Non-CTIMP Study Protocol

PRoGRAM-A (Preventing Gambling Related Harm in Adolescents): a pilot cluster randomised control trial to prevent gambling harm in young people

Co-Sponsors	The University of Edinburgh and/or Lothian Health Board ACCORD The Queen's Medical Research Institute 47 Little France Crescent Edinburgh EH16 4TJ
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LIST OF ABBREVIATIONS

ACCORD	Academic and Clinical Central Office for Research & Development - Joint office for The University of Edinburgh and Lothian Health Board
CI	Chief Investigator
CRF	Case Report Form
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
PI	Principal Investigator
QA	Quality Assurance
REC	Research Ethics Committee
SOP	Standard Operating Procedure

1 INTRODUCTION

1.1 BACKGROUND

The prevalence of gambling in young people in the UK is consistently higher than other addictive behaviours. A 2019 survey of UK youth gambling found that 11% of 11-16 year olds had gambled in the past seven days, compared with 6% who smoked tobacco and 5% who had used drugs[1]. Problem gambling is also increasing among young people. In 2019 it was estimated around 1.7% (or 55,000) young people aged 11-15 experienced problem gambling, increasing from 0.4% in 2016[1].

Gambling-related harms (defined as "adverse impacts from gambling on the health and wellbeing of individuals, families, communities and society") affect young people in the present and may also affect their future potential[2]. Several observational studies have documented associations indicating gambling participation has a negative impact on children's finances, emotional and academic development, relationships, and physical and mental health, which may extend beyond childhood and into later life[2-5]. A recent Public Health England evidence review report of GRH conservatively estimated the overall economic cost of problem gambling in England to be £1.27 billion pounds, with the estimated health harm at £961.3 million pounds[6]. The review also identified peer influence as one of the key risk factors for harmful gambling among children and young people[7]. Due to the potential impact of gambling upon health and wellbeing, children and young people are generally prohibited from most forms of commercial gambling until the age of 18.

The implementation of the Gambling Act 2005 led to a rapid growth of online gambling platforms and associated marketing. The estimated spend on 'paid for' gambling advertising increased from £264 million in 2015 to £328 million in 2018[8]. The result is that in 2019 a cross-sectional survey found that 96% of 11-24 year olds had been exposed to gambling advertising in the last month[8]. Likewise, information from a national survey of children aged 11-16 found that 7% of children exposed to advertising reported that this exposure encouraged them to gamble when they were not otherwise going to do so[1]. Through advertising and sponsorship, gambling is increasingly embedded into the everyday life of young people, and along with easier opportunities to gamble, contributes to the normalisation of gambling for many young people.

This trend has been exacerbated by the increasing intersection of digital gaming and gambling. Loot boxes, skin betting, social casino games and sponsorship of e-sports teams by major gambling companies mean that young people are increasingly exposed to "gambling-adjacent" activities[9]. Evidence suggests that young people who engage in these practices report higher rates of problem gambling severity[10]. Young people are very aware of these trends, often stating that they believe these activities to be forms of gambling, despite the UK regulator not acknowledging this[9]. Taking a child-centred perspective, our study will include these types of activities within its broad definition of gambling, an approach that was supported by findings from the feasibility study which underpins this study. Our definition of gambling participation focuses on the betting or wagering of things of value (including but not limited to, flat currency, digital currency and objects of value). This includes all commercial forms of gambling (ranging from lotteries, scratchcards to online casinos and betting) and gambling-adjacent activities like loot boxes, skin betting, and social casino gambling.

1.2 RATIONALE FOR STUDY

While early intervention is considered a critical element of public health policy for tobacco, alcohol and drugs, similar efforts, especially those which are wholly independent from industry funding or influence, are lacking for gambling. This has led to calls for robust, independent early intervention to protect young people from future gambling-related harms (GRH), by delaying or preventing gambling experimentation [8, 12, 13]. To address this gap, we obtained funding from Medical Research Council Public Heath Intervention Development (ref: MR/S019200/1), to adapt a successful anti-smoking intervention (ASSIST) that has been successful in protecting young people from smoking harm (Campbell et al, 2008). This funding supported the development of PRoGRAM-A and a small feasibility study, which took place in one secondary school between August – November 2021.

1.3 Planned intervention

PRoGRAM-A is peer-led, social network intervention to protect young people, their friends and family members from gambling related harm (GRH). It is theoretically grounded in diffusion and network intervention theory. Diffusion theory (also referred to as diffusion of innovation theory), explains how new ideas and social norms are introduced and spread throughout communities[16]. The application of diffusion theory in intervention design relies on identifying influential people who have expertise and credibility among their peers to promote/create new social norms. Social networks are, therefore, a crucial component to support delivery of diffusion theory.

PRoGRAM-A is modelled on an effective school-based peer-led smoking prevention programme called ASSIST (A Stop Smoking in Schools Trial)[18, 20]. ASSIST was evaluated via a large-scale cluster randomised trial of 59 schools in South Wales and Avon. Results from the trial found that ASSIST was effective and cost effective at reducing regular smoking in young people aged 12-13[20, 22]. The aim of PRoGRAM-A is to identify ‘opinion leaders’ in S3 who are trained to become ‘peer supporters’. Peer supporters are then trained to have informal conversations with anyone in their social networks about the risks of gambling, the influence of gambling marketing, and the links between gaming and gambling. The PRoGRAM-A delivery model is summarized in Figure 1.

Figure 1: PRoGRAM-A Delivery model

1.4 Research Team

The study will be undertaken by a team of experienced academic researchers, statisticians and professionals working with young people. The research team spans the University of Edinburgh, University of Stirling, University of Cardiff, and our third sector partners with experience of intervention delivery within secondary school settings; Evidence to Impact, and Larkhall Universal Connections. The table below outlines individual team responsibilities:

Role	Institution	Name/s	Responsibilities
Chief Investigator	University of Edinburgh	Fiona Dobbie	Overall responsibility, leadership & delivery of project.
Project Manager / Senior Research Fellow	University of Edinburgh	Angela Niven	Day to day management. Responsible for: protocol, ethics, reporting, liaising with funder & team, introductions with schools, support PPI strand
Co-Investigator	University of Edinburgh	Christopher Weir	Lead on trial design and offer advice and support on statistical analysis and reporting
Co-Investigator	University of Edinburgh	Martine Miller	Process evaluation lead, Co-lead for PPI (with Conor Maxwell), supporting manual update (with Sally Good and Ashley Lee and input from Heather Wardle, Richard Purves and Leon Noble)

Co-Investigator	University of Edinburgh	Andy Stoddart	Lead health economics study (with support from process evaluation team, led by Martine)
Co-Investigator	Centre for Trials Research / DECIPHer, Cardiff University	Jamie White	Provide strategic and operational support on conducting school RCTs and mentor FD
Co-Investigator	University of Glasgow	Heather Wardle	Provide expertise in young people and gambling, will contribute to interpretation, analysis and impact. Will also assist in PRoGRAM-A manual review and update
Co-Investigator	University of Stirling	Dave Griffiths	Lead social network analysis.
Co-Investigator	University of Stirling	Richard Purves	Expert in gambling marketing and qualitative methods, will contribute to process evaluation and assist in PRoGRAM-A manual review and update (specifically section on gambling marketing)
Co-Investigator	Larkhall Universal Connections	Conor Maxwell	Expert in peer support and youth work, will co-lead PPI with MM and support from Project Manager.
Research Assistant	University of Edinburgh	Leon Noble	Assist in all aspects of set up set-up and delivery, help conduct fieldwork, analysis and reporting.
Collaborators	Evidence to Impact	Sally Good, Paul Harrod and Ashely Lee	Lead intervention delivery (not school recruitment). Identify and manage trainers, develop and deliver train the trainer training and conduct quality assurance of PRoGRAM-A delivery; support development of the scalability plan; support delivery manual updates and lead on website design and content.
Collaborators	Fast Forward	Francesca Howard	Support development and delivery of the train the trainer training, offer advice and support and support school recruitment through their existing network of school contacts across Scotland
Statistician	University of Edinburgh, ECTU	Hannah Ensor	Student survey analysis
Database and data management	University of Edinburgh, ECTU	Kenton D'Mellow, Tim Duncan, Chris White	REDCap database, randomisation, data management.

2 STUDY AIM AND RESEARCH QUESTIONS

2.1.1 Overall aim

The overall aim of the study is to conduct a pilot cluster randomised control trial (cRCT) of a gambling prevention intervention among young people aged 13-15 to determine the utility of conducting a Phase III RCT assessing effectiveness and cost-effectiveness.

2.1.2 Secondary research questions

Our research questions are grouped under two blocks:

Recruitment and randomised trial delivery

1. Can a sufficient number of schools and students be recruited, randomly allocated and retained?
2. How can the collection of baseline and follow-up data be optimised?
3. What gambling prevention activities occur in control schools and how is the impact perceived?
4. Following the pilot cluster RCT (cRCT), is a Phase III cRCT justified in relation to our progression criteria?

