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Can brain training lead to short term and sustained improvements in cognitive function?

Submission date	Recruitment status	[X] Prospectively registered
21/05/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/09/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/08/2020	Nervous System Diseases	

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
Protocol version 9 21/05/09

Study information

Scientific Title
A randomised single-blind three-armed controlled trial comparing evidence-based reasoning brain training (RBT), general brain training (GBT) and a control treatment to determine short term and sustained improvements in cognitive function

Acronym
BrainTrain

Study objectives
Study 1: All adults

Primary hypothesis:
1. In adults of all ages, there will be significant improvements in global cognition measured by a composite cognitive score in people allocated to RBT compared to those allocated to control after 6 weeks and 12 months of brain training.

Secondary hypotheses:
1. There will significant improvements in fluid intelligence and other aspects of cognition including attention, memory and working memory in people allocated to RBT compared to those allocated to the control treatment after 6 weeks or 12 months of training
2. There will no significant improvements in cognitive outcomes in people allocated to GBT compared to those allocated to the control treatment after 6 weeks or 12 months of training
3. There will significant improvements in a broad range of cognitive outcomes and a composite cognitive score and specifically in fluid intelligence and reasoning in people allocated to RBT compared to those allocated to the GBT treatment after 6 weeks or 12 months of training

Study 2: Adults aged greater than 60 years

Primary hypothesis:
1. In people over the age of 60, instrumental activites of daily living (IADL) will be significantly improved in people allocated to RBT compared to those allocated to a control treatment after 12 months of brain training.

Secondary hypotheses:
1. In people with age-associated cognitive decline (AACD), there will be significant improvement in a broad range of cognitive outcomes, a composite cognitive score and IADL in people allocated to RBT compared to those allocated to the control treatment over 12 months of brain training
2. There will significant improvements in attention, memory, working memory, fluid intelligence and a composite cognitive score in people over 60 allocated to RBT compared to those allocated to the control treatment after 6 weeks or 12 months of training
3. There will no significant improvements in cognitive outcomes in people over 60 allocated to GBT compared to those allocated to the control treatment after 6 weeks or 12 months of training
4. There will significant improvements in a broad range of cognitive outcomes and a composite cognitive score in people over 60 allocated to RBT compared to those allocated to the GBT treatment after 6 weeks or 12 months of training

Ethics approval required

Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised single-blind three-armed controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Dementia prevention

Interventions
1. RBT will focus upon tasks related to reasoning and problem solving. In the Willis et al (2006) study, which provides the best evidence base for sustained benefit, reasoning training was the only brain training that conferred generalised benefits on other aspects of cognition and everyday activities. The recommendation is for participants to complete the training for 10 minutes every day, although with flexibility to do more or less than the recommended amount. An initial feasibility pilot of the brain training package has been completed on 22 older individuals which has been very well received and enabled minor presentational issues to be addressed.
2. GBT will cover a range of cognitive tests other than reasoning/problem solving found in commercial brain training games. Again the recommendation is for participants to complete the training for 10 minutes every day.
3. Control: the control group will perform an internet search based task every day.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

1. Overall performance on cognitive tasks (composite score) at 6 weeks and 12 months in all participants comparing RBT and dummy/placebo treatment
2. Everyday activities at 12 months in participants over 60 comparing RBT and dummy/placebo treatment

Secondary outcome measures
1. All participants:
Cognitive test battery including:
1.1. Memory
1.2. Working memory
1.3. Speed
1.4. Fluid intelligence
1.5. Executive function:
1.5.1. Paired Associate Learning task
1.5.2. Spatial Working Memory
1.5.3. Digit span
1.5.4. Grammatical reasoning
2. Participants over 60 years old:
2.1. Hopkins verbal learning test (HVLT - recognition subscale)
2.2. Self-reported assessment of Instrumental Activities of Daily Living (IADL) from the Minimum Data-set Home Care scale

Overall study start date
01/01/2010

Completion date
01/01/2012

Eligibility

Key inclusion criteria
As part of an exciting partnership between the BBC and the Alzheimer's Society, the BBC will invite all adults in the UK and internationally to take part in a randomised controlled trial (RCT) of brain training. It is anticipated that between 75,000 and 100,000 participants will take part. The population will be analysed as two separate studies:
1. All adults, either sex
2. Adults aged greater than 60 years, either sex

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
75000 - 100000

Total final enrolment
52617

Key exclusion criteria
1. Aged less than 20 years
2. Dementia
3. Not living in UK

Date of first enrolment
01/01/2010

Date of final enrolment
01/01/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wolfson Centre for Age-Related Diseases
London
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Sponsor information

Organisation
King's College London (UK)

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Sponsor type
University/education

Website

http://www.kcl.ac.uk

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
British Broadcasting Corporation (BBC) (UK)

Funder Name
Alzheimer's Society (UK)

Alternative Name(s)
alzheimerssoc

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

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	01/06/2010	07/08/2020	Yes	No
Results article	results	01/11/2015	07/08/2020	Yes	No