

The effect of using prism adaptation treatment on performance of self care and mobility tasks in patients with unilateral inattention following stroke

Submission date 06/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/10/2009	Condition category Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

PSYC.RJ4292

Study information

Scientific Title

Acronym

PATMOS

Study objectives

1. Does prism adaptation have an effect on the patients behaviour in daily living tasks?
2. Does prism adaptation have an effect on the patients mobility in the environment?
3. Does prism adaptation differentially affect different domains of space?
4. Are the effects of the treatment long lasting (in this case evident after 8 weeks)?
5. What sample size is required and which measures should be included in a definitive randomised controlled trial?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised placebo controlled parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Stroke

Interventions

Experimental intervention: Pointing training with prism goggles that shift field of view 10 degrees to the right, once a day, Monday to Friday for 2 weeks.

Control intervention: pointing training with goggles containing clear flat glass, once a day, Monday to Friday for 2 weeks.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Score of selfcare on Catherine Bergego Scale at 3 days after end of intervention

Secondary outcome measures

1. Behavioural inattention test
2. Corridor navigation (distance from wall)
3. Motricity index
4. Sensory Assessment
5. Barthel Index

Overall study start date

01/12/2004

Completion date

31/08/2006

Eligibility**Key inclusion criteria**

1. Right hemisphere damaged stroke patients who are judged by their Occupational Therapists to be having difficulty with self-care as a result of unilateral inattention.
2. Scoring below cut off on Star Cancellation and Line Bisection tests from the Behavioural Inattention Test.
3. Able to sit and point with the unaffected hand.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

40

Key exclusion criteria

Patients judged unable to follow instructions for the study procedures

Date of first enrolment

01/12/2004

Date of final enrolment

31/08/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Bristol

Bristol

United Kingdom

BS8 1TN

Sponsor information

Organisation

University of Bristol (UK)

Sponsor details

Research and Enterprise Development

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Sponsor type

University/education

Website

<http://www.bris.ac.uk/research/>

ROR

<https://ror.org/0524sp257>

Funder(s)

Funder type

Charity

Funder Name

The Stroke Association (UK) (ref: TSA 2004/01)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2010		Yes	No