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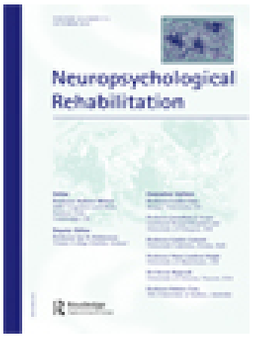
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Effects of neurological music therapy on behavioural and emotional recovery after traumatic brain injury: A randomized controlled cross-over trial

Sini-Tuuli Siponkoski [a], Sanna Koskinen [b], Sari Laitinen[c], Milla Holma[d], Mirja Ahlfors[e], Päivi Jordan-Kilkki[f], Katja Ala-Kauhaluoma[g], Noelia Martínez-Molina[a], Susanna Melkas[h], Matti Laine[i], Aarne Ylinen[h,j,k], Nathan Zasler[l], Pekka Rantanen[m,n], Jari Lipsanen[b] and Teppo Särkämö[a]

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ABSTRACT

Traumatic brain injury (TBI) causes deficits in executive function (EF), as well as problems in behavioural and emotional self-regulation. Neurological music therapy may aid these aspects of recovery. We performed a cross-over randomized controlled trial where 40 persons with moderate-severe TBI received a 3-month neurological music therapy intervention (2 times/week, 60 min/session), either during the first (AB, $n = 20$) or second (BA, $n = 20$) half of a 6-month follow-up period. The evidence from this RCT previously demonstrated that music therapy enhanced general EF and set shifting. In the current study, outcome was assessed with self-report and caregiver-report questionnaires performed at baseline, 3-month, 6-month, and 18-month stages. The results showed that the self-reported Behavioural Regulation Index of the Behaviour Rating Inventory of Executive Function (BRIEF-A) improved more in the AB than BA group from baseline to 3-month stage and the effect was maintained in the 6-month follow-up. No changes in mood or quality of life questionnaires were observed. However, a qualitative content analysis of the feedback revealed that many participants experienced

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Traumatic brain injury; Music therapy; Randomized controlled trial; Executive functioning; Behavioural regulation

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the intervention as helpful in terms of emotional well-being and activity. Our results suggest that music therapy has a positive effect on everyday behavioural regulation skills after TBI.

Introduction

Traumatic brain injury (TBI) is a major health problem affecting over 50 million people annually worldwide (Maas et al., 2017). Typically, TBI causes disability in cognitive, social and emotional functioning (Dikmen et al., 2009; Hoofien et al., 2001; Langlois et al., 2006). These aspects are in fact closely intertwined with each other (Wood & Worthington, 2017). Frontal lesions and diffuse axonal injuries caused by TBI typically give rise to disruptions in executive functions (EF) (Kinnunen et al., 2011; Sharp et al., 2014), which is a broad term referring to high-level cognitive processes guiding goal-directed behaviour (Banich, 2009). There is no consensus of the exact definition of EF, and many different models of EF have been proposed (Cicerone et al., 2006; Miyake et al., 2000; Stuss, 2011). The model of Miyake et al. (2000), which identifies inhibition, task switching and working memory updating as key components of EF, has been widely adopted (Miyake et al., 2000). Additionally, a broader view integrating the regulation of emotions and social behaviour into the concept of EF has been suggested (Chan et al., 2008). According to this view, EF is divided into so-called "hot" elements including for example experiences of reward and punishment, and decision making involving emotional and personal interpretation, and more traditional "cold" elements, which cover purely cognitive processes, such as planning and problem solving (Chan et al., 2008). Overall, EF seems to be central in integrating and appraising the environment in terms of cognitive, emotional and social significance (Wood & Worthington, 2017). This is why rehabilitation targeted on EF could potentially have an effect on social and emotional recovery after TBI as well. Furthermore, mood disorders, which are common after TBI, have a complex etiology linked to biological alterations in the brain's functioning, psychosocial changes, and cognitive functioning (Jorge et al., 1993; Jorge & Robinson, 2003; Spitz et al., 2017). Interestingly, it has been suggested that different coping strategies applied by persons with TBI may be modulated by their EF skills (Krpan et al., 2007). This view emphasizes the importance of supporting cognitive recovery in treating and preventing emotional problems.

Considering the significant burden caused by TBI on an individual as well as on a societal level, new effective rehabilitation methods are sorely needed. Music is a very promising rehabilitation tool in the way that it combines cognitive, emotional, and social elements in a unique fashion. Music has the ability to engage the brain's reward system, which is of high importance in persons with

TBI, considering that problems of initiation and motivation are often linked to the injury (Blood & Zatorre, 2001; Koelsch, 2014; Marin & Wilkosz, 2005; Zatorre & Salimpoor, 2013) Music-based interventions have previously shown to enhance mood and quality of life (QoL) in patients with neurological disorders (Raglio et al., 2015; Sarkamo et al., 2008). The evidence supporting the positive effects of music on cognitive functions continues to accumulate; for example daily music listening can enhance attention and verbal memory after stroke (Sarkamo et al., 2008). Importantly, musical activities, such as instrument playing and musical improvization, have been associated with enhanced executive functioning in both healthy individuals and clinical populations, although more evidence is still needed to confirm these observations and to uncover the exact mechanisms behind them (Koshimori & Thaut, 2019).

To date, most of the music intervention studies conducted with neurological patients have concentrated on other patient groups, particularly stroke (Magee et al., 2017). The effects of music-based interventions after TBI have been largely unexplored and the use of controlled research paradigms has been rare. Positive results from music-based interventions in early stages of recovery after TBI, supporting awareness, arousal and decreasing agitation, have been reported (Baker, 2001; Formisano et al., 2001; Froutan et al., 2020) Only few studies have evaluated the efficacy of music therapy on cognitive recovery using a pure sample of TBI patients. Thaut and colleagues reported positive intervention effects of neurologic music therapy (NMT) on EF (mental flexibility) in a quasi-experimental study ($n = 31$). (Thaut et al., 2009). Lynch and LaGlasse conducted a small scale feasibility study on Musical Executive Function Training (MEFT) on EF in persons with brain injury ($n = 14$) (Lynch & LaGasse, 2016). A trend toward enhancement of mental flexibility was detected, although these findings were not significant. In a more recent study, Vik et al. reported results from a piano training intervention on persons with mild TBI ($n = 7$) (Vik et al., 2018). They found improvement in verbal memory performance after the intervention, both in persons with TBI and healthy participants who received the same intervention ($n = 11$) compared to healthy controls ($n = 12$). The Cochrane review on music interventions for acquired brain injury (Magee et al., 2017) additionally mention two small-scale randomized controlled trials by Pool (2012) and Mueller (2013) with acquired brain injury samples, including also participants with TBI. The study of Mueller exploring the effect of NMT on endogenous task shifting ($n = 15$) resulted in inconclusive results. Pool found positive effects of NMT on sustained attention, memory recall as well as emotional functioning ($n = 10$). All the studies mentioned above relied on neuropsychological test performance to demonstrate the cognitive effects of music therapy. Therefore, a complementary, more ecologically valid assessment of intervention effects at the level of daily living is still lacking (Gioia & Isquith, 2004).

There are some studies mapping the effects of music on emotional wellbeing, QoL, and social functioning after TBI. However, the sample sizes are relatively small and no randomized controlled trials (RCT) targeted at TBI population alone have been reported. The studies focusing on the effects of music based interventions exclusively on TBI, all report some positive effects on mood and emotional well-being: Thaut et al. reported positive effects of NMT on self-reported mood and self-efficacy ($n = 31$) (Thaut et al., 2009), Guetin et al. found significant short-term improvement in mood and reduction in anxiety and depression symptoms followed by individual music therapy in institutionalized persons with TBI ($n = 13$), (Guetin et al., 2009) and Baker et al. ($n = 4$) described positive long-term changes in various mood states after a song-singing programme (Baker et al., 2005; Baker & Wigram, 2004).

Studies using heterogeneous samples have revealed a similar pattern of results. Baker et al. (2019) (*RCT with acquired brain injury or spinal cord injury,* $n = 47$) found that song writing intervention improved significantly life satisfaction (Baker et al., 2019), and their earlier study (Baker et al., 2015) (*acquired brain injury including TBI or spinal cord injury,* $n = 10$) suggested that song-writing programme could support emotional adjustment after injury. (Baker et al., 2015) Nayak et al. (*stroke and TBI,* $n = 18$) reported a trend towards improvement in self- and family-reported mood following a music therapy intervention in acute rehabilitation setting (Nayak et al., 2000). Furthermore, the intervention group showed a significant improvement in the family members' assessment of the participants' social interaction. Magee et al. (*TBI, multiple sclerosis, stroke or anoxia,* $n = 14$) reported significant difference in pre- and post-music therapy intervention regarding various mood states (*composed-anxious, energetic-tired, agreeable-hostile*) in a single-subject design (Magee & Davidson, 2002) and Pool (*TBI and stroke,* $n = 10$) also found significant effect of NMT on various emotional needs including needs of feeling confident, productive/useful, supportive, valued, feeling part of a group and enjoyment (Pool, 2012). Roddy et al. (*TBI and stroke,* $n = 5$) have further explored the feasibility of song-writing intervention with neurological patients in a descriptive case series study (Roddy et al., 2020).

All in all, the results from previous studies suggest that music could support both cognitive recovery, social functioning, and emotional adjustment after TBI. However, the evidence is limited by the lack of RCTs and the fact that most studies have been conducted using small and often heterogeneous samples, including also other types of brain injuries than TBI. This is understandable considering the challenges in recruiting study participants. Nevertheless, a more detailed picture of the efficacy of music-based interventions after TBI is clearly needed. The characteristics of both the injury and sociodemographic variables are different between for example survivors of stroke and persons with TBI. Therefore, the circumstances and goals of the rehabilitation also differ from each other. TBI often leads to life-long disabilities in young

people, causing considerable challenges in their daily lives and affecting their personal and vocational choices. When evaluating the effects of the treatment, a multilevel approach should be adopted, assessing cognitive recovery, and functioning on the level of daily life and social activities, in addition to emotional adjustment. Furthermore, aside from using objective measures to evaluate the person's level of functioning, it is paramount to also explore subjective rehabilitation experiences. This can lead to a better understanding of motivational factors that enhance engagement and the rehabilitation process as a result (Prigatano, 2011; Teasdale et al., 1997). Additionally, different approaches of music-based interventions have been applied, some of which are more oriented toward cognitive rehabilitation, while other have a heavy emphasis on emotional adjustment.

In our previous study, we reported findings from the first randomized controlled trial (RCT) exploring the effectiveness of neurological music therapy after TBI (Siponkoski et al., 2020). For the purpose of this study we developed a new form of music therapy specially designed to meet the needs of TBI patients, with main focus on training of executive function and attention. We use the term neurological music therapy to describe this approach focusing on supporting neurological and cognitive recovery after TBI, as a distinction from other types of music therapy that might focus more on for example emotional aspects. We used a cross-over design (AB/BA) where persons with moderate-severe TBI ($n = 40$) received individual neurological music therapy twice a week for a 3-month period; AB received the intervention during the first 3-month follow-up period and BA during the last follow-up period. The intervention was specifically designed to improve EF and attention. Additionally, elements supporting emotional wellbeing and adjustment were included. In neuropsychological test performance, we found that the general EF (measured by the Frontal Assessment Battery) and set shifting ability (measured by the Number-Letter Task) improved in the intervention group (AB) compared to the control group (BA) during the first 3-month follow-up period (Siponkoski et al., 2020). The effect on general EF was maintained over the 6-month follow-up (Siponkoski et al., 2020). Additionally, voxel-based morphometry (VBM) results revealed that grey matter volume (GVM) in the right inferior frontal gyrus (IFG) increased significantly in both groups during the intervention versus control period and correlated with improvement in set shifting (Siponkoski et al., 2020).

In the current study, we used the same sample as in the previous study (Siponkoski et al., 2020) and aimed to determine the effects of neurological music therapy on everyday cognitive and emotional functioning as indicated by self-report and caregiver-report questionnaires on executive dysfunction, depression, and QoL. Moreover, we obtained subjective quantitative and qualitative feedback from the persons with TBI and their caregivers regarding their experience of the music therapy intervention. Thus, in an effort to improve

the ecological validity of the findings, the general aim of the study was to determine if the benefits of the music therapy intervention extended beyond gains in EF performance and linked structural neuroplasticity (Siponkoski et al., 2020) to better cognitive and emotional functioning in daily life. As the focus of the intervention and previous cognitive findings were in the domain of EF, we hypothesized that music therapy would lead to improvement in the level of executive function in everyday situations. Furthermore, as a secondary hypothesis, we expected that the intervention would lead to improvement in mood and QoL.

Methods

Participants and study design

Forty persons with TBI from the Helsinki and Uusimaa region area were recruited through the Brain Injury Clinic of the Helsinki University Central Hospital (HUCH), Validia Rehabilitation Helsinki, and the Department of Neurology of Lohja hospital during 2014–2017 to this RCT (trial number NCT01956136). The inclusion criteria were: (1) diagnosed (ICD-10) TBI fulfilling the criteria of at least moderate severity (Glasgow Coma Scale [Wilson et al., 1998]: $\leq$12 p and/or posttraumatic amnesia (PTA) $\geq$24 h); (Traumatic Brain Injury, 2008) (2) time since injury $\leq$24 months at the time of recruitment; (3) cognitive symptoms caused by TBI (attention, executive function, memory; based on clinical evaluation and previous medical records); (4) no previous neurological or severe psychiatric illnesses or substance abuse; (5) age 16–60 years; (6) native Finnish speaking or bilingual with sufficient communication skills in Finnish; (7) living in the Helsinki-Uusimaa area; and; (8) understanding the purpose of the study and being able to give an informed consent. The criteria for time since injury was initially defined as maximum of 6 months, however the time window was later extended to 24 months due to problems in recruiting enough suitable participants. The sample size ($n = 40$) was set to gather a representative number of participants within a reasonable period. No power analysis was conducted due to the exploratory nature of the study. The trial protocol was approved by the Coordinating Ethics Committee of the Hospital District of Helsinki and Uusimaa (reference number 338/13/03/00/2012) and all participants signed an informed consent.

The study was a cross-over RCT, in which participants were randomly assigned to one of two groups, AB ($n = 20$) and BA ($n = 20$). The cross-over design was chosen to enable gathering subjective of experiences of music therapy from all participants in the study. Providing a possibility for intervention for all participants was considered important from an ethical point of view. To ensure steady allocation to both groups across the trial, the randomization was done in batches of two consecutive participants. The randomization was stratified for lesion laterality (left / right / bilateral). Randomization was

performed using an online random number generator (https://www.random.org/) by a person not involved in recruitment or assessments.

During the first three months, the AB group received neurological music therapy in addition to standard care whereas the BA group received only standard care. The standard care included mostly individual therapies such as physiotherapy, occupational therapy, neuropsychological rehabilitation and speech therapy provided by the health care system. The amounts of rehabilitation received did not differ between the AB and BA groups at any time point. During the second 3-month period, the BA group received the music therapy intervention and standard care and the AB group received only standard care. Baseline measurements were administered at time point 1 (TP1) and follow-up measurements were conducted at the 3-month cross-over point (TP2) and at the 6-month completion point (TP3). All these measurement points included questionnaires filled out by the person with TBI and caregiver in addition to cognitive testing and cerebral MRI scanning. The questionnaires (see below) were sent to the participants prior to the neuropsychological measurements and they were returned to the assessing psychologist (authors S-T.S. and K. A-K.) who also helped read/clarify the questions and answering options if needed. The neuropsychological assessments took place in Validia Rehabilitation Helsinki. The research personnel conducting the outcome assessments was blinded regarding the group allocation of the participants. At the final 18-month follow-up (TP4, one year after completion of the 6-month study period), all participants were once again contacted to complete the same set of questionnaires and a subjective evaluation of the music therapy.

During 2014–2017, 4,994 persons with TBI were screened for eligibility, 190 met the inclusion criteria, and 40 were randomized to the AB and BA groups ($n = 20$ in each). Of these, one participant (BA) dropped out before the baseline measurements and one (BA) failed to return the questionnaires at TP1 and dropped out before TP2. Both were excluded from the study due to insufficient data. An additional participant (BA) dropped out before TP2 and one more participant (BA) failed to return the questionnaires. Another five participants dropped out before TP3 (AB: 1, BA: 4). 18-month follow-up data was gathered from 21 participants. In the flowchart (Figure 1), all of the participants discarded from the current questionnaire data analysis are marked as dropouts, although some of them continued in the cognitive and MRI study (Siponkoski et al., 2020). The dropouts were mainly due to patient lack of energy and motivation. Most of the dropouts occurred in the BA group, which was likely linked to the long waiting period before the intervention. Altogether thirty-five caregivers (family members or friends of the persons with TBI) were recruited to the study as informants. Thirty-three of them returned the questionnaires at TP1 (AB: $n = 18$, BA: $n = 15$) and were included in the analysis. At TP2 questionnaire data was received from 30 caregivers (AB: $n = 17$, BA: $n = 13$), at TP3 from 24 (AB: $n = 16$, BA: $n = 8$) and at TP4 from 16 (AB: $n = 10$, BA: $n = 6$). The subjective

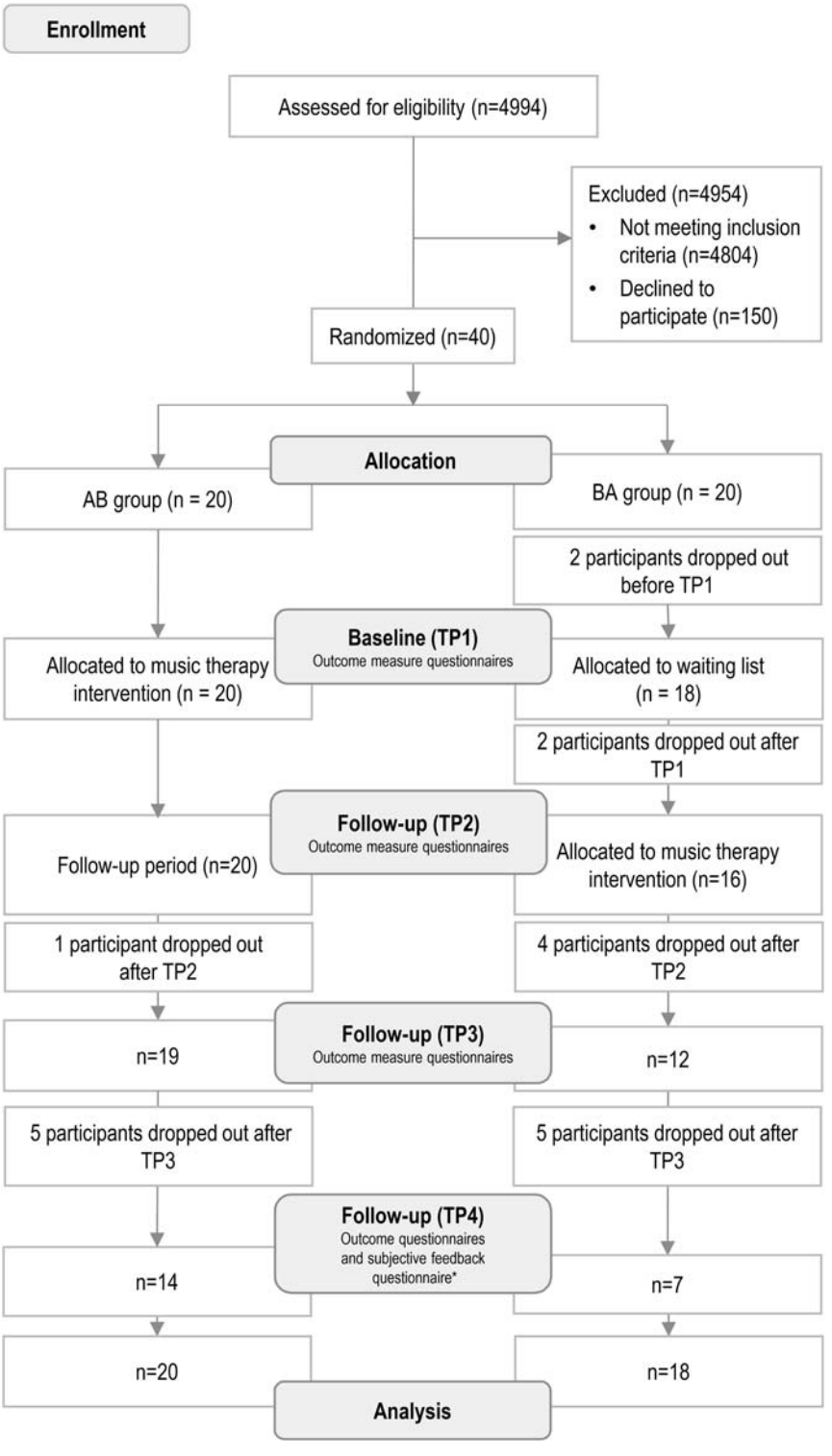


Figure 1. Flowchart outlining the design and progress of the trial. The outcome measures presented to the persons with TBI include BRIEF-A, QOLIBRI and BDI-II. *The subjective feedback was received from 20 persons with TBI (AB: $n = 12$ and BA: $n = 8$). (Overall N in the study differs from Siponkoski et al. (2020) because one subject who participated in the cognitive measurements failed to return questionnaire data and was excluded from the present study).

feedback regarding the intervention was obtained from 20 individuals with TBI (AB: $n = 14$, BA $n = 6$) and 15 caregivers (AB: $n = 10$, BA $n = 5$). Of these, 18 individuals with TBI and 11 caregivers provided answers to the qualitative open-ended questions, others provided only numeric ratings. The results from this RCT were reported according to CONSORT guidelines for cross-over trials (Dwan et al., 2019) and COREQ-guidelines for reporting qualitative data (Tong et al., 2007).

Intervention

The neurological music therapy intervention was targeted primarily for the rehabilitation of (i) cognitive deficits, especially EF, attention and working memory. Secondary goals were to enhance (ii) mood and emotional adjustment and (iii) upper extremity motor functions. The intervention was specifically designed to meet the needs of persons with TBI with different levels of cognitive impairments. The intervention model was adapted from two existing music therapy methods: *Functionally-Oriented Music Therapy* (FMT) (https://www.fmt-metoden.se/fmtsiteng/index.html) and *Music-Supported Training* (MST) method, which have both been applied in stroke rehabilitation (Rodriguez-Fornells et al., 2012; Schneider et al., 2007, 2010). Since the music therapy literature covering TBI is scarce, methods proven efficient in other neurological patient groups were utilized in planning of the intervention and were modified using the existing scientific knowledge and clinical experience in TBI rehabilitation. The intervention consisted of 20 individual therapy sessions (2 times/week, 60 min/session) held by a trained music therapist (authors S.L., M.H., and M.A.) at Validia Rehabilitation Helsinki. The treatment dosage of the intervention was decided based on the clinical experience of the music therapists as well as experiences obtained from using a similar intervention protocol with stroke patients in an unpublished pilot study at University of Jyväskylä. The length, frequency, and total duration (10 weeks) of the intervention were selected to balance training intensity with maintaining participant motivation and endurance as well as logistic practicalities (e.g., travelling to sessions). The focus was on active music production with different instruments including drum and piano. Each session included three modules (20 min each): (i) rhythmical training, (ii) structured cognitive-motor training, and (iii) assisted music playing. *Rhythmical training* involved playing sequences of musical rhythms and coordinated bimanual movements using hands on a djembe drum and on own body (e.g., drumming knees and shoulders). *Structured cognitive-motor training* involved playing musical exercises on a drum set with varying levels of movement elements and composition of drum pads and drumsticks, accompanied with piano by the therapist. *Assisted music playing* comprised of learning to play the participant's own favourite songs on the piano with the help of the therapist and using Figure Notes (https://www.figurenotes.org/

what-is-figurenotes), a special musical notation system utilizing colours and shapes originally developed in Finland, which makes music playing easily accessible without prior musical education. During all training, therapist provided a visual and auditory model and the participants were encouraged to make their own observations of their playing. When the participants were able to produce a certain rhythmical entity or melody, the therapist would add accompaniment. Emphasis was on musical, non-linguistic communication, in which the auditory feedback from the therapist was essential. Additionally, playing familiar songs on the piano using Figure Notes, provided an intuitive, direct form of feedback for the participants. The training was increasing in complexity in all areas, and the difficulty level was adjusted for each participant according to a clear protocol. Importantly, the intervention did not require prior musical training, and the difficulty level of the exercises was initially adjusted and increased in a step-wise manner within and across the sessions to meet the skill level and progression of the individual participant. In addition, *musical improvization* was included in all modules and encouraged throughout the therapy to provide a means of emotional expression. This was implemented through encouraging the participant to create individual playing styles and techniques of drumming and creating own rhythms in drum playing and melodies in piano playing, while the therapist provided a safe background through playing e.g., beat or chord progression. The therapist also adjusted the accompaniment to the musical ideas expressed by the participant to reinforce and validate them. The participants took part in choosing their favourite music for the sessions and on the level of performance, adjusted dynamics, tempo and rhythm according to their individual style.

Measures

Background information

Clinical and demographic information from the participants were gathered upon recruitment. Glasgow Outcome Scale Extended (GOSE) and the Neurological Outcome Scale for Traumatic Brain Injury (NOS-TBI) were administered before start of the study to establish the level of functioning and neurological symptoms of the participants. (Wilde et al., 2010; Wilson et al., 1998) GOSE evaluates areas of communication, activities of daily living, life participation, social relationships and occupational performance, whereas NOS-TBI is designed to assess difference aspects of the neurological state including orientation, cranial nerve function, strength, sensation, language and coordination.

