Multimodal Approach to Preventing Suicide in Schools (MAPSS) project: A regionally based feasibility trial of an integrated response to suicide risk among secondary school pupils

STUDY PROTOCOL

Liverpool John Moores University

FULL/LONG TITLE OF THE TRIAL

Multimodal Approach to Preventing Suicide in Schools (MAPSS) project: A regionally based feasibility trial of an integrated response to suicide risk among secondary school pupils

SHORT TRIAL TITLE / ACRONYM

MAPSS Feasibility Study

PROTOCOL VERSION NUMBER AND DATE

1.0 19th January 2024

RESEARCH REFERENCE NUMBERS

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FUNDERS Number:	NIHR156862
REC	Liverpool John Moores University Research Ethics Committee (ref 23/PSY/003).

This protocol has regard for the NHS Health Research Authority (HRA) guidance and order of content.

KEY TRIAL CONTACTS

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Sponsor	School of Psychology, Faculty of Health, Liverpool John Moores University
Funder(s)	National Institute for Health and Care Research: Public Health Research Programme Cheshire and Merseyside Public Health Collaborative
Clinical Trials Unit	N/A
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Committees	Trial Steering Committee, Public Advisory Group and Young People's Public Advisory Group Contact details as above (Chief Investigator)

i. LIST of CONTENTS

ii. LIST OF ABBREVIATIONS

AE	Adverse Event
CBT	Cognitive Behavioural Therapy
Co-I	Co-investigator
CTU	Clinical Trials Unit
CYP	Children and Young People
ICF	Informed Consent Form
MAPSS	Multi-Modal Approach to Preventing Suicide in Schools
NHS R&D	National Health Service Research & Development
PI	Principal Investigator
PIS	Participant Information Sheet
PAG	Public Advisory Group
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
STB	Suicidal Thoughts and Behaviour
T	Timepoint
TSC	Trial Steering Committee
YP	Young People
YPAG	Young People's Public Advisory Group

iii. TRIAL SUMMARY

Trial Title	Multimodal Approach to Preventing Suicide in Schools (MAPSS) project: A regionally based feasibility trial of an integrated response to suicide risk among secondary school pupils	
Internal ref. no. (or short title)	MAPSS Feasibility Study	
Trial Phase	Feasibility	
Trial Design	Two-arm cluster RCT, with mixed-methods implementation and process evaluation	
Trial Participants	Young people aged 14-15 in Year 10 in secondary schools across Cheshire and Merseyside. School staff and intervention deliverers.	
Planned Sample Size	Approximately 810 young people across six schools (average 135 pupils per school).	
Treatment duration	4 months	
Follow up duration	12 months after start of intervention	
Planned Trial Period	01/02/24 Start 31/01/26 End	
Control	Usual practice	
	Objectives	Outcome Measures
Primary	The primary aims of this study are to assess: 1) The acceptability and safety of conducting a trial of a suicide prevention programme in a school setting, operationalised in terms of adverse events and self-reported adverse consequences at post-intervention assessments. 2) The social validity (feasibility, utility, and acceptability) and implementation (including fidelity, quality, and dosage) of the MAPSS intervention, through a process evaluation consisting of bespoke quantitative surveys and qualitative interviews and focus groups. 3) The feasibility of delivering a large-scale, appropriately powered, cluster-RCT with economic evaluation in the future, including assessment of	*Acceptability:* Operationalised in terms of acceptability of the intervention. The proportion of pupils who complete all agreed sessions will be recorded (>60% excellent. 40%-60% acceptable; <40% not acceptable) on the Reframe IT-UK website. Acceptability of the suicide prevention lesson, including whether or not participants thought it was “useful”, “interesting”, or “upsetting”, will be assessed at T2 only using purpose designed items. Participant views on the Reframe IT-UK intervention will be assessed at T3. *Social validity:* We will test this through a process evaluation using bespoke quantitative surveys following the delivery of each component of the MAPSS programme at T2 and T3. We will

	recruitment methods, retention rates, and outcome measures-and to assess links between these short-term trial outcomes and longer terms costs and outcomes.	also conduct qualitative interviews with staff and focus groups with pupils across the study period. *Feasibility of the trial:* We will collect data on1) the missing data on completed assessment (<15%); 2) change or variability on outcome measures (e.g., suicide ideation, depressive or hopelessness symptoms); and, 3) whether schools implemented and supported the accessibility of the online intervention.
Secondary	We aim to test the following as secondary outcomes: 1) Comparison of suicide literacy and help-seeking intentions for suicidal thoughts or behaviours between the control group and pupils attending the suicide prevention workshop. 2) The identification of pupils at-risk of suicide who had not previously sought help. 3) Comparison of suicidal ideation, depression, and hopelessness between the control group and pupils in the Reframe IT-UK intervention group. 4) Rates of health-service use to inform an economic evaluation - levels of health-related quality of life. 5) Help-seeking intentions from informal sources.	1) Change in past four-week suicidal ideation at T3 and T4, compared to T2, assessed via the Suicide Ideation Attributes Scale (SIDAS). The SIDAS is a self-report measure designed to screen individuals in the community for presence of suicidal thoughts and assess the severity of these thoughts. 2) Change in symptoms of depression at T3 and T4, compared to T2 and T1, assessed using the Patient Health Questionnaire – 9 item version. 3) Changes in hopelessness at T3 and T4, compared to T2, will be assessed using the Brief-H-Pos, a 2-item positively worded measure of hopelessness. 4) Differences in health service use and other resource use (education and local authority) comparing intervention and control group at T2, T3 and T4, using a bespoke questionnaire adapted from the Young Mind Matters Service Use questionnaire. 5) Purposefully designed questions on intentions to seek help from informal sources. 6) Change in health-related quality of life (T1, T2, T3, T4), assessed using the Child Health Utility–9 (CHU9D). The CHU9D

		can be used to derive quality-adjusted life years (QALYs). These data will be used in combination with data from 3) above, to assess the feasibility of the full economic evaluation. 7) Change in suicide literacy at T2, T3 and T4, compared to T1, assessed using an adapted version of the Literacy of Suicide Scale (LOSS).

iv. FUNDING AND SUPPORT IN KIND

FUNDER(S)	FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN
NIHR Public Health Research Programme Tel: 023 8059 9697 Email: phr@nihr.ac.uk	Research grant funding
Cheshire and Merseyside Public Health Collaborative (CHAMPS) PO Box 290 Brighton Street Wallasey CH27 9FQ Tel: 0151 666 5123 Email: champscommunications@wirral.gov.uk	Intervention commissioning
Grassroots Suicide Prevention 113 Queens Road, Brighton, BN1 3XG Tel: 01273 234834	Intervention delivery
Papyrus UK Suicide Prevention Bankside 2, Crosfield Street, Warrington, Cheshire, WA1 1UP Tel: 01925 572 444 Email: admin@papyrus-uk.org	Intervention delivery
Orygen 35 Poplar Road, Parkville, Victoria, 3052, Australia Tel: +61 3 9966 9100 Email: suicideprevention@orygen.org.au	Intervention delivery
Liverpool John Moores University Research and Innovation Services, 1st Floor Exchange Station, Tithebarn Street, Liverpool, L2 2QP Tel: 0151 231 2121 Email: RIS@ljmu.ac.uk	Sponsorship

v. ROLE OF TRIAL SPONSOR AND FUNDER

The study is sponsored and insured by Liverpool John Moores University (LJMU) and will be managed by that institution, in accordance with relevant current policies and standard operating procedures including those pertaining to informed consent, indemnity, data protection and data storage. The study will be managed in collaboration with co-investigators. The study sponsor will have no influence over the study design, conduct, data analysis and interpretation, manuscript writing, or dissemination of results.

The study is funded by the NIHR Public Health Research Programme (NIHR156862). The funder will have no influence over the study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results. It is a contractual requirement that NIHR-funded researchers provide notification and final copies of all their research outputs to the NIHR at least 28 days before they enter the public domain.

Research outputs include research papers and press releases. Research outputs will appropriately acknowledge all NIHR funding and support received for the research and include the NIHR disclaimer. Outputs may display the 'Funded by NIHR' logo, where appropriate.

vi. ROLES AND RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

- Trial Steering Committee (TSC)

The TSC has a majority independent representation, including the Chair. The group includes academics, health professionals, public health, lay members and patient representatives Data Monitoring (and ethics) Committee (DMEC).

The DMEC includes independent committee members who are completely uninvolved in the running of the trial and who cannot be unfairly influenced (either directly or indirectly) by people, or institutions, involved in the trial. The group includes academics, health professionals, public health, lay members and patient representatives.

- Trial Management Group

The Trial Management Group will include all trial investigators. The group will meet monthly to ensure all practical details of the trial are progressing well and working well and everyone within the trial understands them.

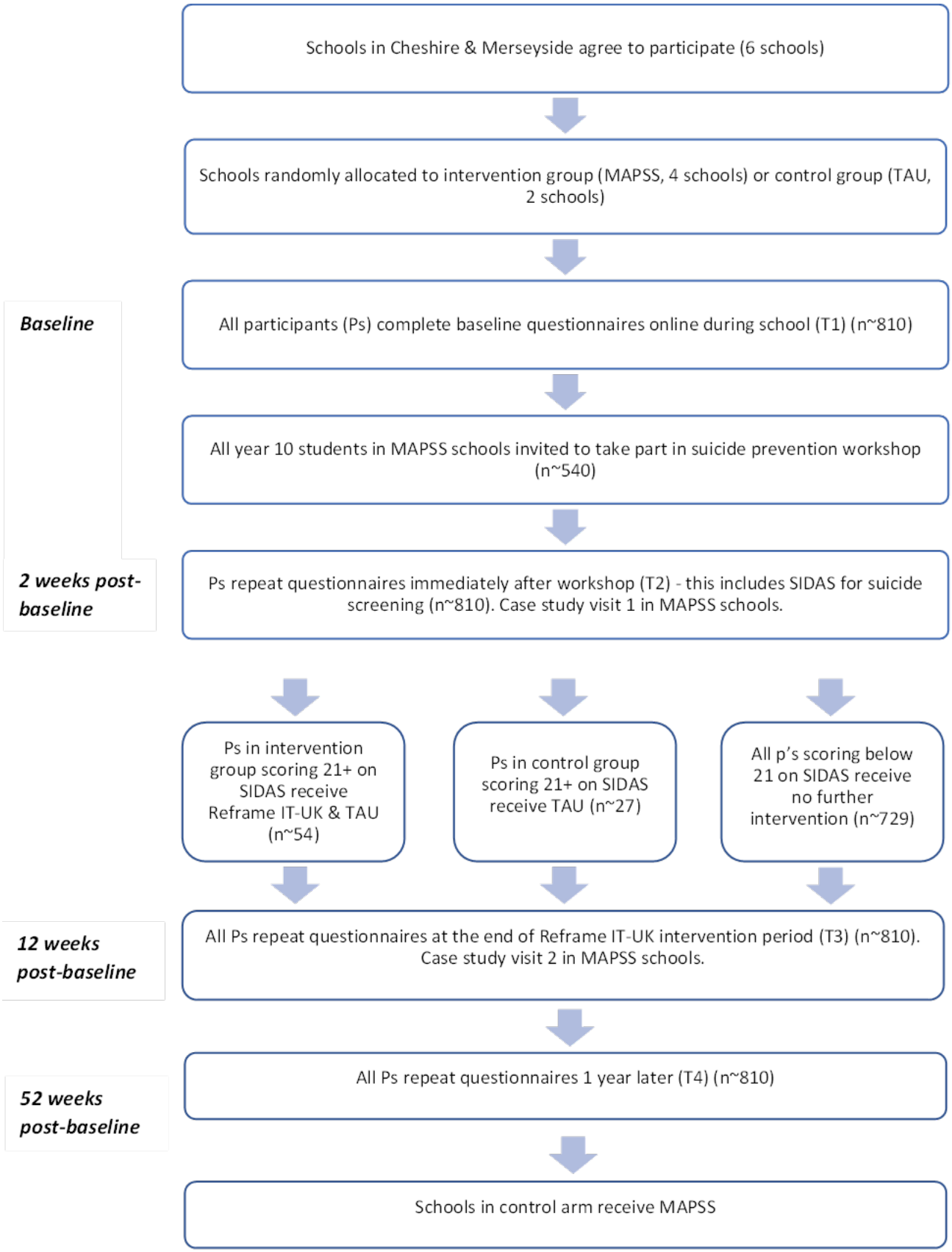
vii. Protocol contributors

Dr Pooja Saini, Dr Emma Ashworth, Prof Gerry Richardson (health economist), Dr Steven Lane (statistician), and Molly McCarthy (trial manager).

Patient and public advisors have contributed to the lay summary, research design, participant recruitment, and intervention delivery.

viii. KEY WORDS: Suicide prevention; child and adolescent mental health; multi-modal approach; school-based intervention; cluster randomised controlled trial

ix. TRIAL FLOW CHART



1 BACKGROUND

Rates of suicidal crisis among children and young people (CYP) are on the rise, with suicide rates per 100,000 adolescents having increased by 7-9% per year since 2010.[1] Suicide is one of the leading causes of death in adolescents worldwide. In Northwest England, there has been an increase in attendances to Emergency Departments for CYP in suicidal crisis and/or for self-harm,[2] and the number of CYP presenting is significantly worse than the UK average.[3] Suicidal ideation and behaviour are associated with a host of negative outcomes including risk of future suicide.[4] The impact of suicide on a young person's family, friends, and wider community can be devastating, and also increases their own risk of suicide[5]. There is therefore an urgent need to develop and test acceptable and effective approaches to preventing suicide in this population.

Schools are an appropriate setting for the delivery of mental health prevention programmes, offering a 'universal access point' to all CYP, and have been identified as important locations for suicide prevention and early intervention activities. Although school wellbeing staff may be able to provide support to pupils, CYP are often reluctant to seek help from professionals, preferring informal sources of support.[6] School-based prevention efforts must therefore not only target school staff, but also fellow pupils. Historically, there has been a reluctance to deliver suicide prevention efforts to pupils, due to concerns about potentially iatrogenic impacts. However, increasing evidence suggests that it is safe to do.[7,8] According to international best practice, suicide prevention programmes should incorporate universal, selective, and indicated approaches. Such approaches have shown promise in both community and school settings.[9] To date, only one study[10] is applying rigorous economic methodology to evaluate short- and longer-term cost-effectiveness of an intervention comprising universal, selective, and indicated elements in schools.

The Multimodal Approach to Preventing Suicide in Schools (MAPSS) project, a suicide prevention intervention in Australia, has demonstrated feasibility and acceptability and is currently undergoing an RCT in Melbourne.[10] The MAPPS intervention consists of three parts: suicide prevention lesson for all pupils, risk screening, and online CBT (Reframe-IT) for those deemed to be at high risk for suicide ideation. Training is also provided for school staff and parents.

Suicide prevention lessons such as those included in MAPSS have been evaluated in youth populations[7,8], and "Reframe-IT" has also been found to be associated with reduced suicidal ideation, depression, and hopelessness in Australian CYP.[7,11] However, cultural transferability of interventions cannot be assumed, and so we need to establish whether MAPSS could be effective in the UK.[12]

A recent scoping study of MAPSS for UK schools[13], conducted by the Co-PIs, interviewed CYP, school staff, parents, and health professionals. All participants advocated the importance of school-based suicide prevention and gave feedback on the adaptations needed to the MAPSS intervention for the UK. An adapted version of MAPSS has been developed and examined in a pilot study in two schools, commissioned by Cheshire and Merseyside Public Health Collaborative (CHAMPS). Findings showed it is feasible to recruit schools, have Papyrus deliver suicide prevention training to school staff and suicide awareness sessions to parents, for researchers to conduct surveys within the school setting at study timepoints, to identify pupils who may be at risk of suicide, deliver suicide prevention lessons with Year 10 pupils, and to recruit pupils to test the online CBT therapy programme, Reframe IT-UK.

The proposed study aims to build on this work, employing a feasibility study design across six schools to assess: 1) the acceptability and safety of delivering MAPSS in a school setting in England; 2) the social validity (feasibility, utility, and acceptability) of the MAPSS intervention; and 3) the feasibility of delivering a large-scale, appropriately powered, cluster-RCT and economic evaluation of this intervention in the future.

2 RATIONALE

Schools have been identified as a promising location to deliver suicide prevention, providing universal access to CYP [14]. In line with World Health Organisation (WHO) guidance[15], post-primary school-based suicide prevention interventions should incorporate universal (delivered to a whole population), selective (for those with increased risk), and indicated (for those who are already experiencing suicidal thoughts or behaviours) approaches, in addition to general wellbeing promotion that can prevent STBs through targeting related factors[16]. A recent systematic review by Walsh et al.[17] identified 28 studies that evaluated 36 suicide prevention trials in secondary schools since 1991. Meaningful reductions in STBs were evident in around half of all trials, with some trials also identifying longer-term effects. Further work by Robinson et al.[9] identified similar beneficial effects of suicide prevention interventions for youth across various settings, although comparatively less evidence was found for interventions delivered in educational settings. However, their results did suggest that school-based psycho-educational interventions (i.e., universal approaches) coupled with screening have the potential to be effective, although higher-quality studies are needed to confirm this.

To date, the most commonly evaluated programmes include the Signs of Suicide (SOS) intervention, Youth Aware of Mental Health (YAM), and Question, Persuade and Refer (QPR[17]). In particular, YAM, a brief duration (five hours across four weeks) classroom-based psychoeducation programme has gained traction in recent years across Europe. One randomised controlled trial, consisting of 11,110 secondary school pupils across 10 European countries, identified significant reductions in the number of suicide attempts and severe suicidal ideation in adolescents at the 12-month follow-up stage[18]. Similarly, a trial of the classroom-based SOS intervention with 2,100 pupils in North American high schools[19] also evidenced reductions in suicide attempts at a three-month follow-up, although no significant effects were identified for suicidal ideation, and no longer-term follow-up was conducted. However, little research has been conducted into the benefits of multi-modal school-based prevention interventions that encompass universal, selected, and indicated approaches, despite tentative evidence that they may be more effective [9].

Although there is emerging evidence for the effectiveness of school suicide prevention programmes [17,20], there are few being implemented in the UK, and they have not been rigorously tested. Furthermore, the cultural transferability of interventions cannot be assumed[12]; interventions that have worked in one setting or context too often do not work across other settings, particularly in school contexts[21], given the wide ranging contextual and cultural factors influencing implementation[22]. Further to this, if an intervention does not have high social validity, meaning that it is not viewed as acceptable, useful, and feasible by intervention deliverers (e.g., school staff) and/or recipients (e.g., pupils), then it is likely to fail [23,24]. Therefore, before any suicide prevention interventions are delivered at-scale in UK schools, the social validity of such interventions should be established, along with any necessary cultural or contextual adaptations, in order to ensure success.

Thus, findings from the proposed study will help to inform the development and delivery of a suicide prevention intervention for CYP in schools, with the potential to improve lives and reduce the number of adolescent deaths. The cost of one suicide is approximately £1.5 million;[25] therefore, there are wider economic and societal benefits, including reduced costs associated with mental health difficulties across the life-course, and reduced strain on the NHS. In the Northwest, many CYP experience poor mental health, particularly children living in poverty. With public and patient involvement and engagement (PPIE) and stakeholder consultation, there will be enhanced interdisciplinary working, sharing of expertise and resources, and a greater sense of connectedness. Delivering the programme to 14-15 year olds provides an opportunity for early education and intervention. 50% of lifetime mental health conditions start by the age of 14[26] and 7.4% of 17- year-olds have previously attempted suicide,[27] therefore intervening early may prevent early suicide attempts and improve adolescent mental health. This could incur long-term benefits into adulthood, as having a mental health condition and previously attempting suicide are both risk factors for future suicidal behaviours and service use.[4]

This project aligns with the National Suicide Prevention Strategy's critical actions and will contribute to the Zero Suicide initiative and the national awareness campaign by the 'Three Dads Walking'. This year there has been increasing discussions about suicide prevention in schools following a petition by the Dads that received over 150,000, and the subsequent debate within Parliament (https://commonslibrary.parliament.uk/research-briefings/cdp-2023-0060/). The Baton of Hope are also developing an education charter highlighting how suicide prevention should be introduced into schools (https://batonofhopeuk.org/). Additionally, a national webinar hosted by The Jordan Legacy in England highlighted further the importance of including young people's voices when designing and implementing suicide prevention curriculum content for schools (https://thejordanlegacy.com/the-role-of-education-and-training-in-preventing-suicides/).

2.1 Assessment and management of risk

Assessment of unanticipated outcomes: A MAPSS Safety Monitoring Committee (SMC) as part of the TSC will be established (members of the steering group and research team) as the main vehicle for both safety and investigator oversight of the MAPSS project, including data monitoring, endpoint adjudication, and data management strategy. This committee's composition and charter will be described in the co-produced MAPSS Safety Monitoring Plan. It is comprised of the Co-Is and other representatives of the named investigators, as well as independent internal and external subject matter experts including young people. The composition of the group is designed to incorporate transparency and ensure that no one set of competing interests can unduly influence other stakeholders and is appropriate for this non-commercially funded study. This committee has a dual safety role: it incorporates a risk-appropriate safety, endpoint adjudication and data management strategy which is responsive to study issues as they eventuate. A formal Data Safety and Management Committee (DSMC) will be convened if and when the SMC deem this escalation is required. A comprehensive safety protocol is being co-developed, which will be activated if: 1) participants return a score of 21 or higher on the SIDAS at any time-point; 2) participants report current suicidal ideation at any time-point; 3) participants report suicide risk via the Reframe IT-UK platform. Ultimately all risk information will be communicated to the school, who will be responsible for ongoing management. Adverse events (AEs) or serious adverse events (SAEs) that arise during the trial will be recorded in the study database.

An AE is the development of an untoward effect, undesirable clinical occurrence or medical condition, or the deterioration of a pre-existing medical condition following or during exposure to a study intervention, whether or not considered causally related to the study intervention. For the purposes of safety reporting, any research activity is considered to be part of the "study intervention". An AE can therefore be any unfavourable and unintended clinical sign, symptom, observation, or disease temporally associated with the use of an intervention, whether or not related to the intervention. An SAE is any untoward medical occurrence that: results in death or is life-threatening ('life-threatening' in the definition of SAE refers to an event in which the participant 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 inpatient hospitalisation or prolongation of existing hospitalisation; results in persistent or significant disability/incapacity; is an important medical event that although not immediately life-threatening or result in death or hospitalisation, based upon appropriate medical and scientific judgment, may jeopardise the participant and/or require intervention to prevent one of the outcomes listed above. Outpatient treatment in an emergency department is not in itself an SAE, although the reasons for it may be (e.g., suicide attempt). Hospital admissions and/or surgical procedures planned before or during a study are not considered SAEs if the illness or disease existed (or the surgery was planned) before the participant was enrolled in the study, provided that it did not deteriorate in an unexpected way during the study.

Assessment and documentation of AEs: All AEs and SAEs that arise during the trial will be recorded in the study database. The causality of AEs and SAEs (i.e., their relationship to intervention treatment) will be assessed by a suitably qualified study team member. Any SAE will be reported to the Sponsor and to the relevant ethics committees within 24 hours of the research team becoming aware of its occurrence.

3 OBJECTIVES AND OUTCOME MEASURES

Research question: What is the feasibility of a school-based suicide prevention programme comprising universal, selective, and indicated components in reducing suicide risk, improving risk recognition, and increasing health service use among young people aged 14-15 years in Northwest England?

MAPSS involves the delivery and evaluation of universal psychoeducation workshops to school pupils, screening pupils for suicide risk (universal and selective approaches), and online CBT (Reframe IT-UK) delivered to pupils identified as being at-risk (indicated approach).

3.1 Primary objectives

The primary aims of this study are to assess:

1) The acceptability and safety of conducting a trial of a suicide prevention programme in a school setting, operationalised in terms of adverse events and self-reported adverse consequences at post-intervention assessments.

2) The social validity (feasibility, utility, and acceptability) and implementation (including fidelity, quality, and dosage) of the MAPSS intervention, through a process evaluation consisting of bespoke quantitative surveys and qualitative interviews and focus groups.

3) The feasibility of delivering a large-scale, appropriately powered, cluster-RCT with economic evaluation in the future, including assessment of recruitment methods, retention rates, and outcome measures-and to assess links between these short-term trial outcomes and longer terms costs and outcomes.

3.2 Secondary objectives

We aim to test the following as secondary outcomes:

1) Comparison of suicide literacy and help-seeking intentions for suicidal thoughts or behaviours between the control group and pupils attending the suicide prevention workshop.

2) The identification of pupils at-risk of suicide who had not previously sought help.

3) Comparison of suicidal ideation, depression, and hopelessness between the control group and pupils in the Reframe IT-UK intervention group.

4) Rates of health-service use to inform an economic evaluation - levels of health-related quality of life.

5) Help-seeking intentions from informal sources.

3.3 Primary outcome measures

Acceptability: Operationalised in terms of the acceptability and safety of the intervention. A mixed-methods approach will be used to determine acceptability and safety of trialling a suicide prevention programme in UK schools. The proportion of pupils who complete all agreed sessions will be recorded

(>60% excellent. 40%-60% acceptable; <40% not acceptable) on the Reframe IT-UK website. Acceptability of the suicide prevention lesson, including whether or not participants thought it was "useful", "interesting", or "upsetting", will be assessed at T2 only using purpose designed items. Participant views on the Reframe IT-UK intervention will be assessed at T3.

Social validity: We will test this through a process evaluation using bespoke quantitative surveys following the delivery of each component of the MAPSS programme at T2 and T3. We will also conduct qualitative interviews with staff and focus groups with pupils across the study period.

Feasibility of the trial: We will collect data on: 1) the missing data on completed assessment (<15%); 2) change or variability on outcome measures (e.g., suicide ideation, depressive or hopelessness symptoms); and, 3) whether schools implemented and supported the accessibility of the online intervention.

3.4 Secondary outcome measures

1) Change in **past four-week suicidal ideation** at T3 and T4, compared to T2, assessed via the SIDAS.[28] The SIDAS is a self-report measure designed to screen individuals in the community for presence of suicidal thoughts and assess the severity of these thoughts.

2) Change in **symptoms of depression** at T3 and T4, compared to T2 and T1, will be assessed using the Patient Health Questionnaire – 9 item version.[29]

3) Changes in **hopelessness** at T3 and T4, compared to T2, will be assessed using the Brief-H-Pos, a 2-item positively worded measure of hopelessness.[30]

4) Differences in **health service use** and other resource use (education and local authority) comparing intervention and control group at T2, T3 and T4, will be assessed using a bespoke questionnaire adapted from the Young Mind Matters Service Use questionnaire.[31]

5) Purposefully designed questions on **intentions to seek help from informal sources**.

6) Change in **health-related quality of life** during the trial (T1, T2, T3, T4) will be assessed using the Child Health Utility–9 (CHU9D).[32] The CHU9D can be used to derive quality-adjusted life years (QALYs). These data will be used in combination with data from 3) above, to assess the feasibility of the full economic evaluation.

7) Change in **suicide literacy** at T2, T3 and T4, compared to T1, will be assessed using an adapted version of the Literacy of Suicide Scale (LOSS).[33]

8) School staff (key contact or safeguarding lead) will complete a usual practice survey at T1 and T4, to ascertain current provision (i.e., establish a clear counterfactual), identify the level of programme differentiation, and to account for any potential compensatory rivalry or contamination in control schools.

3.5 Table of endpoints/outcomes

Objectives	Outcome Measures	Timepoint(s) of evaluation of this outcome measure (if applicable)
Primary Objective 1 To assess the acceptability and safety of a suicide prevention programme in schools.	The proportion of pupils who complete all agreed sessions will be recorded (>60% excellent. 40%-60% acceptable; <40% not acceptable) on the Reframe IT-UK website. Acceptability of the suicide prevention lesson, including whether or not participants thought it was "useful", "interesting", or "upsetting", will be assessed at T2 only using purpose designed items. Participant views on the Reframe IT-UK intervention will be assessed at T3. Safety will be operationalised in terms of adverse events linked to the intervention (e.g., suicidal behaviour, crises, or increased self-harm), and in terms of self-reported adverse consequences at post-intervention assessments.	Suicide awareness lesson – T2. Reframe IT-UK – T3. Safety – ongoing.
Primary Objective 2 To assess the social validity of MAPSS.	Participants will complete bespoke social validity measures adapted from the Australian trial. We will also undertake a qualitative process evaluation, consisting of semi-structured interviews and focus groups in four 'case study' schools with pupils, in addition to as many pupils as possible who dropout (estimated to be a much smaller group), to determine their experience of MAPSS, what was helpful or not helpful, and problems in completing sessions. We will also carry out interviews with teachers and members of the senior leadership team to investigate facilitators and barriers to delivering MAPSS within school. Module utilisation of Reframe IT-UK, attendance at suicide prevention lessons, and screening will be monitored to review whether all aspects of the programme are used and when and where they are used.	T2 and T3.
Primary Objective 3 To assess the feasibility of delivering a large-scale trial of this intervention in the future.	This will be monitored through a mixed-methods evaluation encompassing quantitative and qualitative indicators. Quantitative indicators will include: a) comparisons of recruitment methods (for	T3.

	schools and then pupils into the study); b) successful data collection rates (low missing data); c) presence of floor/ceiling effects in collected data; d) whether responses on potential outcome measures remain static (or show 'movement') between baseline and follow-up; e) calculation of the precision of estimates of key parameters, which will inform a future trial. Qualitative indicators will include evaluation of the perceived mechanism of change and contextual factors impacting upon the effectiveness of the intervention for pupils and teachers. We will seek to interview participants who do not complete follow-up questionnaires to determine their reasons for not doing so and any factors that would improve completion rates. Factors that will determine stop/go procedures to a definitive trial will include: evidence that recruitment to a definitive study, using optimum recruitment pathways in one region, would be as follows: number of schools recruited at 9 months (6 excellent, 3-4 acceptable, 1-2 unacceptable), number of high-risk pupils recruited in the cluster-RCT per school (10-15 excellent, 5-10 acceptable, 0-5 unacceptable), and proportion of complete data collected (>80% acceptable). Retention will be judged by the following criteria: >80% completion excellent; 60-80% acceptable; below 60% unacceptable.	
Secondary Objectives To assess changes over time in mental health and wellbeing outcomes for pupils taking part in MAPSS.	SIDAS PHQ-9 Brief-H-Pos Bespoke help-seeking intentions measure CHU9D LOSS	T1, T2, T3, T4

3.6 Progression Criteria

A set of eight provisional progression criteria for the MAPSS programme have been established to determine whether a full RCT is warranted, and will be further developed in collaboration with the Trial Steering Committee (TSC; see Table). All progression criteria will need to be met for the MAPSS programme to be seen as acceptable and feasible, and to progress to a full efficacy trial.

Progression Criteria	Red (stop)	Amber (discuss and amend)	Green (go)
School recruitment (targeting n=6)	1-2 schools recruited	3-4 schools recruited	6 schools recruited
Pupil participant recruitment (targeting n~810)	<20% of eligible pupils	20-74% of eligible pupils	≥75% of eligible pupils
School staff training recruitment	≤2 teachers per school	3-6 teachers per school	≥6 teachers per school
Suicide Prevention workshop	<80% of scheduled workshops delivered	80-99% of scheduled workshops delivered	100% of scheduled workshops delivered
Pupils screening at high-risk of suicide	<5 pupils per school	5-10 pupils per school	10-15 pupils per school
Reframe IT-UK Online CBT	<40% of eligible pupils engage with ≥75% of modules	40-69% of eligible pupils engage with ≥75% of modules	≥70% of eligible pupils engage with ≥75% of modules
Acceptability of intervention	<50% of pupils found MAPSS acceptable	50-79% of pupils found MAPSS acceptable	≥80% of pupils found MAPSS acceptable
Outcome data collected at baseline	Data collected from <50% of pupils	Data collected from 50-79% of pupils	Data collected from ≥80% of pupils
Follow-up outcome data attrition at T3	>40% data attrition at T3	21-40% data attrition at T13	≤20% data attrition at T3

4 TRIAL DESIGN

The study will be conducted over a 2-year period (Feb 2024-Feb 2026), with 3 months for set up, 18 months feasibility, and 3 months consolidation.

This study adopts a multiphase feasibility design, consisting of 3 work packages (WP):

WP1: A three-month set-up stage to: i) make any adjustments to the interventions as determined from the pilot study, ii) recruit the RA, and iii) spend dedicated time recruiting schools from a diverse range of backgrounds, with two schools recruited in the first 3 months and the remaining four schools within 9 months, to enable alignment with school academic terms.

WP2: An 18-month feasibility study evaluating MAPSS in 6 schools: a feasibility cluster-RCT (schools as the unit of randomisation). Four schools will be randomised to receive MAPSS (intervention arm) and two schools will be randomised to continue with usual practice (control arm). Surveys will be completed by both arms at all timepoints. The trial will include i) baseline survey, ii) universal suicide prevention lesson (e.g., safeTALK) in intervention arm, iii) survey and screening 2 weeks after suicide prevention lesson, iv) an indicated Reframe IT-UK CBT intervention in intervention arm for pupils identified as high suicide risk, and usual care in control arm v) survey 2-weeks after Reframe IT-UK CBT, vi) survey 12-months post baseline.

WP3. A parallel process evaluation, to establish perceptions of social validity of the programme for use in the UK, and the appropriateness of the research design for effectiveness trials.

The study is facilitated by an extensive partnership with Local Authorities, schools, public advisors, professional educators, and researchers (see Letters of Support attached from collaborators and partner organisations).

5 TRIAL SETTING

Mainstream secondary schools and Pupil Referral Units (PRU) in Northwest England will be approached to participate. Papyrus' SP-OT training for teachers will be delivered in all schools. The suicide prevention lesson will be delivered in all 6 schools (4 in the intervention arms and 2 in the control arm after the trial is complete, if deemed safe), in typical classroom settings. Pupils participating in Reframe IT-UK in the 4 intervention schools will complete the modules online during school time, in the presence of a pastoral member of staff, with the option of accessing additional resources during their own time.

6 PARTICIPANT ELIGIBILITY CRITERIA

6.1 Inclusion criteria

- Pupils in Year 10 at school, aged 14-15 years
- Attending a mainstream secondary school or pupil referral unit
- For Reframe IT-UK only: a score of 21 or above on the SIDAS

6.2 Exclusion criteria

- Age below 14 or over 15 years
- Attending a special school or other specialist education provision
- No significant learning disability
- For Reframe IT-UK: a score below 21 on the SIDAS

7 TRIAL PROCEDURES

7.1 Recruitment

To ensure recruitment of a diverse range of schools and CYP in the feasibility trial, we propose purposeful maximum variation sampling. This is widely used in research to pragmatically identify and select participants that are effective in addressing the research aims, while also maximising diversity and limiting bias.[34] The key characteristics we would seek variation on include: rural/urban status, proportion of ethnic minority pupils, schools' deprivation levels (IDACI), schools' academic achievement (proportion of pupils achieving benchmarks GCSE grades).

We will monitor recruitment rates from the different methods and associated costs by collecting data on:

i) The proportion of eligible young people who consented;

ii) The number of participants recruited during the recruitment stage of feasibility compared with the target;

iii) Assessment of contamination of MAPSS programme in control schools;

iv) Assessment of CYP satisfaction with intervention and outcome measures.

This will provide evidence on recruiting to trials in school settings, as well as informing the full trial design.

The sample will consist of ~810 adolescent pupils in Year 10, recruited from 6 mainstream secondary schools across Cheshire and Merseyside. Six schools will be randomly assigned to one of two arms as part of a cluster-RCT: intervention (n=4) or control arm (n=2). Year 10 pupils in the intervention schools will receive: 1) suicide prevention lesson (n~540 pupils); and 2) pupils scoring 21 or above on the SIDAS[33] or indicating past suicide ideation will also be offered Reframe IT-UK plus TAU (n~54 pupils). Those in the control arm will receive TAU only (n~27 pupils).

7.1.1 Participant identification and screening

Participants will complete a suite of quantitative measures (see details below) online in school at 4 time-points. At T2, pupils will complete the SIDAS and a single-item question relating to suicide ideation in the past month. The survey system will flag participants who score in the at-risk range for suicidal ideation and the research team will then contact the school about these pupils to determine eligibility for participation in the Reframe IT-UK in intervention schools. Eligible pupils will then be offered the intervention and TAU (or TAU only in control schools). Pupils receiving the Reframe IT-UK intervention will complete the 8 modules in the 10 weeks between T2 and T3 (i.e., approximately one module per week).

7.2 Consent

As delivery of the intervention is being arranged by local Public Health bodies, consent will only be sought for completion of the measures. While opt-in gatekeeper consent will be sought from the participating schools, opt-out consent will be sought from parents of CYP. Findings from both our scoping and pilot study consistently showed that opt-out consent is feasible and desirable for this project. Given the potentially sensitive nature of the measures, parents/carers will be informed of the project on two separate occasions (via the schools' usual communication channels), to help ensure information is not missed. Schools will also be asked to advise parents/carers of the date scheduled for survey completion, so they are aware. All parents will be provided with detailed information sheets (alternative format/easy-read will also be developed), outlining the importance of the study, any risk of harm (and procedures put in place to reduce this), and will be provided with detailed signposting. Parents will be able to view the items in the survey if requested and attend an online information session about suicide prevention in young people. Parents and carers who are Co-Is and PPI advisory members will be consulted to ensure 1) improved attendance at the parent information sessions and 2) parents/carers are effectively informed about any young people who may be at risk of suicide and equipped with appropriate resources and support.

Schools will be provided with a detailed support pack for completing the measures with pupils, including age-appropriate lesson plans, PowerPoint slides, and a glossary. A researcher will attend the school during survey completion to review the PowerPoint slides with the CYP, ensuring they understand the nature of the study and their rights as a participant (including being able to withdraw). CYP will then be able to indicate if they are happy to proceed by ticking a box at the beginning of the survey.

For pupils eligible for Reframe IT-UK, they will be provided with an information leaflet/video (co-developed with our young person's advisory group), advising them about the content of Reframe IT-UK, and the voluntary nature of participation. The school's guidance pack will also remind staff to ensure that pupils are provided information discretely and are made aware that they do not have to take part.

Fully informed opt-in consent will be sought for participation in the qualitative strand of the process evaluation. Participants will be verbally reminded of their rights prior to the interviews/focus groups beginning. protocol. All participants will be given a participant information sheet and consent form prior to taking part in interviews. Personal data will be documented in a password protected and encrypted computer. No identifiable patient data will be extracted.

7.3 The randomisation scheme

The unit of randomisation is the schools. After baseline data collection is complete, 6 schools will be randomised to one of two study groups. We will be comparing both arms to test which, if any, is better. To create balance in terms of deprivation, ethnicity, rurality and educational outcomes, a minimisation algorithm will be used at an intervention-to-control ratio of 2:1 across Cheshire and Merseyside. Two schools will be allocated to the control arm and four schools will be allocated to the intervention arm by a university statistician, who is independent of the study and blind to school identities (blinding of schools and participants themselves is not possible due to obvious differences in intervention delivery). Methods of allocation concealment and randomisation processes will follow CONSORT. Schools will be randomised to receive a suicide prevention lesson and Reframe IT-UK and TAU, or TAU only, via a random sequence generation computer algorithm. The method of randomisation will be conducted using a routine within STATA to generate (stratified) randomised (block sizes of 2, 4 and 6) allocations. Researchers completing study assessments will be masked to intervention allocation. The trial will follow an Intent-To-Treat (ITT) protocol. Attrition will be recorded and reasons for drop-out recorded where possible.

7.4 Trial assessments

Participants will complete a suite of quantitative measures online in school at 4 time-points: baseline (T1); 2-4 weeks post-baseline (after suicide prevention lesson; T2); 12 weeks post-baseline (after Reframe IT-UK; T3); and 1-year post-baseline (T4). Surveys will consist of the measures noted in sections 3.3 and 3.4 above. Schools will be asked to book an IT room for pupils to complete the surveys and will be provided with a detailed support pack for completing the measures with pupils, including links to the surveys, age-appropriate lesson plans, PowerPoint slides, and glossary. Surveys will not be anonymous as pupils will need to be monitored for risk and screened for potential participation in Reframe IT-UK. Thus, data linkage across time points will not be an issue. A 'usual practice' survey will be completed at T1 by one staff member at each school, to determine what 'usual care' looks like, and levels of program differentiation.

7.5 Qualitative assessments

We will conduct a parallel qualitative implementation and process evaluation. We will conduct longitudinal case studies of the 4 schools randomised to receive MAPSS. The case studies will explore inter-related issues of 1) social validity of MAPSS and 2) *how* MAPSS was implemented and *why* it was implemented in this way. In terms of social validity, we will utilise Wolf's framework,[24] focusing on key tenets of acceptability, feasibility, and utility (e.g., does the intervention meet schools' perceived needs? How well received is the intervention among staff and pupils? Can the intervention be delivered successfully?). Here we will draw upon relevant studies of school-based interventions (e.g., Kendal et al[35]) and adapt existing rubrics from the implementation literature (e.g., Bird et al[36]) to inform our data generation.

In terms of how MAPSS was implemented, we will focus on the following dimensions: fidelity (e.g., to what extent teachers adhered to MAPSS guidance), dosage (e.g., how much of MAPSS pupils accessed), quality (e.g., how well MAPSS was delivered), participant responsiveness (e.g., the extent to which pupils engaged), reach (e.g., the rate and scope of participation), programme differentiation (e.g., to what extent MAPSS can be distinguished from other, existing mental health programmes), and adaptations (e.g., the nature and extent of changes made during implementation). We will also explore a range of factors that may have affected implementation at the different domains/levels consistently:

preplanning and foundations (e.g. buy-in), implementation support system (e.g. ongoing external support), implementation environment (e.g. time constraints), implementer factors (e.g. experiences, skills and confidence in delivery), and programme characteristics (e.g. flexibility).[37,38]

Longitudinal case study fieldwork visits will be conducted at T2 (after suicide prevention lesson) and T3 (after Reframe IT-UK). We will use semi-structured interviews with school staff and intervention deliverers (N=3 per school x 2 visits = 8 interviews), and interviews (for Reframe IT-UK) and focus groups (for suicide prevention lesson) with pupils (N=1 per school x 1 visit = 4 focus groups; N=2 per school x 1 visit = 8 interviews), as well as observations and document analysis of intervention delivery.

Class teachers and members of the senior leadership (e.g., safeguarding leads) will be interviewed individually at each case study visit. Small groups (n=4-6) of pupils will participate in semi-structured focus groups regarding suicide prevention lesson (to reduce power imbalances and ease nerves), and one-to-one interviews (with a teacher present if requested) will be conducted with pupils who have taken part in Reframe IT-UK (due to the sensitive and personal nature of intervention participation). Bespoke semi-structured interview schedules have been developed for each key stakeholder group. All interviews/focus groups will cover trial feasibility and acceptability, and factors affecting implementation; overarching this will be a social validity framework.[24] However, each schedule will be tailored to the relevant time point and stakeholder group. Prompts and probes will be utilised where necessary to clarify unclear responses and elicit further detail. Interviews and focus groups will be conducted in private and quiet parts of the school, and fully informed consent will be ensured.

Professionals who delivered the interventions in the case study schools will also be invited to be interviewed, to ascertain fidelity, quality, and dosage, and gain their perspectives on participant engagement and reach, as well as the feasibility of an efficacy trial. Interviews will be conducted at a time and place to suit them (face-to-face or online). Observations and document analysis will be arranged where possible with the intervention deliverers for additional context. All interviews/focus groups will be audio recorded and transcribed verbatim.

7.6 Withdrawal criteria

Schools or pupils can withdraw from the trial at any time. If an individual pupil withdraws, no further action will be taken. If a school withdraws prior to intervention delivery beginning, we will seek to replace the school. If a school withdraws after this point, we will not seek to replace the school and the trial will continue. We will aim to complete exit interviews with any schools that withdraw, to ascertain their reasons for withdrawal.

The trial may be prematurely stopped if a significant adverse event occurs as a result of the trial procedures.

8 TRIAL TREATMENTS

8.1 Planned Intervention

1) A minimum of 6 staff from each school will receive training from Papyrus: **Suicide Prevention – Overview Tutorial (SP-OT)**, to ensure staff are equipped to manage any risk identified from the screening. SP-OT is delivered in a single session over 1.5 hours online. Papyrus will also provide an online information session, **Suicide Prevention - Awareness, Resource, Knowledge (SP-ARK),** along with support packs, for parents of all children in Year 10 at each participating school. #MyGPGuide; a guide for CYP with lived experience of self-harm and suicidality will be shared with schools and families.[39]

2) **Suicide prevention lesson**, a suicide alertness training workshop suitable for anyone over the age of 14. The lesson comprises a single 3-hour face-to-face workshop, designed to help participants understand suicide warning signs in themselves and others, gain knowledge about sources of support, and signpost others. Suicide prevention lessons will be delivered by trained Suicide Prevention Facilitators at Grassroots Suicide Prevention to classroom-sized groups of pupils (maximum 30 pupils per session with at least one teacher present).

3) The **screening** will take the form of self-report measures embedded into the questionnaires at each timepoint. Researchers will inform each school after each timepoint of any pupils who are assessed to be at risk. Pupils who report suicidal ideation within the past four weeks (Suicide Ideation Attributes Scale [SIDAS] score of 21 or higher) or any level of current suicidal ideation (single multiple-choice item) will be flagged by the research team and followed up by the school safeguarding lead.

4) **Reframe IT-UK** has been adapted from the Reframe-IT intervention developed in Australia.[7,11] It comprises eight 20-minute online self-guided CBT modules, following the stories of two young people who make video diaries about their day-to-day life and their experience of feeling suicidal. There is also a message board through which the participants can communicate with a moderator, a mood diary, and signposting information.

8.2 Control/comparator group

Participants in schools randomised to the control group will receive treatment as usual (TAU; e.g., from the school nurse or external mental health services), based on the typical provision at each school. The pastoral staff will be asked to record what TAU comprises in each school through the completion of a ‘usual practice’ survey prior to randomisation and at T4, to establish programme differentiation, any changes over time, and to control for any compensatory rivalry that may occur over the course of the trial. To ensure safety and appropriate support in the event of pupils being flagged as at-risk in the control group, schools who do not engage with the SP-OT (suicide prevention training for designated teachers in recruited schools) training will be unable to progress through the trial.

9 STATISTICS AND DATA ANALYSIS

9.1 Sample size calculation

As this is a feasibility study, a sample size calculation is not needed. In line with similar work,[40] we will recruit 6 schools to provide sufficient variety of schools and pupil numbers in which to test recruitment, retention and acceptability of the intervention, and feasibility of the research design for evaluation. This is based on the assumption of a potential attrition rate of 50% at T3 (the primary outcome point for Reframe IT-UK). This is common for feasibility trials, realistic in terms of recruitment, and would allow adequate precision in estimating rates (e.g., attrition, adverse events) relevant to trial outcomes.[40] This would allow an overall attrition rate of 50% to be estimated with 95% confidence intervals of +/- 12% or, 16% for a single arm. This sample size is also adequate for estimating relevant analysis parameters such as the standard deviation of effects, which are needed for determining the feasibility of a later efficacy trial. Based on findings from the pilot study, we anticipate that 10% of pupils will score in the at-risk range in the screening and will thus be eligible for Reframe IT-UK.

9.2 Statistical analysis plan

As this is a feasibility study no formal hypothesis testing will be undertaken. Data will be initially cleaned and checked for missing values, where possible missing values will be obtained from source or infilled using standard techniques, regression, hot deck imputation etc. This will be an ongoing process throughout the trial, to minimise the amount of missing data in the final dataset. Demographics and other baseline variables will be reported using summary statistics, mean, medians, counts, percentages depending on the nature, categorical or continuous, and the distribution, parametric or non-parametric, of the data, along with corresponding measures of variability. Key outcomes from the study, for example, recruitment and retention rates will be reported using counts and percentages, along with 95% confidence intervals. If we assume a 50% retention rate from an initial sample size of 810, we will be able to estimate the true retention rate (95%) with an accuracy of +/-6%. Clinical outcomes, for example, depression scores on a continuous scale, will be reported using means or medians depending on the distribution and corresponding confidence intervals. These clinical measures will also be reported at the three subsequent follow-up time points. Graphical methods will be used to identify trends across time. Differences between the intervention and the control groups in key outcome variables will also be calculated and reported graphically, along with 95% confidence intervals.

9.2.1 Summary of baseline data and flow of patients

Baseline variables -

Age (continuous), Gender (Categorical), Ethnicity (categorical)

As this a feasibility study data will only be reported using summary statistics and 95% confidence intervals. Continuous variables will be reported using means, medians and corresponding measures of variability. Categorical variables will be reported using counts and percentages. As there will be no formal between group comparisons, baseline comparability will not be an issue at this stage, but any potential differences will be reported in preparation for the future definitive trial.

9.2.2 Primary outcome analysis

There will be two primary analyses. The first analysis will assess the key recruitment and retention of participants required for a full study to be feasible. These will be reported as counts and percentages with appropriate 95% confidence intervals. If we assume a conservative retention rate of 50% and with a sample size of 810, we can estimate the true retention rate with a precision of 6%. Clinical outcomes, which are measured on a continuous scale, for example, quality of life, suicidal ideation, depression and hopelessness, will be reported using means and medians along with appropriate measures of variability. Again, no formal hypothesis testing will be carried out, between group MAPS intervention and control, differences will be reported with 95% confidence intervals. As this is feasibility study there is no gain from infilling missing data; however, rates of missing data will be highlighted and measures to minimise future missing data will be incorporated into the design of the full trial. All analysis will be carried out on the intention to treat basis, some sensitivity analysis maybe undertaken including only per-protocol participants.

9.2.3 Secondary outcome analysis

Secondary outcomes will be reported and assessed in a similar manner to the primary outcomes using summary statistics and confidence intervals.

9.3 Subgroup analyses

The data will contain two groups, those receiving the MAPSS intervention and a control group. Data will only be reported using summary statistics and confidence intervals. As this is a feasibility study, the study is not powered to detect between group differences, so no formal hypothesis testing is planned.

9.4 Adjusted analysis

There will be no adjusted analysis at this stage.

9.5 Interim analysis and criteria for the premature termination of the trial

As this is a feasibility study no interim analysis is planned.

9.6 Participant population

Randomisation will be done using block randomisation to ensure equality in both groups. This will be done at school level, rather than the individual level. Participants, therefore, will be entered into the treatment arm that the school has been randomised to receive.

9.7 Procedure(s) to account for missing or spurious data

As this is feasibility study there is nothing to gain from infilling missing data. Rates of missing data will be reported and, if necessary, procedures included in the design of the future definitive trial to minimise missing data.

9.8 Economic evaluation

We will collect data to assess the feasibility of conducting a full cost-effectiveness analysis in a future study. As with the statistical analysis, we will not conduct a full cost-effectiveness analysis as this is inappropriate for a feasibility study. Initially we will consider an NHS and Personal Social Services perspective and this will allow us to collect health related resource use such as GP visits and any hospital attendances. We will then explore the possibility of expanding this to incorporate impacts on other (non-health) sectors using the resource use questions described in section 4.10 (for example education and Local Authority resource use). For this feasibility study, participants will complete the CHU9D health service resource use questionnaire,[46] and other instruments described above. Data will be collected on resource use required to deliver the service (e.g., the time required for staff to deliver the intervention and their level of experience/grade) to estimate the cost of the intervention. Data required to estimate health-related utility and quality-adjusted life-years (QALYs) in a subsequent trial will be collected using the CHU9D. QALYs will not be calculated in this feasibility study; rather, disaggregated data based on health-related resource use data and health related quality of life (CHU9D) for intervention and control groups will be presented together with estimates of the cost of the intervention.

We will conduct a review of economic models to assess whether there are other comparator interventions and to establish a link between the short-term outcomes of this trial (suicidal ideation/mental health) to longer term costs and health-related quality of life. This will inform the longer-term model conceptualisation that will form part of the economic evaluation alongside the main definitive trial, but will also provide a useful assessment of the longer-term impact of these short-term outcomes. In the main trial, we will assess the impact of inequality on cost-effectiveness (that is, establishing on which groups the main costs and effects impact) using Distributional Cost Effectiveness Analysis (DCEA). In this feasibility study, we will assess which variables (e.g., socio-economic status) can be used as categories in the DCEA.

9.9 Qualitative data analysis

Qualitative data will be treated in two ways. First, we will produce detailed case profiles of each school that document their implementation, paying attention to how individual context and circumstances have influenced progress in each. Secondly, interview and focus group transcripts will be analysed via thematic analysis using the framework approach.[41] A hybrid approach will be taken, which will be informed by conceptual models of implementation in school settings[42] and our primary orienting concepts (social validity, acceptability, feasibility), while allowing for unanticipated themes specific to this project/context. We will also adopt Normalisation Process Theory (NPT)[43] as a broad framework through which to make sense of the qualitative data and draw conclusions relating to how readily MAPSS might be implemented amongst schools and embedded into school systems.

The qualitative framework analysis approach was developed to meet information needs and to provide outcomes or recommendations.[44] It offers a highly visible and systematic approach to data analysis, showing very clearly how findings are derived from the data. This approach also facilitates analysis of

specific concepts and issues that are particularly important to address, and so facilitates the use of NPT in interpreting the data. Analysis will follow the five suggested stages of framework analysis (Familiarisation with the data; Identifying a thematic framework; Indexing the data; Charting the data; Mapping and interpretation).[53] In order to monitor and limit the impact of a single perspective, PS will examine parts of the transcripts to compare their perceptions of the interview data and analysis with the analyst's interpretation. Further data analysis will be completed in research team meetings with the research assistant SW, trial manager MM and EA, TN, DC, LH and PS.

NPT provides a framework for understanding the barriers and facilitating processes that underlie the implementation and integration of complex interventions into systems. The theory has been developed from qualitative research and identifies four key processes that underlie the adoption of new interventions (coherence of intervention; cognitive participation; collective action; reflexive monitoring). Previous research has shown that NPT can be applied effectively to qualitative data in healthcare contexts and, more recently, in school-based research.[43,45,46] NPT will be drawn upon as a putative framework within the qualitative analysis, and an attempt will be made to map the links between qualitative themes arising from the data and the core processes outlined in NPT. This process will be aided through use of the NPT toolkit (http://www.normalizationprocess.org/) and application of the NPT statements generated by May et al.[43,46] in order to further promote integrity and rigor during the data analysis process, field notes will be written immediately after the interview and a reflective diary maintained.

10 DATA MANAGEMENT

10.1 Source data and documents

Source data for this trial will consist of paper copies of the consent form, data from online questionnaires (collected via QuestionPro), and audio recordings of interviews and focus groups.

When a participant consents to take part in the trial, they will be provided with a unique participant identification number which will be used to link survey data across timepoints. Personal data entered via QuestionPro will be anonymised and stored on a password-protected database, housed on LJMU's secure systems, and will only be accessible to members of the core research team.

Consent forms and letters with personal identifiable data will be stored separately in a locked filing cabinet. Participant details will be anonymised in any publications that result from the trial.

Encrypted Dictaphones will be used to record interviews and focus groups. Audio files will be immediately transferred to LJMU's secure servers after the interviews are complete and will subsequently be deleted from the Dictaphone. Once transcribed, audio files will also be deleted from LJMU's systems. Transcripts will be anonymised, with any identifiable information removed, and pseudonyms used. Only the research team will have access to the transcripts.

10.2 Data handling and record keeping

This information is included in a data management plan so is not duplicated here.

10.3 Access to Data

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections - in line with participant consent.

10.4 Archiving

This trial will be sponsored by LJMU who are also the data custodian. All research data will be retained in a secure location during the conduct of the trial and for 5 years after the end of the trial, when all paper records will be destroyed by confidential means. An archiving plan will be developed for all trial materials in accordance with the LJMU archiving policy.

11 MONITORING, AUDIT & INSPECTION

The study will be monitored and audited in accordance with the Sponsor's policy, which is consistent with the UK Policy Framework for Health and Social Care Research. All study related documents will be made available on request for monitoring by the REC.

The sponsor usually delegates some of the monitoring to the central research team. The following checks would be typical:

- That written informed consent has been properly documented
- That data collected are consistent with adherence to the study protocol
- That SAE recording and reporting procedures are being followed correctly
- That no key data are missing
- That data are valid
- Review of recruitment rates, withdrawals and losses to follow up.

The TSC will be kept informed of any significant findings.

12 ETHICAL AND REGULATORY CONSIDERATIONS

12.1 Governance and legislation

This trial will be conducted in accordance with:

- Good Clinical Practice (GCP) guidelines
- UK Policy Framework for Health and Social Care Research
- Data Protection Act 2018
- General Data Protection Regulation

12.2 Research Ethics Committee (REC) review & reports

Ethical approval has been obtained from the university's REC. The study will always be undertaken in compliance with the research protocol. All participants will be given a participant information sheet and consent form prior to taking part in interviews. Personal data will be documented in a password protected and encrypted computer. No identifiable patient data will be extracted.

As delivery of the intervention is being arranged by local Public Health bodies, consent will only be sought for completion of the measures. While opt-in gatekeeper consent will be sought from the participating schools, opt-out consent will be sought from parents of YP. Findings from both our scoping and pilot study consistently showed that opt-out consent is feasible and desirable for this project. Given the potentially sensitive nature of the measures, parents/carers will be informed of the project on two separate occasions (via the schools' usual communication channels), to help ensure information is not missed. Schools will also be asked to advise parents/carers of the date scheduled for survey completion, so they are aware. All parents will be provided with detailed information sheets (alternative format/easy-read will also be developed), outlining the importance of the study, any risk of harm (and procedures put in place to reduce this), and will be provided with detailed signposting. Parents will be able to view

the items in the survey if requested and attend an online information session about suicide prevention in young people. Parents and carers who are Co-Is and PPI advisory members will be consulted to ensure 1) improved attendance at the parent information sessions and 2) parents/carers are effectively informed about any young people who may be at risk of suicide and equipped with appropriate resources and support.

Schools will be provided with a detailed support pack for completing the measures with pupils, including age-appropriate lesson plans, PowerPoint slides, and glossary. The slides inform the CYP of the nature of the study and their rights as a participant (including being able to withdraw) and they be delivered to them by the teacher supporting their survey completion. CYP will then be able to indicate if they are happy to proceed by ticking a box at the beginning of the survey. This method has been used successfully in previous trials by EA, in the pilot study, and is recommended in good practice guidance.[38] For pupils eligible for Reframe IT-UK, they will be provided with an information document/leaflet/video (co-developed with our young person's advisory group), advising them about the content of Reframe IT-UK, and the voluntary nature of participation. The school's guidance pack will also remind staff to ensure that pupils are provided information discretely and are made aware that they do not have to take part. Fully informed opt-in consent will be sought for participation in the qualitative strand of the process evaluation. Participants will be verbally reminded of their rights prior to the interviews/focus groups beginning. In case of distress to teachers during MAPSS, the school guidance packs will provide information on promoting staff wellbeing, including details of 24-hour helplines (one specifically for educators, and local NHS crisis lines). In case of distress to parents/carers during MAPSS, the parent/carer participant information sheets will provide details of charities e.g. Papyrus and NHS services including NHS 24-hour crisis helplines.

12.3 Amendments

Study document amendments will be submitted to the REC for approval. A 'notification of amendment' form, along with all amended documents (with highlighted changes) will be completed by the PIs and submitted to the Research Governance and Ethics Officer, who will facilitate a review with the REC chair. If the amendment is deemed to be substantial by the REC chair, the amendment will be additionally reviewed by the committee.

12.4 Peer review

The proposal for this trial has been peer-reviewed through the NIHR PHR 2-stage peer-review process, which includes independent expert and lay reviewers. The applicants addressed all issues raised by the reviewers. The protocol also benefited from substantial PPI input at different stages in the application and review process.

The conduct and progress of the study will be reviewed throughout by an expert Advisory Group, and PPI input will be sought at several points. Interim reports to the funders will be provided as required.

12.5 Public and Patient Involvement (PPI)

To ensure the research meets the needs of, and is sensitive to, pupils and teachers in a school community, the proposed work has been developed as part of the Suicide and Self-Harm Research Group (SSHRG) at LJMU and with PPI co-applicants including parents and youth worker leads. PPI members have advised on overall study design, research questions, recruitment, and have helped write the plain English summary. The following approaches were taken towards involving the public in the development of this study:

- Liverpool NHS CCG commissioned a qualitative scoping study for us to gain views from key stakeholders, including young people, parents of children with a history of suicidal behaviours, teachers, mental health professionals and General Practitioners. Four themes were identified: inadequate service provision for young people; clinical need for school-based suicide prevention services; improved pathways for young people at suicidal risk; and adaption of the MAPSS programme. Data indicated strong support for MAPSS to bridge the current gap in clinical service provision and to support schools in managing/signposting the increasing number of young people communicating suicidal ideation.
- The scoping study informed the development of the study design, e.g., trial recruitment procedures.
- Findings from the scoping study have informed the adaptations required to MAPSS to ensure it meets the cultural needs of the UK population. These adaptations have now been made and are detailed below.
- 6 parents were active members in the development of this application, with 2 as named co-applicants.
- A young person's advisory group has been established via Merseyside Youth Association, who are helping us to design information documents/leaflets/videos to empower young people, helping them to understand what both MAPSS and the CBT element will entail, and fully understand their rights throughout the process.

