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A School Based Interventions Study Examining Approaches for Wellbeing and Mental Health Literacy of pupils in Year Nine in England: Study Protocol for a Multi-school, Cluster Randomised Control Trial (AWARE)

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ABSTRACT

Introduction: The prevalence of emotional difficulties in young people is increasing. This upward trend is largely accounted for by escalating symptoms of anxiety and depression. As part of a public health response, there is increasing emphasis on universal prevention programmes delivered in school settings. This protocol describes a three-arm cluster randomised control trial, investigating effectiveness and cost-effectiveness of two interventions, alongside a process and implementation evaluation, to improve mental health and wellbeing of year 9 pupils in English secondary schools.

Method: A three-arm cluster randomised control trial, comparing two different interventions, Youth Aware of Mental Health (YAM) or The Guide, to Usual Provision. Overall, 144 secondary schools in England will be recruited, involving 8,600 year 9 pupils. The primary outcome for YAM is depressive symptoms, and for The Guide it is intended help-seeking. These will be measured at baseline, three to six months and one year after the intervention commenced. Secondary outcomes measured concurrently include changes to: positive wellbeing, behavioural difficulties, support from school staff, stigma related knowledge, attitudes and behaviours, and mental health first aid. An economic evaluation will assess cost-effectiveness of the interventions, and a process and implementation evaluation (including a qualitative research component) will explore several aspects of implementation (fidelity, quality, dosage, reach, participant responsiveness, adaptations), social validity (acceptability, feasibility, utility), and their moderating effects on the outcomes of interest, and perceived impact.

Ethics and dissemination: This trial has been approved by the UCL Research Ethics Committee. Findings will be published in a report to the Department for Education, in peer reviewed journals and at conferences.

Trial registration: ISRCTN17631228 – This covers the pilot study and subsequent RCT.

Protocol: V1 03/01/2019. Substantial changes to the protocol will be communicated to the Trials Manager to relevant parties (e.g. ISRCTN).

STRENGTHS AND LIMITATIONS OF THIS STUDY

This is the first randomised control trial to examine YAM and The Guide compared to usual provision in England.

- The trial is powered to detect small effects.
- Both interventions are only compared to the control group, rather than to each other.
- Only the trial statistician, economist and the individual conducting quantitative analysis are blind to what intervention each school has been allocated.

Keywords: Adolescent, Young Person, Teacher, Cluster Randomised Controlled Trial, Mental Health, Wellbeing

INTRODUCTION

Half of presenting mental health difficulties appear before the age of 14, and three-quarters before the age of 24.[1] Such instances are associated with poorer physical health outcomes and educational attainment.[1,2] Within the UK, a recent survey of 30,000 young people in schools found that 18.4% reported experiencing high levels of emotional distress.[3] The latest prevalence survey suggests that one in eight 5 to 19 year olds have at least one mental health difficulty and that emotional difficulties are increasing in young people.[4]

Childhood and adolescence are important developmental phases for prevention and early intervention initiatives for mental health and wellbeing (MHW).[5,6] Seeking help for depressive symptoms at 14 decreases the risk of developing clinical depressive symptoms at 17 sevenfold.[7] Prevention and early intervention programmes have demonstrated a good return on investment, with a 6–10%

annual rate of return on investment spent.[8] However, young people report barriers to help seeking, such as difficulty identifying that there is a problem and perceived and internalised stigma.[9,10] Improving help-seeking knowledge and the ability to recognise distress are suggested ways to improve mental health.[11,12]

Schools are often viewed as a universal point of access to children and young people, offering an important opportunity to embed MHW initiatives.[13] Schools can provide a non-stigmatising environment where young people and parents/carers can engage, outside of mental health services,[14] and can also present opportunities for pupils to develop self-management strategies.[15]

Universal prevention programmes

There is growing evidence for the role of school-based promotion and prevention programmes for MHW. A meta-analysis examining interventions aimed at social and emotional learning demonstrated that pupils who received interventions had significantly improved social and emotional skills, behaviour, and academic performance.[16] However, impact is often highly dependent on successful implementation; interventions that are implemented well in schools can produce outcomes that are 2–3 times higher than those implemented poorly.[17] Multiple factors can influence implementation at different levels of the system, including policy, provider and intervention characteristics and factors related to the prevention support system.[17] Organisational capacity and the feasibility of delivery within specific contexts are also repeatedly highlighted. Despite this, there is often an expectation that the evidence base for interventions delivered in one context will successfully transfer to other quite different settings. Relatedly, few studies tend to run implementation and process evaluations in parallel with examining effectiveness, and those that do tend to focus on fidelity.[18] Examining aspects such as social validity and cultural validity are important, particularly when importing interventions from other countries.[19]

Some universal programmes place emphasis on improving individual's mental health literacy (MHL). MHL interventions traditionally focus on educating and changing beliefs about mental disorders to aid their recognition, management or prevention, and increasingly include mental health first aid.[20,21] Kutcher, Wei and Coniglio recently defined MHL as having four main components, including the addition of mental health promotion: '1) understanding how to obtain and maintain positive mental health, 2) understanding mental disorders and their treatments, 3) decreasing stigma related to mental disorders and 4) enhancing help-seeking efficacy (knowing when and where to seek help and developing competencies designed to improve one's mental health care and self-management capabilities'. [22] Youth Aware of Mental Health (YAM) is an example of a universal intervention that aims to improve awareness and promote mental health.[23] As part of the Saving and Empowering Young Lives in Europe (SEYLE) cluster randomised controlled trial, a suicide prevention programme across 12 European countries, YAM was compared to two active interventions, 'Professional screening' and 'Question, Persuade, and Refer', and a control group.[24] No difference between arms on suicidal ideation or attempts was found at three month follow-up, however YAM significantly reduced the risk of suicide attempts and suicidal ideation at 12 month follow-up compared to the control group.[23] Interviews with young people have found they prefer YAM to regular classroom activities, however differences were reported in how actively involved they wanted to be in YAM.[25]

The Mental Health and High School Curriculum Guide (The Guide)[26] also aims to increase awareness of mental disorders and their treatments, as well as increasing understanding of how to obtain and maintain mental health, reduce stigma and improve help-seeking efficacy. Delivery of The Guide in Canada was found to increase student and staff knowledge, reduce stigma and increase help-seeking in students.[26–29] In Tanzania, The Guide has been shown to increase teacher knowledge and reduce stigma,[30–32] teacher reports also highlighted positive changes to knowledge, attitude and behaviour in their pupils.[31] Significantly improved mental health knowledge, reduced stigma, more adaptive coping, better

lifestyle choices, and lower perceived stress was also found for students who received The Guide in Nicaragua.[33]

Whilst YAM and The Guide have a developing evidence base in multiple countries, evidence for the effectiveness of such approaches in the UK is sparse. A scoping exercise conducted by the Department for Education (DfE) in England, concluded that both should be tested to contribute to the UK evidence base for effective interventions to improve mental health in children and young people. As the interventions were developed in other countries, undertaking a process and implementation evaluation to understand factors beyond fidelity and effectiveness is important.[19] Thus, alongside an RCT examining effectiveness, a process and implementation evaluation will be undertaken to investigate YAM and The Guide compared to usual provision in English schools.

AIMS AND HYPOTHESIS

Effectiveness measurement

Primary aims:

1. To examine whether YAM is more effective than the usual school-based provision in reducing emotional difficulties in young people.
2. To examine whether The Guide is more effective than the usual school-based provision in increasing intended help-seeking of young people around mental health.

Primary hypotheses:

H_1 Young people receiving YAM will report lower emotional difficulties at between 3–6 and 12 months follow-up than those who receive the usual school curriculum.

H_2 Young people receiving The Guide will report increased intended help-seeking of mental health at 3–6 and 12 months follow-up than those who receive the usual school curriculum.

Implementation and process evaluation research questions

1. What is the state of participating schools' existing provision for supporting mental health and wellbeing, and their relationship with local mental health services, and does the nature of provision change over the course of the trial?
2. To what extent does implementation follow the guidelines of the specified interventions, e.g. in terms of fidelity and dosage?
3. What is the relationship between implementation variability (e.g. in terms of different levels of fidelity) and intervention outcomes?
4. What are the experiences of schools (pupils and staff) and instructors/teachers in delivering/receiving YAM and The Guide?

METHODS AND ANALYSIS

Design

AWARE (Approaches for Wellbeing and Mental Health LiterAcy: Research in Education) is a three-arm cluster randomised control trial: YAM or The Guide versus usual school provision (control). Interventions are delivered to whole school classes as part of the school curriculum. Assessment is undertaken at baseline (prior to intervention randomisation), 3–6 and 12 months after interventions have been delivered.

Site recruitment

The study opened for school recruitment in March 2018 and will finish in July 2019. This study aims to recruit 144 secondary schools across England. Within each school, three Year 9 classes will be required to take part, resulting in participation of approximately 8,600 young people.

Schools will be recruited via a variety of sources, including a paid-for school database (school mailings), the Schools in Mind network hosted by the Anna Freud National Centre for Children and Families (AFNCCF), AFNCCF collaborators, Public Health England, the National Institute for Health Research, local authorities and

school commissioners. The project will also be advertised on social media platforms and in education publications and resources.

Participant recruitment

Following school recruitment, participants are recruited via a two-stage process. First, schools select delivery groups who will receive an intervention (if allocated). Second, letters are sent out to parents/guardians of these delivery groups informing them of the study, as well as their right to opt out. The letter also explains that all children will only be involved in the project if they assent in class prior to completion of the baseline survey. Finally, assent is provided by young people reading through the information sheet and ticking boxes online agreeing to take part. If they do not assent, they cannot be part of the trial. The first young person joined the trial on the 17/09/2018.

Inclusion/Exclusion criteria

Schools are eligible to participate if:

1) They are willing to deliver/have an intervention delivered to around 60 year 9 pupils in three delivery classes

2) They are able to allocate one hour per week to deliver the intervention for six weeks in the spring term of 2019 or 2020

3) They are able send staff to one of the training sessions, if required

4) They sign a Memorandum of Understanding, data sharing agreement and provide pupil lists to the research team.

Young people are eligible to take part if:

1) Their parents/guardians provide consent

2) They provide written assent.

Interventions

Youth Aware of Mental Health (YAM).[23]

YAM is a five-session structured programme to improve awareness via discussions on risk, protective factors, and knowledge around mental health. The aim is to provide young people aged 14–16 years with a non-judgmental platform to explore topics such as depression, anxiety and suicidal thoughts, and reflect on problem-solving in emotionally charged situations and dilemmas. Role plays are central to YAM, allowing pupils the opportunity to explore relevant issues from their everyday lives (e.g. in relation to parents, peers, teachers etc.). The role-play sessions comprise three themes: awareness about choices; depression and suicidal thoughts and feelings; how to manage stress and crisis situations. These are supported by learning materials including posters which will be displayed in classrooms for the duration of YAM. Posters focus on: awareness of mental health; self-help advice; stress and crisis; depression and suicidal thoughts; helping a troubled friend; getting advice. Pupils are also provided with booklets which address the same key themes and contain information on local support services. Pupils who think they may need support are encouraged to talk to staff and utilise local and national support networks. In the original intervention, the five-hour programme spans three weeks, but this has been adapted to five consecutive weeks in English schools. Sessions are delivered by instructors in a classroom setting with the support of a trained helper. Instructors completed a five-day workshop delivered by YAM developers; instructors and helpers are professionals with a background in education, psychology, nursing, social work or youth work.

The Mental Health and High School Curriculum Guide (The Guide).[34]
The Guide was developed in Canada by Dr Kutcher in collaboration with the Canadian Mental Health Association. It aims to increase MHL in young people and school staff. Adapted for delivery in English schools, The Guide will be delivered through six one-hour lessons taught in consecutive weeks. All adaptations to The Guide for an English school setting have been approved by Dr Kutcher and were informed by a pilot study. The Guide will be delivered by teachers who have attended a one-day face-to-face training. The training aims to improve teachers' knowledge of mental health and mental illness and reduce stigma. The training day will familiarise teachers with the adapted Guide materials, including six lesson plans

on: stigma of mental illness; understanding the relationship between mental health and mental illness; understanding specific mental illnesses; adolescents' experiences of mental illness; seeking help and finding support; the importance of positive mental health.

Outcome measures

All primary and secondary measures will be completed prior to the intervention and follow up will take place at 3–6 and 12 months post intervention. All questionnaires will be completed online.

Primary outcome measures:

- For YAM: depressive symptoms (Short Mood and Feelings Questionnaire (SMFQ).[35]
- The Guide (intended help-seeking): General Help-seeking Questionnaire (GHSQ).[36]

Secondary outcome measures:

- Emotional difficulties: SMFQ for the guide only.[35]
- Intended help-seeking: General Help-seeking Questionnaire (GHSQ) for YAM only.[36]
- Positive wellbeing: Huebner Life Satisfaction Scale (LSS).[37]
- Behavioural problems: Me & My Feelings (M&MF) questionnaire – behavioral difficulties subscale.[38]
- Support from school staff: Student Resilience Survey (SRS) [39] – School Connection subscale.[40]
- Stigma (knowledge): Mental Health Knowledge Schedule (MAKS) – Non-vignette items (items 1-6).[41]
- Stigma (behaviour): Reported and Intended Behaviour Scale – intended behavioural subscale (RIBS).[42]
- Mental health first aid.[43]
- Stigma (attitudes): Attitudes towards mental health.[29]
- Paediatric Quality of Life (Child Health Utility – 9D).[44]

Measures for economic evaluation

Information on service use will be completed online by pupils alongside the outcome measures. Data required to calculate cost will be collected online from both those who delivered an intervention and either a member of the school finance team (The Guide) or AFNCCF (YAM) after intervention delivery.

- Client Service Receipt of Inventory (CSRI; adapted for the study population).[45]
- Service Information Schedule (SIS).[46]

Implementation and process monitoring measures

Usual Provision Survey

A member of the school's senior leadership team will be asked to complete two online surveys regarding current whole-school mental health provision. This will be prior to delivery of the intervention and approximately one year after the start of intervention delivery.

Implementation surveys and outcome measures

Intervention deliverers will complete one online implementation survey per delivery group after delivery has finished. Questions will cover six key aspects of implementation, namely fidelity, quality, dosage, participant responsiveness, reach and adaptations. Within this, three aspects relating to the social validity of the intervention (acceptability, feasibility and utility) will also be assessed using a standardised questionnaire.[47]

Qualitative data and observations

Qualitative implementation and process data will be collected towards the end of delivery of the interventions. Eight schools will be recruited from the main sample as qualitative case study schools in Year 1 of the project; one school per intervention at four of the hubs (excluding control). Case study schools will be

recruited via expression of interest and sampled based on variation in their usual provision around mental health and wellbeing, drawing on data from two items in the Usual Provision Survey:

1. Please identify, in the last two years, the activities and approaches that have been used in your school and indicate who has delivered/provided these activities.
2. How significant are the following potential barriers to providing effective mental health support within your school?

