Can 1 month of daily computer training help improve memory and attention in people who have had a brain injury?

Submission date	Recruitment status No longer recruiting	Prospectively registered		
01/03/2018		Protocol		
Registration date	Overall study status	Statistical analysis plan		
07/03/2018	Completed	[X] Results		
Last Edited 24/04/2019	Condition category Mental and Behavioural Disorders	 Individual participant data 		

Plain English summary of protocol

Background and study aims

We are interested in seeing if daily practice of either memory skills, or your ability to focus (selective attention), improve your attention.

Who can participate?

Members of the Cambridge Clinical Neurosciences Research Panel (CCNRP) who have indicated an interest in taking part in this type of research.

What does the study involve?

This study involves 2 or more sessions lasting 1-2 hours with one of the investigators as well as 20 practice sessions lasting 20-30 minutes over a period of (usually) 1 month. All these sessions can be completed at home at a time convenient to you. During this time you will be asked to complete a number of short tests on the computer and some questionnaires.

During the sessions with the investigator you will complete a number of questionnaires and computerised tasks. These tests involve simple problem solving tasks (for example finding the odd one out in a series of shapes), spatial tasks (for example marking where you think the midpoint of a line is), memory tasks (for example remembering the sequence in which boxes are uncovered) and concentration tasks (reporting as many letters as you can from briefly presented displays). All of the tasks will be explained in detail before you start and you will have the opportunity to ask any questions you may have. You will then be asked either to participate in regular training sessions on the computer, or to be part of the control group (who can participate in the training sessions at a later date). You will be given a demonstration of your training battery and it will be set up for you to practice daily at home. These tasks that adapt to your ability. You will receive feedback on how well you are doing. You will be asked to complete your training battery 5 days a week, usually for a period of a month. You can contact us at any time during this period with questions and you may be offered regular calls to check things are

going OK. At the end of the month the investigator will come to visit you again at home to complete the post-training assessment and, if you were assigned to the "wait" group, to get you started on the training phase. This assessment will be much the same as the initial assessment.

What are the possible benefits and risks of participating?

We will reimburse you for your time and you will have made a contribution to our understanding of the impact of training on performance. This study is quite time intensive however the training tasks have been developed to be engaging and can be completed at home. You are of course free to withdraw from the study at any time.

Where is the study run from? MRC Cognition & Brain Sciences Unit, Cambridge, UK

When is the study starting and how long is it expected to run for? May 2012 to September 2014

Who is funding the study? The Medical Research Council

Who is the main contact? Dr. Polly Peers (polly.peers@mrc-cbu.cam.ac.uk)

Contact information

Type(s) Scientific

Contact name Dr Polly Peers

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Investigating the effects of home based working memory vs selective attention training on cognitive functions and self-reported everyday functioning in individuals with chronic brain lesions - an exploratory proof of concept study.

Study objectives

This exploratory study was designed to examine the feasibility and tolerability of home based computerised interventions for patients who had suffered brain injuries, and whether positive effects of training could be observed in a small sample of patients with chronic brain lesions in regions thought to impact on attentional functioning. The aim was to examine whether training could improve cognitive functions in individuals who might be expected to have poor attentional skills. Individuals with chronic brain injuries to frontal and parietal cortices who might be expected to have issues with

their attention were recruited. The study assessed whether patients would improve on trained tasks after 20 days of training, and whether any improvements could also be seen on untrained tasks. The hypothesis was that working memory training would lead to improvements on working memory tasks, and that selective attention training may lead to improvements on closely related attentional tasks. Another aim was to evaluate whether cognitive training had the potential to lead to broader improvements in cognitive functions and everyday function, which would give some indication as to whether such an approach may be useful as a positive intervention in brain injured patients. The study enabled collection of preliminary data in order to decide whether a full RCT would be appropriate and to help power any subsequent RCT appropriately.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cambridge Psychology Research Ethics Committee, 6/11/2012, Pre.2012.70

Study design

Single-centre randomised non-blinded study

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Internet/virtual

Study type(s) Treatment

Participant information sheet

Uploaded as an additional file

Health condition(s) or problem(s) studied

Poor attention associated with chronic brain injuries to frontal and parietal cortices

Interventions

The commercially available Cogmed working memory training battery was compared with an internally developed selective attention training and a wait-list control sample. The individuals were randomised to one of the three initial groups: working memory training (WMT), selective attention training (SAT) or wait-list, with patients in the wait-list group further randomised to one of the two intervention groups at the end of their wait-list period. Prior to starting training all individuals completed an extensive evaluation of their cognitive functioning (including tests of visual acuity, premorbid IQ, fluid intelligence, working memory and attentional performance) and everyday functioning (as measured by the European Brain Injury Questionnaire). The active interventions required participants to complete 20 sessions of training over a month period (though for some patients this took substantially longer). Each training session was completed in the patient's own home and delivered over the internet. Training took 20-40 min per day to complete. During this time participants complete a series of short tasks. Participants were telephoned once a week during the training phase by the investigators to discuss the training and help deal with any problems individuals had with the training. After completion of the training participants were revisited and completed assessments of their working memory, attention, fluid intelligence, and everyday functioning. Following this assessment, wait-list participants started their training as outlined above and were reassessed following completion of their training.

Intervention Type

Behavioural

Primary outcome measure

Change in spatial bias from initial assessment to follow-up.

Secondary outcome measures

1. Working memory (as indexed by the Automated working memory assessment (AWMA) dot matrix task and AWMA spatial span task).

 Attention measured using a partial and whole report paradigm as described in Bundesen's Theory of Visual Attention (TVA), Bundesen 1990. This task involves briefly presenting letters on a screen and asking participants to report any letters they saw presented in a target colour (say black) whilst ignoring any presented in a distracting colour (say white). From this a number of attentional parameters can be derived including spatial bias (the preference in reporting letters that appearing on one side of the screen compared to the other), visual short-term memory capacity (the number of items that can be recalled at any one time) and attentional selection (the ability to focus attention on the target letters and ignore the distractors).
 Everyday functioning measured using the European Brain Injury Questionnaire.

Each of these measures were taken before the active interventions and were repeated after the completion of the intervention (or waitlist). As this was an exploratory study all endpoints were explored though the spatial bias end-point was considered the most important one.

Overall study start date

01/05/2012

Completion date

17/09/2014

Eligibility

Key inclusion criteria

1. Individuals who had previously had a brain injury and were interested in research but were not currently undergoing clinical treatment 2. Included in the Cambridge Clinical Neuroscience Research Panel.

Participant type(s)

Patient

Age group Adult

Sex

Both

Target number of participants 25

Key exclusion criteria

1. Colour blindness

- 2. History of or current evidence of other neurological or psychiatric illnesses
- 3. Severe language impairments

Date of first enrolment

15/03/2014

Date of final enrolment 06/08/2014

Locations

Countries of recruitment England

United Kingdom

Study participating centre MRC Cognition & Brain Sciences Unit 15 Chaucer Road Cambridge Cambridge United Kingdom CB2 7EF

Sponsor information

Organisation MRC Cognition & Brain Sciences Unit

Sponsor details 15 Chaucer Road Cambridge United Kingdom CB2 7EF

Sponsor type Research council

ROR https://ror.org/055bpw879

Funder(s)

Funder type Not defined

Funder Name Medical Research Council (Directors strategic award)

Results and Publications

Publication and dissemination plan We intend to publish the findings in a peer reviewed journal

Intention to publish date 01/05/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		05/03/2018	22/01/2019	No	Yes

Results article

No