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Research Letter | Neurology

Music Listening and Multiple Dimensions of Well-Being in Acute Stroke
A Randomized Clinical Trial

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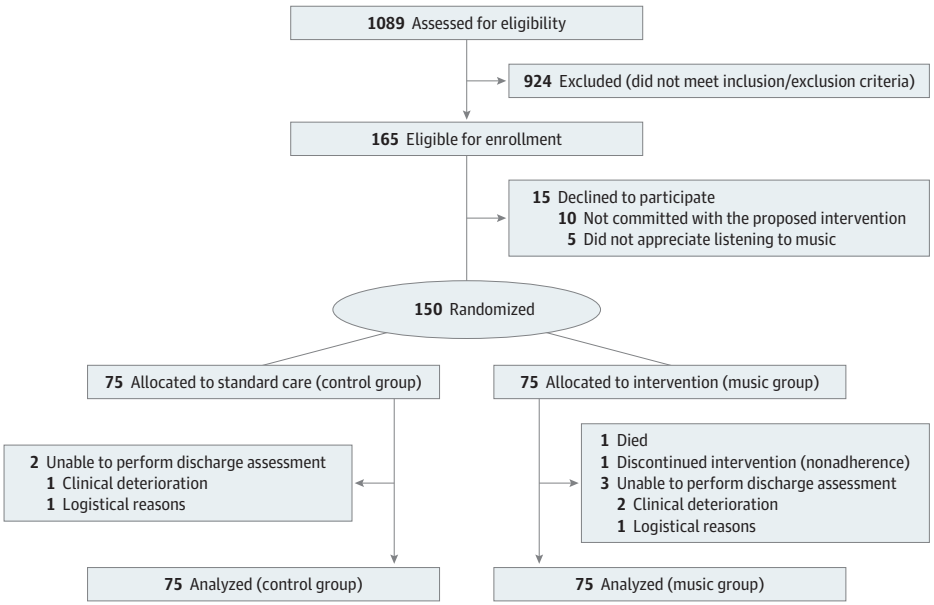
Introduction

Music listening, by engaging widespread neural networks,[1] may be associated with improved mood and cognition.[2-6] Data in acute stroke remain limited. We hypothesized that during acute stroke hospitalization early listening of structured and personalized vocal music could improve psychological well-being and conducted a randomized clinical trial to assess its feasibility, acceptability, and effects on patient-reported outcomes (PROMs) at discharge.

Methods

This single-center prospective randomized clinical trial with blinded outcome assessment enrolled patients aged 18 to 85 years with acute ischemic or hemorrhagic stroke within 24 to 96 hours of symptom onset, a National Institutes of Health Stroke Scale (NIHSS) score of less than 10, had preserved comprehension and communication, and were without major cognitive or psychiatric disorders. Participants were randomized 1:1 to music listening or standard care. The intervention consisted of 1-hour weekday sessions of personalized listening of Italian vocal music delivered via tablet and headphones until discharge. Primary outcomes at discharge were feasibility, measured as enrollment rate (>90% of eligible patients), dropout (<10%), listening time (>70% of days-in-study); acceptability, evaluated with a 5-item Likert questionnaire (eTable in Supplement 1); Hospital Anxiety

Figure. Participant Flow Diagram



+ Supplemental content

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and Depression Scale scores (HADS-a, HADS-d); EQ-visual analog scale (EuroQol-VAS). Secondary PROMs at discharge were Insomnia Severity Index (ISI) and EuroQoL 5-dimensions 3-level (EQ-5D-3L). Sample size estimation was based on the 3 coprimary PROMs: assuming a 2-sided α-level of 0.015 and 80% power, 150 participants were planned. Missingness analyses supported the plausibility of the missing-at-random assumption. Multiple imputation was used for missing data. Between-group differences at discharge were assessed using analysis of covariance adjusted for baseline values, followed by multivariable linear regression for covariate adjustment according to the intention-to-treat approach, including sensitivity analyses. All statistical tests were 2-sided, with statistical significance set at $P < .015$ to account for the 3 coprimary outcomes. Analyses were conducted using SPSS version 26 (IBM). All participants provided written informed consent. This randomized clinical trial followed the CONSORT reporting guideline and was approved by the San Raffaele Hospital ethics committee (NCT06743412). Data were analyzed from June 2022 to November 2024.

Table. Clinical and Demographic Characteristics of Patients in the Control and Music Groups

	Patients, No. (%)	
Variables[a]	Control (n = 75)	Music (n = 75)
Age, median (IQR), y	71 (64-75)	70 (60-76)
Sex		
Female	29 (39)	26 (35)
Male	46 (62)	49 (65)
Education, median (IQR), y	11 (8-13)	13 (8-15)
Diagnosis		
Ischemic stroke	69 (92)	66 (88)
Cerebral hemorrhage	6 (8)	9 (12)
Thrombectomy	11 (15)	7 (9)
Thrombolysis	12 (16)	17 (23)
Dominant hemisphere affected	32 (43)	31 (41)
Premorbid mRS, median (IQR)	0 (0-0)	0 (0-0)
Pre-morbid psychotropic medication	11 (15)	12 (16)
Arrival scale, median (IQR)		
NIHSS	4 (2-6)	3 (2-6)
Enrollment scale, median (IQR)		
NIHSS	2 (1-4)	2 (1-4)
BMRQ	62 (54-73)	67 (57-75)
HADS-d[b,c]	8 (4-11)	9 (4-13)
HADS-a[b]	6 (3-9)	7 (4-10)
EQ-VAS[b]	60 (50-80)	60 (50-80)
EQ-5D-3L		
Mobility[b]	2 (1-3)	2 (1-4)
Self-care[b,c]	2 (1-4)	2 (1-4)
Usual activities[b]	2 (1-4)	2 (1-4)
Pain or discomfort[b]	1 (1-2)	1 (1-3)
Anxiety or depression[b]	2 (1-3)	2 (1-3)
ISI[b,d]	5 (1-10)	8 (2-13)
Onset-to-randomization time, median (IQR), h	54 (40-76)	52 (45-71)
Days of hospitalization, median (IQR), d	8 (6-11)	8 (5-11)
Days in study during hospitalization, median (IQR), d	7 (4-8)	7 (4-9)
Physiotherapy or speech therapy during hospitalization	34 (45)	39 (52)
Discharge type		
Home	55 (73)	56 (75)
Rehabilitation clinic	20 (27)	18 (24)
Death	0 (0)	1 (1.3)
Discharge scale		
NIHSS, median (IQR)	1 (0-3)	1 (0-3)
mRS, median (IQR)	1 (0-3)	1 (0-3)

Abbreviations: BMRQ, Barcelona Music Reward Questionnaire (higher score indicates higher reward response to music); EQ-VAS, EuroQol visual analog scale; EQ-5D-3L, EuroQol-5 dimension–3 levels scale (higher score indicates more symptom severity); HADS-a, Hospital Anxiety and Depression Scale-anxiety (higher score indicates more symptom severity); HADS-d, Hospital Anxiety and Depression Scale-depression (higher score indicates more symptom severity); ISI, Insomnia Severity Index (higher score indicates more symptom severity); mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale.

[a] Continuous variables are reported as median (IQR) and compared using the Mann-Whitney U test. Categorical variables are reported as No. (%) and compared using the χ^2 test.

[b] Proportion of missingness at discharge assessment: 7 of 150 patients (4.7%).

[c] Variable associated with missingness in univariable logistic regression analyses ($P < .05$).

[d] $P < .05$ in the comparison between groups at baseline.

Results

Of 165 eligible patients, 150 (mean [SD] age, 67.9 [11.4] years; 55 females [36.7%] and 95 males [63.3%]) were randomized (75 per group) and included for analyses (**Figure**). Clinical-demographic characteristics were comparable (**Table**). Feasibility results were: enrollment rate 91%, dropout 6.7%, median (IQR) cumulative listening time 6 (4-7) hours, intervention delivered on median (IQR) 100% (80%-100%) of days-in-study. More than 80% rated the intervention highly acceptable (4 to 5 on a 5-point Likert scale) for each questionnaire item (eTable in Supplement 1). Perceived quality of care was comparable between groups (P = .37). At discharge, the music group had lower HADS-d (adjusted mean difference [aMD], −2.68; 95% CI, −3.90 to −1.47) and HADS-a (aMD, −1.86; 95% CI, −2.93 to −0.79) scores than controls (P < .001). EQ-VAS was comparable between music and control groups (aMD, −0.19; 95% CI, −6.03 to 5.64; P = .94). Music listening was associated with better sleep quality (ISI) (aMD, −2.83; 95% CI, −4.43 to −1.24; P < .001) and lower EQ-5D-3L-pain/discomfort scores (aMD, −0.35; 95% CI, −0.60 to −0.09; P = .008). In multivariable analyses, music listening (β = −2.6; 95% CI, −3.8 to −1.4; P < .001) and male sex (β = −1.7; 95% CI, −2.9 to −0.5; P = .005) were independently associated with lower HADS-d scores at discharge, whereas higher baseline HADS-d scores were associated with higher HADS-d scores at discharge (β = 0.5; 95% CI, 0.4 to 0.6; P < .001). Music listening was independently associated with lower HADS-a scores at discharge (β = −1.9; 95% CI, −2.9 to −0.8; P = .001), whereas higher baseline HADS-a values were associated with higher HADS-a scores at discharge (β = 0.6; 95% CI, 0.5 to 0.7; P < .001). Music listening was independently associated with lower ISI scores at discharge (β = −2.8; 95% CI, −4.3 to −1.2; P < .001), whereas higher baseline ISI (β = 0.4; 95% CI, 0.3 to 0.5; P < .001) and baseline HADS-d values (β = 0.3; 95% CI, 0.2 to 0.5; P < .001) were associated with higher ISI scores at discharge. In sensitivity analyses, intervention remained associated with lower HADS-d and ISI scores at discharge (P < .001). No adverse events related to the intervention were observed.

Discussion

Early initiation of structured and personalized vocal music listening during acute stroke hospitalization is feasible, acceptable, and associated with improved mood and self-perceived sleep quality. Limitations include the single-center design and the prevalence of patients with low NIHSS scores, which restrict the generalizability. The absence of an active sham control raises the possibility of nonspecific effects that could be mitigated in light of the similar perceived quality of care between groups. As a low-cost and minimally demanding intervention, music listening could be integrated into acute stroke management, even in resource-limited settings.

ARTICLE INFORMATION

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Supervision: Giacalone, De Boni, Filippi, Roveri.

Conflict of Interest Disclosures: Dr Filippi reported receiving grants from Biogen, Merck-Serono, Novartis, Roche, Italian Ministry of Health, Italian Ministry of University and Research, Fondazione Italiana Sclerosi Multipla; receiving consulting fees from Almirall, Biogen, Bristol-Myers Squibb, Eli Lilly, Merck, Novartis, Roche, and Sanofi; receiving personal fees for speaking activities from Amgen, Bayer, Biogen, Bristol-Myers Squibb, Celgene, Chiesi Italia SpA, Eisai, Eli Lilly, Fujirebio, Genzyme, Janssen, Merck, Neopharmed Gentili, Neuraxpharm, Novartis, Novo Nordisk, Roche, Sanofi, and Takeda; receiving personal fees for the scientific direction of educational events from Merck, Roche, Celgene, Bristol-Myers Squibb, Lilly, Novartis, and Sanofi-Genzyme; and serving on advisory boards for Alexion, Biogen, Bristol-Myers Squibb, Eli Lilly, GE Healthcare Ltd, Merck, Neuraxpharm, Novartis, Roche, Sandoz, Sanofi, and Takeda outside the submitted work. Dr Filippi also reported being the editor in-chief of the *Journal of Neurology* and an associate editor of *Human Brain Mapping*, *Radiology*, and *Neurological Sciences*. No other disclosures were reported.

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SUPPLEMENT 1.
eMethods.
eReferences
eTable.

SUPPLEMENT 2.
Trial Protocol

SUPPLEMENT 3.
Data Sharing Statement