486/AB
vom 27.03.2014 zu 529/J (XXV.GP)

BUNDESMINISTERIUM
FÜR GESUNDHEIT

Alois Stöger
Bundesminister

Frau
Präsidentin des Nationalrates
Mag.[a] Barbara Prammer
Parlament
1017 Wien

GZ: BMG-11001/0017-I/A/15/2014

Wien, am 25. März 2014

Sehr geehrte Frau Präsidentin!

Ich beantworte die an mich gerichtete schriftliche parlamentarische **Anfrage Nr. 529/J der Abgeordneten Dr. Franz, Kolleginnen und Kollegen** nach den mir vorliegenden Informationen wie folgt:

Fragen 1, 6, 7, 13 und 14:
Hinsichtlich der Fragen zu näheren Details der in Rede stehenden Studie ersuche ich um Verständnis, dass eine detaillierte Darstellung von Methodik, Ergebnissen und Auswertungen über den Rahmen einer parlamentarischen Anfragebeantwortung hinausgehen würde. Ich darf dazu aber auf entsprechende Publikationen verweisen, die auch in der Beilage angeschlossen sind:

Carli, V., Wasserman, C., Wasserman, D., Sarchiapone, M., Apter, A., Balazs, J., ... & Hoven, C. W. (2013). The Saving and Empowering Young Lives in Europe (SEYLE) randomized controlled trial (RCT): methodological issues and participant characteristics. BMC public health, 13(1), 479 (BEILAGE 1).

Balazs, J., Miklósi, M., Keresztény, Á., Hoven, C. W., Carli, V., Wasserman, C., ... & Wasserman, D. (2013). Adolescent subthreshold-depression and anxiety: psychopathology, functional impairment and increased suicide risk. Journal of Child Psychology and Psychiatry, 54(6), 670-677 (BEILAGE 2).

Brunner, R., Kaess, M., Parzer, P., Fischer, G., Carli, V., Hoven, C. W., ... & Wasserman, D. (2013). Life-time prevalence and psychosocial correlates of adolescent direct selfinjurious behavior: A comparative study of findings in 11 European countries. Journal of Child Psychology and Psychiatry (BEILAGE 3).

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Wasserman, C., Hoven, C. W., Wasserman, D., Carli, V., Sarchiapone, M., Al-Halabí, S., ... & Poštuvan, V. (2012). Suicide prevention for youth-a mental health awareness program: lessons learned from the Saving and Empowering Young Lives in Europe (SEYLE) intervention study. BMC public health, 12(1), 776 (BEILAGE 4).

Sarchiapone, M., Mandelli, L., Carli, V., Iosue, M., Wasserman, C., Hadlaczky, G., ... & Wasserman, D. (2014). Hours of sleep in adolescents and its association with anxiety, emotional concerns, and suicidal ideation. Sleep Med (BEILAGE 5).

Kaess, M., Brunner, R., Parzer, P., Carli, V., Apter, A., Balazs, J. A., ... & Wasserman, D. (2013). Risk-behaviour screening for identifying adolescents with mental health problems in Europe. European child & adolescent psychiatry, 1-10 (BEILAGE 6).

Wasserman, D., Carli, V., Wasserman, C., Apter, A., Balazs, J., Bobes, J., ... & Hoven, C. W. (2010). Saving and Empowering Young Lives in Europe (SEYLE): a randomized controlled trial. BMC public health, 10(1), 192 (BEILAGE 7).

Fragen 2 bis 5:
Der Projektantrag an die europäische Kommission wurde - entsprechend dem üblichen Vorgehen bei Einreichungen von EU-Projekten - durch ein Konsortium, bestehend aus den Repräsentant/inn/en der verschiedenen an diesem Projekt beteiligten Länder eingereicht; federführend war das Karolinska Institut in Stockholm.

Das Karolinska Institut ist im Rahmen der SEYLE Studie hinsichtlich der Übernahme des Österreich-Teiles an Univ.-Prof. Dr. Haring herangetreten, der zu dieser Zeit eine „Research Division (RD) for Mental Health" an der UMIT leitete und das Projekt über diese RD abwickelte. Das Projekt wurde durch die EU (FP7) mit € 123.000,- gefördert, nach Auskunft des Projektleiters erfolgte keine andere Förderung durch die öffentliche Hand.

Fragen 8 bis 12:
<u>In Tirol:</u>

- Baseline: 36 gefährdete Schüler/innen (3,75%)
- Follow up 1: 12 gefährdete Schüler/innen (1,3%)
- Follow up 2: 8 gefährdete Schüler/innen (0,9%)

Diese Schüler/innen wurden im Anschluss an jede Fragebogenuntersuchung telefonisch kontaktiert und zu einem persönlichen Gespräch eingeladen. Ein Teil von ihnen wurde an qualifiziertes Fachpersonal (s. Auflistung Helfernetzwerk) weitervermittelt.

Auflistung Helfernetzwerk:

- KIZ – Hilfe für Kinder und Jugendliche in Not
  www.kiz-tirol.at
- Transform – Psychotherapie & Beratung
  www.transformberatung.com
- Frauen im Brennpunkt – Mädchenberatung
  www.fib.at/maedchenberatung
- Kinder & Jugendanwaltschaft
  www.kija-tirol.at
- Schulpsychologie – Bildungsberatung
  www.schulpsychologie.tsn.at
- Tiroler Kinderschutz
  www.kinderschutz-tirol.at
- Mannsbilder – Männerberatung
  www.mannsbilder.at
- EVITA – Mädchen & Frauenberatungsstelle
  www.evita-frauenberatung.at
- RAINBOWS – für Kinder in stürmischen Zeiten
  www.rainbows.at
- Univ.-Klinik für Psychiatrie und
  Psychosomatik des Kindes– und Jugendalters
- Erziehungsberatung
  https://www.tirol.gv.at/gesellschaft-soziales/erziehungsberatung/
- Jugendwohlfahrt
  http://www.tirol.gv.at/themen/gesellschaft-und-soziales/jugend/

Inhaltliche Schwerpunkte der präventiven und gesundheitsfördernden Maßnahmen:

- Gatekeeper Training (QPR): Dem Lehr- und Schulpersonal wurden Kenntnisse und Fertigkeiten vermittelt, die dazu befähigen, gefährdete Schüler/innen zu identifizieren und an professionelle Helfer/innen weiter zu verweisen.
  (Paul Quinnett, 1995)

- Selbstwahrnehmung (Awareness): An drei Terminen wurden Schüler/innen für die Wahrnehmung von Risikoverhaltensweisen sensibilisiert. Weiterhin wurden Wege zur Risikovermeidung aufgezeigt.
  (Columbia University and Karolinska Institute/National Centre for Suicide Research and Prevention of Mental Ill-Health - NASP)

- Screening und Beratung (ProfScreen): Schüler/innen, die in der Eingangsuntersuchung besondere Risiken oder selbstschädigendes Verhalten berichteten, wurden zu einem Beratungstermin eingeladen.

- Posteraktion (Control): Im Klassenraum der Schüler/innen wurden Aufklärungsplakate über riskante und selbstschädigende Verhaltensweisen mit Kontaktadressen professioneller Anlaufstellen ausgehängt.

Alle teilnehmenden Schüler/innen haben im Anschluss an die erste Fragebogenuntersuchung an einem der vier verschiedenen Präventionsprogramme teilgenommen. Die Zuteilung zu diesen Programmen erfolgte immer für eine ganze Schule und nach dem Zufallsprinzip. Somit hat jede Schülerin/jeder Schüler an einer präventiven und gesundheitsfördernden Maßnahme teilgenommen.

Frage 15:
Nach den meinem Ressort vorliegenden Informationen kann SEYLA (SEYLA - Saving and Empowering Young Lives in Austria) als Folgeprojekt gesehen werden, ein Schulprojekt zur Erfassung von psychischem Wohlbefinden und Risikofaktoren für selbstschädigendes Verhalten bei Jugendlichen in Österreich, das ebenfalls unter der Projektleitung von Univ.-Prof. Dr. Christian Haring durchgeführt werden soll.

Im Rahmen dieses Projektes sollen Jugendliche aus vier Bundesländern (Wien, Oberösterreich, Steiermark und Tirol) bezüglich psychischer Faktoren und Verhaltensweisen befragt werden, die zu selbstschädigendem Verhalten führen können. Es geht darum, die im SEYLE Projekt gewonnenen Erkenntnisse im Hinblick auf ihre Gültigkeit für Gesamtösterreich zu überprüfen. Die daraus resultierenden Ergebnisse zum psychischen Wohlbefinden österreichischer Jugendlicher sollen wichtige Erkenntnisse ergeben, um zukünftige effektive Präventionsmaßnahmen optimal planen, gestalten und umsetzen zu können.

Fragen 16a), b), d) und e):
Meinem Ressort liegen keine diesbezüglichen Informationen vor.

Frage 16c):
Im Rahmen der WHO-Studie „Health Behaviour in School-aged Children", die im Auftrag des Bundesministeriums für Gesundheit vom Ludwig Boltzmann Institute Health Promotion Research (LBIHPR) durchgeführt wird, werden u.a. auch Daten zum Gesundheits- und Risikoverhalten, wie z.B. Suchtmittelkonsum, Gewalt, Bewegung und sitzendes Freizeitverhalten von 11-, 13-, 15- und 17-jährigen Schülerinnen und Schülern erhoben. Diese Daten stellen eine wichtige Basis für Strategien zur Gesundheitsförderung von Kindern und Jugendlichen dar.

Die Prävention von Risikofaktoren und die Förderung von Schutzfaktoren für die Gesundheit sind wesentliche Ziele der österreichischen Kinder- und Jugendgesundheitsstrategie.

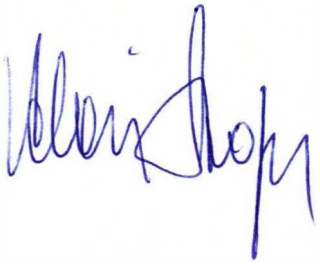
Die 2012 beschlossenen Rahmen-Gesundheitsziele für Österreich (R-GZ) sollen zur Verbesserung der Gesundheit aller in Österreich lebenden Menschen, unabhängig von Bildungsstatus, Einkommenssituation oder Lebensumständen beitragen. Es geht dabei darum, die Gesundheit der Menschen zu erhalten und nicht erst auf das Kranksein zu reagieren. Determinantenorientierung, Health in All Policies-Ansatz, Förderung der Chancengleichheit und Ressourcenorientierung sind wichtige Grundprinzipien der R-GZ. Insbesondere das R-GZ 6 soll das gesunde Aufwachsen für alle Kinder und Jugendlichen bestmöglich gestalten und unterstützen. Im Rahmen einer intersektoriell besetzten Arbeitsgruppe konnten zu diesem R-GZ bereits konkrete Umsetzungsmaßnahmen erarbeitet werden.

Im Rahmen des R-GZ 9 „Psychosoziale Gesundheit bei allen Bevölkerungsgruppen fördern" soll besonderes Augenmerk auf die Stärkung der Lebenskompetenzen und auf Maßnahmen zur Gewalt- und Suchtprävention gelegt werden. Das Wissen und die Sensibilität in Bezug auf psychische Erkrankungen soll erhöht werden, mit dem Ziel einer umfassenden Entstigmatisierung.

Im Rahmen der Initiative GIVE - Servicestelle für Gesundheitsbildung www.give.or.at wird Lehrkräften, Schulärzt/inn/en, Mitarbeiter/inne/n von Bildungs- und Gesundheitseinrichtungen Information und Beratung in Fragen der Gesundheitsförderung bereitgestellt. Als gemeinsame Initiative des Bundesministeriums für Bildung und Frauen, des Bundesministeriums für Gesundheit und des Österreichischen Jugendrotkreuzes bietet die bundesweite Servicestelle Materialien, Auskunft über „good practice"-Beispiele, Initiativen und Maßnahmen und regionale Angebote zur Gesundheitsförderung an Schulen und unterstützt so die Planung und Umsetzung von gesundheitsfördernden Projekten und Aktivitäten. Insbesondere werden auch Informationsmaterialien zu den Themen Lebenskompetenzen, Suchtvorbeugung in der Schule, Selbstwert und Umgang mit Gefühlen, Kommunikation und Konfliktkultur oder weniger Stress in der Schule angeboten.

Die Homepage „Gesunde Schule" www.gesundeschule.at, eine Initiative des Bundesministeriums für Bildung und Frauen, des Bundesministeriums für Gesundheit und des Hauptverbandes der österreichischen Sozialversicherungsträger versteht sich als Anlaufstelle für alle interessierten Akteurinnen und Akteure im Lebensraum Schule. Sie bietet Information zu den Angeboten und Aktivitäten der drei Partner und stellt nützliche Information zum Thema Gesundheit und Schule zur Verfügung.

Auch der Fonds Gesundes Österreich (FGÖ) widmet eines seiner Handlungsfelder Kindern und Jugendlichen und fördert u.a. gesundheitsfördernde Projekte im Bereich der frühkindlichen und schulischen Bildung sowie im außerschulischen Bereich.



Beilage

Parl. Anfrage 529/J

BEILAGE 1

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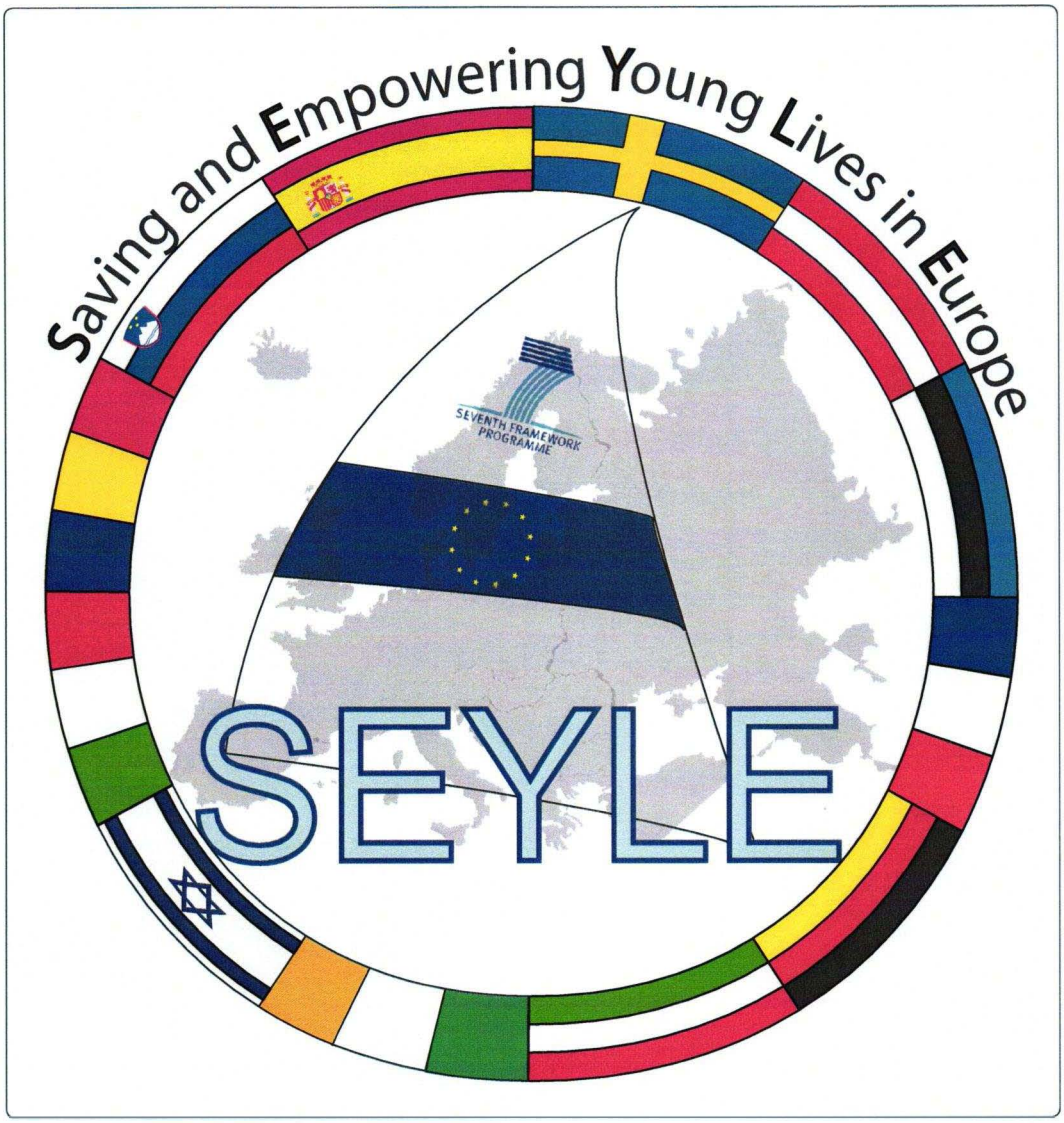

The Saving and Empowering Young Lives in Europe (SEYLE) Randomized Controlled Trial (RCT): methodological issues and participant characteristics

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http://www.biomedcentral.com/1471-2458/13/479

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BMC Public Health

RESEARCH ARTICLE Open Access

The Saving and Empowering Young Lives in Europe (SEYLE) Randomized Controlled Trial (RCT): methodological issues and participant characteristics

Vladimir Carli[1,2*], Camilla Wasserman[3,4], Danuta Wasserman[1,2], Marco Sarchiapone[4], Alan Apter[5], Judit Balazs[6,7], Julio Bobes[8], Romuald Brunner[9,10], Paul Corcoran[11], Doina Cosman[12], Francis Guillemin[13], Christian Haring[14], Michael Kaess[9,10], Jean Pierre Kahn[15], Helen Keeley[11], Agnes Keresztény[7,16], Miriam Iosue[4], Ursa Mars[17], George Musa[3], Bogdan Nemes[12], Vita Postuvan[17], Stella Reiter-Theil[18,19], Pilar Saiz[8], Peeter Varnik[20], Airi Varnik[21] and Christina W Hoven[3,21]

Abstract

Background: Mental health problems and risk behaviours among young people are of great public health concern. Consequently, within the VII Framework Programme, the European Commission funded the Saving and Empowering Young Lives in Europe (SEYLE) project. This Randomized Controlled Trial (RCT) was conducted in eleven European countries, with Sweden as the coordinating centre, and was designed to identify an effective way to promote mental health and reduce suicidality and risk taking behaviours among adolescents.

Objective: To describe the methodological and field procedures in the SEYLE RCT among adolescents, as well as to present the main characteristics of the recruited sample.

Methods: Analyses were conducted to determine: 1) representativeness of study sites compared to respective national data; 2) response rate of schools and pupils, drop-out rates from baseline to 3 and 12 month follow-up, 3) comparability of samples among the four Intervention Arms; 4) properties of the standard scales employed: Beck Depression Inventory, Second Edition (BDI-II), Zung Self-Rating Anxiety Scale (Z-SAS), Strengths and Difficulties Questionnaire (SDQ), World Health Organization Well-Being Scale (WHO-5).

Results: Participants at baseline comprised 12,395 adolescents (M/F: 5,529/6,799; mean age=14.9±0.9) from Austria, Estonia, France, Germany, Hungary, Ireland, Israel, Italy, Romania, Slovenia and Spain. At the 3 and 12 months follow up, participation rates were 87.3% and 79.4%, respectively. Demographic characteristics of participating sites were found to be reasonably representative of their respective national population. Overall response rate of schools was 67.8%. All scales utilised in the study had good to very good internal reliability, as measured by Cronbach's alpha (BDI-II: 0.864; Z-SAS: 0.805; SDQ: 0.740; WHO-5: 0.799).

(Continued on next page)

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(Continued from previous page)

Conclusions: SEYLE achieved its objective of recruiting a large representative sample of adolescents within participating European countries. Analysis of SEYLE data will shed light on the effectiveness of important interventions aimed at improving adolescent mental health and well-being, reducing risk-taking and self-destructive behaviour and preventing suicidality.

Trial registration: US National Institute of Health (NIH) clinical trial registry (NCT00906620) and the German Clinical Trials Register (DRKS00000214).

Keywords: SEYLE, Mental Health Promotion, Suicide prevention, Promotion, Well-being, Adolescents, Schools, RCT, Intervention, ProfScreen, QPR, Awareness

Background

In the transition from childhood to adulthood adolescents make lifestyle choices and initiate patterns of behaviour that affect both their current and future well-being and health [1-6]. Many adverse health behaviours emerge in adolescence and track into adulthood, with increasing consequences for negative and sometimes long-lasting outcomes. Given the importance of this transitional period, it is essential to systematically assess the mental health and well-being of adolescents and young adults, and to implement and evaluate interventions for at-risk individuals. Several large studies have been carried out, mostly in the US, to gather information on both healthy and risk behaviours as well as psychiatric symptoms, based on robust methodologies [7-11]. Other studies analysed the effects of interventions to promote mental health and prevent suicide among adolescents [12-14].

However, to the best of our knowledge, no previous study compared the effectiveness of interventions based on different approaches with a Randomized Controlled Trial (RCT). The Saving and Empowering Young Lives in Europe (SEYLE) project was designed with this in mind.

SEYLE, supported by the European Union Seventh Framework Program (FP7), (Grant agreement number HEALTH-F2-2009-22309), is an RCT to evaluate school-based preventive interventions of risk-taking and self-destructive behaviours in eleven European countries, including: Austria, Estonia, France, Germany, Hungary, Ireland, Israel,[a] Italy, Romania, Slovenia and Spain, with the National Centre for Suicide Research and Prevention of Mental Ill-Health (NASP) at Karolinska Institutet (KI) in Sweden responsible for the scientific coordination of the project. The Child Psychiatric Epidemiology Group at Columbia University and New York State Psychiatric Institute served as methodological experts. SEYLE is registered in both the US National Institute of Health (NIH) clinical trial registry (NCT00906620) and the German Clinical Trials Register (DRKS00000214). The full protocol of the study has been previously published [15]. The key objectives of the study were: (i) to collect assessment data on a cohort of European adolescents, including demographic information, psychopathology, lifestyles, values and risk-behaviours, in order to produce an epidemiological database on the general health status of European adolescents; (ii) to evaluate three types of school-based interventions in comparison to a minimal intervention control group. The three active interventions included (1) teacher training, (2) increasing adolescents' awareness about mental health, and (3) professional screening of adolescents for mental health problems and risk behaviours. Teachers were trained through the gatekeeper program: Question, Persuade and Refer, developed in the US by the QPR Institute [16]. Pupils were trained through a standardized awareness-increasing program [15,17] designed to promote knowledge of mental health, healthy lifestyles and behaviours among adolescents. A professional screening program performed by psychiatrists and psychologists was specifically designed for the SEYLE study. All pupils were screened with a questionnaire and, if responses exceeded a predetermined cut-off score for depression, anxiety, phobia, alcoholism, substance abuse, non-suicidal self-injury (NSSI) or suicidality, pupils were interviewed and then referred for professional treatment if necessary. More details about the SEYLE interventions have been previously published [15].

The objectives of this article are to describe: 1) the study sites; 2) the main methodological issues employed; 3) the characteristics of the recruited sample including its representativeness; and 4) the internal reliability of the psychometric scales utilized for evaluation of the outcomes of the RCT: the Zung Self-Rating Anxiety Scale (Z-SAS, [18]), the Beck Depression Inventory, Second Edition (BDI-II, [19]), the World Health Organization Well-Being Scale (WHO-5 [20], and the Strengths and Difficulties Questionnaire (SDQ, [21].

Methods

Study sites

SEYLE had one study site in each of the eleven European countries described above. At each site at least one study catchment area, reasonably consistent with an administratively established geographic area was selected.

The selected catchment areas in each country are described in Table 1. To meaningfully interpret the potential representativeness, key parameters, such as mean age, number of immigrants, population density, net income and gender proportion for each site were compared to the corresponding national data. Data at the national and local levels were extracted from Eurostat [22] and collected for each participant site. Effect sizes of mean age and number of immigrants at the country and study site levels were calculated for each country according to Cohen's d, measured as small (d=0.3), medium (d=0.5) and large (d=0.8). Differences in gender distribution among 15-year olds at the country and study site levels were evaluated with a test of proportions. Population density and net income were compared between each country's national data and the respective study site.

School and participant selection

At each site, eligible schools were randomly selected to participate in SEYLE. A list containing all available schools was generated at each site, and the schools were categorized as large or small and randomized into one of the four study arms for possible inclusion according to a randomized order. Simple randomization was used as a method of randomization of schools through a random number generator. Schools were categorized as small if they had less than or equal to the median number of students in all schools in the study area/region; and large if they had greater than the median number of students in all schools in the study area/region. Schools were considered eligible if they were public, contained at least forty 15-year-old pupils, had more than two teachers for pupils 15 years of age and no more than 60% of the pupils were of the same gender. These inclusion criteria were selected to allow for the recruitment of a comparable sample of schools and pupils across study sites, in spite of differences in sociocultural factors and in the organization of the educational system. However, a few exceptions were made in the case of sociocultural particularities of a specific country's education system and applying the exact same criteria would increase selection bias instead of reducing it across sites. In particular in Ireland, single gender schools were allowed to participate in pairs with a single gender school of the opposite sex and of similar size. In Germany, due to the unique design of the school system, a sample of schools in the three categories of German high schools were selected and randomized separately. National and/or regional school authorities were contacted and informed about the project in general terms in order to get approval, which was obtained in all participating countries. The representatives of SEYLE at each study site then met with the school principals in the respective areas to describe the intervention of the Arm to which their school had been randomized and to explain the general objectives and procedures of that Arm. Each school was selected to participate in one Arm only and no information was disclosed about the interventions to be performed in other Arms of the RCT. On the basis of general information about SEYLE objectives and specific information about the specific intervention Arm into which the school was randomized, the school could accept or refuse to join. When a school refused to participate, the next school randomized in the same category was approached to replace it. It is important to note that schools were replaced only with other schools that were already in the randomization list. This procedure was designed to generate a balanced number of large and small schools in each intervention Arm, to minimize bias and increase the validity of the results.

Table 1 Demographics of SEYLE study sites, according to Eurostat[1-2]

Country	Study site	Population	Mean age[3]	% females	Pop. density	Income (net,EURO per year) [4]	Eurostat area
Austria	Tirol	704,472	39.9	51.1	56.1	22,192	Tirol
Estonia	Tallinn	524,938	-	54.0	122	7,905	Põhja-Eesti
France	Lorraine	2,348,384	40.3	51.2	99.7	19,182	Lorraine
Germany	Heidelberg	10,749,506	41.8	50.8	300.7	24,719	Baden-Württemberg
Hungary	Budapest	2,925,500	40.7	53.3	179.4	8,735	Közép-Magyarország
Ireland	Cork and Kerry	648,700	-	50.7	53.5	-	Ireland South West
Italy	Region Molise	320,795	44.0	51.4	73.4	14,315	Molise
Romania	Cluj and Maramures counties	2,721,468	38.7	51.3	77.8	2,755	Romania Nord-Vest
Slovenia	Osrednjeslovenska, Podravska and Obalno-kraška region	965,200	-	50.8	155.4	9,889	Podravska, Osrednjeslovenska and Obalno-kraska
Spain	Oviedo, Gijon and Aviles	1,058,923	45.3	52.2	101.9	14,767	Principado de Asturias

[1]Eurostat. Statistics database. European Union; 2010. Available from: http://epp.eurostat.ec.europa.eu/portal/page/portal/eurostat/home/.
[2]Data from Israel is not included as the study site was the whole country.
[3]Not available for study sites in Estonia, Ireland and Slovenia.
[4]Not available for study site in Ireland.

Within each school, all classes with a majority of 15 year olds were approached for participant recruitment, with a minimum of two schools per Arm. This procedure was repeated until a minimum of 250 students were recruited in a each Arm. Prior to requesting consent from the parents and assent from the pupils, general information about the SEYLE study and details about the specific Arm they were invited to participate in, was provided. Not all pupils for whom parental consent and adolescent assent were obtained actually participated, as some students were absent from school on the day the questionnaire was administered. Consent rates were calculated as the percentage of approached pupils for whom parental consent and pupil's assent were both given. Participation rates were calculated as the percentage of assented pupils with parental consent who actually took part in the baseline questionnaire. In order to evaluate the impact of the consent rates of schools and pupils on the external validity of the collected data; school size, in terms of number of attending pupils, was compared between participating and non-participating schools. Moreover, gender proportion of pupils with and without consent were compared. Drop-out rates were calculated as the number of pupils assessed at baseline who did not participate at the first (3-months) and/or second (12-months) follow-up. Sociodemographic variables obtained at baseline and average scores on the scales employed, were used to evaluate differences between Arms.

Instruments and interventions

A full description of assessment instruments and interventions was previously published [15].

Standardization of methodology

Each SEYLE site used the same methodology in an effort to obtain comparable study results. Homogenous methodology was achieved through two different means. First, a detailed procedures manual (328 pages) was developed, containing information regarding every aspect of the study implementation, including school selection, recruitment, randomization, clinical backup, ethical issues, translation procedures and methods of cultural adaptation, detailed descriptions of each intervention and intervention time-lines, as well as the baseline and follow-up questionnaires. Second, uniform training procedures were conducted. All site leaders were initially trained centrally, in Stockholm. Site leaders then conducted local training for their own teams that included a minimum of 27 hours of group work, with at least 4 hours devoted to each intervention. To ensure study fidelity to the methodology, a series of monitoring site visits were carried out by representatives of the coordinating centre (NASP), together with the two consultants from Columbia University visiting each site. The site visits took place to overlap with training by site leaders and consisted of two-day consultations with local staff involved in the SEYLE project. Present at the site visit were the Intervention Arm coordinators, as well as the site leader (Table 2). During the site visit, local staff were required to present their understanding of the study and its procedures, as described in the manual, as well as the requirements of conducting each of the interventions. Site visits also provided an opportunity to correct any misunderstandings and to provide additional training, if necessary, to assure adherence to the protocol.

Cross-site collaboration was an important study objective and was facilitated prior to data collection, throughout implementation and up until study completion. For example, most sites assumed primary responsibility for one major study requirement, called a Work Package (e.g., translations, cultural adaptation, quality control, ethical requirements, data management, etc.) and collaborated with each of the other sites concerning this specific topic. Some of the major collaborative efforts are described below.

Quality control procedures

As part of the SEYLE project, a method for quality control was developed and implemented. A series of questionnaires were sent to intervention coordinators in each country in order to ensure that all preparatory procedures were correctly conducted and that the interventions implemented at each site were faithful to the initial intervention models of SEYLE.

Analysis of these data allowed for assessment of the degree of discrepancy between different sites and between implementation in each site compared with the SEYLE model, as well as the effect variations had on the projects overall results and conclusions. Three quality control assessment tools were used - I. A questionnaire administered during site visits to assess the preparedness for intervention implementation; II. A pre-intervention questionnaire focused on questionnaire coding and on specific requirements to be carried out prior to and immediately after the intervention, and; III. A post-intervention questionnaire focused on the implementation of each intervention. Analyses of these questionnaires showed very small differences between the sites in the implementation process and did not identify any major modification in the implementation of the interventions in any site.

