Swallowing Therapy in People with Parkinson's Disease using Principles of Motor Learning and Ultrasound Biofeedback

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STATEMENT OF COMPLIANCE FOR NON-DRUG OR DEVICE CLINICAL TRIALS

This document is a protocol for a clinical research study. The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (as updated) and the Handbook for Good Clinical Research Practice (GCP). The Therapeutic Goods Act has adopted ICH Guideline for Good Clinical Practice.

Contents

TITLE	Effect of Swallowing Therapy on Efficiency of Eating and Drinking in People with Parkinson's Disease using Principles of Motor Learning and Ultrasound Biofeedback
CLINICAL PHASE	I/II
STUDY TYPE:	Behavioural intervention
PRIMARY HYPOTHESES	Participants will show an improvement in swallowing outcomes with the use of rehabilitation combining principles of motor learning and ultrasound biofeedback. No improvement in control outcomes will be observed.
DESIGN	Part 1 - Single Case Experimental Design to determine feasibility of treatment paradigm in a single participant with PD followed by Part 2 - a multiple baseline within participants Single Case Experimental design to determine treatment efficacy.
BLINDING/MASKING	This is a pilot, behavioural intervention trial. Therefore, treating clinicians and participants cannot be blinded to intervention.

	Clinicians assessing outcome measures will be blinded to the sequence in which the probe data is collected and the stage of the study the participant is in.

OUTCOMES	The primary outcome measures include:
	• Timed Water Swallow Test (TWST) (Hughes & Wiles, 1996; Sarve et al., 2021)
	• Test of Masticating and Swallowing Solids (TOMASS) (Athukorala et al., 2014; Huckabee et al., 2018)
	Secondary outcome measures:
	• Texture of food as per the International Dysphagia Diet Standardisation Initiative Level (IDDSI) (Cichero et al., 2017)
	• Consistency of liquid as per the the International Dysphagia Diet Standardisation Initiative Level (IDDSI) (Cichero et al., 2017)
	• Observational measures rated with an ultrasound probe under the chin.
	  ○ Changes in components 2, 3, 4 and 5 listed on the Modified Barium Swallow Impairment Profile (MBSImP) (Martin-Harris et al., 2008) which is a rating scale that rates key physiological aspects of swallowing in the different phases. Components 2, 3, 4, and 5 are specifically related to the oral phase of swallowing.
	  ○ Average time taken to swallow a single sip of liquid (ml/s)
	  ○ Time taken to swallow (a) ½ biscuit (b) a dessert spoon of diced fruit and (c) a dessert spoon of puree
	  ○ Number of times the participant needs to swallow to clear a single, controlled sip of liquid (number of swallows/ml)
	  ○ Number of times the participant needs to swallow to clear (a) ½ biscuit (b) a dessert spoon of diced fruit and (c) a dessert spoon of puree from their mouth
	• Patient reported measures:
	  ○ Time taken to complete meals
	  ○ Swallowing Quality of Life Questionnaire (SWAL-QoL) (McHorney et al., 2002)
	  ○ Theoretical Framework of Acceptability based questionnaire (Sekhon, Cartwright & Francis, 2022)
	
	Control measures
	• Maximum Phonation Time (Speyer et al., 2010)
	• Speech Rate (Syllables per minute during a 30 second monologue)
	• Average decibels in 30 second monologue
	• Intelligibility Rating of monologue using the Frenchay-2 Rating scale (perceptual) (Enderby & Palmer, 2008)

STUDY DURATION	Estimated study duration from initial enrolment until completion of data analyses is 24 months.
INTERVENTION/S	Behavioural dysphagia rehabilitation with ultrasound biofeedback

NUMBER OF PARTICIPANTS	n=6 based on requirement of at least 3 participants to carry out a single case experimental design as part of a pilot study and to account for attrition.
POPULATION	Sample Size: n=6 Gender: Male and Female Age: Adults > 50 years old Demographic group: Those diagnosed with Idiopathic Parkinson's Disease General Health Status: To be eligible for this study, participants will have to be living in the community Geographic Location: Assessment and treatment will be conducted at The University of Sydney or at participants' place of residence within Sydney metropolitan area
SELECTION AND ENROLMENT	*Inclusion Criteria: Participants with:* 1. Confirmed diagnosis of Idiopathic Parkinson's Disease by a neurologist 2. Self-reported change in swallow function in the last 12 months 3. Ability to assent to participation in study (either verbal or written) 4. Presence of oral phase dysphagia as assessed by a speech pathologist. *5.* Medically stable and living in the community. *Exclusion Criteria: Participants who are/have:* 1. Other concomitant neurological disorders 2. A history of head and neck cancer 3. Unmanaged hearing or vision difficulties (self-report) 4. Nil by Mouth status. 5. Unable to communicate in English 6. Hospitalised with a respiratory tract infection in the last 12 weeks.

3. RATIONALE / BACKGROUND

Up to 82% of people with Parkinson's Disease (PD) experience dysphagia (swallowing difficulties) (Kalf et al., 2012). The presence of dysphagia in people with Parkinson's Disease (PwPD) is associated with poorer quality of life (Leow, Huckabee, Anderson & Beckert, 2010), increased burden of care (Perry, Borders, Dakin, & Troche, 2022), and increased risk of malnutrition, dehydration, and chest infections (Carrión et al., 2019).

One of the key features of Parkinson's Disease is bradykinesia where movements are slower and smaller than desired, impacting multiple body functions like speaking, walking, eating and drinking (Beradelli, Rothwell, Thompson & Hallett, 2001). With eating and drinking, the slower and more inefficient movements make it difficult for PwPD to safely and efficiently move food, liquid and saliva in their mouth (oral phase) and throat (pharyngeal phase) (Suttrup & Warnecke, 2016). While there are effective swallowing rehabilitation

options for the pharyngeal phase of swallowing, there is limited research evidence on rehabilitating the oral phase in PwPD (Gandhi, & Steele, 2022).

In other body functions such as speech and walking, drawing attention to the overall movement and providing external or augmented feedback during rehabilitation was effective in combatting bradykinesia and improving speech intelligibility and gait respectively (Schulz et al., 2021; Muthukrishnan, Abbas, Shill & Krishnamurthi, 2019). Therefore, incorporating external or augmented feedback which allows PwPD to be aware of the movement of their tongue while swallowing will be helpful in rehabilitating the oral phase in PwPD.

Ultrasound is a low-cost, portable and non-invasive tool that allows a person to see the way their tongue is moving in real time while eating or drinking (Potente et al., 2023). Ultrasound has been used in other patient groups as a visual biofeedback tool to rehabilitate the oral phase of swallowing (Hsiao, Wu & Wang, 2021). For example, amongst tongue cancer survivors the use of ultrasound tongue visual biofeedback during the oral phase of swallowing resulted in increased efficiency in swallowing food and liquids (Blyth, McCabe, Madill, & Ballard, 2017). In this approach, an ultrasound probe was placed under the chin and a real time video image of the tongue within the mouth was seen by the speech pathologist and patient while the patient was eating or drinking (Blyth, McCabe, Madill, & Ballard, 2017).

Given the usefulness of external feedback in rehabilitation for PwPD, integrating the use of ultrasound biofeedback technique as per Blyth and colleagues is likely to enhance swallowing rehabilitation of the oral phase in PwPD. Ultrasound visual biofeedback will be provided in a structured swallow rehabilitation program. The rehabilitation program will incorporate principles of motor learning such as systematically practising swallowing food and liquid multiple times instead of practising isolated tongue movements as use of these improves the overall effectiveness of swallow therapy (e.g., Zimmerman, Carnaby, Lazarus, & Malandraki, 2020).

4. AIMS & HYPOTHESES

4.1 Aims:

1) To develop and determine the feasibility of a training program which targets movement of food / liquid in the mouth with the use of ultrasound visual feedback and principles of motor learning to rehabilitate oral phase swallowing disorders amongst PwPD.

2) To determine the effectiveness of the developed training program on improving the efficiency of swallowing and QOL in PwPD.

4.2 Hypotheses:

People with Parkinson's Disease with dysphagia who participate in a four-week intervention using ultrasound visual feedback and principles of motor learning will show improvements in their swallowing efficiency (i.e., reduction in time taken to swallow liquid and food)

5. PARTICIPATING SITES

The SPEECH Clinic
The University of Sydney,
Susan Wakil Health Building
D18 Western Avenue
Camperdown, NSW 2006

