*Full-length research article*

# Development and pilot implementation of a music and rhythm-based cognitive remediation program for individuals with traumatic brain injury

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Abstract

**Background:** Cognitive remediation (CR) is an evidence-based intervention method targeting cognitive deficits. CR has shown small to moderate levels of efficacy in Traumatic Brain Injury (TBI). Over the past decade, with growing scientific evidence, novel approaches to CR have emerged parallelly. Music-based CR is one such approach that has been gaining significant momentum. Neuro-scientific evidence for music-based interventions in cognitive and emotional recovery after TBI has grown in sizeable numbers.

**Aim:** To develop and examine the feasibility of a music and rhythm-based cognitive remediation program (CogniTune) for patients with TBI.

**Method:** CogniTune, a music and rhythm-based cognitive remediation program, was developed using a theory and evidence-driven approach, grounded in principles of cognitive rehabilitation and music-cognitive neuroscience, following a stepwise iterative process. Tasks were validated by five experts. Subsequently, the refined program was pilot tested with five adults with TBI. Neurocognitive and functional outcomes were assessed pre- and post-intervention. Feedback was obtained from patients and their caregivers to understand their experiences and the perceived usefulness of the intervention program.

**Results:** Preliminary findings showed trends towards improvement in cognitive functions such as attention, fluency, working memory, verbal learning and memory, along with mood, quality of life and caregiver rated overall functioning after receiving CogniTune. Patients and caregivers reported positive experiences and perceived the intervention to be beneficial. This pilot study supports our plan to test the efficacy of CogniTune through a larger study, and presence of control groups.

**Conclusion:** CogniTune, a novel music- and rhythm-based CR program, was systematically developed and demonstrated preliminary feasibility and acceptability in patients with TBI, warranting evaluation in a larger controlled trial.

**Keywords:** music-based cognitive remediation, traumatic brain injury, attention, executive function, learning and memory.

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Shantala Hegde | **E-mail:** shantala.hegde@gmail.com / shegde@nimhans.ac.in | **COI statement**: Author PAR received PhD research fellowship from the University Grants Commission (UGC), Ministry of Human Resource and Development, Government of India (Grant no. 367/NET-July2016). During the study period, author SH was Clinical and Public Health Intermediate Fellow of the DBT/Wellcome Trust India Alliance (IA/CPHI/17/1/503348). The authors have no conflict of interest to declare. **Declaration of generative AI use:** During manuscript preparation, OpenAI (ChatGPT) was used to assist with language refinement including improving clarity, grammar and readability. The tool was not used to generate scientific content, data, analyses, figures, interpretations, or conclusions. The author(s) reviewed and edited all output and take full responsibility for the content of this publication.

Cognitive remediation (CR) is an evidence-based non-pharmacological intervention aimed to restore, enhance, or optimize cognitive functions and facilitate functional recovery. [1–3] With principles of experience-dependent neural plasticity as its edifice,[4] CR employs restorative approaches (structured, hierarchical, and repetitive cognitive exercises) and/or internal compensatory strategies such as encoding specificity, elaborative rehearsal, visual imagery, and metacognitive strategies.

Although CR has been broadly proven to improve cognitive functions such as attention, executive functions, learning, memory, and emotional well-being,[2,5] evidence for stand-alone restorative approaches is inconsistent,[6,7] and varying in effect sizes (Cohen's d= 0.30 to 0.7), with limited sustainability and generalisability of

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improvements.[3,8,9] Perhaps this is due to the limited cognitive complexity of tasks, with most CR programs focusing on a single cognitive component or selected cognitive functions (e.g., attention drills; memory training), that engage specific cognitive processes. [10] Often, these CR programs are based on tasks that are quite similar to the cognitive outcome measures, thereby raising questions about their generalizability to tasks that differ from the focus of training. [11]

The recent recommendations from the Cognitive Rehabilitation Task Force (CRTF), International Cognitive Rehabilitation Guidelines (INCOG), and the American Speech-Language-Hearing Association (ASHA) guidelines [1,2,12] advocate the use of combination approaches (e.g., direct retraining along with the use of metacognitive strategies) over purely restorative approaches. Significant emphasis has been placed on multimodal, comprehensive, therapist-facilitated, and person-centred treatment approaches to CR. [5,12] Music-based interventions with strong neuroscientific evidence are one of the recommended methods.

**Music-based cognitive remediation in TBI**

Over the past decade, newer methods have been explored in the field of CR, including music-based CR. [13,14] While music has been considered beneficial in enhancing emotional health and well-being in individuals with mental disorders for decades, advances in neuroscience have contributed to an empirical understanding of the mechanisms underlying its therapeutic efficacy. [3,15,16] Music engagement activates widespread neural networks and enriches the brain functions by promoting structural and functional neuroplasticity. [17,18,19] Not surprisingly, music is considered one of the best cognitive exercises. The strong temporal structure of music provides timing, grouping and organization, which can facilitate attention, language processing, executive functions and memory. [20,21] The evidence supporting the potential of music in enhancing cognitive functions primarily derives from studies involving music-trained children and adults [22,23] and has been later extended as a therapeutic approach to several clinical populations.

Music can be integrated into CR through active or receptive tasks. Both active (e.g., singing, playing instruments, rhythmic activities, and musical improvisation) and receptive (e.g., listening) music interventions have demonstrated benefits in regulating cognitive and emotional processes across various neurological conditions. [14,24] Music interventions are also naturally engaging and enjoyable, leading to better treatment adherence, supported by a strong therapeutic connection.[25]

So far, a handful of randomised controlled trials (RCTs) in TBI have demonstrated the efficacy of music interventions in improving executive functions,[26,27] mood and emotional adjustment.[28,29] Neuroimaging studies have also reported structural and functional changes in the brain induced by music interventions, such as an increase in structural grey matter, white matter plasticity, and functional connectivity in fronto-parietal areas, orbitofrontal networks, the corpus callosum, and the right cortico-striatal tracts, associated with cognitive functions.[27,30–32] With growing evidence, the recent INCOG guidelines endorsed the use of music intervention in the form of (1) rhythmical training, (2) structured cognitive-motor training, and (3) assisted music playing to target executive functions in the TBI population. [13]