Face-to-face or telephone interviews will be conducted with two to three members of staff (including a senior leadership team member and a staff member delivering the intervention) and one to two focus groups will be conducted face-to-face with young people (approximately four to five young people in each focus group) at each school. Learning from the feasibility study indicated that this sample size would yield a large amount of rich qualitative data, while still being manageable in terms of the research team's capacity.

Interviews/focus groups will be semi-structured, enabling the research team to guide the interviews/focus groups according to their topics of interest, but with the conversation around these topics being led by participants in terms of the issues that are most pertinent to them. The topics that the interviews/focus groups will cover include: staff experiences of delivering the interventions and receiving training; staff perceptions of barriers and facilitators to delivery; staff perceptions of impact; staff suggestions for improvement of the interventions; pupils' experiences of taking part in the interventions; pupils' perceptions of impact and helpful aspects of the interventions; pupils' suggestions for improvement of the interventions. All interviews/focus groups will be audio recorded and transcribed verbatim.

The research team will also conduct an observation of a session of the intervention (excluding YAM) at each school to gather contextual information about what the

interventions look like on the ground. No individual pupil or staff responses will be recorded, but field notes will be taken during the observation on the process of delivery, the layout of the room, and the atmosphere during delivery.

As schools who express interest in taking part as a case study are likely to be the more engaged schools, there is an opportunity in Year 2 of the project for a small number of telephone interviews to be conducted with staff at schools who have engaged less with the trial in Year 1. This could include schools who have dropped out of the trial.

Randomisation of schools

To ensure approximate distribution across conditions, randomisation will be carried out by Kings Clinical Trials Unit (KCTU) minimising for regional representation, current mental health provision, deprivation (as indicated by free school meal eligibility) and urban/rural situation. Randomisation will take after place after baseline data (staff and pupil questionnaires) have been collected. Only the statistician, quantitative data analyst and economist are blind to intervention allocation.

Sample size calculation

The schools will be randomised to three groups (YAM, The Guide and Usual Provision). Due to the delivery of the intervention within classes, the trial will be analysed on class level, controlling for school- and class-level clustering. While cluster effects of emotional distress on *school*-level are usually small [48,49] no data on *class*-level clustering was available. To our knowledge, no study has investigated school-level intra-class correlations of help-seeking. Cluster effects for psychometric measures were evaluated in a joint feasibility study with the INSPIRE trial with N = 1531 secondary students nested within 79 delivery groups at five schools at baseline. We found ICCs of .02 for both SMFQ and GHSQ (with upper borders of bootstrapped 95%-confidence intervals of .04 for the GHSQ and .05 for the SMFQ). Our sample size is based on an intra-class correlation of ρ = .10, which is conservative given the estimates found in the literature and pilot.

The only school-level variables that will be used as predictors in the proposed analysis are the stratification variables which were assumed not to have any predictive power. Pre-test values of the outcome measures will be used as predictors of within-school variance (conservative estimate of R2 = .20 was used). Given these assumptions, a Minimally Detectable Effect Size MDES = .20 without controlling for any additional variables can be detected (significance level α=.05; statistical power β=.80) with a sample size of 90 schools (45 control, 45 intervention); and for the analysis taking pre-test values into account an MDES = .198. Since no evidence suggests that the two interventions show different effects, our sample size calculations for the YAM and The Guide trial arms are the same. The overall sample size is 135 schools (45 schools per arm; with 60 students each) of which the 45 control schools serve as comparators for both interventions. Incorporating the geographical spread and recruitment areas of the study, we plan to recruit 144 schools overall.

Data Management

All quantitative data will be stored on the University of Manchester's secure sever. The Data Manager (JS), along with the Research Assistants (EA and RM) will be responsible for cleaning and coding the data. Qualitative data will be stored at the EBPU. The Qualitative Data Lead (ES), supported by the Trials Manager (DH), Research Officer (AM) and Research Assistants (RM and EA), will be responsible for storing and checking transcripts and ensuring their accuracy.

Analysis plan

Effectiveness analysis

A detailed statistical analysis plan will be written and documented with the funder at least three months before the data is shared with the analyst (JB). However, the analysis will mirror the power analysis in that a mixed model will be used to analyse the data with classes defining the clusters and an orthogonal random effect for schools. The primary analysis will only use the intervention (dummy-coded on class level) and stratification variables (on school level) as independent variables.

Sensitivity analyses will be conducted for adding pre-tests and imputation of missing data. If subgroup analyses are to be conducted these will be defined in the statistical analysis plan as well.

Economic evaluation

Service use and costs

A Service Information Schedule will be designed to facilitate microcosting of the interventions. Information on services and supports used by the young people in the study will be collected using a specially adapted version of the Client Service Receipt Inventory.[45] From these data, we will investigate whether patterns of service use and associated costs differ between the intervention and control groups and explore whether any differences are driven by individual characteristics or baseline level of need.

Cost-effectiveness analysis

Cost-effectiveness and cost-utility analyses will be undertaken for change in a) the primary outcome measure and b) quality-adjusted life years (derived from CHU9D).[44] We will employ an analytical approach that allows for adjustment for confounders, the likely non-normal distribution of cost data, the joint analysis of cost and outcome measures, and sub-group analyses. Results will be presented as cost-effectiveness acceptability curves [50] plotting the probability that the intervention will be considered cost-effective compared to treatment as usual against different levels of willingness to pay for an improvement in outcome. Sensitivity analyses will be undertaken by varying assumptions used to calculate the intervention cost.

Process and implementation analysis

Descriptive statistics will be used to document usual school provision and how this changes over the course of the project, as well as to document the implementation of YAM and The Guide. Additionally, for documenting the implementation, we will compare 'implementation as delivered' from our survey data with 'intervention as

planned'. Where applicable, the latter can be used to determine the proportion of participating schools who can be deemed to have achieved at least a minimum standard of intervention delivery (e.g. 'on treatment' status). To assess the relationship between implementation variability and outcomes, multi-level modelling will be used, in which we fit the implementation data noted above (or on treatment status derived from said data) as explanatory variables at the school or class level, to assess the extent to which they are predictive of intervention outcomes at the pupil level.

Qualitative interview and focus group transcripts will be analysed using thematic analysis.[51] Three members of the research team will code or assign extracts of the transcripts to broad overarching categories, derived from the research questions (e.g. perceptions of impact). The researchers will then break down the content (transcript extracts) coded within these overarching categories into themes and subthemes relevant to the categories. A fourth member of the research team will then code 10% of staff and pupil interviews to the coding frame (themes and subthemes) devised by the other members of the team. Refinements to the coding frame will then be made as necessary.

ETHICS AND DISSEMINATION

Ethical approval and consent

The study was approved by University College London Research Ethics Committee (6735/009 and 6735/014). Consent/assent will be undertaken in a series of stages. Schools that have expressed an interest in the project, meet inclusion criteria and are selected for the programme will be asked to return a Memorandum of Understanding signed by a member of the senior leadership team. Further consent will then vary according to the different parts of the study. This study is congruent with GDPR legislation; the collection and processing of this data falls under Article 6,1,e. (public task).

Pupil data

For outcome data, opt-out consent will be used for research purposes. Schools will send letters to parents/carers of participating pupils. Parents/carers can then contact the Data Manager if they do not want their child to take part in the evaluation. These pupils' data will be removed from the pupil lists provided by the school. For each remaining pupil, a unique password will be created to allow access to the online survey. Prior to completing online surveys, pupils will be presented with an information sheet and assent form which they must tick if they want to proceed the survey. All information sheets outline confidentiality procedures for collecting, processing, and storing data.

All other data (staff surveys, implementation surveys, qualitative data)

All other surveys, completed online, will require opt-in consent. As with pupils, individuals will be presented with an information sheet and consent form which they must tick prior to accessing the survey.

For qualitative interviews/focus groups, opt-in consent will be required. School staff and YAM instructors will be required to read and sign an information sheet and consent form. For pupils under the age of 16, letters will be sent home to parents/carers, which require a signed consent form to be returned if they are happy for their child to take part. Prior to interviews/focus groups commencing, the young people will also be asked to read an information sheet and sign an assent form. Consent/assent will not be sought for observations of intervention sessions as no individual staff or pupil responses will be recorded.

Monitoring of adverse events (AEs)

AEs, defined as a negative, emotional and behavioural occurrence, or sustained deterioration in a research participant, will be captured as part of the study. This includes serious adverse events (SAEs) which are a threat to life: suicidal ideation, suicidal intent, hospitalisation due to psychiatric of use of substances, death including suicide. Other adverse events: violent behaviour, self-harm, or any other event that an individual feels it is important to report, will also be captured. School safeguarding leads will judge whether they believe the AE is likely related to the intervention.

The ongoing conduct and progress of this study is monitored by an independently chaired Advisory Group Ethics Sub-Committee (AGESC) and Trial Steering Committee at the Department for Education. On becoming aware of SAEs, the CI/TM will report SAEs or AEs which are likely to be related to the intervention to the AGESC within two working days. Other AEs will be collated and reported quarterly to the AGESC. The University College London Research Ethics Committee will also be informed of AEs and SAEs using the same mechanisms. School and research safeguarding protocols will also be followed as standard in addition to the reporting and documenting of AEs.

Dissemination plan

Results will be disseminated through a report to the DfE, as well as at conferences and in international peer review journals.

Trial sponsor. The trial is sponsored by University College London.

TRIAL STATUS

Recruitment for schools opened in March 2018 and will stay open until June 2019. The last participants will be followed up at a one year follow up in January/February 2021.

FUNDING STATEMENT

This research was commissioned and funded by the Department for Education. The Department selected the interventions to be trialled and also chairs a steering committee the researchers report to regarding the progress and quality of the research. However, the department had no role in the design of this study and will not have any role in the analyses, interpretation of the data, or decision to submit results. The views expressed are those of the authors and not necessarily those of the Department for Education.

ROLE AND RESPONSIBILITIES

JD is the Principle Investigator. NH is the Implementation Lead. DH is the Trials Manager. JS is the Data Manager. ES is the Qualitative Lead. AM is Research

Officer/School Liaison Lead. RM & EA are Research Assistants. JB is the Trials Statistician. PP provides expertise around measures and statistical analysis. EB is the Health Economist.

AUTHOR CONTRIBUTORS

All authors contributed to the writing of the protocol. All authors read and approved the final version of the manuscript.

COMPETING INTERESTS STATEMENT

The authors state they have no competing interests to declare.

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ACCESSING DATASETS

An anonymised dataset of the quantitative analysis will be made available to researchers in 2022. A decision regarding storage location is yet to be finalised.

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Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

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		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2

Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	#3	Date and version identifier	3
Funding	#4	Sources and types of financial, material, and other support	18
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	17
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	18
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	18
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies	3-6

		(published and unpublished) examining benefits and harms for each intervention	
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
Objectives	#7	Specific objectives or hypotheses	6-7
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	7
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-9
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or	9

		improving / worsening disease)	
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	11-12
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9-10
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	n/a
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	11, 13-14
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	7

Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	13
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	13
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	13
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg,	7, 9-12

		questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	n/a
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14-15
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14-15
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be	17

		found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	17
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	17
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	2
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	3
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	16
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a

Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	16
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	19
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	18
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	19
Informed consent	#32	Model consent form and other related documentation given	n/a

materials		to participants and authorised surrogates	
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

BMJ Open

A School Based Interventions Study Examining Approaches for Wellbeing and Mental Health Literacy of pupils in Year Nine in England: Study Protocol for a Multi-school, Parallel Group, Cluster Randomised Controlled Trial (AWARE)

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A School Based Interventions Study Examining Approaches for Wellbeing and Mental Health Literacy of pupils in Year Nine in England: Study Protocol for a Multi-school, Parallel Group, Cluster Randomised Controlled Trial (AWARE)

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ABSTRACT

Introduction: The prevalence of emotional difficulties in young people is increasing. This upward trend is largely accounted for by escalating symptoms of anxiety and depression. As part of a public health response, there is increasing emphasis on universal prevention programmes delivered in school settings. This protocol describes a three-arm parallel group cluster randomised controlled trial, investigating effectiveness and cost-effectiveness of two interventions, alongside a process and implementation evaluation, to improve mental health and wellbeing of Year 9 pupils in English secondary schools.

Method: A three-arm parallel group cluster randomised controlled trial, comparing two different interventions, Youth Aware of Mental Health (YAM) or The Guide, to Usual Provision. Overall, 144 secondary schools in England will be recruited, involving 8,600 Year 9 pupils. The primary outcome for YAM is depressive symptoms, and for The Guide it is intended help-seeking. These will be measured at baseline, three to six months and nine to twelve months after the intervention commenced. Secondary outcomes measured concurrently include changes to: positive wellbeing, behavioural difficulties, support from school staff, stigma related knowledge, attitudes and behaviours, and mental health first aid. An economic evaluation will assess cost-effectiveness of the interventions, and a process and implementation evaluation (including a qualitative research component) will explore several aspects of implementation (fidelity, quality, dosage, reach, participant responsiveness, adaptations), social validity (acceptability, feasibility, utility), and their moderating effects on the outcomes of interest, and perceived impact.

Ethics and dissemination: This trial has been approved by the University College London Research Ethics Committee. Findings will be published in a report to the Department for Education, in peer reviewed journals and at conferences.

Trial registration: ISRCTN17631228 – This covers the pilot study and subsequent Cluster Randomised Controlled Trial.

Protocol: V1 03/01/2019. Substantial changes to the protocol will be communicated to the Trials Manager to relevant parties (e.g. ISRCTN).

STRENGTHS AND LIMITATIONS OF THIS STUDY

This is the first randomised controlled trial to examine YAM and The Guide compared to usual provision in England.

- The trial is powered to detect small effects.
- Both interventions are only compared to the control group, rather than to each other.
- Only the trial statistician, economist and the individual conducting quantitative analysis are blind to what intervention each school has been allocated.

Keywords: Adolescent, Young Person, Teacher, Cluster Randomised Controlled Trial, Mental Health, Wellbeing

INTRODUCTION

Half of presenting mental health difficulties appear before the age of 14, and three-quarters before the age of 24.[1] Such instances are associated with poorer physical health outcomes and educational attainment.[1,2] Within the UK, a recent survey of 30,000 young people in schools found that 18.4% reported experiencing high levels of emotional distress.[3] The latest prevalence survey suggests that one in eight 5 to 19 year olds have at least one mental health difficulty and that emotional difficulties are increasing in young people.[4]

Childhood and adolescence are important developmental phases for prevention and early intervention initiatives for mental health and wellbeing.[5,6] Seeking help for depressive symptoms at 14 decreases the risk of developing clinical depressive symptoms at 17 sevenfold.[7] Prevention and early intervention programmes have demonstrated a good return on investment, with a 6–10% annual rate of return on

investment spent.[8] However, young people report barriers to help seeking, such as difficulty identifying that there is a problem and perceived and internalised stigma.[9,10] Improving help-seeking knowledge and the ability to recognise distress are suggested ways to improve mental health.[11,12]

Schools are often viewed as a universal point of access to children and young people, offering an important opportunity to embed mental health and wellbeing initiatives.[13] Schools can provide a non-stigmatising environment where young people and parents/carers can engage, outside of mental health services,[14] and can also present opportunities for pupils to develop self-management strategies.[15]

