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Investigating the effects of cognitive training on attention

Submission date	Recruitment status	[X] Prospectively registered
23/10/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/10/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/04/2021	Circulatory System	

Plain English summary of protocol

Background and study aims
Cognitive problems, including in attention and working memory, are common consequences of a stroke. Studies have suggested that progressive computerized training (i.e. training exercises that become more challenging as performance improves) can enhance cognitive function not simply on the exercises that people have practiced, but more generally.

Who can participate?
People aged over 18 who have had a stroke

What does the study involve?
Participants are randomly allocated to one of three groups: home-based online working memory training, a similar training programme focused on attention skills, or a waiting list control group. All participants are first assessed on a range of cognitive tasks and questionnaires about everyday function. These assessments are repeated after the 4 weeks of training and again at a 3-month follow-up. Participants in the training groups are asked to try to complete 20 minutes per working day over the 4 weeks. Participants in the waiting list control group are allocated to one of the active training programmes after the follow-up. In addition to the relative effectiveness of the training programmes, this study examines the feasibility of recruiting participants, the acceptability of the interventions to participants, and other factors that will inform a larger study if the results are positive.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
MRC Cognition and Brain Sciences Unit (UK)

When is the study starting and how long is it expected to run for?
November 2014 to September 2017

Who is funding the study?
Stroke Association (UK)

Who is the main contact?
Dr Polly Peers
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Contact information

Type(s)
Scientific

Contact name
Dr Polly Peers

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17621

Study information

Scientific Title
Progressive home-based working memory and attention training following stroke, implications for spatial bias: a preliminary study

Study objectives
In addition to the relative efficacy of the training programmes compared with the waiting list condition, the study will examine the feasibility of recruitment, the acceptability of the interventions to participants and other factors that will inform a definitive trial if the results are positive.

More details can be found at: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=17621

Ethics approval required
Old ethics approval format

Ethics approval(s)

14/EE/0149

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Topic: Stroke; Subtopic: Rehabilitation; Disease: Therapy type

Interventions
In this study we aim to recruit people who have had a stroke and randomly allocate them to one of three conditions: home-based online working memory training, a similar training programme focused on attention skills; or a waiting list control group. All participants will be first assessed on a range of cognitive tasks and questionnaires about everyday function. These assessments will be repeated after the 4 weeks of training/waiting list and again at a 3 month follow-up. Participants in the training groups will be asked to try to complete 20 minutes per working day (MonFri) over the 4 weeks. Participants in the waiting list study will be allocated to one of the active training conditions after the followup.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Spatial Bias measure derived from Theory of Visual Attention paradigm

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2014

Completion date

01/09/2017

Eligibility

Key inclusion criteria
1. Over 18 years old
2. Able to give informed consent
3. Ability to interact with the computer with either hand or via the mouse

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

Total final enrolment
80

Key exclusion criteria
1. Medical problems likely to prevent participation
2. Language problems likely to prevent comprehension of consent or the training instructions.

Date of first enrolment
01/11/2014

Date of final enrolment
01/09/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

MRC Cognition and Brain Sciences Unit
Cambridge
United Kingdom
CB2 7EF

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
MRC Cognition and Brain Sciences Unit
15 Chaucer Road
Cambridge
United Kingdom
CB2 7EF

Sponsor type
Research council

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Charity

Funder Name
Stroke Association

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Open access data will be available through the University of Cambridge sympletic repository. They will become publically available on publication of the paper at the link: https://doi.org/10.17863/CAM.66310. The data is currently under embargo and will become available once the paper is accepted for publication. The data is fully anonymised and the anonymised data along with copies of the analyses will be available in the repository. At the time of consent patients gave consent for anonymised data to be made freely available to other researchers.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results	non-peer-reviewed results in preprint	01/07/2013	08/04/2021	No	No
HRA research summary			28/06/2023	No	No