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Effect of orofacial physiotherapeutic and hygiene interventions on oral health-related quality of life in patients with Parkinson’s disease: A randomised controlled trial

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Abstract
Background: Parkinson’s disease (PD) has a negative effect on oral health and orofacial function, but the subjective experience of orofacial symptoms and their impact on the quality of life is not fully investigated. In addition, knowledge of how to improve the subjective oral symptoms is lacking.

Objectives: To assess the self-reported orofacial function and oral health in patients with PD. Furthermore, to investigate the effect of interventions for improvement of oral hygiene and function on oral health–related quality of life (OHRQoL).

Methods: A randomised controlled study with delayed intervention was conducted in 29 patients with moderate to advanced PD. Patients were instructed in a standardised exercise programme for the jaw and orofacial muscles and given an individualised oral hygiene programme. The effect on self-reported orofacial function and OHRQoL was measured after 2 and 4 months using the Nordic Orofacial Test—Screening (NOT-S), the oral health impact profile (OHIP-14), self-reported drooling score and subjective mastication ability.

Results: Self-reported oral health and function before the intervention was significantly correlated to the severity and duration of PD. The NOT-S and drooling score were significantly improved by the interventions after 2 months and the OHIP-14 after 4 months.

Conclusion: The interventions improve the self-reported orofacial function and OHRQoL. These simple interventions can be implemented in the allied multidisciplinary health care surrounding the PD patient.

KEYWORDS
OHRQoL, oral health, orofacial function, Parkinson’s disease, physiotherapy, self-assessment

1 | BACKGROUND

Parkinson’s disease (PD) is a slowly progressing neurodegenerative disease. The global prevalence of PD is about 1% in people over 60 years.1 PD mainly affects the substantia nigra in the brain with gradual destruction of the dopaminergic nerve cells and the development of symptoms of dopamine deficiency. PD cannot be cured but early diagnosis and treatment can relieve symptoms and increase the quality of life.2,3
The disease is clinically characterised by motor and non-motor symptoms, which demonstrate strong diurnal oscillations related to dopamine. The motor symptoms of PD include bradykinesia, resting tremor, stiffness, postural instability and difficulty in walking. Most patients also experience non-motor symptoms that include sleep disorders, pain, cognitive symptoms, neuropsychiatric dysfunctions and gastrointestinal symptoms. The non-motor manifestations may be interrelated as poor sleepers seem to have more problems such as low mood, apathy and impaired cognition.

Problems with oral health (dental and oral diseases) as well as orofacial function (jaw opening, chewing, swallowing and drooling problems) are significant challenges for many people with PD. Both oral health and function appear to be associated with the duration and severity of the disease. The deterioration in motor skills (tremor, instability and bradykinesia) inhibits the ability to hold a toothbrush and move it properly while keeping the mouth open. These challenges in performing daily oral hygiene tasks as well as the reduced self-cleaning of the oral cavity lead to an increased risk of developing dental and oral diseases. The cognitive impairments, such as memory loss, depression and, in later stages, dementia, may also necessitate support to maintain a sufficient daily oral hygiene routine. Furthermore, Parkinson's medication can cause xerostomia and hyposalivation, thereby contributing to impaired oral health. Barbe et al found that 50% of a PD study population reported xerostomia and up to 87% showed hyposalivation; furthermore, PD patients might have a deviation in the circadian controlled salivary flow rates. Thus, it is important that the dentists have insight into the mechanisms behind xerostomia and decreased salivary secretion and contribute to diagnostics and treatment. Dysphagia, that is, impaired or difficult swallowing, is a common problem in neurodegenerative diseases including PD. There is also strong indication that dysphagia may cause drooling. Drooling can be either primary or secondary. Primary drooling is secretion of an excessive amount of saliva. Secondary drooling is caused by disorders that affect the centres in the brain that initiate, control and regulate the swallowing process, as well as the motor neurons. In PD, drooling is generally secondary and associated with reduced swallowing frequency and efficiency, and impaired orofacial and oropharyngeal muscle function. Therefore, drooling in patients with PD can occur even when there are low salivary flow rates. Excessive drooling may cause skin irritation, perioral dermatitis and odour and, in severe cases, can lead to aspiration pneumonia, pulmonary infections and choking. Patients may also develop side effects of dopamine replacement therapy in the form of a “sweet tooth”. Thus, there are several challenges for oral and dental health. The poor oral health of PD patients is primarily related to increased incidence of caries, gingivitis, periodontitis, tooth loss and consequently significant costs of dental care services.