Acceptability, feasibility and fidelity of intervention delivery

5. Is it feasible and acceptable to implement the intervention in four schools?
6. What do qualitative and quantitative data suggest in terms of refinements to programme theory, implementation, fidelity, reach, scalability and acceptability?
7. Are there potential harms and unintended consequences of the intervention? How might these be reduced? How can these be measured?
8. What characteristics are associated with being nominated as a peer supporter?
9. What is the potential and actual extent of message diffusion in peer supporter networks and to whom and why?
10. What contextual factors influence message diffusion (e.g. size of student networks, where, when and how conversations are initiated, what communication methods are used, what is discussed? level of peer supporter confidence)
11. What are the key issues to consider to support future scalability?
12. What are the direct implementation costs associated with delivering PRoGRAM-A
13. What economic measures are appropriate and available for use in a future health economic evaluation as part of a definitive cRCT?

2.2 OUTCOME MEASURES

The primary outcome for this pilot trial is whether progression to a full-scale Phase III cRCT of the intervention is warranted. This will be assessed against the following progression criteria:

Progression Criterion	Red	Amber	Green
1. Successful recruitment of six schools	<6		6
2. Five schools remain in the pilot study	<4	4	≥5
3. The intervention being delivered with 80% fidelity to the manual	≤69%	70-79%	≥80%
4. The process evaluation indicates the intervention is acceptable to students and staff	Low	Medium	High
5. 70% of students complete the student questionnaire at baseline and follow-up	≤59%	60-69%	≥70%

3 STUDY DESIGN

3.1 Study design summary

The study design for PRoGRAM-A is comprised of an 18 month, two-arm, pilot cluster RCT with an embedded process evaluation (which will include social network analysis and a health economic study) conducted in six schools. The study will be based in state-funded secondary schools in Scotland. Students will be asked to complete a baseline student survey (See Section 6.1) assessing gambling attitudes, awareness and behaviour, four schools will be randomised to receive the intervention (PRoGRAM-A) and two will continue with usual practice. The two comparator schools have been included to test the acceptability of randomisation.

3.2 Process evaluation

Following the MRC guidelines for process evaluations of complex interventions with a focus on implementation, our mixed methods process evaluation (summarised in Table 1) will: examine intervention feasibility, fidelity, reach and acceptability; provision of education on GRH in all six schools to assess potential contamination; and explore context and potential mechanisms of action, including unintended effects. It will also inform the health economic scoping study and the social network work analysis.

Table 1: Process evaluation summary

Research method	**Sample group**	**Timescales**	**Key area covered**
Semi-structured interviews	• Trainers (n=4) • Teaching staff (n=6) Intervention schools only (n=4) • Key stakeholders (n= 8-10 Government policy leads, Directors of Education, Gambling Commission) • Alters (peer supporter friends and family members, n=10-12)	Months 12-14	Acceptability and feasibility of intervention; mechanisms of change Health economic outcomes of interest assessment (see section 3.12)
Mini focus group discussion/paired interviews	• Peer supporters (n=8 groups in total, 2 per intervention school (approximate sample size of 32-48) • Students who were not nominated to become a peer supporter (intervention schools only, 2 groups in total, one per school (approximate sample size of 8-16)	Months 12-14	Acceptability and feasibility of intervention; mechanisms of change

Observation	Using a semi-structured observation log book, two entire delivery cycles of PRoGRAM-A will be observed, in two separate schools.	Months 4-12	Fidelity of delivery
Social network data	• Whole school network constructed from baseline survey • Peer support network sociograms (approximate sample size of 32-48)	Months 4-6 and 14-16	Contamination, reach, mechanisms of change, feasibility of intervention; equality of diffusion

The teaching staff invited to interview will be those involved in the practical aspects of the study. Mixed gender groups are not always the best way to encourage pupils to speak up so school staff will be involved in discussions when arranging focus groups/paired interviews with pupils. In all instances gender balance will be taken into consideration.

3.3 Health economic evaluation

A health economic scoping study will be integrated with the process evaluation. Stakeholder consultation exercises will be built into the qualitative interviewing to identify economic outcomes of interest to different stakeholder groups with a view to developing recommendations for cost-consequence and/or social return on investment analyses for a Phase III future trial.

The following intervention delivery costs will be considered in the pilot study: staff time, equipment, and materials for training sessions plus overheads and any additional items identified through consultation with associated staff.

