

**Sing For Your Saunter – Dementia Supplement**

**NCT04518917**

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## Study Design

This study was a single center, cross-sectional, interventional study.

## Participants

Participants were recruited through the Movement Disorders Clinic (MDC) at Washington University in St. Louis School of Medicine. Inclusion criteria for this study were as follows: a diagnosis of idiopathic, typical Parkinson disease according to the UK Brain Bank Criteria; Hoehn & Yahr stage 2-3 (mild to moderate disease severity); stable on all PD medications for at least two months prior to study entry; normal or corrected to normal hearing; score of  $\geq 1$  on the Movement Disorders Society Unified Parkinson Disease Rating Scale – Part III – Motor Aspects (MDS-UPDRS-III) item #10 indicating observable gait impairment; able to walk for ten continuous minutes independently; a score of one or less on item #7 on the New Freezing of Gait Questionnaire (nFOG-Q), indicating freezing episodes are not moderately or significantly disturbing to daily walking; and dementia as defined by a Clinical Dementia Rating (CDR) score of 0.5-1.0 (very mild to mild dementia). Seventeen individuals met these inclusion criteria and were enrolled in the study.

As this was a within-group cross-over study, there was no control group and no group randomization. This study was approved by the Institutional Review Board (IRB) of Washington University in St. Louis School of Medicine.

## Protocol

This study consisted of one in-person lab visit. All testing was done with participants in their on-state for medication. During the lab visit, participants were first assessed using the MDS-UPDRS-III and nFOG-Q to confirm eligibility for the study. Participants were also asked if they had any previous musical training. After eligibility was confirmed, participants were fitted with six APDM Opal sensors worn on the feet, wrists, lumbar spine, and sternum. These sensors sample at a frequency of 128 Hz and were used to collect various gait parameters, with a focus on velocity, cadence, and stride length. For all gait tasks, participants completed three

30-second trials of each cueing type and condition in a 100-foot hallway. All participants were followed by a trained physical therapist during walking trials to reduce fall risk during the intervention. No falls or adverse events occurred during data collection.

All participants first completed three 30-second uncued walking trials to determine baseline gait parameters. The average cadence over these uncued trials was then used to calculate four cueing tempos for each participant: 90%, 100%, 110%, and 120% of uncued walking cadence. These cues were selected based upon previous work in our group looking at internal vs. external cues in people with PD without dementia. Cues were rounded to the nearest five beats per minute. While cueing tempos were being calculated, participants were presented with a list of songs to choose from for the cued walking tasks. The list included songs selected with the help of a music therapist that have a 4/4 beat, salient tempo, and are likely to be familiar to many individuals. The songs available were as follows: "I've Been Working on the Railroad", "You Are My Sunshine", "This Land is Your Land", "Skip to My Lou", "She'll Be Coming Around the Mountain", "Don't Sit Under the Apple Tree", "When the Saints Go Marching In", "You Can't Hurry Love", "When Johnny Comes Marching Home Again", and "Seventy-Six Trombones." Participants were provided with the song lyrics prior to starting the cued tasks to ensure they knew the words. After reviewing the lyrics, participants were recorded singing the song out loud without reading the lyrics from the sheet to ensure they remembered the lyrics correctly. Additionally, they practiced walking and singing out loud to ensure they were able to perform the two tasks simultaneously.

After cueing tempos were determined, participants received two different cueing methods at each tempo. The two cueing methods were A) Music and B) Mental. Music served as the externally generated cue, while Mental served as the internally generated cue. For all cued trials, one chorus of the selected song was played at the correct tempo while the participant was standing still as a reminder of the tempo. Cues were delivered via speakers and volume was adjusted so participants could hear throughout the entire trial. During the Music

task, the cue kept playing and participants were instructed to walk to the beat, rather than the melody, of the song as they listened. During the Mental task, the cue turned off and participants were instructed to walk to the beat of the song while singing in their heads in silence. To ensure participants were doing the task, they were asked if they were singing in their heads after each trial. Participants were instructed not to move their mouths during the mental singing task, and this was monitored by the physical therapist who was walking with the participant for safety. Prior to the start of the cued trials, a member of the research team demonstrated walking on the beat to ensure all participants received the same instruction. To mitigate order effects, task order for each participant was randomized first by tempo, then Music vs Mental condition order was randomized within each tempo. This meant that both cueing types at a given tempo occurred one after the other, but the order of cue type presented at each tempo was random. In total, participants completed 27 walking trials of 30 seconds each.

### Statistical Analysis

All data were analyzed using R statistical software. Gait parameters including velocity and stride length were averaged across the three trials for a given condition (i.e., Mental 110%). Mixed-effect models were used to predict velocity and stride length as a function of cue type and tempo (as fixed effects) and to account for the within-subject nature of the design (as random effects) using the lmer4 package in R. These models tested the main effects of Cue Type (Music v. Mental), Tempo (90, 100, 110, and 120%), and their interaction as categorical factors. Random effects of participant, the interaction of participant:cue type, and the interaction of participant:tempo were included to account for the within-subject nature of the manipulation. To determine the statistical significance of these effects, we used F-tests with Satterthwaite's approximation for the degrees of freedom. The Type I error rate for all tests was set at  $\alpha=.017$  to account for multiple comparisons.