Universal prevention programmes

There is growing evidence for the role of school-based promotion and prevention programmes for mental health and wellbeing. A meta-analysis examining interventions aimed at social and emotional learning demonstrated that pupils who received interventions had significantly improved social and emotional skills, behaviour, and academic performance.[16] However, impact is often highly dependent on successful implementation; interventions that are implemented well in schools can produce outcomes that are 2–3 times higher than those implemented poorly.[17] Multiple factors can influence implementation at different levels of the system, including policy, provider and intervention characteristics and factors related to the prevention support system.[17] Organisational capacity and the feasibility of delivery within specific contexts are also repeatedly highlighted. Despite this, there is often an expectation that the evidence base for interventions delivered in one context will successfully transfer to other quite different settings. Relatedly, few studies tend to run implementation and process evaluations in parallel with examining effectiveness, and those that do tend to focus on fidelity.[18] Examining aspects such as social validity and cultural validity are important, particularly when importing interventions from other countries.[19]

Some universal programmes place emphasis on improving individual's mental health literacy. Such interventions traditionally focus on educating and changing beliefs about mental disorders to aid their recognition, management or prevention, and increasingly include mental health first aid.[20,21] Kutcher, Wei and Coniglio recently defined mental health literacy as having four main components, including the addition of mental health promotion: '1) understanding how to obtain and maintain positive mental health, 2) understanding mental disorders and their treatments, 3) decreasing stigma related to mental disorders and 4) enhancing help-seeking efficacy (knowing when and where to seek help and developing competencies designed to improve one's mental health care and self-management capabilities'. [22] Youth Aware of Mental Health (YAM) is an example of a universal intervention that aims to improve awareness and promote mental health.[23] As part of the Saving and Empowering Young Lives in Europe (SEYLE) cluster randomised controlled trial, a suicide prevention programme across 12 European countries, YAM was compared to two active interventions, 'Professional screening' and 'Question, Persuade, and Refer', and a control group.[24] No difference between arms on suicidal ideation or attempts was found at three month follow-up, however YAM significantly reduced the risk of suicide attempts and suicidal ideation at 12 month follow-up compared to the control group.[23] Interviews with young people have found they prefer YAM to regular classroom activities, however differences were reported in how actively involved they wanted to be in YAM.[25]

The Mental Health and High School Curriculum Guide (The Guide)[26] also aims to increase awareness of mental disorders and their treatments, as well as increasing understanding of how to obtain and maintain mental health, reduce stigma and improve help-seeking efficacy. Delivery of The Guide in Canada was found to increase student and staff knowledge, reduce stigma and increase help-seeking in students.[26–29] In Tanzania, The Guide has been shown to increase teacher knowledge and reduce stigma,[30–32] teacher reports also highlighted positive changes to knowledge, attitude and behaviour in their pupils.[31] Significantly improved mental health knowledge, reduced stigma, more adaptive coping, better

lifestyle choices, and lower perceived stress was also found for students who received The Guide in Nicaragua.[33]

Whilst YAM and The Guide have a developing evidence base in multiple countries, evidence for the effectiveness of such approaches in the UK is sparse. A scoping exercise conducted by the Department for Education in England, concluded that both should be tested to contribute to the UK evidence base for effective interventions to improve mental health in children and young people. As the interventions were developed in other countries, undertaking a process and implementation evaluation to understand factors beyond fidelity and effectiveness is important.[19] Thus, alongside this randomised controlled trial examining effectiveness, a process and implementation evaluation will be undertaken to investigate YAM and The Guide compared to usual provision in English schools.

AIMS AND HYPOTHESIS

Effectiveness measurement

Primary aims:

1. To examine whether YAM is more effective than the usual school-based provision in reducing emotional difficulties in young people.
2. To examine whether The Guide is more effective than the usual school-based provision in increasing intended help-seeking of young people around mental health.

Primary hypotheses:

H_1 Young people receiving YAM will report lower emotional difficulties at between 3–6 and 9-12 months follow-up than those who receive the usual school curriculum.

H_2 Young people receiving The Guide will report increased intended help-seeking of mental health at 3–6 and 9-12 months follow-up than those who receive the usual school curriculum.

Implementation and process evaluation research questions

1. What is the state of participating schools' existing provision for supporting mental health and wellbeing, and their relationship with local mental health services, and does the nature of provision change over the course of the trial?
2. To what extent does implementation follow the guidelines of the specified interventions, e.g. in terms of fidelity and dosage?
3. What is the relationship between implementation variability (e.g. in terms of different levels of fidelity) and intervention outcomes?
4. What are the experiences of schools (pupils and staff) and instructors/teachers in delivering/receiving YAM and The Guide?
5. To what extent are interventions sustained after the mandated delivery period, and what do sustained interventions look like?

METHODS AND ANALYSIS

Design

AWARE (Approaches for Wellbeing and Mental Health LiterAcy: Research in Education) is a three-arm parallel group cluster randomised controlled trial: YAM or The Guide versus usual school provision (control). Interventions are delivered to whole school classes as part of the school curriculum. Assessment is undertaken at baseline (prior to intervention randomisation), 3–6 and 9-12 months after interventions have been delivered. See the supplementary file for a detailed timeline of all measures and assessments.

Site recruitment

The study opened for school recruitment in March 2018 and will finish in July 2019. This study aims to recruit 144 secondary schools across England. Within each school, three Year 9 classes will be required to take part, resulting in participation of approximately 8,600 young people.

Schools will be recruited via a variety of sources, including a paid-for school database (school mailings), the Schools in Mind network hosted by the Anna Freud National Centre for Children and Families (AFNCCF), AFNCCF collaborators, Public Health England, the National Institute for Health Research, local authorities and school commissioners. The project will also be advertised on social media platforms and in education publications and resources.

Participant recruitment

Following school recruitment, participants are recruited via a two-stage process. First, schools select delivery groups who will receive an intervention (if allocated). Second, letters are sent out to parents/guardians of these delivery groups informing them of the study, as well as their right to opt out. The letter also explains that all children will only be involved in the project if they assent in class prior to completion of the baseline survey. Finally, assent is provided by young people reading through the information sheet and ticking boxes online agreeing to take part. If they do not assent, they cannot be part of the trial. The first young person joined the trial on the 17/09/2018.

Inclusion/Exclusion criteria

Schools are eligible to participate if:

1) They are willing to deliver/have an intervention delivered to around 60 Year 9 pupils in three delivery classes

2) They are able to allocate one hour per week to deliver the intervention for six weeks in the spring term of 2019 or 2020

3) They are able send staff to one of the training sessions, if required

4) They sign a Memorandum of Understanding, data sharing agreement and provide pupil lists to the research team.

Young people are eligible to take part if:

1) Their parents/guardians provide consent

2) They provide written assent.

Interventions

Youth Aware of Mental Health (YAM).

YAM is a five-session structured programme to improve awareness via discussions on risk, protective factors, and knowledge around mental health. Developed by researchers in Columbia University, New York, and the National Prevention of Suicide and Mental Ill Health (NASP), Karolinska Institude Sweeden, it aims to provide young people aged 14–16 years with a non-judgmental platform to explore topics such as depression, anxiety and suicidal thoughts. It also encourages young people to reflect on problem-solving in emotionally charged situations and dilemmas and incorporates methods used in suicide prevention programmes. It covers six main themes: 1) What is mental health? 2) Self-help advice, 3) Stress and crisis, 4) Depression and suicidal thoughts, 5) Helping a friend in need, and 6) Who can I ask for advice?

In the original intervention the five-hour programme spans three weeks, but this has been adapted to five consecutive weeks in English schools to account for how the curriculum is structured. Sessions are delivered by instructors in a classroom setting with the support of a trained helper. Instructors completed a five-day workshop delivered by YAM developers; instructors and helpers are professionals with a background in education, psychology, nursing, social work or youth work.

The sessions are supported by learning materials including posters (reflecting the six themes mentioned above) which are displayed in classrooms for the duration of YAM. Pupils are also provided with tailored booklets which address the same key themes and contain information on local support services that pupils can access. Pupils who think they may need support are encouraged to talk to YAM instructors, helpers, or school staff and utilise the local and national support networks provided in the booklets and on the posters.

Role plays are are a key component of YAM, allowing pupils the opportunity to explore and act out relevant issues from their everyday lives (e.g. in relation to

parents, peers, teachers etc.) in a safe and confidential enviroment. The role-play sessions comprise three themes: awareness about choices; depression and suicidal thoughts and feelings; how to manage stress and crisis situations. However, the exact content can be adapted to the cultural needs of the group.

The Mental Health and High School Curriculum Guide (The Guide).

The Guide was developed in Canada by Dr Kutcher in collaboration with the Canadian Mental Health Association in recognition of the increasing awareness of the importance of health literacy as a necessary foundation for improving health, extrapolated into the area of youth mental health. Originally a web-based curriculum, it aims to increase mental health literacy in both young people and school staff. The Guide is made up of six modules: 1) stigma of mental illness, 2) understanding the relationship between mental health and mental illness, 3) understanding specific mental illnesses, 4) adolescents' experiences of mental illness, 5) seeking help and finding support 6), the importance of positive mental health. It was originally developed to be delivered over 10-12 hours.

Adapted for a UK setting, The Guide is delivered over six consecutive, one hour lessons by school staff. Modules remain the same, however, content has been modified to include more resources from England and less emphasis on Powerpoint presentations in favour of interactive discussions. The sessions in the first four weeks focus on a specific disorder or specific disorders and cover: bipolar disorder (week 1), panic disorder (week 2), schizophrenia and eating disorders (week 3), depression, OCD, ADHD, and ADHD (week 4). Week five covers support and where to get help, while week 6 focuses on stress. Homework exercises, such as a task on famous people with mental illness, are included as part of the Guide. All adaptations to The Guide for an English school setting have been approved by Dr Kutcher and were informed by a pilot study conducted prior to the parallel group cluster randomised controlled trial. School staff who deliver The Guide attend a one-day face-to-face training delivered by an individual from the Anna Freud National Centre for Children and Families. The training aims to improve teachers' knowledge of

mental health and mental illness and reduce stigma, as well as familiarise teachers with the adapted Guide materials so they are able to deliver the content.

Usual Practice

Schools allocated to the Usual Practice group are not required to deliver a specific mental health intervention during the programme (June 2018 – Jan 2021).

Outcome measures

Pupil measures

All primary and secondary measures for pupils will be completed prior to the intervention and follow up will take place at 3–6 and 9-12 months after the intervention has started. All questionnaires will be completed online.

Primary outcome measures:

- For YAM: depressive symptoms (Short Mood and Feelings Questionnaire (SMFQ).[34]
- The Guide (intended help-seeking): General Help-seeking Questionnaire (GHSQ).[35]

Secondary outcome measures:

- Emotional difficulties: SMFQ for The Guide only.[34]
- Intended help-seeking: General Help-seeking Questionnaire (GHSQ) for YAM only.[35]
- Positive wellbeing: Huebner Life Satisfaction Scale (LSS).[36]
- Behavioural problems: Me & My Feelings (M&MF) questionnaire – behavioral difficulties subscale.[37]
- Support from school staff: Student Resilience Survey (SRS) [38] – School Connection subscale.[39]
- Stigma (knowledge): Mental Health Knowledge Schedule (MAKS) – Non-vignette items (items 1-6).[40]

- Stigma (behaviour): Reported and Intended Behaviour Scale – intended behavioural subscale (RIBS).[41]
- Mental health first aid.[42]
- Stigma (attitudes): Attitudes towards mental health.[29]
- Paediatric Quality of Life (Child Health Utility – 9D).[43]

School staff

Similar to pupils, school staff will complete measures around mental health literacy [20,28,44–46] prior to the intervention and follow up will take place at 3–6 and 8-11 months after intervention has started. All questionnaires will be completed online.

Measures for economic evaluation

Information on service use will be completed online by pupils alongside the outcome measures. Data required to calculate cost will be collected online from both those who delivered an intervention and either a member of the school finance team (The Guide) or the Anna Freud National Centre for Children and Families (YAM) after intervention delivery.

- Client Service Receipt of Inventory (CSRI; adapted for the study population).[47]
- Service Information Schedule (SIS).[48]

Implementation and process monitoring measures

Usual Provision Survey

A member of the school's senior leadership team will be asked to complete two online surveys regarding current whole-school mental health provision. This will be prior to delivery of the intervention and approximately 9-12 months after the start of intervention delivery.

Sustainability Survey

School staff who delivered an intervention will be asked to complete an online survey in relation to whether they, or others in the school, intend to continue delivering the intervention, and whether this has been adapted in any form. This will administered approximately 8-11 months after the start of intervention delivery.

Implementation surveys and outcome measures

Intervention deliverers will complete one online implementation survey per delivery group after delivery has finished. Questions will cover six key aspects of implementation, namely fidelity, quality, dosage, participant responsiveness, reach and adaptations. Within this, three aspects relating to the social validity of the intervention (acceptability, feasibility and utility) will also be assessed using a standardised questionnaire.[49]

Qualitative data and observations

Qualitative implementation and process data will be collected towards the end of delivery of the interventions. Eight schools will be recruited from the main sample as qualitative case study schools in Year 1 of the project; one school per intervention at four of the hubs (excluding control). Case study schools will be recruited via expression of interest and sampled based on expression of interest and variation in their usual provision around mental health and wellbeing, drawing on data from two items in the Usual Provision Survey:

1. Please identify, in the last two years, the activities and approaches that have been used in your school and indicate who has delivered/provided these activities.
2. How significant are the following potential barriers to providing effective mental health support within your school?

Face-to-face or telephone interviews will be conducted with two to three members of staff (including a senior leadership team member and a staff member delivering

the intervention) and one to two focus groups will be conducted face-to-face with young people (approximately four to five young people in each focus group) at each school. Learning from the feasibility study indicated that this sample size would yield a large amount of rich qualitative data, while still being manageable in terms of the research team's capacity.

Interviews/focus groups will be semi-structured, enabling the research team to guide the interviews/focus groups according to their topics of interest, but with the conversation around these topics being led by participants in terms of the issues that are most pertinent to them. The topics that the interviews/focus groups will cover include: staff experiences of delivering the interventions and receiving training; staff perceptions of barriers and facilitators to delivery; staff perceptions of impact; staff suggestions for improvement of the interventions; pupils' experiences of taking part in the interventions; pupils' perceptions of impact and helpful aspects of the interventions; pupils' suggestions for improvement of the interventions. All interviews/focus groups will be audio recorded and transcribed verbatim.

The research team will also conduct an observation of a session of the intervention (excluding YAM) at each school to gather contextual information about what the interventions look like on the ground. No individual pupil or staff responses will be recorded, but field notes will be taken during the observation on the process of delivery, the layout of the room, and the atmosphere during delivery.

Follow-up case study visits will be conducted in Year 2 of the project with a small number of schools from Year 1 who have sustained implementation of The Guide beyond the initial project delivery period, as identified through staff responses on the sustainability survey. In addition, as schools who express interest in taking part as a case study are likely to be the more engaged schools, there is also an opportunity in Year 2 of the project for a small number of telephone interviews to be conducted with staff at schools who have engaged less with the trial in Year 1.

This could include schools who have dropped out of the trial, as well as those who have not sustained implementation of The Guide over time.

Randomisation of schools

To ensure approximate distribution across conditions randomisation will be carried out by Kings Clinical Trials Unit, minimising for regional representation, current mental health provision, deprivation (as indicated by free school meal eligibility) and urban/rural situation. Randomisation will take after place after baseline data (staff and pupil questionnaires) have been collected. Schools (clusters) will be randomised in an equal allocation ratio (i.e., 1:1:1). Only the statistician, quantitative data analyst and economist are blind to intervention allocation. Datasets provided to these individuals will reference schools by a unique ID number (000-999).

Sample size calculation

As described, two different outcomes will be used to evaluate the interventions in this study. The primary outcome for YAM will be depressive symptoms as measured by the Short Mood and Feelings Questionnaire (SMFQ); and the primary outcome for the Guide the General Help-seeking Questionnaire (GHSQ). For both interventions the primary endpoint is between 3-6 months post intervention. The choice of a short-term assessment as the primary endpoint seems more appropriate since we would expect effects to be observable in the short term. There is also a greater likelihood of attrition in the longer follow up. Secondary analysis will be conducted examining long-term implementation fidelity and long-term effects.
The schools will be randomised to three groups (YAM, The Guide and Usual Provision). Due to the delivery of the intervention within classes, pupil level data will be analysed allowing for school- and class-level clustering. While cluster effects of emotional distress on *school*-level are usually small [50,51] no data on *class*-level clustering were available. To our knowledge, no study has investigated school-level intra-class correlations of help-seeking. Cluster effects for psychometric measures were evaluated in a joint feasibility study with the INSPIRE trial with N = 1531 secondary students nested within 79 delivery groups at five schools at

baseline. We found ICCs of .02 for both SMFQ and GHSQ (with upper borders of bootstrapped 95%-confidence intervals of .04 for the GHSQ and .05 for the SMFQ). Our sample size is based on an intra-class correlation of ρ = .10, which is conservative given the estimates found in the literature and pilot.

The only school-level variables that will be used as predictors in the proposed analysis are the stratification variables which were assumed not to have any predictive power. Pre-test values of the outcome measures will be used as predictors of within-school variance (conservative estimate of R squared = .20 was used). The study was planned for a Minimally Detectable Effect Size MDES = .20 for the scores of the primary outcome of the respective trial arm. For the SMFQ this would translate into a group difference of between 1.13 (our feasibility study) and 1.59 score points (Millennium Cohort Study at age 14;[52]) for the GHSQ this would translate in a group difference of .25 (item average based on our feasibility study; no relevant external reference data identified).
Given these assumptions, an MDES = .20 can be detected without controlling for any additional variables (significance level α=.05; statistical power β=.80) with a sample size of 90 schools (45 control, 45 intervention); and for an analysis taking pre-test values into account an MDES = .198 can be detected.
Since no evidence suggests that the two interventions show different effects, our sample size calculations for the YAM and The Guide trial arms are the same. The overall sample size is 135 schools (45 schools per arm; with 60 students each) of which the 45 control schools serve as comparators for both interventions. Incorporating the geographical spread, recruitment areas of the study, and potential drop-out both at student- and school-level we plan to recruit at least 144 schools overall. To evaluate the potential impact of drop-out, simulation studies were run and even under severe drop-out (20% of schools and 10% of students in remaining schools) an MDES=.22 was evaluated to be achievable, which was agreed by the research group, the funder, and the advisory group as an acceptable margin.

Data Management

All quantitative data will be stored on the University of Manchester's secure sever. The Data Manager (JS), along with the Research Assistants (EA and RM) will be responsible for cleaning and coding the data. Qualitative data will be stored at the EBPU. The Qualitative Data Lead (ES), supported by the Trials Manager (DH), Research Officer (AM) and Research Assistants (RM and EA), will be responsible for storing and checking transcripts and ensuring their accuracy.

Analysis plan

Effectiveness analysis

A detailed statistical analysis plan will be written and documented with the funder at least three months before the data are shared with the analyst (JB). However, the analysis will mirror the power analysis in that a mixed model will be used to analyse the data, specifying random effects at the school (cluster) and class levels. The primary analysis will only use the intervention (dummy-coded on class level) and stratification variables (on school level) as independent variables. Sensitivity analyses will be conducted for adding pre-tests and imputation of missing data. If subgroup analyses are to be conducted these will be defined in the statistical analysis plan as well.

Economic evaluation

Service use and costs

A Service Information Schedule will be designed to facilitate microcosting of the interventions. Information on services and supports used by the young people in the study will be collected using a specially adapted version of the Client Service Receipt Inventory.[47] From these data, we will investigate whether patterns of service use and associated costs differ between the intervention and control groups and explore whether any differences are driven by individual characteristics or baseline level of need.

Cost-effectiveness analysis

Cost-effectiveness and cost-utility analyses will be undertaken for change in: a) the primary outcome measure and b) quality-adjusted life years (derived from

CHU9D).[43] We will employ an analytical approach that allows for adjustment for confounders, the likely non-normal distribution of cost data, the joint analysis of cost and outcome measures, and sub-group analyses. Results will be presented as cost-effectiveness acceptability curves [53] plotting the probability that the intervention will be considered cost-effective compared to treatment as usual against different levels of willingness to pay for an improvement in outcome. Sensitivity analyses will be undertaken by varying assumptions used to calculate the intervention cost.

Process and implementation analysis

Descriptive statistics will be used to document usual school provision and how this changes over the course of the project, as well as to document the implementation of YAM and The Guide. Additionally, for documenting the implementation, we will compare 'implementation as delivered' from our survey data with 'intervention as planned'. Where applicable, the latter can be used to determine the proportion of participating schools who can be deemed to have achieved at least a minimum standard of intervention delivery (e.g. 'on treatment' status). To assess the relationship between implementation variability and outcomes, multi-level modelling will be used, in which we fit the implementation data noted above (or on treatment status derived from said data) as explanatory variables at the school or class level, to assess the extent to which they are predictive of intervention outcomes at the pupil level.

Qualitative interview and focus group transcripts will be analysed using thematic analysis.[54] Up to three researchers will code or assign extracts of the transcripts to broad overarching categories, derived from the research questions (e.g. perceptions of impact). The researchers will then break down the content (transcript extracts) coded within these overarching categories into themes and subthemes relevant to the categories. Finally, an additional member of the research team will re-code 10% of the transcripts using the themes and subthemes for each category devised by the original researchers, suggesting additions or edits where necessary.

PATIENT AND PUBLIC INVOLVEMENT

Views from school staff, pupils, and experts by experience via Common Room Consulting were sought into the design and content for The Guide intervention. School staff and pupils also provided input into the finalised measures. The Anna Freud Young Champions, who are experts by experience, will be involved in dissemination of findings to school staff and young people via PDFs and reports. School staff and pupils did not provide input to the study design or recruitment and did not assess study burden of the parallel group cluster randomised controlled trial.

ETHICS AND DISSEMINATION

Ethical approval and consent

The study was approved by University College London Research Ethics Committee (6735/009 and 6735/014). Consent/assent will be undertaken in a series of stages. Schools that have expressed an interest in the project, meet inclusion criteria and are selected for the programme will be asked to return a Memorandum of Understanding signed by a member of the senior leadership team. Further consent will then vary according to the different parts of the study. This study is congruent with GDPR legislation; the collection and processing of this data falls under Article 6,1,e. (public task).

Pupil data

For outcome data, opt-out consent will be used for research purposes. Schools will send letters to parents/carers of participating pupils. Parents/carers can then contact the Data Manager if they do not want their child to take part in the evaluation. These pupils' data will be removed from the pupil lists provided by the school. For each remaining pupil, a unique password will be created to allow access to the online survey. Prior to completing online surveys, pupils will be presented with an information sheet and assent form which they must tick if they want to

proceed the survey. All information sheets outline confidentiality procedures for collecting, processing, and storing data.

All other data (staff surveys, implementation surveys, qualitative data)

All other surveys, completed online, will require opt-in consent. As with pupils, individuals will be presented with an information sheet and consent form which they must tick prior to accessing the survey.

For qualitative interviews/focus groups, opt-in consent will be required. School staff and YAM instructors will be required to read and sign an information sheet and consent form. For pupils under the age of 16, letters will be sent home to parents/carers, which require a signed consent form to be returned if they are happy for their child to take part. Prior to interviews/focus groups commencing, the young people will also be asked to read an information sheet and sign an assent form. Consent/assent will not be sought for observations of intervention sessions as no individual staff or pupil responses will be recorded.

Monitoring of adverse events (AEs)

AEs, defined as a negative, emotional and behavioural occurrence, or sustained deterioration in a research participant, will be captured as part of the study. This includes serious adverse events (SAEs) which are a threat to life: suicidal ideation, suicidal intent, hospitalisation due to psychiatric of use of substances, death including suicide. Other adverse events: violent behaviour, self-harm, or any other event that an individual feels it is important to report, will also be captured. School safeguarding leads will judge whether they believe the AE is likely related to the intervention.

The ongoing conduct and progress of this study is monitored by an independently chaired Advisory Group Ethics Sub-Committee (AGESC) and advisory group at the Department for Education. On becoming aware of SAEs, the CI/TM will report SAEs or AEs which are likely to be related to the intervention to the AGESC within two working days. Other AEs will be collated and reported quarterly to the AGESC. The University College London Research Ethics Committee will also be informed of AEs and SAEs using the same mechanisms. School and research safeguarding protocols

will also be followed as standard in addition to the reporting and documenting of AEs.

Dissemination plan

Results will be disseminated through a report to the Department for Education, as well as at conferences and in international peer review journals.

Trial sponsor. The trial is sponsored by University College London.

TRIAL STATUS

Recruitment for schools opened in March 2018 and will stay open until June 2019. The last participants will be followed up at a one year follow up in January/February 2021.

FUNDING STATEMENT

This research was commissioned and funded by the Department for Education. The Department selected the interventions to be trialled and also chairs an advisory group the researchers report to regarding the progress and quality of the research. However, the department had no role in the design of this study and will not have any role in the analyses, interpretation of the data, or decision to submit results. The views expressed are those of the authors and not necessarily those of the Department for Education. JD was (in part) supported by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care (CLAHRC) North Thames at Bart's Health NHS Trust. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care

ROLE AND RESPONSIBILITIES

JD is the Principle Investigator. NH is the Implementation Lead. DH is the Trials Manager. JS is the Data Manager. ES is the Qualitative Lead. AM is Research Officer/School Liaison Lead. RM & EA are Research Assistants. JB is the Trials Statistician. PP provides expertise around measures and statistical analysis. EB is the Health Economist.

AUTHOR CONTRIBUTORS

NH, EA, RM and ES lead on decisions for the process and implementation strand of the project and contributed to the writing of this section of the protocol. EB leads on decisions for the economic strand of the project and contributed to the writing of this section of the protocol. JB leads on statistical and study design elements of the project, contributed to the writing of the sample size calculation and analysis plan, and contributed to the writing of these sections of the protocol. PP leads on measures and their psychometric properties as well as mediation and moderation analysis. JS leads on decisions relating to data management and contributed to the writing of this section of the protocol. DH, supported by AM, leads on decisions relating to trial management, wrote the first draft of the protocol, and contributed to edits and amendments in subsequent drafts. DH also leads on ethical procedures and contributed to writing this section of the protocol. JD is the Principle Investigator, conceptualised the overall trial design, has final sign decision sign off, and contributed to the writing of this protocol. A measures group consisting of PP, JD, DH, AM, NH, EA, RM, JS, EB, and JB finalised measures for the trial. All authors read and approved the final manuscript.

COMPETING INTERESTS STATEMENT

The authors state they have no competing interests to declare.

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ACCESSING DATASETS

An anonymised dataset of the quantitative analysis will be made available to researchers in 2022. A decision regarding storage location is yet to be finalised.

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Figure 1. Schedule of enrolment, intervention, and assessments for AWARE. P = Pupil, SM = Staff Member, PG = Parent/Guardian

					STUDY PERIOD														
	Enrolment (months)		Allocation (months)		(months)														
TIMEPOINT**	***-7 to -2***	***-1***	***0***	***1***	***2***	***3***	***4***	***5***	***6***	***7***	***8***	***9***	***10***	***11***	***12***	***13***	***14***	***15***	***16***
ENROLMENT:																			
School eligibility screen (EoI)	X																		
School completes MOU and DSA	X																		
Consent/Assent	PG	CYP																	
Allocation			X																
INTERVENTIONS																			
School staff training in interventions				←	→														
YAM						←	—	—	→										
The Guide						←	—	—	→										
Usual Provision						←	—	—	→										

TIMEPOINT**	-7 to -2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
ASSESSMENTS:																			
Usual Provision survey[b]	X	X																	
SMFQ[a]		X								←	—	→						←	→
GHSQ[a]		X								←	—	→						←	→
MHFA[a]		X								←	—	→						←	→
CHU9D[a]		X								←	—	→						←	→
LSS[a]		X								←	—	→						←	→
MAKS[a]		X								←	—	→						←	→
RIBS[a]		X								←	—	→						←	→
Attitudes[a]		X								←	—	→						←	→
M&MF[a]		X								←	—	→						←	→
SRS[a]		X								←	—	→						←	→
CSRI[a]		X								←	—	→						←	→
SIS[b]										←	—	→				X			
Mental health literacy[b]		X								←	—	→				X			

TIMEPOINT**	-7 to -2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Implementation survey [b]								←	—	→									
Sustainability survey [b]																X			
Qualitative interviews								←	→									←	→
Observations								←	→										

[a] Young person completes
[b] School staff member completes

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

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		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2

Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	#3	Date and version identifier	3
Funding	#4	Sources and types of financial, material, and other support	18
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	17
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	18
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	18
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies	3-6

		(published and unpublished) examining benefits and harms for each intervention	
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
Objectives	#7	Specific objectives or hypotheses	6-7
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	7
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-9
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or	9

		improving / worsening disease)	
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	11-12
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9-10
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	n/a
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	11, 13-14
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	7

Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	13
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	13
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	13
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg,	7, 9-12

		questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	n/a
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14-15
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14-15
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be	17

		found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	17
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	17
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	2
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	3
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	16
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a

Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	16
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	19
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	18
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	19
Informed consent	#32	Model consent form and other related documentation given	n/a

materials		to participants and authorised surrogates	
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

Correction: *School-based intervention study examining approaches for well-being and mental health literacy of pupils in Year 9 in England: study protocol for a multischool, parallel group cluster randomised controlled trial (AWARE)*

Hayes D, Moore A, Stapley E, *et al*. School-based intervention study examining approaches for well-being and mental health literacy of pupils in Year 9 in England: study protocol for a multischool, parallel group cluster randomised controlled trial (AWARE). *BMJ Open* 2019;9:e029044. doi: 10.1136/bmjopen-2019-029044

The authors would like to notify that the co-authors Sara Evans-Lacko, Bettina Moltrecht, Kirsty Nisbet, Emma Thornton, Aurelie Lange, Paul Stallard, Abigail Thompson were missed including in the authorship list of the paper.

The supplementary file has been also updated.

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