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# Can adolescent emotion regulation be improved with an app-based training?

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 04/12/2018 | Suspended | [X] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 10/12/2018 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 09/07/2020 | Mental and Behavioural Disorders | [ ] Record updated in last year |

## Plain English summary of protocol

Background and study aims
75% of all mental health problems have their onset before the end of adolescence. Adolescence, thus may be a particularly sensitive time period for preventing mental health problems. In this study, we will explore the usefulness of an app-based training for improving adolescents' ability to control their emotions. As an app, the training can be made available to anyone who has access to a smartphone or a tablet device anywhere in the world. We are particularly interested whether the training can improve adolescents' mental health.

Who can participate?
Individuals aged between 11-19 years, without a history of head injury, diagnosed neurodevelopmental disorder or learning difficulty.

What does the study involve?
To investigate the effectiveness of our training app, we will compare our training app to another training app, which we don't think will improve adolescents' ability to control their emotions. We will ask 200 (~50% females) adolescents to train on the two apps for 14 days. Before adolescents start with their training we will measure their mental health as well as their ability to control their emotions. We will then measure these things again immediately after they have finished their training, one month after the training and one year after the training. We are measuring them repeatedly to explore whether the training has lasting benefits to adolescents' mental health and emotional control.

What are the possible benefits and risks of participating?
There are no known risks or benefits to the individual for participating in the study.

Where is the study run from?
The study is run from the University College Institute of Cognitive Neuroscience.

When is the study starting and how long is it expected to run for?
The study start date is September 2018 and it will run until January 2018.

Who is funding the study?
The study is funded by the Wellcome Trust.

Who is the main contact?
Dr Susanne Schweizer, s.schweizer@ucl.ac.uk

# Contact information

### Type(s)
Scientific

### Contact name
Dr Susanne Schweizer

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
1

# Study information

### Scientific Title
Trial comparing the effectiveness of an app-based Affective Control Training to a placebo training App for improving adolescent mental health and emotion regulation

### Acronym
ACTA

### Study objectives
1. Affective control can be improved in adolescents (affective control training hypothesis).
2. AC-Training compared to P-Training will lead to greater improvements in all facets of affective control as measured by non-trained affective control tasks, including affective inhibition, updating and shifting tasks (affective control facets hypothesis).

3. The benefits of AC-Training will decrease with age (age-related change hypothesis).
4. Increases in affective control from pre- to post-training will be associated with fewer self-reported mental health problems and emotion regulation difficulties, as well as higher levels of self-reported self-control, at each assessment time point (mental health hypothesis).

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
The University College London Research Ethics Committee, 23/04/2018, ref. 12753/002.

## Study design
Proof-of-principle double-blind randomized control trial

## 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
Adolescent mental health and emotion regulation

## Interventions
Training procedure and timeline
The study will have two training arms. An active Affective Control Training (AC-Training) and a placebo training (P-Training). The training will be administered via an app. Included participants will be randomized to either the AC-Training or the P-Training groups. Both training groups train for 14 days over a four-week period. They are asked to complete at least 10 minutes of training per day. The total duration of a session is There is no upper limit to the duration of the daily training session.

Affective training
In the affective training participants train on three different working memory tasks including neutral and affective stimuli (faces and words). The tasks are a visuospatial, auditory and dual n-back task. They require participants to maintain and update the location of faces, words, or both in working memory.

Placebo training
The placebo training task requires participants to indicate whether two panels display exactly the same stimuli in the same positions on a grid. As with the affective control training there are

three versions: a shapes version including geometric shapes as stimuli, and the other two versions include the same faces and words as the affective control training task.

Randomization
Condition allocation will be concealed to experimental staff by using computer-generated condition assignment stratified by age (young adolescents, 11-14 years, and mid-late adolescents, 15-19 years). Allocation will be based on a blocked randomization sequence with randomly mixed block sizes (2-6), which prevents the experimenter from deducing any potential sequencing even with awareness of the randomization type. To investigate this hypothesis, we will compare individuals' performances on the affective n-back task, which is a slightly modified (i.e., including different stimuli and fewer trials) version of the AC-Training task, across the two training groups.

### Intervention Type
Behavioural

### Primary outcome measure
1. Mental health will be measured using the strengths and difficulties questionnaire before training, immediately after training, one month after training and one year after training.
2. Affective control will be measured using computerized assessments of affective inhibition, updating and shifting before training, immediately after training, one month after training and one year after training.
3. Emotion regulation will be measured with the Difficulties in Emotion Regulation Scale will be assessed before training, immediately after training, one month after training and one year after training.

### Secondary outcome measures
1. Self-regulation will be assessed with the Brief version of the Self-control Scale before training, immediately after training, one month after training and one year after training. 1.1. It will also be assessed by deriving a ratio of the time spent on the most demanding versus less demanding training tasks.

### Overall study start date
21/09/2018

### Completion date
01/01/2022

## Eligibility

### Key inclusion criteria
1. Aged between 11-19 years old
2. Speak English fluently

### Participant type(s)
Healthy volunteer

### Age group
Other

### Sex
Both

### Target number of participants
200

### Key exclusion criteria
1. History of traumatic head injury
2. Diagnosed neurological or neurodevelopmental disorder
3. Currently enrolled in another cognitive training intervention.

### Date of first enrolment
01/06/2018

### Date of final enrolment
01/06/2021

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**UCL Institute of Cognitive Neuroscience**
17 Queen Square
London
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## Sponsor information

### Organisation
University College London

### Sponsor details
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**Sponsor type**
University/education

**Website**
http://www.ucl.ac.uk/

**ROR**
https://ror.org/02jx3x895

# 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

# Results and Publications

**Publication and dissemination plan**
Standard academic dissemination of the study results will be sought through journal publications. Findings will also be communicated at scientific conferences and where permitted by journal regulations published on pre-print archives.

**Intention to publish date**
01/06/2022

**Individual participant data (IPD) sharing plan**
Participants consent will be obtained to share anonymised data. We will share data on request with researchers that consent to storing and analysing the data in accordance with the General Data Protection Regulation and the British Psychological Society’s Code of Ethics and Conduct.

No de-identified data will be shared that data will be stored for 10 years on encrypted drives at the University College London Institute of Cognitive Neuroscience and looked filing cabinets in the case of paper data.

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 02/10/2019 | 10/10/2019 | Yes | No |