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Working memory training for children who have survived a brain injury

Submission date
19/07/2013

Recruitment status
No longer recruiting

Registration date
19/07/2013

Overall study status
Completed

Last Edited
20/02/2018

Condition category
Nervous System Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
An acquired brain injury (ABI) in childhood can lead to problems with working memory (i.e., the ability to hold information in our mind when doing things like trying to solve a problem or learn something new). This can cause further difficulties with learning, academic achievement, behaviour, and social functioning. Such difficulties can result in problems in everyday life, including school, which can impact on the quality of young people's lives and that of their families. This study is evaluating a computerised working memory training programme with young people who have survived an ABI, and their families. We are interested in finding out what young people and their families think about the computerised training programme (e.g., how easy is it to use?) and whether the training programme helps with memory, attention, numeracy and literacy. This study will also investigate how young people who have survived an ABI compare with age- sex-, and IQ-matched individuals who have not experienced an ABI, on measures of general cognitive function, memory and attention.

Who can participate?
Children between the ages of 8 and 16 who have survived a brain injury and have difficulties with working memory.

What does the study involve?
The participating children complete a brief assessment of their working memory. If the child does not have working memory difficulties then they do not continue with the study. If the child does have working memory difficulties then we arrange to meet with them again within a week to complete further assessments and questionnaires. We also invite the child's parents and teacher to complete some questionnaires. A researcher then visits the participants to introduce them to the computerised working memory training programme. We invite participants to use it for up to five weeks, about 35 minutes per session. These sessions are completed by the child and we ask parents to support their children if they have any questions when using the programme. There are two different types of programme – one aims to train working memory, and the other does not. All children participating in the research are randomly assigned to either the training programme or the non-training programme. We do not know which version of the programme the child is given until the end of the study. At the end of the study, if the child has used the non-training programme then they are offered the opportunity to use the training

programme in their own time separately from the study. At the end of the training we ask the child's parents and teachers to complete some further questionnaires and we invite the child to complete some assessments. We visit the participants again 6 months after completing the training to repeat the questionnaires and measures.

What are the possible benefits and risks of participating?
Participants will be contributing to research investigating working memory and attention in children who have survived an ABI. We are asking participants to commit to the study for about 6 months in total. Although this is quite a lot of work, the time involved each day during the computerised training programme may typically be quite small, about 35 minutes. Each training session can be saved and completed in several attempts if needed (i.e., over a few days). Children might become tired during the assessments or training sessions. To minimise the risk of becoming tired, the assessments are conducted over two to three relatively short sessions of 60 minutes each, and regular breaks for a rest will be included. In the unlikely event that the child becomes stressed or upset in any way, the assessments will be stopped immediately and reasons for distress will be explored. Information collected during the study will be kept anonymous and safe. At the end of each training session the anonymised data will be uploaded to a server via the internet. The company who own the training programme (and the server) may use the data for research purposes. With your permission we will let the child's GP know that s/he is participating in this study but no results will be shared with the GP without permission. The only time we would disclose any of the information that the child has given us would be if criminal or other potentially harmful behaviour was made known. We would, however, aim to discuss this with parents first. We can give parents a brief report summarising how their child performed on the tests and an overall summary of the study findings.

Where is the study run from?
University of East Anglia, the MRC Cognition and Brain Sciences Unit, and the Cambridge Centre for Paediatric Neuropsychological Rehabilitation (UK)

When is the study starting and how long is it expected to run for?
September 2012 to March 2017

Who is funding the study?
The British Academy and Action Medical Research (UK)

Who is the main contact?
Dr Anna Adlam
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Study website
http://www.uea.ac.uk/medicine/neuropsychology/research

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13091

Study information

Scientific Title
An evaluation of computerised working memory training in children who have survived a brain injury

Study objectives
Study aims:
1. To investigate the feasibility and acceptability of a home-based computerised WM training programme (Cogmed RM) for children with an ABI and their parents
2. To investigate whether WM capacity will improve with training
3. To investigate whether training effects transfer to other cognitive functions (e.g., executive function and attention) and functional abilities (e.g., academic performance, classroom engagement and participation), and reduce perceived family burden and improve the patients' quality of life)
4. To evaluate whether working memory training reduces health costs
5. To extend these findings to a larger sample of 90 children with acquired brain injury (ABI). This study will employ a randomised controlled parallel design.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Research Ethics Committee – Cambridge South, 01/02/2012, ref: 11/EE/0434

