NORDIC JOURNAL OF MUSIC THERAPY
2021, VOL. 30, NO. 4, 314–337
https://doi.org/10.1080/08098131.2020.1795704

Routledge
Taylor & Francis Group

ORIGINAL RESEARCH ARTICLE

Functional electrical stimulation+iPad-based music therapy for upper limb recovery after stroke: Study protocol for a mixed methods randomised controlled trial

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ABSTRACT

Introduction: Music therapy offers an effective avenue for simultaneously addressing goals of upper limb function and wellbeing post stroke. However, there are currently no trials of therapeutic music-making interventions for stroke survivors with a very weak upper limb (Grade 0–3 level of strength). This randomised controlled trial will examine the effect of Functional Electrical Stimulation (FES) with iPad-based music therapy on upper limb recovery and wellbeing outcomes for stroke survivors.
Method: This convergent mixed methods study will take place at seven participating hospitals in Sydney, Australia. Forty participants will be randomly allocated to usual care only or usual care plus daily FES+iPad-based music therapy for four weeks (20 sessions). Standardised assessments of the paretic upper limb and self-report well-being measures will be administered at three time points (pre- and post- intervention, and at three months follow up) by a blinded assessor. All participants will be interviewed about their perceptions of the way the treatment they received (usual care only or usual care plus daily FES+iPad-based music therapy) supported their recovery.
Results: Ethics approval has been granted and data collection has commenced.
Discussion: This treatment approach has the potential to improve upper limb function and wellbeing for stroke survivors. The intervention is novel in its capacity to engage stroke survivors with a very weak upper limb in therapeutic music-making.

ARTICLE HISTORY Received 27 June 2019; Accepted 11 June 2020

KEYWORDS Music therapy; upper limb; stroke; iPad; FES

Background

Each year approximately 50,000 people suffer a stroke in Australia alone (Queensland Brain Institute, 2018). On a global scale, stroke now impacts approximately 15 million people each year, leaving 5 million people with a permanent disability (World Health Organisation, 2020).

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Motor impairment in the form of hemiparesis is the most prevalent consequence of stroke, impacting at least 80% of survivors (Hatem et al., 2016). Of the 80% with hemiparesis, 50% of survivors will have long-lasting loss of upper limb function (Intercollegiate Stroke Working Party, 2016), thereby significantly limiting their ability to engage with Activities of Daily Living (e.g. bathing, eating, etc), leisure activities and work (Aparicio et al., 2019; Mehrholz et al., 2012). Though literature identifies the benefits of various interventions for mild impairment, regaining function of the upper limb of stroke survivors with moderate-to-severe impairment is still challenging (Carmona et al., 2018). The most commonly evaluated factors potentially influencing outcomes of stroke include; the location of stroke onset (Cheng et al., 2014; Feng et al., 2015), the severity of the stroke (Rost et al., 2016), and the time frame in which intensive rehabilitation commenced (Lynch et al., 2014). Further, approximately one-third of stroke survivors suffer from post-stroke depression (Hackett & Pickles, 2014; Persaud et al., 2018). This is a significant statistic, especially considering the fact that the presence of cognitive decline and depression in stroke survivors are indicative of a negative prognosis (Dušica et al., 2015; Paolucci, 2017).

Given the frequency of hemiparesis and depression post stroke, innovative rehabilitation approaches with potential to target both these factors would be beneficial to long-term outcomes. Music therapy has been reported to address wellbeing and physical goals simultaneously (Särkämö, 2018; Silveira et al., 2018). Whilst addressing the physical goal of music-making, the individual is given an avenue to engage in expressive acts as part of their rehabilitation (Raglio et al., 2017), which may have a positive effect on mood and reduce symptoms of depression post-stroke (Kim et al., 2011).

A recent Cochrane review found that there were only six randomised controlled trials examining the effect of musical interventions for upper limb stroke rehabilitation (Magee et al., 2017). Studies that identify benefits of using musical instruments for upper limb stroke rehabilitation include music therapy and music-supported therapy interventions. In music therapy, a credentialed music therapist uses music within a therapeutic relationship to address patient goals (Australian Music Therapy Association, 2012). Randomised controlled trials suggest that music therapy has a moderate (Scholz et al., 2016) to significant effect on the functional activity of the paretic upper limb in stroke survivors (Chouhan & Kumar, 2012; Raglio et al., 2017; Scholz et al., 2016; Thaut et al., 1998; Yakupov et al., 2017). One study also reported decreased anxiety and depression for stroke survivors participating in music therapy (Raglio et al., 2017).

Music-supported therapy is a novel approach utilised for post-stroke motor rehabilitation (Tong et al., 2015). Generally facilitated by physiotherapists and/or occupational therapists, this approach focuses on the use of instrument playing to address physical goals only (Rodriguez-Fornells et al., 2012). Research on music-supported therapy suggests that using musical instruments for post-stroke upper limb rehabilitation is feasible (Hill et al., 2011) and can improve upper limb function (Altenmüller et al., 2009), particularly with respect to speed and precision of movement (Schneider et al., 2007). Randomised controlled trials found that participants who engaged in playing musical instruments as part of their upper limb therapy exhibited clinically significant increases in active shoulder and elbow range (Hill et al., 2011; Paul & Ramsey, 1998). Therefore, there is some evidence for the efficacy of combining therapy-focused musical instrument playing with conventional treatment (physiotherapy and occupational therapy) for upper limb stroke (Tong et al., 2015).

Previous research implies that stroke survivors must have some level of function in the paretic upper limb to engage in music-making, whether they be in sub-acute care (Grau-Sánchez et al., 2018) or in the community setting (Street et al., 2018). Therefore, referrals for music therapy specifically aimed at post-stroke upper limb rehabilitation typically exclude individuals with limited to no functional movement in the paretic upper limb (Silveira et al., 2018). In order to give this subgroup of stroke survivors access to music therapy for the purpose of upper limb rehabilitation, a new approach may be required.

Functional Electrical Stimulation (FES) is a commonly used intervention for post-stroke motor rehabilitation (Eraifej et al., 2017). The purpose of FES in stroke rehabilitation is to improve the performance of a specific activity by increasing muscle activation. During FES, weakened muscle groups are electrically stimulated at the specific moment that the stroke survivor is to engage in a particular action (De Kroon et al., 2002). A recent systematic review found a statistically significant benefit of FES on success with activities of daily living when applied within two months of stroke onset (SMD 1.24; CI [0.46, 2.03]; n = 32) (Eraifej et al., 2017). Another systematic review found an overall effect size of 0.47 (95% CI 0.26–0.68) for strength and an overall effect size of 0.30 (95% CI 0.05–0.56) for functional activity in favour of electrical stimulation, where the majority of the included studies (10/16) specifically looked at the effect of electrical stimulation on the upper limb (Nascimento et al., 2014). It has also been suggested that electrical stimulation may contribute to neuroplastic changes (Stinear & Hubbard, 2012).

In recent times, tablet applications have been shown to be particularly useful for people with dense hemiparesis as they utilise touch-sensitive mechanisms requiring minimal strength and range of movement (Silveira et al., 2018). The growing inclusion of tablet technology in stroke rehabilitation indicates that it is a feasible and acceptable modality for treatment delivery (Ameer & Ali, 2017; Saposnik et al., 2014). Further, the accessibility of tablet technology offers the stroke survivor the opportunity to independently practice repetitive, intensive and task-specific training of the paretic upper limb between formal treatment sessions (Hubbard et al., 2009).

A global challenge faced by stroke survivors is the restoration of self (Raghavan et al., 2016). A solution to this challenge could be in combining therapies to simultaneously address the physical, psychological and social domains of rehabilitation (Raghavan et al., 2016). Therefore, engaging the upper limb in instrument playing through improvisation may also foster non-verbal expression, which can have a significantly positive impact in neurorehabilitation (Magee et al., 2017). Further, by encouraging the participant to explore a novel touch-sensitive musical instrument, they may see abilities that they were previously not aware of. This is particularly significant in rehabilitation, where increases in confidence may promote continued engagement for stroke survivors (Jones, Mandy et al., 2008).

The literature indicates individual benefits of music therapy, FES and tablet technology for post-stroke rehabilitation. Until now, music therapy interventions (for upper limb rehabilitation) have only been reported for stroke survivors with some level of upper limb function. As FES can be used to stimulate movement for stroke survivors with minimal to no function, its inclusion in music-based interventions may make music therapy available to stroke survivors for whom it was previously inaccessible. The music-making aspect of the intervention can also address goals of wellbeing. Based on these theoretical underpinnings we have created the FES+iPad-based music

therapy treatment protocol in order to utilise the combined benefits of music therapy, FES and tablet technology for upper limb rehabilitation and wellbeing outcomes post stroke.

Study Aims and Objectives

This research aims to examine the impact of FES+iPad-based music therapy (as an addition to usual care) on upper limb functional activity and wellbeing outcomes for stroke survivors. The primary objective is to identify whether the functional activity of the paretic upper limb improves with FES+iPad-based music therapy. The secondary objective is to identify whether wellbeing outcomes (self-efficacy, depression, anxiety and stress) improve with FES+iPad-based music therapy. Additional qualitative data gathered will be used to explore the participant experience about how the treatment they received (usual care only or usual care plus daily FES+iPad-based music therapy) supported their recovery.

Method

Study design

This study has a mixed methods design as shown in Figure 1. The primary quantitative component of the design includes a randomised controlled trial with concealed allocation, intention to treat analysis and blinded assessors. Forty participants will be recruited from seven rehabilitation hospitals in Sydney, Australia. As this is a multi-site study, a separate randomisation sequence will be generated for each site to ensure even distribution of intervention and control participants at each site (block randomization of 4). An offsite researcher who has no contact with participants holds the concealed random allocation sequences. Following baseline assessment, the recruiter will contact this offsite researcher to reveal group allocation for each participant.

The required sample size was calculated for the primary outcome: functional activity of the paretic upper limb as measured by the motor assessment scale. Using published data by Lannin et al. (2003) we calculated that a sample size of 19 will give an 80% probability of detecting a difference of 3/18 (approximately 20%) between the two groups on the upper limb items of the motor assessment scale. This has been calculated with an alpha level of 0.05 and a 15% dropout rate. This number has been rounded to 20 participants per group, giving a total sample size of 40.

Participants and recruitment

Participants eligible for this study will be adult inpatients at the participating hospitals, with recent stroke onset (of any type) resulting in upper limb impairment. Screening will take place once patients have commenced the rehabilitation phase of their treatment. Patients to be included in the screening process will be identified by the advice of a liaison staff member based on the selection criteria. Identified eligible patients will then be provided detailed information about the study and given the Participant Information Statement and Consent Form by the first author. Consenting patients will then complete the formal screening assessments and baseline assessment session prior to randomization.

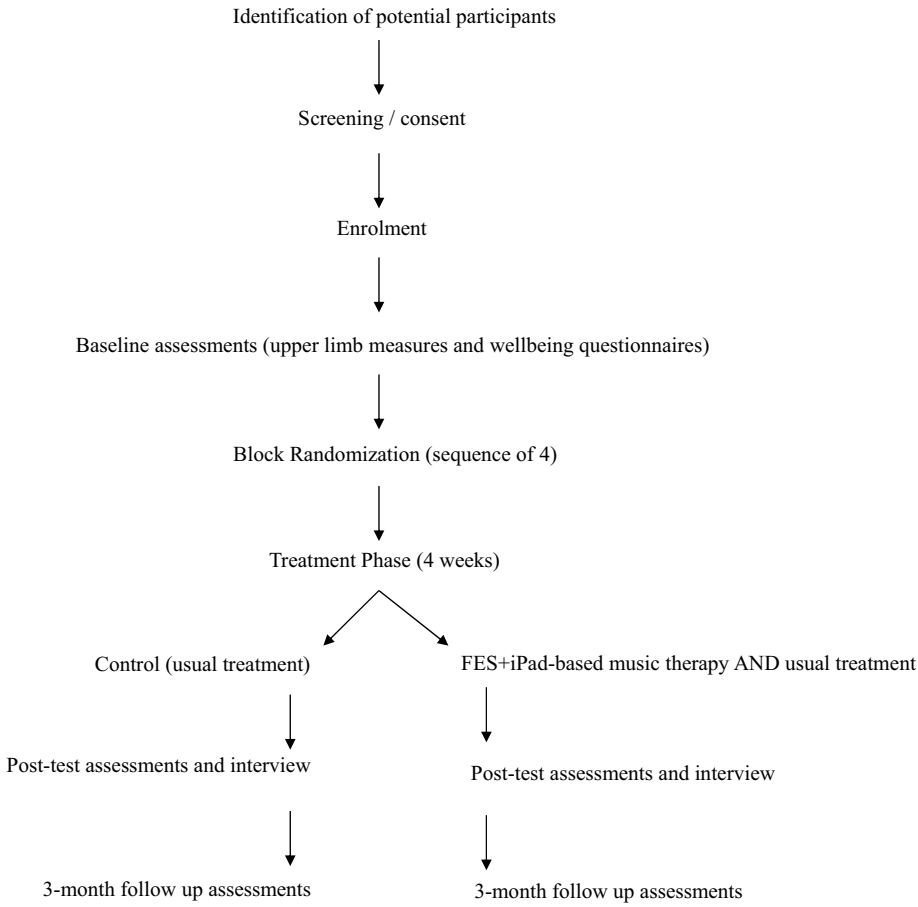

Figure 1. The study design flow chart

Inclusion criteria

To be eligible for inclusion in this study, participants need to meet the following criteria:

1. *Age 18 years old or over (no upper limit)*
2. *Medical diagnosis of stroke of any cause*
3. *Recruitment within 4 weeks of stroke onset*
4. *Inpatient status at one of the hospital recruitment sites*
5. *Less than grade 3 level of strength (inclusive) in at least 3 out of 5 muscle groups of the affected upper limb (shoulder flexors, elbow extensors, elbow flexors, wrist extensors and wrist flexors)*[1]
6. *Score at least 24 on the Mini Mental State Examination*
7. *Able to follow 2-stage commands*
8. *Predicted length of stay to be a minimum of 4 weeks from recruitment*[2]

[1]Stroke survivors that have a level of strength greater than level 3 do not require electrical stimulation.
[2]Intervention period is four weeks.

