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Parkinson's disease, temporomandibular disorder pain and bruxism and its clinical consequences: a protocol of a single-centre observational outpatient study

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ABSTRACT

Introduction A recent questionnaire-based study suggested that bruxism and painful temporomandibular disorders (TMD pain) may be more prevalent in patients with Parkinson's disease (PD) compared with controls. The presence of both bruxism and TMD pain may negatively influence patients' quality of life. The present study is designed to clinically and more objectively investigate the presence of bruxism and TMD pain in patients with PD. The secondary aim of the study is to identify factors associated with bruxism and TMD pain in patients with PD, such as disease severity and dopaminergic medication usage. Furthermore, the presence of tooth wear in patients with PD will be studied as this can be a major consequence of bruxism. Finally, deviations in saliva composition that may contribute to tooth wear will be studied.

Methods and analysis This is a single-centre observational outpatient study at the Amsterdam University Medical Centres, location VUmc. All patients with a clinical diagnosis of PD will be eligible for inclusion. Participants will fill in a set of questionnaires. Subsequently, patients will be examined clinically for, among others, TMD pain, presence and severity of tooth wear, and deviations in saliva composition. Sleep-time registrations will take place for 5 nights with the GrindCare GC4 (ie, a portable, single-channel electromyographic recorder) to assess sleep bruxism and simultaneously by the use of the BruxApp for 5 days to assess awake bruxism. We will partly use data collected during standard clinical care to minimise patient burden.

Ethics and dissemination The scientific and ethical aspects of this study protocol have been approved by the Medical Ethics Review Committee of the Amsterdam UMC, location VUmc; NL. 2019.143. Informed consent will be obtained from all participants. The results will be published in a peer-reviewed journal, if relevant presented at conferences, and published as part of a PhD thesis.

Trial registration number NL8307.

Strengths and limitations of this study

- This observational study will provide accurate data on the presence of painful temporomandibular disorders and bruxism in patients with Parkinson's disease (PD) attending the outpatient clinic for movement disorders of Amsterdam UMC, location VUmc, and their possible associated factors like disease severity and medication usage.
- Novel information about tooth wear and saliva composition and quantity in patients with PD will be collected.
- Since polysomnographic recordings for the assessment of definite sleep bruxism are not feasible in this study, a portable, single-channel electromyographic recorder is used instead.
- Electromyographic recordings will be performed for several nights in a row, thus taking into account the fluctuating nature of sleep bruxism.
- Because of the absence of a control group, no direct comparisons between individuals with PD and similar individuals without PD can be made.

INTRODUCTION

Parkinson's disease (PD) is a neurodegenerative movement disorder characterised by motor symptoms, in particular rigidity, bradykinesia and tremor.[1 2] Patients with PD experience motor symptoms, and non-motor symptoms like anxiety, depression, sleep problems and cognitive dysfunction.[3 4] Besides, pain has been reported as one of the most troublesome non-motor symptoms in patients with PD, early in their disease, which could affect patients' quality of life.[5 6]

Due to global ageing, the prevalence of PD is estimated to increase significantly in the near future. Ageing is associated with oral health-related issues, which may therefore occur more frequently in the near future as well.[7] Dentists regularly see patients with bruxism in the dental office, which is an oral health-related issue that is not necessarily associated with systemic diseases. Bruxism is currently defined as 'a repetitive jaw-muscle

activity characterised by clenching or grinding of the teeth and/or by bracing or thrusting of the mandible'.[8] It can occur during sleep, indicated as sleep bruxism, or during wakefulness, indicated as awake bruxism.[8] Bruxism and its possible consequences, such as mechanical tooth wear and temporomandibular disorders (TMD), have hardly been studied in patients with PD. TMD is a collective term embracing disorders of the temporomandibular joint, masticatory muscles and adjacent anatomical structures.[9] TMD can present as painful and non-painful conditions. Patients with TMD can report, for example, orofacial pain (including headache), limitations in the movement of the mandible and joint noises.[9] Both tooth wear and TMD may affect the oral health-related quality of life.[10]

In a population with patients with PD, oral health was recently studied.[11] It was shown that the oral health in patients with PD is deteriorated as compared with their peers without PD. Besides, medication usage can influence salivation production, which in turn influences the oral environment.[12] Also, gastrointestinal problems are more frequently shown in patients with PD. In turn, this could influence the presence of tooth wear due to reflux.[13 14]

While oral health in PD has not been studied widely,[11] oral (dys-)function in PD has been studied even less, even though PD, bruxism and TMD have been suggested to share several common characteristics (figure 1). Similar to PD, bruxism is considered to be regulated centrally and not peripherally.[15] In addition, in the pathophysiology of both PD and bruxism, the brain dopamine system plays an important role.[16–18] Besides, sleep disturbances[19] that are present both in PD[20] and in sleep bruxism, are associated with arousal activity.[19 21] As a result of such arousal activity, sleep bruxism may occur more frequently in people with sleep disturbances than in those without.[21] Also, in the prodromal phase of PD, a higher rhythmic masticatory muscle activity on polysomnography in non-rapid eye movement sleep has been observed, compared with controls.[22] This is a characteristic that is also seen in patients with sleep bruxism.[23] Furthermore, bruxism may be considered as a risk factor for TMD, depending on the assessment methods used.[24] TMD itself shares some characteristics with PD. For example, musculoskeletal pain (of which TMD pain is a subtype) is frequently reported by patients with PD.[3 25] Finally, suggestions have been put forward that alterations in the dopaminergic system are also present in patients with pain in the orofacial region,[26] although this remains to be confirmed in patients with TMD pain.

Recently, a questionnaire-based pilot study in 368 patients with PD and 340 controls suggested a higher prevalence of bruxism and TMD pain in patients with PD.[27] Also, patients with PD reported a higher mean TMD pain intensity than controls.[27] Besides, a large Taiwanese study showed a twofold increased risk of TMD in patients with PD as compared with controls.[28] However, because of the limitations of the described studies (eg, questionnaire-based study[27]; no international validated clinical examination used; no detailed explanation of the clinical examination given and only patients with newly diagnosed TMD included),[28] extrapolation of these findings requires further verification through clinical and instrumental data. Hence, to overcome some of the limitations, the present protocol was designed. The planned study will acquire more objective clinical and instrumental measures for awake and sleep bruxism and TMD pain, which can give more valid information on outcomes like the presence of bruxism in this population. Also, additional factors, such as the severity of PD and cognitive function, will be included as possible predictors for bruxism and/or TMD pain in patients with PD. Knowledge of the factors that can influence bruxism and/or TMD pain in patients with PD will help dentists and other oral healthcare providers to provide individualised care to prevent and/or alleviate symptoms of bruxism and/or TMD pain and their consequences in this vulnerable group of patients.

Based on the above-summarised evidence, the primary aim of this study is to investigate the presence of bruxism and TMD pain in patients with PD, through objective clinical and instrumental measurements. Based on our pilot

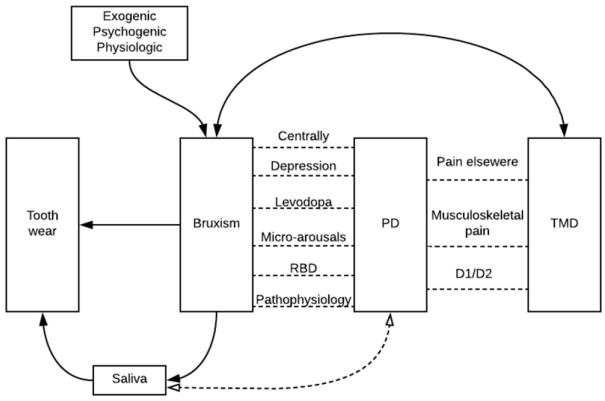

Figure 1 Visualisation of the possible interactions between the different research variables. Parkinson's disease (PD) is associated with bruxism through different variables: the dopaminergic system (pathophysiology) plays a role in both PD and bruxism; the prodromal phase of PD (RBD) shows the same characteristics during sleep as does bruxism; sleep disturbances lead to micro-arousals that can lead to bruxism; dopaminergic medication (levodopa) can influence bruxism; depression is one of the risk factors for bruxism and is more prevalent in patients with PD and finally, both PD and bruxism are regulated centrally and not peripherally. PD is also associated with temporomandibular disorders (TMD): patients with PD experience pain in the entire body (ie, widespread pain), which is a risk factor for TMD pain; also, musculoskeletal pain (as in TMD pain) is frequently present and finally, alterations in the striatal dopaminergic system (D1/D2 ratio) could play a role in TMD pain. Bruxism itself is a risk factor for TMD pain and vice versa. Besides, tooth wear can be a consequence of bruxism. When bruxism occurs, saliva can be increased, which can be a protective factor for tooth wear. Also, saliva can be changed due to PD medication. Finally, several exogenic, psychogenic and physiological factors can be a risk for bruxism.

study outcomes,[27] we hypothesise that the prevalence of bruxism and TMD pain in the current population will be higher than in their peers without PD, as described in the literature.[29 30]

In addition, the secondary aims and their corresponding hypotheses are the following:

1. To identify which factors are associated with bruxism and TMD pain in patients with PD. We hypothesise that factors like medication usage,[16] disease severity,[15 17] psychosocial factors[31–33] and lifestyle factors[31 32 34] are influencing the studied associations.
2. To investigate whether the salivary flow, the pH and the buffer capacity of saliva in patients with PD are related to the severity of tooth wear. Our hypothesis is that in patients with PD, the saliva composition and salivary flow deviate from normal standards and that this is associated with the severity of tooth wear.[14]
3. To investigate with dopamine transporter single photon emission CT (DAT-SPECT) whether there is a relationship between the degree of presynaptic dopaminergic loss and the presence of bruxism in these patients. The hypothesis is that there is a difference in striatal dopaminergic deficit between patients with PD with and without bruxism, in which patients without bruxism show a smaller deficit.

METHODS AND ANALYSIS

The design of this study is a single-centre observational outpatient study that will take place at the Department of Neurology of the Amsterdam University Medical Centres (Amsterdam UMC), location VUmc. The data collection will take place for 2 years. Due to the COVID-19 pandemic, the start date is delayed. However, the estimated start and end dates will be January 2023 and January 2025, respectively.

Participants and eligibility

Patients already clinically diagnosed with PD or planned for an intake appointment with presumable PD at the outpatient clinic for movement disorders of the VUmc will be eligible to participate in the study. Yearly, about 100–120 new consultations for PD are seen in the outpatient clinic. In addition, patients already receiving treatment at the VUmc are eligible for participation as well. The inclusion and exclusion criteria are listed in table 1.

Study procedure

In figure 2, the study procedure is visualised. If patients agree to participate in the study, they will be asked to sign an informed consent. This study will be performed in parallel to the routine clinical care (box 1) at the Amsterdam UMC, location VUmc. When questionnaires/screenings were filled in ≥1 year ago, participants will be asked to repeat this. Specifically, for this study, additional information will be obtained in the form of a set of questionnaires that participants can fill in at home and of a clinical examination at the hospital (table 2). The neurologist will determine whether additional brain imaging (viz, MRI or DAT-SPECT) is necessary, mainly in cases of clinical doubt. The estimated percentage of additional brain imaging in newly referred patients is 40%.