In addition, to jaw tremor and stiffness of the facial and masticatory muscles, PD patients have poorer chewing function as well as less bite force and jaw mobility than people of the same age without PD. PD patients experience rigidity and slowness of movement in the orofacial muscles, involuntary facial movements and reduced tongue movements, which can cause problems with chewing, speech and jaw mobility, orofacial pain, temporomandibular joint symptoms, and fracture, attrition and infracted teeth.

The orofacial impairments impair the oral health-related quality of life (OHRQoL) and constitute a social handicap with reduced facial expression, which is a major psychosocial strain.

We have recently described that an intervention consisting of individual instruction in oral hygiene and exercises improved objective measurements of jaw mobility, masticatory function and oral hygiene. These interventions significantly improved the jaw opening mobility by 6%, and the chewing efficiency by 49% and also reduced the dental plaque deposits by 49%. In this paper, we investigate whether the same interventions also have an impact on the subjective assessments such as OHRQoL and self-reported orofacial function in the same group of patients. The purpose of this study was to analyse the subjectively experienced orofacial function and oral health in patients with PD in relation to the severity and duration of their disease and furthermore to investigate whether the above interventions improved the self-reported orofacial function and OHRQoL. We hypothesised that the intervention would result in improvement of these parameters, making it relevant to implement these simple interventions as part of the multidisciplinary health care of PD patients.

2 | MATERIALS AND METHODS

2.1 | Ethics

The study complies with the guidelines of the Declaration of Helsinki and was approved by the Regional Committee on Research Health Ethics of the Capital Region (H-17039142), and the Faculty of Health and Medical Sciences and the Danish Data Protection Agency (SUND-2017-68). Before inclusion, informed and written consent was obtained from the participants. The participants were also informed that no adverse events, risks or disadvantages associated with the study were expected and they were free to decline the offer without consequences for their treatment at the hospital.

2.2 | Participants and recruitment

This study was performed from February 2018 until November 2019 at the Department of Neurology in Bispebjerg University Hospital (Copenhagen, Denmark). The neurologist in the Outpatient Clinic performed the recruitment and enrolment of the patients. The participants were chosen among the patients who fitted the inclusion criteria: moderate to advanced PD corresponding to UK Brain Bank Criteria, Hoehn & Yahr Stages 2 to 4, in stable medical treatment for PD motor symptoms the last month prior to inclusion, and able to cooperate in the entire project. Patients were excluded from the study if they suffered from any other serious illness that might affect the trial results or if they were cognitively affected (demented),...
thereby unable to understand the information given and not be able to cooperate during the course of the study. The neurologist (MK) informed about the study, obtained the informed and written consent and performed all the neurological assessments at the hospital. The aim was to include 30 patients, and 33 were recruited to account for dropouts. Four patients backed out shortly after because of long travel time to the hospital and/or they felt too weak to participate (Figure 1).

2.3 | Study design

The study was designed as a non-blinded randomised controlled study with delayed intervention for one group (Figure 1). Patients who agreed to take part in the study received an appointment at the dentist (SB) and were asked to draw a paper from a bag containing folded pieces of paper numbered 1–33. Depending on whether the number was even or odd, patients were assigned to one of two groups (group A and group B). Patients in each group visited the department three times at two-month intervals. At the first visit, patients were assigned to Group A or B, both groups received information about the study and were examined. Group A additionally received a standardised exercise programme for the muscles around the mouth and individual counselling and instruction in oral hygiene, while Group B did not receive counselling or instruction. The patients were re-examined 2 months later. Patients in group A were re-instructed and re-counseled and Group B patients received the same standardised exercise programme for the muscles around the mouth and individual counselling and instruction in oral hygiene. Four months after the first visit (two months after the second visit), the patients came for their third and final visit and were re-examined.

SB, MK and MB planned the project and applied for funding. MK recruited, informed and included the participants, and SB examined and instructed the participants. SB collected the data and performed the statistical analyses with contribution from MB and EBØ. SB and MB wrote the first draft, and all the authors corrected and approved the final draft.

2.4 | Interventions

The treatment consisted of a standardised exercise programme and an individualised oral hygiene programme both performed at home with training and oral care aids. The training programme consisted of three exercises for jaw, cheek and lip muscles. The first exercise aimed to improve jaw opening mobility with a JawTrainer, which is a specially designed clamp placed between the teeth, which when pressed, opens the mouth. The second exercise aimed to train the lip and cheek muscles with an Oral Screen (Ulmer model), which consists of a ring-formed mouth screen placed behind the lips in front of the teeth which the patient pulls to activate the muscles. The third exercise aimed to improve the chewing function by training the masticatory muscles during chewing Proxident fluoride gums. The oral hygiene programme was individualised for

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**FIGURE 1** Flow diagram of the study design and clinical characteristics of the participants. Randomised controlled trial with delayed intervention for Group B showing inclusion, exclusion and randomisation of the participants. Clinical characteristics including age, gender, duration of Parkinson’s disease (PD), Hoehn and Yahr staging (H&Y) \(^{27}\) and the Unified Parkinson’s Disease Rating Scale (UPDRS II and III) \(^{28}\)
each patient, and counselling and instruction were given to obtain the best possible home care. The patients were also provided with and instructed in using a special toothbrush (Dr. Barman’s Special). At their next visit after 2 months the patients were asked about the weekly frequency of the home exercises, and 83–89% of the patients reported performing the exercises 4–5 days per week. 69% reported that they had used Dr. Barman’s Special toothbrush either as their main toothbrush or as a supplement to their own electric toothbrush.

2.5 | Outcomes

2.5.1 | Self-perception of oral health and function

The OHRQoL was assessed by the Oral Health Impact Profile 14 (OHIP-14). The questionnaire is composed of 14 items distributed between seven subscales (functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap) addressing oral health status and its impact on social aspects. The items are rated by the frequency, social disability and handicap addressing oral health status and it's impact on social aspects. The items are rated by the frequency of impact within the last month. This results in a score between 0 and 56, with a high score indicating high impact and poor psychological discomfort, physical disability, psychological disability, social disability and handicap addressing oral health status and its impact on social aspects. The items are rated by the frequency of impact within the last month. This results in a score between 0 and 56, with a high score indicating high impact and poor OHRQoL.

2.5.2 | Neurological outcomes

The progression of PD was described using Hoehn and Yahr staging (H&Y) consisting of the following stages: stage 1: unilateral involvement; stage 2: bilateral or midline involvement without impairment of balance; stage 3: mild to moderate bilateral disability with impaired postural reflexes; and stage 4: severely disabling disease but still able to walk or stand unassisted. The Unified Parkinson’s Disease Rating Scale (UPDRS) Part II is a self-evaluation of the motor aspects of daily living including speech, swallowing, hygiene, salivation and cutting food; Part III is a clinician-scored motor evaluation including speech volume, reduced facial expressions, rigidity and slowed hand movements etc.

2.6 | Statistics

2.6.1 | Sample size

The sample size was determined on the basis of a power calculation of the maximum jaw opening capacity. Assuming an improvement in maximum jaw capacity of ≥5 mm after 2 months of intervention, and estimating that 4% random increase could occur in Group B (control) and 50% increase in Group A (experimental), then with 90% power and a significance of 5%, we needed 15 patients in each group.

2.6.2 | Statistical analysis

Data were analysed using IBM SPSS Statistics 27. The initial analysis was performed using descriptive analysis and the characteristics regarding age, PD characteristics and complement of teeth were compared between Group A and B using t test and chi-square. Then, non-parametric analyses were performed on the outcome parameters, as the data were not normally distributed.

The scores of the subjective self-experienced ORHQoL and orofacial function before intervention were first associated with the values describing the severity and duration of the PD and complement of teeth using Spearman’s rank-order correlation analysis (r).

Outcome measurements for the two groups at the three visits were first described and changes between visit 1 and 2 and between visit 1 and 3 were investigated with paired Wilcoxon signed-rank test. In addition, the change in scores from first to second visit in Group A (2 months of intervention) and Group B (2 months of control) was compared with Mann-Whitney U test, but showed no significant changes between the two groups. Therefore, we also pooled the results and investigated the changes in outcome parameters 2 months after the intervention in all the participants, using paired Wilcoxon signed-rank test.