Translation and cultural adaptation

The Hungarian site coordinated the translation processes in collaboration with the site-specific translation coordinators and the coordinating centre in Sweden

Table 2 SEYLE study key personnel

Executive committee		
Coordinator and Project Leader	Danuta Wasserman	National Centre for Suicide Research and Prevention of Mental Ill-Health (NASP) at Karolinska Institutet (KI), Stockholm, Sweden
Deputy Coordinator	Marco Sarchiapone	Department of Health Sciences, University of Molise, Campobasso, Italy
Project Manager and Assistant Project Leader	Vladimir Carli	National Centre for Suicide Research and Prevention of Mental Ill-Health (NASP) at Karolinska Institutet (KI), Stockholm, Sweden
Consultants for Methodology	Christina Hoven	Department of Child and Adolescent Psychiatry, Columbia University-New York State Psychiatric Institute, New York, US
	Camilla Wasserman	
Intervention arm coordinators		
QPR	Vladimir Carli	National Centre for Suicide Research and Prevention of Mental Ill-Health (NASP) at Karolinska Institutet (KI), Stockholm, Sweden
ProfScreen	Romuald Brunner / Michael Kaess	Clinic of Child and Adolescent Psychiatry, Centre of Psychosocial Medicine, University of Heidelberg, Heidelberg, Germany
Awareness	Camilla Wasserman	Department of Child and Adolescent Psychiatry, Columbia University-New York State Psychiatric Institute, New York, US
Minimal Intervention/ Control	Marco Sarchiapone	Department of Health Sciences, University of Molise, Campobasso, Italy

Study sites

Country	Site leader	Site coordinator	Arm coordinators			Translation coordinator	Workpackage leadership
			QPR	*ProfScreen*	*Awareness*		
Austria	C. Haring	P. Olesky	C. Pajek	P. Olesky	C. Haring	-	-
Estonia	A. Värnik	R. Soonets	M. Sisask	L. Heidmets	R. Soonets	K. Valling	P.Varnik (Data management)
France	JP. Kahn	F. Guillemin	A. Tubiana	H. Vann	B. Bucki	JP Kahn	-
Germany	R. Brunner	M. Kaess	N. Schönbach	M. Kaess	K. Klug	M. Kaess	R. Brunner (Intervention Coordinator)
Hungary	J. Balazs	J. Balazs	M. Balint	G. Meszaros	L. Farkas	J. Balazs	J. Balazs (Translation procedures)
Ireland	P. Corcoran	H. Keeley	C. McAuliffe	F. Elahi/ P. Cotter	J. McCarthy	H. Keeley	L-A. Burke (Analysis of cost-effectiveness)
Israel	A. Apter	D. Feldman	C. Burzstein	S. Hen-Gal	Y. Apter	Y. Apter	D. Feldman (Quality control)
Italy	M. Sarchiapone	G. Nicolais	V. Carli	F. Basilico	M. Iosue	M. Sarchiapone	M. Iosue (Dissemination)
Romania	D. Cozman	B. Nemes	O. Dobrescu	B. Nemes	D. Herta	B. Nemes	D. Cozman (Materials for Schools)
Slovenia	V. Postuvan	V. Postuvan	U. Mars	T. Podlogar/ V. Košir	V. Postuvan/ J. Žiberna	V. Postuvan	-
Spain	J. Bobes	P. Saiz	E. Diaz-Mesa	M. Garrido	S. Al-Halabi	P. Saiz	P. Saiz (Cultural adaptation)
Sweden	D. Wasserman	V. Carli	-	-	-	-	D. Wasserman (Project coordination and data analysis)

Table 2 SEYLE study key personnel *(Continued)*

Administrative assistants	
Tony Durkee	National Center for Suicide Research and Prevention of Mental Ill-Health (NASP) at Karolinska Institutet (KI)
Brigit Frisen-Andersson	
Pierre Bodin	
Anna Lundgren	
External Ethical Advisor	
Stella Reither-Theil	University Hospital Basel, Psychiatric Clinics of the University of Basel, IBMB, University of Basel, Switzerland

(NASP). Translation coordinators oversaw site-specific translations, back translations and pilot interviews of all SEYLE materials. All materials were forward and back translated in each participating language. German was used in both Germany and Austria but was translated by the German site. All SEYLE materials (instruments & intervention Arm packages) were developed originally in English and then translated into the following languages: Gaelic (Irish), German, Estonian, French, Hebrew, Hungarian, Italian, Romanian, Slovenian and Spanish. In order to confirm the quality of the translations, staff from each site reviewed all back translations, evaluated reports on the respective pilot interviews and provided feedback to the Hungarian site. The site translation coordinators also implemented cultural adaptation: primarily concerning local linguistic phenomena and expressions. Focus groups were then conducted at each site to provide feedback on the cultural adaptation resulting from the pilot testing. In the case of ambiguity, consultation with a cultural linguistic advisor was sought. Based on these procedures, culturally adjusted language replaced the original in the final versions. A report concerning language issues, including possible ambiguity was sent to the coordinating centre for resolution, when necessary.

The scales used in the SEYLE questionnaires were included in the officially translated and validated version, when available, in the respective language, e.g., the SDQ [21], the WHO-5 etc. [15]. If the scale was not available in the required language it was translated (and back-translated) for SEYLE, using the same procedure as for the other study materials. Internal reliability for all scales used in SEYLE was assessed through Cronbach's alpha [23].

Data entry and data quality control

Data were collected on paper questionnaires, with the exception of the Austrian site, where data were collected electronically for direct data entry. In Germany, data collection forms were scanned for automatic data entry while in the other nine countries manual independent double data entry procedures were followed. In those countries information was entered twice using the Statistical Software Package SPSS 17.0. The Estonian site, which was responsible for the data management procedures, provided continuous oversight to other centers and promptly responded to any queries arising during the data entry process. A two-stage data cleaning and quality control procedure was performed to guarantee clean and reliable data. The first stage of quality control was performed locally, based on the two data files generated through double data entry. These files were compared and inconsistencies were resolved by checking the paper material. Based on this corrective action an accurate data file was generated. The second stage of quality control was performed centrally at the Estonian site, by double-checking each local dataset, attempting to detect other errors, such as incompleteness (missing values), inconsistencies (incorrectly followed skip-outs), irregularities (numbers inserted in text variables), and out of range data (i.e. very large number of siblings or sexual partners). The results of these control procedures generated a list of queries that was sent for resolution to the specific site. After finalizing quality control procedures, the Estonian site pooled the data into one database for all respondents for each wave (i.e., baseline, 3-month and 12-month follow-up). Pooled databases for each wave were then merged into one longitudinal pooled database.

Ethics and emergency issues

Ethical issues were discussed with an independent ethical advisor from Basel University in Switzerland. Each site obtained permission from the local ethics committee to implement the SEYLE study in their respective country. According to guidelines from the local ethics committees, after thorough examination of the SEYLE study objectives and procedures, decisions were made locally to obtain consent through an opt-in method (parents had to sign a consent form if they allowed their child to participate) or an opt-out method (parents had to sign a refusal form if they did not want their child to participate). Study subjects were then recruited into the study accordingly, after obtaining the required informed consents from parents and assent from pupils [24].

A specific procedure to identify and immediately assist emergency cases with acute suicidality was implemented at each site in all four Arms. A minimum set of requirements regarding the identification of emergency cases was followed by each center. However each centre had the opportunity to reinforce the ethical requirements, according to the indications of the local Ethics Committee. Emergency cases were identified through responses to two specific questions in the questionnaire: those who reported moderate or severe suicidal ideation in the previous two weeks, or those who reported attempting suicide in the previous two weeks. Subjects identified as emergency cases were followed-up by local SEYLE personnel until successful referral to the local healthcare system. However, since it was not possible to follow up individuals while in treatment due to confidentiality, it is not known if the clinical intervention had impact on the collected data. However, all emergency cases were allowed to participate in the active interventions and in the control arm. Therefore, these pupils are included in the total data set.

Subsequent to conducting SEYLE, an interdisciplinary workshop[b] was held in the Psychiatric Clinics of the University Basel, to analyse ethical issues, especially confidentiality towards minors involved in SEYLE Study.

Additionally, relevant codes and guidelines for guidance in mental health research with minors were analysed. While unresolved questions may remain, such as whether and when confidentiality might or should be overridden in cases of emergency [25], within the SEYLE study, all problems of confidentiality were determined to have been handled according to the indications of the local ethical committees and the local laws and regulations of the participating countries.

Results

Consent, participation and drop-out rates

Response rates for SEYLE are reported in terms of consent and participation rates for schools and pupils.

Schools

If a school refused to participate, no pupil in that school was approached. The school randomization with replacement methodology, however, required refusal schools to be replaced by the next school of the same size on the school randomization list. Response rates for SEYLE schools, by country, are reported in Table 3. A total of 264 schools were approached for participation. Of these, 179 schools accepted, with an overall response rate of 67.8%. However, the school response rate was 72.0% when Israel, the only study site to have a low response rate (37.5%), was excluded. School size, measured by the total number of students in the school, of participating and non-participating schools did not differ in any country, with the exception of Slovenia, where participating schools were smaller than non-participating schools.

Table 3 SEYLE study school response rates, including number randomized, approached and participated, by country

Country	Randomized schools	Approached schools	Accepted to participate	Response rate*
Austria	22	22	15	68.2%
Estonia	23	23	19	82.6%
France	25	25	20	80.0%
Germany	100	41	26	63.4%
Hungary	23	19	15	78.9%
Ireland	24	24	17	70.8%
Israel	32	32	12	37.5%
Italy	18	18	14	77.8%
Romania	27	19	16	84.2%
Slovenia	32	20	13	65.0%
Spain	23	21	12	57.1%
Total	**349**	**264**	**179**	**67.8%**

* percentage of approached schools that accepted to participate in the SEYLE study.

Pupils

Rates of pupils' consent have been calculated for the eight countries (Estonia, Germany, Hungary, Ireland, Israel, Italy, Romania and Spain) that used similar ethical procedures in collecting pupils consent. The overall rate of consent in these eight countries was 76% (10,665 pupils with consent out of 14,086 approached). In the other three countries (Austria, France and Slovenia), extended procedures for collection of the informed consent were imposed by the local ethics committees (i.e., multiple forms to be signed; pupil could be enrolled only if both parents signed the form, etc.). This resulted in a consent rate of 23% (3,452 pupils with consent out of 14,803 approached) in these three countries. When combining these three countries with the other eight the overall rate of consent decreased to 49% (14,117 pupils with consent out of 28,889 approached). Of the total 14,117 pupils whose parents gave consent, 12,395 participated in SEYLE, yielding a participation rate of 87.8%. Gender proportion of consented and non-consented pupils did not significantly differ in any country with the exception of France and Slovenia, where more girls were present among participating pupils. Information regarding gender proportion of non-participating pupils was not available in Ireland and Germany.

Overall, in the 3 months follow-up assessment, 10,823 pupils participated and 9,846 pupils participated at 12 months. The overall 12-month drop-out rate from baseline was 20.6%, including a 12.7% at 3 months. The drop-out rate did not differ significantly between countries and ranged between a minimum of 18.6% in the Control Arm and a maximum of 23.2% in the Awareness Arm. The differences in the socio-demographic and psychopathological characteristics at baseline, between those who participated in all waves of data collection and those who dropped out, did not differ significantly between Arms (Table 4). All schools remained actively involved through the three waves of data collections with no school drop-out. Differences in the socio-demographic and psychopathological characteristics between those who participated in all waves of data collection and those who did drop out did not differ significantly between Arms.

Sample characteristics

Age and gender

The age and gender distribution of the sample, stratified by country, is shown in Table 5. Gender distribution of the 12,395 participating pupils was 6,799 females and 5,529 males (67 with missing gender data); the mean age was 14.91±0.90 (83 with missing age data). The largest sample was recruited in Germany (n=1444). Austria (n=960) was the only country that did not reach the target of 1000 pupils at baseline. Eight study sites

Table 4 Participation in SEYLE according to Intervention Arm, including baseline, 3 and 12 month follow-up and drop out rates, by gender

Intervention arm	Gender	Baseline number (gender %)	3 Month follow-up number (gender %)	3 Month drop-out rate^ (%)	12 Month follow-up n (gender %)	12 Month drop-out rate* (%)
QPR	Males	1323 (43.6)	1158 (43.1)	12.5	1043 (43.3)	21.2
	Females	1694 (55.8)	1515 (56.3)	10.6	1352 (56.1)	20.2
	Both genders	3036	2689	11.4	2410	20.6
Awareness	Males	1351 (44.6)	1106 (43.4)	18.1	979 (42.1)	27.5
	Females	1664 (54.9)	1430 (56.1)	14.1	1333 (57.2)	19.9
	Both genders	3032	2551	15.9	2329	23.2
ProfScreen	Males	1301 (42.4)	1158 (42.1)	11.0	1024 (41.7)	21.3
	Females	1752 (57.1)	1583 (57.5)	9.7	1423 (58.0)	18.8
	Both genders	3070	2752	10.4	2455	20.0
Minimal Intervention	Males	1554 (47.7)	1323 (46.7)	14.9	1239 (46.7)	20.3
	Females	1689 (51.9)	1494 (52.8)	11.6	1403 (52.9)	16.9
	Both genders	3257	2831	13.1	2652	18.6
Total		12395	10823	12.7	9846	20.6

*From baseline.

recruited more females than males (Table 5). A larger number of males were recruited only in Ireland (54.7%), Israel (81.4%) and Spain (51.7%). In an analysis of representativeness, on the basis of Eurostat data [22], very small effect sizes were found concerning variations in the mean age between study sites and the respective country. Cohen's d effect size also remained lower than 0.3 for the total sample when stratifying the analysis by gender. The largest effect size for both genders was found in Spain (d=0.205). For all other countries, the effect size of age was below 0.1. Differences in the proportion of 15-year old males and females and the respective country's data were not statistically significant at any site. Analysis of representativeness was not conducted in Israel as the study site was of the entire country.

Table 5 SEYLE pupil participation by Country, according to mean age and gender

Country	Pupils		Gender			
	N[a]	Mean age (SD)	Male		Female	
			N[b]	%	N[b]	%
Austria	960	15.1 (0.8)	350	36.8	602	63.2
Estonia	1,036	14.2 (0.5)	477	46.0	560	54.0
France	1,000	15.2 (0.8)	319	31.7	688	68.3
Germany	1,444	14.7 (0.8)	692	47.9	752	52.1
Hungary	1,009	15.1 (0.8)	415	41.1	594	58.9
Ireland	1,091	13.7 (0.7)	600	54.7	496	45.3
Israel	1,256	15.9 (0.8)	1,023	81.4	233	18.6
Italy	1,189	15.3 (0.7)	381	32.0	811	68.0
Romania	1,139	15.0 (0.4)	395	34.6	745	65.4
Slovenia	1,165	15.2 (0.7)	347	29.7	823	70.3
Spain	1,023	14.5 (0.7)	530	51.7	496	48.3
Total	12,312	14.9 (0.9)	5,529	44.8	6,799	55.2

[a]83 pupils with missing age data have been excluded.
[b]67 pupils with missing gender data have been excluded.

Population density

Population density at the study sites was higher than in the respective country in Estonia, Germany, Hungary, Ireland and Spain. Population density was lower at the study site in Austria, France, Italy, Romania and Slovenia.

Income

The difference in net income per inhabitant between each country and the respective study site was below 10%, with the exception of Estonia (+17%), Germany (+15%), Hungary (+42%) and Italy (-24%).

Immigrants

The proportion of immigrants in each study site population was not significantly different from the proportion of immigrants in the respective country in all countries with the exception of Italy (-5%), Slovenia (-8%), and Spain (-10%).

Unemployment rates

In no country were unemployment rates at the study site significantly different than in the respective country as a whole.

Therefore, based on these key parameters, the pupils participating in the SEYLE study can be considered reasonably representative of their respective country.

Additionally, the main socio-demographic indicators such as age, gender, belonging to a single parent household, belonging to a religious denomination and parental

unemployment did not significantly differ between Arms.

Internal reliability of psychometric scales

The internal reliability of each scale was assessed separately for each country. The results are reported in Table 6. The internal reliability for the Z-SAS [18], the BDI-II [19], the WHO-5 [20] and the SDQ [21] was high or very high in most countries.

Discussion

A large landmark intervention study, using RCT design, necessitates an article dedicated to the description of methodological issues and their complexity, which requires more space than is usually allowed in the Methods section of an ordinary article in the majority of scientific journals. This paper describes the complex methodological issues in the SEYLE study, which will allow for adequate interpretation of study's results generated over-time, as well as appropriate replication and development of the study in the future.

SEYLE is a multi-site RCT of interventions to promote mental health and prevent risk behaviours and suicide in European schools. Very few RCTs have been conducted on youth mental health and most of them have focused on a single intervention or treatment method on a small sample or at only one site or within only one country, or alternatively with a clinical population [26-35]. SEYLE was designed to evaluate three different active intervention methods that respectively empower students, teachers and professionals, compared to controls, to identify early mental health problems and risk behaviours, while facilitating appropriate referral to the healthcare system. The interventions were performed on a large sample (N=12,395) in eleven sites, located in eleven different European countries. Extensive procedures were implemented in order to guarantee a homogeneous methodology across sites, including high quality forward and back-translations of manuals, instruments, standardized interventions, as well as cultural adaptation for each participating country and expert review of all ethical issues related to the investigation.

Table 6 Cronbach alpha of scales administered in the SEYLE study, by country (n=12,395)

Country	Z-SAS	BDI-II[1]	WHO-5	SDQ
Austria	.826[3]	.871	.752	.876
Estonia	.803[3]	.849[3]	.760[3]	.839[3]
France	.844[3]	.869	.810	.824
Germany	.829[3]	.875	.746	.789
Hungary	.811[3]	.835[3]	.796	.730
Ireland	.821	.872	.804	.848
Israel	.783[3]	.890[3]	.907[3]	.863[2]
Italy	.638[3]	.806	.765	.717
Romania	.811[3]	.864[3]	.748[3]	.806[3]
Slovenia	.855[3]	.867	.734	.716
Spain	.773[3]	.872	.773	.612
Total	**.805**	**.864**	**.799**	**.740**

Z-SAS, Zung Self-Rating Anxiety Scale; *BDI-II*, Beck Depression Inventory, Second Edition; *WHO-5*, World Health Organization Well-Being Scale; *SDQ*, Strengths and Difficulties Questionnaire;
[1]Item 21 of the BDI-II was not administered.
[2]Item 6 not administered in Israel and not included in the assessment of internal reliability.
[3]translated by the SEYLE study.

The SEYLE project achieved the sampling size objective of enrolling at least 1,000 participating pupils at each site (except Austria; n=960), for a total sample of N=12,395 school-based adolescents. Female participants (55.2%) exceeded the number of male participants. It may be hypothesized that girls are more interested and/or collaborative in participating in a study dealing with psychological issues than males, leading to a higher participation. However, in most countries, there were no significant differences between the gender proportion in the school and the gender proportion in our sample.

Analysis of representativeness indicates that the study sites are reasonably representative of their respective countries, thus allowing for in-country and between-country comparisons. The overall response rate of schools was high (67.8%). Only Israel had a low response rate of schools (37.5%). Without Israel, response rate of schools was 72%. It can be hypothesized that the low response rate of schools in Israel was attributed to the nearly uniform attitude of school principals' against using school time for additional non-educational activities, in view of the many such activities already taking place. Israel, along with Cork, Ireland and Oviedo, Spain, were the only sites where a majority of the participating adolescents were male. The Cork study site had the lowest pupil participation rate (64.6%), which can possibly be attributed to factors outside the scope of the study, as an environmental emergency affecting the region (flooding) at the time of the SEYLE study, thus preventing many pupils attending school when the baseline questionnaire was administered. However, overall pupil participation rates in SEYLE were high and thus assure adequate external validity of the collected data.

Drop-out rates at follow-up were low: 20.6% at 12-months, including 12.7% at three months follow-up, indicating broad acceptance of the interventions and questionnaires by both schools and pupils. Drop-out rates did not vary significantly among countries. Importantly, the study methodology required that the school randomization include all eligible schools in the area. This allowed for comparability of study Arms within and across sites. The main demographic indicators at baseline, such as mean age, family structure and parental

unemployment did not differ significantly between the Active interventions and the Control Arm.

Internal reliability of each scale administered in each country also provides reassuring results. Cronbach's alpha values were measured for both instruments translated for the purposes of SEYLE, as well as for instruments already available officially, in the respective languages. As reported in Table 6, Cronbach's alpha values were quite homogenous across countries with very small variations and can be considered good or very good for all administered scales. The lowest internal reliability was reported for the SDQ (alpha=0.740). This result is more than acceptable and in agreement with previous studies [36].

Strengths

The major strength of the SEYLE RCT is its application of a robust and homogenous methodology applied across eleven study sites in eleven different countries, selected to provide a broad geographical representation of Europe. Due to extensive collaboration across sites through Work Packages, that required cross-site cooperation of all participating sites throughout the study, uniform adherence to the study methodology was assured. Moreover, the standardized translation methodology and cultural adaptation allowed for the fine-tuning of interventions to be responsive to local cultural contexts, thus ensuring that the project was meaningful and useful data were collected at each site. Another major strength of the project is the inclusion of a control group and the selection of outcome measures, which are related to mental health and wellness, as well as risk behaviours, thus allowing for the study outcomes to be associated with three distinct interventions. Finally, the SEYLE interventions are able to be tested on a combined, large sample of European adolescents, generating the first such findings from a large-scale RCT of adolescent well-being in Europe, providing an important cohort that can be followed over time.

Limitations

In any large-scale multi-site study using a complex methodology, securing sufficient funding is always an important challenge. In the case of SEYLE, there were two major limitations due to funding: namely, the funding duration precluded a long follow-up after the intervention ended. It would have been of greater value to identify the long-term effects of the SEYLE interventions by having a longer follow-up, as many preventive effects may only be observed after a longer time post-intervention. In fact, a five-year instead of a three-year timetable for SEYLE would probably have allowed for more knowledge to be gained regarding the study's outcomes. In SEYLE, one site per country was chosen for study participation. Sufficient funds to allow the inclusion of more than one site per country would significantly have improved representation of the urban and rural areas and therefore understanding of different populations. Moreover, the analysis of representativeness of the recruited sample in relation to the respective country was limited by the availability of sociodemographic indicators in Eurostat at the local level (NUTS2). It was not possible to directly compare the SEYLE data and the same indicators at the country level because these were not available for the adolescent population or were collected with different methodologies, ultimately being incompatible.

Consent rates of schools and pupils varied across countries. The consent rates of pupils were very good in eight countries and lower in the three countries where extended consent procedures were imposed by the local ethics committees. However, it has been reported that response rates between 30% and 70% are, at most, only weakly associated with bias [37]. Available indicators such as school size did not differ significantly between participating and non-participating schools with the exception of Slovenia, where more small schools participated in the study. The study was necessarily performed during school hours and consequently there was limited opportunity to collect other than questionnaire data regarding pupil's behaviour. This school-based approach necessarily required a very limited number of outcome measures. Another limitation is that all data were collected through self-report questionnaires.

Conclusions

The SEYLE RCT study was successful in recruiting a reasonably representative sample of over 12,000 European school-based adolescents. The study is unique in its' robust and uniform methodology applied across eleven sites, including a large number of sociodemographic, lifestyle and mental health outcomes, allowing for evaluation of the effects of three Intervention Arms compared to a Control Arm. Several important indicators, such as response and participation rates, differences between Arms and reliability of scales show very good validity of the collected data and ensure that the selected outcome measures are reliable and useful for carrying out school-based identification of at-risk adolescents. The SEYLE database contains up-to-date information about lifestyles and mental health problems of European adolescents and will be of great benefit for mental health professionals, policy makers and other stakeholders throughout the European Union.

Endnotes

[a]Israel belongs to the WHO European Region and is eligible to receive funding under the European VII Framework Programme.

[b]Workshop (When) Theory meets Practice – Ethical Issues in Research with Minors and other Vulnerable Groups, 14.2.2012 Research Ethics – Botnar Project.

Competing interests
The authors declare that they have no competing interests.

Authors' contributions
VC wrote most of the manuscript, including critical revision of the manuscript, participated in the design of the project and supervised data analysis. CW wrote several sections of the manuscript, revised it and provided critical input to the study design and the methodology. DW, the project leader and scientific coordinator of the consortium, devised the study design and methodology, and critically revised all the phases of the writing of the manuscript. MS participated in the design of the study and critically revised the manuscript. CH participated in the design of the study, provided consultation for epidemiological issues, advised on research methodology and critically revised the manuscript. AP, JBa, JBo, RB, PC, DC, CH, JPK, VP, AV, MS and DW are the site leaders for the SEYLE project in their respective countries. SRT is the expert ethical advisor for the SEYLE project, providing consultation for the ongoing interventions. The other authors are the site and/or Arm coordinators for the SEYLE center in their respective countries. All the authors critically revised the manuscript before submission.

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The authors were independent of the funders in all aspects of study design, data analysis, and writing of this manuscript. The Project Leader and Coordinator of the SEYLE project is Professor in Psychiatry and Suicidology Danuta Wasserman, Karolinska Institutet (KI), Head of the National Centre for Suicide Research and Prevention of Mental Ill-Health and Suicide (NASP), at KI, Stockholm, Sweden. Other members of the Executive Committee are Professor Marco Sarchiapone, Department of Health Sciences, University of Molise, Campobasso, Italy; Senior Lecturer Vladimir Carli, National Centre for Suicide Research and Prevention of Mental Ill-Health (NASP), Karolinska Institutet, Stockholm, Sweden; Professor of Child and Adolescent Psychiatry Christina Hoven and Anthropologist Camilla Wasserman, Department of Child and Adolescent Psychiatry, New York State Psychiatric Institute and Mailman School of Public Health, Columbia University, New York, USA. The SEYLE Consortium comprises centers in 12 European countries. Site leaders for each respective center and country are: Danuta Wasserman (NASP, Karolinska Institutet, Sweden, Coordinating Centre), Christian Haring (University for Medical Information Technology, Austria), Airi Varnik (Estonian-Swedish Mental Health & Suicidology Institute, Estonia), Jean-Pierre Kahn (University of Nancy, France), Romuald Brunner (University of Heidelberg, Germany), Judit Balazs (Vadaskert Child and Adolescent Psychiatric Hospital, Hungary), Paul Corcoran (National Suicide Research Foundation, Ireland), Alan Apter (Schneider Children's Medical Centre of Israel, Tel-Aviv University, Tel Aviv, Israel), Marco Sarchiapone (University of Molise, Italy), Doina Cosman (Iuliu Hatieganu University of Medicine and Pharmacy, Romania), Vita Postuvan (University of Primorska, Slovenia), Julio Bobes and Pilar Saiz (University of Oviedo, Spain). Dr. Stella Reiter-Theil (Professor in Ethics, Basel University) was the external advisor for ethical issues in the study.

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BEILAGE 2

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Adolescent subthreshold-depression and anxiety: psychopathology, functional impairment and increased suicide risk

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Background: Subthreshold-depression and anxiety have been associated with significant impairments in adults. This study investigates the characteristics of adolescent subthreshold-depression and anxiety with a focus on suicidality, using both categorical and dimensional diagnostic models. **Methods:** Data were drawn from the *Saving and Empowering Young Lives in Europe (SEYLE)* study, comprising 12,395 adolescents from 11 countries. Based on self-report, including Beck Depression Inventory-II (BDI-II), Zung Self-Rating Anxiety Scale (SAS), Strengths and Difficulties Questionnaire (SDQ) and Paykel Suicide Scale (PSS) were administered to students. Based on BDI-II, adolescents were divided into three groups: nondepressed, subthreshold-depressed and depressed; based on the SAS, they were divided into nonanxiety, subthreshold-anxiety and anxiety groups. Analyses of Covariance were conducted on SDQ scores to explore psychopathology of the defined groups. Logistic regression analyses were conducted to explore the relationships between functional impairments, suicidality and subthreshold and full syndromes. **Results:** Thirty-two percent of the adolescents were subthreshold-anxious and 5.8% anxious, 29.2% subthreshold-depressed and 10.5% depressed, with high comorbidity. Mean scores of SDQ of subthreshold-depressed/anxious were significantly higher than the mean scores of the non-depressed/nonanxious groups and significantly lower than those of the depressed/anxious groups. Both subthreshold and threshold-anxiety and depression were related to functional impairment and suicidality. **Conclusions:** Subthreshold-depression and subthreshold-anxiety are associated with an increased burden of disease and suicide risk. These results highlight the importance of early identification of adolescent subthreshold-depression and anxiety to minimize suicide. Incorporating these subthreshold disorders into a diagnosis could provide a bridge between categorical and dimensional diagnostic models. **Keywords:** Categorical diagnostic model, dimensional diagnostic model, subthreshold-depression, subthreshold-anxiety, adolescent, suicide, SEYLE.

Introduction

There is mounting criticism of the current classification systems (Diagnostic and Statistical Manual of Mental Disorders Text Revised (DSM-IV-TR) (American Psychiatric Association, 2000) and International Classification of Mental and Behavioral Disorders (ICD-10) (World Health Organization, 1992), with increasing evidence for the advantages and disadvantages of both categorical and dimensional approaches (Lecrubier, 2008; Möller, 2008; Okasha, 2009). Individuals requiring psychiatric intervention may not receive a standard diagnosis based on the

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DSM-IV-TR or ICD-10 due to an insufficient number or duration of symptoms (Johnson, Weissman, & Klerman, 1992). Patients with substantial functional impairment who do not meet diagnostic criteria are regarded as having subthreshold disorders (Judd, Rapaport, Paulus, & Brown, 1994). Helmchen and Linden (2000) suggest that subthreshold diagnoses are not solely artefacts from potentially outdated definitions, but rather unique conditions demanding recognition. It has been suggested that implementing a hybrid of categorical and dimensional approaches in DSM-V would be useful, as both are important for clinical work and research (Okasha, 2009).

A large number of studies have focused on child and adolescent subthreshold-depression (Fergusson, Horwood, Ridder, & Beautrais, 2005; Foley, Goldston, Costello, & Angold, 2006; Keenan et al., 2008; Klein, Shankman, Lewinsohn, & Seeley, 2009; Lewinsohn, Solomon, Seeley, & Zeiss, 2000), showing that subthreshold-depression increases the risk of developing a major depressive episode (MDE) (Pine, Cohen, Cohen, & Brook, 1999; Shankman et al., 2009). Although the high comorbidity of anxiety [specifically generalized anxiety disorder (GAD)] and MDE are well described (Kessler, Chiu, Demler, Merikangas, & Walters, 2005; Unick, Snowden, & Hastings, 2009; Wittchen, Zhao, Kessler, & Eaton, 1994), there are still few studies on subthreshold-GAD among children/adolescents (Foley et al., 2006; Guberman & Manassis, 2011; Nauta et al., 2012).

Epidemiological data on child/adolescent subthreshold-depression vary, with 12-month prevalence ranging from 3% to 12%, and lifetime prevalence through late adolescence as high as 26% (Fergusson et al., 2005; Wittchen, Nelson, & Lachner, 1998). To our knowledge, no study has examined the prevalence of subthreshold-GAD among youth, whereas among adults, the 12-month prevalence was found to be 3.6–15.7% (Carter, Wittchen, Pfister, & Kessler, 2001; Rucci et al., 2003).

This variability in epidemiological data may be explained, in part, by different definitions and diagnostic methodologies. Some studies used standardized clinical interviews to screen for subthreshold-depression and subthreshold-GAD (Carter et al., 2001; Fergusson et al., 2005; Foley et al., 2006; Guberman & Manassis, 2011; Keenan et al., 2008; Rucci et al., 2003; Shankman et al., 2009), others used self-report (Lewinsohn et al., 2000) or both (Nauta et al., 2012).

Broad and narrow definitions of child/adolescent subthreshold-depression and subthreshold-GAD exist with respect to both the number and the duration of symptoms and additional criteria (e.g. presence of distress), but there is no accepted definitions of these conditions (Angst, Merikangas, & Preisig, 1997; Fergusson et al., 2005; Foley et al., 2006; Karsten, Nolen, Penninx, & Hartman, 2011; Keenan et al., 2008; Kertz & Woodruff-Borden, 2011; Klein et al., 2009; Rucci et al., 2003; Shankman et al., 2009).

Psychiatric disorders, especially MDE, are major risk factors for suicidal behaviour (Gould et al., 1998). Comorbidity, mainly anxiety disorders, increases the risk of suicidal behaviour among adolescents (Wunderlich, Bronisch, & Wittchen, 1998). Balázs, Bitter, Lecrubier, Csiszér, and Ostorharics (2000) found that almost two thirds of adult suicide attempters had MDE, half had GAD, one tenth had subthreshold-depressive episode and one fifth had subthreshold-GAD. Only a few adolescent studies have focused on subthreshold mental disorders, including subthreshold-depressive episodes and GAD, as a possible risk factor for suicide. Foley et al. (2006) examined subjects aged 9–16 years and found that suicidal youth without a full DSM-IV-TR; psychiatric disorder had significantly higher prevalence of subthreshold conditions than nonsuicidal youth without psychiatric disorders.

The aim of the present study of European adolescents was the examination of the prevalence of subthreshold-depression and subthreshold-anxiety and its relationships with psychopathology, functional impairment and suicidal behaviour.

Method

Participants

The sampling procedures of the *Saving and Empowering Young Lives in Europe* (SEYLE) study were previously described (Wasserman et al., 2010). SEYLE's sample of 12,395 adolescents (aged 14–16 years) is from 11 European countries: Austria, Estonia, France, Germany, Hungary, Ireland, Israel, Italy, Romania, Slovenia and Spain, with Sweden serving as the coordinating centre. Ethical approval was obtained from each site's local ethics committee. Local school authorities granted access to randomly selected school(s) and informed assent and consent were obtained, as required.

Data collection

Students were administered a self-report questionnaire that included well-established measures and items developed for SEYLE (Wasserman et al., 2010).

Beck Depression Inventory-II (BDI-II) measured severity of depression by assessing specific symptoms experienced over the preceding 2 weeks (Beck, Steer, Ball, & Ranieri, 1996; Byrne, Stewart, & Lee, 2004). BDI-II item 'loss of interest in sex' was excluded from the SEYLE version because it was considered inappropriate in some cultural settings (Byrne et al., 2004).

Symptoms of current anxiety were assessed using Zung Self-Rating Anxiety Scale (SAS) (Zung, 1971), a 20-item self-report questionnaire. Zung referred to the scores as an 'Index score' ('normal range': ≤44; 'minimal to moderate anxiety': 45–59; 'marked to severe anxiety': 60–74; 'extreme anxiety': ≥75) (McDowell, 2006).

Psychopathology was evaluated using Strengths and Difficulties Questionnaire (SDQ), a brief instrument for

screening childhood behaviours, consisting of 25 items (Goodman, Meltzer, & Bailey, 1998). The extended version of the SDQ was used, which includes an impact supplement, a measure of functional impairment.

Frequency of suicidal thoughts/ideations was assessed during the past 2 weeks using Paykel Suicide Scale (PSS) (Paykel, Myers, Lindenthal, & Tanner, 1974).

Definitions

Adolescents were divided into three groups based on BDI-II score: ≥20 = depressed (Beck et al., 1996); <20 (BDI-II) and being positive (>0) on items assessing core symptoms of DSM-IV-TR MDE (sadness or loss of pleasure) = subthreshold-depression; all others = non-depressed.

Adolescents were also divided into three groups based on the SAS: ≥60 = anxious; 45 ≤ and <60 = subthreshold-anxious; <45 = nonanxious.