6. STUDY DESIGN

6.1 Type of Study

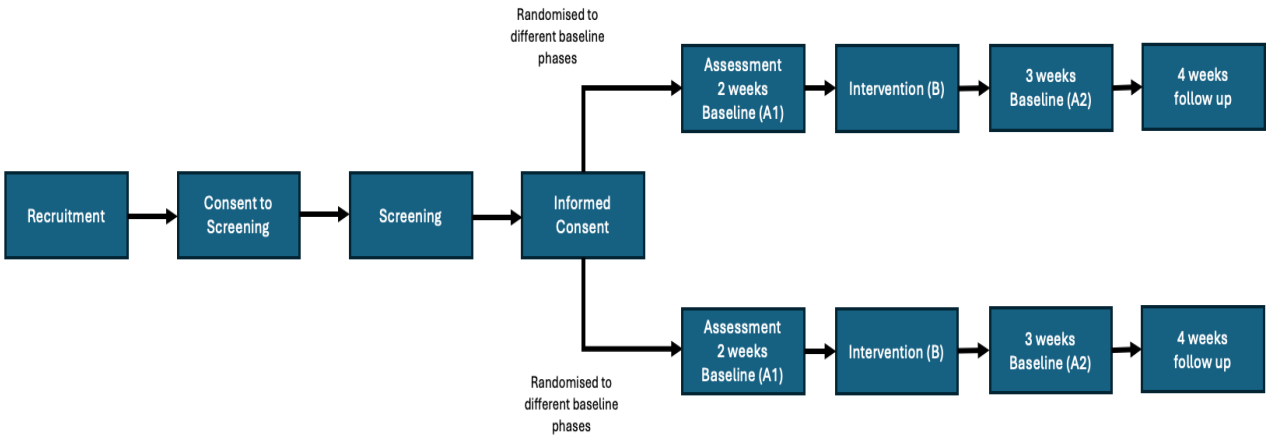
This is a Single Case Experimental Design with multiple baselines within participant study

6.2 Schedule of Events/ Treatment Phases

Table 1 study timeline (subject to approval timeframe)

Events and Time		
September - October 2024	November 2024- September 2026	October 2026
Ethics, Clinical trial registration	Rolling recruitment, assessment and therapy	Close Trial

Schedule for individual participants from recruitment to follow-up:



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Tasks and Data Collected during Assessment and Probes:

TIMING	Screener	Assessment	Phase: A1 Baseline Pre-treatment Baseline Probes	Phase: B Treatment Probes	Phase: A2 Baseline post-treatment		Phase C: Four week follow up
					Post-treatment Assessment	Maintenance Probes	
TASKS		*1-2 visits*	*three times weekly across baseline period*	*1st and 3rd therapy session each week,*	*same day as the 1st maintenance probe*	*three times weekly across the baseline period*	*once, 4 weeks after the last therapy session*
Screening (Questionnaire of demographic Information and inclusion/exclusion criteria)	X						
Timed Water Swallow Test (Hughes & Wiles, 1996; Sarve et al., 2021) (Video Recording)		X	X	X	X	X	X
Test of Mastication and Swallowing Solids (Athukorala et al., 2014; Huckabee et al., 2018) (Video Recording)		X	X	X	X	X	X
Information regarding time taken to complete meal and IDDSI Level (Cichero et al., 2017) (Images of food, Questionnaire)		X	X	X	X	X	X
Clinical Swallow Evaluation with Ultrasound using the MBSImp Rating Scale (Martin-Harris et al., 2008) for oral phase components (Video recording)		X	X	X	X	X	X

Swallowing Quality of Life Questionnaire (SWAL-QoL) (Questionnaire) (McHorney et al., 2002)		X			X		X
Theoretical Framework of Acceptability Questionnaire (Sekhon, Cartwright & Francis, 2022) (Questionnaire)					X		
Maximum Phonation Time (MPT) (Speyer et al., 2010) (Audio Recording)		X	X	X	X	X	X
Swallowing Disturbance Questionnaire (SDQ-PD) (Manor et al., 2007) (Questionnaire)	X				X		X
30 second monologue (Audio Recording)		X	X	X	X	X	X
North Wind and the Sun passage (Amundsen & Hansen, 2014) (Audio Recording)		X			X		X
Picture description (Audio Recording)		X			X		X
Rate at which participants can accurately repeat a series of rapid, alternating sounds as per published normative data (Kent, Kim & Chen, 2022) (Video Recording)		X	X	X	X	X	X

PROCEDURES

Recruitment

Participants will be recruited from The University of Sydney speech pathology clinic (The SPEECH Clinic), speech-language pathology services in Sydney and the public. The study will be advertised on the researchers' social media accounts (Instagram, Facebook, LinkedIn and Twitter/X) the University of Sydney SPEECH Clinic Facebook page, Speech Pathology Australia e-newsletter and website, and the University of Sydney research participation page. The study advertisement will also be sent to Parkinson's Disease support groups, Parkinson's Disease advocacy groups (e.g., Parkinson's Australia, Parkinson's NSW), Parkinson's Disease clinics, Parkinson's Disease research teams as well as neurologists and speech pathologists working with PwPD in New South Wales. Contact details of the support groups, advocacy groups, clinics, research teams and clinicians are publicly available.

