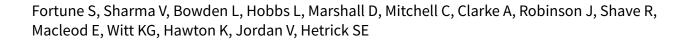![Cochrane Library logo]

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Prevention of self-harm and suicide in young people up to the age of 25 in education settings (Protocol)

Fortune S, Sharma V, Bowden L, Hobbs L, Marshall D, Mitchell C, Clarke A, Robinson J, Shave R, Macleod E, Witt KG, Hawton K, Jordan V, Hetrick SE

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[Intervention Protocol]

Prevention of self-harm and suicide in young people up to the age of 25 in education settings

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A B S T R A C T

Objectives

This is a protocol for a Cochrane Review (intervention). The objectives are as follows:

To assess the effects of interventions delivered in educational settings to prevent self-harm and suicide in young people (up to the age of 25) and examine whether the relative effects on repetition of self-harm are modified by education setting.

BACKGROUND

Description of the condition

Suicide and self-harm are both highly distressing and we acknowledge that the content of this protocol (and the review that will follow) is sensitive. We acknowledge that the content, and in particular the figures presented below, represent individuals and those who care for them, and acknowledge the impact for these people.

There is a range of operational definitions of self-harm, and in this review we have adopted the broad term "self-harm". Self-harm refers to intentional self-poisoning or self-injury, irrespective of motive or the extent of suicidal intent (Hawton 2003; NICE 2011). This is inclusive of the term "Non-Suicidal Self Injury" (NSSI) and suicide attempt, terms which are used in this background at times when cited studies have measured these specific constructs.

In most high-income countries, the classification of suicide is part of the births and deaths registration process and a finding of suicide is the outcome of a death review by a coroner or medical examiner. There are variations in the extent to which official findings of suicide reflect the true suicide rate (Gunnell 2012; Tait 2015; personal communication).

There is a range of estimates of both self-harm and suicide because of the different methods of ascertainment. Overall, the peak prevalence of self-harm is in young people (Nock 2008), making this an important age group to focus on. Estimates of community rates of self-harm vary greatly, with relatively few nationally representative studies that are up-to-date, partly reflecting the significant cost of conducting such studies. A recent systematic review and meta-analysis (statistical analysis combining the results of several studies) of longitudinal studies (participants are repeatedly observed over time) of adolescents and young adults suggests that females have an elevated risk of suicide attempt (OR 1.96, 95% CI 1.54 to 2.50) and males for death by suicide (OR 2.50, 95% CI 1.8 to 3.6) (Miranda-Mendizabal 2019). A meta-analysis of community-based studies of self-harm by adolescents 12 to 18 years old conducted between 1990 and 2015 suggests a lifetime prevalence of 16.9% (95% CI 15.1 to 18.9), with higher prevalence among females (RR 1.72, 95% CI 1.57 to 1.88) (Gillies 2018). Self-cutting was the most commonly reported method (45%), with around half of participants reporting one to two episodes of self-harm. The prevalence of self-harm increased with age with a mean age of starting of 12.81 years (95% CI 11.78 to 13.84). Among those who had sought help, friends and family were the most commonly reported source of help and fewer than 10% had sought hospital treatment (Gillies 2018). A recent, repeated cross-sectional study of community-based adolescents undertaken in New Zealand suggests that the prevalence of suicide attempts has increased since 2000. This study showed that indigenous and ethnic minority youth were particularly likely to report suicide attempts (Fleming 2020).

Estimates of self-harm in young adults are likely to be influenced by the greater number of studies among university students, which tend to report higher prevalence than community-based studies. A large international collaboration, the World Mental Health International College Student Survey, surveyed 13,984 students across eight countries and found lifetime prevalence of 32.7% for suicidal ideation, 17.5% for plans to attempt suicide and 4.3% for suicide attempts (Mortier 2018).

Hospital-treated self-harm events are an important proxy measure of self-harm in the community, although, as noted above, the majority of episodes of self-harm do not result in hospital attendance. Sentinel surveillance studies (where data are gathered from a selected group of individuals or sites rather than an entire population) of self-harm in the Europe, Australasia and the USA have yielded varying estimates. These range from 61.12/100,000 in New Zealand using routinely reported official government data to 283.54/100,000 across several European countries including the UK, Italy and Turkey (Carter 2016). Older studies suggested a preponderance of female presentations; however this pattern appears to be changing. Around one in four young people who present to hospital with self-harm will repeat. This group is around thirty times more likely to die by suicide in the 12 months after their hospital presentation compared with their same aged peers, with males, older adolescents, those using self-injury, and those attending hospital more than once particularly at risk of death by suicide (Hawton 2020).

In a recent review of community studies of NSSI, Swannell and colleagues estimated the pooled lifetime prevalence to be 17.2% (8.0 to 26.3) in adolescents (10 to 17 years), 13.4% (4.5 to 22.3) in young adults (18 to 24 years) and 5.5% (1.7 to 16.3%) in adults (25 years and older) with equivalent prevalence across gender (Swannell 2014). There are mixed findings on whether the prevalence of NSSI is increasing over time, with variations in methodology accounting for a good deal of the observed differences. However, at least one robust repeated cross-sectional study of NSSI in England between 2000 and 2014 suggests an increase, particularly evident for females, from 6.5% in 2000 to 19.7% in 2014 (McManus 2019).

Globally, suicide was the second leading cause of death among those aged 15 to 29 years in 2016. Males are around three times more likely than females to die by suicide in high income countries although women are more likely to die, in several countries including Bangladesh and China (WHO 2019). Based on WHO data from 2010 to 2016, the rates of suicide among young people aged 10 to 19 years is 4.83 for males and 1.95 per 100,000 for females, with highest rates observed in former Soviet countries and New Zealand (Glenn 2020).

People who have engaged in self-harm are at much greater risk of future episodes of self-harm and suicide than the general population (Hawton 2012a, Hawton 2015a). Evidence suggests that the risk of suicide is elevated 30-fold in the year following hospitalisation for self-harm with males, older adolescents, self-injury (rather than poisoning), and repeated self-harm associated with particularly elevated suicide risk (Hawton 2020).

Both self-harm and suicide are associated with a complex array of risk factors. There is a large literature examining risk factors associated with self-harm and suicide in young people with broad convergence on key risk factors that include: early adversity including as a result of structural determinants (like economic and social policies) that result in poverty and discrimination; parental death and other family factors such as a family history of self-harm and marital discord, separation or divorce; experiences of physical and/or sexual abuse; mental health disorders broadly but, particularly, mood and alcohol and substance use, and personality

factors such as hopelessness and personality disorder; stressful life events; and previous self-harm or exposure to self-harm or suicide in others or in the media; and access to means (Beautrais 2000, Hawton 2012b, Witt 2018a).

Despite robust evidence about these risk factors, a clear case has also been made against using these risk factors in clinical settings to stratify people according to likely future risk and allocate interventions accordingly (Carter 2017). This points to the need to ensure interventions are delivered broadly, in a multisystem and multilevel way (universal, selected and targeted approaches), target modifiable risk factors and are evidence-based.

Description of the intervention

In general, suicide prevention occurs across three levels: universal programmes that target a whole population; selective programmes that target subgroups who experience risk factors for suicide or self-harm; and indicated programmes that target specific individuals who display symptoms or behaviours indicative of risk for suicide (Institute of Medicine 1994; Robinson 2013; Robinson 2018a; Robinson 2018b; Singer 2019; WHO 2014).

Common universal suicide prevention programmes include, but are not limited to, mental health and/or suicide awareness education programmes and skills development programmes that are delivered to the whole educational institution. These are designed to teach students specific skills that act as protective factors, such as coping and problem-solving skills, which more recently may be delivered via digital means (Robinson 2013, Robinson 2018a; Robinson 2018b). Universal programmes are either administered by qualified external personnel, or by teachers who are known to the students but trained in the specific intervention.

While not limited to only these programmes, there are several common selective suicide prevention approaches. Gatekeeper training programmes involve training adults who engage with young people to recognise young people in distress and provide support. Peer support programmes involve training peers with some specific skills given a young person might be more likely to disclose to peers (Rowe 2014). Screening programmes involve trained school staff or external personnel administer self-report questionnaires, or interviews to identify at-risk students, with identified students referred for mental health treatment, or to take part in a specific prevention programme (Gould 2003 ; Mo 2018; Robinson 2013; Robinson 2018a; Robinson 2018b; Singer 2019).

Indicated suicide prevention interventions target students who have engaged in self-harm or have suicidal ideation and provide specific interventions. These interventions, for example, cognitive behavioural therapy and dialectical behavioural therapy (Brent 2013; Hawton 2015b; Ougrin 2015; Robinson 2018b), have typically been developed, tested and delivered in clinical settings rather in education-based settings.

How the intervention might work

The interventions in this area are varied and so work in diverse ways to ultimately reduce self-harm and suicide. Broadly, these interventions are designed to detect and treat those with modifiable risk factors, including treating mental illness associated with suicide, or have a broader aim of building resiliency by increasing protective factors.

Universal interventions often aim to increase mental health and self-harm/suicide prevention literacy and increase the likelihood of people seeking help when it is needed. It is likely that increased help-seeking is due to increased literacy as well as by reducing stigma and improved attitudes to mental health and self-harm and suicide (Rowe 2014). There is also a role for increasing protective factors such as coping skills and problem-solving skills (often grounded in therapeutic approaches used in treatment settings such as cognitive behaviour therapy).

Selective interventions are more directly focused on ensuring detection to facilitate access to care via specific screening for young people at risk or because adults who engage with young people, as well as peers can recognise who might need support.

The mechanisms of change of the various indicated interventions that exist vary depending on the underlying theoretical model. A range of psychological interventions is used to prevent self-harm and suicide (Hawton 2015b; Robinson 2018b) and key mechanisms of change are outlined in the Cochrane Review on these interventions used in clinical settings. For example, cognitive behavioural therapy is designed to identify, challenge, and modify the unhelpful way that young people might interpret events and emotions that can lead to self-harm or thoughts of suicide. Dialectical behavioural therapy (DBT) focuses on reducing life-threatening behaviours by increasing young people's abilities both to accept, and to change, painful emotions and other responses.

Why it is important to do this review

Self-harm and suicide in young people are significant public health issues that cause distress for the young people themselves, their peers and family, and lead to substantial healthcare costs (Kinchin 2017; Sinclair 2011). Young people may not want to, nor be able to, access support in treatment settings (Rowe 2014). There is widespread public and political belief that educational settings are a logical and appropriate place in which to provide prevention and treatment, and a growing expectation that well-being support will be provided within educational settings (Barry 2017; Denny 2018; Ministry of Education 2017). At the same time, there is concern about possible iatrogenic effects (i.e. that harms will be caused by introducing the intervention e.g. teachers and counselling staff may feel more overburdened, incompetent and isolated in their role as gatekeepers) (Nadeem 2011; Te Maro 2019). The focus in this area has tended to be secondary schools, perhaps because young people (up to the age of 18 years) receive, or are entitled to, formal education in most high-income countries. However, suicide is the second leading cause of death for those aged between 15 and 29 years globally, with little prevention focused on tertiary settings (Robinson 2018b). More recent reviews in this area have limited scope, e.g. based on only one database (Katz 2013), provided only narrative summary (Cusimano 2011; Robinson 2013; Robinson 2018a), or are limited to narrowly defined populations (Witt 2019a). We are aware of one recent large systematic review of suicide prevention in young people that includes studies undertaken in education settings, including in university settings; however, as no risk of bias assessment was conducted (Robinson 2018b); therefore, the findings need to be interpreted with caution.

There is a need to provide a comprehensive high-quality systematic review of self-harm and suicide prevention programmes in all education settings (not limited to schools) and investigate the impact of the particular education setting on outcomes. This will

support evidence-informed decision-making to facilitate rational investment in prevention efforts in educational settings.

OBJECTIVES

To assess the effects of interventions delivered in educational settings to prevent self-harm and suicide in young people (up to the age of 25) and examine whether the relative effects on repetition of self-harm are modified by education setting.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs), cluster-randomised trials and cross-over trials, although these are unlikely to be used in this field. Given the high likelihood of few RCTs and cluster-RCTs, we will also include quasi-randomised trials in the review. We will include non-English studies, and both published and unpublished studies.

We will include studies where the primary aim of the study was to evaluate an intervention specifically designed to reduce self-harm or prevent suicide.

Types of participants

Participant characteristics

Our review will include studies directly involving any young person (aged up to 25 years; based on WHO definition of youth and that most students are within this age range) attending any type of educational setting (e.g. school, training institute, college, university), as well as studies focusing on helping the adults who work in these settings to prevent self-harm and suicide. Participants from both mainstream and alternative education will be included.

We will include general population groups to whom a universal suicide or self-harm prevention intervention is delivered as well as populations deemed at risk to whom selected or indicated prevention intervention is delivered.

We will include those who have engaged in self-harm (this is a population at risk of suicide). Self-harm is defined as any intentional act of self-poisoning or self-injury, regardless of degree of suicidal ideation or intent to die (Hawton 2003; NICE 2011). Therefore, it includes acts intended to result in death (often called suicide attempts) as well as those without suicidal intent (sometimes termed non-suicidal self injury; NSSI) (NICE 2011). This broader definition is used because suicidal intent is a multifaceted phenomenon, therefore it is often difficult to differentiate behaviours that are associated with the intent to die from those that are not associated with the intent to die (Andover 2012; Nock 2006), and it is also the case that intent fluctuates (Silverman 2007a, Silverman 2007b) and regardless of intent, the risk of dying by suicide is elevated in those who engage in self-harm (Hawton 2015a; Grandclerc 2016).

We will include studies that focus solely on NSSI and studies that focus solely on suicide attempts, as well as studies that include those with suicidal ideation even if they have not engaged in self-harm.

Diagnosis

Participants are not required to have a psychiatric diagnosis to be included in the review; those with a psychiatric diagnosis will not be excluded as long as the primary aim of the study was prevention of self-harm or suicide.

Comorbidities

We will exclude studies where participants are recruited primarily on the basis of the presence of a psychiatric diagnosis where self-harm was a comorbid issue and not the focus of intervention. This includes excluding studies of those with diagnoses such as Autistic Spectrum Disorder where some behaviours of children and young people with this diagnosis may fit the definition of self-harm described above.

Setting

We will include studies undertaken in any educational settings e.g. school, training institute, college, university. This includes where students and those working in educational settings are selected for an intervention within an educational setting or because they attend or work within an educational setting. It does not include trials where the intervention happens to be provided by an education provider but where the intervention is not exclusively relevant to educational settings e.g. gatekeeper training delivered by a University but those trained are not working or studying exclusively within an educational setting.

Subset data

In the case of studies in which only a subset of data is relevant, if the data for the subset can be isolated (including means, standard errors, participant details such as age, number), we will independently extract these data. For example, in a study that includes participants beyond the age of 25, we would aim to extract data for participants up to 25 years old. In the case where data for the relevant subset of participants cannot be isolated and extracted independently, and relevant information about the participants is available, we will include the data for the whole study as long as the majority of participants are under the age of 25 (mean/median age minus the standard deviation must be less than 25 or if numbers or interquartile ranges are provided 50% must be less than 25). The impact of the inclusion of such studies will be investigated using sensitivity analysis.

Types of interventions

Experimental interventions

We will include studies that test the efficacy of psychosocial universal, selected and indicated interventions that aim to prevent self-harm and suicide.

We will exclude pharmacological interventions and postvention programmes (a separate review of postvention programmes is being undertaken). We will exclude studies that examine the efficacy of interventions delivered in education settings that aim to promote well-being. While it is acknowledged that such interventions are impacting on pathways that may impact on self-harm or suicide, unless the primary and explicit aim of the study is stated as reducing self-harm or suicide (including measuring these as outcomes), these studies will not be included in this review.

Control conditions

Control conditions will include no intervention, usual care, waiting list (inactive control), or non-pharmacological interventions that are not designed or used for suicide or self-harm prevention (suicide prevention is not directly addressed and so they act as attention control). Attention controls could include, for example, educational physical health interventions (e.g. exercise, healthy eating), or educational mental health interventions (e.g. mental well-being, peer support).

Types of outcome measures

We will include studies that meet the above inclusion criteria regardless of whether they report on the following outcomes.

Primary outcomes

1. Self-harm

While the aim of any suicide prevention intervention and, arguably, self-harm intervention is to reduce the rate of suicide, suicide is a relatively rare event, particularly in intervention studies (that usually have a relatively small number of participants and are undertaken over a relatively short period of time). Given self-harm represents a key risk factor for suicide (Hawton 2015a), it is likely that any reduction in self-harm will have an impact on rates of suicide, therefore self-harm is the best available proxy measure for suicide and will be the primary outcome in this review. This will be measured as a proportion of young people who engage in self-harm post-intervention. This could be measured by self-report, significant other or assessor/clinician report, health records, and hospital representation. If multiple ascertainment methods are reported, we will use health record and hospital representation data in the first instance, given findings that these may provide more realistic estimates (Mars 2016), although it is noted that for interventions that increase awareness, such as gatekeeper training, there may appear to be increases in incidents of self-harm that are the result of ascertainment bias (i.e. a reported increase is more likely where rates of self-harm are obtained via other/clinical report and hospital or health records).

Self-harm, as noted, is defined as any intentional act of self-poisoning or self-injury, regardless of degree of suicidal ideation or intent to die and includes acts intended to result in death (often called suicide attempts) as well as those without suicidal intent (sometimes termed non-suicidal self injury; NSSI). For this outcome, we will include self-harm as defined by the authors of the study. Where, within one study, authors have measured several outcomes within this broad concept, e.g. both self-harm and suicide attempts as separate constructs, we will present data for all outcomes within a subgroup analysis but won't include total scores across the subgroups of outcomes to ensure we don't double count participants within one trial who provide data for both outcomes.

2. Acceptability (rates of dropout).

Secondary outcomes

3. Proportion of young people who engage in self-harm at short-term (up to and including three months), medium-term (four to 12 months) and long-term (> 12 months) follow-up.

4. Frequency of repeated self-harm measured as the total frequency of acts of self-harm that each young people engaged in.

This could be measured by self-report, significant other or assessor/clinician report, health records, and hospital representation.

5. Time to repeat self-harm.

6. Suicidal ideation, measured using psychometrically validated measures e.g. Suicidal Ideation Questionnaire (Reynolds 1987)..

7. Hopelessness measured using psychometrically validated measures e.g. Beck Hopelessness Scale (Beck 1974).

Timing of outcome assessment

Our primary outcome time point is at the end of the conclusion of the intervention (post-intervention). We will also investigate effects at short-term (one to three months after completion of the intervention), medium-term (four to 12 months following completion of the intervention) and long-term follow-up (over 12 months after conclusion of the intervention). If there are several measurements within a particular time-frame, we will use the longest term point within that time period, except for short-term where we will use the closest time point to the post intervention assessment. This will most clearly enable us to examine if there is a diminishing effect over time.

Hierarchy of outcome measures

For studies in which there are multiple measures of the same construct (e.g. multiple measures of hopelessness), we will select the most commonly used measure across the included trials.

We will document any cases of prioritising outcomes.

Co-designed outcomes

We undertook a process to co-design outcomes for this review with young people. This activity comprised two face-to-face co-design workshops and two online co-design workshops (due to COVID lockdown). A full description of the methodology will be published in a separate paper. The outcomes of the co-design workshop highlighted several key themes. Young people highlighted the broad diversity of experience and recovery, making the point that what works as an intervention and what young people would define as a good outcome will vary and be idiosyncratic to the individual. Related to this, they highlighted that recovery is not a straight forward linear process but is more dynamic and includes milestones such as the reduction in severity of self-harm and might include relapse as part of the recovery journey. Therefore, the primary outcome for this review, as defined by clinicians and researchers as 'reduction in self-harm', was not seen to reflect the true course of recovery. They noted that the idea of reduction being the goal might potentially have negative impacts, with relapse then seen as 'failure'. There was a more holistic approach to outcomes with a focus on those that were more strengths- or asset-based and were not solely focused on the individual.

The two most important outcomes for young people that emerged were:

1. Better or more coping skills

2. A safer environment, more acceptance and understanding, at school

Rather than attempting to further refine these into more narrowly defined outcomes with associated measurement through the clinician/researcher lens, we have included these as a more broad domain and will examine included studies for outcomes that fit into the two broad domains. For example, coping skills might include specific measurement of coping via validated measures of coping, but maybe also include more specific skills-based and behavioural outcomes such as increased physical or other activities, and increased meditation/mindfulness skills. A safer environment may include specific measures of, for example, perceived sense of connection and belongingness, as well as more broad outcomes such as greater skills of gatekeepers, such as teachers, and reduced stigma and discrimination.

Within each of these broad domains, we will present the range of relevant outcomes within the domain, as well as the measurement tools or approaches to this and provide a narrative summary of the results.

Search methods for identification of studies

Electronic searches

An information specialist with the Cochrane Common Mental Disorders (CCMD) Group will search the following bibliographic databases, using relevant subject headings, keywords, and search syntax appropriate to each resource.

- Cochrane Common Mental Disorders Controlled Trials Register (CCMDCTR) (all available years) (Appendix 1);
- Cochrane Central Register of Controlled Trials (CENTRAL) (current issue);
- Ovid MEDLINE (1946 onwards);
- Ovid PsycINFO (all years) (Appendix 2);
- Web of Science Social Science Citation Index (SSCI) (all years);
- ERIC (1966 to present);
- EBSCOhost Australian Education Index (AEI) (all years);
- EBSCOhost British Education Index (BEI) (all years);
- EBSCOhost Educational Research Abstracts (ERA) (all years).

Embase, CINAHL and the international trial registries (World Health Organization's trials portal (ICTRP) and ClinicalTrials.gov) will be searched via CENTRAL on the Cochrane Library. RCT records from these databases are added to CENTRAL via a highly sensitive, centralised search service (Noel-Storr 2020).

There will be no restriction on date, language or publication status applied to the searches.

Searching other resources

Grey literature

CCMD's information specialist will also search the following sources of grey literature (primarily for dissertations and theses):

- Open Grey (www.opengrey.eu/);
- ProQuest Dissertations & Theses Global (www.proquest.com/products-services/pqdtglobal.html);
- DART-Europe E-theses Portal (www.dart-europe.eu/);

- EThOS – the British Libraries e-theses online service (ethos.bl.uk/);
- Networked Digital Library of Theses and Dissertations (NDLTD) (search.ndltd.org);
- Open Access Theses and Dissertations (oatd.org).

Reference lists

We will check the reference lists of all included studies and key reviews in this area to identify additional studies.

Correspondence

We will attempt to obtain further information on published and unpublished trials by contacting lead researchers in the field of suicide, and also organisations associated with suicide prevention. We will report any personal communication.

Data collection and analysis

Selection of studies

Two review authors will independently screen titles and abstracts of all studies within Covidence. The full text for studies considered likely to be relevant for inclusion will be independently assessed for inclusion according to the pre-determined criteria (above). Disagreements will be resolved by discussion that may include a third member of the review team. We will collate multiple reports describing the same study so that unit of interest is the study, rather than the report. We will describe the reasons for exclusion of studies. We will record this process of study selection in sufficient detail to complete a PRISMA flow diagram according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines (Liberati 2009).

Data extraction and management

Using a standardised data extraction form, piloted on at least one included study, two review authors will independently extract data from the included studies. If necessary, a third team member will be consulted to resolve disagreements. We will extract data about the study design, participants, methods, outcome measurement, results, and other relevant information. One author will transfer this information in to 'Characteristics of included studies' table. A second review author will spot-check 10% of the included studies study characteristics for accuracy against the trial report. If the spot check reveals more than 20% of anomalies, all included studies will be checked.

Main planned comparisons

The main comparisons are as follows (with additional specific comparisons to be added depending on specific interventions of included studies):

Universal interventions vs control

1. Education/awareness and skills training-based type programmes versus control

Selective interventions vs control

2. Gatekeeper training programmes versus control

3. Peer support type programmes versus control

4. Screening type programmes versus control

Indicated interventions vs control

5. CBT-type interventions versus control

6. DBT-type interventions vs control

Multimodel interventions vs control

7. Multimodel interventions vs control

Assessment of risk of bias in included studies

We will evaluate the risk of bias associated with each study based on the Cochrane Collaboration 'Risk of bias' tool (Higgins 2017), including recommendations for assessing risk of bias for cluster-randomised controlled trials and cross-over trials (Higgins 2017). This tool assesses risk of bias in the following domains:

1. Sequence generation: Was the allocation sequence adequately generated? For cluster-randomised trials, we will specifically consider recruitment bias.
2. Allocation concealment: Was allocation adequately concealed?
3. Blinding of a) participants and personnel, and b) outcome assessment, for each main outcome: Was knowledge of the allocated intervention adequately prevented during the study for a) and b)?
4. Incomplete outcome data for each main outcome: Were incomplete outcome data adequately addressed? For cluster-randomised trials, we will specifically consider loss of clusters.
5. Selective outcome reporting: Are reports of the study free of suggestion of selective outcome reporting? For cluster-randomised trials, we will specifically consider incorrect analyses, where clustering was not taken into account.
6. Other sources of bias: Was the study apparently free of other problems that could put it at a high risk of bias?

We will provide a description of what was reported to have happened in each study, and two review authors will independently make a judgement on the risk of bias for each domain, with consensus reached by discussion (that may include an additional review author in the case of disagreement) (Higgins 2017).

We will classify a study as having a low risk of bias if all of the domains of the study outcome are associated with low risk, or if the majority of the domains are associated with low risk and the remaining domains are associated with unclear risk that is unlikely to seriously alter the results. We will classify a study as having unclear risk of bias if there is plausible bias that raises questions about the results in one or more domains, and the remainder of the domains are associated with low risk. We will classify a study as having high risk of bias if any domain is rated as high risk of bias. If necessary, a third team member will be consulted to resolve disagreements.

Measures of treatment effect

Binary data

For binary outcomes, such as the proportion of young people who engage in repeat self-harm, we will summarise outcomes using the odds ratios (OR) and accompanying 95% confidence intervals. In our 'Summary of Findings' tables, we will present estimates of risk difference, in addition to odds ratios, to aid interpretation, for

a range of control group rates (lowest, highest and median rate derived from the placebo groups).

We will analyse time-to-event data (hazard ratios: HRs) using the generic inverse variance method (Higgins 2017). If there is a mixture of studies using analyses of dichotomised and time-to-event data, and log-rank estimates are reported, we will use Peto's method, subject to the required criteria being satisfied (Section 9.4.4.2, Higgins 2017).

Continuous data

We will use mean difference (MD) with 95% confidence intervals where continuous variables (e.g. hopelessness) are measured on the same scale. Where continuous variables are measured on different scales, we will use standardised mean difference (SMD) with 95% confidence intervals.

Unit of analysis issues

Cluster-randomised trials

We will report the methods used to analyse cluster-randomised trials, and whether the risk of unit of analysis error was dealt with appropriately. Where the analysis was carried out appropriately, we will consider the studies for meta-analysis and use the reported effect sizes and standard errors in generic inverse variance meta-analysis. Where the analysis was inappropriate, if the necessary information can be extracted, we may perform approximately correct analyses (Higgins 2011). The approach used will be to adjust standard errors accordingly where a reliable estimate of the intracluster correlation coefficient (ICC) can be obtained, or, in the cases where a reliable estimate of the ICC cannot be obtained, we will use a summary measures approach and perform the analysis at the cluster level (for example, using the proportion of those in each cluster experiencing the event of interest).

Multiple treatment groups

For studies that involve multiple treatment groups, if the treatment groups are similar in rationale and nature (e.g. cognitive behavioural therapy delivered via the internet and cognitive behavioural therapy delivered via telephone, with a control condition of treatment-as-usual), we will combine treatment groups to use a single pairwise comparison for a meta-analysis (cognitive behavioural therapy delivered via the internet/telephone versus the control condition of treatment-as-usual). If there is a small number of studies in which more than one treatment group is of interest (e.g. education, psychological therapy, control), we will use the shared intervention groups approach outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2017).

Cross-over studies

It is not likely that we will find any eligible cross-over trials. If we do, we will only analyse cross-over trials at the first phase of the trial to avoid unit of analysis issues (e.g. issues associated with the inability of those who die by suicide during one treatment to cross over to another treatment). When assessing risk of bias for any cross-over trials, we will only consider the first phase of the trial, due to issues associated with the a) suitability of the design (e.g. prevention of suicidal behaviour does not approximate treatment of a chronic condition), and b) carry-over effects (e.g. the high likelihood that phase one interventions will have lasting effects). If outcomes are

only available from the first period of the trial, however, we will consider the outcomes to be at risk of bias.

Dealing with missing data

We will deal with missing data as recommended in Higgins 2017. We will contact study authors to request data and where authors have omitted standard deviations (SDs) for continuous measures, we plan to estimate these as outlined in Higgins 2017.

We will assess missing data and dropouts for each study. In the review, we will report the number of participants included in each study's final analysis as a proportion of all participants in the study. Where missing data are substantial (> 5%) and Missing-Not-at-Random is a more reasonable assumption, we will perform sensitivity analyses assuming the worst outcome for missing data and re-running the analyses to see how the results are affected. We will discuss the results of any such sensitivity analyses as recommended in Higgins 2017.

Assessment of heterogeneity

To assess heterogeneity, based on the recommendations in Higgins 2017, we will initially visually inspect the meta-analysis and then use the I^2 statistic, with a 95% confidence interval (I^2 values of 0% to 40%: might not be important; 30% to 60%: may represent moderate heterogeneity; 50% to 90%: may represent substantial heterogeneity; 75% to 100%: may represent considerable heterogeneity). In addition to the I^2 value (Higgins 2017), we will present the Chi^2 test and its P value and consider the direction and magnitude of the treatment effects. For meta-analyses with few studies, the Chi^2 test is underpowered to detect heterogeneity should it exist, so we will use a P value of 0.10 as a threshold of statistical significance.

Assessment of reporting biases

If there are sufficient studies (10 or more), we will create funnel plots to investigate the relationship between study power and effect size. An asymmetric plot may indicate biases such as publication bias, location biases, poorer methodological quality of smaller studies, or a true difference related to smaller studies due, for instance, to differences in the delivery of the intervention to smaller samples. We will explore possible reasons for any asymmetry (Egger 1997).

Data synthesis

We will combine quasi-RCT and RCT data in the main analyses, and we will perform a sensitivity analysis to test the robustness of the findings regarding this decision.

In the first instance, we will adopt a common sense approach to assess whether meta-analyses combining data from different studies are appropriate in terms of whether participants, interventions, and outcomes are sufficiently similar, and whether risk of bias is similar (Kristjansson 2007).

We will use a random-effects model to estimate the intervention effects. It is possible that even if the types of intervention are diverse, a meta-analysis could usefully be carried out on studies of similar interventions, with similar research questions and similar outcomes, to provide an indication of the direction, but not the size, of any effect. If the heterogeneity of the available randomised studies prohibits a meta-analysis, we will conduct a narrative synthesis.

Subgroup analysis and investigation of heterogeneity

If there are adequate numbers of studies, we will undertake subgroup analyses for the following groups for the primary outcome.

1. Mainstream education and alternative education. Given that there are higher rates of suicide in alternative education settings (e.g. Kann 1998), it would be valuable to investigate whether the outcomes of interventions to prevent suicidal behaviour differ in alternative compared to mainstream educational settings.
2. Primary vs secondary vs post-secondary education settings. Each setting is associated with different developmental stages, with differences in rates of self-harm and suicide risk observed across these settings.
3. Non-active vs active controls, given the impact on the magnitude of the treatment effect has been shown to vary dependent on the type of control group (Witt 2018b; Witt 2019b)

Subgroup analyses are observational by nature (Higgins 2017). We will therefore interpret the results of these prespecified analyses with caution. We will use any significant differences that are detected between studies to generate hypotheses for future potential research.

Sensitivity analysis

We will conduct sensitivity analyses, as outlined below, to test the robustness of the decisions made in the review process. It has been shown that studies that have an inherent high risk of bias due to their study design are likely to distort the overall summary statistics by either underestimating or overestimating the treatment effect (Higgins 2017). Therefore, in the proposed review, we will conduct the following sensitivity analyses:

1. Using only studies of high quality (i.e. excluding those with high or unclear risk of bias as defined above in Assessment of risk of bias in included studies).
2. Excluding quasi-RCT studies (as noted under 'Data synthesis' above)

'Summary of findings' table

We will create 'Summary of findings' (Higgins 2017) for our primary outcome of self-harm post-intervention for each level of suicide and self-harm prevention across universal, selective, and indicated levels. We will indicate the quality of the evidence in the 'Summary of findings' table using the GRADE approach (GRADE 2004). Assumed control group rates will be based on the best available international population estimates (e.g. provided by the World Health Organization) or the baseline control group rate.

According to the Grade framework, we will assess the quality of evidence across the following domains:

1. Limitations in trial design and implementation;
2. Indirectness of evidence;
3. Unexplained heterogeneity or inconsistency of results;
4. Imprecision of effect estimates; and
5. Potential publication bias.

For each of these domains, we will downgrade the evidence from high quality by one level (for serious) or by two levels (for very serious) concerns.

We will then use these domains to rate the overall quality of evidence for the primary outcome according to the following:

1. High quality: further research is very unlikely to change our confidence in the estimate of effect;
2. Moderate quality: further research is likely to have an important impact on our confidence in the estimate of effect, and may change the estimate;
3. Low quality: further research is very likely to have an important impact on our confidence in the estimate of effect, and may change the estimate; or
4. Very low quality: we are very uncertain about the estimate.

Summary of findings and assessment of the certainty of the evidence

'Summary of findings' tables will be constructed using the GRADEpro GDT software.

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APPENDICES

Appendix 1. Cochrane Specialized Register

Cochrane Common Mental Disorders Controlled Trials Register (CCMDCTR)

The Cochrane Common Mental Disorders Group (CCMD) maintains an archived controlled trials register known as the CCMDCTR. This specialised register contains over 40,000 reference records (reports of RCTs) for anxiety disorders, depression, bipolar disorder, eating disorders, self-harm, and other mental disorders within the scope of this Group. The CCMDCTR is a partially studies-based register with more than 50% of reference records tagged to around 12,500 individually PICO-coded study records. Reports of studies for inclusion in the register were collated from (weekly) generic searches of key bibliographic databases to June 2016, which included: MEDLINE (1950 onwards), Embase (1974 onwards), PsycINFO (1967 onwards), quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL), and review-specific searches of additional databases. Reports of studies were also sourced from international trials registries, drug companies, the handsearching of key journals, conference proceedings and other (non-Cochrane) systematic reviews and meta-analyses. Details of CCMD's core search strategies (used to identify RCTs) are on the Group's website, with an example of the core MEDLINE search displayed below.

[MeSH Headings]: eating disorders/ or anorexia nervosa/ or binge-eating disorder/ or bulimia nervosa/ or female athlete triad syndrome/ or pica/ hyperphagia/ or bulimia/ or self-injurious behavior/ or self mutilation/ or suicide/ or suicidal ideation/ or suicide, attempted/ or mood disorders/ or affective disorders, psychotic/ or bipolar disorder/ or cyclothymic disorder/ or depressive disorder/ or depression, postpartum/ or depressive disorder, major/ or depressive disorder, treatment-resistant/ or dysthymic disorder/ or seasonal affective disorder/ or neurotic disorders/ or depression/ or adjustment disorders/ or exp antidepressive agents/ or anxiety disorders/ or agoraphobia/ or neurocirculatory asthenia/ or obsessive-compulsive disorder/ or obsessive hoarding/ or panic disorder/ or phobic disorders/ or stress disorders, traumatic/ or combat disorders/ or stress disorders, post-traumatic/ or stress disorders, traumatic, acute/ or anxiety/ or anxiety, castration/ or koro/ or anxiety, separation/ or panic/ or exp anti-anxiety agents/ or somatoform disorders/ or body dysmorphic disorders/ or conversion disorder/ or hypochondriasis/ or neurasthenia/ or hysteria/ or munchausen syndrome by proxy/ or munchausen syndrome/ or fatigue syndrome, chronic/ or obsessive behavior/ or compulsive behavior/ or behavior, addictive/ or impulse control disorders/ or firesetting behavior/ or gambling/ or trichotillomania/ or stress, psychological/ or burnout, professional/ or sexual dysfunctions, psychological/ or vaginismus/ or Anhedonia/ or Affective Symptoms/ or *Mental Disorders/ OR *[Title/ Author Keywords]:* (eating disorder* or anorexia nervosa or bulimi* or binge eat* or (self adj (injur* or mutilat*)) or suicide* or suicidal or parasuicid* or mood disorder* or affective disorder* or bipolar i or bipolar ii or (bipolar and (affective or disorder*)) or mania or manic or cyclothymic* or depression or depressive or dysthymi* or neurotic or neurosis or adjustment disorder* or antidepress* or anxiety disorder* or agoraphobia or obsess* or compulsi* or panic or phobi* or ptsd or posttrauma* or post trauma* or combat or somatoform or somati#ation or medical* unexplained or body dysmorphi* or conversion disorder or hypochondria* or neurastheni* or hysteria or munchausen or chronic fatigue* or gambling or trichotillomania or vaginismus or anhedoni* or affective symptoms or mental disorder* or mental health).tw,kf. AND *[RCT filter]:* (controlled clinical trial.pt. or randomised controlled trial.pt. or (randomi#ed or randomi#ation).ab,ti. or randomly.ab. or (random* adj3 (administ* or allocat* or assign* or class* or control* or determine* or divide* or distribut* or expose* or fashion or number* or place* or recruit* or subsitut* or treat*)).ab. or placebo*.ab,ti. or drug therapy.fs. or trial.ab,ti. or groups.ab. or (control* adj3 (trial* or study or studies)).ab,ti. or ((singl* or doubl* or tripl* or trebl*) adj3 (blind* or mask* or dummy*)).mp. or clinical trial, phase ii/ or clinical trial, phase iii/ or clinical trial, phase iv/ or randomised controlled trial/ or pragmatic clinical trial/ or (quasi adj (experimental or random*)).ti,ab. or ((waitlist* or wait* list* or treatment as usual or TAU) adj3 (control or group)).ab.)

Records were screened for reports of RCTs within the scope of the Cochrane Common Mental Disorders Group. Secondary reports of RCTs were tagged to the appropriate study record.

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For this review, the information specialist with CCMD will cross-search the CCMDCTR-Studies and References register using the following terms:

#1 (suicid* or parasuicid* or "auto mutilat*" or automutilat* or "self destruct*" or selfdestruct* or self-harm* or selfharm* or "self immolat*" or selfimmolat* or "self inflict*" or selfinflict* or "self injur*" or selfinjur* or selfmutilat* or "self mutilat*" or "self poison*" or selfpoison* or NSSI* or nonsuicid* or non-suicid*) AND INREGISTER [all fields]
#2 (child* or boys or girls or juvenil* or minors or paediatric* or pediatric* or adolesc* or preadolesc* or "pre adolesc*" or pubert* or pubescen* or prepube* or "pre pube*" or teen* or pupil* or schoolchild* or young* or youth*) AND INREGISTER [all fields]
#3 (educat* or prevent* or protect* or school* or highschool* or curriculum or classroom* or college* or universit* or training institut* or campus* or teacher* or lecture* or staff or personnel or trainee* or gatekeeper* or peer or peers) AND INREGISTER [all fields]
#4 (#1 AND #2 AND #3)
#5 (student* or undergrad* or graduat* or postgrad*) AND INREGISTER [all fields]
#6 (#5 AND #1)
#7 ((suicid* or parasuicid* or "auto mutilat*" or automutilat* or "self destruct*" or selfdestruct* or self-harm* or selfharm* or "self immolat*" or selfimmolat* or "self inflict*" or selfinflict* or "self injur*" or selfinjur* or selfmutilat* or "self mutilat*" or "self poison*" or selfpoison* or NSSI* or nonsuicid* or non-suicid*) AND (prevent* or protect* or reduc* or risk*) AND (child* or boys or girls or juvenil* or minors or paediatric* or pediatric* or adolesc* or preadolesc* or "pre adolesc*" or pubert* or pubescen* or prepube* or "pre pube*" or teen* or pupil* or young or youth* or school* or highschool* or curriculum or classroom* or college* or universit* or training institut* or trainee* or campus* or educat* or teacher* or gatekeeper* or peer or peers)):ti AND INREGISTER [title only field]
#8 (#4 OR #6 OR #7)

Appendix 2. PsycINFO search strategy

PsycINFO will be searched on the OVID platform (1806 to present) using the following strategy:

Ovid APA PsycInfo <1806 onwards>
Search Strategy:

