Evaluating a neuroscience-inspired learning activity to improve science and maths in primary-school age children by training inhibitory control skills (the "UnLocke" project)

| Submission date | Recruitment status No longer recruiting Overall study status | Prospectively registered | | |
|-------------------|--|--|--|--|
| 10/10/2017 | | ☐ Protocol | | |
| Registration date | | Statistical analysis plan | | |
| 20/10/2017 | Completed | [X] Results | | |
| Last Edited | Condition category | [] Individual participant data | | |
| 08/01/2024 | Other | | | |

Plain English summary of protocol

Background and study aims

Children's ability to learn science and maths concepts is limited by their ability to inhibit perceptual evidence (what they see, feel or hear) or pre-existing beliefs. For example, children learn that the world is round, whereas there is no direct visual evidence to support this idea, as the horizon looks flat. Many mistakes in maths and science are made because children have a tendency to answer with an intuitive response. The intervention in this study aims to train children in a cognitive strategy, meant to make them reflect, or "stop and think", about science and maths problems before answering. "Stop and Think" is a computerised learning activity that uses content based on the maths and science curriculum of Year 3 and 5 children in England. "See+", uses a similar computerised platform with content based on the Personal, Social and Health Education (PSHE) curriculum. The main difference between the two tasks is the domain that they target. Whereas Stop and Think ultimately aims to improve academic performance in maths and sciences, See+ aims to help children become more proficient at analysing and understanding different forms of social interactions. The aim of this study is to assess whether "Stop and Think" improves science and maths performance in primary-school age children.

Who can participate?

Children in Years 3 and 5 (ages 8 and 10) from over 80 primary schools across England

What does the study involve?

Classes are randomly allocated to one of three groups. The main intervention group take part in Stop and Think for 12 minutes at the start of a maths or science lesson, three times per week, for 10 weeks. The active control group take part in See+ for 12 minutes at the start of any lesson which is not maths or science, three times per week, for 10 weeks. The passive control group take part in lessons as usual. Both Stop and Think and See+ are run as whole-class computerised interactive whiteboard activities, led by the class teacher. Children are asked to perform penand-paper and computerised tests before and after the intervention assessing maths and science performance, general cognitive abilities (IQ and working memory), and the ability to

inhibit a dominant response or thought (inhibitory control). Eighty of them are also asked to solve maths and science problems and to perform tasks in a magnetic resonance imaging (MRI) scanner before and after the intervention, to study any changes in brain function and structure.

What are the possible benefits and risks of participating?

It is hoped that any knowledge gained as a result of the study will be able to help inform further studies into maths and science reasoning and learning. The MRI scanning procedure requires that children are confined in a small partially enclosed space. Some individuals find this to be uncomfortable and may exhibit symptoms of claustrophobia including nervousness, sweating or other minor discomfort. For this reason children who are uncomfortable in small spaces will not be scanned. The sounds the MRI scanner makes during scanning can be quite loud, and children will be given special earplugs to minimise the noise. In addition, the scanner has a very strong magnet, which means it attracts certain metals. Therefore, people with these metals within their bodies (such as dental braces, pacemakers, infusion pumps, aneurysm clips, metal prostheses, joints, rods, or plates) will be excluded from the study. The "metal" in dental fillings is less responsive to magnetism and is therefore allowed, but children who are wearing dental braces are excluded. There are no other known side effects resulting from the MRI scan.

Where is the study run from?

The Centre for Educational Neuroscience, University College London (UCL) and Birkbeck, University of London. Neuroimaging takes place at the Birkbeck-UCL Centre for Neuroimaging (BUCNI) and behavioural cognitive assessments takes place at participating primary schools.

When is the study starting and how long is it expected to run for? April 2017 to June 2018

Who is funding the study?

- 1. Wellcome Trust (UK)
- 2. Education Endowment Foundation (UK)

Who is the main contact? Prof. Denis Mareschal d.mareschal@bbk.ac.uk

Study website

http://unlocke.org/

Contact information

Type(s)

Scientific

Contact name

Prof Denis Mareschal

Contact details

Centre for Brain and Cognitive Development School of Psychology Birkbeck College University of London Malet Street London United Kingdom WC1E 7HX +44 (0)20 7079-0751/7631-6582 d.mareschal@bbk.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbersUnLocke-science1

Study information

Scientific Title

UNLOCKE: Understanding the learning of counterintuitive concepts in science and mathematics education through a behavioural and neuroimaging study of year 3 and year 5 primary-school children participating in subject-specific inhibitory control training (in comparison to social skills training or lessons as usual)

Acronym

UNLOCKE

Study objectives

Hypothesis 1: The Stop and Think interference control training program is better than a matched computerised training intervention in the socio-emotional domain and than lessons as usual at improving primary school children's performance on: 1a) a science and maths misconceptions task; and 1b) maths and science academic achievement.

Hypothesis 2: The Stop and Think interference control training program will lead to increased recruitment of prefrontal brain regions, and possibly decreased recruitment of occipital and parietal brain regions during science and maths misconceptions reasoning compared to a matched computerised training intervention in the socio-emotional domain and to lessons as usual.

Hypothesis 3: The Stop and Think interference control training program may lead to: 3a) far transfer of interference control skills, with improved performance in domain general inhibitory control tasks and 3b) greater changes in brain activation during domain-general inhibitory control tasks than a matched computerised training intervention in the socio-emotional domain and than lessons as usual.

Hypothesis 4: The Stop and Think interference control training program will lead to brain structure changes in fronto-parietal executive control regions compared to a matched computerised training intervention in the socio-emotional domain and to lessons as usual.

Subsidiary analyses: Behavioural changes following the Stop and Think interference control training program will be greater in children who expected the training to be effective (expectations of change will be measured prior to the start of the intervention).

Ethics approval required

Old ethics approval format

Ethics approval(s)

University College London Research Ethics Committee, 01/07/2017, ref: 1602/006

Study design

Multicentre interventional 10-week trial with random allocation of groups to intervention, active and passive control conditions assessed by blind evaluators

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

School

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Inhibitory control and maths and science performance in primary school education

Interventions

In each school, years 3 and 5 (approximate ages 8 and 10) will be randomly assigned to one of three conditions by the external evaluators (National Foundation for Educational Research; NFER). Each school in the main trial will have one year group in the main intervention (Stop and Think: interference control training in mathematics and science) group and the other in either the active control (See+: socio-emotional cognition training) or the passive control group (lessons as usual). All classes of a given year group within a school will be in the same condition.

The main intervention (Stop and Think) will run for 12 minutes at the start of a maths or science lesson, three times per week, for 10 weeks. The active control group will run See+ for 12 minutes at the start of any lesson which is not maths or science, three times per week, for 10 weeks. Both Stop and Think and See+ run as a whole-class interactive whiteboard activities, led by the class teacher. Training will be provided to all teachers in the main intervention and active control groups by the UnLocke team before the 10-week intervention period, and monitoring and support will be in place by a designated UnLocke field officer throughout the intervention.

Intervention Type

Other

Primary outcome measure

Cognitive and neuroimaging measures will be collected 0-2 months prior to the start of the intervention (T1) and 0-2 months after the end of the intervention (T2). In addition, maths and science performance will be assessed with standardised tests by the external evaluators 0-4 months after the end of the intervention (T2)

- 1. Change in science and maths misconception accuracy from T1 to T2 (Hypothesis 1a). Science and maths misconception performance will be measured using a computerised task in the cognitive sample (N=184) and with an additional computerised task in the neuroimaging subsample (N=80)
- 2. Performance on standardised maths or science maths test at T2 (Hypothesis 1b). Each child in the cognitive sample (N=184) will be randomly allocated by NFER to complete either a science or a maths standardised tests, which will be administered by NFER
- 3. Change in brain activation during maths and science misconceptions reasoning from T1 to T2 (Hypothesis 2). Whole-brain activation during the completion of maths and science misconception trials will be measured using a 1.5T magnetic resonance imaging (MRI) scanner in the neuroimaging subsample (N=80). In addition to whole-brain analyses corrected for multiple comparisons, region of interest (ROI) analyses will be performed in dorsolateral prefrontal cortex, inferior frontal gyrus, and anterior cingulate bilateral clusters. Analyses will be performed with and without RT as a covariate of no interest.

