Hospital physician at Neurological Dept. **Melegnano Hospital** – Milan – Italy

1998 to 2000

Hospital physician at Clinica Neurologica III – **San Paolo Hospital** – Milan – Italy

1989 to 1998

Scholarship holder and contractor at First Neurological Dept., **Istituto Neurologico C Besta** – Milan – Italy

Responsible of the Outpatient Department for Movement Disorders in the several Hospitals with highly professional assignment for Degenerative Disorders of the CNS

Responsible of the Outpatient Department for Demyelinating diseases and Multiple Sclerosis at Melegnano Hospital – Milan.

Active collaboration with the Head of the Neurologic Operative Unit at Melegnano Hospital for the realization of CME events, and in charge of the organization of the activities of Outpatient Department.

Head of the Outpatient Department for Movement Disorders at Fatebenefratelli Hospital – Milan – Italy



EDUCATION AND TRAINING

December 1984 Degree in Medicine, 110/110 e lode

1989 Specialization in Neurology, 70/70

Participation in training courses on Degenerative Disorders of the CNS, both as a speaker and as a learner

Member of several Scientific Societies (SIN, ACCADEMIA LIMPE-DISMOV)

2011 to 2015 Adviser at LIMPE (*Lega Italiana per la Malattia di Parkinson, Sindrome Extrapiramidale e Demenze*)

Scientific director of CME events about neurodegenerative disorder

Scientific board of patients Association (APM Milan)

PERSONAL SKILLS

Mother tongue(s) ITALIAN

Other language(s)

	UNDERSTANDING		SPEAKING		WRITING
	Listening	Reading	Spoken interaction	Spoken production	
English	Intermediate	Intermediate	Decent	Decent	Intermediate
French	Basic	Basic	Basic	Basic	Basic

Levels: A1/A2: Basic user - B1/B2: Independent user - C1/C2 Proficient user

Communication skills Excellent relational skills with positive effects in the work environment; very good communication skills in a spirit of collaboration and group loyalty.

Participation in volunteer activities, making available my professional skills

Digital competence

Good command of commonly used computer programs

Driving licence B



Curriculum Vitae

ADDITIONAL
INFORMATION

-
- | | |
|--------------|---|
| Publications | 26 Indexed published scientific articles
cooperation in some sections of books about Parkinson's disease |
| Hobbies | Theatre; participation to reading circles organized by local library |

The undersigned is aware that, in accordance with art. art. 76 of DPR 445/2000, mendacity in the acts and the use of fake acts are punished under the Italian Penal Code and special laws. In addition, I authorize the processing of personal data, in accordance with Law 196/03.

NAME ALESSIO BARNABA DI FONZO		POSITION TITLE MD, PhD	
EDUCATION/TRAINING			
INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY
University of Milan	M.D. Degree with honors	2002	Neurology
University of Milan	Neurologic specialist certification, with honors	2007	Neurology
Erasmus University, Rotterdam	PhD	2009	Neurogenetics
PRESENT POSITION Neurologist, Neurology Unit, Foundation I.R.C.C.S. “Ca’ Granda” Ospedale Maggiore Policlinico, Milan, Italy. 2014: National Academic Qualification as Associate Professor in Neurology (12/2014) Principal Investigator of the Movement Disorder Group, Department of Neurosciences and Mental Health. POSITIONS and EMPLOYMENT 2000-2006: Fellowship for Board Certified Neurology, University of Milan 2006-2009: PhD course at Erasmus University, Rotterdam, The Netherlands. 2009: Post-Doc Research Fellowship in Neurology, Faculty of Medicine, Department of Neurological Sciences, University of Milan. 2009-present Principal Investigator Movement Disorder Group, Biochemistry and Genetic Laboratory, Department of Neurosciences and Mental Health Foundation I.R.C.C.S. “Ca’Granda” Maggiore Hospital. 2012-present: Clinical Neurologist, Neurology Unit, Foundation I.R.C.C.S. “Ca’ Granda” Ospedale Maggiore Policlinico, Milan, Italy. RESEARCH ACTIVITY I am a board certified neurologist trained as a movement disorders specialist. My clinical activity comprises the in-patient clinic and emergency service, and the direction as Principal Investigator of the out-patient clinic for Parkinson’s disease and other movement disorders. Since 2009, when I have achieved my PhD in Clinical Genetics, I have started to collect biosamples from patients with movement disorders and to perform clinical and genetic analysis of genes involved in Parkinson’s disease and familial dystonia. I am involved in projects aimed to identify novel genetic causes of PD in large families and isolated populations. SCIENTIFIC SOCIETIES MEMBERSHIP Member of the Movement Disorder Society. Member of the Parkinsonisms and Related Disorders Society PUBLICATIONS (2004- 2016) Papers (in peer-reviewed journals) : 37 H-Index: 19 (Scopus); 20 (ISI v.5.16.1) Average citation per year: 136.72 (Scopus)			

BIOGRAPHICAL SKETCH

NAME Volonté, Maria Antonietta		POSITION TITLE Head of Movement Disorders Unit	
EDUCATION/TRAINING			
INSTITUTION AND LOCATION	DEGREE	YEAR(s)	FIELD OF STUDY
University of Milan, Milan, Italy	M.D.	1978-1984	School of Medicine
University of Milan, Milan, Italy	Residency in Neurology	1984-1988	Neurology

A. Positions and HonorsEmployment and experience:

1982-1984 Student Fellowship, Department of Neurology, Scientific Institute H San Raffaele, University of Milan

1984-1988 Medical Fellowship, Department of Neurology, Scientific Institute H San Raffaele, University of Milan

1988-1999 Assistant, Department of Neurology, Scientific Institute H San Raffaele, University of Milan

1999-2009 Senior Assistant, Department of Neurology, Scientific Institute H San Raffaele, University of Milan

2004-present Head Movement Disorders Unit and Deep Brain Stimulation Surgery team; Department of Neurology and Clinical Neurophysiology, INSPE, San Raffaele Hospital Scientific Institute Milan, Italy

Awards and Other Professional Activities:

Academic years 2001/2002, 2002/2003, 2003/2004, 2004/2005, 2005/2006, 2006/2007, 2007/2008, 2008/2009, 2009/2010, 2010/11, 2011/2012, 2012/2013, 2013/2014, 20172015, 2015/2016 (Professor by contract- Scuola di Specializzazione in Neurologia, Università Vita Salute, San Raffaele, Milano).

B. Selected peer-reviewed publications

- 1) Transcranial Doppler Sonography in the Early Phase of Alzheimer' s Disease. Bressi S, Volonté MA, Alberoni M, Canal N, Franceschi M: Dementia 1992; 3: 25-31
- 2) Correlations between Cognitive Impairment, Middle Cerebral Artery Flow Velocity and Cortical Glucose Metabolism in the Early Phase of Alzheimer's Disease. Franceschi F, Alberoni M, Bressi S, Canal N, Comi G, Fazio F, Grassi F, Perani D, Volonté MA Dementia. Vol.6, pag: 32-38. 1995
- 3) Randomised controlled trial of streptokinase, aspirin, and combination of both in treatment of acute ischaemic stroke. Multicentric Acute Stroke Trial- Italy (MAST-I) Group The Lancet. Vol 346: 1509-1514. December 9, 1995
- 4) Pain in multiple system atrophy. F Tison, GK Wennig, MA Volonté, WR Powe, P Henry, NP Quinn. Journal of Neurology. Vol 243, n.2, pag: 153-156. 1996
- 5) Focal Task-Specific Tremors. Movement Disorders. VL Soland, KP Bhatia, MA Volonté, CD Mardsen. Mov Disord Vol 11, n.6, pag 665-670. 1996

- 6) The International Stroke Trial (IST): a randomised trial of aspirin, subcutaneous heparin, both, or neither among 19 435 patients with acute ischaemic stroke. International Stroke Trial Collaborative. The Lancet. Vol 349, n 9065, pag: 1569-1581. May 1997.
- 7) Event-Related desynchronization to Contingent Negative Variation and Self-Paced Movement Paradigms in Parkinson's Disease. G Magnani, M Cursi, L Leocani, MA Volonté, T Locatelli, A Elia, G Comi. " Movement Disorders. Vol 13, n 4, pag: 653-666. 1998
- 8) Differential Distribution of Striatal (123I) betaCIT in Parkinson's disease and Progressive Supranuclear Palsy, evaluated with SPECT. C Messa, MA Volonté, F Fazio, F Zito, A Carpinelli, A D'Amico, G Rizzo, RM Moresco, E Paulesu, M Franceschi, G Lucignani. " E Journal of Nuclear Medicine. Vol 25(9): 1270-6. 1998
- 9) Transcranial magnetic stimulation and silent period in spasmodic torticollis. Amadio S, Panizza M, Pisano F, Maderna L, Miscio C, Nilsson J, Volonte MA, Comi G, Galardi G. Am J Phys Med Rehabil. 2000 Jul-Aug;79(4):361-8.
- 10) Clinical assessment of dysphagia in early phases of Parkinson's disease. Volonte MA, Porta M, Comi G. Neurol Sci. 2002 Sep;23 Suppl 2:S121-2.
- 11) Oculomotor focal dystonia. Galardi G, Volonte MA, Maderna L, Amadio S, Nemni R, Comi G. Mov Disord. 2001 Mar;16(2):366-70.
- 12) A PET study with [11-C]raclopride in Parkinson's disease: preliminary results on the effect of amantadine on the dopaminergic system. Volonte MA, Moresco RM, Gobbo C, Messa C, Carpinelli A, Rizzo G, Comi G, Fazio F. Neurol Sci. 2001 Feb;22(1):107-8.
- 13) Regression of ventral striatum hypometabolism after calcium/calcitriol therapy in paroxysmal kinesigenic choreoathetosis due to idiopathic primary hypoparathyroidism. Volonte MA, Perani D, Lanzi R, Poggi A, Anchisi D, Balini A, Comi G, Fazio F. J Neurol Neurosurg Psychiatry. 2001 Nov; 74(5): 691-5
- 14) New perspectives on neurochemical effects of amantadine in the brain of parkinsonian patients: a PET - [(11)C]raclopride study. Moresco RM, Volonte MA, Messa C, Gobbo C, Galli L, Carpinelli A, Rizzo G, Panzacchi A, Franceschi M, Fazio F. J Neural Transm. 2002 Oct;109(10):1265-74.
- 15) Acute effects of L-dopa on event-related desynchronization in Parkinson's disease. Magnani G, Cursi M, Leocani L, Volonte MA, Comi G. Neurol Sci. 2002 Sep;23 Suppl 2:S121-2.
- 16) Protein misfolding in Alzheimer's and Parkinson's disease: genetics and molecular mechanisms. Forloni G, Terreni L, Bertani I, Fogliarino S, Invernizzi R, Assini A, Ribizzi G, Negro A, Calabrese E, Volonte MA, Mariani C, Franceschi M, Tabaton M, Bertoli A. Neurobiol Aging. 2002 Sep-Oct;23(5):957-76. Review.
- 17) Clinical assessment of dysphagia in early phases of Parkinson's disease. Volonte MA, Porta M, Comi G. Neurol Sci. 2002 Sep;23 Suppl 2:S121-2.
- 17) Cause and course in a series of patients with sporadic chorea. Piccolo I, Defanti CA, Soliveri P, Volontè MA, Cislighi G, Girotti F. J Neurol. 2003 Apr;250(4):429-35.
- 18) Analysis of ferritin genes in Parkinson disease. Foglieni B, Ferrari F, Goldwurm S, Santambrogio P, Castiglioni E, Sessa M, Volontè MA, Lalli S, Galli C, Wang XS, Connor J, Sironi F, Canesi M, Biasiotto G, Pezzoli G, Levi S, Ferrari M, Arosio P, Cremonesi L. Clin Chem Lab Med. 2007;45(11):1450-6.
- 19) How to assess active contact coordinates in deep brain stimulation surgery? Comparison of three methods for determining the position of the active contact. Serra C, Picozzi P, Franzin A, Vimercati A, Volontè MA, Leocani L, Falini A, Mortini P. Stereotact Funct Neurosurg. 2010;88(2):67-74.
- 20) Delayed hyperbaric oxygen treatment after acute Carbon Monoxide (CO) poisoning. Spagnolo F., Costa M, Impellizzeri M, Cardamone R, Falautano M, Martinelli V, Comi G, Volonté MA. Journal of Neurology (2011) Feb 24.

- 21) Frontotemporal Dementia with Parkinsonism Presenting as Posterior Cortical Atrophy Spagnolo F, Ceppi D, Cardamone R, Falautano M, Martinelli V, Comi G, Perani D, Volonté MA. *Movement Disorders* 2011 May 25. DOI: 10.1002/mds.23768.
- 22) Neurodegeneration in the course of Langerhans cell Histiocytosis. Spagnolo F, Leopizzi E, Cardamone R., Falautano M, Martinelli V, Comi G, Volonté MA. *Neurological Science* 2011; DOI: 10.1007/s10072-011-0677-2
- 23) Proteomic identification of aldolase A as an autoantibody target in patients with atypical movement disorders. Privitera D, Corti V, Alessio M, Volonté MA, Lampasona V, Comi G, Martino G, Franciotta D, Furlan R, Fazio R. *Neurol Sci*. 2013 Mar;34(3):313-20. doi: 10.1007/s10072-012-0996-y. Epub 2012 Mar 6. Erratum in: *Neurol Sci*. 2014 Feb;35(2):333. Volonté, Antonietta [corrected to Volonté, Maria Antonietta].
- 24) Painful cervical dystonia triggered by the extension wire of the Deep Brain Stimulator. Spagnolo F, Picozzi P, Franzin A, Martinelli V, Comi G, Volonté MA. *J Clin Neurosci*. 2012 Nov; 19(11): 1582-3.
- 25) Changes in brain glucose metabolism in subthalamic nucleus deep brain stimulation for advanced Parkinson's disease. Volonté MA, Garibotto V, Spagnolo F, Panzacchi A, Picozzi P, Franzin A, Giovannini E, Leocani L, Cursi M, Comi G, Perani D. *Parkinsonism Relat Disord*. 2012 Jul; 18(6): 770-4.
- 26) Migralepsy: a new case confirming the existence of this migraine complication and proposing therapy. Colombo B, Dalla Libera D, Volonté MA, Spagnolo F, Dalla Costa G, Martinelli V, Comi G. *Neurol Sci*. 2012; 12: 1212-1219.
- 27) Teaching Video NeurolImages: Speech-induced oromandibular dystonia relieved by singing. Impellizzeri M, Spagnolo F, Sarro L, Martinelli V, Comi G, Volonté MA. *Neurology* 2012 Nov 20;79(21): e184.
- 28) Deep Magnetic Stimulation in a Progressive Supranuclear Palsy patient with speech involvement. Spagnolo F, Coppi E, Della Rosa PA Fichera M, Barbieri A, Magnani G, Falautano M, Zangen A, Comi G, Perani D, Volonté MA, Leocani L. *Journal of Neurology* 2012; DOI 10.1007/s00415-012-6772-3.
- 29) A complex case of anti-GAD antibody-related syndrome treated with Rituximab. Baroncini D, Spagnolo F, Sarro L, Comi G, Volonté MA. *Neurological Science* 2013 Feb 13; PMID: 23404307.
- 30) Adherence to anti-Parkinson drug therapy in the "REASON" sample of Italian patients with Parkinson's disease: the linguistic validation of the Italian version of the "Morisky Medical Adherence Scale-8 items". Fabbrini G, Abbruzzese G, Barone P, Antonini A, Tinazzi M, Castegnaro G, Rizzoli S, Morisky DE, Lessi P, Ceravolo R; REASON study group. *Neurol Sci*. 2013 Nov;34(11):2015-22. doi: 10.1007/s10072-013-1438-1. Epub 2013 Jun 1
- 31) Intheremispheric balance in Parkinson's Disease. A transcranial magnetic stimulation study. Spagnolo F, Coppi E, Chieffo R, Straffi L, Fichera M, Nuara A, Gonzales-Rosa J, Martinelli V, Comi G, Volonté MA, Leocani L. *Brain stimulation* 20134 Brain Stimul. 2013 Nov;6(6):892-7. doi: 10.1016/j.brs.2013.05.004. Epub 2013 Jun
- 32) Striatal hand in Parkinson's disease: the re-evaluation of an old clinical sign. Spagnolo F, Fichera M, Bucello S, Houdayer E, Baroncini D, Sarro L, Leopizzi E, Impellizzeri M, Martinelli V, Leocani L, Comi G, Volonté MA. *J Neurol*. 2014 Jan;261(1):117-20. doi: 10.1007/s00415-013-7165-y. Epub 2013 Oct 25.
- 33) Secondary cervical dystonic tremor after Japanese encephalitis. Spagnolo F, Scmazzone F, Fichera M, Comi G, Volonté MA. *Neurol Sci*. 2014 Mar;35(3):491-3. doi: 10.1007/s10072-013-1579-2. Epub 2013 Nov 20. No abstract available.
- 34) Excitatory deep repetitive transcranial magnetic stimulation with H-coil as add-on treatment of motor symptoms in Parkinson's disease: an open label, pilot study. Spagnolo F, Volonté MA, Fichera M, Chieffo R, Houdayer E, Bianco M, Coppi E, Nuara A, Straffi L, Di Maggio G, Ferrari L, Dalla Libera D, Velikova S, Comi G, Zangen A, Leocani L. *Brain Stimul*. 2014 Mar-Apr;7(2):297-300. doi: 10.1016/j.brs.2013.10.007. Epub 2013 Oct 29.

- 35) Drawing in Alzheimer-type dementia.Fichera M, Bernasconi MP, Martinelli V, Comi G, Volonté MA.Neurology. 2015 Jul 28;85(4):386-7. doi: 10.1212/WNL.0000000000001789. No abstract available.
- 36) Brain structural and functional connectivity in Parkinson's disease with freezing of gait.Canu E, Agosta F, Sarasso E, Volonté MA, Basaia S, Stojkovic T, Stefanova E, Comi G, Falini A, Kostic VS, Gatti R, Filippi M.Hum Brain Mapp. 2015 Dec;36(12):5064-78. doi: 10.1002/hbm.22994.
- 37) Pisa syndrome in Parkinson disease: An observational multicenter Italian study.Tinazzi M, Fasano A, Geroi C, Morgante F, Ceravolo R, Rossi S, Thomas A, Fabbrini G, Bentivoglio A, Tamma F, Cossu G, Modugno N, Zappia M, Volonté MA, Dallochio C, Abbruzzese G, Pacchetti C, Marconi R, Defazio G, Canesi M, Cannas A, Pisani A, Mirandola R, Barone P, Vitale C; Italian Pisa Syndrome Study Group..Neurology. 2015 Nov 17;85(20):1769-79. doi: 10.1212/WNL.0000000000002122.
- 38) Ceruloplasmin functional changes in Parkinson's disease-cerebrospinal fluid.Barbariga M, Curnis F, Andolfo A, Zanardi A, Lazzaro M, Conti A, Magnani G, Volonté MA, Ferrari L, Comi G, Corti A, Alessio M.Mol Neurodegener. 2015 Nov 4;10:59. doi: 10.1186/s13024-015-0055-2.
- 39) Cognitive impairment in progressive supranuclear palsy-Richardson's syndrome is related to white matter damage.Caso F, Agosta F, Volonté MA, Ferraro PM, Tiraboschi P, Copetti M, Valsasina P, Falautano M, Comi G, Falini A, Filippi M. Parkinsonism Relat Disord. 2016 Oct;31:65-71. doi: 10.1016/j.parkreldis.2016.07.007.
- 40) The Italian dementia with Lewy bodies study group (DLB-SINdem): toward a standardization of clinical procedures and multicenter cohort studies design.Bonanni L, Cagnin A, Agosta F, Babiloni C, Borroni B, Bozzali M, Bruni AC, Filippi M, Galimberti D, Monastero R, Muscio C, Parnetti L, Perani D, Serra L, Silani V, Tiraboschi P, Padovani A; DLB-SINdem study group..Neurol Sci. 2016 Sep 13.
- 41) Brain plasticity in Parkinson's disease with freezing of gait induced by action observation training.Agosta F, Gatti R, Sarasso E, Volonté MA, Canu E, Meani A, Sarro L, Copetti M, Cattrysse E, Kerckhofs E, Comi G, Falini A, Filippi M. J Neurol. 2016 Oct 24.

Capitoli su libri

- MA Volonté, M Comola: " Presentazione clinica e storia naturale dell'ateroma carotideo". In "La Chirurgia dei Tronchi Sopra Aortici"; pag. 84-89. Europa Scienze Umane Editrice. 1997
- M Comola, MA Volonté: "Timing dell'intervento dopo ictus". In " La Chirurgia dei Tronchi Sopra Aortici"; pag.155-159. Europa Scienze Umane Editrice. 1997

CURRICULUM VITAE

MANUELA PILLERI



PERSONAL DATA

*Nationality: Italian**Date of birth: 11/09/1971**Place of birth: Cagliari - Italy**Address: Contrà Pescaria 9- Vicenza- Italy**Mail: manupill@yahoo.it, manuela.pilleri@villamargherita.it**Phone : +390444997068, ; Mobile: +393478768982*

EDUCATION AND TRAINING

*1990 - 1996 Faculty of Medicine and Surgery, Univerity of Cagliari, Italy**Graduation in Medicine**1996 -2000 Department of Neurology, S. Giovanni di Dio Hospital, Cagliari, Italy**Specialization in Neurology**November 1999 –Dicember 2001 Department of Movemet Disorders, Service of Neurology,Hospital Clinic, Barcellona, Spain*

- Fellowship “Erasmus”

*January 2001-Dicember 2001**Department of Movemet Disorders, Service of Neurology,Hospital Clinic, Barcellona, Spain*

- Fellowship of European Neurological Society

WORK EXPERIENCE

*January 2002 –January 2005**Department of Movemet Disorders, Service of Neurology,Hospital Clinic, Barcellona, Spain*

- Neurologist and Research coordinator

*January 2005- May 2011**Private Clinic Villa Margherita- Neurology Service**Arcugnano (Vicenza), Italia*

- Neurologist- Senior Consultant

*May 2011-January 2015**Hospital and Institute for Clinical Research, San Camillo, Venice, Italy*

- Clinical Neurologist and Researcher

*February 2015 –onwards**Casa di Cura Privata Villa Margherita- Neurology Service*

- Director

PUBLICATIONS (in the last 3 years)

Preda F, Cavandoli C, Lettieri C, **Pilleri M**, Antonini A, Eleopra R, Mondani M, Martinuzzi A, Sarubbo S, Ghisellini G, Trezza A, Cavallo MA, Landi A, Sensi M. Switching from constant voltage to constant current in deep brain stimulation: a multicenter experience of mixed implants for movement disorders. Eur J Neurol. 2015 Oct 25.

Pilleri M, Weis L, Zabeo L, Koutsikos K, Biundo R, Facchini S, Rossi S, Masiero S, Antonini A. Overground robot assisted gait trainer for the treatment of drug-resistant freezing of gait in Parkinson disease. J Neurol Sci. 2015 May 29

Levodopa-carbidopa intrajejunal gel in advanced Parkinson disease with "on" freezing of gait.

Cossu G, Ricchi V, **Pilleri M**, Mancini F, Murgia D, Ricchieri G, Mereu A, Melis M, Antonini A. Neurol Sci. 2015 May 5.

Patterns of cortical thickness associated with impulse control disorders in Parkinson's disease.

Biundo R, Weis L, Facchini S, Formento-Dojot P, Valletlunga A, **Pilleri M**, Weintraub D, Antonini A. Mov Disord. 2015 Apr 15;30(5):688-95.

Therapeutic strategies to prevent and manage dyskinesias in Parkinson's disease.

Pilleri M, Antonini A.

Expert Opin Drug Saf. 2015 Feb;14(2):281-94. doi: 10.1517/14740338.2015.988137. Epub 2014 Dec 6.

Identification of circulating microRNAs for the differential diagnosis of Parkinson's disease and Multiple System Atrophy.

Valletlunga A, Ragusa M, Di Mauro S, Iannitti T, **Pilleri M**, Biundo R, Weis L, Di Pietro C, De Iuliis A, Nicoletti A, Zappia M, Purrello M, Antonini A.

Front Cell Neurosci. 2014 Jun 10;8:156.

Cognitive profiling of Parkinson disease patients with mild cognitive impairment and dementia.

Biundo R, Weis L, Facchini S, Formento-Dojot P, Valletlunga A, **Pilleri M**, Antonini A.

Parkinsonism Relat Disord. 2014 Apr;20(4):394-9. doi: 10.1016/j.parkreldis.2014.01.009. Epub 2014 Jan 22.

Novel levodopa formulations in the treatment of Parkinson's disease.

Pilleri M, Antonini A.

Expert Rev Neurother. 2014 Feb;14(2):143-9. doi: 10.1586/14737175.2014.877840. Epub 2014 Jan 13. Review.

Heart rate circadian profile in the differential diagnosis between Parkinson disease and multiple system atrophy.

Pilleri M, Levedianos G, Weis L, Gasparoli E, Facchini S, Biundo R, Formento-Dojot P, Antonini A.

Parkinsonism Relat Disord. 2014 Feb;20(2):217-21. doi: 10.1016/j.parkreldis.2013.11.006. Epub 2013 Nov 15.

Early DETection of wEaring off in Parkinson disease: the DEEP study.

Stocchi F, Antonini A, Barone P, Tinazzi M, Zappia M, Onofri M, Ruggieri S, Morgante L, Bonuccelli U, Lopiano L, Pramstaller P, Albanese A, Attar M, Posocco V, Colombo D, Abbruzzese G; **DEEP study group**.

Parkinsonism Relat Disord. 2014 Feb;20(2):204-11.

Validation of the Italian version of Parkinson's disease-cognitive rating scale (PD-CRS).

Santangelo G, Barone P, Abbruzzese G, Ferini-Strambi L, Antonini A; **IRIS Study Group**.

Neurol Sci. 2014 Apr;35(4):537-44.

Effects of rotigotine on Parkinson's disease-related sleep disturbances.

Antonini A, Calandrella D, Merello M, Koutsikos K, **Pilleri M**.

Expert Opin Pharmacother. 2013 Dec;14(18):2571-80. doi: 10.1517/14656566.2013.849692. Epub 2013 Oct 18. Review.

The MTHFR C677T polymorphism modifies age at onset in Parkinson's disease.

Vallelunga A, Pegoraro V, **Pilleri M**, Biundo R, De Iuliis A, Marchetti M, Facchini S, Formento Dojot P, Antonini A.

Neurol Sci. 2014 Jan;35(1):73-7. doi: 10.1007/s10072-013-1545-z. Epub 2013 Sep 20.

Comparison of the incidence of intracranial hemorrhage in two different planning techniques for stereotactic electrode placement in the deep brain stimulation.

Piacentino M, Zambon G, **Pilleri M**, Bartolomei L.

J Neurosurg Sci. 2013 Mar;57(1):63-7. Review.

Diagnostic and screening power of neuropsychological testing in detecting mild cognitive impairment in Parkinson's disease.

Biundo R, Weis L, **Pilleri M**, Facchini S, Formento-Dojot P, Vallelunga A, Antonini A.

J Neural Transm. 2013 Apr;120(4):627-33. doi: 10.1007/s00702-013-1004-2. Epub 2013 Mar 13.

Is there room for new non-dopaminergic treatments in Parkinson's disease?

Pilleri M, Koutsikos K, Antonini A.

J Neural Transm. 2013 Feb;120(2):349-52.

Cognitive and MRI correlates of orthostatic hypotension in Parkinson's disease.

Pilleri M, Facchini S, Gasparoli E, Biundo R, Bernardi L, Marchetti M, Formento P, Antonini A.

J Neurol. 2013 Jan;260(1):253-9.

Validation of the Italian version of the Movement Disorder Society-Unified Parkinson's Disease Rating Scale.

Antonini A, Abbruzzese G, Ferini-Strambi L, Tilley B, Huang J, Stebbins GT, Goetz CG, Barone P; MDS-UPDRS Italian Validation Study Group, Bandettini di Poggio M, Fabbrini G, Di Stasio F, Tinazzi M, Bovi T, Ramat S, Meoni S, Pezzoli G, Canesi M, Martinelli P, Maria Scaglione CL, Rossi A, Tambasco N, Santangelo G, Picillo M, Morgante L, Morgante F, Quatrone R, Sensi M, **Pilleri M**, Biundo R, Nordera G, Caria A, Pacchetti C, Zangaglia R, Lopiano L, Zibetti M, Zappia M, Nicoletti A, Quattrone A, Salsone M, Cossu G, Murgia D, Albanese A, Del Sorbo F.

Neurol Sci. 2013 May;34(5):683-7

Successful subthalamic stimulation in genetic Parkinson's disease caused by duplication of the alfa-synuclein gene Antonini A, **Pilleri M**, Padoan A, Landi A, Ferla S, Biundo R, D'Avella D.

J Neurol. 2012 Jan;259(1):165-7

LANGUAGES

Italian: mother tongue

English: understading , speaking and writing level B2 (independent user)

Spanish : understanding , speaking and writing: level C2 (proficient user)



Europass Curriculum Vitae



Personal information

First name(s) / Surname(s) **GIULIO RIBOLDAZZI**

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Telephone(s) +39 349 3902513

E-mail g.riboldazzi@fastwebnet.it

Nationality Italian

Date of birth 09/23/1974

Gender Male

Desired employment / Occupational field **Neurology – Movement Disorders and Parkinson's Disease**

Work experience

Dates	05/01/2014 ongoing
Occupation or position held	Head Neurologist of Unit for Rehabilitation of Parkinson's Disease and neurodegenerative diseases
Main activities and responsibilities	Head Management of rehabilitation Unit for patients with PD and Movement disorders
Name and address of employer	Casa di Cura "Fondazione Gaetano e Piera Borghi", via Petrarca 33, Brebbia (VA)
Type of business or sector	Private hospital for rehabilitation and nursing home
Dates	12/01/2004 ongoing
Occupation or position held	Referral Neurologist of Center for Parkinson's Disease and Movement Disorders
Main activities and responsibilities	Management of III level outpatient facility for Parkinson's Disease and Movement Disorders
Name and address of employer	ASST Sette Laghi – Ospedale di Circolo, viale Borri 57, 21100 VARESE
Type of business or sector	Universitary hospital

Education and training

Dates	From 1999 to 2004
Title of qualification awarded	Specialist in Neurology with a score of 50/50 cum laude.
Principal subjects/occupational skills covered	In trials it developed ability to diagnosis and treatment of major diseases of the nervous system with particular risuardo to neurodegenerative disorders such as Parkinson's disease and Alzheimer's disease, the Movement Disorders and headaches. During the specialization he has also actively participated in several research projects.
Name and type of organisation providing education and training	School of Neurology, Faculty of Medicine, University of Insubria, Varese.
Dates	From 1993 to 1999
Title of qualification awarded	Doctor in Medicine and Surgery with 110/110 cum laude

Principal subjects/occupational skills covered	Diagnosis and treatment of major human diseases																																										
Name and type of organisation providing education and training	Faculty of Medicine, University of Insubria, Varese.																																										
Mother Tongue	Italian																																										
Other language(s)	English, Spanish (Castigliano)																																										
Self-assessment																																											
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	<table><tr><th colspan="2">Understanding</th><th colspan="4">Speaking</th><th colspan="2">Writing</th></tr><tr><th colspan="2">Listening</th><th colspan="2">Reading</th><th colspan="2">Spoken interaction</th><th colspan="2">Spoken production</th><th colspan="2"></th></tr><tr><td></td><td>C2</td><td></td><td>C2</td><td></td><td>C1</td><td></td><td>C1</td><td></td><td>C1</td></tr><tr><td></td><td>C2</td><td></td><td>C2</td><td></td><td>C1</td><td></td><td>C1</td><td></td><td>B2</td></tr></table>					Understanding		Speaking				Writing		Listening		Reading		Spoken interaction		Spoken production					C2		C2		C1		C1		C1		C2		C2		C1		C1		B2
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	(*) Common European Framework of Reference for Languages																																										
Organisational skills and competences	Organization and Management and medical units for demented patients with neurodegenerative diseases. Autonomous management of clinical research protocols and developed and put into practice while working in collaboration with the University of Insubria and during the years of specialization. Running Trials of phase 4 and phase 3 as co / sub-investigator. Development of specific projects aimed at the creation of specialized structures for the diagnosis, treatment and care services in long-term care of neurodegenerative diseases.																																										
Technical skills and competences	Experienced in the diagnosis and medical treatment and rehabilitation of neurological diseases characterized by movement disorders and neurodegenerative diseases. Management expert diagnosis of diseases of the vestibular and balance systems. Use of botulinum toxin for the treatment of dystonia and other neurological diseases. Reading and interpretation of EEG. Theoretical and practical knowledge of the techniques of the second level (DBS, sc infusion of apomorphine and Duodopa) for patients with Parkinson's disease. Good knowledge of the use of PCs and programs commonly used in medical practice and research, including multimedia (data base, word processors, spreadsheets, utilities for slides).																																										
Other informations	Since 2000 he is member of the Italian Society of Neurology (SIN) and the Movement Disorder Society (MDS) Since 2001 is a member of the League for Parkinson's Disease (LIMPE), since 2006 the DisMov-SIN and in 2014 the Academy LIMPE -DISMOV. Since 2011 he is member of the Italian Society of Neurological Rehabilitation (SIRN) and the World Federation for Neuro-Rehabilitation. Founding Member of the Lombardy Section of the Italian Society of Nutraceuticals (Sinut) Since January 2007, medical and scientific advisor of the Association Parkinson Insubria (As.P.I.) sections of Varese Cassano Magnago.																																										

Publications or research.

- Martignoni E, Nappi RE, Citterio A, Calandrella D, Corengia E, Fignon A, Zagaglia R, Riboldazzi G, Pacchetti C, Nappi G. Parkinson's disease and reproductive life events. *Neurol Sci.* 2002 Sep;23 Suppl 2:S85-6.
- Martignoni E, Nappi RE, Citterio A, Calandrella D, Zagaglia R, Mancini F, Corengia E, Riboldazzi G, Polatti F, Nappi G. Reproductive life milestones in women with Parkinson's disease. *Funct Neurol.* 2003; 18(4):211-217.
- Martignoni E, Godi L, Citterio A, Zangaglia R, Riboldazzi G, Calandrella D, Pacchetti C, Nappi G; Parkinson's Disease Comorbidity Study Group. Comorbid disorders and hospitalisation in Parkinson's disease: a prospective study. *Neurol Sci.* 2004 Jun;25(2):66-71.
- Blandini F, Cosentino M, Mangiagalli A, Marino F, Samuele A, Rasini E, Fancellu R, Tassorelli C, Pacchetti C, Martignoni E, Riboldazzi G, Calandrella D, Lecchini S, Frigo G, Nappi G. Modifications of apoptosis-related protein levels in lymphocytes of patients with Parkinson's disease. The effect of dopaminergic treatment. *J Neural Transm.* 2004 Aug;111(8):1017-30.
- Di Fonzo A, Tassorelli C, De Mari M, Chien HF, Ferreira J, Rohé CF, Riboldazzi G, et al and The Italian Parkinson Genetics Network. Comprehensive analysis of the LRRK2 gene in sixty families with Parkinson's disease. *Eur J Hum Genet.* 2006 Mar;14(3):322-331.
- Mancini F, Comi C, Oggioni GD, Pacchetti C, Calandrella D, Coletti Moia M, Riboldazzi G, Tunesi S, Dal Fante M, Manfredi L, Lacerenza M, Cantello R, Antonini A. Prevalence and features of peripheral neuropathy in Parkinson's disease patients under different therapeutic regimens. *Parkinsonism and Related Disorders* 20 (2014) 27-31.
- Frazzitta G, Maestri R, Bertotti G, Riboldazzi G, Boveri N, Perini M, Uccellini D, Turla M, Comi C, Pezzoli G, Ghilardi MF. Intensive rehabilitation treatment in early Parkinson's disease: a randomized pilot study with a 2-year follow-up. *Neurorehabil Neural Repair.* 2015 Feb;29(2):123-31. doi: 10.1177/1545968314542981. Epub 2014 Jul 18.
- Frazzitta G, Maestri R, Ferrazzoli D, Riboldazzi G, Bera R, Fontanesi C, Rossi RP, Pezzoli G, Ghilardi MF. Multidisciplinary intensive rehabilitation treatment improves sleep quality in Parkinson's disease. *J Clin Mov Disord.* 2015 Apr 2;2:11. doi: 10.1186/s40734-015-0020-9. eCollection 2015.
- Kustrimovic N, Rasini E, Legnaro M, Bombelli R, Aleksic I, Blandini F, Comi C, Mauri M, Minafra B, Riboldazzi G, Sanchez-Guajardo V, Marino F, Cosentino M. Dopaminergic Receptors on CD4+ T Naive and Memory Lymphocytes Correlate with Motor Impairment in Patients with Parkinson's Disease. *Sci Rep.* 2016 Sep 22;6:33738. doi: 10.1038/srep33738
- Ferrari M, Comi C, Marino F, Magistrelli L, De Marchi F, Cantello R, Riboldazzi G, Bono G, Cosentino M. Polymorphisms of dopamine receptor genes and risk of visual hallucinations in Parkinson's patients. *Eur J Clin Pharmacol.* 2016 Nov;72(11):1335-1341

The undersigned is aware that, in accordance with art. 26 of Law 15/68, false statements, falsified acts and use of false acts are punishable under the Penal Code and special laws. In addition, it authorizes the processing of personal data, as provided by Law 196/03.

Busto Arsizio, 12/02/2016





Paolo Solla

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CURRICULUM VITAE

2012-28 October 2016 Researcher, Department of Medical Science and Public Health, University of Cagliari, Italy

2013 PhD in Cardiovascular Sciences, University of Cagliari, Italy

2009- present Neurologist, Neurology Unit, Department of Neurology, Azienda Ospedaliera-Universitaria Cagliari, Italy

2008-2009 Neurologist, Neurology Unit, Department of Neurology, ASL Cagliari, Italy

2007-2008 Research Fellowship, Binaghi Hospital, University of Cagliari, Italy

2006-2007 Outpatients Clinical Neurologist, ASL Cagliari, Italy

2006 Specialization in Neurology, University of Cagliari, Italy

2005-2006 Medical Fellow, Movement Disorder Center, University of Barcelona, Spain

2001-2006 Neurology Resident, Neurology Unit, University of Cagliari, Italy

2001 Medical Degree (magna cum laude), University of Cagliari, Italy

Current research interests

Motor and non-motor symptoms in Parkinson's disease patients with preminent interesting on behavioral, neuropsychiatric and cardiovascular disorders.

Genetic parkinsonism and study of genotype/phenotype correlation.

Gender differences in neurodegenerative diseases.

Genetically mutated animal models (*Drosophila Melanogaster*) of Parkinson's disease.

Memberships

2003-at present Member of the Italian Society of Parkinson and Extra-pyramidal Diseases (DISMOV-LIMPE)

2003-at present Member of Italian Society of Neurology (SIN).

Collaborations with Scientific Journals

Referee of different Journals: Parkinsonism and Related Disorders, Journal of Neurology, Neurosurgery and Neuropsychiatry, Journal of Neurological Sciences, Gait and Posture, Therapeutic Advances in Psychopharmacology, Human Genetics,

Progress in Neuro-Psychopharmacology & Biological Psychiatry.

Current scientific collaborations

- Department of Pharmacology and Toxicology, School of Pharmacy, University of Kansas, USA.
- Movement Disorders Center, TWH, UHN, Division of Neurology, University of Toronto, Toronto, Ontario, Canada.
- Fondazione IRCCS, Istituto Neurologico "Carlo Besta", Milano
- Department of Neurological, Neuropsychological, Morphological and Motor Sciences, University of Verona, Italy.
- Department of Neurosciences, University of Messina, Italy.
- WHO Collaborating Centre for Research and Training in Mental Health and Service Evaluation, Department of Public Health and Community Medicine, Section of Psychiatry, University of Verona, Italy.

PUBLICATIONS

- 1: Cugusi L, Manca A, Serpe R, Romita G, Bergamin M, Cadeddu C, Solla P, Mercuro G. Effects of a mini-trampoline rebounding exercise program on functional parameters, body composition and quality of life in overweight women. *J Sports Med Phys Fitness*. 2016 Jul 21. [Epub ahead of print] PubMed PMID: 27441918.
- 2: Solla P, Cannas A, Meloni M, Marrosu F. Dopamine dysregulation syndrome and psychosis in 24-h intestinal levodopa infusion for Parkinson's disease. *Parkinsonism Relat Disord*. 2016 Jul 6. pii: S1353-8020(16)30242-5. doi: 10.1016/j.parkreldis.2016.06.022. [Epub ahead of print] PubMed PMID: 27423923.
- 3: Meloni M, Cannas A, Mascia MM, Solla P, Floris G, Di Stefano F, Marrosu F. Fluctuating off-period hemidystonia with Pisa syndrome in advanced Parkinson's disease. *J Neurol Sci*. 2016 Aug 15;367:138-9. doi: 10.1016/j.jns.2016.06.010. Epub 2016 Jun 5. PubMed PMID: 27423577.
- 4: Solla P, Cannas A, Farris R, Orofino G, Meloni M, Marrosu F. Alternating or Metronome Pisa Syndrome in Patients Under Drugs Acting on Dopaminergic Pathways. *Clin Neuropharmacol*. 2016 Jul-Aug;39(4):214. doi: 10.1097/WNF.0000000000000162. PubMed PMID: 27280698.
- 5: Cannas A, Meloni M, Mascia MM, Solla P, Orofino G, Farris R, Marrosu F. Priapism and Hypersexuality Associated With Rotigotine in an Elderly Parkinsonian Patient: A Case Report. *Clin Neuropharmacol*. 2016 May-Jun;39(3):162-3. doi: 10.1097/WNF.0000000000000157. PubMed PMID: 27046660.
- 6: Solla P, Grau O, Gelpi E, Marrosu F, Martí MJ. Pisa syndrome in a patient with pathologically confirmed Parkinson's disease. *Neuropathol Appl Neurobiol*. 2016 Mar 21. doi: 10.1111/nan.12324. [Epub ahead of print] PubMed PMID: 26999006.
- 7: Solla P, Cannas A, Marrosu F. Influence of Parkinsonism on Hitler's Decision-Making. *World Neurosurg*. 2016 Feb;86:4. doi: 10.1016/j.wneu.2015.07.024. PubMed PMID: 26856783.
- 8: De Rose F, Marotta R, Poddighe S, Talani G, Catelani T, Setzu MD, Solla P, Marrosu F, Sanna E, Kasture S, Acquas E, Liscia A. Functional and Morphological Correlates in the Drosophila LRRK2 loss-of-function Model of Parkinson's Disease: Drug Effects of Withania somnifera (Dunal) Administration. *PLoS One*. 2016 Jan 4;11(1):e0146140. doi: 10.1371/journal.pone.0146140. eCollection 2016. PubMed PMID: 26727265; PubMed Central PMCID: PMC4699764.
- 9: Solla P, Cannas A, Arca R, Fonti D, Orofino G, Marrosu F. Focal (123)I-FP-CIT SPECT Abnormality in Midbrain Vascular Parkinsonism. *Case Rep Neurol Med*. 2015;2015:642764. doi: 10.1155/2015/642764. Epub 2015 Oct 15. PubMed PMID: 26550502; PubMed Central PMCID: PMC4624914.
- 10: Tinazzi M, Fasano A, Geroi C, Morgante F, Ceravolo R, Rossi S, Thomas A, Fabbrini G, Bentivoglio A, Tamma F, Cossu G, Modugno N, Zappia M, Volontè MA, Dallochio C, Abbruzzese G, Pacchetti C, Marconi R, Defazio G, Canesi M, Cannas A, Pisani A, Mirandola R, Barone P, Vitale C; Italian Pisa Syndrome Study Group. Pisa syndrome in Parkinson disease: An observational multicenter Italian study. *Neurology*. 2015 Nov 17;85(20):1769-79. doi: 10.1212/WNL.0000000000002122. Epub 2015 Oct 21. PubMed PMID: 26491088.
- 11: Cugusi L, Solla P, Serpe R, Carzedda T, Piras L, Oggianu M, Gabba S, Di Blasio A, Bergamin M, Cannas A, Marrosu F, Mercuro G. Effects of a Nordic Walking program on motor and non-motor symptoms, functional performance and body composition in patients with Parkinson's disease. *NeuroRehabilitation*. 2015;37(2):245-54. doi: 10.3233/NRE-151257. PubMed PMID: 26484516.
- 12: Solla P, Cannas A, Marrosu MG, Marrosu F. Dopamine dysregulation syndrome in Parkinson's disease patients on levodopa-carbidopa intestinal gel. *Parkinsonism Relat Disord*. 2015 Nov;21(11):1383-4. doi: 10.1016/j.parkreldis.2015.09.039. Epub 2015 Sep 25. PubMed PMID: 26453388.
- 13: Solla P, Fasano A, Cannas A, Marrosu F. Suicide and dopamine agonist withdrawal syndrome in Parkinson's disease. *Mov Disord*. 2015 Nov;30(13):1859-60. doi: 10.1002/mds.26443. Epub 2015 Oct 10. PubMed PMID: 26452673.
- 14: Cannas A, Solla P, Mascia M, Muroi A, Floris GL, Borghero G, Orofino G,

Meloni M, Marrosu F. Pisa-Like Syndrome Under Baclofen in a Patient With Spastic Hemiparesis due to Ischemic Stroke. *Clin Neuropharmacol*. 2015 Sep-Oct;38(5):217-9. doi: 10.1097/WNF.000000000000105. PubMed PMID: 26366969.

15: Cugusi L, Massidda M, Matta D, Garau E, Di Cesare R, Deidda M, Satta G, Chiappori P, Solla P, Mercuro G. A New Type of Physical Activity from an Ancient Tradition: The Sardinian Folk Dance "Ballu Sardu". *J Dance Med Sci*. 2015 Sep;19(3):118-23. doi: 10.12678/1089-313X.19.3.118. PubMed PMID: 26349505.

16: Cannas A, Solla P, Borghero G, Floris GL, Chio A, Mascia MM, Modugno N, Muroi A, Orofino G, Di Stefano F, Calvo A, Moglia C, Restagno G, Meloni M, Farris R, Ciaccio D, Puddu R, Vacca MI, Melis R, Murru MR, Tranquilli S, Corongiu D, Rolesu M, Cuccu S, Marrosu MG, Marrosu F. C9ORF72 intermediate repeat expansion in patients affected by atypical parkinsonian syndromes or Parkinson's disease complicated by psychosis or dementia in a Sardinian population. *J Neurol*. 2015 Nov;262(11):2498-503. doi: 10.1007/s00415-015-7873-6. Epub 2015 Aug 15. PubMed PMID: 26275564.

17: Solla P, Fasano A, Cannas A, Mulas CS, Marrosu MG, Lang AE, Marrosu F. Dopamine agonist withdrawal syndrome (DAWS) symptoms in Parkinson's disease patients treated with levodopa-carbidopa intestinal gel infusion. *Parkinsonism Relat Disord*. 2015 Aug;21(8):968-71. doi: 10.1016/j.parkreldis.2015.05.018. Epub 2015 Jun 10. PubMed PMID: 26071817.

18: Solla P, Cadeddu C, Cannas A, Deidda M, Mura N, Mercuro G, Marrosu F. Heart rate variability shows different cardiovascular modulation in Parkinson's disease patients with tremor dominant subtype compared to those with akinetic rigid dominant subtype. *J Neural Transm (Vienna)*. 2015 Oct;122(10):1441-6. doi: 10.1007/s00702-015-1393-5. Epub 2015 Mar 24. PubMed PMID: 25797035.

19: Solla P, Bortolato M, Cannas A, Mulas CS, Marrosu F. Paraphilias and paraphilic disorders in Parkinson's disease: A systematic review of the literature. *Mov Disord*. 2015 Apr 15;30(5):604-13. doi: 10.1002/mds.26157. Epub 2015 Mar 11. Review. PubMed PMID: 25759330; PubMed Central PMCID: PMC4428164.

20: Solla P, Cannas A, Orofino G, Marrosu F. Fluctuating Cotard syndrome in a patient with advanced Parkinson disease. *Neurologist*. 2015 Feb;19(3):70-2. doi: 10.1097/NRL.000000000000010. PubMed PMID: 25692512.

21: Solla P, Cannas A, Orofino G, Marrosu F. Rasagiline and Pisa syndrome in Parkinson's disease patients. *Neurol Sci*. 2015 Mar;36(3):485-6. doi: 10.1007/s10072-014-2024-x. Epub 2014 Dec 7. PubMed PMID: 25481627.

22: Poddighe S, De Rose F, Marotta R, Ruffilli R, Fanti M, Secci PP, Mostallino MC, Setzu MD, Zuncheddu MA, Collu I, Solla P, Marrosu F, Kasture S, Acquas E, Liscia A. *Mucuna pruriens* (Velvet bean) rescues motor, olfactory, mitochondrial and synaptic impairment in PINK1B9 *Drosophila melanogaster* genetic model of Parkinson's disease. *PLoS One*. 2014 Oct 23;9(10):e110802. doi: 10.1371/journal.pone.0110802. eCollection 2014. PubMed PMID: 25340511; PubMed Central PMCID: PMC4207759.

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Curriculum Vitae

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EDUCATION

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RESEARCH AND PROFESSIONAL EXPERIENCE

2013–present Director of the Molecular Neurogenetics Unit. Manager of the Movement Disorders Laboratory, of the Cell Culture Lab and of the Laboratory of Biochemistry for Mitochondrial Diseases.
1994–2013: Associate of Biology, Foundation IRCCS Neurological Institute C. Besta.
1990–1993: Assistant of Biology, Foundation IRCCS Neurological Institute C. Besta.
1983-1989: Research fellow at the Division of Biochemistry and Genetics, Foundation IRCCS Neurological Institute C. Besta

Director of the Biobank for the study of Movement Disorders and Mitochondrial Diseases (www.eurobiobank.org; <http://biobanknetwork.telethon.it>). Member of the Movement Disorders Society and of the Italian Society of Human Genetics. Since 2009, President of the Committee on Equal Opportunities of Foundation IRCCS Neurological Institute C. Besta. Member of the Technical Group on Gender Medicine of the Regione Lombardia (Welfare and Health Care)

RESEARCH MANAGEMENT

1998-present Grants from Italian Health Ministry for projects on genetic movement disorders and mitochondrial diseases
2009-2012 Telethon Grant for biobanking
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PUBLICATIONS

Author of 115 publications H-index =30 (Source: Scopus)

Brief Curriculum Valeria Conti

Valeria Conti received degree in Biology in 2001, PhD in Pharmacology and Clinical and Experimental Medicine in 2010 and Post degree specialization in Pharmacology in 2011.

From 2002 to 2005 she was fellow at the Telethon Institute of Genetics and Medicine (TIGEM) in Naples, where she participated in research projects on Thrombocytopenia and Fanconi Anemia.

From 2005 to 2011 she was Fellow and Ph.D Student at the Second University of Naples where she developed experience in both clinical and basic (*in vivo and in vitro*) research.

From 2011-2012 she was Temporary Research Post-doctoral Associate at the Department of Medicine and Surgery of University of Salerno, where she is dealing of several research projects. In particular, she is studying the effects of cardiac rehabilitation in patients with stable chronic heart failure and she is working at the pharmacogenetic analysis for the project “Prospective Validation Of A Pharmacogenetic Algorithm For Estimating The Appropriate Initial Dose Of Warfarin In Elderly People (≥ 65 Years), With Mechanical Heart Valves Or Non-valvular Atrial Fibrillation, And Comorbidity”, Sponsored by the Italian Medicines Agency (AIFA).

In 2014 Valeria Conti was appointed as Assistant Professor in Pharmacology at the Department of Medicine, Surgery and Dentistry “Scuola Medica Salernitana” at the University of Salerno and she is Coordinator of Operative Unit of Clinical Pharmacology and Pharmacogenetics at University Hospital “San Giovanni di Dio e Ruggi d’Aragona” of Salerno.

Her main research fields are Oxidative Stress, Aging, Physical Exercise in Health and Disease, Cardiovascular and Respiratory diseases, Genetics and Pharmacogenetics and Appropriateness of pharmacological treatment.

Dr. Conti is Tutor for the University of Salerno for the Inter-institutional agreement 2016/2020 of Erasmus+ program with the University of Nantes (France). She is a permanent scientific contributor of Pharmacogenetic Newsletter of Pharmacology Italian Society (SIF) of which she is a member. She has published several papers in peer-reviewed journal and she is referee of international peer review journal (European Journal of Pharmacology, World Journal of Medicine and Medical Science Research, Journal of Clinical Endocrinology & Metabolism).

List of Publications:

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7. Conti V, Corbi G, Manzo V, Pelaia G, Filippelli A, Vatrella A. Sirtuin 1 and aging theory for chronic

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 10. Conti V, Russomanno G, Corbi G, Toro G, Simeon V, Filippelli W, Ferrara N, Grimaldi M, D'Argenio V, Maffulli N, Filippelli A. A polymorphism at the translation start site of the vitamin D receptor gene is associated with the response to anti-osteoporotic therapy in postmenopausal women from southern Italy. *Int J Mol Sci*. 2015 Mar 10;16(3):5452-66. doi: 10.3390/ijms16035452. PMID: 25764158
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6- month
screening period

293 subjects
enrolled



First evaluation
before levodopa
start



1-year
assessment



2-year
assessment



4-month data
cleaning and
analysis

Final report

24-month
observation
period

		Treatment period	
	Baseline Pre-levodopa	Visit 1	Visit 2
Years of levodopa drug exposure	NA	1	2
Physical exam	x	x	x
Vital signs	x	x	x
Body weight, BMI	x	x	x
Neurological exam	x	x	x
Bioimpedanzometry	x	x	x
Calorimetry	x	x	x
Blood sample for genetic testing	x		
Blood sample for MicroRNA	x	x	x
Evaluation of levodopa pharmacokinetics	x	X	x
WOQ-19	X	x	X
MDS-UPDRS-I-II-III-IV	X	X	X
SEADL	X	X	X
Hamilton-depression/anxiety	X	X	X
Apathy scale	X	x	X
NMSS	X	x	X
QUIP	X	x	X
PDQ-39	X	x	X
SCOPA-AUT	x	x	x
MoCA	x	x	x
Morisky Medical Adherence scale 8-items	x	x	x
Concomitant medications	x	x	x
Adverse events	x	x	x

Please tick in column 1 any symptoms that you currently experience during your normal day.
Please also tick the box in column 2 if this symptom usually improves or disappears after you take a dose of your Parkinson's medication.

Mary's example

	Experience symptoms	Usually improves after my next dose
1. Tremor	☒	☒
2. Difficulty in speech	☒	☐
3. Anxiety	☐	☐

During her normal day Mary experiences both tremor and difficulty in speech

But only tremor improves after her next dose of medication

	Experience symptoms	Usually improves after my next dose
1. Tremor	☐	☐
2. Difficulty in speech	☐	☐
3. Anxiety	☐	☐
4. Experiencing sweating	☐	☐
5. Mood changes	☐	☐
6. Weakness	☐	☐
7. Problems with balance	☐	☐
8. Slowness of movement	☐	☐
9. Reduced dexterity	☐	☐
10. Numbness	☐	☐
11. General stiffness	☐	☐
12. Experience panic attacks	☐	☐
13. Cloudy mind / dullness thinking	☐	☐
14. Abdominal discomfort	☐	☐
15. Muscle cramping	☐	☐
16. Difficulty getting out of the chair	☐	☐
17. Experiencing hot and cold	☐	☐
18. Pain	☐	☐
19. Aching	☐	☐

MDS-UPDRS

The *Movement Disorder Society* (MDS)-sponsored new version of the UPDRS is founded on the critique that was formulated by the Task Force for Rating Scales in Parkinson's disease (*Mov Disord* 2003;18:738-750). Thereafter, the MDS recruited a Chairperson to organize a program to provide the Movement Disorder community with a new version of the UPDRS that would maintain the overall format of the original UPDRS, but address issues identified in the critique as weaknesses and ambiguities. The Chairperson identified subcommittees with chairs and members. Each part was written by the appropriate subcommittee members and then reviewed and ratified by the entire group. These members are listed below.

The MDS-UPDRS has four parts: Part I (non-motor experiences of daily living), Part II (motor experiences of daily living), Part III (motor examination) and Part IV (motor complications). Part I has two components: IA concerns a number of behaviors that are assessed by the investigator with all pertinent information from patients and caregivers, and IB is completed by the patient with or without the aid of the caregiver, but independently of the investigator. These sections can, however, be reviewed by the rater to ensure that all questions are answered clearly and the rater can help explain any perceived ambiguities. Part II is designed to be a self-administered questionnaire like Part IB, but can be reviewed by the investigator to ensure completeness and clarity. Of note, the official versions of Part IA, Part IB and Part II of the MDS-UPDRS do not have separate on or off ratings. However, for individual programs or protocols the same questions can be used separately for on and off. Part III has instructions for the rater to give or demonstrate to the patient; it is completed by the rater. Part IV has instructions for the rater and also instructions to be read to the patient. This part integrates patient-derived information with the rater's clinical observations and judgments and is completed by the rater.

The authors of this new version are:

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Part I: Non-Motor Aspects of Experiences of Daily Living (nM-EDL)

Overview: This portion of the scale assesses the non-motor impact of Parkinson's disease (PD) on patients' experiences of daily living. There are 13 questions. Part 1A is administered by the rater (six questions) and focuses on complex behaviors. Part 1B is a component of the self-administered Patient Questionnaire that covers seven questions on non-motor experiences of daily living.

Part 1A:

In administering Part 1A, the examiner should use the following guidelines:

1. Mark at the top of the form the primary data source as patient, caregiver, or patient and caregiver in equal proportion.
2. The response to each item should refer to a period encompassing the prior week including the day on which the information is collected.
3. All items must have an integer rating (no half points, no missing scores). In the event that an item does not apply or cannot be rated (e.g., amputee who cannot walk), the item is marked UR for Unable to Rate.
4. The answers should reflect the usual level of function and words such as "usually", "generally", "most of the time" can be used with patients.
5. Each question has a text for you to read (Instructions to patients/caregiver). After that statement, you can elaborate and probe based on the target symptoms outlined in the Instructions to examiner. You should NOT READ the RATING OPTIONS to the patient/caregiver, because these are written in medical terminology. From the interview and probing, you will use your medical judgment to arrive at the best response.
6. Patients may have co-morbidities and other medical conditions that can affect their function. You and the patient must rate the problem as it exists and do not attempt to separate elements due to Parkinson's disease from other conditions.

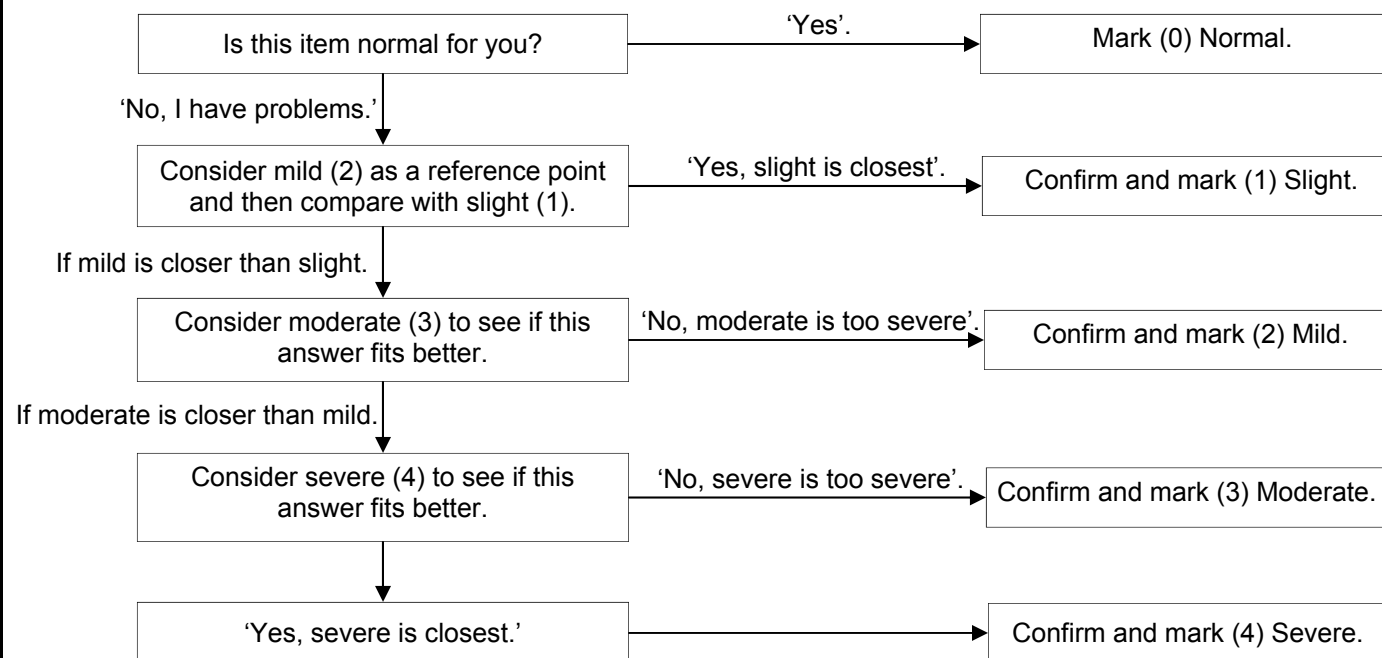
EXAMPLE OF NAVIGATING THROUGH THE RESPONSE OPTIONS FOR PART 1A

Suggested strategies for obtaining the most accurate answer:

After reading the instructions to the patient, you will need to probe the entire domain under discussion to determine Normal vs. problematic: If your questions do not identify any problem in this domain, record 0 and move on to the next question.

If your questions identify a problem in this domain, you should work next with a reference anchor at the mid-range (option 2 or Mild) to find out if the patient functions at this level, better or worse. You will not be reading the choices of responses to the patient as the responses use clinical terminology. You will be asking enough probing questions to determine the response that should be coded.

Work up and down the options with the patient to identify the most accurate response, giving a final check by excluding the options above and below the selected response.



_____	_____	____ - ____ - ____ (mm-dd-yyyy) Assessment Date	_____
Patient Name or Subject ID	Site ID		Investigator's Initials

MDS UPDRS

Part I: Non-Motor Aspects of Experiences of Daily Living (nM-EDL)

Part 1A: Complex behaviors: [completed by rater]

Primary source of information:

- ☐ Patient
 ☐ Caregiver
 ☐ Patient and Caregiver in Equal Proportion

To be read to the patient: I am going to ask you six questions about behaviors that you may or may not experience. Some questions concern common problems and some concern uncommon ones. If you have a problem in one of the areas, please choose the best response that describes how you have felt MOST OF THE TIME during the PAST WEEK. If you are not bothered by a problem, you can simply respond NO. I am trying to be thorough, so I may ask questions that have nothing to do with you.

1.1 COGNITIVE IMPAIRMENT

Instructions to examiner: Consider all types of altered level of cognitive function including cognitive slowing, impaired reasoning, memory loss, deficits in attention and orientation. Rate their impact on activities of daily living as perceived by the patient and/or caregiver.

Instructions to patients [and caregiver]: Over the past week have you had problems remembering things, following conversations, paying attention, thinking clearly, or finding your way around the house or in town? [If yes, examiner asks patient or caregiver to elaborate and probes for information]

- 0: Normal: No cognitive impairment.
- 1: Slight: Impairment appreciated by patient or caregiver with no concrete interference with the patient's ability to carry out normal activities and social interactions.
- 2: Mild: Clinically evident cognitive dysfunction, but only minimal interference with the patient's ability to carry out normal activities and social interactions.
- 3: Moderate: Cognitive deficits interfere with but do not preclude the patient's ability to carry out normal activities and social interactions.
- 4: Severe: Cognitive dysfunction precludes the patient's ability to carry out normal activities and social interactions.

SCORE

1.2 HALLUCINATIONS AND PSYCHOSIS <u>Instructions to examiner:</u> Consider both illusions (misinterpretations of real stimuli) and hallucinations (spontaneous false sensations). Consider all major sensory domains (visual, auditory, tactile, olfactory and gustatory). Determine presence of unformed (for example sense of presence or fleeting false impressions) as well as formed (fully developed and detailed) sensations. Rate the patients insight into hallucinations and identify delusions and psychotic thinking. <u>Instructions to patients [and caregiver]:</u> Over the past week have you seen, heard, smelled or felt things that were not really there? [If yes, examiner asks patient or caregiver to elaborate and probes for information] 0: Normal: No hallucinations or psychotic behaviour. 1: Slight: Illusions or non-formed hallucinations, but patient recognizes them without loss of insight. 2: Mild: Formed hallucinations independent of environmental stimuli. No loss of insight. 3: Moderate: Formed hallucinations with loss of insight. 4: Severe: Patient has delusions or paranoia.	SCORE
1.3 DEPRESSED MOOD <u>Instructions to examiner:</u> Consider low mood, sadness, hopelessness, feelings of emptiness or loss of enjoyment. Determine their presence and duration over the past week and rate their interference with the patient's ability to carry out daily routines and engage in social interactions. <u>Instruction to the patient (and caregiver):</u> Over the past week have you felt low, sad, hopeless or unable to enjoy things? If yes, was this feeling for longer than one day at a time? Did it make it difficult for you carry out your usual activities or to be with people? If yes, examiner asks patient or caregiver to elaborate and probes for information] 0: Normal: No depressed mood. 1: Slight: Episodes of depressed mood that are not sustained for more than one day at a time. No interference with patient's ability to carry out normal activities and social interactions. 2: Mild: Depressed mood that is sustained over days, but without interference with normal activities and social interactions. 3: Moderate: Depressed mood that interferes with, but does not preclude, the patient's ability to carry out normal activities and social interactions. 4: Severe: Depressed mood precludes patient's ability to carry out normal activities and social interactions.	

1.4 ANXIOUS MOOD <u>Instructions to examiner:</u> Determine nervous, tense, worried or anxious feelings (including panic attacks) over the past week and rate their duration and interference with the patient's ability to carry out daily routines and engage in social interactions. <u>Instructions to patients [and caregiver]:</u> Over the past week have you felt nervous, worried or tense? If yes, was this feeling for longer than one day at a time? Did it make it difficult for you to follow your usual activities or to be with other people? [If yes, examiner asks patient or caregiver to elaborate and probes for information.] 0: Normal: No anxious feelings. 1: Slight: Anxious feelings present but not sustained for more than one day at a time. No interference with patient's ability to carry out normal activities and social interactions. 2: Mild: Anxious feelings are sustained over more than one day at a time, but without interference with patient's ability to carry out normal activities and social interactions. 3: Moderate: Anxious feelings interfere with, but do not preclude, the patient's ability to carry out normal activities and social interactions. 4: Severe: Anxious feelings preclude patient's ability to carry out normal activities and social interactions.	SCORE
1.5 APATHY <u>Instructions to examiner:</u> Consider level of spontaneous activity, assertiveness, motivation and initiative and rate the impact of reduced levels on performance of daily routines and social interactions. Here the examiner should attempt to distinguish between apathy and similar symptoms that are best explained by depression. <u>Instructions to patients (and caregiver):</u> Over the past week, have you felt indifferent to doing activities or being with people? If yes, examiner asks patient or caregiver to elaborate and probes for information.] 0: Normal: No apathy. 1: Slight: Apathy appreciated by patient and/or caregiver, but no interference with daily activities and social interactions. 2: Mild: Apathy interferes with isolated activities and social interactions. 3: Moderate: Apathy interferes with most activities and social interactions. 4: Severe: Passive and withdrawn, complete loss of initiative.	

1.6 FEATURES OF DOPAMINE DYSREGULATION SYNDROME

SCORE

Instructions to examiner: Consider involvement in a variety of activities including atypical or excessive gambling (e.g. casinos or lottery tickets), atypical or excessive sexual drive or interests (e.g., unusual interest in pornography, masturbation, sexual demands on partner), other repetitive activities (e.g. hobbies, dismantling objects, sorting or organizing), or taking extra non-prescribed medication for non-physical reasons (i.e., addictive behavior). Rate the impact of such abnormal activities/behaviors on the patient's personal life and on his family and social relations (including need to borrow money or other financial difficulties like withdrawal of credit cards, major family conflicts, lost time from work, or missed meals or sleep because of the activity).

Instructions to patients [and caregiver]: Over the past week, have you had unusually strong urges that are hard to control? Do you feel driven to do or think about something and find it hard to stop? [Give patient examples such as gambling, cleaning, using the computer, taking extra medicine, obsessing about food or sex, all depending on the patients.

- 0: Normal: No problems present.
- 1: Slight: Problems are present but usually do not cause any difficulties for the patient or family/caregiver.
- 2: Mild: Problems are present and usually cause a few difficulties in the patient's personal and family life.
- 3: Moderate: Problems are present and usually cause a lot of difficulties in the patient's personal and family life.
- 4: Severe: Problems are present and preclude the patient's ability to carry out normal activities or social interactions or to maintain previous standards in personal and family life.

The remaining questions in Part I (Non-motor Experiences of Daily Living) [Sleep, Daytime Sleepiness, Pain and Other Sensation, Urinary Problems, Constipation Problems, Lightheadedness on Standing, and Fatigue] are in the **Patient Questionnaire** along with all questions in Part II [Motor Experiences of Daily Living].