The study advertisements will direct potential participants who are interested to contact the PhD student (Ms Dharshini M) for further information or express their interest through a survey on the REDCap secure platform. When participants contact the PhD student, they will be informed about the purpose of the study and provided with the Participant Information Sheet. An opportunity to ask questions will be provided.

Expression of Interest in the Study

Those interested in the study will be asked to contact the PhD student or follow links from social media or study advertisements to express their interest on a REDCap form. Potential participants will be provided with the Participant Information Sheet and participant consent form for the screener.

Screener:

As part of the screening process, participants will answer questions pertaining to the inclusion and exclusion criteria to determine their eligibility for the study. This process should take ~30 minutes and will be completed over the phone. If potentially eligible for the study, potential participants will be invited to enrol in the study and undergo the next steps in the informed consent process.

Informed Consent to Participate:

As part of the informed consent process, the PhD student will go through the information on the Participant Information Sheet and the Participant Consent Form with the participant. Participants will be encouraged to ask questions about the research and the risks and benefits of participation. Potential participants will be informed that their participation is completely voluntary. They are free to decline to attend the study, and free to withdraw from the study at any time. This will have no implications on their relationship with the research team or the University of Sydney. Consent will be recorded in (1) a RedCAP version of the participant consent form or (2) a written consent form which will then be scanned and added to RedCAP.

Allocation to Baseline Phase:

Once enrolled in the study, participants will be randomly allocated to varying baseline duration through a computer-generated block randomisation.

Assessment

Following screening and consent, participants will be assessed by a qualified speech pathologist (one of the investigators) using standard speech pathology tools. As shown on page 8, the assessment will include the (a) Timed Water Swallow Test (TWST) (Hughes & Wiles, 1996; Sarve et al., 2021), (b) Test of Masticating and Swallowing Solids (TOMASS)((Athukorala et al., 2014; Huckabee et al., 2018), (c) a clinical swallow trial with the ultrasound to determine severity of oral phase deficits based on a checklist based on components 2, 3, 4 and 5 of the Modified Barium Swallow Impairment Profile (MBSImP) (Martin-Harris et al., 2008) (d) questions about the type of modification they need for the meal based on the The International Dysphagia Diet Standardisation Initiative Level (IDDSI) (Cichero et al., 2017), (e) the time taken to complete meals, and the (f) Swallowing Quality of Life Questionnaire (SWAL-QoL) (McHorney et al., 2002).

Control measures including the (a) Maximum Phonation Time, (b) Speech Rate (Syllables per minute during a 30 second monologue), (c) Average decibel in 30 second monologue and (d) Percent Intelligibility Rating based on Frenchay-2 Rating scale (perceptual) (Enderby & Palmer, 2008) will be recorded.

The assessment will be audio and video recorded. If participants experience fatigue, the assessments will be conducted over 2 sessions.

Treatment

Treatment will be provided by a trained speech pathologist with more than 5 years of experience following the training schedule at a mutually convenient time. Treatment will consist of swallowing liquids or solids with ultrasound biofeedback on the tongue movement pattern during swallowing. Each visit will take approximately 45-60 minutes and involve up to 50 swallows (either fluid, food, or saliva swallows). Treatment sessions will be recorded for fidelity checking. No home practice is required.

Probes

As shown on page 8, Probes for Phase A1 and A2: The TWST and TOMASS and a measurement of maximum phonation time and a 30 second monologue will be obtained 6 times for those allocated in the 2-week baseline periods and 9 times for those allocated in the 3-week baseline period.

Probes for Phase B: Treatment probes will be taken twice weekly (on the day of the first and last therapy session each week) for 4 weeks. Treatment probes will be identical to the baseline probes and will be collected immediately before therapy commences on that day.

The probes will take approximately 30-40 minutes and breaks will be provided if a participant experiences fatigue.

After the end of Phase B, a repeat assessment will be completed (identical to the one conducted at the start of the treatment program) by a qualified speech pathologist. Participants will also be asked to complete a Theoretical Framework of Acceptability Questionnaire to understand their acceptance and the feasibility of the intervention.

As this is a pilot, the frequency and duration of the treatment sessions, the duration and frequency of breaks provided, the type of foods and fluids used, the amount and type of feedback provided and the number of times the participant is asked to swallow and sets of swallows may be altered based on participants' fatigue level and response to the therapy protocol.

6.3 Population/ Calculation of sample size

Sample size calculation: This is a phase 1 study to acquire data for a sample size calculation. Considering no protocol exists for ultrasound visual feedback in dysphagia rehabilitation in people with Parkinson's, the researchers will first aim to assess the feasibility of use with a single participant. Subsequently, n=6 will be recruited to allow for attrition expected in behavioural rehabilitation. This follows a similar sample size to other pilot studies (Blyth, McCabe, Madill, & Ballard, 2017).

6.4 Participant Enrolment and Randomisation

6.4.1 Recruitment

Participants will be recruited as detailed in the procedure in page 9.

6.4.2 Inclusion and Exclusion Criteria

Inclusion Criteria: Participants with:

1. Confirmed diagnosis of Idiopathic Parkinson's Disease by a neurologist
2. Self-reported change in swallow function since diagnosis of Parkinson's Disease
3. Ability to assent to participation in study (either verbal or written)
4. Presence of oral phase dysphagia as assessed by a speech pathologist.
5. Medically stable and living in the community.

Exclusion Criteria: Participants who are/have:

1. Other concomitant neurological disorders
2. A history of head and neck cancer
3. Unmanaged hearing or vision difficulties
4. Nil by Mouth status.
5. Unable to communicate in English
6. Hospitalised with a respiratory tract infection in the last 12 weeks.

6.4.3 Randomisation and Blinding Processes

As it is a behavioural study, participants and the therapist will not be blinded to the intervention. However, the assessors will be blinded to the sequence in which the probe data is collected (i.e., the assessor will review the task recordings to obtain the probe data and will not know which week a specific recording was obtained). This will be achieved by getting an independent person to re-order the recordings of sessions so that they are not chronological, and the assessors will evaluate the outcome measures without knowing if they are from the baseline or intervention phase. Participants will be randomised into different lengths and onset of baseline phase prior to assessment.

6.5 Primary and Secondary Outcome Measures

The primary outcome measures include:

- Timed Water Swallow Test (TWST) (Hughes & Wiles, 1996; Sarve et al., 2021)

- Test of Masticating and Swallowing Solids (TOMASS) (Athukorala et al., 2014; Huckabee et al., 2018)

Secondary outcome measures:

- Texture of food as per the International Dysphagia Diet Standardisation Initiative Level (IDDSI) (Cichero et al., 2017)
- Consistency of liquid as per the the International Dysphagia Diet Standardisation Initiative Level (IDDSI) (Cichero et al., 2017)
- Observational measures rated with an ultrasound probe under the chin.
    - Changes in components 2, 3, 4 and 5 listed on the Modified Barium Swallow Impairment Profile (MBSImP) (Martin-Harris et al., 2008) which is a rating scale that rates key physiological aspects of swallowing in the different phases. Components 2, 3, 4, and 5 are specifically related to the oral phase of swallowing.
    - Average time taken to swallow a single sip of liquid (ml/s)
    - Time taken to swallow (a) ½ biscuit (b) a dessert spoon of diced fruit and (c) a dessert spoon of puree
    - Number of times the participant needs to swallow to clear a single, controlled sip of liquid (number of swallows/ml)
    - Number of times the participant needs to swallow to clear (a) ½ biscuit (b) a dessert spoon of diced fruit and (c) a dessert spoon of puree from their mouth
- Patient reported measures:
    - Time taken to complete meals
    - Swallowing Quality of Life Questionnaire (SWAL-QoL) (McHorney et al., 2002)
    - Theoretical Framework of Acceptability based questionnaire (Sekhon, Cartwright & Francis, 2022)
    - Swallowing Disturbance Questionnaire - PD (SDQ-PD)

Control measures

- Maximum Phonation Time (Speyer et al., 2010)
- Speech Rate (Syllables per minute during a 30 second monologue)
- Average decibels in 30 second monologue
- Intelligibility Rating of monologue using the Frenchay-2 Rating scale (perceptual) (Enderby & Palmer, 2008)

6.7 Participant Withdrawal

Participants will be advised that they are free to withdraw from the study at any time including before, during or after the treatment has ceased. They may notify any of the research team members of their withdrawal. They may withdraw without any consequences or negative impact on their relationship with the University, the University SPEECH Clinic, the researchers, or the profession (Speech Pathology). The participant's individual data will stop being collected at the point of their withdrawal and their withdrawal will be recorded in the data management system (RedCap) within one business day of their withdrawal.

6.7.1 Reasons for withdrawal

If the participants withdraw from the study prior to the conclusion, they will be asked for their reasons for withdrawal and if they consent to us retaining data that has already been

collected. If the participants consent to their data being retained, the data will be analysed using Intention to Treat Analysis.

The researchers may also withdraw participants from the study if they are non-compliant with the treatment protocol (e.g., cannot commit to the sessions) or are no longer eligible for the study due to changes in medical status (e.g., onset of stroke). If this occurs then the USYD HREC will be advised.

6.7.2 Handling of withdrawals and losses to follow-up
Intention to Treat (ITT) will be used to statistically analyse the results if there is loss to follow up or with participant consent, following withdrawal.

6.7.3 Replacements
Replacements will be sought for participants who withdraw from the study to ensure a minimum data set of n=3

6.8 Expected Duration of Study
The study duration is 24 months. We anticipate recruitment of participants to commence October 2024, pending ethics approval and necessary administrative approvals.

6.9 Ethics Approval
Ethics approval will be sought from The University of Sydney Human Research Ethics Committee (HREC).

6.10 Modifications to the Protocol
Any amendments will be submitted to each HREC for review prior to implementation as per HREC guidelines. Once approved by The University of Sydney, they will be notified to ANZCTR.

6.11 Protocol Violations

6.11.1 Treatment Fidelity
To ensure treatment fidelity, all participants will be treated as per the protocol. A speech pathologist with at least 5 years of experience in managing swallowing difficulties will provide the intervention. Treatment fidelity will be reviewed by an independent speech pathologist for a random 20% selection of intervention sessions during the study using a checklist to ensure adherence to the intended protocol.

6.11.2 Data Monitoring
All adverse events will be recorded and reported using the university systems including RiskWare, MyResearch Ethics and the FMH Clinical Governance procedures. USYD clinical trial support office procedures will be followed.

6.12 Participation Reimbursement
All research participants will receive a free speech pathology assessment and access speech pathology intervention as part of their participation with a discharge report following the block of therapy.

6.13 Continuation of therapy

The trial will continue provided that no adverse/serious events occur until either of the following has been met: (i) enough participants have been recruited, or (ii) the study period has ended.

6.14 Statistical analyses

As per standard procedure for single case within participant studies, experimental and control measures will first be graphed and visually inspected for change. If the visual inspection indicates change over time, statistical analysis will be completed. As multiple, repeated measures will be taken for each participant, the data will first be analysed for correlations. If the correlation coefficient was not significant, the assumption of independence in measurements will be made, and effect sizes within participant will be calculated using d2 as this measure is appropriate for single case data (Beeson & Robey, 2006).

In the presence of serial dependency between data points, the data will be analysed using percent of nonoverlapping data (PND) (Scruggs, Mastropieri & Casto, 1987). PND is a commonly used calculation to measure change in measures taken across research phases. The highest data point in the baseline (A1) phase is compared across all research phases. The number of data points either above or below that value is calculated as a percentage of the total number of data points. The higher the number of nonoverlapping data points, the stronger the effect.

7. ETHICAL CONSIDERATIONS (SEE DATA, SECTION 10 FOR PRIVACY AND CONFIDENTIALITY)

7.1 Conformance with the principles of the "Declaration of Helsinki", Good Clinical Practice (GCP) and within the laws and regulations of the country in which the research is conducted

The University of Sydney HREC is the primary ethics committee for this clinical trial.
The ethical committee will provide ethical oversight and will ensure the current clinical trial is evaluating the research in respect to the NHMRC National Statement. Complying with the National Statement ensures we are complying with the Declaration of Helsinki. All CIs have undertaken Good Clinical Practice (GCP) Training. The clinical trial will also comply with the National Health and Medical Research Council (NHMRC) regulations.

7.2 Potential Risks and Proposed Benefits

7.2.1 Potential Risks

It is unlikely that participants will experience any harm when receiving therapy. Ultrasound as a biofeedback in a skill-based training targeting orolingual control has also been safely used in the head and neck cancer and other populations.