Main study parameters

The main study parameters or end points are 'presence of bruxism (sleep and/or awake)' as well as 'diagnosis of TMD pain'. For the assessment of sleep bruxism, patients will be asked to sleep five complete registration nights with a portable, single-channel electromyographic recorder, viz, the GrindCare GC4 (Sunstar Suisse, Etoy, Switzerland).[35 36] For the assessment of awake bruxism, patients will use, for five complete registration days, the BruxApp,[37 38] which is a mobile application for the recording of bruxism activity based on ecological momentary assessment.[8] According to international consensus, a classification of the probability that bruxism is present can be made as follows: possible, probable and definite bruxism presence.[39] In this research, all probabilities of bruxism presence can be determined, however, the highest probability will be used (viz, both probable and definite). When patients cannot use the GrindCare GC4 and/or BruxApp, and more certainty towards a definite presence is thus impossible, probable bruxism presence will be determined with the use of data from the clinical examination, based on the presence of positive symptoms of bruxism (viz, clenching marks in the soft tissues of the

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
1. ≥18 years of age	1. Atypical parkinsonian syndromes
2. ≥21 on the Montreal Cognitive Assessment[53]	2. For using the GrindCare: pacemaker
3. Fulfil clinical diagnostic criteria for PD[54]	3. For using the BruxApp: no smartphone
	4. For the DAT-SPECT: no deep brain stimulation implant present

When patients have a pacemaker, they cannot use the GrindCare GC4 (ie, a portable, single-channel electromyographic recorder to detect sleep bruxism) and will be excluded from that specific part of the study. When patients do not have a smartphone, participants cannot use the BruxApp (ie, an application on a smartphone to assess awake bruxism) and will be excluded from that specific part of the study.
DAT-SPECT, dopamine transporter single photon emission CT; PD, Parkinson's disease.

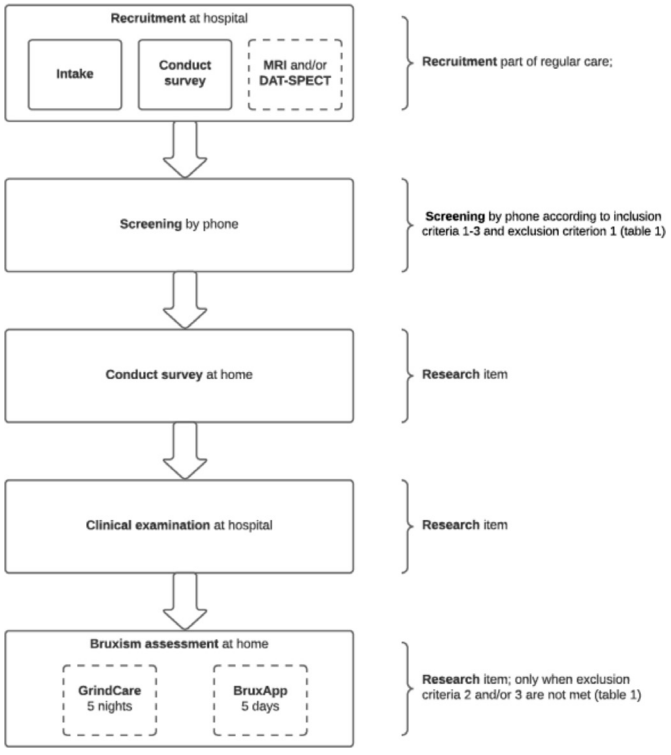

Figure 2 Flow chart of the study in which a distinction was made between the attendance of participants at the hospital and the study components at the participant's home. The intake and first survey is part of the regular care at the hospital, and only followed by an additional MRI and/or dopamine transporter single photon emission CT (DAT-SPECT) scan when indicated (dashed line). When patients are eligible and consent to participate (screening by phone), the additional data are collected after the intake. First, a questionnaire is filled in by the participants. After that, the participant is invited for the clinical examination. When questionnaires/screenings that are part of the regular care were filled in ≥1 year ago, participants will be asked to repeat this procedure simultaneously with the additional questionnaire and/or clinical examination. Finally, participants will sleep for five complete registration nights with the GrindCare for the assessment of sleep bruxism (when exclusion criterion two was not met) and use the BruxApp for five complete registration days for the assessment of awake bruxism (when exclusion criterion 3 was not met).

cheek, tongue or lip, mechanical tooth wear (attrition), and/or hypertrophy of the masseter muscle).[39] Differences in PD symptoms between those who can, and those who cannot complete the instrumental assessments will be tested as to gain insight into the external validity or generalisability of the conclusions involving bruxism modelling.