Music intervention modules specifically designed to target cognitive functions are only a few hitherto. [16,33,34] Neurologic music therapy (NMT) is one such neuroscience-informed approach whose techniques are grounded in two models that explain how music-based interventions can access and regulate cognition in a rehabilitation context – the Rational Scientific Mediating Model (RSMM) and the Transformational Design Model (TDM).[35] NMT consists of standard techniques targeting three functioning domains: sensorimotor, language and cognitive-affective dysfunction.[16,36] Within the cognitive-affective domain, structured musical tasks are designed to improve attention, executive functions, and memory by leveraging various elements of music. These techniques have been proven to be beneficial in improving cognitive function, with persistent changes observed at the 6-month follow-up. [27,29,31,32,37]

With growing interest and evidence of music-based CR worldwide, there is significant potential to conduct systematic research in this area.[38] Particularly in India, systematic investigations of CR remain limited. Moreover, despite the country's rich musical heritage, scientific work on music-based interventions in TBI has largely been restricted to listening-based techniques. [39,40] To our knowledge, there are currently no structured music-based interventions specifically designed to target cognitive functions in the Indian context. Music-based CR is clearly in its infancy, and the extent to which intervention protocols and research findings from the West can be directly applied to our population remains uncertain. Music-based CR, if systematically developed, could potentially be an effective and novel alternative to traditional CR approaches. The primary aim of the present study was to develop and examine the feasibility of CogniTune – a music and rhythm-based cognitive remediation program for patients with TBI. The secondary, exploratory objective was to examine preliminary efficacy through pilot testing.

## Methodology

The present study is a part of an ongoing larger study aimed at developing and testing the effectiveness music and rhythm based cognitive remediation program (CogniTune). The study has been registered in the Clinical Trials Registry of India (CTRI/2023/10/058891). The study was initiated after obtaining ethical clearance from the Institute's ethics committee (NIMH/DO/BEH.Sc.Div./2020-21). The intervention development approach closely aligns with the MRC (Medical Research Council) framework for developing complex interventions, [41,42] and the intervention description follows the latest reporting guidelines for music-based interventions,[43] ensuring transparency and methodological rigour (Supplementary Table 1).

**Development of the Intervention Program**

The intervention development process followed a systematic, theory and evidence-driven, multi-stepped approach, involving (1) conception and planning through evidence synthesis, (2) designing and creating the intervention, (3) expert validation, (4) preliminary pilot phase, and (5) iterative refinement of the intervention. The stages in intervention development are described below.

**1. Conception and Planning**

The initial conceptualization and planning were carried out through a detailed review of published literature covering several key domains:

a. *The nature and severity of cognitive deficits in TBI.*
b. *Identifying the gaps in the literature concerning CR studies.*
c. *Understanding the recent recommendations regarding the structure, format and delivery of an effective CR program*
d. *Evidence for the use of music-based CR in TBI.*
e. *Existing neurosciences informed music interventions and underlying principles.*
f. *Approaches and essential components in intervention development that help integrate insights from cognitive theories and cognitive neuroscience in designing the novel music and rhythm-based CR program.*

**2. Designing and Creating the Intervention**

Based on a detailed review of published literature, a framework was designed with components and features of CogniTune (Table 1).

**Table 1.** *The initial framework for the development of CogniTune*

| | |
|---|---|
| The principle underlying the CR program | *A restorative approach*, employing structured, hierarchical music and rhythm-based cognitive tasks, augmented by *internal compensatory and metacognitive strategies*. |
| Target cognitive domains | Attention, executive functions, learning and memory |
| Theoretical rationale | Cognitive theories, principles of cognitive rehabilitation, models of neuroscience-informed music interventions |
| Levels of gradation | Tasks are graded into four levels, with increasing cognitive demand across each level. Transition across levels based on 80% accuracy and/or qualitative evaluation of the researcher. |
| Duration and intensity of intervention | 20 sessions, 3-5 times a week, each session lasting for about 45-60 minutes |
| Mode of delivery | Hospital-based (in-person), therapist-facilitated |
| Nature of tasks | Both active and receptive components of music-based interventions. Active music exercises require participants to engage in exercises that involve sound, rhythm, and assisted music playing. |

Seven music and rhythm-based tasks were developed, each designed to target specific cognitive domains. Each task is briefly described below, along with the supporting theoretical/empirical basis.

(a) ***Detect the odd:*** This task presents a sequence of frequently and infrequently occurring musical tones, varying in pitch. The patient identifies the target (infrequent) amid the stream of standard stimuli (frequent), with difficulty increasing as pitch differences narrow. Auditory stimuli (with different frequencies for each level) were played on electronic keyboard and recorded over a CM25studio condenser microphone. Each note was recorded separately and saved as .wav files. Recordings were edited to fixed duration of 500ms and consistent loudness was ensured. The stimuli were randomly sequenced to combine frequent and infrequent notes in an 80:20 ratio using the Neuroscan STIM software version 2.2 (for example: Level 1 – Frequent note = C4 on the keyboard (262Hz); Infrequent note = G4 (392Hz)). The inter-stimulus interval was maintained at 1000ms, and the entire block was randomised. Patients were asked to respond to

infrequent tone through tapping with their hand. Therapist noted the omission and commission errors.

This task was designed to target auditory discrimination and sustained attention. Patients are also encouraged to monitor their attentional state and report any distractions. This self-monitoring component promotes metacognitive awareness and supports attentional control.

***(b) Encode and decode:*** This task involves auditory sequences composed of notes varying in their duration (short-S or long-L notes). Each sequence is presented once, and the patient attends, mentally labels the durations and recalls the sequence in order (e.g. SLLS). The difficulty of the task gradually increases with the length of the sequence, from 3 to 8 notes. Feedback is provided during and after the task, and patients were encouraged to monitor the response by mentally repeating the imagined sequence before responding.

