

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

<b>Submission date</b> 25/04/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/06/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/12/2015	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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**  
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## 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
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**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/02dqj223>

# 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?
<a href="#">Results article</a>	results	14/11/2014		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No