Statistical significance was accepted at p ≤ .05.

3 | RESULTS

3.1 | At inclusion

The study group included 29 patients, 15 male and 14 female, 32–79 years, with H&Y 2–4 (Table 1 and Figure 1). The range of the scores on UPDRS Part II was 8–23 and on the UPDRS Part III 12–31. The time of the diagnosis of their PD ranged from 3 to 20 years ago (Table 1). No significant differences were found between the characteristics of Group A and Group B concerning the patient age, PD characteristics and complement of teeth, and there were no significant differences between genders. Therefore, the results from the two groups could be pooled in some of the analyses. The mean and median values for the pooled groups are presented in Table 1.
For all participants, there were significant correlations between the self-evaluations concerning the feeling of impaired oral function (OHIP-14, interview of NOT-S, mastication ability and self-reported drooling) and the PD classification UPDRS II regarding motor aspects of experiences of daily living ($r_s 0.36–0.69$, Table 1). There was also a significant correlation between mastication ability and UPDRS III regarding motor examination. Self-evaluated drooling was significantly correlated with years of PD. Correlations with Hoehn & Yahr Stages and complement of teeth were insignificant.

### 3.2 After intervention

Table 2 shows the pooled results from Group A and B before and after 2 months of intervention, and Table 3 the separate values from each group from the three visits. The pooled values showed a significant reduction in the drooling score after 2 months of intervention ($p = .004$, Table 2). Also taken separately both groups had a significant reduction of drooling 2 months after the intervention (Group A: $p = .05$ and Group B: $p = .01$).
**TABLE 3** Self-evaluation of orofacial function and oral health in 29 patients with Parkinson’s disease (PD) before and after instructions in jaw exercises and oral hygiene

| Visit 1 | Visit 2 | Visit 3 |
|---------|---------|---------|
| **Baseline** | **+2 mo** | **+4 mo** |
| Intervention: | Intervention: | Intervention: |
| A: instruction | A: re-instruction | A: control |
| B: none | | B: re-instruction |

**Wilcoxon signed rank test paired samples**

**Visit 2 versus Visit 1**

**Visit 3 versus Visit 1**

| Group A: 15 patients (9 male, 6 female), median age 65 y | Group B: 14 patients (6 male, 8 female), median age 72 y |
|----------------------------------------------------------|----------------------------------------------------------|
| **OHIP-14** | **OHIP-14** |
| Mean ± SD | 6.3 ± 4.7 | 8.3 ± 10.5 |
| Median (range) | 7 (1–18) | 4 (0–27) |
| **NOT-S interview Part** | **NOT-S interview Part** |
| Mean ± SD | 1.3 ± 1.3 | 2.0 ± 1.0 |
| Median (range) | 1 (0–5) | 2 (0–3) |
| **Subjective mastication ability** | **Subjective mastication ability** |
| Mean ± SD | 0.53 ± 0.52 | 0.8 ± 0.4 |
| Median (range) | 1 (0–1) | 1 (0–1) |
| **Total self-reported drooling score** | **Total self-reported drooling score** |
| Mean ± SD | 4.6 ± 1.6 | 5.0 ± 1.7 |
| Median (range) | 4 (2–8) | 5 (2–7) |

Abbreviations: OHIP-14, Oral Health Impact Profile 14; NOT-S, Nordic Orofacial Test—Screening.

*Independent-samples Mann-Whitney U test showed no significance in outcome measurements from visit 1 to visit 2 when comparing Groups A and B, *p* > .05.

* *p* ≤ .05.
In addition, the pooled NOT-S dysfunction scores after 2 months of intervention were significantly reduced (p = .04, Table 2). The change in the NOT-S domain profile from baseline to 2 months and 4 months after intervention in Group A is presented in Figure 2 and it was most pronounced in the domain of chewing and swallowing. However, the changes of the NOT-S scores in the separate were insignificant (Table 3).

The change in the pooled OHIP-14 scores was insignificant (Table 2), though significantly reduced in Group A 4 months after the intervention (p = .01). The reduction was most pronounced concerning the domain of functional limitation as shown in Figure 3. Further analysis of the pooled results from Group A and Group B, showed that women felt significantly (p = .03) more reduction in OHIP-14 2 months after intervention than the men.

Independent-samples Mann-Whitney U test showed no significance in changes of the outcome measurements from visit 1 to visit 2 between group A and group B.

4 | DISCUSSION AND CONCLUSION

Oral health and orofacial function are affected by the severity and the duration of PD.4–8 Thus, patients with PD have more prevalent orofacial dysfunction, poorer mastication and jaw opening capacity and a negative impact of oral health on daily life as compared with a matched control group.7 However, in our previous publication we showed that with a standardised exercise programme and an individualised oral hygiene programme performed at home it was possible to improve jaw mobility chewing efficiency and oral hygiene.9 The maximum unassisted jaw opening capacity and chewing time of a standardised apple slice were significantly improved by respectively 6% and 49%, and plaque deposits were significantly reduced by 25% 2 months from the start of the invention, and the effects were still significant after 4 months. In the present study, we showed that the effect was not only clinically measurable, but the patients also felt functional improvement and better OHRQoL, four months after the start of the intervention. Thus, the interventions described may diminish and probably delay some of the negative effects of PD on oral health and orofacial function.

Although the clinical measurements such as jaw mobility, chewing time and oral health were already significantly improved after two months of intervention,9 it seems that the subjective feeling of a positive outcome needs more time to develop. It was first significant at four months, but the effect of the interventions beyond this time, and how often patients need reinstruction in order to achieve, maintain and experience improvement, is unclear. However without doubt, it is paramount that patients are followed continuously in order to maintain motivation and ensure that the exercises become an integrated part of their daily routine.

It should also be noted that the effect was significantly better among women than men, which may be due to the finding that PD in women starts with a more benign phenotype due to oestrogens.35 However, their compliance with the treatment regimen may also be better than among men, but as the disease progresses, women are at higher risk of developing treatment-related complications. Gender is also a factor in drooling, as men are more likely to develop drooling than women.8 Therefore, patients should preferably be checked at individually adjusted follow-up intervals, and studies that instruct and follow patients over a longer time are needed.

The goal of all three exercises was to facilitate orofacial function: the JawTrainer for the mobility of the jaw, the Oral Screen for the closure of the lips, and the gum chewing for the function and coordination of muscles and tongue. We hypothesise that the Oral Screen probably diminished the secondary drooling and thus the drooling score. In addition, the exercises may have trained the oropharyngeal muscles, thereby improving the dysphagia. All three exercises may have contributed to chewing training, but the subjective mastication score did not change significantly. We also hypothesise that both the exercises and the individualised oral hygiene would have improved the OHRQoL and the NOT-S.

A larger number of participants may have strengthened the results, but the power calculation of the sample size was based on the objective measurements in the already published study.9 Another limitation is the self-assessment nature of this study, which could be problematic for patients with PD. Earlier studies show that PD patients may underestimate non-motor symptoms,36 for example xerostomia.13 Underestimates could also be present in this study. Also, the investigator should have been blinded, but this would have required several calibrated investigators making the study quite impractical, and the participants would unintentionally be able to breach the blinding during the examination and instruction. Overall, there is a need for studies with a larger number of participants and with a longer follow-up period.

PD is a complex disease with a multifaceted nature. PD patients generally receive standard medical and pharmaceutical treatment,
but to effectively manage individual PD progression over time, clinical practices must implement integrative treatment models.\textsuperscript{37} Such allied interdisciplinary health care can complement the standard treatment and studies suggest that it improves outcome and quality of life for the patients.\textsuperscript{38} Together with the standard treatment, PD patients are often offered several supplementary services such as speech therapy, physiotherapy and mental rehabilitation to relieve symptoms and increase the quality of life. However, patients with PD have also poorer OHRQoL and oral function. This study shows that with relatively simple interventions and cheap assistive devices, it is possible to improve both the oral health and orofacial function as well as the OHRQoL and self-reported orofacial function. We suggest development of new initiatives, guidelines and prophylaxis to promote better oral health and quality of life for this patient group. In addition, strengthening of interdisciplinary collaboration and knowledge sharing between neurologists, dentists and other healthcare providers is recommended. This study may be a step towards the development of such interventions.

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CONFLICT OF INTEREST

The authors have no conflict of interest.

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