ISRCTN11686798 https://doi.org/10.1186/ISRCTN11686798

AI-based mobile apps for supporting adolescents' mental health in schools

Submission date 06/10/2025	**Recruitment status** Recruiting	[X] Prospectively registered
		[X] Protocol
Registration date 06/10/2025	**Overall study status** Ongoing	[ ] Statistical analysis plan
		[ ] Results
Last Edited 13/11/2025	**Condition category** Mental and Behavioural Disorders	[ ] Individual participant data
		[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Children and young people (CYP) are more likely to experience mental health problems because their emotions, behaviour, and thinking abilities are still developing. In 2024, 1 in 4 young people in the United Kingdom said they were struggling with their mental health. It is essential to intervene early to prevent more significant issues as young people mature. Schools could help to improve young people's mental health, but often do not have the right tools. Since most young people use smartphones daily, mobile apps could be a valuable tool to support their mental health. To address this problem, doctors and engineers at Imperial College London have developed a mobile app called MindCraft, in collaboration with young people (Figure 1). This app uses both young people's ratings collected through the app and data from their phones to track their feelings and behaviour in real-time. The app will use "artificial intelligence", a technology that simulates how humans think and make decisions to learn how young people's feelings and behaviours change over time. This information can also be used to create personalised tips (in the form of phone notifications) to help young people when they need it.

The goal of this study is to learn if personalised AI-based recommendations ("nudges") delivered through the MindCraft mobile app can improve mental health in adolescents in schools. The main question it aims to answer is: "Do personalised AI nudges improve mental health outcomes compared to generic advice or self-monitoring alone?". We will compare three groups to see if AI nudges have a greater effect than generic advice or self-monitoring.

Who can participate?

Participants are children and you people attending years 10 to 13 (aged 14-19 years) at a school in the United Kingdom.

What does the study involve?

Participants will complete a mental health questionnaire and use the MindCraft app daily for one month by recording their mood and behaviour. After one month, they will complete the same mental health questionnaire.

What are the possible benefits and risks of participating?

We hope participants will find the app helpful and enjoy learning how to support their own

mental health. This study will help us to understand how to improve the mental health of other young people with our app. Participants will either receive a voucher at the end of the study as a token of appreciation for their participation, or the schools will receive funds to support activities that promote students' wellbeing and learning.

It is possible that participants might find answering questions about their mental health difficult or upsetting. In that case, the research team will signpost participants to external sources of support, which will include those listed in the Help section of the MindCraft app.

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
August 2024 to October 2027.

Who is funding the study?
Imperial College London (UK)

Who is the main contact?
The main contact for the study is Aglaia Freccero, the PhD student leading the study. Email: aglaia.freccero21@imperial.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Dasha Nicholls

ORCID ID
https://orcid.org/0000-0001-7257-6605

Contact details
Division of Psychiatry, Department of Brain Sciences
Imperial College London
Imperial College London Hammersmith Campus
2nd Floor Commonwealth Building
Du Cane Road
London
United Kingdom
W12 0NN
+44 7971847044
d.nicholls@imperial.ac.uk

Type(s)
Public, Scientific

Contact name
Miss Aglaia Freccero

ORCID ID

https://orcid.org/0009-0002-2072-9838

Contact details
Division of Psychiatry, Department of Brain Sciences
Imperial College London
Imperial College London Hammersmith Campus
2nd Floor Commonwealth Building
Du Cane Road
London
United Kingdom
W12 0NN
+44 7551893250
aglaia.freccero21@imperial.ac.uk

Additional identifiers

Protocol serial number
7134492

Integrated Research Application System (IRAS)
349171

Central Portfolio Management System (CPMS)
64670

Study information

Scientific Title
Artificial intelligence-informed mobile behavioural interventions to support adolescents' mental health in schools

Study objectives
Study Aim: to examine the effectiveness of personalised AI-based recommendations ("nudges") on mental health outcomes in children and young people (CYP) within schools across the United Kingdom.

Primary objective: To examine the effectiveness of personalised AI nudges (experimental intervention) vs non-personalised digital self-help using generic CBT principles (active control) vs self-monitoring control on reducing CYP Strengths and Difficulties Questionnaire (SDQ) scores (primary outcome) at 1-month follow-up

Secondary objectives:
1. To examine the effectiveness of personalised AI nudges vs non-personalised digital self-help using generic CBT principles vs self-monitoring control on secondary outcomes [Eating Disorder Diagnostic Scale (EDDS); Sleep Condition Indicator Questionnaire (SCI); Self-Injurious Thoughts and Behaviours Interview (SITBI); Self-Efficacy Questionnaire for Children (SEQ-C); World Health Organisation-Five Well-Being Index (WHO-5)] at 1-month follow-up
2. To examine the efficacy of personalised AI nudges on improving mental health in CYP in a low-

risk group (primary prevention) and reduce poor mental health in a high-risk group (secondary prevention) at 1-month follow-up
3. To explore potential mediators and moderators of effects of AI nudges

Hypothesis: AI nudges will be more effective than non-personalised digital self-help using generic CBT principles (active control group) and self-monitoring control at reducing CYP SDQ scores at 1-month follow-up

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 28/09/2025, Imperial College Research Ethics Committee (White City Campus, Level 1 The Media Works, 191 Wood Lane, London, W12 7FP, United Kingdom; +44 (0)20 7594 9456; rgitcoordinator@imperial.ac.uk), ref: 7134492

Study design
Multicentre interventional double-blinded randomized parallel-group trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Primary and secondary prevention of mental disorders in children and young people.