**Theoretical rationale:** These tasks draw on auditory perception and discrimination abilities, closely related to basic cognitive functions such as attention and working memory.[35] Tasks involving discriminating and detecting a target auditory stimulus engage both bottom-up and top-down attentional control mechanisms,[44,45] activate the right ventral and dorsal alerting network (attentional set maintenance).[44] The 'detect the odd' and 'encode and decode' tasks were modelled on established attentional and working memory paradigms akin to the oddball paradigm (novelty detection), continuous performance paradigm (sustained attention) and auditory working memory.[45,46]

***(c) Tap-No-Tap & Rhythmic gestures task:*** In the Tap-No-Tap task, the patient initially learns to tap in time, to an isosynchronously occurring beat on the metronome, using specific hand gestures and reciting specific rhythmic syllables known as konnokols/bols in the two traditions of Indian classical Music (ICM)- viz., Carnatic classical tradition and Hindustani classical tradition respectively. The difficulty gradually increases with the introduction of variations in tempo (ranging from 45 to 80 beats per minute), accentuation of beats, skipping of beats (either fixed or randomly selected beats as instructed by the therapist), incorporating rhythm-based motor alternation, and bimanual tapping.

In the rhythmic gestures task, the patient is trained to perform rhythmic gestures (e.g., snapping, clapping) in a structured sequence. The therapist begins by demonstrating a sequence, which the patient observes. As the therapist transitions to the following sequence rhythmically, the patient replicates the previous sequence while observing the current one. The complexity progressively increases, with the therapist providing guidance to help patients adjust their responses as needed. With increasing difficulty, the task involves inverse responses, such as the patient snapping when the therapist claps, and so on. These tasks are designed to target response inhibition, working memory and cognitive flexibility at varied levels. Both tasks incorporate self-monitoring, mental rehearsal and auditory feedback to enhance performance.

**Theoretical rationale:** Rhythm, a core musical element, is linked to temporal processing and cognitive integrity. Rhythmic training engages a wide range of neural areas, particularly the prefrontal cortex, which is involved in higher cognitive functions.[47] Simple and complex rhythmic exercises through the mechanism of 'rhythmic entrainment' – an ability to synchronise our internal rhythm to external rhythmic cues (such as a metronome) are known to engage and activate attentional processes,[35,48] executive processes such as working memory,[49] predictive processing, conflict monitoring, inhibitory control and error correction,[50,51] along with memory.[52] Bimanual rhythmic coordination further enhances these effects, with evidence showing improved executive control when motor demands are distributed bilaterally.[53,54]

In addition, rhythm and speech share common neural and cognitive mechanisms, both relying on temporal and prosodic organisation. Combining rhythmic tapping with vocal syllable articulation like konnokol/bols can increase cognitive load by engaging rhythm, speech and motor coordination simultaneously. These rhythm-based tasks were therefore developed to harness the multimodal engagement, grounded in dynamic attending theory, [55] and modelled by Go-No-Go,[56] and the task switching paradigms.[57]

***(d) Melodic recall task:*** This task was designed to target visuo-spatial learning and memory. The task involves learning and reproducing short melodic lines played by the therapist on a piano app (Impala studios, IOS). Patients learn to play these sequences in chunks and combine them to play the entire melodic line. Following this, word lists are presented using the same melody, and the patient is asked to recall the words on the list, targeting verbal memory. The task becomes progressively more challenging with the increasing length of the rhyme. This task is designed to target learning and memory domains in both verbal and visual modalities. The piano inherently provides augmented auditory feedback, allowing patients to hear themselves play, thereby enabling them to learn through auditory-motor integration. This process also facilitates error detection and correction. Verbal feedback was provided during this learning process. While learning longer sequences, the patients were encouraged to break down the task into steps and navigate through each step. They were

also encouraged to monitor for their errors and use a 'stop-plan-do-check' approach.

**Theoretical rationale:** Playing an instrument is a complex mental activity requiring higher-order temporal and spatial processing, and the ability to sequence and organise information.[58] Piano playing places a greater demand on spatial and temporal reasoning and loads on higher order visual processing, visual attention and spatial organisation. It comprises feedback and feedforward interactions between integrated multisensory input (tactile, auditory, and visual), motor output, and higher-order cognitive functions.[19] This feedback system facilitates monitoring, adjusting and updating;[35] modulating the prefrontal activity implicated in executive functions.[26,27,32,59] It therefore demands working memory, learning, memorisation, and selective attention while inhibiting distractors and attentional switching between different parts of the musical piece.

The task also incorporated a music mnemonics approach to facilitate learning and remembering verbal information. Music, with its innate rhythmic and melodic structure, enables the temporal chunking of information into smaller units, thereby facilitating the deeper encoding of any information. [52,60,61] The music mnemonic approach induces plastic changes characterised by higher synchrony in learning-related networks, producing stable neural traces for long-term memory. [35,37] The melodic recall task was developed by building on these theories and evidence. The structure of these tasks was guided by trial-and-error learning approaches and included strategies such as chunking and music mnemonics.[62]

***(e) Mindful music listening*** (hybrid mode): A slow instrumental musical excerpt using the santoor and bansuri (bamboo flute) was used. The excerpt was approximately 10 minutes in duration and was played in a noise-attenuated room. The music is presented via speakers (2.1 speakers). The patient is encouraged to keep focusing on the music while breathing gently. Patients are encouraged to focus their attention on different elements of music and how music makes their body feel light and relaxed. As their mind wanders, they are encouraged to gently bring their attention back to the music. This task was designed to target focused attention, self-awareness, and emotional regulation. There is no gradation to this task. Self-monitoring and attentional refocusing (the stop-refocus strategy) are two strategies incorporated into this activity.

**Theoretical rationale:** Mindful music listening combines music listening with mindfulness, promoting non-judgmental awareness of moment-by-moment experiences.[63] This approach is known to enhance top-down control of attention (concentrative attention),[64] meta-cognitive control,[65] emotional functioning,[66] and cognitive abilities.[67,68] Research supports the use of slow-tempo, lyric-free instrumental tracks for such interventions.[69] Our mindful music listening task is grounded in the theories of music emotion [70] and principles of mindfulness-based stress reduction (MBSR).[63]

***(f) Song learning*** (home-based): In this task, the patient is asked to learn the tune and lyrics of a self-chosen song at home and present it to the therapist in alternate sessions. At higher levels, the therapist selects a song that suits the patient's preferred genre and language. This task was designed to target learning and memory domains and is not distinctly graded. To enhance cognitive targeting, strategies such as chunking of lyrics to smaller units, use of mental imagery and semantic associations were encouraged.

**Theoretical rationale:** Singing is an engaging activity that works as a mnemonic aid to facilitate learning and memory.[60] Learning a song involves learning a verbal material, incorporating the melodic and rhythmic pattern. The musical and rhythmic structure serves as an encoding and retrieval cue during the learning of a song. Studies reveal its benefits in improving language and cognitive abilities through extensive engagement of bilateral language and cognitive areas.[71]

**3. Expert Validation**

Once the intervention program was developed, it was presented to five experts. Of them, four had expertise and clinical experience in the field of clinical neuropsychology and neuropsychological rehabilitation for more than 20 years. One among the four had additional clinical and research experience in the field of music-cognition and music-based interventions. The fifth expert had more than 5 years of experience in neurorehabilitation along with music cognition research and training in NMT. The developed tasks were presented to the experts to obtain feedback regarding task validity. The experts were asked to rate each task on the following dimensions on a scale of 1 (very poor) –10 (very good):

- The relevance of the task to target cognitive deficits
- Ease of administration
- Ease of understanding instructions
- Gradation of each task across levels (level of task difficulty – easy to difficult)
- Task specificity under varied cognitive domains
- Other suggestions/alternatives overall and specifically to each task level

**Assessment of content validity index (CVI)**

Based on expert ratings of each task dimension, the content validity of the intervention was assessed. For each task dimension, an item-level content validity index (I-CVI) [72] was computed as the proportion of experts rating an item as acceptable (≥8 out of 10).[73] For example, on a particular task (e.g., detect the odd), if 4 of the 5 experts give a score of ≥8 on the dimension – 'relevance of the task to target cognitive deficits' – the I-CVI was calculated as: I-CVI = (4/5) = 0.80. Similarly, I-CVIs for all seven tasks and the four dimensions on which experts rated were calculated (Table 2). The task items with I-CVIs less than 0.80 were identified requiring modification through the incorporation of qualitative feedback from experts.

After calculating I-CVIs, a scale-level content validity index (S-CVI) was computed as the average of I-CVIs across all tasks. An S-CVI of ≥0.90 was considered to have excellent content validity, [72] and a score between 0.80 and 0.89 was considered acceptable with modification.

**Table 2.** *Item-level and Scale-level CVI of the preliminary version of CogniTune*

| | Relevance in targeting cognitive deficits | Ease of administration | Ease of Understanding instructions | Quality of task-graded |
|---|---|---|---|---|
| Detect the odd | 1 | 1 | 1 | 0.80 |
| Encode and decode | 1 | 0.80 | 1 | 1 |
| Tap-No-Tap | 1 | 1 | 0.80 | 0.80 |
| Rhythmic gestures | 1 | 0.40 | 0.60 | 0.60 |
| Melodic recall | 1 | 0.80 | 1 | 0.60 |
| Learn a song | 0.60 | 1 | 1 | No gradation |
| Mindful music listening | 0.80 | 1 | 0.80 | No gradation |
| **Scale-level content validity index (S-CVI) (Average score of all I-CVIs)** | **0.86** | | | |

Table 2 shows the I-CVIs and S-CVIs of the newly developed intervention. A careful analysis of the table reveals that, of the 26 items (7 tasks × 4 task dimensions excluding gradation for the two ungraded tasks), 14 items had an I-CVI of 1.00, indicating complete agreement among experts. 07 items had an I-CVI of 0.80, indicating acceptable agreement (4 of 5 experts rated ≥8). However, 04 items had an I-CVI of 6 or below, requiring modification. The overall CVI (S-CVI) of the intervention was 0.86, suggesting a scope for some modification.

Each of the developed tasks targeted specific cognitive functions, namely attention, executive functions, learning and memory as rated by the experts (Table 3 on appendix). The song learning task was rated low on its relevance in treating cognitive deficits (I-CVI=0.6). Two of the five experts highlighted the 'non-specific/broad nature of the task' as reason for lower scores. However, experts suggested to retain this task as a multidomain activity due to its ecological validity and also to consider it primarily as home-based activity in order to promote continued engagement outside structured sessions

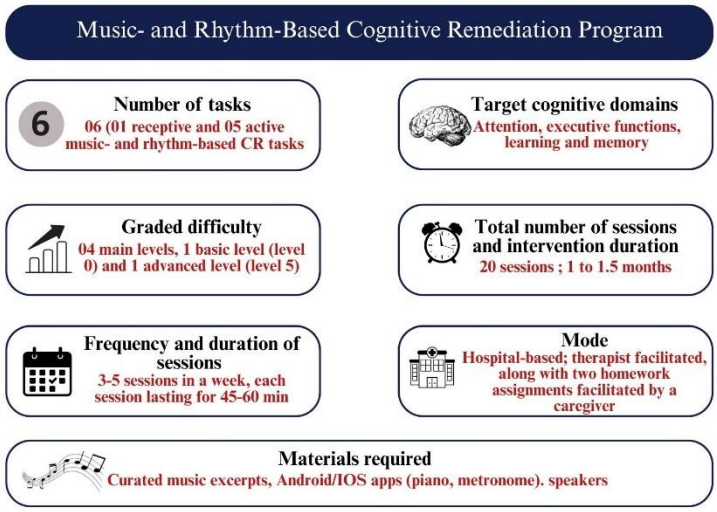
The 'Rhythmic gestures task' received lower scores across dimensions and experts highlighted challenges administering the task, difficulties in replicating and unclear gradation. Experts also highlighted certain overlaps in components between tap-no-tap and rhythmic gestures task, and suggested integrating them to single task. In view of this, rhythmic gestures task was removed.

Other changes to module included – (a) introducing sublevels to facilitate smoother gradation, (b) introducing 2 more levels – level 0 (basic level) and level 5 (advanced level) to cater to those with a range of deficits.

**4. Final program structure, delivery format and content**

The experts' feedback was incorporated into the intervention structure. Figure 1 shows the final structure and delivery format of the intervention.

**Figure 1:** *Overview of the Music and Rhythm-based Cognitive Remediation Program*



The final intervention comprised 6 tasks, of which 5 are active music and rhythm-based tasks and one is a receptive task. The total number of sessions are 20, with frequency of 3-5 sessions in a week. The tasks were hierarchically organized in a total of 6 levels: 1 basic level (level 0), 4 main levels (levels 1-4) and 1 advanced level (level 5). All patients start at level 1 and move higher up after achieving 80% accuracy or as evaluated by the researcher. Those showing difficulties comprehending or carrying out level 1, start from level 0. Patients who complete level 4 prior to 20 sessions, will enter the advanced level. Sessions were designed to be hospital-based and actively facilitated by the therapist, with two homework assignments to be facilitated by caregiver.

**5. Pilot testing (exploratory aim)**

Preliminary pilot testing was carried out between the years 2022-2023, using the final version of the intervention program.

***Sample:*** The sample included 5 patients, diagnosed with TBI of any severity, recruited using a convenience sampling method from outpatient services from the neurosurgery department and the clinical neuropsychology unit in a tertiary mental health and neuroscience institute.

***Inclusion and exclusion criteria:*** Patients aged between 18-50 years, with functional reading and writing skills and normal hearing were included. Patients were excluded if they were in the acute phase of injury (i.e., less than 3 months post-injury), had any comorbid neurodevelopmental, neurological, or psychiatric disorders, had complete vision loss, or had received formal training in music or dance for two years or more.

Pilot testing aimed to (1) obtain feedback and evaluate challenges in carrying out these tasks, (2) assess the difficulty level of these tasks, and (3) assess the potential efficacy of the intervention.

***Tools:*** The primary outcome measures included selected cognitive assessments from standardised neuropsychological test batteries [74,75] (Table 4). Secondary outcome measures included quality of life, as assessed by the Quality of Life after Brain Injury scale (QOLBRI) [76], and mood states, as measured by the Hospital Anxiety and Depression Scale (HADS).[77] Additionally, a visual analogue scale (VAS) was used to obtain ratings from caregivers on the patient's overall functioning.

**Table 4.** *List of cognitive assessments used in the study.*

| Cognitive functions | Tests |
|---|---|
| Focused attention and cognitive flexibility | Color Trails Test 1 & 2 (CT1 & CT2) [78] |
| Sustained attention | Digit vigilance test (DVT) [79] |
| Working memory | Digit span (DS) and Spatial span tests (SS) [75] |
| Response inhibition | Stroop Color-Word Test [80] |
| Fluency | Controlled oral word association test [81] |
| | Animal Names Test [74] |
| Learning and memory | Rey's Auditory verbal learning test (RAVLT); |
| | Rey's Complex figure test (CFT) [82,83] |

***Procedure:*** The intervention was carried out with all the recruited patients by the author PAR. Patients meeting the set inclusion and exclusion criteria were recruited after obtaining written informed consent. Baseline assessments were conducted using the tools described in Table 4. The time required to complete assessments on a patient was about 1.5 hours and were carried out in one or two sessions based on patient's convenience. Short breaks were provided when required to be sure that fatigue did not interfere with the observed findings.

The baseline assessments were followed by 20 sessions of CogniTune as per the study procedure. The intervention was conducted in a sound-attenuated room with each patient, using speakers set to a volume comfortable for the patient. In addition to sessions with the therapist, participants were encouraged to practice a mindful music listening task and learn the chosen song in chunks at home, presenting it to the therapist during the sessions. The therapist reviewed homework adherence, documented by the caregivers/patients themselves, after every 5 sessions. Post assessments were carried out after completion of 20 sessions of CogniTune. Feedback was collected from patients at the end of the intervention.

The caregivers were also asked to provide feedback on the usefulness of the intervention in improving cognitive and behavioural disturbances listed by them before the intervention, on a visual analogue scale. The caregivers were asked to list the difficulties and rate them on a scale of 1 to 10. In addition, they were asked to rate the overall functionality on a scale of 1-100 (higher the score, better the functionality).

## Results

The results from the pilot testing are presented below (table 5 and 6 can be found at the appendix).

The socio-demographic characteristics of patients are depicted in Table 5. The raw scores on cognitive tests (primary outcome measures) were converted to z-scores using means and standard deviations from age, gender and education-appropriate normative samples[74], except for the Stroop-Color Word test for which normative data were unavailable. Mean z-scores were derived from individual z-scores for each measure, allowing comparison of patient performance with normative expectations. For secondary outcome measures, the average raw scores were compared between the time points. Given that this was a pilot testing with a sample size, formal inferential statistical analysis was not performed and findings are reported as descriptive trends for clinical relevance.

At baseline, widespread cognitive deficits were observed. Learning and memory (AVLT trial 5, AVLT total, immediate recall (IR), delayed recall (DR), CFT IR and DR) were most affected (z score <-2SD) followed by difficulties in focussed and sustained attention, attentional switch and fluency.

Pre-post comparisons showed directional trends towards improvement across most cognitive domains except in the domains of digit vigilance (time score) and CFT copy score (visuo-spatial construction) (Table 6). Trends towards improvement were also observed across quality of life domains, mood, anxiety and caregiver's rating of overall functionality.

**Summary of feedback from patients about the newly developed intervention.**

Figure 2 (see appendix) shows the quantitative feedback from the pilot patients (mean scores). Overall feedback from patients indicated ease of understanding instructions across all tasks. The highest degree of engagement was reported for the 'melodic recall' and 'tap-no-tap' tasks. Melodic recall tasks were identified as the most challenging task. On exploring the usefulness of these tasks as CR tasks, Tap-no-Tap was rated most useful and cognitively loaded among other tasks.

After the completion of the intervention, patients were asked to rate their overall experience. The average rating of the intervention experience was given as 8.5. Qualitative feedback from patients indicated that the intervention was overall engaging, interesting, and helpful.

On the Visual Analogue Scale, the most common concerns highlighted by caregivers prior to intervention were forgetfulness (5 out of 5), anger (4 out of 5), lack of self-initiation and motivation (4 out of 5), and poor concentration (3 out of 5). Post-intervention, the primary areas of improvement reported by carers were reduced anger, increased activity, self-initiation and better concentration. There was also an improvement in overall functionality, as reported by the informants, on the VAS (Table 6).

The authors would like to underscore that both the quantitative and qualitative findings of the present study are only preliminary and exploratory in nature requiring cautioned interpretation, given smaller sample size and lack of control group.

## Discussion

The current study primarily aimed to develop CogniTune, a novel music- and rhythm-based cognitive remediation program for patients with TBI. The final CR program includes one receptive and five active, hierarchically organised music-based cognitive exercises targeting attention, executive functions, learning and memory, which form the core cognitive deficits in the TBI population. [84,85]

**Approach and process of intervention development:** The intervention development process followed a structured approach according to the MRC framework.[42] The design of CogniTune was rooted in the principles of neural plasticity and informed by cognitive theories, frameworks of cognitive rehabilitation, clinical neuropsychology and cognitive neuroscience literature. The integration of music and its elements into CR was driven by theoretical and empirical evidence from music therapy and neuroscience, similar to the models of NMT.[35] Consistent with RSMM and TDM, initial steps involved identifying relevant musical elements and exploring their relationship with cognition (e.g., rhythm with cognition). This was followed by evaluating whether these elements can mediate non-musical cognitive domains. Further, specific cognitive functions were identified, relevant non-musical cognitive paradigms were reviewed and integrated into music based exercises. For example, rhythm, a core component of current interventions, is linked to cognitive functions such as attention, executive functions, and memory through motor-cognitive coupling and the activation of attentional and cognitive control networks.[31,51] A careful review of cognitive constructs and standard paradigms exploring cognitive processes (e.g., task-switching paradigms, odd-ball paradigm, etc.) helped integrate rhythm into specific cognitive outcomes (e.g., inhibition, attentional switch). A similar approach was consistently applied to ensure alignment between music-based task design and the target cognitive outcomes. This approach allowed a structured integration of theory and practice, ensuring alignment between musical task and target cognitive domains.

The intervention was conceptualized as a predominantly restorative program, employing hierarchical, structured exercises targeting cognitive domains through repeated practice. In addition, the intervention was augmented by internal compensatory strategies such as chunking, semantic associations, mental imagery and melodic scaffolding. Metacognitive elements such as monitoring, self-guidance and regulation were also incorporated to facilitate better awareness and cognitive regulation.

The involvement of experts and a preliminary pilot phase helped refine the intervention at multiple levels, making the intervention development process more dynamic. The preliminary pilot phase also provided preliminary support for the feasibility of the intervention. All five patients in the pilot phase completed the intervention without attrition, and a preliminary pre-post comparison on cognitive measures also indicated trends towards improvement in various domains. This pilot study revealed that the intervention holds promise for carrying out further studies on a larger sample.

**Format, Structure, and Delivery of Intervention:** The final intervention aligns with the framework of a multi-component-based music intervention, comprising a combination of rhythm, instrument, and listening-based tasks.[24] Use of rhythm and assisted instrument playing is consistent with the recent INCOG guidelines for executive function rehabilitation.[13] Overall, the intervention employed a multisensory approach (integrating auditory, visual, motor, tactile, and emotional processes), an integrative approach (combining restorative, internal compensatory and meta-cognitive strategies), and multifactorial training aspects (targeting multiple cognitive factors), which is known to be more effective.[2,86]

With respect to the structure and delivery of the intervention, the hierarchical organization of tasks, which is a central feature of most CR modules, enhances the flexibility of intervention delivery based on the cognitive status of participants. Furthermore, the active presence of the therapist and joint music activities in our intervention facilitates communication and alliance building, which are essential to the outcomes of CR.

The intervention task stimuli were readily available, including researcher-developed materials and freely accessible apps and music excerpts, which supported the affordability of resources. The intervention tasks were intentionally designed to be implementable by trained neuropsychologists with very minimal or no formal music training, in order to enhance clinical scalability. However, the feasibility of such delivery across diverse clinical settings warrants further empirical evaluation.

The delivery schedule of the intervention (high intensity and moderate duration) was also consistent with the recommendations.[2] Our intervention was primarily delivered at a hospital setup (in person). A hospital-based intervention carries certain advantages, such as close monitoring of changes and challenges, the physical presence and active engagement of the therapist, which is quite crucial in cases of severe TBI. Low digital literacy, limited access to technology, greater severity of cognitive deficits, and poor knowledge about TBI among the general population, can pose challenges in implementing home-based or computer-based interventions are often seen barriers in our settings.[87] In addition, given the novel nature of the intervention an in-person delivery of the intervention was imperative. Overall, the newly developed intervention involves a hierarchical organisation of tasks, motivational engagement, novel stimuli, a multi-factorial approach and multi-sensory integration, which could be essential variables in an optimally designed CR program.[58]

As part of an ongoing larger study, preliminary efficacy testing in small sample showed potential trends towards improvements in most of the cognitive measures except DVT (time score) and complex figure copy scores. Negative direction of change in time scores accompanied by positive direction of change in error scores of DVT (reduced errors at post assessment) may reflect a possible shift in the speed-accuracy trade-off, with better prioritisation of accuracy over speed and attentional monitoring. With regard to CFT copy, the marginal decline (Median 35→33) may be attributed to near-ceiling baseline score (35/36), where sensitivity to change will be limited and minor attentional fluctuations during testing may explain the small score variations. However, reliable interpretations of both improvements and declines may not be possible at this point and requires study with larger cohort. Also, given the primary aim of study to develop the intervention, the outcomes were described only as raw score changes and median z-scores. We acknowledge that the absence of variability measures affects the accuracy of these interpretations and does not account for measurement error or inter-individual variability.

## Limitations

The present study has a few key limitations. Although the intervention was developed using a theory- and evidence-driven approach, the current findings are exploratory and not conclusive. Further research with larger samples, active control groups and robust designs is necessary to establish the efficacy and broader applicability.

There were several confounding factors including varied duration since injury, possible spontaneous recovery, practice effects due to repeated cognitive testing and socio-

demographic variability were not examined and may have influenced the results.

Treatment fidelity was not formally evaluated in the present pilot study. Future studies should incorporate systematic monitoring of fidelity through session checklists, documentations and expert review.

