

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	☒ Prospectively registered ☐ Protocol
Registration date 18/06/2013	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 17/12/2015	Condition category Circulatory System	☐ 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
bchitambira@nhs.net

Contact information

Type(s)
Scientific

Contact name
Mr Benjamin Chitambira

Contact details
Richard Stevens Ward
William Harvey Hospital
Kennington Road
Willesborough
Ashford
United Kingdom
TN24 0LZ
+44 (0)12 3361 6242
bchitambira@nhs.net

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

1. Barthel Index
2. Stroke-Specific Quality of Life

3. Modified Ashworth Scale

4. Cost of formal care

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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

United Kingdom

England

Study participating centre

William Harvey Hospital

Ashford

United Kingdom

TN24 0LZ

Sponsor information

Organisation

East Kent Hospitals University NHS Foundation Trust (UK)

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

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