





BMJ Open ParkinSong Online: protocol for a telehealth feasibility study of therapeutic group singing for people with Parkinson's disease

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ABSTRACT

Introduction Parkinson's disease can be associated with speech deterioration and low communication confidence which in turn compromises social interaction. Therapeutic singing is an engaging method for combatting speech decline; however, face-to-face delivery can limit access to group singing. The aim of this study is to test the feasibility and acceptability of an online mode of delivery for a Parkinson's singing intervention (ParkinSong) as well as remote data collection procedures.

Methods and analysis This ParkinSong Online feasibility trial is a single-arm, pre–post study of online singing delivery and remote data collection for 30 people living with Parkinson's. The primary outcome measure is feasibility: recruitment, retention, attendance, safety, intervention fidelity, acceptability and associated costs. Secondary outcomes are speech (loudness, intelligibility, quality, communication-related quality of life) and wellbeing (apathy, depression, anxiety, stress, health-related quality of life). This mode of delivery aims to increase the accessibility of singing interventions.

Ethics and dissemination Ethics approval was obtained from The University of Melbourne Human Research Ethics Committee (2021-14465-16053-3) and the trial has been prospectively registered. Results will be presented at national and international conferences, published in a peer-reviewed journal, and disseminated to the Parkinson's community, researchers and policymakers.

Trial registration number ACTRN12621000940875.

INTRODUCTION

Parkinson's disease is a chronic, progressive, incurable and disabling neurological condition. In addition to movement symptoms,¹ up to 90% of people with Parkinson's experience impaired speech production,² communication difficulties³ and a range of non-motor symptoms,⁴ such as depression, anxiety and apathy. Disrupted basal ganglia–supplementary motor interactions in Parkinson's affect the amplitude and timing of movement and may explain motor speech dysfunction characterised by mono-pitch, mono-loudness,

Strengths and limitations of this study

- This trial was codesigned with people living with Parkinson's and coproduced with the local Parkinson's disease organisation.
- The study has been designed to gather feasibility data on both the online singing intervention delivery as well as remote data collection procedures.
- This feasibility trial is not powered for efficacy testing.
- The study will be implemented in Australia and the generalisability to other countries is yet to be determined.

reduced volume, reduced stress, imprecise consonants and inappropriate silences.⁵ Preliminary research indicates that face-to-face group singing has positive effects on speech and wellbeing outcomes for people with Parkinson's.^{6,7}

ParkinSong is a collaborative, transdisciplinary intervention informed by music therapy,^{8–10} speech pathology^{6,10} and rehabilitation principles.¹¹ The conceptual framework underpinning the ParkinSong intervention draws on neurobiological understandings of the shared neural networks and structural mechanisms used during singing and speech, and principles of auditory-motor coupling,¹² where rhythmic cues are used to stimulate and organise motor function.^{13–15} Group singing can reduce speech and non-motor symptoms.^{6,10,16} It can also act as a health-promoting resource that builds individual resilience and social capital.^{6,17} Singing brings people together, creates cohesion and increases sense of community or belongingness.^{7,18} Neuroscience research also indicates that during singing, the brain releases neurochemicals that decrease anxiety and stress and increase feelings of pleasure and alertness.¹⁹

The COVID-19 pandemic and social distancing requirements have forced choir facilitators worldwide to make a rapid transition to online singing rehearsals.²⁰ Face-to-face group singing has been highlighted as a high-risk activity for disease transmission due to the degree of aerosol droplets expelled during singing.^{21 22} There is an even greater risk for older populations with existing health conditions such as Parkinson's disease. Existing issues of social isolation, depression and anxiety are compounded by social distancing requirements. There is, therefore, a need to adapt existing face-to-face therapeutic interventions into an online context. Pandemic aside, many people with Parkinson's are isolated, either geographically or socially due to economic, health or mobility-based travel restrictions. People living with Parkinson's need access to service delivery options regardless of location, local service availability or other barriers (mobility, transport, carer availability, etc). The feasibility, including acceptability and safety, of online singing intervention delivery, thus, needs to be examined. Stegemöller and colleagues have reported that telehealth delivery of therapeutic singing for people with Parkinson's is feasible but used recorded sessions rather than live synchronous sessions.²³ Aside from this asynchronous delivery model, telehealth models for music therapy in Parkinson's have not been reported. This study aims to answer the following research questions: (1) Is it feasible and acceptable to deliver a therapeutic group singing intervention online for people living with Parkinson's? and (2) What preliminary information can be obtained to describe the effects of ParkinSong Online on communication and wellbeing outcomes for people with idiopathic Parkinson's?

METHODS AND ANALYSIS

Objectives

The primary aim is to examine the feasibility of an online trial of ParkinSong by assessing recruitment, retention, adherence, adverse events, acceptability, intervention fidelity and associated costs (eg, equipment, internet connection, therapists' time). The secondary aim is to obtain preliminary information to describe the effects of ParkinSong Online on communication and wellbeing outcomes for people with idiopathic Parkinson's. This will assist sample size calculation for an adequately powered randomised controlled trial.

Design

This single-arm, pre-post feasibility study will investigate online intervention delivery and remote data collection with people living with idiopathic Parkinson's disease. Our previously tested 12-week ParkinSong intervention⁶ will be modified to meet the requirements of an online delivery format, that is, 90 min instead of 120 min and muting of participant microphones during most synchronous singing activities due to online latency effects. This will mean that participants will hear the facilitator singing but not each other, the facilitators will also not be

able to hear participants when participant microphones are muted. The weekly synchronous Zoom sessions will be provided over a 12-week intervention period. All consenting participants will complete screening for mild cognitive impairment, and pre and postintervention testing of speech, wellbeing and quality of life outcomes. Data will be collected remotely via online data collection systems by a trained assessor over Zoom.

Patient and public involvement

The development and design of the ParkinSong Online protocol and documentation for this study have involved consultation with people living with Parkinson's and health professionals experienced in working with this population (music therapists, physiotherapists, speech and language therapists, occupational therapists). A consumer representative living with Parkinson's and Fight Parkinson's (formerly Parkinson's Victoria) staff were members of the research steering committee and coauthored this protocol paper. We also convened a consumer reference group to develop a participant information booklet for the study. Their opinions and preferences shaped the ParkinSong Online research protocol through their verbal feedback. The results from this study will be disseminated to the participants through reports written in plain language.

Participants

The trial will be conducted online with 30 eligible consenting participants joining from their homes, located in metropolitan and rural areas in Victoria, Australia. An overall sample size of 30 is recommended for feasibility studies to assist with estimating SD for use in a sample size calculation for a future-powered study.²⁴ Potential participants will be informed of the study via Parkinson's-specific communication channels and research communication channels. Initial eligibility screening will be conducted by Fight Parkinson's (formerly Parkinson's Victoria) health team, and all screening data will be stored in the secure university REDCap online database. (REDCap stands for Research Electronic Data Capture. It is a secure online database system designed to securely collect, store, organise and analyse data collected via online means.) Any applicant who passes initial screening will be electronically sent a link to the plain language statement and consent form. We will provide 1:1 technological support and Zoom training to ensure that all participants know how to log into a Zoom meeting and navigate the Zoom meeting settings (eg, how to mute/unmute, turn video or virtual background on/off, type in chat box, change display name, change between gallery and speaker view, etc.).

Inclusion criteria

People with a medical diagnosis of idiopathic Parkinson's disease will be eligible to participate if they: (1) are still mobile (Hoehn & Yahr score i-iv), (2) have no previous neurological, head and neck or respiratory disorders, (3)

are able to communicate in English, (4) are willing and capable of providing informed consent, (5) score ≥ 18 on the Montreal Cognitive Assessment (MoCA) (or with mandatory carer support if MoCA scores are between 10 and 17), (6) have reported changes in communication (self-reported or reported by their caregiver or health professional) and (7) have access to a computer with webcam and high-speed internet access (minimum download speed—10 mbps; minimum upload speed—1 mbps), which is required for the ParkinSong Online sessions and remote data collection. People will be excluded if they: (1) have a severe cognitive impairment (MoCA score < 10), (2) have significant vision or hearing impairments not alleviated with aids, (3) have undergone deep brain stimulation surgery within the past 6 months, (4) have pre-existing communication deficits not related to Parkinson's or (4) planning to engage in a Lee Silverman Voice Treatment (LSVT) Loud programme during the study intervention period.

Intervention

ParkinSong Online sessions will be implemented weekly for 12 weeks. Online sessions include 60 min of breathing exercises, vocal warmups and song singing and 30 min for conversation and social interaction in smaller breakout groups. Sessions will be cofacilitated via Zoom by a music therapist and a speech pathologist using a transdisciplinary approach and optimising Zoom audio settings for live music sharing. Participants may choose to use headphones or speakers based on individual preference (NB. Headset microphones are provided to all participants for

the assessments and they may use these for the intervention also if they wish).

Facilitators will educate participants on optimal posture for vocal care and voice projection with the aim of increasing awareness of body positioning. Participants will be led through a carefully planned sequence of respiratory and voice exercises designed to develop support and control for high-intensity effort singing. They will be instructed in different techniques to improve vocal projection, articulation, and resonance in spoken sentences. Following singing, participants will be allocated to Zoom breakout groups, providing them with an opportunity to practise the techniques they have been learning to improve their communication. The singing component of the online intervention sessions will be recorded and made available to participants for additional practice during the week if desired. These recordings will also be used for fidelity checking and analysis of facilitation techniques used for online intervention delivery.

Outcomes

The primary aim of this study is to examine the feasibility of the online intervention delivery and data collection process. We will conduct effect size calculations on the primary communication outcome of speech loudness to determine sample size for an adequately powered future study. See [table 1](#) for a list of measures collected and timing of administration.

Recruitment rate will be measured by calculating enrolments as a percentage of all expressions of interest. Reasons for not passing screening will be recorded and

Table 1 Flowchart of study procedures and administration of measures

Assessment/procedure	Enrolment	Baseline (Pre-intervention)	Post-sessions	Post-intervention (13 weeks)
Eligibility screening—stage 1	x			
Informed consent	x			
Demographic information	x			
Montreal Cognitive Assessment—stage 2 eligibility screening		x		
Environmental assessment		x		
Speech measures (loudness, intelligibility and quality)		x		x
Dysarthria Impact Scale		x		x
Depression, Anxiety and Stress Scale		x		x
Lille Apathy Rating Scale—Short Form		x		x
Parkinson's Disease Questionnaire-39		x		x
Unified Parkinson's Disease Rating Scale		x		x
Hoehn and Yahr scale		x		x
Acceptability, Appropriateness and Feasibility of Intervention Measures				x
Affect grid			x	
Participant pre-session practice and use of materials survey			x	
Participant post-session user experience surveys			x	



examined to determine population characteristics and demand for the intervention. Retention and attendance will be captured from attendance records. Intervention acceptability, appropriateness and feasibility will be measured via a brief bespoke postsession participant survey (see online supplemental materials) and brief postprogramme questionnaires: Acceptability of Intervention Measure, Intervention Appropriateness Measure and Feasibility of Intervention Measure.²⁵ Intervention fidelity will be assessed from video analysis of sessions and safety will be assessed through recording adverse events.

The primary measure of intervention effect is speech loudness during conversational speech (ie, monologue). We will assess speech loudness in terms of sound pressure levels during several connected speech conditions (pre and postintervention): monologue, reading (Rainbow passage), loud sentence, speaking over noise and syllable repetition (diadochokinesis). We will also perceptually assess speech intelligibility and voice quality using data collected during monologue, reading (Rainbow passage), picture description task, recitation (days of the week), syllable repetition and sustained vowels (see online supplemental materials for speech assessment battery).