## Implications and future direction

This novel approach to CR can act as an alternative approach to making CR interventions that treat varying levels of cognitive disturbances, and a broad scope exists in implementing the intervention in other cognitive disorders through some modifications suiting the population. A large-scale empirical validation of the intervention is needed to establish its efficacy. There is a broad scope for translating CogniTune into an app-based or computerised version, which would offer a better opportunity to deliver this intervention online.

## Conclusion

The music- and rhythm- based CR program (CogniTune) was developed systematically, backed by empirical evidence and theoretical frameworks of cognitive rehabilitation, music and cognitive neuroscience. Pilot testing supports its feasibility and acceptability, with positive participant feedback. Preliminary findings also suggest potential efficacy to ameliorate cognitive deficits in individuals with TBI. While preliminary support and feasibility are observed, a larger sample with an active control group and robust statistical analyses is required to generalise these findings, and we are working towards this goal by carrying out study on a larger sample with a quasi-randomised control group design.

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## Appendix

**Table 3.** *Expert opinions on the cognitive specificity of each task.*

| Cognitive domains | Focused attention | Sus-tained atten-tion | Atten-tional switch/ cognitive flexibility | Working memory | Response inhibition | Learning and memory | Mood |
|---|---|---|---|---|---|---|---|
| Detect the odd | | ✓ | | | | | |
| Encode and decode | ✓ | | | ✓ | | | |
| Tap-No-Tap | ✓ | | ✓ | | ✓ | | |
| Rhythmic gestures task | | | ✓ | | ✓ | | |
| Melodic recall task | ✓ | | | ✓ | | ✓ | |
| Learn a song | ✓ | | | ✓ | | ✓ | |
| Mindful music listening | ✓ | | | | | | ✓ |

**Table 5.** *Socio-demographic and clinical details of pilot patients (n=5)*

| | | Patient 1 | Patient 2 | Patient 3 | Patient 4 | Patient 5 |
|---|---|---|---|---|---|---|
| Socio-demographic details | Age/Sex | 31/M | 26/M | 19/M | 34/M | 26/F |
| | Years of formal education | 13 | 12 | 12 | 15 | 17 |
| | Occupation before injury | Student | NGE | Student | Engineer | Accounts manager |
| | Current occupation | | | NGE | | |
| | Severity of TBI (as on Glasgow coma scale score) | $E_1V_tM_3$ Severe | $E_1V_tM_5$ Severe | $E_2V_4M_5$ Moderate | $E_1V_tM_4$ Severe | $E_1V_1M_4$ Severe |
| | Duration since injury (in months) | 24 | 34 | 6 | 43 | 5 |
| Clinical details | Cause of injury | RTA | RTA | RTA | RTA | RTA |
| | Surgical intervention (craniotomy or decompressive craniectomy) | Yes | No | No | No | No |

*RTA: Road Traffic Accident; EVM: Eye, verbal and motor response; $V_t$: Intubated; NGE: Not in gainful employment.*

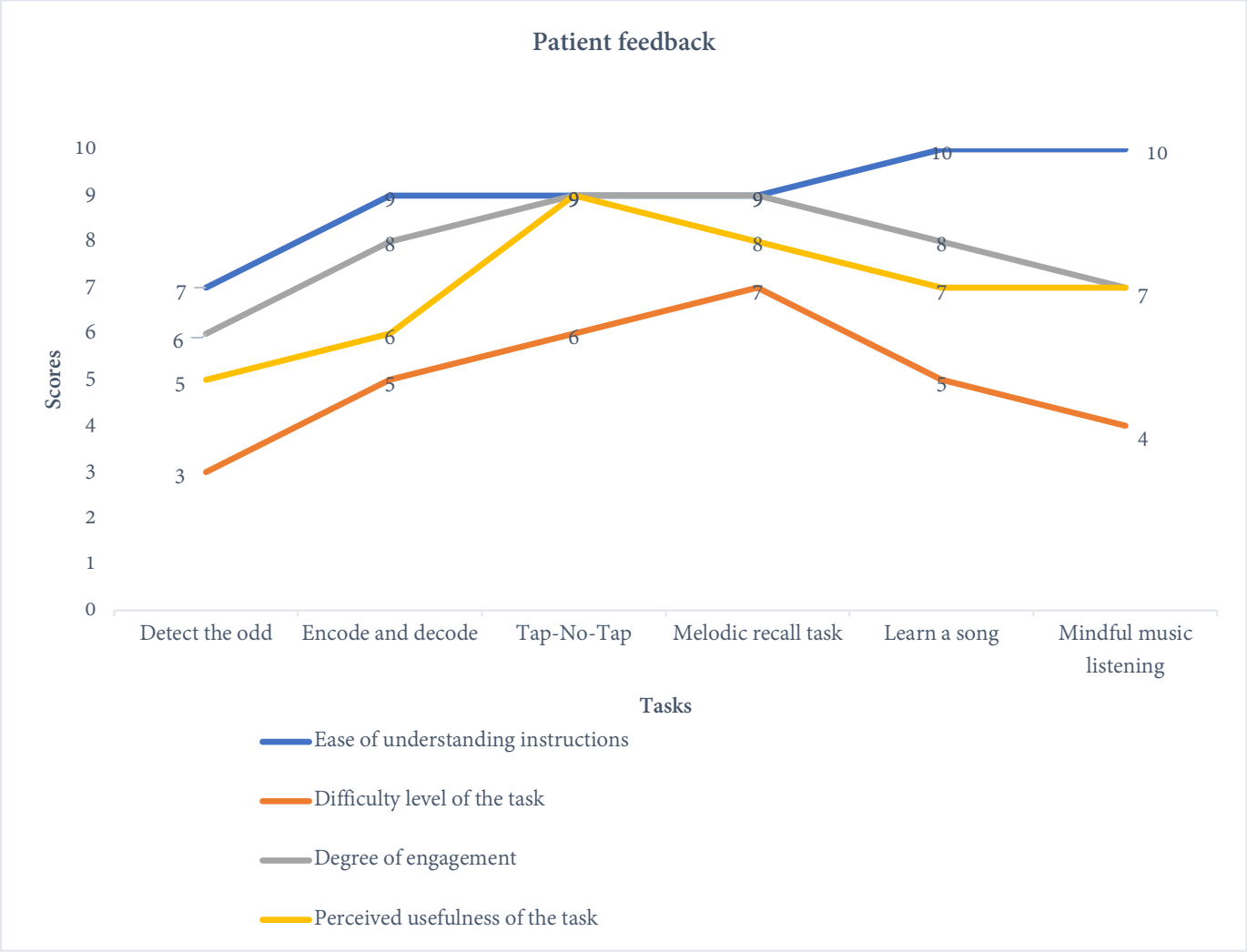
**Table 6.** Pre-post intervention changes on the outcome measures among pilot participants (n=05)

| **Cognitive test** | **Variable** | **Pre-intervention** *Median (Range) Mean z-scores* | **Post-intervention** *Median (Range) Mean z-scores* | **Direction of changes observed** |
|---|---|---|---|---|
| Color trails 1 | *Time (s)* | 68 (58–88)<br>-2.84 | 58 (40–70)<br>-0.95 | ↑improved |
| Color trails 2 | *Time (s)* | 163(118–287)<br>-1.60 | 148(104–196)<br>-0.95 | ↑ improved |
| Digit vigilance | *Time (s)* | 411 (396–978)<br>0.45 | 558 (407–898)<br>-0.87 | ↓worsened |
| | *Errors* | 30 (2–51)<br>-2.97 | 4 (3–5)<br>0.44 | ↑improved |
| ANT | *Total score* | 9 (3–17)<br>-1.47 | 14 (4–19)<br>-0.45 | ↑ improved |
| COWA | *Total score* | 4.6 (2–9.3)<br>-2.34 | 6.3 (4-11)<br>-1.89 | ↑ improved |
| Stroop-Color Word Test | *Interference score* | −3.66 (−6.24–10.1) | 1.07 (−1.67–12.9) | ↑ improved |
| Digit span | *Total score* | 13 (07-18)<br>-0.64 | 17 (9–22)<br>-0.10 | ↑ improved |
| Spatial span | *Total score* | 14 (11–19)<br>-0.45 | 17 (12–24)<br>-0.03 | ↑ improved |
| AVLT | *Trial 1* | 6 (4–9)<br>-0.56 | 8 (4–15)<br>0.34 | ↑ improved |
| | *Trial 5* | 9 (1–15)<br>-3.20 | 13 (8–15)<br>0.12 | ↑ improved |
| | *Total* | 36 (21–65)<br>-3.01 | 54 (51–75)<br>-0.25 | ↑ improved |
| | *Immediate recall(IR)* | 6 (4–15)<br>-4.26 | 12 (8–15)<br>-0.21 | ↑ improved |
| | *Delayed recall (DR)* | 4 (1–15)<br>-4.28 | 10 (8–15)<br>-1.25 | ↑ improved |
| CFT | *Copy score* | 35 (14.5–35)<br>-1.53 | 33 (31–35)<br>-2.98 | ↓ worsened |
| | *Immediate recall* | 4 (3.5–15)<br>-3.79 | 12.75(5–20.5)<br>-3.76 | No change |
| | *Delayed recall* | 4 (2–11)<br>-4.11 | 13 (5–24.5)<br>-3.75 | ↑ improved |
| Secondary Outcome Measures | | | | |
| **Tools/Scales** | **Variable** | **Pre-intervention** *Median (Range)* | **Post-intervention** *Median (Range)* | **Direction** |
| QoLBRI | *Cognition* | 35.5 (21.3–60) | 70 (57–82) | ↑ improved |
| | *Self* | 28.5 (10.5–71.3) | 57 (39.3–82) | ↑ improved |
| | *Daily life & autonomy* | 25 (3.5–53.5) | 35 (3.5–82.5) | ↑ improved |
| | *Social relationships* | 55 (15–70.8) | 75 (56–90) | ↑ improved |
| | *Emotion* | 40 (10–80) | 65 (20–75) | ↑ improved |
| | *Physical problems* | 35 (20–80) | 40 (30–90) | ↑ improved |
| HADS | *Depression* | 11 (3–17) | 5 (4–8) | ↓ improved |
| | *Anxiety* | 7 (1–15) | 5 (2–7) | ↓ improved |
| VAS | *Overall functionality* | 40 | 65 | ↑ improved |

*AVLT = Auditory Verbal Learning Test; CFT = Complex Figure Test; COWAT = Controlled Oral Word Association Test; ANT = Animal Naming Test; DVT = Digit Vigilance Test; HADS = Hospital Anxiety and Depression Scale; QoLBRI = Quality of Life after Brain Injury;*

*VAS = Visual Analogue Scale. For time-based measures (Color Trails I & II, DVT time), lower post-intervention scores indicate improvement. No inferential statistics were computed given the exploratory nature of the pilot and sample size (n = 5).*
*Note: Stroop test and secondary outcome measures are reported as raw scores only; normative data were unavailable for z-score conversion.*

**Figure 2.** Quantitative feedback from patients on different dimensions (on a scale of 10)



**Supplementary Table 1.** *Reporting Guidelines for Music-based Interventions Checklist*[43]

| Sl No | Item | Adherence | Details and Location |
|---|---|---|---|
| 1 | Brief Name or Phrase describing the intervention | ✓ | CogniTune (Music and rhythm-based Cognitive Remediation Program) |
| 2 | Intervention theory and/or scientific rationale. (description of the process in which features of music and music experiences are expected to influence targeted outcomes) | ✓ | Detailed in page numbers – 193,194 & 195 |
| 3 | Intervention Content (Music selection, details about the music attributes, music delivery method, materials and intervention strategies) | ✓ | Detailed in page numbers – 193,194,195 & 197 |
| 4 | Interventionist | ✓ | PAR, the first Author, carried out the intervention. |
| 5 | Individual or Group Intervention | ✓ | Individual intervention |
| 6 | Setting – Location, privacy, ambient sound and/or any other factors affecting the experiences of the participant | ✓ | Detailed in page number 197, under the 'procedure section' |
| 7 | Intervention delivery schedule (Frequency, session length, time interval between sessions, total number of sessions, homework assignments) | ✓ | As detailed in Figure 1 |
| 8 | Treatment fidelity (strategies used to ensure the intervention was delivered as intended). | Not formally evaluated at this preliminary development stage. | |