Study design

Randomised controlled parallel interventional study; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Parent/guardian information: http://www.uea.ac.uk/documents/134927/0/WM+training+parent+information+sheet.pdf/12f41fc5-b5b9-4517-af52-947fc83e3701

Health condition(s) or problem(s) studied
Topic: Neurological, Generic Health Relevance and Cross Cutting Themes; Subtopic: Neurological (all Subtopics), Generic Health Relevance (all Subtopics); Disease: Nervous system disorders, Paediatrics

Interventions
Working memory training: 5-weeks of computerised working memory training (approximately 30-mins per day for 5 days per week)

Study Entry: Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Working memory performance; Timepoints: immediately post-training, and at 6-months follow-up

Secondary outcome measures
Academic performance, with further exploratory measures of: executive function and attention, classroom engagement and participation, and perceived family burden and the patients quality of life

Overall study start date
01/09/2012

Completion date
31/03/2017

Eligibility

Key inclusion criteria
Current inclusion criteria as of 20/02/2018:
Participant inclusion criteria
Potential participants for intervention and placebo group will:
1. Male & female, aged between 8 and 16 years
2. Score at or below the 30th centile on two tasks of verbal WM, listening recall and backward digit recall, from the Automated Working Memory Assessment (AWMA, Alloway, 2007)
3. Be medically stable
4. Be computer literate, and will have access to a computer and the internet
5. Speak English

Participants will have documented evidence of non-progressive ABI, defined as a moderate (Glasgow Coma Scale (GCS) 8 - 12, Post Traumatic Amnesia (PTA 1 - 24 hours) to severe (GCS < 8, PTA > 24 hours) TBI, stroke, herpes encephalitis, and infratentorial tumour with resection or cranial radiotherapy.

Previous inclusion criteria:
Potential participants for intervention and placebo group will:
1. Male & female, aged between 8 and 16 years
2. Score at or below the 30th centile on two tasks of verbal WM, listening recall and backward digit recall, from the Automated Working Memory Assessment (AWMA, Alloway, 2007)
3. Be medically stable
4. Be computer literate, and will have access to a computer and the internet
5. Speak English

For the feasibility/acceptability pilot: participants will have documented evidence of non-progressive ABI, defined as a TBI, stroke, herpes encephalitis, and infratentorial tumour with resection or cranial radiotherapy.

For the full study: participants will have documented evidence of non-progressive TBI and will be survivors of moderate (Glasgow Coma Scale (GCS) 8 12, Post Traumatic Amnesia (PTA 1 24 hours) to severe (GCS < 8, PTA > 24 hours) brain injury.

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
16 Years

Sex
Both

Target number of participants

Planned Sample Size: 138; UK Sample Size: 138

Key exclusion criteria
Participants will be excluded if:
1. There is evidence of severe damage to organs other than the brain, major medical problems, or the presence of significant mood disturbance.
2. There is evidence of a progressive neurodegenerative condition.
3. There is a pre-morbid history of learning disability or a specific learning impairment affecting working memory (e.g., dyslexia, specific language impairment), conduct disorder, current use of medication impacting on cognition, or a lack of English proficiency.

Date of first enrolment
01/11/2013

Date of final enrolment
01/04/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of East Anglia
Norwich
United Kingdom
NR4 7TJ

Sponsor information

Organisation
University of East Anglia (UK)

Sponsor details
Earlham Road
Norwich
England
United Kingdom
NR4 7TJ

Sponsor type
University/education

Website
http://www.uea.ac.uk/

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Charity

Funder Name
Action Medical Research (UK)

Alternative Name(s)
actionmedres, action medical research for children, AMR

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
British Academy (For the Promotion of Historical Philosophical and Philological Studies)

Alternative Name(s)
The British Academy

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

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

IPD sharing plan summary
Not provided at time of registration