This is a relatively low-risk project and does not pose significant foreseeable risks to the participants. It may involve mild distress sometimes as tasks may be difficult for the participant. However, speech pathology care in this study is not different from usual practice.

The participants may experience fatigue and frustration during assessments or treatment. The speech pathologist will note signs of fatigue or frustration and give the person a short break if these occur.

As this is a trial study with adults who have a neurodegenerative disease, there is a risk of no improvement or decline in swallow function at the end of the study due to the progression of the disease. The participants are informed of this at recruitment. Breaches of privacy or confidentiality may pose a risk. This is covered in Section 10 Data Management.

7.2.2 Proposed Benefits
The participants will receive therapy and attending therapy may have a therapeutic effect. They will receive a free summary report of their swallowing therapy and recommendations

7.2.3 Responsibility for liability of injury
The university will be the sponsor of the study and will retain the liabilities associated with the conduct of the study.

7.3 Recruitment

7.3.1 Recruitment Method
The recruitment method was detailed in Section 6, Page 9.

7.3.2 Dual or unequal relationships, potential for coercion or inducement
The participants will not be approached directly by any of the research team members to protect them against potential coercion. Participants will also be informed that if they decline to participate or withdraw from the study, this will not affect their relationship with the research team or the University of Sydney.

7.4 Informed Consent
Participants will be informed about the study and given the Patient Information Statement (PIS) and Participant Consent Form (PCF). The PIS details what the study is about, the researchers involved, the role of the participant, benefits and risks of their involvement and details regarding participant withdrawal.

The participants will be told their participation is voluntary. They are free to decline to attend the study and withdraw from it at any time. The participant can choose whether they want to sign the consent form. If the participant declines to participate in the study, they are assured that this will not impact their relationship with the research team members, The University of Sydney and its staff.

The participant will be provided with the name and contact details of the chief investigator if they require further information. They will also be provided with the contact details of the University of Sydney Ethics committee if they have any concerns or complaints about the study.

7.5 Clinical governance
The clinical governance for the project is provided by the Faculty of Medicine and Health Clinical Governance committee. The protocol will be added to the existing SPEECH Clinic Model of Care.

8. SAFETY CONSIDERATIONS

8.1 Adverse event definition, risk assessment and mitigations

An adverse incident is a harmful, unpleasant, or undesirable response, reaction, or outcome experienced by a research participant or researcher. In the context of this study, Serious Adverse Events include choking or chest infection resulting in hospitalisation or death.

The risk of serious adverse events is no greater than if the participant does not take part in this study. Participants in this study will be medically stable and eating and drinking in the community. Additionally, there is an exclusion criteria excluding participants who have a recent serious upper respiratory tract infection, and the therapy protocol will be carried out by a qualified and experienced speech pathologist with current CPR certification.

The researcher will contact the participants one day prior to each treatment session to ask about their health and discuss postponing the session and referral to their GP if they are unwell. The researcher will also ask the participant about their health again at the beginning of each session to confirm that they are fit to continue. If there are any concerns, they will discuss postponing the session and referral to their GP or other health practitioner with the participant.

Other potential anticipated adverse events include fatigue from the intensity of the therapy protocol and feeling full or nauseous from having to eating or drink as part of the therapy. These risks will be mitigated through:

- scheduling sessions at least 2 hours after a meal and taking their medication as normal
- reminding participants to continue with their current medication regime and that it should not be impacted by this study participation
- informing participants beforehand that they will need to eat and drink during the therapy sessions.
- and regular breaks in the session

8.2 Assessment and Documentation of Adverse Events

Participants will be advised that they should report any adverse events including fatigue, pain, nausea, vomiting, fever, cough, cold, throat irritation.

In the event of a medical emergency (i.e., a serious adverse event related or unrelated to the study), an ambulance will be called, security staff at SWHB will be notified and SWHB safety procedures followed.

In either case, the adverse event or serious adverse event will be reported in Riskware (and technology relevant to the site), to the HREC and ANZCTR

8.3 Adverse event reporting including any special requirements for serious or significant adverse events

All adverse events will be immediately reported to the Chief Investigator and recorded. The University of Sydney procedures for reporting serious adverse incidents will be followed. Standard procedures for completing and submitting HREC adverse event templates and contacting the HREC office directly will be completed within 72 hours. For serious adverse events, this timeline will be within 24 hours.

9. CONSUMER REFERENCE GROUP

Participants within the study will serve as a consumer reference group within the pilot by providing feedback on the intervention based on the theoretical framework of acceptability (TFA). Their involvement as a consumer reference group is included in the participant information statement.

10. DATA MANAGEMENT

10.1 Data collection and storage

Research data, including ultrasound recordings, video recordings of the assessment and treatment sessions, and outcome measures or session data will be collected and stored electronically. Identification codes will replace names in all files. Names, addresses, phone and email details and dates of birth will be stored on a separate password protected file only available to the chief investigator and the PhD student.

Participant information, intervention conditions and outcome measures will be collected and stored on REDCap during the project. Video and audio recordings from the assessment, probes, and treatment sessions will be encrypted and stored on the University's enterprise edition of OneDrive immediately by the PhD student during the project and deleted from the recording device immediately. All other research and study materials (e.g., ethics approval, study advertisements, information sheet) will also be stored on the University's enterprise edition of OneDrive during the project.

On OneDrive, there will be a README.pdf file in each folder which will provide the context of the files within the folder, the naming system of the files, the version controls as well as author attribution and time/date stamps.

Post-completion of the project, all research data will be transferred to and stored in the University's Research Data Store (RDS). Data on OneDrive and REDCap will be deleted.

The data collection procedures will be monitored to ensure the accuracy of the data. Data collection monitoring includes monitoring of the consistency of data analysis, quality of video recordings, and the timeframes for uploading videos to the data storage after each therapy or assessment session. Data collection procedures are discussed at supervision meetings and adjustments are implemented where required.

10.2 Data retention and archiving process

Deidentified study data (e.g., demographic information, outcome measures) will be archived on Open Science Framework. Identifiable study data (e.g., videos of faces and voices) will be kept for 15 years after the research study is completed in the RDS, as the study is a clinical trial. This is in adherence to the university's research code of conduct and the faculty's research data management provisions. At the end of this time the project materials will be permanently deleted from the RDS.

10.3 Participant Confidentiality

Access to REDCap, OneDrive and RDS will be through the unikey and limited to unikey holding HREC approved project team members. User rights on REDCap will be managed

under the user rights settings for the project. Fields containing identifying data will be highlighted and located on an instrument that can be viewed only by designated members (CI, PhD student). Patient data will only reviewed in a secure setting (e.g., private room) over secured internet connection (through university VPN) and headphones will be used to review any audio or video files from the therapy sessions, probes or assessment.

10.4 Data Security Steps

Access to REDCap, OneDrive and RDS will be through the unikey and limited to unikey holding HREC approved project team members. User rights on REDCap will be managed under the user rights settings for the project. Fields containing identifying data will be highlighted and located on an instrument that can be viewed only by designated members.

10.5 Future Use of Data

Adhering to principles of open science, data from this study will be deidentified and shared on Open Science Framework which collects and provides global access to self-archived research. During the informed consent process, participants will be notified of the above and asked if they consent to:

- their deidentified data (e.g., a datasheet containing demographic information, outcome measures) being considered for use in future research projects. Video and audio files will not be uploaded.
- being informed about other research projects.
- sharing their deidentified data on Open Science Framework to allow researchers to use this data in the future for other studies or additional analysis

10.6 Data storage at the conclusion of the clinical trial

At the conclusion of the study, all data will be transferred and stored on the RDS and deleted from all other storage. After 15 years, identifiable data of all patients and all data of patients who did not consent to their data being shared on the Open Science Framework will be securely deleted.

10.7 Quality Management

The PhD student will be responsible for ensuring the quality of processes, data, and documentation associated with the study. Data will be checked for quality and completeness as it is uploaded on university-managed storage infrastructure.

11. FINANCIAL

This study is not externally funded and will be completed as part of a PhD. Equipment required for the study are readily available at the University of Sydney.

12. PUBLICATION POLICY / DISSEMINATION OF RESULTS

This work will be reported in one or more journal articles and conference papers. Authorship will follow the Contributor Roles Taxonomy (Credit) and will be determined by the nature and extent of their contributions to the papers.

The findings from the study will also be disseminated to clinicians, researchers, and policy makers through the following platforms: (a) national and international conferences, (b) workplace seminars and (c) special interest groups associated with dysphagia, rehabilitation, or Parkinson's Disease. Participants will receive an email at the end of the study with a lay summary of the results of the study.

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