DARE to move : feasibility study of a novel dance-based rehabilitation method in severe traumatic brain injury

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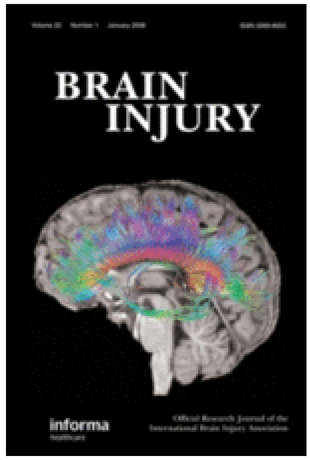

DARE to move: Feasibility study of a novel dance-based rehabilitation method in severe traumatic brain injury

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Sarkamo et al_Supplementary Video 1.mp4 Sarkamo et al_Supplementary Video 2.mp4 Sarkamo et al_Supplementary Video 3.mp4	

DARE to move: Feasibility study of a novel dance-based rehabilitation method in severe traumatic brain injury

Abstract

Objective: Dance is a versatile and multimodal rehabilitation method, which may be useful also in traumatic brain injury (TBI) rehabilitation. Here, we assessed the feasibility and preliminary effects of a novel dance-based intervention called Dual-Assisted Dance Rehabilitation (DARE).

Method: This is a feasibility study with a cross-over design where 11 persons with severe / extremely severe TBI received a 12-week (2 times/week) DARE program during the first (N=6) or second (N=5) half of the study. Motor and neuropsychological tests and questionnaires measuring mood, executive functions, and quality of life were performed at baseline, 3-month, and 6-month stage. Self-perceived benefits were assessed with a post-intervention questionnaire.

Results: Acceptability of and adherence to DARE were encouraging: 91% were fully consistent with protocol, and adherence to DARE sessions was 83–100%. Pre-post treatment effects sizes were medium-large for self-reported depression (BDI-II: d = 1.19 –1.74) and executive deficits (BRIEF-A: d = 0.43 – 1.09) and for test-assessed trunk movement control (TIS: d = 0.47 – 0.76) and cognitive functioning (WAIS-IV subtests: d = 0.34 – 0.89). Other outcome measures did not show similar positive effect sizes. Self-perceived benefits were largest for mobility and cognition.

Conclusion: Dance-based rehabilitation is a feasible and promising method in severe TBI and its efficacy should be assessed with a larger clinical trial.

Keywords: dance rehabilitation, traumatic brain injury, mobility, cognition, mood

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Introduction

Traumatic brain injury (TBI) is a major cause of disability across all ages, affecting over 50 million people each year worldwide and bringing about massive burden on individuals with TBI, their families, and the society (1). Typically, severe TBI causes a combination of motor deficits (e.g., hemiparesis, ataxia), cognitive deficits (e.g., executive dysfunction, attention and memory problems), emotional deficits (e.g., depression), and behavioral deficits (e.g., personality changes, self-control problems), which change the life of the person with TBI in a very profound and lasting way, leading to severe disability, loss of independence and ability to work, and poor quality of life (QOL) (2-4). The heterogeneous and complex nature of severe TBI presents a major challenge for rehabilitation. In TBI, there is a need especially for novel rehabilitation tools that are (i) motivating and engaging, (ii) adaptable to address the specific needs of the person with TBI, (iii) widely applicable and scalable, and (iv) able to address the multiple comorbid deficits caused by the TBI. In this regard, with growing evidence from randomized controlled trials (RCTs), music-based interventions have emerged as highly promising and effective tools in neurological rehabilitation (5,6). Music has thus far been studied less in TBI rehabilitation, but there is emerging evidence that music-based interventions, which utilize rhythmic entrainment, instrument playing, and singing, can have positive motor (7), cognitive (8-10), emotional (10,11), and verbal communicative (12,13) effects in persons with TBI.

Among different music interventions, dance-based rehabilitation is a particularly well-suited and potentially effective method to jointly improve the motor, cognitive, and emotional impairments in TBI. The inherent appeal of dancing lies especially in its multimodal nature: dancing combines the processing and integration of information from auditory, visual, somatosensory, equilibrioceptive (balance) and proprioceptive (kinaesthetic) modalities with the motor control of movements and cognitive processing (e.g., executive function, attention, memory) and with positive emotions, aesthetic pleasure, creative self-expression, and social interaction afforded by music. The temporal matching of own movements with the rhythm of music – an essential embodiment element in dance – builds on the strong reciprocal coupling between the auditory and motor systems, which is a natural and largely inborn capacity in humans (14). In the brain, dance perception and production specifically engage superior and middle temporal regions (auditory perception), premotor and inferior parietal regions (action observation network, AON), superior parietal regions (spatial processing), and striatal and cerebellar regions (motor control) (15-17), coupled with activation in dopaminergic mesolimbic regions (e.g., nucleus accumbens, amygdala, orbitofrontal cortex) associated with the emotional processing of music (18,19). By synchronizing music and movement, dance has been suggested to constitute a "pleasure double play" where music stimulates the brain's reward centers, while dance activates its sensory and motor circuits (20).

In healthy subjects, dance training has been associated with the enhancement of skills closely related to the visuomotor aspects of dance, such as balance, posture, sensorimotor integration, and motion perception (21-25), extending also to the improvement of cognitive skills (e.g., attention, memory) and subjective well-being, especially in older adults (24-27). Neurally, dance training has been linked to structural and functional neuroplasticity in the AON, motor and sensorimotor cortex, cingulate cortex, insula, and basal ganglia as well as with increased cortical phase synchrony and neurotrophin levels (23, 26-32). Overall, dance therapy has been reported to have positive effects primarily on psychosocial wellbeing, including self-esteem, mood, emotional adjustment, and QOL (33,34). Dance-based interventions have also been reported to have positive effects on motor (e.g., balance, gait) and cognitive functions, psychological wellbeing, and QOL in Parkinson's disease (35,36), mild cognitive impairment (37,38), and dementia (39-41). However, the methodological quality of the studies and the level of evidence for clinical efficacy have been variable and the effects of the interventions heterogenous (33-41), and more well designed and controlled trials are needed.

In TBI, experimental research on the efficacy of dance-based rehabilitation is scarce, limited to a few non-randomized group studies and case studies, and the current level of evidence is very low. Berrol et al. (42) compared a 5-month group-based dance and movement therapy (DMT) intervention (2 times/week, 45 min/session) to standard care in a mixed sample of 107 elderly persons with stroke, TBI, or cerebral aneurysm. DMT was found to enhance gait, range of motion, body awareness, cognitive function (e.g., decision making, short-term memory), and social interaction compared to standard care (42). Dault and Dugas (43) compared the effects of 3-month aerobic dancing and muscular training (control) interventions in 8 adults with TBI and observed improvement in motor coordination (synchronization of upper and lower limb movements) and balance (postural sway) in the aerobic dancing group. Finally, in a case study of a person with extremely severe chronic TBI, Kullberg-Turtiainen et al. (44) reported an improvement in motor (balance, posture, mobility, endurance) and cognitive (self-awareness, attention, episodic and working memory) functioning, mood, and functional independence, coupled with enhanced default mode network function measured with electroencephalography (EEG), after a 4-month goal-directed dance training intervention.

Aside from the one case study (44), dance-based rehabilitation has not been studied in severe TBI. The aim of the present pilot study was to explore the feasibility of a novel dance-based intervention (Dual-Assisted Dance Rehabilitation, DARE), which combines dance training and physical therapy, in the individual rehabilitation of persons with chronic TBI who have severe / extremely severe injury and extensive motor and cognitive deficits. This specific type of TBI is highly challenging for rehabilitation, and also incurs the highest individual and societal burden and economic costs (45,46), making it a key priority for rehabilitation research within the TBI population. Utilizing a small-scale version of a cross-over RCT in 11 persons with TBI, the specific feasibility objective of this study was to determine the applicability and safety of DARE and adherence to the intervention and study protocol (including recruitment, consent, and completion rates) as well as provide an estimate of the treatment effect (effect sizes) and its variance across outcome measures, for the purpose of designing a larger full-scale RCT to determine the clinical efficacy of DARE.

Materials and methods

Subjects and study design

The subjects were 11 persons with TBI recruited between April 2015 and June 2017 from Validia Rehabilitation Helsinki, a Finnish centre specialized in the rehabilitation of persons with severe brain or spinal cord injury. Inclusion criteria were: [1] diagnosed severe or extremely severe TBI [loss of consciousness (LOC) > 7 days, post-traumatic amnesia (PTA) ≥ 4 weeks]; [2] time since injury ≥ 12 months (max. 10 years) at the time of recruitment, [3] age 18-50 years, [4] living in the Helsinki-Uusimaa region; [5] presence of motor deficits but sufficient motor function to enable participation in the intervention (activity in both upper extremities, able to stand/walk with aid or support, no severe ataxia), and; [6] understanding the purpose of the study and being able to give an informed consent, and [7] no previous severe neurological or psychiatric illnesses or substance abuse. The demographic and clinical characteristics of the persons with TBI (obtained from clinical reports) are shown in Table 1.

In the study, we used a cross-over design with a 6-month follow-up and three assessment points: baseline (T0), 3-month stage (T1), and 6-month stage (T2). The persons with TBI were randomized to two groups (AB / BA) and received the dance intervention either during the first 3-month phase (from T0 to T1, AB group) or the second 3-month phase (from T1 to T2, BA group). Randomization was performed by a researcher not involved in data collection. The study protocol was approved by the Ethics Committee of the Hospital District of Helsinki and Uusimaa. The persons with TBI signed an informed consent and received standard medical treatment and rehabilitation throughout the study.

There were no significant differences between the groups in any baseline demographic or clinical variable (Table 1).

Dance intervention

Provided for 12 weeks (2 sessions/week, 60 min/session) at Validia Rehabilitation Helsinki, the intervention utilized a novel dance-based rehabilitation method called *Dual-Assisted Dance Rehabilitation* (DARE). DARE features a unique combination of dance training and physical therapy specifically designed for the individual rehabilitation of persons who have severe / extremely severe TBI and extensive motor and cognitive deficits, and for whom dance-based rehabilitation would not otherwise be possible to implement due to the severity of the deficits. DARE is implemented by a two-person team formed by a dance teacher and a neurological physical therapist. During the training, the dance teacher stands or sits in front of the person with TBI and guides the training of the dance movements both verbally and visually (showing the movements with his/her own body, which the person with TBI then imitates and models). The physical therapist is right next to the person with TBI and provides physical support, balance, and somatosensory feedback, preparing his/her body to feel and move and helping him/her to execute the movements as well as possible to the rhythm of the music and with optimal posture. Depending on the type and severity of motor deficits of the person with TBI and the progress made during the training, the exercises are done either sitting down or standing up (alone or supported), and their difficulty level, in terms of the number and type of movements trained, is adjusted individually. A key aspect of individualization is also the use of music which is self-selected by the person with TBI (own favourite music).

In DARE, each 60-minute training session follows a five-part structure: (1) opening phase with exercises that focus concentration on the body (verbally guided mental scan of the body, directing attention to individual body parts), (2) finding rhythm and tempo through clapping and stomping exercises, (3) training isolated movements of individual body parts (while keeping others still, with the help of the physical therapist if needed), (4) training a sequence of movements (dance choreography) by combining the individual movement elements to the rhythm of music, and (5) ending phase with stretching and relaxation. Illustrative video examples of parts 3 and 4 are provided in the Supplementary material (see Supplementary Video 1).

In the choreography part, the movements are combined with reaching, looking, facial expressions, pauses, and other rhythmic variations, bringing an aesthetic and emotionally expressive dance element to the whole training. Depending on the general fitness and motor functioning of the person with TBI, also large circular movements, level changes, and steps are included when possible. The choreography is designed with sequences of 2-3 movement elements, which are trained in a step-wise manner (adding the next sequence when the previous one is learned), finally resulting in a dance choreography that comprises on average 10 movements. During the intervention, two different dance choreographies varying in tempo and energy (one more low-tempo / calm, the other more high-tempo / energetic) are trained.

Outcome measures

Outcome measures comprised standardized motor and neuropsychological tests and self-report questionnaires, which were performed three times (T0 / T1 / T2). The motor and neuropsychological testing was implemented by a physical therapist and a psychology student (supervised by author SK), respectively, who were blinded to the group allocation of the persons with TBI. The outcome measures were not *a priori* defined as primary / secondary since the aim of the present study was to obtain estimates of treatment effect of all outcome measures and use this information to determine, which measures could be included as primary / secondary in a future larger trial.

Motor tests. The motor tests consisted of a modified version of the Trunk Impairment Scale (TIS), which comprises six tasks measuring dynamic coordination of trunk movements (47,48); the Berg Balance Scale (BBS), which comprises 14 tasks measuring static and dynamic balance (49); and the Action Research Arm Test (ARAT), which comprises 19 tasks measuring the fine and gross movements of the left and right upper-extremities (50). In addition, walking speed was measured in a 6-meter walking task using GAITRite (CIR Systems Inc, Franklin, NJ, USA). The duration of the motor testing was around 30 min.

Neuropsychological tests. The neuropsychological test battery comprised the Montreal Cognitive Assessment (MoCA), the Frontal Assessment Battery (FAB), three subtests (Digit Span, Similarities, and Block Design) of the Wechsler Adult Intelligence Scale IV (WAIS-IV), and the Sustained Attention to Response Test (SART). The MoCA has eight short subtests measuring different cognitive functions (51). The FAB has six short tasks measuring executive function (52). The WAIS-IV (53) subtests measure verbal working memory (Digit Span), abstract verbal reasoning (Similarities), and visuospatial processing and problem solving (Block Design). The SART measures visual sustained attention during a 9-minute vigilance task presented on a computer screen (9,54). The duration of the neuropsychological testing was around 60 min.

Questionnaires. The questionnaire part consisted of the Behavior Rating Inventory of Executive Function – Adult version (BRIEF-A), which comprises 75 items measuring executive deficits in everyday life (55); the Beck Depression Inventory II (BDI-II), which comprises 21 items measuring depression (56); and the Quality of Life after Brain Injury (QOLIBRI), which comprises 37 items measuring QOL (57). From BRIEF-A, total score (Global Executive Composite, GEC) and Behavioral Regulation (BRI) and Metacognition (MI) Indices are reported. From BDI-II and QOLIBRI, total scores are reported. In addition to the standardized questionnaires, a custom-made 30-item questionnaire was given after the intervention period, which mapped the subjective benefits of DARE in six domains using a 10-point Likert scale: Mobility, Upper body function, Lower body function, Mood, Cognition, and General well-being and self-image (see Supplementary material). The persons with TBI were also asked to rate the overall benefit of DARE. They filled the questionnaires at home, with the help of a family or care staff member if needed.

Feasibility outcomes. The feasibility outcomes of the study were rates of recruitment, consent, and completion (both for intervention and outcome measures) as well as intervention safety (adverse effects).

Statistical analyses of outcome measures

Statistical analyses were carried out using SPSS (version 25) and Microsoft Excel. Demographic and clinical characteristics of the AB and BA groups were compared using chi-square tests and t-tests. For the outcome measures, change scores (T1-T0, T2-T1) were first calculated for the AB and BA groups and effect sizes (Cohen's d) were then calculated from them using the standard formula (58) and an Excel tool available at https://www.spss-tutorials.com/cohens-d/#excel-tool-for-cohens-d. The effect sizes were utilized for power calculations performed using the G*Power (version 3.1) software (59). Data from the AB and BA groups was also pooled together to compare changes from baseline (T0) to the post-intervention time point (T1 in AB, T2 in BA) across all persons with TBI. The magnitude of this intervention effect was tested using one-sample t-tests (against zero). The data from the benefit questionnaire was analyzed by comparing the domain and overall scores to the mid-point value of the scale (5.5), which indicates a presumed average level of benefit (not low, not high) using one-sample t-tests.

Results

Participant characteristics and feasibility outcomes

Participant flow is shown in Figure 1. During the recruitment period (2015-2017), a total of 3000 neurological patients (with TBI, stroke, spinal cord injury, or other neurological diagnosis) who had underwent a rehabilitation period at Validia Rehabilitation Helsinki between 2007-2015 were screened for eligibility. Of them, 62 met inclusion criteria 1-4 (severe / extremely severe TBI, 1-10 years from injury, age 18-50 years, living in the Helsinki-Uusimaa region). After a closer examination of medical records, 52 persons with TBI were excluded for not meeting inclusion criteria 5-7 [too severe cognitive/motor deficits: N=14, no motor deficits: N=33, other reason (depression, substance abuse, pending surgical operation, developmental disorder): N=5]. The remaining 11 persons with TBI were contacted about participating to the study and they all consented to participate and were then randomized (AB/ BA group). There were no statistically significant differences between the AB and BA groups in the demographic and clinical variables (see Table 1). Overall, the adherence of the persons with TBI to the intervention (DARE) and the study was excellent. All persons with TBI successfully performed the outcome measures at each time point (T0 / T1 / T2). During the intervention period, the persons with TBI were able to participate, on average to 94.6% (SD = 5.9%, range 83.3% – 100%) of the sessions. With one person with TBI, the intervention had to be discontinued for safety reasons after 9 sessions, due to the emergence of epileptic seizures. This person had diffuse axonal injury (DAI) and a localized lesion in the anterior part of the left thalamus, and had suffered from seizures at the post-injury stage. The person underwent the follow-up assessments and his data were retained in the analyses, following the intention-to-treat principle. There were no other adverse events (seizures or any other events, such as falls) during the intervention.

(Figure 1 and Table 1 about here)

Self-perceived benefits of the dance intervention

Nine persons with TBI filled the 30-item questionnaire on self-reported benefits of DARE. The average scores of the six domains and the overall benefit score are shown in Figure 2. One-sample t-tests indicated a higher-than-average benefit (score higher than 5.5) for two domains, Mobility [$t(8) = 3.17$, $p = 0.013$] and Cognition [$t(8) = 2.58$, $p = 0.032$], as well as for the overall benefit score [$t(8) = 6.06$, $p < 0.001$]. Within these two domains, the highest mean benefit ratings for individual items were in Mobility for Perception of body in relation to environment (8.6) and Co-action of movements

(8.2) and in Cognition for Short-term and working memory (7.6) and Executive function (7.4). The other four domains were rated also above-average but did not reach significance.

(Figure 2 about here)

Motor, cognitive, and emotional effects of the dance intervention

The scores of the motor and cognitive tests and questionnaires at different time points are reported in Table 2. Being a pilot study, this study was not designed to assess the clinical efficacy of DARE, but rather to map which domains showed most consistent pre-post changes compared to standard care. Thus, an estimate of short-term treatment effect (Cohen's d) was obtained for each outcome from the change scores at T1 (T1 minus T0; intervention period of the AB group and control period of the BA group) and T2 (T2 minus T1; intervention period of the BA group and control period of the AB group). According to Cohen (56), the effect sizes are classed as small (d = 0.2), medium (d = 0.5), and large (d = 0.8). As shown in Table 2, there was quite a lot of variability in the direction and magnitude of the effect sizes between the AB and BA groups in the T1-T0 and T2-T1 scores, likely owing to the small sample size and the natural variability of clinical data.

