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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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4 Mental Health Literacy of pupils in Year Nine in England: Study Protocol for a Multi-
5 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.

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5 **Protocol:** V1 03/01/2019. Substantial changes to the protocol will be
6 communicated to the Trials Manager to relevant parties (e.g. ISRCTN).
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10 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

11 This is the first randomised control trial to examine YAM and The Guide compared
12 to usual provision in England.
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- 14 • The trial is powered to detect small effects.
- 15 • Both interventions are only compared to the control group, rather than to
16 each other.
- 17 • Only the trial statistician, economist and the individual conducting
18 quantitative analysis are blind to what intervention each school has been
19 allocated.
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26 **Keywords:** Adolescent, Young Person, Teacher, Cluster Randomised Controlled
27 Trial, Mental Health, Wellbeing
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31 **INTRODUCTION**

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35 Half of presenting mental health difficulties appear before the age of 14, and three-
36 quarters before the age of 24.[1] Such instances are associated with poorer
37 physical health outcomes and educational attainment.[1,2] Within the UK, a recent
38 survey of 30,000 young people in schools found that 18.4% reported experiencing
39 high levels of emotional distress.[3] The latest prevalence survey suggests that one
40 in eight 5 to 19 year olds have at least one mental health difficulty and that
41 emotional difficulties are increasing in young people.[4]
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49 Childhood and adolescence are important developmental phases for prevention and
50 early intervention initiatives for mental health and wellbeing (MHW).[5,6] Seeking
51 help for depressive symptoms at 14 decreases the risk of developing clinical
52 depressive symptoms at 17 sevenfold.[7] Prevention and early intervention
53 programmes have demonstrated a good return on investment, with a 6–10%
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3 annual rate of return on investment spent.[8] However, young people report
4 barriers to help seeking, such as difficulty identifying that there is a problem and
5 perceived and internalised stigma.[9,10] Improving help-seeking knowledge and
6 the ability to recognise distress are suggested ways to improve mental
7 health.[11,12]
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13 Schools are often viewed as a universal point of access to children and young
14 people, offering an important opportunity to embed MHW initiatives.[13] Schools
15 can provide a non-stigmatising environment where young people and
16 parents/carers can engage, outside of mental health services,[14] and can also
17 present opportunities for pupils to develop self-management strategies.[15]
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23 **Universal prevention programmes**

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25 There is growing evidence for the role of school-based promotion and prevention
26 programmes for MHW. A meta-analysis examining interventions aimed at social and
27 emotional learning demonstrated that pupils who received interventions had
28 significantly improved social and emotional skills, behaviour, and academic
29 performance.[16] However, impact is often highly dependent on successful
30 implementation; interventions that are implemented well in schools can produce
31 outcomes that are 2–3 times higher than those implemented poorly.[17] Multiple
32 factors can influence implementation at different levels of the system, including
33 policy, provider and intervention characteristics and factors related to the
34 prevention support system.[17] Organisational capacity and the feasibility of
35 delivery within specific contexts are also repeatedly highlighted. Despite this, there
36 is often an expectation that the evidence base for interventions delivered in one
37 context will successfully transfer to other quite different settings. Relatedly, few
38 studies tend to run implementation and process evaluations in parallel with
39 examining effectiveness, and those that do tend to focus on fidelity.[18] Examining
40 aspects such as social validity and cultural validity are important, particularly when
41 importing interventions from other countries.[19]
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3 Some universal programmes place emphasis on improving individual's mental
4 health literacy (MHL). MHL interventions traditionally focus on educating and
5 changing beliefs about mental disorders to aid their recognition, management or
6 prevention, and increasingly include mental health first aid.[20,21] Kutcher, Wei
7 and Coniglio recently defined MHL as having four main components, including the
8 addition of mental health promotion: '1) understanding how to obtain and maintain
9 positive mental health, 2) understanding mental disorders and their treatments, 3)
10 decreasing stigma related to mental disorders and 4) enhancing help-seeking
11 efficacy (knowing when and where to seek help and developing competencies
12 designed to improve one's mental health care and self-management capabilities'.
13 [22] Youth Aware of Mental Health (YAM) is an example of a universal intervention
14 that aims to improve awareness and promote mental health.[23] As part of the
15 Saving and Empowering Young Lives in Europe (SEYLE) cluster randomised
16 controlled trial, a suicide prevention programme across 12 European countries, YAM
17 was compared to two active interventions, 'Professional screening' and 'Question,
18 Persuade, and Refer', and a control group.[24] No difference between arms on
19 suicidal ideation or attempts was found at three month follow-up, however YAM
20 significantly reduced the risk of suicide attempts and suicidal ideation at 12 month
21 follow-up compared to the control group.[23] Interviews with young people have
22 found they prefer YAM to regular classroom activities, however differences were
23 reported in how actively involved they wanted to be in YAM.[25]

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40 The Mental Health and High School Curriculum Guide (The Guide)[26] also aims to
41 increase awareness of mental disorders and their treatments, as well as increasing
42 understanding of how to obtain and maintain mental health, reduce stigma and
43 improve help-seeking efficacy. Delivery of The Guide in Canada was found to
44 increase student and staff knowledge, reduce stigma and increase help-seeking in
45 students.[26–29] In Tanzania, The Guide has been shown to increase teacher
46 knowledge and reduce stigma,[30–32] teacher reports also highlighted positive
47 changes to knowledge, attitude and behaviour in their pupils.[31] Significantly
48 improved mental health knowledge, reduced stigma, more adaptive coping, better
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3 lifestyle choices, and lower perceived stress was also found for students who
4 received The Guide in Nicaragua.[33]
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8 Whilst YAM and The Guide have a developing evidence base in multiple countries,
9 evidence for the effectiveness of such approaches in the UK is sparse. A scoping
10 exercise conducted by the Department for Education (DfE) in England, concluded
11 that both should be tested to contribute to the UK evidence base for effective
12 interventions to improve mental health in children and young people. As the
13 interventions were developed in other countries, undertaking a process and
14 implementation evaluation to understand factors beyond fidelity and effectiveness
15 is important.[19] Thus, alongside an RCT examining effectiveness, a process and
16 implementation evaluation will be undertaken to investigate YAM and The Guide
17 compared to usual provision in English schools.
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27 **AIMS AND HYPOTHESIS**

28 **Effectiveness measurement**

29 Primary aims:

- 30 1. To examine whether YAM is more effective than the usual school-based
31 provision in reducing emotional difficulties in young people.
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- 33 2. To examine whether The Guide is more effective than the usual school-based
34 provision in increasing intended help-seeking of young people around mental
35 health.
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45 Primary hypotheses:

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48 H_1 Young people receiving YAM will report lower emotional difficulties at between 3–
49 6 and 12 months follow-up than those who receive the usual school curriculum.
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52 H_2 Young people receiving The Guide will report increased intended help-seeking of
53 mental health at 3–6 and 12 months follow-up than those who receive the usual
54 school curriculum.
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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

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3 school commissioners. The project will also be advertised on social media platforms
4 and in education publications and resources.
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7 **Participant recruitment**

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

26 Schools are eligible to participate if:
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- 28 1) They are willing to deliver/have an intervention delivered to around 60 year 9
29 pupils in three delivery classes
- 30 2) They are able to allocate one hour per week to deliver the intervention for six
31 weeks in the spring term of 2019 or 2020
- 32 3) They are able send staff to one of the training sessions, if required
- 33 4) They sign a Memorandum of Understanding, data sharing agreement and
34 provide pupil lists to the research team.
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44 Young people are eligible to take part if:

- 45 1) Their parents/guardians provide consent
- 46 2) They provide written assent.
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53 **Interventions**

54 Youth Aware of Mental Health (YAM).[23]
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3 YAM is a five-session structured programme to improve awareness via discussions
4 on risk, protective factors, and knowledge around mental health. The aim is to
5 provide young people aged 14–16 years with a non-judgmental platform to explore
6 topics such as depression, anxiety and suicidal thoughts, and reflect on problem-
7 solving in emotionally charged situations and dilemmas. Role plays are central to
8 YAM, allowing pupils the opportunity to explore relevant issues from their everyday
9 lives (e.g. in relation to parents, peers, teachers etc.). The role-play sessions
10 comprise three themes: awareness about choices; depression and suicidal thoughts
11 and feelings; how to manage stress and crisis situations. These are supported by
12 learning materials including posters which will be displayed in classrooms for the
13 duration of YAM. Posters focus on: awareness of mental health; self-help advice;
14 stress and crisis; depression and suicidal thoughts; helping a troubled friend;
15 getting advice. Pupils are also provided with booklets which address the same key
16 themes and contain information on local support services. Pupils who think they
17 may need support are encouraged to talk to staff and utilise local and national
18 support networks. In the original intervention, the five-hour programme spans
19 three weeks, but this has been adapted to five consecutive weeks in English
20 schools. Sessions are delivered by instructors in a classroom setting with the
21 support of a trained helper. Instructors completed a five-day workshop delivered by
22 YAM developers; instructors and helpers are professionals with a background in
23 education, psychology, nursing, social work or youth work.
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40 The Mental Health and High School Curriculum Guide (The Guide).[34]

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

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3 recruited via expression of interest and sampled based on variation in their usual
4 provision around mental health and wellbeing, drawing on data from two items in
5 the Usual Provision Survey:
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10 1. Please identify, in the last two years, the activities and approaches that have
11 been used in your school and indicate who has delivered/provided these
12 activities.
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15 2. How significant are the following potential barriers to providing effective
16 mental health support within your school?
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20 Face-to-face or telephone interviews will be conducted with two to three members
21 of staff (including a senior leadership team member and a staff member delivering
22 the intervention) and one to two focus groups will be conducted face-to-face with
23 young people (approximately four to five young people in each focus group) at each
24 school. Learning from the feasibility study indicated that this sample size would
25 yield a large amount of rich qualitative data, while still being manageable in terms
26 of the research team's capacity.
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33 Interviews/focus groups will be semi-structured, enabling the research team to
34 guide the interviews/focus groups according to their topics of interest, but with the
35 conversation around these topics being led by participants in terms of the issues
36 that are most pertinent to them. The topics that the interviews/focus groups will
37 cover include: staff experiences of delivering the interventions and receiving
38 training; staff perceptions of barriers and facilitators to delivery; staff perceptions
39 of impact; staff suggestions for improvement of the interventions; pupils'
40 experiences of taking part in the interventions; pupils' perceptions of impact and
41 helpful aspects of the interventions; pupils' suggestions for improvement of the
42 interventions. All interviews/focus groups will be audio recorded and transcribed
43 verbatim.
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53 The research team will also conduct an observation of a session of the intervention
54 (excluding YAM) at each school to gather contextual information about what the
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3 interventions look like on the ground. No individual pupil or staff responses will be
4 recorded, but field notes will be taken during the observation on the process of
5 delivery, the layout of the room, and the atmosphere during delivery.
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10 As schools who express interest in taking part as a case study are likely to be the
11 more engaged schools, there is an opportunity in Year 2 of the project for a small
12 number of telephone interviews to be conducted with staff at schools who have
13 engaged less with the trial in Year 1. This could include schools who have dropped
14 out of the trial.
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20 **Randomisation of schools**

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

36 The schools will be randomised to three groups (YAM, The Guide and Usual
37 Provision). Due to the delivery of the intervention within classes, the trial will be
38 analysed on class level, controlling for school- and class-level clustering. While
39 cluster effects of emotional distress on *school*-level are usually small [48,49] no
40 data on *class*-level clustering was available. To our knowledge, no study has
41 investigated school-level intra-class correlations of help-seeking. Cluster effects for
42 psychometric measures were evaluated in a joint feasibility study with the INSPIRE
43 trial with $N = 1531$ secondary students nested within 79 delivery groups at five
44 schools at baseline. We found ICCs of .02 for both SMFQ and GHSQ (with upper
45 borders of bootstrapped 95%-confidence intervals of .04 for the GHSQ and .05 for
46 the SMFQ). Our sample size is based on an intra-class correlation of $\rho = .10$, which
47 is conservative given the estimates found in the literature and pilot.
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5 The only school-level variables that will be used as predictors in the proposed
6 analysis are the stratification variables which were assumed not to have any
7 predictive power. Pre-test values of the outcome measures will be used as
8 predictors of within-school variance (conservative estimate of $R^2 = .20$ was used).
9 Given these assumptions, a Minimally Detectable Effect Size $MDES = .20$ without
10 controlling for any additional variables can be detected (significance level $\alpha = .05$;
11 statistical power $\beta = .80$) with a sample size of 90 schools (45 control, 45
12 intervention); and for the analysis taking pre-test values into account an $MDES =$
13 $.198$. Since no evidence suggests that the two interventions show different effects,
14 our sample size calculations for the YAM and The Guide trial arms are the same.
15 The overall sample size is 135 schools (45 schools per arm; with 60 students each)
16 of which the 45 control schools serve as comparators for both interventions.
17 Incorporating the geographical spread and recruitment areas of the study, we plan
18 to recruit 144 schools overall.
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30 **Data Management**

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

44 Effectiveness analysis

45 A detailed statistical analysis plan will be written and documented with the funder
46 at least three months before the data is shared with the analyst (JB). However, the
47 analysis will mirror the power analysis in that a mixed model will be used to analyse
48 the data with classes defining the clusters and an orthogonal random effect for
49 schools. The primary analysis will only use the intervention (dummy-coded on class
50 level) and stratification variables (on school level) as independent variables.
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3 Sensitivity analyses will be conducted for adding pre-tests and imputation of
4 missing data. If subgroup analyses are to be conducted these will be defined in the
5 statistical analysis plan as well.
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10 Economic evaluation

11 Service use and costs

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

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

49 Descriptive statistics will be used to document usual school provision and how this
50 changes over the course of the project, as well as to document the implementation
51 of YAM and The Guide. Additionally, for documenting the implementation, we will
52 compare 'implementation as delivered' from our survey data with 'intervention as
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3 planned'. Where applicable, the latter can be used to determine the proportion of
4 participating schools who can be deemed to have achieved at least a minimum
5 standard of intervention delivery (e.g. 'on treatment' status). To assess the
6 relationship between implementation variability and outcomes, multi-level
7 modelling will be used, in which we fit the implementation data noted above (or on
8 treatment status derived from said data) as explanatory variables at the school or
9 class level, to assess the extent to which they are predictive of intervention
10 outcomes at the pupil level.
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18 Qualitative interview and focus group transcripts will be analysed using thematic
19 analysis.[51] Three members of the research team will code or assign extracts of
20 the transcripts to broad overarching categories, derived from the research
21 questions (e.g. perceptions of impact). The researchers will then break down the
22 content (transcript extracts) coded within these overarching categories into themes
23 and subthemes relevant to the categories. A fourth member of the research team
24 will then code 10% of staff and pupil interviews to the coding frame (themes and
25 subthemes) devised by the other members of the team. Refinements to the coding
26 frame will then be made as necessary.
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35 **ETHICS AND DISSEMINATION**

