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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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 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 measure
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.

Secondary outcome measures
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

Overall study start date
01/02/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
72 stroke patients with visuospatial neglect

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
England

United Kingdom

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

Sponsor information

Organisation
East Kent Hospitals University NHS Trust (UK)

Sponsor details
East Kent Hospital Trust Headquarters
Kent and Canterbury Hospital
Ethelbert Road
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CT1 3NG

Sponsor type
Hospital/treatment centre

Website
http://www.ekht.nhs.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration