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A feasibility study exploring a community walking programme using a metronome sound beat to improve stepping and daily activity following a stroke

Submission date
05/03/2018

Recruitment status
No longer recruiting

Registration date
12/03/2018

Overall study status
Completed

Last Edited
14/11/2022

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
A stroke occurs when the blood supply to part of the brain is cut off. People who survive a stroke are often left with long-term problems. The aims of this study are to confirm the acceptability of a home-based auditory rhythmical cueing (ARC) treatment to improve gait and physical activity after stroke, and to assess the feasibility of a larger study of the ARC treatment.

Who can participate?
Community-dwelling stroke survivors aged 18 and over with the ability to walk 10 metres with /without a stick indoors, who are not undertaking active physiotherapy, are able to comply with the intervention and have a gait-related impairment that would potentially benefit from the intervention

What does the study involve?
Participants are randomly allocated to one of two groups. In the intervention group participants undertake 18 ARC home and community treatment sessions over six weeks (3 x 30 minutes per week, 6 supervised by a study provider and 12 self-managed). During the treatment sessions a metronome is used to provide auditory rhythmic cueing during a series of balance and gait exercises which are gradually be progressed over the 6-week programme. Training handouts and videos are provided to support the self-management treatment sessions. Participants in the control group undertake the same duration balance and gait exercise treatment as the intervention group but without ARC. The acceptability of the study treatments and the feasibility of the study protocol are assessed (recruitment, retention, side effects, treatment delivery, outcome measures) to inform the design of a larger study.

What are the possible benefits and risks of participating?
The results of this study will help to plan for a larger study that will test whether the auditory rhythmic cueing programme is an effective treatment for stroke-related gait impairment, and whether this intervention provides good value for money. There are no risks anticipated.

Where is the study run from?
1. Northumbria Healthcare NHS Foundation Trust (UK)
2. Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)
3. Durham and Darlington NHS Foundation Trust (UK)
4. Gateshead Health NHS Foundation Trust. Consent (UK)

When is the study starting and how long is it expected to run for?
July 2017 to June 2020

Who is funding the study?
Stroke Association (UK)

Who is the main contact?
Sarah Moore

Contact information

Type(s)
Scientific

Contact name
Ms Sarah Moore

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
37058

Study information

Scientific Title
Acceptability and clinical trial feasibility evaluation of auditory rhythmical cueing to improve gait and physical activity in community dwelling stroke survivors

Acronym
ACTIVATE V1

Study objectives
Study aim: To confirm the acceptability of a home-based auditory rhythmical cueing (ARC) treatment to improve gait and physical activity after stroke and to assess the feasibility of a multi-centre, observer blind parallel group randomised controlled trial (RCT) of the ARC treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London City and East Research Ethics Board, 22/01/2018, ref: 18/LO/0115

Study design
Randomised; Interventional; Design type: Treatment, Rehabilitation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Stroke

Interventions
Study design: Before and after study followed by a multi-centre observer blind, parallel group, pragmatic pilot randomised controlled trial.

Study setting: Home and community settings in North East England.

Study participants: Adult community dwelling stroke survivors with the ability to walk 10 metres with/without a stick indoors who are not undertaking active physiotherapy, are able to comply with the intervention and have a gait-related impairment that would potentially benefit from the intervention. 12 participants will be recruited to the before and after study (8 intervention and 4 controls) and 60 to the RCT.

Study treatments to be used in the before and after study and RCT:

Intervention treatment: Participants will undertake 18 ARC home and community treatment sessions over six weeks (3 x 30 minutes per week, 6 supervised by a study provider/12 self-managed. During the treatment sessions a metronome will be used to provide auditory rhythmic cueing during a series of balance and gait exercises which will gradually be progressed over the six week programme. Training handouts and videos will be provided to support the self-management treatment sessions.

Control treatment: Participants in the control group will undertake the same duration balance and gait exercise treatment as the intervention group but without ARC.

Study outcomes: The before and after study will confirm the acceptability of the study treatments. The RCT will then test the feasibility of the study protocol (recruitment, retention, adverse events, treatment delivery, outcome measures) and provide data to inform the design of a future multi-centre RCT.

Study duration: 28 months.