36 **Ethical approval and consent**

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38 The study was approved by University College London Research Ethics Committee
39 (6735/009 and 6735/014). Consent/assent will be undertaken in a series of stages.
40 Schools that have expressed an interest in the project, meet inclusion criteria and
41 are selected for the programme will be asked to return a Memorandum of
42 Understanding signed by a member of the senior leadership team. Further consent
43 will then vary according to the different parts of the study. This study is congruent
44 with GDPR legislation; the collection and processing of this data falls under Article
45 6,1,e. (public task).
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53 **Pupil data**

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

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21 All other surveys, completed online, will require opt-in consent. As with pupils,
22 individuals will be presented with an information sheet and consent form which they
23 must tick prior to accessing the survey.
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27 For qualitative interviews/focus groups, opt-in consent will be required. School staff
28 and YAM instructors will be required to read and sign an information sheet and
29 consent form. For pupils under the age of 16, letters will be sent home to
30 parents/carers, which require a signed consent form to be returned if they are
31 happy for their child to take part. Prior to interviews/focus groups commencing, the
32 young people will also be asked to read an information sheet and sign an assent
33 form. Consent/assent will not be sought for observations of intervention sessions as
34 no individual staff or pupil responses will be recorded.
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41 **Monitoring of adverse events (AEs)**

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43 AEs, defined as a negative, emotional and behavioural occurrence, or sustained
44 deterioration in a research participant, will be captured as part of the study. This
45 includes serious adverse events (SAEs) which are a threat to life: suicidal ideation,
46 suicidal intent, hospitalisation due to psychiatric of use of substances, death
47 including suicide. Other adverse events: violent behaviour, self-harm, or any other
48 event that an individual feels it is important to report, will also be captured. School
49 safeguarding leads will judge whether they believe the AE is likely related to the
50 intervention.
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3 The ongoing conduct and progress of this study is monitored by an independently
4 chaired Advisory Group Ethics Sub-Committee (AGESC) and Trial Steering
5 Committee at the Department for Education. On becoming aware of SAEs, the
6 CI/TM will report SAEs or AEs which are likely to be related to the intervention to
7 the AGESC within two working days. Other AEs will be collated and reported
8 quarterly to the AGESC. The University College London Research Ethics Committee
9 will also be informed of AEs and SAEs using the same mechanisms. School and
10 research safeguarding protocols will also be followed as standard in addition to the
11 reporting and documenting of AEs.
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18 **Dissemination plan**

19 Results will be disseminated through a report to the DfE, as well as at conferences
20 and in international peer review journals.
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25 **Trial sponsor.** The trial is sponsored by University College London.
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28 **TRIAL STATUS**

29 Recruitment for schools opened in March 2018 and will stay open until June 2019.
30 The last participants will be followed up at a one year follow up in January/February
31 2021.
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37 **FUNDING STATEMENT**

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

53 JD is the Principle Investigator. NH is the Implementation Lead. DH is the Trials
54 Manager. JS is the Data Manager. ES is the Qualitative Lead. AM is Research
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3 Officer/School Liaison Lead. RM & EA are Research Assistants. JB is the Trials
4 Statistician. PP provides expertise around measures and statistical analysis. EB is
5 the Health Economist.
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8 9 10 **AUTHOR CONTRIBUTORS**

11 All authors contributed to the writing of the protocol. All authors read and approved
12 the final version of the manuscript.
13
14

15 16 17 **COMPETING INTERESTS STATEMENT**

18 The authors state they have no competing interests to declare.
19
20

21 22 **ACKNOWLEDGMENTS**

23 We would like to thank the Education for Wellbeing advisory group for providing
24 comments on earlier versions of the manuscript.
25
26

27 28 29 **ACCESSING DATASETS**

30 An anonymised dataset of the quantitative analysis will be made available to
31 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.

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:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *Ann Intern Med.* 2013;158(3):200-207

