

# cluster-randomised, controlled trial

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#### Summary

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Background Suicidal behaviours in adolescents are a major public health problem and evidence-based prevention programmes are greatly needed. We aimed to investigate the efficacy of school-based preventive interventions of suicidal behaviours.

Methods The Saving and Empowering Young Lives in Europe (SEYLE) study is a multicentre, cluster-randomised controlled trial. The SEYLE sample consisted of 11110 adolescent pupils, median age 15 years (IQR 14-15), recruited from 168 schools in ten European Union countries. We randomly assigned the schools to one of three interventions or a control group. The interventions were: (1) Question, Persuade, and Refer (QPR), a gatekeeper training module targeting teachers and other school personnel, (2) the Youth Aware of Mental Health Programme (YAM) targeting pupils, and (3) screening by professionals (ProfScreen) with referral of at-risk pupils. Each school was randomly assigned by random number generator to participate in one intervention (or control) group only and was unaware of the interventions undertaken in the other three trial groups. The primary outcome measure was the number of suicide attempt(s) made by 3 month and 12 month follow-up. Analysis included all pupils with data available at each timepoint, excluding those who had ever attempted suicide or who had shown severe suicidal ideation during the 2 weeks before baseline. This study is registered with the German Clinical Trials Registry, number DRKS00000214.

Findings Between Nov 1, 2009, and Dec 14, 2010, 168 schools (11110 pupils) were randomly assigned to interventions (40 schools [2692 pupils] to QPR, 45 [2721] YAM, 43 [2764] ProfScreen, and 40 [2933] control). No significant differences between intervention groups and the control group were recorded at the 3 month follow-up. At the 12 month follow-up, YAM was associated with a significant reduction of incident suicide attempts (odds ratios [OR] 0.45, 95% CI 0.24-0.85; p=0.014) and severe suicidal ideation (0.50, 0.27-0.92; p=0.025), compared with the control group. 14 pupils (0.70%) reported incident suicide attempts at the 12 month follow-up in the YAM versus 34 (1.51%) in the control group, and 15 pupils (0.75%) reported incident severe suicidal ideation in the YAM group versus 31 (1.37%) in the control group. No participants completed suicide during the study period.

Interpretation YAM was effective in reducing the number of suicide attempts and severe suicidal ideation in schoolbased adolescents. These findings underline the benefit of this universal suicide preventive intervention in schools.

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#### Introduction

Worldwide, suicide is one of the three leading causes of death in young people.1,2 Globally, in 2009, suicide accounted for 7.3% of all deaths in the age group 15-19 years, after road traffic accidents (11.6%), and preceding violence (6.2%), respiratory tract infections (5.4%), tuberculosis (4.8%), and HIV (2.3%). According to the latest data from WHO, figures are similar in 2014.4 The lifetime prevalence of suicide attempts in adolescents in the USA is 4.1%.5 In Europe, the lifetime self-reported prevalence for similar age groups is 4.2%.6

Suicide attempts and severe suicidal ideation have potentially serious consequences, including substantial psychological effects, increased risk of subsequent suicide attempt, and death.7,8 Importantly, suicidal behaviour also has profound negative effects on relatives and other people in the person's life.9 The medical, financial, and emotional costs to communities affected by suicide are also substantial.<sup>10</sup> Consequently, the prevention of suicidal behaviour should be a national health priority, with the development of existing11-13 and new evidence-based, suicide preventive interventions. Research lends support to the theory that the vast proportion of psychopathological changes has its onset in childhood and adolescence,14 and therefore young people are an especially important target. 15,16 Most children and adolescents attend school, which makes these an appropriate setting for reaching young people.<sup>17</sup> The authors of two systematic reviews of school-based suicide preventive interventions<sup>18,19</sup> concluded that assessments of school-based intervention programmes tested in randomised controlled trials are needed. The theoretical framework of suicide prevention programmes generally acknowledges universal, selective, or indicated

approaches.20-22 School-based universal programmes include all pupils, whereas selective and indicated efforts focus on those regarded at high risk or presenting suicidal behaviour. The few randomised trials based on a universal or a selective approach have focused almost exclusively on generating change in knowledge and attitudes.19 Very few trials, all from the USA and none from Europe, have investigated changes in the reduction of severe suicidal ideation or suicide attempts.23-26 In this Article, we report the results of the Saving and Empowering Young Lives in Europe (SEYLE) study, the first large-scale, multicountry, European randomised controlled trial of school-based prevention of suicidal behaviour in adolescents.27 The main hypothesis is that preventive interventions are more effective than a control condition in reducing new cases of suicide attempt and severe suicidal ideation between baseline and follow-up assessments.

