ISRCTN13104282 https://doi.org/10.1186/ISRCTN13104282

# Music interventions in hyperacute and acute stroke patients

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 04/11/2024 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 12/11/2024 | Completed | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 12/11/2024 | Signs and Symptoms | [X] Record updated in last year |

## Plain English summary of protocol

Background and study aims
Music and sounds have been shown to have beneficial effects on pain, anxiety and blood pressure in various settings. However, music and sound have not been studied specifically in patients with acute stroke. It is possible music or pleasant sounds may help control pain, anxiety or blood pressure abnormalities which may occur immediately following a stroke. This may supplement or negate the need for pharmacological medications which are commonly used but have known side effects.

Who can participate?
Patients aged 18 to 100 years old who are hospitalized within 24 hours from the onset of a suspected stroke

What does the study involve?
This study involves participants being randomly allocated, like a coin Filip, to listen to music or pleasant sounds for up to 12 hours following the onset of a stroke or to standard stroke care alone (without listening to music).

What are the possible benefits and risks?
There may be less pain or anxiety in those listening to music as compared to no music. Additionally, there may be less variability in blood pressure which is possibly harmful to stroke patients. Risks may include a patient not liking the use of music resulting in agitation or confusion.

Where is the study run from?
The University of Michigan Health-West, USA

When is the study starting and how long is it expected to run for?
January 2019 to September 2024

Who is funding the study?
The University of Michigan Health-West, USA

Who is the main contact?
Dr Jeffrey Fletcher, Jeffrey.fletcher@umhwest.org, jflet10121@aol.com

# Contact information

### Type(s)
Public, Scientific, Principal Investigator

### Contact name
Dr Jeffrey Fletcher

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
Nil known

# Study information

### Scientific Title
Do music interventions, as compared to no music, reduce systolic blood pressure variability, pain and anxiety in hyperacute stroke

### Acronym
MIHAS

### Study objectives
Patients or their legally authorized representatives will be highly supportive of music interventions in hyperacute stroke. Music interventions will reduce pain, anxiety and systolic blood pressure variability in hyperacute stroke patients.

### Ethics approval required
Ethics approval required

## Ethics approval(s)
Approved 30/01/2020, University of Michigan Health-West Institutional Review Board (University of Michigan Health-West Professional Building, 2122 Health Dr. SW, Suite 233, Wyoming, MI 49519, United States of America; +1 616 252 5026; irb@umhwest.org), ref: 2020-010

## Study design
Randomized controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital, Medical and other records

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

## Health condition(s) or problem(s) studied
Treatment of pain, anxiety and systolic blood pressure variability in patients hospitalized with acute stroke

## Interventions
Eligible patients (or their legally authorized representative) were approached in the emergency department or obtained on admission to the inpatient ward and electronic consent. Staff not involved in the study implementation used a computer random number generator to generate a randomization sequence and allocation concealment was obtained by sealed opaque envelopes. Excluding the randomization process and use of the music or sound intervention (in the intervention group), all medical care of participants followed usual, disease-specific, care plans. Participants randomized to the intervention arm had 19 relaxation or pleasant sound stations to ambiently listen to on their in-room televisions. They also had options to listen to various music genres. Participants were asked to listen ambiently to music or sounds for the first hour of the trial and encouraged to listen to it frequently for the duration of the trial period however, there was not a specific time requirement. The trial period was a minimum of 6 hours with trial termination when the patient was discharged from the stroke unit, or neurological ICU, or after a maximum of 12 hours of data collection.

## Intervention Type
Behavioural

## Primary outcome measure

1. The percentage of eligible patients approached for consent who were recruited into the trial measured using data collected in study records at one timepoint
2. The percentage of enrolled patients who completed the 6-hour trial data collection measured using data collected in study records at one timepoint

### Secondary outcome measures
1. The systolic blood pressure variability (SBPV) in the first 6 hours of the trial period, defined by the standard deviation of the SBP in the treatment arms, measured using cuff blood pressure measurements hourly
2. Secondary exploratory outcomes included the effect of treatment arm assignment (intention to treat) on the visual analog pain scale (0-10) and anxiety (visual analog scale 0-100) burden at 6 hours from enrollment

### Overall study start date
03/01/2019

### Completion date
15/09/2024

## Eligibility

### Key inclusion criteria
Patients with acute stroke of any subtype admitted to the hospital within 24 hours of ictus

### Participant type(s)
Patient

### Age group
Mixed

### Lower age limit
18 Years

### Upper age limit
100 Years

### Sex
Both

### Target number of participants
50

### Total final enrolment
30

### Key exclusion criteria
1. Patients who refused consent
2. Patients at the end of life
3. Patients expected to have an operation or procedure

**Date of first enrolment**
15/06/2024

**Date of final enrolment**
15/09/2024

# Locations

**Countries of recruitment**
United States of America

**Study participating centre**
**University of Michigan Health-West**
5900 Byron Center Ave
Wyoming
United States of America
49519

# Sponsor information

**Organisation**
Michigan Medicine

**Sponsor details**
University of Michigan Health-West, 5900 Byron Center Ave
Wyoming
United States of America
49519
+1-616-252-5020
Research@umhwest.org

**Sponsor type**
Hospital/treatment centre

**Website**
https://uofmhealthwest.org/

**ROR**
https://ror.org/01zcpa714

# Funder(s)

**Funder type**

Hospital/treatment centre

### Funder Name
Michigan Medicine, University of Michigan

### Alternative Name(s)
MEDICINE AT MICHIGAN, Michigan Medicine, MM

### Funding Body Type
Government organisation

### Funding Body Subtype
Universities (academic only)

### Location
United States of America

## Results and Publications

### Publication and dissemination plan
Planned publication in a peer-reviewed journal

### Intention to publish date
01/12/2024

### Individual participant data (IPD) sharing plan
The dataset generated during the study will be available upon request from Dr Jeffrey Fletcher, Jeffrey.fletcher@umhwest.org, jflet10121@aol.com. Data will be stored for 7 years from publication date. The type of data that will be shared is anonymized individualized-level patient data.

### IPD sharing plan summary
Available on request