ISRCTN12969079 https://doi.org/10.1186/ISRCTN12969079

Sonic Sleeve: investigating whether music feedback can help reduce compensatory movements in stroke rehabilitation patients with paralysis affecting one side of the body

Submission date
12/04/2019

Recruitment status
No longer recruiting

Registration date
03/05/2019

Overall study status
Completed

Last Edited
04/03/2022

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
We aim to understand how music can help stroke survivors with their upper limb rehabilitation. The key goal of the research is to see if providing auditory feedback on compensation (such as trunk leaning) can help to promote better movement patterns. Research suggests that if stroke patients can reduce undesirable compensatory movements then they may achieve more consistent and efficient movement patterns.

Who can participate?
Stroke patients who are enrolled on the Upper Limb Programme at Queen Square in London.

What does the study involve?
Patients will have an assessment with staff as followed by some simple tests to make sure they are able to take part in the study. Patients will also be asked to choose 10 of your favourite pieces of music at the practice session. We will have lots of music and songs to listen to from Spotify (an online streaming service) to help patients choose ones that they like.

Patients will then be required to make some active forward reaching movements while they sit at a table. The participant will sit and move forward to touch a target marked with an X. They will be listening to music while you move. There will be a 2D webcam that sends video to a system we have built for the study to provide feedback on compensatory movements (i.e. trunk leaning).

There will be a 10 second rest after every 10 movements patients make. Then there will be at least two minutes rest after every 50 movements they undertake. Participants will be able to rest at any time during the session if they feel too tired. Participants may receive feedback if they compensate by 1) leaning forward, 2) if their elbow comes out to the side too much or 3) if their shoulder lifts up too much. If this happens the music may stop and they will need to try and get the music to play again.

What are the possible benefits and risks of participating?
Participants may enjoy moving while listening to your favourite music and they may well have a lot of fun taking part in the study. Participation will help us better understand how music may be helpful in upper limb rehabilitation.

Where is the study run from?
The study will be run on the Upper Limb Neurorehabilitation Service (ULS) in the National Hospital for Neurology and Neurosurgery.

When is the study starting and how long is it expected to run for?
September 2017 to September 2022

Who is funding the study?
The study is funded Goldsmiths University of London as part fulfillment of a PhD student research project (UK)

Who is the main contact?
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Study website
N/A

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Version 0.1

Study information

Scientific Title
Sonic Sleeve: reducing compensatory movements in stroke rehabilitation with the aid of auditory feedback

Acronym
Sonic Sleeve

Study objectives
1. Stroke patients undertaking active forward reaching movements while listening to self-selected favourite music will reduce compensatory movements when they receive feedback compared to no feedback.
2. Stroke patients who engage in a training session with this feedback for 200 repetitions will learn to reduce compensation even when this feedback is no longer present. This will be investigated at two time points: immediately after the training phase and 24 hours later.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/04/2019, London - Dulwich Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH; 020 7972 2561), ref: 19/LO/0579.

Study design
Two-phase randomised controlled trial design using within and between group designs.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied

Paralysis affecting one side of the body in stroke patients.

Interventions

Participants who are able to complete the whole study will require four separate sessions that will take around 2 hours 45 minutes over the first few weeks of participants three-week stay on the Upper Limb Programme. The research will involve two phases where participants will undertake seated active forward reaching movements. The first session is to practice and will help familiarize patients with the study taken in the first week of the Upper Limb Course. Phase 1 starts during the second session lasting 45 minutes the day after session 1.

Phase 1
This will use a within-subject design with two conditions (experimental vs. control) presented in a counterbalanced order. Patents will be assigned to start with either the experimental or control condition using a random number generator common in psychology research (https://www.randomizer.org/#randomize) and based on their study ID number. In the experimental condition, patients will undertake 50 repetitions of an active forward reaching movement while listening to self-selected favourite music that incorporates real-time auditory feedback. If patients use compensatory movements (i.e. trunk leaning or shoulder abduction) the music will be muted until they correct their posture and continue with the ongoing movement. In the control condition, patients will undertake 50 repetitions, again moving to the same self-selected music but without any feedback to signal when compensatory movements are occurring.

Phase 2
Patients who show a significant effect of feedback on the reduction of compensatory movements will be randomized into the experimental or control group of Phase 2 using a between-group design. The third session will last 1 hour and be one week after session 2. The final session will last 30 minutes and take place 24 hours after session 3. In Phase 2, participants will train on the forward reach movement for a total of 200 repetitions, either with feedback (experimental group) or without (control group). By comparing the amount of compensatory movement occurring in a single session of 50 repetitions after training, compared with a session of 50 repetitions before training, we will investigate whether training with feedback, compared with training without feedback, reduces compensation even when the feedback signal is no longer present. Randomisation will be undertaken with the same online random generator as listed for Phase 1 to assign patients to either group (experimental vs. control) based on their study ID number. As we are not sure how many of the 45 patients will take part in Phase 2 of the study we will randomise 20 numbers in advance to ensure we get a sample size of at least 10 patients per group. Once 20 patients have been taken through Phase 2 we will then randomise the remaining patients in smaller groups. No follow-up will be carried out as the study is looking at within session and short term learning effects of auditory feedback.

Intervention Type

Behavioural

Primary outcome measure

The primary dependent variable is a compensation percentage change score. The relative score for each movement will be calculated as (time in optimum movement - time in error movement) / time in optimum movement * 100. This means a lower percentage score signals less time spent in undesirable compensatory movement. The scores will be collected in milliseconds at all time points in the study over four separate sessions with data taken from the custom made system called Sonic Sleeve.

Secondary outcome measures
1. The total number of repetitions are measured to track how many times the patient reaches the target X and back. The measure will be taken at all time points over four separate sessions with data taken from the custom made system called Sonic Sleeve that gives the start pose and end position of each target movement.
2. The number of quality repetitions is determined by counting the number of repetitions with no compensatory movements and is worked out by referring to the primary outcome data. If no compensatory movement is detected above a noise threshold then repetitions will be added as a quality repetition.
3. Fatigue is measured using the Likert scale post-session in all four sessions. After each session patients will answer the Likert scale question: How tiring did you find taking part in this session? [Not at all, a little, rather, very, extremely]. This will help to keep track of how tired they feel and may help understand differences in the data.

Overall study start date
20/09/2017

Completion date
30/09/2022

Eligibility

Key inclusion criteria
1. Acceptance on the Upper Limb Neurorehabilitation Service at the National Hospital For Neurology and Neurosurgery.
2. Diagnosis of stroke resulting in hemiparesis at least 6 months prior to study.
3. Cognitive ability to follow the tasks.
4. Ability to lift the affected hand onto a table whilst seated, unaided by their unaffected limb.
5. Ability to sit unsupported for at least 10 minutes.
6. Aged between18-75.
7. Inefficiency in their movement pattern that can be tracked by the machine learning system in the study.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
45

Total final enrolment
21

Key exclusion criteria
High level of functioning in the upper limb (i.e. with little or no further improvement possible)

Date of first enrolment
10/05/2019

Date of final enrolment
30/11/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Professor Nick Ward
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Sponsor type

University/education

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ROR
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Funder(s)

Funder type
University/education

Funder Name
Goldsmiths University of London

Results and Publications

Publication and dissemination plan
Following the study, we plan to publish the results in academic/health-based journals and to present our findings at conferences and meetings so that others can learn from the research. We can also provide you with a copy of any published outputs on request.

Intention to publish date
28/02/2022

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	pilot results	03/03/2022	04/03/2022	Yes	No
HRA research summary			28/06/2023	No	No