[Condition]
1 Attempted Suicide/
2 Suicide/
3 Suicidal Ideation/
4 Suicidology/
5 (suicid* or parasuicid*).tw,id.
6 Self-Destructive Behavior/
7 exp Self-Injurious Behavior/
8 (auto mutilat* or automutilat* or (self adj (destruct* or harm* or immolat* or inflict* or injur* or mutilat* or poison*)) or selfdestruct* or selfharm* or selfimmolat* or selfinflict* or selfinjur* or selfmutilat* or selfpoison*).tw,id.
9 or/1-8
[Prevention]
10 Suicide Prevention/
11 Mental Health Programs/
12 Intervention/
13 prevent*.tw,id,hw.
14 (reduction? or (reduc* adj3 (attempt* or behavi* or ideation or thoughts or rate or rates or repeat* or repetition*))).tw,id.
15 risk?.ti,id.
16 awareness.tw,id.
17 (suicide adj3 (attempt* or ideation or potential* or repeat* or repetition*)).tw,id.
18 ((harm* or injur* or selfharm* or selfinjur*) adj3 (attempt* or ideation or potential* or repeat* or repetition*)).tw,id.
19 suicidal*.tw,id.
20 ("no harm?" adj (agreement? or contract*)).tw,id.
21 ((suicid* or self harm* or selfharm* or self injur* or selfinjur*) adj2 (agreement? or contract?)).tw,id.
22 (nonsuicid* or non-suicid* or NSSI).tw,id.
23 or/10-22
[Setting]
24 ("3580" or "3530" or "3500").cc.
25 exp Education/
26 exp Educational Personnel/

27 Educational Programs/
28 Program Development/
29 exp Schools/
30 exp Colleges/
31 School Based Intervention/
32 School Principals/
33 School Psychologists/
34 Student Personnel Services/
35 Teaching/
36 Peers/ or Peer Counseling/
37 exp Students/
38 school*.tw,id,sh.
39 (school* or highschool* or college* or universit* or campus* or classroom* or curriculum or teacher* or lecture* or student* or graduate* or undergraduate* or postgraduate* or pupil* or trainee* or training institut* or educat*).tw,id.
40 peer?.tw,id.
41 gatekeeper*.tw,id.
42 or/24-41
43 (9 and 23 and 42)
[Study Design: RCTs]
44 clinical trials.sh.
45 (randomi#ed or randomi#ation or randomi#ing).ti,ab,id.
46 (RCT or at random or (random* adj3 (administ* or allocat* or assign* or class* or control* or crossover or cross-over or determine* or divide* or division or distribut* or expose* or fashion or number* or place* or recruit* or split or subsitut* or treat*))).ti,ab,id.
47 (control* and (trial or study or group) and (placebo or waitlist* or wait* list* or ((treatment or care) adj2 usual))).ti,ab,id,hw.
48 ((single or double or triple or treble) adj2 (blind* or mask* or dummy)).ti,ab,id.
49 trial.ti.
50 placebo.ti,ab,id,hw.
51 treatment outcome.md.
52 treatment effectiveness evaluation.sh.
53 mental health program evaluation.sh.
54 or/44-53
55 (43 and 54)
56 ((suicid* or parasuicid* or auto mutilat* or automutilat* or (self adj (destruct* or harm* or immolat* or inflict* or injur* or mutilat* or poison*)) or selfdestruct* or selfharm* or selfimmolat* or selfinflict* or selfinjur* or selfmutilat* or selfpoison*) and (prevent* or protect* or reduc* or risk*) and (child* or boys or girls or juvenil* or minors or paediatric* or pediatric* or adolesc* or preadolesc* or "pre adolesc*" or pubert* or pubescen* or prepube* or "pre pube*" or teen* or pupil* or young or youth* or school* or highschool* or curriculum or classroom* or college* or universit* or training institut* or trainee* or campus* or educat* or teacher* or gatekeeper* or peer or peers)).ti.
57 954 and 56)
58 (55 or 57) (569 hits, as of 11-Oct-2020)

Key:
3580.cc.: Educational/Vocational Counseling & Student Services (Concept Code)
3530.cc.: Curriculum & programs & Teaching Methods
3500.cc.: Educational Psychology

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WHAT'S NEW

Date	Event	Description
14 January 2021	New citation required and major changes	This is a new protocol based on the protocol 'Primary prevention of suicide and suicidal behaviour for adolescents in school settings' published in 2015 (and withdrawn in 2018) (Macleod 2015; Macleod 2018).

HISTORY

Protocol first published: Issue 1, 2021

Date	Event	Description
18 November 2015	New citation required and major changes	Original protocol 'Prevention of suicide and suicidal behaviour in adolescents' was split into a suite of reviews by setting and methods updated Stevens 2008.

CONTRIBUTIONS OF AUTHORS

The protocol was originally written by Emily Macleod, with considerable advice, additions, and amendments from Annette Beautrais, Shyamala Nada-Raja, Roger Shave, and Vanessa Jordan. This team were unable to progress the protocol and new authors have joined the team, rewritten the protocol, updating methods in line with Cochrane requirements.

DECLARATIONS OF INTEREST

Sarah Fortune is the Chair of the New Zealand Suicide Mortality Review Group.

Vartika Sharma has no declarations of interest to disclose.

Linda Bowden has no declarations of interest to disclose.

Linda Hobbs has no declarations of interest to disclose.

David Marshall has no declarations of interest to disclose.

Claire Mitchell has no declarations of interest to disclose.

Alison Clarke has no declarations of interest to disclose.

Jo Robinson has no declarations of interest to disclose.

Roger Shave has no declarations of interest to disclose.

Emily MacLeod has no declarations of interest to disclose.

Vanessa Jordan has no declarations of interest to disclose.

Katrina Witt is an editor for the Cochrane Common Mental Disorders Group, and senior editor for the Self-Harm and Suicide Satellite of the group.

Keith Hawton has no declarations of interest to disclose.

Sarah Hetrick is the joint co-ordinating editor of the Cochrane Common Mental Disorders Group. She is funded by an Auckland Medical Research Foundation Douglas Goodfellow Repatriation Fellowship to develop and test a digital intervention for young people who engage in self-harm. She is the Principal Clinical Advisor of the Suicide Prevention Office of the Ministry of Health for the New Zealand Government.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- Health Research Council of New Zealand, New Zealand

Funding was provided for a project on adolescent mental health and well-being to pilot online therapy programmes for depression and other mental health issues, including self-harm (Principal Investigator: Nada-Raja S, and Co-Investigators: McGee R, Christensen H, Mackinnon A, 2010). One component of the project was to conduct a literature review of the relevant adolescent literature, which has been subsumed under the registered Cochrane title. Dr Emily Macleod (lead author on the Cochrane title) was recruited to work on this project, including leading the Cochrane relevant review. Therefore, her salary for this review was paid from the above described grant.