(Table 2 about here)

Of the motor and neuropsychological tests, the most consistent positive, medium-large effect sizes favouring the intervention were observed for TIS (d = 0.47 – 0.76) and for the Digit Span, Similarities, and Block Design subtests of the WAIS-IV (d = 0.34 – 0.89), indicating improvement in the control of trunk movements as well as in verbal working memory and reasoning ability. In the questionnaire data, a consistent large effect size favouring the intervention was seen in the BDI-II (d = 1.19 –1.74), indicating improvement of mood. There were consistent medium-large positive effect sizes (d = 0.43 – 1.09) also in the BRI, MI, and GEC scores of the BRIEF-A, indicating abatement of executive deficits in daily life.

One-sample t-tests from the pooled data (AB and BA groups combined) yielded similar effects, showing a significant positive change from baseline (T0) to the post-intervention stage (T1 in AB, T2 in BA) in TIS [t(10) = 3.19, p = 0.010], WAIS-IV Similarities [t(10) = 3.55, p = 0.005], and BDI-II [t(9) = 4.20, p = 0.002], suggesting that the medium-large treatment effect sizes for these outcome measures (see above) were attributable to positive changes during the intervention period. Since these exploratory analyses did not contain a control condition and were not adjusted for the total number of comparisons (type I error), they should be considered tentative and do not provide any evidence for the efficacy of DARE. At the individual level, the improvement in the control of body movements (reflected by the TIS score) was evident also in the video material recorded at the starting and ending phase of the intervention (see Supplementary Videos 2 and 3).

Sample size calculation for a full trial

Measures of variance in change scores were used to derive an estimate of sample size for a full-scale RCT comparing DARE to standard care. Based on the results reported above, the primary outcome measure that captures the clinically most important effect of the intervention is the TIS. A power calculation using G*Power with an effect size d = 0.62 (average of 0.76 and 0.47, see Table 2), two-tailed, significance level 0.05, 80% power, and an estimated 10% attrition rate indicates that for a two-arm trial altogether 92 persons with TBI are required to detect a substantial improvement in TIS. This same sample size would be sufficient for detecting a significant change also in BDI and BRIEF-A as potential secondary outcome measures.

Discussion

This pilot study provides the first evidence that the DARE intervention model, which combines dance training and physical therapy, was feasible to deliver and acceptable to participants, with high treatment adherence. The study was not powered as an efficacy trial, but the treatment effect sizes (medium-large) were promising and consistent with the self-reported subjective benefits of the persons with TBI. The effects were also in line with previous research on the motor, cognitive, and emotional benefits of dance training in healthy subjects (21-27) as well as in TBI (42-44) and other neurological illnesses (35-41). From a clinical standpoint, these results are important and encouraging and extend previous findings by demonstrating that dance-based rehabilitation is indeed possible and potentially effective motorically, cognitively, and emotionally also in the more severely and pervasively impaired TBI population, in which this type of rehabilitation is usually not considered possible.

Results on the acceptability of and adherence to DARE were excellent, showing, first of all, that all contacted persons with TBI who met the inclusion criteria (N=11) agreed to participate in the study (100% consent rate) and were able to complete the follow-up and outcome measures (100% study completion rate). Second, 10/11 (91%) of the persons with TBI were able to complete the 12-week intervention period and they participated on average to 95% of the intervention sessions. Together, these results suggest that DARE was very well accepted and motivating for persons with TBI. Notably, with one person with TBI, the intervention had to be discontinued after 9 sessions due to the emergence of epileptic seizures. In this person, it is possible that the intervention sessions provoked seizures, potentially due to the multimodal (auditory, visual, tactile, motor) nature of the intervention coupled with the location the lesion in the thalamus, which is a key sensory-motor-cognitive relay center (60). However, since the other seven persons with TBI who also had a history of post-TBI epilepsy did not experience any seizures during the intervention, epilepsy does not seem to be a contraindication for the dance intervention. Given also that there were no other adverse effects, DARE appears to be a generally safe intervention for persons with TBI, although a minor possibility of seizure provocation should be borne in mind for safety. All in all, based on the feasibility results, no modifications to the DARE protocol or study design are needed for a larger trial.

Based on the results from the test-based outcome measures and the subjective benefit ratings, the most apparent and potentially clinically most meaningful and direct gains from DARE were in motor control of trunk movements (indicated by the TIS) and in self-reported mobility, especially in perceiving the body in relation to environment and in the co-action of movements. This pattern of results is highly sensible given that the control of the mid-body is essential for good posture and for initiating much of the movements that were performed in the dance exercises, and that the co-action of movements and body-environment perception are the key characteristics of dance. In general, these results are also well in line with previous studies reporting benefits of dance training on posture, sensorimotor integration, and motion perception in healthy subjects (21-25) as well as with clinical studies reporting benefits of dance interventions on balance and gait in Parkinson's disease (35,36) and on gait, balance, motor coordination, and body awareness in TBI (40-44). The lack of consistent positive effects on tasks measuring balance (BBS), arm and hand movements (ARAT), and walking (GAITRite) in the present study may be related to the severity of motor deficits (especially hemiparesis) in our persons with TBI.

Cognitively, the most consistent positive effects of DARE were observed in neuropsychological tests measuring verbal working memory and reasoning (WAIS-IV subtests) and in a self-report questionnaire measuring executive deficits (BRIEF-A). Also the ratings on the subjective benefits questionnaire showed that the persons with TBI experienced notable improvement in cognitive functioning, especially in short-term and working memory and executive function, after the intervention. These results tentatively suggest that in addition to the motor benefits the learning process associated with acquiring the movement sequences in dancing may have far transfer effects on working memory and executive function, likely mediated by dopaminergic reward-based learning networks in limbic and prefrontal regions (61,62). Similar cognitive transfer effects have been reported for music interventions that involve playing musical instruments or performing other types of sequential movements to music in persons with stroke (63-65) and TBI (8-10). Also in one previous study of a mixed sample of persons with stroke, TBI, or cerebral aneurysm, dance and movement therapy (DMT) was reported to improve scores on the Cognitive Performance Scale, which is a simple assessor-based rating tool for decision making, communication, and short-term memory (42).

At the emotional level, large and consistent effect sizes favouring DARE compared to standard care were observed in a self-report questionnaire measuring depression (BDI-II). Again, this finding fits well with previous results on the positive effects of dance training on subjective well-being in healthy persons (24-27) and of dance therapy on mood, emotional adjustment, and self-esteem in different clinical populations (33,34), including Parkinson's disease (35,36) and mild cognitive impairment or dementia (37-41). Based on neuroimaging evidence, this mood-enhancing effect is likely mediated by deep mesolimbic regions, such as the nucleus accumbens and the orbitofrontal cortex, which are associated with the emotional processing of pleasant music (18,19) and have also been reported to show specific neuroplasticity changes after a music intervention in persons with stroke (66) and TBI (67). Also behavioural evidence from persons with TBI suggests that music interventions can be beneficial for mood and emotional adjustment (10,11). Overall, the cognitive and emotional gains of the DARE intervention seemed to go hand in hand and, according to the subjective experience of the therapists, were reflected by a strong atmosphere of positive doing where working was intensive, goal-oriented, and disciplined but also a lot of fun, with room for laughter and joyful interaction between the person with TBI and the therapists.

Although the findings were promising, some limitations and challenges were also identified, which need to be discussed and also taken into account when planning future studies. First of all, finding persons with TBI who met the inclusion criteria turned out to be challenging, particularly regarding the suitable severity of the motor (and cognitive) deficits. Of the 62 potential candidates who had severe / extremely severe TBI, 47 (76%) had to be excluded because they did not have any motor deficit to be targeted by DARE or they had too severe cognitive / motor deficits to enable participation in DARE or the study. For a full-scale RCT, it would be advisable to implement the study in a large TBI outpatient / rehabilitation centre or as a multicenter trial to enable sufficient patient flow. Second, the current study focused on young and middle-aged adults with TBI (age 18-50 years); older adults were excluded to avoid potential comorbidity with other age-related neurological disorders and to make the current sample more homogenous in terms of TBI type [for example, TBI is more often caused by falls and results in mass lesions in older adults (68)]. In practice, DARE could be utilized also in older adults with TBI, and a future trial could include also this population, as long as other inclusion criteria are met. Third, DARE is provided as individual rehabilitation by two therapists (a dance teacher/therapist and a physical therapist) and therefore requires personnel resources, which may be seen as a limiting factor in the clinical implementation and scalability of the intervention. However, given that the target group for DARE represents the most demanding part of the TBI population in terms of the level of disability, care costs, and societal burden (45,46), the potential benefits of the intervention may offset its costs; the actual cost effectiveness of DARE needs to be addressed in a larger trial. Finally, our recommendation of outcome measures for a larger trial is naturally limited by the measures that were included in the present trial. Our study focused on persons with TBI who have a motor deficit and included specific motor, cognitive, and emotional outcome measures. Also more generic outcome measures, such as participation or activity level, could have been included. However, based on the (i) nature of the DARE and its key component (dancing), (ii) clinical observations of the therapists (also evident in the video material, see Supplementary Videos), (iii) self-perceived benefits of the persons with TBI, and (iv) results of the motor outcome measures, our view is that the enhancement of whole body motor function (measured by TIS) is the most important clinical outcome of DARE and thus should be considered as a primary outcome measure in a larger trial.

In conclusion, the present study provides to our best knowledge the first-ever group-level evidence that dance-based rehabilitation is applicable and feasible also in severe / extremely severe TBI and that it may potentially enhance motor, cognitive, and emotional functioning. The clinical efficacy of DARE should be established in a larger RCT, for which our study provides the necessary proof-of-concept, effect sizes of potential outcome measures, and a power calculation.

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of the DARE concept and the present pilot study.

Declaration of interest statement

The authors declare no conflicts of interest.

Data availability statement

Anonymized data will be shared with qualified investigators on request.

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Figure legends

Figure 1. Flow chart outlining the design and progress of the study.

Figure 2. Self-perceived benefits of the dance intervention. Data are shown as mean (SEM). Significant difference from the mid-point value (5.5, shown with a dashed line) is marked with an asterisk (*p < 0.05, **p < 0.01, ***p < 0.005).

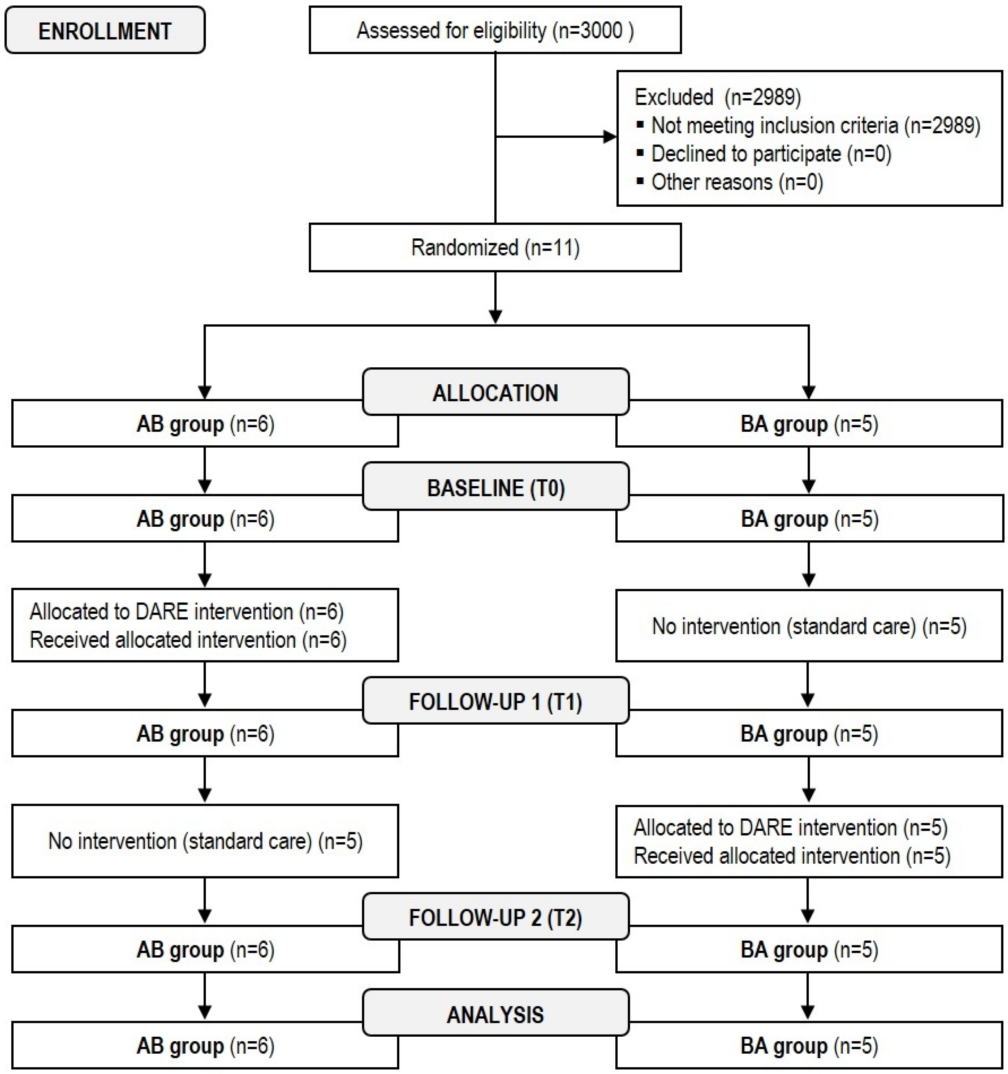

Figure 1. Flow chart outlining the design and progress of the study.

149x160mm (150 x 150 DPI)

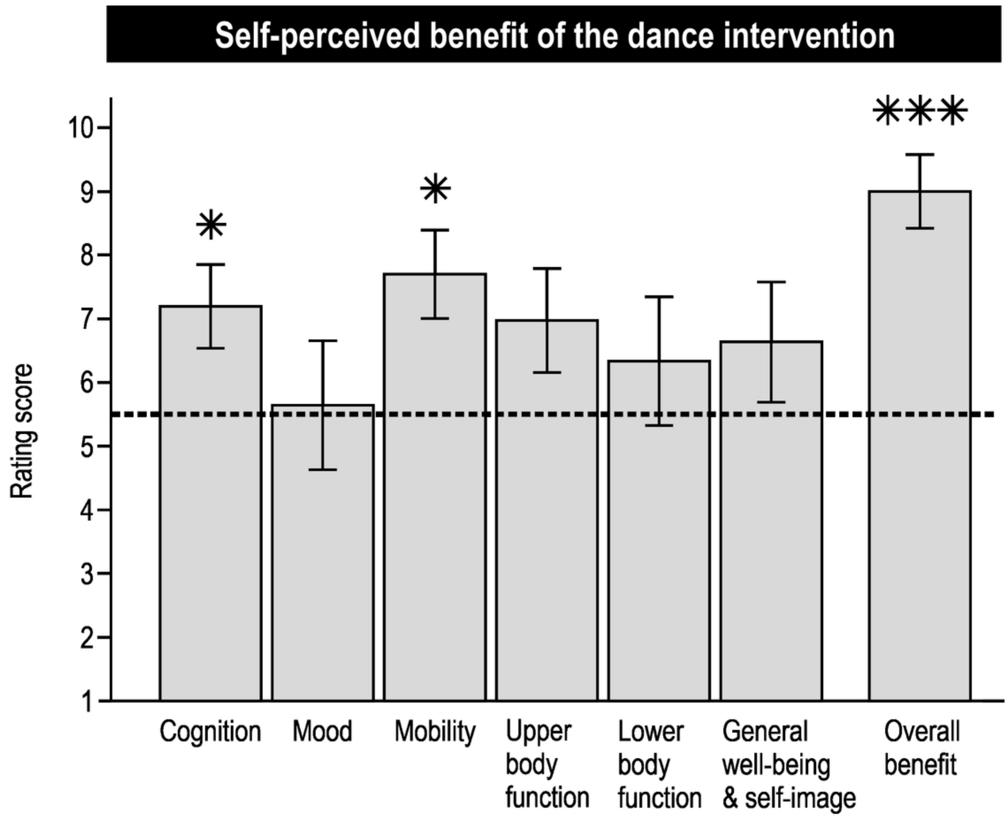

Figure 2. Self-perceived benefits of the dance intervention. Data are shown as mean (SEM). Significant difference from the mid-point value (5.5, shown with a dashed line) is marked with an asterisk (*p < 0.05, **p < 0.01, ***p < 0.005).

95x77mm (300 x 300 DPI)

Table 1. Demographic and clinical characteristics of the participants

	AB group (N = 6)	BA group (N = 5)	p value
Demographic factors			
Gender (male/female)	3/3	4/1	0.545 ($\chi 2$)
Age (years)	36.3 (6.5)	35.0 (13.9)	0.838 (t)
Education level[a]	2.5 (1.2)	1.4 (0.5)	0.098 (t)
Clinical factors			
Time since TBI (years)	9.2 (2.5)	5.8 (3.1)	0.078 (t)
TBI type: diffuse axonal injury (yes/no)	5 / 1	3 / 2	0.545 ($\chi 2$)
TBI type: local intracerebral injury (yes/no)	6/0	5/0	NA
TBI type: extracerebral hemorrhage (yes/no)	3/3	3/2	1.000 ($\chi 2$)
Loss of consciousness after TBI (days)	53.2 (54.1)	27.0 (21.8)	0.345 (t)
Post-traumatic amnesia after TBI (days)	120.0 (42.4)	128.8 (68.6)	0.835 (t)
Neurosurgery after TBI (yes/no)	5/1	4/1	1.000 ($\chi 2$)
GCS score after TBI	4.0 (1.0)	3.3 (0.5)	0.243 (t)
Epileptic seizures after TBI (yes/no)	4/2	3/2	1.000 ($\chi 2$)
Motor deficits (hemiparesis) after TBI (yes/no)	5/1	5/0	1.000 ($\chi 2$)
Physical therapy (yes/no)[b]	6/0	5/0	NA
Occupational therapy (yes/no)[b]	6/0	5/0	NA
Speech therapy (yes/no)[b]	6/0	5/0	NA
Neuropsychological rehabilitation (yes/no)[b]	6/0	5/0	NA
GOSE score at study onset	4.0 (0.6)	3.4 (0.5)	0.131 (t)

Data is mean (SD) unless otherwise stated. Abbreviations: $\chi 2$ = chi square (Fisher's exact test), GCS = Glasgow Coma Scale, GOSE = Glasgow Outcome Scale Extended, t = t-test

[a]Measured with a 6-point Likert scale (1 = primary education, 6 = doctorate level)

[b]Received rehabilitation after the TBI (from onset until start of study)

