ISRCTN35657537 https://doi.org/10.1186/ISRCTN35657537

Optokinetic chart stimulation-based protocol and conventional functional activities versus conventional physiotherapy alone for treatment of stroke

Submission date
25/04/2013

Recruitment status
No longer recruiting

Registration date
18/06/2013

Overall study status
Completed

Last Edited
17/12/2015

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Stroke is one the major common causes of severe disability in the UK with over a quarter of a million people living with disability. Stroke is also the third most common cause of death in the UK. It costs society, based on treatment of stroke and productivity loss, £8.9 billion annually. The aim of this study is to find out whether use of the optokinetic chart stimulation protocol (OKCSIB) and conventional activities such as transfers and walking, restore movements, improve function and improve quality of life in new stroke patients who are completely paralysed on their affected side when compared to conventional physiotherapy alone.

Who can participate?
Written informed consent will be obtained from patients who are completely paralysed on one side and are between the ages of 55 and 85 years when they are admitted to the stroke ward at the William Harvey Hospital.

What does the study involve?
The study treatment consists of an optokinetic chart that is moved in front of the patient horizontally, vertically and forwards for three minutes. Sensory interaction for balance will be tested once patients can stand with assistance of, at most, two members of staff. Conventional therapy activities such as sitting, transfers and walking, as appropriate, will continue to be carried out. The control group will receive only the conventional therapy.

What are the possible benefits and risks of participating?
The benefits of participating in the study are not yet fully known as this is a new treatment. However, early studies report improvements in voluntary movements, function and walking. You may feel dizzy and tired during the therapy.

Where is the study run from?
The study will be run from the William Harvey Hospital, UK. This will be the only centre.

When is the study starting and how long is it expected to run for?
The study starts in June 2013 and will run for 18 months.

Who is funding the study?
East Kent Hospitals University NHS Foundation Trust, UK.

Who is the main contact?
Mr Benjamin Chitambira
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
OKS4 Version 2.1

Study information

Scientific Title
Comparison of the extent of the restoration of voluntary movement, functional abilities and quality of life between dense strokes treated by optokinetic chart stimulation based OKCSIB protocol and those treated by conventional neurophysiotherapy: a prospective single-blind pilot randomised controlled trial

Acronym
OKCSIB

Study objectives
It is hypothesised that the optokinetic chart based OKCSIB protocol and conventional activities such as transfers and mobilisation will lead to improved recovery of voluntary movements of affected upper and lower limbs, function, quality of life as well as reduce cost of formal care when compared to conventional neurophysiotherapy.

On 15/09/2014 the overall trial end date was changed from 31/10/2014 to 31/12/2014.
On 07/01/2015 the overall trial end date was changed from 31/12/2014 to 30/06/2015.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Surrey Borders Research Ethics Committee, 10/05/2013, ref: 13/LO/0483

Study design
Single-blind pilot randomised controlled trial

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 the contact details below to request a patient information sheet

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

Interventions
1. Optokinetic chart stimulation in three planes (horizontal, vertical and forward) for three minutes in each plane, sensory interaction for balance added once patients can stand with assistance and conventional functional activities VS
2. Conventional neurophysiotherapy as control

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measures as of 15/09/2014:
STREAM: The outcomes will be taken at 8 weeks, 14 weeks and the 3 months after the 14th week. This is because up to 8 weeks intervention may be in hospital, then 6 weeks intervention

in the community, after which the participants are discharged. Follow-up outcomes are then taken 3 months after the final discharge to see if effects are long lasting.

Previous primary outcome measures:
STREAM: The outcomes will be taken at 8 weeks, 14 weeks and the 3 months after the 14th week. This is because 8 weeks intervention will be in hospital, then 6 weeks intervention in the community, after which the participants are discharged. Follow-up outcomes are then taken 3 months after the final discharge to see if effects are long lasting.

Secondary outcome measures
1. Barthel Index
2. Stroke-Specific Quality of Life
3. Modified Ashworth Scale
4. Cost of formal care

Overall study start date
01/06/2013

Completion date
30/06/2015

Eligibility

Key inclusion criteria
Current inclusion criteria as of 15/09/2014:
1. Patients with stroke that completely paralyses the affected side with loss of voluntary movement on assessment as signified by 0/5 on the Oxford Scale, 0/20 on the Stroke Rehabilitation Assessment of Movement (STREAM) Scale for each of the affected upper and lower limb or a score of 4/4 on the NIHSS Scale for each affected upper and lower limb
2. Between 55 and 85 years of age
3. Full use of affected limbs before current admission
4. Independently mobile before the stroke
5. Conscious
6. Living within the catchment area of William Harvey Hospital for follow-up purposes
7. Able to consent

Previous inclusion criteria:
1. Patients with stroke that completely paralyses the affected side with loss of voluntary movement on assessment as signified by 0/5 on the Oxford Scale, 0/20 on the Stroke Rehabilitation Assessment of Movement (STREAM) Scale for each of the affected upper and lower limb or a score of 4/4 on the NIHSS Scale for each affected upper and lower limb
2. Between 75 and 85 years of age
3. Full use of affected limbs before current admission
4. Independently mobile before the stroke
5. Conscious
6. Living within the catchment area of William Harvey Hospital for follow-up purposes
7. Able to consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
8

Key exclusion criteria
Current exclusion criteria as of 15/09/2014:
1. Patients with stroke that leads to simultaneous involvement of temporal and parietal lobes.
2. Under 55 years of age and over 85 years of age
3. Pure posterior circulation stroke without middle cerebral artery territory involvement
4. Extensive small vessels disease co-morbidity as reported by an expert neuro-radiologist
5. Partial loss of movement as denoted by scores of 1/5 or above on the Oxford Scale
6. Unconscious
7. Lack of voluntary movements before current stroke
8. Living out of William Harvey Hospital catchment area
9. Dementia and other forms of cognitive impairment
10. Blindness

Previous exclusion criteria:
1. Patients with stroke that leads to simultaneous involvement of temporal and parietal lobes.
2. Under 75 years of age and over 85 years of age
3. Pure posterior circulation stroke without middle cerebral artery territory involvement
4. Extensive small vessels disease co-morbidity as reported by an expert neuro-radiologist
5. Partial loss of movement as denoted by scores of 1/5 or above on the Oxford Scale
6. Unconscious
7. Lack of voluntary movements before current stroke
8. Living out of William Harvey Hospital catchment area
9. Dementia and other forms of cognitive impairment
10. Blindness

Date of first enrolment
11/02/2014

Date of final enrolment
12/02/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

William Harvey Hospital
Ashford
United Kingdom
TN24 0LZ

Sponsor information

Organisation
East Kent Hospitals University NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.ekhuft.nhs.uk/staff/clinical/research-development/

ROR
https://ror.org/02dqqj223

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
East Kent Hospitals University NHS Foundation Trust (UK)

Funder Name
Internal Project Grant Scheme 2012

Results and Publications

Publication and dissemination plan
Local NHS Trust conference abstract submission by 19/03/2015
Abstract submission for conference proceedings by 31/05/2015
Scientific journal submission by 31/05/2015
Dissmination to local stroke survivors and carers organisation by 31/07/2015

Intention to publish date
31/05/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/11/2014		Yes	No
HRA research summary			28/06/2023	No	No