Questionnaires

Our primary outcome in this RCT was defined as change in EF. In this study focusing on the subjective questionnaire data, our primary measure of interest was the Behaviour Rating Inventory of Executive Function – Adult version

(BRIEF-A) (Roth et al., 2005). This questionnaire was given to the person with TBI (self-report version) and their caregiver (informant-report versions) to assess possible changes in EF. BRIEF-A is a 75-item scale that consists of nine subscales: Inhibit, Shift, Emotional control, Self-monitor, Initiate, Working memory, Plan/Organize, Task Monitor and Organization of materials. A three-point scale is used for rating and a higher score indicates more problems. In the original measure, the subscales form two indices (Behavioural Regulation Index and Metacognition Index) which together form the Global Executive Composite Index. However, later research has suggested a three-factor model (Egeland & Fallmyr, 2010). Donders and Strong (2016) studied the factor structure of BRIEF-A in persons with TBI and found that the three-factor structure was particularly well fitting to the self-report data. Even the updated version of the questionnaire for children (BRIEF-2) has adopted this new factor structure (Jacobson et al., 2020). In the current study, we utilized three indices: Behavioural Regulation Index (comprising the Inhibit and Self-monitor scales), Emotional Regulation Index (comprising the Shift and Emotional control scales) and Metacognition Index (comprising of the remaining scales). These indices together formed the Global Executive Composite Index.

The subjective experience of mood and QoL was assessed with questionnaires filled out by the person with TBI. The Beck Depression Inventory II (BDI-II) was used to evaluate the presence of depressive symptoms, with higher scores indicating more severe depression (Beck et al., 1996/2005). Health-related QoL was assessed using the Quality of Life after Brain Injury (QOLIBRI), which is specifically designed for persons with TBI (von Steinbuchel, Wilson, Gibbons, Hawthorne, Höfer, Schmidt, Bullinger, Maas, Neugebauer, Powell, von Wild, Zitnay, Bakx, Christensen, Koskinen, Formisano, et al., 2010, 2010). The QOLIBRI consists of six scales: Cognition, Self, Daily Life & Autonomy, Social Relationships, Emotions, and Physical. The total score indicates the level of life satisfaction on a percentage scale.

Subjective experience of the therapy

At the 18-month timeframe (12 months after the initial 6-month study period), a questionnaire about the experienced benefits of the rehabilitation was sent to the persons with TBI and their caregivers, along with the other measures (see above). The questionnaire included both a numeric rating (1–10) and an open-ended question inquiring the benefits of the music therapy intervention in the following domains: overall, cognitive, motor, emotional and quality of life (*How beneficial has the music therapy been for your / your relative's overall recovery / mood / quality of life / cognitive functioning (e.g., concentration, memory) / motor functioning (e.g., hand movements)? What benefits have you noticed?*) The aim of the questionnaire was to collect complementary information in a short and structured fashion along with the other questionnaires,

according to the preset hypothesis. Additionally, ratings of the current musical activities and their intensity during the past 12 months were collected.

Other measures

Neuropsychological testing and MRI scans were conducted at TP1-TP3. The main results from these measures have previously been reported with a detailed description of the test battery (Siponkoski et al., 2020). In the current study, we correlated our findings with the cognitive tests that yielded significant findings in our first study, namely the Frontal Assessment Battery (FAB) and the Number-Letter Task. FAB is a measure of global executive functioning and it consists of six subtests covering different aspects of frontal lobe functions (conceptualization, mental flexibility, motor programming, sensitivity to interference, inhibitory control and environmental autonomy) (Dubois et al., 2000). Number-Letter Task is a computerized test measuring set shifting ability (Martin et al., 2012).

Statistical analyses

Intention-to-treat analysis

Statistical analyses of the data were performed using SPSS (version 25) (IBM SPSS Statistics for Windows, 2016). First, sporadic missing values from scales were imputed by using the individual mean of the subscale based on the participant's other answers at the same measurement point. To reduce potential bias introduced by the drop-outs, an intention-to-treat (ITT) analysis was conducted for all persons with TBI and caregivers who had filled out the questionnaires during the first measurement (T1) using multiple imputation, which is considered to be a reliable method when handling data missing under various missingness mechanisms (van Ginkel et al., 2019). We detected a significant relationship between background variables (belonging to the BA group / delayed treatment start, more severe injury defined by longer PTA and higher GCS score, lower education level) and missing values. Because the absolute amount of missing data was relatively small (persons with TBI: TP1 1.7%, TP2 7.9%, TP3: 18.4%; caregivers: TP1 0.34%, TP2: 9.2%, TP3: 18.3%) and most important cases were identified, we concluded that missing value structure was missing at random (MAR). Twenty parallel datasets, which is considered to be a sufficient number to reduce sampling variability from the imputation process, were created using a fully conditional specification imputation method (Huque et al., 2018; Sterne et al., 2009). The dataset was imputed over the first three time points to replace missing observations. The imputations were conducted on the level of subscales. Due to the large amount of data and use of different predictors, the imputation was conducted separately for two datasets. First, the questionnaires filled out by the persons with TBI (BRIEF-A, QOLIBRI, BDI-II; AB: $n = 20$ and BA $n = 18$) were imputed. Sociodemographic and clinical variables presented in Table 1 were used as predictors in the

Table 1. Demographic, clinical and musical background information of the persons with TBI.

	All	AB	BA	Difference between groups (*p*)
Demographic information				
Age m (sd)	41.7 (13.2)	41.6 (14.7)	41.8 (11.6)	0.957 (t)
Gender (female / male)	16 / 22	10 / 10	6 / 12	0.299 (X^2)
Handedness (right/left/both)	36 / 1 / 1	19 / 0 / 1	17 / 1 / 0	0.730 (F)
Education in years m (sd)	14.7 (3.2)	14.7 (2.8)	14.6 (3.7)	0.935 (t)
Clinical information				
GCS m (sd)	11.7 (4.2)	12.3 (3.6)	10.9 (4.8)	0.446 (U)
PTA classification[a] m (sd)	2.1 (1.1)	1.9 (1.1)	2.3 (1.0)	0.279 (t)
Cause of injury[b] (traffic-related / fall / other)	16 / 15 / 7	8 / 11 / 1	8 / 4 / 6	**0.034** (F)
Time since injury (months) m (sd)	8.8 (6.5)	8.6 (6.7)	9.0 (6.5)	0.853 (t)
Lesion laterality[c] (left / right / both)	7 / 2 / 25	4 / 1 / 13	3 / 1 / 12	0.847 (F)
Contusion (yes / no)	22 / 15	13 / 6	9 / 9	0.254 (X^2)
DAI (yes / no)	21 / 16	9 / 10	12 / 6	0.236 (X^2)
Hemorrages, bleeds or ischemic injury (yes / no)	24 / 14	10 / 9	13 / 5	0.219 (X^2)
GOSE[d] m (sd)	5.2 (1.3)	5.0 (1.5)	5.5 (0.9)	0.183 (t)
NOS-TBI[e] m (sd)	2.0 (2.5)	2.2 (2.4)	1.9 (2.7)	0.462 (U)
Musical background				
Instrument playing (yes / no)	25 / 12	14 / 6	11 / 6	0.732 (X^2)
Years of playing m (sd)	4.2 (8.4)	4.8 (10.3)	3.5 (5.4)	0.613 (U)
Singing (yes / no)	17 / 20	11 / 9	6 / 11	0.231 (X^2)
Years of singing m (sd)	4.7 (9.9)	6.7 (12.7)	2.6 (5.3)	0.369 (U)
Dancing (yes/no)	20 / 17	12 / 8	7 / 10	0.254 (X^2)
Years of dancing m (sd)	6.1 (10.8)	6.3 (10.6)	5.8 (11.4)	0.546 (U)

[a]1=mild (<24 h); 2=moderate (1–7 days); 3=severe (>7days); 4=very severe (>4 week).
[b]Other causes of injury consist violence (AB: $n = 1$, BA: $n = 2$), diving accident, horse riding accident, being hit by a falling object and unknown etiology.
[c]Based on MRI-findings.
[d]Glasgow Outcome Scale Extended.
[e]Neurological Outcome Scale for TBI.

model along with the answers provided by the persons with TBI. In the second imputation model, we imputed the responses from caregivers to BRIEF-A (AB: $n = 18$ and BA: $n = 15$). In this model, we included information on how well the caregiver knew the person with TBI and how often they were in contact (Likert scales 1–5) as predictors along with the imputed measures and clinical and sociodemographical background information. Categorical variables were included using dummy coding. Imputation was no longer implemented for TP4 because the number of dropouts was understandably very high at this point (60% for the persons with TBI and 52.9% for the caregivers).