We plan to assess wellbeing and health-related quality of life outcomes. Specifically, we will assess communication-related quality of life using the Dysarthria Impact Scale, which has been validated for use in neurodegenerative disease. (This scale was developed by Vogel et al. and the publication for this measure is currently in preparation). Depression, anxiety and stress will be measured using the Depression, Anxiety and Stress Scale²⁶ and apathy, via the Lille Apathy Rating Scale—Short Form.²⁷ Parkinson's specific health-related quality of life will be assessed across eight dimensions using the Parkinson's Disease Questionnaire-39 (PDQ-39).²⁸ Short-term effects on affect will be measured using the Affect Grid²⁹ before and after every ParkinSong Online session.

The MoCA³⁰ is a 16-item validated test of cognitive function that will be completed after an initial phone screening to assess eligibility for the study. The Unified Parkinson's Disease Rating Scale (UPDRS)³¹ will be used to assess disease severity. It is the most used scale in the clinical examination of Parkinson's disease, made up of six sections, evaluated by interview, self-report and clinical observation. The UPDRS assessment will be conducted online using published protocols for remote assessment,³² that is, self-report rather than observation for some items due to safety issues. Assessments of rigidity and postural instability will be omitted.

Assessment

All assessment sessions will be conducted via Zoom by trained assessors. First, the MoCA will be conducted (following remote testing instructions—<https://www.mocatest.org/remote-moca-testing/>) as this is the final step in eligibility screening. Following this, an environmental assessment will be conducted to identify any potential safety issues. Next, speech data will be collected

remotely via the Redenlab secure online speech data capture system using a Microsoft LifeChat USB microphone (with a mouth-to-microphone distance of 5 cm) connected via USB (universal serial bus) to the participant's computer. Participants will receive a link to Redenlab with instructions for how to complete the speech assessment recordings. The assessor will remain available on Zoom to support participants as needed and ensure that the microphone is positioned correctly. To control for influences on the recording configuration, we have controlled for mouth-mic distance, recording environment (quiet room with no external sources of noise) and recording software. We will calculate the sound pressure level of speech samples by recording a short, broad frequency (speech-like) reference sound, at a specific decibel level using the same recording configuration, and calculate the relative decibel level from this reference point.

Questionnaire data will be collected using the REDCap secure online data collection programme. Participants will be given the option to complete the questionnaires prior to the session or during the Zoom session if they want assessor support. They can either enter responses for self-report measures directly into REDCap or via interview with the assessor. The UPDRS can be performed remotely with the exception of rigidity testing and postural instability testing.³² Part III and IV of the UPDRS will be completed by self-report and observation as per current practice for online assessment. We will record rigidity, postural instability as missing data if required, due to safety concerns.

The timing of assessments will be scheduled at the midpoint between medication dosages, when possible, to minimise the potential for medication effects to influence outcomes. Participants will complete the single item Affect Grid measure before and after each ParkinSong Online session and a brief user experience survey at the end of each session. Facilitators will also complete a brief post-session survey to capture feasibility data on attendance, engagement and safety. After the completion of the study period, all participants will be invited to complete a brief feasibility assessment and an online focus group interview via Zoom to gather qualitative data about their experience of the ParkinSong Online intervention.

Analyses

Feasibility results will be reported descriptively. Speech data will be rated perceptually by speech clinicians and analysed acoustically via purpose-built scripts within Matlab and Praat software.³³ Examination of intervention effects will be conducted using appropriate inferential statistics (eg, paired t tests if normally distributed) for all quantitative measures. Effect size calculations will also be conducted, in addition to the probability analyses, to determine the size of any clinically significant changes. We will analyse interview data using Braun and Clark's³⁴ six-phase guide to conduct a methodologically rigorous thematic analysis. The six phases include

familiarisation, coding, generating themes, reviewing themes, defining and naming themes and writing up. A second author will check and verify codes and themes generated as part of the analysis process. Examination of the intervention facilitation will be conducted via observational video analysis of Zoom session recordings, specifically focusing on facilitation techniques used to enhance online participation, maximal effort and sense of group cohesion.