Exclusion criteria

The below criteria have been considered to impact the patients' ability to partake in the FES+iPad-based music therapy intervention. The exclusion criteria for this study are:

1. *Impairment in receptive communication*
2. *Cardiac pacemaker, hypersensitivity to electrical stimulation, severe skin conditions, and/or epilepsy*[3]
3. *Any pre-existing condition affecting upper limb function, e.g. Arthritis*

The study was approved by the South East Sydney Local Health District (SESLHD) Human Research Ethics Committee. The study was registered with the Australian New Zealand Clinical Trials Registry (www.anzctr.org.au – registration number ACTRN12618000344291). Written informed consent will be obtained from all participants.

Outcomes

Outcomes from this study will be measured using standardised assessments of upper limb function, self-report questionnaires and semi-structured interviews.

Primary outcome: Functional activity of the paretic upper limb

The functional activity of the paretic upper limb will be measured using standardised quantitative tests. The principle outcome measure for testing functional activity will be the upper limb items from the Motor Assessment Scale (UL-MAS) (Carr & Shepherd, 1994). The motor assessment scale contains a total of eight items that assess the functional activity of the individual after stroke onset. For the purpose of this study, the three items of upper limb function will be assessed, including; upper arm function, hand movements and advanced hand activities. Other measures of upper limb strength and function to be included are the Manual Muscle Tests of the upper limb (MMT-UL) (Kendall et al., 1993), the 9-Hole-Peg test (9HPT) (Mathiowetz et al., 1985) and the grip dynamometer (Hamilton et al., 1992). The MMT-UL is used to measure upper limb strength. In this study, five muscle groups will be assessed: shoulder flexors, elbow extensors, elbow flexors, wrist extensors and wrist flexors. The 9HPT is used to measure finger dexterity; in this test, the participant is instructed to move pegs from one container (one-by-one) to a hole in a board (as quickly as possible). A dynamometer is a hand-held device used for measuring the hand strength of an individual (Hamilton et al., 1992).

Secondary outcome: Wellbeing

Participant wellbeing will be assessed using the Stroke Self-Efficacy Questionnaire (SSEQ) and the Depression Anxiety and Stress Scale (DASS). The SSEQ is a psychometrically robust 13-item self-report measure used to assess a stroke survivor's level of confidence in functional performance post-stroke (Jones, Partridge et al., 2008;

[3]Patients with a cardiac pacemaker, hypersensitivity to electrical stimulation, severe skin conditions and epilepsy are not recommended to receive electrical stimulation (Roy, n.d.).

Riazi et al., 2014). The DASS is a 21-item self-report measure assessing depression, anxiety and stress (Henry & Crawford, 2005). Each subscale of the DASS has seven items, with a total possible score range of 0–21 (higher scores indicate greater severity of symptoms).

All quantitative assessments and questionnaires will be conducted by an assessor (either a physiotherapist or occupational therapist) who is blinded to group allocation at the following designated time points; at baseline (prior to group allocation), immediately post the 4-week intervention period, and 3 months following intervention completion.

Semi-structured interviews

The conclusion of the intervention period will be marked by the completion of the 20th session (intervention participants) and/or 4-week treatment period (control participants). However, should a participant be scheduled for an early discharge, the conclusion of the intervention period will be marked by their final session and/or inpatient day. On conclusion of the intervention period, the clinician-researcher (first author) will interview all participants about their perception of the way the treatment they received (usual care only or usual care plus daily FES+iPad-based music therapy) supported their recovery.

Data analysis

Quantitative analysis

The Blinded Assessors will be instructed to enter the quantitative data into REDCap; a secure online data management program. Using the baseline data as the covariate, an Analysis of Covariance (ANCOVA) will be used to determine whether there are any significant differences in functional activity (primary outcome) of the paretic upper limb or emotional wellbeing (secondary outcome) between the control and experimental conditions. We will report on all mean group differences and 95% confidence intervals.

Qualitative analysis

The semi-structured interview recordings will be transcribed verbatim. Using the 6-step procedure outlined by Braun and Clarke (2006), thematic analysis will be employed to generate themes from the interview data (Braun & Clarke, 2006). The purpose of this analysis will be in uncovering patterns related to the overall research question: How did engaging in the intervention you receive (usual treatment vs. usual treatment and FES+iPad-based music therapy) support your recovery?

Integration of data sets

After completing the quantitative and qualitative analyses separately, the data sets will be merged either by comparision or relation (Creswel, 2009). The results of this merge will then be used to address the initial research question of the study.

Interventions

Control group and experimental conditions – Usual therapy

Participants in both the control and experimental conditions receive the usual rehabilitation therapies provided at each hospital. As a multi-site trial, the following descriptor detailing usual therapy for post-stroke upper limb rehabilitation was created and accepted by each site:

> Both groups will undergo inpatient rehabilitation, which will continue as usual, including usual arm therapy. Usual arm therapy [for stroke rehabilitation] is delivered as three to five hours per week of group therapy and one to five hours per week of individual therapy, plus some independent practice. For very weak muscles (i.e. Grade 0, 1 and 2), usual arm therapy involves providing an environment where repetitive active movements could be attempted using gravity-eliminated positions, decreasing friction and shortening the lever arm of the limb. For stronger muscles (i.e. Grade 3 or 4) usual arm therapy includes progressive resistance exercise and task specific training.

The type, frequency and dose of usual treatment for each participant will be documented to account for variation in treatment between participants and sites.

Experimental condition – FES+iPad-based music therapy

In addition to usual therapy, the participants in the experimental condition will receive FES+iPad-based music therapy. The intervention was developed and expanded from previously published clinical work (Silveira et al., 2018). This music therapy intervention combines electrical stimulation with iPad-based music-making (using the iOS application "ThumbJam©"). The purpose of the intervention is to engage stroke survivors with a very weak upper limb in therapeutic music-making, whereby the movement of the paretic upper limb on the iPad-based instrument is initially triggered by electrical stimulation. Electrical stimulation will initially focus on the simultaneous movement of wrist and finger extension of the paretic hand to engage in producing sound on the iPad-based instrument. Over the course of the intervention period, participants will work toward initiating movement without electrical stimulation.

Participants in the experimental group will receive 20 individual sessions of daily FES+iPad-based music therapy plus their usual treatment (as described above), over a 4-week period. The type, frequency and dose of usual treatment for each participant will be documented. Sessions will take place 5 days a week (weekdays) and each session is allocated 1 hour (30–45 minutes of music-making). Sessions 5, 10, 15 & 20 will be video recorded for further analysis and fidelity checking.

The FES will initially be applied to the participant's paretic upper limb by the treating physiotherapist or occupational therapist. As this intervention is centred on music-making, triggered electrical stimulation (external triggering of on/off periods of electrical stimulation) will be used. Continuous stimulation will be applied as determined by the musical task or length of musical engagement. To ensure that the participant's upper limb is appropriately supported, a firm cushion will be placed under the elbow and forearm during the intervention.

Participants will select at least two of the three streams of music-making from the FES+iPad-based music therapy intervention protocol (as described below). The impact of the various combinations of music-making streams on the participants' functional activity, motivation and self-reported wellbeing over the course of the intervention period will be examined.

Terminology

It is important to identify and define the terminology that will be used throughout the protocol. The decision trees used for the intervention protocols reference the following terms:

- *Pt.*: the participant receiving FES+iPad-based music therapy (experimental group).
- *Active wrist extension*: the participant engaging in the movement of *wrist extension* without the aid of electrical stimulation (i.e. during "off" periods of electrical stimulation).
- *x beats*: the programming of meter for the metronome.
- *Maintain*: in the *maintain* phase, electrical stimulation will initiate the extension of the wrist and fingers and the participant will be asked to hold this position once the electrical stimulation ceases (i.e. during "off" periods of electrical stimulation). Participants will then be asked to *slowly* release the hand back down.
- *Finger tapping*: the ability of the participant to extend and flex the finger/s to produce sound on the iPad-based instrument.
- *Isolated finger tapping*: the ability of the participant to purposefully isolate each finger movement and produce single note sounds on the iPad-based instrument.
- *Patterned finger tapping*: the ability of the participant to follow a pattern of isolated finger movement when producing single note sounds that are in a specific order on the iPad-based instrument.
- *Initiate*: the ability of the participant to begin the movement without the aid of electrical stimulation.
- *Phrase*: if the participant is learning a song with lyrics, one phrase will be determined by one full lyrical line.

The music-making streams

Participants may determine the ordering and time spent engaging with the music-making streams each session. Each session will include 30 to 45 minutes of music-making, depending on fatigue. Prior to commencing music-making, the music therapist will perform light massage on the paretic hand of the participant to promote blood flow. The three music-making streams of directed improvisation, song learning and free improvisation are described below. Free improvisation is different to directed improvisation and song learning as it is the only stream of music-making that does not involve specific task progression. Participants engaging in directed improvisation and song learning may only progress on successful completion of previous exercises as per the relevant decision tree. Participants will be asked to select at least 2 streams of music making to engage with over the course of the 4-week intervention period – participants may engage in multiple music-making streams or one music-making stream each session. On repetition of the decision trees, if the FES is no longer needed, the participants will engage in the same indicated exercises without FES (as per the decision tree). Electrical stimulation will be delivered via the NeuroTrac device on program 12 (350/45), with the appropriate level of stimulation as indicated by the participant and treating clinician. The intensity of electrical stimulation may vary dependent on the participant's responsiveness, progression of exercises and/or potential muscle fatigue. Once the treating physiotherapist or occupational therapist identifies the optimum stimulation

level, the trigger will be used to control on and off electrical stimulation. The participant may choose to control the triggering of on/off electrical stimulation if appropriate. The on/off periods of electrical stimulation will be indicated by the below decision tree protocols and at the discretion of the participant.

Directed improvisation

The theoretical underpinnings of the directed improvisation music-making stream stem from neurologic music therapy concepts. Though this intervention will not utilise specific neurologic music therapy techniques, it will draw upon modified approaches. Neurologic music therapy techniques that have been considered in developing this protocol include: Therapeutic Instrumental Music Performance (TIMP) and Patterned Sensory Enhancement (PSE). The aspects of TIMP that have been considered for directed improvisation are its focus on the inclusion of instrument playing to encourage exercise and stimulate functional movement patterns (Thaut, 2005). Perhaps more obvious is the link between directed improvisation and PSE, in which the training of specific movement and exercise is facilitated by temporal, spatial and force cues (Thaut, 2005). A common feature to both TIMP and PSE is the training of specific functional movement patterns through music participation activities. Though this current study focuses on the use of one instrument (iPad-based) to train functional movement patterns, the notion of stimulating functional movement patterns using auditory cuing is central to the directed improvisation stream of music making.

In the directed improvisation stream, the participant will be encouraged to engage in repetitive task practice by playing the iPad-based instrument. Over the course of this stream, there will be a focus on rhythmic aspects of music to promote timing and accuracy of motor output. Auditory stimulation is central to directed improvisation through use of metronome and instrumental accompaniment. Initially, the music therapist will use the metronome to guide wrist and finger extension movement at a pace that is manageable for the participant. To further support the participant as they progress, the music therapist will use live musical accompaniment. The purpose of the decision tree in directed improvisation is for the participant to engage in structured and supported motor output training (see Figure 2).

As indicated in Figure 2, the music therapist must assess the participant's ability to maintain wrist extension during off periods of electrical stimulation. During this assessment, the music therapist will trigger electrical stimulation and then instruct the participant to actively maintain extension during the "off" period. The music therapist will then program the metronome sequence to match appropriate on/off periods for the participant. However, if the participant does not respond to maintaining wrist extension, an alternative approach that draws upon any presenting movement has been included (as indicated in Figure 2). The music therapist has a specific role in facilitating progress in the directed improvisation stream of music making via appropriately programming the meter and tempo of the metronome and continuing to musically support the participant's musical output.

The programming of the iPad-based instrument will change over the course of the directed improvisation stream to meet changing participant preferences and requirements of task progression as per the decision tree. Each session, the participant may choose a different instrumental sound and/or scale to be programmed, providing an opportunity to engage in daily choice making, throughout the

