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Breath-focused mindfulness and compassion training for parent-child dyads

Submission date
07/10/2024

Registration date
09/10/2024

Last Edited
09/10/2024

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[_] Results

[_] Individual participant data

[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Depression in children is a huge mental health concern and can further impact parental stress and well-being. A parent-child co-training digital application was developed in this study for practicing breath-focused mindfulness and compassion together. This study tests the hypothesis that the parent-child digital co-training of breath-focused mindfulness and compassion together will improve mental health symptoms, and cognition and facilitate neuroplasticity.

Who can participate?
Parent-child dyads where the child has Child Depression Index (CDI) scores in the average or above-average range (T-score>40)

What does the study involve?
The parent-child dyads receive the digital app intervention for about 3 months with pre and post-intervention assessments of mental health, cognition and electroencephalography (EEG)-derived brain function. Families also complete a 3-month follow-up of mental health assessments.

What are the possible benefits and risks of participating?
Benefits to participants may include improvements in well-being and/or cognition. This is a minimal-risk study.

Where is the study run from?
The University of California San Diego School of Medicine (USA)

When is the study starting and how long is it expected to run for?
February 2021 to August 2023

Who is funding the study?
1. Sanford Institute for Empathy and Compassion at the University of California San Diego
2. National Institutes of Health

Who is the main contact?
Jyoti Mishra, jymishra@ucsd.edu (USA)

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
National Institutes of Health subaward grant: NIH/NCCIH 5U24AT011289

Study information

Scientific Title
Breath-focused mindfulness and compassion training in parent-child dyads: a pilot intervention study

Acronym
CoCo

Study objectives
The parent-child digital co-training of breath-focused mindfulness and compassion together will improve mental health symptoms, and cognition and facilitate neuroplasticity

Ethics approval required
Ethics approval required

Ethics approval(s)

Study design
Interventional non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community, Home, Internet/virtual

Study type(s)
Prevention, Quality of life

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Depression

Interventions
The digital Cooperative Compassion (CoCo) training for parent-child dyads was delivered on the HIPAA-compliant BrainE© app with a de-identified and password-protected login provided to each family. Participants accessed the iOS/Android compatible smartphone app in their own free time and engaged in ~10 minutes of training per session for up to 30 sessions. The training was delivered in a game-like format and was performance-adaptive. Specifically, to practice breath-focused mindfulness, individuals were requested to close their eyes, pay attention to their breathing, and tap the mobile screen after a specific number of breaths from 1 breath up to 10 breaths at a time. Consistency of performance was monitored as users tapped the mobile screen after the instructed number of breaths while keeping their eyes closed; the screen was digitally split to simultaneously track both parent and child performance, i.e., one-half of the screen kept track of child finger traps while the other half kept track of parent taps. If both parent and child consistently monitored breathing for at least two-thirds of the duration at any given level, where level refers to the number of breaths monitored, then they would together progress to monitoring the next level/count of breaths. At every sixth session of training, compassion instructions were relayed by text and audio before the start of the breath-focused exercises so that users could discuss and keep these instructions in mind during their practice. Over 30 sessions, there were a total 5 levels of standard compassion training instructions provided focusing on (1) settling the mind, (2) compassion for a loved one, (3) compassion for self, (4) loving-kindness for self and (5) embracing common humanity; these instructions followed guidance from the Compassion Cultivation Training program. Finally, a distinct, calming nature scene is unveiled at the end of each session as a form of training reward. Parents received app notifications once a day reminding them to complete their training.

Intervention Type
Behavioural

Primary outcome measure

The following primary outcome measures were assessed using self-report scales at baseline (pre), post-intervention completion and 3 month follow-up:

For parents:
1. Stress was measured using the Depression Anxiety Stress Scale-21 (DASS-21)
2. General anxiety was measured using the General Anxiety Disorder-7 (GAD-7)
3. Depression measured using the Patient Health Questionnaire (PHQ-9)
4. Mindfulness was measured using the 14-item Mindful Attention Awareness Scale (MAAS)

For children:
1. Child depression was measured using the Children Depression Index by child (CDI-Child): 12-item self-report by child
2. Child depression was measured using the Children Depression Index by parent (CDI-Parent): 17-item report by parent

Secondary outcome measures

1. Emotional bias measured using a cognitive assessment at pre- and post-intervention
2. Interoceptive attention to breathing measured using an objective neurophysiological assessment at pre- and post-intervention

Overall study start date

01/02/2021

Completion date

13/08/2023

Eligibility

Key inclusion criteria

1. Children assessed in teh average and above-average range (T-score>40) on the Child Depression Index (CDI)
2. Parents were healthy and did not report any current diagnoses or medications

Participant type(s)

Healthy volunteer

Age group

Mixed

Lower age limit

5 Years

Upper age limit

54 Years

Sex

Both

Target number of participants

48

Total final enrolment

48

Key exclusion criteria

1. Self-reported severe illness for a parent or child that would not allow time for study participation

Date of first enrolment

19/07/2021

Date of final enrolment

17/03/2023

Locations

Countries of recruitment

United States of America

Study participating centre
University of California San Diego School of Medicine

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Sponsor information

Organisation

University of California, San Diego

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Sponsor type

University/education

Website

https://empathyandcompassion.ucsd.edu/

ROR
https://ror.org/0168r3w48

Funder(s)

Funder type
University/education

Funder Name
University of California, San Diego

Alternative Name(s)
UC San Diego, University of California San Diego, UCSD

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United States of America

Funder Name
NIH

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
12/01/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository, https://datadryad.org/. The type of data stored includes all data outcome variables collected and analysed for the study. The data will be freely available for download post-publication of the research. Consent was obtained from participants for de-identified data sharing. The data will be de-identified and do not have any personal health information for participants. The data are de-identified with no ethical or legal restrictions.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
[Participant information sheet](#)			09/10/2024	No	Yes