Linear mixed model analyses (LMM) were conducted for the imputed data. The model included main effects and interaction between group (AB/BA) and time points. The main Group x Time interaction analyses were conducted between TP1 and TP2, because of the possibility interfering carry-over effect in AB group over TP2-TP3. However, TP1-TP2 provides a clear comparison between the intervention and control-conditions, whereas the stability of the intervention effect in AB group between TP2-TP3 was only assessed within group. The random intercept model, which is a special case of more general LMM framework, was used to account for the within-subject variation. These

analyses were performed using the method described by van Ginkel and Kroonenberg, which involves reformulation of the ANOVA model as a regression model using effect coding of the predictors and applying existing combination rules for regression models in order to pool the F-tests (Magee & Davidson, 2002). This procedure is equivalent to a repeated measures (mixed-model) ANOVA. Significant findings were further assessed by conducting a within-subject repeated measures LMM over the three time points separately for both groups to assess the possible longitudinal intervention effects.

Finally, the change scores over the intervention period (TP1 – TP2 for AB, TP2-TP3 for BA) in the significant measure determined by ANOVA/MLL was correlated with the change scores of significant cognitive measures (FAB, Number-Letter Task) and mood (BDI-II) to determine connections between these measures.

Per-protocol analysis

To assess the sensitivity of our analysis, we also performed a per-protocol (PP) analysis using the dataset of participants who adhered to the study protocol and participated in all measurements. The PP analysis was only performed for the significant finding (BRIEF BRI-index). One participant in the BA group reported having practiced piano intensively (3 h/week) with both piano lessons and independent between TP1-TP2 and was therefore excluded from the PP analysis. Also one participant who failed to return the BRIEF-A along with other questionnaires at TP1 was discarded. Therefore, the PP sample was reduced to thirty-five (AB: $n = 20$ and BA: $n = 15$).

Analysis of the subjective rehabilitation experience

The subjective evaluations of the persons with TBI ($n = 20$) and the caregivers ($n = 14$) regarding the benefits of the music therapy in different domains were compared with each other using paired sample t-tests. A repeated measures ANOVA was conducted across different domains to see if some of the values differed significantly from the other. This analysis was carried out separately for persons with TBI and caregivers. A pairwise comparison using FDR-correction was conducted to determine which areas were experienced as more or less beneficial.

Content analysis

In the 18-month follow-up questionnaire, the persons with TBI and the caregivers were asked to give written feedback regarding the experienced benefits of the intervention in five domains: Overall rehabilitation, Cognition, Motor, Mood, and QoL. The inquiry letters were sent by and returned to the two psychologists who conducted the neuropsychological assessments. (S-T.S. and K. A.-K.). The feedback was analysed using a directed qualitative content

analysis approach, since we had a clear theoretical hypothesis of the expected benefits of the intervention (effects on cognitive, motor, and emotional recovery) (Assarroudi et al., 2018). The method included coding answers into categories by developing a formative categorization matrix. Along with deriving pre-existing categories based on prior research, we also aimed to recognize new, emerging categories.

First, the question regarding overall benefits of the therapy was analysed by categorizing the answers into preset categories: Cognitive, Motor, Mood, QoL, Other benefits, and Overall no benefit. Since the answers in Mood and QoL were largely overlapping in the entire dataset, these were combined into one theme called Mood / QoL. In the next step of the analysis, the goal was to find more specific underlying categories within the large themes. At that point, we combined all the answers given to different questions into one categorizing matrix. In cases where the participant had mentioned a topic that would thematically best belong to another section, the answer was coded according to the content. All the themes mentioned in the Overall section were integrated into the other sections (Cognitive, Motor, Mood / QoL, Other benefits). Several themes could be coded from one participant's answer. However, if the same participant produced answers belonging to the same category in answers to different questions (e.g., Overall and Cognitive), only one was considered in the final quantification. Rare answers were classified into categories "other positive". "No experienced benefit" was reported when the participant did not experience benefit or was unsure of it. One answer was discarded because it was not legible.

The answers belonging to certain themes were quantified and the data was managed using SPSS (Vaismoradi et al., 2013). The first author, who has a background in clinical neuropsychology and TBI rehabilitation, was responsible for the coding process. The categorization was then validated by the second author (S.K.) who has extensive clinical and scientific experience in TBI rehabilitation. No feedback was gathered from the participants regarding the coding and interpretation because the analysis concentrated on the manifest content of the data and was anchored in the verbatim expression of the participants. A complete list of answers and their coding can be found in the supplementary material (Supplementary Tables 2–4).

Results

Recruitment procedure and characteristics of the participants

Recruitment of the participants started in March 2014 and ended in May 2017 after reaching the pre-set goal of 40 participants with TBI. The last follow-up measurements (TP3) were completed in November 2017 and the last questionnaires were sent to the participants in November 2018. Sociodemographic and

Table 2. Demographic background information of the caregivers. *P*-values for group differences (AB/BA) are presented under the title.

	Caregiver gender $p = 0.041$ (X^2)	
	male	**female**
All	12	21
AB	9	8
BA	3	13

	Caregiver role $p = 0.209$ (X^2)				
	parent	**spouse**	**sister/ brother**	**child**	**other**
All	6	18	2	3	4
AB	5	8	0	1	3
BA	1	10	2	2	1

	Caregiver relationship $p = .104$ (t), $p = .374$ (t)	
	How well does the caregiver know the subject (1–5)	**How often does the caregiver contact the subject (1–5)**
All	4.9 (0.4)	5.0 (0.2)
AB	4.8 (0.6)	5.0 (0.0)
BA	5.0 (0.0)	4.9 (0.3)

clinical background information of the persons with TBI is presented in Table 1. The only significant difference between the two groups was found in the cause of injury ($p = 0.034$). However, this was not regarded to be of clinical significance, particularly because the traffic-related accidents involving high energy were evenly divided between the two groups (Majdan et al., 2011). No differences were found between AB and BA groups in terms of rehabilitation amount before the start of the study or between any of the measurement points. Along with the persons with TBI, 33 caregivers with sufficient data at TP1 were included in the final analysis. There was a significant difference between AB and BA groups regarding the caregiver gender, with more male caregivers represented in AB than in BA ($X^2 = 4.164$, $p = 0.041$). Detailed information of the caregiver characteristics is presented in Table 2. Subsample characteristics of participants who gave subjective feedback regarding the intervention at TP4, is presented in Supplementary Table 1.

Effects of the intervention on the questionnaire outcome measures

Following the intention-to-treat (ITT) protocol, we first performed multiple imputation as described in the Methods section. The linear mixed model (LMM) analysis were carried out using the whole sample ($n = 38$) with Time (TP1/TP2) as a within-subject factor and Group (AB/BA) as a between-subject factor for the questionnaire data to assess the short-term (pre–post) effects of music therapy compared with standard care. The F- and *p*-values presented were derived from the imputed data as described in the Methods section. Effect sizes were calculated based on the observed data using repeated measures ANOVA, because the LMM procedure does not produce η_p^2 values.

A significant Time x Group interaction was found in self-reported BRIEF-A Behaviour Regulation Index (BRI; $F_{1,33} = 5.16$, $p = 0.030$, $\eta_p^2 = 0.078$). The AB group showed a significant improvement as indicated by lowering of the BRI score compared to BA group between TP1 and TP2. The development of the scores between TP1-TP3 is presented in Figure 2. No significant interactions were found in the other BRIEF-A indices or in the other questionnaires (BDI-II, QOLIBRI). All results from the Time x Group LMM analysis are presented in Table 3. To evaluate the stability of the treatment effect, we conducted repeated measures LMM group-wise (separately for AB and BA groups) over the three time points for the BRI measure. A significant change in the AB group was detected ($F_{2,36} = 5.17$, $p = 0.011$). The pairwise comparisons revealed that the BRI ratings improved between TP1 and TP2 ($p = 0.002$) and between TP1 and TP3 ($p = 0.020$), but not between TP2 and TP3 ($p = 0.439$) in the AB group. Both significant comparisons survived after the False Discovery Rate (FDR) correction (Glickman et al., 2014; Haynes, 2013), which indicate that the intervention effect was maintained over the 6-month follow-up period. The change