Analyses

Data were analysed using IBM SPSS Statistic 20 software package (SPSS, Inc, 2011). Gender differences among nondepressed, subthreshold and depressed, as well as nonanxious, subthreshold and anxious groups were analysed using chi-squared tests. One-way ANOVAs were conducted to explore age differences. Means and standard deviations, as well as percentages of borderline and elevated SDQ total and impact scores are reported for the three groups of anxiety/depression, using the cut-off defined by Goodman et al. (1998). Due to cross-cultural variation in cut-off scores of the SDQ (Vostanis, 2006) continuous scores were used to explore levels of overall psychopathology. Bivariate relationships between measures of anxiety and depression, and SDQ total score were explored using Spearman correlations. Analyses of Covariance (ANCOVA) with Tukey post hoc test were conducted separately for girls and boys with age as covariate to detect differences among the three study groups. To differentiate the effects of anxiety and depression, each analysis was controlled for by depression/anxiety (for BDI-II total score when exploring the effect of subthreshold and full anxiety on functional impairments and for SAS total score when the effects of subthreshold and full depression were studied). Logistic regression analyses with dummy-coded SDQ impact score (0 'normal' and 0 < 'borderline/elevated scores') and PSS total score (0 or greater) as independents, were conducted to explore the relationships between functional impairments, as well as suicidality and subthreshold and full anxiety/depression. All analyses were adjusted for gender, age and continuous score of anxiety/depression. Due to sensitivity of Hosmer and Lemeshow goodness of fit test for very large sample sizes (Kramer & Zimmerman, 2007), the area under the Receiver operating characteristic (ROC) curve [area under the roc curve (AUC)] was reported. A p-value of .05 was considered statistically significant. Effect size measures are also reported for all analyses.

Multiple imputations (MI) were conducted using the IBM SPSS Statistics 20 (2011) to account for missing data. Five imputed datasets were created. Variables included in the model: age, country of origin, gender, all SDQ items, PSS, SAS and BDI-II as target variables and predictors. Each completed dataset was analysed using standard methods for assessing differences among non-depressed/nonanxious, subthreshold-depressed/anxious and depressed/anxious groups. Pooled estimates were calculated using Rubin's Rules (Rubin, 1987).

Results

Subjects

Complete data were obtained for 11,109 (89.6%) of the 12,395 adolescents in SEYLE: 4,506 (40.7%) boys and 6,565 (59.3%) girls. Mean age: 14.80 years (SD = .84).

Only 17,652 (1.8%) of the total 961,553 data items were missing. The proportion of the missing data was greatest on the sixth item of the SDQ ('I am usually on my own. I generally play alone or keep to myself.') (10.8%), whereas all other variables had less than 5% missing. Complete cases and incomplete cases differed significantly in age ($t(12310) = -48.356$, $p < .001$, Cohen's $d = 1.384$) and gender ($\chi^2(1) = 755.363$, $p < .001$, $\phi = -.248$), indicating that adolescents with incomplete data tended to be older and male subject.

MI analyses used data of all 12,395 participants: 5,529 males and 6,799 females (67 missing gender cases). The mean age was 14.91 years (SD = .90).

Anxiety and depression

Among all 12,395 adolescents, 7,476 (60.3%) were identified as nondepressed, 3,618 (29.2%) subthreshold-depressed and 1,301 (10.5%) depressed.

Analysis showed a significant age effect on group membership ($F(2) = 28.321$, $p < .001$). However, the effect size for this analysis ($\eta^2 = .005$) was not found to exceed Cohen's (1988) convention for a small effect ($\eta^2 = .01$).

Gender differences of small effect size were found among groups of nondepressed, subthreshold-depressed and depressed youth ($\chi^2(2) = 254.956$, $p < .001$, Cramer's $V = .143$). Girls more frequently were both subthreshold-depressed and depressed (Table 1) ($p < .001$, $\phi = .106$ and .143 respectively).

Among all subjects, 7,708 (62.2%) were identified as nonanxious, 3,964 (32.0%) subthreshold-anxious and 723 (5.8%) anxious.

Among the three levels of anxiety, a significant effect of group membership was found for age ($F(2) = 44.846$, $p < .001$). Again, the effect size ($\eta^2 = .007$) was not found to exceed Cohen's (1988) convention for a small effect.

Gender had a small effect on group membership across levels of anxiety ($\chi^2(2) = 290.362$, $p < .001$, Cramer's $V = .154$). Girls more frequently were both subthreshold-anxious and anxious (Table 1) ($p < .001$, $\phi = .115$ and .147 respectively).

Results revealed a strong relationship between SAS and BDI-II scores ($r = .503$ and .656 for boys

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Table 1 Gender distribution among nondepressed/nonanxious, subthreshold-depressed/anxious and depressed/anxious groups

	Levels of anxiety		Levels of depression	
	Boys %	Girls %	Boys %	Girls %
No anxiety/depression	50.35	49.65	50.35	49.65
Subthreshold- anxiety/ depression	38.24	61.76	38.24	61.76
Full anxiety/depression	24.07	75.93	24.07	75.93

N = 12,395.

and girls respectively). When using a categorical approach, a strong association was also found between levels of anxiety and depression ($\chi^2(4) = 3{,}807.565$, $p < .001$, $\gamma = .682$) (Table 2).

Psychopathology

SDQ total score was found to be strongly related to both SAS ($r = .513$, $p < .001$ and .619, $p < .001$ for boys and girls respectively) and BDI-II scores ($r = .542$, $p < .001$ and .654, $p < .001$ for boys and girls respectively). After adjusting for the scores of depression/anxiety, associations between SDQ total score and SAS score ($r = .287$, $p = .004$ and .302, $p < .001$ for boys and girls respectively), as well as between SDQ and BDI-II score ($r = .346$, $p < .001$ and .396, $p < .001$ for boys and girls respectively) decreased, but remained significant, showing small to medium effect.

Descriptive statistics, as well as percentages of borderline and elevated scores of SDQ scales among groups of nondepressed/nonanxious, subthreshold-depressed/anxious and depressed/anxious are shown in Table 3.

Controlling for age and BDI-II score, mean SDQ problem score differed significantly across the nonanxious, subthreshold-anxious and anxious groups for both genders ($F(2) = 136.154$, $p < .001$, $\eta^2 = .047$ for boys and $F(2) = 213.552$, $p < .001$, $\eta^2 = .059$ for girls). All pair-wise post hoc comparisons were significant ($p < .001$), indicating that mean scores of subthreshold-anxious adolescents were higher than the mean scores of the nonanxious group (Cohen's $d = .920$ and .994 for boys and girls respectively), but lower than the mean scores of the anxious group (Cohen's $d = .839$ and 1.102 for boys and girls respectively).

Table 2 Percents of levels of anxiety and depression

		Levels of Anxiety			
		NonA %	SubA %	A %	Totals
Levels of depression	NonD %	46.32	13.39	.60	60.31
	SubD %	14.75	12.98	1.46	29.19
	D %	1.11	5.61	3.77	10.50
Totals		62.18	31.98	5.83	100.00

$\chi^2(4) = 3{,}807.565$ $p < .001$; $\gamma = .682$.
N = 12,395. NonA, nonanxious group; SubA, subthreshold-anxious group; A, anxious group; NonD, nondepressed group; SubD, subthreshold-depressed group; D, depressed group.

Analysis resulted in a significant effect of group membership across levels of depression on SDQ total score for both genders ($F(2) = 190.553$, $p < .001$, $\eta^2 = .064$ for boys and $F(2) = 292.788$, $p < .001$, $\eta^2 = .079$ for girls). Nondepressed adolescents had significantly lower scores than subthreshold-depressed adolescents ($p < .001$, Cohen's $d = .632$ and .776 for boys and girls respectively), whereas subthreshold-depressed adolescents had significantly lower scores then depressed adolescents ($p < .001$, Cohen's $d = 1.126$ and 1.171 for boys and girls respectively).

Functional impairment

Logistic regression analysis revealed a significant effect of age (OR = 1.219; 95% CI = 1.171–1.269) on dummy-coded SDQ impact score as dependent (0 = no impairment; 1 = borderline/elevated scores), indicating that for each year of increase in age increases the probability of having functional impairments with 21.9%. Gender also had a significant effect (OR = .726; 95% CI = .675–.780), indicating that boys were predicted to have functional impairment with lower probability than girls.

Adjusting for the effect of age, gender and BDI-II score, the odds for a subthreshold-anxious adolescent having functional impairment was 1.795 (95% CI = 1.638–1.967) times greater than the odds for a nonanxious adolescent. Similarly, anxious adolescents were predicted to have functional impairment with a 2.519 (95% CI = 1.982–3.201) times greater probability than their nonanxious counterparts ($\chi^2(5) = 2845.482$, $p < .001$, Nagelkerke-$R^2 = .276$, AUC = .773, 95% CI = .776–.780).

In the second logistic regression model, when the effect of age, gender and SAS score were controlled, there were significant main effects of being subthreshold-depressed (OR = 1.960; 95% CI = 1.795–2.140) and depressed (OR = 4.102; 95% CI = 3.455–4.871) on having functional impairment ($\chi^2(5) = 2589.091$, $p < .001$, Nagelkerke-$R^2 = .254$, AUC = .756, 95% CI = .749–.764).

Suicidality

Descriptive statistics of PSS and percentages of positive responders, by item, in nonanxious/nondepressed, subthreshold-anxious/depressed and anxious/depressed groups are reported in Table 4.

A significant effect of age (OR = 1.174, 95% CI = 1.126–1.225) was found when using dummy-coded PSS total score (0 or greater) as dependent in the logistic regression model, indicating that for each year increase on age increases the probability of suicidality with 17.4%. Gender had also a significant effect on the dependent variable (OR = .546, 95% CI = .506–.590), indicating that boys were predicted to have suicidal thoughts/ideations with lower probability than girls.

Adjusting for the effect of age, gender and BDI-II score, the odds for a subthreshold-anxious adolescent for having suicidal thoughts/ideations were 1.788 (95% CI = 1.622–1.971) times greater than the odds for a nonanxious adolescent. Similarly, anxious adolescents were predicted to have suicidal thoughts/ideations with a 2.756 (95% CI = 2.159–3.518) times greater probability than their nonanxious counterparts ($\chi^2(5) = 3739.359$,

Table 3 Mean scores, standard deviations, as well as percentages of borderline and elevated scores of SDQ scales among groups of nondepressed/nonanxious, subthreshold-depressed/anxious and depressed/anxious.

		Levels of anxiety			Levels of depression		
SDQ	Total sample	NonA	SubA	A	NonD	SubD	D
Problem scale							
Borderline %	11.7	5.1	20.6	33.3	5.5	16.6	33.4
Elevated %	5.7	1.5	8.6	34.9	1.5	5.5	30.0
M (*SD*)	10.74 (5.10)	8.89 (4.22)	13.07 (1.80)	17.77 (4.76)	8.97 (4.30)	12.45 (4.46)	17.07 (4.57)
Impact scale							
Borderline %	4.2	4.8	3.0	1.1	5.1	3.6	1.4
Elevated %	37.2	23.9	55.3	83.6	23.7	49.1	82.0
Median (Interquartile Range)	0 (0–3)	0 (0–1)	2 (0–5)	6 (3–10)	0 (0–1)	1 (0–4)	6 (3–10)

N = 12,395. SDQ, Strength and Difficulties Questionnaire; NonA, nonanxious group; SubA, subthreshold-anxious group; A, anxious group; NonD, nondepressed group; SubD, subthreshold-depressed group; D, depressed group.

Table 4 Descriptive statistics of PSS and per cent of positive responders by item in nondepressed/nonanxious, subthreshold-depressed/anxious and depressed/anxious groups

		Levels of anxiety			Levels of depression		
	Total sample	NonA	SubA	A	NonD	SubD	D
PSS Median (Intequartile Range)	0 (0–1)	0 (0–0)	1 (0–3)	4 (1–10)	0 (0–0)	0 (0–2)	4 (2–9)
Life not worth living during past 2 weeks %	27.00	14.78	41.95	75.29	12.46	38.93	77.35
Wish that were dead during past 2 weeks %	18.52	8.21	30.00	65.61	6.99	25.08	66.52
Thought of taking own life during past 2 weeks %	16.79	7.86	26.74	57.50	6.74	21.76	60.70

N = 12,395. PSS, Paykel Suicide Scale; NonA, nonanxious group; SubA, subthreshold-anxious group; A, anxious group; NonD, nondepressed group; SubD, subthreshold-depressed group; D, depressed group.

$p < .001$, Nagelkerke-$R^2 = .361$, AUC = .812, 95% CI = .805–.819).

When assessing the effect of levels of depression on suicidality, we found significant main effects of being subthreshold-depressed (OR = 3.065; 95% CI = 2.792–3.364) and depressed (OR = 9.210; 95% CI = 7.700–11.016) when the effect of age, gender and SAS scores were controlled for ($\chi^2(5) = 3492{,}978$, $p < .001$, Nagelkerke-$R^2 = .340$, AUC = .800, 95% CI = .793–.807).

Discussion

Similar to the study of Angst et al. (1997) on a community sample of individuals ages 19–20, in the current study approximately half of the adolescents met the criteria for threshold and/or subthreshold-depression and/or anxiety. Although our focus was on subthreshold-depression and subthreshold-anxiety, it is noteworthy that based on screening tools an exceptionally high proportion of this sample was categorized as depressed (10.5%) and anxious (5.8%). Similar to prior findings, our results show a high prevalence of subthreshold-depression and anxiety among adolescents throughout Europe (Fergusson et al., 2005; Wittchen et al., 1998). According to our data, almost one third of adolescents had current subthreshold-depression and one third had current subthreshold-anxiety. Importantly, even these less severe cases were associated with elevated levels of psychopathology, and increased risk for functional impairment and suicidality.

No difference in the prevalence of depression among preadolescent boys and girls has been described (Anderson, Williams, McGee, & Silva, 1987; Kashani et al., 1983). After ages 11–13 and throughout adulthood, this trend changes and female subjects are approximately twice as likely as male subjects to be depressed and the same prevalence estimate is true for anxiety disorders (Angold, Costello, & Worthman, 1998; Mackinaw-Koons & Vasey, 2000). In the current study, we observed similar gender distributions in the depressed and anxiety groups and in the subthreshold-depressed and subthreshold-anxiety groups as well.

In this large international sample, we found a strong correlation between depression according to BDI-II and anxiety according to SAS. While high comorbidity of both threshold and subthreshold-depression and anxiety was expected (Kessler et al., 2005; Unick et al., 2009; Wittchen et al., 1994), it is still surprising that only one tenth of all adolescents with threshold-depression or threshold-anxiety had 'pure forms' of the disorders. The presence of comorbid (even subthreshold) MDE and anxiety is associated with more severe psychopathology, greater impairment, increased suicidality and worse outcome than in noncomorbid conditions (Altamura, Montresor, Salvadori, & Mundo, 2004; Foley et al.,

2006; Guberman & Manassis, 2011). Our results highlight the importance of assessing comorbidity of depression and anxiety in adolescents. In contrast to the high comorbidity of threshold psychopathology, the percentage of pure forms of subthreshold-depression and subthreshold-anxiety were found to be much higher (up to 40–50).

Based on both dimensional and categorical diagnostic models, our data revealed a strong association between the SDQ total score and SAS/BDI scores. According to the SDQ Impact scale, after adjusting for age, gender and SAS scores, being subthreshold-depressed increased the probability of having functional impairment, the odds for having functional impairment for depressed was four times more than being nondepressed. Similarly, adjusting for the effects of age, gender and BDI-II score, adolescents with both subthreshold-anxiety and threshold-anxiety showed greater probability of having functional impairment than nonanxious adolescents. The elevated level of psychopathology and the increased risk of functional impairment suggest that adolescents with subthreshold-depression and with subthreshold-anxiety already have clinically meaningful symptoms, requiring professional intervention.

Gender here had a significant effect on suicide behaviour, similar to earlier findings (Wunderlich, Bronisch, Wittchen, & Carter, 2001). According to the PSS total score, subthreshold conditions increased the probability of having suicidal thoughts/ideations, and the odds for having suicidal thoughts/ideations in a full syndrome condition were even greater in both anxiety and depression. Namely, after adjusting for age, gender and BDI-II scores, the odds for a subthreshold-anxious adolescent to have suicidal thoughts/ideations were approximately two times greater than the odds for a nonanxious adolescent, and being anxious increased the probability of having suicidal thoughts/ideations almost two and a half times. We found the same pattern in the case of depression: adjusting for age, gender and SAS score, adolescents with subthreshold-depression showed three times greater probability of having suicidal thoughts/ideations than nonanxious adolescents, whereas being threshold-depressed increased the probability of having suicidal thoughts/ideations nine times more than being nondepressed. These data indicate that both subthreshold and threshold forms of depression increase the risk of having suicidal thoughts/ideations, even more than subthreshold and threshold-anxiety. From a clinical standpoint, early recognition and intervention of subthreshold-depression and subthreshold-anxiety may prevent full-onset depression/anxiety and significantly reduce the related suicide risk.

This study's results contribute to the current discussions about categorical and dimensional systems. We used a dimensional diagnostic model of depression and anxiety and introduced a third condition, subthreshold-depression/subthreshold-anxiety, based on classical categorical approaches. Our findings, that the level of risk for increased burden and suicide among adolescents with subthreshold-depression/anxiety is between the risk for those nondepressed/nonanxious and depressed/anxious, supports the suggestion of previous studies that show that subthreshold and full DSM-IV-TR depression/anxiety could be on the same continuum (Fergusson et al., 2005; Klein et al., 2009; Lewinsohn et al., 2000; Shankman et al., 2009). Based on our data, inputting subthreshold-depression and subthreshold-anxiety into the diagnostic systems could provide an important bridge between traditional categorical diagnostic approaches and dimensional models.

Limitations of these findings include their being cross-sectional. Longitudinal studies are needed to understand the potential negative sequel of subthreshold-depression and anxiety. As this study took place in eleven European countries, cross-cultural differences must also be taken into account. Finally, our data are based on self-report, which can be biased.

In conclusion, our study supports the dimensional rather than the categorical nature of adolescent subthreshold and full syndrome depression and anxiety. It highlights the importance of early detection especially, as it may be associated with suicidal behaviour. Recognition and appropriate intervention for adolescent subthreshold conditions may significantly save lives of young people.

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Key points

- This study investigates the characteristics of adolescent subthreshold-depression and subthreshold-anxiety in a large European sample, with a focus on suicidality.
- According to our data, both subthreshold-depression and subthreshold-anxiety are very prevalent, and associated with an increased burden of disease and suicidal risk.
- Our study highlights the importance of early detection of subthreshold-depression and subthreshold-anxiety to reduce psychopathology and distress in adolescents, especially as it may be associated with suicidal behaviour.
- The current study supports the continuum, that is the dimensional rather than categorical nature of adolescent subthreshold and full syndrome depression and anxiety.

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Life-time prevalence and psychosocial correlates of adolescent direct self-injurious behavior: A comparative study of findings in 11 European countries

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Objectives: To investigate the prevalence and associated psychosocial factors of occasional and repetitive direct self-injurious behavior (D-SIB), such as self-cutting, -burning, -biting, -hitting, and skin damage by other methods, in representative adolescent samples from 11 European countries. **Methods:** Cross-sectional assessment of adolescents was performed within the European Union funded project, Saving and Empowering Young Lives in Europe (SEYLE), which was conducted in 11 European countries. The representative sample comprised 12,068 adolescents (F/M: 6,717/5,351; mean age: 14.9 ± 0.89) recruited from randomly selected schools. Frequency of D-SIB was assessed by a modified 6-item questionnaire based on previously used versions of the Deliberate Self-Harm Inventory (DSHI). In addition, a broad range of demographic, social, and psychological factors was assessed. **Results:** Overall lifetime prevalence of D-SIB was 27.6%; 19.7% reported occasional D-SIB and 7.8% repetitive D-SIB. Lifetime prevalence ranged from 17.1% to 38.6% across countries. Estonia, France, Germany, and Israel had the highest lifetime rates of D-SIB, while students from Hungary, Ireland, and Italy reported low rates. Suicidality as well as anxiety and depressive symptoms had the highest odds ratios for both occasional and repetitive D-SIB. There was a strong association of D-SIB with both psychopathology and risk-behaviors, including family related neglect and peer-related rejection/victimization. Associations between psychosocial variables and D-SIB were strongly influenced by both gender and country. Only a minor proportion of the adolescents who reported D-SIB ever received medical treatment. **Conclusion:** These results suggest high lifetime prevalence of D-SIB in European adolescents. Prevalence as well as psychosocial correlates seems to be significantly influenced by both gender and country. These results support the need for a multidimensional approach to better understand the development of SIB and facilitate culturally adapted prevention/intervention. **Keywords:** Direct self-injurious behavior, self-harm, nonsuicidal self-injury, psychopathology, gender, adolescents, suicide.

Introduction

At the broadest level, all behaviors that are performed intentionally, and with the knowledge that they can or will result in some degree of physical or psychological injury to oneself, could be conceptualized as self-injurious or self-harm behavior (Nock, 2010). During the past decades, various terms have been used to describe and define such human self-injury. Nonsuicidal self-injury (NSSI), which is now clearly defined in the section 3 of the new Diagnostic and Statistical Manual of Mental Disorders (DSM-5), is described as intentional self-inflicted damage to the surface of an individual's body without conscious suicidal intent (American Psychiatric Association, 2013). Frequently the term 'deliberate self-harm' (DSH) has been used

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synonymously with both self-injury and even NSSI. However, there are important differences in the definition of DSH and NSSI: (a) DSH includes suicidal behavior (Hawton & James, 2005; Muehlenkamp, Claes, Havertape, & Plener, 2012); (b) the definition of DSH commonly includes indirect damage to an individual's body as well (e.g., severe substance abuse, taking overdoses, or ingestion of sharp implements).

There has been an on-going discussion whether determination of a person's intent during self-injury can reliably be performed, especially within the adolescent population and using self-report measures. Kapur, Cooper, O'Connor and Hawton (2013) have recently questioned the concept of NSSI due to its strong association with suicidal behavior. We propose that self-injuring adolescents may often do this with ambivalent suicidal intent and that intent should not be considered as a categorical construct, but rather represented as a continuum. However, it is possible to differentiate between direct self-injury to an individual's body surface, which typically involves cutting or carving the skin (Nock, 2010), but also other forms like self-biting, hitting self on purpose, or burning skin (Lloyd-Richardson, Perrine, Dierker, & Kelley, 2007), and indirect harm to an individual as defined within the term of DSH. Therefore, this study will focus on direct self-injurious behavior (D-SIB), which is defined as intentional self-inflicted damage to the surface of an individual's body, which includes self-cutting, -burning, -biting, -hitting, and skin damage by other methods, regardless of the suicidal intent.

In community samples, approximately 13%–45% of adolescents reported to engage in self-injury during their lifetime (Nock, 2010). It remains unclear to what extent these variations represent true intercultural variation in the prevalence of self-injury, rather than an artifact caused by differences in the definition of self-injury, assessment tools, study samples and methods. Nock (2010) argued that the wide variation in prevalence estimates of self-injury is largely caused by the fact that measures of self-injury have not been included in any of the large-scale epidemiologic surveys that have generated mental and physical disorder prevalence estimates. Consequently, estimates have been based on small, regional studies that vary according to the above noted confounding factors. According to two international studies on the intercultural prevalence of NSSI, comparable prevalence rates among adolescents from different countries have been suggested (Giletta, Scholte, Engels, Ciairano, & Prinstein, 2012; Plener, Libal, Keller, Fegert, & Muehlenkamp, 2009). However, two other studies on this topic of DSH revealed intercultural differences with regards to both self-injurious thoughts (Kokkevi, Rotsika, Arapaki & Richardson, 2012) and behavior (Madge et al., 2008). Thus, data on this topic remains conflicting, and a recent review concluded that research would benefit from adopting a common approach to assessment to aide cross-cultural studies and comparisons (Muehlenkamp et al., 2012).

Although the prevalence of self-injury seems generally high, there is a substantial amount of adolescents who only engage in low frequent self-harm during a short episode in their lifetime, and another group that rather engages in repetitive self-harm, which has been shown to be associated with a higher load of psychological problems (Brunner et al., 2007). In general, self-injury has been shown to be associated with a broad variety of socio-demographic and psychological factors (Nock, 2010). Female gender has been shown to be associated with higher prevalence of self-injury (Brunner et al., 2007; O'Connor, Rasmussen, Miles, & Hawton, 2009; Plener et al., 2009). Because self-injury typically first occurs between ages 10–20 years (Whitlock, Eckenrode ,& Silverman, 2006), higher mean age would be hypothesized to increase lifetime prevalence. Socioeconomic status has been reported to influence the prevalence of self-harm (Brunner et al., 2007; Hilt, Cha, & Nolen-Hoeksema, 2008; Nada-Raja, Skegg, Langley, Morrison, & Sowerby, 2004), but remains controversial since high prevalence occurs in various samples consisting mainly of Caucasian adolescents from middle to upper class (Yates, Tracy, & Luthar, 2008). Regarding the role of parenting and family in the development of self-injury, data are much less controversial. Experiences of sexual, physical, or emotional abuse (Muehlenkamp, Kerr, Bradley, & Adams Larsen, 2010; Weierich & Nock, 2008; Yates, Carlson, & Egeland, 2008), but also family discord and parental criticism have been found to be closely linked to NSSI (Kaess et al., 2012, 2013; Wedig & Nock, 2007; Yates, Tracy et al., 2008). Peer relationship problems also seem to be associated with NSSI (Giletta et al., 2012). Self-injury is well-known to be positively correlated with a variety of adolescent risk behaviors (e.g., smoking, binge drinking, truancy), as well as comorbid mental health problems (e.g., depression, anxiety, conduct disorder, suicidal ideation) (Brunner et al., 2007; Gollust, Eisenberg, & Golberstein, 2008; Haw, Hawton, Casey, Bale, & Shepherd, 2005; Serras, Saules, Cranford, & Eisenberg, 2010). In general, all of these factors could potentially influence or bias the prevalence estimate of self-injury, where there is an uneven distribution between study samples. In fact, a recent study provided first evidence of a country-specific impact of psychosocial variables (e.g., substance abuse) on self-harm thoughts and suicide attempts (Kokkevi et al., 2012). In addition, it is important to distinguish the influence of these factors while differentiating occasional from repetitive self-injury.

Nock (2010) argued that obtaining accurate estimates of the rate of self-injury in community and clinical samples is essential for understanding the scope of this problem, allocating services and other resources, and for monitoring changes in this behavior overtime. Therefore, the aim of this study was to

(a) map the lifetime prevalence (differentiated into occasional and repetitive forms) and methods of D-SIB among adolescents in different European countries by utilizing a homogenous methodology; (b) to examine potential cross-national differences and their association with gender, age, household composition, parental and peer relationships, comorbid risk-behaviors and mental health problems; and (c) to investigate interactions of countries and psychosocial correlates to detect particular cultural-specific influences of psychosocial factors on D-SIB.

Methods

Description of study sample

The study was conducted within the framework of the EU funded project, *Saving and Empowering Young Lives in Europe* (SEYLE). The detailed protocol of the SEYLE study [registered at the US National Institute of Health (NIH) clinical trial registry (NCT00906620), and the German Clinical Trials Register (DRKS00000214)] has been published elsewhere (Wasserman et al., 2010). The main study comprises a sample of 12,395 adolescents recruited from 179 randomly selected schools, within 11 study sites, in the following European countries: Austria, Estonia, France, Germany, Hungary, Ireland, Israel, Italy, Romania, Slovenia, and Spain, with Sweden serving as the coordinating center. In each country, a list of all eligible schools, within the study sites, was generated according to specific inclusion and exclusion criteria (Wasserman et al., 2010).

The response rate of the elected schools was 67.8%; there was no significant difference in school size (except in Slovenia) between nonparticipating and participating schools (Carli et al., 2013). Of the 14,115 students who consented to participate, 1,720 were absent the day of the survey. This resulted in a total of 12,395 students who completed the questionnaire. An additional 327 subjects were excluded based on missing D-SIB data in the questionnaire. This resulted in a total sample of 12,068 adolescents (F/M: 6,717/5,351; mean age: 14.9 ± 0.89) included in these analyses. The overall consent rate within the study was 49% (14,117 pupils with consent out of 28,889). In eight countries, the consent rate of the pupils and their parents/caregivers was 76% (10,665 pupils with consent of 14,086 approached). In the three remaining countries, the consent rate was only 23% (3,452 pupils with consent of 14,803 approached) due to national requirements of their local ethics committees (i.e. both parents had to sign the consent form) (Carli et al., 2013).

An analysis with regard to the representativeness of the SEYLE study sites revealed that the demographic characteristics (such as income, immigrant rate, unemployment rate) of the participating study sites were reasonably representative of their respective national population (Carli et al., 2013).

Study procedures

Ethical approval was obtained from the local ethical committees at each site before commencing the study. Subjects were included into the study only if both pupils and caregivers had given their written consent. Caregivers and children were informed about the purposes, content as well as risks and benefits of the study by a letter, and an accompanying separate consent form, which was collected by the survey personnel before the study's baseline assessment.

All questionnaires were administered in the official language(s) of the respective country and culturally adapted, if required. Cultural adaption was only required if professional translations resulted in cultural inappropriateness and compromised feasibility and acceptability of the assessment. This adaption process involved experienced researchers and clinicians who were native speakers of the respective language, and every cultural adaption was documented and sent to the translation coordinator of the SEYLE project for approval. This procedure aimed to make sure that cultural adaptation never changed the core structure and content of each assessment instrument or intervention program.

The self-report assessment took up to 90 min. Students were supervised by research staff during the assessment, and could ask questions with regards to a better understanding of the questions. The self-report data analyzed for the SEYLE study was collected between October 2009 and December 2010.

Measurements

The 6-item questionnaire used in the SEYLE study to assess pupils who engaged in direct self-injurious behavior (D-SIB) refers to the intentional self-inflicted damage of the surface of an individual's body by self-cutting, -burning, -hitting, -biting, and skin damage by other methods. This 6-item questionnaire is based on the 9-item DSHI questionnaire from Bjärehed and Lundh (2008), which is a shortened version of the 16-item DSHI by Lundh, Karim, and Quilisch (2007) that originated from the original 17-item DSHI by Gratz (2001). The modified version comprised the same facets on frequency, severity and duration; however, self-injurious acts were combined to simplify and shorten the measure and assess direct self-injury to one's body surface only.

The following 6-items were used in SEYLE: (a) Have you ever intentionally cut your wrist, arms, or other area(s) of your body, or stuck sharp objects into your skin such as needles, pins, staples (NOT INCLUDING tattoos, ear piercing, needles used for drugs, or body piercing)? (b) Have you ever intentionally burned yourself with a cigarette, lighter, or match? (c) Have you ever intentionally carved words, pictures, designs, or other markings into your skin,

or scratched yourself to the extent that scarring or bleeding occurred? (d) Have you ever intentionally prevented wounds from healing, or bit yourself to the extent that it broke skin? (e) Have you ever intentionally banged your head or punched yourself thereby causing a bruise? (f) Have you ever intentionally hurt yourself in any of the above-mentioned ways so that it led to hospitalization or injury severe enough to require medical treatment? Occasional D-SIB was defined as 1–4 reported lifetime acts of D-SIB; repetitive D-SIB was defined as ≥5 previous events of D-SIB acts during lifetime. The cut-off of ≥5 has been chosen according to the diagnostic criteria of frequency in the new proposed diagnostic entity of NSSI according to DSM-5 (American Psychiatric Association, 2013).

Moreover, data were collected on demographics, household composition, place of birth, parental involvement, peer relationships, parental unemployment, and religiosity using questions procured from the Global School-Based Pupil Health Survey (GSHS) (WHO, 2009) and European Values Study (EVS) (EVS, 2009). Data on different comorbid risk behaviors and psychopathology were assessed using questions from the Global School-Based Student Health Survey (GSHS) (WHO, 2009), the Beck Depression Inventory (BDI-II) (Beck, Steer, Ball, & Ranieri, 1996), the Zung Self-Rating Anxiety Scale (SAS) (Zung, 1971), and the Paykel Suicide Scale (PSS) (Paykel, Myers, Lindenthal, & Tanner, 1974).

All psychosocial variables were dichotomized according to cut-off criteria previously defined and published for the SEYLE study (Wasserman et al., 2010), and can also be found in the Table S1. Defined cut-offs for all variables had been established to sensitively detect at-risk students.

Statistical analyses

All analyses were calculated on lifetime prevalence of D-SIB. However, additional categories of occasional and repetitive self-harm was used for description of prevalence as well as regression of psychosocial variables on D-SIB only. These categories were not used for further calculations for reasons due to increased complexity and difficulties of interpretability.