Intervention Type
Other

Primary outcome measure
This study includes a before and after study and a pilot to assess the feasibility of a multicentre, randomised controlled trial of auditory rhythmic cueing to improve gait and physical activity after stroke. Both study designs do not require a primary outcome as only collecting descriptive and feasibility data are collected.

The primary aim of this study is to establish the feasibility of a future randomised controlled trial; as such its aims are:
1. To confirm acceptability of study treatments (intervention and control)
2. To confirm treatment delivery in a subsequent pilot randomised controlled trial

The trialists will also evaluate whether the following objectives have been met, prior to planning a future randomised controlled trial:
1. To seek views of participants and providers on the intervention and control treatments
2. To ensure appropriate fidelity of the delivery and enactment of treatments
3. To collate summary data on outcome measures and accelerometer data
4. To collate summary data on falls and adverse events pertaining to the treatments
5. To collate findings from the above to confirm acceptability of the treatments which will then be used in the pilot randomised controlled trial

Secondary outcome measures
Demographic and stroke characteristics, taken at baseline assessment only:
1. Stroke impairment measured using NIHSS
2. Disability measured using Modified Rankin Scale
3. Cognition measured using Montreal Cognitive Assessment
4. Depression measured using Physical Health Questionnaire
5. Fatigue measured using Fatigue Assessment Scale

Gait, balance, physical activity and health outcome measures. completed at baseline, 6 week and 10 week assessments:
1. Ambulation ability measured using Functional Ambulation Category and Rivermead Mobility

Assessment
2. Gait characteristics measured using 4 metre walk test x 5 and postural control 2 minute standing test (Stop watch and accelerometer measured)
3. Balance measured using Mini Balance Evaluation Systems Test and Activities-Specific Balance Confidence Scale
4. Ambulatory participation measured using Stroke Impact Scale
5. Physical activity measured using 7-day data recorded by accelerometry
6. Health outcome measured using the EuroQol 5 Dimension 3 Level EQ-5D-3L

Further data collection on completion of study:
1. Participant self-report views of treatment
2. Treatment providers views of the treatment

Overall study start date
01/07/2017

Completion date
30/06/2020

Eligibility

Key inclusion criteria
1. Adults (≥ 18 years)
2. Diagnosed with any stroke subtype
3. Within 24 months of stroke onset
4. Able to mobilise independently >10 metres with/without stick indoors but presenting with a gait-related mobility impairment (e.g. gait asymmetry, reduced walking speed, reduced balance, reduced walking confidence based on clinical observation or patient subjective feedback) that would potentially benefit from this intervention
5. Community dwelling
6. Living within the community services catchment area of a participating study centre
7. Able to provide informed consent to participate in the study
8. Able to follow study treatment (i.e. does not have significant cognitive impairment or communication difficulties)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 72; UK Sample Size: 72

Total final enrolment
60

Key exclusion criteria
1. Currently undertaking active physiotherapy
2. Unable to follow programme due to significant cognitive impairment or communication difficulties
Marked expressive/receptive dysphasia
3. Diagnosis likely to interfere with adherence to treatment or predispose to falls e.g. uncorrected hearing problems, registered blind, severe visual/inattention problems as a result of stroke, upper limb impairment restricting use of cueing device and able to mobilise 10 metres but extremely slow gait speed limited intervention adherence
4. Other neurological or orthopaedic conditions affecting gait (e.g. Parkinson's Disease, Multiple Sclerosis, osteoarthritis, rheumatoid arthritis and back pain) and cardiopulmonary conditions limiting walking ability (e.g. chronic obstructive disorders, angina pectoris) and palliative treatment

Date of first enrolment
01/04/2018

Date of final enrolment
28/02/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northumbria Healthcare NHS Foundation Trust
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Road
High Heaton
Newcastle Upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Durham and Darlington NHS Foundation Trust
Dr Piper House
King Street
Darlington
United Kingdom
DL3 6JL

Study participating centre
Gateshead Health NHS Foundation Trust
Sheriff Hill
Gateshead
United Kingdom
NE9 6SX

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust

Sponsor details
c/o Ms Caroline Potts
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England
United Kingdom
NE29 8NH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Charity

Funder Name
Stroke Association; Grant Codes: TSA 2016/06

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
01/07/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	19/05/2020	01/06/2020	Yes	No
Results article		12/11/2022	14/11/2022	Yes	No
HRA research summary			26/07/2023	No	No