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Engage: mindful attention training to improve attention and reading abilities in children with language-based learning differences

Submission date
23/07/2021

Recruitment status
No longer recruiting

Registration date
27/07/2021

Overall study status
Completed

Last Edited
09/08/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Reading is an essential skill to master during childhood that relies on reading-specific skills as well as domain-general processes, such as attention. However, difficulties in reading are prevalent in youth and, importantly, failing to master reading can cause problems in both academic settings and in later life. Children who have below-basic reading abilities are 6-8 times more likely to drop out of high school and have more pronounced mental health difficulties, such as anxiety. Fortunately, there is mounting evidence that different types of cognitive interventions can be used to improve reading skills in children and adolescents.

The goal of this study is to determine whether a novel mindful attention training video game (Engage) improves attention in youth with language-based reading and learning difficulties, such as dyslexia. Engage is a tablet-based video game intervention designed to improve aspects of attention through a kid-friendly meditation platform. The study team hopes that in addition to improving attention skills, Engage will also have downstream effects on reading abilities due to synergistic effects on training attention through mindfulness via a video game platform.

In this study, we are partnering with the Chartwell School in Seaside CA to achieve these aims. Chartwell is a school dedicated to meeting the needs of students who have a range of language-based learning differences, including dyslexia. Students are provided individualized instruction needed to overcome these challenges. We will compare improvements in attention, reading, and other aspects of cognition and behavior when Engage is combined with the Chartwell-based instruction to growth following the standard Chartwell-based instruction alone.

Who can participate?
Children in 7th and 8th grade at the Chartwell School in Seaside, CA.

What does the study involve?
Students will be allocated to one of two groups, to receive either 7 weeks of Engage training combined with school-based instruction or school-based instruction alone, with an equal chance of being in either group (like tossing a coin) for the first half of the study. In the second half of

the study, participants will receive the treatment/intervention that they did not receive in the first half of the study.

Students are given access to the Engage training intervention via an iPad app. They are asked to use the app for approximately 20-minute sessions in their homerooms at school, over the course of 7 weeks. Participants can play up to 21 sessions of Engage over this period. Students' teachers and our UCSF study staff monitor gameplay to encourage training adherence. Students will be assessed at 3 time points over the school semester (at the start of the semester, after either 7 weeks of Engage training combined with school-based instruction or school-based instruction alone, and after a further 7 weeks where all students will have completed Engage training).

What are the possible benefits and risks of participating?
There are no direct benefits or risks associated with participating in this study.

Where is the study run from?
The University of California, San Francisco (USA)

When is the study starting and how long is it expected to run for?
From October 2020 to June 2021

Who is funding the study?
The Schwab Center for Dyslexia and Cognitive Diversity (USA) and the Patrick J. McGovern Foundation (USA)

Who is the main contact?
Dr. Courtney Gallen (scientific)
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
Improving attention and reading abilities in youth with language-based learning differences through mindful attention training

Study objectives
Children with language-based learning differences will show improvements in attention following training with Engage. Engage-related improvements will have downstream effects on improving their reading abilities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/10/2020, University of California, San Francisco Human Research Protection Program Institutional Review Board (IRB) (UCSF, Human Research Protection Program, Box 1288, 490 Illinois Street, Floor 6, San Francisco, CA 94143; +1 415-476-1814; IRB@ucsf.edu), ref: 20-30666

Primary study design
Interventional

Study design
Interventional cluster-randomized cross-over study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Language-based learning differences

Interventions
This study employs a randomised crossover design with two groups (Groups 1 and 2) who are assessed at 3 timepoints over the school semester (T1, T2, and T3). Students are cluster randomized into Group 1 or 2. Specifically, four homerooms total (2 homerooms in each group) are randomized to either Group 1 or 2 prior to any data collection. All students are assessed with our outcome measures at baseline, the start of the semester (T1). Then, Group 1 completes the Engage training combined with Chartwell instruction while Group 2 participants serve as a waitlist control and receive school-based instruction alone. After the first 7-week training period, all students will be assessed using the outcome measures again (T2). The study then employs the crossover design, where Group 2 completes the Engage training combined with Chartwell instruction while Group 1 participates in school-based instruction alone. Finally, all students are assessed for a final time at the end of the second 7-week period (T3).

The Engage intervention is a meditation-inspired tablet-based video game designed to improve sustained attention in children and adolescents. The game gradually progresses from a fast-paced, rapid reward environment that is rich in visual and auditory stimuli, much like a traditional video game, to a slower reward environment (‘Engage Mode’) that is more sensory impoverished, much more like real-world academic settings. During each session, participants

start the game in the immersive environment and gain points as they respond to target stimuli and ignore distractors (i.e., bugs) based on auditory and visual features. When enough points are accumulated, participants enter the sparse environment ('Engage Mode'), where they play with their eyes closed and collect target bugs only based on auditory features, a unique mindful meditative activity that is easier for children and adolescents than traditional meditation practices. Once a round of Engage Mode is complete, participants are returned to the immersive environment and this process is repeated for the duration of the session. Of note, as gameplay continues, participants enter Engage Mode more quickly and stay in this sparse environment for progressively longer periods of time. Critically, the immersive and sparse environments independently increase in difficulty in an adaptive manner over the course of training.

In this study, students play Engage for approximately 20 min per day in their homerooms at school over the course of 7 weeks, up to 21 sessions total.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
Attention measured using computer-based visual continuous performance tasks (CPTs) at baseline, 7, and 14 weeks

Key secondary outcome(s)
1. Reading ability measured using the following at baseline, 7, and 14 weeks:
1.1. Computerized test of reading fluency
1.2. Sub-test from the Woodcock-Johnson (WCJ) battery
1.3. Sub-test from the Test of Word Reading Efficiency (TOWRE)
1.4. Sub-test from the Kaufman Test of Educational Achievement (KTEA)
2. Delay discounting and impulsivity measured using a computerized delay discounting test at baseline, 7, and 14 weeks
3. Aspects of cognitive control measured using the computerized Adaptive Cognitive Evaluation (ACE) battery at baseline, 7, and 14 weeks

Exploratory outcome measures:
1. Working memory abilities measured using the WISC forward and backward digit span at baseline, 7, and 14 weeks
2. Math ability measured using a computerized test of math fluency at baseline, 7, and 14 weeks
3. Self-reported behaviors measured at baseline, 7, and 14 weeks:
3.1. Attention measured by student self-report using the Mindful Attention Awareness scale (MAAS)
3.2. Mental health measured by student self-report using the Warwick-Edinburgh Mental Wellbeing Scale
3.3. Sleep quality measured by student self-report using the Insomnia Severity Index (ISI)

Completion date
09/06/2021

Eligibility

Key inclusion criteria
7th and 8th-grade students at the Chartwell School in Seaside CA

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Sex
All

Total final enrolment
34

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
04/01/2021

Date of final enrolment
25/05/2021

Locations

Countries of recruitment
United States of America

Study participating centre
University of California, San Francisco
675 Nelson Rising Lane
San Francisco
United States of America
94143

Sponsor information

Organisation
University of California, San Francisco

ROR

https://ror.org/043mz5j54

Funder(s)

Funder type
University/education

Funder Name
Schwab Center for Dyslexia and Cognitive Diversity

Funder Name
Patrick J. McGovern Foundation

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date