IMPERIAL

Study Protocol: MindCraft in Schools

Artificial Intelligence-informed mobile behavioural interventions to support adolescents' mental health in schools

Study Management Group

Chief Investigator: Prof Dasha Nicholls
Co-investigators: Aglaia Freccero, Dr Martina Di Simplicio, Dr Lindsay Dewa, Dr Balasundaram Kadirvelu, Prof Aldo Faisal
Statistician: Jack Elkes
Study Management: Aglaia Freccero

IREC reference: 7134492

Sponsor

Imperial College London is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact the Head of Regulatory Compliance at:

Research Governance and Integrity Team
Imperial College London and Imperial College Healthcare NHS Trust
Room 215, Level 2, Medical School Building
Norfolk Place
London, W2 1PG
Tel: **0207 594 9480**
Imperial College - Research Governance and Integrity Team (RGIT) Website

Funder

Imperial College London

This protocol describes the "MindCraft in Schools" study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the UK Policy Framework for Health and Social Care Research. It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

IMPERIAL

Table of Contents

1. INTRODUCTION

1.1. BACKGROUND

Children and Young People's Mental Health

Children and young people (CYP) are highly susceptible to mental disorders due to developmental changes in emotion, behaviour and cognition, with over 75% of mental disorders emerging before age 25 (Kessler et al., 2005). The worldwide prevalence of mental disorders in CYP is estimated to be 13.4%, and anxiety, depression, and eating and sleep disorders are prevalent issues among CYP globally (Polanczyk et al., 2015; GBD 2019, 2022). In the United Kingdom (UK), one in four CYPs is estimated to have a probable mental disorder (NHS Digital, 2023). However, more than 70% of CYPs with mental health problems do not receive treatment (Henderson et al., 2013). The increased burden on the NHS and the commitments made in the NHS Long Term Plan (NHS, 2019) demand access to cost-effective and evidence-based methods to provide mental health support to CYP at scale.

Mobile Mental Health Apps and Artificial Intelligence

With the widespread use of smartphones among CYP (Ofcom, 2022), digital health interventions are an attractive, cost-effective, and scalable solution for mental health prevention and early intervention in CYPs. In the last ten years, there has been a surge in the usage of mental health apps (Larsen et al., 2019). There are now over 20,000 mental health apps available on the App Store/Android equivalent. Systematic reviews and meta-analyses provide evidence of the positive impact of mental health apps on mental health outcomes (Dubaud et al., 2018; Lecomte et al., 2020; Linardon et al., 2024), and qualitative studies show that CYP think mental health apps are acceptable (Dewa et al., 2019). However, most mental health apps are not empirically validated, lack long-term engagement and do not involve CYP in their development, remaining insufficiently tailored to their needs.

There is a significant relationship between lifestyle factors such as exercise, diet and sleep and mental disorders (Firth et al., 2020). Active and passive sensing have become common in digital monitoring technologies for mental health. Active sensors can collect subjective data through repeated self-reports of emotions and behaviours (active data), while passive sensors collect objective data by detecting changes in the physical environment without user participation (passive data), including GPS, accelerometer, microphone and battery usage. Active and passive data represent digital behavioural markers as they can be used to model individuals' mental health states in their contextual and temporal dimensions (Oudin et al., 2023). Based on this data, Ecological Momentary Interventions (EMI) can deliver personalised behaviour change support in real-time and in natural settings (Balaskas et al., 2021). A subset of EMIs, just-in-time adaptive interventions (JITAD), can be delivered in the moment and tailored in terms of time of delivery.

Artificial Intelligence (AI) and Machine Learning (ML) present new opportunities for real-time interventions. A systematic review of 17 studies examined the feasibility of using AI-enabled mobile solutions using active and passive data to support mental health (Milne-Ives et al., 2022). Across the 17 studies, the most common use of AI was to predict mental health outcomes, provide natural language support, and develop risk profiles. Only 2 studies used AI/ML to deploy context-sensitive notifications (Morrison et al., 2017) and CBT-based JITADs (Wahle et al., 2016). All studies were conducted in adults, with small sample sizes and short intervention durations. None of these studies was carried out in the UK. Only 3 studies were RCTs, and they had small sample sizes. Overall, AI/ML can be integrated into mental health apps, but the lack of evidence and weaknesses in study designs highlight the need for high-quality RCTs to demonstrate the effectiveness of AI-based apps in improving mental health.

MindCraft

MindCraft is an AI-based mental health app that combines active and passive tracking to monitor CYP's emotions and behaviour while encouraging user participation with a modern and appealing user interface (Kadirvelu et al., 2023). It is available for both IOS and Android. We conducted a pilot study of MindCraft that aimed to investigate the feasibility of using ML modelling to predict the risk of mental health problems in a non-clinical population of adolescent school children (PI: Dasha Nicholls; ICREC Reference number: 20IC6132) (Kadirvelu et al., 2025 JMIR preprint). These yet-unpublished findings support the use of ML to analyse combined datasets for early detection of mental health problems among CYP.

A new version of the MindCraft app has been developed in collaboration with CYP. This version features an AI-reinforced learning-based recommendation system designed to promote behavioural change and enhance CYP mental health. This system dynamically detects early signs of changes in mental health states from active and passive data collected through the app and responds by delivering personalised, instantaneous AI-informed recommendations (“nudges”) (Figure 1). Intervention outcomes are measured in real-time and fed back to generate novel, individually tailored candidate nudges. This technology learns specific CYPs’ emotional and behavioural profiles and contexts and recognises by “trial-and-error” successful from non-successful interventions.

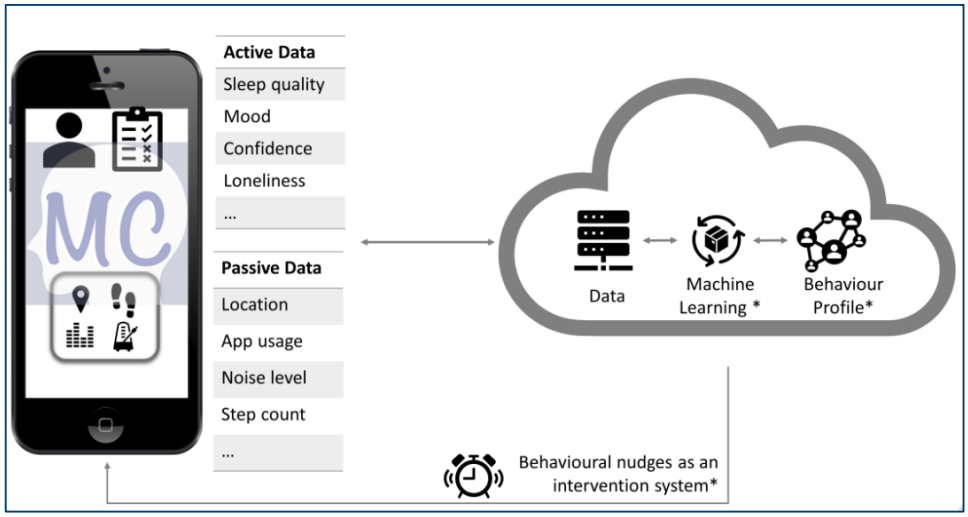

Figure 1. Reinforcement learning-based recommendation system.

1.2. RATIONALE FOR CURRENT STUDY

Internalising and externalising are two broad categories of behavioural problems, which in adolescence are associated with an increased likelihood of developing a psychiatric disorder later in adulthood (Copeland et al., 2009). While internalising problem behaviour is focused on the own self (e.g. withdrawal, anxiety, depression, emotional problems), externalising problem behaviour particularly occurs in interaction with the social environment (e.g. aggression, impulsivity, deviance, hyperactivity). School-based research suggests that the school environment plays a critical role in shaping students' behaviour and has a significant impact on CYP's health (Bonell et al., 2013). This makes schools well-placed to identify and address multiple determinants of mental health risk at the individual and community levels.

School-based interventions may be central to the early intervention and prevention of mental health problems in CYP. A recent meta-analysis showed a small positive effect of brief school-based interventions on mental health outcomes for up to one month, six months and one year (Cohen et al., 2025). In particular, digital mental health intervention programs offered in schools could present a readily accessible and flexible means for educating, empowering, and supporting adolescents in maintaining good mental health (Pandey et al., 2018). The integration of AI/ML offers the opportunity for individually tailored intervention. However, there is a lack of research on the efficacy of digital interventions, particularly those informed by AI/ML, on mental health outcomes in community CYP.

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

Research Question: Can AI nudges delivered through a mobile app improve CYP mental health in schools?

2. STUDY OBJECTIVES

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 Difficulty Questionnaire (SDQ) scores (primary outcome) at 1-month follow-up

Secondary objectives:

- 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
- 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
- To explore potential mediators and moderators of beneficial 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

3. STUDY DESIGN

3.1 Study Design and Timeline

The study will be conducted and reported according to Consolidated Standards of Reporting Trials (CONSORT) and CONSORT-EHEALTH for improving and standardising evaluation reports for mobile interventions (Eysenback, 2011). The trial will be registered on ClinicalTrials.gov (www.clinicaltrials.org).

The trial design is a 3-arm randomised controlled trial (RCT) conducted using a prospective cohort. Our study has been divided into an internal pilot phase and a main trial phase (Figure 2). We have conducted an internal pilot from October to May 2025 to test the quality of the trial design and the conduct of the study in relation to recruitment, adherence, outcome assessment, sample size and follow-up. Interim analyses were conducted to calculate the sample size needed for the main trial. We will also integrate any changes and release an improved version of the MindCraft app (e.g. correct bugs, upgrade systems and user interface). The duration of the main trial study will be roughly 8 months from recruitment to the end of data collection.

	2024			2025						2026					
	July - Aug	Sept - Oct	Nov - Dec	Jan - Feb	March - April	May - June	July - Aug	Sep - Oct	Nov - Dec	Jan - Feb	March - April	May - June	July - Aug	Sept - Oct	Nov - Dec
Ethics application															
Ethics approval															
Internal Pilot															
Recruitment															
Data Collection															
Data Analysis															
Main Trial															
Recruitment															
Data Collection															
Data Analysis															

Figure 2. Gantt chart of the study.

In the main trial, all participants will join a prospective longitudinal cohort. Once trial eligibility has been determined and informed written consent to participate in the trial has been obtained, participants will be individually randomised (initially in a 1:1:1 ratio) into one of three arms:

1) Active experimental: Receipt of personalised AI-based recommendations within the MindCraft app in addition to self-monitoring
2) Active control: Generic psychoeducation recommendations using CBT principles within the app and self-monitoring through the app
3) Control: Access to self-monitoring through the app only

Given the rate of technological advancements of behavioural interventions, we will adopt the Trial of Intervention Principles methodology (Mohr et al., 2015), which focuses on the evaluation of intervention principles rather than a locked-down version of the intervention. This approach allows for ongoing quality improvement modifications to the behavioural intervention technology based on the underlying behavioural strategy while continuously improving the functionality of the technology without compromising trial integrity.

3.2 Randomisation, Intervention Delivery and Masking

Participants will be randomised (in a 1:1:1 ratio) to the three intervention arms and will be instructed to record data every day for four weeks. Stratification will be accounted for by considering SDQ scores to ensure balanced distribution of baseline characteristics.

Randomisation will be undertaken using a computer-based randomisation tool or software platform designed for clinical trials (such as https://www.sealedenvelope.com), ensuring unbiased allocation of participants across the three arms. Randomisation will be independent of the lead researcher.

Participants in the intervention and active control groups and the outcome assessor will be blind to intervention allocation.

3.3 Intervention

Frontend design

The MindCraft app is designed with a modular and adaptable framework to facilitate future improvements, support different study questions and provide customisation options to meet individuals' needs and favour engagement (Kadirvelu et al., 2023). The MindCraft app is not classed as a medical device and is not CE-marked. The MindCraft app will be used as a research tool only, and we do not intend to commercialise the app in the future. The key modular components include:

1. Customisable active questions: MindCraft allows users to select daily active questions tailored to their unique mental health objectives. Participants are free to select among 8 required and 11 optional trackers.

2. Configurable passive data: users can choose which passive data they wish to share, ensuring that they have control over their privacy. The passive trackers include phone and app usage, battery level, location (collected when there is a significant change in the user's location), steps, background noise (collected only when the app is in the foreground) and ambient lighting.

Users can set their active and passive data sharing preferences during the initial onboarding process and can also modify them at any time through the app's settings. MindCraft app is available for free download from the Apple Store and Google Play Store. A valid study ID code is required to use the app (Figure 3). The MindCraft app comprises 3 main tabs in its User Interface: the main tab, the progress tab, and the settings tab (Figure 4)

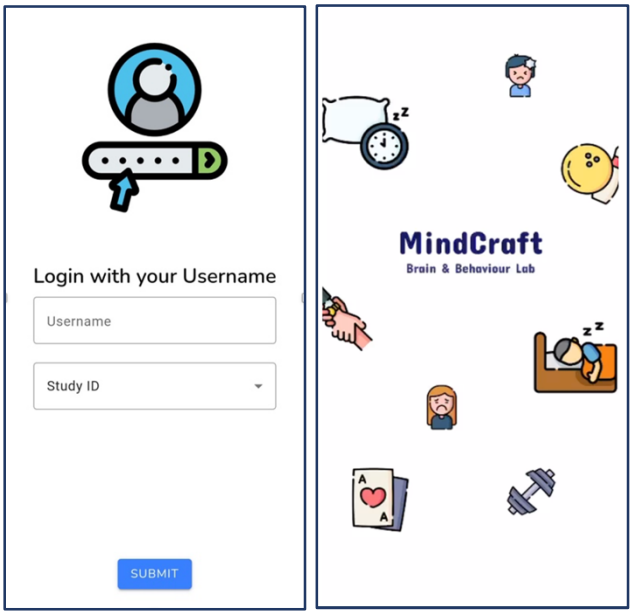

Figure 3. Login screen.