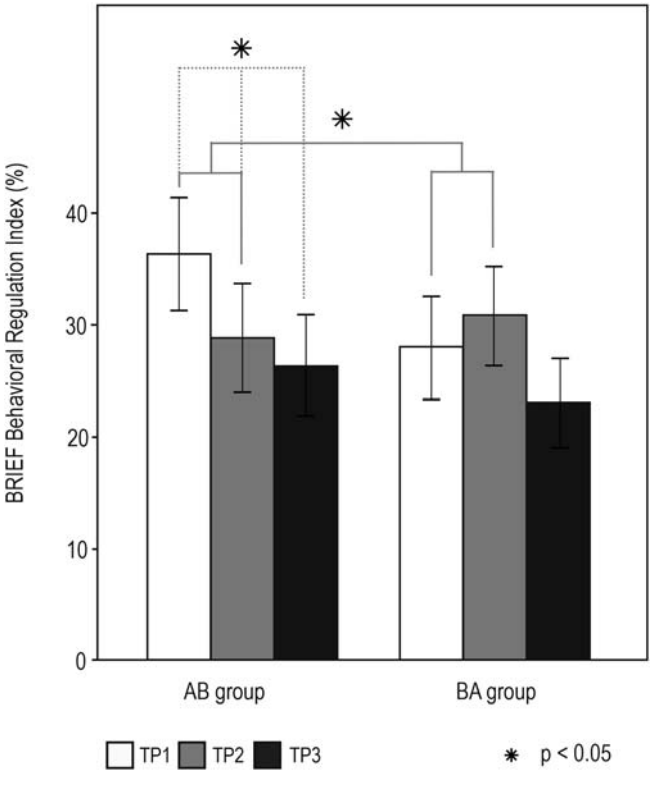


Figure 2. Results from the intention-to-treat (ITT) analysis BRIEF-A Behavioral Regulation Index. The bar plots (mean ± SEM) show changes in test scores over TP1-TP3 presented group-wise (AB/BA) from the imputed data set (depicting the mean of 20 imputations). Significant Time × Group interaction is shown with solid gray line and significant within-group Time main effects are shown with dashed gray lines. SEM, standard error of the mean.

Table 3. Linear mixed model analysis (LMM) results between time points 1–2 using the complete dataset (persons with TBI: $n = 38$, caregivers: $n = 33$), means and standard deviations are based on means of the imputed datasets. All of the results are presented in percentages compared to the maximum score. The baseline differences have been evaluated using independent samples t-test (t).

	Group	T1 (baseline) m (sd)	T2 (3-month) m (sd)	Baseline differences (p)	F value	Δ T1 – T2 (p)
BRIEF-A SELF-REPORT						
Global Executive Composite Score	AB	41.8 (23.4)	38.1 (22.2)	0.281	1.112	0.299
	BA	34.45 (18.2)	35.0 (18.8)			
Behavioural Regulation Index	AB	36.3 (22.6)	28.8 (21.8)	0.231	5.162	0.030*
	BA	28.0 (19.5)	30.8 (18.8)			
Emotional Regulation Index	AB	42.2 (25.3)	40.5 (25.7)	0.257	1.126	0.296
	BA	33.5 (21.5)	37.6 (25.1)			
Metacognition Index	AB	43.5 (23.9)	40.4 (24.2)	0.393	0.112	0.740
	BA	37.1 (19.2)	35.4 (18.2)			
BRIEF-A INFORMANT						
Global Executive Composite Score	AB	45.6 (20.7)	41.0 (21.4)	0.083	0.673	0.419
	BA	32.1 (22.5)	31.3 (20.7)			
Behavioural Regulation Index	AB	36.9 (23.6)	33.6 (21.3)	0.271	0.044	0.836
	BA	28.1 (21.0)	25.9 (18.7)			
Emotional Regulation Index	AB	50.0 (22.4)	46.3 (23.1)	0.124	0.713	0.406
	BA	36.5 (26.9)	38.2 (21.5)			
Metacognition Index	AB	46.8 (21.6)	41.5 (22.8)	0.060	0.821	0.373
	BA	31.7 (22.8)	30.5 (22.2)			
EMOTIONAL AND QOL MEASURES						
BDI-II	AB	25.1 (16.7)	22.9 (17.7)	0.221	0.194	0.663
	BA	19.5 (10.4)	18.4 (9.8)			
QOLIBRI	AB	56.5 (17.8)	62.0 (18.3)	0.143	0.473	0.407
	BA	65.1 (18.1)	67.8 (16.1)			

within BA group did not reach significance ($F_{2,31} = 1.34$, $p = 0.275$). At TP4, 9 persons with TBI had dropped out from the AB group, which is why longitudinal analysis was no longer conducted on this sample. Additionally, to assess the changes in BRI related to the intervention in both groups combined, we conducted a paired sample t-test to compare performance before and after intervention (between TP1 and TP2 for AB, between TP2 and TP3 for BA), which yielded a significant result [$t(39) = 2.50$, $p = 0.012$]. To test the sensitivity of the ITT analysis, we performed a per-protocol (PP) analysis for the BRI scores, which showed significant findings in the LMM, using the original non-imputed data set. Although the Time x Group interaction in repeated measures ANOVA did not reach significance ($F_{1,32} = 2.79$, $p = 0.104$, $\eta_p^2 = 0.80$), the longitudinal within-group analyses revealed a significant main effect of time in the AB group ($F_{1,22} = 6.45$, $p = 0.014$, $\eta_p^2 = 0.26$) with a similar pattern of results in the pairwise FDR-corrected comparisons as in the main ITT analysis (TP1 vs.TP2: $p = 0.007$, TP1 vs. TP3: $p = 0.026$, TP2 vs.TP3: $p = 0.934$). We also conducted the paired samples t-tests before and after the intervention using the PP sample. For the AB and BA groups combined, the result was again significant [$t(30) = 2.25$, $p = 0.032$].

To examine the relationship between the BRI scores and our previous main results from cognitive tests measuring different aspects of EF (FAB, Number-Letter Task), we conducted Pearson correlations between the intervention period change scores (AB: TP1-TP2, BA: TP2-TP3) of these measures. No significant correlations were found. Additionally we examined the relationship between BRI and BDI-II in a similar fashion to explore the possible link between self-reported EF and emotional wellbeing. A significant positive correlation was found between these measures ($r = 0.484$, $p = 0.004$) during the intervention period, but not during the control period ($r = 0.163$, $p = 0.358$).

Subjective experience of the intervention

Numeric ratings

The numeric ratings of the subjective experience regarding different domains of the intervention are presented in Table 4. The only domain in which the ratings of the persons with TBI and the caregivers differed significantly was Motor: persons with TBI experienced more benefits in motor functioning than the caregivers. Of note, the caregivers' ratings were significantly higher than 5.5 ($p \leq 0.05$) in all domains except in Motor. The repeated measures ANOVA revealed that there were significant differences between the evaluations of different domains both in the answers of the persons with TBI ($F = 6.24_{2,42}$, $p = 0.002$, $\eta_p^2 = 0.269$) and the caregivers ($F = 9.43_{2,23}$, $p = .001$, $\eta_p^2 = 0.440$). The pairwise comparisons showed that the only domains differing from each other in self-report after were Cognitive and Mood ($p = 0.003$) and Cognitive and Overall recovery ($p = 0.009$), The Emotional benefits were evaluated as most beneficial and Cognitive as least beneficial. Caregiver responses demonstrated significant differences between the Motor domain, which received the lowest rating, compared to Overall benefits ($p = 0.006$), Mood ($p = 0.002$) and QoL ($p = 0.001$) domains, which received high ratings. Additionally Cognitive benefits were rated significantly lower than in the Overall ($p = 0.011$) and Emotional ($p = 0.012$) domains. All of the above mentioned findings survived after FDR-correction.

Table 4. Subjective evaluations regarding the efficacy of the intervention in five different domains, as rated by the persons with TBI and caregivers. A numeric scale 1 – 10 (no benefit – very beneficial) was applied. The differences between the estimates of caregivers and persons with TBI have been assessed using paired sample t-test.