		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

1	Trial registration:	#2b	All items from the World Health Organization Trial	n/a
2				
3	data set		Registration Data Set	
4				
5				
6	Protocol version	#3	Date and version identifier	3
7				
8				
9	Funding	#4	Sources and types of financial, material, and other support	18
10				
11	Roles and	#5a	Names, affiliations, and roles of protocol contributors	17
12				
13	responsibilities:			
14	contributorship			
15				
16	Roles and	#5b	Name and contact information for the trial sponsor	n/a
17				
18	responsibilities:			
19	sponsor contact			
20				
21	information			
22				
23	Roles and	#5c	Role of study sponsor and funders, if any, in study design;	18
24				
25	responsibilities:		collection, management, analysis, and interpretation of	
26	sponsor and funder		data; writing of the report; and the decision to submit the	
27			report for publication, including whether they will have	
28			ultimate authority over any of these activities	
29				
30	Roles and	#5d	Composition, roles, and responsibilities of the coordinating	18
31				
32	responsibilities:		centre, steering committee, endpoint adjudication	
33	committees		committee, data management team, and other individuals or	
34			groups overseeing the trial, if applicable (see Item 21a for	
35			data monitoring committee)	
36				
37	Background and	#6a	Description of research question and justification for	3-6
38				
39	rationale		undertaking the trial, including summary of relevant studies	
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1		(published and unpublished) examining benefits and harms	
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3		for each intervention	
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6	Background and	#6b Explanation for choice of comparators	6
7			
8	rationale: choice of		
9			
10	comparators		
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13	Objectives	#7 Specific objectives or hypotheses	6-7
14			
15			
16	Trial design	#8 Description of trial design including type of trial (eg, parallel	7
17		group, crossover, factorial, single group), allocation ratio,	
18		and framework (eg, superiority, equivalence, non-inferiority,	
19		exploratory)	
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26	Study setting	#9 Description of study settings (eg, community clinic,	7
27		academic hospital) and list of countries where data will be	
28		collected. Reference to where list of study sites can be	
29		obtained	
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36	Eligibility criteria	#10 Inclusion and exclusion criteria for participants. If applicable,	8
37		eligibility criteria for study centres and individuals who will	
38		perform the interventions (eg, surgeons, psychotherapists)	
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44	Interventions:	#11a Interventions for each group with sufficient detail to allow	8-9
45		replication, including how and when they will be	
46	description	administered	
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51	Interventions:	#11b Criteria for discontinuing or modifying allocated	9
52		interventions for a given trial participant (eg, drug dose	
53	modifications	change in response to harms, participant request, or	
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		improving / worsening disease)	
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4	Interventions:	#11c Strategies to improve adherence to intervention protocols,	11-12
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6	adherence	and any procedures for monitoring adherence (eg, drug	
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8		tablet return; laboratory tests)	
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11	Interventions:	#11d Relevant concomitant care and interventions that are	n/a
12			
13	concomitant care	permitted or prohibited during the trial	
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16	Outcomes	#12 Primary, secondary, and other outcomes, including the	9-10
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18		specific measurement variable (eg, systolic blood pressure),	
19		analysis metric (eg, change from baseline, final value, time	
20		to event), method of aggregation (eg, median, proportion),	
21			
22		and time point for each outcome. Explanation of the clinical	
23		relevance of chosen efficacy and harm outcomes is strongly	
24		recommended	
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33	Participant timeline	#13 Time schedule of enrolment, interventions (including any	n/a
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35		run-ins and washouts), assessments, and visits for	
36			
37		participants. A schematic diagram is highly recommended	
38			
39		(see Figure)	
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43	Sample size	#14 Estimated number of participants needed to achieve study	11, 13-
44			
45		objectives and how it was determined, including clinical and	14
46			
47		statistical assumptions supporting any sample size	
48			
49		calculations	
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53	Recruitment	#15 Strategies for achieving adequate participant enrolment to	7
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55		reach target sample size	
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1	Allocation: sequence	#16a	Method of generating the allocation sequence (eg,	13
2			computer-generated random numbers), and list of any	
3	generation		factors for stratification. To reduce predictability of a random	
4			sequence, details of any planned restriction (eg, blocking)	
5			should be provided in a separate document that is	
6			unavailable to those who enrol participants or assign	
7			interventions	
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18	Allocation	#16b	Mechanism of implementing the allocation sequence (eg,	13
19	concealment		central telephone; sequentially numbered, opaque, sealed	
20			envelopes), describing any steps to conceal the sequence	
21	mechanism		until interventions are assigned	
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28	Allocation:	#16c	Who will generate the allocation sequence, who will enrol	13
29	implementation		participants, and who will assign participants to	
30			interventions	
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35	Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg,	13
36			trial participants, care providers, outcome assessors, data	
37			analysts), and how	
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43	Blinding (masking):	#17b	If blinded, circumstances under which unblinding is	n/a
44	emergency		permissible, and procedure for revealing a participant's	
45			allocated intervention during the trial	
46	unblinding			
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51	Data collection plan	#18a	Plans for assessment and collection of outcome, baseline,	7, 9-12
52			and other trial data, including any related processes to	
53			promote data quality (eg, duplicate measurements, training	
54			of assessors) and a description of study instruments (eg,	
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1		questionnaires, laboratory tests) along with their reliability	
2		and validity, if known. Reference to where data collection	
3		forms can be found, if not in the protocol	
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8	Data collection plan:	#18b Plans to promote participant retention and complete follow-	n/a
9	retention	up, including list of any outcome data to be collected for	
10		participants who discontinue or deviate from intervention	
11		protocols	
12			
13	Data management	#19 Plans for data entry, coding, security, and storage, including	14
14		any related processes to promote data quality (eg, double	
15		data entry; range checks for data values). Reference to	
16		where details of data management procedures can be	
17		found, if not in the protocol	
18			
19	Statistics: outcomes	#20a Statistical methods for analysing primary and secondary	14-15
20		outcomes. Reference to where other details of the statistical	
21		analysis plan can be found, if not in the protocol	
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23			
24	Statistics: additional	#20b Methods for any additional analyses (eg, subgroup and	14-15
25	analyses	adjusted analyses)	
26			
27			
28	Statistics: analysis	#20c Definition of analysis population relating to protocol non-	14
29	population and	adherence (eg, as randomised analysis), and any statistical	
30	missing data	methods to handle missing data (eg, multiple imputation)	
31			
32			
33	Data monitoring:	#21a Composition of data monitoring committee (DMC); summary	17
34	formal committee	of its role and reporting structure; statement of whether it is	
35		independent from the sponsor and competing interests; and	
36		reference to where further details about its charter can be	
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1		found, if not in the protocol. Alternatively, an explanation of	
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3		why a DMC is not needed	
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6	Data monitoring:	#21b Description of any interim analyses and stopping guidelines,	17
7			
8	interim analysis	including who will have access to these interim results and	
9			
10		make the final decision to terminate the trial	
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12			
13	Harms	#22 Plans for collecting, assessing, reporting, and managing	17
14			
15		solicited and spontaneously reported adverse events and	
16			
17		other unintended effects of trial interventions or trial conduct	
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21	Auditing	#23 Frequency and procedures for auditing trial conduct, if any,	n/a
22			
23		and whether the process will be independent from	
24			
25		investigators and the sponsor	
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29	Research ethics	#24 Plans for seeking research ethics committee / institutional	2
30			
31	approval	review board (REC / IRB) approval	
32			
33			
34	Protocol	#25 Plans for communicating important protocol modifications	3
35			
36	amendments	(eg, changes to eligibility criteria, outcomes, analyses) to	
37			
38		relevant parties (eg, investigators, REC / IRBs, trial	
39			
40		participants, trial registries, journals, regulators)	
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43			
44	Consent or assent	#26a Who will obtain informed consent or assent from potential	16
45			
46		trial participants or authorised surrogates, and how (see	
47			
48		Item 32)	
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50			
51	Consent or assent:	#26b Additional consent provisions for collection and use of	n/a
52			
53	ancillary studies	participant data and biological specimens in ancillary	
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55		studies, if applicable	
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1	Confidentiality	#27	How personal information about potential and enrolled	16
2			participants will be collected, shared, and maintained in	
3			order to protect confidentiality before, during, and after the	
4			trial	
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11	Declaration of	#28	Financial and other competing interests for principal	18
12	interests		investigators for the overall trial and each study site	
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16	Data access	#29	Statement of who will have access to the final trial dataset,	19
17			and disclosure of contractual agreements that limit such	
18			access for investigators	
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24	Ancillary and post	#30	Provisions, if any, for ancillary and post-trial care, and for	n/a
25	trial care		compensation to those who suffer harm from trial	
26			participation	
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31				
32	Dissemination policy:	#31a	Plans for investigators and sponsor to communicate trial	18
33	trial results		results to participants, healthcare professionals, the public,	
34			and other relevant groups (eg, via publication, reporting in	
35			results databases, or other data sharing arrangements),	
36			including any publication restrictions	
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44	Dissemination policy:	#31b	Authorship eligibility guidelines and any intended use of	n/a
45	authorship		professional writers	
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49	Dissemination policy:	#31c	Plans, if any, for granting public access to the full protocol,	19
50	reproducible		participant-level dataset, and statistical code	
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54	research			
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57	Informed consent	#32	Model consent form and other related documentation given	n/a
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1 materials to participants and authorised surrogates
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4 Biological specimens #33 Plans for collection, laboratory evaluation, and storage of n/a
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6 biological specimens for genetic or molecular analysis in the
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8 current trial and for future use in ancillary studies, if
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10 applicable
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14 BY-ND 3.0. This checklist was completed on 03. January 2019 using <https://www.goodreports.org/>, a
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16 tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)
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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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3 A School Based Interventions Study Examining Approaches for Wellbeing and
4 Mental Health Literacy of pupils in Year Nine in England: Study Protocol for a Multi-
5 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.

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5 **Protocol:** V1 03/01/2019. Substantial changes to the protocol will be
6 communicated to the Trials Manager to relevant parties (e.g. ISRCTN).
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10 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

11 This is the first randomised controlled trial to examine YAM and The Guide
12 compared to usual provision in England.
13

- 14 • The trial is powered to detect small effects.
- 15 • Both interventions are only compared to the control group, rather than to
16 each other.
- 17 • Only the trial statistician, economist and the individual conducting
18 quantitative analysis are blind to what intervention each school has been
19 allocated.
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26 **Keywords:** Adolescent, Young Person, Teacher, Cluster Randomised Controlled
27 Trial, Mental Health, Wellbeing
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31 **INTRODUCTION**

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34 Half of presenting mental health difficulties appear before the age of 14, and three-
35 quarters before the age of 24.[1] Such instances are associated with poorer
36 physical health outcomes and educational attainment.[1,2] Within the UK, a recent
37 survey of 30,000 young people in schools found that 18.4% reported experiencing
38 high levels of emotional distress.[3] The latest prevalence survey suggests that one
39 in eight 5 to 19 year olds have at least one mental health difficulty and that
40 emotional difficulties are increasing in young people.[4]
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48 Childhood and adolescence are important developmental phases for prevention and
49 early intervention initiatives for mental health and wellbeing.[5,6] Seeking help for
50 depressive symptoms at 14 decreases the risk of developing clinical depressive
51 symptoms at 17 sevenfold.[7] Prevention and early intervention programmes have
52 demonstrated a good return on investment, with a 6–10% annual rate of return on
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3 investment spent.[8] However, young people report barriers to help seeking, such
4 as difficulty identifying that there is a problem and perceived and internalised
5 stigma.[9,10] Improving help-seeking knowledge and the ability to recognise
6 distress are suggested ways to improve mental health.[11,12]
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11 Schools are often viewed as a universal point of access to children and young
12 people, offering an important opportunity to embed mental health and wellbeing
13 initiatives.[13] Schools can provide a non-stigmatising environment where young
14 people and parents/carers can engage, outside of mental health services,[14] and
15 can also present opportunities for pupils to develop self-management
16 strategies.[15]
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23 **Universal prevention programmes**

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25 There is growing evidence for the role of school-based promotion and prevention
26 programmes for mental health and wellbeing. A meta-analysis examining
27 interventions aimed at social and emotional learning demonstrated that pupils who
28 received interventions had significantly improved social and emotional skills,
29 behaviour, and academic performance.[16] However, impact is often highly
30 dependent on successful implementation; interventions that are implemented well
31 in schools can produce outcomes that are 2–3 times higher than those implemented
32 poorly.[17] Multiple factors can influence implementation at different levels of the
33 system, including policy, provider and intervention characteristics and factors
34 related to the prevention support system.[17] Organisational capacity and the
35 feasibility of delivery within specific contexts are also repeatedly highlighted.
36
37 Despite this, there is often an expectation that the evidence base for interventions
38 delivered in one context will successfully transfer to other quite different settings.
39
40 Relatedly, few studies tend to run implementation and process evaluations in
41 parallel with examining effectiveness, and those that do tend to focus on
42 fidelity.[18] Examining aspects such as social validity and cultural validity are
43 important, particularly when importing interventions from other countries.[19]
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3 Some universal programmes place emphasis on improving individual's mental
4 health literacy. Such interventions traditionally focus on educating and changing
5 beliefs about mental disorders to aid their recognition, management or prevention,
6 and increasingly include mental health first aid.[20,21] Kutcher, Wei and Coniglio
7 recently defined mental health literacy as having four main components, including
8 the addition of mental health promotion: '1) understanding how to obtain and
9 maintain positive mental health, 2) understanding mental disorders and their
10 treatments, 3) decreasing stigma related to mental disorders and 4) enhancing
11 help-seeking efficacy (knowing when and where to seek help and developing
12 competencies designed to improve one's mental health care and self-management
13 capabilities'. [22] Youth Aware of Mental Health (YAM) is an example of a universal
14 intervention that aims to improve awareness and promote mental health.[23] As
15 part of the Saving and Empowering Young Lives in Europe (SEYLE) cluster
16 randomised controlled trial, a suicide prevention programme across 12 European
17 countries, YAM was compared to two active interventions, 'Professional screening'
18 and 'Question, Persuade, and Refer', and a control group.[24] No difference
19 between arms on suicidal ideation or attempts was found at three month follow-up,
20 however YAM significantly reduced the risk of suicide attempts and suicidal ideation
21 at 12 month follow-up compared to the control group.[23] Interviews with young
22 people have found they prefer YAM to regular classroom activities, however
23 differences were reported in how actively involved they wanted to be in YAM.[25]

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40 The Mental Health and High School Curriculum Guide (The Guide)[26] also aims to
41 increase awareness of mental disorders and their treatments, as well as increasing
42 understanding of how to obtain and maintain mental health, reduce stigma and
43 improve help-seeking efficacy. Delivery of The Guide in Canada was found to
44 increase student and staff knowledge, reduce stigma and increase help-seeking in
45 students.[26–29] In Tanzania, The Guide has been shown to increase teacher
46 knowledge and reduce stigma,[30–32] teacher reports also highlighted positive
47 changes to knowledge, attitude and behaviour in their pupils.[31] Significantly
48 improved mental health knowledge, reduced stigma, more adaptive coping, better
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3 lifestyle choices, and lower perceived stress was also found for students who
4 received The Guide in Nicaragua.[33]
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8 Whilst YAM and The Guide have a developing evidence base in multiple countries,
9 evidence for the effectiveness of such approaches in the UK is sparse. A scoping
10 exercise conducted by the Department for Education in England, concluded that
11 both should be tested to contribute to the UK evidence base for effective
12 interventions to improve mental health in children and young people. As the
13 interventions were developed in other countries, undertaking a process and
14 implementation evaluation to understand factors beyond fidelity and effectiveness
15 is important.[19] Thus, alongside this randomised controlled trial examining
16 effectiveness, a process and implementation evaluation will be undertaken to
17 investigate YAM and The Guide compared to usual provision in English schools.
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27 **AIMS AND HYPOTHESIS**

28 **Effectiveness measurement**

29 Primary aims:

- 30 1. To examine whether YAM is more effective than the usual school-based
31 provision in reducing emotional difficulties in young people.
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- 33 2. To examine whether The Guide is more effective than the usual school-based
34 provision in increasing intended help-seeking of young people around mental
35 health.
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45 Primary hypotheses:

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48 H_1 Young people receiving YAM will report lower emotional difficulties at between 3–
49 6 and 9-12 months follow-up than those who receive the usual school curriculum.
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52 H_2 Young people receiving The Guide will report increased intended help-seeking of
53 mental health at 3–6 and 9-12 months follow-up than those who receive the usual
54 school curriculum.
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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 Institute Sweden, 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 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

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3 parents, peers, teachers etc.) in a safe and confidential environment. The role-play
4 sessions comprise three themes: awareness about choices; depression and suicidal
5 thoughts and feelings; how to manage stress and crisis situations. However, the
6 exact content can be adapted to the cultural needs of the group.
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10 11 ***The Mental Health and High School Curriculum Guide (The Guide).***

12 The Guide was developed in Canada by Dr Kutcher in collaboration with the
13 Canadian Mental Health Association in recognition of the increasing awareness of
14 the importance of health literacy as a necessary foundation for improving health,
15 extrapolated into the area of youth mental health. Originally a web-based
16 curriculum, it aims to increase mental health literacy in both young people and
17 school staff. The Guide is made up of six modules: 1) stigma of mental illness, 2)
18 understanding the relationship between mental health and mental illness, 3)
19 understanding specific mental illnesses, 4) adolescents' experiences of mental
20 illness, 5) seeking help and finding support 6), the importance of positive mental
21 health. It was originally developed to be delivered over 10-12 hours.
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31 Adapted for a UK setting, The Guide is delivered over six consecutive, one hour
32 lessons by school staff. Modules remain the same, however, content has been
33 modified to include more resources from England and less emphasis on Powerpoint
34 presentations in favour of interactive discussions. The sessions in the first four
35 weeks focus on a specific disorder or specific disorders and cover: bipolar disorder
36 (week 1), panic disorder (week 2), schizophrenia and eating disorders (week 3),
37 depression, OCD, ADHD, and ADHD (week 4). Week five covers support and where
38 to get help, while week 6 focuses on stress. Homework exercises, such as a task on
39 famous people with mental illness, are included as part of the Guide. All adaptations
40 to The Guide for an English school setting have been approved by Dr Kutcher and
41 were informed by a pilot study conducted prior to the parallel group cluster
42 randomised controlled trial. School staff who deliver The Guide attend a one-day
43 face-to-face training delivered by an individual from the Anna Freud National Centre
44 for Children and Families. The training aims to improve teachers' knowledge of
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3 mental health and mental illness and reduce stigma, as well as familiarise teachers
4 with the adapted Guide materials so they are able to deliver the content.
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8 **Usual Practice**