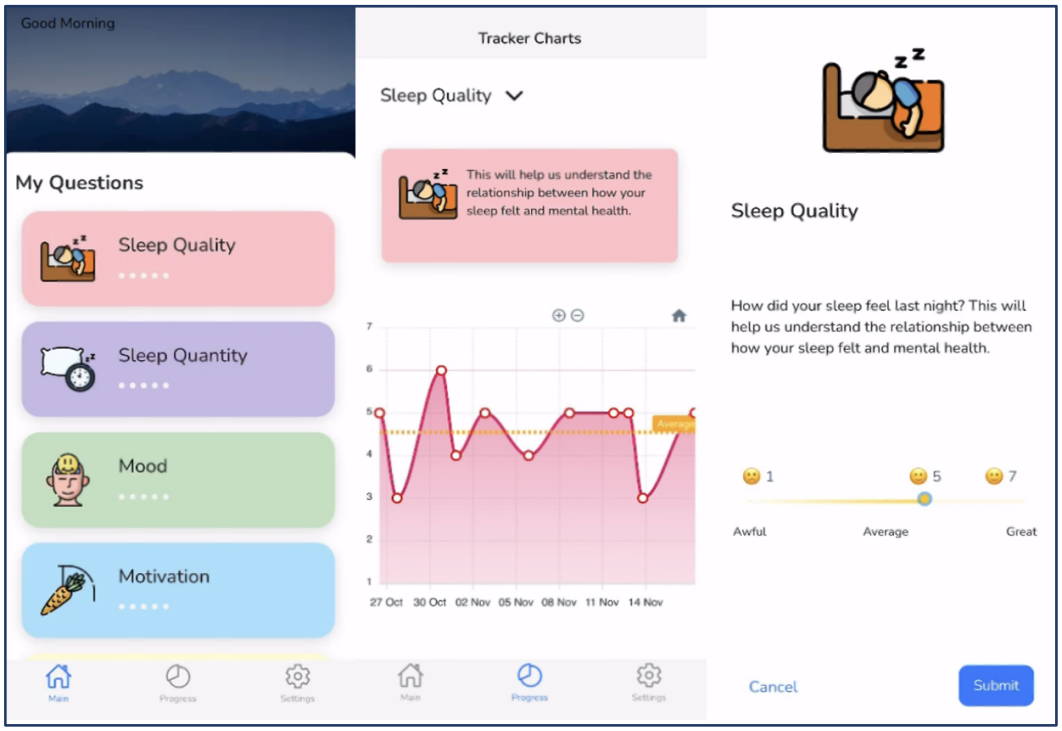

Figure 4. Main Tab and Progress Tab.

- Main tab (Figure 4): The app incorporates visual representations of users' mood and mental well-being markers, which have been shown to increase engagement. The main tab is the first view of the app when launched by a registered user. Here, the user can self-report a questionnaire related to their mood and well-being. The questionnaire contains 8 required questions (sleep quality, sleep quantity, mood, motivation, anxiety, loneliness, appetite, and

exercise), as well as 11 additional questions (racing thoughts, negative thinking, hopefulness, headaches, irritability, confidence, sociability, energy levels, productivity, self-care, leisure, and a custom metric called “your measure”). The user can manage the optional questions through the settings tab. Each question can only be answered once a day; thus, the question will disappear after each submission. Most of the self-reported questions (such as mood and sleep quality) are on a scale of 1-7 and contain a slider. Other questions (such as sleep quantity and exercise time) collect numerical data from text boxes, and the input is type-checked to ensure only valid inputs are stored (e.g., numerical numbers and not text).

- Progress tab (Figure 4): The progress tab charts the self-reported updates given by the user throughout the study. Selecting the data of interest causes the graph view to display the historical data and the average score for the selected period.

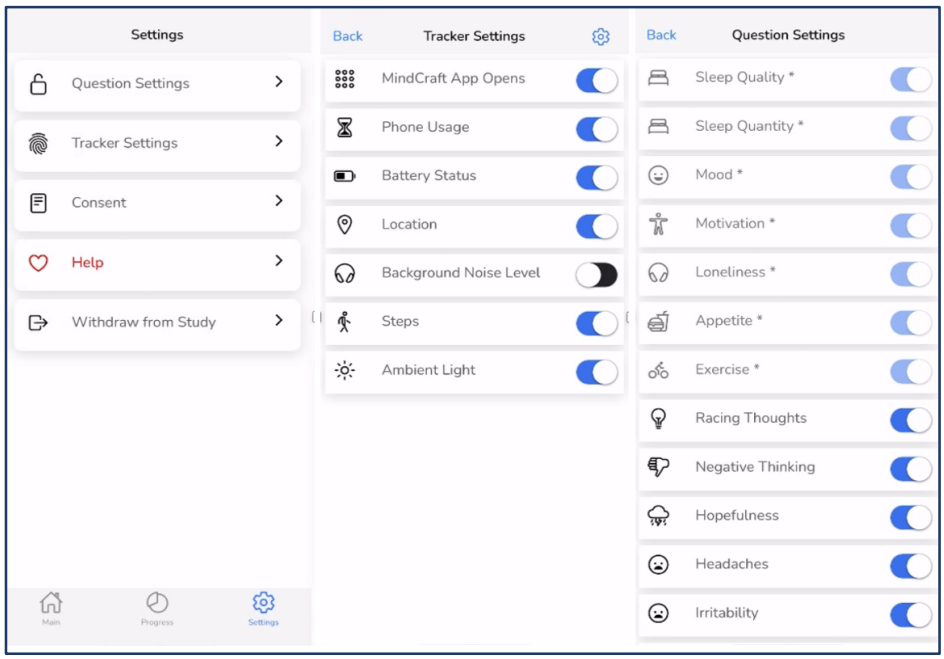

Figure 5. Settings Tab.

- Settings tab (Figure 5): In the settings tab, the user can manage the active and passive data settings, read the privacy policy, and withdraw from the study. The app allows the user to enable or disable the optional active data questions that are most relevant to them. The “Help” option under the Settings tab allows users to seek support when needed. To facilitate this, MindCraft lists four external organisations: Shout, YoungMinds, Best For You NHS, and Kooth - along with a brief description of each organisation and links to their websites.

Personalised digital AI-based recommendations (experimental intervention group)
The experimental arm will deliver personalised behavioural recommendations (AI nudges) via the MindCraft mobile app (Figure 6). This reinforcement learning

recommendation system (Figure 1) personalises and dynamically delivers digital AI nudges based on user mental health states (as measured by active and passive trackers) and ratings of the nudges to improve mental health and well-being.

For example, participants self-reporting low mood and/or low step count might be nudged to “take a walk outside”. Then, if participants rate this nudge positively, they will be provided with similar recommendations in the future. However, if they rate the nudge negatively because, for example, they do not like walking (and maybe prefer different forms of exercise), they will receive different future nudges, such as “do some light stretching”.

Non-personalised digital self-help using generic CBT principles (active control group)
The active control will be non-personalised digital self-help recommendations based on generic principles derived from cognitive behavioural therapy (CBT) (general nudges). These will include tips, advice, strategies and psychoeducation on behavioural activation. Recommendations will be delivered via the MindCraft app, using the same format as the personalised AI recommendations, to make the interventions appear similar.

Self-monitoring only (control group)
The control will consist of self-monitoring through the MindCraft app and usual practice. Self-monitoring will include daily ratings and charts of active trackers. Usual practice, as received by the young person outside the trial, may include no provision of intervention, local provision of intervention, support from a GP, local health services or youth services, or provision of intervention within the school.

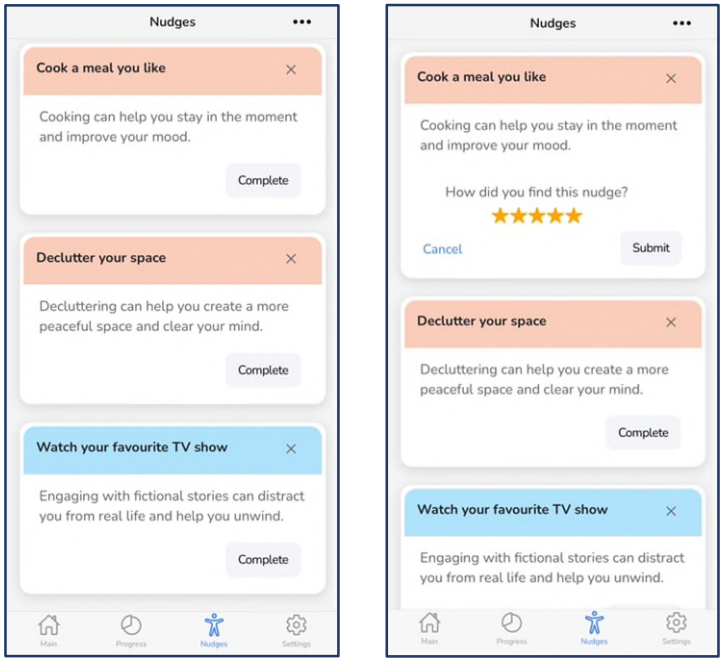

Figure 6. Examples of nudges.