3.4 Adaptation of the ATGS-8 gambling attitudes scale

As no validated instrument for the systematic measurement of gambling attitudes among adolescents exists, we will work with our PPI group and /or with one or more of our survey schools to adapt the eight-item Attitudes To Gambling Scale (ATGS-8) validated for use among the general population.

4 STUDY POPULATION

4.1 NUMBER OF PARTICIPANTS

Six schools across Scotland will take part in the study (four intervention, two control). Depending on the size of the school, the year group size for S3 students could vary between 100-150 students. The projected sample size for the baseline survey is between 510-765 students with approximately 100-150 children from each secondary school.

4.2 INCLUSION CRITERIA

Students in S3 aged between 13-15 years who give their assent to take part in the study.

4.3 EXCLUSION CRITERIA

- Schools for young people with special needs
- Residential schools
- Students who do not give their assent
- Student parent/carer who opt their child out of the study or do not give consent for peer supporter training
- Schools who do not consent to participate.

5 PARTICIPANT SELECTION AND ENROLMENT

5.1 IDENTIFYING PARTICIPANTS

Schools will be invited to take part by approaching Local Authorities across Scotland (South Lanarkshire, West, East and Mid-Lothian, Edinburgh City, Glasgow City, Dundee City, Angus, and Perth and Kinross and Clackmannnshire). Members of the team have existing contacts with secondary schools in these areas and some of them have already agreed to take part of the funding application.

The entire school year (S3) student population will be eligible to take part for each participating school. Prior to commencement of the study, an information letter will be sent to parents/carers to notify them that their child's school is participating in a pilot trial of PRoGRAM-A and give them the option to withdraw their child from data collections if they do not want them to take part. Prior to baseline data collection, written student assent will be obtained.

As mentioned in section 1.3 (and illustrated in Figure 1) PRoGRAM-A is comprised of a four stage model, each stage is explained further below with detail on how participants will be identified.

Stage 1: Peer nomination. Peer supporters will be identified through a process of 'peer nomination', conducted in schools via completion of a short survey. This is completely separate to the student baseline survey and requires students to write down the name of a fellow student in their year in response to the following three questions:

- Q1 - Who do you respect in **your year** at your school?
- Q2 - Who are good leaders in sports or other group activities in **your year** at your school?
- Q3 - Who do you look up to in **your year** at your school?

Students are asked to list up to five people in their year group in response to the three questions above.

Stage 2: Peer recruitment. After peer nomination, PRoGRAM-A trainers will score the student responses to create a list of the top 18% most nominated students across the S3 year group.

The peer nomination process is conducted under exam conditions. This is a tried and tested method that has been used in the previous ASSIST model and in our PRoGRAM-A development study. While there is potential for pupils to feel under pressure or stressed to

nominate their peers, pupils will be assured that this process is confidential and that their nominations will not be made available to anyone other than the PRoGRAM-A trainers.

The list of selected students will be passed to the school contact member of staff, who will inform students on the list that they have been nominated by their fellow students to take part in PRoGRAM-A. Students, will then be encouraged to come along to a recruitment meeting. This meeting will be delivered by the PRoGRAM-A trainers where they will explain more about the role and what is required. Students will then have time to decide if they want to become a Peer Supporter or not.

Stage 3: Peer supporter training. Peer supporters will require written consent from their parent/carer to attend the training workshop. Peer Supporters will take part in an interactive session that, in day 1, will cover four main themes that will encourage them to think critically about their own and others' exposure to gambling, and in turn, to minimise their risk of experiencing gambling-related harms. The four main themes covered in the workshop are:

- What is gambling?
- Gambling and Gaming
- Gambling advertising and marketing
- Gambling related harm and keeping safe

Day 2 of the training workshop focuses on developing Peer Supporters social skills and confidence when approaching and starting up conversations with their friends and family. After attending the two day workshop, Peer Supporters will have created a social network map that will help them to identify friends and family to initiate a conversation with. Over a 10-12 week period, Peer Supporters will be asked to have informal conversations based on what they have learned from the training and the additional resources available to them (e.g. PRoGRAM-A website, banner pen with facts to share.)

Stage 4: Follow-up sessions. Peer Supporters will receive three follow-up sessions within school with PRoGRAM-A trainers. These sessions are both interaction and supportive, with the aim to help peer Supporters discuss any issues that have had and/or identify new people within their network that they would like to approach. The sessions can also be an opportunity to readdress any topic materials that Peer Supporters feel are required.

Stakeholders will be identified via our existing networks and emailed directly by a member of the research team and invited to take part in the study. Teaching staff (1 from each of the six schools) will be invited to take part via email by a member of the school's senior management team. They will be invited to opt-in to interview by contacting the research team directly. This will mitigate the risk of coercion. Trainers will be invited to take part directly by a member of research team and social network members will be recruited using 'respondent driven sampling'. Due to data protection regulations, peer supporters cannot volunteer contact details for members of their social network. Peer supporters will, therefore, be provided with 'opt-in' invites to pass onto people in their social network which will contain a study information leaflet, with options to contact the research team to opt-in to the study for interview (i.e. study email or a mobile contact number).

Some Peer Supporters will be asked if they would like to take part in a short video recorded discussion about taking part in the study. Clips from some of the video recordings will be used in a findings webinar that will be seen by professionals in government, education and public health sectors. They will also be seen by schools that took part in the study along with other schools interested in taking part in future studies. The webinar will be publicly available

on the PRoGRAM-A website. Written consent/assent will be sought from parent/carers and Peer Supporters.

5.2 CONSENTING PARTICIPANTS

Prior to entering schools, school staff will provide information sheets and opt-out consent forms one week in advance for students to take home to their parents'/guardians. Study information will discuss how the school will be participating in a public health intervention. If parents/guardians **do not** wish their child to participate in the intervention (baseline and follow-up survey), they will be asked to return the opt-out consent form.

Prior to baseline data collection, written student assent will be obtained.

As noted in section 5.1, students who have been nominated by their year group will be invited by a member of school staff to attend an information session run by PRoGRAM-A trainers within their school. This will explain what it is involved and it is up to the student to decide whether they want to take part as a peer supporter or not. At the end of this session, students will be provided with an information sheet and assent form to take away and consider whether they would like to become Peer Supporters. Students who decide to become a Peer Supporter must return their signed assent forms along with their signed parental consent form to their PSE teacher before they can attend the training session.

Students will not receive any financial payment for taking part, but schools will be given a payment of £500 to cover any back fill costs for staff time or put towards school funds for student activities.

Stakeholders, teaching staff and trainers will not receive any financial contribution for taking part, but parents/carers and social network members will receive a £30 voucher as a thank you for their time. Stakeholders, teaching staff, trainers and social network members will be all be required to given written or recorded verbal informed consent prior to fieldwork and will be reassured that their data will be stored securely and anonymised.

5.2.1 Withdrawal of Study Participants

Participants are free to withdraw from the study at any point. The participant will have the option of withdrawal from all aspects of the trial but continued use of data collected up to that point. To safeguard rights, minimum personally identifiable information will be collected, and a withdrawal form completed. The trial management and trial steering committee will monitor these withdrawals from the trial.

Participants will be informed that up to the point of analysis of data, their transcripts or questionnaire data will be deleted, if they so wish. However, in the event that analysis has begun, participants will be informed that it will no longer be possible to delete the information they have provided. The research team will stress that all identifiable information will have been removed from the data that they have provided and it will no longer be possible to identify them from any write ups/analysis.

6 DATA COLLECTION

The following data will be collected describing the characteristics of schools invited to take part: those that accepted and declined: location (SIMD for the location of school); total

student population for S3; whether any gambling prevention education is taught and what it comprises of.

6.1 Quantitative Data

Pre randomisation, baseline data will be collected using a self-reported student survey with the entire year group in all six study schools. Follow up surveys will occur six months post baseline in all six schools. Surveys will assess: attitudes, awareness and knowledge of gambling, gambling harm and gambling marketing and self-reported gambling behaviour. In addition, there will be collection of routine monitoring data on: student attendance for peer nomination; peer supporter recruitment meeting; peer supporter training; training and follow-up sessions.

6.1.1 Process for quantitative data collection

Baseline and follow-up questionnaires will be completed in school assembly or PSE (personal and social education) lesson times. The research team will be on site to facilitate survey completion with assistance from school staff. When questionnaires are complete, students will place them into a sealed envelope and a member of the research team will collect and return them to the University of Edinburgh. Questionnaires will then be stored in a locked drawer in the research team's locked office and the data entered on to the study database on REDCap. A member of the research team will revisit schools where there were students absent on the day the questionnaire was delivered to facilitate survey competition.

6.2 Qualitative Data

Focus group and individual interviews will be recorded using encrypted digital recorders. Audio files will be uploaded to a secure folder within the encrypted project folder on DataStore. Lesley Gardner, a member of staff within the Centre for Population Health Sciences, Usher Institute, University of Edinburgh, will transcribe all audio files. Ms Gardner, will have access to the secure folder and will then upload completed transcribed documents into the secure folder. When audio files have been transcribed and checked, audio files will be deleted.

6.3 Case Report Forms (Survey Data)

Survey data will be collected on paper and then entered on to an electronic data collection system (REDCap) which will be set up by the Edinburgh Clinical Trials Unit (ECTU) using local software. There will also be the option for pupils to enter their survey data directly on to REDCap if the school prefers. The survey data collected on paper will be sent to Adetiq Ltd – an accredited data processing company to complete data entry. They will return the survey data on an encrypted spreadsheet for direct upload to REDCap. They will not have access to the REDCap study database or any identifiable data. The study database will be created and maintained by ECTU. The database will be compliant with the relevant regulations and sponsor Standard Operating Procedures (SOPs). Trained members of the research team will be given password protected logins to the database. The data will be stored on a secure server in the University of Edinburgh.

7 DATA MANAGEMENT

7.1 Personal Data

For each participant we will collect the minimum level of personal detail (see Table 2 below). All data will be stored on the University of Edinburgh's networked storage space, DataStore DataStore is accessed via password protected desktops or encrypted laptop. Files holding sensitive information such as raw data, participant information, etc. will be held in a separate folder within the encrypted project folder on DataStore. DataStore will be accessed via password protected desktops and an encrypted laptops. Once the data collection is complete and transcripts checked interview and focus group discussion recordings will be deleted.

Assent forms and parental opt-out forms for the survey data collection, along with assent and consent forms for becoming a peer supporter will be kept in a locked cabinet in the research team's locked office. All trial related documents will be archived for five years in accordance with the Sponsor's archiving policy unless an alternative longer archiving period is specified by the Sponsor or the funder.

Consent/Assent forms for the Process Evaluation aspect of the study will be scanned and saved electronically in the secure project folder. They will then be destroyed. Verbal consent (where relevant and only in the case of telephone interviews with service staff/professionals) will be recorded on an encrypted digital recorder and uploaded into an encrypted folder on DataStore. The researcher will talk through each item on the consent form and obtain verbal consent for each item from the participant. The recording will be deleted from the digital recorder immediately after uploading to DataStore.

Prior to being destroyed, all paperwork will be kept in a locked cabinet in the research team's locked office (pin entry system) in room 2.682, Doorway 1, Old Medical Building, Teviot place, University of Edinburgh, EH8 9AG.

Participant information sheets and consent/assent forms have been designed to inform participants about the nature of the research and outline what will happen to the information provided throughout the fieldwork period. Researchers will also address and queries or concerns that participants may have.

Table 2: Personal data to be collected

Study Component	Mode	Type of Participant	Age	Male/ Female	Ethnicity	Role/relationship to peer supporter	School/ Venue	Contact (mobile/email)
Delivery	baseline/ follow-up survey	S3 student	✓	✓	✓		✓	
Process Evaluation	Individual interview	School staff., friends or family of peer supporters	✓	✓		✓	✓	✓

Process Evaluation	Focus group	Peer supporters	✓	✓		✓	✓	✓

7.2 Data Information Flow

For each participant group we will collect the minimum level of personal detail. No personal contact details will be collected except for friends and family members of peer supporters. In this instance, friends and family of peer supporters will be provided with information about the interview and asked to opt-in to taking part in an interview. Participants who opt-in will provide the research team with contact details in order to arrange a convenient time to conduct an interview. The research team will only store contact details for the duration of the study (18 months). All personal contact details will be deleted at the end of the study.

All participants will be assigned a unique ID and any reports incorporating participant quotes will use a pseudonym.

Project data will be retained securely in line with University of Edinburgh research governance and NIHR requirements until the process of peer-reviewed publication is complete. Destruction or secure archiving for research, historical and statistical purposes will then be undertaken in line with regulations in place at that time. Non- identifiable data will be held in a designated folder in a secure datastore in line with regulations in place at that time. These files will only be accessible by the researchers on the team. The files will include the dataset, the coding framework (which will be made publicly available) and the results of the analysis.

Data flow table

Throughout the project set up and delivery, all data will be stored on DataStore. At the end of the project lifecycle, data will be archived using DataVault.

Project set up and delivery		End of project archiving
DataStore	DataSync (where appropriate for sharing files with research team outwith University of Edinburgh	All data from the study will be achieved on DataVault

7.3 External Transfer of Data

Identifiable data collected or generated by the study (including personal data) will not be transferred to any external individuals or organisations outside of the Sponsoring organisation(s).