Descriptive analysis was used to determine the prevalence of D-SIB, and was calculated separately for each gender and country, as well as for gender according to method. Lifetime prevalence was compared between countries by Bonferroni adjusted Wald tests after a multinomial logistic regression analysis with D-SIB categories as the dependent variable, with country as the explanatory factor. Univariate and multivariate multinomial logistic regression analyses were calculated with D-SIB (lifetime, occasional and repetitive) as the dependent variable and psychosocial factors as explanatory variables. Relative Risk Ratios (RRR) and 95% confidence intervals (95% CIs) are presented. In addition, psychosocial factor × gender and psychosocial factor × country interactions were calculated within a multiple logistic regression with factor, gender and country as explanatory variables. In 16.7% of the subjects, at least one missing value in the explanatory variables occurred in the regression analysis. To prevent estimation bias resulting from the exclusion of these subjects, missing values were replaced with imputed values, using the multivariate imputation by chained equations algorithm (van Buuren & Oudshoorn, 1999). The regression was then calculated for the 20 imputed datasets and the results were combined (Rubin, 2004). Finally, the frequencies of medical treatment due to D-SIB were calculated separately for each country by D-SIB. Because even small effects are statistically significant in large samples the presentation of the results focuses on the report of effect sizes.

Results

Prevalence of D-SIB

Prevalence of D-SIB for each gender and country separately is presented in Table 1. The lifetime prevalence of D-SIB was 27.56% (n = 3,326). Prevalence of occasional D-SIB was 19.73% (n = 2,381), prevalence of repetitive D-SIB was 7.83% (n = 945). In total, significantly more females were reporting D-SIB [$\chi^2(2) = 41.99$; $p < .001$]. In most countries, female gender was significantly associated with higher rates of both occasional and repetitive D-SIB. With regards to occasional D-SIB, no gender differences were found in Hungary, Ireland, Israel, Italy, and Romania. With regards to repetitive D-SIB, no gender differences were found in Austria, Ireland, Israel, and Romania. In Italy, males even showed significant higher rates of repetitive D-SIB (p = .015).

Prevalence of D-SIB ranged from 17.12% to 38.55% with countries differing significantly in rates of D-SIB [$\chi^2(10) = 266.96$; $p < .001$]. France, Germany, Estonia, and Israel showed the highest lifetime rates of D-SIB, while students from Hungary, Ireland, Romania, and Italy reported low lifetime rates of D-SIB; p-values indicated significant differences for total D-SIB between countries and are presented in Table S2 of this article. Prevalence of occasional D-SIB ranged from 12.51% to 25.60% with countries differing significantly in rates of D-SIB [$\chi^2(10) = 144.45$; $p < .001$]. Prevalence for repetitive D-SIB ranged from 2.68% to 12.95% also showing significant differences between countries [$\chi^2(10) = 191.92$; $p < .001$].

The proportions of different forms of D-SIB for each gender are presented in Table 2. Skin damage, by using 'other' methods, was most commonly reported, followed by self-cutting. Self-burning and self-hitting were less common. The proportion of self-cutting and skin damage by using other methods

Table 1 Prevalence of D-SIB by country and gender

	Any lifetime D-SIB						Occasional D-SIB						Repetitive D-SIB					
	D-SIB females		D-SIB males		D-SIB total		D-SIB females		D-SIB males		D-SIB total		D-SIB females		D-SIB males		D-SIB total	
Country	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Austria	179	30.2	74	21.3	253	26.9	132	22.26	56	16.14	188	20.00	47	7.93	18	5.19	65	6.91
Estonia	209	37.6	130	27.4	339	32.9	144	25.90	101	21.26	245	23.76	65	11.69	29	6.11	94	9.12
France	296	43.1	91	28.6	387	38.5	192	27.99	65	20.44	257	25.60	104	15.16	26	8.18	130	12.95
Germany	333	44.5	169	24.8	502	35.1	207	27.67	120	17.62	327	22.88	126	16.84	49	7.20	175	12.25
Hungary	112	19.0	59	14.4	171	17.1	75	12.71	50	12.22	125	12.51	37	6.27	9	2.20	46	4.60
Ireland	91	18.7	124	21.9	215	20.4	67	13.76	93	16.46	160	15.21	24	4.93	31	5.49	55	5.23
Israel	79	34.8	300	32.0	379	32.6	59	25.99	203	21.66	262	22.51	20	8.81	97	10.35	117	10.05
Italy	171	21.1	78	20.5	249	20.9	142	17.53	51	13.39	193	16.20	29	3.58	27	7.09	56	4.70
Romania	144	19.6	86	22.4	230	20.6	127	17.33	73	19.01	200	17.91	17	2.32	13	3.39	30	2.69
Slovenia	235	29.6	71	21.8	306	27.3	157	19.75	49	15.03	206	18.38	78	9.81	22	6.75	100	8.92
Spain	159	32.3	136	25.8	295	28.9	125	25.41	93	17.61	218	21.37	34	6.91	43	8.14	77	7.55
Total	2,008	29.9	1,318	24.6	3,326	27.6	1,427	21.24	954	17.83	2,381	19.73	581	8.65	364	6.80	945	7.83

Table 2 Proportion of self-harm methods in adolescents with any lifetime D-SIB

	Frequency of methods (%)			Gender differences	
Methods[a]	Females	Males	Total	OR	95% CI
Self-cutting	54.4	34.2	46.4	2.30**	2.00–2.66
Self-burning	15.9	33.4	22.8	0.38**	0.32–0.44
Self-hitting	25.4	34.3	28.9	0.65**	0.56–0.76
Skin damage by using other methods[b]	68.9	59.3	65.1	1.53**	1.32–1.76

[a]Multiple answers possible.
[b]Self-scratching, -carving, -biting, or preventing wounds from healing.
**$p < .01$.

was higher among female students. Both self-burning and self-hitting, however, were less frequent among females.

Psychosocial correlates of D-SIB

Table 3 gives an overview of the distribution of demographic and psychological factors among the different D-SIB groups. Demographic and psychosocial correlates as predictors of D-SIB are presented in Table 4. Strongest predictors of D-SIB in the univariate regression (RRR ranging from 6.31 to 1.67), that also showed an independent effect in the multivariate regression model, are as follows (in hierarchical order of the strength of effect sizes): suicidality, anxiety and depressive symptoms, illegal drug consumption, peer victimization, sensation-seeking and delinquent behaviors, tobacco use, alcohol consumption, 'parents do not understand student's problems', 'parents to not pay attention to student', and parental unemployment. Male gender and being a religious person negatively predicted D-SIB. Age was positively predictive for D-SIB in the univariate regression, but negatively predictive for D-SIB in the multivariate model. The effects of household composition, immigration status and loneliness/peer relationship problems on D-SIB were sufficiently explained by the other variables in the multivariate regression models.

With regards to differentiation between occasional and repetitive D-SIB, both showed high levels of significance for all psychosocial variables in the univariate regression model. RRRs were higher for repetitive D-SIB (RRRs ranging from 15.45 to 1.12) compared with occasional D-SIB (RRRs ranging from 4.11 to 1.07). In the multivariate regression model, occasional D-SIB was not associated with illegal drug consumptions and loneliness/peer relationship problems compared with repetitive D-SIB. In contrast with occasional D-SIB, repetitive D-SIB was not associated with gender.

Table 3 Frequencies of demographic and psychological factors by D-SIB-group

	No lifetime D-SIB	Occasional D-SIB	Repetitive D-SIB	Total study sample
Age; mean (*SD*)	14.9 (.89)	14.9 (.89)	15 (.94)	14.9 (.89)
Female gender; *n* (%)	4,709 (53.9)	1,427 (59.9)	581 (61.5)	6,717 (55.7)
Student perceived himself/herself as a religious person; *n* (%)	3,961(46.6)	925(40.1)	294(32.2)	5,180 (44.2)
Parental unemployment; *n* (%)	736(8.6)	290(12.5)	164(17.9)	1,190 (10.1)
Student does not live with biological parent or relative; *n* (%)	109(1.3)	52(2.2)	27(2.9)	188 (1.6)
Parents do not understand student's problems; *n* (%)	3,442(39.8)	1,306(55.4)	650(69.2)	5,398 (45.2)
Parents do not pay attention to student; *n* (%)	2,934(33.9)	1,156(49.3)	545(58.7)	4,635 (38.9)
Loneliness/Social relationship problems; *n* (%)	262(3.0)	192(8.1)	192(20.5)	646 (5.4)
Peer victimization; *n* (%)	424(4.9)	282(12.0)	210(22.5)	916 (7.7)
Depression; *n* (%)	932(10.8)	670(28.5)	537(58.1)	2,139 (17.9)
Anxiety; *n* (%)	312(3.7)	267(11.5)	306(33.7)	885 (7.6)
Suicidality; *n* (%)	612(7.1)	561(23.8)	505(54.0)	1,678 (14.0)
Sensation-seeking and delinquent behaviors; *n* (%)	477(5.5)	297(12.6)	224(24.0)	998 (8.4)
Tobacco use; *n* (%)	1.390(16.7)	771(34.6)	419(48.3)	2,580 (22,6)
Alcohol consumption; *n* (%)	2,035(23.4)	976(41.2)	533(56.8)	3,544 (29,5)
Illegal drug consumption; *n* (%)	237(2.7)	162(6.9)	147(15.8)	546 (4.6)
Truancy; *n* (%)	229(2.6)	132(5.6)	84(9.0)	445 (3.7)

Interactions of psychosocial correlates and gender

Significant psychosocial variable × gender interactions were found for 'parents do not understand student's problems' ($p = .026$), use of tobacco ($p = .026$), alcohol consumption ($p = .019$), and illegal drug consumption ($p = .015$). For these psychosocial variables, female students were at significantly higher risk of engaging in D-SIB when reporting those psychosocial correlates compared with males.

Interactions of psychosocial correlates and countries

Significant psychosocial variable × country interactions were found for several psychosocial variables and are presented in Table 5. 'Student does not live with biological parent or relative', anxiety, tobacco use, illegal drug consumption, and truancy did not show significant country interactions.

Medical treatment after D-SIB

Table 6 presents the percentage of students who ever had to get medical treatment after an incident of D-SIB for each group. Interestingly, there was a gender [$\chi^2(1) = 10.97$; $p < .001$] and country [$\chi^2(10) = 39.90$; $p < .001$] specific effect regarding the medical treatment. In the whole sample, males more frequently received medical treatment following D-SIB; however, this was not true in all countries. In Israel, medical treatment after incidents of D-SIB was most common and least common in France (Table 6). There was no gender × country interaction.

Discussion

This study assessed prevalence and psychosocial correlates of D-SIB, within the same timeframe and with a homogenous methodology, in a large multinational sample of European adolescents. As recently published, the SEYLE sample can be considered reasonably representative for the adolescent population of their respective country (Carli et al., 2013).

Prevalence

Overall lifetime prevalence of D-SIB was 27.6%, which lies within the range previously reported in epidemiological studies among adolescents (Nock, 2010). The prevalence of occasional D-SIB was 19.7% with significantly lower number of adolescents (7.8%) reporting to engage in repetitive D-SIB. Significant differences in the frequency of D-SIB were found among the participating countries. These results confirm the large variation in prevalence estimates previously reported (Nock, 2010), and are consistent with previous studies reporting country differences in self-harming behavior among adolescent samples in Europe (Kokkevi et al., 2012; Madge et al., 2008; Portzky, De Wilde, & Van Heeringen, 2008). The results differ, however, from population-based samples of adolescents –from Germany and from the United States – using the same sampling and assessment methods of NSSI (Plener et al., 2009). This study reported no significant differences regarding the frequency of NSSI, and their results were confirmed by another cross-national study of community samples from Italy, the Netherlands, and the United States (Giletta et al., 2012). It may be of note that all studies including a concept of self-harm regardless of suicidal intent have reported country differences (including our study), whereas studies focusing on NSSI did not.

A comparison of prevalence data from the Child & Adolescent Self-harm in Europe (CASE) study with the present study indicates both similarities and differences. The main and most striking difference is that reported lifetime prevalence, in general, was

Table 4 Logistic univariate and multivariate regression model of D-SIB by demographic, social, and psychological factors

Explaining factors	Any lifetime D-SIB				Occasional D-SIB				Repetitive D-SIB			
	Univariate analyses		Multivariate analysis		Univariate analyses		Multivariate analyses		Univariate analyses		Multivariate analyses	
	OR	95% CI	OR	95% CI	RRR	95% CI	RRR	95% CI	RRR	95% CI	RRR	95% CI
Age	1.09**	1.04–1.14	0.91**	0.86–0.96	1.07**	1.02 -1.13	0.92**	0.87–0.98	1.12**	1.04–1.21	0.86**	0.79–0.94
Female gender	1.30**	1.20–1.42	1.20**	1.10–1.32	1.28**	1.17–1.40	1.25**	1.13–1.38	1.37**	1.19–1.57	1.04	0.88–1.23
Student perceived himself/herself as a religious person	0.70**	0.64–0.76	0.82**	0.75–0.90	0.77**	0.70–0.84	0.87**	0.78–0.95	0.54**	0.47–0.63	0.68**	0.57–0.80
Parental unemployment	1.73**	1.53–1.96	1.30**	1.13–1.50	1.52**	1.31–1.75	1.25**	1.07–1.46	2.31**	1.92–2.78	1.48**	1.19–1.85
Student does not live with biological parent or relative	1.93**	1.44–2.58	1.27	0.90–1.80	1.77**	1.27–2.47	1.30	0.90–1.87	2.33**	1.52–3.58	1.18	0.70–2.00
Parents do not understand student's problems	2.20**	2.03–2.39	1.26**	1.14–1.39	1.88**	1.71–2.06	1.23**	1.10–1.36	3.40**	2.94–3.93	1.44**	1.20–1.72
Parents do not pay attention to student	2.11**	1.94–2.29	1.30**	1.18–1.44	1.89**	1.73–2.08	1.33**	1.20–1.48	2.78**	2.42–3.19	1.22*	1.03–1.45
Loneliness/Social relationship problems	4.22**	3.59–4.97	1.21	0.9–1.48	2.83**	2.34 3.43	1.11	0.89–1.39	8.29**	6.78–10.13	1.39*	1.07–1.81
Peer victimization	3.39**	2.96–3.89	1.68**	1.43–1.98	2.62**	2.24–3.07	1.60**	1.35–1.91	5.59**	4.66–6.70	1.90**	1.52–2.34
Depression	4.84**	4.38–5.3	1.8**	1.65–2.14	3.30**	2.95–3.70	1.67**	1.45–1.92	11.47**	9.90–13.29	2.78**	2.27–3.40
Anxiety	5.65**	4.89–6.53	1.65**	1.38–1.98	3.40**	2.87–4.04	1.30*	1.06–1.69	13.31**	11.14–15.91	2.56**	2.03–3.22
Suicidality	6.31**	5.65–7.04	2.85**	2.50–3.26	4.11**	3.63–4.66	2.29**	1.98–2.65	15.45**	13.27–18.00	4.87**	4.02–5.89
Sensation-seeking and delinquent behaviors	3.22**	2.83–3.68	1.51**	1.29–1.77	2.47**	2.12–2.88	1.38**	1.16–1.64	5.40**	4.53–6.44	1.87**	1.48–2.33
Tobacco use	3.11**	2.84–3.42	1.76**	1.56–1.97	2.64**	2.38–2.93	1.71**	1.51–1.93	4.67**	4.04–5.40	1.93**	1.58–2.35
Alcohol consumption	2.75**	2.53–3.00	1.74**	1.56–1.94	2.30**	2.09–2.53	1.63**	1.45–1.83	4.32**	3.76–4.96	2.27**	1.89–2.72
Illegal drug consumption	3.69**	3.10–4.40	1.34**	1.08–1.65	2.63**	2.14 -3.22	1.17	0.93–1.47	6.70**	5.38–8.33	1.80**	1.35–2.39
Truancy	2.59**	2.14–3.13	1.17	0.93–1.48	2.18**	1.75–2.72	1.21	0.95–1.54	3.65**	2.81–4.73	1.06	0.76–1.47

*$p < .05$.
**$p < .01$.

much lower in the CASE study performed in 2006, namely, 13.5% for girls and 4.3% for boys across their European sample (Madge et al., 2008). It is possible that prevalence rates reported in the present study of 29.9% for girls and 24.6% for boys reflect an increase from 2006 to 2010 in self-harming behavior across Europe, particularly among boys. However, the CASE and SEYLE samples overlapped only in two countries (Hungary and Ireland), the age range was different (in SEYLE students were 2 years younger) and different assessment tools were used (the CASE did investigate DSH incl. suicide attempts), which decreases comparability. Nevertheless, most comparisons (young versus old, D-SIB vs. DSH) would be expected to result in lower lifetime prevalence within the SEYLE sample, which is not the case.

Gender differences

Female adolescents reported higher frequencies of engaging in D-SIB compared with male adolescents. However, gender differences in D-SIB were not found in all study countries, suggesting cultural influence, as confirmed by significant country-gender interactions. Higher prevalence rates of self-injury in females seems to be a very consistent finding both in population-based samples (Brunner et al., 2007; O'Connor et al., 2009; Plener et al., 2009), as well as in clinical samples (Kirkcaldy, Brown, & Siefen, 2006). The reasons for these gender differences are not yet clear. It has been argued that higher rates of depression and anxiety in girls could account for this (Hilt et al., 2008). However, we found that repetitive self-injury seems to be associated with severe emotional and behavioral problems in both genders. We also found that increased age on its own was a predictor of lifetime D-SIB (as expected); and younger age predicted D-SIB when controlling for all other psychosocial variables. A possible interpretation could be that younger adolescents with a similar load of psychosocial risk factors may be at higher risk of harming themselves.

The majority of adolescents from this study reported using multiple methods of self-injurious acts besides 'self-cutting', which is in line with former results (Whitlock et al., 2006). Gender differences were found for most of the methods reported. Girls reported higher frequency of overall D-SIB and self-cutting. In contrast, there was a gender-specific over-representation of self-burning and self-hitting in male adolescents.

Psychopathology

Consistent with previous studies, significant associations with depressive and anxiety symptoms were found in adolescents who engaged in D-SIB (Brunner et al., 2007; Hawton, Rodham, Evans, & Weatherall, 2002; Lloyd-Richardson et al., 2007). These

Table 5 Psychosocial variables showing significant interactions with country in the univariate regression model of D-SIB. In addition, both range and difference of change in probability of D-SIB [p(D-SIB)] by psychosocial variable are presented including the country with the lowest and highest change in p(D-SIB)

Explaining factors	Range of change in p(D-SIB)	Difference of change in p(D-SIB)	Country with highest decrease/lowest increase of p(D-SIB)	Country with highest increase of p(D-SIB)
Age	−3.6%–6.6%	10.2%**	Israel	Spain
Gender	−3.3%–19.7%	23.0%**	Ireland	Germany
Student perceived himself/herself as a religious person	−15.5%–14.1%	29.6%**	Ireland	Estonia
Parental unemployment	2.4%–21.6%	19.2%*	Austria	Germany
Parents do not understand student's problems	6.6%–23.4%	16.8%**	Italy	Germany
Parents do not pay attention to student	3.5%–20.0%	16.5%**	Italy	Germany
Loneliness/Social relationship problems	18.7%–58.6%	39.9%*	Romania	Ireland
Peer victimization	1.2%–37.4%	36.2%*	Romania	Austria
Depression	23.6%–44.0%	20.4%*	Italy	Ireland
Suicidality	27.3%–52.0%	24.7%**	Romania	Ireland
Sensation-seeking and delinquent behaviors	21.0%–43.5%	22.5%*	Romania	Ireland
Alcohol consumption	13.3%–40.1%	26.8%**	Italy	Ireland

*$p < .05$.
**$p < .01$.

Table 6 Medical treatment in the group of adolescents with D-SIB

	Frequency of medical treatment (%)			Gender differences	
Country	Females	Males	Total	OR	95% CI
Austria	1.35	0.58	1.06	2.36	0.50–11.19
Estonia	1.80	1.05	1.46	1.72	0.58–5.07
France	1.46	0.63	1.20	2.3	0.51–10.68
Germany	2.81	3.68	3.22	0.76	0.42–1.37
Hungary	1.02	0.74	0.90	1.39	0.34–5.58
Ireland	0.41	2.32	1.44	0.17*	0.04–0.78
Israel	3.98	6.10	5.69	0.64	0.31–1.31
Italy	0.37	1.57	0.76	0.23*	0.06–0.94
Romania	0.68	1.04	0.81	0.65	0.17–2.44
Slovenia	1.51	2.78	1.88	0.54	0.22–1.29
Spain	0.81	3.80	2.36	0.21**	0.07–0.61
Total	1.34	2.74	1.96	0.48**	0.37–0.63

*$p < .05$.
**$p < .01$.

findings indicate that D-SIB is strongly indicative of psychological problems that require professional attention. A strong relationship between D-SIB and suicidality (i.e., suicidal thoughts and suicide attempts) was shown in this study, as well as in former studies (Brunner et al., 2007; Nock, Joiner, Gordon, Lloyd-Richardson, & Prinstein, 2006). This relationship requires further investigation to address the current debate about whether self-injuries should be considered on a continuum of self-harm or regarded as a phenomenon separate from suicidal behavior (Nock, 2010). Joiner (2005) sees self-harm as a moderator that may increase the likelihood of suicidal thoughts being translated into actions. Consistent with this theory, longitudinal research showed that DSH is strongly associated with future suicide attempts (Cooper et al., 2005). In addition, the strong association with a broad range of risk-behaviors (substance use, sensation-seeking, and delinquent behaviors) has clinical implications, as D-SIB may be indicative of other risk-taking and self-destructive behaviors. These associations have been demonstrated in previous studies (Brunner et al., 2007), but whether risk-behavior may serve similar functions as D-SIB (e.g., to regulate intense negative emotional states) should be a focus of future research. The question whether D-SIB (e.g., self-cutting) and indirect harmful behaviors (e.g., substance abuse) should be considered on a continuum of self-harm has been raised by Holinger (1979) and Nock (2010), who proposed a model on a *'continuum of self-destructiveness'* in adolescents.

Psychosocial factors

The strong association between peer victimization and self-reported D-SIB emphasizes the crucial role of interpersonal factors, in addition to intrapersonal factors, in the occurrence of D-SIB among adolescents (Klonsky, 2007). To avoid punishment or to get attention have been described as important interpersonal functions of self-injury (Nock & Prinstein, 2004). Family related factors, like reduced parental involvement, but also parental unemployment, were strongly associated with D-SIB in our study, whereas family related factors like disruption of family composition did not show a strong relationship with D-SIB. These findings indicate that the quality of relationships within the family environment is a very important concomitant of self-harm, as stated in previous reports (Kaess et al., 2012; Wedig & Nock, 2007; Yates, Tracy et al., 2008).

It needs to be noted that in this study, the associations between psychological variables and D-SIB were much stronger for repetitive D-SIB compared with occasional D-SIB. However, all psychosocial variables also showed significant

associations with regards to occasional D-SIB. Given the large study sample, statistical significance should be interpreted cauciously. While variables with high RRR's like suicidality, anxiety, and depressive symptoms (all OR >3) seem to have large effects and may be of important clinical relevance in many cases, other variables (e.g. parental unemployment, parental attention to student) with lower RRR's may only have small effects, however, may be equally clinically important in the individual case.

In the present study, gender interactions have been found for variables related with parental involvement, as well as alcohol and substance abuse. The stronger association between lack of parental involvement and D-SIB in females may suggest a gender-specific vulnerability to lack of care or relationship difficulties with parents. A higher sensitivity to parent-child relationship has previously been reported for females with respect to suicidal behavior (Ponnet et al., 2005). Also, girls who engage in alcohol and substance abuse seem to be at higher risk of D-SIB compared with their male peers. Finally, male gender remained a significantly negative predictor of D-SIB when adjusting for all psychosocial variables in the multivariate model, which may suggest at least some gender-specific vulnerability for D-SIB.

Intercultural variations

Psychosocial correlates of self-harm thoughts have recently been reported to show intercultural variations. Kokkevi et al. (2012) found that substance abuse was more predictive for suicide attempts when it was reported in countries with a generally low prevalence of substance abuse. Our study is the first to show that several psychosocial risk factors of D-SIB have high intercultural variability. In Germany, for example, variables of family environment had a very strong influence on D-SIB, whereas risk behaviors and psychopathology showed the highest influence in Ireland. In Romania, only a marginal influence of psychopathology and risk behavior on D-SIB was present, whereas parenting variables showed almost no influence on D-SIB in Italy. The results on country interactions are very complex, and may be difficult to interpret. However, they indicate that cultural differences may strongly impact the relevance and influence of certain risk factors, which should be taken into account in prevention and clinical intervention among adolescents engaging in self-injury.

Medical treatment

Only a small minority of the affected adolescents reported to have had received medical treatment after D-SIB, which is in agreement with several other population-based studies (Deliberto & Nock, 2008; Hawton et al., 2002; Ystgaard et al., 2009). The reason for this can be that the D-SIB physical injuries are often mild and kept in secret as self-harmers find consolation in peers with similar behaviors, which constitutes a challenge to the public health system to identify those who self-harm (Heath, Ross, Toste, Charlebois, & Nedecheva, 2009; Sanci, Lewis, & Patton, 2010; Tylee, Haller, Graham, Churchill, & Sanci, 2007). The observed gender differences in our study may show that males are likely to engage in more severe D-SIB, which could consequently lead to higher rates of medical treatment. A gender pattern of lower frequency but higher severity among males is a well-known phenomenon, based on suicide attempts among adolescents (Beautrais, 2002).

In general, our findings suggest that both repetitive and occasional D-SIB require professional attention, but this is not to say that all young people with occasional self-injury need mental health treatment. A study from the general population (Moran et al., 2012) indicates that the majority of young people's self-injury behavior will remit in short periods of time, but other findings (e.g. Bergen et al., 2012; Wilkinson, Kelvin, Roberts, Dubicka, & Goodyer, 2011) suggest that a history of self-harm is an important clinical marker for subsequent suicide attempts, other negative health outcomes and death. Therefore, young people with occasional D-SIB might at least deserve further investigation and examination of their mental health status. Future longitudinal studies are needed to identify young people with risk constellation who require mental health care or other preventive interventions according to a staging model (McGorry, Hickie, Yung, Pantelis, & Jackson, 2006). Further research on specialized treatments for self-harming adolescents is critical (Fischer, Parzer, Resch, Brunner, & Kaess, 2013) as there are currently no independently replicated efficacious interventions available (Ougrin, Tranah, Leigh, Taylor, & Asamow, 2012).

Limitations and strengths

A limitation of these analyses is that the prevalence estimates of D-SIB, as well as the assessment of all psychosocial variables in this study, relied on self-report. However, standardized and validated instruments were used in SEYLE, although our modified 6-item D-SIB questionnaire did not distinguish between direct self-injury with and without suicidal intent, which may be another limitation. It needs to be noted that judgment of suicidal intent of self-harming acts by adolescents' self-report is questionable and may lack reliability. The fact that the study reports on a cross-sectional analyses is another limitation. Only longitudinal data can give information about causality.

A major strength of this study is the large non-clinical population-based sample of adolescents, recruited from randomly selected schools, across

eleven study sites, which were reasonably representative of their respective European country (Carli et al., 2013). The students were recruited and evaluated in each country with homogenous procedures and measurements. Furthermore, to our knowledge, this study of adolescent lifetime D-SIB comprises the largest geographic area distributed over many countries ever reported.

Conclusion

More than every fourth adolescent in Europe was found to have engaged in D-SIB during lifetime; females showing higher rates of occasional self--injury, with a special preference for self-cutting.

Suicidality demonstrated the strongest association with D-SIB, which confirms the role of direct self--injury as a possible indicator or mediator of adolescent suicidal behavior. A strong association of D-SIB was also shown with other psychopathology, risk behaviors, family related problems and neglect, as well as peer-related rejection/victimization.

The majority of adolescents who engaged in D-SIB did not receive any professional help nor did they seek help after their self-injury. Although this may often be due to mild injuries, it is important to enhance our understanding of the barriers in receiving specialized treatment services. In addition, there is an urgent need to improve treatment development and research in the field of adolescent self-harm.

Across the eleven European countries, the frequency of D-SIB was wide ranged, which calls not only for psychiatric and medical, but also for multidimensional explanations including social and anthropological studies on cultural differences.

Supporting information

Additional Supporting Information may be found in the online version of this article:

Table S1. Cut-offs in the SEYLE study for adolescent risk-behaviour and psychopathology

Table S2. Odds ratios of the prevalence of total D-SIB by country

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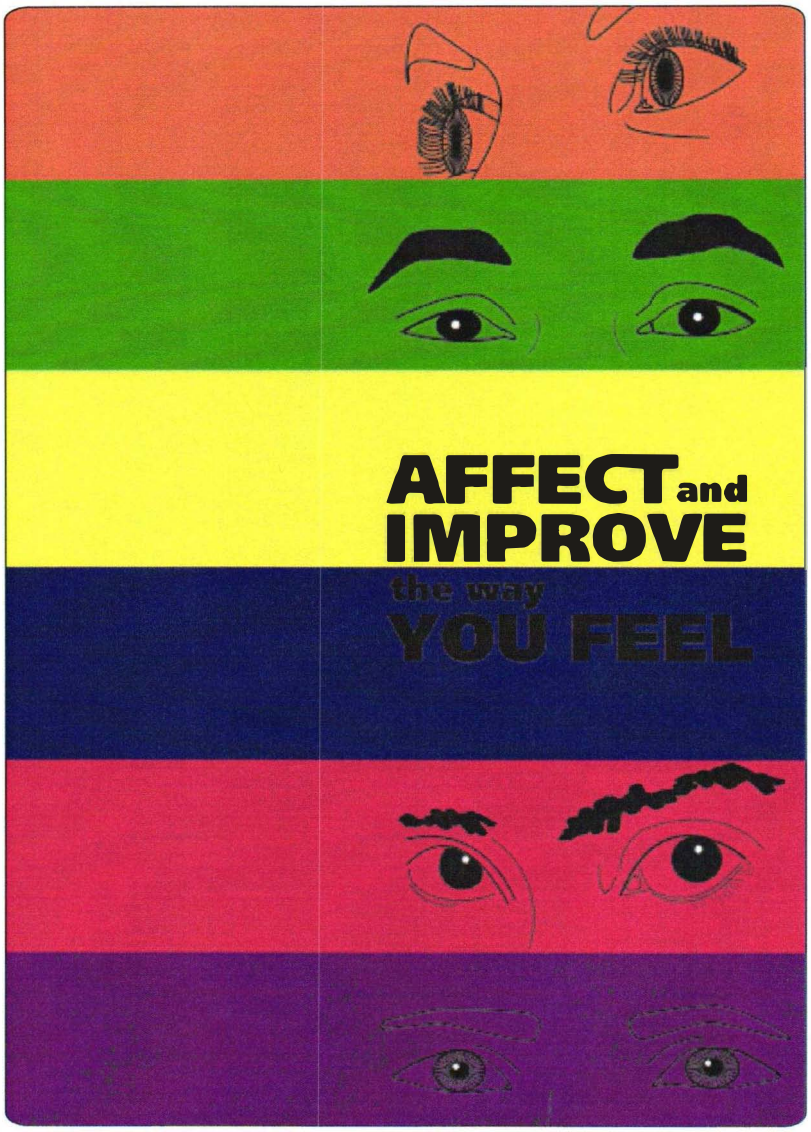

Suicide prevention for youth - a mental health awareness program: lessons learned from the Saving and Empowering Young Lives in Europe (SEYLE) intervention study

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Suicide prevention for youth - a mental health awareness program: lessons learned from the Saving and Empowering Young Lives in Europe (SEYLE) intervention study

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Abstract

Background: The Awareness program was designed as a part of the EU-funded Saving and Empowering Young Lives in Europe (SEYLE) intervention study to promote mental health of adolescents in 11 European countries by helping them to develop problem-solving skills and encouraging them to self-recognize the need for help as well as how to help peers in need.

Methods: For this descriptive study all coordinators of the SEYLE Awareness program answered an open-ended evaluation questionnaire at the end of the project implementation. Their answers were synthesized and analyzed and are presented here.

Results: The results show that the program cultivated peer understanding and support. Adolescents not only learned about mental health by participating in the Awareness program, but the majority of them also greatly enjoyed the experience.

Conclusions: Recommendations for enhancing the successes of mental health awareness programs are presented. Help and cooperation from schools, teachers, local politicians and other stakeholders will lead to more efficacious future programs.

Keywords: Youth, Adolescents, Mental health, School-based, Awareness program, Suicide prevention, SEYLE, Intervention

Background

Suicide prevention in youth

Every completed suicide has a devastating effect, but when a young life is cut short, the shock is oftentimes even greater. Suicide is a complex phenomenon, thus, the prevention of it needs to be tailored accordingly [1,2]. Prevention can occur on both the individual and societal level, with the most effective strategies being a combination of efforts [1,3]. An obstacle in the effort to combat suicide is the difficulty in identifying exactly which at-risk individuals will commit suicide [4-6]. Consequently, by informing the public and encouraging a general awareness of mental health problems including suicide, an increased alertness and responsiveness to suicidal individuals will follow [7]. In an effort to make such suicide preventive strategies effective and culturally appropriate, it is important to consider local attitudes toward suicide, and how to target suicide prevention and

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mental health interventions. Furthermore, it is imperative to take into account the feelings of pain and grief experienced by any community or individual that has encountered a suicide.

Stigma, developmental changes and peer pressure lead to adolescents being particularly in need of specifically tailored preventive strategies [8,9]. Youth rarely look for help from professionals. The reasons for this are many and difficult to disentangle; perhaps the healthcare system is not adequate, or there are none or few mental health professionals available, but it can also be related to developmental changes, increasing sense of self-autonomy and attitudes toward adult intervention. Young people may not ask for help because they see it as a failure in the process of becoming self-sufficient [10-12]. They may believe growing up means being able to cope with their problems by themselves. Perhaps they consider their problems unique and therefore unsolvable, be it by professionals or anyone else. Oftentimes young people are reluctant to look for professional help because of the stigma of mental illness and, for similar reasons, they may also be afraid to address the issues of mental pain to their peers [13]. Thus, it is important to consider all of these factors when creating suicide prevention programs for youth.

Awareness programs for youth

It is well known that the majority of young people will not actively seek help from professionals, parents, teachers, and oftentimes not even from their peers [9]. With this in mind, how can youth suicide effectively be prevented? In 2002, the World Psychiatric Association (WPA) launched a 9-country pilot study in order to raise the knowledge and awareness about mental health in young people. The assumption was that sound information would facilitate communication about mental health concerns, without raising unrealistic expectations about professional help that was generally unavailable [14,15]. In the WPA 9-country study, the awareness campaigns were locally designed and, thus, culturally adjusted to be acceptable for the local population. The results showed that it was possible to change attitudes, including those about suicide, by influencing the behavioral responses of the pupils and parents that partook in the study with slightly poorer results for the participating teachers. Building on that pilot study, an awareness program for adolescents was designed for the Saving and Empowering Young Lives in Europe (SEYLE) study, funded by the European Union within the 7^{Th} Framework Health Theme.

The SEYLE study

SEYLE is a randomized-controlled intervention trial (RCT) designed to assess the effects of three different health-promoting intervention programs in comparison with a control group in which a minimal intervention was carried out. The study methodology has been described previously in detail [16]. The intervention programs consisted of:

1. Awareness Program – a health promotion program, designed to empower pupils by increasing their awareness of mental health, as well as healthy/unhealthy behavior and teaching them skills to diminish unhealthy behaviors [developed for the SEYLE study by Columbia University and Karolinska Institutet/National Centre for Suicide Research and Prevention of Mental Ill-Health (NASP)].
2. QPR (Question, Persuade & Refer) – a gate keeping program designed to educate teachers and other school-based adults in identifying at–risk adolescents and referring them to mental health facilities [17].
3. ProfScreen – screening by professionals for the purpose of identifying pupils at high risk for mental illness and/or suicidal behavior. The program includes a referral procedure, wherein pupils identified as at-risk of mental illness or suicidality were referred to mental health treatment; this program was specifically tailored for the SEYLE study, by the Heidelberg University and Karolinska Institutet/NASP research groups.
4. Minimal Intervention (control group) – providing pupils with information materials (posters on the classroom walls), containing basic information about mental health (e.g., warning signs of crisis and mental illness, how and where to seek help). This intervention served as the control arm.

In the SEYLE study, effectiveness of the respective interventions on adolescents was compared between the interventions and the control group.

Awareness program in the SEYLE study

In the SEYLE study, the Awareness program was developed to target adolescents between 14–16 years old and to meet their mental health-related needs. The strategy of the program was to integrate different types of learning in order to guide the adolescents through difficult topics. One of the most effective ways to target changes in youth is to combine both a cognitive and emotional training program [18,19]. Cognitive learning was achieved through lectures about mental health and mental disorders, and experiential and emotional learning through role-play sessions, as well as an overall hands-on approach to sensitive issues. The four-week interactive program prescribed a stimulating environment without involvement of the regular schoolteachers/staff in order to diminish concerns of being judged. Guided by a trained instructor and at least one assistant, the adolescents were given an

opportunity to learn from peers, whilst reflecting on personal experiences and problem-solving techniques by actively using their newly acquired skills in the role-play sessions [20,21].

Before the implementation of the program and during the preparatory phase, site-visits were made by members of the SEYLE consortium steering group in order to ascertain that the protocol was followed. The site leaders, along with the coordinators of the Awareness program and the instructors appointed to lead the role-play sessions were trained in the many facets of the study methodology; the procedures were stipulated in a detailed 31-page instruction manual [21]. The Awareness coordinators were child psychiatrists or psychologists, many of whom had prior experience with psychodrama or role-play.

The program started with a baseline assessment. The core of the program consists of an opening lecture, three role-play sessions, and a closing lecture with a discussion. In the SEYLE study, each session lasted 45–60 min and the whole program was carried out during four weeks, in a total of five hours plus one additional hour for the baseline questionnaire that served as an introduction and first contact with the students (Figure 1).

A didactic and pedagogical booklet (Figure 2): "Affect and Improve the Way You Feel" [20], specifically created for the Awareness program was distributed to all students. The booklet contained the following themes:

1) Awareness of mental health
2) Self-help advice
3) Stress and Crisis
4) Depression and Suicidal thoughts
5) Helping a troubled friend and
6) Getting advice: Who to contact

The booklet of approximately 25 pages was designed for the SEYLE study in close collaboration with a graphic designer who had prior experience in public mental health research and prevention. It was translated, back translated and, when needed, culturally adapted to fit the local languages of the participating sites. In Israel the booklet was translated into both Hebrew and Arabic. The booklet was designed so that it could be kept as a future resource for the pupils at the end of the Awareness program. The content of the booklet served as a framework for the role-play sessions and was introduced to the pupils during the opening lecture in a power point presentation. Similar information was also briefly summarized in the six posters that were hung in the classrooms.

In the SEYLE study it was recommended that 10–15 students per instructor participate in the role-play sessions. Through role-play sessions and the ensuing discussions, the students learn about mental health related problems, whilst developing a set of problem-solving skills to assist them in distress, as well as the ability to identify circumstances in which the skills should be applied. They get the opportunity to identify reasons for, and ways to prevent the escalation of problems and to explore the potential effects on the people directly and indirectly involved. In order for role-play to be an effective tool, all questions and thoughts expressed by the pupils need to be thoroughly discussed. This provides the pupils with an opportunity to explore specific situations (e.g. being bullied in school, a family crisis, moving to a new town, feelings of depression and suicidal thoughts) that could otherwise appear threatening or difficult in an unsafe environment. They were taught and given the chance to practice how to express empathy, to appreciate other peoples' perspectives and how to stand up against peer-pressure. The sessions gave also the opportunity to talk about the responsibility of school staff and adults, for example in the case of bullying. Finally, in the closing lecture, all the topics discussed are summarized by using the same power point presentation as in the opening lecture. In

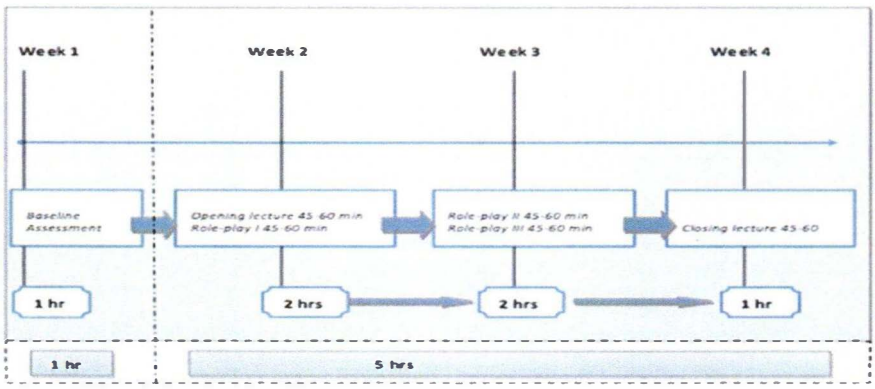

Figure 1 Awareness program timeline in the SEYLE study.

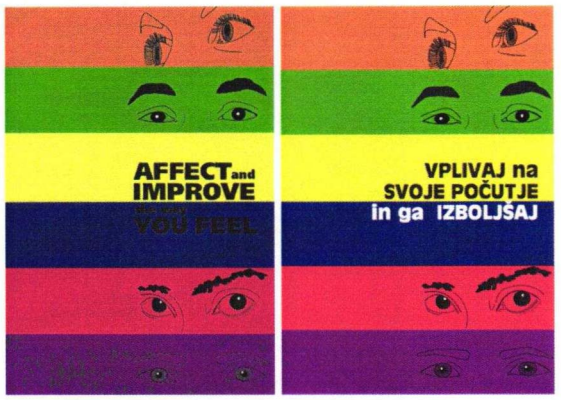

Figure 2 Booklet cover pages (English and Slovene booklets).

this final meeting with the students, particular attention is given to the contact information found at the end of the booklets. In every SEYLE site, local information with the names and telephone numbers of people in the healthcare system and other community-based support networks were provided for students to seek help.

The instructor's role

In addition to the Awareness coordinators, the program was carried out by a team of competent instructors (also called facilitators). The procedures manual stated that the instructor should hold a Masters or higher degree in psychology, public health, social work, pedagogy, or of an equivalent discipline. It was also recommended that the instructor have at least one assistant during the labor-intensive role-play sessions. Some sites even decided to hire professional psychodrama therapists to lead the role-play sessions. The instructors were asked to keep a journal during the time of the intervention program, keeping track of any and all deviations from the protocol and all cultural adaptations.

Aim

In this descriptive study, the Awareness program field experiences are captured by using first-hand information from the 11 SEYLE sites, as such, generating recommendations and enhancing the future potential of such a suicide prevention strategy.

Ethical permission

Ethical permission for the project, including the permission to follow up individual pupils, was obtained in each one of the eleven participating countries by their respective Research Ethics Committees, namely: Austria: Ethikkomission der Medizinischen Universität Innsbruck; Estonia: Tallinna Meditsiiniuuringute Eetikakomitee; France: Comité de Protection des Personnes Sud-Méditerranée II; Germany: Ethikkommission Medizinische Fakultät Heidelberg; Hungary: Egészségügyi Tudományos Tanács Titkárság, Tudományos És Kutatásetikai Bizottság; Ireland: Clinical Research Ethics Committee of the Cork Teaching Hospital; Israel: Helsinki Committee at the Rabin Medical Center; Italy: Comitato Bioetico Di Ateneo, Università Degli Studi Del Molise; Romania: Comisia De Etica, A Universitatii De Medicina Si Farmacie, Cluj Napoca; Slovenia: Komisija Republike Slovenije za medicinsko etiko; Spain: Comité Ètico de Investigación Clinica, regional del Principado de Asturias.

Methods

Sample

The SEYLE Awareness program was carried out within well-defined catchment areas in eleven countries: Austria, Estonia, France, Germany, Hungary, Ireland, Israel, Italy, Romania, Slovenia and Spain. In those eleven catchment areas, 179 schools were randomized into one of the four non-overlapping intervention study Arms. The participation rate of pupils was 88% at baseline. A total of 12, 395 pupils from both metropolitan and micropolitan areas participated in the study, of which 6799 were females and 5529 were males (67 subjects had missing gender data), with a mean age of 14.9 ± 0.9. Description of the methodology and material employed is given in another paper [22]. A total of 3016 pupils participated in the Awareness program Arm (55.2% females and 44.8% males).

In this paper, we examine the experiences and opinions about the Awareness program of the 11 SEYLE Awareness coordinators.

Procedure

In order to examine the strengths and weaknesses of the program in this descriptive study, we asked all the Awareness coordinators the following set of open-ended questions about the program implementation.

1) What did you like most about the Awareness program?
2) What did you like least about the Awareness program?
3) What did the pupils like most about the Awareness program?
4) What did the pupils like least about the Awareness program?
5) How did the schools and teachers like the Awareness program?
6) What would you change in the Awareness program if you could?
7) What parts of the intervention needed to be culturally adapted for your specific country?

8) Was there a difference between the participating schools? Classes? In their willingness to participate, how they participated, what they thought, etc.
9) How much effort did the organisation of the Awareness program take?
10) In your opinion, was the effort worth the outcome?

Upon completion of the Awareness program, the coordinators in all sites were asked to answer the above-mentioned questions in writing.

Data analysis

The written answers to the open-ended questions were analyzed by the first and the last author of this paper independently, with the processing of the material performed in a number of steps. As recommended by Pope et al. [23] the coding process was conducted with researchers from different backgrounds (in psychology, public health and anthropology).

To begin, each response was reviewed independently by two assessors (VP and CW). Secondly, in order to identify emergent topics and to ascertain meaningful and broader themes, words and sentences were grouped together [23-25]. After distinguishing the themes, the two assessors independently scrutinised the whole material again before comparing their results. The interpretations were mostly congruent, but in the case of discrepancy regarding which theme an answer belonged to or having different opinions about the naming of the theme clusters, a third independent assessor (DW) was consulted and the final classification and grouping of responses into theme clusters was obtained with consensus.

Importantly, the themes describe multifaceted phenomena that are broad in nature, but for the purpose of analysis are grouped together [24]. Several themes describing similar topics were combined, e.g. *role play and expressing feelings* includes what the coordinators described as the possibility of practicing the expression of emotions through acting and *improved coordination (with schools and staff)* represents organisational difficulties such as scheduling with schools, meeting teachers and headmasters as well as recruiting staff. As a last step, a general description of the responses was written, serving as the basis for the results reported in this article. Issues that were voiced by some sites in particular are emphasised in the result description by adding the name of the country in parenthesis. The Awareness coordinators as well as the principal investigators of each of the sites were given the opportunity to comment on the interpretation of the responses.

Results

Strengths of the awareness program

The Awareness coordinators from all sites drew attention to the particular design of the program that gave space for discussing important mental-health related topics, which otherwise go unaddressed. In 6 of the 11 participating sites (Austria, Estonia, Germany, Hungary, Italy, Slovenia), the coordinators underscore that talking about mental health problems and emotions is still uncommon, shameful and stigmatised. Figure 3 shows the aspects of the Awareness program that were most appreciated across sites.

From the evaluation results, and as intended, the adolescents used the role-play as an opportunity to discuss their feelings, and they were eager for this kind of experience (Austria). Adolescents particularly appreciated the opportunity to talk about topics such as problem-solving, depression, anxiety, bullying (Austria, Germany, Israel), stress and crisis situations (Spain), pregnancy, conflicts with parents and teachers (Romania), and also suicidal behavior (Slovenia, Israel). The experience in France also showed that it was important that positive aspects of health were addressed. In Estonia, it was noticed that, in schools with a higher

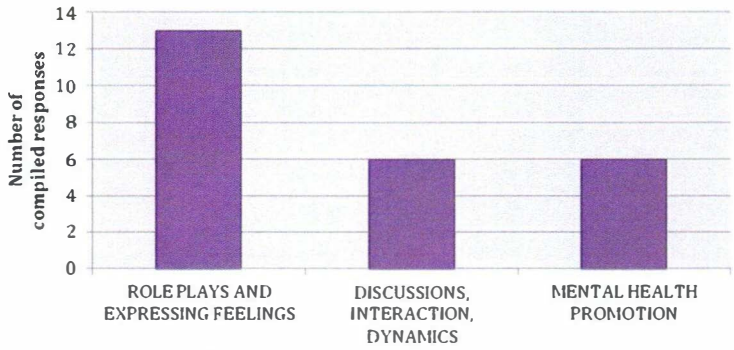

Figure 3 Reasons for appreciation of the awareness program. Due to the fact that the Awareness coordinators responses were compiled into theme clusters the charts show the number of compiled responses and not the percentage of responses.

proportion of children with social problems, more serious topics emerged during the role-play sessions.

According to the Awareness coordinators, the program successfully promoted social networks in all countries. Pupils often reported that, when they are in distress, they do not have anyone to talk to (Hungary, Israel). The Awareness program addresses this problem in two ways: First, pupils are informed about different kinds of professional support. Second, the Awareness program promotes peer support. The importance of peer support is emphasised directly with guidelines on how to help a friend in need and indirectly by developing empathy. By participating in the program, the youth got to know each other in a deeper way, often realising that they were not alone with their problems, and that classmates, who they often didn't know very well, shared similar problems (Hungary). Students also learned the importance of offering support to peers, instead of avoiding their problems, and learned how to do it more effectively. All countries report positive outcomes in this regard. In some cases, the Awareness program also contributed to stronger class bonds (Hungary) or an improved general school-climate (Israel) as reported by students to the instructors.

Interactive workshops as a means of prevention

The adolescents and instructors alike appreciated the interactive approach of the Awareness program. The relaxed atmosphere of the role-play sessions proved to be a good point of departure for discussion, and a way to approach the youths' thoughts and feelings. The instructors often noticed that pupils had difficulties expressing their feelings in words (Austria, Germany, Israel, and Slovenia). The role-play sessions provided them with the opportunity to communicate, express and verbalise their feelings, not only to the facilitator, but also to their peers. They were able to overcome their fears of expression, and open up in a more relaxed way (Austria, Italy). The interactive approach engaged pupils, and they preferred it to the standard classroom set-up, or the ex-cathedra approach, which is still the predominant way of teaching in many schools across Europe. Not only the pupils, but also the instructors, liked the variety of verbal and written materials used in the Awareness program, as well as the more interactive components in contrast to the lectures (Austria). There were reports from all participating countries about students approaching the facilitators after the end of the program, telling them about their problems. Moreover, school counsellors noted that the Awareness program lead to the development of networks with the clinical sector, specifically by providing information on the treatment of pupils in distress, much to the benefit of the perceived quality of care in the schools (Slovenia).

The instructor from the Irish site gave the example of how a young boy actively used the booklet as a means to speak to his mother about his feelings and worries. The mother came to the school after one of the sessions to speak to the instructor; she had noticed a marked change in his mood and was very thankful. The instructor also noticed that the boy had become more vocal as the Awareness sessions proceeded.

Moreover, the instructors reported changes in the adolescents' behaviors as the 4-week program progressed; it was evident that, from participating in the role-play sessions, the youth developed problem-solving skills when faced with different situations (Ireland). Additional analyses are required to learn how this potentially translates into everyday life and in preventing mental health problems.

The schoolteachers expressed the importance of having a person from outside the school-system to perform the program (Austria), avoiding possible distrust of more familiar instructors. The emotion that they could express their views and emotions in a safe environment, without prejudice and fear of ridicule, was a very powerful aspect (Ireland, Romania). Pupils indicated that they liked that the instructors were open-minded and young, and someone to whom the pupils easily could make a connection with and feel close to. With all of this in mind, it is very important to assemble, train and manage a team able to deliver this kind of program to young people (Ireland, Romania).

The shortcomings of the awareness program and proposals for future modifications

The shortcomings of the Awareness program, as voiced by the instructors, mostly concern the lack of flexibility due to the RCT design and the tight time frame in the implementation of the workshops. It was difficult to assure that the needs of all pupils were met, or that all topics were equally addressed, explained and/or understood with the same depth. Some topics (e.g., serious mental health problems like depression or suicide) were more difficult to comprehend for some adolescents and, thus, a challenge for the instructors to convey in such a brief period of time.

The question of allocating more time for role-play sessions, e.g. 2 h instead of 45–60 min, was raised. The current program included an opening lecture that was considered by some to be too theoretical in nature and, consequently, not as well accepted as the interactive role-play sessions (Austria, Israel). Moreover, pupils thought the time frame for each session was too short (France).

Burden of the program for the school system

A potential obstacle to successfully implementing the Awareness program is the response of the school authorities, school staff, and their parents. In some cases,

teachers and school staff were sceptical about the pupils' motivation to participate in such a program. Ensuring that the entire teaching body appreciates the benefits and efforts of such a program is beneficial to the implementation (Ireland). As the Awareness coordinator typically was in touch with the school principal and guidance counsellors across their site, many coordinators underscored that it proved to be helpful when the principal and/or guidance counsellor were asked to inform all teaching staff about the program. It also happened that some parents and teachers refused or discouraged pupil participation in the program, because they would miss too many classes (Austria, France, Germany, Hungary, Israel, and Slovenia). It would be helpful therefore to place hand-outs with information about the Awareness program in the staff room in order to ensure familiarity among the entire teaching staff (Ireland). In fact, the benefits of this kind of intervention program may not be obvious to everyone, especially parents (Hungary, Slovenia). In some schools, the Awareness sessions were scheduled after school and since many pupils attend other after-school activities, this could have influenced participation rates in the program.

A more holistic program and a longer time frame

The most important aspects that the coordinators wish to change in the program are shown in Figure 4 below. Many of them mention the short time frame of the program and the value of a more flexible schedule, as well as the advantage of a less rigid approach to the dissemination of content, expressing some reservation regarding the structure of the opening lecture and the somewhat intrusive posters. Instructors and students alike expressed the desire for an Awareness program that would last longer (Germany, Hungary, Ireland, Italy, Slovenia, and Spain), and for the structure of the program to be changed to two longer workshops, instead of three shorter ones (Estonia). Additionally, a wish to address other topics was expressed by the coordinators, such as: sexual behavior (Slovenia), sexual orientation (France), influence of emotions and thoughts on behavior (Romania), practice with behavioral techniques about how to talk to peers in distress (Hungary).

Materials and tools of interaction

In addition to the role-play, discussions and problem solving that were part of the SEYLE Awareness program, adding other kinds of interactive teaching could further strengthen the program. Among these learning from videos (Italy) expressive arts techniques or even action teaching were mentioned (Slovenia).

Moreover, in some countries (Germany, Slovenia) pupils did not like the posters, as their design or style was not appealing and was sometimes considered too intrusive. This issue can be dealt with by minimising the amount of text on them and by giving more attention to the design. One problem with the posters, in addition to their somewhat simple design, was that they were printed locally, and the quality of the prints varied greatly from site to site. The Awareness and instruction booklets were all printed in Sweden at a printing company and, consequently, were of high quality and uniform across sites.

A cross-country comparable awareness program

In the SEYLE study, the Awareness program was implemented in an identical fashion across the 11 countries. According to the SEYLE protocol, the sites were encouraged to, if needed, culturally adjust the content of the role-play examples and to account for these adjustments by keeping a journal at the time of program. In some

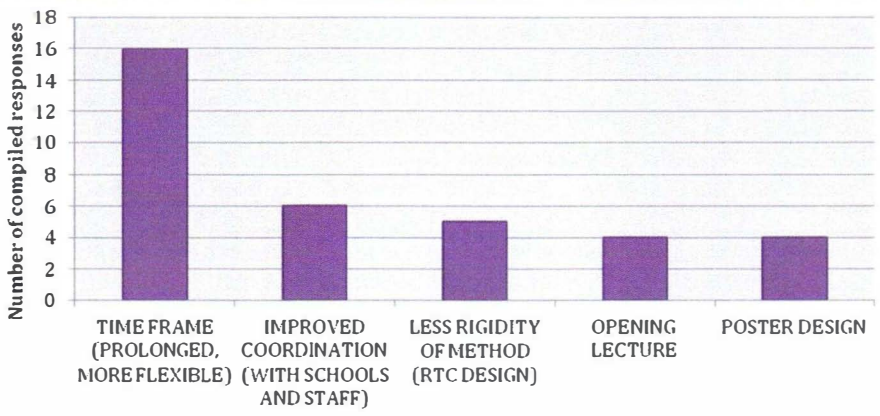

Figure 4 Proposed modifications of the awareness program. Due to the fact that the Awareness coordinators responses were compiled into theme clusters the charts show the number of compiled responses and not the percentage of responses.

cases, some of the role-play examples from the instruction manual were not used or, if used, applied in a modified fashion. Nonetheless, all participating sites addressed the same topics, as it is important in a cross-country primary preventive RCT to have well-structured tools and clear guidelines on how to work with pupils, so that the instructors could be easily trained, and the obtained intervention results to be comparable across schools and countries.

Flexibility vs. uniqueness

The short time frame of the program (four weeks) was stipulated because of the SEYLE study research-design, aiming to compare different intervention outcomes. For future implementation of this kind of preventive program, the structure and the time frame of the intervention can also be tested, since it is often difficult to offer it in an identical way in different countries and school-settings. The Awareness program stimulates the pupils' thoughts and feelings, as such, creating a need for a space for continuous discussion, something that should probably be integrated into the ordinary school curriculum. In the Hungarian case, a group of pupils decided to continue meeting together weekly to discuss their problems among themselves at the end of the program. Moreover, coordinators from most of the sites underscored that the program was more successful in those schools where the number of pupils per session was fewer, as well as when more time was given for discussion. It was interesting to note that, in Austria, girls were more interested and open than the participating boys and, in Ireland, boys offered better advice when taking part in the role-play sessions compared to girls, especially, around the topic of pregnancy. In Romania, pupils from smaller towns were more involved and had a lot of questions during the introductory lecture, whilst pupils from bigger towns had higher expectations, expressing views about mental health that they had read about on the Internet and in other sources. Schools with pupils of lower Social Economic Status (SES) had lower participation rates (Hungary) and some adjustments of the program had to be made according the type of school (Slovenia).

In summary, the key lesson is to uphold flexibility in discussion with the adolescents, taking into consideration the specific context of every classroom. Despite many challenges with the scheduling of the workshops in different schools and classes and other organisational efforts, all site Awareness coordinators reported that these were well worth it in relation to the satisfaction and appreciation expressed by the pupils (see Figure 5).

To overcome logistical difficulties as well as those related to the attitudes of the schools and parents, it is important that stakeholders, politicians, school-rincipals, teachers and parents understand the importance of such a mental health and Awareness intervention program, including its' aims and design and that they support it (Israel, Germany, Hungary). It is also important to have close collaboration with other systems (e.g. social and health care system) as specified in the SEYLE protocol, to be able to provide professional help and back-up to adolescents in need.

Discussion

By asking the field coordinators open-ended questions about their experiences we have been able to gain a deeper understanding of the implementation of the Awareness program, complete with its' difficulties and real-life situations. Research shows that a self-administered instrument of open-ended questions is practical and useful tool for evaluation [25].

The major strength of the Awareness program as proclaimed by the coordinators is its' subtlety in content and execution. When addressing sensitive issues such as mental health, risky life-styles and suicide, it is important not only to be cautious and sensitive to cultural differences, but also to personal histories. Awareness programs for adolescents that are both effective and culturally adaptable need to be carefully developed, considering attitudes towards suicide and mental healthcare in general. Moreover, suicidal behaviors vary across countries, by gender and across the lifespan [26-28], with many other factors influencing these behaviors, such as a variety of cultural expressions, stigma, access to lethal means of suicide, lack of a medical/mental healthcare infrastructure; all of them usually linked. Risk and protective factors at the individual, as well as the larger societal level, need to be taken into consideration. A preventive effort specifically tailored for adolescents needs to be thorough in its approach; yet open to flexibility, allowing the youth to express themselves freely in a safe environment. Since it is very difficult to identify which adolescents are most at risk for suicide, increasing the general mental health awareness whilst encouraging youth to self-recognize the need for help, as well as to help peers in need, may lead to fewer suicides.

The SEYLE Awareness program helps the adolescents to develop a large set of skills and knowledge about mental-health: functional knowledge (knowing about Mental Health), procedural knowledge (knowing how/having skills) and conditional knowledge (knowing the circumstances in which to use the skills). This know-how is expected to lead to a heightened responsiveness to individuals with psychiatric, behavioral and/or emotional problems, or suicidal individuals, whilst diminishing the general stigma surrounding mental health. Accounts from the field demonstrate that the pupils not only learned new information by participating in the

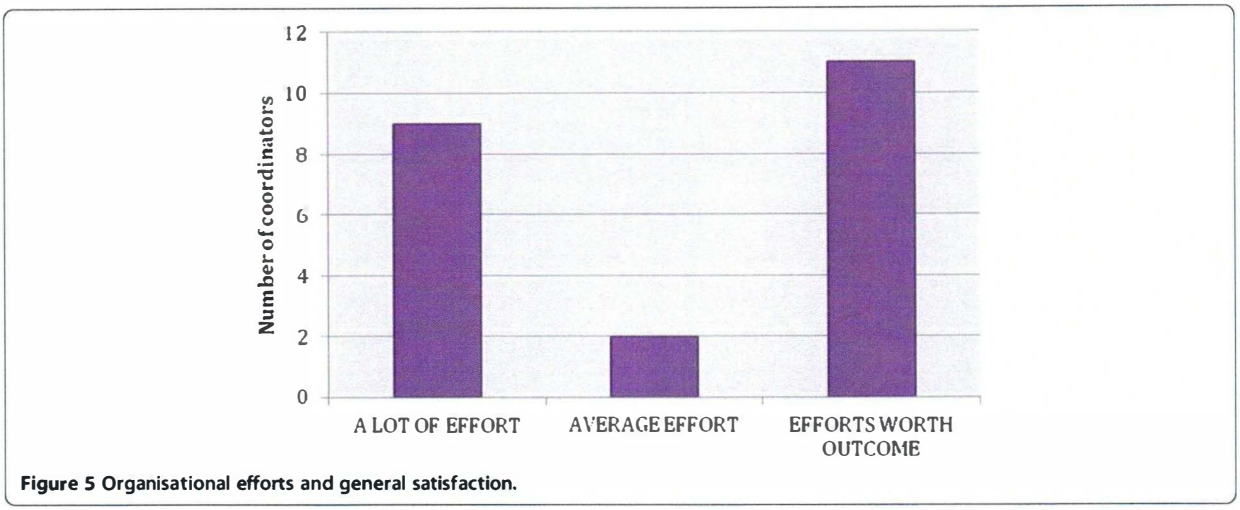

Figure 5 Organisational efforts and general satisfaction.

Awareness program, but the majority of them greatly enjoyed the experience.

Schools provide a well-structured environment that allows large international interventions, such as the SEYLE Awareness program, to run according to a *priori* defined rules that can be compared across different countries in spite of the many potential, imagined and real cultural differences. Though the school environment provides us with the best setting for programs aimed at adolescents, it is by no means an easy system to navigate and one of the more difficult aspects of the Awareness program was, in fact, the enormous organisational effort required from of the coordinators and their teams working with many different schools and teachers, during a short time period, especially to achieve adequate time in the school curriculum. Of course, the conditions of a study are in many ways much different than those encountered in real life, and we recommend that future Awareness programs take into account the problems encountered in the SEYLE field and the suggestions given here. The structured nature of the current program is inherent to a research study, but in a real-life setting, the time frame for each of the topics raised could be more flexible according to the specific class context and issues raised during the session. The incorporation of video materials and other types of learning methods may also be effective, but needs to be evaluated.

Suppleness in organisation and structure and listening to the thoughts and wishes of the participating adolescents is key to a successful program. The Awareness program is highly contextual and the feedback from the coordinators shows that the local context significantly influences the outcome of the program; every classroom is different, and consequently flexibility is central to a successful implementation. In the case of the SEYLE randomized controlled trial, it was necessary to execute the program in a structured manner to allow for effective comparison across sites through standardised methods. Much of the criticism from the Awareness coordinators dealt specifically with the more rigid aspects of the program; specifically the time frame but also the posters that were deemed too conspicuous in relation to other more adaptable aspects of the program.

In summary, the following guidelines can be helpful for people working with youth mental health awareness:

- Prepare a well-structured program with clearly defined aims, but allow flexibility and an individual approach.
- More time should be allocated to the variety of topics raised and to role-play and discussions with at least an additional five hours added to the program, resulting in a ten-hour program.
- Facilitators need to have a proper professional background and training, but also need to have specific personality traits (e.g. openness, ability to listen and make quick decisions) to create a safe environment.
- Topics should be addressed in a way that gives an opportunity to develop problem-solving skills and empathic attitude whilst creating an enjoyable and inspiring experience. Difficult topics should not be avoided, rather need to be addressed with care and close involvement of the participants.
- The key messages need to be disseminated through different materials and tools of interaction.
- Cooperation, understanding and support from stakeholders are crucial for success; the school system is the most effective system to use.

Therefore, logistical issues (schedules, size of group, etc.) need to be tailored according to the needs and available resources.

- Holding an information event prior to the Awareness program to encourage teachers and parents to allow the children to participate by providing them with the opportunity to gain a better understanding of the aims and benefits of the program is beneficial. This informal meeting gives the parents an opportunity to meet the awareness coordinator and helps to demystify the program and make it more tangible for parents.
- Evaluation of the program should be done with pre-post assessments and also with process-evaluation.

Limitations of this paper

The above-mentioned suggestions for successful awareness programs only take into account the issues raised by the set of questions the SEYLE Awareness coordinators were asked. For a more profound understanding of the program and it's successes and failures, similar questions need to be asked to the participating adolescents as well as to teachers and other school personnel.

Only questions with open-ended answers were used in this evaluation. On the one hand, this enabled us to gather a variety of unexpected answers, important for exploring the field experiences. On the other hand, this approach limited the measurable comparisons of the responses to the same items, which is possible when using visual analogue scales. Importantly, this limitation was countered by using a systematic and rigorous approach in the content analysis of the material and summarising results in a meaningful way.

Conclusions

The SEYLE Awareness program was developed with a large heterogeneous group of adolescents in mind. The main goals, to increase general mental health awareness whilst encouraging youth to self-recognize the need for help, were, of course, very ambitious. In such large-scale efforts, it is difficult to ensure that the needs of all participants are addressed and that all topics raised are adequately explained and actually understood. However, reports from the SEYLE sites in 11 European countries show that the adolescents not only learned about mental health by participating in the Awareness program, but that it was also an enjoyable and inspiring experience. The role-play sessions and ensuing discussions were a welcome diversion from ordinary classes and as such an excellent tool for communicating knowledge and diminishing mental health related stigma. Different from many other school endeavours, the program engendered understanding between pupils, encouraged peer support and allowed the pupils to get to know each other better, hopefully leading them to understand that they are not alone with their problems.