Researchers can also access an administrator dashboard (Figure 7) to track the usage of the app by the participants. The dashboard allows the researchers to easily

track the engagement of users and oversee the general performance of the algorithm via the star rating feedback for the nudges.

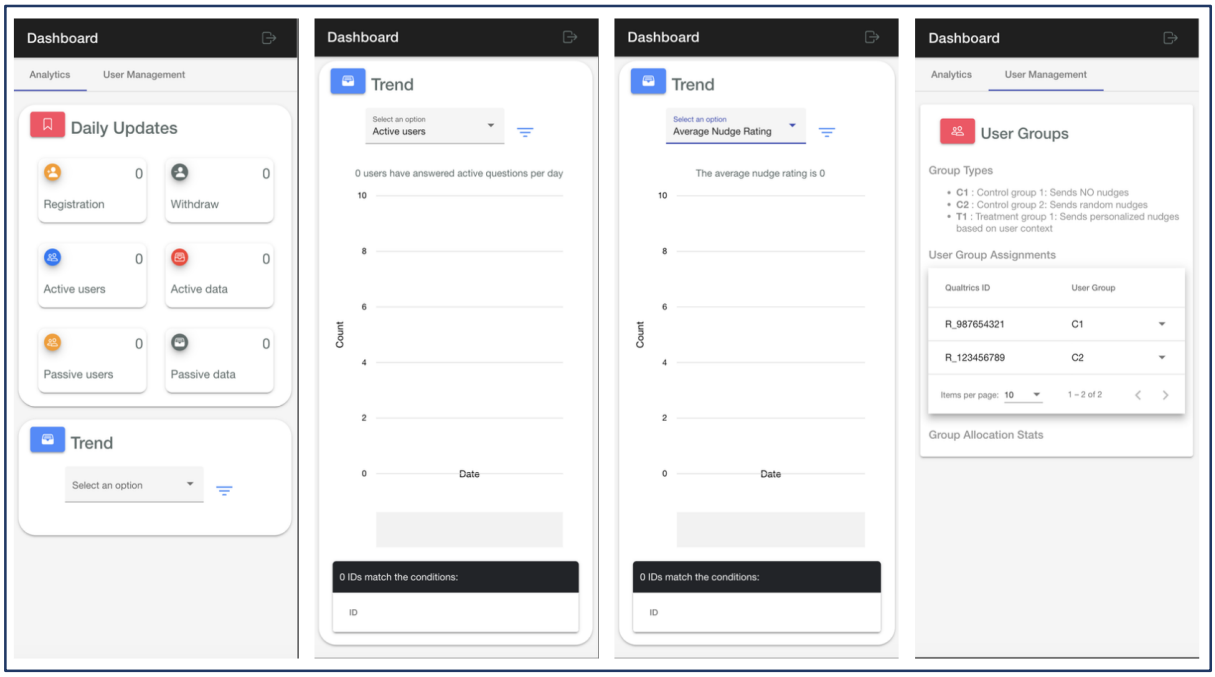

Figure 7. Administrator dashboard.

3.4 Recruitment and Study Setting

We will recruit CYP in years 10 to 13 (age 14-19) attending schools in the United Kingdom. We aim to recruit around 5-10 schools, depending on how many students they accommodate. The research team will reach out to schools via email to the school principal/school staff and send information about the study. The research team will offer schools the option to learn more about the research and participate in educational activities related to mental health and digital interventions as part of the mandatory Social and Emotional Aspects of Learning (SEAL) framework.

3.5 Screening and Consent Procedures

Potential participants will be informed about the study by their school. If data collection is carried out remotely, teachers will distribute information about the study via email to students and parents/guardians. Teachers will also send students a link to a Consent to Contact online form, where they will be asked to include their contact details and those of parents/guardians. On first contact with the students, the lead researcher (Aglaia Freccero) will email the full Participant Information Sheet and Consent/Assent Form to the students. Students over 16 will sign the Consent Form and email it back to the researcher. For any young person under 16, we will obtain informed parental consent by using opt-out consent (see Consent). The researcher

will send the Opt-out Consent Form to parents/guardians. Parents/guardians will sign and email back the Opt-out Consent Form to the researcher if they do not wish their child to participate. Parents will have at least two weeks to complete the opt-out form before any data is collected from children. Participants under 16 years old will also be required to provide written assent by signing the Assent Form and emailing it back to the researcher.

Alternatively, if the school prefers to carry out data collection in person on school premises, teachers will circulate the Participant Information Sheet to students and Parent/Guardian Information Sheet and Opt-out Consent Form for parents/guardians via email at least two weeks before the day of data collection. Students over 16 years old will provide informed consent electronically via Qualtrics on the day of data collection. They will also be asked to include their contact details and those of their parents/guardians. For participants under 16 years old, consent from a parent/guardian will be required for participation. Parents/guardians will sign and email back the Opt-out Consent Form to the researcher if they do not wish their child to participate. Parents will have at least two weeks to complete the opt-out form before any data is collected from children on school premises. Participants under 16 years old will provide written assent online via Qualtrics on the day of data collection.

Participants will be followed up at 1 month. If data collection is carried out remotely, baseline and follow-up measures will be collected via an online Qualtrics questionnaire sent to the participant's email. If data collection is carried out in person, participants will complete the baseline (and follow-up) questionnaires through a Qualtrics link (separate from the Consent Form) on their mobile phones.

Completion of the baseline and outcome assessments should take a maximum of 30 minutes. No identifiable information will be collected. Participants will be assigned a unique participant ID, which they will use to complete the baseline and follow-up assessments and sign in to the study app (see Data Management section). Based on their ID, participants will be randomised to different versions of the MindCraft app (see Randomisation).

Reimbursement will be provided upon completion of the study, with the mode of reimbursement determined by each participating school. Schools may choose to distribute vouchers to students or receive the funds centrally to support research- and mental health–related activities, such as travel for workshops at Imperial.

3.6 Baseline and Follow-Up Assessments

The baseline assessment consists of web-based self-reported validated mental health measures and demographic information (see Outcomes):

- Screening Measures: Mood Disorder Questionnaire (MDQ); Screening to Brief Intervention (S2BI). MDQ and S2BI questionnaires will be used to characterise the sample.
- Primary Outcomes: Strengths and Difficulties Questionnaire (SDQ)

- Secondary Outcomes: Eating Disorders 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)
- Demographics: age, gender, sexual orientation, ethnicity, education level, socioeconomic status, location (school)
- Presence of learning difficulties, organic brain disease, or severe neurological impairment that prevents independent use of smartphone app (yes/no)

3.7 Outcome Measures

Screening measures

- The Mood Disorder Questionnaire (MDQ) (Hirschfeld et al., 2000) is a screening instrument for bipolar disorder. The MDQ includes 13 questions plus items assessing symptoms and functional impairment. A total score is calculated where a “Yes” provides a score of 1 and “No” is 0. To meet the threshold for bipolar disorder, respondents need to have a score of 7 or more for questions 1-13, “yes” for symptoms clustered in the same time period and symptoms causing either “moderate” or “serious”.

