ISRCTN17744284 https://doi.org/10.1186/ISRCTN17744284

# Do brief mindfulness training and attention training games improve self control in 6-10 year-old children adopted internationally?

**Submission date**
30/06/2016

**Recruitment status**
No longer recruiting

**Registration date**
18/07/2016

**Overall study status**
Completed

**Last Edited**
04/02/2019

**Condition category**
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

## Plain English summary of protocol

Background and study aims
During middle childhood, between ages six and ten, children enter formal schooling and start forming more social relationships outside the home. This time involves a host of new challenges and tasks that children master as they develop. Being able to pay attention and regulate behavior for stretches of time are necessary for success in the classroom as well as in the playground. Over the early school years, children's social world becomes much more complex as they begin to form close friendships and navigate peer groups. It is during this time they will develop and refine strategies for social interactions across a variety of situations. Children who have experienced difficulties in their early years have a higher risk of developing problems with attention regulation and self-control, as well as difficulties understanding other people's thoughts and emotions. Studies on both internationally adopted children and non-adopted children with attention difficulties suggest that these difficulties may underlie some problems with social functioning. If children have trouble paying attention to subtle social cues (signs), like facial expressions, they may have a harder time interpreting other people's behaviors and developing effective means of managing different social situations. Previous research also suggests that some of the behaviors related to indiscriminate friendliness may reflect a decreased ability to control behavior more generally. The aim of this study is to look at two training strategies which have been designed to help improve attention and social and emotional skills in internationally adopted children.

Who can participate?
Internationally adopted children aged between six and ten who live within a 50-mile radius of the university campus where the study takes place.

What does the study involve?
Participants are randomly allocated to one of three groups. Those in the first group continue as normal for the duration of the study, and do not complete any training sessions. Those in the second group take part in two hour-long sessions a week at the university in which they learn mindfulness skills. This involves learning to become more aware of the self and current moment by training children to consciously direct and maintain focus on their breath, body sensations,

and experiences. Children also learn to pay attention to and identify thoughts and feelings. Children are also given “homework” exercises to complete with their parents at home to further practice the skills they learn in the training sessions. Those in the third group take part in two hour-long sessions a week at the university in which they learn to train attention and self-control skills more directly. This program focuses on three major areas: self-control (stopping oneself from performing impulsive or automatic actions), selective attention (learning to pay attention to certain parts of a situation while ignoring others), and creative thinking (using imagination to understand possibilities and alternatives). Children practice these skills at home by playing fun games like “Simon Says”, “Sound Bingo”, and “Imagination Island”. Participants in both groups complete a number of questionnaires and tasks designed to measure their attention and self-control at the start of the study and 1-2 weeks after the training program has ended. Children also have their brain responses measured through an EEG scan (recording of electrical activity in the brain, measured through sticky, electricity-conducting pads attached to the head). Four months later, teachers of participating children are interviewed in order to assess the children’s’ emotional state.

What are the possible benefits and risks of participating?
Children in the mindfulness group and attention training group may directly benefit from training designed to lead to improvements in self-regulation if these programs prove effective. There is no anticipated risk or harm associated with the training. At testing sessions, participants may dislike the experience of the EEG net or might experience frustration due to the nature of the tasks. Parents of participants may feel uncomfortable answering certain questions. Parents or children can choose to skip any part of the testing session as needed.

Where is the study run from?
University of Minnesota (USA)

When is the study starting and how long is it expected to run for?
January 2012 to September 2015

Who is funding the study?
1. Center for Neurobehavioral Development, University of Minnesota (USA)
2. Center for Personalized Prevention Research, University of Minnesota (USA)
3. Institute of Child Development, University of Minnesota (USA)

Who is the main contact?
Dr Jamie Lawler
lawle084@umn.edu

# Contact information

### Type(s)
Public

### Contact name
Dr Jamie Lawler

### ORCID ID
http://orcid.org/0000-0002-7325-2095

### Contact details

University of Michigan Depression Center
Rachel Upjohn Building
4250 Plymouth Road
Ann Arbor
United States of America
48109

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
1201S09544

# Study information

### Scientific Title
A randomized controlled trial of mindfulness and executive function trainings to promote self-regulation in internationally adopted children

### Study objectives
Both interventions will improve behavioral self-regulation (attention, inhibitory control, delay of gratification and inattention/hyperactivity), while only the mindfulness intervention is expected to improve emotion-regulation.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
University of Minnesota Social & Behavioral Sciences Institutional Review Board, 15/02/2012, ref: 1201S09544

### Study design
Single-center three arm randomized controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Other

### Study type(s)
Prevention

## 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
Self-regulation

## Interventions
A two-wave stratified random sampling technique is used to assign participants into the mindfulness training group, executive function training group, or control group in a 1:1:1 multi-arm parallel design.

Mindfulness training (MT) group: Participants attend two hour-long training sessions per week for six weeks in groups of seven to nine children with 2-3 instructors, on a Midwest university campus, in addition to completing training-related activities with their parents at home. The curriculum for this training involves learning mindfulness and relaxation practices adapted for children. These include brief, concrete exercises such as breathing activities, sensory awareness exercises, brief guided meditation sessions (1-5 minutes, increasing in length over the course of the intervention), arousal modulation practice, and compassion activities. To maintain young children's interest while building a foundation of skills in mindful awareness, the training curriculum includes both variety and repetition. The "homework" activities completed at home with parents mirror the progression of the training curriculum by beginning with reinforcing basic skills and ending with scaffolded use of those skills as regulation strategies.

Executive function training (EF) group: Participants attend two hour-long training sessions per week for six weeks in groups of seven to nine children with 2-3 instructors, on a Midwest university campus, in addition to completing training-related activities with their parents at home. The curriculum for this training involves child-friendly attention, inhibitory control, and mental flexibility/imagination games. The small-group, non-computerized games involved paying attention, following instructions, inhibiting behaviors, and using the imagination (cognitive flexibility). The curriculum also includes "homework" activities and games that parents were instructed to complete with their children that offer additional practice on these skills, and methods for integrating practice into daily routines (e.g. chores, play time).

Control group: Participants receive no intervention for the duration of the study period.

Participants in all groups are followed up 1-2 weeks post intervention, in which they complete a range of questionnaires and game tasks as well as undergoing an EEG. Teachers of the children are interviewed four months later to rate emotional regulation.

## Intervention Type
Behavioural

## Primary outcome measure
1. Inhibitory control is measured using the Dinky Toys task at baseline and 1-2 weeks post intervention
2. Delay of gratification is measured using the Star Game at baseline and 1-2 weeks post intervention
3. Selective attention is measured using the Color Flanker Task at baseline and 1-2 weeks post intervention
4. Emotion regulation is measured by experimenter (blind to condition) rating of participant

behavior over the course of the testing session at baseline and 1-2 weeks post intervention
5. Event-related potentials measured by EEG during Color Flanker Task at baseline and 1-2 weeks post intervention
6. Child internalizing and externalizing symptoms measured using the MacArthur Health and Behavior Questionnaire at baseline and 1-2 weeks post intervention

### Secondary outcome measures
1. Emotional regulation and emotion lability are measured using the Emotion-regulation Checklist (ERC) 4 months post intervention (rated by classroom teachers)
2. Emotional problems and hyperactivity/inattention problems are measured using the Strengths and Difficulties Questionnaire: (SDQ) 4 months post intervention (rated by classroom teachers)

### Overall study start date
01/01/2012

### Completion date
04/09/2015

## Eligibility

### Key inclusion criteria
1. Internationally adopted
2. Aged between 6 and 10 years old at the start of the intervention
3. The family lives within a 50-mile radius of the university campus where the study takes place

### Participant type(s)
Other

### Age group
Child

### Lower age limit
6 Years

### Upper age limit
10 Years

### Sex
Both

### Target number of participants
105

### Key exclusion criteria
1. A diagnosis of fetal alcohol syndrome, autism spectrum disorders, or severe cognitive impairment
2. Children with extensive yoga or traditional martial arts participation were excluded (due to the mindfulness components of each)

**Date of first enrolment**
16/02/2012

**Date of final enrolment**
15/06/2014

# Locations

**Countries of recruitment**
United States of America

**Study participating centre**
**University of Minnesota**
55 East River Road
Minneapolis
United States of America
55455

# Sponsor information

**Organisation**
University of Minnesota

**Sponsor details**
55 East River Road
Minneapolis
United States of America
55455

**Sponsor type**
University/education

**ROR**
https://ror.org/017zqws13

# Funder(s)

**Funder type**
University/education

**Funder Name**
Center for Neurobehavioral Development, University of Minnesota

**Funder Name**
Center for Personalized Prevention Research, University of Minnesota

**Funder Name**
Institute of Child Development, University of Minnesota

# Results and Publications

**Publication and dissemination plan**
Planned publication in a high-impact peer reviewed journal.

**Intention to publish date**
31/12/2016

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/10/2019 | | Yes | No |