ETHICS AND DISSEMINATION

Ethics approval was obtained from The University of Melbourne Human Research Ethics Committee on 28 July 2021 (approval number: 2021-14465-16053-3) and the trial was registered with the Australian and New Zealand clinical trials registry on 19 July 2021. All participants will provide informed consent prior to commencing the study. Any amendments will be agreed on by the research steering committee and submitted for ethics committee approval prior to implementation. Results will be presented at national and international conferences, published in a peer-reviewed journal, and disseminated to the Parkinson's community, researchers and policymakers.

DATA MANAGEMENT AND SHARING

Decisions about the study design, data management and planned outputs will be ratified by the research steering committee. All assessments and data entry will be conducted by trained assessors who will follow procedures outlined in a comprehensive assessment manual. As a chief investigator, JT will maintain responsibility for custody of the data and research outputs and store these at The University of Melbourne in a secure research drive until they are made publicly accessible in deidentified format or destroyed. Following completion of the study, deidentified, anonymised data (with participant consent) will be available from the corresponding author. Data made available will include individual-level deidentified, anonymised participant data, excluding audiovisual recordings.

SAFETY AND REPORTING

Because this study will be conducted remotely in participants' homes, we will conduct an environmental check at the start of the baseline assessment and use a pre-session survey to confirm environment for each intervention session remains safe (as specified in participant manual). A safety and emergency protocol also forms part of the assessment and intervention, and this information is included in the assessor and facilitator manuals. Safety information and risks are also included in the participant manual, and a brief safety check will be performed by facilitators at the start of each online intervention session. Adverse events

and unintended negative effects of the intervention will be recorded and reported to the human research ethics committee.

Participants will be informed of study risks in the plain language statement. Although unlikely, it is possible that the vocal exercises and singing may cause physical discomfort, such as a sore throat or hoarse voice. If this occurs, participants will be encouraged to take a break and drink some water. It is also possible that singing certain songs or completing questionnaires about wellbeing might cause participants to reflect and feel sad. Experienced therapists are employed to conduct the assessments and intervention in a way that is sensitive to participants' emotional status and supportive if they need to stop or take a break. Any participants who experience physical or psychological distress due to their participation in the study will be referred to an appropriate healthcare professional and/or withdrawn from the study. Participants will be reminded that they may opt-out of assessments or withdraw from the study at any time.

RELEVANCE AND BENEFIT TO SOCIETY

The results of this feasibility study will contribute to the growing global literature on telehealth treatment options for addressing communication needs for people living with Parkinson's disease. Previous research has shown the impact of group singing interventions on speech loudness, communication confidence and voice-related quality of life.^{6 7 10} There is also preliminary evidence that face-to-face group singing can improve emotional wellbeing and mental health for people with Parkinson's.¹⁰ However, to date, only one prerecorded group singing feasibility study has been investigated in relation to Parkinson's.²³ There is a need to examine whether live, online delivery of group singing interventions is acceptable to participants with Parkinson's and feasible to provide. There is also a need to explore whether a telehealth delivery model can deliver improvements in speech and wellbeing equivalent to previous Parkinson's studies using in-person group singing interventions. The results of this study will have great application not only during the pandemic but also beyond, as shown by Morris and colleagues, in relation to online dance therapy in Parkinson's.¹¹ The advantage of online delivery of group singing interventions is that it is scalable and more accessible than in-person group programmes for people living with Parkinson's who are geographically or socially isolated. There are also challenges with online group singing, such as latency issues that make synchronous singing almost impossible,³⁵ which may affect the degree of effort inspired and lead to a potentially reduced sense of group connection. The trade-off in benefits between telehealth accessibility and sense of presence in face-to-face group singing is an area that will require further investigation.

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Contributors JT took the initiative for the study; JT, MM, FAB and APV developed the concept, design and statistical analysis plan and TVS designed the cost analysis plan. SH, SD and VT helped to revise the concept and design. JT drafted the manuscript; all authors revised the manuscript for important intellectual content. All authors approved the final version of the manuscript.

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