Patient Questionnaire:

Instructions:

This questionnaire will ask you about your experiences of daily living.

There are 20 questions. We are trying to be thorough, and some of these questions may therefore not apply to you now or ever. If you do not have the problem, simply mark 0 for NO.

Please read each one carefully and read all answers before selecting the one that best applies to you.

We are interested in your average or usual function over the past week including today. Some patients can do things better at one time of the day than at others. However, only one answer is allowed for each question, so please mark the answer that best describes what you can do most of the time.

You may have other medical conditions besides Parkinson's disease. Do not worry about separating Parkinson's disease from other conditions. Just answer the question with your best response.

Use only 0, 1, 2, 3, 4 for answers, nothing else. Do not leave any blanks.

Your doctor or nurse can review the questions with you, but this questionnaire is for patients to complete, either alone or with their caregivers.

Who is filling out this questionnaire (check the best answer):

☐ Patient ☐ Caregiver ☐ Patient and Caregiver in Equal Proportion

Part I: Non-Motor Aspects of Experiences of Daily Living (nM-EDL)

1.7 SLEEP PROBLEMS

Over the past week, have you had trouble going to sleep at night or staying asleep through the night? Consider how rested you felt after waking up in the morning.

- 0: Normal: No problems.
- 1: Slight: Sleep problems are present but usually do not cause trouble getting a full night of sleep.
- 2: Mild: Sleep problems usually cause some difficulties getting a full night of sleep.
- 3: Moderate: Sleep problems cause a lot of difficulties getting a full night of sleep, but I still usually sleep for more than half the night.
- 4: Severe: I usually do not sleep for most of the night.

SCORE

1.8 DAYTIME SLEEPINESS

Over the past week, have you had trouble staying awake during the daytime?

- 0: Normal: No daytime sleepiness.
- 1: Slight: Daytime sleepiness occurs but I can resist and I stay awake.
- 2: Mild: Sometimes I fall asleep when alone and relaxing. For example, while reading or watching TV.
- 3: Moderate: I sometimes fall asleep when I should not. For example, while eating or talking with other people.
- 4: Severe: I often fall asleep when I should not. For example, while eating or talking with other people.

1.9 PAIN AND OTHER SENSATIONS		SCORE
Over the past week, have you had uncomfortable feelings in your body like pain, aches tingling or cramps? 0: Normal: No uncomfortable feelings. 1: Slight: I have these feelings. However, I can do things and be with other people without difficulty. 2: Mild: These feelings cause some problems when I do things or am with other people. 3: Moderate: These feelings cause a lot of problems, but they do not stop me from doing things or being with other people. 4: Severe: These feelings stop me from doing things or being with other people.		
1.10 URINARY PROBLEMS Over the past week, have you had trouble with urine control? For example, an urgent need to urinate, a need to urinate too often, or urine accidents? 0: Normal: No urine control problems. 1: Slight: I need to urinate often or urgently. However, these problems do not cause difficulties with my daily activities. 2: Mild: Urine problems cause some difficulties with my daily activities. However, I do not have urine accidents. 3: Moderate: Urine problems cause a lot of difficulties with my daily activities, including urine accidents. 4: Severe: I cannot control my urine and use a protective garment or have a bladder tube.		

1.11 CONSTIPATION PROBLEMS		SCORE
Over the past week have you had constipation troubles that cause you difficulty moving your bowels? 0: Normal: No constipation. 1: Slight: I have been constipated. I use extra effort to move my bowels. However, this problem does not disturb my activities or my being comfortable. 2: Mild: Constipation causes me to have some troubles doing things or being comfortable. 3: Moderate: Constipation causes me to have a lot of trouble doing things or being comfortable. However, it does not stop me from doing anything. 4: Severe: I usually need physical help from someone else to empty my bowels.		
1.12 LIGHT HEADEDNESS ON STANDING Over the past week, have you felt faint, dizzy or foggy when you stand up after sitting or lying down? 0: Normal: No dizzy or foggy feelings. 1: Slight: Dizzy or foggy feelings occur. However, they do not cause me troubles doing things. 2: Mild: Dizzy or foggy feelings cause me to hold on to something, but I do not need to sit or lie back down. 3: Moderate: Dizzy or foggy feelings cause me to sit or lie down to avoid fainting or falling. 4: Severe: Dizzy or foggy feelings cause me to fall or faint.		

2.2 SALIVA & DROOLING

Over the past week, have you usually had too much saliva during when you are awake or when you sleep?

- 0: Normal: Not at all (no problems).
- 1: Slight: I have too much saliva, but do not drool.
- 2: Mild: I have some drooling during sleep, but none when I am awake.
- 3: Moderate: I have some drooling when I am awake, but I usually do not need tissues or a handkerchief.
- 4: Severe: I have so much drooling that I regularly need to use tissues or a handkerchief to protect my clothes.

☐**2.3 CHEWING AND SWALLOWING**

Over the past week, have you usually had problems swallowing pills or eating meals? Do you need your pills cut or crushed or your meals to be made soft, chopped or blended to avoid choking?

- 0: Normal: No problems.
- 1: Slight: I am aware of slowness in my chewing or increased effort at swallowing, but I do not choke or need to have my food specially prepared.
- 2: Mild: I need to have my pills cut or my food specially prepared because of chewing or swallowing problems, but I have not choked over the past week.
- 3: Moderate. I choked at least once in the past week.
- 4: Severe: Because of chewing and swallowing problems, I need a feeding tube.

☐

2.4 EATING TASKS		SCORE
Over the past week, have you usually had troubles handling your food and using eating utensils? For example, do you have trouble handling finger foods or using forks, knives, spoons, chopsticks? 0: Normal: Not at all (No problems). 1: Slight: I am slow, but I do not need any help handling my food and have not had food spills while eating. 2: Mild: I am slow with my eating and have occasional food spills. I may need help with a few tasks such as cutting meat. 3: Moderate: I need help with many eating tasks but can manage some alone. 4: Severe: I need help for most or all eating tasks.		
2.5 DRESSING Over the past week, have you usually had problems dressing? For example, are you slow or do you need help with buttoning, using zippers, putting on or taking off your clothes or jewelry? 0: Normal: Not at all (no problems). 1: Slight: I am slow but I do not need help. 2: Mild: I am slow and need help for a few dressing tasks (buttons, bracelets). 3: Moderate: I need help for many dressing tasks. 4: Severe: I need help for most or all dressing tasks.		

2.6 HYGIENE Over the past week, have you usually been slow or do you need help with washing, bathing, shaving, brushing teeth, combing your hair or with other personal hygiene? 0: Normal: Not at all (no problems). 1: Slight: I am slow but I do not need any help. 2: Mild: I need someone else to help me with some hygiene tasks. 3: Moderate: I need help for many hygiene tasks. 4: Severe: I need help for most or all of my hygiene tasks.	SCORE
2.7 HANDWRITING Over the past week, have people usually had trouble reading your handwriting? 0: Normal: Not at all (no problems). 1: Slight: My writing is slow, clumsy or uneven, but all words are clear. 2: Mild: Some words are unclear and difficult to read. 3: Moderate: Many words are unclear and difficult to read. 4: Severe: Most or all words cannot be read.	
2.8 DOING HOBBIES AND OTHER ACTIVITIES Over the past week, have you usually had trouble doing your hobbies or other things that you like to do? 0: Normal: Not at all (no problems). 1: Slight: I am a bit slow but do these activities easily. 2: Mild: I have some difficulty doing these activities. 3: Moderate: I have major problems doing these activities, but still do most. 4: Severe: I am unable to do most or all of these activities.	

2.12 WALKING AND BALANCE		SCORE
Over the past week, have you usually had problems with balance and walking? 0: Normal: Not at all (no problems). 1: Slight: I am slightly slow or may drag a leg. I never use a walking aid. 2: Mild: I occasionally use a walking aid, but I do not need any help from another person. 3: Moderate: I usually use a walking aid (cane, walker) to walk safely without falling. However, I do not usually need the support of another person. 4: Severe: I usually use the support of another persons to walk safely without falling.		
2.13 FREEZING Over the past week, on your usual day when walking, do you suddenly stop or freeze as if your feet are stuck to the floor. 0: Normal: Not at all (no problems). 1: Slight: I briefly freeze but I can easily start walking again. I do not need help from someone else or a walking aid (cane or walker) because of freezing. 2: Mild: I freeze and have trouble starting to walk again, but I do not need someone's help or a walking aid (cane or walker) because of freezing. 3: Moderate: When I freeze I have a lot of trouble starting to walk again and, because of freezing, I sometimes need to use a walking aid or need someone else's help. 4: Severe: Because of freezing, most or all of the time, I need to use a walking aid or someone's help.		
This completes the questionnaire. We may have asked about problems you do not even have, and may have mentioned problems that you may never develop at all. Not all patients develop all these problems, but because they can occur, it is important to ask all the questions to every patient. Thank you for your time and attention in completing this questionnaire.		

Part III: Motor Examination

Overview: This portion of the scale assesses the motor signs of PD. In administering Part III of the MDS-UPDRS the examiner should comply with the following guidelines:

At the top of the form, mark whether the patient is on medication for treating the symptoms of Parkinson's disease and, if on levodopa, the time since the last dose.

Also, if the patient is receiving medication for treating the symptoms of Parkinson's Disease, mark the patient's clinical state using the following definitions:

ON is the typical functional state when patients are receiving medication and have a good response.

OFF is the typical functional state when patients have a poor response in spite of taking medications.

The investigator should "rate what you see". Admittedly, concurrent medical problems such as stroke, paralysis, arthritis, contracture, and orthopedic problems such as hip or knee replacement and scoliosis may interfere with individual items in the motor examination. In situations where it is absolutely impossible to test (e.g., amputations, plegia, limb in a cast), use the notation "**UR**" for Unable to Rate. Otherwise, rate the performance of each task as the patient performs in the context of co-morbidities.

All items must have an integer rating (no half points, no missing ratings).

Specific instructions are provided for the testing of each item. These should be followed in all instances. The investigator demonstrates while describing tasks the patient is to perform and rates function immediately thereafter. For Global Spontaneous Movement and Rest Tremor items (3.14 and 3.17), these items have been placed purposefully at the end of the scale because clinical information pertinent to the score will be obtained throughout the entire examination.

At the end of the rating, indicate if dyskinesia (chorea or dystonia) was present at the time of the examination, and if so, whether these movements interfered with the motor examination.

3a Is the patient on medication for treating the symptoms of Parkinson's Disease? ☐ No ☐ Yes

3b If the patient is receiving medication for treating the symptoms of Parkinson's Disease, mark the patient's clinical state using the following definitions:

☐ ON: On is the typical functional state when patients are receiving medication and have a good response.

☐ OFF: Off is the typical functional state when patients have a poor response in spite of taking medications.

3c Is the patient on Levodopa ? ☐ No ☐ Yes

3.C1 If yes, minutes since last levodopa dose: _____

3.1 SPEECH <u>Instructions to examiner:</u> Listen to the patient's free-flowing speech and engage in conversation if necessary. Suggested topics: ask about the patient's work, hobbies, exercise, or how he got to the doctor's office. Evaluate volume, modulation (prosody) and clarity, including slurring, palilalia (repetition of syllables) and tachyphemia (rapid speech, running syllables together). 0: Normal: No speech problems. 1: Slight: Loss of modulation, diction or volume, but still all words easy to understand. 2: Mild: Loss of modulation, diction, or volume, with a few words unclear, but the overall sentences easy to follow. 3: Moderate: Speech is difficult to understand to the point that some, but not most, sentences are poorly understood. 4: Severe: Most speech is difficult to understand or unintelligible.	SCORE
3.2 FACIAL EXPRESSION <u>Instructions to examiner:</u> Observe the patient sitting at rest for 10 seconds, without talking and also while talking. Observe eye-blink frequency, masked facies or loss of facial expression, spontaneous smiling and parting of lips. 0: Normal: Normal facial expression. 1: Slight: Minimal masked facies manifested only by decreased frequency of blinking. 2: Mild: In addition to decreased eye-blink frequency, Masked facies present in the lower face as well, namely fewer movements around the mouth, such as less spontaneous smiling, but lips not parted. 3: Moderate: Masked facies with lips parted some of the time when the mouth is at rest. 4: Severe: Masked facies with lips parted most of the time when the mouth is at rest.	

3.3 RIGIDITY	SCORE
<u>Instructions to examiner:</u> Rigidity is judged on slow passive movement of major joints with the patient in a relaxed position and the examiner manipulating the limbs and neck. First, test without an activation maneuver. Test and rate neck and each limb separately. For arms, test the wrist and elbow joints simultaneously. For legs, test the hip and knee joints simultaneously. If no rigidity is detected, use an activation maneuver such as tapping fingers, fist opening/closing, or heel tapping in a limb not being tested. Explain to the patient to go as limp as possible as you test for rigidity. 0: Normal: No rigidity. 1: Slight: Rigidity only detected with activation maneuver. 2: Mild: Rigidity detected without the activation maneuver, but full range of motion is easily achieved. 3: Moderate: Rigidity detected without the activation maneuver; full range of motion is achieved with effort. 4: Severe: Rigidity detected without the activation maneuver and full range of motion not achieved.	Neck RUE LUE RLE LLE
3.4 FINGER TAPPING	
<u>Instructions to examiner:</u> 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. 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. 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. 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. 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions or decrements.	R L

3.5 HAND MOVEMENTS	SCORE
<u>Instructions to examiner:</u> Test each hand separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to make a tight fist with the arm bent at the elbow so that the palm faces the examiner. Have the patient open the hand 10 times as fully AND as quickly as possible. If the patient fails to make a tight fist or to open the hand fully, remind him/her to do so. Rate each side separately, evaluating speed, amplitude, hesitations, halts and decrementing amplitude. 0: Normal: No problem. 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the movement; b) slight slowing; c) the amplitude decrements near the end of the task. 2: Mild: Any of the following: a) 3 to 5 interruptions during the movements; b) mild slowing; c) the amplitude decrements midway in the task. 3: Moderate: Any of the following: a) more than 5 interruptions during the movement or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing; c) the amplitude decrements starting after the 1st open-and-close sequence. 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions or decrements.	☐ R ☐ L
3.6 PRONATION-SUPINATION MOVEMENTS OF HANDS	
<u>Instructions to examiner:</u> Test each hand separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to extend the arm out in front of his/her body with the palms down; then to turn the palm up and down alternately 10 times as fast and as fully as possible. Rate each side separately, evaluating speed, amplitude, hesitations, halts and decrementing amplitude. 0: Normal: No problems. 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the movement; b) slight slowing; c) the amplitude decrements near the end of the sequence. 2: Mild: Any of the following: a) 3 to 5 interruptions during the movements; b) mild slowing; c) the amplitude decrements midway in the sequence. 3: Moderate: Any of the following: a) more than 5 interruptions during the movement or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing c) the amplitude decrements starting after the 1st supination-pronation sequence. 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions or decrements.	☐ R ☐ L

3.7 TOE TAPPING	SCORE
<u>Instructions to examiner:</u> Have the patient sit in a straight-backed chair with arms, both feet on the floor. Test each foot separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to place the heel on the ground in a comfortable position and then tap the toes 10 times as big and as fast as possible. Rate each side separately, evaluating speed, amplitude, hesitations, halts and decrementing amplitude. 0: Normal: No problem. 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) amplitude decrements near the end of the ten taps. 2: Mild: Any of the following: a) 3 to 5 interruptions during the tapping movements; b) mild slowing; c) amplitude decrements midway in the task. 3: Moderate: Any of the following: a) more than 5 interruptions during the tapping movements or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing; c) amplitude decrements after the first tap. 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions or decrements.	R L
3.8 LEG AGILITY	
<u>Instructions to examiner:</u> Have the patient sit in a straight-backed chair with arms. The patient should have both feet comfortably on the floor. Test each leg separately. Demonstrate the task, but do not continue to perform the task while the patient is being tested. Instruct the patient to place the foot on the ground in a comfortable position and then raise and stomp the foot on the ground 10 times as high and as fast as possible. Rate each side separately, evaluating speed, amplitude, hesitations, halts and decrementing amplitude. 0: Normal: No problems. 1: Slight: Any of the following: a) the regular rhythm is broken with one or two interruptions or hesitations of the movement; b) slight slowing; c) amplitude decrements near the end of the task. 2: Mild: Any of the following: a) 3 to 5 interruptions during the movements; b) mild slowness; c) amplitude decrements midway in the task. 3: Moderate: Any of the following: a) more than 5 interruptions during the movement or at least one longer arrest (freeze) in ongoing movement; b) moderate slowing in speed; c) amplitude decrements after the first tap. 4: Severe: Cannot or can only barely perform the task because of slowing, interruptions or decrements.	R L

3.9 ARISING FROM CHAIR	SCORE
Instructions to examiner: Have the patient sit in a straight-backed chair with arms, with both feet on the floor and sitting back in the chair (if the patient is not too short). Ask the patient to cross his/her arms across the chest and then to stand up. If the patient is not successful, repeat this attempt a maximum up to two more times. If still unsuccessful, allow the patient to move forward in the chair to arise with arms folded across the chest. Allow only one attempt in this situation. If unsuccessful, allow the patient to push off using his/her hands on the arms of the chair. Allow a maximum of three trials of pushing off. If still not successful, assist the patient to arise. After the patient stands up, observe the posture for item 3.13 0: Normal: No problems. Able to arise quickly without hesitation. 1: Slight: Arising is slower than normal; or may need more than one attempt; or may need to move forward in the chair to arise. No need to use the arms of the chair. 2: Mild: Pushes self up from arms of chair without difficulty. 3: Moderate: Needs to push off, but tends to fall back; or may have to try more than one time using arms of chair, but can get up without help. 4: Severe: Unable to arise without help.	
3.10 GAIT Instructions to examiner: Testing gait is best performed by having the patient walking away from and towards the examiner so that both right and left sides of the body can be easily observed simultaneously. The patient should walk at least 10 meters (30 feet), then turn around and return to the examiner. This item measures multiple behaviors: stride amplitude, stride speed, height of foot lift, heel strike during walking, turning, and arm swing, but not freezing. Assess also for “freezing of gait” (next item 3.11) while patient is walking. Observe posture for item 3.13 0: Normal: No problems. 1: Slight: Independent walking with minor gait impairment. 2: Mild: Independent walking but with substantial gait impairment. 3: Moderate: Requires an assistance device for safe walking (walking stick, walker) but not a person. 4: Severe: Cannot walk at all or only with another person’s assistance.	