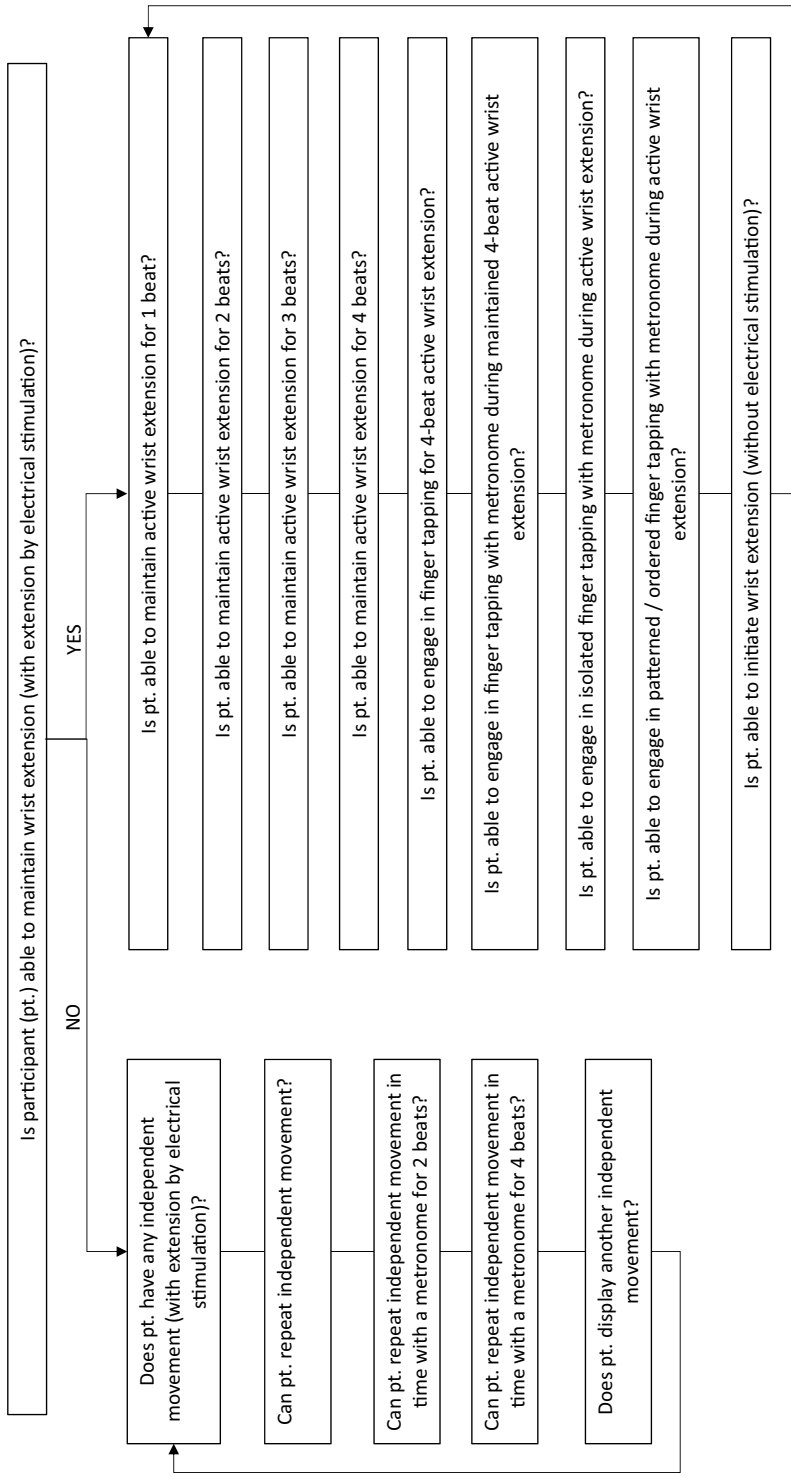

Figure 2. The decision tree for the directed improvisation music-making stream

intervention period. The only element of programming that is dictated by the decision tree is the number of octaves: as the number of octaves increase, the width of the notes decrease. For example: the iPad may initially be positioned vertically and multiple octaves will be programmed to encourage more auditory feedback as the participant engages in wrist extension exercises (See Figure 3). In

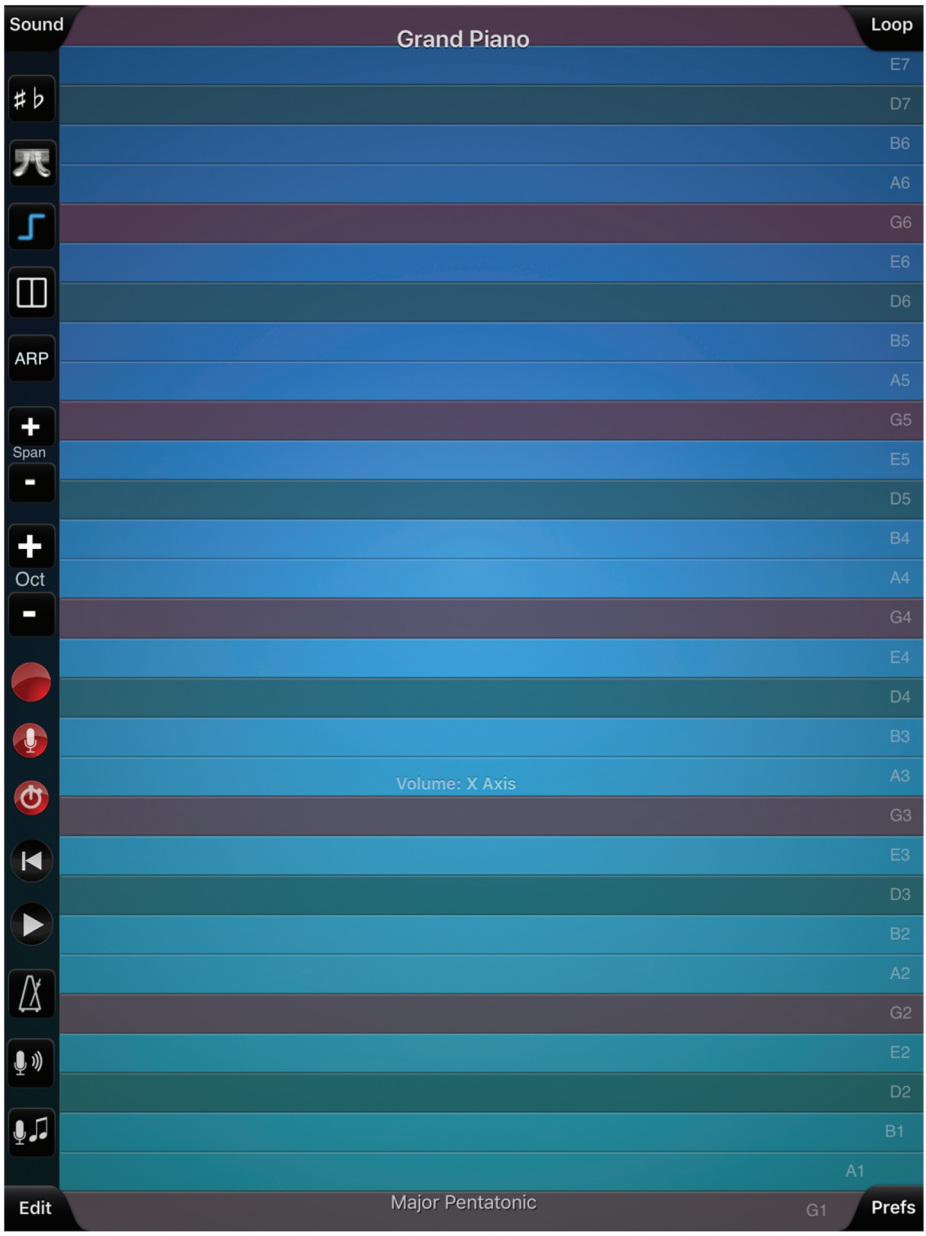

Figure 3. Programming of iPad-based instrument ("ThumbJam") for wrist/finger extension (Directed Improvisation and Free Improvisation)

programming multiple octaves, a greater number of notes will sound as the participant engages in movement on the iPad-based instrument. However, when the focus of movement progresses to finger tapping, only one octave will be programmed to allow for auditory distinction between individual notes and finger movement, and the iPad will be placed horizontally (See Figure 4). The wider bars that eventuate from fewer octaves will give the participant more opportunity to engage successfully

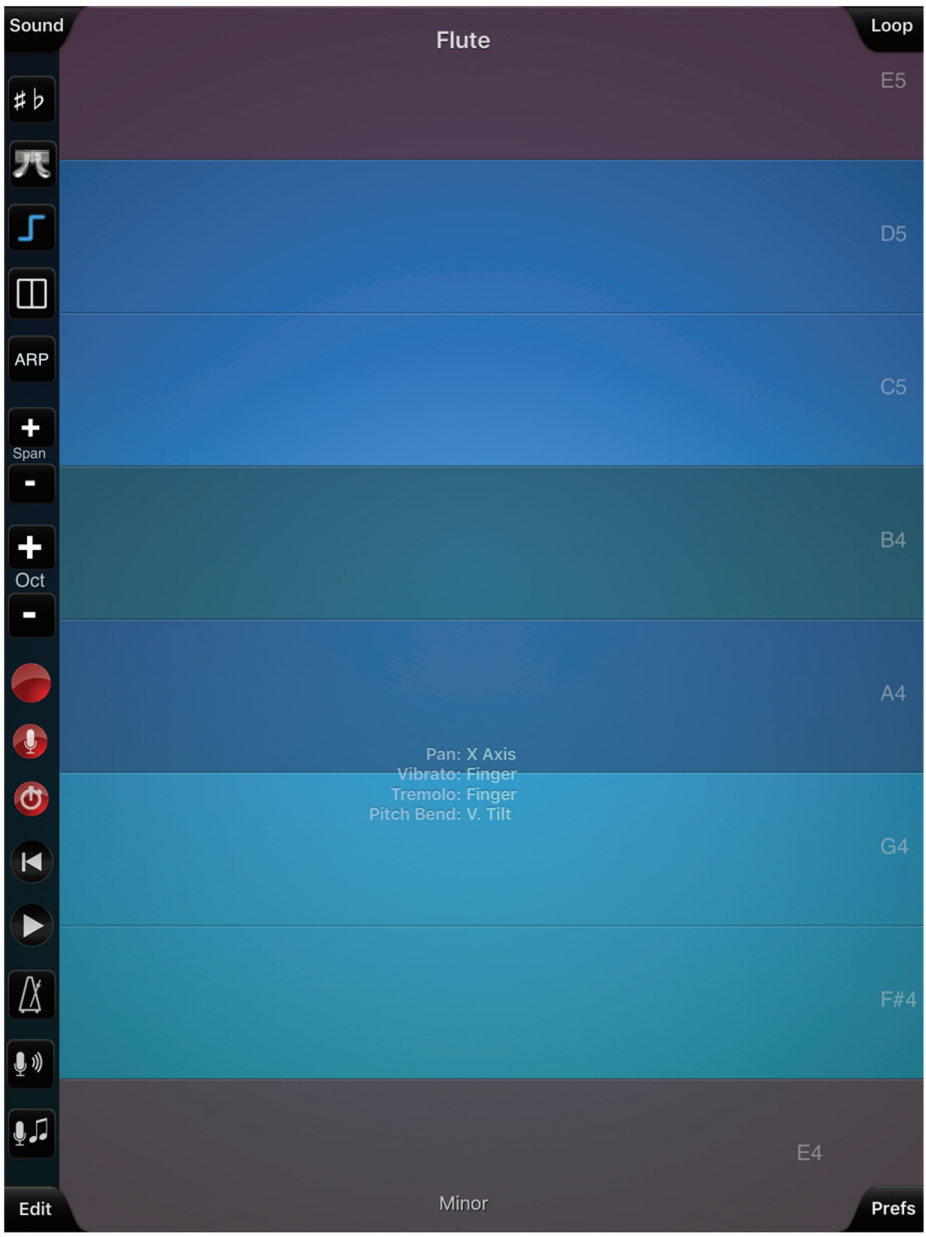

Figure 4. Programming of iPad-based instrument ("ThumbJam") for finger tapping exercises (Directed Improvisation and Song Learning

during the finger-tapping component of the protocol. This is an important change in programming to promote the individuation of finger use and specificity of movement on the instrument.

Song learning

The purpose of the decision tree in the song learning stream (Figure 5) is to promote greater control of the specificity of movement through familiar and structured training. This stream is based upon theories regarding the reported benefits of music for leisure (Särkämö, 2018), familiar song singing (Daykin et al., 2017) and song learning in older adults (Reid et al., 2017). Even though the focus of this music-making stream is to encourage task-specific motor output by learning a song, the wellbeing (Daykin et al., 2017) and rehabilitative benefits of singing (Stegemöller et al., 2017) have also been considered.

In the song learning stream, the participant will learn to play an excerpt of a familiar song. The participant will select a familiar song and the music therapist will transcribe an excerpt of this song in a format that is achievable for the participant to learn. Over the course of the song learning stream, there is a focus on melodic aspects of music-making. The participant will be encouraged to enhance their audio-motor connections by recognising the congruency between the singing of the song and the motor output on the iPad-based instrument. By encouraging the participant to sing whilst learning to play the song on the iPad-based instrument, the aim is to improve rhythmic accuracy by matching motor output to internalised rhythmic patterns. Singing may also encourage the participant to reflect upon the significance of the song during various points in their life (Rolvsjord, 2001).

Though there are some similarities to the directed improvisation stream, the purpose of song learning is different. The first distinction is the absence of the metronome as an auditory cue in song learning – the music therapist will guide the progression of song learning with gestural instruction whilst singing and eventually accompanying. In working through the decision tree, the participant is working toward a specific outcome: the ability to produce an excerpt of a familiar song on the iPad-based instrument. The language used in the song learning decision tree refers to lyrics and phrases of the musical excerpt, rather than beats. As this stream of music making is based on a familiar song, the scale input is to be determined by the music therapist, and an appropriate key centre is selected based on the participant's vocal range to encourage singing while they play. Participants will be given choice in the song they use for this stream, as well as the instrumental sound to be programmed (which can be changed each session).

The role of the music therapist in the song learning stream of music-making is to work with the participant to encourage maximum learning and retention of the relevant motor output sequences. The format of the song transcription may vary from participant to participant depending on their musical background and training. Potential modes of transcription include but are not restricted to: formal notation onto manuscript, colour coded notation, alphabetical notation, and graphical notation. All modes of transcription will include the lyrics to ensure that the link between the note output and lyrics are apparent. When learning the song excerpt, the music therapist will encourage the participant to utilise the fingers that have most movement and include finger patterns as part of the transcription. Figure 6 contains an example of the numerical and alphabetical notation of "Bye Bye Blackbird" for a stroke survivor with

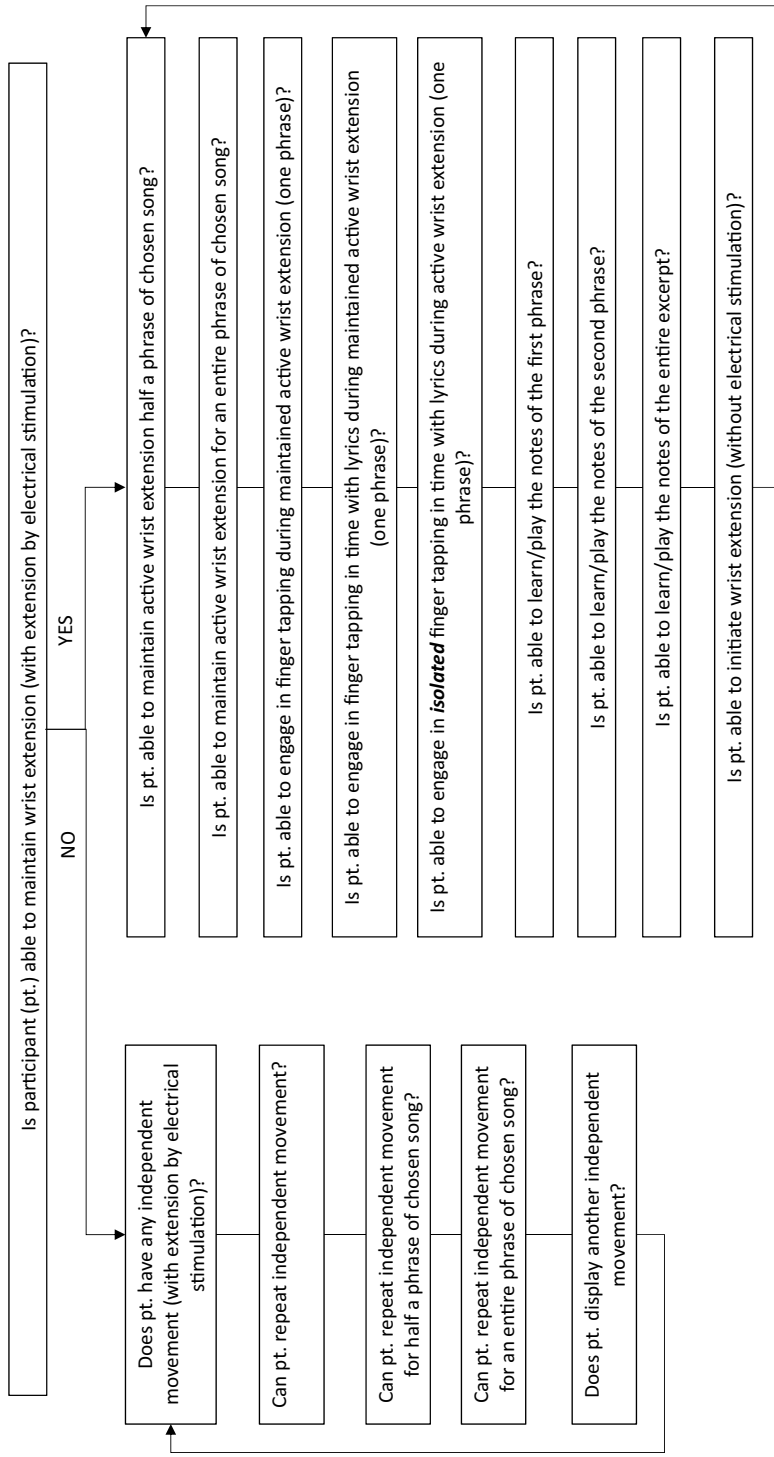

Figure 5. The decision tree for the Song Learning music-making stream

Alphabetical notation

B	B	B	B	C	B	B
Pack	up	all	your	cares	and	woe
B	A	A	A	G	G	
Here	I	go,	sing -	ing	low	
G	A	G	F#			
Bye	bye	black -	bird			
C	C	C	C	D	C	C
When	some -	bo -	dy	waits	for	me
C	B	B	B	A	A	
Su -	gar	sweet,	so	is	he,	
A	B	A	G			
Bye	bye	black -	bird			

Numerical notation

2	2	2	2	3	2	2
B	B	B	B	C	B	B
2	1	1	1	2	2	
B	A	A	A	G	G	
2	3	2	1			
G	A	G	F#			
2	2	2	2	3	2	2
C	C	C	C	D	C	C
2	1	1	1	2	2	
C	B	B	B	A	A	
2	3	2	1			
A	B	A	G			

Figure 6. Numerical and alphabetical notation of "Bye Bye Blackbird"

activity in the index finger (2), middle finger (3) and thumb (1) of the right hand (in reference to the programming of ThumbJam in Figure 4):

As the participant gains confidence in learning the motor output sequences, the music therapist will provide less verbal and gestural prompting and will accompany the participant's playing using matching and complimentary musical accompaniment techniques (Wigram, 2004), whilst continuing to sing the song in synchrony with the participant's motor output. To monitor progress in the song learning stream of music making, the music therapist will transcribe the motor output (the notes played by the participant) from the session recordings and compare this to the transcription initially provided by the music therapist.

Free improvisation

The theoretical underpinnings of the free improvisation component of the protocol are based on the therapeutic benefits of musical improvisation (Erkkilä et al., 2011). The focus of the free improvisation stream is to give the participant the opportunity to freely create music without any pre-determined parameters. Each session, the music therapist will encourage and support the participant to select an instrumental sound and scale to be used. The iPad-based instrument will initially be programmed for multiple octaves, with a minimum of 4 (please refer to Figure 3), to promote the attainment of audible notes and/or tone clusters through subtle movements of the hand. As the iPad-based instrument is touch-sensitive, there is potential for the participant to generate sound via subtle movements in the hand. The participant will be encouraged to choose the number of octaves to be programmed, as well as their preference for the positioning of the iPad-based instrument prior to playing (e.g. flat, vertical or horizontal).

The purpose of the free improvisation music-making stream is to encourage the participant to engage in self-directed free playing. As this stream draws upon the benefits of therapeutic musical improvisation, a decision tree is not required. The participant will determine the amount of time spent improvising and the music therapist will follow this both musically (accompanying the participant) and by managing the electrical stimulation on/off periods. Depending on the participant's progressing level of strength, they may choose to engage in free improvisation without electrical stimulation. The participant may also engage in multiple improvisations each session.

The role of the music therapist in the free improvisation music-making stream is to musically support the participant as they explore the iPad-based instrument through free improvisation. In order to do this, the music therapist will draw upon pre-existing frameworks for therapeutic improvisation (Meadows & Wimpenny, 2017) that are individualised to each participant. These frameworks include, but are not restricted to: empathic improvisation, reflective improvisation, grounding and holding (Wigram, 2004).