#### Methods

### Trial design and participants

SEYLE was a multicentre, cluster-randomised trial designed to investigate the efficacy of school-based preventive interventions for suicidal behaviour. Pupils were recruited from 168 schools in ten European Union countries (Austria, Estonia, France, Germany, Hungary, Ireland, Italy, Romania, Slovenia, and Spain). Schools were deemed eligible if they were public, contained at least 40 pupils aged 15 years, had more than two teachers for pupils aged 15 years, and had no more than 60% of pupils of the same sex.27 Within each country, the cluster design first led to randomisation of eligible schools to one of four trial groups. Within the schools, all classes with pupils aged mainly 15 years were approached for participant recruitment. To avoid discrimination, all pupils in the participating classrooms, including those aged 14 and 16 years, were also approached for recruitment.

Study site characteristics are described in the appendix. We assessed all behaviours at an individual level with a structured self-report questionnaire administered in one classroom session at baseline, 3 months, and 12 months. All pupils who reported suicide attempts ever, or severe suicidal ideation in the past 2 weeks before the baseline assessment, and those with missing data regarding these two variables were not included in the final analysis. Pupils with incident (new) suicide attempt(s) or severe suicidal ideation at 3 months and 12 months follow-up were identified to investigate the preventive effects of the interventions. A procedures manual covering all aspects of SEYLE was available to each site. Local teams were trained in the study methods before their implementation and a steering group monitored adherence to the procedures during the entire study period. Pupils in each group completed the same questionnaire, which assessed risk behaviours, symptoms of psychopathology and suicidal thoughts, plans, and suicide attempts, at baseline (before any intervention) and at a 3 month and 12 month follow-up. Ethics approval was obtained from each of the local research ethics committees. We obtained informed assent from each participant and written consent from at least one parent, which was a prerequisite for participation. SEYLE prescribed a specific procedure to assess and immediately assist every emergency case at each site. Emergency cases were pupils who reported either suicide attempts or severe suicidal ideation in the 2 weeks before baseline assessment. These pupils were immediately contacted for clinical assessment and referred to health-care services for treatment, if necessary. All referrals were done before implementation of the interventions. To avoid any stigma, all such emergency cases were allowed to continue in the study, but their results were excluded from the final analysis. SEYLE used an independent ethics adviser from Basel University, Basel, Switzerland.

## Randomisation and masking

A list of all schools that met the study inclusion or exclusion criteria was generated at each site. Schools were then stratified into large (more than the site median) and small groups, to create a pool of potential participants that was homogeneous with respect to sociocultural factors, school environment, and school system structure. A random number generator was used to place schools at each site, first into one of the four trial groups, then schools within each group were placed in a random order within each of the two school size classifications (large or small). We identified schools (one large for every two small) for invitation into the SEYLE project according to a predefined order established by the randomised list. In the event that a selected school did not choose to participate or the trial group's target was not met, we approached the next same-size school from the randomised list. Each school was randomly assigned to participate in one intervention (or control) group only and was unaware of the interventions undertaken in the other three trial groups. During school recruitment, the same general information that SEYLE is a mental health promotion project was presented to all schools. We also presented a general, non-specific overview about the procedures of the intervention to which a particular school was randomly assigned, but did not disclose that alternative interventions were part of the project. On the basis of the information provided, each school could accept or refuse to join the study. Overall, 168 schools (72%) of 232 schools approached agreed to participate and no school dropped out of the study during the 12 month SEYLE trial. randomisation procedures developed by researchers from Columbia University (New York, NY, USA) and each site leader was responsible for implementing the plan.

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See Online for appendix

#### **Procedures**

Three intervention programmes were compared with a control group. All interventions were undertaken during a 4 week period, after a baseline assessment.

Question, Persuade, and Refer (QPR) is a manualised gatekeeper programme, developed in the USA.28 In SEYLE, QPR was used to train teachers and other school personnel to recognise the risk of suicidal behaviour in pupils and to enhance their communication skills to motivate and help pupils at risk of suicide to seek professional care. OPR training materials included standard power point presentations and a 34-page booklet distributed to all trainees. Teachers were also given cards with local health-care contact information for distribution to pupils identified by them as being at risk. Although QPR targeted all school staff, it was, in effect, a selective approach, because only pupils recognised as being at suicidal risk were approached by the gatekeepers (trained school personnel).

The Youth Aware of Mental Health Programme (YAM) was developed for the SEYLE study29 and is a manualised, universal intervention targeting all pupils, which includes 3 h of role-play sessions with interactive workshops combined with a 32-page booklet that pupils could take home, six educational posters displayed in each participating classroom and two 1 h interactive lectures about mental health at the beginning and end of the intervention. YAM aimed to raise mental health awareness about risk and protective factors associated with suicide, including knowledge about depression and anxiety, and to enhance the skills needed to deal with adverse life events, stress, and suicidal behaviours. This programme was implemented at each site by instructors trained in the methodology through a detailed 31 page instruction manual.

Question, persuade, and refer (40 schools, 2692 pupils)	Youth aware of mental health programme (45 schools, 2721 pupils)	Screening by professionals (43 schools, 2764 pupils)	Controls (40 schools, 2933 pupils)
14.80 (0.82)	14-80 (0-85)	14-81 (0-80)	14.78 (0.89)
10.47 (4.96)	10.83 (4.96)	10.70 (5.11)	10.14 (4.95)
1675 (63%)	1637 (60%)	1607 (58%)	1647 (56%)
592 (22%)	601 (22%)	605 (22%)	626 (21%)
158 (6%)	205 (8%)	142 (5%)	158 (5%)
273 (10%)	257 (10%)	247 (9%)	292 (10%)
83 (3%)	115 (4%)	102 (4%)	86 (3%)
99 (4%)	106 (4%)	96 (4%)	103 (4%)
	persuade, and refer (40 schools, 2692 pupils)  14-80 (0-82) 10-47 (4-96) 1675 (63%) 592 (22%)  158 (6%)  273 (10%)  83 (3%)	persuade, and refer (40 schools, 2692 pupils)  14-80 (0-82)  10-47 (4-96)  1675 (63%)  1637 (60%)  592 (22%)  158 (6%)  273 (10%)  257 (10%)  83 (3%)  115 (4%)	persuade, and refer (40 schools, 2692 pupils)         mental health programme (43 schools, 2764 pupils)         professionals (43 schools, 2764 pupils)           14-80 (0-82)         14-80 (0-85)         14-81 (0-80)           10-47 (4-96)         10-83 (4-96)         10-70 (5-11)           1675 (63%)         1637 (60%)         1607 (58%)           592 (22%)         601 (22%)         605 (22%)           158 (6%)         205 (8%)         142 (5%)           273 (10%)         257 (10%)         247 (9%)           83 (3%)         115 (4%)         102 (4%)

Data are mean (SD) or n (%). SDQ=Strengths and Difficulties Questionnaire. Counts of suicide attempts and suicide ideation might overlap.

Table 1: Baseline characteristics

The Screening by Professionals programme (ProfScreen), which was also developed for the SEYLE study, is a selective or indicated intervention based on responses to the SEYLE baseline questionnaire. When pupils had completed the baseline assessment, health professionals reviewed their answers and pupils who screened at or above pre-established cutoff points were invited to participate in a professional mental health clinical assessment and subsequently referred to clinical services, if needed.<sup>30</sup>

For ethical reasons, the control group was exposed to the same six educational posters displayed in their classrooms as those used in the YAM. Pupils in the control group who self-recognised the need for help could contact local health-care providers whose information was provided on a poster.

Process assessments and quality control were done in a standard manner at each site through a series of structured questionnaires to ensure that all preparatory procedures were executed correctly and that interventions were implemented in a standard way across sites and adhered to the SEYLE protocol. Analyses of these data suggest congruence between sites in both study implementation procedures and in undertaking of the interventions (data not shown).