The school-environment is the best system we have to perform primary prevention programs designed to improve mental health and give information about unhealthy life-styles among youth, whilst at the same time raising the general awareness-level about mental health and mental problems. However, the help and support of schools, local politicians and other stake-holders, along with teachers, parents and adolescents, is needed for efficacious implementation of forthcoming awareness programs. Finally, the healthy functioning and understanding of mental health related issues for children and adolescents have profound consequences for society, both presently and in the future. Therefore, our expectations for the future are that comparable mental health and suicide preventive awareness programs will be included in the curriculums of schools across Europe.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

CW ideated and developed the content of the Awareness intervention program, coordinated the implementation, trained the personnel, analyzed the data and jointly drafted the manuscript. CH ideated and developed the content of the Awareness intervention program, coordinated the implementation, trained the personnel and contributed to the manuscript for relevant intellectual content. DW is the principal investigator of SEYLE, ideated and developed the content of the Awareness intervention program, coordinated the implementation and contributed to the manuscript for relevant intellectual content. VC coordinated the implementation of SEYLE, trained the personnel and contributed to the manuscript for relevant intellectual content. SAH, LF, GF, NG, DCH, MI, JMC, JZ led the Awareness intervention program at the respective study sites, collected the information presented in this manuscript and contributed to the manuscript for relevant intellectual content. DF, KK, PV, AT collected the information presented in this manuscript and contributed to the manuscript for relevant intellectual content. AA, JB, JB, DC, CH, JPK, HK, AV, MS are site leaders of SEYLE in the respective countries. They coordinated and provided support to the implementation of the Awareness intervention program in the respective study sites and contributed to the manuscript for relevant intellectual content. VP was site-coordinator and oversaw the implementation of the Awareness intervention program in Slovenia, analyzed the data and jointly drafted the manuscript with CW. All authors read and approved the final manuscript.

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Original Article

Hours of sleep in adolescents and its association with anxiety, emotional concerns, and suicidal ideation

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ABSTRACT

Objectives: Anxiety and concerns in daily life may result in sleep problems and consistent evidence suggests that inadequate sleep has several negative consequences on cognitive performance, physical activity, and health. The aim of our study was to evaluate the association between mean hours of sleep per night, psychologic distress, and behavioral concerns.

Methods: A cross-sectional analysis of the correlation between the number of hours of sleep per night and the Zung Self-rating Anxiety Scale (Z-SAS), the Paykel Suicidal Scale (PSS), and the Strengths and Difficulties Questionnaire (SDQ), was performed on 11,788 pupils (mean age ± standard deviation [SD], 14.9 ± 0.9; 55.8% girls) from 11 different European countries enrolled in the SEYLE (Saving and Empowering Young Lives in Europe) project.

Results: The mean number of reported hours of sleep per night during school days was 7.7 (SD, ±1.3), with moderate differences across countries ($r = 0.06$; $P < .001$). A reduced number of sleeping hours (less than the average) was more common in girls ($\beta = 0.10$ controlling for age) and older pupils ($\beta = 0.10$ controlling for sex). Reduced sleep was found to be associated with increased scores on SDQ subscales of emotional ($\beta = -0.13$) and peer-related problems ($\beta = -0.06$), conduct ($\beta = -0.07$), total SDQ score ($\beta = -0.07$), anxiety (Z-SAS scores, $\beta = -10$), and suicidal ideation (PSS, $\beta = -0.16$). In a multivariate model including all significant variables, older age, emotional and peer-related problems, and suicidal ideation were the variables most strongly associated with reduced sleep hours, though female gender, conduct problems measured by the SDQ, and anxiety only showed modest effects ($\beta = 0.03–0.04$).

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Conclusions: Our study supports evidence that reduced hours of sleep are associated with potentially severe mental health problems in adolescents. Because sleep problems are common among adolescents partly due to maturational processes and changes in sleep patterns, parents, other adults, and adolescents should pay more attention to their sleep patterns and implement interventions, if needed.

1. Introduction

Adequate sleep is essential for good health and optimal physical and cognitive performance [1,2]. Insufficient sleep not only interferes with quality of life and general well-being, but it also may be hazardous to one's health and the well-being of the public. There is evidence that sleep loss may affect emotional function [3] and chronically disrupted sleep may increase the risk for developing affective symptoms [4,5]. In particular, high prevalence and comorbidity of anxiety and sleep problems suggest an important association between these two disorders. There is evidence of a bidirectional relationship in the course of disturbances (i.e., poor sleep increasing the risk for later anxiety disorder and primary anxiety developing into insomnia) [6]. Importantly, there is evidence that sleep complaints are more common in suicidal patients [7,8]. Indeed insufficient sleep and sleep disturbances are common in depressive disorders and other psychopathologic conditions potentially associated with suicidal risk. In a large community sample of 5692 adults in the United States, the presence of sleep problems (e.g., early morning waking, difficulty initiating or maintaining sleep) was significantly related to each measure of suicidality, including suicidal ideation, suicide planning, and suicide attempts [9].

Sleep problems in children and adolescents are common and sleep disruption is associated with a wide range of behavioral, cognitive, and mood impairments [10]. Biologic studies indicate considerable changes in sleep architecture during adolescence, such as changes in melatonin secretion and a need for greater total sleep time, possibly due to maturational changes in the neuronal connectivity [11,12]. Due to circadian changes, teenagers also have a delayed sleep pattern and prefer to go to sleep between 2:00 am and 6:00 am and wake up between 10:00 am and 1:00 pm [13]. However, despite a physiologic need for 9 h of sleep each night, teenagers on average only sleep 7 h per night [14] to meet the challenges of school, sports, part-time jobs, family, and friends [15].

Many clinical studies in adolescents have consistently reported that reduced hours of sleep are associated with emotional problems such as depressive and anxiety symptoms [16,17], in addition to self-harm and suicidal ideation [18]. Poor sleep also has been correlated with increased aggression, irritability, and hostility in both adults and adolescents; conduct problems and bullying behavior in schoolchildren [19–21]; and habitual substance use [22], self-injurious behaviors [23], and suicide attempt overall [24–26]. It has been hypothesized that the relationship between sleep problems and aggression may be mediated by the negative effect of sleep loss on prefrontal cortical functioning, resulting in loss of control over emotions and regulation of aggressive impulses. Other potentially contributing mechanisms connecting sleep problems with aggression and violence have been linked to alterations in functioning of the central serotoninergic system and the hypothalamic–pituitary–adrenal-axis [5].

Given this evidence, our study was designed to investigate the effect of number of sleep hours on both emotional and behavioral problems in adolescents. Indeed we had a unique opportunity to analyze data collected on a large cohort of pupils (12,395 pupils from 11 European countries; average age, 15 years) extensively evaluated for emotional and behavioral problems, including anxiety, suicidal ideation and hyperactivity, together with information regarding average hours of sleep during school days. Because most studies mentioned above focused on clinical samples (i.e., adolescents with recognized emotional and behavioral problems), it was of interest to evaluate if the same association was present in adolescents recruited from community settings; this evaluation also enabled us to evaluate the potential benefit of widespread preventive interventions at the same time.

2. Methods

2.1. Description of study sample

The SEYLE study comprises a sample of 12,395 adolescents recruited from 179 randomly selected schools within 11 study sites in the following countries: Austria, Estonia, France, Germany, Hungary, Ireland, Israel, Italy, Romania, Slovenia, and Spain; Sweden served as the coordinating center [27]. All questionnaires were administered in the official languages of the respective countries. In each country, a list of all eligible schools within the study sites was generated according to specific inclusion and exclusion criteria to assure that representativeness and schools were then randomly selected [27]. Baseline evaluations were performed during the autumn of 2009 (eight countries) and spring of 2010 (three countries).

2.2. Participation rates

The overall rate of consent in the first eight countries was 76% (Estonia, Germany, Hungary, Ireland, Israel, Italy, Romania, and Spain). In the other three countries (Austria, France, and Slovenia) extended procedures for collection of the informed consent were imposed by the local ethics committees (i.e., multiple forms to be signed, pupil could only be enrolled only if both parents signed the form). This consent resulted in the postponement of pupil recruitment and a lower rate of consent in these countries (23%). When including these three countries in the analysis, the overall rate of consent decreased to 49%; however, the results of the study did not differ when analyzing the whole sample or when excluding the three countries with lower rates of consent. This finding suggests that the external validity of our sample was high.

2.3. Representativeness of the study sample

To assess the potential representativeness of the data from each study site key parameters, such as mean age, number of immigrants, population density, net income, and sex proportion, were compared to the corresponding national data. Data at the national and local levels were extracted from Eurostat (http://epp.eurostat.ec.europa.eu). According to our previous analysis, the adolescents participating in the SEYLE study were reasonably representative of their respective country [28].

2.4. Measures

A structured questionnaire was administered to adolescents to collect a large number of demographic, psychosocial, and behav-

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ioral data within the context of the SEYLE project [27]. The employed questionnaire used a process translation and cultural adaptation. All the scales included in the questionnaire were included in the officially translated and validated version in the respective language when available. If the scale was not available in the required language, it was translated (and back-translated) using the same procedure as the other study materials. Internal reliability for all scales used in SEYLE was assessed using Cronbach α. The questionnaire included the question, "On average, how many hours per night do you sleep (Monday–Friday) (Answer in hours)?" The note in brackets (Monday–Friday) was specifically incorporated in the question to focus on sleep during school days. The questionnaire also included scales for the evaluation of anxiety symptoms (Zung Self-rating Anxiety Scale [Z-SAS] [29]), suicidal ideation (Paykel Suicidal Scale [PSS]) [30], and emotional and behavioral disturbances (Strengths and Difficulties Questionnaire [SDQ]) [31]. The Z-SAS is a 20-item self-report assessment instrument, which includes measures of state and trait anxiety based on scoring in four groups of manifestations: cognitive, autonomic, motor, and central nervous system symptoms. The PSS is a 5-item scale that assesses thoughts of death ("Have you felt that life was not worth living?" "Have you wished that you were dead?"), suicide ideation ("Have you thought of taking your life, even if you would not really do it?" "Have you reached the point where you seriously considered taking your life or perhaps made plans how you would go about doing it?"), and suicide attempt ("Have you tried to take your own life?") in the past 2 weeks. The SDQ is a brief behavioral screening questionnaire comprising 25 items divided in five subscales: (1) emotional symptoms (i.e., "I worry a lot," "I am often unhappy, down-hearted, or tearful"); (2) conduct problems (i.e., "I am constantly fidgeting or squirming," "I am often accused of lying or cheating"); (3) hyperactivity/inattention (i.e., "I am restless and I cannot stay still for long," "I am easily distracted or I find it difficult to concentrate"); (4) peer relationship problems (i.e., "I am usually on my own," I generally play alone or keep to myself," "I get on better with adults than with people my own age"); and (5) prosocial behavior (i.e., "I try to be nice to other people," I care about their feelings," "I usually share with others [food, games, pens etc.]"). A total SDQ score is derived from the sum of scores of the first four scales summarizing emotional, behavioral, and interpersonal problems. These scales showed adequate internal consistency in each country [27] and in the overall sample (Z-SAS, = 0.81; PSS, = 0.76; SDQ, = 0.74).

2.5. Statistical analyses

All analyses were performed using the Statistical Package for the Social Sciences (SPSS) software [32]. Descriptive statistics, such as mean, standard deviation (SD), and percentages (%) were calculated. Normal distribution of hours of sleep in the whole sample n addition to other continuous variables, were tested by the Kolmogorov–Smirnov (K–S) test. The variable age was transformed in an ordinal variable at 3 levels (⩽14, 15, ⩾16), as less than 8% of pupils were younger than the age 14 years or older than 16 years. Because the distribution of hours slept per night was skewed to the left (K–S, $d = 0.18$; $P < .01$ [skewness, 0.13; standard error, 0.02]), nonparametric tests, such as the Mann–Whitney U test, the Kruskal–Wallis analysis of variance, the nonparametric χ^2 test, and the Spearman rank correlation test were utilized. The Cronbach α coefficient for each scale in each language in which the scale was administered was calculated to test its internal consistency (i.e., reliability of the scale) in our sample of pupils. Significant associations were further controlled for age and sex by regression analysis (all effects). A further regression (all effects) was performed to test the strength of association of significant variables in the same model with the average number of hours of sleep in adolescents.

The variance inflation factor was calculated to test for collinearity. For significant associations, effect sizes in r coefficients, and standardized β coefficients for regression analyses also were calculated to have an estimate of the strength of associations. In our sample, we had a high power of 0.95 to detect small effect sizes of $r = 0.005$ when comparing two groups by a nonparametric test on a continuous variable; for example, we corresponded variables to a difference of 0.12 points when comparing boys and girls on the number of hours of sleep, with an α value as small as 0.001. However, only medium–large differences ($r > 0.06$ or standardized $\beta > 0.05$ in regression analysis) were considered as relevant.

3. Results

There were 11,788 pupils who provided data on their number of sleep hours per night during school days (Monday–Friday). The main sociodemographic and psychopathologic features of the responding pupils stratified for countries are summarized in Table 1. Remarkable differences were observed in the number of sleep hours, conduct problems at the SDQ self-evaluation, and age.

Overall, adolescents reported sleeping an average of 7.7 ± 1.3 h per night (Monday–Friday). As reported in Table 1, the Kruskal–Wallis analysis of variance test (H) revealed that number of hours of sleep per night was moderately different across countries ($P < .001$; $r = 0.06$) (Fig. 1). Further mean hours of sleep tended to slightly decrease with age ($r = 0.015$) and to be lower among girls ($r = 0.015$) (see Table 2 for details).

Controlling for age and sex, the mean number of hours of sleep per night was inversely correlated to emotional problems, conduct problems, peer problems, and total SDQ scores. A negative correlation also was found with Z-SAS scores (anxiety symptoms) and PSS scores (suicidal ideation) (Table 3).

We finally performed a regression model in which we simultaneously entered all significant variables as independent variables and the average number of hours of sleep during school days in adolescents' dependent variable to test the independent impact of each variable. Results are reported in Table 4. Variables maintaining significant a association with hours of sleep per night were older age, emotional and peer problems at the SDQ, and suicidal ideation as measured by the PSS. Female gender, conduct problems at the SDQ, and high anxiety at the Z-SAS showed small–medium associations with hours of sleep per night.

4. Discussion

The major finding of our study was the correlation between reduced number of hours of sleep per night during school days and emotional problems, as well as the risk for suicidal ideation in adolescents. Due to the large sample size and the fact that the SEYLE sites have been shown to be representative of their respective countries [28], the findings reported here, which focused on the effect of sleep on adolescents' emotional and behavioral adjustment, can be considered valid within each of the 11 participating countries. Our results indicate that pupils between the ages of 14–16 years generally sleep approximately 8 h per night during school days. Hours of sleep tended to decrease with age and girls generally slept less than boys. Although this amount of sleep is not strikingly low, it is of considerable interest to examine if there is any association between hours of sleep and psychologic and behavioral problems, respectively.

The association between emotional problems (SDQ) and reduced sleep is in line with established evidence that inadequate sleep affects emotional symptoms [3] and increases risk for devel-

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Table 1
Main sociodemographic and psychopathologic features of the sample stratified across countries.

	Country of pupil																				χ^2 test	*P* value	Effect (φ)*
	Austria (*N* = 932)		Estonia (*N* = 1033)		France (*N* = 1004)		Germany (*N* = 1439)		Hungary (*N* = 985)		Ireland (*N* = 963)		Israel (*N* = 1183)		Italy (*N* = 1188)		Romania (*N* = 1127)		Slovenia (*N* = 1162)		Spain (*N* = 1025)				
	n	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%			
Sex (boys)	341	38	453	46	312	31	676	48	364	41	528	54	882	81	379	32	389	35	331	30	526	52	950.62	<.001	0.28
Living with biological parents	814	87	812	82	884	89	1188	84	749	85	868	88	852	79	1122	95	1039	93	1024	92	867	85	227.40	<.001	0.14
	Med	L-UQ	Med	L-UQ	Med	L-UQ	Med	L-UQ	Med	L-UQ	Med	L-UQ	Med	L-UQ	Med	L-UQ	Med	L-UQ	Med	L-UQ	Med	L-UQ	*H*	*P* value	*r***
Sleep (h)	7	7–9	7	7–9	7	7–9	8	7–10	7	7–9	8	8–10	8	7–11	8	7–9	8	7–10	7	7–9	8	7–10	749.09	<.001	0.06
Age (y)	15	15–16	14	14–15	15	15–16	15	14–16	15	15–16	14	13–15	16	15–17	15	15–16	15	15–16	15	15–16	14	14–16	4892.74	<.001	0.40
SDQ subscales																									
Emotional problems	2	1–7	2	1–7	3	1–8	3	1–7	2	1–7	2	1–7	3	1–7	2	1–7	2	1–7	3	2–7	3	2–7	259.10	<.001	0.02
Hyperactivity	5	4–7	4	3–6	4	3–7	4	3–7	4	3–7	4	4–7	4	3–7	4	3–7	4	4–7	4	3–7	5	4–8	350.40	<.001	0.03
Prosocial	8	7–10	7	6–10	8	7–10	8	6–10	7	6–10	8	6–10	7	5–10	7	6–9	8	6–10	8	7–10	8	7–10	626.51	<.001	0.05
Z-SAS	35	32–44	33	31–42	34	31–45	35	32–45	34	31–42	33	30–42	32	29–46	35	32–48	34	31–44	35	32–45	34	30–43	366.61	<.001	0.03
PSS	0	0–7	0	0–6	0	0–9	0	0–9	0	0–5	0	0–5	0	0–11	0	0–6	0	0–5	0	0–8	0	0–7	252.59	<.001	0.03

Abbreviations: Med, median; L-UQ, lower–upper quartiles; h, hours; y, years; SDQ, Strengths and Difficulty Questionnaire; Z-SAS, Zung Self-rating Anxiety Scale in grey medium-large effects; PSS, Paykel Suicidal ideation Scale.

* Cramer φ effect: small, 0.1; medium, 0.3; large, 0.50.

** *r* effect: small, 0.01; medium, 0.06; large, 0.14.

oping affective symptoms [4,5]. Association between reduced number of sleep hours and suicidal ideation (PSS) also is in line with previous reports [23–26]. We did not control for depressive symptoms in our study, but the study by Lee et al. [18] reported a strong association between reduced sleep (<7 h) and suicidal ideation, independent of depressive symptoms. However, we did control for anxiety symptoms at the Z-SAS and emotional problems at the SDQ. Controlling for these variables, the association between reduced sleep per night and suicidal ideation was independently maintained. This finding is noteworthy and confirms the results by Lee et al. [18], who suggested that suicidal ideation may not be fully explained by depression or emotional problems alone. In these data, emotional problems were strongly correlated with suicidal ideation ($r = 0.41$; $P < .001$). Anxiety also was found to be associated with sleep hours per night in adolescents, though the association was small. This finding is in line with previous evidence [4,5].

Overall it is not possible to determine if reduced sleep results in emotional disturbances or if emotional problems increase the risk for reduced sleep from these cross-sectional data. It has been reported that there may be a bidirectional relation in the course of these disturbances (i.e., poor sleep increases the risk for a later emotional disorder and primary emotional problems increasing the risk for later insomnia) [6]. Although cross-sectional data are not able to determine causality, it is well-known that sleep is essential for recovery of central nervous system injury, optimal physical and cognitive performance, quality of life, and general well-being [3]. A reduced number of sleep hours also may be associated with a number of other explanations apart from emotional distress (i.e., primary insomnia, sleep disturbance induced by a medical condition, familial or individual lifestyles, and natural individual need of sleep). In our study we were unable to check for these variables, with the exception of an extra sleep during weekend days, as we specifically asked for the average number of sleep hours during school days (Monday–Friday). However, it is reasonable to think that specific conditions did not have an impact on the overall significance of the results obtained from such a large sample.

We also found that reduced sleep correlated with behavioral problems such as conduct and peer problems. These observations may support the hypothesis that sleep problems may be associated with deviant behavior and interpersonal problems [20,21]. The major strength of our study was its large sample size allowing for a robust picture of adolescents regarding their sleep patterns and associated indicators of their psychosocial well-being. Because the adolescents participating in the SEYLE study were reasonably representative of their respective country [28], these findings are most likely to be valid for all European adolescents.

A limitation of our study is that all data collected were derived from a self-administered questionnaire, including measurement of the individual mean number of hours of sleep. Self-evaluation tools are unfortunately at risk for being affected by cognitive biases, including recall bias, erroneous self-perception, as well as the desire to please or displease, or to provoke, particularly in adolescents. In particular, some variables such as overcommitment, low level of social support, and poor self-rated health have been shown to be associated with overreporting of sleep difficulties and underestimation of sleep efficiency regarding sleep in working adults. Therefore, self-reported evaluations among adolescents of hours of sleep also may be influenced by psychosocial characteristics to some extent [33]. Furthermore concerning participation rates, it should be noted that there were slightly more girls (55.8%) than boys in our study. We may hypothesize that girls may be more collaborative and sensitive to psychologic and emotional factors than boys overall, leading to a higher consent rate in girls and participation rate; we also can hypothesize that sex-related cultural factors

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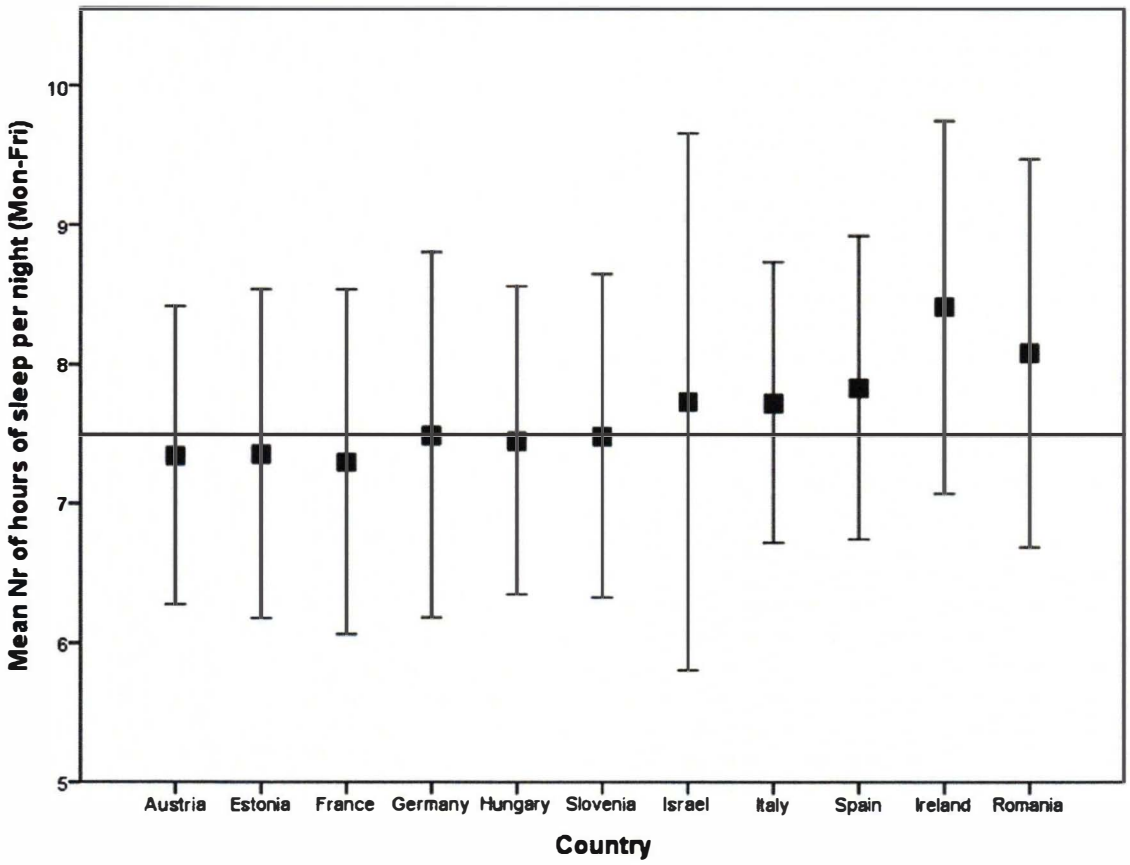

Fig. 1. Mean hours of sleep stratified by country.

Table 2
Mean hours of sleep stratified for sex and age cohorts.

Sex	Mann–Whitney test[§]					
	n	Median	Lower–upper quartiles	*z* score	*P* values	Effect size (*r*)
Boys	5181	8	7–9	−10.54	<.001[§]	0.10
Girls	6552	8	7–8			
	11,733	(missing *n* = 55)				
Age (y)*	Kruskal–Wallis ANOVA[§§]					
	N	Median	Lower–upper quartiles	*H*	*P* value	Effect size (*r*)
⩽14	3809	8	7–9	197.42	<.001	0.015
15	5134	8	7–8			
⩾16	2776	7	7–8			
	12,313	(missing = 82)				

Abbreviations: y, years; ANOVA, analysis of variance.
* Adolescents aged 12 or 19 years or older were removed from the analysis due to insufficient data.
[§§] Controlling for sex, the difference among age cohorts remained significant (β = 0.10; P < .001).
[§] Controlling for age, the difference between sexes remained significant (β = 0.10; P < .001).

may have had an impact on consent to participate. Finally, the cross-sectional design of our study cannot account for causality of relationships, as previously noted.

Our study supports previous evidence that reduced sleep may have consequences on the psychosocial adjustment of adolescents, particularly on negative emotions and suicidal risk. Because sleep problems are common among young individuals [10] and are at least partially the result of significant changes in sleep architecture during adolescence due to maturational changes in neuronal connectivity [11,12], individuals who deal with this age population should consider sleep problems as an important factor and implement necessary interventions to help adolescents better engage in healthy lifestyles and habits. Parents and adolescents should be advised about the importance of adequate hours of sleep.

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Table 3
Correlations between hours of sleep per night (Monday–Friday), Strengths and Difficulty Questionnaire subscales, Zung Self-rating Anxiety Scale, Paykel Suicidal ideation Scale scores.

Hours of sleep per night (Monday–Friday)					
	N	Spearman Rho	*P* value	β coefficients* (95% CI)	*P* value
Emotional problems (SDQ)	11,768	−0.17	<.001	−0.13 (−0.34 to 0.09)	<.001
Hyperactivity (SDQ)	11,768	−0.05	<.001	−0.05 (−0.07 to −0.03)	<.001
Prosocial (SDQ)	11,768	−0.01	.20	0.03 (0.01 to 0.05)	<.001
Z-SAS	11,532	−0.10	<.001	0.14 (−0.06 to 0.34)	<.001
PSS	11,397	−0.16	<.001	−0.11 (−0.15 to −0.07)	<.001

Abbreviations: CI, confidence interval; SDQ, Strengths and Difficulty Questionnaire; Z-SAS, Zung Self-rating Anxiety Scale; PSS, Paykel Suicidal ideation Scale in grey medium-large effects.
* Controlling for age and sex by regression analysis.

Table 4
Emotional problems, anxiety and Suicidal ideation regressed on nr. of hours of Sleep.

Hours of sleep	Standardized β (95% CI)	*P* value	Collinearity test (VIF value)
Age	−0.07 (−0.10 to −0.03)	<.001	1.00
Sex	0.03 (−0.001 to 0.07)	.05	1.13
Emotional problems (SDQ)	−0.09 (−0.13 to −0.05)	<.001	1.48
Hyperactivity (SDQ)	−0.04 (−0.07 to −0.002)	.04	1.04
Anxiety (Z-SAS)	−0.04 (−0.08 to −0.002)	.04	1.29
Suicidal ideation (PSS)	−0.08 (−0.12 to −0.04)	<.001	1.26

Abbreviations: CI, confidence interval; VIF, Variance Inflation Factor; SDQ, Strengths and Difficulty Questionnaire; Z-SAS, Zung Self-rating Anxiety Scale; PSS, Paykel Suicidal ideation Scale in grey medium-large effects.

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Conflict of interest

The ICMJE Uniform Disclosure Form for Potential Conflicts of Interest associated with this article can be viewed by clicking on the following link: http://dx.doi.org/10.1016/j.sleep.2013.11.780.

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BEILAGE 6

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ORIGINAL CONTRIBUTION

Risk-behaviour screening for identifying adolescents with mental health problems in Europe

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Abstract Indicated prevention of mental illness is an important public health concern among youth. The aim of this study was to establish a European school-based professional screening among adolescents, which included variables on both a broad range of risk-behaviours and psychopathology; and to investigate the indicative value of adolescent risk-behaviour and self-reported psychopathology on help-seeking and psychological problems that required subsequent mental healthcare. A two-stage professional screening approach was developed and performed within the multi-centre study "Saving and Empowering Young Lives in Europe" (SEYLE). The first stage of screening comprised a self-report questionnaire on a representative sample of 3,070 adolescents from 11 European countries. In the second stage, students deemed at-risk for mental health problems were evaluated using a semi-structured clinical interview performed by healthcare professionals. 61 % of participants ($n = 1,865$) were identified as being at-risk in stage one. In stage two, 384 participants (12.5 % of the original sample) were found to require subsequent mental healthcare during semi-structured, clinical assessment. Among those, 18.5 % of pupils were identified due to screening for psychopathology alone; 29.4 % due to screening for risk-behaviours alone; and 52.1 % by a combination of both. Young age and peer victimization increased help-seeking, while very low body

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mass index, depression, suicidal behaviour and substance abuse were the best predictors of referral to mental healthcare. Screening of risk-behaviours significantly increased the number of detected students requiring subsequent mental healthcare. Screening of risk-behaviours added significant value in identifying the significant amount of European pupils with mental health problems. Therefore, attention to adolescent risk-behaviours in addition to psychopathology is critical in facilitating prevention and early intervention. Identifying factors that increase compliance to clinical interviews are crucial in improving screening procedures.

Keywords SEYLE · Adolescence · Psychopathology · Risk-behaviour · Mental health · Self-injury · Depression · Substance abuse · Peer victimization · Screening · Help-seeking · Health-care

Introduction

A review by Gore et al. [8] reported that neuropsychiatric disorders were the most common causes of disability (45 %) in individuals aged 10–24 years and were strongly associated with several risk-behaviours. However, there is evidence showing that only 20–40 % of those with mental health problems are detected by health services and only 25 % receive appropriate professional treatment [29]. Adolescents with psychological problems often do not receive treatment due to low help-seeking behaviour [9, 14], which could potentially be explained by barriers in accessing mental health services [33]. Additionally, severe psychological problems, such as suicidal behaviour, have been reported to be associated with a decrease in help-seeking behaviour among young people [14]. Early detection of at-risk adolescents increases the chance of early treatment and diminishes the risk of recurrence and/or serious long-term consequences, thereby, providing an opportunity to improve psychosocial outcomes among adolescents with mental health problems [12, 26].

Professional screening is a strategy that is often used in school-based prevention programmes [23]. It generally involves an initial assessment of all pupils by using a self-report questionnaire. If specified cut-off values are exceeded, positive cases are further investigated and confirmed by a clinical interview conducted by mental health professionals. To date, the Columbia SuicideScreen and its successor, the TeenScreen Program, are the most well-known, two-stage screening procedures, which have been extensively evaluated and established in the United States (US) [31, 32]. Studies on the TeenScreen concluded that help-seeking and treatment engagement could be significantly improved by screening interventions [9]. However, one limitation of the Teen Screen is that it was particularly designed for suicide screening, and only comprises topics such as suicidal behaviour, emotional problems (anxiety, depression, irritability and social withdrawal) and substance abuse.

According to the "problem-behaviour-theory" [18], risk-behaviours are defined as behaviours that may compromise the physical or psychosocial adolescent development, and include a broad range of behaviours that often accompany adolescent development including substance abuse, withdrawal from school or unprotected sexual intercourse as a few examples [18]. A strong correlation between adolescent risk-behaviours and psychological problems has previously been reported; for example, adolescents presenting depressive symptoms are more likely to be involved in several risk-behaviours [19]. Moreover, there is evidence indicating that engaging in risk-behaviours during adolescence is associated with ensuing suicidal behaviour [1, 21] and psychiatric disorders in adulthood [24]. Therefore, risk-behaviours could potentially be a marker for early identification of psychiatric disorders [21].

This study describes the implementation and evaluation of a two-stage professional screening programme, the "ProfScreen", among a large, representative sample of European adolescents. Unlike previous programmes, the respective screening procedure was aimed at detecting all pupils requiring mental healthcare by screening for a broad range of risk-behaviours in addition to emotional problems, substance abuse and suicidality. The objectives of the study were to: investigate which screening items predict help-seeking behaviour in terms of attendance in the clinical interview; investigate which screening items predict psychological problems requiring mental healthcare; and determine the added value of screening for risk-behaviours.

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Methods

Study sample and procedure

The study sample was recruited within the multi-centre study "Saving and Empowering Young Lives in Europe" (SEYLE). During this study, prevention programmes concerning adolescent risk-taking and self-destructive behaviours were developed, implemented and consequently evaluated. The detailed protocol for the SEYLE study [registered at the US National Institute of Health (NIH) clinical trial registry (NCT00906620), and the German Clinical Trials Register (DRKS00000214)] has been published elsewhere [35]. SEYLE comprises a representative sample of 12,395 adolescents from 179 randomly selected schools in 11 different European countries (Austria, Estonia, France, Germany, Hungary, Ireland, Israel, Italy, Romania, Slovenia and Spain). Permission from local ethical committees was granted in each participating centre. Baseline assessment and subsequent interventions took part between October 2009 and December 2010. The ProfScreen was one of four interventions implemented during the SEYLE study; each school was randomly assigned one treatment arm in order to ensure that the treated subsamples were still representative. A quarter of the total sample (n = 3,070) took part in the professional screening arm in SEYLE. Sociodemographic characteristics of the sample are presented in Table 1. Because some analyses were calculated on the German subsample only, the characteristics are presented for both the European and the German sample.

Table 1 Sociodemographic characteristics of the total European ProfScreen sample as well as the German subsample

Sociodemographic characteristics	European sample		German sample	
	n	%	*n*	%
Gender				
Female	1,752	57.39	225	52.96
Male	1,301	42.61	199	47.04
Living situation				
Both parents	2,377	77.81	306	72.51
One parent	637	20.85	108	25.59
Other	41	1.34	8	1.90
Born in the country				
Yes	2,871	94.19	395	93.60
No	172	5.64	27	6.40
Don't know	5	0.16	0	0
Sociodemographic characteristics	European sample		German sample	
	m	SD	*m*	SD
Age	14.93	0.86	14.66	0.79

Screening procedure

The "ProfScreen" was developed in a collaborative effort between Heidelberg University and the SEYLE Steering Group in order to identify pupils who are at-risk for mental health problems through the detection of risky and self-destructive behaviours, as well as psychopathological features.

The first stage of the screening programme took part during the baseline assessment of the SEYLE study. The baseline questionnaire comprised questions on pupils' socio-demographics, mental health, lifestyles, values and risk-behaviours [35], and included well-known instruments such as the Global School-Based Student Health Survey (GSHS) [36] for the assessment of risk-behaviours (substance abuse, sensation seeking and delinquent behaviours, excessive use of media, truancy), the Beck Depression Inventory (BDI-II) [2]; the Zung Self-Rating Anxiety Scale (SAS) [38], the Paykel Suicide Scale (PSS) [27], and a modified version of the Deliberate Self-Harm Inventory (DSHI) [4, 10]. Defined cut-offs for all measures were ascertained to detect at-risk pupils with a high degree of sensitivity. These cut-offs were established during a consensus conference among the steering group and several child and adolescent psychiatrists and psychologists within the SEYLE consortium. Cut-off criteria in Stage 1 of the screening programme are presented in Table 2, divided into those representing adolescent risk-behaviour, and those representing psychopathology. For further information on the psychometric properties of the instruments used, please see supplemental table A. Detailed descriptions of the study protocol, assessment tools and participants characteristics can be found in previous publications from the SEYLE study [5, 34].

In Stage 2, pupils who exceeded one or more of the cut-offs in the initial screening questionnaire, were invited to a semi-structured clinical interview, which was developed on the basis of the Schedule for Affective Disorders and Schizophrenia for School-Age Children (K-SADS) [20]. This interview was performed by experienced mental healthcare clinicians (psychologists or psychiatrists), and was used to distinguish between pupils indicating psychological problems that required referral to mental healthcare and those who did not (i.e. false positives). Wherever possible, cut-offs were defined according to the DSM-IV diagnostic criteria. For domains that lacked established criteria, cut-offs were determined, based on a previous pilot study at the German study centre (which aimed to ensure sufficient sensitivity of our cut-offs), and in accordance to the previously mentioned consensus conference within the SEYLE consortium. The ProfScreen clinical interview was developed to assess the need for mental healthcare, rather than to determine a psychiatric diagnosis.

Table 2 Cut-off criteria in Stage 1 of the screening

Topics	Assessment of thresholds/cut-offs	Invited to clinical interview when …
Risk-behaviour		
Self-injury	Shortened Deliberate Self-Harm Inventory (DSHI)	…pupil reported a life-time history of 2 or more incidents of intentional self-injury
Substance abuse		
Tobacco	Tobacco use (lifetime measure)	…pupil reported using tobacco with a frequency between 2 and 10 cigarettes or more per day[a]
	Tobacco consumption frequency	
Alcohol	Alcohol consumption frequency	…pupil reported consuming alcohol (e.g. a bottle of beer, a glass of wine or 4 cl of hard liquor) 2 times per week or more
	Alcohol consumption amount	…pupil reported consuming 3 or more drinks (e.g. a bottle of beer, a glass of wine or 4 cl of hard liquor) in a typical drinking day
	Alcohol intoxication	…pupil reported a life-time history of being clearly drunk 3 times or more
	Alcohol hangover	…pupil reported a life-time history of having a hangover 3 times or more
Illegal drugs	Illicit drug consumption	…pupil reported a life-time history of illegal drug consumption 3 times or more
Sensation seeking and delinquent behaviours	Riding with someone who has been drinking*	
	Skateboarding or riding roller-blades in traffic and without a helmet*	
	Subway cart jumping, or held on the back of a moving vehicle*	…pupil gave a sum of ≥3 affirmative answers to the respective questions*
	Visiting known areas that are dangerous during night*	
	Sexual promiscuity (more than 5 sexual partners in life)*	
	Several experiences of unprotected sex*	
Excessive use of media	Media exposure frequency	…pupil reported spending of at least 5-6 h per day watching television, playing computer games etc.
Truancy	Truancy	…pupil reported missing 3 or more days of school or class without permission in the last 2 weeks
Psychopathology		
Suicidal ideation and attempts (PSS)	Paykel-Scale was calculated based on the pupils' self-report	…pupil reported any suicidal thoughts or attempts in the last 2 weeks
	Question about previous suicide attempt	…pupil reported a life-time history of suicide attempts
Depression (BDI)	BDI score was calculated based on the pupils' self-reports	…pupil presented with a BDI score of ≥14 (mild depression)
Anxiety (SAS)	SAS-score was calculated based on the pupils' self-reports	…pupils presented with a SAS-score of ≥45 (mild anxiety)
Loneliness/social relationship problems	Loneliness frequency	…pupils reported feeling lonely at least most of the time within the last 12 months
Peer victimization	Frequency of experiences of peer victimization	…pupils reported ≥5 incidents of being bullied within the last 12 months
Eating behaviour	Calculation of the BMI score	…pupils presented with a BMI score less than 16·5

[a] Due to the intercultural differences in tobacco consumption, each country was allowed to define an individual cut-off for smoking. The cut-offs were: ≥2 cigarettes per day in Estonia, Germany, Hungary, Ireland, and Romania; ≥5 cigarettes per day in Italy and Slovenia; ≥7 cigarettes per day in France; and ≥10 cigarettes per day in Austria, Israel, and Spain

Data analyses

Descriptive statistics regarding the screening participants were calculated for each stage of the procedure. Interview attendees (IA) and non-attendees (NA) at Stage 2 were compared using t tests for dimensional and χ^2 tests for categorical variables. All screenings were dichotomized as exceeding or not-exceeding established cut-offs. Logistic regressions were performed to calculate the predictive value of the cut-offs concerning attendance to the clinical interview (Model 1) and referral of positive cases after the interview (Model 2). In a stepwise procedure, the best predictors for both models were extracted using the Bayes Information Criterion (BIC). The BIC allows the comparison of models according to their estimated ability to predict new data [30]. The model with the minimum BIC is the best predictive model.

To investigate the influence of risk-behaviours within the model, regression coefficients of risk-behaviour parameters were tested for significance with the Wald test. Finally, in order to compare screening of risk-behaviours to screening of psychopathology, tests of proportions were used to compare true-positive and false-positive referral rates of screening procedures that would include only psychopathology or include only risk-behaviours.

Results

Participation in different screening stages and sample characteristics

Figure 1 shows the number and percentages of pupils that participated in Stage 1 and Stage 2 of the screening. Of the 3,070 pupils who entered the initial screening at Stage 1, almost two-thirds were screened as being at-risk, and one-third ($n = 712$) of them participated in the Stage 2 clinical interview. Over half of the Stage 2 attendees ($n = 384$), which means 12.5 % of the entire sample ($n = 3{,}070$), required referral to the mental healthcare system for treatment of severe psychological problems. Of those, 71 pupils (18.5 %) were initially screened due to psychopathology alone, 113 pupils (29.4 %) due to risk-behaviours alone, and 200 (52.1 %) by a combination of both.

Significant age differences were found in IA ($M = 14.9$; SD = 0.86) and NA ($M = 15.1$; SD = 0.84) ($t = 5.96$, $df = 1{,}851$, $p < 0.001$), but not for gender [$\chi^2(1) = 0.005$, $p = 0.94$].

Predictors for participation in the clinical interview (Stage 1)

Frequency of scores exceeding established cut-offs at Stage 1, as well as their predictive value for interview attendance

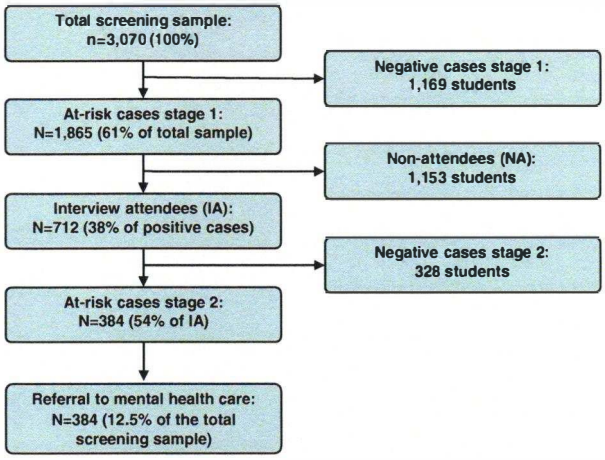

Fig. 1 Participation rates and samples of the different screening stages. 'At-risk cases of Stage 1' refers to students who scored above the cut-offs included in the SEYLE baseline questionnaire. 'At-risk cases of Stage 2' refers to students who scored above the cut-offs in the clinical interview. 'Negative cases' refers to students who did not score above the cut-offs in the respective stages

at Stage 2, are presented in Table 3. The regression model significantly predicted interview participation [LR $\chi^2(15) = 111.02$; $p < 0.001$]. After applying stepwise regression to minimize the BIC, four predictors were retained in the regression model: age, nonsuicidal self-injury, tobacco use and peer victimization.

A qualitative analysis (data not shown here) revealed that an important contributing factor for adolescent help-seeking behaviours and compliance was the proximity and short waiting times for the clinical interview and positive attitudes among parents. Secondary analysis was conducted on the German subsample only, because data were not available for the other study centres. IA differed from NA in terms of travel time and distance from the respective school to the study centre. On average, IA had a significantly shorter distance ($t = 3.14$, $df = 289$, $p = 0.002$) and significantly less travel time ($t = 3.01$, $df = 289$, $p = 0.003$) to get to the interview at the study centre.

Predictors for referral to mental health care (Stage 2)

Frequency of scores exceeding established cut-offs in the baseline questionnaire at Stage 1, as well as their predictive value for identifying cases for referral to mental healthcare, are presented in Table 4. The regression model did significantly predict referral to mental healthcare due to severe psychological problems that required treatment [LR $\chi^2(15) = 123.5$; $p < 0.001$]. After applying stepwise regression, predictors for referrals following the clinical interview were: a very low body mass index (BMI), suicidal behaviour, depression, use of tobacco and the use of illegal drugs. The mean number of exceeded cut-offs at

Table 3 Frequencies of exceeded cut-offs at Stage 1 and results of the regression model for prediction of interview attendance as dependent variable and age, gender and screening parameters as explanatory variables

	Interview attendees (IA) (n = 707)[a]	Interview non-attendees (NA) (n = 1,139)	Odds ratio[b]	95 % CI
Age			0.72**	0.64–0.81
Male gender			0.86	0.70–1.06
Screening parameters [n (%)][c]				
Self-injury	208 (29.4)	246 (21.6)	1.32*	1.04–1.67
Tobacco	145 (20.6)	304 (26.6)	0.68**	0.53–0.87
Alcohol	360 (50.9)	590 (51.8)	1.06	0.86–1.32
Illegal drugs	60 (8.5)	83 (7.3)	1.33	0.91–1.95
Sensation seeking and delinquency	109 (15.5)	138 (12.1)	1.21	0.90–1.63
Excessive media exposure	102 (14.4)	206 (18.1)	0.76*	0.58–1.00
Truancy	34 (4.8)	78 (6.8)	0.72	0.47–1.12
Suicidal behaviour	201 (28.4)	252 (22.1)	1.12	0.87–1.44
Depression	254 (35.9)	305 (26.8)	1.32*	1.02–1.71
Anxiety	105 (14.9)	128 (11.2)	0.96	0.68–1.34
Loneliness/ social relationship problems	87 (12.3)	98 (8.6)	1.23	0.87–1.75
Peer victimization	139 (19.7)	108 (9.5)	1.96**	1.48–2.62
BMI	37 (5.2)	68 (6.0)	0.81	0.53–1.25

* Significance with $p \leq 0.05$

** Significance with $p \leq 0.01$

[a] 19 subjects were excluded from the analyses due to missing values in age and gender

[b] Odds ratio = odds of interview attendance in presence of screening parameter divided by the odds of interview attendance in absence of screening parameter

[c] Percentage of all participating/non-participating adolescents

Stage 1 was 3.2 (SD = 1.9) for referrals and 1.9 (SD = 1.4) for non-referrals. The groups showed significant differences (t = 10.3, df = 723, $p < 0.001$), which suggests that a higher number of screening criteria met was associated with a referral to mental healthcare.

Risk-behaviour as an indicator of adolescent psychopathology

To investigate the additive impact of risk-behaviours assessed by the ProfScreen, we tested the hypothesis that the odds ratios of all risk-behaviours in the regression are 1

Table 4 Frequencies of adolescents who exceeded cut-offs in Stage 1 and results of the regression model for the prediction of clinical referral to mental health care as dependent variable and age, gender and screening parameters as explanatory variables

	Clinical referral to mental health care (n = 380)[a]	No clinical referral to mental health care (n = 327)	Odds ratios[b]	95 % CI
Age			1.06	0.87–1.30
Male gender			1.22	0.86–1.74
Screening parameters [n (%)][c]				
Self-injury	132 (34.7)	76 (23.2)	1.19	0.81–1.75
Tobacco	108 (28.4)	37 (11.3)	2.81**	1.79–4.43
Alcohol	210 (55.3)	150 (45.9)	1.31	0.92–1.87
Illegal drugs	46 (12.1)	14 (4.3)	2.42*	1.20–4.87
Sensation seeking and delinquency	72 (18.9)	37 (11.3)	1.56	0.94–2.59
Excessive use of media	64 (16.8)	38 (11.6)	1.68*	1.04–2.73
Truancy	27 (7.1)	7 (2.1)	2.35	0.91–6.08
Suicidal behaviour	143 (37.6)	58 (17.7)	2.34**	1.56–3.52
Depression	172 (45.3)	82 (25.1)	1.78**	1.18–2.67
Anxiety	77 (20.3)	28 (8.6)	1.36	0.78–2.38
Loneliness/ social relationship problems	61 (16.1)	26 (8.0)	1.31	0.75–2.30
Peer victimization	73 (19.2)	66 (20.2)	0.91	0.60–1.40
BMI	24 (6.3)	13 (4.0)	3.52**	1.67–7.43

* Significance with $p \leq 0.05$

** Significance with $p \leq 0.01$

[a] 5 subjects were excluded from the analyses due to missing values in age and gender

[b] Odds ratio = odds of clinical referral in presence of screening parameter divided by the odds of clinical referral in absence of screening parameter

[c] Percentage of all participating/non-participating adolescents

[Wald test $\chi^2(7) = 49.25$; $p < 0.001$]. Results show that screening of risk-behaviours contributed to the detection of additional pupils presenting severe psychological problems and requiring mental healthcare.

Of the adolescents who were referred to mental healthcare, 271 pupils (70.6 %; CI 66.0–75.1 %) could have been detected by the screening of psychopathology only. Similarly, screening of risk-behaviours alone could have detected 313 pupils (81.5 %; CI 77.6–85.4 %). Screening of risk-behaviours alone identified a significantly higher amount of total referred pupils ($p < 0.001$).

Screening of psychopathology versus screening of risk-behaviours differed slightly in terms of the number of false positives yielded in both groups. A greater number of false positives were identified when screening parameters were

based only on risk-behaviours ($n = 238$; 43.2 %; CI 39.1–47.3 %) in comparison to psychopathology ($n = 167$; 38.1 %; CI 33.6–42.7 %). However, this difference did not reach statistical significance ($p = 0.108$).

Discussion

To our knowledge, this is the first study that performed a school-based professional mental health screening among a large and representative sample of adolescents in Europe. The novelty of this European screening programme (ProfScreen) was the inclusion of distinctive risk-behaviours. Previous studies have primarily focused on emotional problems, substance abuse and suicidal behaviours [31, 32]; whereas the present study has expanded the range of risk-behaviours and psychopathology to also include: tobacco use, sensation seeking, truancy, excessive media exposure, and a broader spectrum of psychopathological variables.

Sample and screening procedure

During Stage 1, approximately two-thirds of adolescents in this sample were screened as being at-risk for the leading causes of morbidity and mortality in this age group. These results corroborate previous reports of a high prevalence of risk-behaviour and psychological problems among adolescents [7]. As many as 381 pupils (12.5 %), out of the 3,070 screened, were identified by the clinical interview because they presented mental health problems that required subsequent mental healthcare. Similar numbers have been previously confirmed in the US [15]. However, this number must be considered as the minimum, due to the drop-out rate from the clinical interview at Stage 2, which limits representativeness of the interview sample. Our results strongly support a high burden of mental health disease in adolescent populations, and call for further public health attention.

In contrast to other screening programmes, Stage 1 of the ProfScreen identified a substantially higher number of adolescents at-risk. For example, "TeenScreen" identified an at-risk rate for adolescents ranging from 23 to 45 %, during the first stage of screening [3, 14, 31]. This higher rate of at-risk adolescents identified in this study (61 %) may be due to the additional screening of risk-behaviours, which are generally quite prevalent among adolescents [7]. Moreover, the SEYLE study comprised an extended range of psychopathological variables (e.g. loneliness/social relationship problems, peer victimization and low BMI); and the larger number of constructs evaluated may be associated with the number of positive screens. However, the results from this study could also potentially reflect the current situation of mental health among European youth: our representative, multi-cultural sample might differ from the more selected and local samples in the US with regard to the prevalence of risk-behaviours and psychopathology.

The purpose of the European ProfScreen was to identify and refer pupils requiring mental healthcare. Some low thresholds may have potentially increased the sensitivity of the screening programme; if thresholds were higher, many at-risk pupils would have gone undetected. Exploratory and descriptive analyses for each screening item indicated that every increase of cut-offs, resulting in a decrease of false positives, would have also resulted in a loss of referrals (false negatives); this underlines the importance of sensitive screening.

In Stage 2, during the clinical interview, more than half of the at-risk sample (53.6 %) was diagnosed with serious psychological problems requiring mental healthcare; rates were higher [9, 31] or similar to previous screening procedures [28].

Participation to clinical interview

The participation rate for the clinical interview at Stage 2 was generally low (38 %), which may reflect general lack of help-seeking among European adolescents including fear of stigma and little trust in the mental healthcare systems. In this context, it should be mentioned that the SEYLE study ensured a professional follow-up of all students reporting serious suicidal thoughts or even suicide attempts during the past weeks at Stage 1 (so-called emergency cases), including those who did not attend the clinical interview (e.g. via clinical exploration of adolescents or caregivers on the phone).

In some study sites, the clinical interview was administered at the study research centre, while other sites performed the clinical interview at the respective schools. The predictive value concerning the average travel time from pupils' school to the study centre was examined; results indicated a significant negative correlation between travel time and attendance to the clinical interview ($p < 0.01$). In previous screening programmes, clinical interviews that were performed onsite at the respective school or conducted via telephone suggested an increase in participation rates [3, 32]. This finding could also support public health systems that have made efforts to establish social and psychological support directly available at schools (e.g. school counselling), which is not the case in many European countries.

Age differences regarding interview participation may be due to the fact that younger adolescents were more likely to adhere to rules, procedures and recommendations. While higher attendance rates in girls have been reported previously [3], significant gender differences in the clinical interview attendance were not found in the present study.

Victimization by peers demonstrated the highest predictive value for participating in the clinical interview. Victimization by fellow peers may potentially cause a substantial psychological strain for adolescents. The high participation rate of this adolescent group may also reflect a lower fear of stigmatization and denial of their problems, because these problems are externalized, as opposed to being internalized [11].

Self-injury was also a significant predictor of help-seeking behaviour in our study. These results potentially mirror the psychological strain that arises from repetitive self-injury as well as actual desire for professional help among these adolescents. It has been reported that adolescents with nonsuicidal self-injury often lack motivation to seek help, especially on their own [6, 37]; however, our results differ from these findings, and show that self-injury may even have a signalling effect for adolescents that they might be in need of mental health care. This function of self-injury has previously been described among the interpersonal functions of self-injury [22]. Additionally, our results may indicate that this group could potentially benefit from particularly proactive support (e.g. by participating in a screening procedure) since educational prevention programmes (e.g. the "signs of self-injury" programme) were not able to increase help-seeking actions in adolescents engaging in self-injury [25].

Suicidal adolescents are frequently resistant to seek professional help [7]. This suggests that acute suicidality may be associated with a decrease in help-seeking behaviour [14]. Our results indicate that suicidal behaviour among adolescents was neither a positive nor negative predictor of participation in the clinical interview, which paints a less pessimistic picture on suicidal adolescents' help-seeking behaviour compared to previous findings, and may refer to cultural differences.

Interestingly, excessive media exposure significantly predicted non-attendance in the clinical interview, which suggests that this specific group of adolescents is particularly difficult to engage to seek professional help. This finding may be important with regard to newly appearing disorders, such as Internet addiction (ICD-11) or Internet Gaming Disorder (DSM-5), which mainly occur among adolescents and currently are on the rise; they also match the clinical experience that those subjects are hard to motivate or engage for treatment.

Smoking predicted non-attendance to the clinical interview, which implies that this behaviour seems to be associated with a reluctance to seek help. Other research has shown that certain risk-behaviours may serve as an important coping function, wherein adolescents utilize these behaviours in order to be accepted by peers and/or adapt to their environment [17]. This might result in decreased motivation to change some of these behaviours.

Referral to mental health care

In general, pupils who met more screening criteria were also more likely to receive a referral to mental healthcare. This result points to the fact that multiple rather than isolated problems and risk-behaviours may indicate the development of mental health problems during adolescence.

Suicidal behaviour and depression were significant predictors of referral to mental healthcare, similar to previous research [21, 32]. Anxiety and self-injury were not independently predictive of severe psychological problems requiring mental healthcare in the regression model. This might occur due to high inter-correlation between depression, anxiety, self-injurious and suicidal behaviour, as shown in a previous study [16]. Due to this overlap, future screening development could consider one shorter questionnaire including those variables.

Use of tobacco and illicit drugs was also predictive of referral to mental healthcare, which is in agreement with previous studies [13, 21]. Although a correlation between alcohol use, depression and suicidal behaviour was found, excessive alcohol use did not appear to be independently predictive of subsequent referral to. This could eventually be explained by the overall high percentage (55 %) of European adolescents who drink alcohol.

Another significant predictor for the referral to mental healthcare, in this study, was a low BMI. During the early stages of adolescent eating disorders, symptoms often go unnoticed. Screening for BMI may be an effective strategy in identifying at-risk pupils not recognized as at-risk during previous screening [34].

Due to the attrition rate, the sample at Stage 2 may not be representative for the normal adolescent population anymore. However, the final sample is representative for a help-seeking adolescent population which will be found in other prevention or early intervention settings when performed in clinical practice, and therefore has high external validity.

Added value of risk-behaviours in a school-based screening

Our results demonstrate that a broader screening of risk-behaviours has an added value in identifying adolescents requiring mental healthcare. Moreover, screening of risk-behaviours may have certain advantages, as behaviours are potentially more observable compared to thoughts and feelings.

These data show that screening of risk-behaviours alone detects a higher percentage of referred pupils requiring mental healthcare compared to the screening of psychopathology alone. Therefore, assessing risk-behaviours provides a higher sensitivity than screening only for psychopathology and is a potential strategy for detecting

pupils requiring mental healthcare. Of course, the highest sensitivity may be achieved by assessing both risk-behaviours and psychopathology. However, it causes slightly higher rates of false-positive cases. Further research is needed to examine the sensitivity and specificity of screening procedures when using risk-behaviours alone.

Strengths, limitations and future research

The strength of the study includes the standardized methodology and the large sample size. The screening questionnaire comprised a substantial number of variables allowing for extensive scrutiny of specific psychological and risk-behaviours, which could be analysed in various models.

The relatively low compliance rate regarding the attendance in the clinical interview is a limitation. Future studies and clinical approaches should try to increase interview participation rates by providing clinical interviews onsite in the respective schools. In addition, studies including interviews with a random group of students who did not screen in Stage 1 should be performed to further assess the validity (particularly sensitivity) of the screening procedure. However, due to the implementation of the ProfScreen as a practical intervention within 11, culturally diverse, non-artificial settings and samples, our results may reflect high ecological validity, allowing us to provide new knowledge about factors contributing to help-seeking or help-avoiding behaviour among adolescents at-risk. Furthermore, the clinical interview was a semi-structured, professional-based interview specifically developed for prevention purposes in the SEYLE study. A potential limitation, however, is that cut-offs for clinical referral were arbitrarily defined by the SEYLE group and their validity, however, has not been assessed in comparison to ICD-10 or DSM-IV psychiatric diagnoses.

With regard to the ProfScreen as a tool of prevention or early intervention, future research will be necessary to evaluate both effectiveness and cost-effectiveness of such screening procedures. The large number of screening variables requires time which may be related to costs and burden of participants. The sensitive self-report screening, indeed, leads to the need of a two-stage screening which is accompanied by the problem of high attrition rates. Therefore, longitudinal assessment of long-term benefits (e.g. increased help-seeking, improved mental health or quality of life), which will need to be compared to the high costs of school-based screening procedures, is urgently needed.

Conclusion

The SEYLE results call for public mental health actions, as 12.5 % of the adolescents were identified as being in need of mental health care. Accessibility of interviews and younger age were predictors for help-seeking behaviour, which may be interpreted as a signpost to easy accessible and early interventions. Attention to adolescent risk-behaviours in addition to psychopathology is critical in facilitating prevention and early intervention since risk behaviours may influence adolescent help-seeking and may also serve as indicators of adolescent psychopathology. Screening in schools for both risk-behaviour and psychopathology could be a valuable approach in detecting students with psychological problems that require subsequent mental health care, but further research on both effectiveness and cost-effectiveness is critical. Strategies to increase compliance to clinical interviews are needed to improve the value of screening procedures.

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Conflict of interest The authors declare that they have no conflict of interest.

Ethical standards The study has been approved by the appropriate ethics committee of each study centre and has therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

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Saving and Empowering Young Lives in Europe (SEYLE): a randomized controlled trial

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Abstract

Background: There have been only a few reports illustrating the moderate effectiveness of suicide-preventive interventions in reducing suicidal behavior, and, in most of those studies, the target populations were primarily adults, whereas few focused on adolescents. Essentially, there have been no randomized controlled studies comparing the efficacy, cost-effectiveness and cultural adaptability of suicide-prevention strategies in schools. There is also a lack of information on whether suicide-preventive interventions can, in addition to preventing suicide, reduce risk behaviors and promote healthier ones as well as improve young people's mental health.

The aim of the SEYLE project, which is funded by the European Union under the Seventh Framework Health Program, is to address these issues by collecting baseline and follow-up data on health and well-being among European adolescents and compiling an epidemiological database; testing, in a randomized controlled trial, three different suicide-preventive interventions; evaluating the outcome of each intervention in comparison with a control group from a multidisciplinary perspective; as well as recommending culturally adjusted models for promoting mental health and preventing suicidal behaviors.

Methods and design: The study comprises 11,000 adolescents emitted from randomized schools in 11 European countries: *Austria, Estonia, France, Germany, Hungary, Ireland, Israel, Italy, Romania, Slovenia and Spain*, with *Sweden* serving as the scientific coordinating center. Each country performs three active interventions and one minimal intervention as a control group. The active interventions include gatekeeper training (QPR), awareness training on mental health promotion for adolescents, and screening for at-risk adolescents by health professionals. Structured questionnaires are utilized at baseline, 3- and 12-month follow-ups in order to assess changes.

Discussion: Although it has been reported that suicide-preventive interventions can be effective in decreasing suicidal behavior, well-documented and randomized studies are lacking. The effects of such interventions in terms of combating unhealthy lifestyles in young people, which often characterize suicidal individuals, have never been reported. We know that unhealthy and risk-taking behaviors are detrimental to individuals' current and future health. It is, therefore, crucial to test well-designed, longitudinal mental health-promoting and suicide-preventive interventions by evaluating the implications of such activities for reducing unhealthy and risk behaviors while concurrently promoting healthy ones.

Trial registration: The German Clinical Trials Register, DRKS00000214.

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Background

Suicide is one of the leading causes of death worldwide, and the third leading cause of death among people aged below 25. Globally, every year, there are nearly a million deaths from suicide -- roughly one every 40 seconds [1,2]. Each year, in the 27 EU member states, approximately 63,000 Europeans commit suicide [3]; and, in 2006, suicide mortality exceeded the number of deaths due to traffic accidents [4]. Europe currently includes seven countries among the top 15 with the highest suicide mortality rates worldwide [5]. Moreover, among the 15-24 age group, it is estimated that approximately 100 to 200 suicide attempts take place for every completed suicide [6]. Research has demonstrated that suicidal behaviors are underestimated [2,7]: the actual prevalence of suicidal behavior is much higher than the reported rate. Unfortunately, comprehensive knowledge of the many risk factors associated with suicidal behavior in young people is lacking. It is, therefore, essential for research to focus on understanding the multiple underlying factors that contribute to or prevent suicidal behavior.

Suicidal behavior does not consist of isolated acts. Rather, it is the outcome of a long process usually associated with a psychiatric disorder [8-11] that, in many cases, goes undiagnosed and untreated [12]. There is, thus, evidence that suicidal behavior coincides with many underlying psychological and psychiatric conditions, ranging from depressive episode [13], anxiety [14] and alcoholism [15] to psychotic manifestations [16]. Psychological factors, though substantially interrelated with suicidal behaviors, are far from being the sole causes. In addition to psychiatric illnesses, certain risk behaviors have also been identified. For example, suicidal behaviors have been shown to be strongly associated with various types of risk behaviors, including peer victimization [17-19], risky sexual behavior [20], delinquency [21], substance abuse [22], non-suicidal self-injury (NSSI) [23], physical inactivity [24,25] and poor nutrition [26]. Risk behaviors rarely occur in isolation; rather, they tend to be integrated and often overlap in what is known as a *'risk behavior syndrome'*. Studies have demonstrated that risk behaviors are significantly correlated with one another and often appear in clusters [27-30]. Since unhealthy behaviors are significant predictors of subsequent mental health problems, and often occur in clusters, there is a paramount need to promote the adoption of healthy and positive lifestyles, especially during the early years of life.

Where unhealthy and risky behaviors are established in adolescence, the risk of health problems in adulthood is elevated. The association of such behaviors, with the leading causes of mortality and morbidity, underscores the importance of carrying out preventive interventions, particularly among young people [31], for the purpose of modeling healthy behaviors.

Effective prevention strategies should comprise measures that specifically focus on defined target groups. They should include evidence-based efforts designed to address an immediate problem, and, its underlying factors, through long-term follow-up. Accordingly, those few suicide prevention studies, which have been pursued among young people have included (i) gatekeeper training programs in schools [32] (ii) awareness-raising training among school pupils [33], combination of both [34], and (iii) professional screening [12,35,36] with subsequent clinical referral [37].

There is an ongoing debate in the scientific community about which strategy represents the most effective and efficient approach [38]. Reports indicate that suicide-preventive interventions in adults can reduce suicidal behavior [38,39], but well-documented and randomized studies for young people are still lacking.

The SEYLE (Saving and Empowering Young Lives in Europe) longitudinal research project is, therefore, based on a multi-site mental health promotion and suicide prevention program; studying the three above-mentioned strategies separately to understand which approach is the most effective and pragmatic across the participating schools, and considers cultural and national differences; as well as recommending evidence-based, combined and multifaceted interventions.

Objectives

The key objectives of the study are:

(i) to collect baseline and follow-up assessments of the mental health and well-being, alongside demographic data, information about lifestyles, values, risk behaviors and other psychosocial information of European adolescents and compile an epidemiological database;

(ii) to carry out an evaluation of three types of interventions: gatekeeper training involving referrals by teacher and school staff, awareness-raising training for pupils encouraging self-referral and professional screening with subsequent clinical referral among adolescents; in comparison with a control group that comprises self-referral;

(iii) to focus on reducing risk-taking and suicidal behavior while simultaneously promoting improved mental health;

(iv) to evaluate the intervention outcomes (in terms of the efficacy, maintenance, effectiveness and cost-effectiveness of the programs), in a multidisciplinary (i.e. social, psychological and economic) perspective, in comparison with a control group;

(v) to evaluate treatment and social support outcomes for referred pupils.

Methods

Study design

The study is a randomized controlled trial (registered in the German Clinical Trials Register, DRKS00000214) that assesses three different types of intervention strategies in comparison with a control group. Using a factorial design, the study estimates and compares the effects of different suicide-prevention programs on unhealthy lifestyles, in the form of risk and suicidal behaviors (Table 1).