Suicide Prevention Lesson changes:

- Pupils requested that workshops include activities, they do not want parents/carers present, and are happy with teachers being present. The deliverer (Grassroots Suicide Prevention) implemented these changes in the pilot study.

- Parents, teaching staff, and health professionals emphasised the importance of adding the extra element of an online information session for parents/carers of pupils attending the suicide prevention lesson. This was added in the pilot study, although was not well attended. The team are gaining feedback on possible reasons for low attendance.

- Feedback suggested implementing school-based suicide prevention interventions to younger pupils. Young people shared that their suicidal ideation started much younger than 15 and that they would have benefited from more knowledge about suicide earlier. Grassroots confirmed they could deliver workshops to Year 10 pupils from age 14- this was implemented in the pilot study.

Reframe IT-UK changes:

- Participants were positive about the online intervention; however, areas for adaption were:

1) improving diversity of actors in videos and using British actors;
2) updating sources of support information on the website;
3) a UK moderator checking the online support forum;
4) having a teacher/mental health worker present when pupils complete the online modules. We have a licence for us to host the UK website. All changes have been implemented, and a UK-based website has been launched (https://reframeituk.org.uk/). We have added support content relevant to the UK, updated videos, and study researchers will manage the online forum.

- Adults raised concerns about Reframe IT-UK being online but young people preferred this in order to use the modules in their own time as well as in school with a member of staff. This is currently being piloted in 2 schools.

Moving forward in the current feasibility trial, the research team will work with the Co-Is to develop 2 advisory groups: one for adults (n=6) with lived experience of parenting/caring/working with young people with suicidal ideation (Public Advisory Group; PAG) and one for young people (n=6) with lived experience of suicidal ideation or with an interest in MAPSS (YPAG). Two public representatives (MJ, DC) and PS will co-lead and co-ordinate the PAG. Public representatives (LH, TN) and EA will co-lead and co-ordinate the YPAG. We will work with our existing community links to ensure members from under-served communities (e.g., ethnic minority groups) are members. Involvement will be flexible and will use multiple methods to ensure members can engage according to their abilities and preferences. Members will have an induction to the project and a discussion of working practices, delivered by the research team, who have extensive experience in involving CYP and adults as advisors in research. The team will invest time building trust with and develop safeguarding protocols for engagement. Members will advise the team on all elements of study conduct and dissemination, to ensure that findings are appropriately translated and are culturally sensitive and accessible.

Funds (using NIHR rates) are included to ensure that all members may continue to support the research throughout the project. Altogether, 6 PAG and 6 YPAG members plus the adult YPAG members are costed in for the study to attend meetings over the 2-year study period, representatives will attend the Trial Steering Group (TSG) and an end of study conference.

PS and EA have 16 years combined experience engaging, involving, and training public members in research. Training will be available throughout the programme and an induction to the project will be delivered. This will include an overview of the MAPSS programme, and the methodology being used to evaluate the intervention, to enable the groups to be better informed about the project and their role in advising the research team. The ADAPT guidance and Health Inequalities Assessment Toolkit are being used to address the adaptation of this intervention in a different population and to review health inequalities and access for young people communicating/displaying suicidal behaviours.

Throughout the program:

- We will engage carers, young people, and other professionals working within schools, communities and children's mental health settings to become members of the PAG and YPAG. The proposed evaluation will ensure that we capture and monitor the experience of people targeted by the programme, at school, and community events.
- Meetings will take place 4 times a year (8 times for the research programme). One representative per group has been costed in to attend the monthly research meetings.
- One/two members of the PAG and YPAG will attend 4 TSG meetings and be involved at each stage of the research, from the design, analysis, interpretation of findings, dissemination and further implementation work.
- Two members of the TSG will also attend the PAG and YPAG to feed information from each group.

For capturing, evaluating, and reporting the impact of PPI activities, the team will record minutes from all meetings. We will conduct focus groups with the PAG and YPAG to explore their experience of being part of the programme and use these findings to inform the effectiveness trial funding application.

PPI Leads

The Co-PIs (PS and EA) will lead the PPI groups alongside PPI co-applicants (MJ, TN, LH, DC). PS have worked in research with public advisors for the NIHR ARC Northwest Coast (NWC) for over 10 years and will be able to mentor and train other PPI members, and other public advisors who join the trial. DC and MJ have both experienced engaging with schools when their children were in a suicidal crisis and have since wanted to influence changes for other parents who may be going through similar difficulties. MJ is from a South Asian community and brings her experience in navigating the system and the barriers to communicating with a school when you are from a different cultural background. DC is a bereaved father of a daughter who died by suicide and the Founder of The Holly Clacy Foundation. DC

and the 3 other dads of young women who died by suicide are passionate about suicide prevention being part of the school curriculum and are members of the group. TN and LH work for Merseyside Youth Association (MYA) on delivering mental health lessons for pupils including suicide prevention. Members are located across the country in Chelmsford, Manchester, Liverpool, Cumbria and Norfolk and some have been meeting with the All-Parliamentary Suicide Prevention Group about suicide prevention in schools including a government petition being debated in the Houses of Parliament recently.

12.6 Protocol compliance

There will be no prospective, planned deviations or waivers to the protocol. The study research team will assume compliance with the study protocol. It will be the responsibility of each team member to adhere to the protocol and this will be checked at the regular team meetings. The regular Advisory Group meetings will serve as opportunities to check protocol compliance and ensure that accidental deviations are detected early and minimised.

12.7 Data protection and patient confidentiality

The trial is sponsored by LJMU, who are also the data custodian. Data will be collected and retained in accordance with the Caldicott Principles, UK Data Protection Act 2018 and General Data Protection Regulation (GDPR). For this trial, research data will be kept for at least 5 years. Personal data (e.g., name, or any data from which a participant might be identified) will not be kept for longer than is required for the purpose for which it has been acquired, and data will be anonymised as soon as possible. A unique participant identifier will be used to link anonymised data across timepoints. Documents will be reviewed by the PI before being destroyed.

All data will be confidential with the exception of SIDAS scores, as this is required to determine eligibility for Reframe IT-UK. The names of pupils who score in the at-risk range on the SIDAS will be passed to their school's safeguarding lead within 24 hours of data collection, in order to manage any potential risk. The schools will then assume responsibility for safeguarding, and no further data will be shared by the research team.

Interview transcripts will be anonymised, and pseudonyms used in reports. Confidentiality will be maintained for interview participants unless they are suspected to be at risk of harm, in which case the school's safeguarding team will be alerted by the researcher.

12.8 Financial and other competing interests for the chief investigator, PIs at each site and committee members for the overall trial management

The research team and all PIs must disclose any ownership interests that may be related to products, services, or interventions considered for use in the trial or that may be significantly affected by the trial. Competing interests will be reported in all publications and in the final report.

12.9 Indemnity

All co-researchers have institutional affiliations. Their respective institutions provide public indemnity insurance.

12.10 Access to the final trial dataset

Anonymous research data will be stored securely and kept for future analysis. All research team members will have access to the full study dataset.

13 DISSEMINIATION POLICY

13.1 Dissemination policy

Data arising from the trial is owned by the research team. On completion of the trial, the data will be analysed and tabulated, and a Final Trial Report prepared, which will be available via the trial funder's website.

Project findings will be shared through reports developed in close consultation with schools, NHS professionals, public health and third sector organisations, and those affected by suicide. Findings will be of interest to various stakeholder groups, and so bespoke reports will be developed for education, health and social care organisations, and researchers in the field.

Outputs will include:

- Publications in high impact peer-reviewed journals
- Presentations/symposia at national and/or international conferences
- Summary briefs for different audiences
- Policy evidence briefings
- Public-facing website, including short videos/animations, infographics, and blogs/vlogs
- to highlight the work.

We are aiming to have a real-world impact by collaborating with clinicians, PPI members, academics, and third sector organisations. The outcomes from the trial are important to both clinical practice and research as they help practitioners understand what they are doing, how effective it is and improve understanding about this specific patient group. Our impact strategy will be carefully designed to maximise impact and dissemination of results across the main stakeholder groups affected by this research. The main impact goals are to:

1) Contribute to the body of knowledge on effective school-based suicide prevention intervention in schools.
2) Influence public bodies and policymakers on implementing school-based suicide prevention interventions in schools, whereby an intervention can take place within a child's own community, including more deprived communities where suicide ideation appears more prevalent.
3) Contribute to economic development by reducing admissions to Emergency Departments for suicidal behaviours by providing quicker psychological interventions within school settings.

For dissemination to be effective, dialogue is needed with relevant audiences. Project findings will be disseminated in close consultation not only with academics but also with schools, clinicians, community mental health professionals, public health, third sector organisations (e.g., PAPYRUS), and those affected by suicide behaviours in young people.

The work will be of considerable interest to education, social, clinical, and academic professionals in the field of suicide prevention and community mental health. Publications in renowned, high-impact journals, alongside presentations at regional, national, and international conferences will be pursued to maximise

dissemination amongst academic and research audiences. A high specification executive summary of the key findings will be disseminated to schools, clinical practitioners, and researchers across the UK.

A one-day national conference will be hosted, funded jointly (by organisations working on this project), focusing on dissemination and discussion of the project findings. Academics, researchers, schools, third sector organisations, social and clinical service staff, and the public will be invited, ensuring a range of voices and perspectives are present on the day. The one day conference will be used as a platform to gain initial interest from NHS England Public Health Suicide Prevention Leads across England, through which future engagement can then be supported. Within the conference we will ensure that individuals and carers affected by suicidal behaviours are participating within the programme; their voices will be actively encouraged and listened to in considering the development and implementation of the subsequent trial.