#### Outcomes

The primary outcome was incident suicide attempt(s) ie, all new cases of suicide attempt(s) identified at either the 3 month or 12 month follow-up. Another outcome was severe suicidal ideation in the 2 weeks preceding the follow-ups—ie, all new cases of suicidal ideation identified at either of the two follow-ups. All pupils reporting ever making a suicide attempt before the baseline date or having severe suicidal ideation in the 2 weeks before baseline were excluded from the analyses. Pupils were identified as having an incident suicide attempt if, at the 3 month and 12 month follow-up, they answered "yes" to the question: "have you ever made an attempt to take your own life?" Pupils were identified as having severe suicidal ideation, if they answered: "sometimes, often, very often or always" to the question: "during the past 2 weeks, have you reached the point where you seriously considered taking your life, or perhaps made plans how you would go about doing it?"

Suicide attempts and severe suicidal ideation were studied with the above mentioned questions from the five item Paykel Hierarchical Suicidal Ladder<sup>31</sup> that measures the intensity of suicidal behaviour, from feelings that life is not worth living, to death wishes, suicidal thoughts, severe suicidal ideation with plans, and suicide attempts.

Symptoms of psychopathology, assessed with the Strengths and Difficulties Questionnaire (SDQ),  $^{32,33}$  and the sociodemographic variables presented in table 1 were used as covariates in all analyses.

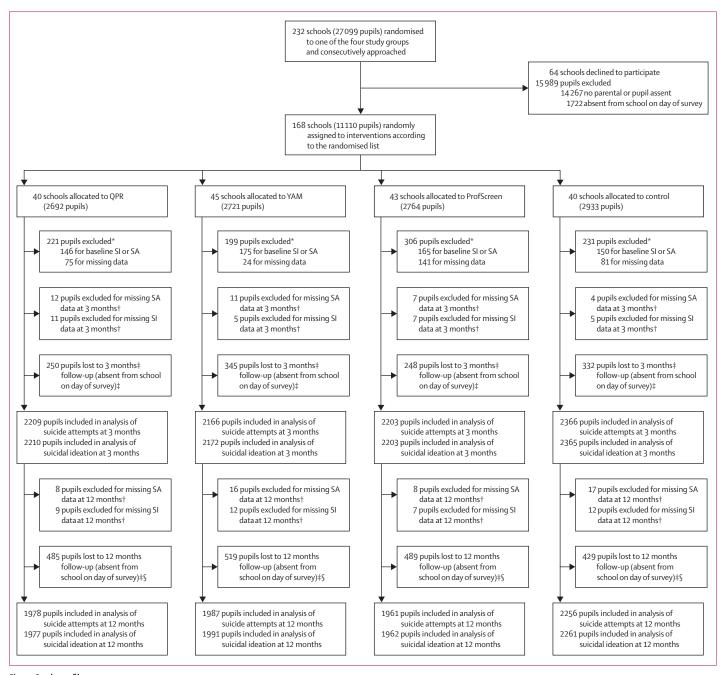


Figure: Study profile

QPR=Question, Persuade, and Refer. YAM=Youth Aware of Mental Health Programme. ProfScreen=screening by professionals. SI=suicidal ideation. SA=suicide attempt. \*Pupils who had ever attempted suicide or who reported severe suicidal ideation in the 2 weeks before baseline or who had missing data for the respective variable at baseline were excluded from analysis. †Pupils were excluded only in the analysis for the corresponding outcome. ‡Does not include lost-to-follow-up with other exclusion criteria. §Lost to follow-up between baseline and 12 months.

# Statistical analysis

We established the sample size by incorporating a cluster-randomised design with assumptions about potential participants, based on previous school-based studies of suicidal behaviour such as that the intraclass correlation of outcomes within schools would be  $0\cdot01$  or smaller and that the incident rate of the primary

outcome, suicide attempt at 12 months, would be 3% or more in the control group. About 2500 pupils from 40 schools in each of the four groups (ie, 160 schools and 10000 pupils), were judged to be a group of sufficient size to detect a 50% reduction in incidence of suicide attempt in any of the intervention groups, compared with the control group, with a power of 80%

	3 month follow-up			12 month follow-up				
	n	Cases (%)	OR (95% CI)	p value	n	Cases (%)	OR (95% CI)	p value
Question, persuade, and refer	2209	15 (0·68%)	0.62 (0.32-1.18)	0.147	1978	22 (1·11%)	0·70 (0.39-1.25)	0.229
Youth aware of mental health programme	2166	19 (0·88%)	0·78 (0·42-1·44)	0-422	1987	14 (0·70%)	0·45* (0·24–0·85)	0.014*
Screening by professionals	2203	27 (1·23%)	1·10 (0·61–1·97)	0.752	1961	20 (1·02%)	0.65 (0.36-1.18)	0.158
Controls	2366	27 (1·14%)	Reference		2256	34 (1·51%)	Reference	

ORs and 95% CIs were generated from generalised linear mixed models with a logistic link, adjusted for age, sex, Strengths and Difficulties Questionnaire total score, not being born in the country of residence, parental job loss in the previous year, not living with both biological parents, and country of residence. Missing covariates were included through use of multiple imputation. OR=odds ratio.\*Significant at p<0.05.

Table 2: Incident suicide attempts at 3 and 12 month follow-up

with a two-sided significance level of 0.05. The risk of severe suicidal ideation was assumed to be higher and thus this sample size would yield greater power to detect group differences. Despite the overall large sample size, because the risk of the primary outcome being investigated was expected to be very low, significance could only be achieved with adequate power if the intervention effects were very large (ie, about a two-fold decrease or more). Means and proportions of individual characteristics (age, sex, not being born in their country of residence, parental job loss in the previous year, not living with both biological parents, country of residence, and SDQ total score) and baseline reports of suicide attempts or severe suicidal ideation were calculated for each intervention group and tested with a model controlled for clustering of pupils within schools. To investigate the preventive effects of the interventions at 3 months and 12 months, all subsequent analyses of pupils with available questionnaire data at that timepoint excluding those who reported a lifetime suicide attempt at baseline or who reported severe suicidal ideation within the past 2 weeks at baseline. Raw counts and proportions of each outcome (suicide attempts and severe suicidal ideation) were tabulated within each intervention group at 3 months and 12 months. The intraclass correlation was calculated for each outcome to quantify variability across schools. Assessment of whether differential dropout (ie, missing both 3 month and 12 month outcomes) across intervention groups was dependent on outcomes was examined with logistic regression of dropout status and testing of an interaction between group and baseline attempt or ideation.

Generalised linear mixed models (GLMM)<sup>34</sup> with a logistic link, a random effect to account for clustering of pupils within schools, and a nested random effect to account for repeated (3 months and 12 months) measures within pupils, were used to test for intervention group differences. The GLMMs for each outcome included fixed effects for intervention group, categorical

month, a group-by-month interaction, and controlled for individual characteristics. On the basis of the GLMMs, the adjusted odds ratios (OR) and 95% CIs for each of the three experimental intervention groups compared with the control group at 3 and 12 months, were used to test significance. Intervention groups were compared with the control group only; no mutual comparisons were made. The associated absolute risk difference and number needed to prevent were also calculated based on the adjusted risk of each outcome by intervention group estimated from the GLMM. A multiple imputation procedure<sup>35</sup> (50 imputations with full conditional specification for dichotomous variables)36 was used to manage missing values of individual characteristics (<1% missing for each individual characteristic), so that all pupils with an outcome at 3 months or 12 months were included in the GLMMs. Additional models, including sex-by-intervention group interactions, and age-by-intervention group interactions were tested for differential intervention effects by sex and age. To assess the robustness of the findings, tests for intervention group differences were redone including only the subset of pupils with complete outcome data at both 3 months and 12 months. All analyses were done with SAS version 9.3. The trial is registered at the German Clinical Trials Registry, number DRKS00000214.

### Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author (DW) had full access to all the data in the study and had final responsibility for the decision to submit for publication.

#### Results

Of 232 schools that were approached and randomly assigned to one of four study groups, 168 schools (72%) accepted to participate. 27099 pupils were approached: 14267 were not enrolled because parental consent or pupils' assent were not given, and 1722 pupils were absent from school on the day of baseline assessment. We recruited 11110 pupils (median age 15 years [IQR 14-15], mean age 14.8 years [SD 0.8]; 59% girls). Of the 11110 pupils with baseline assessment, 9798 (88%) were available at 3 months and 8972 (81%) at 12 months (figure), with only 622 (5.6%) pupils not participating at either follow-up. Our recruitment procedures generated about an equal number of pupils in each group (figure): 2692 pupils were assigned to QPR; 2721 were assigned to the YAM; 2764 were assigned to ProfScreen, and 2933 were assigned to the control group. 221 pupils in the QPR group, 199 in YAM, 306 in the ProfScreen group, and 231 in the control group were excluded from the analysis because they reported a previous suicide attempt or severe suicidal ideation in the 2 weeks before baseline, or were missing data for the respective variables (figure, table 1). Pupils referred at baseline for psychiatric treatment and

thus excluded from analysis were 23 (0.8%) in the QPR group, 22 (0.8%) in the YAM group, 28 (1.0%) in the ProfScreen group, and 24 (0.8%) in the control group. There was no significant interaction between any intervention group and baseline suicide attempt (p=0.533) or severe suicidal ideation (p=0.456) for dropout status.

Table 1 shows baseline characteristics of the sample for each intervention group. Differences in mean SDQ total score between groups were less than 1 point and are not considered clinically significant, because the scale ranges from 0 to 40 points and has a borderline region of 3 points.<sup>32</sup>

At 3 months, of 9724 pupils who answered both outcome questions, 333 (3·4%) reported either an attempt or ideation and 85 (0·9%) reported both. At 12 months, of 8885 pupils who answered both questions, 261 (2·9%) reported either and 55 (0·6%) reported both. Intraclass correlations across schools at 12 months were 0·003 for suicide attempt and 0·007 for severe suicidal ideation.

Analyses of the interaction between intervention groups and time (3 months and 12 months) showed no significant effect on incident suicide attempts in the three intervention groups, compared with the control group at the 3 month follow-up. However, at the 12 month follow-up, we noted a significant effect (OR 0.45, 95%CI 0.24-0.85; p=0.014) of the YAM on incident suicide attempts, compared with the control group (table 2).

After analyses of the interaction between intervention groups and time (3 months and 12 months), we noted the following results for severe suicidal ideation: at the 3 month follow-up, there were no significant effects of QPR, YAM, or ProfScreen compared with the control group. However, at the 12 month follow-up, we noted a significant effect of the YAM (OR 0.50, 0.27-0.92; p=0.025), compared with the control group (table 3).

Neither sex nor age significantly modified the intervention effect for either outcome (interaction p=0.2658 for sex and 0.8933 for age for suicide attempts, and 0.1315 for sex and 0.9324 for age for severe suicidal ideation). YAM showed stronger effects for incident suicide attempts (OR 0.36, 95% 0.18–0.72; p=0.004) and severe suicidal ideation (0.46, 0.24–0.88; p=0.018) when the analysed sample included pupils who participated in all waves of data collection (n=8282).

Overall, in terms of suicide attempts, at 12 months in the YAM group absolute risk fell by 0.60% (ie, 6.0 of 1000 pupils) and relative risk (RR) was reduced by 54.6% (ie, of 1000 pupils, 11 attempted suicide in the control group vs five attempts in YAM). Therefore, the number needed to have an intervention with YAM to prevent one suicide attempt per year was 167. In terms of severe suicidal ideation, in the YAM group absolute risk fell by 0.50% and RR fell by 49.6%. The number needed to have an intervention with YAM to prevent one case of severe suicidal ideation per year was 200.

Site leaders in each country had contact with SEYLE school principals throughout the whole investigation period and were instructed to obtain information about

	3 month follow-up			12 month follow-up				
	n	Cases (%)	OR (95% CI)	p value	n	Cases (%)	OR (95% CI)	p value
Question, persuade, and refer	2210	25 (1·13%)	0.69 (0.40-1.19)	0.182	1977	29 (1·47%)	0·95 (0·55–1·63)	0.856
Youth aware of mental health programme	2172	32 (1·47%)	0.88 (0.52–1.48)	0.629	1991	15 (0·75%)	0·50* (0·27–0·92)	0.025*
Screening by professionals	2203	27 (1·23%)	0·72 (0·42-1·23)	0.229	1962	22 (1·12%)	0·71 (0·40-1·25)	0.234
Controls	2365	35 (1·48%)	Reference		2261	31 (1·37%)	Reference	

ORs and 95% CI were generated from generalised linear mixed models with a logistic link, adjusted for age, sex, baseline Strengths and Difficulties Questionnaire total score, not being born in the country of residence, parental job loss in the previous year, not living with both biological parents, and country of residence. Missing covariates were included through use of multiple imputation. OR=odds ratio. \*Significant at p<0.05.

Table 3: Incident severe suicidal ideation at 3 and 12 month follow-up

any completed suicides. No completed suicides were reported for any study participants.

#### Discussion

This study represents the first European, multicountry, randomised controlled trial of the prevention of suicidal behaviour in adolescents (panel). The results show that the YAM, a universal, school-based intervention of short duration (5 h in 4 weeks),<sup>29</sup> was significantly more effective in preventing new cases of suicide attempts and severe suicidal ideation, including planning, than no intervention (the control group). The reported reduction in incident suicide attempts was more than 50% with YAM than for the control group. This effect is higher than those noted in other successful public health interventions—eg, for bullying and bully victimisation (17–23%),<sup>37</sup> or specific types of school-based interventions addressing smoking cessation (14%).<sup>38</sup>

So far, trials of only two other interventions undertaken in the USA have shown a significant decrease in suicide attempts. Results from a classroom-based intervention, Signs of Suicide (SOS), with 2100 pupils in five North American high schools, showed a reduced risk of suicide attempts at a 3 month follow-up, although there were no differences in suicidal ideation.23 Similar results were reported on the basis of an extension of this programme undertaken with 4133 pupils in nine US high schools, for which again, the incidence of suicide attempts at a 3 month follow-up was significantly lower, but no improvement in suicidal ideation compared with controls was noted.24 Neither study, however, followed up beyond 3 months. Only one other trial, a classroom-based behavioural intervention called the Good Behaviour Game with two cohorts of about 1000 and 2000 North American first-grade pupils, showed a reduced incidence of suicidal ideation and suicide attempts when followed up at ages 21-22 years.26

In SEYLE, the YAM not only prevented suicide attempts, an important predictor of completed suicides, 39,40 but it

#### Panel: Research in context

#### Systematic review

We searched PubMed, PsycINFO, Cochrane Library, and Google Scholar with no date restrictions for English-language, peerreviewed articles of the outcomes of school-based suicide preventive interventions in April, 2014. The search terms included "suicide", "attempted suicide", "prevention", "intervention", "adolescent", "school", "gatekeeper", "screening", "mental health promotion", "mental health education", and "randomised controlled trial". References included in searched articles were also screened for relevant publications. The articles identified by the searches were read by two researchers. Articles that reported randomised controlled trials of suicide preventive interventions undertaken in a school setting, with suicide attempt or suicidal ideation as outcome measures, and systematic reviews, were analysed. Three trials undertaken in a school setting in the USA were identified. They showed significant reductions in suicide attempts, and one of them also in suicidal ideation. Systematic reviews underlined the need for more randomised controlled trials.

#### Interpretation

Suicide attempt and suicidal behaviours in adolescents are known predictors of mental health problems and future suicidal behaviours throughout their lifecourse, which calls for early preventive measures. The results of our SEYLE trial in ten European Union countries with 11110 school-based adolescents show that the Youth Aware of Mental Health Programme (YAM) is effective in significantly reducing incident severe suicidal ideation and suicide attempts, which are the negative results of adverse life events, stress, and mental health problems. This is the first multicentre, European study of a large sample of adolescents, and is a step forward in view of the shortage of studies of the effectiveness of school-based suicide prevention programmes. The SEYLE results provide evidence for the effectiveness of a universal suicide prevention programme (YAM) and, in addition to previous studies, the validity of a universal approach to adolescent suicide-prevention in a school setting.

also reduced new cases of severe suicidal ideation, including suicide planning-all important markers of poor psychological wellbeing. The design of the YAM, aimed at changing pupils' negative perceptions and improving their coping skills in the management of adverse life events and stressors, which often are triggers of suicidal behaviour, could account for its significant effects. The YAM, through active participation might also have provided the pupils, most probably for the first time, with an opportunity to think, verbalise, and discuss among themselves a range of issues related to mental health. Such opportunities are especially important, because people showing suicidal behaviour tend to suppress their emotions and have difficulties in identifying their feelings.41 These potentially sustained interactive processes and integration of new knowledge29 need time, and the

associated cognitive processes were further helped by the adolescents becoming 1 year older and thus more mature at the 12 month follow-up. Additionally, effects of the YAM could not have been detected before the 12 month follow-up because no additional intermediate measurements between 3 months and 12 months were available.

The QPR and ProfScreen interventions did not have significant effects. Changes in suicidal behaviour are perhaps more likely to occur if pupils are personally engaged in the intervention, than with adult-driven interventions, which adolescents might be reluctant to accept. Importantly, QPR is designed to empower teachers to recognise pupils at risk of suicide. However, previous SEYLE findings have shown that teachers' readiness to help pupils with mental health disorders is dependent on the teachers' subjective psychological wellbeing, which could possibly affect the effectiveness of the QPR interventions in this study. 42 Moreover, for QPR, teachers need to be able to identify signs of suicide risk; but because suicidality is mainly an internal process, many warning signs might be scarcely visible or very well hidden in adolescents, even if teachers are well trained to recognise them. ProfScreen had the objective of identifying pupils at risk of mental health problems, and early detection and treatment of adolescents with psychopathology. This is an important approach to diminishing the burden of mental disorders in adulthood. 43 However, as previous investigations have shown, the acceptability of screening is difficult and this intervention approach would most probably benefit from concurrent activities designed to reduce the stigma of mental health issues among pupils and parents, and thus to help society to be more open about mental health problems. 30,44

Limitations of this study include reliance on self-report, as with other, similar studies. 23,24 However, we regard it as unlikely that training in mental health awareness, as was done in the YAM, would negatively affect self-report of suicide attempts and severe suicidal ideation. Rather, with deeper knowledge and language skills reporting is more likely to increase and therefore diminish the significance of the results found in this study. For ethical reasons the control group was exposed to the same mental-health information as the YAM group, displayed on posters in the classrooms. Therefore, we assume that the effect sizes for the YAM are probably underestimated. A reported difference at baseline between groups for SDQ Total Score is less than one point and therefore not clinically significant. 32

The strengths of SEYLE, in addition to being a randomised controlled trial, include having the largest number of adolescent participants of any school-based suicide preventive study up to now, good follow-up participation rates, and the inclusion of new suicide attempts and severe suicidal ideation as outcome measures.

This study provides much-needed empirical evidence of the effectiveness of a universal school-based public health

intervention by showing that the YAM can prevent suicide attempts and severe suicidal ideation, including the planning of suicide, in adolescents. According to these data, YAM can prevent one suicide attempt by targeting 167 pupils. These findings are important in view of research showing that young people who attempt suicide are more likely to have persistent mental health disorders in adulthood45 and complete suicide, than those who do not attempt suicide in childhood.40 The results underline the necessity for action46,47 regarding large-scale implementation of universal, school-based suicide prevention programmes. Further studies are needed to replicate these results, and to assess the cost-effectiveness of the YAM intervention, and the potential added benefit of booster activities and combinations of different kinds of interventions. Further research is also needed to study the effect of a larger-scale implementation of the YAM intervention, including alternative methods of delivery. 48

#### Contributors

DW led the development of the study design and methodology, and supervised all phases of the study and analyses. DW and VC wrote several sections of the manuscript and critically revised the final version of the manuscript. VC advised on research methodology, and supervised the quality control of data collection and data analyses. CWH advised on research methodology and provided consultation for epidemiological issues. CW participated in the design of the study and advised on implementation of the methods for the RCT interventions. MW was responsible for the statistical analyses and wrote the sections of the manuscript about data analysis. RE did the statistical analyses and designed the tables. GH performed quality control of the statistical analyses. IK participated in conducting exploratory statistical analyses and critically revised the manuscript. MS participated in the study design. PV performed quality control and management of the SEYLE databases. GM participated in the randomisation process and along with AA, in the quality control of the implementation of RCT interventions. FG provided input to the statistical analysis. SR-T provided ethical consultation for the ongoing interventions. All authors critically revised and approved the manuscript before submission.

#### Declaration of interests

We declare no competing interests.

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