

The IRL Trial: Protocol

The IRL Trial: A school-based trial to reduce social media use and improve mental health among adolescents.

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Study contacts

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Funder:	The Wellcome Trust; National Institute for Health Research
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Role of study sponsor and funder

The sponsor has overall responsibility for proportionate, effective arrangements being in place to set up, run and report the research, with responsibilities as per the UK Policy Framework for Health and Social Care Research.⁽¹⁾ The funder has no role in the study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

Key words

Adolescence; mental health; social media; intervention; coproduction; Born in Bradford

WHO data set items

Item	Value
Plain English summary	This trial will test an intervention designed to reduce social media use and improve mental health in young people aged 12 to 15. Many teenagers use social media every day and there are concerns that high use may be harmful in terms of mental health. School year groups will be randomly assigned to one of two groups. In one group, students will use a specially designed app that limits social media use to two hours per day and blocks access between 9pm and 7am. In the other group, students will use the same app, but it will only track their usage and will not set limits. The study will last six weeks. Students will complete short questionnaires at the start and end of the study about their mental health, sleep, and experiences such as bullying. A small number of students will also take part in interviews to share their experiences. The main aim is to test whether this app-based intervention reduces anxiety. We will also look at depression and overall wellbeing, and explore the mechanisms through which social media might affect mental health.
Background and study aims	Social media use among children and adolescents has been linked to harms including bullying, sexual risks, and mental health problems. Adolescence is a sensitive period for mental health, with increased risk-taking, ongoing brain development, and the onset of many mental health conditions. Observational studies suggest heavier social media use is associated with more mental health symptoms, but scientific authorities in the UK and US have concluded the average causal effect remains unclear. The IRL Trial is a randomised controlled trial evaluating the effects of an intervention designed to reduce social media use on mental health among secondary school pupils (academic Years 8–10, corresponding to ages 12–15). We will explore potential mechanisms underlying these effects.
Who can participate?	Students who will be enrolled in Year 8, 9 or 10 from September 2026 at a secondary school.
What does the study involve?	This will be a parallel-arm cluster randomised trial in which school year groups (academic years 8–10) will be randomised to either (i) a bespoke social media restriction app, limiting use to 2 hours per day between 7am–9pm, or (ii) a treatment-as-usual control conditions where the app tracks screen time but applies no restrictions. The intervention will last six weeks. Participants will complete a self-reported questionnaire on topics including mental health, bullying and sleep at baseline (week 0) and follow-up (week 6). Around 30 participants in the intervention group will also take part in qualitative interviews to share their experiences and explore how reducing social media use may affect mental health.

What are the possible benefits and risks of participating?	Benefits: 1. Possible benefits of the intervention itself (a benefit in terms of mental health). 2. Financial compensation. Risks: 1. Reduced opportunity for social engagement, support, or fear of missing out due to reduced use of social media. 2. Bullying due to participants being left out of social events. 3. Distress experienced during quantitative or qualitative data collection.
Where is the study run from?	Bradford Teaching Hospital NHS Trust
When is the study starting and how long is it expected to run for?	1 April 2026 – 1 April 2028
Who is funding the study?	The Wellcome Trust (337689/Z/25/Z); National Institute for Health Research (NIHR205448)
Who is the main contact?	Dr Dan Lewer borninbradford@bthft.nhs.uk
Study information	
Primary study design	Interventional
Study design	Cluster randomised controlled trial
Scientific title	The In Real Life (IRL) Trial: A school-based trial to reduce social media use and improve mental health among adolescents.
Study acronym	IRL
Study objectives	1. To estimate the effect of social media restriction versus a usual-treatment control on anxiety (primary outcome) as well as depression and mental wellbeing (secondary outcomes) among adolescents in Years 8, 9 and 10. 2. To explore possible mechanisms underlying the effect of social media restriction.
Ethics approval(s)	HRA and Health and Care Research Wales provided a favourable opinion provided on 2 June 2026; reference 26/EE/0127
Health condition(s) or problem(s) studied	Mental health outcomes (primarily anxiety)
Intervention	The intervention will be a smartphone app for Android and iOS (iPhone) installed on participants' primary mobile devices, which will limit participants' use of a pre-defined list of social media and internet browser apps. The app will limit social media through two mechanisms: (i) a daily time 'budget' across all linked social media apps, and (ii) a 'curfew' that prevents linked app use during nighttime hours. Motivational messaging, engagement features (e.g.,

	leaderboards), and performance-based incentives will encourage adherence. Based on co-production with teenagers, we are planning a daily budget of two hours, and a curfew from 9pm - 7am. We will deliver the intervention over six weeks.
Intervention type	Behavioural intervention
Primary outcome measure	Anxiety, measured using the RCADS-25 anxiety subscale.
Key secondary outcome measure(s)	- Symptoms of depression: RCADS-25 depression subscale. - Mental wellbeing: SWEMWBS.
Completion date	1 April 2028
Eligibility	
Participant type	Student
Age group	Mixed
Lower age limit	12
Upper age limit	15
Sex	All
Target sample size at registration	4,500
Key inclusion criteria	- Currently enrolled in a secondary school in academic Year 8-10 - Can speak and read English
Key exclusion criteria	No specific exclusion criteria (all school types and young people will be eligible)
Date of first enrolment	7 September 2026
Date of final enrolment	31 March 2027
Locations	
Countries of recruitment	United Kingdom; England
Study participating centres	Bradford Teaching Hospital NHS Trust
Results and Publications	
Individual participant data (IPD) Intention to share	Yes
IPD sharing plan	The datasets generated during and/or analysed during the current study will be available upon request from Dr Dan Lewer (borninbradford@bthft.nhs.uk)

1 Summary

The IRL Trial will evaluate the effects of social media using an intervention designed to reduce its use among secondary school pupils (academic years 8 - 10) in Bradford, UK. This will be a parallel-arm cluster randomised trial in which school year groups are randomised in a 1:1 ratio to either the intervention or a treatment-as-usual control condition. The intervention will entail a smartphone app that limits the use of social media apps such as TikTok and Snapchat, using a co-produced combination of a daily 'budget' and a nighttime 'curfew'. The primary study outcome will be self-reported anxiety, with secondary outcomes of wellbeing and depression. We will also investigate potential mechanisms underlying this effect, such as social media use, changes in sleep, time spent with friends and family, and bullying. The trial will also include qualitative interviews with a subset of participants from the intervention condition.

2 Background

2.1 Social media and adolescent mental health

Documented harms of social media use among children and adolescents include deaths, sexual risks, and bullying.(2–6) There is substantial public concern about these harms, particularly during adolescence,(7) a period characterised by increased risk-taking, ongoing brain development and the onset of many mental health problems.(8–10)

The prevalence of mental health problems among adolescents is increasing globally.(11) In 2023, the NHS reported that one in five 8-16 year-olds in the UK has a ‘probable mental disorder’ based on population surveys.(12) The rise in smartphone and social media use is a possible driver of this trend.(13,14) Many observational studies show that adolescents who are heavier users of social media tend to have more mental health symptoms and are more likely to feel unhappy about their online interactions.(15,16) However, the current observational evidence has several methodological limitations, including likely residual confounding and reverse causality, meaning the true effect of social media use on adolescent mental health is uncertain. Scientific authorities in the UK and US have concluded that it is currently not possible to estimate the overall causal effect of digital technology on the wellbeing of children.(17,18) Despite this, many governments are actively considering or implementing interventions that limit time children spend using social media, including nighttime ‘curfews’ on social media(19) and age restrictions.(20) Experimental studies are needed to provide evidence regarding the causal relationship between social media use and mental health and to identify social media interventions that may benefit young people.(21,22)

2.2 Rationale for this trial

This is a randomised controlled trial of a social media restriction intervention. We will use a smartphone-based app to limit social media use and examine its effects on mental health among the general population of adolescents. We will also investigate the potential mechanisms underlying this effect, such as changes in sleep, time spent with friends and family, and bullying.

Bradford is an ethnically and economically diverse city in West Yorkshire, UK. We will aim to recruit a representative sample of the city’s population of young people. The trial will be conducted in secondary schools, and will include students in academic Years 8, 9, and 10 (corresponding to ages 12-15 years). Year-groups will be randomised to either a social media restriction intervention or a treatment-as-usual control. Cluster randomisation (rather than individual level randomisation) is designed to mitigate participant anxiety about missing out on social interactions via social media and to capture group-level effects such as greater in-person socialising or reduced online bullying.

Co-production sessions with teenagers identified social media use as a key concern related to mental health. In addition, almost universal smartphone ownership among this age group demonstrates the relevance of a smartphone-based intervention (97% according to a recent Ofcom survey; preliminary Bradford data from Age of Wonder suggest 90% ownership overall, with around 80% ownership among South Asian adolescents).(23) This research will estimate the effects of the intervention on time spent on social media and mental health, and will also explore the mechanisms underlying these effects. Through engagement with young people, we have identified four key potential mechanisms of harm that the intervention could disrupt: (i) poor or disrupted sleep due to social media use at night, given established links between sleep disturbance and anxiety;(24) (ii)

displacement of other activities such as physical activity and time spent with friends and family; and (iii) bullying and cyberbullying. These mechanisms will be explored through quantitative and qualitative methods.

3 Aim and objectives

3.1 Aim

To estimate the effect of a social media restriction intervention on adolescent mental health.

3.2 Objectives

1. To estimate the effect of a social media restriction intervention on anxiety (primary outcome) as well as depression and mental wellbeing (secondary outcomes); using a usual-treatment control condition, among adolescents in academic Years 8, 9 and 10.
2. To explore possible mechanisms underlying the effect of a social media restriction intervention.

4 Study design, recruitment, and randomisation

4.1 Study design

This is a parallel-arm cluster randomised trial in which school year groups will be randomised to one of two conditions: (i) an intervention aiming to reduce social media use, or (ii) a treatment-as-usual control condition.

4.2 Population

We will include students in academic Years 8, 9 and 10 at secondary schools. We have decided not to include academic Year 7 (aged 11–12) because under General Data Protection Regulation they are not allowed to sign up for social media accounts, which have a minimum age of 13. This age group could benefit from reduced social media use since data from Bradford suggest that 86% of 10-12 year-olds have their own social media profile(23) and in Bradford 12 year olds spend on average more than 2.5 hours per day on social media apps. (25) However, we are concerned that participants, parents, teachers, and research staff may be uncomfortable with the inclusion of academic Year 7 given that use of social media is not legally allowed in this age group. Based on our engagement with schools and parents, research into social media in Year 8 is acceptable (even though Year 8 includes both 12 year olds and 13 year olds).

4.3 Inclusion/exclusion criteria

All secondary schools will be eligible for participation in the trial regardless of their funding source, type of provision, or sex at entry. Although eligible for participation, schools with alternative provision will be excluded from the primary analysis and sample size calculation, as they have different educational models and the intervention is likely to work differently in these settings. There will be no selection based on existing school phone policies because we expect benefits primarily from reduced evening and nighttime use of social media (rather than reduced use at school).

Inclusion criteria for students will be:

- i. in academic year groups 8, 9, or 10 at enrolment;
- ii. can speak and read English.

We will ensure our research is inclusive of pupils from all backgrounds by providing extra support (e.g. special educational needs and disabilities/SEND workers, teaching assistants) where needed; ensuring materials are available in different languages for parents; and reporting inclusivity via data collected about participants' sex and/or gender identity, ethnicity, SEND status.

4.4 School recruitment

Based on power calculations (see Section 4.9 for more detail), we will aim to recruit 10-12 secondary schools. With three year groups per school, this equates to 30-36 year groups.

Secondary schools will be invited to take part in the trial using a range of contact methods such as email, newsletters, local events and professional contacts between members of the research team and school staff.

When a school is interested, an initial meeting with the headteacher or other key staff members will be arranged to further explain the trial, intervention and data collection methods, answer any queries and discuss consent procedures. If the school agrees to take part, the headteacher (or relevant trust executive where appropriate) will sign a data sharing agreement and school consent form.

4.5 Participant recruitment

Quantitative

Following the initial meeting with the headteacher, we will arrange a launch assembly with the school in which we will present key details of the trial to students. Following standard practice for public health research in secondary schools,(26) we will use parental opt-out consent and student opt-in consent. Students will be given an opt-out consent form to take home at the end of the assembly, providing parents with information about the trial and giving them the opportunity to opt-out their child. We will work with schools to determine the best way of disseminating information about the trial to parents. Parents will be given at least 2 weeks to provide opt-outs.

After parental opt-out consent forms are returned, the school will compile class lists of participants, including their sex, ethnicity, free school meals and SEND statuses, which will be shared with the research team. These lists will be used to create unique student enrolment forms and to assess inclusivity and assignment equivalence.

On the scheduled date of the baseline survey in each school, researchers will visit in-person, explain the trial, answer questions and provide students with an opt-in consent form, which will be delivered electronically through students' smartphones, or using tablets provided by the research team (for those without a smartphone). To minimise disruption to school timetables, participants will complete the baseline questionnaire and then download and configure the bespoke research app (see Section 4.10) during this session, immediately following consent. The year group randomised intervention status will be revealed after participants have configured the app. Schools will have the option of surveys being done using tablets provided by the research team, with app-onboarding sessions arranged at the end of the school day in which they have completed the survey.