The TMD pain diagnosis will be established according to the diagnostic criteria for TMD (DC/TMD),[40] with the use of standardised questionnaires and clinical examination procedures. Based on the collected data, the following diagnoses can be set: myalgia (local myalgia, myofascial pain, myofascial pain with referral), arthralgia, headache attributed to TMD and non-painful joint disorders (disc displacement with reduction, disc displacement with reduction with intermitted locking, disc displacement without reduction with limited mouth opening, disc displacement without reduction without limited mouth opening, degenerative joint disease, subluxation). The main focus of this research protocol will be the TMD pain

Box 1 Questionnaires and clinical data collected as part of the regular care at the hospital, which is used in this observational study

Variables standard care hospital:

- Cognitive function (Montreal Cognitive Assessment[35]; Parkinson's Disease Cognitive Functional Rating Scale).[62]
- Disease stage (Hoehn and Yahr)[63]; disease severity (Unified Parkinson's Disease Rating Scale-III).[52]
- Dopaminergic medication (levodopa equivalent daily dose).[64]
- Neuropsychiatric symptoms: depression (Beck Depression Inventory-ii)[65]; apathy (Apathy Evaluation Scale)[66]; anxiety (Parkinson Anxiety Scale)[67]; psychotic (Parkinson's disease-adapted scale for assessment of positive symptoms)[68]; impulse control (Questionnaire for Impulsive-Compulsive Disorders in Parkinson's Disease-Rating Scale).[69]
- Presynaptic dopaminergic loss, when applicable (brain imaging) (dopamine transporter single photon emmission CT).[42 44]
- Quality of sleep (Scales for Outcomes PD Sleep).[70]
- Stimulants usage: alcohol (per unit, daily), drugs (per unit, daily), smoking (per unit, daily).

See online supplemental appendix 1 for a description per questionnaire/instrument.

Table 2 Additional research components, that is, performed in addition to the regular appointments at the hospital

Questionnaires	1. Reflux (GerdQ-NL)[55]
	2. TMD pain (according to the DC/TMD)[40] and intensity (graded chronic pain scale)[56]
	3. Tooth wear
	4. Sleep (obstructive sleep apnoea, STOP-Bang NL)[57]
Clinical examination	1. Intra-oral examination (positive symptoms of bruxism (viz, clenching marks in the soft tissues of the cheek, tongue or lip, mechanical tooth wear, hypertrophy of the masseter muscle))[40]
	2. Quantitative tooth wear screening (part of the tooth wear evaluation system)[58]
	3. A brief screening of the dental prosthesis (when applicable)
	4. Dry mouth screening (clinical oral dryness score)[59]
	5. Jaw-mobility examination (DC/TMD)[40]
	6. Joint noises examination (DC/TMD)[40]
	7. Palpation of masticatory muscles and temporomandibular joints (DC/TMD)[40]
	8. Dynamic/Static tests[60]
	9. Bruxoprovocation test[60]
	10. Saliva test (Saliva-Check Buffer)[61]
Registration	1. BruxApp[37]
	2. GrindCare GC4[35 36]

See online supplemental appendix 1 for a description per questionnaire/instrument.
DC, diagnostic criteria; TMD, temporomandibular disorders.

diagnosis, for the establishment of which the diagnostic flow chart of the DC/TMD will be used.[40]

Dentists making clinical assessments for bruxism or TMDs will blinded to the results of the instrumental assessments (ie, GrindCare GC4 and BruxApp for sleep bruxism and awake bruxism, respectively).

Secondary study parameters

To identify which factors are associated with bruxism and TMD pain in patients with PD, several variables will be evaluated (table 2, box 1), using different clinical/instrumental measures (online supplemental appendices 1-3). Most of these variables have already been reported as possible risk factors for bruxism[32] and/or TMD[41] in the general population.[31–33] However, the variables dopaminergic medication usage and disease stage/severity of PD have not been studied yet in the association with bruxism or TMD pain in patients with PD. Finally, if DAT-SPECT imaging is available, we will compare the measured presynaptic striatal dopaminergic deficit between participants with and without bruxism.[42]

Sample size

According the pilot study, the prevalence of awake bruxism, sleep bruxism and TMD pain in patients with PD is 46%, 24% and 29.5%, respectively.[23] Taking the cautious approach, we calculated the sample size for awake bruxism, sleep bruxism and TMD pain and chose the largest sample size. Aiming for a precision of 5% with a level of confidence of 95%, 246 participants are needed[43] (see online supplemental appendix 2 for the sample size calculation). Furthermore, the approach to calculate the sample size for the most important secondary aim (viz, to identify which factors are associated with bruxism and TMD pain in patients with PD) is also shown in online supplemental appendix 2. The numbers are obtained when reaching the sample size for the primary aim.

Statistical approach

With the use of descriptive tests, demographic data will be summarised. In figure 3, it is shown how the dataset is analysed to give an answer on which factor is associated with the presence/absence of probable bruxism/TMD pain or with the frequency (ie, the number of bruxism events per hour) of definite bruxism. The forward selection procedure will be used for the (strongest) independent variables (box 2) until all variables in this regression model show a p value <0.05 (see step 2, figure 3). Finally, to analyse if there is an association between tooth wear and composition of saliva, Spearman's correlation coefficient will be used. For the DAT-SPECT, a semi-quantitative analysis will be used. Ratios for specific versus non-specific binding will be calculated for the regions of interest (viz, left and right putamen and caudate nucleus, using the occipital cortex as a reference area) and analysed using the independent sample t-test.[42 44]

Patient and public involvement

Neither patients nor the community were involved in the design of this study. However, feedback from participants of the earlier pilot study[23] was used to design this study. Patients with PD will be involved in the performance of the study. The burden for the participants will be kept as minimal as possible. On request, the outcomes of this study will be disseminated to the participants.

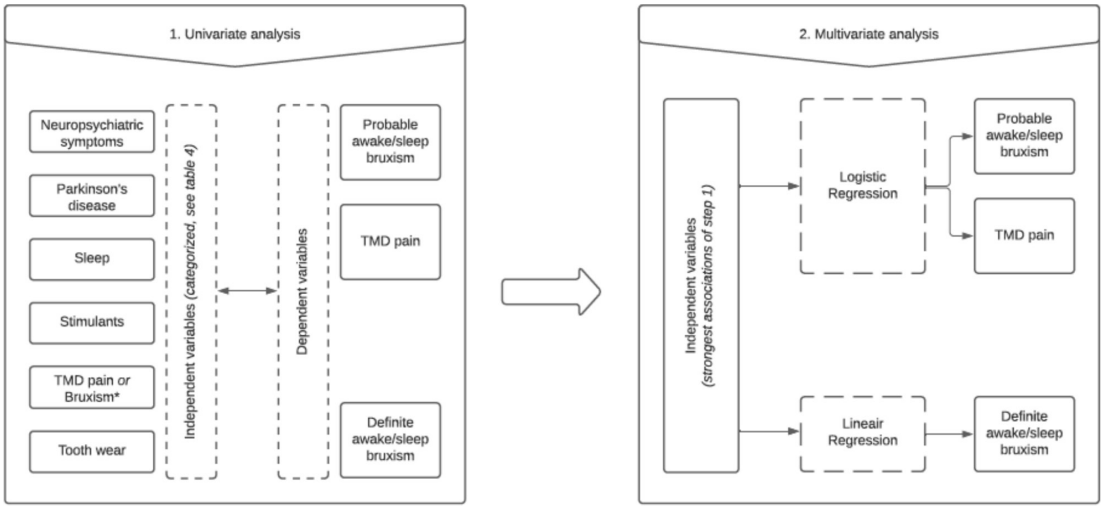

Figure 3 Flow chart of the data analysis related to the first secondary aim: 'to investigate which factors are influencing the presence of probable awake/sleep bruxism, temporomandibular disorders (TMD) pain and the frequency of definite awake/sleep bruxism'. All variables will be tested individually to see whether an association with the dependent variable (awake and sleep bruxism and TMD pain) exists, and to see how strong this association is (step 1). This dataset will be analysed for both probable bruxism and TMD pain with the use of logistic regression analyses. For definite bruxism, a linear regression analysis will be used (step 2). The forward selection procedure will be used for the (strongest) independent variables until all variables in this regression model show a p value <0.05 (step 2). In both step 1 and step 2, a distinction will be made between sleep and awake bruxism.

Box 2 The independent variables (categorised) that will be investigated for one of the secondary aims: which factors are associated with the presence of bruxism and temporomandibular disorders (TMD) pain in patients with Parkinson's disease (PD)?

Independent variables (categorised)

- Bruxism (*when analysing which factors are associated with the presence of TMD pain in patients with PD*).
- Neuropsychiatric symptoms (depression, anxiety, apathy, psychosis, impulse disorders).
- PD (disease stage, disease severity, medication usage, cognitive function).
- Sleep (quality of sleep, obstructive sleep apnoea).
- Stimulants usage (alcohol, smoking, drugs).
- TMD pain (*when analysing which factors are associated with the presence of bruxism in patients with PD*).
- Tooth wear related (reflux, saliva, dry mouth).

DISCUSSION

The primary aim of this study is to objectively measure the presence of bruxism and TMD pain in a population of patients with PD. Furthermore, the three secondary aims are described as follows: (i) to identify which factors are associated with bruxism and TMD pain in patients with PD, (ii) to investigate whether the salivary flow, the pH and the buffer capacity of saliva in patients with PD are related to the severity of tooth wear and finally (iii) to investigate with DAT-SPECT whether there is a relationship between the degree of presynaptic dopaminergic loss and the presence of bruxism in these patients.

To the best of our knowledge, this is the first study that attempts to objectively measure the presence of awake bruxism, sleep bruxism and TMD pain in a population of patients with PD. Previous studies investigated the prevalence of awake bruxism in this population, however only few participants were included or only questionnaires were used.[23 45] When quantifying bruxism with continuous data, recent insights showed a better quality of a definite bruxism diagnosis.[39] Nevertheless, we used a dichotomous outcome in this protocol study to answer our first aim, that is, to investigate the presence of bruxism. Besides, we also included self-report and clinical data, which do not yield continuous outcomes. Despite this, in the present study, the use of the GrindCare GC4 and the BruxApp can give more certainty towards a definite establishment of sleep and awake bruxism, respectively.[39] This enables the analysis of continuous outcomes, which has been suggested by several authors.[46 47] However, as mentioned earlier, not every participant will be able to use the GrindCare GC4 and/or the BruxApp. Therefore, this protocol is designed to include all probability levels for the assessment of bruxism, which contributes to the feasibility of this protocol.[39] Importantly, participants able to complete all assessments may differ from those who cannot complete instrumental assessments due to differences in severity of their PD symptoms. Fine motor problems which occur in PD create barriers for electrode placement and cell phone use as required for instrumental assessments of sleep and awake bruxism. Therefore, we will test for PD symptom differences between subgroups defined by comparing participants completing or not completing instrumental assessments. If differences are found, this will indicate limitations to the external validity or generalisability of conclusions involving bruxism modelling.

In addition, the clinical examination according to the DC/TMD[40] enables setting a valid TMD pain diagnosis, making a distinction between several TMD complaints, and comparing the outcomes with other (inter-) national research. An important aspect of a TMD pain diagnosis according to the DC/TMD is that it considers the aspect of 'familiar pain' as part of the diagnostic algorithm. As such, PD-related pain characteristics like pain exacerbation due to 'wearing off' of dopaminergic medication and lower pain thresholds in individuals living with PD as compared with similar individuals without PD[48] will be taken into account.

Because patients with PD are vulnerable and burdened with frequent visits to multiple caregivers (eg, their neurologist, physiotherapist and speech therapist), it is important to burden the participants as minimally as possible. Therefore, during the process of designing this study and collecting the data, a multidisciplinary approach was established between neurologists and dentists to enable an as efficient as possible usage of the patient's time and energy.

The targeted number of inclusions will be a challenge. However, the calculated sample size is an estimation, because no clinical prevalences are known as yet. Like in otherwise healthy individuals, clenching and grinding are not always recognised by the patients themselves,[49 50] thus the prevalence of sleep bruxism in the pilot study could have been underestimated. This means that the calculated sample size in this study might be higher than eventually required. Therefore, an interim analysis will be performed after 130 included participants or 6 months.

This study has no longitudinal character and therefore, no causal relations can be observed between the (in-) dependent variables. Also, polysomnography is the golden standard to detect sleep bruxism while in the present study, a portable electromyographic recorder will be used.[39] However, since this device will be used for several nights in a row, the fluctuating character of sleep bruxism can be taken into account and is therefore considered a good proxy for definite sleep bruxism.[36] It should be noted, however, that the portable recorder will fail to enable a distinction between jaw-muscle activities related to sleep bruxism and those related to other orofacial movement disorders like oral dyskinesia and oromandibular dystonia.[51] This is an important issue, because such movement disorders can be present in patients with PD related to their medication usage. In fact, in their updated international consensus paper on bruxism, Lobbezoo *et al* added the phrase that bruxism is a masticatory muscle activity in 'otherwise healthy individuals'.[39] People living with PD are certainly not 'otherwise

healthy'. In the later stages of levodopa-treated PD, dyskinesias, including oral dyskinesias, commonly occur.[51] Hence, the question could be raised if the masticatory muscle activity observed in people with PD is 'bruxism' at all. This calls for caution in the interpretation of the bruxism-related findings of this study. Fortunately, in the questionnaire and clinical examination of the Movement Disorder Society-Unified Parkinson's Disease Rating Scale-III[52] (box 1), the presence of oral dyskinesia and oromandibular dystonia is included. Hence, it is possible to correct for their presence in the data analysis.

This study does not include a control group. This limits the interpretation of whether the prevalence of bruxism or TMDs is low or high in people with PD, which will only be possible by comparing the findings with prevalences as reported in the literature. In addition, since tooth wear in older people reflects a lifetime of factors, it will be also difficult to interpret the tooth wear findings in people with PD without having the possibility for a direct comparison with similar individuals without PD. Also in this case, comparisons should be sought with literature data. These issues should be considered limitations of this study.

In conclusion, this study will give more detailed information about the presence of bruxism and TMD pain in patients with PD, as well as about possible associated factors like medication usage and severity of the disease. Finally, more clinically relevant information will become available for dentists and other oral healthcare professionals about the amount of tooth wear and the composition of saliva in patients with PD.

ETHICS AND DISSEMINATION

This study protocol has been approved by the Medical Ethics Review Committee of Amsterdam UMC, location VUmc; NL. 2019.143. Informed consent will be obtained from all participants. A data monitor will meet annually to primarily concentrate on the safety of patients, and will be monitoring the collected data and informed consents. The results will be published in peer-reviewed journals, if relevant presented at conferences, and published as part of a PhD thesis.

Due to the sensitive nature of personal information, all data will be blinded and stored in secure environments. Only the executive researcher and the head of the department can reach the unblinded informed consents and the key for unblinding. These are stored separately. Digital data will be stored pseudonymised in a secure database using Castor EDC (CDISC, Amsterdam, The Netherlands). Detailed methods for data management and storage can be obtained by contacting the corresponding author.

Contributors All authors were involved in designing this study. MCV obtained the approval of the Medical Ethics Review Committee and drafted the manuscript. Finally, all authors gave feedback on the draft and approved the final manuscript.

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Competing interests FL reports grants and other from Sunstar Suisse, grants from Somnomed, Airway Management, Vivisol-Resmed, Health Holland/TKI, outside the submitted work.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Consent obtained directly from patient(s)

Provenance and peer review Not commissioned; externally peer reviewed.

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