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10 Schools allocated to the Usual Practice group are not required to deliver a specific
11 mental health intervention during the programme (June 2018 – Jan 2021).
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13

14 **Outcome measures**

15 **Pupil measures**

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

- 27 ● For YAM: depressive symptoms (Short Mood and Feelings Questionnaire
28 (SMFQ)).[34]
- 29 ● The Guide (intended help-seeking): General Help-seeking Questionnaire
30 (GHSQ).[35]
- 31
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36 Secondary outcome measures:

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

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

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

29 Qualitative implementation and process data will be collected towards the end of
30 delivery of the interventions. Eight schools will be recruited from the main sample
31 as qualitative case study schools in Year 1 of the project; one school per
32 intervention at four of the hubs (excluding control). Case study schools will be
33 recruited via expression of interest and sampled based on expression of interest
34 and variation in their usual provision around mental health and wellbeing, drawing
35 on data from two items in the Usual Provision Survey:
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- 43 1. Please identify, in the last two years, the activities and approaches that have
44 been used in your school and indicate who has delivered/provided these
45 activities.
46
- 47 2. How significant are the following potential barriers to providing effective
48 mental health support within your school?
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53 Face-to-face or telephone interviews will be conducted with two to three members
54 of staff (including a senior leadership team member and a staff member delivering
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3 the intervention) and one to two focus groups will be conducted face-to-face with
4 young people (approximately four to five young people in each focus group) at each
5 school. Learning from the feasibility study indicated that this sample size would
6 yield a large amount of rich qualitative data, while still being manageable in terms
7 of the research team's capacity.
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13 Interviews/focus groups will be semi-structured, enabling the research team to
14 guide the interviews/focus groups according to their topics of interest, but with the
15 conversation around these topics being led by participants in terms of the issues
16 that are most pertinent to them. The topics that the interviews/focus groups will
17 cover include: staff experiences of delivering the interventions and receiving
18 training; staff perceptions of barriers and facilitators to delivery; staff perceptions
19 of impact; staff suggestions for improvement of the interventions; pupils'
20 experiences of taking part in the interventions; pupils' perceptions of impact and
21 helpful aspects of the interventions; pupils' suggestions for improvement of the
22 interventions. All interviews/focus groups will be audio recorded and transcribed
23 verbatim.
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33 The research team will also conduct an observation of a session of the intervention
34 (excluding YAM) at each school to gather contextual information about what the
35 interventions look like on the ground. No individual pupil or staff responses will be
36 recorded, but field notes will be taken during the observation on the process of
37 delivery, the layout of the room, and the atmosphere during delivery.
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43 Follow-up case study visits will be conducted in Year 2 of the project with a small
44 number of schools from Year 1 who have sustained implementation of The Guide
45 beyond the initial project delivery period, as identified through staff responses on
46 the sustainability survey. In addition, as schools who express interest in taking part
47 as a case study are likely to be the more engaged schools, there is also an
48 opportunity in Year 2 of the project for a small number of telephone interviews to
49 be conducted with staff at schools who have engaged less with the trial in Year 1.
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3 This could include schools who have dropped out of the trial, as well as those who
4 have not sustained implementation of The Guide over time.
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8 **Randomisation of schools**

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10 To ensure approximate distribution across conditions randomisation will be carried
11 out by Kings Clinical Trials Unit, minimising for regional representation, current
12 mental health provision, deprivation (as indicated by free school meal eligibility)
13 and urban/rural situation. Randomisation will take after place after baseline data
14 (staff and pupil questionnaires) have been collected. Schools (clusters) will be
15 randomised in an equal allocation ratio (i.e., 1:1:1). Only the statistician,
16 quantitative data analyst and economist are blind to intervention allocation.
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18 Datasets provided to these individuals will reference schools by a unique ID number
19 (000-999).
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26 **Sample size calculation**

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28 As described, two different outcomes will be used to evaluate the interventions in
29 this study. The primary outcome for YAM will be depressive symptoms as measured
30 by the Short Mood and Feelings Questionnaire (SMFQ); and the primary outcome
31 for the Guide the General Help-seeking Questionnaire (GHSQ). For both
32 interventions the primary endpoint is between 3-6 months post intervention. The
33 choice of a short-term assessment as the primary endpoint seems more appropriate
34 since we would expect effects to be observable in the short term. There is also a
35 greater likelihood of attrition in the longer follow up. Secondary analysis will be
36 conducted examining long-term implementation fidelity and long-term effects.
37
38 The schools will be randomised to three groups (YAM, The Guide and Usual
39 Provision). Due to the delivery of the intervention within classes, pupil level data
40 will be analysed allowing for school- and class-level clustering. While cluster effects
41 of emotional distress on *school*-level are usually small [50,51] no data on *class*-
42 level clustering were available. To our knowledge, no study has investigated school-
43 level intra-class correlations of help-seeking. Cluster effects for psychometric
44 measures were evaluated in a joint feasibility study with the INSPIRE trial with $N =$
45 1531 secondary students nested within 79 delivery groups at five schools at
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3 baseline. We found ICCs of .02 for both SMFQ and GHSQ (with upper borders of
4 bootstrapped 95%-confidence intervals of .04 for the GHSQ and .05 for the SMFQ).
5 Our sample size is based on an intra-class correlation of $\rho = .10$, which is
6 conservative given the estimates found in the literature and pilot.
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11 The only school-level variables that will be used as predictors in the proposed
12 analysis are the stratification variables which were assumed not to have any
13 predictive power. Pre-test values of the outcome measures will be used as
14 predictors of within-school variance (conservative estimate of R squared = .20 was
15 used). The study was planned for a Minimally Detectable Effect Size MDES = .20 for
16 the scores of the primary outcome of the respective trial arm. For the SMFQ this
17 would translate into a group difference of between 1.13 (our feasibility study) and
18 1.59 score points (Millennium Cohort Study at age 14;[52]) for the GHSQ this
19 would translate in a group difference of .25 (item average based on our feasibility
20 study; no relevant external reference data identified).
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28 Given these assumptions, an MDES = .20 can be detected without controlling for
29 any additional variables (significance level $\alpha = .05$; statistical power $\beta = .80$) with a
30 sample size of 90 schools (45 control, 45 intervention); and for an analysis taking
31 pre-test values into account an MDES = .198 can be detected.
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35 Since no evidence suggests that the two interventions show different effects, our
36 sample size calculations for the YAM and The Guide trial arms are the same. The
37 overall sample size is 135 schools (45 schools per arm; with 60 students each) of
38 which the 45 control schools serve as comparators for both interventions.
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41 Incorporating the geographical spread, recruitment areas of the study, and
42 potential drop-out both at student- and school-level we plan to recruit at least 144
43 schools overall. To evaluate the potential impact of drop-out, simulation studies
44 were run and even under severe drop-out (20% of schools and 10% of students in
45 remaining schools) an MDES=.22 was evaluated to be achievable, which was
46 agreed by the research group, the funder, and the advisory group as an acceptable
47 margin.
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54 **Data Management**