Qualitative

Participants will be recruited from intervention year-groups. Schools will support the research team in identifying potentially eligible students, and will support the distribution of participant information sheets and consent forms. Researchers will work with schools to identify a diverse sample of young people, with particular regard to inclusion of students who may not typically volunteer for this type of research. Written opt-in parental consent and student assent will be obtained prior to participation. Approximately 30 participants will be recruited using purposive sampling to ensure diversity by school type as well as individual-level sex and ethnicity.

Physical copies of signed consent forms will be returned to the researcher on the day of the interview, at which point the researcher will co-sign the consent form and provide a copy to the participant for their/their parent's records. When consent forms are transported between the school and the research institute, they will be transferred by authorised members of the research team and will not be left unattended in unsecured locations. The researcher will create electronic copies of physical consent forms at the earliest opportunity following data collection. Digital copies will be

stored on a secure password-protected network drive at Bradford Teaching Hospitals NHS Foundation Trust in accordance with institutional data protection policies, and separately from research data. Access to this folder will be restricted to authorised members of the research team. Physical copies of consent forms will then be confidentially destroyed. Electronic copies of consent forms will be retained in accordance with the sponsor institution's records retention schedule.

4.6 Incentives

Individual participants will receive a £20 voucher in the follow-up session (see Section 4.15), regardless of their group assignment. Every school that takes part will receive £2,000.

Participants may override the restrictions once exceed their budget or during the curfew (see app specification). Feasibility research showed that individual incentives could increase the compliance and appeal to a diverse and representative sample. We will use the following prize draw approach to awarding compliance-based incentives:

Each day participants in the intervention group can score a maximum of 2 points while they have the study app installed:

- 1 point for staying within their daily screen time limit of 2 hours
- 1 point for not using apps during curfew hours (9pm–7am)

At the end of the trial, an anticipated 100–200 prizes of value £100 will be awarded based on these points. Each participant will have as many tickets as points. Tickets will be drawn at random. Each student will be limited to one prize, with their remaining tickets removed from the pool once they have been selected. This incentive model is designed to maintain engagement throughout the study.

Students winning a prize will choose between three formats: (a) a vouchers; (b) an experience, eg. a trip to a theme park; or (c) a donation to the Bradford Hospitals Charity. We will inform parents or guardians, who will have an opportunity to request a different prize format.

Schools will also compete for a top prize of £5,000, which will be awarded to the school that shows the highest level of engagement during the trial. Engagement will be measured in the following way:

- Students in the control group will earn 1 point for each day they keep the app installed. Each school will receive a percentage score across students in the control group.
- Students in the intervention group will earn 1 point each day they keep the app installed, in addition to the 2 points they can earn for adhering to restrictions as above. Each school will receive a percentage score across students in the intervention group.

The two percentage scores will then added together to give the school's overall score out of 200. This system is designed to make the competition fair, given that some schools will have more year groups in the control group or intervention group than others. The school with the highest overall score will win the £5,000 prize.

Participating schools will make an advanced pledge to their students on what the prize money would be spent on.

4.7 Randomisation

Schools in Bradford differ with regard to students' ethnic composition, sex at entry (single sex/mixed), and type of funding (public/private). Table 1 shows characteristics of the 37 secondary schools in Bradford, based on data from the school census and Department for Education.(27,28)

The school census does not provide ethnicity at a more granular level (e.g. Asian Indian vs Asian Pakistani, or White Irish vs White Polish).

Table 1: Secondary schools in Bradford (N = 37) stratified by student ethnic composition, sex at entry and type of funding.

Variable		n (%)
Sex at entry	Single sex	5 (13.5)
	Mixed	32 (86.5)
	Missing	0 (0.0)
State/private	State	36 (97.3)
	Private	1 (2.7)
	Missing	0 (0)
Type of Provision	Mainstream	36 (97.3%)
	Alternate provision	1 (2.7)
	Missing	0 (0)
Ethnicity	Majority Asian/Asian British ⁱ	14 (37.8)
	Majority White/White British ⁱⁱ	6 (16.2)
	Mixed ⁱⁱⁱ	14 (37.8)
	Missing	3 (8.1)

ⁱMajority Asian/Asian British if $\geq 75\%$ of pupils were Asian/Asian British. ⁱⁱMajority White/White British if $\geq 75\%$ of pupils were White/White British. ⁱⁱⁱMixed if neither of the above applied.

We will randomise year groups within schools. This will mean each participating school will have at least one intervention and one control year group. Randomisation will be balanced so that year groups are evenly distributed across the trial arms. Randomisation will be done by the London School of Hygiene and Tropical Medicine Clinical Trials Unit (LSHTM CTU), which will retain a pseudonymous ID for the clusters to facilitate masking of the analyst.

4.8 Masking

Schools and participants will not be fully masked to their exposure status, as there is no plausible 'sham' intervention. The exposure status will be revealed to schools and participants after participants configure the app, to prevent knowledge of exposure status affecting participants' responses to the baseline questionnaire or engagement in the configuration process. Trial analysts at LSHTM CTU will be masked to the exposure status.

4.9 Sample size

Power calculations were conducted using methods provided by Hemming et al(29,30) for cluster randomised trials. Our trial will use a cohort design with baseline and follow-up measurements. Assumptions include the average number of students per year group (200 students), participation rate (75%), intracluster correlation (0.03), alpha (0.05), beta (0.8), and a baseline-follow-up correlation of 0.8. For our primary outcome (the RCADS-25 anxiety subscale), we assumed a baseline mean score of 9.9 points (out of a maximum of 45) with a standard deviation of 8.3, based on data from Age of Wonder in 2023/24. To detect an effect size (standardised mean difference) of 0.16 among all students, we will need to randomise 30 year-groups (15 in each arm), equating to approximately 10 schools (4,500 participants). We will therefore aim to recruit 12 schools to allow drop out of 1-2 schools.

Table 2: Power estimates for varying numbers of recruited schools and year groups.

Schools	Year group clusters	Detectable effect size
8	24	0.18
10	30	0.16
12	36	0.14

4.10 Conditions

Intervention

The intervention will include a smartphone app for Android and iOS (iPhone) installed on participants' primary mobile device, which will limit the participant's use of social media and internet browser apps. The intervention excludes secondary devices (e.g., tablets, computers, and other phones). Apps included in the intervention will be:

1. Facebook
2. Instagram
3. X (formerly Twitter)
4. TikTok (including TikTok Lite)
5. Snapchat
6. YouTube
7. Reddit
8. Twitch
9. Threads
10. Kick

Android users will additionally have internet browsers included, to prevent participants from accessing web-versions of the included platforms. This will include Chrome, Safari, Samsung Internet, Firefox, Edge, Opera, Brave, Ecosia, and Yandex Browser. iOS users will be able to access their browsers, but URLs for web-versions of the included social media platforms will be blocked.

The app will limit social media through two mechanisms: (i) a daily time 'budget' across all social media apps listed above, and (ii) a 'curfew' that prevents app use during nighttime hours. Based on co-production with teenagers, we are planning a daily budget of two hours, and a curfew from 9pm - 7am. Any pre-existing parental controls that are stricter than the intervention will take precedent over restrictions imposed by the intervention. The intervention does not exclude installation or use of other app that support participants to manage or reduce their screen time.

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There is some evidence from older adolescents and young adults that benefits of social media reductions can be seen after 1-3 weeks.(32–34) We will deliver the intervention over six weeks to maximise the opportunity to observe a benefit.(35) Immediately after the baseline questionnaire, all participants will download and configure the restriction app. In schools with a no-phone policy, this will be conducted at the end of the schoolday in which the questionnaire is completed. This will be the first day of restriction for the intervention group. For all participants the intervention period will end six weeks later ($\pm$ three days to accommodate school scheduling constraints) when we return to

the schools to administer the follow-up questionnaire. After the follow-up questionnaire students will delete the app.

Adaptation of the intervention

Patient and public involvement and engagement (PPIE) has underpinned each stage in the development of the social media restriction intervention.

We consulted a group of young people aged 16–24 years in July 2025. They were presented with seven social media intervention options derived from a scoping review, including phone abstinence, parental restrictions, and app-based methodologies. Their preferred delivery option was a restriction over a ban, to be delivered by an app over which they had control. In December 2025, we consulted with young people aged 12–16 focusing on engagement features, demonstrated a strong preference for within-app streaks, peer-based competition linked to incentives and feedback on their own activity via notifications/affirmations. Thirdly, we consulted with an adolescent and young adult group in January 2026, who indicated a preference for an overnight restriction between the hours of 9pm and 7am. Considering this feedback, the chosen intervention is a restriction (2 hour limit) rather than a complete ban, combined with an overnight curfew (9pm – 7am).

In July 2026 we consulted a group of parents about the individual-level incentives. They supported prizes based on compliance with the intervention, and suggested the overall value (£250 per prize) and the approach of notifying parents of the prize and allowing them to choose the format of the prize.

Control

The control condition will be ‘usual practice’ with the same data collection procedures as the intervention group. Participants will also download the app and link social media apps to it for data collection, but no restriction will be applied.

4.11 Outcomes

Primary outcome

The primary outcome will be anxiety, measured using the RCADS-25 anxiety subscale.⁽³⁶⁾ This includes 15 questions on a 4-point Likert scale. The summary score ranges from 0 (not anxious) to 45 (very anxious).⁽³⁶⁾

Secondary outcomes

The secondary outcomes will be:

1. Symptoms of depression: RCADS-25 depression subscale.⁽³⁶⁾
2. Mental wellbeing: SWEMWBS.⁽³⁷⁾

Other outcomes of interest

Other outcomes of interest will include:

1. total time spent on linked apps and social media on the main device in the past two weeks: app logs.

2. Time spent on social media use on other devices: self-reported in a coproduced questionnaire.
3. Time spent doing physical activities: self-reported in a coproduced questionnaire.
4. Time spent doing sedentary activities: self-reported in a coproduced questionnaire.
5. Loneliness: UCLA-loneliness scale (4-item version).(38)
6. Cyberbullying: the Cyber bullying victimisation scale (CYBVICS).(39)
7. In-person bullying: a single question self-reported in a coproduced questionnaire
8. Sleep time: mean hours sleep per night over the past four weeks derived from the Munich ChronoType Questionnaire (MCTQ) for children and adolescents.(30)
9. Hobbies: a single question self-reported in a coproduced questionnaire.
10. Time spent with friends/family: two questions adapted from those used in the Millenium Cohort Study.(40)

The final list of will depend on coproduction and testing of the participant questionnaire, with particular regard to the length of the questionnaire and feasibility of completing it within a school session.

4.12 Adherence

We will collect data on adherence to the intervention. Non-adherence among the intervention group will be defined as failure to meet time restrictions on more than 50% of the days, in the four weeks prior to the follow-up survey. This will be based on app data generated by the app provider. Non-adherence among both the intervention group and the control group is additionally defined as those who have un-installed the study app prior to the follow-up survey being collected.

4.13 Harms

Harms can be defined as harmful effects of the intervention, safeguarding events, and serious adverse reactions.

- **Harmful effects.** Harmful effects of the intervention may occur if the intervention prevents pre-existing beneficial uses of social media, for example providing a space for self-expression, enabling friendships, and social support. We do not anticipate significant harmful effects of the intervention because: (a) participants will be allowed sufficient use of social media to maintain these relationships; (b) participants have the ability to suspend restrictions and/or uninstall the app at any time. Nevertheless, we will design the study to capture potential harms such as reduced social support or closeness with friends, feelings of exclusion and bullying, for example because participants are not aware of discussions that happened on social media. These harms would be captured by our measured outcomes where there is an average negative effect across the population or key subgroups. We will also explore harms and negative experiences of the intervention in our qualitative research.
- **Safeguarding events.** The trial will have a documented safeguarding policy. Each school will designate a named safeguarding representative to work with researchers. Disclosures are most likely to occur in qualitative research and coproduction sessions, which will be assessed according to the policy and where necessary reported to the school safeguarding representative and logged. Quantitative surveys will not have free text data entry, so relevant events will not be captured.

- **Serious adverse reactions.** The trial will follow a documented policy for identifying serious adverse events (e.g. deaths, serious illnesses, life-threatening risks, or substantial unexplained school absences). Events may be detected during data collection, coproduction sessions, or reported by schools. Safeguarding or other necessary responses will be triggered, and any event plausibly caused by the research will be promptly reported to the Trial Steering Committee and NHS Research Ethics Committee (NHS REC).

4.14 Data collection

Quantitative

Quantitative data will be collected from three sources: (i) app data generated from the developer including installation date, app usage (including per-app timestamps for opening and closing), uninstall date, and details of the phone make, model and operating system; (ii) self-reported questionnaires at baseline, and at follow-up six weeks later; and (iii) data collected routinely by schools, including, sex, age, ethnicity, SEND and free school meals status. These variables are known to be associated with mental health and will therefore be included as covariates in the analysis. The questionnaires will be administered in school facilities with teaching staff and members of the research team present. We expect the baseline and follow-up questionnaire will each take approximately 20 minutes, with the full session including app configuration taking approximately 50 minutes.

Qualitative

Qualitative data will be collected through semi-structured interviews with approximately 30 students participating in the qualitative component of the trial (Section 4.5). Interviews will take place in the final week of the intervention period, with follow-up interviews conducted approximately three months post-intervention. Interviews will be conducted by a trained qualitative researcher and will take place in person at participating schools.

Interviews will follow a semi-structured interview guide designed to explore participants' experiences of the intervention, including acceptability, perceived impacts and factors that may have influenced how it operated in different contexts (e.g. peer groups, school environment, and individual experiences). Interviews will last approximately 30-45 minutes and will be audio recorded using an encrypted, password-protected Dictaphone belonging to the research institute. Following each recording, audio files will be transferred via USB connection directly onto a secure, password-protected network drive hosted by BTHFT. Transfer will take place on the same working day where possible, and no later than the next working day.

Once transferred, files will be deleted from the Dictaphone. No interim storage will occur outside of the secure network drive. Access to the network drive will be restricted to authorised members of the research team. The folder containing audio recordings will be additionally password-protected.

Recordings will be retained only for the purposes of transcription and transcript checking. They will be permanently deleted from the secure network drive once all transcripts have been produced, anonymised, and checked for accuracy. Audio recordings will not be retained beyond transcription for any secondary purpose.

Audio recordings will be transcribed by a BTHFT-approved transcription company, The Typing Works, which has previously been used by the research institute and is an approved data processor, and meets Cyber Essentials and ISO27001. Full audio recordings will be securely transferred to the transcription provider. The transcription provider, The Typing Works, will act solely as a data processor on behalf of BTHFT and will not retain, use or share the data for any purpose other than transcription of the interview recordings. A formal Data Processing Agreement (DPA) and confidentiality agreement are in place between BTHFT and the transcription provider, ensuring compliance with UK GDPR and data security requirements.

All transcription will be carried out under strict confidentiality conditions. Transcripts will be returned securely to the research team, at which point they will be checked for accuracy and anonymised. Recordings will then be securely deleted.

5 Analysis

Quantitative

The primary quantitative analyses will be done by the LSHTM Clinical Trials Unit (CTU), following the intention-to-treat principle. Our primary outcome (anxiety) will be treated as a continuous variable. We plan to estimate the effect of the intervention on anxiety using generalized estimating equations (GEE) with a Gaussian link, accounting for clustering at year group level. We will assess the distribution of the outcome and if appropriate consider bootstrapping to allow for any non-normality. In secondary analyses we will analyse dichotomous outcomes using GEEs with a log link to obtain risk ratios. The primary analysis will adjust for key factors known to be associated with outcome: age sex, ethnicity, free school meals status and SEND status. We anticipate high questionnaire completion rates, and do not expect that missing data will need to be accounted for. However, sensitivity analyses will be conducted for the primary outcome, using inverse probability weighting if there is more missing data than expected and/or differential attrition between the trial arms.

Exploratory analysis will include: (a) a pre-specified subgroup analyses for participants with high baseline anxiety (defined as participants with baseline RCADS anxiety subscale scores in the top 20%); (b) a complier average causal effect analysis using participant-level data on intervention compliance; (c) potential moderation by sex and age; (d) examination of mechanisms linking social media restriction to mental health outcomes, including sleep, social interactions, and bullying.

Qualitative

Qualitative interview data will be analysed using dimensional analysis, a variant of grounded theory that focuses on identifying and exploring relationships between key dimensions within the data to develop explanatory theory.⁽⁴¹⁾ Analysis will proceed iteratively, beginning with open coding of interview transcripts to identify relevant dimensions of participants' experiences, followed by comparison across interviews to examine how these dimensions interact with different contexts. Initial coding will be led by the qualitative researcher who conducted the interviews, with regular discussions with the wider research team to review emerging interpretations and to refine the coding framework.

The analysis will aim to develop and refine context-mechanism-outcome configuration explanations to theorise how the intervention's mechanisms operate for different students and contexts. The analysis will also explore participants' perceptions of the acceptability and perceived consequences of the intervention.

6 Approvals and governance

6.1 Ethical approvals

The research will be led by the NHS as the lead organisation is Bradford Teaching Hospitals NHS Foundation Trust. We will seek regulatory approval from the Health Research Authority and ethical approval from an NHS Research Ethics Committee. There will also be a consideration of trial ethics by the LSHTM ethics committee.

6.2 Governance

This trial is a partnership between Bradford Institute for Health Research (Bradford Teaching Hospital NHS Foundation Trust), the University of Cambridge, and LSHTM CTU. The sponsor is Bradford Teaching Hospital NHS Foundation Trust. There will be an independent Trial Steering Committee (TSC) in accordance with guidance from the World Health Organisation and UK Health Research Authority. The TSC will approve the trial protocol and monitor and supervise the trial. Membership will include an independent chair, two independent scientific members (including a statistician), a public representative, the co-Principal Investigators, and a trial advisor. Due to the short timeline of the intervention (six weeks), no interim analyses will be conducted. Given both this and the trial's low-risk nature, with severe adverse effects considered unlikely, the sponsor has decided that a separate Data Monitoring and Ethics Committee will not be established. The TSC will be responsible for evaluating adverse effects. The funder will have observer status on the TSC.

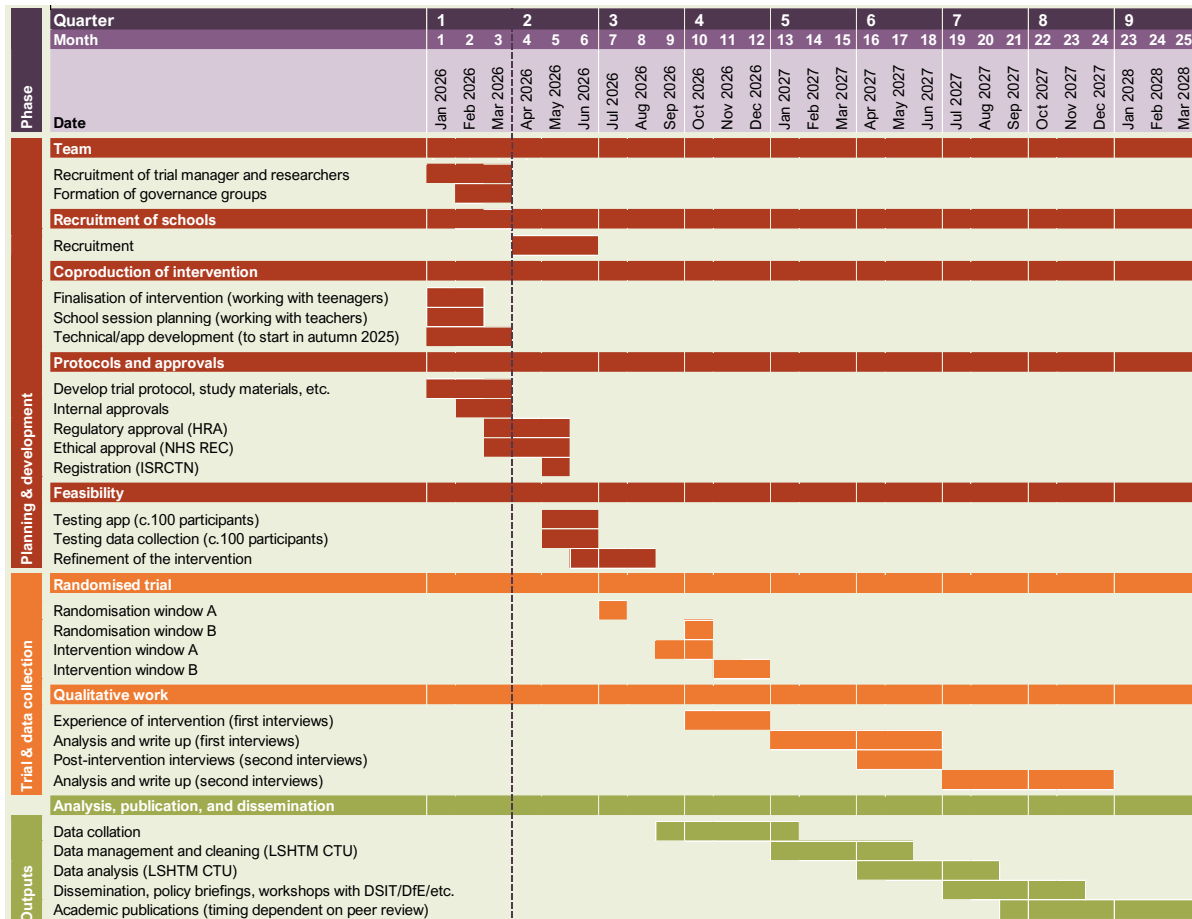
6.3 End of study definition

The end of the study will be defined as the completion of final data collection for all participants, completion of data analysis, and finalisation of the study dataset. At this point, all study procedures will be complete and identifiable data can be deleted.

7 Project timeline

School recruitment will occur from April 2026 to July 2026. We have two proposed waves for the 6-week trial: (1) between the 1 Sept 2026 and autumn half term (26-30 October 2026), and (2) after autumn half term, finishing before Christmas 2026 (see Figure 1 for the Gantt chart).

Figure 1: Gantt chart for The IRL Trial



8 Abbreviations

HRA - Health Research Authority

NHS REC - National Health Service Research Ethics Committee

ISRCTN - International Standard Randomised Controlled Trial Number

PHSE - Personal, Social, Health and Economic education

LSHTM CTU - London School of Hygiene and Tropical Medicine Clinical Trial Unit

DSIT - Department for Science, Innovation and Technology

DfE - Department for Education.

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