DOMAIN	LIKERT RATINGS				
	Persons with TBI Mean (sd)	Caregivers	Difference		
			t	df	*p*
Overall	8.2 (1.6)	8.3 (1.5)	−0.25	13	0.807
Cognitive	6.9 (1.8)	7.1 (1.9)	−1.42	13	0.179
Motor	7.9 (1.7)	5.5 (2.5)	3.16	12	**0.008**
Mood	8.5 (1.5)	8.7 (1.3)	0.31	13	0.765
QoL	7.9 (1.4)	8.2 (1.3)	1.59	12	0.139

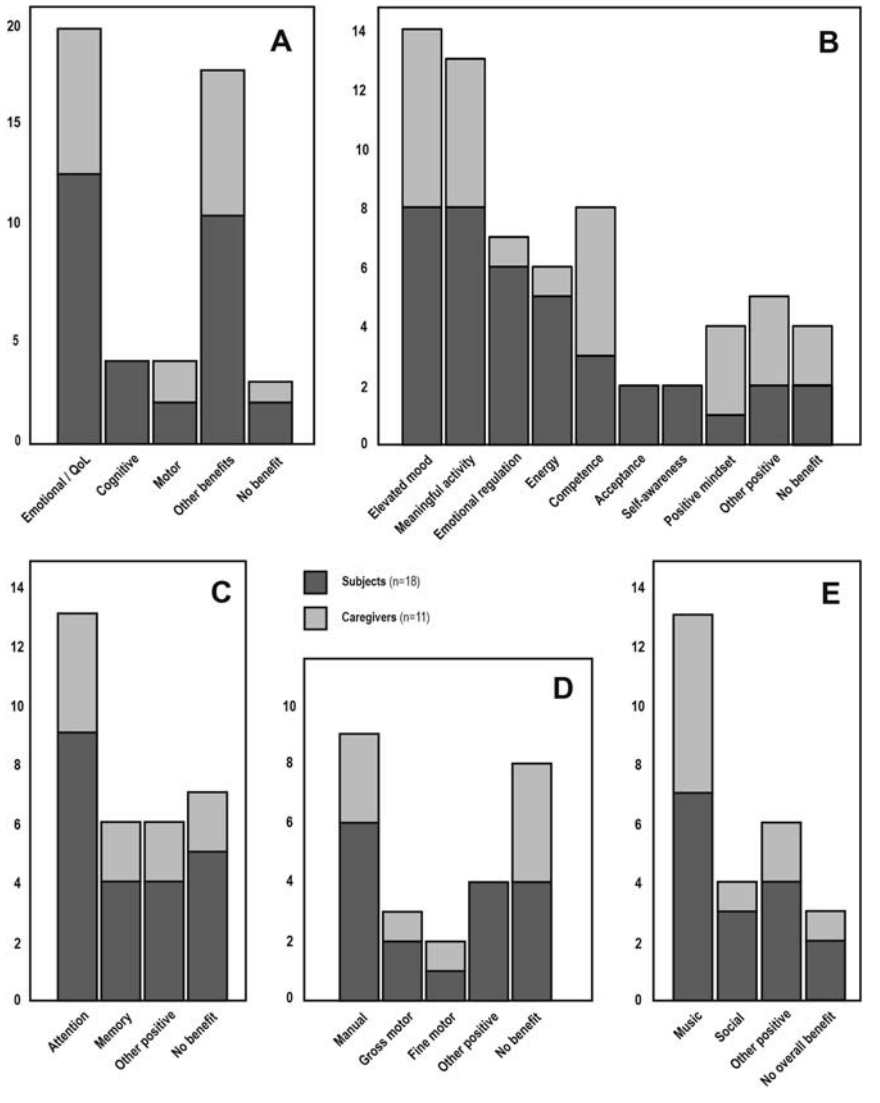


Figure 3. Findings from the qualitative content analysis presenting the amount of subjects' and caregivers' answers belonging to different categories (A) presents overall benefits as categorized into preset themes. B-E depict quantification of all answers across the sample belonging to the following themes: (B) Mood and Quality of life, (C) Cognitive; (D) Motor (E) Other benefits. Only one mention belonging to the same category per subject/caregiver was taken in account in the quantification.

Qualitative data. Findings from the qualitative data regarding the experienced benefits for the persons with TBI are presented in Figure 3. In the open-ended question covering overall benefits of the therapy, the Mood and QoL benefits were clearly emphasized (Figure 3(A), Supplementary Table 2). In a more detailed analysis (Supplementary Table 3), the most common answers belonging to the Mood and QoL theme tapped into elevated mood and meaningful activity (Figure 3(B)). The descriptions of elevated mood varied from reduced

feeling of depression to feelings of joy, which was mentioned by several participants. One person with TBI phrased her answer to the question regarding the effects of the therapy on her QoL: "Particularly joy". These feelings were closely linked to positive emotional experiences induced by music and increased enthusiasm for musical activities. Other mood-related topics mentioned were emotional regulation, enhanced level of energy, feelings of competence, self-awareness, and positive mindset. The comments tapping into emotional regulation included experiences of ability to detach from negative feelings and fear, handle stress/anxiety, and control impulsive behaviour.

Within the Cognitive domain, positive effects were mostly experienced in attention and concentration and some benefits were also described in memory and learning (Figure 3(C)). The answers falling into the Other positive category were mostly general comments on enhanced cognitive functioning. The subcategories belonging to Motor benefits are presented in Figure 3(D). Enhancement in manual functioning was the most commonly mentioned topic, but improvements in gross and fine motor functioning were also endorsed. Finally, answers that did not clearly belong to any of the preset themes are presented in Figure 3(E). Comments on enjoying and rediscovering music in one's life were included in this category together with mentions of social contacts. Although many of these comments were mentioned in the Mood and QoL sections, they could not be purely thematically integrated under these themes and seemed to form an entity of their own.

At a group level, no significant increase was found in the frequency of instrument playing, music listening or singing activity at T4 compared to the intensity of musical activities two years prior injury. However, many persons with TBI reported that the therapy helped and inspired them to start musical activities again after their injury, which provided meaningful activity, social contacts, and positive experiences. One caregiver of a young persons with TBI described that the therapy was "very meaningful" for the person with TBI, and particularly getting a piano of her own had "changed the course of her entire life". One year after the intervention, she was still active in bands and was composing music of her own. Some persons with TBI also reported adopting music listening to their daily routines, which helped them to concentrate and enhanced their cognitive and motor functioning.

Evaluation of harms

The wellbeing of the subjects was monitored during the intervention by the music therapists and any adverse events were reported to the primary investigator of the study. The intervention was safe for the participants, and no significant harms were reported by the participants or caregivers. The drop-out rate after the start of the intervention was remarkably low. Some participants reported fatigue due to the extra effort needed to participate in the intervention

and evaluations, which is understandable considering the low energy levels typically linked to TBI. One caregiver also reported the person with TBI having transient sleep problems during the therapy.

Discussion

Our study reports findings from the first RCT investigating cognitive and emotional effects of neurological music therapy focusing exclusively on TBI. The first results from this RCT were published in our previous paper, in which we reported that music therapy intervention had a positive effect on the general EF and set shifting ability evaluated by neuropsychological test performance (Siponkoski et al., 2020). Specifically, the focus of the current study was on self-reported and caregiver-reported executive dysfunction, mood, and QoL as well as subjective experiences of the intervention. In line with our hypothesis, we found a positive intervention effect on everyday EF functioning measured by the self-reported BRIEF-A Behavioural Regulation Index, which maintained in the 6-month follow-up. Previous research also suggests that music therapy has the ability to enhance EF after TBI (Lynch & LaGasse, 2016; Thaut et al., 2009) and this view fits nicely together with our previous results from the same RCT (Siponkoski et al., 2020). Our current results extend these findings by showing that that the persons with TBI also experience enhancement in EF on the level of daily life performance and social interactions, thereby increasing the ecological validity of the previous findings.

It is perhaps not surprising that the intervention effect was found in the domain of behavioural regulation, since the music therapy consisted mainly of instrument playing in close interaction with the therapist. Monitoring for one's own behaviour lies at the very core of learning to play an instrument. In a cross-sectional study investigating amateur musicians, Jentzsch et al. found that compared to non-musicians, instrumental musicians are better able to detect conflicts and errors as indicated by systematic increase in the amplitude of the error-related negativity and the N200 in EEG (Jentzsch et al., 2014). Furthermore, high levels of musical training were associated with more efficient and less reactive responses after experience of conflict and errors. Based on their findings, the authors suggest that playing a musical instrument could improve the ability to monitor behaviour and adjust responses effectively when needed. It is intuitively appealing to think that these skills could be transferred to social situations, which also require sensitive online monitoring of one's own and other people's actions and rapid accommodation. Moreover, this effect could be emphasized when instrument playing includes interaction with other players. Rhythmic interpersonal coordination involves complex cognitive, motor, social and psychological factors, which form a microcosm of human social interaction (Keller et al., 2014). All these elements make music therapy an ideal platform to practice behavioural regulation in a social context.

An important critical question regarding our results is why did the intervention effect not reach significance in the per-protocol analysis, which included only subjects who adhered to the study protocol and did not drop out before TP2 (AB: $n = 20$, BA $n = 15$). Intention-to-treat analysis is traditionally viewed as a more conservative approach that takes into account possible biases created by dropouts (Thabane et al., 2013). In our sample, this approach likely helped in detecting the signal, because the sample size was small and all the dropouts between TP1 and TP2 occurred in the control group (BA). The significant result was based on an interaction between the two groups; as the intervention group was experiencing enhancement, the results in the control group were simultaneously declining. This is typical for TBI with many factors affecting the course of recovery, which is not always linear (Himanen et al., 2006; Rabinowitz et al., 2018; Vasquez et al., 2018) and a similar pattern of results was already found in our previous study (Siponkoski et al., 2020).

Another critical question arising from our results is why the intervention effect on behavioural regulation was not detected in the BRIEF-A caregiver reports. The caregivers were overall very close to the persons with TBI and participated actively in their daily lives. On the other hand, important evidence that the EF skills actually improved during the music therapy intervention, comes from our first study showing gains in neuropsychological test performance (Siponkoski et al., 2020), and the questionnaire data should also be interpreted in the light of these findings. In the qualitative feedback, persons with TBI also reported experiences of becoming better at inhibiting impulsive behaviour and having an enhanced understanding of their injury after the intervention. One possible explanation for this discrepancy is that the problems of EF are typically manifested in novel situations (Gilbert & Burgess, 2008). In the everyday life, which is mostly shared with close relatives, routines often prevail and situations presenting a challenge for the EF skills occur less often.

Interestingly, we found that changes in everyday EF functioning were not directly connected to enhanced neuropsychological test performance. One explanation for this is that the reported cognitive tests and questionnaires measure different aspects of EF. Previous research has shown that correlations between neuropsychological test results and BRIEF-A / BRIEF are weak, while the measure correlates strongly with emotional distress (Lovstad et al., 2012; Vriezen & Pigott, 2002). As stated above, EF is not a unified construct. The neuropsychological tests typically measure the "cold" components of EF, which refer to purely cognitive and logically based processes such as planning and problem-solving, whereas the BRIEF has been reported to tap more into the "hot" components covering more emotional and motivational aspects of the EF (Lovstad et al., 2012). Therefore, it could be concluded that the music therapy intervention affected several domains of the EF, which may be partially independent of each other. Another possible explanation is that the performance-based neuropsychological tests measure optimal/maximal performance,

while the ratings describe typical performance of the persons with TBI (Toplak et al., 2013).

Contrary to our expectations, we did not find any effect of the intervention on mood or QoL of the persons with TBI measured by quantitative questionnaires (BDI-II, QOLIBRI). The results also diverge from previous literature, where most studies report positive changes in mood following music therapy in patients after TBI (Guetin et al., 2009; Magee & Davidson, 2002; Nayak et al., 2000; Thaut et al., 2009; Wheeler et al., 2003). One possible explanation is that our model of music therapy, which was particularly targeted at cognitive training, did not result in emotional benefits on a group level. Possibly, a therapy form concentrating more on emotional adjustment could potentially show clearer benefits in mood and QoL. Additionally, the result could be related to the properties of the instruments. Although BDI-II has been acknowledged as a valid screening instrument for depression in TBI patients, some concerns have been expressed out about the possibility that symptoms of TBI are very similar and overlapping with somatic symptoms of depression, measured by the BDI-II (Green et al., 2001; Homaifar et al., 2009). Moreover, the participants were all in a relatively early stage of their recovery (6–24 months post injury), which entailed many major life changes, such as returning to work or applying for retirement, that coincided with the intervention period. Therefore, due to the small sample size and confounding factors, no definite conclusions can be drawn about the effects of music therapy on mood and QoL, particularly as the previous literature and the findings from our own qualitative data indicate at least some positive effects on emotional well-being Interestingly, in support of this we found a significant correlation between the mood (BDI-II) and behavioural regulation (BRI) during the intervention period, which indicates that the change in BRIEF-A could actually be somehow linked to emotional adjustment.

In the qualitative feedback, most of the participants' answers in fact emphasized the emotional and QoL benefits. Experience of elevated mood and importance of having meaningful activity emerged as central themes. The findings are contradictory with the above mentioned objective measures (BDI-II, QOLIBRI), which highlights the importance of subjective reports as complementary source of information. Additionally, persons with TBI experienced least benefit in the cognitive domain, which is surprising because the evidence from this RCT point to an intervention effect, specifically on EF. However, it should also be borne in mind that in addition to methodological differences, the quantitative and qualitative samples actually differ in size and they were gathered at different time points. The 18-month follow-up and qualitative data were presumably somewhat selective due to the large dropout rate at that point. It is likely that most of the answers were received from the persons with TBI and the caregivers who experienced the intervention as beneficial. On the other hand, enhancement in high-level cognitive skills such as EF can be difficult to

detect or evaluate subjectively. Most of the cognitive changes reported in the qualitative feedback were in the domains of attention and memory, which are relatively concrete and easy to notice. A significant limitation of the questionnaire is the structured format of the questions inquiring for certain outcomes, which could have led to a treatment expectancy effect, particularly in the numeric ratings. The aim of the questionnaire was to compare and investigate differences within the domains, and it should not be considered as a proof of an intervention effect. More extensive qualitative research exploring this question is beyond the scope of this study.

In spite of these limitations, the subjective feedback provided an important insight into the experience of music therapy from the subjective point of view. The ratings revealed that the persons with TBI and their caregivers perceived the benefits in different areas in a similar fashion. The only area showing discrepancy between the ratings, was the motor domain. One possible explanation to this is that the motor benefits were more subjectively experienced and perhaps not as visible to caregivers, because motor disorders were very mild in this sample. It is also possible that these functions were mostly challenged during the therapy sessions, where the progression was clear to the persons with TBI but not perceived by the caregivers.

The qualitative feedback was also in line with our findings regarding behavioural regulation, as some of the persons with TBI reported for example enhanced impulse control. Overall, several participants mentioned using music as an aid in regulating emotions and stress. This is again in line with previous research showing that emotional regulation is one of the most important reasons for musical engagement across the life span (Saarikallio, 2011; Saarikallio & Erkkilä, 2007). Another common trait in the qualitative answers was emphasis on positive experiences and inspiration linked to musical activities, which formed an independent category of answers. These reports emphasize how the unique ability of music to engage the brain's reward system and to bring positive emotions has a great value in and of itself. Many participants also reported continuing musical activities after the therapy and adopting music as part of their daily lives.

Overall, the qualitative feedback revealed that many persons with TBI experienced positive effects on their emotional well-being on an individual level. These individual reports also have a significance and they can afford additional information easily lost in group-level analysis. In addition to the fact that music-based interventions are suitable for most persons with TBI, they can have even a profound and life-changing effect for some individuals. Recognizing particularly these persons during the recovery process after TBI is of great importance as it can help in targeting and tailoring music therapy to meet individual needs and optimize treatment efficacy. It is also important to note that many of the participants had a musical background. It is possible, that these individuals are more likely to attach to the therapy and continue musical activities in their daily lives.

In addition to the above-mentioned limitations, it should be noted that our sample size was relatively small. Recruiting suitable participants at early stage of recovery, willing to commit to the study protocol, was challenging. This could due to many factors, but the recent injury and the uncertainty caused by it in addition to and low functional level and lack of energy linked to TBI could play an important role. In order to reach the desired sample size, the initial inclusion criteria had to be loosened from the initially planned maximum of 6 months to 24 months post injury. The goal was to find participants with optimal recovery capacity and plasticity, which is greatest soon after injury (Kleim & Jones, 2008; Ruttan et al., 2008). Our present findings are only generalizable to persons with TBI who have experienced a moderate or severe brain injury in the first 24 months post-injury. The possible benefits of music intervention in more chronic stages and individuals with milder injury need to be further investigated. This approach could also be fruitful in expanding the evidence, as finding participants would likely be easier in chronic later stages and studies could aim for bigger sample sizes. Additional challenge arise from the cross-over design; although focusing the analysis between TP1-TP2 eliminate the possibility of carry-over effect and provide a pure comparison between the intervention and control period, interpretation of the longitudinal data between TP2-TP3 is more complex and there is a lack of control data during this period. In future studies an additional group of alternative therapy form should also be considered. Also the type of music therapy and the impact of the intensity/length of the therapy on the outcome should be further studied.

Limitations of the qualitative data include the late stage at which the subjective reports were gathered (18 months). This clearly affected the drop-out rate as all participants could no longer be reached. On the other hand, the subject-reports from this long-term follow-up consolidate our findings, because benefits from the intervention were still experienced over one year after the end of therapy. Many of the previously reported studies have focused on short-term benefits from the therapy, although long-term recovery and the profound changes obtained in everyday lives of the persons with TBI are crucial in evaluating the utility and cost-effectiveness of the intervention. Our follow-up data suggests that at least some individuals gain long-term benefits from the intervention, which can lead to changes in daily routines and activities and support both cognitive and emotional well-being, long time after the active music therapy intervention has ended.

Despite the above-mentioned limitations, this study deepens our understanding of the effects of music therapy after TBI. The current results uncover the positive impact of the intervention on everyday behavioural regulation. Additionally, the qualitative feedback given by the persons with TBI and their caregivers further emphasizes the meaningfulness of music therapy intervention on an individual level. All in all, this evidence supports the view that music can play a central role in recovery after TBI.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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