- The Screening to Brief Intervention (S2BI) is a brief screening tool developed by the National Institute on Drug Abuse (NIDA) to assess for substance use disorder risk among adolescents 12-17 years old (NIDA, 2019). S2BI ask respondents about the frequency of past-year use of tobacco, alcohol, marijuana, unprescribed prescription drugs, illegal drugs, inhalants and herbs/synthetic drugs. According to their responses (“Never”, “Once or twice”, “Monthly”, “Weekly or more”), this tool triages respondents into one of three levels of substance use disorder risk: no reported use, lower risk and higher risk. The questionnaire has been validated in adolescent samples (Kelly et al., 2014).

Primary outcome measures

- The Strengths and Difficulties Questionnaire (SDQ) (Goodman et al., 1998) is a brief behavioural screening questionnaire used in 2-17-year-olds. It consists of 25 items divided between 5 scales: emotional symptoms (5 items), conduct problems (5 items), hyperactivity/inattention (5 items), peer relationship problems (5 items), and prosocial behaviour (5 items). The first 20 items are added together to generate a total difficulties score. In low-risk or general population samples, an alternative three-subscale version of the SDQ can be used, divided into 'internalising problems' (emotional + peer symptoms, 10 items), 'externalising problems' (conduct + hyperactivity symptoms, 10 items) and the prosocial scale (5 items).

Secondary outcome measures

- The Eating Disorder Diagnostic Scale (EDDS) (Stice et al., 2000) is a 22-item self-report tool designed for individuals aged 13 to 65 that simultaneously assesses diagnostic symptoms of anorexia nervosa, bulimia nervosa, and binge-eating disorder by asking about body image, eating patterns, and compensatory behaviours over the past 3 to 6 months. Items use a combination of Likert, yes-no, frequency, and write-in response formats.

- The Sleep Condition Indicator Questionnaire (SCI) (Espie et al., 2014) is an 8-item rating scale measuring sleep problems. The eight items consist of a general question on the period of time the individual has had sleep problems. These items are rated on a scale from 0 to 4; 4 being the best (e.g., no problem/less minutes to fall asleep/very good sleep quality) and 0 being the worst (e.g. >1 year sleep problems/more than an hour to fall asleep/very poor sleep quality).

- The Self-Injurious Thoughts and Behaviours Interview (SITBI) (Nock et al., 2007) is a structured interview that assesses the presence, frequency, and characteristics of a wide range of self-injurious thoughts and behaviours, including suicidal ideation, suicide plans, suicide gestures, suicide attempts, and non-suicidal self-injury (NSSI). Only the NSSI section of the interview will be used, modifying the term NSSI to “self-harm” to include all self-harm behaviour regardless of intent.

- The Self-Efficacy Questionnaire for Children (SEQ-C) (Muris, 2001) includes three 8-item scales that measure academic, social, and emotional self-efficacy. The academic self-efficacy scale includes questions about the person's perception of achieving academic goals. The social self-efficacy scale addresses social challenges, and the emotional self-efficacy scale includes questions about coping with unpleasant problems or events.

- The World Health Organisation- Five Well-Being Index (WHO-5) (WHO, 1998) is a short self-reported measure of current mental well-being suitable for children aged 9 and above. The WHO-5 consists of five statements, which respondents rate on a scale from 0 to 5 in relation to the past two weeks (0 = “At no time”, 1 = “Some of the time”, 2 = “Less than half of the time”, 3 = “More than half of the time”, 4 = “Most of the time”, 5 = “All of the time”). The total raw score, ranging from 0 to 25, is multiplied by 4 to give the final score, with 0 representing the worst imaginable well-being and 100 representing the best imaginable well-being. Item response theory analyses in studies of CYP indicate that the measure has good construct validity as a unidimensional scale measuring well-being in this population (Winther Topp et al., 2015).

- Active trackers: the questionnaire contains 8 compulsory questions (sleep quality, sleep quantity, mood, motivation, anxiety, loneliness, appetite, and exercise) and 11 optional questions (racing thoughts, negative thinking, hopefulness, headaches, irritability, confidence, sociability, energy levels, productivity, self-care, leisure, and a custom metric called “your measure”). Most self-reported questions are on a scale of 1-7 and contain a slider. Sleep quantity and exercise time record the number of hours and minutes completed per day.

- Passive trackers on the app: location, step count, background noise level, ambient light, battery level, app usage on phone (Android only)

Acceptability and usability measures

- Usability/engagement metrics over the study period on the MindCraft app, such as the number of data entries per active tracker, the number of individuals who enabled passive tracking, the number of individuals who enabled each optional active tracker, and the total number of days/weeks the app was accessed.

3.8 Sample Size

The sample size for the internal pilot was 50 participants per group, defined a priori. A power analysis using the observed effect size from our internal pilot interim analyses (average Cohen's d = 0.137; f = 0.139) suggested that a total of 505 participants (168 per group) would be needed to detect between-group differences with 80% power at α = .05. After adjusting for an anticipated 40% attrition rate, this increases to 842 participants (281 per group). However, our sub-analysis of high-risk participants showed a substantially larger effect size (average Cohen's d = −0.419; f = 0.462), suggesting that a smaller sample may be sufficient to detect meaningful intervention effects in this group. The sample size is an estimate and may differ from the actual sample size.

3.9 Statistical Analysis

Where not specified, we will use an Intention-to-treat (ITT) analysis approach, meaning all participants will be included in the analyses according to their randomised allocation.

Primary analyses:

- Repeated measures analyses (using a mixed effects linear regression model with a random effect on participant) will be used to compare primary outcomes across follow-up points. Baseline SDQ scores will be included as covariates. The primary endpoint is the intervention difference at 1 month. As multiple analyses are performed to compare both the experimental interventions and the active control with the control, and to compare the experimental intervention with the active control, a multiplicity adjustment will be made with a Bonferroni correction. We will also carry out sub-analyses of primary outcomes based on participants' demographic characteristics/adding them as covariates in the MLM.

Secondary analyses:

- The same modelling approach as primary analyses will be used for secondary outcomes where possible.

- A Complier Average Causal Effect (CACE) analysis will be used to provide an estimate of intervention effect, accounting for pre-specified per-protocol adherence and compliance with the intervention while retaining the benefits of randomisation. Such models will be performed for the primary and secondary outcomes at 1-month follow-up using observed data only and will include the covariates adjusted for in the regression models.
- The pattern of missing outcomes will be examined, and multiple imputations will be used to impute primary and secondary continuous outcomes. Imputation models will be informed by treatment arm, baseline scores, other covariates to be included in the model, and other baseline characteristics found to predict outcome or propensity for missingness (logistic regression models will be used to investigate the associations between baseline characteristics and missingness). Results of imputed models will be compared to the primary analysis complete case ITT models. We will carry out sensitivity analyses to estimate the intervention effect, including all missing data.
- We will estimate the causal effect of the intervention using two-stage least squares (2SLS) regression to account for potential endogeneity in nudge exposure. Random assignment to treatment group (T1 or C2 vs. control) will be used as an instrument for actual exposure. The first stage will model nudge exposure as a function of assignment; the second stage will regress the outcome on predicted exposure. This approach will yield a local average treatment effect (LATE) among compliers. Robust standard errors will be used throughout.
- Mediation analyses using structural equation modelling or parametric regression models will be carried out to gain insight into the mechanisms that could explain the potential effect of the interventions on primary outcomes.

3.10 Data Handling and Record Keeping

Participants' data will be pseudonymised. The study will comply with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so. A study-specific ID number identifying the participant will be randomly generated. A document matching identity and participant ID will be stored securely in a password-protected file on the Imperial College London computer network drive, only accessed by named research team members. No personal identifiable information will be included in any study electronic database compiled for the purpose of statistical analysis of the research outcomes. Analysis of the data from the study will be undertaken by the lead researcher (Aglaia Freccero).

Data from the questionnaires will be collected using Qualtrics, a research data collection platform (https://www.qualtrics.com/uk/). This data will be stored on a server owned by Qualtrics, whose data storage is compliant with OECD privacy rules and the European Union Directive on Data Protection. Data will be downloaded from

Qualtrics and later stored on Imperial College London's secure network drives. No hard copy of data will be stored.

Smartphone data is uploaded automatically via a secure link (https) to an Imperial College London digital client server (in an ISO 27001 compliant data centre). The data are stored in a dedicated data server in a physically secure, restricted-access environment. Backups are made each night, with a separate full weekly backup. All sources of data are backed up using state-of-the-art encryption technology to protect against the failure of any single hardware device and stored for a minimum of 1 year. Access and transfer logs are kept for two years. Two back-up servers are used and located in physically secure, swipe-card-controlled data centres.

Ethics approval for the pilot study using the earlier version of the app (with the same data storage/transfer aspects) was granted by the Imperial College London Research Ethics Committee (PI: Prof Dasha Nicholls; ICREC 20IC6132).

Imperial College London will keep identifiable information about participants:
• 10 years after the study has finished in relation to data subject consent forms
• 10 years after the study has completed in relation to primary research data following Imperial College London's retention periods.

During this time, the Principal Investigator will be custodian for the data archived following the Imperial College London archiving procedures. The Principal Investigator will preserve the confidentiality of participants taking part in the study and fulfil transparency requirements under the General Data Protection Regulation for health and care research.

Participants will be able to withdraw from the study at any point up until data analysis has commenced by contacting the research team at mindcraft@imperial.ac.uk. All data will be deleted from Imperial College London network drives. If the participant grants consent, any anonymised data collected up to the point of withdrawal will be used. Participants will not be able to withdraw their data after the results have been published, as data will be anonymous and will not be linked to the participant.

Anonymised data may be made available to other researchers after the end of the study via data repositories such as Open Science Framework and disseminated through peer-reviewed journals and conference presentations. This will be explained to participants in the Participant Information Sheet and Informed Consent form.

3.11 Patient and Public Involvement and Engagement (PPIE)

A Young People's Advisory Group, comprising five young people (4 females and one male) with diverse ages, ethnicities, sexual orientations, and experience with digital mental health interventions, was recruited through social media in 2023. The YPAG has contributed to the design and management of the research during the pilot phase, including informing project documentation, recruitment strategies and app development. The YPAG will be further involved in the main trial to interpret and

disseminate findings. The YPAG will be compensated 25£/hr in accordance with NIHR guidance on PPI. Patient and public involvement activities will be reported using the Guidance for Reporting Involvement of Patients and the Public, Version 2-short version.

3.12 Risks and Risk Management

There are no foreseeable serious risks associated with this project. Participants' well-being and safety will be considered a priority concern at all points in the study. However, theoretically, it is possible that a number of procedures (listed below) included in the study may result in (i) revealing elevated mental health risk or (ii) causing increased levels of distress.

If this is the case, the necessary steps to guarantee the participant's well-being and safety will be taken as described below. We will follow Imperial College London's Safeguarding policy.

Study procedures that may result in increased perceived distress include:

- Responding to questionnaires during baseline and outcome assessments
- Self-reporting data and mental health monitoring through the MindCraft app
- Cognitive/behaviour change following MindCraft app use and nudges recommendations

The risk (i), i.e. of revealing elevated mental health risk as measured by high SDQ scores at baseline, will be addressed by putting in place the following series of procedures:

- If the presence of elevated mental health risk is disclosed, the participant will be signposted to specific support resources on managing poor mental health including those to manage suicidal thoughts (https://patient.info/mental-health/depression-leaflet/suicidal-thoughts), as well as additional external sources of support, which will include those listed in the Help section of the MindCraft app (i.e. Shout, YoungMinds, Best For You NHS, and Kooth).

  We will also offer participants the option of being contacted by clinicians part of the research team. In case of disclosure of actual or intended harm, in order to protect the immediate safety of the participant, the participant's parents/guardians will be informed by the lead researcher (Aglaia Freccero) via email or phone call. The contact details of the parents/guardians will be provided on the consent-to-contact form.
- In case participants choose to be contacted by the research team, they will be informed that all information is confidential. The limits of confidentiality (e.g. that the researcher may have an ethical duty to disclose information to a third party to protect the immediate safety of the participant or someone else in the rare

circumstance in which it is judged that the participant or someone else is at risk of serious harm) are made explicit to participants in both the Participant Information Sheet and the Consent Form.

The risk (ii), i.e. of distress being caused by the above study procedures, will be minimised in the following ways:

- Participants will be informed about the assessments so that they can prepare themselves and give fully informed consent to participate.
- Trained researchers will oversee the collection of outcome measures and, if needed, consult clinicians on the research team.
- Recommendations delivered through the app will follow evidence-based CBT and behaviour change principles and be approved by clinicians on the research team.
- A safety checklist curated by the clinicians and informed by CBT protocols will be built into the app to ensure that nudges that might be triggering are not shown to vulnerable groups of users.
- In case of worsening of a participant's mental health state for a prolonged period as predicted by the app (e.g. the participant moves from a low-risk to a high-risk SDQ score), the nudges will be disabled by the research team, and participants will be signposted to external sources of support, which will include those listed in the Help section of the MindCraft app (i.e. Shout, YoungMinds, Best For You NHS, and Kooth).
- For participants who score in the high-risk category of the SDQ at follow-up, the participant will be signposted automatically via a link in the online questionnaire to external sources of support, which will include those listed in the Help section of the MindCraft app (i.e. Shout, YoungMinds, Best For You NHS, and Kooth).

4. PARTICIPANT ENTRY

4.1. PRE-REGISTRATION EVALUATIONS

N/A

4.2. INCLUSION CRITERIA

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

4.3. EXCLUSION CRITERIA

- Have learning difficulties, organic brain disease, severe neurological impairment that prevents independent use of smartphone app

4.4. WITHDRAWAL CRITERIA

Participants will be able to withdraw from the study at any point up until data analysis has commenced by contacting a member of the research team via email at mindcraft@imperial.ac.uk. Any anonymised data collected up to the point of withdrawal will be used.

5. ADVERSE EVENTS

5.1. DEFINITIONS

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

Serious Adverse Event (SAE): any untoward medical occurrence or effect that:

- **Results in death**
- **Is life-threatening** – *refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe*

- **Requires hospitalisation, or prolongation of existing inpatients' hospitalisation**
- **Results in persistent or significant disability or incapacity**
- **It is a congenital anomaly or birth defect**

Medical judgment should be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above should also be considered serious.

5.2. REPORTING PROCEDURES

All adverse events should be reported. Depending on the nature of the event, the reporting procedures below should be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

5.3.1 Non-serious AEs

All such events, whether expected or not, should be recorded.

5.3.2 Serious AEs

An SAE form should be completed and emailed to the Chief Investigator within 24 hours.

All SAEs should be reported to the Ethics and Research Governance Coordinator where, in the opinion of the Chief Investigator, the event was:

- 'related', ie resulted from the administration of any of the research procedures; and
- 'unexpected', ie an event that is not listed in the protocol as an expected occurrence

Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the NRES SAE form for non-IMP studies. The Chief Investigator must also notify the Sponsor of all related and unexpected SAEs.

Local investigators should report any SAEs as required by their Local Research Ethics Committee, Sponsor and/or Research & Development Office.

6. ASSESSMENT AND FOLLOW-UP

N/A

7. REGULATORY ISSUES

7.1. ETHICS APPROVAL

The Study Coordination Centre has obtained approval from the Imperial College London Research Ethics Committee (ICREC ID 7134492). The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

7.2. CONSENT

Potential participants will be informed about the study by their school. If data collection is carried out remotely, teachers will distribute information about the study via email to students and parents/guardians. Teachers will also send students a link to a Consent to Contact online form, where they will be asked to include their contact details and those of parents/guardians. On first contact with the students, the lead researcher (Aglaia Freccero) will email the full Participant Information Sheet and Consent/Assent Form to the students. Students over 16 will sign the Consent Form and email it back to the researcher. The Consent Form, signed by both participant and researcher, will be emailed back to the participant.

For any young person under 16, we will obtain informed parental consent by using opt-out consent (see below). The researcher will send the Opt-out Consent Form to parents/guardians via email along with a Parent/Guardian Information Sheet, which gives a full description of what children are expected to do and how participant data are stored. Parents/guardians will sign and email back the Opt-out Consent Form to the researcher if they do not wish their child to participate. Parents will have at least two weeks to complete the opt-out form before any data is collected from children. The Opt-Out Consent Form, signed by both the parent/guardian and researcher, will be emailed back to the parent/guardian. Participants under 16 years old will also be required to provide written assent by signing the Assent Form and emailing it back to the researcher. The Assent Form, signed by both participant and researcher, will be emailed back to the participant.

All participants will be told that participation is voluntary, and they may withdraw at any point without giving a reason. All Forms (Consent Form, Assent Form, Opt-out Consent Form) will be stored in an Imperial College London secure OneDrive.

We will use “opt-out” rather than “opt-in” parental consent. Several research studies have shown that using active “opt-in” parental consent leads to sample bias and results in the under-representation of disadvantaged groups (Shaw et al., 2014). Utilising opt-in parental consent is regarded as a barrier to student participation in school-based identification programmes (Humphrey & Wigelsworth, 2016; Levitt et al., 2007). Additionally, it is thought that “opt-out” procedures would put less strain on school staff compared to active “opt-in” procedures, which can be more labour-intensive. Through using an “opt-out” procedure, we aim to reach high levels of student participation, particularly for those from more disadvantaged backgrounds.

Alternatively, if the school prefers to carry out data collection in person on school premises, teachers will circulate the Participant Information Sheet to students and Parent/Guardian Information Sheet and Opt-out Consent Form to parents/guardians via email at least two weeks before the day of data collection. Students over 16 years old will provide informed consent electronically via Qualtrics on the day of data collection. They will also be asked to include their contact details and those of their parents/guardians. For participants under 16 years old, consent from a parent/guardian will be required for participation. Parents/guardians will sign and email back the Opt-out Consent Form to the researcher if they do not wish their child to participate. Parents will have at least two weeks to complete the opt-out form before any data is collected from children on school premises. The Opt-Out Consent Form, signed by both the parent/guardian and researcher, will be emailed back to the parent/guardian. Participants under 16 years old will provide written assent online via Qualtrics on the day of data collection.

7.3. CONFIDENTIALITY

Participants’ data will be pseudonymised. The study will comply with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so. A study-specific ID number identifying the participant will be randomly generated. A document matching identity and participant ID will be stored securely in a

password-protected file on the Imperial College London computer network drive, only accessed by named research team members. No personal identifiable information will be included in any study electronic database compiled for the purpose of statistical analysis of the research outcomes.

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act. The Principal Investigator will preserve the confidentiality of participants taking part in the study and fulfil transparency requirements under the General Data Protection Regulation for health and care research. Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study, including the follow-up period.

In the informed consent, we will explain to all participants that any information they provide will be treated with complete confidentiality. Circumstances in which breach of confidentiality might occur are clearly explained in the consent material. This will occur only if participants disclose information that may put them at risk. We will balance the ethical duty of respecting participant autonomy and confidentiality with the ethical duty of protecting participant health and safety.

7.4. INDEMNITY

Imperial College London holds negligent harm and non-negligent harm insurance policies which apply to this study.

7.5. SPONSOR

Imperial College London will act as the main Sponsor for this study.

7.6. FUNDING

Imperial College London is funding this study. The PhD student (Aglaia Freccero) is sponsored by the Imperial College London President's Scholarship. Study costs are covered by the student's scholarship and the research team (supervisors) discretionary funds.

7.7. AUDITS

The study may be subject to audit by Imperial College London/ Imperial College Healthcare NHS Trust under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Framework for Health and Social Care Research.

8. PUBLICATION POLICY

The results from this study will be reported and disseminated through peer-reviewed journals, conference presentations, and publications on websites, including the Imperial website and other innovative methods.

9. REFERENCES

Balaskas A, Schueller SM, Cox AL, Doherty G. Ecological momentary interventions for mental health: A scoping review. PLOS ONE. 2021;16(3): e0248152.

Bannink R, Broeren S, Joosten-van Zwanenburg E, van As E, van de Looij-Jansen P, Raat H. Effectiveness of a Web-based tailored intervention (E-health4Uth) and consultation to promote adolescents' health: randomized controlled trial. J Med Internet Res. 2014;16(5):e143.

Bonell C, Jamal F, Harden A, Wells H, Parry W, Fletcher A, Petticrew M, Thomas J, Whitehead M, Campbell R, Murphy S, Moore L. Systematic review of the effects of schools and school environment interventions on health: evidence mapping and synthesis. Southampton (UK): NIHR Journals Library; 2013 Jun. PMID: 25642578.

Cohen KA, Ito S, Ahuvia I L, Yang Y, Zhang Y, Renshaw TL, Larson M, Cook C, Hill S, Rapoport A, Smock A, Yang M, Schleider JL. Brief School-Based Interventions Targeting Student Mental Health or Wellbeing: A Systematic Review and Meta-Analysis. Clinical Child and Family Psychology Review. 2024; 27(3): 732-806.

Copeland WE, Shanahan L, Costello EJ, Angold A. Childhood and adolescent psychiatric disorders as predictors of young adult disorders. Arch Gen Psychiatry. 2009; 66(7): 764-72.

Dewa LH, Lavelle M, Pickles K, Kalorkoti C, Jaques J, Pappa S, Aylin P. (2019) Young adults' perceptions of using wearables, social media and other technologies to detect worsening mental health: a qualitative study. PloS One. 14 (9), e0222655. 10.1371/journal.pone.0222655 [doi].

Dubad M, Winsper C, Meyer C, Livanou M, Marwaha S. A systematic review of the psychometric properties, usability and clinical impacts of mobile mood-monitoring applications in young people. Psychological Medicine. 2018; 48 (2): 208-228.

Eysenbach G; CONSORT-EHEALTH Group. CONSORT-EHEALTH: improving and standardizing evaluation reports of Web-based and mobile health interventions. J Med Internet Res. 2011; 13(4):e126.

Espie CA, Kyle SD, Hames P, Gardani M, Fleming L, Cape J. The Sleep Condition Indicator: a clinical screening tool to evaluate insomnia disorder. BMJ Open. 2014;4(3):e004183.

Firth J, Solmi M, Wootton RE, Vancampfort D, Schuch FB, Hoare E, Gilbody S, Torous J, Teasdale SB, Jackson SE, Smith L, Eaton M, Jacka FN, Veronese N, Marx W, Ashdown-Franks G, Siskind D, Sarris J, Rosenbaum S, Carvalho AF Stubbs B. A meta-review of “lifestyle psychiatry”: the role of exercise, smoking, diet and sleep in the prevention and treatment of mental disorders. World Psychiatry. 2020; 19(3): 360-380.

GBD 2019 Mental Disorders Collaborators. Global, regional, and national burden of 12 mental disorders in 204 countries and territories, 1990-2019: a systematic analysis for the Global Burden of Disease Study 2019. Lancet Psychiatry. 2022; 9(2): 137-150.

Goodman R, Meltzer H, Bailey V. The Strengths and Difficulties Questionnaire: a pilot study on the validity of the self-report version. Eur Child Adolesc Psychiatry. 1998; 7(3):125-30.

Henderson C, Evans-Lacko S, Thornicroft G. Mental illness stigma, help seeking, and public health programs. Am J Public Health. 2013;103(5): 777-80.

Hirschfeld RM, Williams JB, Spitzer RL, Calabrese JR, Flynn L, Keck PE Jr, Lewis L, McElroy SL, Post RM, Rapport DJ, Russell JM, Sachs GS, Zajecka J. Development and validation of a screening instrument for bipolar spectrum disorder: the Mood Disorder Questionnaire. Am J Psychiatry. 2000; 157(11):1873-5.

Humphrey N, Wigelsworth M. Making the case for universal school-based mental health screening. Emotional and Behavioural Difficulties. 2016; 21(1): 22-42.

Kadirvelu B, Bellido Bel T, Wu X, et al. Mindcraft, a Mobile Mental Health Monitoring Platform for Children and Young People: Development and Acceptability Pilot Study. JMIR Form Res. 2023;7:e44877.

Kadirvelu B, Bel TB, Freccero A, Simplico MD, Nicholls D, Faisal AA. Digital Phenotyping for Adolescent Mental Health: A Feasibility Study Employing Machine Learning to Predict Mental Health Risk From Active and Passive Smartphone Data. JMIR Preprints. 11/02/2025:72501

Kessler RC, Berglund P, Demler O, Jin R, Merikangas KR, Walters EE. Lifetime prevalence and age-of-onset distributions of DSM-IV disorders in the National Comorbidity Survey Replication. Archives of General Psychiatry. 2005; 62(6): 593-602.

Larsen DL, Attkisson CC, Hargreaves WA, Nguyen TD. Assessment of client/patient satisfaction: development of a general scale. Evaluation and Program Planning. 1979; 2(3):197-207.

Larsen ME, Huckvale K, Nicholas J, Torous J, Birrell L, Li E, Reda B. Using science to sell apps: Evaluation of mental health app store quality claims. 2019. npj Digit. Med. 2, 18.

Laugwitz B, Held T, Schrepp M. Construction and evaluation of a user experience questionnaire. Symposium of the Austrian HCI and usability engineering group. 2008. Springer. pp.63-76

Lecomte T, Potvin S, Corbière M, Guay S, Samson C, Cloutier B, Francoeur A, Pennou A, Khazaal Y. Mobile Apps for Mental Health Issues: Meta-Review of Meta-Analyses. JMIR Mhealth Uhealth. 2020; 8(5):e17458.

Levitt JM, Saka N, Romanelli LH, Hoagwood K. Early identification of mental health problems in schools: The status of instrumentation. Journal of School Psychology. 2007; 45(2):163-191.

Levy S, Weiss R, Sherritt L, Ziemnik R, Spalding A, Van Hook S, Shrier LA. An electronic screen for triaging adolescent substance use by risk levels. JAMA Pediatrics. 2014; 168(9):822-828.

Linardon J, Torous J, Firth J, Cuijpers P, Messer M, Fuller-Tyszkiewicz M. Current evidence on the efficacy of mental health smartphone apps for symptoms of depression and anxiety. A meta-analysis of 176 randomized controlled trials. World Psychiatry. 2024; 23(1): 139-149.

Milne-Ives M, Selby E, Inkster B, Lam C, Meinert E. Artificial intelligence and machine learning in mobile apps for mental health: A scoping review. PLOS Digital Health. 2022;1(8): e0000079.

Mohr DC, Schueller SM, Riley WT, Brown CH, Cuijpers P, Duan N, Kwasny MJ, Stiles-Shields C, Cheung K. Trials of Intervention Principles: Evaluation Methods for Evolving Behavioral Intervention Technologies. J Med Internet Res. 2015; 17(7):e166.

Morrison LG, Hargood C, Pejovic V, Geraghty AWA, Lloyd S, Goodman N, Michaelides DT, Weston A, Musolesi M, Weal MJ, Yardley L. The Effect of Timing and Frequency of Push Notifications on Usage of a Smartphone-Based Stress Management Intervention: An Exploratory Trial. PLoS One 2017; 12:e0169162.

Muris P. A Brief Questionnaire for Measuring Self-Efficacy in Youths. Journal of Psychopathology and Behavioral Assessment. 2001;23:145–149.

NHS Digital. (2019) The NHS Long Term Plan. https://www.longtermplan.nhs.uk/publication/nhs-long-term-plan/.

NHS Digital. (2023) Mental health of children and young People in England 2023.

Nock MK, Holmberg EB, Photos VI, Michel BD. Self-Injurious Thoughts and Behaviors Interview: development, reliability, and validity in an adolescent sample. Psychol Assess. 2007;19(3):309-17.

Ofcom. (2022) Children and parents: media use and attitudes report 2022. Ofcom.

Oudin A, Maatoug R, Bourla A, Ferreri F, Bonnot O, Millet B, Schoeller F, Mouchabac S, Adrien V. Digital Phenotyping: Data-Driven Psychiatry to Redefine Mental Health. J Med Internet Res. 2023; 25:e44502.

Pandey A, Hale D, Das S, Goddings AL, Blakemore SJ, Viner RM. Effectiveness of Universal Self-regulation-Based Interventions in Children and Adolescents: A Systematic Review and Meta-analysis. JAMA Pediatr. 2018; 172(6): 566-575.

Polanczyk GV, Salum GA, Sugaya LS, Caye A, Rohde LA. Annual research review: A meta-analysis of the worldwide prevalence of mental disorders in children and adolescents. J Child Psychol Psychiatry. 2015; 56(3):345-65.

Shaw T, Cross D, Thomas L, Zubrick, SR. Bias in student survey findings from active parental consent procedures. British Educational Research Journal. 2015; 41(2): 229-243.

Stice E, Telch CF, Rizvi SL. Development and validation of the Eating Disorder Diagnostic Scale: a brief self-report measure of anorexia, bulimia, and binge-eating disorder. Psychol Assess. 2000; 12(2):123-31.

Wahle F, Kowatsch T, Fleisch E, Rufer M, Weidt S. Mobile Sensing and Support for People With Depression: A Pilot Trial in the Wild. JMIR mHealth and uHealth 2016;4.

WHO. (1998). Wellbeing Measures in Primary Health Care/The Depcare Project. WHO Regional Office for Europe: Copenhagen.