Secondary outcome measures

- 1. Change in science and maths misconception reaction times (RT) from T1 to T2 (Hypothesis 1a). Science and maths misconception performance will be measured using a computerised task in the cognitive sample (N=184) and with an additional computerised task in the neuroimaging subsample (N=80)
- 2. Change in inhibitory control tasks performance from T1 to T2 (Hypothesis 3a). Two domaingeneral computerised inhibitory control tasks (Fish Flankers task, Whack-a-mole) and one pen and paper task (Chimeric animals) will be assessed in the cognitive sample (N=184). Key measures will be the accuracy and RT congruency costs (incongruent vs. congruent trials) and reversing costs (reverse vs. congruent trials) in the Fish Flankers task, the percentage No-Go errors in the Whack-a-mole task, and the mixing cost in the Chimeric animals task (difference in accuracy scores between sheets of congruent-only trials and mixed sheets of incongruent and congruent trials)
- 3. Change in brain activation during domain-general inhibitory control tasks from T1 to T2 (Hypothesis 3b). Whole-brain activation in mixed (congruent + incongruent) vs. congruent blocks during the Animal size Stroop task and whole-brain activation in Go/No-Go vs. Go blocks during the Pokemon Go/No-Go will be measured using a 1.5T magnetic resonance imaging (MRI) scanner in the neuroimaging subsample (N=80)
- 4. Change in brain structure from T1 to T2 (Hypothesis 4). Changes in local grey matter and white matter volumes (analysed with VBM or Freesurfer) will be analysed in the whole-brain using family wise error correction

Overall study start date 01/04/2017

Completion date 30/06/2018

Eligibility

Key inclusion criteria

- 1. In Years 3 and 5 (approximate ages 8 and 10) of one of our participating UnLocke schools
- 2. Male or female
- 3. Informed parental consent (opt-in)

Participant type(s)

Other

Age group

Child

Lower age limit

8 Years

Upper age limit

10 Years

Sex

Both

Target number of participants

Total target enrolment 184. 184 participants for behavioural cognitive testing, of which 80 will also take part in the neuroimaging study. In both, 50% will be in Year 3, 50% in Year 5. In the cognitive sample (N=184), 50% will be from the Stop and Think intervention group (n=92), 25% will be from the active See+ control group (n=46) and 25% will be from the passive control group (n=46). For the neuroimaging (N=80), 50% will be in the Stop and Think intervention group (n=40), 25% will be from the active See+ control group (n=25) and 25% will be in the passive control group (n=25)

Key exclusion criteria

- 1. No developmental or neurological disorder
- 2. Neuroimaging subsample: metal in the participants' body (e.g. dental braces, cochlear implant)
- 3. Neuroimaging subsample: claustrophobia
- 4. Neuroimaging subsample: difficulties lying on the back

Date of first enrolment

04/09/2017

Date of final enrolment

01/06/2018

Locations

Countries of recruitment

United Kingdom

Study participating centre

Centre for Educational Neuroscience

London United Kingdom WC1E 7HX

Sponsor information

Organisation

Birkbeck College

Sponsor details

Centre for Brain and Cognitive Development School of Psychology University of London Malet Street London England United Kingdom WC1E 7HX +44 (0)20 7079-0751/7631-6582 d.mareschal@bbk.ac.uk

Sponsor type

University/education

ROR

https://ror.org/02mb95055

Funder(s)

Funder type

Charity

Funder Name

Wellcome Trust

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

United Kingdom

Funder Name

Education Endowment Foundation

Results and Publications

Publication and dissemination plan

The experimental protocol and statistical analyses plans are described in the current preregistration document and will not be published separately. The trialists plan to publish the initial analyses in high impact peer reviewed journals in 2019 and 2020.

Intention to publish date

30/06/2019

Individual participant data (IPD) sharing plan

Participant level data can be obtained by writing to Prof. Denis Mareschal (d.mareschal@bbk.ac. uk). The data will consist of reaction time data, accuracy scores on math and science performance tests, standardised IQ and language tests, MRI scans, gender, age, and free schools meal eligibility. The data will become available after the publications of the results in a scientific journal or no later than the end of 2020. The data will be kept for 10 years. The data will remain entirely anonymous.

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-----------------|---------|--------------|------------|----------------|-----------------|
| Results article | | 12/12/2019 | 27/10/2022 | Yes | No |
| Results article | | 21/09/2023 | 08/01/2024 | Yes | No |