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

16 Effectiveness analysis

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

36 Service use and costs

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

52 Cost-effectiveness and cost-utility analyses will be undertaken for change in: a) the
53 primary outcome measure and b) quality-adjusted life years (derived from
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3 CHU9D).[43] We will employ an analytical approach that allows for adjustment for
4 confounders, the likely non-normal distribution of cost data, the joint analysis of
5 cost and outcome measures, and sub-group analyses. Results will be presented as
6 cost-effectiveness acceptability curves [53] plotting the probability that the
7 intervention will be considered cost-effective compared to treatment as usual
8 against different levels of willingness to pay for an improvement in outcome.
9 Sensitivity analyses will be undertaken by varying assumptions used to calculate
10 the intervention cost.
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18 Process and implementation analysis

19 Descriptive statistics will be used to document usual school provision and how this
20 changes over the course of the project, as well as to document the implementation
21 of YAM and The Guide. Additionally, for documenting the implementation, we will
22 compare 'implementation as delivered' from our survey data with 'intervention as
23 planned'. Where applicable, the latter can be used to determine the proportion of
24 participating schools who can be deemed to have achieved at least a minimum
25 standard of intervention delivery (e.g. 'on treatment' status). To assess the
26 relationship between implementation variability and outcomes, multi-level
27 modelling will be used, in which we fit the implementation data noted above (or on
28 treatment status derived from said data) as explanatory variables at the school or
29 class level, to assess the extent to which they are predictive of intervention
30 outcomes at the pupil level.
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41 Qualitative interview and focus group transcripts will be analysed using thematic
42 analysis.[54] Up to three researchers will code or assign extracts of the transcripts
43 to broad overarching categories, derived from the research questions (e.g.
44 perceptions of impact). The researchers will then break down the content
45 (transcript extracts) coded within these overarching categories into themes and
46 subthemes relevant to the categories. Finally, an additional member of the research
47 team will re-code 10% of the transcripts using the themes and subthemes for each
48 category devised by the original researchers, suggesting additions or edits where
49 necessary.
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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

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3 proceed the survey. All information sheets outline confidentiality procedures for
4 collecting, processing, and storing data.
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7 **All other data (staff surveys, implementation surveys, qualitative data)**

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9 All other surveys, completed online, will require opt-in consent. As with pupils,
10 individuals will be presented with an information sheet and consent form which they
11 must tick prior to accessing the survey.
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15 For qualitative interviews/focus groups, opt-in consent will be required. School staff
16 and YAM instructors will be required to read and sign an information sheet and
17 consent form. For pupils under the age of 16, letters will be sent home to
18 parents/carers, which require a signed consent form to be returned if they are
19 happy for their child to take part. Prior to interviews/focus groups commencing, the
20 young people will also be asked to read an information sheet and sign an assent
21 form. Consent/assent will not be sought for observations of intervention sessions as
22 no individual staff or pupil responses will be recorded.
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29 **Monitoring of adverse events (AEs)**

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31 AEs, defined as a negative, emotional and behavioural occurrence, or sustained
32 deterioration in a research participant, will be captured as part of the study. This
33 includes serious adverse events (SAEs) which are a threat to life: suicidal ideation,
34 suicidal intent, hospitalisation due to psychiatric of use of substances, death
35 including suicide. Other adverse events: violent behaviour, self-harm, or any other
36 event that an individual feels it is important to report, will also be captured. School
37 safeguarding leads will judge whether they believe the AE is likely related to the
38 intervention.
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45 The ongoing conduct and progress of this study is monitored by an independently
46 chaired Advisory Group Ethics Sub-Committee (AGESC) and advisory group at the
47 Department for Education. On becoming aware of SAEs, the CI/TM will report SAEs
48 or AEs which are likely to be related to the intervention to the AGESC within two
49 working days. Other AEs will be collated and reported quarterly to the AGESC. The
50 University College London Research Ethics Committee will also be informed of AEs
51 and SAEs using the same mechanisms. School and research safeguarding protocols
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3 will also be followed as standard in addition to the reporting and documenting of
4 AEs.
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6 7 **Dissemination plan**

8 Results will be disseminated through a report to the Department for Education, as
9 well as at conferences and in international peer review journals.
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14 **Trial sponsor.** The trial is sponsored by University College London.
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16 17 **TRIAL STATUS**

18 Recruitment for schools opened in March 2018 and will stay open until June 2019.
19 The last participants will be followed up at a one year follow up in January/February
20 2021.
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24 25 **FUNDING STATEMENT**

26 This research was commissioned and funded by the Department for Education. The
27 Department selected the interventions to be trialled and also chairs an advisory
28 group the researchers report to regarding the progress and quality of the research.
29 However, the department had no role in the design of this study and will not have
30 any role in the analyses, interpretation of the data, or decision to submit results.
31 The views expressed are those of the authors and not necessarily those of the
32 Department for Education. JD was (in part) supported by the National Institute for
33 Health Research (NIHR) Collaboration for Leadership in Applied Health Research
34 and Care (CLAHRC) North Thames at Bart's Health NHS Trust. The views expressed
35 are those of the author(s) and not necessarily those of the NHS, the NIHR or the
36 Department of Health and Social Care
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46 47 **ROLE AND RESPONSIBILITIES**

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

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3 An anonymised dataset of the quantitative analysis will be made available to
4 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

	Enrolment (months)		Allocation (months)	STUDY PERIOD (months)																
	-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 (Eol)	X																			
School completes MOU and DSA	X																			
Consent/Assent	PG	CYP																		
Allocation			X																	
INTERVENTIONS																				
School staff training in interventions				↔																
YAM						↔														
The Guide						↔														
Usual Provision						↔														

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

TIMEPOINT**	-7 to -2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
<i>Implementation survey^b</i>								←→											
<i>Sustainability survey^b</i>																X			
<i>Qualitative interviews</i>								←→										←→	
<i>Observations</i>								←→											

^a Young person completes

^b School staff member completes

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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:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. *Ann Intern Med.* 2013;158(3):200-207

		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

1	Trial registration:	#2b	All items from the World Health Organization Trial	n/a
2				
3	data set		Registration Data Set	
4				
5				
6	Protocol version	#3	Date and version identifier	3
7				
8				
9	Funding	#4	Sources and types of financial, material, and other support	18
10				
11				
12	Roles and	#5a	Names, affiliations, and roles of protocol contributors	17
13				
14	responsibilities:			
15				
16	contributorship			
17				
18				
19				
20	Roles and	#5b	Name and contact information for the trial sponsor	n/a
21				
22	responsibilities:			
23				
24	sponsor contact			
25				
26	information			
27				
28				
29				
30	Roles and	#5c	Role of study sponsor and funders, if any, in study design;	18
31				
32	responsibilities:		collection, management, analysis, and interpretation of	
33				
34	sponsor and funder		data; writing of the report; and the decision to submit the	
35				
36			report for publication, including whether they will have	
37				
38			ultimate authority over any of these activities	
39				
40				
41				
42	Roles and	#5d	Composition, roles, and responsibilities of the coordinating	18
43				
44	responsibilities:		centre, steering committee, endpoint adjudication	
45				
46	committees		committee, data management team, and other individuals or	
47				
48			groups overseeing the trial, if applicable (see Item 21a for	
49				
50			data monitoring committee)	
51				
52				
53				
54	Background and	#6a	Description of research question and justification for	3-6
55				
56	rationale		undertaking the trial, including summary of relevant studies	
57				
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		(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

1		improving / worsening disease)	
2			
3			
4	Interventions:	#11c Strategies to improve adherence to intervention protocols,	11-12
5			
6	adherence	and any procedures for monitoring adherence (eg, drug	
7			
8		tablet return; laboratory tests)	
9			
10			
11	Interventions:	#11d Relevant concomitant care and interventions that are	n/a
12			
13	concomitant care	permitted or prohibited during the trial	
14			
15			
16	Outcomes	#12 Primary, secondary, and other outcomes, including the	9-10
17			
18		specific measurement variable (eg, systolic blood pressure),	
19		analysis metric (eg, change from baseline, final value, time	
20		to event), method of aggregation (eg, median, proportion),	
21			
22		and time point for each outcome. Explanation of the clinical	
23		relevance of chosen efficacy and harm outcomes is strongly	
24		recommended	
25			
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32			
33	Participant timeline	#13 Time schedule of enrolment, interventions (including any	n/a
34			
35		run-ins and washouts), assessments, and visits for	
36			
37		participants. A schematic diagram is highly recommended	
38			
39		(see Figure)	
40			
41			
42			
43	Sample size	#14 Estimated number of participants needed to achieve study	11, 13-
44			
45		objectives and how it was determined, including clinical and	14
46			
47		statistical assumptions supporting any sample size	
48			
49		calculations	
50			
51			
52			
53	Recruitment	#15 Strategies for achieving adequate participant enrolment to	7
54			
55		reach target sample size	
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1	Allocation: sequence	#16a	Method of generating the allocation sequence (eg,	13
2			computer-generated random numbers), and list of any	
3	generation		factors for stratification. To reduce predictability of a random	
4			sequence, details of any planned restriction (eg, blocking)	
5			should be provided in a separate document that is	
6			unavailable to those who enrol participants or assign	
7			interventions	
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18	Allocation	#16b	Mechanism of implementing the allocation sequence (eg,	13
19	concealment		central telephone; sequentially numbered, opaque, sealed	
20			envelopes), describing any steps to conceal the sequence	
21	mechanism		until interventions are assigned	
22				
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28	Allocation:	#16c	Who will generate the allocation sequence, who will enrol	13
29	implementation		participants, and who will assign participants to	
30			interventions	
31				
32				
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34				
35	Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg,	13
36			trial participants, care providers, outcome assessors, data	
37			analysts), and how	
38				
39				
40				
41				
42				
43	Blinding (masking):	#17b	If blinded, circumstances under which unblinding is	n/a
44	emergency		permissible, and procedure for revealing a participant's	
45			allocated intervention during the trial	
46	unblinding			
47				
48				
49				
50				
51	Data collection plan	#18a	Plans for assessment and collection of outcome, baseline,	7, 9-12
52			and other trial data, including any related processes to	
53			promote data quality (eg, duplicate measurements, training	
54			of assessors) and a description of study instruments (eg,	
55				
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1		questionnaires, laboratory tests) along with their reliability	
2		and validity, if known. Reference to where data collection	
3		forms can be found, if not in the protocol	
4			
5			
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7			
8	Data collection plan:	#18b Plans to promote participant retention and complete follow-	n/a
9	retention	up, including list of any outcome data to be collected for	
10		participants who discontinue or deviate from intervention	
11		protocols	
12			
13	Data management	#19 Plans for data entry, coding, security, and storage, including	14
14		any related processes to promote data quality (eg, double	
15		data entry; range checks for data values). Reference to	
16		where details of data management procedures can be	
17		found, if not in the protocol	
18			
19	Statistics: outcomes	#20a Statistical methods for analysing primary and secondary	14-15
20		outcomes. Reference to where other details of the statistical	
21		analysis plan can be found, if not in the protocol	
22			
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30	Statistics: additional	#20b Methods for any additional analyses (eg, subgroup and	14-15
31	analyses	adjusted analyses)	
32			
33			
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37			
38	Statistics: analysis	#20c Definition of analysis population relating to protocol non-	14
39	population and	adherence (eg, as randomised analysis), and any statistical	
40	missing data	methods to handle missing data (eg, multiple imputation)	
41			
42			
43	Data monitoring:	#21a Composition of data monitoring committee (DMC); summary	17
44	formal committee	of its role and reporting structure; statement of whether it is	
45		independent from the sponsor and competing interests; and	
46		reference to where further details about its charter can be	
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1		found, if not in the protocol. Alternatively, an explanation of	
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3		why a DMC is not needed	
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6	Data monitoring:	#21b Description of any interim analyses and stopping guidelines,	17
7			
8	interim analysis	including who will have access to these interim results and	
9			
10		make the final decision to terminate the trial	
11			
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13	Harms	#22 Plans for collecting, assessing, reporting, and managing	17
14			
15		solicited and spontaneously reported adverse events and	
16			
17		other unintended effects of trial interventions or trial conduct	
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20			
21	Auditing	#23 Frequency and procedures for auditing trial conduct, if any,	n/a
22			
23		and whether the process will be independent from	
24			
25		investigators and the sponsor	
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29	Research ethics	#24 Plans for seeking research ethics committee / institutional	2
30			
31	approval	review board (REC / IRB) approval	
32			
33			
34	Protocol	#25 Plans for communicating important protocol modifications	3
35			
36	amendments	(eg, changes to eligibility criteria, outcomes, analyses) to	
37			
38		relevant parties (eg, investigators, REC / IRBs, trial	
39			
40		participants, trial registries, journals, regulators)	
41			
42			
43			
44	Consent or assent	#26a Who will obtain informed consent or assent from potential	16
45			
46		trial participants or authorised surrogates, and how (see	
47			
48		Item 32)	
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51	Consent or assent:	#26b Additional consent provisions for collection and use of	n/a
52			
53	ancillary studies	participant data and biological specimens in ancillary	
54			
55		studies, if applicable	
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1	Confidentiality	#27	How personal information about potential and enrolled	16
2			participants will be collected, shared, and maintained in	
3			order to protect confidentiality before, during, and after the	
4			trial	
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11	Declaration of	#28	Financial and other competing interests for principal	18
12	interests		investigators for the overall trial and each study site	
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16	Data access	#29	Statement of who will have access to the final trial dataset,	19
17			and disclosure of contractual agreements that limit such	
18			access for investigators	
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24	Ancillary and post	#30	Provisions, if any, for ancillary and post-trial care, and for	n/a
25	trial care		compensation to those who suffer harm from trial	
26			participation	
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31	Dissemination policy:	#31a	Plans for investigators and sponsor to communicate trial	18
32	trial results		results to participants, healthcare professionals, the public,	
33			and other relevant groups (eg, via publication, reporting in	
34			results databases, or other data sharing arrangements),	
35			including any publication restrictions	
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44	Dissemination policy:	#31b	Authorship eligibility guidelines and any intended use of	n/a
45	authorship		professional writers	
46				
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49	Dissemination policy:	#31c	Plans, if any, for granting public access to the full protocol,	19
50	reproducible		participant-level dataset, and statistical code	
51				
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54	research			
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57	Informed consent	#32	Model consent form and other related documentation given	n/a
58				
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1 materials to participants and authorised surrogates
2
3
4 Biological specimens #33 Plans for collection, laboratory evaluation, and storage of n/a
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6 biological specimens for genetic or molecular analysis in the
7
8 current trial and for future use in ancillary studies, if
9
10 applicable
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12

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16 tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)
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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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