This 12-country study comprises a random selection of schools in 11 European countries, including *Austria, Estonia, France, Germany, Hungary, Ireland, Israel, Italy, Romania, Slovenia and Spain*, with *Sweden* serving as the scientific coordinating center. The interventions are implemented in the school premises and coordinated by each country's respective SEYLE center. The general study design of SEYLE is illustrated in Figure 1.

Population and sampling procedures

The target sample for each intervention 'arm' as well as for the control 'arm' is 250 pupils, i.e. 1,000 subjects in each participating country (totaling 11,000 subjects overall).

In each study site, a catchment area is identified and a list of eligible schools generated. Eligible schools are categorized by size as (1) **small** (less than or equal to the median number of pupils in all schools in the study catchment area or region) and (2) **large** (greater than the median number of pupils in all schools in the study catchment area or region). Every class in each school selected (regardless of size) where 15-year-old pupils make up a majority is surveyed. This age group is selected because of its risk propensity and the feasibility of performing 12-month follow-ups. Schools are randomized on the basis of their size category and sequentially assigned to respective intervention and control arms, comprising both large and small schools. The remaining large and small schools are then sequentially numbered.

To avoid contamination and confounding, only one type of intervention is performed in each school. Given the insufficient evidence of effectiveness of the interventions, equipoise can be assumed so that no institution or group will be put at (dis)advantage systematically. Schools are only aware of the respective intervention arm implemented at their facility, i.e. pupils are not informed of the other types of intervention performed in other schools. The effect that information could eventually spread through informal suggestions can be neglected; in case this becomes a topic, project members would apply a strategy to openly give appropriate additional information. A coordinator is assigned to each intervention arm and its implementation. Coordinators in the respective schools for each arm are instructed only on how to implement their own intervention arm, and have no prior experience of the procedures for the other interventions. Informed consent to participate in the study is obtained from all the adolescents and their parents.

Inclusion and exclusion criteria

Schools and adolescents in the study areas are eligible to participate if they meet all the following criteria:

(1) the school authority agrees to participate;

(2) the adolescents attend non-specialist public schools;

(3) school contains at least 40 pupils aged 15;

(4) school has more than two (3+) teachers for pupils aged 15;

(5) no more than 60% of pupils are of either sex;

(6) informed consent from parents and pupils is obtained.

If the school-based adolescents meet the following exclusion criteria, they are ineligible to participate:

(1) the school authority refuses to participate;

(2) the adolescents attend a specialist and/or independent or private school;

(3) the adolescents attend single-sex schools;

(4) a school has fewer than 40 pupils aged 15;

(5) the parents of pupils in a participating school, or the pupils themselves, have refused to sign the consent document.

Table 1: Factorial design of interventions

ARM (*n = 250 subjects per arm in each country*)	Gatekeeper Training (QPR)	Awareness training	Professional Screening
I	X		
II		X	
III			X
IV	Control Group/Minimal Intervention		

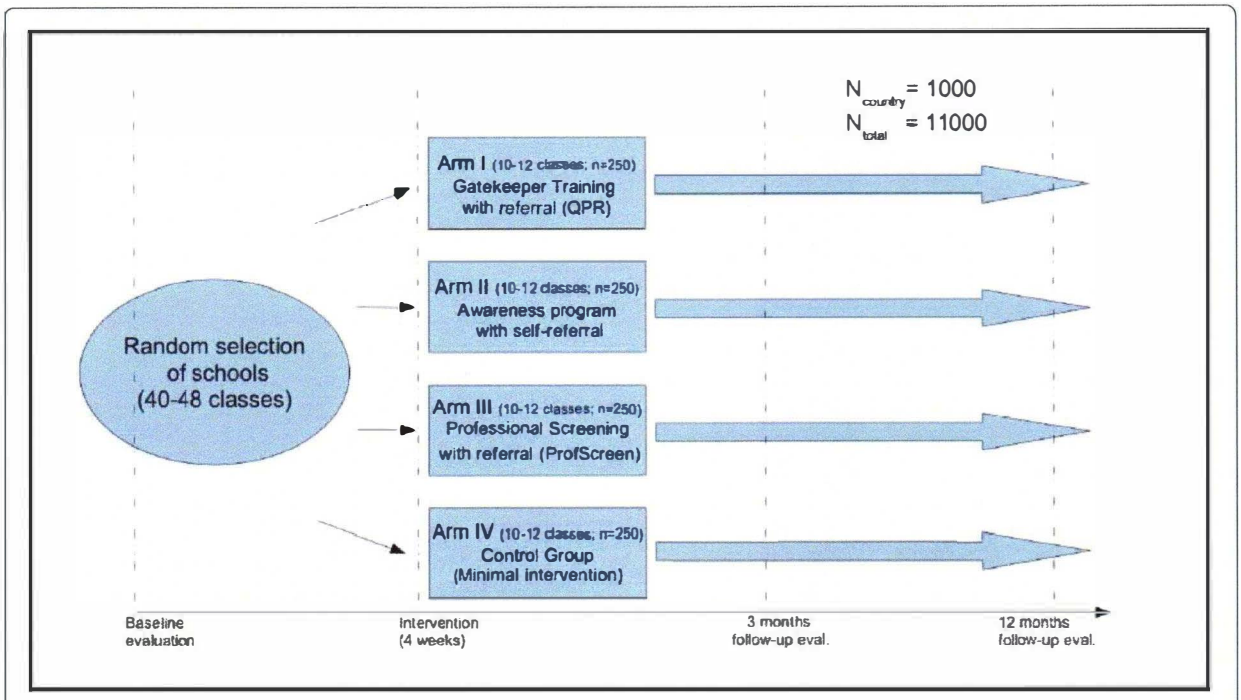

Figure 1 General study design of SEYLE.

Identification of referral facilities

In the SEYLE project, healthcare facilities that are available to receive the referral of pupils and provide treatment are identified within each respective community prior to the commencement of the project. Pupils who are categorized as high risk for mental ill-health or suicidal behavior are remitted to the local healthcare facilities for professional treatment. Pupils who do not meet the criteria of high risk for mental illness or suicidal behaviors, but necessitate changing or improving their lifestyles, are referred to a non-clinical healthy lifestyle group for social support and development.

Healthcare services

Prior to the launch of the SEYLE project, all local healthcare services in each respective center are identified, including general practitioners, public healthcare facilities and specialized psychiatrists and psychologists. Personnel is informed about the project and notified regarding the possibility of subsequent increases of pupil referrals. Information describing the SEYLE project is provided to all local healthcare services, including contact information for SEYLE researchers, and information on suicide prevention interventions [40,41]. All adolescents ascertained to be at-risk are referred by professionals, or self-referred, to the local healthcare facilities for treatment.

Healthy Lifestyle Group

Pupils who are referred by teachers, or by themselves, for perceiving to have at-risk behaviors, but who are not in need of professional help, are recommended to a non-clinical healthy lifestyle group. The healthy lifestyle groups comprise facilities in which pupils are positively encouraged to adopt or improve healthy behaviors. On the local level, this could be a boy scouts club, organized sport activities and other local activities in the community. On the national level, healthy lifestyle groups could be national adolescent self-help programs, etc. Moreover, SEYLE centers unable to identify sufficient healthy lifestyle groups are encouraged to create their own version of a healthy lifestyle group in which they choose the topics and involve local volunteers to organize the meetings. The concept of the healthy lifestyle group is to provide a positive and uplifting localized atmosphere for adolescents who are not classified as high risk and do not fit the criteria for professional help; however, do need positive support for adopting healthy behaviors and changing unhealthy ones.

Baseline assessment of pupils

The baseline evaluation questionnaire, completed within the confines of the classroom, is followed up with a post-intervention evaluation questionnaire 3- and 12-months post-baseline to study changes in attitudes, lifestyles, behaviors and mental health problems of pupils. The baseline assessment obtains data on lifestyles, behaviors, values, mental health and suicidality. Data are collected by means of structured questionnaires, including:

(i) the *Global School-Based Pupil Health Survey* (GSHS) [42], which assesses lifestyles and risk-taking behaviors;

(ii) the *WHO Well-being Scale* (WHO-5) [43], which evaluates mood (good spirits, relaxation), vitality (being active and waking up fresh and rested) and general interests (being interested in things);

(iii) the *Beck Depression Inventory* (BDI) [44], which measures depressive symptoms;

(iv) the *Paykel Suicide Scale* (PSS) [45], which determines suicidal ideation and suicidal behavior;

(v) the *Strengths and Difficulties Questionnaire* (SDQ) [46], which collects information on emotional symptoms, conduct problems, hyperactivity and/or inattention, peer relationship problems and pro-social behavior;

(vi) the *Deliberate Self-Harm Inventory* (DSHI) [47], which evaluates deliberate self-harm behavior;

(vii) the *Young's Diagnostic Questionnaire* (YDQ) [48] for Internet Addiction, which identifies Internet dependency among adolescents;

(viii) questions from the *European Values Study* (EVS) [49], which examines values, such as religion, family, marriage, work and friendship;

(ix) specific items developed or modified for the SEYLE study, concerning reading, music, and internet habits, as well as coping, trauma and bullying, stressful life events, stigma and discrimination, peer and parent-child relations, children's physical health, alcohol and substance use, and future outlook.

Emergency cases

A specific procedure to evaluate and immediately assist emergency cases is compulsory for all pupil participation of the SEYLE project. Emergency cases are identified by means of two specific questions prompted in the baseline questionnaire. Pupils are considered emergency cases if they respond "sometimes", "often", "very often" or "always" to the question "*During the past two weeks, have you reached the point where you seriously considered taking your life or perhaps made plans how you would go about doing it*?"; and/or if they respond "Yes" to the question "*Have you tried to take your own life during the past 2 weeks*?". Pupils identified in the baseline questionnaire as emergency cases are immediately referred for clinical evaluation and directed to healthcare services for treatment if necessary. However, once evaluated, and even when subjected to treatment, pupils are permitted to continue in the intervention arm to which they were originally assigned.

Interventions

The preventive interventions comprise: Gatekeeper Training (QPR), training of pupils in awareness of mental health and crisis management (Awareness Training), and screening of at-risk pupils by health professionals (Professional Screening) with subsequent clinical evaluation. These three types of intervention arms are compared with the control group. Interventions are designed to promote overall healthy behaviors; raise awareness; improve lifestyles; refer subjects who demonstrate signs of suicidal risk and mental ill-health for treatment or to a non-clinical healthy-lifestyle group; and ultimately, enhance psychological well-being while reducing suicidal risk and mental illness.

I. Question, Persuade and Refer (QPR)

The QPR 'preventive intervention' program, developed in the US http://www.qprinstitute.com/, focuses primarily on training gatekeepers to identify and intervene when individuals are engaged in risk behaviors. It involves asking the individuals questions concerning their behavior, *persuading* them to seek help if they are displaying suicidal warning signs and, when appropriate, *referring* the individual to a treatment facility. In medical ethics, the doctrine of Informed Consent and respecting the individual's rights does not preclude persuasion [50,51]. Gatekeepers, in this study, are teachers and school staff who are in daily contact with the subjects concerned. Teachers and school staff in the randomly selected schools are trained by staff in the SEYLE project that have undergone the official QPR training program in the USA, or online, and are certified trainers of this method. Training consists of a two-hour interactive lecture and a one-hour role-play session. Teachers and school staff receive a QPR booklet on suicide prevention with education that focuses on describing the epidemiology and risk factors of the phenomenon of suicide; deals with common myths and facts about suicide; provides detailed guidance on how to recognize young people at-risk; and gives basic information about how to support pupils who are contemplating suicide and persuade them to get help. SEYLE has, however, modified one aspect of the QPR intervention in order to fit the needs of the project. In the original QPR intervention, business cards with information concerning contact information for local healthcare services are distributed to the gatekeepers during the training, in which case, gatekeepers keep the business cards on their person in the occurrence they need to utilize the information when referring someone presumed to be at-risk.

In the SEYLE modified version, the business cards contain contact information not only for healthcare services, but for non-clinical healthy lifestyle groups as well. Moreover, business cards are dispersed to each teacher and school staff participant during the training advising them to distribute the business cards to adolescents who they presume to be at-risk for mental ill-health or suicidal behavior.

The active intervention period for the QPR in SEYLE is a period of four weeks.

II. Awareness Training of Pupils

The awareness intervention is designed to promote knowledge of mental health, healthy lifestyles and behaviors among adolescents enrolled in the SEYLE project. It is an extended, refined version of an awareness trial conducted in nine countries [33] developed by researchers from Columbia University, New York and the National Prevention of Suicide and Mental Ill-Health (NASP), Karolinska Institutet, Sweden and incorporates methodology used in preventive interventions for suicidal behavior [52]. All pupils in the schools concerned are provided with a customized educational, awareness-raising booklet covering six specific topics concerning: (i) awareness of mental health; (ii) self-help advice; (iii) stress and crisis; (iv) depression and suicidal thoughts; (v) helping a troubled friend; and (vi) getting advice - who to contact [53,54] with telephone numbers and email addresses to local healthcare facilities and healthy lifestyle groups in case pupils wish to seek help. Once the intervention commences, six posters are hung in the classroom covering the six key topics as in the awareness booklets. Lessons, which are also combined with role-play sessions, address the six topics covered in the awareness booklet and posters.

During the classroom sessions, the instructor and an assistant distribute the awareness booklets to all the pupils. The instructor addresses these six topics along with role-play sessions during subsequent five one-hour sessions over 4-week duration (Figure 2).

In the role-play sessions, the adolescents have the opportunity to act out conflict issues they experience in their everyday lives (i.e. with parents, peers, teachers etc.) under the supervision of the same trained instructor who gives the lectures and leads role-play sessions, along with an assistant, while pupils acquire skills in resolving such problems. The role-play sessions comprise the following three themes: **Theme I**, *Awareness about choices*; **Theme 2**, *Awareness about feelings and how to manage stress and crisis situations*; and **Theme 3**, *Awareness about depression and suicidal thoughts*. Pupils who, through this intervention, recognize their own need for help have the opportunity and are encouraged to self-refer themselves to contact an appropriate mental-healthcare provider, or join a healthy lifestyle group by using the country-specific contact information that is provided in the booklets and on a business card, which is distributed to each pupil.

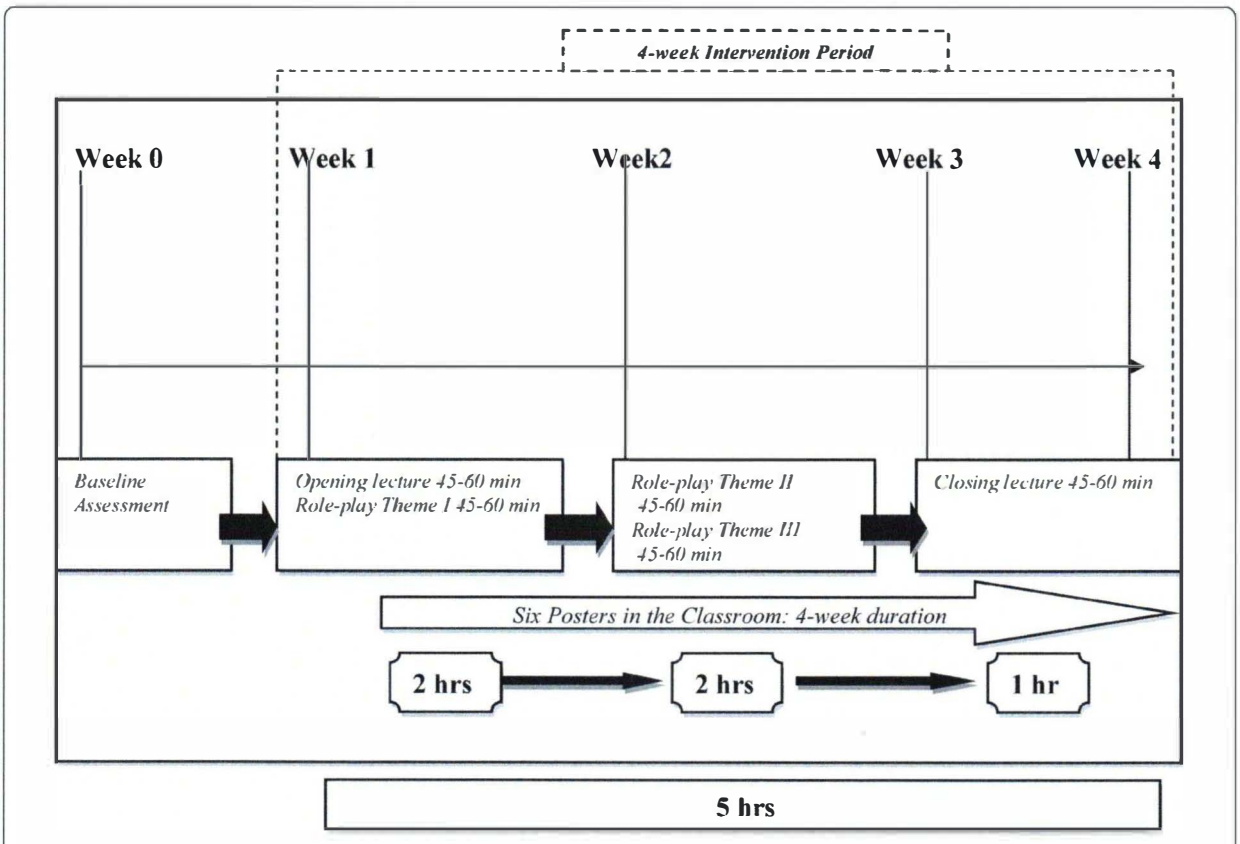

Figure 2 Timeline for the Awareness Intervention.

III. Professional Screening

This intervention is designed to help health professionals to identify at-risk adolescents by using cut-off points for positive responses based on specific scales of adolescent mental health in the baseline questionnaire. This intervention was developed by the University of Heidelberg, a SEYLE center, and NASP at Karolinska Institutet, the coordinating center, and pilot-tested in the Heidelberg clinic. Based on the results of the pilot test, cut-off points were assigned accordingly (*see* Table 2). Pupils who screen at or above specific cut-off points are referred for professional clinical assessment. This assessment is conducted by a psychiatrist or clinical psychologist, who performs a semi-structured clinical interview designed for the evaluation of mental health problems, as well as self-destructive and risk-taking behaviors for adolescents screened as 'at-risk' in the baseline evaluation in accordance to the cut-off criteria.

The time period for the active intervention in the Professional Screening arm is 4-week duration.

All pupils with a predetermined cut-off for depression, anxiety, phobia, alcoholism, substance abuse, non-suicidal self-injury (NSSI) and suicidality are referred for professional treatment. Pupils with social problems are referred to an appropriate non-clinical healthy-lifestyle group.

IV. Control group/Minimal Intervention

For ethical reasons (nonmaleficence/preventing harm; fairness/equitable access), the control group cannot be completely excluded from any intervention [55]. Therefore, a minimal intervention comprising six educational posters, which are the same as those utilized in the awareness training intervention (*see above*), are displayed in the classrooms. The posters display six key points, the same as in the awareness arm booklet, and provide contact details for the local healthcare services and healthy lifestyle groups. Pupils who recognize their own need for help have the opportunity to contact (self-referral) healthcare providers or a healthy lifestyle group. This minimal intervention for the control group includes no other form of intercession.

The posters hang in the classroom for four weeks, as all interventions performed in SEYLE have an active intervention period of 4 weeks.

Pupil referrals in each intervention

During and after the SEYLE interventions, students at-risk are actively referred to local health-care facilities and to healthy lifestyle groups. Students are referred according to the arm they were randomized to. In the QPR arm, teachers and school staff refer pupils; in the Awareness and Control arms, pupils self-refer; and in the Professional Screening arm, the healthcare professional refers the pupils. Pupil consignment is based on the level of risk for each pupil.

3- and 12-month follow-up assessment for pupils

The assessment instruments used for the baseline measurement (GSHS, WHO-5, PSS, SDQ, BDI, DSHI, EVS questions and SEYLE-specific questions) are also used for the 3- and 12-month follow-up evaluations. These measures cover the same outcome variables as those in the baseline assessment in order to investigate changes. The follow-up questionnaire also includes key questions covering information on the use of referrals by teachers, school staff, health professionals and self-referrals. The follow-up assessment comprises the description of treatment received, as well as an evaluation of the intervention study activities performed by teachers, school staff and health professionals.

Outcome measures

Outcome variables that are assessed in the project include well-being, depression, anxiety, emotional and conduct problems, coping, self-destructive and addictive behaviors, values, and lifestyles. Table 3 illustrates the outcome variables and the corresponding assessment tools utilized to measure them.

Another outcome variable is pupil referrals, i.e. the total number of referrals inclusive all emergency cases identified during the baseline evaluation, and treatment outcomes. For data collection, SEYLE has developed a systematic method of recording and monitoring all referrals and obtaining feedback on their appropriateness. Pupils are asked whether they have been referred and to whom, what kinds of treatment they have received (medication, psychotherapy, both or neither etc.) and for how long. Phone calls are performed with pupils who do not participate in the follow-up evaluations, and, where possible, facilitators maintain contact with the pupils' parents. In cases, where parents or family represent a source of concern in the perception of the pupil or staff member, contacts will be handled in a particularly careful manner [56].

Professionals, teachers and school staff assessment

Baseline and 3- and 12-month evaluations is also performed among health professionals, teachers and school staff involved in the project. Health professionals are assessed by a short 12-item questionnaire on their knowledge and preparedness of treating adolescents displaying suicidal behaviors. Teachers and school staff undergo a more detailed assessment questionnaire that collects data on mental health and suicidal behavioral knowledge, perception and attitudes towards mental health and suicide, employment satisfaction, their personal well-being and perspective of the SEYLE project.

Table 2: Cut-off criteria in the baseline questionnaire and in the professional screening intervention for selected at-risk pupils referral to clinical assessment

Theme		Cut-off value/threshold value	Risky and self-injurious behavior is diagnosed when
Depression (BDI)		BDI-score ≥ 14; depending on the responses, from 0 to 3 points are assigned (cf. manual) and added.	A BDI score of ≥ 14 is obtained.
Anxiety (ZUNG)		ZUNG-score ≥ 45; depending on the responses, from 1 to 4 points are assigned and added.	A ZUNG score of ≥ 45 is obtained.
Suicidal Ideation and Attempts		PAYKEL Scale	The cut-off of at least one single item is obtained.
		Yes/No response: previous suicide attempt.	'Yes' is the response given.
Non-suicidal self-injury		Deliberate Self-Harm Inventory (DSHI)	A sum of ≥ 2 is obtained and all points must therefore be added.
Eating behavior		Both responses are needed to calculate the BMI score.	The BMI score is less than 16.5.
Sensation-seeking and delinquent behaviors		Yes/No response: riding with someone who has been drinking.	The sum of ≥ 3 for the theme 'risk behavior' is obtained. All points must therefore be added.
		Yes/No response: skateboarding or riding roller-blades in traffic and without a helmet.	
		Yes/No response: subway cart jumping, or held on the back of a moving vehicle.	
		Yes/No response: visiting known areas that are dangerous during night.	
		Sexual Promiscuity Unprotected Sex	
Substance abuse	**Tobacco**	Tobacco Use (lifetime measure)	'Yes' is the response given to tobacco use, **and** 2 cigarettes per day or more for tobacco consumption frequency.
		Tobacco Consumption Frequency	
	Alcohol	Alcohol Consumption Frequency (12-month measure)	2 times per week or more
		Alcohol Consumption Amount (12-month measure)	3 or more drinks in a typical drinking day
		Alcohol Intoxication (lifetime measure)	3 times or more
		Alcohol Hangover (lifetime measure)	3 times or more

Table 2: Cut-off criteria in the baseline questionnaire and in the professional screening intervention for selected at-risk pupils referral to clinical assessment (Continued)

Illegal drugs	Illicit Drug Consumption (lifetime measure)	3 times or more
Exposure to media	Media Exposure Frequency	Option 4, 5 or 6 is ticked, i.e. a pupil spends at least 'five to six hours per day' watching television, playing computer games etc.
Social relationships	Loneliness Frequency (12-month measure)	Option 4 ('most of the time') or 5 ('always') is checked.
Bullying	Peer Victimization (12-month measure)	The sum of ≥ 5 is obtained. All response options must therefore be added.
School attendance	Truancy (2-week measure)	Option 3, 4 or 5 is ticked, i.e. respondents have missed three or more days of school or class without permission.

Data analysis

The SEYLE project generates a total sample of 11,000 European adolescents, with 8,250 (750 per site) receiving one or other of the three interventions being tested. The control arm contributes 2,750 adolescents (250 per site) to the total sample.

Power calculations adhere to the widely accepted proposals made by Cohen (1988) [57] for detection of small, medium and large effects. For all outcome measures, the sample size gives the study more than 80% statistical power to detect medium effects within the individual centers and small effects at the aggregate level of centers. Overall, the SEYLE intervention project is expected to show medium effect changes.

The SEYLE study sample potentially exceeds the sample size requirements in order to detect statistically significant changes. This will ensure the required statistical power, taking into account the possibility of some center recruiting fewer pupils than expected, attrition rates at follow-up and missing data. An initial stage of statistical analysis involves examining the consistency of psychometric properties across sites of the measures used in the SEYLE study. Reliability analysis is performed on the relevant data from each participating center. The suitability of continuous variables for parametric tests is assessed.

In cases where the diagnostics indicate that the reliability of the parametric tests may be significantly undermined, the appropriate non-parametric test is carried out. These include the Mann-Whitney test, the Kruskal-Wallis test, the Wilcoxon test and Friedman's ANOVA. Comparisons between study arms in relation to dichotomous and polychotomous variables are initially made using Fisher's exact test and chi-square tests, as appropriate. Logistic regression compares the intervention arms to the control arm in relation to the risk of an event of interest occurring in the follow-up period. The odds ratio, with its 95% confidence interval, is used as the measure of relative risk. An adjusted odds ratio is produced from multivariate logistic regression models, which include relevant covariates. Statistical analyses are carried out at the level of the individual centers and at the aggregate level. Variation in the experimental effects is examined across the 11 participating centers.

Research Ethics

The study was approved ethically by the European Commission as a precondition of funding approval for the project. Ethical permission for the project, including permission to follow up individual pupils, has also been obtained in each participating country by the Research Ethics Committees. All requirements of obtaining Informed Consent from pupils and parents are followed carefully. In order to maintain confidentiality and to allow for analyzing follow-up data in the individual, questionnaires include a specific code to identify each participating pupil, enabling data to be obtained at individual and not only aggregate level. An independent ethical advisor supervises the implementation of the ongoing project in order to ensure maximum protection of vulnerable individuals such as adolescents and articulate any sensitive issues [58].

Discussion

The three prevention strategies that are tested in SEYLE are built upon the concept of empowering different key persons. Each prevention strategy is governed by different scientific perspectives of empowerment.

The first strategy, gatekeeper training, encompasses education concerning mental health and suicidal behavior for key persons or 'gatekeepers', i.e. persons in fre-

Table 3: Correspondence between questionnaire measures and study outcomes

Tool for measurement	Outcome variables
WHO-5	General well-being
Beck Depression Inventory (BDI)	Depression
Paykel Suicide Scale (PSS)	Suicidal behavior
Global School-Based Pupil Health Survey (GSHS)	Alcohol use and abuse
	Drug use and abuse
	Eating habits
	BMI
	Physical activity
	Sexual habits
	Tobacco use
	Violent behaviors
	Risky behaviors
Strengths and Difficulties Questionnaire (SDQ)	Emotional symptoms
	Conduct problems
	Hyperactivity/inattention
	Peer relationship problems
	Pro-social behavior
European Values Study Questionnaire (EVS)	Values (religion, family, marriage, work, friendship)
Specific SEYLE questions	Coping
	General child health
	Peer relations
	Child-parent relations
	Stigma and discrimination
	Future outlook

Table 3: Correspondence between questionnaire measures and study outcomes (Continued)

Deliberate Self Harm Inventory (DSHI)	Self-harm behavior
Young's Diagnostic Questionnaire (YDQ) for Internet Addiction	Internet addictive behavior

quent contact with adolescents such as teachers and school staff. Through this training, the gatekeepers learn how to persuade at-risk adolescents to seek clinical help, which essentially empowers the 'gatekeeper'. This strategy has been moderately successful [32,59-62].

The second strategy, awareness-raising training, involves interactively teaching school pupils the importance of mental health. Consequently, it empowers individuals to identify their personal level of risk, as well as that of their peers, while informing them how best to seek appropriate care, and, if necessary, helping them to do so.

Finally, professional screening with subsequent clinical referral is an approach designed to evaluate a specific target group by utilizing a well-structured assessment instrument based on cut-off scores for meeting certain criteria for mental health problems. Individuals meeting these criteria are referred for clinical evaluation, if necessary, with appropriate treatment determined by the professional in charge. This strategy empowers the professional involved in the screening.

To date, the effects of suicide-preventive interventions in young people in terms of improving unhealthy lifestyles have not yet been reported. We know that unhealthy and risk-taking behaviors are detrimental to one's current and future health. For a number of disorders and illnesses, they are important factors contributing to premature mortality and morbidity. These types of behavior may be expected to be modifiable and even preventable with appropriate intervention measures. It is, therefore, crucial to test well-designed, longitudinal health-promoting and suicide-preventive interventions by evaluating to what extent such activities reduce unhealthy behaviors while simultaneously promoting healthy ones. The SEYLE project is unique in this respect, since suicide-preventive interventions have not previously been tested with long-term follow-up measures to assess changes in unhealthy behaviors.

The strength of SEYLE in comparison with other school-based prevention and health promotion programs is the active referral of all emergency cases to professionals. According to Mann et al. [38], prevention programs for children and adolescents, such as curriculum-based programs, have shown mixed results in terms of effectiveness and impact. Knowledge about suicide has improved, but there have been both beneficial and harmful effects in terms of help-seeking, attitudes and peer support. Curriculum-based programs increase knowledge and improve attitudes concerning mental illness and suicide, but the evidence that they prevent suicidal behavior is insufficient [63]. Such programs may even be detrimental for emergency cases or high-risk pupils, if they do not provide direct access to care [63]. This risk will be systematically prevented in SEYLE. Moreover, psychiatric and psychological treatment are preferred options for pupils who are identified as high risk; however, some pupils may not fit the criteria to receive professional treatment, thus, it is of interest to examine the effectiveness of healthy lifestyle groups for those particular adolescents.

There are also some limitations of the study. Some families may pose problems to allow for an informed consent of an adolescent child to join the project. This may be related to dysfunctional processes in the family affecting the child's health [64]. In the SEYLE project, due to economical limitations, we are unable to examine the source of such family conflicts and, as a result, it can cause some selection bias of pupils joining the interventions. Other limitations of the study include pupils' refusal to partake in the referral process to healthcare facilities or follow-up evaluations in all intervention arms. Moreover, the information collected on treatment for pupils referred to healthcare services and healthy lifestyle groups is based on self-reports by the pupil, and is not collected from medical records or from leaders in the healthy lifestyle groups, however, in respective centers, this option is a possibility and data is collected from medical records wherever possible.

In conclusion, the proposed pragmatic SEYLE trial is expected to provide scientific evidence for understanding the effects of different preventive interventions, their cost-effectiveness and how they can also be combined and practically utilized.

Ethical approval

The SEYLE protocol has been granted ethical approval in each participating country where the research project is implemented:

- **Austria**: Ethikkomission der Medizinischen Universität Innsbruck
- **Estonia**: Tallinna Meditsiiniuuringute Eetikakomitee
- **France**: Comité de Protection des Personnes Sud-Méditerranée II
- **Germany**: Ethikkommission Medizinische Fakultät Heidelberg

- **Hungary**: Egészségügyi Tudományos Tanács Titkárság, Pályázati Iroda, Tudományos És Kutatásetikai Bizottság
- **Ireland**: Clinical Research Ethics Committee of the Cork Teaching Hospital
- **Israel**: Helsinki Committee at the Rabin Medical Center
- **Italy**: Comitato Bioetico Di Ateneo, Università Degli Studi Del Molise
- **Romania**: Comisia De Eticã, A Universitãtii De Medicinã Si Farmacie, Cluj Napoca
- **Slovenia**: Komisija Republike Slovenije Za Medicinsko Etiko
- **Spain**: Comité Ètico de Investigación Clinica, regional del Principado de Asturias

Competing interests
The authors declare that they have no competing interests.

Authors' contributions
DW is the principal investigator, participated in the study design and coordination, and critically revised all the phases of the manuscript. VC participated in the study design and coordination, co-drafted the manuscript, and participated in the critical revision of the manuscript. MS participated in the design of the study and coordination, and critically revised the manuscript. TD participated in the coordination of the study, co-drafted the manuscript, and implemented all revisions to the manuscript. CW participated in the design of the study and coordination, provided consultation on anthropological issues, advised on research methodology, critically revised the manuscript, and drafted the final version of the manuscript. CH participated in the design of the study, provided consultation for epidemiological issues, advised on research methodology and critically revised the manuscript. CH, AV, JPK, RB, JB, PC, AA, MS, DC, DM and JB are the principal investigators for the SEYLE project in their respective countries. SRT is the expert ethical advisor for the SEYLE project, providing consultation for the study design and ongoing interventions. The other authors are the site coordinators for the SEYLE center in their respective countries. All authors read and approved the final manuscript.
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