The implementation of this intervention protocol requires the skill set of a music therapist for the following reasons: (a) The music therapist is required to have a thorough understanding of time signatures and tempo in order to appropriately program the metronome to best suit the presenting abilities of the participant; (b) Should the participant choose the song learning stream of music making, the music therapist will be required to transcribe an excerpt of the chosen song; (c) The music therapist may need to accompany the participant using an instrument (e.g. guitar) in order to provide complimentary accompaniment (e.g. in Free Improvisation), guided

accompaniment (e.g. in Directed Improvisation) and/or supported accompaniment (e.g. in Song Learning).

Discussion

This study offers clinical relevance as it aims to test a newly developed rehabilitation intervention for people with a very weak upper limb post stroke. As previous research has separately identified the effectiveness of music therapy (Chouhan & Kumar, 2012; Raglio et al., 2017; Scholz et al., 2016; Thaut et al., 1998; Yakupov et al., 2017) and Functional Electrical Stimulation (Cuesta-Gómez et al., 2017) on the functional activity of the paretic upper limb, we hypothesize that the two combined will be beneficial to post-stroke upper limb function. The auditory feedback of music-making with FES may further motivate stroke survivors with limited to no function to engage in repetitive, intensive and task-specific practice (Hubbard et al., 2009) throughout their rehabilitation.

Further, by using the paretic upper limb for music-making, stroke survivors will concurrently engage in upper limb retraining and non-verbal expression (Magee et al., 2017). By fostering non-verbal expression through therapeutic music-making, this intervention also has potential to enhance emotional wellbeing for stroke survivors. As depression is highly prevalent in stroke survivors and leads to poor outcomes (Dušica et al., 2015; Paolucci, 2017), addressing the emotional wellbeing of the individual can be as important as addressing functional outcomes.

In combining an already established therapy (FES) with an emergent therapy (iPad-based music therapy) for post-stroke rehabilitation, this intervention is unique. Further to this, no randomised controlled trials have examined musical interventions for the very weak upper limb post-stroke until now. Therefore, there is a clear need to examine the effectiveness of FES+iPad-based music therapy. As this combined approach utilises existing rehabilitation technology (FES), it may also be of interest to a broader audience (e.g. physiotherapists and occupational therapists). The direction and flexibility in the music-making streams may also encourage clinicians to recognise, understand and incorporate more innovative approaches applicable to upper limb stroke rehabilitation. Further, as an adequately powered randomised controlled trial, this study should generate results that can be generalised to similar contexts.

As the recommendation and implementation of FES requires the expertise of an occupational therapist or physiotherapist, there may prove to be barriers for music therapists wishing to use this method. To overcome this challenge within the context of the current research, the clinician-researcher received training on the use of FES for upper limb stroke rehabilitation. An agreement was then formed between the clinician-researcher and each site whereby the clinician-researcher had permission to independently apply FES with the participants after receiving an initial handover of ideal placement from the treating clinician (occupational therapist or physiotherapist).

Limitations

This study seeks to compare the combined impact of FES and iPad-based music therapy (as an addition to usual therapy) with usual therapy alone. We are not aiming to compare FES +iPad-based music therapy with FES alone as the efficacy of FES has already been demonstrated in upper limb stroke rehabilitation. As FES is not isolated from the iPad-based music therapy component, it would not be possible to differentiate the effect of the

FES component from the music therapy component. However, this combination is essential as FES is needed to enable and assess music-making for stroke survivors with a very weak upper limb. Further to this, our study protocol necessitates a trained clinician other than the music therapist (e.g. physiotherapist or occupational therapist) to apply the FES to the stroke survivor prior to the first session. This may prove challenging due to the availability of these clinicians.

Another limitation is the lack of strict standardisation of the usual care control condition. In a multi-site trial, there is potential for the type and dosage of upper limb therapy, received as part of usual care, to vary. Along with this, the use and frequency of FES in usual treatment may vary from site to site; some participants may or may not receive FES, and the time spent engaged in FES may vary for each site and/or participant. However, as a pragmatic trial seeking to evaluate the effectiveness of the FES+iPad-based music therapy intervention, usual therapy for all participants will be carefully documented, including time engaged in FES per week, and compared across participants.

The use of self-report questionnaires could be criticised for biases due to potential social desirability effects (Gold et al., 2005). To mitigate this risk, an assessor who is blinded to group allocation will administer the questionnaires. Both the Stroke Self-Efficacy Questionnaire (SSEQ) (Jones, Partridge et al., 2008) and the Depression Anxiety and Stress Scale (DASS) (Henry & Crawford, 2005) are evidence-based questionnaires which are widely used and validated for use with stroke survivors.

Finally, the inclusion criteria for stroke survivors for this study are quite broad. Although this means that the sample may be more heterogeneous, broad inclusion criteria have been incorporated to maximise the potential to recruit participants with a level of strength appropriate for FES use. As eligible stroke survivors will have varying strength (Grades 0–3 on the Manual Muscle Test), participants will have varying levels of ability to engage in the intervention and potential for recovery during the session period. For example, participants with grade 3 level of strength at baseline will most likely be able to progress through the interventions at a greater pace than participants with grade 0 level of strength. As the primary purpose of this study is to test a music-making intervention designed for stroke survivors with limited to no upper limb function, this variation in baseline strength is unavoidable.

Conclusion

We anticipate that the findings drawn from this study will contribute to the growing body of evidence-based treatment options for stroke survivors. This randomised controlled trial will test the effectiveness of FES+iPad-based music therapy as a treatment option for upper limb stroke rehabilitation. In combining a music therapy approach with FES, this study is innovative, and its conclusions may be of interest to music therapists and non-music therapists. Further, this protocol's unique collaboration may encourage other clinicians to consider and potentially create more innovative approaches applicable to post-stroke upper limb rehabilitation.

Disclosure statement

Grace Thompson is Associate Editor of the Nordic Journal of Music Therapy. To avoid conflict of interest, Grace Thompson was fully masked to the editorial process including peer review and editorial decisions and had no access to records of this manuscript.

Funding

No funding was received for this study. TS created the basis of the protocol based on clinical work and drafted the manuscript. JT, SD and GT provided insight and advice to shape and clarify the protocol in the context of the research project and contributed to the development of the manuscript.

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Grace Thompson is a music therapist and senior lecturer at the University of Melbourne. Grace has worked with children, young people and families for over 20 years within the early childhood intervention and special education sector. In her clinical work, Grace developed a collaborative approach to music therapy practice with families guided by ecological theories and family-centred philosophy. Her research continues to explore the ways music therapists can foster relationships and social connection through participating in engaging and accessible music making. Grace is past president of the Australian Music Therapy Association and co-editor of the book "Music Therapy with Families: Therapeutic Approaches and Theoretical Perspectives". She is currently an Associate Editor with the Nordic Journal of Music Therapy.

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