Press releases at key project milestones will be disseminated via an ongoing social media campaign, designed to further disseminate project progress and findings. Summary and guidance documents will be created and made available to schools managing pupils with suicidal behaviours via the study website page. The next step of the research (efficacy RCT) will be supported by a pro-active engagement with schools across the region via NHS England Public Health Suicide Prevention Leads and the CRN.

Study participants will be asked if they would like to be updated on forthcoming publications, and a note will be made of their responses.

13.2 Authorship eligibility guidelines and any intended use of professional writers

All research team members will be co-authors on the final report and any peer reviewed publications (provided they have contributed to the expected extent that is now commonly specified by scientific journals). PPI contributors will also be offered authorship where they have met the contribution criteria. The contributions of members of the Advisory Group will be acknowledged in any publication.

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15. APPENDICIES

TIDieR framework: Suicide Awareness Lesson

Brief name	Suicide awareness lesson
Why *Rationale, theory and/or goal of essential elements of intervention*	Suicide is becoming an increasing concern among children and young people, and adolescent suicide rates per 100,000 have increased by 7-9% annually since 2010 (Bould et al., 2019). Research indicates that CYP can be reluctant to seek professional help for mental health difficulties (Rickwood et al., 2007) and they may be more likely to seek support from friends than professionals (Rickwood et al., 2005). The lesson aims to teach participants to identify and support people with suicidal thoughts and connect them to further help. Therefore CYP who attend this course may be more equipped to support peers.
Who *Recipients of the intervention*	The training course is offered to anyone aged 14 and above.
What *Physical or informational materials used in the intervention*	Presentations and video clips are used to teach the relevant information and participants engage in practice-based tasks during the course. On completion of the session, all participants receive a certificate and a resource pack with information on the sources of support available for people who are experiencing suicidal thoughts.
What *Procedures, activities and/or processes used in the intervention*	During the course, participants are taught how to identify people with suicidal thoughts. They are also taught practical steps that can be taken to support someone with suicidal thoughts using presentations, video clips and discussions. Participants engage in practice-based tasks to enable them to apply the steps.
Who *Intervention providers/ implementers*	The lesson is delivered by trained Grassroots facilitators. For participants aged 14 years old, an additional adult must be present (e.g., teacher).
How *Mode of delivery*	The training course is delivered face-to-face to groups of up to 30 people.
Where *Location of the intervention*	The intervention is delivered in the participants usual place of school.

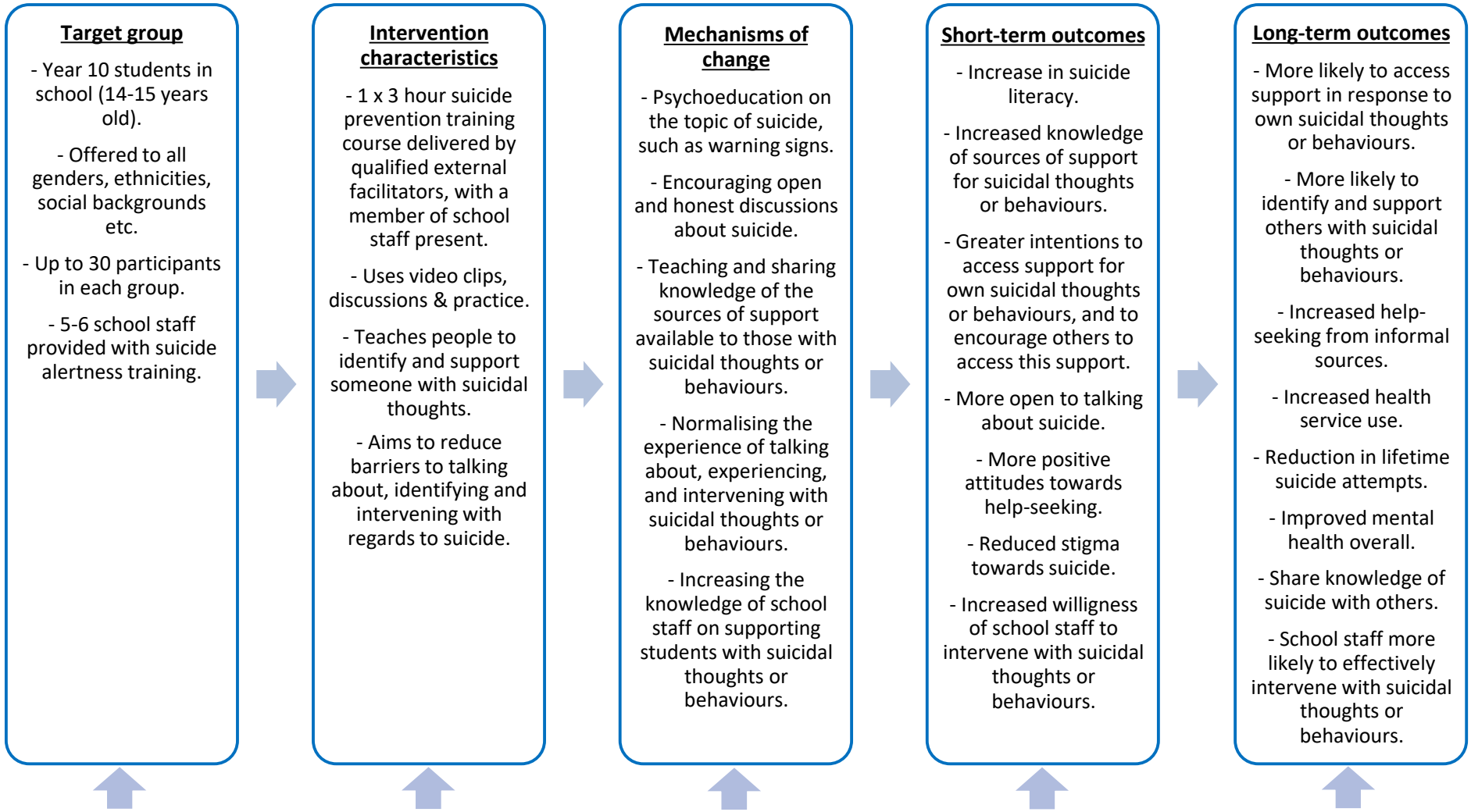
When and how much *Duration and dosage of the intervention*	The training course lasts up to 3 hours including breaks. It is delivered in a single session and participants are only required to attend once.
Tailoring *Adaptation of the intervention*	Several adaptations are made when delivering to youth participants, to promote engagement. This includes: smaller groups for some activities, short breaks, additional brainstorming exercises, and more illustrative stories or humorous anecdotes (not related to suicide). The facilitator is encouraged to be energetic, uplifting, and motivating, and they are able to use supplementary material.
How well (planned) *Strategies to maximise effective implementation*	Facilitators from Grassroots are trained and experienced at delivering and adapting the workshop for youth audiences. When delivered in schools, at least one member of school staff is also present during the course to manage behaviour and encourage pupil participation.

TIDieR framework: Reframe IT-UK

Brief name	Reframe IT-UK - online Cognitive Behavioural Therapy (CBT) for young people with suicidal ideation.
Why *Rationale, theory and/or goal of essential elements of intervention*	Patalay and Fitzsimons (2021) found that 7.4% of 17-year-olds in the UK have previously attempted suicide, which highlights the need for early intervention and prevention in regards to suicide. Research has found CBT to be an effective treatment for reducing suicidal ideation in adolescents (Alavi et al., 2013). Robinson et al. (2014) designed Reframe-IT, an online CBT-based intervention for secondary school students with suicidal ideation. This intervention has been found to reduce suicidal ideation, depressive symptoms, and feelings of hopelessness (Robinson et al., 2016). Reframe IT-UK is an adapted version of Reframe-IT to be used with UK adolescents; it is hoped that this programme will incur similar benefits.
Who *Recipients of the intervention*	Reframe IT-UK is offered to year 10 students (14-15 years old) who have recently experienced suicidal ideation.
What *Physical or informational materials used in the intervention*	The online CBT-based intervention is delivered from the Reframe IT-UK website, and all participating young people are provided with their own login for the website. To use the programme, participants need access to a device with internet e.g., computer, iPad, smartphone. The website contains 8 online modules with videos from a host and video diaries from 2 young people (actors) who are experiencing suicidal ideation. The website also includes activities, factsheets, a message board (to speak to a facilitator), and details of helplines and services. In addition, participants can create and subsequently access their own safety plan.
What *Procedures, activities and/or processes used in the intervention*	Participants complete 8 online CBT-based modules on the following topics: identifying problems, recognising feelings, automatic thoughts, help seeking, positive activities and behaviours, goal planning, reframing thoughts, and coping strategies. During the modules, they are taught a number of CBT-based skills and techniques (e.g., reframing thoughts, problem solving) and they have opportunities to practise these techniques in relation to themselves and one of the characters. The young people are also able to read a number of factsheets on topics such as alcohol and sleep difficulties, and they are

	given details of helplines and services which they may wish to use. If appropriate, participants may follow their safety plan to manage a crisis situation.
Who *Intervention providers/ implementers*	After receiving appropriate training, school wellbeing staff support the students to complete the 8 modules. Alongside this, the students have 24 hour access to Reframe IT-UK so they can use the programme independently at any time. Participants are also able to speak to a moderator online via the message board.
How *Mode of delivery*	The intervention is delivered online via the Reframe IT-UK website however participants receive face to face support from school wellbeing staff to complete the modules. The programme is completed individually.
Where *Location of the intervention*	Modules are initially completed in the school setting. However, the young people can access the programme from anywhere once they have their login, providing they have internet access and an appropriate device on which to visit the website. Therefore they may choose to access the intervention at home or in other locations.
When and how much *Duration and dosage of the intervention*	The intervention lasts for 10 weeks and there are eight 20-minute modules to complete. Participants meet with a member of school wellbeing staff on a weekly basis to complete the modules. They also have 24 hour access to Reframe IT-UK outside of this time, so how often and how long they spend on the programme is an individual choice. Schools may be able to provide access to IT equipment in and out of school.
Tailoring *Adaptation of the intervention*	School staff can provide support where necessary to students with additional learning needs. Students can decide which elements of the programme to access.
How well (planned) *Strategies to maximise effective implementation*	School wellbeing staff are appropriately trained in order to effectively support the students with the intervention. Students meet with staff on a weekly basis to ensure they complete the modules, and they are encouraged to use the other features of the programme independently. An email reminder is sent once each weekly module is available.

Logic model: Suicide Awareness Lesson



Logic model: Reframe IT-UK