3.11 FREEZING OF GAIT <u>Instructions to examiner:</u> While assessing gait, also assess for the presence of any gait freezing episodes. Observe for start hesitation and stuttering movements especially when turning and reaching the end of the task. To the extent that safety permits, patients may NOT use sensory tricks during the assessment. 0: Normal: No freezing. 1: Slight: Freezes on starting, turning or walking through doorway with a single halt during any of these events, but then continues smoothly without freezing during straight walking. 2: Mild: Freezes on starting, turning or walking through doorway with more than one halt during any of these activities, but continues smoothly without freezing during straight walking. 3: Moderate: Freezes once during straight walking. 4: Severe: Freezes multiple times during straight walking.	SCORE
3.12 POSTURAL STABILITY <u>Instructions to examiner:</u> The test examines the response to sudden body displacement produced by a <u>quick, forceful</u> pull on the shoulders while the patient is standing erect with eyes open and feet comfortably apart and parallel to each other. Test retropulsion. Stand behind the patient and instruct the patient on what is about to happen. Explain that s/he is allowed to take a step backwards to avoid falling. There should be a solid wall behind the examiner, at least 1-2 meters away to allow for the observation of the number of retropulsive steps. The first pull is an instructional demonstration and is purposely milder and not rated. The second time the shoulders are pulled briskly and forcefully towards the examiner with enough force to displace the center of gravity so that patient MUST take a step backwards. The examiner needs to be ready to catch the patient, but must stand sufficiently back so as to allow enough room for the patient to take several steps to recover independently. Do not allow the patient to flex the body abnormally forward in anticipation of the pull. Observe for the number of steps backwards or falling. Up to and including two steps for recovery is considered normal, so abnormal ratings begin with three steps. If the patient fails to understand the test, the examiner can repeat the test so that the rating is based on an assessment that the examiner feels reflects the patient's limitations rather than misunderstanding or lack of preparedness. Observe standing posture for item 3.13 0: Normal: No problems: Recovers with one or two steps. 1: Slight: 3-5 steps, but subject recovers unaided. 2: Mild: More than 5 steps, but subject recovers unaided. 3: Moderate: Stands safely, but with absence of postural response; falls if not caught by examiner. 4: Severe: Very unstable, tends to lose balance spontaneously or with just a gentle pull on the shoulders.	

3.13 POSTURE

Instructions to examiner: Posture is assessed with the patient standing erect after arising from a chair, during walking, and while being tested for postural reflexes. If you notice poor posture, tell the patient to stand up straight and see if the posture improves (see option 2 below). Rate the worst posture seen in these three observation points. Observe for flexion and side-to-side leaning.

- | | |
|--------------|---|
| 0: Normal: | No problems. |
| 1: Slight: | Not quite erect, but posture could be normal for older person. |
| 2: Mild: | Definite flexion, scoliosis or leaning to one side, but patient can correct posture to normal posture when asked to do so. |
| 3: Moderate: | Stooped posture, scoliosis or leaning to one side that cannot be corrected volitionally to a normal posture by the patient. |
| 4: Severe: | Flexion, scoliosis or leaning with extreme abnormality of posture. |

3.14 GLOBAL SPONTANEITY OF MOVEMENT (BODY BRADYKINESIA)

Instructions to examiner: This global rating combines all observations on slowness, hesitancy, and small amplitude and poverty of movement in general, including a reduction of gesturing and of crossing the legs. This assessment is based on the examiner's global impression after observing for spontaneous gestures while sitting, and the nature of arising and walking.

- | | |
|--------------|--|
| 0: Normal: | No problems. |
| 1: Slight: | Slight global slowness and poverty of spontaneous movements. |
| 2: Mild: | Mild global slowness and poverty of spontaneous movements. |
| 3: Moderate: | Moderate global slowness and poverty of spontaneous movements. |
| 4: Severe: | Severe global slowness and poverty of spontaneous movements. |

3.15 POSTURAL TREMOR OF THE HANDS

Instructions to examiner: All tremor, including re-emergent rest tremor, that is present in this posture is to be included in this rating. Rate each hand separately. Rate the highest amplitude seen. Instruct the patient to stretch the arms out in front of the body with palms down. The wrist should be straight and the fingers comfortably separated so that they do not touch each other. Observe this posture for 10 seconds.

- | | |
|--------------|--|
| 0: Normal: | No tremor. |
| 1: Slight: | Tremor is present but less than 1 cm in amplitude. |
| 2: Mild: | Tremor is at least 1 but less than 3 cm in amplitude. |
| 3: Moderate: | Tremor is at least 3 but less than 10 cm in amplitude. |
| 4: Severe: | Tremor is at least 10 cm in amplitude. |

R

L

3.16 KINETIC TREMOR OF THE HANDS		SCORE
<u>Instructions to examiner:</u> This is tested by the finger-to-nose maneuver. With the arm starting from the outstretched position, have the patient perform at least three finger-to-nose maneuvers with each hand reaching as far as possible to touch the examiner's finger. The finger-to-nose maneuver should be performed slowly enough not to hide any tremor that could occur with very fast arm movements. Repeat with the other hand, rating each hand separately. The tremor can be present throughout the movement or as the tremor reaches either target (nose or finger). Rate the highest amplitude seen.		
0: Normal:	No tremor.	☐
1: Slight:	Tremor is present but less than 1 cm in amplitude.	R
2: Mild:	Tremor is at least 1 but less than 3 cm in amplitude.	
3: Moderate:	Tremor is at least 3 but less than 10 cm in amplitude.	☐
4: Severe:	Tremor is at least 10 cm in amplitude.	L
3.17 REST TREMOR AMPLITUDE <u>Instructions to examiner:</u> This and the next item have been placed purposefully at the end of the examination to allow the rater to gather observations on rest tremor that may appear at any time during the exam, including when quietly sitting, during walking and during activities when some body parts are moving but others are at rest. Score the maximum amplitude that is seen at any time as the final score. Rate only the amplitude and not the persistence or the intermittency of the tremor. As part of this rating, the patient should sit quietly in a chair with the hands placed on the arms of the chair (not in the lap) and the feet comfortably supported on the floor for 10 seconds with no other directives. Rest tremor is assessed separately for all four limbs and also for the lip/jaw. Rate only the maximum amplitude that is seen at any time as the final rating.		
Extremity ratings		
0: Normal:	No tremor.	☐
1: Slight.:	< 1 cm in maximal amplitude.	RUE
2: Mild:	> 1 cm but < 3 cm in maximal amplitude.	
3: Moderate:	3 - 10 cm in maximal amplitude.	☐
4: Severe:	> 10 cm in maximal amplitude.	LUE
Lip/Jaw ratings		
0: Normal:	No tremor.	☐
1: Slight:	< 1 cm in maximal amplitude.	RLE
2: Mild:	> 1 cm but < 2 cm in maximal amplitude.	
3: Moderate:	> 2 cm but < 3 cm in maximal amplitude.	☐
4: Severe:	> 3 cm in maximal amplitude.	LLE
		☐
		Lip/Jaw

3.18 CONSTANCY OF REST TREMOR <u>Instructions to examiner:</u> This item receives one rating for all rest tremor and focuses on the constancy of rest tremor during the examination period when different body parts are variously at rest. It is rated purposefully at the end of the examination so that several minutes of information can be coalesced into the rating. 0: Normal: No tremor. 1: Slight: Tremor at rest is present < 25% of the entire examination period. 2: Mild: Tremor at rest is present 26-50% of the entire examination period. 3: Moderate: Tremor at rest is present 51-75% of the entire examination period. 4: Severe: Tremor at rest is present > 75% of the entire examination period.	SCORE
DYSKINESIA IMPACT ON PART III RATINGS A. Were dyskinesias (chorea or dystonia) present during examination? ☐ No ☐ Yes B. If yes, did these movements interfere with your ratings? ☐ No ☐ Yes	
HOEHN AND YAHR STAGE 0: Asymptomatic. 1: Unilateral involvement only. 2: Bilateral involvement without impairment of balance. 3: Mild to moderate involvement; some postural instability but physically independent; needs assistance to recover from pull test. 4: Severe disability; still able to walk or stand unassisted. 5: Wheelchair bound or bedridden unless aided.	

Part IV: Motor Complications

Overview and Instructions: In this section, the rater uses historical and objective information to assess two motor complications, dyskinesias and motor fluctuations that include OFF-state dystonia. Use all information from patient, caregiver, and the examination to answer the six questions that summarize function over the past week including today. As in the other sections, rate using only integers (no half points allowed) and leave no missing ratings. If the item cannot be rated, place UR for Unable to Rate. You will need to choose some answers based on percentages, and therefore you will need to establish how many hours generally are awake hours and use this figure as the denominator for "OFF" time and Dyskinesias. For "OFF dystonia", the total "Off" time will be the denominator. Operational definitions for examiner's use.

Dyskinesias: Involuntary random movements

Words that patients often recognize for dyskinesias include "irregular jerking", "wiggling", "twitching". It is essential to stress to the patient the difference between dyskinesias and tremor, a common error when patients are assessing dyskinesias.

Dystonia: contorted posture, often with a twisting component:

Words that patients often recognize for dystonia include "spasms", "cramps", "posture".

Motor fluctuation: Variable response to medication:

Words that patients often recognize for motor fluctuation include "wearing out", "wearing off", "roller-coaster effect", "on-off", "uneven medication effects".

OFF: Typical functional state when patients have a poor response in spite of taking medication or the typical functional response when patients are on NO treatment for parkinsonism. Words that patients often recognize include "low time", "bad time", "shaking time", "slow time", "time when my medications don't work."

ON: Typical functional state when patients are receiving medication and have a good response:

Words that patients often recognize include "good time", "walking time", "time when my medications work."

A . DYSKINESIAS [exclusive of OFF-state dystonia]

4.1 TIME SPENT WITH DYSKINESIAS

Instructions to examiner: Determine the hours in the usual waking day and then the hours of dyskinesias. Calculate the percentage. If the patient has dyskinesias in the office, you can point them out as a reference to ensure that patients and caregivers understand what they are rating. You may also use your own acting skills to enact the dyskinetic movements you have seen in the patient before or show them dyskinetic movements typical of other patients. Exclude from this question early morning and nighttime painful dystonia.

Instructions to patient [and caregiver]. Over the past week, how many hours do you usually sleep on a daily basis, including nighttime sleep and daytime napping? Alright, if you sleep ____ hrs, you are awake ____ hrs. Out of those awake hours, how many hours in total do you have wiggling, twitching or jerking movements? Do not count the times when you have tremor, which is a regular back and forth shaking or times when you have painful foot cramps or spasms in the early morning or at nighttime. I will ask about those later. Concentrate only on these types of wiggling, jerking and irregular movements. Add up all the time during the waking day when these usually occur. How many hours ____ (use this number for your calculation).

- 0: Normal: No dyskinesias.
- 1: Slight: $\leq 25\%$ of waking day.
- 2: Mild: 26 - 50% of waking day.
- 3: Moderate: 51 - 75% of waking day.
- 4: Severe: $> 75\%$ of waking day.

1. Total Hours Awake: _____
2. Total Hours with Dyskinesia: _____
3. % Dyskinesia = $((2/1)*100)$: _____

SCORE

SCORE

Instructions to patient [and caregiver]: Over the past week, did you usually have trouble doing things or being with people when these jerking movements occurred? Did they stop you from doing things or from being with people?

- 7

4.3 TIME SPENT IN THE OFF STATE

Instructions to patient [and caregiver]: Some patients with Parkinson's disease have a good effect from their medications throughout their awake hours and we call that "ON" time. Other patients take their medications but still have some hours of low time, bad time, slow time or shaking time. Doctors call these low periods "OFF" time. Over the past week, you told me before that you are generally awake _____ hrs each day. Out of these awake hours, how many hours in total do you usually have this type of low level or OFF function _____ (Use this number for your calculations).

1. Total Hours Awake: _____
2. Total Hours OFF: _____
3. % OFF = $((2/1)*100)$: _____

4.4 FUNCTIONAL IMPACT OF FLUCTUATIONS		SCORE
<u>Instructions to examiner:</u> Determine the degree to which motor fluctuations impact on the patient's daily function in terms of activities and social interactions. This question concentrates on the difference between the ON state and the OFF state. If the patient has no OFF time, the rating must be 0, but if patients have very mild fluctuations, it is still possible to be rated 0 on this item if no impact on activities occurs. Use the patient's and caregiver's response to your question and your own observations during the office visit to arrive at the best answer. <u>Instructions to patient [and caregiver]:</u> Think about when those low or "OFF" periods have occurred over the past week. Do you usually have more problems doing things or being with people than compared to the rest of the day when you feel your medications working? Are there some things you usually do during a good period that you have trouble with or stop doing during a low period? 0: Normal: No fluctuations or No impact by fluctuations on performance of activities or social interactions. 1: Slight: Fluctuations impact on a few activities, but during OFF, the patient usually performs all activities and participates in all social interactions that typically occur during the ON state. 2: Mild: Fluctuations impact many activities, but during OFF, the patient still usually performs all activities and participates in all social interactions that typically occur during the ON state. 3: Moderate: Fluctuations impact on the performance of activities during OFF to the point that the patient usually does not perform some activities or participate in some social interactions that are performed during ON periods. 4: Severe: Fluctuations impact on function to the point that, during OFF, the patient usually does not perform most activities or participate in most social interactions that are performed during ON periods.		
4.5 COMPLEXITY OF MOTOR FLUCTUATIONS <u>Instructions to examiner:</u> Determine the usual predictability of OFF function whether due to dose, time of day, food intake or other factors. Use the information provided by the patients and caregiver and supplement with your own observations. You will ask if the patient can count on them always coming at a special time, mostly coming at a special time (in which case you will probe further to separate slight from mild), only sometimes coming at a special time or are they totally unpredictable? Narrowing down the percentage will allow you to find the correct answer. <u>Instructions to patient [and caregiver]:</u> For some patients, the low or "OFF" periods happen at certain times during day or when they do activities like eating or exercising. Over the past week, do you usually know when your low periods will occur? In other words, do your low periods <u>always</u> come at a certain time? Do they <u>mostly</u> come at a certain time? Do they <u>only sometimes</u> come at a certain time? Are your low periods totally unpredictable?" 0: Normal: No motor fluctuations. 1: Slight: OFF times are predictable all or almost all of the time (> 75%). 2: Mild: OFF times are predictable most of the time (51-75%). 3: Moderate: OFF times are predictable some of the time (26-50%). 4: Severe: OFF episodes are rarely predictable. (≤ 25%).		

C. "OFF" DYSTONIA

4.6 PAINFUL OFF-STATE DYSTONIA

Instructions to examiner: For patients who have motor fluctuations, determine what proportion of the OFF episodes usually includes painful dystonia? You have already determined the number of hours of "OFF" time (4.3). Of these hours, determine how many are associated with dystonia and calculate the percentage. If there is no OFF time, mark 0.

Instructions to patient [and caregiver]: In one of the questions I asked earlier, you said you generally have ____ hours of low or "OFF" time when your Parkinson's disease is under poor control. During these low or "OFF" periods, do you usually have painful cramps or spasms? Out of the total ____ hrs of this low time, if you add up all the time in a day when these painful cramps come, how many hours would this make?

0: Normal: No dystonia OR NO OFF TIME.

1: Slight: < 25% of time in OFF state.

2: Mild: 26-50% of time in OFF state.

3: Moderate: 51-75% of time in OFF state.

4: Severe: > 75% of time in OFF state.

1. Total Hours Off: _____

2. Total Off Hours w/Dystonia: _____

3. % Off Dystonia = $((2/1)*100)$: _____



Summary statement to patient: READ TO PATIENT

This completes my rating of your Parkinson's disease. I know the questions and tasks have taken several minutes, but I wanted to be complete and cover all possibilities. In doing so, I may have asked about problems you do not even have, and I may have mentioned problems that you may never develop at all. Not all patients develop all these problems, but because they can occur, it is important to ask all the questions to every patient. Thank you for your time and attention in completing this scale with me.

_____	_____	____-____-____ (mm-dd-yyyy) Assessment Date	____-____-____ Investigator's Initials
Patient Name or Subject ID	Site ID		

MDS UPDRS Score Sheet

1.A	Source of information	☐ Patient ☐ Caregiver ☐ Patient + Caregiver	3.3b	Rigidity– RUE	
			3.3c	Rigidity– LUE	
Part I			3.3d	Rigidity– RLE	
1.1	Cognitive impairment		3.3e	Rigidity– LLE	
1.2	Hallucinations and psychosis		3.4a	Finger tapping– Right hand	
1.3	Depressed mood		3.4b	Finger tapping– Left hand	
1.4	Anxious mood		3.5a	Hand movements– Right hand	
1.5	Apathy		3.5b	Hand movements– Left hand	
1.6	Features of DDS		3.6a	Pronation- supination movements– Right hand	
1.6a	Who is filling out questionnaire	☐ Patient ☐ Caregiver ☐ Patient + Caregiver	3.6b	Pronation- supination movements– Left hand	
			3.7a	Toe tapping–Right foot	
1.7	Sleep problems		3.7b	Toe tapping– Left foot	
1.8	Daytime sleepiness		3.8a	Leg agility– Right leg	
1.9	Pain and other sensations		3.8b	Leg agility– Left leg	
1.10	Urinary problems		3.9	Arising from chair	
1.11	Constipation problems		3.10	Gait	
1.12	Light headedness on standing		3.11	Freezing of gait	
1.13	Fatigue		3.12	Postural stability	
Part II			3.13	Posture	
2.1	Speech		3.14	Global spontaneity of movement	
2.2	Saliva and drooling		3.15a	Postural tremor– Right hand	
2.3	Chewing and swallowing		3.15b	Postural tremor– Left hand	
2.4	Eating tasks		3.16a	Kinetic tremor– Right hand	
2.5	Dressing		3.16b	Kinetic tremor– Left hand	
2.6	Hygiene		3.17a	Rest tremor amplitude– RUE	
2.7	Handwriting		3.17b	Rest tremor amplitude– LUE	
2.8	Doing hobbies and other activities		3.17c	Rest tremor amplitude– RLE	
2.9	Turning in bed		3.17d	Rest tremor amplitude– LLE	
2.10	Tremor		3.17e	Rest tremor amplitude– Lip/jaw	
2.11	Getting out of bed		3.18	Constancy of rest	
2.12	Walking and balance			Were dyskinesias presen	☐ No ☐ Yes
2.13	Freezing			Did these movements interfere with ratings?	☐ No ☐ Yes
3a	Is the patient on medication?	☐ No ☐ Yes		Hoehn and Yahr Stage	
3b	Patient's clinical state	☐ Off ☐ On	Part IV		
3c	Is the patient on Levodopa?	☐ No ☐ Yes	4.1	Time spent with dyskinesias	
3.C1	If yes, minutes since last dose:		4.2	Functional impact of dyskinesias	
Part III			4.3	Time spent in the OFF state	
3.1	Speech		4.4	Functional impact of fluctuations	
3.2	Facial expression		4.5	Complexity of motor fluctuations	
3.3a	Rigidity– Neck		4.6	Painful OFF-state dystonia	

July 1, 2008

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Non-Motor Symptom assessment scale for Parkinson's Disease

Patient ID No: _____

Initials: _____

Age: _____

Symptoms assessed over the last month. Each symptom scored with respect to:

Severity: 0 = None, 1 = Mild: symptoms present but causes little distress or disturbance to patient;

2 = Moderate: some distress or disturbance to patient; 3 = Severe: major source of distress or disturbance to patient.

Frequency: 1 = Rarely (<1/wk); 2 = Often (1/wk); 3 = Frequent (several times per week);

4 = Very Frequent (daily or all the time).

Domains will be weighed differentially. Yes/ No answers are not included in final frequency x severity calculation.

(Bracketed text in questions within the scale is included as an explanatory aid).

Domain 1: Cardiovascular including falls

- | | Severity | Frequency | Frequency
x Severity |
|--|--------------------------|--------------------------|--------------------------|
| 1. Does the patient experience light-headedness, dizziness, weakness on standing from sitting or lying position? | ☐ | ☐ | ☐ |
| 2. Does the patient fall because of fainting or blacking out? | ☐ | ☐ | ☐ |

SCORE:

Domain 2: Sleep/fatigue

- | | | | |
|---|--------------------------|--------------------------|--------------------------|
| 3. Does the patient doze off or fall asleep unintentionally during daytime activities? (For example, during conversation, during mealtimes, or while watching television or reading). | ☐ | ☐ | ☐ |
| 4. Does fatigue (tiredness) or lack of energy (not slowness) limit the patient's daytime activities? | ☐ | ☐ | ☐ |
| 5. Does the patient have difficulties falling or staying asleep? | ☐ | ☐ | ☐ |
| 6. Does the patient experience an urge to move the legs or restlessness in legs that improves with movement when he/she is sitting or lying down inactive? | ☐ | ☐ | ☐ |

SCORE:

Domain 3: Mood/cognition

- | | | | |
|--|--------------------------|--------------------------|--------------------------|
| 7. Has the patient lost interest in his/her surroundings? | ☐ | ☐ | ☐ |
| 8. Has the patient lost interest in doing things or lack motivation to start new activities? | ☐ | ☐ | ☐ |
| 9. Does the patient feel nervous, worried or frightened for no apparent reason? | ☐ | ☐ | ☐ |
| 10. Does the patient seem sad or depressed or has he/she reported such feelings? | ☐ | ☐ | ☐ |
| 11. Does the patient have flat moods without the normal "highs" and "lows"? | ☐ | ☐ | ☐ |
| 12. Does the patient have difficulty in experiencing pleasure from their usual activities or report that they lack pleasure? | ☐ | ☐ | ☐ |

SCORE:

Domain 4: Perceptual problems/hallucinations

- | | | | |
|--|--------------------------|--------------------------|--------------------------|
| 13. Does the patient indicate that he/she sees things that are not there? | ☐ | ☐ | ☐ |
| 14. Does the patient have beliefs that you know are not true?
(For example, about being harmed, being robbed or being unfaithful) | ☐ | ☐ | ☐ |
| 15. Does the patient experience double vision?
(2 separate real objects and not blurred vision) | ☐ | ☐ | ☐ |

SCORE:

	<u>Severity</u>	<u>Frequency</u>	<u>Frequency x Severity</u>
Domain 5: Attention/memory			
16. Does the patient have problems sustaining concentration during activities? (For example, reading or having a conversation)	☐	☐	☐
17. Does the patient forget things that he/she has been told a short time ago or events that happened in the last few days?	☐	☐	☐
18. Does the patient forget to do things? (For example, take tablets or turn off domestic appliances?)	☐	☐	☐
SCORE:			
Domain 6: Gastrointestinal tract			
19. Does the patient dribble saliva during the day?	☐	☐	☐
20. Does the patient have difficulty swallowing?	☐	☐	☐
21. Does the patient suffer from constipation? (Bowel action less than three times weekly)	☐	☐	☐
SCORE:			
Domain 7: Urinary			
22. Does the patient have difficulty holding urine? (Urgency)	☐	☐	☐
23. Does the patient have to void within 2 hours of last voiding? (Frequency)	☐	☐	☐
24. Does the patient have to get up regularly at night to pass urine? (Nocturia)	☐	☐	☐
SCORE:			
Domain 8: Sexual function			
25. Does the patient have altered interest in sex? (Very much increased or decreased, please underline)	☐	☐	☐
26. Does the patient have problems having sex?	☐	☐	☐
SCORE:			
Domain 9: Miscellaneous			
27. Does the patient suffer from pain not explained by other known conditions? (Is it related to intake of drugs and is it relieved by antiparkinson drugs?)	☐	☐	☐
28. Does the patient report a change in ability to taste or smell?	☐	☐	☐
29. Does the patient report a recent change in weight (not related to dieting)?	☐	☐	☐
30. Does the patient experience excessive sweating (not related to hot weather)?	☐	☐	☐
SCORE:			
<u>TOTAL SCORE:</u>			

Parkinson's Disease Impulsive-Compulsive Disorders Questionnaire (QUIP)

Completed by:	☐ Patient	☐ Informant	☐ Investigator
Informant:	☐ Patient only	☐ Informed other*	☐ Both
Time frame:	☐ Past 6 months	☐ Since PD onset	☐ Pre-PD onset

***If completed by an informed other, answer questions based on your understanding of the patient**

IMPULSE CONTROL DISORDERS

1. Do you or others think you have an issue with gambling, sexual behavior, buying, or eating (causing distress to you or others, or causing problems in your social, personal, financial or work life)? Answer for all four behaviors listed below. "Y"=yes, "N"=no.

Gambling (such as casinos, internet gambling, lotteries, scratch tickets, sports, slot or poker machines, or betting among friends)

Y N

Sexual behavior (such as making sexual demands on others, promiscuity, prostitution, change in sexual orientation, masturbation, internet or telephone sexual activities, or pornography) ____ Y ____ N

_____Y_____N

Buying (such as buying excessively or too much of the same thing)

Y		N
<u> </u>		<u> </u>

Eating (such as eating larger amounts or different types of food than in the past, more rapidly than normal, until feeling uncomfortably full, or when not hungry)

Y	N
<u> </u>	<u> </u>

2. Do you think a lot about gambling, sex-related activities, buying, or eating (such as having trouble keeping thoughts out of your mind, or feeling guilty about the thoughts or related behaviors)?

	Y	N
Gambling		

	Y	N
Sexual behavior		

Buying	<u>Y</u>	<u>N</u>
Y	10	10
N	10	10

Eating Y N

3. Do you have urges or desires to gamble, engage in sexual-related activities, buy, or eat which you or others feel are excessive or cause you distress (such as becoming restless or irritable when unable to participate in the activity)?

Gambling	___ Y	___ N
Sexual behavior	___ Y	___ N
Buying	___ Y	___ N
Eating	___ Y	___ N

4. Do you experience difficulty controlling gambling, sexual, buying, or eating behaviors (such as increasing the behaviors over time, or having trouble cutting down or stopping behaviors)?

Gambling	___ Y	___ N
Sexual behavior	___ Y	___ N
Buying	___ Y	___ N
Eating	___ Y	___ N

5. Do you engage in activities specifically to continue gambling, sexual, buying, or eating behaviors (such as hiding or lying about activities, borrowing from others, accumulating debt, floating checks, getting involved in illegal acts, hiding or hoarding food)?

Gambling	___ Y	___ N
Sexual behavior	___ Y	___ N
Buying	___ Y	___ N
Eating	___ Y	___ N

DOPAMINE DYSREGULATION SYNDROME

1. Do you or others (including your physicians) think you take too much of your Parkinson's medications or more of your Parkinson's medications than prescribed?

___ Y ___ N

2. Over time, have you increased on your own the amount of Parkinson's medications that you take to achieve the desired physical or mental effects (such as to elevate your mood or to avoid 'off' motor states)?

___ Y ___ N



4. Have you had trouble controlling or cutting down the amount of PD medications taken (such as experiencing withdrawal symptoms, or feeling down, irritable or anxious when trying to)?

___Y ___N

5. Do you engage in activities to continue taking extra amounts of Parkinson's medications (such as hiding or hoarding your medications, or seeking out extra supplies of medications)?

___Y ___N

OTHER COMPULSIVE BEHAVIORS

1. Do you or others think that you spend too much time thinking about and spending time on a specific task, hobby or other any other organized activity (such as writing, painting, gardening, or taking things apart)?

___Y ___N

If yes, specify activity: _____

2. Do you or others think that you spend too much time on repetitive motor activities (such as handling, examining, cleaning, sorting, ordering, or arranging objects)?

___Y ___N

If yes, specify activity: _____

3. Do you walk or drive great distances with no intended goal or specific purpose?

___Y ___N



MONTREAL COGNITIVE ASSESSMENT (MOCA)
- ITALIA -

NOME: _____
Scolarità: _____ Data di nascita: _____
Sesso: _____ DATA: _____

VISUOSPAZIALE / ESECUTIVO										PUNTI	
				Copi Il cubo		Disegni un orologio (undici e dieci) (3 punti)		[] Contorno [] Numeri [] Lancette		___/5	
DENOMINAZIONE											
						[] [] []		___/3			
MEMORIA		Leggere la lista di parole: il soggetto deve ripeterle. Fare le prime 2 prove di seguito e il "Richiamo" dopo 5 min.		1° prova	2° prova	Faccia	Velluto	Chiesa	Margherita	Rosso	0 punti
ATTENZIONE		Leggere la serie di cifre (una cifra / sec.)		Il soggetto deve ripeterle Il soggetto deve ripeterle in ordine inverso		[] 2 1 8 5 4 [] 7 4 2		Leggere la serie di lettere. Il soggetto deve dare un colpo con la mano sul tavolo ad ogni lettera "A". 0 punti se ≥ 2 errori		___/2 ___/1	
		[] F B A C M N A A G H L B A F A H D E A A G A M O F A A B								___/3	
		Sottrazione di 7 partendo da 100 per 5 volte		[] 93 [] 86 [] 79 [] 72 [] 65		4 o 5 sottrazioni corrette: 3 pt, 2 o 3 corrette: 2 pt, 1 corretta: 1 pt, 0 corrette: 0 pt				___/3	
LINGUAGGIO		Ripeta: So solo che oggi dobbiamo aiutare Giovanni. Il gatto si nascondeva sempre sotto il divano quando c'erano cani nella stanza.		[] []						___/2	
		Fluenza / In 1 minuto, nomini il maggior numero possibile di parole che iniziano con la lettera "F".		[] ___ (N ≥ 11 parole)						___/1	
ASTRAZIONE		Similitudini tra per es. banana / arancio = frutti;		[] treno / bicicletta [] orologio / righello						___/2	
RICHIAMO DIFFERITO		Deve ricordarsi le parole SENZA AIUTO		Faccia	Velluto	Chiesa	Margherita	Rosso	Punti solo per ripetizione SENZA AIUTO		___/5
		AIUTO		Categoria Seman.						___/5	
Opzionale		Scelta multipla								___/5	
ORIENTAMENTO		[] Data [] Mese [] Anno [] Giorno [] Luogo [] Città								___/6	

SCHWAB AND ENGLAND

SCHWAB AND ENGLAND ACTIVITIES OF DAILY LIVING SCALE

100% = Completely independent. Able to do all chores without slowness, difficulty or impairment. Essentially normal. Unaware of any difficulty.

90% = Completely independent. Able to do all chores with some degree of slowness, difficulty and impairment. Might take twice as long. Beginning to be aware of difficulty.

80% = Completely independent in most chores. Takes twice as long. Conscious of difficulty and slowness.

70% = Not completely independent. More difficulty with some chores. Three to four times as long in some. Must spend a large part of the day with chores.

60% = Some dependency. Can do most chores, but exceedingly slowly and with much effort. Errors; some impossible.

50% = More dependent. Help with half, slower, etc. Difficulty with everything.

40% = Very dependent. Can assist with all chores, but few alone.

30% = With effort, now and then does a few chores alone or begins alone. Much help needed.

20% = Nothing alone. Can be a slight help with some chores. Severe invalid.

10% = Totally dependent, helpless. Complete invalid.

0% = Vegetative functions such as swallowing, bladder and bowel functions are not functioning. Bedridden.



PDQ-39 QUESTIONNAIRE

Please complete the following

Please tick one box for each question

***Due to having Parkinson's disease,
how often during the last month
have you....***

		Never	Occasionally	Sometimes	Often	Always or cannot do at all
1	Had difficulty doing the leisure activities which you would like to do?	☐	☐	☐	☐	☐
2	Had difficulty looking after your home, e.g. DIY, housework, cooking?	☐	☐	☐	☐	☐
3	Had difficulty carrying bags of shopping?	☐	☐	☐	☐	☐
4	Had problems walking half a mile?	☐	☐	☐	☐	☐
5	Had problems walking 100 yards?	☐	☐	☐	☐	☐
6	Had problems getting around the house as easily as you would like?	☐	☐	☐	☐	☐
7	Had difficulty getting around in public?	☐	☐	☐	☐	☐
8	Needed someone else to accompany you when you went out?	☐	☐	☐	☐	☐
9	Felt frightened or worried about falling over in public?	☐	☐	☐	☐	☐
10	Been confined to the house more than you would like?	☐	☐	☐	☐	☐
11	Had difficulty washing yourself?	☐	☐	☐	☐	☐
12	Had difficulty dressing yourself?	☐	☐	☐	☐	☐
13	Had problems doing up your shoe laces?	☐	☐	☐	☐	☐

*Please check that you have ticked **one box for each question** before going on to the next page*

***Due to having Parkinson's disease,
how often during the last month
have you....***

Please tick one box for each question

		Never	Occasionally	Sometimes	Often	Always or cannot do at all
14	Had problems writing clearly?	☐	☐	☐	☐	☐
15	Had difficulty cutting up your food?	☐	☐	☐	☐	☐
16	Had difficulty holding a drink without spilling it?	☐	☐	☐	☐	☐
17	Felt depressed?	☐	☐	☐	☐	☐
18	Felt isolated and lonely?	☐	☐	☐	☐	☐
19	Felt weepy or tearful?	☐	☐	☐	☐	☐
20	Felt angry or bitter?	☐	☐	☐	☐	☐
21	Felt anxious?	☐	☐	☐	☐	☐
22	Felt worried about your future?	☐	☐	☐	☐	☐
23	Felt you had to conceal your Parkinson's from people?	☐	☐	☐	☐	☐
24	Avoided situations which involve eating or drinking in public?	☐	☐	☐	☐	☐
25	Felt embarrassed in public due to having Parkinson's disease?	☐	☐	☐	☐	☐
26	Felt worried by other people's reaction to you?	☐	☐	☐	☐	☐
27	Had problems with your close personal relationships?	☐	☐	☐	☐	☐
28	Lacked support in the ways you need from your spouse or partner?	☐	☐	☐	☐	☐
	<i>If you do not have a spouse or partner tick here</i>		☐			
29	Lacked support in the ways you need from your family or close friends?	☐	☐	☐	☐	☐

Please check that you have ticked one box for each question before going on to the next page

***Due to having Parkinson's disease,
how often during the last month
have you....***

Please tick one box for each question

		Never	Occasionally	Sometimes	Often	Always
30	Unexpectedly fallen asleep during the day?	☐	☐	☐	☐	☐
31	Had problems with your concentration, e.g. when reading or watching TV?	☐	☐	☐	☐	☐
32	Felt your memory was bad?	☐	☐	☐	☐	☐
33	Had distressing dreams or hallucinations?	☐	☐	☐	☐	☐
34	Had difficulty with your speech?	☐	☐	☐	☐	☐
35	Felt unable to communicate with people properly?	☐	☐	☐	☐	☐
36	Felt ignored by people?	☐	☐	☐	☐	☐
37	Had painful muscle cramps or spasms?	☐	☐	☐	☐	☐
38	Had aches and pains in your joints or body?	☐	☐	☐	☐	☐
39	Felt unpleasantly hot or cold?	☐	☐	☐	☐	☐

*Please check that you have ticked **one box for each question** before going on to the next page*

Thank you for completing the PDQ 39 questionnaire

Hamilton Anxiety Rating Scale (HAM-A)

Reference: Hamilton M. The assessment of anxiety states by rating. *Br J Med Psychol* 1959; 32:50–55.

Rating Clinician-rated

Administration time 10–15 minutes

Main purpose To assess the severity of symptoms of anxiety

Population Adults, adolescents and children

Commentary

The HAM-A was one of the first rating scales developed to measure the severity of anxiety symptoms, and is still widely used today in both clinical and research settings. The scale consists of 14 items, each defined by a series of symptoms, and measures both psychic anxiety (mental agitation and psychological distress) and somatic anxiety (physical complaints related to anxiety). Although the HAM-A remains widely used as an outcome measure in clinical trials, it has been criticized for its sometimes poor ability to discriminate between anxiolytic and antidepressant effects, and somatic anxiety versus somatic side effects. The HAM-A does not provide any standardized probe questions. Despite this, the reported levels of inter-rater reliability for the scale appear to be acceptable.

Scoring

Each item is scored on a scale of 0 (not present) to 4 (severe), with a total score range of 0–56, where <17 indicates mild severity, 18–24 mild to moderate severity and 25–30 moderate to severe.

Versions

The scale has been translated into: Cantonese for China, French and Spanish. An IVR version of the scale is available from Healthcare Technology Systems.

Additional references

Maier W, Buller R, Philipp M, Heuser I. The Hamilton Anxiety Scale: reliability, validity and sensitivity to change in anxiety and depressive disorders. *J Affect Disord* 1988;14(1):61–8.

Borkovec T and Costello E. Efficacy of applied relaxation and cognitive behavioral therapy in the treatment of generalized anxiety disorder. *J Clin Consult Psychol* 1993; 61(4):611–19

Address for correspondence

The HAM-A is in the public domain.

Hamilton Anxiety Rating Scale (HAM-A)

Below is a list of phrases that describe certain feeling that people have. Rate the patients by finding the answer which best describes the extent to which he/she has these conditions. Select one of the five responses for each of the fourteen questions.

0 = Not present, 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Very severe.

1 **Anxious mood** 0 1 2 3 4

Worries, anticipation of the worst, fearful anticipation, irritability.

2 **Tension** 0 1 2 3 4

Feelings of tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax.

3 **Fears** 0 1 2 3 4

Of dark, of strangers, of being left alone, of animals, of traffic, of crowds.

4 **Insomnia** 0 1 2 3 4

Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors.

5 **Intellectual** 0 1 2 3 4

Difficulty in concentration, poor memory.

6 **Depressed mood** 0 1 2 3 4

Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing.

7 **Somatic (muscular)** 0 1 2 3 4

Pains and aches, twitching, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone.

8 **Somatic (sensory)** 0 1 2 3 4

Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation.

9 **Cardiovascular symptoms** 0 1 2 3 4

Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, missing beat.

10 **Respiratory symptoms** 0 1 2 3 4

Pressure or constriction in chest, choking feelings, sighing, dyspnea.

11 **Gastrointestinal symptoms** 0 1 2 3 4

Difficulty in swallowing, wind abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation.

12 **Genitourinary symptoms** 0 1 2 3 4

Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, premature ejaculation, loss of libido, impotence.

13 **Autonomic symptoms** 0 1 2 3 4

Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair.

14 **Behavior at interview** 0 1 2 3 4

Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing, etc.

THE HAMILTON RATING SCALE FOR DEPRESSION

(to be administered by a health care professional)

Patient's Name _____

Date of Assessment _____

To rate the severity of depression in patients who are already diagnosed as depressed, administer this questionnaire. The higher the score, the more severe the depression.

For each item, write the correct number on the line next to the item. (Only one response per item)

1. DEPRESSED MOOD (Sadness, hopeless, helpless, worthless)

- _____ **0=** Absent
1= These feeling states indicated only on questioning
2= These feeling states spontaneously reported verbally
3= Communicates feeling states non-verbally—i.e., through facial expression, posture, voice, and tendency to weep
4= Patient reports VIRTUALLY ONLY these feeling states in his spontaneous verbal and non-verbal communication

2. FEELINGS OF GUILT

- _____ **0=** Absent
1= Self reproach, feels he has let people down
2= Ideas of guilt or rumination over past errors or sinful deeds
3= Present illness is a punishment. Delusions of guilt
4= Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. SUICIDE

- _____ **0=** Absent
1= Feels life is not worth living
2= Wishes he were dead or any thoughts of possible death to self
3= Suicidal ideas or gesture
4= Attempts at suicide (any serious attempt rates 4)

4. INSOMNIA EARLY

- _____ **0=** No difficulty falling asleep
1= Complains of occasional difficulty falling asleep—i.e., more than 1/2 hour
2= Complains of nightly difficulty falling asleep

5. INSOMNIA MIDDLE

- _____ **0=** No difficulty
1= Patient complains of being restless and disturbed during the night
2= Waking during the night—any getting out of bed rates 2 (except for purposes of voiding)

6. INSOMNIA LATE

_____ **0=** No difficulty

1= Waking in early hours of the morning but goes back to sleep

2= Unable to fall asleep again if he gets out of bed

7. WORK AND ACTIVITIES

_____ **0=** No difficulty

1= Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies

2= Loss of interest in activity; hobbies or work—either directly reported by patient, or indirect in listlessness, indecision and vacillation (feels he has to push self to work or activities)

3= Decrease in actual time spent in activities or decrease in productivity

4= Stopped working because of present illness

8. RETARDATION: PSYCHOMOTOR (Slowness of thought and speech; impaired ability to concentrate; decreased motor activity)

_____ **0=** Normal speech and thought

1= Slight retardation at interview

2= Obvious retardation at interview

3= Interview difficult

4= Complete stupor

9. AGITATION

_____ **0=** None

1= Fidgetiness

2= Playing with hands, hair, etc.

3= Moving about, can't sit still

4= Hand wringing, nail biting, hair-pulling, biting of lips

10. ANXIETY (PSYCHOLOGICAL)

_____ **0=** No difficulty

1= Subjective tension and irritability

2= Worrying about minor matters

3= Apprehensive attitude apparent in face or speech

4= Fears expressed without questioning

11. ANXIETY SOMATIC: Physiological concomitants of anxiety, (i.e., effects of autonomic overactivity, "butterflies," indigestion, stomach cramps, belching, diarrhea, palpitations, hyperventilation, paresthesia, sweating, flushing, tremor, headache, urinary frequency). Avoid asking about possible medication side effects (i.e., dry mouth, constipation)

_____ **0=** Absent

1= Mild

2= Moderate

3= Severe

4= Incapacitating

12. SOMATIC SYMPTOMS (GASTROINTESTINAL)

_____ **0=** None

1= Loss of appetite but eating without encouragement from others. Food intake about normal

2= Difficulty eating without urging from others. Marked reduction of appetite and food intake

13. SOMATIC SYMPTOMS GENERAL

_____ **0=** None

1= Heaviness in limbs, back or head. Backaches, headache, muscle aches. Loss of energy and fatigability

2= Any clear-cut symptom rates 2

14. GENITAL SYMPTOMS (Symptoms such as: loss of libido; impaired sexual performance; menstrual disturbances)

_____ **0=** Absent

1= Mild

2= Severe

15. HYPOCHONDRIASIS

_____ **0=** Not present

1= Self-absorption (bodily)

2= Preoccupation with health

3= Frequent complaints, requests for help, etc.

4= Hypochondriacal delusions

16. LOSS OF WEIGHT

_____ **A.** When rating by history:

0= No weight loss

1= Probably weight loss associated with present illness

2= Definite (according to patient) weight loss

3= Not assessed

17. INSIGHT

_____ **0=** Acknowledges being depressed and ill

1= Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc.

2= Denies being ill at all

18. DIURNAL VARIATION

_____ **A.** Note whether symptoms are worse in morning or evening. If NO diurnal variation, mark none

0= No variation

1= Worse in A.M.

2= Worse in P.M.

_____ **B.** When present, mark the severity of the variation. Mark "None" if NO variation

0= None

1= Mild

2= Severe

19. DEPERSONALIZATION AND DEREALIZATION (Such as: Feelings of unreality;
Nihilistic ideas)

- _____ **0=** Absent
1= Mild
2= Moderate
3= Severe
4= Incapacitating

20. PARANOID SYMPTOMS

- _____ **0=** None
1= Suspicious
2= Ideas of reference
3= Delusions of reference and persecution

21. OBSESSIONAL AND COMPULSIVE SYMPTOMS

- _____ **0=** Absent
1= Mild
2= Severe

Total Score _____

Presented as a service by

GlaxoWellcome

Glaxo Wellcome Inc.
Research Triangle Park, NC 27709
Web site: www.glaxowellcome.com

Rating Scale*

Table 1. Apathy Evaluation Scale, Clinician Version [AES-C]

Name: _____

Date: _____

Rater: _____

Rate each item based on an interview of the subject. The interview should begin with a description of the subject's interest, activities and daily routine. Base your ratings on both verbal and non-verbal information. Ratings should be based on the past 4 weeks. For each item ratings should be judged:

Not at All Characteristic 1	Slightly Characteristic 1	Somewhat Characteristic 3	A Lot Characteristic 4
___ 1. S/he is interested in things.			+ C Q
___ 2. S/he gets things done during the day.			+ B Q
___ 3. Getting things started on his/her own is important to her/him.			+ C SE
___ 4. S/he is interested in having new experiences.			+ C Q
___ 5. S/he is interested in learning new things.			+ C Q
___ 6. S/he puts little effort into anything.			- B
___ 7. S/he approaches life with intensity.			+ E
___ 8. Seeing a job through to the end is important to her/him.			+ C SE
___ 9. He/she spends time doing things that interest her/him.			+ B
___ 10. Someone has to tell her/him what to do each day.			- B
___ 11. S/he is less concerned about his/her problems than her/him should be.			- C
___ 12. S/he has friends.			+ B Q
___ 13. Getting together with friends is important to her/him.			+ C SE
___ 14. When something good happens, he/she gets excited.			+ E
___ 15. S/he has an accurate understanding of her/him problems.			+ O
___ 16. Getting things done during the day is important to her/him.			+ C SE
___ 17. S/he has initiative.			+ O
___ 18. S/he has motivation.			+ O

Note: Items that have positive versus negative syntax are identified by +/- . Type of item: C = cognitive; B = behavior; E = emotional; O = other. The definitions of self-evaluation (SE) and quantifiable (Q) items are discussed in the administration guidelines [see Syllabus]. (Marin, 1991 [see References]) For self-rated and informant-rated versions of AES, the response options are Not at all true, Slightly true, etc. The Apathy Evaluation Scale was developed by Robert S. Marin, M.D. Development and validation studies are described in Marin et al., 1991 [see References]. Supplementary administration guidelines are available from the author.

*Reprinted from Seminars in Clinical Neuropsychiatry, Vol 1(4), Marin RS, Apathy: concept, syndrome, neural mechanisms, and treatment, 304-314, copyright 1996, with permission from Elsevier.

SCOPA-AUT

By means of this questionnaire, we would like to find out to what extent in the past month you have had problems with various bodily functions, such as difficulty passing urine, or excessive sweating. Answer the questions by placing a cross in the box which best reflects your situation. If you wish to change an answer, fill in the 'wrong' box and place a cross in the correct one. If you have used medication in the past month in relation to one or more of the problems mentioned, then the question refers to how you were while taking this medication. You can note the use of medication on the last page.

1. In the past month, have you had difficulty swallowing or have you choked?

☐

never

☐

sometimes

☐

regularly

☐

often

2. In the past month, has saliva dribbled out of your mouth?

☐

never

☐

sometimes

☐

regularly

☐

often

3. In the past month, has food ever become stuck in your throat?

☐

never

☐

sometimes

☐

regularly

☐

often

4. In the past month, did you ever have the feeling during a meal that you were full very quickly?

☐

never

☐

sometimes

☐

regularly

☐

often

5. *Constipation is a blockage of the bowel, a condition in which someone has a bowel movement twice a week or less.*

In the past month, have you had problems with constipation?

☐

never

☐

sometimes

☐

regularly

☐

often

6. In the past month, did you have to strain hard to pass stools?

☐

never

☐

sometimes

☐

regularly

☐

often

7. In the past month, have you had involuntary loss of stools?

☐

never

☐

sometimes

☐

regularly

☐

often

Questions 8 to 13 deal with problems with passing urine. If you use a catheter you can indicate this by placing a cross in the box “*use catheter*”.

8. In the past month, have you had difficulty retaining urine?

☐

never

☐

sometimes

☐

regularly

☐

often

☐

*use
catheter*

9. In the past month, have you had involuntary loss of urine?

☐

never

☐

sometimes

☐

regularly

☐

often

☐

*use
catheter*

10. In the past month, have you had the feeling that after passing urine your bladder was not completely empty?

☐

never

☐

sometimes

☐

regularly

☐

often

☐

*use
catheter*

11. In the past month, has the stream of urine been weak?

☐

never

☐

sometimes

☐

regularly

☐

often

☐

*use
catheter*

12. In the past month, have you had to pass urine again within 2 hours of the previous time?

☐

never

☐

sometimes

☐

regularly

☐

often

☐

*use
catheter*

13. In the past month, have you had to pass urine at night?

☐

never

☐

sometimes

☐

regularly

☐

often

☐

*use
catheter*

14. In the past month, when standing up have you had the feeling of either becoming lightheaded, or no longer being able to see properly, or no longer being able to think clearly?

☐

never

☐

sometimes

☐

regularly

☐

often

15. In the past month, did you become light-headed after standing for some time?

☐

never

☐

sometimes

☐

regularly

☐

often

16. Have you fainted in the past 6 months?

☐

never

☐

sometimes

☐

regularly

☐

often

17. In the past month, have you ever perspired excessively during the day?

☐

never

☐

sometimes

☐

regularly

☐

often

18. In the past month, have you ever perspired excessively during the night?

☐

never

☐

sometimes

☐

regularly

☐

often

19. In the past month, have your eyes ever been over-sensitive to bright light?

☐

never

☐

sometimes

☐

regularly

☐

often

20. In the past month, how often have you had trouble tolerating cold?

☐

never

☐

sometimes

☐

regularly

☐

often

21. In the past month, how often have you had trouble tolerating heat?

☐

never

☐

sometimes

☐

regularly

☐

often

The following questions are about sexuality. Although we are aware that sexuality is a highly intimate subject, we would still like you to answer these questions. For the questions on sexual activity, consider every form of sexual contact with a partner or masturbation (self-gratification). An extra response option has been added to these questions. Here you can indicate that the situation described has not been applicable to you in the past month, for example because you have not been sexually active. Questions 22 and 23 are intended specifically for **men**, 24 and 25 for **women**.

The following 3 questions are only for men

22. In the past month, have you been impotent (unable to have or maintain an erection)?

☐

never

☐

sometimes

☐

regularly

☐

often

☐

*not
applicable*

23. In the past month, how often have you been unable to ejaculate?

☐

never

☐

sometimes

☐

regularly

☐

often

☐

*not
applicable*

23a. In the past month, have you taken medication for an erection disorder? (If so, which medication?)

☐

no

☐

yes: _____

Proceed with question 26

The following 2 questions are only for women

24. In the past month, was your vagina too dry during sexual activity?

☐

never

☐

sometimes

☐

regularly

☐

often

☐

*not
applicable*

25. In the past month, have you had difficulty reaching an orgasm?

☐

never

☐

sometimes

☐

regularly

☐

often

☐

*not
applicable*

The following questions are for everyone

The questions below are about the use of medication for which you may have or have not needed a doctor's prescription. If you use medication, also give the name of the substance.

26. In the past month, have you used medication for:

- | | | |
|---|--------------------------|--------------------------|
| a. constipation? | ☐ | ☐ |
| | no | yes: _____ |
| d. urinary problems? | ☐ | ☐ |
| | no | yes: _____ |
| e. blood pressure? | ☐ | ☐ |
| | no | yes: _____ |
| f. other symptoms
(not symptoms related to
Parkinson's disease) | ☐ | ☐ |
| | no | yes: _____ |
-

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Visser M, Marinus J, Stiggelbout AM, Van Hilten JJ. Assessment of autonomic dysfunction in Parkinson's disease: the SCOPA-AUT. *Mov Disord* 2004;**19**:1306-12.

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