Interventions
The study is a 3-arm RCT. Participants are individually randomised into one of three arms:
1. Active experimental: Receipt of personalised AI nudges + self-monitoring
2. Active control: Generic recommendations + self-monitoring
3. Control: Self-monitoring through the MindCraft app only

Participants use a mental health app (MindCraft) for 4 weeks and are followed up at 1 month.

Randomisation will be undertaken using a computer-based randomisation tool designed for clinical trials and will be independent of the lead researcher. Participants in the intervention and active control groups, as well as the outcome assessor, will be blinded to the intervention allocation.

Intervention Type
Behavioural

Primary outcome(s)
Total difficulties score measured using the Strengths and Difficulties Questionnaire (SDQ) at baseline and 4 weeks.

Key secondary outcome(s))
1. Externalising score measured using the SDQ at baseline and 4 weeks.
2. Internalising score measured using the SDQ at baseline and 4 weeks.

3. Emotional symptoms score measured using the SDQ at baseline and 4 weeks.
4. Conduct problems score measured using the SDQ at baseline and 4 weeks.
5. Hyperactivity/inattention score measured using the SDQ at baseline and 4 weeks.
6. Peer relationship problems measured using the SDQ at baseline and 4 weeks.
7. Prosocial behaviour score measured using the SDQ at baseline and 4 weeks.
8. Eating Disorder Diagnostic Scale (EDDS) scores measured using the EDDS at baseline and 4 weeks.
9. Total score measured using the Sleep Condition Indicator Questionnaire (SCI) at baseline and 4 weeks.
10. Non-suicidal self-injury score measured using the Self-Injurious Thoughts and Behaviours Interview (SITBI, NSSI section) at baseline and 4 weeks.
11. Well-being total score measured using the World Health Organisation-Five Well-Being Index (WHO-5) at baseline and 4 weeks.
12. Total self-efficacy score measured using the Self-Efficacy Questionnaire for Children (SEQ-C) at baseline and 4 weeks.
13. Academic self-efficacy score measured using the Academic Self-Efficacy scale of the SEQ-C at baseline and 4 weeks.
14. Social self-efficacy score measured using the Social Self-Efficacy scale of the SEQ-C at baseline and 4 weeks.
15. Emotional self-efficacy score measured using the Emotional Self-Efficacy scale of the SEQ-C at baseline and 4 weeks.
16. App engagement (active tracker completion, passive tracker enablement, usage frequency, and nudges completed) measured using in-app analytics from baseline through week 4.
17. Self-reported well-being (mood, sleep quality, motivation, anxiety, loneliness, and appetite) measured using app active tracker Likert scales (1–7) from baseline through week 4.
18. Sleep quantity and exercise duration measured as average hours of sleep and minutes of exercise reported per day on app from baseline through week 4.
19. Participant attrition measured as the number and percentage of participants who withdraw or are lost to follow-up, categorised by reason, from baseline through week 4.

Completion date
29/10/2027

Eligibility

Key inclusion criteria
1. Young people in School Years 10 to 13 (aged 14–19 years) attending any school in the United Kingdom that has been approached.
2. Sufficient English to allow completion of experimental measures and use of the app.
3. Access to an iOS or Android-compatible smartphone with an embedded activity monitor.
4. Have the capacity to consent (if over 16 years old).
5. Have the capacity to assent and seek consent from parents/guardians (if under 16 years old).

Participant type(s)
Population

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit

14 years

Upper age limit

19 years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Severe learning difficulties
2. Organic brain disease
3. Severe neurological impairment that prevents independent use of smartphone app

Date of first enrolment

15/10/2025

Date of final enrolment

29/09/2027

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Imperial College London

Division of Psychiatry, Department of Brain Sciences
Imperial College London Hammersmith Campus
2nd Floor Commonwealth Building
Du Cane Road
London
England
W12 0NN

Sponsor information

Organisation

Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
University/education

Funder Name
Imperial College London

Alternative Name(s)
Imperial College of Science, Technology and Medicine, Imperial College London, UK, Imperial College London, London, England, Imperial College London in United Kingdom, imperialcollege, ICL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
All non-identifiable data will be shared. This includes self-reported mental health and well-being measures, mobile app usage data, and demographic information from participants. No directly identifiable data will be included in the research databases. Participants' data will be pseudo-anonymised. Each participant will be assigned a unique study ID, which will be used to link baseline, follow-up, and app-based data. A separate password-protected document linking participant identity to study ID will be stored securely on Imperial College London's network drive, accessible only to authorised members of the research team. Questionnaire data will be collected using Qualtrics and securely transferred to Imperial College London's servers, which are protected within an ISO 27001–compliant data centre. Data backups are encrypted and retained for a minimum of 1 year. After completion of the study, all identifiable information (e.g. consent forms) will be stored securely for 10 years in accordance with Imperial College London's data retention policy. Anonymised data will be made available for secondary analysis following publication of the main results, approximately 12 months post-publication. The anonymised dataset and accompanying metadata will be deposited on Open Science Framework (OSF) on https://osf.io/qb8f9/. Requests for additional or early access should be directed to the Study Lead (Aglaia Freccero, mindcraft@imperial.ac.uk). Participants (and parents/guardians where applicable) provide informed consent or assent prior to participation, including agreement for

anonymised data to be shared for future research. The study complies with the UK Data Protection Act and General Data Protection Regulation (GDPR). Ethical approval has been obtained from the Imperial College London Research Ethics Committee (ICREC ID 7134492). There are no anticipated legal restrictions beyond standard data protection requirements.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	22/09/2025	06/10/2025	No	No