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Mindfulness skills training for children

Submission date
07/10/2026

Recruitment status
Recruiting

Registration date
12/10/2026

Overall study status
Ongoing

Last Edited
09/10/2026

Condition category
Mental and Behavioural Disorders

[X] 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
Mental health difficulties are becoming increasingly common among children, and many children experience delays in accessing support. Mindfulness could help children develop skills to manage stress, emotions and everyday challenges, but existing mindfulness programmes are not always engaging or suitable for younger children. Stix Mindfulness is a screen-free mindfulness programme delivered through handheld electronic devices that use sounds, vibrations and lights to guide children through mindfulness activities. The aim of this study is to examine whether Stix Mindfulness is acceptable to children and their families, whether children are willing to use it, and whether the study procedures are feasible for a future larger trial evaluating its effectiveness.

Who can participate?
Children aged between 8 and 10 years (at the point of consent) who need support for their mental health and wellbeing, but who are not currently receiving support from an NHS mental health professional or are on a waiting list to receive such support, will be invited to participate. Parents or caregivers of eligible children and relevant school staff may also take part in some aspects of the study, where relevant.

What does the study involve?
Each child will participate for around 13 weeks, including baseline assessment, a 6-week intervention or standard care period, and a further 6-week follow-up period.
Following parental consent and child assent, children will complete baseline questionnaires about their mental health, mindfulness skills, and sleep. Participants will then be randomly allocated to either receive Stix Mindfulness training (intervention group) or no intervention (standard care control group).
Children practicing the Stix Mindfulness training will receive a pair of Stix devices and will be encouraged to practice mindfulness activities at home for 6 weeks, for about 10 minutes a day, with support from parents or caregivers as needed. Children continuing with standard care will continue with their usual support, but will not receive the Stix Mindfulness training immediately - they will be offered the same 6 weeks Stix Mindfulness training after they finish being part of the control group for the study. All participants will complete follow-up assessments at 6 and 12 weeks after randomisation.
Parents/caregivers will be asked to provide information about the child’s behaviour, specifically their attention, hyperactivity, impulsivity as well as social skills, attention to details,

communication and imagination at study entry, and both parents/caregivers and teachers will be asked about the child's engagement at home and school at baseline, 6 and 12 weeks. Some children, parents/caregivers and school staff may be invited to participate in interviews, lasting about 1 hour, to share their experiences of the intervention and study procedures.

What are the possible benefits and risks of participating?
The training involves a range of fun activities to improve children's mindful awareness of their breath, body, feelings, and thoughts. The training is both fun to take part in, and participants may benefit from learning mindfulness skills that could help them manage everyday stress, improve emotional wellbeing, develop coping strategies, improve their personal relationships, and enhance their overall wellbeing. You may also feel intrigued and decide to further read into the topic of mindfulness and increase your knowledge base around this.
Stix has already been tested in children without any safety issue or risk at St Mary's CofE Primary School in Kent, Hewens Primary School in Hayes, as well as by Youth Resilience UK CIC. Some participants may find mindfulness activities or questions about their mental health upsetting. Participants can withdraw from the study at any time without giving a reason. If a child is identified as experiencing severe anxiety or depression during assessment, the research team will follow an agreed safeguarding pathway and inform appropriate services through procedures agreed with participating schools and the ethics committee.

Where is the study run from?
The study is sponsored and coordinated by Brunel University of London in collaboration with the University of Surrey, University of Birmingham, Health Innovation East, and NIHR ARC East of England, and will be conducted through participating schools in and around London. Assessments may take place at school or at home, according to participant preference.

When is the study starting and how long is it expected to run for?
October 2026 to August 2028

Who is funding the study?
The study is funded by the National Institute for Health and Care Research (NIHR209767) (UK)

Who is the main contact?
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Additional identifiers

National Institute for Health and Care Research (NIHR)
209767

Study information

Scientific Title
Supporting the mental health of children through stix innovation: a feasibility trial

Acronym
STIX

Study objectives
1. To determine feasibility of recruitment and willingness to be randomised to Stix (intervention) or standard care (control) condition
2. To estimate retention and follow-up rate, and acceptability of outcome data collection
3. To identify characteristics (sociodemographic and clinical) that may prevent children from being able to engage with a full-scale RCT
4. To determine user and parental acceptability of Stix, and the level of engagement with Stix training modules
5. To determine practicality of using Stix in a home setting (the level of parental/caregiver support that will be required)
6. To determine contamination rate in the control arm
7. To determine suitability of instruments to measure the effects of the intervention (outcomes) in a definitive trial

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/08/2026, College of Health, Medicine and Life Sciences Research Ethics Committee (Brunel University of London, Kingston Lane, Uxbridge, London, UB3 3PH, United Kingdom; +44 (0)1895 274 000; DLS-Ethics@brunel.ac.uk), ref: 39784-A-Jul/2026-55423-2

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Parallel

Purpose
Prevention

Study type(s)

Health condition(s) or problem(s) studied
Children’s mental health and wellbeing

Interventions
After receiving both parental consent and child assent, participants will be screened for anxiety and depression using the Revised Child Anxiety and Depression Scale-Short Version (RCADS-25). Those meeting the study inclusion and exclusion criteria will then be randomised on a 1:1 basis by a team member (who is not involved in study assessments) to receive Stix Mindfulness training (intervention group) or no intervention (standard care control group), stratified by participant’s sex.

Participants allocated to the intervention group will receive 6 weeks of Stix Mindfulness training using handheld, screen-free, electronic devices (Stix remotes) that deliver mindfulness exercises through audio, vibration and light-based feedback. Participants will be encouraged to practice at home for at least 10 minutes per day (approximately three activities daily) over the 6-week intervention period, with parental support as required (i.e., for charging devices etc).

Participants allocated to the standard care group will continue routine as usual, and will not receive 6 weeks of Stix Mindfulness training at the same time as the intervention group.

All participants will complete outcome assessments at baseline, 6 and 12 weeks, including questionnaires on anxiety, depression (RCADS-25), mindfulness (Mindful Attention Awareness Scale for Children), and a subjective sleep quality question. Parents/caregivers will be asked to provide information about the child’s behaviour, specifically their attention, hyperactivity, impulsivity (using the ADHD Rating Scale-IV: Home Version) as well as social skills, attention to

details, communication and imagination (using The Autism Spectrum Quotient – Child's Version) at study entry, and both parents/caregivers and teachers will be asked about the child's engagement at home and school at baseline, 6 and 12 weeks.

A subgroup of children, parents/caregivers and school staff may also take part in semi-structured interviews, lasting up to 1 hour, to explore the acceptability and feasibility of the Stix Mindfulness intervention and overall study procedures.

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment feasibility measured using the recruitment rate (% of eligible participants providing parental consent and child assent) at the end of the recruitment period

2. Intervention adherence measured using Stix usage data collected via the Stix application and device records at 6 weeks (T1)

3. Acceptability of the Stix Mindfulness intervention measured using the Stix acceptability questionnaire using a five-point Likert scale at 6 weeks (T1)

4. Participant retention rate measured using the proportion of participants completing all 6 weeks of activities and follow-up assessments at 12 weeks (T2)

Key secondary outcome(s)

Completion date
30/08/2028

Eligibility

Key inclusion criteria
Children aged between 8-10 years who:
1. Have mild-to-moderate anxiety and/or depression but are not receiving, or are currently on a waiting list for receiving help from mental health professional
2. Are able to provide assent, with parental/guardian consent

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 Years

Upper age limit
10 Years

Sex

All

Total final enrolment
0

Key exclusion criteria
1. Unable to hold the Stix device and therefore practice Stix Mindfulness training due to a physical disability and/or impairment
2. Participant has clinical levels of depression and/or anxiety, identified during the initial assessment through the relevant psychometric test, due to wellbeing concerns and immediate need for clinical interventions

Date of first enrolment
16/10/2026

Date of final enrolment
30/11/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Brunel University London
Kingston Lane
Uxbridge
England
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Sponsor information

Organisation
Brunel University of London

ROR
https://ror.org/00dn4t376

Funder(s)

Funder type

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in publicly available repositories (brunel.figshare.com). Only de-identified (without participants' names and any other personal information) quantitative data will be stored in publicly available repositories. The quantitative data will be available within 4 months of the end of the study and will be preserved for the long term. Qualitative data will not be stored in repositories due to the potential of compromising confidentiality. Consents from participants will be sought for storing the de-identified data collected in this study in the repositories. Only the data that will have participants' consent will be stored in the repositories.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website			09/10/2026	No	No