Table 2. Outcome measure scores at different time points

	G	T0	T1	T2	T1-T0		T2-T1		Δ Intervention	
		mean (SD)	mean (SD)	mean (SD)	mean (SD)	d (95% CI)[a]	mean (SD)	d (95% CI)[a]	mean (SD)[b]	p value
MOTOR TESTS										
TIS total score (max. 16)	AB	7.8 (4.2)	9.3 (3.8)	10.0 (3.6)	1.5 (1.6)	0.76 (-0.61, 2.13)	0.7 (1.2)	0.47 (-0.90, 1.84)	1.7 (1.0)	**0.010**
	BA	7.8 (1.5)	8.2 (2.6)	9.8 (2.3)	0.4 (1.1)		1.6 (2.4)			
BBS total score (max. 56)	AB	27.6 (18.9)	27.2 (18.5)	30.0 (19.2)	-0.2 (1.5)	0.01 (-1.36, 1.38)	2.8 (3.2)	-1.21 (-2.58, 0.16)	-0.6 (2.5)	0.426
	BA	44.2 (12.5)	44.0 (10.8)	43.0 (10.7)	-0.2 (2.9)		-1.0 (3.2)			
ARAT left score (max. 57)	AB	48.8 (11.7)	47.3 (14.2)	48.0 (11.8)	-1.5 (6.9)	-0.48 (-1.85, 0.89)	0.7 (2.8)	0.83 (-0.54, 2.20)	-0.5 (2.1)	0.483
	BA	45.4 (17.0)	46.4 (15.7)	50.0 (11.7)	1.0 (1.6)		3.6 (4.0)			
ARAT right score (max. 57)	AB	32.8 (26.6)	31.8 (27.9)	31.7 (27.2)	-1.0 (1.3)	-0.39 (-1.76, 0.98)	-0.2 (1.6)	0.49 (-0.88, 1,86)	1.3 (6.8)	0.548
	BA	46.2 (21.5)	45.8 (21.2)	46.4 (22.0)	-0.4 (1.8)		0.6 (1.5)			
GAITRite walking speed (cm/sec)	AB	61.2 (64.7)	61.1 (64.4)	62.0 (60.4)	-0.02 (14.5)	-0.07 (-1.66, 1.52)	0.9 (5.6)	0.06 (-1.53, 1.64)	1.1 (13.5)	0.814
	BA	76.1 (36.7)	76.9 (44.3)	78.1 (45.5)	0.82 (10.1)		1.2 (5.8)			
NEUROPSYCHOLOGICAL TESTS										
MoCA total score (max. 30)	AB	15.5 (3.7)	17.8 (5.3)	19.7 (4.5)	2.3 (3.3)	-0.02 (-1.39, 1.35)	1.8 (3.5)	-1.00 (-2.37, 0.37)	1.3 (2.7)	0.152
	BA	16.8 (2.3)	19.2 (1.6)	18.2 (2.7)	2.4 (2.1)		-1.0 (1.6)			
FAB total score (max. 18)	AB	13.3 (2.1)	13.3 (1.0)	13.5 (2.4)	0.0 (1.7)	-1.47 (-2.84, -0.10)	0.2 (2.3)	0.12 (-1.25, 1.49)	1.5 (2.5)	0.087
	BA	12.4 (0.9)	15.2 (1.9)	15.6 (1.7)	2.8 (2.2)		0.4 (1.5)			
SART correct resp. (max. 50)	AB	34.0 (6.5)	37.0 (9.3)	39.7 (6.2)	3.0 (12.0)	0.46 (-0.91, 1.83)	2.7 (5.6)	-0.83 (-2.20, 0.54)	-0.2 (11.1)	0.958
	BA	15.4 (7.2)	13.8 (8.0)	11.4 (6.1)	-1.6 (6.5)		-2.4 (6.6)			
WAIS-IV Digit Span (max. 32)	AB	13.3 (12.0)	14.5 (12.5)	14.8 (11.7)	1.3 (2.7)	0.57 (-0.80, 1.94)	0.3 (1.4)	0.34 (-1.03, 1.71)	1.3 (3.3)	0.232
	BA	19.0 (5.4)	19.0 (4.7)	20.2 (7.3)	0.0 (1.9)		1.2 (3.6)			
WAIS-IV Similarities (max. 36)	AB	13.7 (11.5)	16.0 (13.1)	16.3 (12.7)	2.3 (2.6)	0.89 (-0.48, 2.26)	0.3 (1.9)	0.63 (-0.74, 2.00)	2.2 (2.0)	**0.005**
	BA	26.2 (3.5)	26.2 (5.6)	28.2 (3.6)	0.0 (2.6)		2.0 (3.4)			
WAIS-IV Block Design (max. 66)	AB	37.3 (7.9)	39.2 (4.9)	41.8 (6.9)	1.8 (7.5)	0.72 (-0.65, 2.09)	2.7 (6.9)	0.32 (-1.05, 1.69)	2.0 (6.0)	0.297
	BA	30.4 (11.8)	27.8 (11.0)	32.6 (12.0)	-2.6 (3.8)		4.8 (6.2)			
QUESTIONNAIRES										
BRIEF-A GEC score (max. 100)	AB	54.4 (43.2)	43.8 (30.9)	44.4 (32.4)	-10.6 (17.7)	0.84 (-0.62, 2.30)	0.6 (7.1)	0.56 (-0.90, 2.02)	-6.3 (14.1)	0.194
	BA	41.5 (22.3)	45.1 (21.9)	39.5 (28.4)	3.6 (15.9)		-5.6 (13.8)			
BRIEF-A BRI score (max. 100)	AB	25.6 (20.4)	20.8. (14.3)	21.8 (14.6)	-4.8 (11.5)	0.65 (-0.81, 2.11)	1.0 (6.8)	0.52 (-0.94, 1.98)	-2.7 (8.6)	0.351
	BA	16.6 (10.8)	19.2 (11.1)	16.0 (12.5)	2.6 (11.0)		-3.2 (9.0)			
BRIEF-A MI score (max. 100)	AB	28.8 (23.5)	23.0 (17.3)	22.6 (20.0)	-5.8 (6.9)	1.09 (-0.37, 2.54)	-0.4 (3.6)	0.43 (-1.03, 1.89)	-3.6 (6.3)	0.104
	BA	24.9 (13.4)	25.9 (13.8)	23.5 (17.7)	1.0 (5.5)		-2.4 (5.3)			
BDI-II total score (max. 63)	AB	17.4 (10.3)	11.2 (7.9)	13.2 (9.0)	-6.2 (4.4)	1.19 (-0.27, 2.65)	2.0 (1.9)	1.74 (0.28, 3.2)	-4.9 (3.7)	**0.002**
	BA	11.0 (5.6)	11.2 (7.6)	7.4 (5.4)	0.2 (6.0)		-3.8 (4.3)			
QOLIBRI total score (max. 100)	AB	86.6 (26.4)	90.0 (25.3)	95.8 (22.0)	3.4 (7.9)	0.70 (-0.76, 2.16)	5.8 (4.9)	-0.27 (-1.72, 1.19)	0.2 (21.2)	0.977
	BA	96.4 (23.9)	93.0 (14.8)	93.6 (23.1)	-3.4 (11.2)		0.6 (27.2)			

Abbreviations: ARAT = Action Research Arm Test, BBS = Berg Balance Scale, BDI-II = Beck Depression Inventory II, BRI = Behavioral Regulation Index, BRIEF-A = Behavior Rating Inventory of Executive Function – Adult version, CI = confidence interval, d = effect size (Cohen's d), FAB = Frontal Assessment Battery, G = Group, GEC = Global Executive Composite, MI = Metacognition Index, MoCA = Montreal Cognitive Assessment, QOLIBRI = Quality of Life after Brain Injury, SART = Sustained Attention to Response Test, SD = standard deviation, TIS = Trunk Impairment Scale, T0 = baseline, T1 = follow-up 1 (3-month stage), T2 = follow-up 2 (6-month stage), WAIS-IV = Wechsler Adult Intelligence Scale IV

[a]Positive effect sizes (d > 0) favour the group receiving the intervention (AB in the T1-T0 and BA in the T2-T1); the sign (+/-) of the effect size is reversed for outcome measures where smaller scores indicate better outcome (BDI and BRIEF-A)

[b]Difference score calculated by subtracting the baseline (T0) score from the post-intervention score (T1 for AB, T2 for BA)

Supplementary Table. Items in the post-intervention questionnaire on subjective benefits of DARE (scale 1: no benefit at all – 10: extremely beneficial). The items within each domain are listed in descending order based on the mean ratings score.

Domain	Item	Mean	SD
Cognition	Short-term and working memory	7.6	2.2
	Executive function	7.4	1.5
	Attention	7.1	2.3
	Long-term memory	6.7	3.0
	Domain average	7.2	2.0
Mood	Mood	7.7	2.4
	Mental health	6.7	3.5
	Depression	5.3	4.2
	Anxiety	4.3	4.1
	Irritability	4.2	4.0
	Domain average	5.6	3.0
Mobility	Perception of body in relation environment	8.6	1.0
	Co-action of movements	8.2	1.8
	Balance	7.3	2.8
	General mobility	7.3	2.7
	Walking	7.1	3.7
	Domain average	7.7	2.1
Upper body function	Stiffness of arms	7.6	2.2
	Weakness of arm motor functions	6.8	3.1
	Stiffness of upper body	6.8	3.1
	Weakness of upper body motor functions	6.8	2.9
	Domain average	7.0	2.5
Lower body function	Standing posture	7.1	2.7
	Weakness of lower body motor functions	6.4	3.1
	Stiffness of legs	6.6	3.5
	Weakness of leg motor functions	6.0	3.6
	Stiffness of lower body	5.6	3.7
	Domain average	6.3	3.0
General wellbeing & self-image	Wellbeing	7.3	2.5
	Self-esteem	6.8	3.2
	View of own body	6.7	3.6
	Fear of falling	6.7	2.7
	Quality of life	6.6	3.4
	View of self as man / woman	6.3	3.3
	Physical health	6.0	3.1
	Domain average	6.6	2.8
Overall benefit		9.0	1.7

CONSORT Checklist for pilot studies (Thabane et al. 2010 BMC Medical Research Methodology)

Section/Topic	Item No	Checklist item	Reported on page #
Title and abstract			
	1	Does the title or abstract indicate that the study is a "pilot"?	1
Introduction			
Background	2	Scientific background for the main study and explanation of rationale for assessing feasibility through piloting	2-4
Methods			
Participants and setting	3	Eligibility criteria for participants in the pilot study (these should be the same as in the main study -- if different, state the differences)	4
		The settings and locations where the data were collected	4
Interventions	4	Provide precise details of the interventions intended for each group and how and when they were actually administered (if applicable) -- state clearly if any aspects of the intervention are assessed for feasibility	5-6
Objectives	5	Specific scientific objectives and hypotheses for the main study	4
		Specific feasibility objectives	4
Outcomes	6	Clearly defined primary and secondary outcome measures for the main study	6-7
		Clearly define the feasibility outcomes and how they were operationalized -- these should include key elements such as recruitment rates, consent rates, completion rates, variance estimates, etc	7
Sample size	7	Describe how sample size was determined	NA
		In general for a pilot of a phase III trial, there is no need for a formal sample size calculation. However, confidence interval approach may be used to calculate and justify the sample size based on key feasibility objective(s).	NA
Feasibility Criteria	8	Clearly describe the criteria for assessing success of feasibility -- these should be based on the feasibility objectives	7
Statistical methods	9	Describe the statistical methods for the analysis of primary and secondary feasibility outcomes	7-8
Ethical Aspects	10	State whether the study received research ethics approval	5
		State how informed consent was handled -- given the feasibility nature of the study	5
Results			
Participant flow	11	Flow of participants through each stage (a flow-chart is strongly recommended)	8 (Figure 1)
		Describe protocol deviations from pilot study as planned, together with reasons	NA
		State the number of exclusions at each stage and reasons for exclusions	8 (Figure 1)

Recruitment	12	Report the dates defining the periods of recruitment and follow-up	4, 8
Baseline data	13	Report the baseline demographic and clinical characteristics of the participants	8 (Table 1)
Outcomes and estimation	14	For each primary and secondary feasibility outcome, report the point estimate of effect and its precision (e.g., 95% confidence interval [CI]) -- if applicable	8-10 (Table 2)
Discussion			
Interpretation	15	Interpretation of the results should focus on feasibility, taking into account	11
		the stated criteria for success of feasibility;	11
		study hypotheses, sources of potential bias or imprecision -- given the feasibility nature of the study	13
		the dangers associated with multiplicity of analyses and outcomes	NA
Generalizability	16	Generalizability (external validity) of the feasibility. State clearly what modifications in the design of the main study (if any) would be necessary to make it feasible	11
Overall evidence of feasibility	17	General interpretation of the results in the context of current evidence of feasibility	10-14
		Focus should be on feasibility	10-14