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# Electroencephalogram-neurofeedback (EEG-NF) to improve neglect in stroke patients

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| **Submission date**<br>01/10/2008 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>10/12/2008 | **Overall study status**<br>Completed | |
| **Last Edited**<br>13/04/2017 | **Condition category**<br>Circulatory System | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
EEG-NF Protocol v 1.0

## Study information

**Scientific Title**
A novel neurofeedback-based intervention to reduce neglect and improve function in stroke patients

## Acronym
The EEG-NF Study

## Study objectives
Electroencephalogram-neurofeedback (EEG-NF) techniques, shown to improve attention and functional abilities in patients of comparable age and with attention deficits due to neurological diseases, will result in a sustained improvement in general attention in stroke patients with neglect. This will be associated with improvements in spatial neglect, activities of daily living and quality of life in these patients. Furthermore, EEG-NF will result in changes in the reorganisation of brain activity in these subjects, which will underpin the improvements in attention.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
East Kent Research Ethics Committee (REC) approval pending as of 10/12/2008

## Study design
Pragmatic open randomised controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

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

## Interventions
In the intervention group, patients will receive a 30-minute session of EEG-NF training, 5 days a week for a total duration of 6 weeks (30 sessions). The EEG will be recorded from three sensors placed on the head. Signal will be acquired at 160 Hz, A/D converted and band-filtered to extract beta1 (15 - 18 Hz), SMR (12 - 15 Hz), theta (4 - 7 Hz), and 'high beta' (22 - 30 Hz). The selected frequency bands will be fed back to patients on a computer screen, via a Nexus Biofeedback System. Through this online feedback patients will learn to regulate their EEG. Enhancement or diminution of a frequency band will be shown by a contemporaneous change on the screen - an icon may move up and down the screen. Operant contingencies will be such that rewards ('points') will be gained whenever patients enhance either beta1 or SMR activity without concurrent rises in theta and high beta activity, relative to a 2-minute pre-feedback baseline. The success of patients in enhancing desired frequencies will be recorded, as will the number of sessions completed.

The control group will receive the standard treatment on stroke units for neglect, which comprises of occupational therapist supervised exercises and tasks to improve spatial attention.

## Intervention Type
Other

## Phase
Not Applicable

### Primary outcome(s)
The Behavioural Inattention Test (BIT) measured at 6 weeks after randomisation. BIT will also be measured 12 weeks after randomisation (6 weeks after completion of EEG-NF training) to assess sustainability.

### Key secondary outcome(s))
1. Attentional Network Test (ANT), measured 6 and 12 weeks after randomisation
2. Barthel Index (BI), measured 6 and 12 weeks after randomisation
3. Nottingham Extended Activities of Daily living (NEADL) for activity and participation, measured 6 and 12 weeks after randomisation
4. Hospital Anxiety and Depression Scale (HADS) for mood, measured 6 and 12 weeks after randomisation
5. Five dimensional EuroQol (EQ-5D) and the visual analogue scale (EQ-VAS) for quality of life, measured 6 and 12 weeks after randomisation
6. Quantitative-EEG (Q-EEG) and functional magnetic resonance imaging, measured at baseline and 6 weeks in 36 patients to investigate underlying cortical changes with recovery and intervention
7. The number of patients consenting to EEG-NF training, number completing the programme, sessions completed and ability to modulate various EEG frequencies will be documented to assess acceptability
8. Ease of use including staff training requirements and the feasibility of integrating with existing therapy programmes
9. The semi-structured interview will be analysed for patient views on benefits of treatment, acceptability of training and perceived benefits of the training programme

### Completion date
31/01/2012

## Eligibility

### Key inclusion criteria
1. Two to 12 weeks from stroke onset
2. First ever stroke
3. Right hemisphere cortical involvement, confirmed on neuroimaging
4. Significant visual neglect, defined as a behavioural inattention test (BIT) score of 129 or less (maximum possible 146)
5. No other significant cognitive or communication problem
6. Informed consent for participation and follow-up
7. Both sexes, aged 18 - 85 years

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit

18 years

**Sex**
All

**Key exclusion criteria**
1. Unable to provide consent
2. Unable to comply with training or assessment procedures for any reason

**Date of first enrolment**
01/02/2009

**Date of final enrolment**
31/01/2012

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**William Harvey Hospital**
Kent
United Kingdom
TN24 0LZ

# Sponsor information

**Organisation**
East Kent Hospitals University NHS Trust (UK)

**ROR**
https://ror.org/02dqqj223

# Funder(s)

**Funder type**
Government

**Funder Name**

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme (ref: PB-PG-0807-14152)

# 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? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |