CONSORT 2025 checklist of information to include when reporting a randomised trial*

Section / Topic	No	CONSORT 2025 checklist item description	Reported on page no.
Title and abstract			
Title and structured abstract	1a	Identification as a randomised trial	Page 1 (Title and Abstract, clearly stated as a randomized controlled trial)
	1b	Structured summary of the trial design, methods, results, and conclusions	Page 1 (Abstract includes trial design, methods, results and conclusions)
Open science			
Trial registration	2	Name of trial registry, identifying number (with URL) and date of registration	Not applicable. This is a social science artistic music behavioral intervention study, not a medical clinical trial. No clinical

			trial registration is required.
Protocol and statistical analysis plan	3	Where the trial protocol and statistical analysis plan can be accessed	Page 4–11 (Methods section); Detailed trial protocol is provided as supplementary file “Trial Protocol.pdf
Data sharing	4	Where and how the individual de-identified participant data (including data dictionary), statistical code and any other materials can be accessed	ndividual research data are available from the corresponding author upon reasonable request
Funding and conflicts of interest	5a	Sources of funding and other support (e.g., supply of drugs), and role of funders in the design, conduct, analysis and reporting of the trial	Page end (No external funding was received for this study)
	5b	Financial and other conflicts of interest of the manuscript authors	age end (The authors declare no potential conflicts of interest)

Introduction			
Background and rationale	6	Scientific background and rationale	age 2 (Introduction, research background and research rationale)
Objectives	7	Specific objectives related to benefits and harms	Page 3 (Introduction, research research objectives)
Methods			
Patient and public involvement	8	Details of patient or public involvement in the design, conduct and reporting of the trial	Page 3 (Introduction, research research objectives)
Trial design	9	Description of trial design including type of trial (e.g., parallel group, crossover), allocation ratio, and framework (e.g., superiority, equivalence, non-inferiority, exploratory)	Page 4 (Methods, parallel-group randomized controlled trial design)
Changes to trial protocol	10	Important changes to the trial after it commenced including any outcomes or analyses that were not prespecified, with reason	No important changes were made to the trial protocol during the whole

			research process
Trial setting	11	Settings (e.g., community, hospital) and locations (e.g., countries, sites) where the trial was conducted	Page 4 (Conducted in university community setting)
Eligibility criteria	12a	Eligibility criteria for participants	Page 5 (Methods, inclusion and exclusion criteria of participants)
	12b	If applicable, eligibility criteria for sites and for individuals delivering the interventions (e.g., surgeons, physiotherapists)	Not applicable
Intervention and comparator	13	Intervention and comparator with sufficient details to allow replication. If relevant, where additional materials describing the intervention and comparator (e.g., intervention manual) can be accessed	Page 6–7 (Methods, detailed intervention and comparator group arrangement)
Outcomes	14	Pre-specified primary and secondary outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome	Page 8 (Methods, primary and secondary outcome indicators and test time points)
Harms	15	How harms were defined and assessed (e.g., systematically, non-systematically)	Not

			applicable. The intervention is low-risk non-invasive music therapy with no harm assessment needed.
Sample size	16a	How sample size was determined, including all assumptions supporting the sample size calculation	Page 9 (Methods, sample size basis and illustration)
	16b	Explanation of any interim analyses and stopping guidelines	Not applicable, no interim analysis or early stopping guideline
Randomisation:			
Sequence generation	17a	Who generated the random allocation sequence and the method used	Page 10 (Methods, random sequence generation method)
	17b	Type of randomisation and details of any restriction (e.g., stratification, blocking and block size)	Page 10 (Methods, random grouping

			design)
Allocation concealment mechanism	18	Mechanism used to implement the random allocation sequence (e.g., central computer/telephone; sequentially numbered, opaque, sealed containers), describing any steps to conceal the sequence until interventions were assigned	Page 10 (Methods, allocation concealment description)
Implementation	19	Whether the personnel who enrolled and those who assigned participants to the interventions had access to the random allocation sequence	Page 10 (Research staff implemented random grouping independently)
Blinding	20a	Who was blinded after assignment to interventions (e.g., participants, care providers, outcome assessors, data analysts)	Not applicable, this trial adopts open-label design without blinding
	20b	If blinded, how blinding was achieved and description of the similarity of interventions	Not applicable
Statistical methods	21a	Statistical methods used to compare groups for primary and secondary outcomes, including harms	Page 11 (Methods, statistical analysis methods for each indicator)
	21b	Definition of who is included in each analysis (e.g., all randomised participants), and in which group	Page 11

			(Description of analysis participants dataset)
	21c	How missing data were handled in the analysis	Page 11 (Missing data processing method)
	21d	Methods for any additional analyses (e.g., subgroup and sensitivity analyses), distinguishing prespecified from post-hoc	Page 11 (Subgroup analysis and additional statistical description)
Results			
Participant flow, including flow diagram	22a	For each group, the numbers of participants who were randomly assigned, received intended intervention, and were analysed for the primary outcome	Page 12 (Results, participant flow and participant distribution of each group)
	22b	For each group, losses and exclusions after randomisation, together with reasons	Page 12 (No obvious loss and exclusion of participants during the research)
Recruitment	23a	Dates defining the periods of recruitment and follow-up for outcomes of benefits and harms	Page 13 (Recruitment

			time and follow-up time arrangement)
	23b	If relevant, why the trial ended or was stopped	The trial was completed strictly according to the research plan
Intervention and comparator delivery	24a	Intervention and comparator as they were actually administered (e.g., where appropriate, who delivered the intervention/comparator, how participants adhered, whether they were delivered as intended [fidelity])	age 13 (Results, implementation status and adherence of intervention measures)
	24b	Concomitant care received during the trial for each group	age 13 (No additional auxiliary treatment in both groups)
Baseline data	25	A table showing baseline demographic and clinical characteristics for each group	Page 14 (Baseline demographic data and baseline comparison table of all participants)

Numbers analysed, outcomes and estimation	26	For each primary and secondary outcome, by group: ● the number of participants included in the analysis ● the number of participants with available data at the outcome time point ● result for each group, and the estimated effect size and its precision (such as 95% confidence interval) ● for binary outcomes, presentation of both absolute and relative effect size	Page 14–16 (Results, all outcome indicators data, group comparison and effect analysis)
Harms	27	All harms or unintended events in each group	Not applicable. No adverse events or unintended incidents occurred in this non-invasive music intervention research.
Ancillary analyses	28	Any other analyses performed, including subgroup and sensitivity analyses, distinguishing pre-specified from post-hoc	Page 17 (Results, additional auxiliary analysis results)
Discussion			
Interpretation	29	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page 18 (Discussion, comprehensive interpretation of research

			results)
Limitations	30	Trial limitations, addressing sources of potential bias, imprecision, generalisability, and, if relevant, multiplicity of analyses	Page 19 (Discussion, research limitations and future research suggestions)

*We strongly recommend reading this statement in conjunction with the CONSORT 2025 Explanation and Elaboration and/or the CONSORT 2025 Expanded Checklist for important clarifications on all the items. We also recommend reading relevant CONSORT extensions. See www.consort-spirit.org.

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