Impact of Music Improvisation Training on Cognitive Function in Older Adults

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Study Protocol and Statistical Analysis Plan

We conducted a 2-arm "outcomes assessor" blind randomized pilot trial. Focus groups were done at the conclusion of the intervention. Adults age 60 and above with and without mild cognitive impairment (MCI)were individually randomized in random blocks of two, four and six to either the (i) attention control (music listening) or (ii) improvisation training experimental condition – frequency and format refined in Aim 1. We administered all outcome measures at baseline (pre) and after the intervention (post). Feasibility and acceptability metrics were assessed during the duration of the trial and at the conclusion of the intervention, as appropriate.

Randomization Procedures. Participants were stratified by center and cognitive status (MCI or healthy) and randomly assigned 1:1 to one of the two groups (experimental or control conditions). The statistician provided a secure and unpredictable allocation sequence (e.g., A B B A…) for each center, labeled with sequential study ID numbers. The sequences were generated using random block sizes to maximize balance between groups throughout accrual while ensuring the sequences remain unpredictable. As participants consented to study participation, the clinical research coordinator assigned the next available study ID number in the sequence and identified the allocated group. Participants were informed of their group assignment after all baseline assessments were completed. Study personnel responsible for outcome assessment were blinded to what group A or B represented.

Primary quantitative analyses estimated feasibility and acceptability indicators (retention in study, adherence to intervention, and satisfaction with intervention) with frequency and percentage for categorical indicators and mean and standard deviation for continuous indicators. Each estimated indicator (e.g., % retained) was compared to its pre-specified threshold based on professional consensus. Participants' demographics and clinical characteristics at baseline were examined for covariate balance between the two groups. We also reviewed descriptive statistics (frequency, percentage, mean, standard deviation, effect size) of the cognitive and psychosocial measures at baseline and after the intervention-

by-intervention group. The average outcome measures and corresponding standard deviations pre- and post-intervention, as well as average outcome changes, were estimated by group for the purpose of planning the bigger study. Given the feature of the pilot study, no formal hypothesis tests were conducted.