7.4 Data Controller

The University of Edinburgh is the data controller for the current study.

7.5 Data Breaches

Any data breaches will be reported to the University of Edinburgh (dpo@ed.ac.uk) Data Protection Officers who will onward report to the relevant authority according to the appropriate timelines if required.

8 STATISTICS AND DATA ANALYSIS

8.1 CLUSTER RANDOMISATION

Clusters (schools) will be randomised using a remote web-based randomisation system set up by Edinburgh Clinical Trials Unit in order to conceal the allocation sequence. The randomisation will be stratified by school size (</ >=200 pupils on the school roll in 3rd year). The randomisation ratio is 2:1 PRoGRAM-A intervention to comparator group within each stratum. The allocation sequence will be stored on a secure server and concealed from all personnel involved in the trial. It will be created, using computer-generated pseudo random numbers, by a clinical trials unit member of staff with no link to, or contact with, any of the participating schools.

Once all schools have been identified, confirmed they wish to take part, and baseline forms have been completed, a designated member of the trial team will contact the ECTU data management team requesting the randomised assignment of all schools. These assignments will then be communicated to the schools by the trial team member. Prior to baseline form completion all trial team members, schools and pupils will be blinded; after this point all these stakeholders will be unblinded.

8.2 SAMPLE SIZE CALCULATION

Using a conservative assumption of 85%[22] for attendance on the day of baseline survey and assent to participate, this gives a projected sample size for the baseline survey of between 510-765 students. This range of sample size will enable the proportion of enrolled students completing the baseline questionnaire to be estimated with 95% confidence interval width +/-2.3% to +/-2.9%, informing planning of the definitive trial.

8.3 PROPOSED ANALYSES

Statistical analysis: Findings from the pilot cRCT will be reported using the CONSORT guidelines for pilot and cluster RCTs. The primary analysis of the pilot trial will determine whether the pre-specified criteria for progression to a full-scale Phase III trial are met. Analyses will be primarily descriptive, providing realistic estimates of recruitment, response and retention rates. Recruitment and retention of schools and students will be summarised in CONSORT flow diagrams. The proportion (and exact binomial 95% confidence interval, CI) of students assenting to participate will be estimated, overall and stratified by school. The proportion of students (and exact binomial 95% CI) completing baseline and follow-up questionnaires (progression criterion 5) will be reported overall and by school. We will

summarise demographic characteristics of students by randomised group and by school using descriptive statistics.

For each of the quantitative outcome measures on gambling participation, harms, knowledge and attitudes, the proportion of missing data will be reported overall, by intervention group and by school. Data will be summarised descriptively by randomised group and by school, recording the potential for floor and ceiling effects. We will then pilot the analyses of outcomes that would be performed in a full-scale trial. Outcomes at follow up will be analysed by multi-level regression modelling, adjusting for baseline values. Estimates for differences between intervention and control (odds ratios, mean differences) will be adjusted for clustering (students nested within schools) and presented alongside 95% CIs. We will also make preliminary estimates of the clustering of outcomes within schools by estimating intra-cluster correlation coefficients (and 95% CIs). As this is a pilot trial, not powered for effectiveness, no hypothesis testing will be performed and no p-values presented.

Qualitative analysis

Interviews and mini/focus groups will be digitally recorded and transcribed verbatim. We will use a thematic approach to analyse the data (including observational data), facilitated by NVivo 12. First, we will read the transcripts to identify the key topics and issues which emerge from data. Next, a draft analytical framework will be created, piloted, refined and finalised by the project team. Each transcript will then be coded and summarised into key themes using Framework matrices, or charts. This approach reduces large volumes of data and facilitates systematic between and within case analysis. The use of NVivo 12 ensures that analysis is fully documented and conclusions can be clearly linked back to the original source data.

Social network analysis

All social network analysis data will be created in CSV files and analysed in R. For each *peer supporter* an anonymized ego-network will be produced. This will include contextualizing information on alters (e.g. age, gender, ethnicity etc.), whether a conversation had taken place and an assessment of perceived impact. To evaluate the scope of the intervention in terms of reach and equality of access, social network measures will explore who is selected, based on both personal (socio-demographic) and network characteristics (centrality and clusters within ego-network). This will facilitate exploration of the potential and actual reach by each peer supporter, including peer supporter perception of the impact of conversations. The effectiveness of peer supporter selection will be assessed by mapping the structure of respondent's ego-network (such as density and centralization) and positioning of individuals talked to against perceived outcomes, including monitoring of socio-demographic differences in terms of who the intervention reached. Comparing the actual and anticipated flows of the intervention by comparison to the baseline survey will provide important insights for how to exercise best practice in the selection of peer supporters for further projects utilizing similar methods.

Analysis of the *whole school year network*, gathered from the baseline survey, will identify inequalities around who the intervention reaches. This will enable more robust understanding of the mechanisms of change within the year group, as well as identifying whether particular individuals, or cliques, are reached by different peer supporters. Perception of impacts on the nominated friends of those that the peer supporters spoke to will provide an understanding of spread. Such analyses will also help determine overlap in social connections, providing estimations of likely crossover of receiving the intervention amongst the wider community.

9 GOOD CLINICAL PRACTICE

9.1 ETHICAL CONDUCT

The study will be conducted in accordance with the principles of the International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice (ICH GCP). Before the study can commence, all necessary approvals will be obtained and any conditions of approvals will be met.

9.2 INVESTIGATOR RESPONSIBILITIES

The Investigator is responsible for the overall conduct of the study at the site and compliance with the protocol and any protocol amendments. In accordance with the principles of ICH GCP, the following areas listed in this section are also the responsibility of the Investigator. Responsibilities may be delegated to an appropriate member of study site staff.

9.2.1 Informed Consent

The Investigator is responsible for ensuring informed consent/assent is obtained before any fieldwork take place. The decision of a participant to participate in research is voluntary and should be based on a clear understanding of what is involved.

Participants must receive adequate oral and written information – appropriate Participant Information and Informed Consent/Assent Forms will be provided. The oral explanation to the participant will be performed by the Investigator or qualified delegated person, and must cover all the elements specified in the Participant Information Sheet and Consent Form. The participant must be given every opportunity to clarify any points they do not understand and, if necessary, ask for more information. It should be emphasised that the participant may withdraw their consent/assent to participate at any time without loss of benefits to which they otherwise would be entitled.

The Investigator or delegated member of the study team and the participant will sign and date the Informed Consent/Assent Form(s) to confirm that consent/assent has been obtained.

9.2.2 Data Protection Training

All University of Edinburgh employed researchers and study staff will complete the Data Protection Training through Learn.

9.2.3 Information Security Training

All University of Edinburgh employed researchers, students and study staff will complete the Information Security Essentials modules through Learn and will have read the minimum and required reading setting out ground rules to be complied with.

10 STUDY CONDUCT RESPONSIBILITIES

10.1 PROTOCOL AMENDMENTS

Any changes in research activity, except those necessary to remove an apparent, immediate hazard to the participant in the case of an urgent safety measure, must be reviewed and approved by the Chief Investigator.

Proposed amendments will be submitted to the Sponsor for classification, review and authorisation.

Amendments to the protocol must be submitted in writing to the Edinburgh Medical School Research Ethics Committee for approval prior to implementation and prior to participants being enrolled into the amended protocol.

10.2 SERIOUS BREACH REQUIREMENTS

A serious breach is a breach which is likely to effect to a significant degree:
(a) the safety or physical or mental integrity of the participants of the study; or
(b) the scientific value of the study.

If a potential serious breach is identified by the Chief investigator, Principal Investigator or delegates, the Sponsor(s) (qa@accord.scot) must be notified within 24 hours. It is the responsibility of the Sponsor(s) to assess the impact of the breach on the scientific value of the study, to determine whether the incident constitutes a serious breach and report to research ethics committees as necessary.

10.3 INSURANCE AND INDEMNITY

The Sponsor(s) are responsible for ensuring proper provision has been made for insurance or indemnity to cover their liability and the liability of the Chief Investigator and staff.

11 AUTHORSHIP POLICY

Ownership of the data arising from this study resides with the study team.

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DOCUMENT HISTORY

Version No	Date	Summary of Revisions
1.0	06 June 2023	Initial Protocol - Not implemented
2.0	07 Aug 2023	Addition of progression criteria, further detail re statistical analysis and randomisation. Clarifications re consent/assent. Admin changes.
3.0	07 Nov 2023	Addition of information relating to outsourcing of questionnaire data entry and returning to schools to collect data from missing pupils. Addition of information regarding the adaption the ATGS-8 scale
4.0	15 Dec 2023	Clarifications regarding progression criteria and process evaluation interviews
5.0	01 Oct 2024	Addition of the request for some Peer Supporters to take part in video recorded discussions for use in study webinar.