# 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 [ ] Statistical analysis plan Registration date Overall study status 18/09/2009 Completed [X] Results [ ] Individual participant data **Last Edited** Condition category 07/08/2020 Nervous System Diseases

# Plain English summary of protocol

Not provided at time of registration

# **Contact information**

# Type(s)

Scientific

#### Contact name

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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 United Kingdom SE1 1UL

# Sponsor information

# Organisation

King's College London (UK)

# Sponsor details

Guy's Campus London England United Kingdom SE1 1UL

clive.ballard@kcl.ac.uk

#### 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