



FOCUS ON RESEARCH

Non-Invasive Brain Stimulation in Stroke Patients

Researchers

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Aim

Up to 80% of people who experience a stroke that affects the right side of the brain have a symptom called hemispatial neglect, an inability to respond to events to their left hand side, including unawareness of vision, touch, or even of having had a stroke. This symptom is debilitating, impedes rehabilitation, and is a strong independent predictor of poor recovery. At present, there are no available treatments. It is essential that proposed treatments are evaluated in properly conducted clinical trials in order to inform clinicians and health services.

We set out to undertake a pilot trial of two potential treatments in order to establish the feasibility of a larger, definitive trial. The trial aimed to investigate electrical stimulation of the brain and a behavioural training programme, alone or in combination, among patients with neglect. We aimed to assess the long term outcomes after the interventions and at 6 months follow up, both in terms of neglect recovery, activities of daily living, and quality of life.

Project Outline/Methodology

In patients with neglect after a stroke, we randomly allocated patients to undergo 10 sessions of electrical stimulation, 10 sessions of behavioural training, both interventions, or standard care with a control task only. Patients underwent a range of tests, before and after the interventions and at a 6 months followup.

Key Results

- 7% (288) of confirmed stroke cases over the study period were referred to the research team
- 34% (91) of referred cases were excluded due to significant medical problems that were judged to prevent them from undergoing the multiple interventions sessions
- We recruited 24 patients over 29 months (with 6 each being allocated to each group), a randomisation rate of 8% of all referred cases and 0.6% of the stroke cases overall

- 88% (21) completed testing after the interventions and 67% (14) were available for 6 month follow up (2 died, 5 did not respond)

Conclusions

We obtained recruitment and retention rates (our primary outcome measures) to inform a definitive trial. We were able to establish that feasibility for a larger trial was poor with lower recruitment than originally planned, with too few patients judged to be able to complete the 10 intervention sessions.

What does this study add to the field?

The latest Cochrane Review states that it is essential that neglect treatments are evaluated in properly conducted randomised controlled trials in order to inform clinicians and health services with respect to clinical endpoints. This trial gives feasibility data and guidance for translating the proposed interventions into a definitive, pragmatic multicentre trial.

Implications for Practice or Policy

Our study suggests that a definitive neglect trial using non-invasive brain stimulation, either with or without behavioural training, will require a broad recruitment base, and that intensity, duration and the location of interventions will have to be selected carefully in order to maximise recruitment and retention. Fewer treatment sessions and home based interventions should be considered, as the 10 hospital intervention sessions proved the greatest hurdle in terms of achieving the planned randomisation numbers.

Where to next?

Earlier versions of the recruitment data have contributed already to a preliminary application to Brain Research UK for a Phase 2 multi-site RCT project (in collaboration with the University of East Anglia). A similar application will be submitted to NIHR later in 2018/19.

Further analysis of the brain scans will be undertaken in collaboration with researchers from the UK, Switzerland and Germany.

Further details from:

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