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RESEARCH REPORT

An intensive neurorehabilitation programme with sEMG biofeedback to improve swallowing in idiopathic Parkinson's disease (IPD): A feasibility study

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Abstract

Background: Studies suggest swallow intervention programmes that incorporate visual biofeedback and motor programming principles can improve swallowing and quality of life for people with idiopathic Parkinson's disease (IPD) and dysphagia. Few studies have examined outcomes using instrumentation.

Aims: Using fibreoptic endoscopic examination of swallowing (FEES), this study examines the effectiveness of a neurorehabilitation intervention involving biofeedback via surface electromyography (sEMG) to improve swallowing in people with IPD, and to explore the feasibility of the intervention approach.

Methods & Procedures: We recruited 12 participants with IPD and dysphagia. A total of 10 completed the study. Intervention was delivered for 1 h per day, 5 days per week, for 4 weeks (20 h). Swallowing tasks using sEMG biofeedback incorporated principles of motor learning and neuroplasticity. Instrumental and non-instrumental assessment, including quality-of-life measures carried out at four different time points (two pre-treatment and two post-treatment). The final assessment was at 3 months post-intervention.

Outcome & Results: Statistically significant improvement ($p < 0.05$) in oral intake methods (95% confidence interval (CI) = 4.70–5.50) and in pharyngeal residue from saliva (95% CI = 2.14–3.15) and solids (95% CI = 2.4–3.5) post-intervention were confirmed using FEES with improvements at 3 months. The intervention protocol was well tolerated. Participants reported positive change in saliva control and duration of mealtimes as well as unanticipated improvements in voice and cognitive attention.

Conclusions & Implications: An intensive neurorehabilitation with biofeedback shows positive effects in improving swallow function in IPD. This protocol is feasible with amendments to inform a larger clinical trial.

KEYWORDS
dysphagia, intensive treatment, motor learning, Parkinson's disease, swallowing

What this paper adds

What is already known on the subject

- Biofeedback has positive effects on increasing swallowing function and quality of life in people with IPD and dysphagia. sEMG is the most common method used to deliver swallowing biofeedback in this population. The quality of the evidence on the intervention, based on findings from a recent systematic review, is low. Included studies in this review were heterogeneous in terms of type and frequency of biofeedback, study design and outcome measures. The majority of outcome measures were subjective and higher quality studies to examine the efficacy of biofeedback using sEMG are needed.

What this study adds

- Recognizing the limitations of earlier studies, this within-subject feasibility study examined the efficacy and effectiveness of an intensive biofeedback intervention using sEMG in a sample of people with dysphagia and IPD. Valid and reliable outcome measures were used and repeated after a 3-month period. The feasibility of the methodological approach was also tested and a qualitative component was included in the study. Positive findings were evident. Qualitative information added new perspectives and provided direction for new outcomes to be included in future studies. This study helps to inform further research trials as well as clinical practice.

Clinical implications of this study

- This intensive intervention using principles of neuroplasticity and motor programming with sEMG biofeedback led not only to positive swallowing outcomes but also to unexpected benefits such as improved voice production and general attention skills. No adverse events were reported. Improvement in function was retained at 3 months post-intervention. Despite the small sample size, participants described the benefits of the treatment, and enjoyed sEMG biofeedback tasks, especially using an sEMG game mode. This suggests that intensive biofeedback not only improved swallowing but also was acceptable to these participants. This intensive protocol has merit and is worth considering further in clinical practice.

INTRODUCTION

Damage to basal ganglia and its cortical connections in people with idiopathic Parkinson's disease (IPD) are recognized to cause an impairment of motor learning at different levels from proprioception, initiation, control and coordination of motor performance (Bartels & Leenders, 2009; Ginis et al., 2017; Hayes et al., 2015). There is strong evidence that the use of augmentative cues and feedback play a key role in helping the acquisition of new skills in IPD individuals because they act as compensatory mechanisms different from the dopaminergic circuits (Ginis et al., 2017; Kearney et al., 2018, 2019).

In swallowing rehabilitation, the use of biofeedback has gained increasing interest over the last two decades (Arone et al., 2021; Dockx et al., 2016; Huckabee & Macrae, 2014; Kearney et al., 2019; Nordio et al., 2021; Petzinger et al., 2013). Huckabee and Burnip analysed the role of swallowing biofeedback during motor learning, showing its fundamental contribution to improving swallowing tasks (Huckabee & Burnip, 2018). In 2019, Benfield and colleagues completed a systematic review and meta-analysis on the use of biofeedback as adjunct for swallow rehabilitation in people with dysphagia, arising for a range of aetiologies, including people with head and neck cancer, neurological disease and psychogenic dysphagia (Benfield et al., 2019). They found positive effects on hyolaryngeal displacement. Nevertheless, no firm results were found for other functional, physiological, and clinical outcome measures.

A recent systematic review on biofeedback focusing specially for swallowing rehabilitation in people with IPD (Battel et al., 2021) indicated that biofeedback during skill based swallowing tasks had positive effects not only on the quality of life of the person with IPD and dysphagia but also on swallowing rate for liquids and solids and in reducing pharyngeal residue. Despite the methodological limitations of many of the studies included in the review, it concluded that swallowing biofeedback using visual modalities may be beneficial for coordination and skill of swallowing in IPD. One of the limitations of the studies within this systematic review concerned the lack of instrumental and validated swallowing assessments to confirm change in swallow function post-intervention (Battel et al., 2021). Carrying out instrumental assessment is fundamental to detect changes in swallow function such as swallow timing, pharyngeal residue and overall safety of swallowing in people with IPD (Curtis et al., 2020; Kalf et al., 2012; Kwon & Lee, 2019; Miller, 2017). There may be reduced pharyngeal sensation with residue in the valleculae and pyriform sinus placing the person at risk of aspiration, some recent studies report the presence not only of a food bolus but also of medication in the valleculae. The failure of medicines, prescribed to manage IPD, to move beyond the upper digestive tract can cause a cascade of negative effects such as freezing episodes and motor coordination (Buhmann et al., 2019; Warnecke et al., 2016). Besides instrumental swallowing assessments with valid outcome measures and a validated quality-of-life scale, future studies should include measures of the acceptability of the treatment from the patient perspective. A treatment may be highly effective, but if it is not acceptable to patients then it is of limited use. A recent study revealed the long-term positive maintenance effects of a self-management program, where participants with IPD were involved in identifying the personally relevant strategies to maintain speech and communication skills following LSVT LOUD treatment (Finnimore et al., 2021).

These studies provide the foundations of the present study.

The aim was to examine the effectiveness of a specific neurorehabilitation intervention involving biofeedback via surface electromyography (sEMG) in people with IPD and dysphagia using instrumental as well as clinical non-instrumental assessment and qualitative feedback in order to improve swallowing outcomes and adverse effects. We also want to investigate the feasibility of an intervention approach to inform a larger clinical trial.

MATERIALS AND METHODS

Study design

This is a quasi-experimental within-subject prospective feasibility case series. This study received ethical approval from university and hospital ethics committees (Refs 180304 and AU34567). This study took place in an acute hospital setting in Italy.

Participants

Inclusion criteria were: (1) a diagnosis of IPD, confirmed by neurologist on the International Parkinson Disease and Movement Disorder Society diagnostic criteria (Berg et al., 2015); (2) clinical stability as evaluated by a neurologist with no changes required to medication for IPD for the duration of the study; (3) oropharyngeal dysphagia confirmed by fibreoptic examination of swallowing (FEES) with scores > 2 on the Penetration Aspiration Scale (PAS) (Rosenbek et al., 1996) suggesting some difficulties in airway protection; and (4) an ability to provide written and verbal consent.

Participants were excluded if they: (1) had a history of stroke or transient ischemic attack; (2) were not on full oral intake (score > 4 on the Italian version of the Functional Oral Intake Scale (FOIS-It); Battel et al., 2018); (3) had dysphagia caused by pathologies other than IPD; (4) had cognitive impairment with a Montreal Cognitive Assessment (MOCA) score > 26 (Dalrymple-Alford et al., 2010); (4) had a deep brain stimulation implant; and (6) facial hair that would impede sEMG electrodes placement.

Participants with IPD attending the hospital were screened at the clinic for eligibility by neurologists not involved in the study. The neurology team at the research site identified potential candidates. The criteria for

selection was rating from mild to severe on 2.2 (saliva and drooling) and 2.3 (chewing and swallowing) section of the MD-UPDRS (Goetz et al., 2007).

From October 2018 to February 2019, the neurology team screened 128 participants for potential inclusion in the study.

A total of 31 people with IPD were identified as eligible participants and 12 met the inclusion criteria. All 12 were enrolled and two participants dropped out at the beginning of week 1 of treatment (Table 1).

Treatment programme

Intervention was provided by the first author (IB), who was trained in placing the surface electrodes and in recognizing the sEMG waveform during swallowing. Biofeedback with sEMG was provided using NeuroTrac® MyoPlusPro Three electrodes were used. Two active electrodes were placed on the submental muscles to detect the anterior movement of hyo-laryngeal elevation. The third reference electrode was placed on the cheek (Stepp, 2012). Neuro-Trac Software was installed on a Dell, Latitude E6420 laptop computer. Two programs on the device were selected: 'open display' and 'plane game'. The program 'open display' shows the wave line of activation. In 'plane game', the goal was to move up the plane by swallowing acts to collect as many stars as possible, thus coordinating swallowing and increasing submental muscle activity.

Intervention was delivered at the hospital site in a clinical setting. Participants were seated in front of the sEMG screen. Treatment was scheduled for 1 h a day, 5 days a week, for 4 weeks and was carried 1 h after intake of medication (Fonda et al., 1995; Sutton, 2013) and scheduled at the same time for the 4 weeks of treatment. The frequency of the treatment was based on the treatment protocol of the expiratory muscle strength training (EMST) (Troche et al, 2010).

The programme involved a progression of specific motor tasks based on motor learning and neuroplasticity principles. These included dry swallowing and yogurt swallowing, the number of repetitions increased week by week, from 18 swallowing tasks at weeks 1–27 by week 4 (see Supplementary Material 1 in the additional supporting information) shows the treatment protocol.

The type and frequency of verbal and visual feedback were strictly planned week by week (Table 2). Verbal feedback was delivered by the therapist in order to increase internal error-detection and correction skills. Verbal feedback was delayed 3–4 s after swallowing and scheduled randomly in accordance with the principles of motor learning (Maas et al., 2008) .

Outcome assessment

Quantitative assessments were used to measure swallowing outcomes and qualitative measures explored feedback focusing on acceptability of the intervention. The assessment protocol was scheduled at the same time for each participant. Assessment timing was linked with anti-Parkinsonian medications. These were scheduled to ensure they were 'on-phase'. Three clinicians—a speech and language therapist and two ear, nose and throat (ENT) consultants—acted as outcome assessors. All three were not involved in recruitment and were blinded to the intervention. Assessments were completed at four time points (1) 4 weeks before treatment (Time 0; T0), immediately before treatment (Time 1; T1), after 4 weeks of treatment (Time 2; T2) and at 3 months follow-up (Time 3; T3).

Quantitative assessments

Quantitative assessments comprised FEES with two validated scales: PAS (Rosenbek, 1996) (range from 1 normal to 8 severe) and the Yale Pharyngeal Residue Severity Rating Scale (YPRSRC) (Neubauer et al., 2015) (range from 1 none to 5 severe) (Rocca et al. 2022) (0–5). FEES assessment involved food trials. Instructions were: 'Try to eat or drink as normally as you can, without rushing'. Two 5 ml spoons of yogurt or applesauce (IDDSI Level 3) were given followed by 150 ml of water (IDDSI Level 0) and a piece of cracker (IDDSI Level 7), The size of cracker was 5 × 6.5 cm, 3.75 g based on the TOMASS test (Huckabee et al., 2018). FEES assessments were video recorded and recordings were used to evaluate the reliability of the scores among the two ENT outcome assessors.

Quality of life was investigated using the Italian version of 'Swallowing Quality of Life' (I-SWAL-QOL) (Ginocchio et al., 2016). Method of food intake was rated using the Italian version of the Functional Oral Intake Scale-FOIS-IT (range from 1 no oral intake to 7 total oral intake with no restrictions) (Battel, 2018). Drooling severity and frequency were measured using Radboud Oral Motor Inventory for Parkinson's Disease for saliva—ROMP-Saliva (Kalf, 2011), which is patient reported outcome measure to evaluate perceived problems with saliva in people with PD or parkinsonism (range from 1 normal to 45 severe).

Qualitative assessment

This consisted of two open questions posed by the researcher (IB) at the end of each treatment session: How do you feel after this treatment session? and What are your

TABLE 1 Descriptive information of participants ($N = 12$)

ID	Gender	Age (years)	Duration of disease (years)	MoCA[a]	H&Y[b]	MD-UPDRS[c]		PAS 1[d]				PAS 2[d]				PAS 3[d]				PAS 4[d]			
						TOT	*2°*	Saliva	IDDS0	IDDS3	IDDS7	Saliva	IDDS0	IDDS3	IDDS7	Saliva	IDDS0	IDDS3	IDDS7	Saliva	IDDS0	IDDS3	IDDS7
1P	M	68	4	26	2.5	61	13	4	4	3	3	4	4	4	4	4	4	3	3	4	4	3	3
2P	F	73	5	27	3	79	17	4	3	2	3	4	4	2	3	4	3	2	2	4	3	4	4
3P	F	57	4	28	2	59	12	2	3	2	4	3	3	2	5	2	3	2	3	2	3	2	3
4P	M	72	9	26	3	64	12	3	4	3	3	3	4	3	3	3	4	3	3	3	4	4	3
5P	M	74	10	26	3	67	14	3	4	2	4	3	4	2	4	3	4	2	4	4	4	2	4
6P	F	69	6	29	2	48	11	2	4	4	5	3	4	3	5	2	3	3	4	2	3	4	5
7P	M	68	11	26	3	72	20	3	3	1	3	3	2	3	3	3	3	2	3	3	3	2	3
8P[e]	M	69	6	27	1.5	48	12	2	3	2	3	–	–	–	–	–	–	–	–	–	–	–	–
9P	M	58	8	27	2	52	10	4	4	2	3	4	5	2	3	2	4	2	3	2	4	2	3
10P	F	74	7	28	2.5	63	17	3	5	3	5	3	5	3	5	3	4	3	3	4	5	3	3
11P[e]	M	75	9	27	2	65	13	2	3	2	–	–	–	–	–	–	–	–	–	–	–	–	–
12P	M	77	8	25	3	78	20	2	3	5	4	2	4	5	4	2	3	4	3	2	3	4	4
Mean		69.1	7.25	27.08	3	65.92	15.83	3	3.7	2.7	3.7	3.2	3.9	2.9	3.9	2.8	3.5	2.6	3.1	3	3.6	3	3.5
SD		6.24	2.6	1.32	0.43	10.19	5.08	0.8	0.6	1.1	0.8	0.6	0.8	0.9	0.8	0.7	0.5	0.7	0.5	0.9	0.7	0.9	0.7

Notes: [a]MoCa, Montreal Cognitive Assessment.
[b]H&Y, Hoehn and Yahr scale.
[c]MD-UPDRS, Movements-Disorders Unified Parkinson's Disease Rating Scale.
[d]Penetration and aspiration scale.
[e]Participants who withdraw from the study.

TABLE 2 sEMG swallowing tasks accordingly to neuroplasticity principles

	Description of swallowing treatment tasks
Use it or lose it	The intervention incorporated swallowing tasks as the goal was to improve swallowing
Use it and improve it	The swallowing tasks were planned in an incremental order of difficulty week by week. sEMG and verbal feedback were set to increase efficiency and accuracy of the participant's swallowing function
Experience specific	Exercises were tailored according to each participant's swallowing skills
Repetition matters	Repetition and consistent practice of swallowing exercises were incorporated into the programme
Intensity matters	The treatment was intense, 1 h a day, 5 days a week, for 4 weeks
Salience	The treatment incorporated food trials and a visual game using sEMG

Note: sEMG, surface electromyography.

thoughts, feelings and feedback about this treatment? This verbal feedback was audio recorded. At 3-month follow up assessment, acceptability of the procedure was examined further using a 4-point Likert rating scale on a specifically devised form given by a nurse not involved in the project. Participants were asked to rate their perception of study protocol. Participants were also asked if they would recommend any changes to the intervention.

Statistical analysis

The results of the assessments at the different time points were entered into Microsoft Excel Database. Quantitative data analysis was completed using the software R (Development Core Team, 2019). The Shapiro–Wilk test for normality was used to assess distribution of the variables. The Bartlett test was used to assess homoscedasticity of variances. Statistical significance of the results across the four different assessment timepoints was calculated using analysis of variance (ANOVA). In case of non-parametric distribution, a Kruskal–Wallis test was used. The level of significance was set at a p-value <0.05.

Interrater reliability was calculated in order to verify the level of homogeneity among assessors. Videos of FEES were used to evaluate the reliability of the scores among two different examiners using the intraclass correlation coefficients (ICC).

Qualitative data analysis

Audio recordings were transcribed and were inserted into NVivo software (https://www.qsrinternational.com/nvivo-qualitative-data-analysis-software/home). Transcriptions were analysed using thematic analysis (TA) systematically identifying, categorizing and offering insight into patterns of meaning (themes) (Braun, 2012). These themes were checked for agreement with the second author blinded to the first author's coding and themes. Any discrepancy was resolved through discussion.

RESULTS

Laryngeal penetration and aspiration

None of participants presented with aspiration events during the FEES examinations at any time period. PAS scores ranged from 2 to 5. No statistically significant differences were found for laryngeal penetration across four FEES assessment time points for any swallowing trial on any food or fluid consistency including saliva (Saliva $p > 0.05$, 95% confidence interval (CI) = 3–3; IDDS0 95% CI = 3.7–3.6; IDDS3 95% CI = 1.1–1.0; IDDS7 95% CI = 3.7–3.6).

Pharyngeal residue

Pharyngeal residue was observed more in the valleculae than in the pyriform sinus for all participants. Three participants (5P, 7P and 9P) had medication residue at the base of tongue and vallecula during the FEES pre-treatment examination (T0; T2) but not at later time points. YPR-SRS scores indicated more residue for saliva and cracker than water and yogurt swallowing trials for all participants. Overall, these scores were almost consistent during the two pre-treatment assessments. Only residue from saliva and crackers in the valleculae decreased significantly ($p < 0.001$, 95% CI = 2.14–3.15 and 2.4–3.5) after treatment and these improvements were retained at 3-month follow-up (Table 3). Residue from water and yogurt was small, suggesting traces of residue. No statistically significant differences for water and yogurt were found across the residue scores at all four assessment time points.

Residue from saliva in the pyriform sinus slightly diminished after treatment, although the change was small, it was maintained at the follow-up assessment. Whereas, pooling of solid food (cracker) in pyriform sinus was slightly increased at the follow-up assessment, indicating that the improvement was not maintained after treatment.

The interrater reliability analysis showed a strong level of agreement between the two examinations (ICC = 0.79).

TABLE 3 Pharyngeal residue results of the Yale Pharyngeal Residue Severity Rating Scale

			Shapiro–Wilk test	Bartlett test	Kruskal–Wallis test	ANOVA
Saliva scores	Valleculae	T0	0.171	0.9639	<0.02*	
		T1	0.171			
		T2	0.021			
		T3	0.035			
	Pyriform	T0	0.073	0.0998	0.2476	
		T1	0.073			
		T2	0.023			
		T3	0.021			
Water scores (IDDSI 0)	Valleculae	T0	0.683	0.9999		0.6116
		T1	0.683			
		T2	0.881			
		T3	0.881			
	Pyriform	T0	0.399	0.9953		0.7305
		T1	0.395			
		T2	0.335			
		T3	0.586			
Yoghurt scores (IDDSI 3)	Valleculae	T0	0.035	0.5693	0.8799	
		T1	0.021			
		T2	0.021			
		T3	0.014			
	Pyriform	T0	0.034	0.2656	0.9144	
		T1	0.032			
		T2	0.031			
		T3	0.234			
Solid food-cracker (IDDSI 7)	Valleculae	T0	0.043	0.4426	<0.01*	
		T1	0.039			
		T2	0.110			
		T3	0.029			
	Pyriform	T0	0.018	0.1515	0.1574	
		T1	0.023			
		T2	0.022			
		T3	0.015			

*Note: T,*time of assessment.

Level of oral intake

All participants were on an oral diet at the time of recruitment. At the pre-treatment assessments, five participants (4P, 6P, 7P, 9P, 12P) could eat only single consistency food (FOIS-It: 4). Four participants (2P, 3P, 5P, 10P) consumed food that required special preparation (FOIS-It: 5) and one had to avoid specific foods (FOIS-It: 6). The mean FOIS-It score at T0 was 4.8 and at T1 was 4.7, showing no important difference amongst both assessments for the group. After treatment, the FOIS-It scores increased significantly ($p < 0.05$; 95% CI = 4.70–5.50) and the improvement was retained at the 3-month follow-up assessment.

Self-rating saliva

The self-rating drooling scale (ROMP-Saliva) (Kalf, 2011) showed slight improvement after treatment but this was not statically significant ($p > 0.05$; 95% CI = 20.76–26.34) and these changes were maintained at T3 (ROMP-Saliva: 21.7 ± 5.8), indicating that perception of drooling was mild.

Quality of life

The overall score of the quality of life (I-SWAL-QOL) (Ginocchio et al, 2016) assessment did not change

significantly across all the four assessment time points ($p > 0.05$; 95% CI = 124.14–150.68). There was a small increase after treatment, but this was not retained at the follow-up assessment. However, the subsection of I-SWAL-QOL associated with the food selection showed a statistically significant change after treatment ($p < 0.05$; 95% CI = 5.76–7.73) and this was retained at the follow-up assessment.

Adverse events

No adverse events occurred during the treatment protocol and the outcome measure did not show an increase or deterioration of swallowing symptoms. Three participants (3P, 4P, 10P) reported fatigue after treatment and considered it an intense and demanding intervention.

Adherence to treatment

Two participants (8P, 11P) decided to stop the treatment during the first treatment week because they thought that their swallowing disorders were not so severe as to require an intensive intervention. The remaining participants attended the clinic for treatment following a specific timetable. Two participants asked to change the time of treatment due to transport issues. All participants who completed the treatment, also completed the follow-up assessment (T3).

Acceptability and feedback from participants on intervention

The data from the interview transcriptions were categorized into thirteen basic themes on data analysis. These basic themes were grouped into five broad 'organizing themes' (Braun, 2012): 'benefits on swallowing'; 'benefits on swallowing related function'; 'feedback on intervention'; 'unexpected feedback' and 'adverse effects' (Figure 1).

The theme 'Benefits on swallowing' included: (1) improvements in diet modifications reported by four participants (3P, 4P, 7P, 11P); (2) benefits on saliva control also in non-swallowing tasks by five participants (1P, 5P, 6P, 9P, 10P); (3) increase of the 'timing and frequency of swallowing' by two participants (5P, 6P); and (4) the reduction of 'coughing episodes' during meals (4P, 6P, 7P).

The theme 'Benefits on swallowing related associated function' included: (1) benefits on voice production after this intervention (3P, 6P); (2) increase of attention skills during eating by five participants (1P, 2P, 5P, 7P, 10P); and (3) reduction of fear during meals. Two participants (3P, 4P) said that after treatment they felt less frightened of eating.

The 'Feedback on intervention' theme combined positive feedback related to delivery of the intervention and the sEMG equipment. Two participants (1P, 3P) referred to positive effects on the use of yogurt during treatment. Five participants (4P, 5P, 7P, 9P, 10P) commented on how the intervention was delivered. Five participants complained about the intensity of the treatment schedule and difficulties encountered. Seven participants (1P, 2P, 3P, 4P, 5P, 9P, 10P) described the positive aspects and their satisfactions with the treatment procedures. Six participants who reported comments on sEMG. Of these, three participants (1P, 4P, 9P) remarked positively on the entertainment features of the software and three participants (5P, 6P, 7P) described the issues with the signal responses and the electrodes used.

The 'Unexpected feedback' theme included (1) 'positive caregiver feedback from' and (2) participants 'learning more about swallowing function'. The caregivers of two participants (6P, 9P) made positive comments that are reported by participants. Four participants (2P, 3P, 5P, 7P) mentioned that they acquired new swallowing skills.

The 'Adverse Events' theme provided important information on the drawbacks of the treatment for people and there was just one basic theme which was 'fatigue'. Three participants (3P, 4P, 6P) reported that they were tired after treatment because the treatment was too intense

On the four-point Likert scale ('Not comfortable' to 'Very Comfortable') used to rate the comfort of biofeedback procedure all participants selected the 'Very Comfortable' rating. To the open question: 'Would you like to recommend any changes?'. Four main themes emerged: 'Treatment extension'; 'Reduction in treatment sessions'; 'Telerehabilitation'; 'Inclusion of non-swallowing treatment'. Four participants indicated their desire to continue treatment after the intervention trial. Three participants recommended reducing the amount of treatment sessions in future studies. Two participants made this suggestion because it was difficult to attend therapy every day. Two participants suggested the use of technology to deliver the rehabilitation programme at home.

DISCUSSION

Preliminary results suggested that an intensive neurorehabilitation programme with sEMG biofeedback had positive effects on swallowing outcomes in a small cohort with IPD and dysphagia, leading to consistent modification of the oral intake and reducing saliva and pharyngeal vallecular residue of solids that was maintained at 3 months. In

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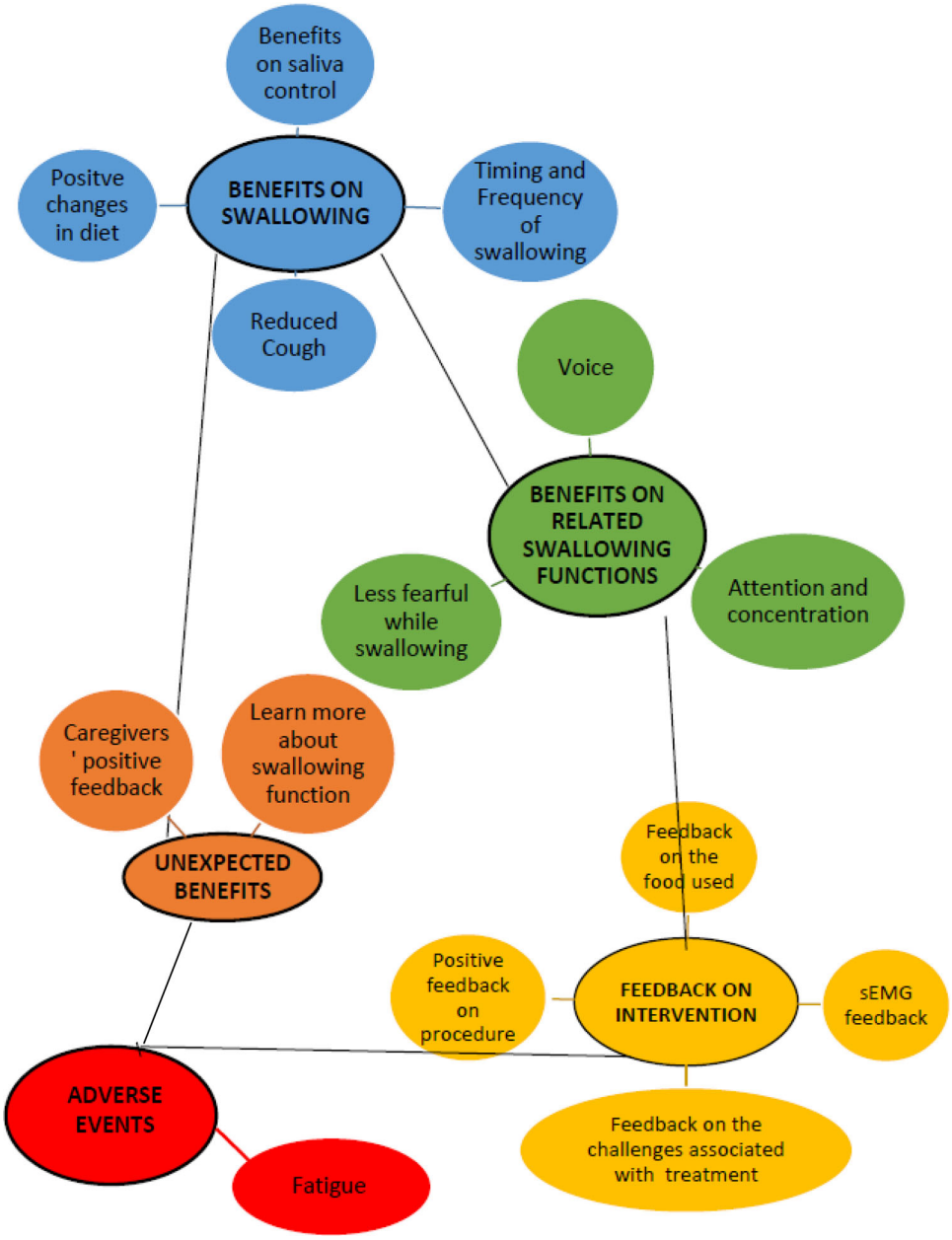

FIGURE 1 The figure shows the organizing themes and the relative basic themes [Colour figure can be viewed at wileyonlinelibrary.com]

addition, participants reported benefits in areas not related to swallowing function. The main findings are discussed as follows:

Changes to oral intake

Although all participants were on an oral diet, the majority ate one single food consistency, which was semisolid (FOIS 4). After treatment almost all participants reported that they could take food of different consistencies requiring special preparation. Furthermore, some improvements positively impacted their social life. These improvements occurred in the third to fourth weeks of treatment. One participant described that he had better swallow coordination, which meant that he could drink an espresso, something that he could not do for the previous 3 years.

Reduction of saliva

The scores of self-perceived drooling using the ROMP-Saliva scale, decreased slightly after treatment, although the findings were not statistically significant. In

contrast to the ROMP-Saliva scale scores, qualitative findings from interviews showed that five participants reported a decreased drooling with better saliva control, suggesting an important effect on anterior saliva control.

The discrepancy between the ROMP-Saliva scale results and participants' feedback could be attributed to sensitivity of the saliva rating scale. McNaney et al. have found the ROMP-Saliva did not detect statistically significant improvements, which were observed using visual analogue scales (VAS) in people with IPD. They suggested that ROMP-Saliva is not reliable or sensitive to capture the changes over the intervention period in this population (McNaney, 2019). Saliva control assessments are not widely available for IPD and a range of assessment methods may be required drooling assessments sensitive to change over time in people with IPD (Miller et al., 2019).

Improvements in anterior drooling and reduction of saliva in the pharynx were likely to be attributed to increased frequency of saliva swallowing and use of sEMG biofeedback. In the literature, several studies confirm that augmentation of saliva frequency produces a decrease in drooling (Carnaby et al., 2019; Miller et al., 2017, 2019). McNaney et al. (2019) trialled the use of a wrist-worn digital cueing device, which produces vibratory feedback in order to remind IPD participants to swallow saliva often (McNaney et al., 2019). They found positive results in the perceived severity and in the frequency of drooling. Based on these results, it is suggested that the increased number of swallows prompted by sEMG biofeedback in this feasibility study may have played a key role in the improvement of saliva management in cohort.

In addition, it is important to emphasize that this study was the first study, to our knowledge, which documented positive effects of biofeedback swallowing treatment in reducing posterior drooling using instrumental assessment (FEES). Although the YPR-SRS was not specifically validated to assess secretions (Neubauer et al., 2015), it showed a statistically significant reduction of pooling of saliva in the vallecula after treatment and this positive finding was maintained also at 3 months follow-up assessment.

Pharyngeal residue

A positive reduction in pharyngeal residue after intervention was documented for all the food trials on FEES assessment. The solid food residue was higher than water and yogurt residue in the study sample at the four assessment points (T0, T1, T2, T3), indicating an increased difficulty swallowing this food consistency. Findings showed a statistically significant decrease of pooling of solid in both valleculae and pyriform sinus after intervention, suggesting an effect of the intervention approach in oral–pharyngeal clearance of solid food ingestion.

Solid food ingestion difficulties included also swallowing of medication, which is critical to the management of IPD symptoms. In the present study, FEES assessments at T0 and T1 before intervention noticed traces of medication in the valleculae in three participants. This is not unusual. A recent study found pharyngeal residue with medication occurred in up to 28% of people with IPD, altering drug therapy effects (Miller et al., 2019). Of note, post-treatment FEES assessments in this study showed no medication residue for any participants, suggesting a possible direct effect of sEMG swallowing treatment in medication swallowing. Although this improvement may not be retained for all participants at 3 months, as in this study, it remains an important finding as it suggests a potential contribution of this intervention in the medication swallowing and pharyngeal clearance. In addition, the reduction of pharyngeal residue after treatment potentially has an effect on limiting aspiration and penetration of residues after swallowing. Although in this study participants did not demonstrate penetration or aspiration episodes during instrumental assessment, there is strong evidence that residue post-swallowing contributes to airways invasions and swallowing safety (Curtis et al., 2020a, 2020b; Gaeckle et al., 2019).

Retention of intervention effects

The reduction of saliva and pharyngeal residue on solids as well as the positive dietary changes were retained at 3 months after treatment confirming that the swallowing skills learnt were consolidated and automatized into daily life in this time period.

Several studies in physical rehabilitation showed that retention of motor improvements is significantly compromised in people with IPD (Abbruzzese et al., 2016; Heremans, 2016). The intensity of the current intervention may be an important contributing factor for the maintenance effects in people with IPD in this feasibility study and requires further investigation. A recent study by Arone et al. using an intensive rehabilitation programme with just six people with IPD and dysphagia found that intervention effects were maintained at 3 and 6 months post-intervention (Arone et al., 2021). They also used biofeedback with greater retention in the biofeedback group. This is an important finding as it suggests that while the intervention programme is intensive for both clinician and person with IPD, its effects may be long lasting. For future studies, the length of time for follow up also needs to be expended and outcome measured also at 6, 12, 18 and 24 months.

Unpredicted benefits

This feasibility study revealed unpredicted benefits of this intensive neurorehabilitation intervention. Participants reported several positive effects also on non-related swallowing function indicating a transference effect of the intervention into other areas. Half of participants reported an increase in attention and concentration during swallowing. Other authors have found that IPD participants with mild cognitive and attention impairments presented worsening of swallowing safety during dual task conditions (Brodsky et al., 2012; Troche et al., 2014). They hypothesized that a modified digit span task and swallowing tasks share the same neurological structures. This could partially explain benefits reported by the participants. Nevertheless, future studies should investigate this aspect in order to analyse the potential involvement of swallowing biofeedback treatment in enhancing overall swallowing attention.

Adverse effects

We did not find any adverse effects such as increased cough or choking episodes defined as an obstruction of the airway. Nevertheless, three participants reported that they were tired and fatigued because the treatment was intensive and demanding. Fatigue is a common and disabling nonmotor symptom in IPD, which can manifest even during premotor stages of disease and limits participation in social activities, leading to impact on quality of life (Kluger, 2017; Obeso, 2017). In this study, the fatigue did not affect the completion of the intervention. However, this aspect should be monitored in future study design, as it could impact adherence to treatment.

Limitations

Despite the fact that this is predominantly a feasibility study, the small sample size was a barrier to assess fully the efficacy and effectiveness of the treatment. This sample size lends to the possibility of a Type 1 or Type 2 error so the statistical significance must be interpreted with a degree of caution. In addition, the recruitment phase showed that more than half of eligible candidates were not enrolled in the study. This could be caused by the restricted inclusion criteria. Among the criteria, the presence of cognitive impairment was one of the most common for exclusion of the study, which was needed in order to be able to follow this intervention but should be reviewed in the future study. In addition, some assessments were not appropriate to detect some changes such as the changes in the frequency and severity of drooling, which should be documented by objective scales. Also, the level of the FOIS revealed to be too generic to describe the changes of food intake. Another limitation concerned the follow-up assessment at 3 months post-treatment which did not detect the long-term effects. Future studies should include long-term retention of skills after treatment.

CONCLUSIONS

This intervention using principles of neuroplasticity and motor programming with sEMG biofeedback led not only to positive swallowing outcomes but also to unexpected benefits. Despite the small sample size, participants described benefits of the treatment, and enjoyed the sEMG biofeedback tasks, reporting benefits on diet changes and saliva control as well as unexpected positive effects on attention skills and voice production. This suggests that an important contributor of this tool in increasing compliance and acceptability of this treatment.

We suggest this study protocol based on neuroplasticity principles is appropriate and should benefit swallowing function in IPD with some minor amendments. This study provides the basis for implementation of a larger randomized trial.

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CONFLICT OF INTEREST

The authors have no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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