ISRCTN03493594 https://doi.org/10.1186/ISRCTN03493594

Active music therapy for post-stroke recovery

Submission date	Recruitment status	[ ] Prospectively registered
05/06/2009	No longer recruiting	[ ] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
08/10/2009	Completed	[ ] Results
Last Edited	Condition category	[ ] Individual participant data
04/11/2009	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Esa Ala-Ruona

Contact details
University of Jyvaskyla
Finnish Centre of Excellence in Interdisciplinary Music Research
Music Therapy Clinic for Research and Training
Department of Music
P.O Box 35 (M)
Jyvaskyla
Finland
40014
+358 (0)142 601 342
esa.ala-ruona@jyu.fi

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Examining the effects of active music therapy on post-stroke recovery: a randomised controlled cross-over trial

Study objectives
1. To examine if active music therapy, added to standard care, has a beneficial effect on recovery from stroke (acute ischemic stroke or ICH) and enhances neurological function
2. To examine if active music therapy, added to standard care, improves recovery of cognitive function of post-stroke patient
3. To examine if active music therapy, added to standard care, has an effect on mood and experienced quality of life of post-stroke patient
4. To examine if active music therapy, added to standard care, has a positive impact on recovery of motor functions after stroke
5. To examine if active music therapy has different effects on post-stroke recovery when conducted as an early intervention versus delayed intervention
6. To examine if patient's awareness of deficits will improve during the course of active music therapy
7. To examine how patient's performance in playing rhythmic motor patterns changes during the course of active music therapy
8. To examine if there are changes in brain activity when processing auditory, spatial and musical information related to rhythmic motor patterns and musical emotions before active music therapy and after the intervention

Please note that as of 03/11/09 this trial has been updated to include both acute ischaemic and intracerebral haemorrhage (ICH) forms of stroke

Ethics approval required
Old ethics approval format

Ethics approval(s)
Keski-Suomen sairaanhoitopiiri (Central Finland Health Care District) Eettinen toimikunta (Ethical Board) approved on the 19th August 2008, and revised documents approved on the 19th May 2009 (ref: Poytakirja 5/2009).

Study design
Randomised controlled crossover trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
MCA stroke (acute ischaemic or intracerebral haemorrhage (ICH)

Interventions
All participants will receive standard care, and in addition to this, two (60 minutes) weekly sessions of active music therapy in individual setting over a period of 3 months. Standard care follows the Finnish Current Care guidelines for stroke.

The clinical model of active music therapy is based on combination of structured musical exercises in different levels of difficulty, interactive clinical improvisation, rhythmic dynamic playing with changing movement sequences, music assisted relaxation, and therapeutic discussion. Active music therapy is conducted by clinically trained music therapists. The target

number of bi-weekly sessions is 20, but patients with fewer sessions are not excluded from data analysis.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Measured in four phases: before randomisation, and after three, four (washout) and seven months after stroke. Magnetic resonance imaging (MRI) will be used for ensuring the diagnosis before initial tests.
1. Functional disability and activities of daily living (ADL) independency will be measured with the Barthel Index (BI)
2. Level of impairment will be evaluated with National institutes of Health Stroke Scale (NIHSS)
3. Disability grade will be assessed with Modified Rankin Scale (mRS)
4. Neglect will be evaluated with Behavioural Inattention Test (BIT)
5. Motor function of upper extremity will be assessed with Action Research Arm Test (ARAT)

Key secondary outcome(s))
Measured in four phases: before randomisation, and after three, four (washout) and seven months after stroke. Magnetic resonance imaging (MRI) will be used for ensuring the diagnosis before initial tests.
1. An extensive test battery of neuropsychological tests will cover the following areas: verbal and visual memory functions, working memory, visual perception, attention, executive functions and basic verbal functions. In addition, the neuropsychological assessment includes finger tapping, mood, quality of life, and self-awareness questionnaires.
2. Continuous and selective attention will be studied with Go/No-Go event-related potential (ERP) procedure. In addition, the electroencephalogram (EEG) recordings will include rest, musical stimulus, and mismatch negativity parts for studying auditory perception and activations of brain areas.
3. Motor function will be assessed with the help of following tests: box and block for measuring unilateral gross manual dexterity, pinch meter for measuring pinch force, jamar-meter for measuring grip force, and postural control and balance by sitting with Postural Control and Balance for Stroke (PCBS) test
4. Changes in motor function and skills (e.g. overall amount of movement, the range of movement and accuracy in motion) will be measured with Motion capture (MoCap) recording
5. Music analysis will be conducted by using special computational methods: Music Therapy Toolbox (MTTB) and Music Information Retrieval (MIR) for extracting particular musical features. Analysis is focused on musical interaction between patient and therapist, and to examine if clinical change is mediated by observable and measurable changes in music (such as synchronisation, clarity of pulse etc.). Musical data and special features will be used for complementing the data from MoCap (e.g. velocity on studying the accuracy in motion).
6. Every therapy session will be video-recorded, and the data will be used for studying the individual therapy processes, and as a resource for the interpretation of results. In addition, video-recordings will be used for monitoring treatment fidelity, and as a resource for supervision of the clinical music therapists involved.

Completion date
31/12/2012

Eligibility

Key inclusion criteria
Current information as of 03/11/09:
1. Middle cerebral artery (MCA) stroke (an acute ischaemic stroke or ICH) in the right temporal, parietal frontal and/or subcortical brain region 2. No prior clinically diagnosed cerebral stroke, but old ischemic or stroke changes may be detected as an incidental finding in the brain MRI. 3. No prior significant neurological or psychiatric disease excluding vascular aetiology (e.g. transient ischaemic attack [TIA]), migraine, epilepsy, non-symptomatic tumour or mild depression 4. Under 21 days post-stroke 5. No hearing impairment 6. No significant visual impairment 7. Aged less than or equal to 75 years old, either sex 8. Right-handed 9. Native Finnish speaker 10. Understands the aim of the study and is able to give own consent

Initial information at time of registration
1. An acute ischaemic middle cerebral artery (MCA) stroke in the right temporal, parietal frontal and/or subcortical brain region
2. No prior cerebral stroke
3. No prior significant neurological or psychiatric disease excluding vascular aetiology (e.g. transient ischaemic attack [TIA]), migraine, epilepsy, non-symptomatic tumour or mild depression
4. Under 21 days post-stroke
5. No hearing impairment
6. No significant visual impairment
7. Aged less than or equal to 75 years old, either sex
8. Right-handed
9. Native Finnish speaker
10. Understands the aim of the study and is able to give own consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Stroke (an acute ischaemic stroke or ICH) in any other region than right-hemisphere MCA
2. Prior cerebral stroke
3. Prior neurological and or psychiatric disease, which significantly affects patient functioning
4. Over 21 days post-stroke
5. Hearing impairment
6. Significant visual impairment
7. Aged greater than 75 years old
8. Left-handed
9. Native language other than Finnish
10. Patient displays cognitive disorders and is, in turn, unable to understand the aim of the study

or to give own consent to participate in this study
11. Patient is bedridden or has a modified Rankin scale score ≥4

Date of first enrolment
08/06/2009

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Finland

Study participating centre
University of Jyvaskyla
Jyvaskyla
Finland
40014

Sponsor information

Organisation
University of Jyvaskyla (Finland)

ROR
https://ror.org/05n3dz165

Funder(s)

Funder type
Government

Funder Name
Academy of Finland (Finland) - Finnish Centre of Excellence in Interdisciplinary Music Research (ref: SA 20/510/2007)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration