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Assessing the effects of digital meditation on the cognitive function of adolescents with childhood trauma

Submission date
25/04/2019

Recruitment status
No longer recruiting

Registration date
30/04/2019

Overall study status
Completed

Last Edited
04/10/2022

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
Traumatic childhood experiences, of neglect and/or abuse, are linked to poor attentive behaviors and related cognitive deficits during adolescence, as well as increased risk for mental health disorders in adults. Adolescence is the critical time period for the development of functional brain networks dictating higher-level cognition. Yet, developing brain networks that control cognition are not well understood in adolescents with childhood trauma, and no study has yet tested targeted interventions to optimize neuro-cognitive processes in this population.

The aims of this study are to investigate how closed-loop, digital interventions that either train internal or external attention can benefit adolescents with childhood trauma.

Who can participate?
Adolescents aged 10-18 years old with a history of traumatic early childhood experiences can participate in the study.

What does the study involve?
The study uses multimodal methods of brain imaging (magnetic resonance imaging or MRI), and cognitive, behavioral and academic assessments.

1. Participants undergo a functional MRI scan that measures brain activity while resting at baseline and at post-intervention.
2. Participants are assessed on objective cognitive tests of sustained attention and distractor processing at baseline and at post-intervention.
3. Behavioral assessments include ADHD inattentive and hyperactivity ratings from caregivers at baseline, post-intervention, and one-year follow-up.
4. Secondary academic assessments include teacher-ratings of academic performance at post-intervention and one-year follow-up.

What are the possible benefits and risks of participating?
There is no direct benefit to participating in the study, although improved cognitive

performance may be seen from doing digital training. We hope that the knowledge gained from this research will be useful in the future enrichment of children with cognitive deficits.

The study protocol is only associated with minor risks of occasional mental fatigue or boredom; frequent breaks are recommended to prevent this.

The MRI is not invasive, and it does not expose participants to treatments with energy such as X-rays or CT scans do. Many people have been safely studied using MRI techniques. While there are no significant risks from MRI as it is to be performed, the MRI procedures are not appropriate for people with pacemakers or metal in their bodies; such individuals will not be asked to participate in the MRI portion of the study. The space inside the bore of the MRI machine is just large enough for an average person. Because the space is confined, some people feel claustrophobic once inside the MRI machine; individuals with a history of claustrophobia will not be asked to participate in the MRI study. Because the MRI scan makes loud noises, earplugs will be provided to dampen the sound. If participants do not like being in the scanner for any reason, we will immediately stop the experiment.

There is minimal risk of breach of privacy due to electronic data collection. The study researchers will do their best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy; personal information may be given out if required by law. Organizations that may look at and/or copy your research records for research, quality assurance, and data analysis include the Ethics Committees that oversee the study. If information from this study is published or presented at scientific meetings, participant names and other personal information will not be used.

Where is the study run from?
The study is an international collaborative research project. Participants in the study are recruited in New Delhi from the Udayan Care Center that provides child and youth care for individuals with a history of childhood trauma. Study research personnel are from Udayan Care, the All India Institute of Medical Sciences, and the University of California.

When is the study starting and how long is it expected to run for?
The study began on 18/05/2015 and ended on 29/09/2017.

Who is funding the study?
A University of California Global Health Basic Science Award & a Global Brain Health Institute award has funded the study.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
ROCKON

Study information

Scientific Title
Research On Cognition in Kids to Overcome Neglect: a cluster randomised controlled trial.

Acronym
ROCKON

Study objectives
1. Adolescents with a history of traumatic childhood experiences will show deficits in developing brain networks important for control of sustained attention.
2. A closed-loop digital approach that implements basic breath-focused meditative practice to train sustained attention, will demonstrate positive outcomes in brain network function dictating sustained attention control, and in objective cognitive assessments, ADHD (attention deficit and hyperactivity disorder) behaviors and academic performance ratings.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/09/2019, University of California San Francisco (Human Research Protection Program, Box 0962, 3333 California Street, Suite 315, San Francisco, CA 94143, USA; IRB@ucsf.edu; +001-415-476-1814), ref: 14-14460.
Approved 25/07/2014, All India Institute for Medical Sciences Institute Ethics Committee (Room No 102, 1st Floor Old O.T. Block, Ansari Nagar, New Delhi 110029, India; +91-11-26594579), ref: IEC/NP-117/2014.
Approved 30/09/2014, the Indian Council of Medical Research (Ansari Nagar PO Box 4911, New Delhi 110029, India; icmrhqds@sansad.nic.in; +91-11-26588980), ref: Indo-Foreign/5/M/2014-NCD-I.

Study design
Interventional single-centre study with double-blind cluster randomized controlled trial.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Disturbance of activity and attention in adolescents with a history of traumatic early childhood experiences

Interventions
Study participants were cluster-randomized into either the internal-attention intervention (IAI) or external-attention intervention (EAI) or no intervention (NI). Cluster randomization was based on enrollment in pre-existing after-school groups. Both IAI and EAI were self-administered on digital tablet applications for up to 30 minutes of practice per session (25 minutes training interspersed with short 1 min breaks every 5 minutes), for 30 sessions over 6 weeks. To facilitate full adherence and troubleshoot any technical issues, a research staff member was present during all after-school group training sessions; participants sat in a group, yet, performed their individual training sessions. The intervention arms were double-blinded; both IAI and EAI arms were experimental, hence, neither the participants nor the research staff interacting with the participants had any knowledge as per the relative efficacy of one or the other arm, and the NI arm did not have knowledge of the other IAI/EAI arms, thereby, equating placebo effects in all study arms as much as possible. Caregivers and teachers were also intervention blind.

At the end of each intervention session, progress and performance data were automatically transferred to a secure study data server in de-identified format.

Participants in the IAI group practiced attending to the sensations of their breath, with monitoring guided using a digital app – Meditrain – which recently revealed benefits on sustained attention in healthy young adults (Ziegler et al., Nature Human Behaviour, 2019 in press). Participants were instructed to acknowledge internally distracting thoughts when they occurred during the practice, then disengage from the thought and shift their attention back to their breath. Participants practiced attention to breath in adaptive trial durations starting as short as 10 seconds and progressively building up to several minutes of breath focus. Trial durations were adapted based on end-of-trial feedback from participants. At the end of each trial, participants were prompted to report, via screen-tap, whether their attention remained on their breath throughout the trial, or if their attention was diverted by distracting thoughts. If they reported successful attention to their breath for the entire trial, the duration (in seconds) of the next trial was increased by 10%; if unsuccessful, the duration of the next trial was decreased by 20%. Using this adaptive, closed-loop algorithm, the training targeted the participants' ability to self-regulate internal attention on an individualized basis. Training sessions were linked, such that the next session began at the level attained at the end of the previous session.

Participants in the EAI group practiced attention to sensory (visual and auditory) stimuli amidst sensory distractors in the context of five different game modules, practiced 5 min each per session. All training modules were closed-loop, i.e., performance-adaptive. Game modules challenged focused attention as well as divided selective attention and exercised working

memory when a given sensory target had to be retained amidst varied distractors over several trials. The Freeze Frame, Double Decision, Mind's Eye, Target Tracker visual game modules and the Hear Hear and Memory Grid auditory modules available at brainhq.com were selected for the EAI training based on demonstrated efficacy of these individual training modules in prior research (Mishra et al., Neuron, 2014; Mishra et al., Translational Psychiatry, 2016; DeGutis & VanVleet, Frontiers in Human Neurosciences, 2010; Smith et al., Journal of the American Geriatric Society, 2009; Edwards et al., Neuroscience & Biobehavioral Reviews, 2018). In Freeze Frame, participants practiced focused attention to visual targets, selectively withholding their response to these while non-selectively responding to all distractors. In Double Decision, participants practiced divided attention to central and peripheral visual targets. In Mind's Eye, participants identified visual targets amidst simultaneous visual distractors as the features of the visual distractors adaptively resembled the visual target over successive trials. In Target Tracker, participants attended to moving object targets amidst moving distractors and were adaptively challenged to retain a larger number of target objects in working memory. In Hear Hear, participants attended to target sounds within sequences of distractor sounds that adaptively resembled the target sound over successive trials. In Memory Grid, participants matched pairs of sound clips shuffled among a set of several sound clips of adaptively increasing set size.

The one-year follow-up was conducted for ADHD symptom ratings from caregivers. For this, caregivers rated ADHD symptoms on the standard ADHD rating scale (DuPaul et al., Guilford Press, 1998). The same caregivers rated ADHD symptoms on this scale at baseline time 1, post-intervention time 2 and one-year follow-up time 3. Caregivers were blind to the intervention.

The one-year follow-up was also conducted for the secondary outcome of academic performance ratings from teachers. For this, teachers provided ratings on the Academic Performance Rating Scale (APRS, DuPaul & Rapport, School Psychology Review 1991). Different teachers rate the APRS at post-intervention time 2 and one-year follow-up time 3. Teachers were blind to the intervention.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
N/A

Primary outcome(s)
1. Functional connectivity of the dorsal anterior cingulate cortex region is measured using resting-state functional magnetic resonance imaging at baseline time 1 and post-intervention time 2.
2. Sustained attention and interference resolution is measured using computerised cognitive assessments at baseline time 1 and post-intervention time 2.
3. ADHD symptoms are measured using caregiver-based ADHD ratings at baseline time 1, post-intervention time 2 and one-year follow-up time 3.

Key secondary outcome(s))

Academic performance is measured using the teacher-rated observations of academic performance recorded on the Academic Performance Rating scale at post-intervention time 2 and one-year follow-up time 3.

Completion date
29/09/2017

Eligibility

Key inclusion criteria
Reported a history of childhood trauma as per the Childhood Trauma Questionnaire (Bernstein et al., 2003).

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Sex
All

Total final enrolment
45

Key exclusion criteria
Not present at the study location throughout the entire period.

Date of first enrolment
18/05/2015

Date of final enrolment
23/07/2015

Locations

Countries of recruitment
India

Study participating centre
Udayan Care
A-43, Chittaranjan Park

New Delhi
India
110019

Sponsor information

Organisation
University of California San Diego

ROR
https://ror.org/0168r3w48

Funder(s)

Funder type
University/education

Funder Name
University of California Global Health Basic Science Award

Funder Name
Global Brain Health Institute

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/05/2020	04/10/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes